Volume 7 | Number 1 EJRR 1|2016

# EJRR EUROPEAN JOURNAL OF RISK REGULATION

## MINI-SYMPOSIUM ON THE VOLKSWAGEN SCANDAL

*Editor: Marie-Eve Arbour*
*Contributors: Nicolas de Sadeleer, Raymonde Crête and Eric Lane*

## MINI-SYMPOSIUM ON THE PARIS AGREEMENT ON CLIMATE CHANGE

*Editor: Lucas Bergkamp*
*Contributors: Jaap C. Hanekamp, Lucas Bergkamp, Arden Rowell, Josephine van Zeben and Jonathan Verschuuren*

## SPECIAL ISSUE ON REGULATING CLIMATE ENGINEERING IN THE EUROPEAN UNION

*Editor: Jesse L. Reynolds*
*Contributors: Floor Fleurke, Anne Therese Gullberg, Jon Hovi, Janine Sargoni and Han Somsen*

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Cultivation Restrictions for Genetically Modified Plants
*Gerd Winter*

Handling Uncertain Risks: An Inconsistent Application of Standards
*Anne-May J.P. Janssen and Nele F. Rosenstock*

The Definition of Nudge and Libertarian Paternalism
*Pelle Guldborg Hansen*

## CASE NOTES

Scotch Whisky Association: Minimum Unit Pricing for Alcohol May Not be a Proportionate Public Health Intervention
*Oliver Bartlett*

Tilly Sabco: Another Step towards the Definition of 'Implementing Measures'?
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Güntzelstraße 63 · 10717 Berlin · Germany
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www.lexxion.de

*Typeset*
Automatic typesetting by metiTEC-software
me-ti GmbH, Berlin

*EJRR annual subscription* rates 2016 (4 issues)*

| | |
|---|---|
| printed version only | 407,00 € |
| printed version + online edition (incl. archive)** | 472,00 € |
| online edition only (incl. archive)** | 407,00 € |

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This journal may be cited as [2016] EJRR.

*ISSN (Print) 1867-299X · ISSN (Online) 2190-8249*

# Editorial

The EJRR greets the New Year with a wealth of timely new analysis and comments to the most controversial risk regulation issues of our times. This first issue of 2016 hosts two mini-symposia devoted to the infamous *Volkswagen scandal* – which revealed that the carmaker used for some its vehicles defeat devices and software to cheat on tests for smog-causing nitrous oxides (NOx) – and the *Paris Agreement on Climate Change*, concluded at COP-21 in December of last year. In addition, it features a Special Issue, which delves into the EU law and policy of one of the most contentious, yet potentially necessary, strategies to counter the effects of natural and anthropogenic climate change: *geoengineering*.

Under the guest-editorship of *Marie-Eve Harbour* (Université Laval) the homonymous mini-symposium that involves the Volkswagen group offers a first tentative analysis of the debacle. By providing a kaleidoscopic answer – considering that its contributions provide different legal perspectives – be it business law, consumer law, criminal law, environmental law and torts –, the authors offer a useful mapping for future research. Despite their different backgrounds, all contributors highlight the need to enhance controls by regulators on the market economy.

The "world's greatest diplomatic success" or an "epic failure"? This is the provocative line opening the Paris Agreement mini-symposium edited by *Lucas Bergkamp* (Hunton & Williams). This collection of essays illustrates and exemplifies the breadth of the issues associated with the Paris Agreement on Climate Change. They address inter alia the Agreement's relation to science, how the agreement's aspirational objectives may affect future behaviour by states, and how it treats agriculture and food security. More generally, the Paris Agreement also epitomizes the contradictions of Beck's world risk society, characterized by perceived threats confirmed by politicized science and governed by sub-politics beyond democratic control.

On a different, yet related line of thought, the Special Issue on Geoengineering looks from an EU perspective at what was once viewed as a "freak show in otherwise serious discussions of climate science and policy"[1]. Geoengineering – also referred to as climate engineering – is broadly defined by the Royal Society as "the deliberate large-scale manipulation of the planetary environment to counteract anthropogenic climate change". With the declared aim to address the gap between the EU's role in regulating climate engineering and its actual risks, *Jesse L. Reynolds* (Tilburg Law School) our guest editor, took the initiative to host at his own institution an international workshop gathering environmental policy, legal and regulatory experts. This resulted into a well-timed and insightful reflection providing the need to enhance the dialogue regarding the intersections among climate change, geoengineering and European law.

1 David G. Victor, "On the Regulation of Geoengineering", 24(2) *Oxford Review of Economic Policy* (2008), 322, 323.

In addition to these dedicated collections, our issue contains several original research articles that deal with some of the most controversial risk regulatory challenges facing the European and global risk world: an exhaustive analysis of the state of the art of GMO cultivation in Europe, a fresh look at how the European Courts have applied the precautionary principle, a sophisticated treatment of what qualifies as a "nudge" and how exactly it relates to "libertarian paternalism", and finally, an epidemiological perspective of causal inference in law.

Professor *Gerd Winter*, from the University of Bremen, explores in a comprehensive EU and WTO-law analysis what grounds may justify GM-cultivation restrictions beyond those identified in a concrete environmental risk assessment. By distinguishing between grounds of general environmental policy and trans-environmental grounds (like socio-economic or ethical grounds), he convincingly demonstrates how trade restrictions for reasons of health and environmental protection are increasingly justified by a broadened variety of risk perceptions and cultures.

*Anne-May Janssen* and *Nele Rosenstock* examine how the European Courts have recently been handling uncertain risks. Confirming the pattern – originally identified by Marjolein Van Asselt and Ellen Vos in the seminal Precautionary Paradox – that the EU judiciary has been inconsistent in dealing with the relationship between uncertainty and the precautionary principle, they also demonstrate that the existing EU risk regulation framework does not sufficiently address the complexities of uncertain risks, by taking into due account the role of the Courts and that of the EU Commission.

"Nudge" and "libertarian paternalism" have become concepts of increasing interest and debate amongst public policy makers and academics alike. Yet, their respective definitions and relation to one another have raised semantic and inevitably conceptual confusion. This has in turn led to a series of disagreements and ambiguities. To improve the clarity and value of the definition of nudges, *Pelle Guldborg Hansen*, from Roskilde University, ventures to tackle the resulting theoretical confusion. In his essay, he reconciles them with their theoretical foundations in behavioural economics, and offers an astute explanation of how they relate to incentives and information.

Last but not least, *Bob Siegerink, Wouter den Hollander, Maurice Zeegers and Rutger Middelburg* discuss the problem of causal inference in law, by providing an epidemiological viewpoint. More specifically, by scrutinizing the concept of the so-called "proportional liability", which embraces the epidemiological notion of multi-causality, they demonstrate how the former can be made more proportional to a defendant's relative contribution in the known causal mechanism underlying a particular damage.

Thanks to our correspondents EJRR readers are kept updated on some of the latest developments in different risk regulation sectors by covering various issues, such as the EU's new framework for food for specific groups, like sportspeople or infants, or how the concept of "performativity" constitutes a useful mechanism to analyse the relation between risk communication and risk regulation.

A couple of risk regulation annotations on important EU risk-relevant judgments and book reviews complete the issue.

With every good wish for a lively and fulfilling 2016!

*Alberto Alemanno and Cliff Wirajendi*
*Editor and Executive Editor, EJRR*

# Volkswagen: Bugs and Outlooks in Car Industry Regulation, Governance and Liability

*Marie-Eve Arbour**

## I. Introduction

The scandal involving the Volkswagen group broke out last Fall, at the dawn of the very delicate UN Conference on Climate Change (COP21) held in Paris, and the posting of an unofficial version of the Comprehensive Economic and Trade Agreement (CETA)[1]. This so, just when a leaked version Transatlantic Trade and Investment Partnership (TTIP) ran through the veins of the Internet[2] and the Trans-Pacific Partnership (TPP)[3] was just about to be signed in New Zealand, fostering market integration by pushing further national treatment and mutual recognition, against the backdrop -albeit one small step at a time- of an increasing demand for environmental protection through the setting, among other regulation tools, of emission thresholds[4]. Almost ironically, indeed, the Volkswagen scandal raises very serious conformity assessment loopholes, just when a blowing wind in international trade seeks to reach out for greater uniformity and mutual recognition of regulatory procedures, knowing, too, that car industry lobbyists are important players in defining thresholds.

Most importantly and even before entering courtrooms, the scandal also illustrates the impossibility of greenhouse gas (GHG) reduction if corporate social responsibility is not taken seriously, given that actual regulation techniques and assessment conformity procedures move away from the outdated domestic command-and-control paradigm. Albeit to different extents in North America and the EU, for example, many features of industries' self-regulation are central to an effective protection of thresholds. As a corollary and unless research and development (R&D) enables domestic or supranational regulators to crosscheck industries' home testing, conformity assessment procedures are destined to remain an inadequate regulation tool. From a legal perspective, what can be learned from VW's debacle? The questions invite to a kaleidoscopic answer, considering that is touches upon many legal disciplines: be it trade law, business law, consumer law, criminal law, environmental law or liability law. Having in mind to bringing up a useful mapping for future research, the present EJRR number gathers different, yet complementary, short opinion pieces against the backdrop of the VW scandal.

In the absence of courts' judgements that usually underlie most legal reasoning, lawyers generally hesitate to comment on contemporary events. Nonetheless, the scandal has so far inspired authoritative au-

* Université Laval, Québec (Canada). This special endeavour surrounding VW is also the product of peer-reviewers, who revised around the world the present pieces within extremely short delays. Their comments and availability was most appreciated as the Number could not have been rapidly out without their exceptional contribution. Translated and adapted, my own piece builds upon "Volkswagen, le commerce et les seuils GES: la régulation des produits mise à mal", *Repères*, Jan. 2016, EYB2016REP1843.

1 Canada and European Union (EU) Comprehensive Economic and Trade Agreement, signed on Sept. 26th 2014 [" CETA "], whose Chapter XX on Technical Barriers to Trade provides for greater cooperation in the field or Motor Vehicle Regulation, in order " …to strengthen cooperation and communication, *including the exchange of information on motor vehicle safety and environmental performance research activities linked to the development of new technical regulations or related standards, to promote the application and recognition of Global Technical Regulations under the framework of the 1998 Global Agreement administered by the WP.29 and possible future harmonization*, between the Parties, concerning improvements and other developments in the areas of motor vehicle technical regulations or related standards " : Annex, art. 1 (emphasis added).

2 The TTIP specifically addresses motor vehicle regulatory issues : see EUROPEAN COMMISSION, " The Transatlantic Trade and Investment Partnership (TTIP) Regulatory Issues – EU position on motor vehicles", May 2014, online at http://trade.ec.europa.eu/doclib/docs/2014/may/tradoc_152467.pdf

3 The Trans-Pacific Parternship does not encompass a special, industry-focused section on motor vehicle trade. However, Chapter 2 entitled National Treatment and Market Access for Goods lists specific multilateral Annexes that target US/Japan and Canada/Japan relationships (see 2-D: Canada Appendix D Appendix between Japan and Canada on Motor Vehicle Trade, 2-D: United States Appendix D Appendix between the US and Japan on Motor Vehicle Trade, 2-D: Japan Appendix D-1 Appendix between Japan and the US on Motor Vehicle Trade, 2-D: Japan Appendix D-2 Appendix between Japan and Canada on Motor Vehicle Trade).

4 Regarding the political dimension of thresholds, see Agathe VAN LANG, *Droit de l'environnement*, Paris, PUF, pp. 78-80.

thors[5], just as extrajudicial confessions by VW itself continue fusing here and there on social networks. Within this context, the very features of the scandal already gathered relevant sources that can be looked upon to construe a first tentative analysis. In the end, it represents the perfect example of an infra-disciplinary case-study, which stimulated the present endeavour. There is, indeed, sufficient evidence to comment on the case, considering that an unambiguous *mea culpa* has been officially released by Volkswagen as to the use of a defeat device in 11 million cars, and knowing that further measures were taken by the company in the context of a damage control strategy (while printing the present lines, a recall of vehicles is currently being organized in Germany[6] and the US). From a methodological standpoint, the gathered comments probably all over-emphasise the relevant materials that were released by VW itself. Albeit overly prudent, such attitude is undoubtedly excusable, considering that some peripheral facts and liabilities still need to be pinpointed and assessed in a near future. Such consideration brings about another intellectual caveat. The debacle may be global from a mass media and stock market perspectives, but some of its core features remain regional, or even domestic.

In facts, antibodies to such corporate misbehavior are to be found in some federal or harmonized legislation (such as EU or US environmental legislation). Besides, however, national legislation on corporate governance, consumer protection likewise criminal and civil liability may provide solutions that vary from a legal system to another. As a result, addressing VW's debacle from a domestic standpoint does not offer cut and paste solutions to all raised legal issues; but it shall, at least conceptually, highlight the legal categories that come into play in finding remedies -if there are- for the involved stakeholders. Within this context, this introductory piece to VW's case study shall, after synthesizing the factual background (Section I) touch upon three legal areas: trade and the protection of human health and the environment (Section II), corporate governance (Section II) and greenwashing as an anti-consumer marketing strategy (Section IV).

## II. The Volkswagen Scandal: Some Facts

"*Software installed on some of our vehicles permitted deviations in nitrogen oxide emissions (NOx) performance* depending on whether the vehicle was running during a regulatory compliance-related test cycle or running outside the test cycle during normal road use. This is the subject of the current investigations[7]", admitted Volkswagen. Seemingly, the scandal was born of a corporate attitude that was destined to increase benefits by curbing out environmental standards, relying on sophisticated technology to blur the results of vehicle testing in artificial conditions. Initially, the scandal blew out of the allegations released by the American Environmental Protection Agency (EPA) to the effect that the German group has, between 2009 and 2015, falsified data on polluting nitrogen oxide (NOx) and carbon dioxide ($CO_2$) in occasion of conformity assessment procedures[8]. Pursuant to the *Clean Air Act*, the EPA issued a Notice of Violation[9] (NOV), which stated that the company "manufactured and installed defeat devices in certain model year 2009 through 2015 diesel light-duty vehicles equipped with 2.0 liter engines." The NOV further alluded that the "defeat devices bypass, defeat, or render inoperative elements of the vehicles' emission control system that exist to comply with [federal american] emission standards." Knowing that in the US -and, by extension, in Canada- the area of product safety is closer to the "market diplomacy paradigm", the issuing of the NOV is a strong gesture.

Whilst meeting with the California Air Resources Board ("CARB") and the EPA on September 3, 2015, indeed, Volkswagen AG had revealed that some mod-

5 See Nicolas DE SADELEER, " La réponse politique à VW ressortit de la chirurgie lourde ", *L'écho*, Oct. 6th, 2015, at p. 15.

6 On reads on VW's website : " Kundenfreundliche Lösungen waren bei der Erarbeitung der technischen Maßnahmen ein wichtiger Aspekt. Für die betroffenen EA189-Dieselmotoren sehen die Maßnahmen wie folgt aus: Die 1,2- und 2,0-Liter-Aggregate bekommen ein Software-Update. [1] Die reine Arbeitszeit wird knapp eine halbe Stunde betragen. [2] Die 1,6-Liter Aggregate bekommen ebenfalls ein Software-Update. Zusätzlich wird direkt vor dem Luftmassenmesser ein sogenannter Strömungsgleichrichter befestigt. Die Umsetzung wird weniger als eine Stunde Arbeitszeit in Anspruch nehmen " : http://www.volkswagen.de/de/volkswagen-aktuell/News.suffix.html/2015~2Fnox-thematik.html (last visited Feb. 18th, 2016).

7 VOLKSWAGEN CANADIAN WEBSITE, at https://www.vwemissionsinfo.ca/ [last visited on Feb. 18, 2016].

8 See " Scandale Volkswagen : comment un logiciel a-t-il pu tromper les tests antipollution ? ", *Le Monde*, Sept. 22, 2015 (online at http://www.lemonde.fr/pixels/article/2015/09/22/scandale-volkswagen-comment-un-logiciel-a-t-il-pu-tromper-les-tests-antipollution_4767405_4408996.html).

9 EPA, " Notice of Violation ", online at https://yosemite.epa.gov/opa/admpress.nsf/a883dc3da7094f97852572a00065d7d8/dfc8e33b5ab162b985257ec40057813b!OpenDocument.

els among marketed diesel vehicles contained a hidden software that could distinguish between testing conditions and road conditions. However, the alarm had been launched by an American NGO (the International Council for Clean Transportation, (ICCT)) mandated by the EPA, which, unable to duplicate the manufacturer's data in real traffic conditions[10], has relied upon further expertise of a research center nested at the University of West Virginia[11]. The subsequent report highlighted important discrepancies between laboratory data, and those obtained in real driving condition[12]; in particular, a software destined to distort emission data in "test" mode was discovered. Put differently: another greenwashing episode had been discovered.

Among the most stunning details surrounding the alleged defeat practice is the fact that the involved vehicles *are* actually equipped with a GHG reduction system. The software's task consists in deactivating the device in real driving conditions. Therefore, most incriminated vehicles have the mechanical and technical potential to meet the environmental thresholds fixed by law; a recall suffices to give free rein to the GHGs filters. Nonetheless, such restoration in terms of environmental protection weakens the engine power and increases fuel consumption: hence the sufficient *leitmotif* to cheat. Searching for details, one soon realizes that such deceit practice is anything but new: a specific offense is even nested in EU regulation, as it prohibits manufacturers to equip a vehicle with a defeat device, defined as " [...] any element of design which senses temperature, vehicle speed, engine speed (RPM), transmission gear, manifold vacuum or any other parameter for the purpose of activating, modulating, delaying or deactivating the operation of any part of the emission control system, *that reduces the effectiveness of the emission control system under conditions which may reasonably be expected to be encountered in normal vehicle operation and use*[13]". The avoidance maneuver, thus, is anything but new to the car industry (or regulators, for the matter); and not even to VW[14].

Having admitted the allegations later released by the EPA, the CEO of the famous German group resigned, apologizing at the same time of having deceived the public trust. Among others, the French site of the company made a similar apology[15]; followed by those verbalized by delocalized CEO's[16].

Recalls were organized in Europe and compensation schemes were also drafted[17]. Several countries have banned the sale of the involved vehicles on their territory, and initiated further investigation procedures.

## III. Trade and Human Health & Environment Protection Tools

It is no secret to anyone that contemporary international trade fights unjustified obstacles to trade, including quotas, tariffs and discriminatory measures of any kind[18]. The car industry being increasingly

10 See " Une ONG à l'origine du scandale Volkswagen ", *Le Monde*, Sept. 22, 2015, (online at http://www.lemonde.fr/planete/article/2015/09/22/l-ong-a-l-origine-du-scandale-volkswagen_4767318_3244.html. The NGO is partially financed by the ClimateWorks Foundation.

11 That is, the *Center for Alternative Fuel Engines and Emissions* (http://cafee.wvu.edu/).

12 *JG* Thompson, DK Carder, MC Besch, A Thiruvengadam et HK Kappanna, *In-use emissions testing of light-duty diesel vehicles in the United States Final Report Center for Alternative Fuels, Engines & Emissions,* West Virginia University, 2014 (http://www.theicct.org/sites/default/files/publications/WVU_LDDV_in-use_ICCT_Report_Final_may2014.pdf).

13 Regulation 715/2007 on type approval of motor vehicles with respect to emissions from light passenger and commercial vehicles (Euro 5 and Euro 6) and on access to vehicle repair and maintenance information, OJ. L 171/1, at art. 3 (10). See similarly,in the US, 40 C.F.R. § 86.1803-01 (penalties at CAA § 205(a), 42 U.S.C. § 7524(a), 40 C.F.R. § 19.4), and, in Canada, the *Passenger Automobile and Light Truck Greenhouse Gas Emission Regulations*, SOR/2010-201, at art. 9, par. 2 (emphasis added).

14 CNBC WEBSITE, " VW had previous run-in over 'defeat devices' " (online at http://www.cnbc.com/2015/09/23/vw-had-previous-run-in-over-defeat-devices.html) [accessed on Feb. 24th].

15 " Le groupe Volkswagen a récemment reconnu qu'il existait des écarts entre les émissions d'oxydes d'azote (NOx) obtenues lors de conditions de circulation réelles et celles obtenues lors de tests sur banc. […] Nous souhaitons aussi vous exprimer nos plus sincères regrets et vous dire que nous ferons tout pour regagner votre confiance " (https://informations.volkswagengroup.fr/ last visited Dec. 3rd, 2015).

16 See Michael Horn, President and CEO of Volkswagen Group of America, Inc. before the House Committee on Energy and Commerce Subcommittee on Oversight and Investigations, Oct. 8th, 2015, online at: http://docs.house.gov/meetings/IF/IF02/20151008/104046/HHRG-114-IF02-Wstate-HornM-20151008.pdf (last accessed Feb. 23th, 2016): " On behalf of our company, and my colleagues in Germany, I would like to offer a sincere apology for Volkswagen's use of a software program that served to defeat the regular emissions testing regime ".

17 See " Volkswagen fait un premier pas dans l'indemnisation des clients américains", *Le Monde* du 10 novembre (en ligne à http://abonnes.lemonde.fr/economie/article/2015/11/10/volkswagen-fait-un-premier-pas-vers-l-indemnisation-de-clients-americains_4806209_3234.html).

18 Jean-Maurice ARBOUR, Sophie LAVALLÉE and Hélène TRUDEAU, *Droit international de l'environnement*, 2ème éd., Yvon Blais, Cowansville, 2012, at pp. 910ff.

global, both GHG emissions threshold and conformity assessment procedures are at the very core of contemporary international trade law. Much like the North American Free Trade Agreement (NAFTA[19]), the Agreement on Technical Barriers to Trade (TBT[20]) concluded under the auspices of the World Trade Organization (WTO) provides that trade barriers on products themselves can be maintained if they pursue legitimate objectives[21], including environmental protection[22]. Emission thresholds represent one of these exceptions, especially because they stem out of an international technical consensus that meets the standard of objectiveness, rationality, "scientificity" underlying standardization. Hence, States are encouraged to rely on international standards to set acceptable thresholds. And they do so. *Mutatis mutandis*, the EU embraces similar regulatory schemes, ideally ensuring the free circulation of goods within the internal market whilst protecting the environment. This complex equilibrium is reached by way of a regulatory cocktail (directive, regulations, etc.) which is precisely the object of Nicolas De Sadeleer's contribution.

From a technical point of view, authorized thresholds are quite similar in North America and the EU: 80mg/km NOx under the new standard Euro 6[23], or 50 mg/km under the US *Clean Air Act* and its Canadian twin, the *Regulation on emissions from road vehicles and engines*[24] adopted under the *Canadian Environment Protection Act*[25]: according to the author, "the level of protection is more the result of a gradual, pragmatic approach and a search for the possibilities than a desire to implement in detail the scientific experts' recommendations". However, whomever violates these standards incurs administrative penalties, including heavy fines: on January 4th, 2016, the US Department of Justice filed a civil action on behalf of the EPA Volkswagen *et al.* for alleged violations of the *Clean Air Act*[26] and regulations, thus seeking injunctive reliefs and civil penalties[27].

In the EU, likewise, many Member States[28] are carrying out investigations surrounding the use of a defeat device in the diesel car industry (thus, not only Volkswagen). Ultimately, national regulators could, based on Directive 2007/46/EC[29], withdraw their market approval if recalls do not suffice to ensure environmental regulations' compliance. In Canada, manufacturers and sellers must notify Transport Canada and vehicle owners of all "design defect, manufacturing or operation that affects or is likely to undermine human security--fnref:31" as well as non -consistency vehicles or their equipment with the regulations[31]. Unlike other regulators, it may force a product recall.

Greater distinctions between the US and the EU regulatory attitudes are to be found in approval processes of vehicle compliance: whereas, in the absence of any Agency, it is incumbent to domestic national authorities in the EU (Directive 2007/46/EC sets a framework for a type-approval regime then subject to the mutual recognition principle), manu-

19 North American Free Trade Agreement (NAFTA), which came into effect on January 1, 1994.

20 April 15th, 1994, 1868 RTNU 141.

21 See art. 904, NAFTA and art. 2.2, TBT.

22 Art. 2.5, TBT.

23 Contained at Commission Regulation (EU) No 459/2012 of 29 May 2012 amending Regulation (EC) No 715/2007 of the European Parliament and of the Council and Commission Regulation (EC) No 692/2008 as regards emissions from light passenger and commercial vehicles (Euro 6) Text with EEA relevance, *OJ L 142, 1.6.2012, p. 16–24*, *OJ* no. L 142, 1.6.2012, p. 16.

24 DORS/2003-2, <http://canlii.ca/t/69jq1>

25 (1999), LC 1999, c 33, <http://canlii.ca/t/69g3p>

26 Pursuant to Sections 204 and 205 of the Clean Air Act ("Act"), 42 U.S.C. §§ 7523 and 7524.

27 See complaint at UNITED STATES OF AMERICA, Ministry of justice, http://www.justice.gov/opa/file/809826/download and further settlement at https://www.toyotaelsettlement.com/, whereby the company alleges that " Toyota denies that it has violated any law, denies that it engaged in any and all wrongdoing, and denies that its ETCS is defective. The parties agreed to resolve these matters before these issues were decided by the Court " (see, similarly in Canada http://www.toyotaelsettlement.ca/index_en .html, and full settlement at http://www.toyotaelsettlement.ca/Documents/Compiled%20Toyota%20Canada%20Minutes%20Settlement%20Agreement%20-%20Executed%20August%206%202013%20%282%29.pdf).

28 For instance, in the UK : the Vehicle Certification Agency (VCA).

29 Directive 2007/46/EC establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, OJ no. L 263/1. The text replaces national approval systems " with a Community approval procedure based on the principle of total harmonisation " (2d Recital)

31 *Id.*, art. 10.1 (1). In this case, the Minister may " […] require any company that applies a national safety mark to any vehicle or equipment, sells any vehicle or equipment to which a national safety mark has been applied or imports any vehicle or equipment of a class for which standards are prescribed to give a notice of non-compliance in the manner specified by the Minister, if the Minister considers that it is in the interest of safety " (art. 10 (7)). Such powers could be used for Fiat models which alledgely do not comply to standard 108 of the Canada Motor Vehicle Safety Standard (CMVSS) 108 (which requires the backup lights to light up when the driver turns on the ignition switch and puts the vehicle in reverse). See TRANSPORT CANADA, Preliminary Determination -2012-2014 Fiat 500 and 500c with Automatic Transmission (online at http://www.tc.gc.ca/eng/motorvehiclesafety/safevehicles-defectinvestigations-1435.html).

facturers self-assess environmental compliance of their own vehicles both in Canada and the US. Of course, *ex-post* sales compliance checks may be carried on by competent authorities (in this case, EPA and Environment Canada). It may therefore seem paradoxical that the scandal broke out in a legal system where controls accrue primarily to the private sphere; just as it escaped the attention of the European authorities. Doesn't defeat, hence, go beyond compliance assessment strategies? Corporate misconduct here comes into play.

## IV. Bugs in Corporate Good Governance

An observer noted: "The Volkswagen debacle should be treated as an Enron moment for sustainability measurement and evaluation, with a comparable overhaul of the requirements for corporate accounting an evaluation".[32] In the stream of infamous Enron's heritage, truly enough, the scandal shook the very paradigm of corporate social responsibility (CSR) and responsible business conduct, which refer to "[...] companies taking responsibility *for their impact on society and to their actions over and above their legal obligations towards society and the environment*, strengthen the contribution of trade and investment to a sustainable growth and [...] support high levels of environmental and labour protection".FUßNOTE 103 NICHT GEFUNDEN Considering the responsible and "greenish" image, Volkswagen projected and nourished thoughtfully through marketing strategies, the debacle has taken enormous proportion that immediately bounced back into stock markets. Was the cost of the fraud to be deliberately internalized by the company? After all, safety was not the issue; *Ford Pinto*'s phantom never came into play. The anecdotical documentation and good sense –admittedly- seem to suggest that the installation of a software on a production line may not be done at the initiative of "a few engineers".

"What when wrong", however, still need to be assessed, as the different hypothesis formulated hereby analyzed by Raymonde Crête remain to be verified by internal and external inquiries. The very first step, she adds, consists in rapidly pinpointing liability *on someone* for the alleged misconduct. In the VW context, organizational features of the Group–stock options may well have backfired as they were precisely destined to stimulate productivity. Rather, she explains, race for profit may explain a deliberate strategy destined to lower production costs by curbing out environmental threshold, candidly waiting for fines, damages compensation and penalties, recalls, knowing that such trade-offs still allow a significant mark-up. After all, isn't the internalization of mishaps part of any good corporate governance?

The massive dimension of the "case" –in non-legal parlance- invites to a negative answer, considering that the incommensurable reputational damage caused to the Group rather suggests that such cowboy corporate practices were born of an unethical corporate strategy, or were the result of a more subtle faulty behavior that could not be neutralized with classical good governance tools, which include "accountability and to adherence, implementation, follow-up and dissemination of internationally agreed guidelines and principles".[34]

## V. Greenwashing: Between Unfair Practices and Product Liability Law

Facts to be confirmed at a later stage of the procedure and if they do not renounce contractually to their right of action following, say, a recall, most consumers will be in a position to ask for damages. At least two general legal categories could enter the picture: unfair commercial practices and/or product liability. These rights of action are not mutually exclusive; which means that they both could be embedded in the same line of procedure, as they fall into the greenwashing category Eric Lane has chosen to address in "Volkswagen and the High-tech Greenwash", describing the matter as "communicating false or misleading information about purported environmental benefits". Greenwashing has precedents in the car industry. Lane offers examples of previous cases involving misrepresentation of fuel consumption. What appears striking in the VW case –he adds- is the use of high-tech technology to deceive, "deep inside the vehicle where nobody could detect its actions". Does high-tech greenwashing fall into a legal black hole? Beyond problems linked to its actual discovery, this remains to be seen.

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32 G. WHITEMAN, "Volkswagen and the road to Paris", (2015) vol. 15 *Nature*, p. 38.

34 "Leaked" TTIP, at art. […] (art. 21).

Most –if not all- industrialized countries provide legal solutions to combat unfair commercial practices. In the EU, the Unfair Commercial Practical Directive (2005/29/EC[35]) provides that misleading acts and omissions are among unfair commercial practices. Using a defeat device certainly fits into the general category of unfair practices as defined at article 5 of the said Directive[36], as well as more specific ones – releasing false information about the main characteristics of a product- tucked in article 6 to 8. Penalties, however, are left to the Member States, who shall " shall take all necessary measures to ensure that these are enforced. These penalties must be effective, proportionate and dissuasive[37] ". In the present case, false representations consist in inducing the idea that the chosen vehicle would offer an economical energetic solution, whilst being environmentally friendly. From a domestic standpoint, this factual basis is likely to infringe Article 220 of Quebec's *Consumer Protection Act*[38], as "no merchant, manufacturer or advertiser may, falsely, by any means either: a) assign to a property or a particular benefit service; [...]".

Liability may also stem at the initiative of some States, by virtue of special legislation, as product liability may also provide grounds for litigation, as the information defect may have caused economic losses. In the US, more than 30 class actions have already been filed: plaintiffs altogether argued they purchased their cars "at least in part" because they thought they were purchasing environmentally friendly vehicles which met or exceeded federal emissions standards. In the past, some consumer-friendly States such as California have been willing to grant consumer compensation amounting to the difference between what they actually paid for a product and what they *would* have paid, had they known the defect. In the Toyota sudden-acceleration case, for example, a settlement was reached[39].

## VI. Conclusion

In the end, however, the consequences of the scandal may not proclaim any winner, and, by contrast, many losers. Unless VW executives have been blinded by an extraordinary race for profit (which seems unlikely, given the expected skills of its top managers), the Volkswagen case inspires two comments.

Ultimately and regardless of the legal outcome, the Volkswagen case shows that it may be unrealistic to rely on private industries to ensure "internalizing negative externalities" here, the costs associated with environmental protection- in the context of implementing sustainable development and corporate social responsibility. Through these lenses, sought for mutual recognition of assessment compliance procedures may be illusory if it is not counterbalanced by specific accountability measures. Hence there appears to be a need to maintain controls exercised by regulators on the economy, although there is a need, too, to ensure scientific and technological modernity in testing cars[40]. In the end, the scandal pinpoints classic questions linked to the multilevel state of motor vehicle regulation: is mutual recognition of assessment procedures sufficient to ensure safety and good business practices? Shouldn't a centralized, impartial regulator be endowed with the task of ensuring compliance?

There is, though, something stunning about VW's looping comment about the fact the scandal is related to emission, whereas "The safety of the vehicles is not affected[41] ". In view of traffic accidents: surely enough. Nevertheless, they weren't safe from a col-

35 Directive 2005/29/EC concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC and Regulation (EC) No 2006/2004, OJ no. 149, p. 22.

36 By virtue of the provision: " 1. Unfair commercial practices shall be prohibited. 2. A commercial practice shall be unfair if: (a) it is contrary to the requirements of *professional diligence* [which means « the standard of special skill and care which a trader may reasonably be expected to exercise towards consumers, commensurate with honest market practice and/or the general principle of good faith in the trader's field of activity » (art. 2 (h))]; and (b) *it materially distorts or is likely to materially distort* the economic behaviour with regard to the product of the average consumer whom it reaches or to whom it is addressed, or of the average member of the group when a commercial practice is directed to a particular group of consumers [that is, « to materially distort the economic behaviour of consumers' means using a commercial practice to appreciably impair the consumer's ability to make an informed decision, thereby causing the consumer to take a transactional decision that he would not have taken otherwise » (art. 2 (e))]" (emphasis added).

37 Directive 2005/29/EC, art. 13.

38 L.R.Q., c P-40.1.

39 See United States Judicial Panel on Multidistrict Litigation, *In re: Toyota Motor Corp. Unintended Acceleration Marketing, Sales Practices, and Products Liability Litigation*, MDL No. 2151, 9 April 2010 (J. Selna).

40 That is, " Real Driving Emission Tests " : voir De Sadeleer, *id*.

41 https://www.vwemissionsinfo.ca/ (last visited Feb. 18th.); see also the same comment on German site : " Fest steht: Die Fahrzeuge sind weiterhin technisch sicher und fahrbereit und können deshalb uneingeschränkt im Straßenverkehr genutzt werden " http://www.volkswagen.de/de/volkswagen-aktuell/News.suffix.html/2015~2Fnox-thematik.html (last visited Fed. 18th).

lective perspective. The reduction of GHG is part of the worldwide fight against climate changes. Underestimating the causal link between these two variables –GHG and health problems- precisely explains the difficulties experienced by the international community to combat them, whereas it discredits those companies who are precisely asked to self-regulate themselves.

# Harmonizing Car Emissions, Air Quality, and Fuel Quality Standards in the Wake of the VW Scandal

## How to Square the Circle?

*Nicolas de Sadeleer**

## I. Introduction

Given that cars have become icons for flexibility, individuality, and freedom,[1] it comes as no surprise that the passenger car fleet in almost all of the EU Member States is constantly growing. In 2010 there were about 239 million heavy-duty vehicles and 35 million light-duty vehicles in the then 27 Member States, more than a quarter of the cars and trucks on the road worldwide. It is expected that this number will grow by 31% by 2030.[2] Not only has the number of vehicles grown constantly over recent decades, but the distance travelled by each has increased as well. Cars, and the industries producing them, do however have significant impacts on the environment ranging from smog to climate change.

In the wake of the VW scandal, it is the purpose of this article to explore some of the key issues arising out of the discussion of the EU environmental regulatory techniques aiming at tackling air pollution. Given that we have attempted to capture where the law stands at present, there is no need to delve into the technical and scientific controversies.

To shed light on the effectiveness of EU law, the next section looks at the principles governing the choice of legal bases in the area of air pollution (Section II). It concludes by outlining the two-pronged approach that the EU institutions have followed since the early 70s. The merits and drawbacks of the different regulatory techniques are adumbrated in Section III. We put our finger on the following paradox: though car emission standards have been gradually tightened, ambient air quality has not really improved in a number of cities. Last but not least, in Section IV, we closely examine the inappropriateness of the different test methods that are implemented in a haphazard fashion by 28 State authorities.

This article primarily aims at discussing pollution impacts from light cars powered by gasoline and diesel. Accordingly, CO2 emissions are debated incidentally.[3]

## II. Principles Governing the Choice of Legal Bases in the Area of Air Pollution

Each piece of EU legislation must be rooted in one or more legal basis set out either in the Treaty on the European Union (TEU) or in the Treaty on the Functioning of the European Union (TFEU). The determination of the relevant legal base is required in light of the principle of the allocation of powers, the duty to preserve the prerogatives of the EU institutions, the obligation to state reasons, and the requirement of legal certainty.[4] Needless to say, the choice of legal basis of pieces of legislation aiming at protecting the air quality represents a critical juncture in relations between institutions, as well as the relations between the Member States and the EU. First, in defining the scope of the EU's intervention, the legal base enables the EU to exercise its legislative competence in such

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1 N.A. Ashford and C.C. Caldart, *Environmental Law, Politics, and Economics* (Cambridge: MIT Press, 2008) p. 462.

2 The International Council on Clean Transportation (ICCT), *European Vehicle Market Statistics,* 2013, p. 6.

3 Attention should be drawn to the fact that light-duty vehicles – cars and vans – produce around 15% of the EU's emissions of $CO_2$. These emissions are regulated by Regulation (EC) No 443/2009 of the European Parliament and of the Council of 23 April 2009 setting emission performance standards for new passenger cars as part of the Community's integrated approach to reduce $CO_2$ emissions from light-duty vehicles, OJ L 140, p. 1.

4 Case C-370/07 *Commission v Council* [2009] ECR I-8917, paras. 37, 39, 46, and 48. It must be noted that AG Kokott stressed in addition to these obligations the principle of transparency (paras. 37 and 38).

a field.[5] Moreover, the basis chosen determines not only which institution has competence to take action but also the procedure to follow and the objective pursued. Furthermore, it also determines the types of acts that can be adopted. Just as the powers of the Commission, the Parliament and the Council are capable of varying considerably depending on the procedure used, they can also end up expressing contradicting preferences as regards the choice to be made between the different legal bases provided for.

Regarding the EU secondary legislation on pollution caused by light cars, it is possible to trace the dividing line between the Treaty provisions governing the internal market and the environment, respectively.

On the one hand, the rise of environmental policy was undeniably born out of the concern to avoid distortions of competition between undertakings. To give the national authorities free rein to enact unilateral product and operating standards would entail the risk of fragmenting the internal market and hindering the free movement of goods within that market. Against this backdrop, a significant number of product-oriented directives and regulations which have a direct impact on the internal market, and in particular those which lay down product standards, were adopted on the basis of the old Article 100a EC (Article 114 TFEU) within the perspective of the completion of the internal market. This has been the case of the first generation of directives on car emissions (Directive 70/220/EEC). It follows that the directives and regulations laying down fuel quality standards and limiting the emissions from cars[6] have been founded exclusively on Article 114 TFEU.

On the other side of the dividing line, a residual category embraces all acts for which an analysis of the aim and the content of the measure shows that they seek to achieve a high level of environmental protection and that they at most affect the establishment of the internal market on an ancillary base. Despite their direct or potential impact on the functioning of the internal market, these acts should be adopted on the basis of Article 192 TFEU. This is the case of the directives laying down air quality standards (Directive 2008/50/EC).

Neither Article 192 TFEU nor Article 114 TFEU specify that a particular legal act should be used in order to harmonize environmental measures. Accordingly, the environmental policy reckons upon the five legal acts listed in Article 288 TFEU (directive, regulation, decision, recommendation and opinion).

That being said, the stakes are high given that the power to enact more stringent standards than the ones embodied in secondary law varies depending on the legal basis chosen by the Union legislator. In effect, for each of these provisions, the TFEU provides for fundamentally distinct exceptions.[7] In virtue of Article 193 TFEU, any Member State may at any time freely decide to maintain or adopt more stringent standards than those provided for under the act adopted on the basis of Article 192 TFEU. It follows that nothing precludes a Member State from applying more stringent quality standards than the ones set out in Directive 2008/50/EC. The ability for the lawmaker to rely on that provision amounted to a notable exception to the concept of maximum harmonization.

In sharp contrast to Article 193 TFEU, Article 114 restricts the Member States' powers to enact derogating provisions. In that connection, the Dutch Diesel restrictive measure is a case in point. Arguing that the limits on concentrations of particulate matter laid down by the former Air Quality Directive 1999/30 were exceeded in several areas of its territory, the Netherlands notified the Commission in 2005, pursuant to Article 95(5) EC (new Article 114(5) TFEU), of its intention to adopt a decree subjecting, from 1 January 2007 and by derogation from the provisions of Directive 98/69,[8] new diesel-powered vehicles in Categories $M_1$ and $N_1$, Class I, to a limit on emissions of particulate matter of 5 mg/km. Paragraph 5 of Article 114 authorizes the Member States to implement, in certain conditions, more stringent measures than those provided for by a EU harmonizing norm, even though the relevant directive, decision or regulation does not expressly recognize this right. The Dutch

5 Article 5(1) TEU provides that 'The limits of Union competence are governed by the principle of conferral'. Accordingly, competence is conferred on the EU by a swathe of Treaty provisions in order to achieve objectives particular to those provisions, read in the light of the general objectives of the EU. As a result, the legal base occupies centre stage inasmuch as it identifies the competence under which EU institutions act.

6 Directive 2006/40/EC of the European Parliament and of the Council of 17 May 2006 relating to emissions from air-conditioning systems in motor vehicles, OJ L 161/12.

7 N. de Sadeleer, *EU Environmental Law and the Internal Market* (Oxford: OUP, 2014) pp. 349-382; I. Maletic, *The Law and Policy of Harmonisation in Europe's Internal Market* (Chelttenham: E. Elgar, 2013) pp. 94-105.

8 See infra, section II, 3.

authorities emphasized, in that context, the high demographic density and greater concentration of infrastructure in the Netherlands than in other Member States, which gave rise to a higher rate of emissions of particulate matter per square kilometre. Residents were thus very exposed to air pollution, particularly, in the immediate proximity of automobile traffic zones and residential zones.

Pursuant to Article 114(5) TFEU, national measures derogating from EU internal market legislation should satisfy three requirements: the risk that the measure is supposed to counter should be specific to the Member State requesting the derogation, it should manifest itself after the adoption of the harmonization measure, and should be supported by scientific proof. In its request in favour of more stringent limits on the emissions of particulate matter by diesel-powered vehicles, the Dutch authorities were claiming that for a problem to be specific to a Member State within the meaning of paragraph 5, it was not necessary that it be the result of an environmental danger within that State alone. Though the General Court acknowledged, indeed, that for a problem to be specific 'it is not necessary that it is the result of an environmental danger within that State alone', the Court rejected the Government's argument relating to the interpretation of the criterion of specificity as lacking any factual basis.[9] That judgment was set aside by the Court of Justice of the EU (CJEU) on the grounds that the Commission was obliged to demonstrate that there were no specific problems. Such an obligation flows from the Commission's obligation 'both to examine all the relevant elements of the individual case and to give an adequate statement of the reasons for its decision'.[10]

## III. Clean Air Regulatory Techniques

Environmental law is partly reckoning upon a flurry of technical standards. A division can be made between those that are set by reference to the medium (air) being subject to protection and those that are set by reference to the sources of pollution. Among the source-related standards, a further division must be made between emission standards (emission limit values) and product standards.[11] These techniques are not exclusive from each other.

### 1. Emission Limit Values

#### a. General Considerations

Let us begin by considering emission limit values (ELV), or disposal standards, that limit the direct or indirect release of substances, vibrations, heat or noise and other pollutants by fixed polluting facilities (plants, facilities, and industries) or diffuse sources into the air, water or land. These standards are 'expressed in terms of certain specific parameters, concentration and/or level of an emission, which may not be exceeded during one or more periods of time'.[12]

Most EU harmonization measures are therefore based on thresholds which may not be exceeded. Concretely speaking, motor vehicle emissions have originally been regulated by Directive 70/220/EEC (light-duty vehicles) and 88/77/EC (heavy-duty vehicles), as further amended. In fact, a whole series of modifications have been issued to gradually tighten the limit values.

For *heavy-duty vehicles*, Directives 2005/55/EC[13] and 2005/78/EC (implementing provisions)[14] define the emission standards currently in force. In addition, they define a non-binding standard called Enhanced Environmentally-friendly Vehicle (EEV).

For *light-duty vehicles,* the emissions standards were laid down by Directive 98/69/EC relating to measures to be taken against air pollution by emissions

9 Case T-182/06 *Netherlands v Commission* [2007] ECR I-1983, paras. 63-72.

10 Case C-405/07 P *Netherlands v Commission* [2008] ECR I-8301, para. 66.

11 S. Bell, D. McGillivray, O. Pedersen, *Environmental Law,* 8th ed. (Oxford: OUP, 2013), p. 239.

12 Article 3(4) and (5) of Directive 2010/75/EU of the European Parliament and the Council of 24 November 2010 on industrial emissions, OJ L344/17.

13 Directive 2005/55/EC of the European Parliament and of the Council of 28 September 2005 on the approximation of the laws of the Member States relating to the measures to be taken against the emission of gaseous and particulate pollutants from compression-ignition engines for use in vehicles, and the emission of gaseous pollutants from positive-ignition engines fuelled with natural gas or liquefied petroleum gas for use in vehicles, OJ L 275, pp. 1–163.

14 Commission Directive 2005/78/EC of 14 November 2005 implementing Directive 2005/55/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to the measures to be taken against the emission of gaseous and particulate pollutants from compression-ignition engines for use in vehicles, and the emission of gaseous pollutants from positive ignition engines fuelled with natural gas or liquefied petroleum gas for use in vehicles and amending Annexes I, II, III, IV and VI thereto, OJ L 313, p. 1.

from motor vehicles, which was one of the directives amending Directive 70/220/EEC.

The type-approval emission requirements for motor vehicles pollutants (CO, NOx) have been gradually and significantly tightened through the introduction and subsequent revision of a flurry of Euro standards.[15] The Euro standards are formulated using a split-level approach: the key aspects are encapsulated in a legal act (Directive 70/220 and, later, Regulation 75/2007) that the Council and the European Parliament may adapt in accordance with the ordinary legislative procedure, whereas technical aspects are regulated by means of implementing measures to be adopted in accordance with Article 291 TFEU by the Commission flanked by a Committee. With respect to implementing powers, the European Commission is endowed with much leeway in setting out the thresholds. In sharp contrast, given the risk of regulatory capture, the US Congress chose in the 70s to establish the car emission standards itself rather than delegate the task to an administrative body.[16]

The introduction of the Euro 1 standard in 1992 required the switch to unleaded petrol and the fitting of catalytic converters to petrol cars to reduce carbon monoxide (CO) emissions. The Euro 2 standard further reduced the limit for CO emissions and also reduced the combined limit for unburned hydrocarbons and oxides of nitrogen for both petrol and diesel vehicles. Since the Euro 2 stage, EU regulations introduced different emission limits for diesel and petrol vehicles. Euro 3 also added a separate NOx limit for diesel engines and introduced separate HC and NOx limits for petrol engines. With respect to light vehicles, Euro 4 lowered NOx emissions from 0,50 to 0,25 g/km and PM10 emissions from 0,005 to 0,0025 g/km.

In 2007, Directive 70/220/EEC was repealed and replaced by Regulation (EC) No 715/2007 of the European Parliament and of the Council of 20 June 2007 which harmonizes the technical emission standards - known as EC type-approval - for motor vehicles.[17] Tighter emission limits, known as Euro 5 and Euro 6, of atmospheric pollutants such as particulates and nitrogen oxide for vehicles sold in the EU market were established. Manufacturers are called on to prove that all new vehicles sold, registered or put into service comply with the emission standards set out in the regulation.

Euro 5 applied to passenger cars and light-duty vehicles of categories M1, M2, N1 and N2 (all with a reference mass not exceeding 2,610kg) and was mandatory for vehicles registered from the 1st January 2011 or from the 1st January 2012 for some vehicles. Euro 5 further tightened the limits on particulate emissions from diesel engines from 25mg/km to 5mg/km. In addition, all diesel cars needed particulate filters to comply with the new requirements.

Given that the share of diesel vehicles in the overall sales of light-duty vehicles is increasing, Euro 6 requires the reduction of emissions of NOx from diesel cars from 180mg/km to 80mg/km. Euro 6 thresholds apply to new vehicle registrations from 2015. The Euro 6 emission limits range from 68% (gasoline carbon monoxide) to 96% (diesel particulates) lower than those established under Euro 1 in 1992. Accordingly, their implementation was somewhat challenging given that in 2012, less than 1% of new vehicles already complied with the Euro 6 standard, while 91% of all cars sold complied with the Euro 5 standard.[18]

The Euro 5 and Euro 6 ELVs are summarized in the tables 1 and 2.

*Table 1: European emission standards for gasoline passenger cars, g/km*

| | Date | CO | NOx | PM |
|---|---|---|---|---|
| Euro 5 | September 2011 | 0,50 | 0,180 | 0,005 |
| Euro 6 | September 2014 | 0,50 | 0,80 | 0,005 |

15 Given the absence of harmonization of eco-taxes, Member States have significant freedom to carry out their environmental tax policies with a view to encouraging the best environmental standards. Taxation on second-hand vehicles compatible with Euro standards has been giving rise to litigation. See N. de Sadeleer, *EU Environmental Law and the Internal Market*, supra note 7, pp. 237-259. Regarding the compatibility of a pollution tax levied on first registration of second-hand vehicles compatible with Euro 3 and Euro 4 air pollution standards is consistent with Article 110 TFEU, see Case C-254/13 *Orgacom BVBA* [2014] C:2014:2251. Whether a Rumanian environmental tax levied on first registration of motor of second-hand vehicle compatible with Euro 2 air pollution standards is discriminatory, see Case C-263/10 *Iulian Nisipeanu v Direcția Generală a Finanțelor Publice Gorj and Others* [2011] C:2011:466.

16 N.A. Ashford and C.C. Caldart, supra note 1, p. 472.

17 The specific technical provisions necessary to implement that regulation were adopted by Commission Regulation (EC) No 692/2008.

18 The International Council on Clean Transportation, *European Vehicle Market Statistics 2013*, p. 6.

*Table 2: European emission standards for diesel passenger cars, g/km*

| | Date | CO | NOx | PM |
|---|---|---|---|---|
| Euro 5 | September 2011 | 1,0 | 0,180 | 0,005 |
| Euro 6 | September 2014 | 1,0 | 0,80 | 0,005 |

All in all, NOx emissions limits for diesel vehicles have been tightened as illustrated by table 3.

*Table 3*

| Euro standards | NOx emissions thresholds | Entry into force |
|---|---|---|
| Euro 3 | 500 mg/km | January 2000 |
| Euro 4 | 250 mg/km | January 2005 |
| Euro 5 | 180 mg/km | September 2009 |
| Euro 6 | 80 mg/km | September 2014 |

19 N. de Sadeleer, *EU Environmental Law and the Internal Market*, supra note 7, pp. 199-202.

20 ACEA – European Automobile Manufacturers' Association; JAMA – Japanese Automobile Manufacturers' Association, and KAMA – Korean Automobile Manufacturers' Association.

21 See Communication from the Commission, Results of the review of the EU Strategy to reduce $CO_2$ emissions from passenger cars and light-commercial vehicles, COM (2007) 19 final. E.g. L. Krämer, *EC Environmental Law*, 6th ed. (London: Sweet & Maxwell, 2007), p. 316.

22 Given that the car industry was unable to reach its own objectives as set out in these three agreements, in February 2007 the Commission acknowledged the need to replace this conciliatory approach with a genuine regulatory approach. As a result, the Commission proposed the Council and the European Parliament to adopt a regulation setting emission performance standards for new passenger cars as part of the EU's integrated approach to reduce $CO_2$ emissions from light-duty vehicles. See Regulation (EC) No 443/2009 of the European Parliament and of the Council of 23 April 2009 setting emission performance standards for new passenger cars [2009] OJ L 140/1–15.

23 N. de Sadeleer, *EU Environmental Law and the Internal Market*, supra note 7, pp. 211-212.

24 The articulation between the two techniques is somewhat haphazard. In Joined Cases C-165/09 to C-167/09 *Stichting Natuur en Milieu and Others* [2011] C:2011:348, the Court looked into the question of the interpretation of IPPC Directive 2008/1, which establishes the principles that govern the procedures and conditions for granting permits for the construction and operation of large industrial installations, and of Directive 2001/81, which introduces a system of national emission ceilings for certain

## b. Advantages and Drawbacks of ELVs

The ELV technique plays an essential yet controversial role in EU environmental law. From the outset, it is against the background of self-regulation that the value of ELVs must be assessed.[19] It must be noted that self-regulation has been seen as a response to deficiencies both of administrative regulation and economic instruments. However, several participatory approaches endorsed by the European Commission failed. Among the agreements concluded under the aegis of the European Commission, the most well-known and controversial was the one concluded between the federations of carmakers, which undertook to apply measures reducing $CO_2$ emissions - below the threshold of 140 gm/km. In 1999 and 2000, the Commission endorsed the three agreements concluded by the business federations regrouping carmakers.[20] The Commission endorsed the reduction targets relating to $CO_2$.[21] Given that this approach has not borne fruit, the EU lawmaker adopted a decade later Regulation (EC) No 443/2009 setting emission performance standards for new passenger cars.[22]

The enactment of the Euro ELVs entails three obvious advantages.[23]

First, given that the Euro ELVs are binding, an infringement is an automatic result of any failure to respect them. The binding thresholds thus set a dividing line between what is lawful and what is unlawful.

Second, the harmonisation of ELVs on EU level is particularly valued by the car industry, since the adoption of uniform standards limits the distortions in competition resulting from decisions taken on a case by case basis by 28 national agencies, which creates uncertainty. Hence, thresholds are likely to buttress legal certainty and enhance a smooth functioning of the internal market.

Third, ELVs are in principle set in line with scientific criteria. Experts, who play an essential role, are accordingly consulted in order to identify the threshold above which pollution becomes problematic, and should accordingly be prohibited by EU law. However, ELVs do offer absolute environmental protection provided that they are set and applied in order to avoid that EQS are exceeded.[24] As discussed below, the interconnection between ELVs and EQS is far from obvious.

In spite of their benefits, the scientific foundation of the ELVs is likely to be undermined where the

thresholds result from a compromise between the car industry and the EU institutions.[25] It comes as no surprise that the protection level offered by setting out emission thresholds essentially remains the fruit of a political compromise, which proves to be particularly problematic since it is science itself that is uncertain. Indeed, the level of protection is more the result of a pragmatic, gradual approach and a search for the possibilities than a desire to implement in detail the scientific experts' recommendations. It is noteworthy that the more stringent Euro 5 standards have fallen short in addressing major ambient air pollution events in London, Paris, Brussels, Madrid, Lyon, etc.

Three factors explain why a clean air policy in major cities is doomed for failure. On the one hand, EU emission standards do not influence the manner in which cars are driven, which significantly impacts the air quality.[26] On the other hand, the reductions in air emissions have constantly been eaten up by an overall increase in traffic.[27] Indeed, accumulation of car exhausts within cities gives rise to significant concerns on the grounds that quality thresholds are exceeded. What indeed is the point of equipping cars with new technologies if the number of cars and total kilometres travelled constantly increases?

Last, the technique of compartmentalising the regulations that applied to different media makes it possible to circumvent ELVs. In effect, as discussed below, the laboratory New European Driving Cycle (NEDC) tests did not accurately reflect the amount of air pollution emitted during real driving conditions. As a result, while vehicles in general have delivered substantial emission reductions across the range of regulated pollutants, this was not the case for NOx emissions from diesel engines, in particular light-duty vehicles.[28]

## 2. Product Standards

### a. General Considerations

Product standards are those which set limits on pollution or nuisance levels and may not be exceeded both as regards the product's composition as well as its emissions.[29] In the course of the 90s, under the Auto/Oil programme, initiatives were taken to carve out combined solutions concerning car emissions and fuel composition.

Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998, relating to the quality of petrol and diesel fuels and amending Council Directive 93/12/EEC,[30] sets technical specifications on health and environmental grounds for fuels to be used for vehicles equipped with positive-ignition and compression-ignition engines.'[31] From 1 January 2000, the Member States were prohibited from allowing lead in petrol within their territory.[32] Directive 2009/30/EC[33] amended Directive 98/70/EC as regards the specification of petrol, diesel and gas-oil. In addition, the 2009 directive establishes sustainability criteria that must be met by biofuels if they are to count towards the greenhouse gas intensity reduction obligation.

Since 1 January 2009, the Member States are called on to ensure that diesel fuel may be marketed in their territory provided it complies with the environmen-

pollutants (SO2 and NOx). The Court held that, when granting an environmental permit for the construction and operation of an industrial installation, the Member States are not obliged to include among the conditions for grant of that permit the national emission ceilings for SO2 and NOx laid down by Directive 2001/81.

25 In the course of the 90s, under the Auto/Oil I programme, the European Commission set up working groups where the representatives of European car associations and petrol industries were invited to share their expertise. NGOs did not take part in these groups. In contrast, different stakeholders among which environmental NGOs took part in the Auto/Oil II programme. See L. Krämer, *EC Environmental Law*, above, pp. 315-316.

26 S. Bell, D. McGillivray, O. Pedersen, supra note 11, p. 245.

27 L. Krämer, *EC Environmental Law*, supra note 21, p. 316.

28 Preamble, para. 4 Commission Regulation amending Regulation (EC) No 692/2008 as regards emissions from light passenger and commercial vehicles (Euro 6).

29 A product standard is defined by ISO as 'a document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that products, … are fit for their purpose'.

30 OJ 1998 L 350, p. 58.

31 Article 1. Directive 98/70/EC was amended by Directive 2009/30/EC of the European Parliament and of the Council of 23 April 2009 with the aim of dealing with the marketing of diesel fuels with a higher biofuel content.

32 Article 3(1).

33 Directive 2009/30/EC of the European Parliament and of the Council of 23 April 2009 amending Directive 98/70/EC as regards the specification of petrol, diesel and gas-oil and introducing a mechanism to monitor and reduce greenhouse gas emissions and amending Council Directive 1999/32/EC as regards the specification of fuel used by inland waterway vessels and repealing Directive 93/12/EEE, OJ L 140, pp. 88–113.

tal specification set out in Annex IV except for the sulphur content which shall be a maximum of 10 mg/kg. [34] Limits are laid down in that annex for the following parameters: cetane number, density at 15° C, distillation, polycyclic aromatic hydrocarbons and sulphur content.

Departing from the principle of maximum harmonization, Article 6 of the directive empowers the Member States to enact more stringent environmental specifications. That provision states:

> '1. By way of derogation from Articles 3, 4 and 5 and in accordance with Article 95(10) of the Treaty, a Member State may take measures to require that in specific areas, within its territory, fuels may be marketed only if they comply with more stringent environmental specifications than those provided for in this Directive for all or part of the vehicle fleet with a view to protecting the health of the population in a specific agglomeration or the environment in a specific ecologically or environmentally sensitive area in that Member State, if atmospheric or ground water pollution constitutes, or may reasonably be expected to constitute, a serious and recurrent problem for human health or the environment.
>
> 2. A Member State wishing to make use of a derogation provided for in paragraph 1 shall submit its request in advance, including the justification for it, to the Commission. The justification shall include evidence that the derogation respects the principle of proportionality and that it will not disrupt the free movements of persons and goods.'

The CJEU ruled recently that Directive 98/70/EC does not preclude a Member State 'from laying down in its national law quality requirements that are additional to the ones contained in that directive for the marketing of diesel fuels, such as that relating to the flash point at issue in the main proceedings, since it does not constitute a technical specification of diesel fuels relating to the protection of health and the environment for the purposes of that directive'.[35]

### b. Advantages and Drawbacks of Product Standards

One is always facing the risk that the product thresholds reflect more of a political compromise than a genuine technical judgment.

As discussed above,[36] whether the provisions of Directive 98/69 contribute effectively to limit the emissions of particulate matter in very populated countries with a great concentration of infrastructure remains to be seen.

## 3. Environmental Quality Standards

### a. General Considerations

Environmental quality standards *(EQS)*, or quality targets, means 'the set of requirements which must be fulfilled at a given time by a given environment or particular part thereof'. [37] Regarding air pollution, EQS are set numerically (parts of a substance per million or mg/m3).

A key outcome of the 2005 Thematic Strategy on air pollution adopted by the Commission in September 2005, Directive 2008/50/EC on ambient air quality and cleaner air for Europe entered into force on 11 June 2008. Directive 2008/50/EC merges several air quality directives in a single legislation - except for the fourth daughter directive[38] - with no change to existing air quality objectives.

Directive 2008/50/EC sets out limit values and target values for several pollutants (sulphur dioxide, PM10 and PM2.5, benzene, CO, lead, nitrogen dioxide and oxides of nitrogen). In addition, it distinguishes alert and limit values (for human beings) from critical levels (for ecosystems, plants, and trees).

Regarding PM10 values, it establishes a daily limit value for PM10 of 50µg/m³ not to be exceeded more than 35 times a calendar year; annual limit value for PM10 of 40µg/m³; hourly limit value for NO2 of 200µg/m³ not to be exceeded.

It introduced new air quality objectives for PM2.5 (fine particles) including the limit value and exposure related objectives – exposure concentration obligation and exposure reduction target.

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34 Article 4.

35 Case C-251/14, *György Balázs* [2015] C:2015:687, para. 44.

36 Case T-182/06 *Netherlands v Commission* [2007] ECR I-1983.

37 Article 1(6) of Directive 2010/75/EU of the European Parliament and the Council of 24 November 2010 on industrial emissions, OJ L 344, p. 17.

38 Directive 2004/107/EC of the European Parliament and of the Council relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air.

What is more, where target values or limit values are exceeded Member States are called on to enact an air quality plan.[39] Such plan shall contain the appropriate measures to attain the relevant values.

Although air quality has improved over the past decade thanks to these standards, all EU citizens are still exposed to levels of air pollution that the WHO considers harmful to health.[40] Given the high levels of air pollution, there are 400,000 premature deaths annually, 10 times the number killed in road accidents. The health problems are particularly acute throughout the EU, especially in urban areas and densely populated regions. In addition, the Commission is of the view that pollution is giving rise to 15 billion annual workday losses and annual damage between 330 and 940 billion euro.[41] According to the EEA 2015 report, 'the annual limit value for nitrogen dioxide (NO2) was widely exceeded across Europe in 2013, with 93% of all exceedances occurring close to roads. A total of 19 of the 28 EU Member States recorded exceedances of this limit value at one or more stations. Of the EU-28 urban population, 9% lives in areas in which the annual EU limit value and the WHO AQG for NO2 were exceeded in 2013'.[42]

This is giving rise to litigation at both the EU and domestic levels. On the one hand, the European Commission has initiated infringement proceedings in accordance with Article 258 TFEU against 18 Member States for breaching the limits on PM10 and NO2. On the other hand, several NGOs have initiated proceedings against their national agencies on the grounds that they do not comply with Directive 2008/50/EC EQS. By way of illustration, in *ClientEarth v Secretary of State for the Environment, Food and Rural Affairs,* the Supreme Court referred certain questions to the CJEU, who answered them in a judgment dated 14 November 2014 (Case C- 404/13).[43] Following these precisions, in April 2015, ClientEarth won a landmark case against the UK Government for failing to tackle air pollution. In its judgment, the Supreme Court ordered the UK Government to produce new plans to bring air pollution within legal limits as soon as possible. [44]

## b. Advantages and Drawbacks of EQS

The advantages of setting EQS are threefold.

Firstly, EQS cover all pollutants irrespective of their sources whereas ELVs tend to permit the accumulation of a specific pollutant (NOx, for instance) given the rise in traffic transportation in urban areas.[45] These standards provide guarantees of the quality of the air striking a balance between the quality of the environmental medium and the concentration of pollutants.

Secondly, ELVs and EQS should go hand in hand. Indeed, emission standards have to be set with a view to improving air quality. Accordingly, air quality should improve thanks to the introduction of the tougher Euro 6 ELVs.

Thirdly, EQS offer more flexibility to regional or local authorities. Given the sensitivity of some areas (urban areas) more stringent EQS have to be applied in accordance with Article 193 TFEU.

On the negative side, Directive 2008/50/EC EQS offers plenty of grist for debate on the grounds that the legislation leaves the Member States a considerable amount of leeway.[46]

Traditionally, the breach of EQS does not provide an immediate indication of the action to be taken. It signals that the concentration of pollutants exceeds the threshold.[47] Accordingly, they tend to be set as objectives rather than as legal requirements. [48] As a result, they may give 'no incentive to polluters to improve their performance in areas in which the standard is already being met'. [49] Last but not least, EQS are less easy to control and to enforce than ELVs.

Table 4 differentiates the three regulatory techniques discussed above.

Furthermore, EU policy regarding the impacts of cars on air quality can also be conveniently divided into two headings: air quality and product standards. Table 5 summarizes the techniques applied with respect to both the quality of the air and the emission sources (fuels and cars).

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39 Article 23(1).

40 EEA, *Air quality in Europe —2013 Report.*

41 Report of the European Commission, Improving Air Pollution, 2013.

42 EEA, *Air quality in Europe — 2015 report,* 5/2015, p. 8.

43 Case C-404/13 *ClientEarth* [2014] C:2014:2382.

44 *ClientEarth v Secretary of State for the Environment, Food and Rural Affairs,* 29 April 2015.

45 S. Bell, D. McGillivray, O. Pedersen, *supra* note 11, p. 244.

46 J.H. Jans and H.H.B. Vedder, *European Environmental Law,* 4th ed. (Groeningen: Europa Law, 2012), p. 421.

47 N. Haigh, *EEC Environmental Policy and Britain,* 2nd ed. (Longman, 1990), p. 17.

48 S. Bell, D. McGillivray, O. Pedersen, *supra* note 11, p. 244.

49 Ibid., p. 244.

*Table 4: Typology of environmental regulatory techniques applied to air polution caused by cars*

| | EQS | ELV | Product standards |
|---|---|---|---|
| Legislation | Directive 2008/50 | Regulation 715/2007 | Directive 98/70 |
| Objective | Set of concentrations of pollutants which must be fulfilled at a given time in the air | Standards expressed in terms of level of an emission | Standards setting limits on concentrations of pollutants in the gasoline and in the diesel |
| Addressees | Authorities | Car producers or importers | Gasoline or diesel producers or importers |
| Level of stringency | Different course of actions can be triggered in case of exceedances (alert values, limit values, enactment of an air quality plan, etc.) according to the pollutant at issue | Inasmuch as the operator does not exceed the ELVs, he is free to choose the technology | Standards not to be exceeded as regards the fuel's composition |
| Sanctions | Administrative measures | Administrative and criminal sanctions | Administrative and criminal sanctions |

## IV. Emission Test cycle

Just as important as the emission standards are the tests needed to ensure the proper compliance with these standards. These are laid out in a standardized emission test cycle aiming at measuring emissions performance against the regulatory thresholds applicable to the tested vehicle. At this stage, two separate, albeit related, issues must be distinguished. The first issue concerns the CE certificate procedure. Closely related to this is the issue of whether the tests are rigorous enough.

### 1. The Flaws of the Type-approval Procedure

Directive 2007/46/EC [50] provides the Member States with a common legal framework for the approval of motor vehicles. Under the type-approval regime, before being placed on the market, the vehicle type is tested by a national technical service. The national approval authority then delivers the approval ('CE certificate') on the basis of these tests. The manufacturer may make an application for approval in any EU country. Thanks to the principle of mutual recognition, the CE certificate is valid throughout the EU. In other words, it suffices that the vehicle is approved in one EU Member State for all vehicles of its type to be registered with no further checks throughout the EU on the basis of their certificate of conformity. However, from an environmental perspective, the system appears to be somewhat flawed. Firstly, given that the national approval authorities' incomes stem from the manufacturers, one could call into question their independence. Secondly, given that the type-approval granted is valid throughout the EU, the national approval authorities are likely to compete with each other.[51] Thirdly, these authorities do not have access to the software which the manufacturer uses.

### 2. The Flaws of the Testing of Air Emissions Limits

With respect to light vehicles, since the Euro 3 regulations in 2000, performance has been measured us-

50 Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (Framework Directive), OJ L 263, p. 1.

51 L. Krämer, personal communication.

*Table 5: Air quality and product standards*

| LEGAL INSTRUMENTS | AIR QUALITY | PRODUCTS |
|---|---|---|
| Legal bases | Article 192 TFEU | Article 114 TFEU |
| Instruments | Framework directives (Directive 2008/50) | Directives and regulations laying down product standards and ELVs (Regulation 715/2007, Directive 2009/30/EC) |
| Level of integration | Decentralisation | Centralisation at EU level |
| Principles | Prevention, precaution, and rectification at source | Prevention, precaution, and substitution |
| Ex ante assessments | Impact Assessment of proposed legislation | Substance risk assessments |
| Authorisation | — | No product can be placed on the market without a prior authorisation |
| Restrictions | Traffic restrictions, process standards likely to be underpined by EQS | Prohibition or restrictions on the use of hazardous products either in cars or in fuels |
| Participation | Public enquiry decided at domestic level with respect to the establishment of air quality plans | — |
| Information for the public | Alert and information values (Directive 2008/50); Access to environmental information (Directive 2003/4) | Environmental labelling (Regulation 443/2009) |
| Control | Administrative enforcement | Life-cycle approach |

ing the New European Driving Cycle (NEDC). Emissions standards for heavy-duty vehicles have been subject to different test requirements.

In spite of the fact that air emissions limits for cars have been progressively tightened, obsolete laboratory testing contribute to explain why they actually remained unenforced. In effect, laboratory tests do not accurately reflect the amount of air pollution emitted during real driving conditions. Several devices are likely to be applied with a view to reducing the emissions (electrical instruments being switched off, battery fully charged, over-inflated tyres, folding of side mirrors, etc.). A consequence of the disparity between the recent Euro standards and the NEDC has been persistent air quality problems, in particular in urban areas.[52] It comes thus as no surprise that according to Commission data, currently produced Euro 6 diesel cars exceed the NOx limit 4-5 times (400%) on average in real driving conditions compared to laboratory testing. In testing 15 Euro 6 diesel cars, the International Council on Clean Transportation (ICTT) found breaches of the 80 mg/km NOx threshold ranging from 2 to 22 times in different vehicles.[53]

52 International Council for Clean Transportation (ICTT), *European Vehicle Market Statistics 2013*, p. 11.

53 International Council for Clean Transportation (ICTT), *Assessment of PEMS Datasets from Modern Diesel Passenger Cars*, 20th International Transport and Air Conference, 2014.

To make matters worse, though EU law expressly forbids the use of a defeat device,[54] VW admitted on 20 September 20 2015 that it had systematically used a so-called defeat device in its engines with the aim of optimizing apparent emission performance during the emissions test cycle. On 23 September 2015, the undertaking admitted that worldwide, some 11.5 million cars had been manipulated. On 3 November, it acknowledged that up to 800,000 cars had been manipulated to demonstrate low CO2 emissions. As a result, emissions from typical driving conditions were deliberately left much higher than promised or tested. Was the VW scandal just the tip of the iceberg?

At the very least, the VW scandal highlighted the need to shift the tests out of the lab and onto the road. Given that the Commission's review found that these are no longer adequate or no longer reflect real world emissions,[55] this institution was called on in virtue of Article 14(3) of Regulation (EC) No 715/2007 to adapt them 'so as to adequately reflect the emissions generated by real driving on the road'. The necessary measures, which are designed to amend non-essential elements of this regulation, by supplementing it, have to be adopted in accordance with the regulatory procedure with scrutiny pursuant to Decision 1999/468/EC.

In the wake of the VW scandal, the European Commission was intent upon introducing testing in real-world conditions called Real Driving Emissions (RDE) in addition to laboratory tests in adopting a regulation amending Regulation (EC) No 692/2008 as regards emissions from light passenger and commercial vehicles (Euro 6). The amending regulation follows the principles already applied to heavy-duty vehicles by Euro VI Regulation (EC) 595/2009 and its implementing measures. It provides for a RDE procedure that shall complement the laboratory based procedure with a view to checking that the emission levels of NOx are not exceeded. At a later stage, particle numbers (PN), measured during the laboratory test, are also confirmed under real driving conditions. Practically speaking, cars will be tested on roads according to random acceleration and deceleration patterns. The pollutant emissions will be measured by portable emission measuring systems (PEMS) that will be attached to the car. In reflecting real-world driving style to a greater degree, the new tests should score more accurate results than the lab tests.[56] What is more, in addressing the problem of NOx emissions from diesel vehicles, the amending regulation should contribute to the decrease of the current sustained high levels of NO2 concentrations in ambient air, which are a major concern regarding human health.[57]

On 27 October 2015 the European Parliament adopted a resolution calling on the European Commission and the Member States to introduce an ambitious on-the-road test in 2017 to finally meet the current Euro 6 limit for diesel cars of 80 mg of NOx per km. However, the Commission and the Member States were still at pains to finalize the dates of implementation and the stringency of the new tests.

On 28 October 2015, the Technical Committee of Motor Vehicles (TCMV) voted on the second package of measures on the regulatory not-to-exceed (NTE) emission limits applicable in RDE testing, which needs to enter into force so that RDE testing has implications on the conformity certificate issued by the national type-approval authority (TAA). Though the TCMV voted by a large majority on the second package of implementing measures, it watered down the proposal from the European Commission. Initially, NOx readings primarily associated with diesel cars could exceed an 80 mg/km limit by 60%, before falling to 20%. In order to allow manufacturers to gradually adapt to the RDE rules, the final quantitative RDE requirements should be introduced in two subsequent steps, although with laxer requirements.

- in a first step, car manufacturers will have to bring down the discrepancy to a conformity factor of maximum 2.1 (110%) for new models by September 2017 (for new vehicles by September 2019); and
- in a second step, this discrepancy will be brought down to a factor of 1.5 (50%), taking account of

54 Article 13 of Regulation (EC) No 715/2007.

55 The Commission has performed a detailed analysis of the procedures, tests and requirements for type approval that are set out in Regulation (EC) No 692/2008 on the basis of own research and external information and found that emissions generated by real driving on the road of Euro 5/6 vehicles substantially exceed the emissions measured on the regulatory New European Driving Cycle (NEDC), in particular with respect to NOx emissions of diesel vehicles. See Recital 3, Preamble of the Commission Regulation amending Regulation (EC) No 692/2008 as regards emissions from light passenger and commercial vehicles (Euro 6).

56 Transport & Environment, *Realistic real-world driving emission tests: the last chance for diesel cars?,* July 2015.

57 Recital 6, Preamble.

| Timetable | Vehicles | Conformity factor | Maximum overshoot |
|---|---|---|---|
| September 2019 | New models | Maximum 2.1 (110%) | 168 mg/km NOx |
| September 2019 | New vehicles | Maximum 2.1 (110%) | 168 mg/km NOx |
| January 2020 | All new vehicles | Maximum 1.5 (50%) | 120 mg/km NOx |

*Table 6*

technical margins of error, by January 2020 for all new models (by January 2021 for all new vehicles). Table 6 sets forth these new arrangements.

In spite of these changes, the Commission hammered out a deal with the TCMV calling it a breakthrough on emissions testing.[58] In particular, Commissioner Elżbieta Bieńkowska, responsible for Internal Market, Industry, Entrepreneurship and SMEs, welcomed the TCMV' agreement. She issued a clarion call: *'The EU is the first and only region in the world to mandate these robust testing methods. ... We will complement this important step with a revision of the framework regulation on type-approval and market surveillance of motor vehicles. We are working hard to present a proposal to strengthen the type-approval system and reinforce the independence of vehicle testing'.*

Given that the new tests have to be adopted by the Commission in accordance with the regulatory procedure with scrutiny,[59] the European Parliament was empowered under Decision 1999/468/EC to object to it. In Brussels, on 14 December 2015, the Parliament Environment Committee drafted a formal objection to the Commission's proposal stating that the requirements were too lax. The objection was adopted by 40 votes to 9 with 13 abstentions. However, in January 2016 in Strasbourg a deeply divided European Parliament could not muster the objection endorsed by its Environment Committee. Whereas EEP and ECR political groups supported the compromise and the Greens opposed it, other groups, like the Liberals and the Socialists, broke ranks. Moreover, MPs from countries with car industries opposed the resolution. Hence, it failed to overturn the standards agreed in comitology in October 2015 by 317 to 323 MEPs, with 61 abstaining. Commissioner Elżbieta Bieńkowskaba promised the review of the emissions overshoot in order to eliminate it by 2020 at the latest.

To assess whether the new RDE requirements amount to a breakthrough or to a hoax depends on which end of the telescope one peers through at the issue. Peering from one end, one could take the view that the allowed divergence between the regulatory limit measured in real driving conditions and measured in laboratory conditions is still a significant reduction compared to the current discrepancy (400% on average). A look from the other end, however, produces a quite different picture. In effect, thanks to a conformity factor of 2.1 from late 2017, diesel cars could emit more than twice the Euro 6 legally binding thresholds. The permitted overshoot shall fall to 50% by 2020. Needless to say, the new measure is especially controversial in the wake of the VW emissions cheating scandal and is likely to even further dent consumer confidence.[60] In addition, given the high concentrations of NOx emissions in urban areas and the flurry of infringements of Directive 2008/50/EC, urgent consideration should be given to

58 European Commission - Press Release, 'Commission welcomes Member States' agreement on robust testing of air pollution emissions by cars', Brussels, 28 October 2015.

59 The European Parliament and the Council has the right of scrutiny that enables it to pass a resolution if the institution believes that the proposed measure exceeds the implementing powers provided for in the basic act. the "Comitology" Regulation No. 182/2011 on 16 February 2011 did not have the effect of abrogating the RPS introduced by Council Decision 2006/512/EC. Although Regulation No. 182/2011 introduced considerable changes to existing comitology mechanisms, nonetheless the RPS 'shall be maintained for the purposes of existing basic acts making reference thereto'. See Regulation (EU) 182/2011, Article 12(2) and Recital No 21.

60 N. de Sadeleer, 'Dieselgate. Quand l'enfer est pavé de bonnes intentions', *L'Echo,* 25th November 2015, p. 12; A. Gurzu, 'Parliament fails to overturn weak emissions tests' *Politico*, 4 February 2016, p. 14.

robust RDE test with a view to ensuring a significant reduction of NOx emissions.

### 3. Penalties

In virtue of Article 13 of Regulation (EC) No 715/2007, Member States are called on to lay down the provisions on penalties applicable for infringement by manufacturers of the provisions of this regulation and to take all measures necessary to ensure that they are implemented. One has to bear in mind that Article 197 TFEU refers to an 'effective implementation of Union law by the Member States'.[61]

The types of infringements which are subject to a penalty include falsifying test results for type approval[62]. The use of a defeat device that reduces the effectiveness of emission control systems is prohibited.[63] The penalties provided for must be 'effective, proportionate and dissuasive'. Given that the penalties have not been harmonized, Member States are empowered to choose the penalties which seem to them to be appropriate. In contrast to US federal law,[64] the national sanctions for marketing a car that does not conform to a type-approved car appear to be ineffective.[65] What is more, in order to assess whether the penalty in question is consistent with the principle of proportionality, account must be taken of different factors (the economic benefits for the wrongdoer, previous convictions, etc.). In particular, the national courts will have to pay heed to the nature and degree of seriousness of the infringement which the penalty seeks to sanction and of the means of establishing the amount of the penalty.[66] In a recent judgment regarding a case of transfrontier movement of waste, the CJEU held that:

'As regards the penalties imposed for infringement of the provisions of Regulation No 1013/2006, which aims to ensure a high level of protection of the environment and human health, the national court is required, in the context of the review of the proportionality of such penalty, to take particular account of the risks which may be caused by that infringement in the field of protection of the environment and human health.'[67]

Given a shortage of data, it is difficult to assess the impact of the national penalties. Moreover, whether recent infringements of Regulation 715/2007 are likely to be prosecuted remains to be seen.

## V. Conclusions

According to the EEA, air pollution poses the single largest environmental health risk in Europe today.[68] In spite of many improvements, substantial challenges remain and considerable impacts on human health and the environment persist.

Against this backdrop, several regulatory issues arise for comment here.

The core issue is whether EU environmental regulations on cars resemble more an approach accompanying the growth of the car industry and enhancing the automotive society rather than a move to call the environmental legacy of car transportation into question. As a matter of fact, all noise, pollution, nuisances, or attacks on the natural environment cannot be prohibited: were this to be done, life within society would become impossible. The only viable solution therefore involves authorising polluting activities and requiring compliance with thresholds (ELVs, EQS, product standards) over which the environmental harm is considered to be unacceptable. Therefore, since a certain level of environmental pollution can be sustained without significant environmental harm, certain limits have been set by the EU institutions on the technical characteristics of cars and fuels and the ability of the ecosystems and human beings to withstand their environmental impacts. In fact, the aim of the EU environmental law model is not to eliminate pollution, but rather to contain its most serious consequences. Yet, the picture is not as idyllic as one might think. The following paradox lies at the heart of the EU clean air policy: though car emission standards have been gradually tightened, ambient air quality in a number of cities has not re-

61 P. Nicolaides and M. Geilmann, 'What is Effective Implementation of EU Law?' (2012) 19: 3 *MJ* 383-399.

62 Article 13 (2) b.

63 Article 5 (2). Regarding the definition of defeat device, see Article 1(3).

64 § 7522(a) (1) Clean Air Act.

65 L. Krämer, personal communication.

66 See, inter alia, C-259/12 *Rodopi-M 91* [2013] EU:C:2013:414, para. 38; Case C-487/14*, SC Total Waste Recycling SRL* [2015] C:2015:780, para. 53.

67 Case C-487/14 *SC Total Waste Recycling SRL* [2015] C:2015:780, para. 55.

68 European Environment Agency, *Air quality in Europe — 2015 report,* 5/2015, p. 7.

ally improved. In particular, emissions of NOx from road transport have not sufficiently decreased to meet air quality standards in many urban areas.[69] Accordingly, air quality standards and economic imperatives appear to clash.

Needless to say, the path ahead which must be followed in order to reconcile growth with environmental protection, under the aegis of sustainable development, remains littered with at least three pitfalls.

The success of a clean air policy depends upon a genuine coordination of regulations on fuel efficiency, tailpipe emissions, engine performance, and fuel content. EU law is falling short of meeting that objective. In order to understand the subject matter, one has to juggle numerous directives and regulations spewing out excessive detailed technical measures, measurements, and controls which are constantly modified. Given the absence of consolidating texts, one is struck by the lack of transparency[70] and the shortage of interactions between these different regulations.

What is more, given the sheer increase of cars placed on the market and the distances covered by drivers, the EU standards should be technology-forcing. However, account must be taken of the fact that, so far, the EU standards did not succeed in forcing the manufacturers and importers to produce alternatively powered vehicles that release a lesser amount of pollutants. In fact, the vast majority of Europe's new cars remain powered by gasoline or diesel motors.[71] Despite an increase over the last few years, passenger cars powered by alternative fuels, including hybrid cars, only made up a small share of the fleet of passenger cars in the EU in 2013.

A final issue touches upon the question of inefficacy of EU law regarding testing car emissions. Here, it is necessary to face hard facts: the main weakness of EU rules is, as recognised by the Commission, their lack of efficacy, with directives and regulations appearing as paper tigers. As a matter of principle, the Commission, as Guardian of the Treaties, should pursue these infringements relentlessly. Here, too, there are numerous pitfalls. Firstly, given the decentralized nature of the EU, compliance with EU emission standards depends on at least 28 different legal and administrative systems underpinned by different cultural factors.[72] Secondly, the Commission is not sufficiently well informed. Since it does not have any general powers of inspection, nor a body of inspectors, the control exercised by this institution over the national authorities is based largely on the reports transmitted by the Member States. Thirdly, the EU institutions do not appear willing to take bold steps in improving the enforcement. The Commission has been criticised for its inaction in the aftermath of the VW scandal. The European Parliament has been unwilling to object the amending regulation on RDE.

In hindsight, it appears that the EU approach to air pollution caused by light cars has turned out to be little more than a bandaid on a gaping sore.

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69 Ibid., p. 9.

70 L. Krämer, *EC Environmental Law*, supra note 21, p. 317.

71 International Council for Clean Transportation, *European Vehicle Market Statistics 2013,* p. 6.

72 C. Sobotta, 'Compliance with European Environmental Law – Deficiencies and Approaches' *JEEPL* 9(1) (2012), p. 93.

# The Volkswagen Scandal from the Viewpoint of Corporate Governance

*Raymonde Crête**

## I. Introduction

Like some other crises and scandals that periodically occur in the business community, the Volkswagen ("VW") scandal once again highlights the devastating consequences of corporate misconduct, once publicly disclosed, and the media storm that generally follows the discovery of such significant misbehaviour by a major corporation. Since the crisis broke in September 2015, the media have relayed endless details about the substantial negative impacts on VW, on various stakeholder groups such as employees, directors, investors, suppliers and consumers, and on the automobile industry as a whole.[1] The multiple and negative repercussions at the economic, organizational and legal levels have quickly become apparent, in particular in the form of resignations, changes in VW's senior management, layoffs, a hiring freeze, the end to the marketing of diesel-engined vehicles, vehicle recalls, a decline in car sales, a drop in market capitalization, and the launching of internal investigations by VW and external investigations by the public authorities. This comes in addition to the threat of numerous civil, administrative, penal and criminal lawsuits and the substantial penalties they entail, as well as the erosion of trust in VW and the automobile industry generally.[2]

A scandal of this extent cannot fail to raise a number of questions, in particular concerning the cause of the alleged cheating, liable actors, the potential organizational and regulatory problems related to compliance, and ways to prevent further misconduct at VW and within the automobile industry. Based on the information surrounding the VW scandal, it is premature to capture all facets of the case. In order to analyze in more depth the various problems raised, we will have to wait for the findings of the investigations conducted both internally by the VW Group and externally by the regulatory authorities.

While recognizing the incompleteness of the information made available to date by VW and certain commentators, we can still use this documentation to highlight a few features of the case that deserve to be studied from the standpoint of corporate governance. This Article remains relatively modest in scope, and is designed to highlight certain organizational factors that may explain the deviant behaviour observed at VW. More specifically, it submits that the main cause of VW's alleged wrongdoing lies in the company's ambitious production targets for the U.S. market and the time and budget constraints imposed on employees to reach those targets. Arguably, the corporate strategy and pressures exerted on VW's employees may have led them to give preference to the performance priorities set by the company rather than compliance with the applicable legal and ethical standards. And this corporate misconduct could not be detected because of deficiencies in the moni-

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1 Jack Ewing, "Volkswagen C.E.O. Martin Winterkorn Resigns Amid Emissions Scandal", *New York Times,* Sept. 23, 2015, Online: http://www.nytimes.com/2015/09/24/business/international/volkswagen-chief-martin-winterkorn-resigns-amid-emissions-scandal.html (last accessed Feb. 9, 2016); Russell Hotten, "Volkswagen: The Scandal explained", *BBC News*, Dec. 10, 2015, Online: http://www.bbc.com/news/business-34324772 (last accessed Feb. 9, 2016); Antony Currie and Olaf Storbeck, "Volkswagen Debacle on Financial Par With BP Oil Spill", *New York Times*, Sept. 22, 2015, Online: http://www.nytimes.com/2015/09/23/business/dealbook/volkswagen-debacle-on-financial-par-with-bp-oil-spill.html?_r=0 (last accessed Feb. 9, 2016); William Boston, Friedrich Geiger and Mike Spector, "Audi Engines Implicated in Volkswagen Emissions Scandal". *Wall Street Journal*, Nov. 27, 2015, Online: http://www.wsj.com/articles/audi-engines-implicated-in-emissions-scandal-1448575533 (last accessed Feb. 9, 2016); Richard Milne, "Volkswagen seeks greater efficiency with new executive team", *Financial Times*, Dec. 17, 2015; Monica Houston-Waesch, "Volkswagen Sales Drop for First Time in 13 Years; Auto maker's global sales fell 2% in 2015 as emissions-cheating scandal hit company", *Wall Street Journal* (Online), Jan. 8, 2016; Oscar Williams-Grut, "CREDIT SUISSE: The Emission scandal could cost Volkswagen €78 billion and shares need to fall another 20%", *Business Insider Australia*, Oct. 2, 2015, Online: http://www.businessinsider.com.au/credit-suisse-volkswagen-shares-could-fall-another-20-2015-10 (last accessed Feb. 9, 2016); Aruna Viswanatha and Mike Spector, "Shares Fall on Fears of U.S. Penalty; Investors worry German auto maker could face bigger than $18 billion first estimated", *Wall Street Journal* (Online), Jan. 5, 2016; William Boston, "Volkswagen Begins Recall of Diesel Cars in Europe", *Wall Street Journal*, Jan. 28, 2016. Online: http://www.wsj.com/articles/volkswagen-begins-recall-of-diesel-cars-in-europe-1453996552, (last accessed Feb. 9, 2016).

2 Ibid.

toring and control mechanisms, and especially in the compliance system established by the company to ensure that legal requirements were respected.

Although limited in scope, this inquiry may prove useful in identifying means to minimize, in the future, the risk of similar misconduct, not only at VW but within other companies as well.[3] Given the limited objectives of the Article, which focuses on certain specific organizational deficiencies at VW, the legal questions raised by the case will not be addressed. However, the Article will refer to one aspect of the law of business corporations in the United States, Canada and in the EU Member States in order to emphasize the crucial role that boards in publicly-held companies must exercise to minimize the risk of misconduct.[4]

## II. A Preliminary Admission by VW: Individual Misconduct by a few Software Engineers

When a scandal erupts in the business community following a case of fraud, embezzlement, corruption, the marketing of dangerous products or other deviant behaviour, the company concerned and the regulatory authorities are required to quickly identify the individuals responsible for the alleged misbehaviour. For example, in the Enron, WorldCom, Tyco and Adelphia scandals of the early 2000s, the investigations revealed that certain company senior managers had acted fraudulently by orchestrating accounting manipulations to camouflage their business's dire financial situation.[5] These revelations led to the prosecution and conviction of the officers responsible for the corporations' misconduct.[6] In the United States, the importance of identifying individual wrongdoers is clearly stated in the Principles of Federal Prosecutions of Business Organizations issued by the U.S. Department of Justice which provide guidelines for prosecutions of corporate misbehaviour.[7] On the basis of a memo issued in 2015 by the Department of Justice (the "Yates memo")[8], these principles were recently revised to express a renewed commitment to investigate and prosecute individuals responsible for corporate wrongdoing. While recognizing the importance of individual prosecutions in that context, the strategy is only one of the ways to respond to white-collar crime. From a prevention standpoint, it is essential to conduct a broader examination of the organizational environment in which senior managers and employees work to determine if the enterprise's culture, values, policies, monitoring mechanisms and practices contribute or have contributed to the adoption of deviant behaviour.[9]

In the Volkswagen case, the company's management concentrated first on identifying the handful of individuals it considered to be responsible for the deception, before admitting few weeks later that organizational problems had also encouraged or facilitated the unlawful corporate behaviour. Once news broke of the Volkswagen scandal, one of VW's officers quickly linked the wrongdoing to the actions of a few employees, but without uncovering any governance problems or misbehaviour at the VW management level.[10]

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3 Volkswagen, *News*: "Volkswagen making good progress with its investigation, technical solutions, and Group realignment", Dec. 10, 2015: Online: http://www.volkswagenag.com/content/vwcorp/info_center/en/news/2015/12/VW_PK.html (last accessed Feb. 9, 2016).

4 This Article refers to the crucial role assigned to the board of directors in a one-tier board structure, as prescribed under American and Canadian corporation law as well as to the management board and supervisory board in a two-tier board structure, as prescribed under German stock corporation law.

5 Securities and Exchange Commission, *Report Pursuant to Section 704 of the Sarbanes-Oxley Act of 2002*, 24 January 2003, on-line: <https://www.sec.gov/news/studies/sox704report.pdf> (last accessed Feb. 9, 2016)); Kenneth R. Gray, Larry A. Frieder and George W. Clark Jr., *Corporate Scandals – The Many Faces of Greed*, (St-Paul: Paragon House) 2005; Jeffrey N. Gordon, "Governance Failures of the Enron Board and the New Information Order of Sarbanes-Oxley", 35 *Conn. L. Rev.* (2002-2003) 1125.

6 Kenneth R. Gray, Larry A. Frieder and George W. Clark Jr., ibid.

7 United States Department of Justice, *Federal Prosecutions of Business Organizations*, Online : http://www.justice.gov/usam/usam-9-28000-principles-federal-prosecution-business-organizations (last accessed Feb. 26, 2016).

8 U.S. Department of Justice, Office of the Deputy Attorney General, Memorandum from Deputy Attorney General, Sally Quillian Yates, Sept. 9, 2015, Online : http://www.justice.gov/dag/file/769036/download (last accessed Feb. 26, 2016).

9 Roger Baker, Stuart Weinstein and Charles Wild, "Risk management and the board of directors: lessons to be learned from UBS", in Stuart Weinstein and Charles Wild (eds.), *Legal Risk, Management, Governance and Compliance: A Guide to Best Practice from Leading Experts*, (London: Globe Law and Business, 2013), 165, p. 175; Margaret Woods, *Risk Management in Organizations. An Integrated Case Study Approach*, ( London : Routledge), 2011; Martin Lipton, Daniel A. Neff, Andrew R. Brownstein, Steven A. Rosenblum, Adam O. Emmerich, "Risk Management and the Board of Directors", Harvard Law School Forum on Corporate Governance and Financial Regulation, July 28, 2015, Online : https://corpgov.law.harvard.edu/2015/07/28/risk-management-and-the-board-of-directors-3/ (last accessed Feb. 26, 2016).

10 Jim Puzzanghera and Jerry Hirsch, "VW exec blames 'a couple of' rogue engineers for emissions scandal", *Los Angeles Times*, Oct. 8, 2015, Online: http://www.latimes.com/business/autos/la-fi-hy-vw-hearing-20151009-story.html (last accessed Feb. 9, 2016); Associated Press, "Volkswagen exec blames rogue engineers for emissions scandal", *New York Post*, Oct. 8, 2015, Online: http://nypost.com/2015/10/08/volkswagen-exec-blames-rogue-engineers-for-emissions-scandal/ (last accessed Feb. 9, 2016); REUTERS, "UPDATE 3-Volkswagen's US boss blames "individuals" for cheating", Oct. 8, 2015, Online: http://www.reuters.com/article/volkswagen-emissions-update-3-pix-tv-gra-idUSL8N1281NL20151008 (last accessed Feb. 9, 2016).

In October 2015, the President and Chief Executive Officer of the VW Group in the United States, Michael Horn, stated in testimony before a Congressional Subcommittee: "[t]his was a couple of software engineers who put this for whatever reason" [...]. To my understanding, this was not a corporate decision. This was something individuals did."[11] In other words, the U.S. CEO considered that sole responsibility for the scandal lay with a handful of engineers working at the company, while rejecting any allegation tending to incriminate the company's management.

This portion of his testimony failed to convince the members of the Subcommittee, who expressed serious doubts about placing sole blame on the misbehaviour of a few engineers, given that the problem had existed since 2009. As expressed in a sceptical response from one of the committee's members: "I cannot accept VW's portrayal of this as something by a couple of rogue software engineers [...] Suspending three folks – it goes way, way higher than that."[12]

Although misconduct similar to the behaviour uncovered at Volkswagen can often be explained by the reprehensible actions of a few individuals described as "bad apples", the violation of rules can also be explained by the existence of organizational problems within a company.[13]

## III. Recognition of Organizational Failures by VW

In terms of corporate governance, an analysis of misbehaviour can highlight problems connected with the culture, values, policies and strategies promoted by a company's management that have a negative influence on the behaviour of senior managers and employees. Considering the importance of the organizational environment in which these players act, regulators provide for several internal and external governance mechanisms to reduce the risk of corporate misbehaviour or to minimize agency problems.[14] As one example of an internal governance mechanism, the law of business corporations in the U.S., Canada and the EU Member States gives the board of directors (in a one-tier board structure, as prescribed under American and Canadian corporation law) and the management board and supervisory board (in a two-tier board structure, as provided for in some EU Member States, such as Germany) a key role to play in monitoring the company's activities and internal dealings.[15] As part of their monitoring mission, the board must ensure that the company and its agents act in a diligent and honest way and in compliance with the regulations, in particular by establishing mechanisms or policies in connection with risk man-

11 Jim Puzzanghera and Jerry Hirsch, ibid. See also the testimony of Michael Horn, President and CEO of Volkswagen Group of America, Inc. before the House Committee on Energy and Commerce Subcommittee on Oversight and Investigations, October 8, 2015, Online: http://docs.house.gov/meetings/IF/IF02/20151008/104046/HHRG-114-IF02-Wstate-HornM-20151008.pdf (last accessed Feb. 9, 2016).

12 Jim Puzzanghera and Jerry Hirsch, "VW exec blames 'a couple of' rogue engineers for emissions scandal", *supra* note 10.

13 J. N. Gordon, *supra* note 5, pp. 1129-1131; Marianne M. Jennings, "A Primer on Enron : Lessons from a Perfect Storm of Financial Reporting, Corporate Governance and Ethical Culture Failures", 39 *Cal. W. L. Rev.*(2003) 163, pp. 180-190; Securities and Exchange Commission, *supra* note 5, p. 7 and ff.; Roger Baker, Stuart Weinstein and Charles Wild, "Risk management and the board of directors: lessons to be learned from UBS", supra note 9, pp. 170-172; International Federation of Accountants, *Rebuilding Public Confidence in Financial Reporting, An International Perspective*, August 2003, pp. 5-17, Online: <http://www.ifac.org/publications-resources/rebuilding-public-confidence-financial-reporting-international-perspective> (last accessed Feb. 9, 2016); Michael R. Young, *Financial Fraud Prevention and Detection: Governance and Effective Practices*, (Hoboken: Wiley, 2014), p. 10 and ff.

14 John Armour, Henry Hansman et Reinier Kraakman, « Agency Problems and Legal Strategies », in Reinier Kraakman, John Armour, Paul Davies, Luca Enriques, Henry Hansmaan, Gerard Hertig, Klaus Hopt, Hideki Kanda and Edward Rock (eds.), *The Anatomy of Corporate Law – A Comparative and Functional Approach*, 2nd ed., (Oxford: Oxford University Press), 2009, pp. 37-53; Ejan Mackaay and Stéphane Rousseau, *Analyse économique du droit*, 2nd ed., (Paris: Dalloz), 2008, p. 512-523, 526-544, 545 and ff.

15 On the role of the board of directors under U.S. corporation law, see Stephen M. Bainbridge, *Corporation Law and Economics*, (New York : Foundation Press), 2002, pp. 191 and ff. ; in Canada, see Raymonde Crête and Stéphane Rousseau, *Droit des sociétés par actions*, 3rd ed., (Montréal : Éditions Thémis), 2011, pp. 326-329, 355-367 ; in the EU Member States, the law of business corporations provides for a one-tier board structure or a two-tier board structure : see Carsten Gerner-Beuerle, Philipp Paech and Edmund Philipp Schuster, *Study on Directors' Duties and Liabilities*, Report prepared for the European Commission DG Markt, London, April 2013, Online : http://ec.europa.eu/internal_market/company/docs/board/2013-study-analysis_en.pdf (last accessed Feb. 27, 2016). In Germany, stock corporation law provides for a mandatory two-tier board structure which includes a supervisory board and a management board. On German company law, see the *Study on Directors' Duties and Liabilities,* ibid, pp. 15 ; Grit Tüngler, "The Anglo-American Board of Directors and the German Supervisory Board – Marionnettes in a Puppet Theatre of Corporate Governance or Efficient Controlling Devices?", Vol. 12, iss.2, Article 7 *Bond Law Review* (2000), Online : http://epublications.bond.edu.au/cgi/viewcontent.cgi?article=1194&context=blr (last accessed Feb. 27, 2016) ; Government Commission, *German Corporate Governance Code*, as revised on May 5, 2015, Online : http://www.dcgk.de//files/dcgk/usercontent/en/download/code/2015-05-05_Corporate_Governance_Code_EN.pdf (last accessed Feb. 27, 2015).

agement, internal controls, information disclosure, due diligence investigation and compliance.[16]

When analysing the Volkswagen scandal from the viewpoint of its corporate governance, the question to be asked is whether the culture, values, priorities, strategies and monitoring and control mechanisms established by the company's management board and supervisory board – in other words "the tone at the top"-, created an environment that contributed to the emergence of misbehaviour.[17]

In this saga, although the initial testimony given to the Congressional Subcommittee by the company's U.S. CEO, Michael Horn, assigned sole responsibility to a small circle of individuals, VW's senior management later recognized that the misconduct could not be explained simply by the deviant behaviour of a few people, since the evidence also pointed to organizational problems supporting the violation of regulations.[18] In December 2015, VW's management released the following observations, drawn from the preliminary results of its internal investigation:

> "Group Audit's examination of the relevant processes indicates that the software-influenced NOx emissions behavior was due to the interaction of three factors:
> – The misconduct and shortcomings of individual employees
> – Weaknesses in some processes
> – A mindset in some areas of the Company that tolerated breaches of rules."[19]

Concerning the question of process, VW released the following audit key findings:

> "Procedural problems in the relevant subdivisions have encouraged misconduct;
> Faults in reporting and monitoring systems as well as failure to comply with existing regulations;
> IT infrastructure partially insufficient and antiquated."[20]

More fundamentally, VW's management pointed out at the same time that the information obtained up to that point on "the origin and development of the nitrogen issue [...] proves not to have been a one-time error, but rather a chain of errors that were allowed to happen.[21] The starting point was a strategic decision to launch a large-scale promotion of diesel vehicles in the United States in 2005. Initially, it proved impossible to have the EA 189 engine meet by legal means the stricter nitrogen oxide requirements in the United States within the required timeframe and budget."[22]

In other words, this revelation by VW's management suggests that "the end justified the means" in the sense that the ambitious production targets for the U.S. market and the time and budget constraints imposed on employees encouraged those employees to use illegal methods in operational terms to achieve the company's objective. And this misconduct could not be detected because of deficiencies in the monitoring and control mechanisms, and especially in the compliance system established by the company to ensure that legal requirements were respected. Among the reasons given to explain the crisis, some observers also pointed to the excessive centralization of decision-making powers within VW's senior management, and an organizational culture that acted as a brake on internal communications and discouraged mid-level managers from passing on bad news.[23]

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16 In US, see S.M. Bainbridge, ibid, p. 194, 195 ; Martin Lipton, Daniel A. Neff, Andrew R. Brownstein, Steven A. Rosenblum, Adam O. Emmerich, supra note 9 ; in Canada, see R. Crête and S. Rousseau, ibid, pp. 326-328 ; in Germany, see Government Commission, *German Corporate Governance Code*, ibid.

17 For details on VW's corporate governance, see Volkswagen, *Annual Report 2014*, Group Management Report¸ Online: http://annualreport2014.volkswagenag.com/group-management-report/structure-and-business-activities.html (last accessed Feb. 27, 2016).

18 Volkswagen, *News*: "Volkswagen making good progress with its investigation, technical solutions, and Group realignment", *supra* note 3; Graham Ruddick, "VW admits emissions scandal was caused by 'whole chain' of failures", *The Guardian*, Dec. 2015, Online: http://www.theguardian.com/business/2015/dec/10/volkswagen-emissions-scandal-systematic-failures-hans-dieter-potsch (last accessed Feb. 9, 2016); Graeme Wearden and Julia Kollewe, "VW emissions scandal: misconduct, process failure and tolerance of rule-breaking blamed – as it happened", *The Guardian,* Dec. 10, 2015, Online: http://www.theguardian.com/business/live/2015/dec/10/volkswagen-vw-grilling-emissions-scandal-bank-of-england-business-live (last accessed Feb. 9, 2016).

19 Volkswagen, *News*: "Volkswagen making good progress with its investigation, technical solutions, and Group realignment", ibid., pp. 1, 2.

20 Volkswagen, "The Volkswagen Group is moving ahead: Investigation, customer solutions, realignment", Conference Press, Dec. 10, 2015, at 14.

21 Volkswagen, *News*: "Volkswagen making good progress with its investigation, technical solutions, and Group realignment", *supra* note 3, at 2.

22 Ibid.

23 Jack Ewing, "Volkswagen C.E.O. Martin Winterkorn Resigns Amid Emissions Scandal", *supra* note 1; for other comments on VW' corporate governance, see James B. Stewart, "Problems at Volkswagen Start in the Boardroom", *New York Times,* Sept. 24, 2015, Online: http://www.nytimes.com/2015/09/25/business/international/problems-at-volkswagen-start-in-the-boardroom.html?_r=0 (last accessed Feb. 9, 2016);

## IV. Organizational Changes Considered as a Preliminary Step

In response to the crisis, VW's management, in a press release in December 2015, set out the main organizational changes planned to minimize the risk of similar misconduct in the future. The changes mainly involved "instituting a comprehensive new alignment that affects the structure of the Group, as well as its way of thinking and its strategic goals."[24]

In structural terms, VW changed the composition of the Group's Board of Management to include the person responsible for the Integrity and Legal Affairs Department as a board member.[25] In the future, the company wanted to give "more importance to digitalization, which will report directly to the Chairman of the Board of Management," and intended to give "more independence to brand and divisions through a more decentralized management."[26] With a view to initiating a new mindset, VW's management stated that it wanted to avoid "yes-men" and to encourage managers and engineers "who are curious, independent, and pioneering".[27] However, the December 2015 press release reveals little about VW's strategic objectives: "Strategy 2025, with which Volkswagen will address the main issues for the future, is scheduled to be presented in mid 2016."[28]

Although VW's management has not yet provided any details on the specific objectives targeted in its "Strategy 2025", it is revealing to read the VW annual reports from before 2015 in which the company sets out clear and ambitious objectives for productivity and profitability. For example, the annual reports for 2007, 2009 and 2014 contained the following financial objectives, which the company hoped to reach by 2018.

In its 2007 annual report, VW specified, under the heading "Driving ideas":

> "Financial targets are equally ambitious: for example, the Volkswagen Passenger Cars brand aims to increase its unit sales by over 80 percent to 6.6 million vehicles by 2018, thereby reaching a global market share of approximately 9 percent. To make it one of the most profitable automobile companies as well, it is aiming for an ROI of 21 percent and a return on sales before tax of 9 percent."[29]

Under the same heading, VW stated in its 2009 annual report:

> "In 2018, the Volkswagen Group aims to be the most successful and fascinating automaker in the world. [...] Over the long term, Volkswagen aims to increase unit sales to more than 10 million vehicles a year: it intends to capture an above-average share as the major growth markets develop."[30]

And in its 2014 annual report, under the heading "Goals and Strategies", VW said:

> "The goal is to generate unit sales of more than 10 million vehicles a year; in particular, Volkswagen intends to capture an above-average share of growth in the major growth markets."
>
> Volkswagen's aim is a long-term return on sales before tax of at least 8% so as to ensure that the Group's solid financial position and ability to act are guaranteed even in difficult market periods.[31]

Besides these specific objectives for financial performance, the annual reports show that the company's management recognized, at least on paper, the importance of ensuring regulatory compliance and promoting corporate social responsibility (CSR) and sustainability.[32] However, after the scandal broke in September 2015, questions can be asked about the effectiveness of the governance mechanisms, especially of the reporting and monitoring systems put in place by VW to achieve company goals in this area.[33] In light of the preliminary results of VW's in-

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24 Volkswagen, *News*: "Volkswagen making good progress with its investigation, technical solutions, and Group realignment", *supra* note 3, at 3.

25 Ibid.

26 Ibid.

27 Volkswagen, *News*: "Volkswagen making good progress with its investigation, technical solutions, and Group realignment", *supra* note 3, pp. 3, 4.

28 Ibid., at 4.

29 Volkswagen, *Annual Report 2007 – Driving Ideas*, at 22, Online: http://www.volkswagenag.com/content/vwcorp/info_center/en/publications/2008/03/Annual_Report_2007.bin.html/binarystorageitem/file/VW_AG_GB_2007_en.pdf (last accessed Feb. 9, 2016).

30 Volkswagen, *Annual Report 2009,* at 198, Online: http://www.volkswagenag.com/content/vwcorp/info_center/en/publications/2010/03/Annual_Report_2009.bin.html/binarystorageitem/file/Y_2009_e.pdf (last accessed Feb. 9, 2016.

31 Volkswagen, *Annual Report 2014*, Online: http://annualreport2014.volkswagenag.com/group-management-report/goals-and-strategies.html (last accessed Feb. 9, 2016).

32 Volkswagen, *Annual Report 2014*, see the *Corporate Governance Report*.

33 Volkswagen, "The Volkswagen Group is moving ahead: Investigation, customer solutions, realignment", *supra* note 20, at 14.

ternal investigation[34], as mentioned above, it seems that, in the organizational culture, the commitment to promote compliance, CSR and sustainability was not as strong as the effort made to achieve the company's financial performance objectives.

Concerning the specific and challenging priorities of productivity and profitability established by VW's management in previous years, the question is whether the promotion of financial objectives such as these created a risk because of the pressure it placed on employees within the organizational environment. The priorities can, of course, exert a positive influence and motivate employees to make an even greater effort to achieve the objectives.[35] On the other hand, the same priority can exert a negative influence by potentially encouraging employees to use all means necessary to achieve the performance objectives set, in order to protect their job or obtain a promotion, even if the means they use for that purpose contravene the regulations. In other words, the employees face a "double bind" or dilemma which, depending on the circumstances, can lead them to give preference to the performance priorities set by the company rather than compliance with the applicable legal and ethical standards.

In the management literature, a large number of theoretical and empirical studies emphasize the beneficial effects of the setting of specific and challenging goals on employee motivation and performance within a company.[36] However, while recognizing these beneficial effects, some authors point out the unwanted or negative side effects they may have.

As highlighted by Ordóñez, Schweitzer, Galinsky and Bazerman, specific goal setting can result in employees focusing solely on those goals while neglecting other important, but unstated, objectives.[37] They also mention that employees motivated by "specific, challenging goals adopt riskier strategies and choose riskier gambles than do those with less challenging or vague goals".[38] As an additional unwanted side effect, goal setting can encourage unlawful or unethical behaviour, either by inciting employees to use dishonest methods to meet the performance objectives targeted, or to "misrepresent their performance level – in other words, to report that they met a goal when in fact they fell short."[39] Based on these observations, the authors suggest that companies should set their objectives with the greatest care and propose various ways to guard against the unwanted side effects highlighted in their study. This approach could prove useful for VW's management which will once again, at some point, have to define its objectives and strategies.

## V. Conclusion

In the information released to the public after the emissions cheating scandal broke, as mentioned above, VW's management quickly stated that the misconduct was directly caused by the individual misbehaviour of a couple of software engineers. Later, however, it admitted that the individual misconduct of a few employees was not the only cause, and that there were also organizational deficiencies within the company itself.

Although the VW Group's public communications have so far provided few details about the cause of the crisis, the admission by management that both individual and organizational failings were involved constitutes, in our opinion, a lever for understanding the various factors that may have led to reprehensible conduct within the company. Based on the investigations that will be completed over the coming months, VW's management will be in a position to identify more precisely the nature of these organizational failings and to propose ways to minimize the risk of future violations. During 2016, VW's management will also announce the objectives and strategies it intends to pursue over the next few years.

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34 See notes 18-22 and accompanied text.

35 Edwin A. Locke and Gary P. Latham (eds.) *New developments in goal setting and task performance*, (New York : Routledge), 2013; Edwin A. Locke and Gary P. Latham, "Building a Practically Useful Theory of Goal Setting and Task Motivation – A 35 Year Odyssey", 57(9) American Psychologist (2002), 705-717; Edwin A. Locke, *Goal Setting: a motivational technique that works!*, (Englewood Cliffs: Prentice-Hall) 1984.

36 Ibid.

37 Linda D. Ordóñez, Maurice E. Schweitzer, Adam D. Galinsky and Max H. Bazerman, "Goals Gone Wild: The Systematic Side Effects of Overprescribing Goal Setting", 23(1) *Academy of Management Perspectives* (2009), pp. 6-16; see also, Barry E. Litzky, Kimberly A. Eddleston and Deborah L. Kidder, "The Good, the Bad, and the Misguided: How Managers Inadvertantly Encourage Deviant Behaviors", 20(10) *Academy of Management Perspectives* (2006), pp. 91-103; Adam Barsky, "Understanding the Ethical Cost of Organizational Goal-Setting: A Review and Theory Development", 81(1) *Journal of Business Ethics* (2008), pp. 63-81; for a reply to Ordóñez (*et al.*) paper, see: Gary P. Latham and Edwin A. Locke, "What Should Count as Evidence against the Use of Goal Setting?", 23(3) *Academy of Management Perspectives* (2009), pp. 89-91.

38 L.D. Ordóñez *et al.*, ibid, at 9.

39 L.D. Ordóñez *et al.*, ibid, at 10.

As part of its review of the options, it is not hard to imagine that management will, once again, give pride of place to specific and challenging objectives for productivity and profitability. However, in light of the observations mentioned in this study that highlight the potential unwanted side effects that result from promoting this type of objectives, it will also be essential for VW's management to include, among its priorities, clear and convincing objectives to ensure compliance with legal and ethical standards. Similarly, management will also be called to implement effective mechanisms for detection and prevention to reflect a strong commitment to promote compliance, CSR and sustainability within the company.

# Volkswagen and the High-tech Greenwash

*Eric L. Lane**

*In several ways, the revelations that Volkswagen used software to cheat on vehicle emissions tests echo common threads of greenwashing cases against car manufacturers. However, in one significant respect, the Volkswagen scandal is much more than just another example of greenwashing. That is, the German automaker's use of software to deceive brings a novel technological aspect to greenwashing. This article discusses the Volkswagen scandal in the context of automobile greenwashing cases and highlights this new high-tech greenwashing.*

## I. Introduction

On September 18, 2015, the U.S. Environmental Protection Agency (EPA) revealed that some of Volkswagen's diesel vehicles have software that allows the nitrogen oxide (NOx) output to satisfy U.S. emissions standards during testing while producing much higher emissions during actual driving conditions.[1]

The German automaker admitted that it intentionally programmed a number of its diesel vehicles to activate emission controls only during America's NOx emissions tests.[2] Once the tests were complete, however, the software deactivated the emission controls, and the subject vehicles gave off NOx emissions at up to 40 times the permitted level.[3] "Noticeable" deviations between testing results and real-world use, Volkswagen says, affected 11 million vehicles worldwide.[4] The EPA has ordered that Volkswagen recall about 500,000 cars in America to fix the software.[5]

While Volkswagen has admitted to the deception in America, and the software is capable of cheating European emissions tests, it is not clear whether the automaker used the software the same way in Europe.[6]

Although not a conventional marketing statement, this deception is nevertheless an instance of greenwashing – communicating false or misleading information about purported environmental benefits. As such, it may be helpful to view the Volkswagen emissions scandal in the context of greenwashing. As discussed herein, this analysis demonstrates the scandal to have some commonalities with other greenwashing cases, but also reveals a new theme which may portend the future of greenwashing.

## II. The Volkswagen Scandal Comports with Common Threads of Greenwashing

In one sense, the deceptive use of emissions control software by Volkswagen comports with a theme frequently encountered before in greenwashing, i.e., a product's real-world performance does not live up to its testing results.

The most common example is the charge that a car's actual gas mileage is considerably lower than an environmental regulator's fuel efficiency estimates. In recent years, these allegations have been made against Ford, Toyota, and Honda.

Two class action lawsuits filed against Ford in America are illustrative. In those, the plaintiffs alleged that the American automaker misrepresented the miles per gallon achieved by its Fusion and C-Max SE hybrid vehicles.[7] The complaints accused

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1 The Economist, "A Mucky Business," 26 September 2015, available on the Internet at < http://www.economist.com/news/briefing/21667918-systematic-fraud-worlds-biggest-carmaker-threatens-engulf-entire-industry-and> (last accessed on 23 November 2015).

2 The Economist, "Dirty Secrets," 26 September 2015, available on the Internet at < http://www.economist.com/news/leaders/21666226-volkswagens-falsification-pollution-tests-opens-door-very-different-car> (last accessed on 17 December 2015).

3 Supra, note 2.

4 Supra, note 1.

5 Supra, note 1.

6 Richard Westcott, BBC News, "VW cars can also cheat European emissions test, BBC learns," 23 November 2015, available on the Internet at <http://www.bbc.com/news/business-34857404> (last accessed on 23 November 2015).

7 Complaint, Pitkin et al. v. Ford Motor Co. et al., Case No. 8:13-cv-00954-DOC-JPR (C.D. Cal. Feb. 8, 2013) (hereinafter "Pitkin Complaint"); Complaint, Strand et al. v. Ford Motor Co. et al., Case No. 8:12-cv-02232-DOC-JPR (C.D. Cal. Dec. 28, 2012) (hereinafter "Strand Complaint").

Ford of a "widespread misleading and deceptive advertising campaign throughout California and the United States" touting the cars' combined (city and highway) 47 miles-per-gallon (mpg) gas mileage estimate provided to the EPA.[8] According to plaintiffs, the EPA estimates do not provide actual mileage for a vehicle under normal, real life driving conditions because the test conditions were designed to maximize fuel mileage.[9] The EPA tests are conducted using lab machines called dynamometers instead of roads, one of the complaints says.[10] In addition, the highway portion of the test uses a speed range of only about 48-60 miles per hour and is performed by a professional driver.[11]

According to the complaints, Consumer Reports found that the C-Max hybrid achieved a combined 37 mpg, and the Fusion hybrid a combined 39 mpg, well under the advertised 47 mpg figure.[12] The class plaintiffs accused Ford of misleading consumers by advertising the EPA mpg estimates as actual, expected mileage under normal, real world driving conditions while failing to disclose that the ratings are mere estimates based on particular testing conditions.[13]

A variation on this theme is the allegation that the testing protocols themselves are flawed, e.g., in lawsuits against Hyundai and Kia about supposedly overstated fuel economy figures due to testing methods that were not compliant with EPA requirements.[14]

Like the Ford and Hyundai/Kia lawsuits, Volkswagen's greenwash is problematic because of the resulting adverse effects on the environment. In this case, the actual NOx output is considerably greater than the testing output. But just as troubling as the result of the deception is Volkswagen's method of deception.

## III. he High-tech Greenwash

The method seems to reflect a new trend of technological greenwashing. Rather than making false or misleading statements in ads and other marketing materials, or providing express representations of inflated numbers, this new form of greenwashing uses technology to deceive.

Technological greenwashing has appeared at least once before the Volkswagen scandal. A class action lawsuit filed in June 2015 in Los Angeles accused Ford of claiming that a software update for the Fusion Hybrid would increase performance and mileage.[15] According to the lead plaintiff, Dave DeLuca, the car's monitor displayed better mileage and less gas usage after the upgrade, but the numbers were inaccurate and the vehicle's actual mileage did not improve.[16]

What's new in the DeLuca case and the Volkswagen scandal is the software piece. After the dealer installed the software update in his car, Mr. DeLuca tested its performance and found that the vehicle's software relayed inaccurate mileage and incorrect gasoline usage figures.[17] When he drove the car under allegedly optimal conditions, he found that the car's monitor was indeed displaying better mileage and less gas usage when the mileage had not actually increased.[18] Mr. DeLuca performed another test, doing comparative driving runs with a gas-only Ford Fusion.[19] He found that the gas-only Fusion displayed accurate numbers while Fusion Hybrid displayed inaccurate figures.[20]

The high-tech greenwash perpetrated by Volkswagen is more insidious than typical greenwashing cases because the entire deception is cloaked in technology. Specifically, deep inside the vehicle where nobody could detect its actions, Volkswagen's software activated emission controls during testing only and subsequently deactivated them during actual use of the vehicles. It is similar to the allegations made against Ford in that software is the mechanism of deception. However, Volkswagen's greenwash arguably is even worse than the Ford Fusion allegations because there isn't even an affirmative misleading dis-

8 Pitkin Complaint at ¶ ¶ 13-23.

9 Pitkin Complaint at ¶ 27.

10 Supra, note 10.

11 Supra, note 10.

12 Pitkin Complaint at ¶ 33.

13 Pitkin Complaint at ¶ ¶ 9-11.

14 Complaint, Hunter et al. v. Hyundai Motor America et al., Case No. 8:12-cv-01909-JVS-JPR (C.D. Cal. Nov. 2, 2012).

15 Complaint, DeLuca v. Ford Motor Co. et al., Case No. BC583666 (Cal. Sup. Ct. Jun. 1, 2015) (hereinafter "DeLuca Complaint").

16 DeLuca Complaint at ¶ ¶ 15-17.

17 DeLuca Complaint at ¶ 16.

18 DeLuca Complaint at ¶ ¶ 15-17.

19 DeLuca Complaint at ¶ 17.

20 Supra, note 20.

play in the vehicle connected to the software as in the Ford case, so consumers had no idea there were any representations being made at all.

## IV. Conclusion

Volkswagen's use of software to cheat on vehicle emissions tests echoes a common thread of greenwashing cases against car manufacturers. That is the charge that a product's real-world performance, in gas mileage for example, does not live up to its testing results. However, the German automaker's use of software to deceive brings a novel technological aspect to greenwashing. This high-tech greenwash perpetrated by Volkswagen is more insidious and disturbing than typical greenwashing cases because the entire deception is cloaked in technology such that consumers may not even be aware that representations are being made. Government watchdogs and consumer should be vigilant because this is unlikely to be the last of the high-tech greenwash.

# The Paris Agreement on Climate Change: A Risk Regulation Perspective

*Lucas Bergkamp**

This mini-symposium of the *European Journal of Risk Regulation* focuses on the Paris Agreement on Climate Change, which was concluded at COP-21 in December 2015. It has been called the 'world's greatest diplomatic success'[1] and a 'historic achievement,' but also an 'epic failure'[2] and even a 'fraud' and 'worthless words.'[3] Disappointed with the Paris Agreement, a group of eleven climate scientists signed a declaration stating that it suffers from "deadly flaws" and gives "false hope;" they argue that the time for "wishful thinking and blind optimism" is over, and "the full spectrum of geoengineering" should be considered.[4] The broad disagreement over the outcome of COP-21 in Paris (in particular, over its binding effect) illustrates not only the diverging expectations of interest groups, but also the antagonisms that arise in all areas of policy-making between the dogmatic and the pragmatic, the idealistic and the realistic, and the internationalists and nationalists.

When compared with previous attempts under the United Nations Framework Convention on Climate Change (UNFCCC), as epitomized by the Kyoto Protocol, to establish a uniform, binding framework for mitigation, the Paris Agreement represents a paradigm shift. Paris' new paradigm, however, raises both old and new issues. The contributions to this mini-special issue illustrate what these issues are, and why and how they arise.

Objectively viewed, the Paris Agreement would appear to be not much more than a procedural framework for future, flexible "bottoms-up"[5] climate policy-making by the parties to it, dressed up with some non-binding language that emphasizes ambition and progression. To meet the US government's desire to avoid Senate approval, the agreement does not impose any binding substantive obligations, but it does set forth the ambitious objective of limiting the global average temperature increase to well below 2 °C or even 1.5 °C. Put differently, the text that came out of Paris represents yet another example of a target- or performance-based voluntary agreement, the results of which are hard to predict.

## I. Is the Paris Agreement Sufficient?

Whether the Paris Agreement is inadequate or sufficient to attain its stated objectives depends on a wide range of facts and values, only some of which are properly understood and foreseeable, and on new knowledge yet to be developed. A key issue will be whether and how new knowledge will be accommodated under the existing agreement and the extent to which it will be appropriately reflected in its implementation. An open mind to alternatives to the controversial policies of mitigation and wind and solar energy will also be necessary. Research has shown that the intended nationally determined contributions (INDCs) submitted in the run-up to COP-21 will only have a negligible effect on reducing the temperature by the year 2100.[6]

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1 Paris climate change agreement: the world's greatest diplomatic success, http://www.theguardian.com/environment/2015/dec/13/paris-climate-deal-cop-diplomacy-developing-united-nations

2 The Paris Climate Change Agreement is an Epic Failure, http://www.flassbeck-economics.de/the-paris-climate-change-agreement-is-an-epic-failure/

3 Paris climate deal: reaction from the experts, Dec 12, 2015, http://www.theguardian.com/environment/2015/dec/13/paris-climate-deal-reaction-experts?CMP=share_btn_link

4 COP21: Paris deal far too weak to prevent devastating climate change, academics warn, The Independent, 8 January 2015, http://www.independent.co.uk/environment/climate-change/cop21-paris-deal-far-too-weak-to-prevent-devastating-climate-change-academics-warn-a6803096.html

5 Richard Stewart, Benedict Kingsbury & Bruce Rudyk (Eds.), Climate Finance Regulatory and Funding Strategies for Climate Change and Global Development, NYU Press, 2009.

6 B. Lomborg, Impact of Current Climate Proposals, Global Policy, 2015, DOI: 10.1111/1758-5899.12295 (showing that the total temperature reduction of all INDCs will be 0.048°C by 2100). For Lomborg's response to critiques, see the links available at http://www.lomborg.com/press-release-research-reveals-negligible-impact-of-paris-climate-promises Cf. J. Reilly et al., Energy and Climate Outlook, Perspectives from 2015, MIT Joint Program on the Science and Policy of Global Change (showing that proposed cuts extended through 2100 result in about 0.2°C less warming by the end of the century compared with 2014 estimates).

Given the current commitments, the Paris Agreement will likely result in a global mean surface temperature increase of between 3.1–5.2 °C by 2100,[7] not even close to its 2 °C target. Thus, the Paris Agreement is unlikely to solve global warming. Other options, such as investments in research and development of new energy technology, may offer better prospects.[8]

Paris' undefined, loose, bottom-up approach would appear to rely heavily on climate diplomacy and political activism.[9] The big gap between collective ambition and individual obligation is destined to put pressure on national democracies, since a sustained and credible commitment to Paris' long term goals is incompatible with the vagaries of national politics driven by short term economic and other interests. As one commentator put it, "business needed to know that the agreement reached here and that the action that will follow is not dependent on political cycles or the changing political fortunes within countries."[10] Indeed, climate change represents the risk society at its fullest potential: it is deemed to be caused by unrestrained industrialization (*market failure*), it is complex, ambiguous, and uncertain, imposes hazards or risks, and it demonstrates the perversion of regulation (*government failure,* or *dysfunctional democracy*).[11] Based on this conception of the issues, urgent action is deemed to be required to correct both the market and government failures. Should diplomacy turn out to be insufficient, climate activists will not hesitate to knock on the door of the judiciary.[12] Other possible "solutions" proposed by climate and social justice activists to tackle climate change contemplate the suspension of national democracy[13] and the establishment of a world government.[14]

The state of affairs described in the previous paragraph is not a hyperbolic or exaggerated representation of climate policy-making, or a negative, distracting view on an urgent issue. It is a rather accurate depiction of reality. The UNFCCC's current Executive Secretary has called the democratic process in the US "very detrimental" to the fight against global warming, and praised China, which operates a one-party political system, for "doing it right" in terms of reducing emissions.[15] She has also announced that climate policy pursues the more general goal of chang-

7 J. Reilly et al., Energy and Climate Outlook, Perspectives from 2015, MIT Joint Program on the Science and Policy of Global Change (showing that proposed cuts extended through 2100 result in about 0.2°C less warming by the end of the century compared with 2014 estimates).

8 The Copenhagen Consensus on Climate project has found that every euro spent on green R&D avoids 100 times more climate change than money spent on inefficient wind and solar. Copenhagen Consensus Center, http://www.copenhagenconsensus.com

9 L. Bergkamp & S. Stone, The Trojan Horse of the Paris Climate Agreement: How Multi-Level, Non-Hierarchical Governance Poses A Threat to Constitutional Government, [2015] Environmental Liability 4, pp. 119-140. Cf. Samantha Page, No, The Paris Climate Agreement Isn't Binding. Here's Why That Doesn't Matter, Dec 14, 2015, http://thinkprogress.org/climate/2015/12/14/3731715/paris-agreement-is-an-actual-agreement (If a country is missing its [submitted] targets, "domestic constituencies will be mobilizing to force government action (…) That's going to be the primary mover of emissions reductions worldwide.") UN Secretary-General Ban Ki-moon called the climate movement "a huge trend" and said "[n]obody can go against this wave." Cited in: Natasha Geiling, How Paris Turned The Climate Movement Into An Everyone Movement, Dec. 14, 2015, http://thinkprogress.org/climate/2015/12/14/3731402/paris-climate-agreement-movement-is-power/ Lewis argues that "both conservative gloating and green grousing about the treaty being 'toothless' overlook what matters most in climate policy: politics." Marlo Lewis, Paris Agreement: Recycled "Process" Socialism, January 3, 2016, http://www.globalwarming.org/2016/01/03/paris-agreement-recycled-process-socialism/

10 What the Paris Climate Agreement Means for Business: A Conversation with BSR's Edward Cameron, http://www.bsr.org/en/our-insights/blog-view/what-paris-climate-agreement-means-for-business-conversation-edward-cameron

11 L. Bergkamp, The concept of *risk society* as a model for risk regulation – its hidden and not so hidden ambitions, side effects, and risks (forthcoming, 2016).

12 L. Bergkamp, "Adjudicating scientific disputes in climate science: the limits of judicial competence and the risks of taking sides", 3 Environmental Liability, 80-102 (2015). As the headline of an article in Politico put it, "[n]ext stop for Paris climate deal: the courts. First came the agreement. Now comes the litigation." Sara Stefanini, Next stop for Paris climate deal: the courts, Politico, 1/13/16, http://www.politico.eu/article/paris-climate-urgenda-courts-lawsuits-cop21/

13 Climate activists willing to suspend or set aside democracy include Shearman and Smith, who have argued that in order to halt or even slow the disastrous process of climate change, we must choose between liberal democracy and a form of authoritarian government by experts. Likewise, in *The Vanishing Face of Gaia: A Final Warning*, Lovelock observes that survival may require the suspension of democratic government. James Lovelock, The Vanishing Face of Gaia: A Final Warning, Penguin, 2010.

14 According to Thomas Pogge, a top academic philosopher who is a driving force behind the Oslo Principles on Global Climate Change Obligations, in order to realize "a peaceful and ecologically sound future" the world needs "supranational institutions and organizations that limit the sovereignty rights of states more severely than is the current practice." Thomas W. Pogge, World Poverty and Human Rights, 2nd Edition, Oxford: Polity Press, 2008, pp. 219-220. Thomas W. Pogge, Kant's Vision of a Just World Order, in: T.E. Hill (ed.), The Blackwell Guide to Kant's Ethics, Blackwell, 2009, pp. 196–208, at 205-206. See also Oslo Principles on Global Climate Change Obligations, http://globaljustice.macmillan.yale.edu/news/oslo-principles-global-climate-change-obligations.

15 Biggest Emitter China Best on Climate, Figueres Says, January 14, 2014, http://www.bloomberg.com/news/articles/2014-01-13/top-global-emitter-china-best-on-climate-change-figueres-says

ing "the economic development model that has been reigning for at least 150 years."[16] The UNFCC secretariat has become the unofficial leader of the new climate governance movement.[17] This movement is working towards the replacement of the capitalist model by a novel social justice-based model operating beyond traditional democratic controls.[18] In the words of the Czech physicist Luboš Motl, "[t]he totalitarian system rocks while democracy sucks!"[19] It is remarkable how little attention this threat receives in political debates: *if an adequate solution of climate change requires the destruction of democracy, shouldn't we decide to live with the consequences of climate change?*

Although the EU itself is only in part structured as a representative democracy, it seems to be committed to upholding national democratic processes. Recently, the Council committed to enhanced "European climate diplomacy after COP21."[20] According to the Council, the EU-led "High Ambition Coalition" could secure "timely signature, swift ratification, and full implementation by all parties of the Paris Agreement." There is nothing in the conclusions, however, that could help to resolve the collective action problem that resulted in the Paris Agreement's huge disparity between collective ambition and individual obligation. Instead, the Council intends to deploy climate action policy not only to combat climate change, but also to help achieve other "sustainability" goals and the promotion and protection of human rights. This approach is likely to render climate action less effective, as it will have to serve many masters. It also tends to deprive climate action of its objective, science-based, and neutral aura, and subject it to the forces of political polarization. And by increasing the influence of activist groups to the detriment of other constituencies, it may aggravate the democratic deficit.[21] In other words, with the Paris Agreement, the EU may have created the ultimate "*Scylla and Charybdis*" scenario, and set itself up for failure by widening the gap between collective aspiration and individual commitment without establishing any effective structure for bridging the gap.

## II. Issues Raised

In addition to these fundamental and structural issues, the Paris Agreement also raises a host of other legal and policy issues. Much has already been said about the legal status of the COP-21 Decision and Paris Agreement, and the extent to which these instruments are legally binding.[22] However, only a set of thorough analyses of the agreement's substance and procedure may determine what requirements the Agreement does, and does not, impose on its signatories.[23] A particularly important issue is whether a national pledge, once officially submitted without qualifications and conditions, is binding on a party. Enforcement mechanisms and sanctions, of course,

16 U.N. Official Reveals Real Reason Behind Warming Scare, http://news.investors.com/ibd-editorials/021015-738779-climate-change-scare-tool-to-destroy-capitalism.htm Cf. the proposed creation of a "movement of movements." Martin Lukacs, Claim no easy victories. Paris was a failure, but a climate justice movement is rising, http://www.theguardian.com/environment/true-north/2015/dec/15/claim-no-easy-victories-paris-was-a-failure-but-a-climate-justice-movement-is-rising

17 The UNFCCC's executive secretary has declared openly that climate policy pursues the more general goal of changing "the economic development model that has been reigning for at least 150 years." U.N. Official Reveals Real Reason Behind Warming Scare, http://news.investors.com/ibd-editorials/021015-738779-climate-change-scare-tool-to-destroy-capitalism.htm

18 Lukasc notes that the "economic system's drive for endless profits and extraction wasn't up for debate in Paris, but it may be soon." Martin Lukacs, Claim no easy victories. Paris was a failure, but a climate justice movement is rising, http://www.theguardian.com/environment/true-north/2015/dec/15/claim-no-easy-victories-paris-was-a-failure-but-a-climate-justice-movement-is-rising Delingpole has claimed that climate change is an ideological battle, not a scientific one, and that the environmental movement wants to rule, not save, the world. James Delingpole, Watermelons: The Green Movement's True Colors, New York: Publius Books, 2011.

19 UNFCC boss: democracy is "very detrimental" for war on AGW, January 14, 2014, http://motls.blogspot.com/2014/01/unfcc-boss-democracy-is-very.html?utm_source=twitterfeed&utm_medium=twitter

20 Council conclusions on European climate diplomacy after COP-21, 15 February 2016, http://www.consilium.europa.eu/en/press/press-releases/2016/02/15-fac-climate-diplomacy/

21 L. Bergkamp, The EU's ineffective climate diplomacy post-Paris,, 22 February 2016, http://www.euractiv.com/section/climate-environment/opinion/the-eus-ineffective-climate-diplomacy-post-paris/. To reduce the democratic deficit, the national parliaments of the member states should be given an opportunity to have a meaningful debate on the Paris Agreement, and approve the burdens it requires of them. L. Bergkamp, National Parliaments should approve Paris Climate Agreement before it is a done deal, EnergyPost, 8 March 2016, http://www.energypost.eu/national-parliaments-approve-paris-climate-agreement-done-deal/.

22 See, e.g., D. Wirth, The International and Domestic Law of Climate Change: A Binding International Agreement Without the Senate or Congress?, Harvard Environmental Law Review, Vol. 39, No. 2, 2015.

23 The uncertainty and vagueness inherent in the Paris Agreement present issues of democratic control; how should a government decide whether it will join, if it cannot tell what its obligations will be?

are also relevant to understanding the Agreement's impact. Further, implementation of the Paris Agreement raises many legal and policy issues,[24] such as whether "burden" or "efforts sharing" mechanisms could and should be agreed.

'Global climate justice' and, in particular, the issue of 'loss and damage' (i.e., damage caused by climate change that are not avoided), will continue to stir debate. Although the COP-21 Decision provides explicitly that the "loss and damage" clauses of the Agreement[25] do not "involve or provide a basis for any liability or compensation,"[26] climate change liability and litigation against both governments and private companies loom large. Further, there are questions around the agreement's relation to specific sectors of industry, such as fossil fuel, renewable energy, and agriculture, and specific practices, such as de- and reforestation. Both mitigation and adaptation processes under the Paris Agreement require further analysis, and so do the issues around technology transfer and climate finance. There are enough questions to fill several volumes of this journal.

The three papers included in this issue illustrate and exemplify the breadth of the issues associated with the Paris Agreement. They address, in turn, the Agreement's relation to science, how the agreement's aspirational objectives may affect future behavior by states, and how it treats agriculture and food security. There is no overarching theme to this collection of essays other than that they all relate to the Paris Agreement. If there is a common thread, it may be that climate policy-making critically depends on facts in a broad sense.

## III. Science and the Paris Agreement

In the first essay, Hanekamp (and I as co-author) assess the relation between science and the Paris Agreement. At several places, the agreement refers to the 'best available science,' without ever defining it. The suggestion is that policy-making pursuant to the Paris Agreement is science-based. According to Hanekamp and Bergkamp, however, the relation between science and climate policy-making is strained and hampers policy makers' ability to pursue science-based policies. At an early stage, precautionary policy set the direction of climate science, which has been unduly focused on anthropogenic emissions as the predominant cause of climate change.[27] Rather than attempting to understand the whole climate system in all of its complexity, climate scientists got bogged down into studying the influence of human greenhouse gas emissions. The 'capture' of the scientific community (including the science-based policy advice community) by policy-makers, a relatively new phenomenon that is to be distinguished from traditional forms of regulatory capture by interest groups,[28] has resulted in a confluence of climate science, risk assessment, and risk management.[29] 'Scientific capture' produced policy-based science, rather than science-based policy.

The essay's main thesis goes beyond a rejection of the claim that the 'science is settled,'[30] which is a *contradictio in terminis* in any event. They posit a 'scientistic' tendency in climate science, by which they mean a belief that the entire climate can be explained and controlled by reference to one single parameter. Such a scientistic tendency manifests itself in the climate models, which make all policies dependent on computational projections, rather than available empirical knowledge. Although the authors acknowledge that models are an accepted and useful method in many areas of science, the key issue with climate models is whether they meet either the 'hard' test of their predictions' (or projections'[31]) conformity to observations, or the 'softer' test of fitness for purpose. Even if climate models are useful for purposes of research, that does not mean they should be used for

24 Harro van Asselt & Stefan Bößner, Reviewing Implementation under the Paris Agreement, Carisma, February 1, 2016, http://www.sei-international.org/publications?pid=2896

25 Note that the Paris Agreement does not establish a procedure for deciding whether any impact is related to climate change.

26 Article 8, Paris Agreement.

27 Sarewitz has noted that "[c]limate science served one main purpose: to advance [a top-down, coordinated, international emissions governance] regime." D. Sarewitz, Does climate change knowledge really matter?, WIRES Climate Change, 2011.

28 G. Stigler, The theory of economic regulation, Bell J. Econ. Man. Sci. 1971, 2, pp. 3-21.

29 The European Commission, however, has insisted on maintaining the risk assessment- risk management distinction in EU policy-making. European Commission, Communication on the Precautionary Principle, Brussels, 2.2.2000, COM(2000) 1 final.

30 President Obama has opined that the climate debate is settled, and refers to critics as "the flat earth society." Obama: No time for a meeting of the Flat Earth Society, http://www.bbc.com/news/world-us-canada-23057369

31 Projections differ from predictions in that "the future will ultimately be determined by actions taken to stabilize our relationship with the planet," leading to the informal fallacy of circular reasoning. http://globalchange.mit.edu/research/publications/other/special/2015Outlook.

policy applications. Despite the models' inherent limitations, the authors argue, they are deemed to fully capture the future of the Earth's climate. The Paris Agreement implicitly legitimizes the scientistic thinking underlying the use of models in climate policy-making. More critically, it contributes to the further codification of the putative causal relations between anthropogenic emissions and global temperature increase, between temperature increase and climate change, and between climate change and adverse impacts. No matter what climate science will show, the policy direction for this century has been set. In our post-modern world, climate science is not powerful because it is true: it is true because it is powerful.–fnref:300-

One might question whether the conclusions reached by Hanekamp and Bergkamp are consistent with the 'scientific consensus' in climate science. What exactly scientists agree on, however, is not clear. It has been claimed that 97% of the scientific literature endorses anthropogenic climate change,[33] but that claim has been disputed,[34] and the debate about the extent of scientific consensus continues.[35] The argument developed in the essay does not target the scientific consensus, but suggests that the scientific 'consensus' (i.e., that anthropogenic emissions cause dangerous climate change) is an artefact of policy decisions and socio-political processes, including pressure and incentives, not of a spontaneous process of consensus formation based on the available empirical evidence. The 'capture' of the scientific community by policy-makers caused the socio-political construction of scientific consensus in the climate area. Climate activists have denied this claim,[36] but it has not been rebutted on the merits.

An issue that the essay does not discuss is what the term 'best available science' means and why the Paris Agreement uses it, rather than some other term. Determining what constitutes the best available science is not straightforward. A definition proposed in the context of United States environmental protection legislation provides as follows: 'scientific data, regardless of source, that are available to the [decision maker] at the time of a decision or action for which such data are required and that the [decision maker] determines are the most accurate, reliable, and relevant for use in that decision or action.'[37] This definition makes clear that the term 'best available science' itself is a policy (or even political), not a scientific, term. By merely setting a relative standard, without any absolute floor, this definition may be satisfied by science that is inaccurate and unreliable. Instead of 'best available science,' the Paris Agreement should have used the concept of 'sound science,' which sets a higher threshold,[38] with a default assumption that no effect is assumed until it has been established on the basis of sound science. At a more general level, legislative or regulatory texts such as the Paris Agreement can refer to a number of science-related concepts, such as scientific consensus, majority science, strength of the evidence, or weight of the evidence.[39] Policy makers need to develop better, more prescriptive terminology when referring to science, so that it is clear what they mean and political maneuvering can be better scrutinized and monitored.

33 J. Cook et al, Quantifying the consensus on anthropogenic global warming in the scientific literature, Environ. Res. Lett. 8, 024024, http://iopscience.iop.org/article/10.1088/1748-9326/8/2/024024;jsessionid=24BB298175E37DFEA88641E3E90A59F6.c1 For an older study producing the same result, see William R. L. Anderegg et al., Expert credibility in climate change, PNAS, 2010, vol. 107, no. 27, pp. 12107–12109. Cf. Peter T. Doran & Maggie Kendall Zimmerman, Examining the Scientific Consensus on Climate Change, EOS, Vol. 90, No. 3, 20 Jan. 2009, pp. 22-23.

34 R. S.J. Tol, Quantifying the consensus on anthropogenic global warming in the literature: A re-analysis, Energy Policy, Volume 73, October 2014, pages 701–705. See also his op-ed in The Guardian, http://www.theguardian.com/environment/blog/2014/jun/06/97-consensus-global-warming

35 L. Bergkamp, "Adjudicating scientific disputes in climate science: the limits of judicial competence and the risks of taking sides", 3 Environmental Liability, 80-102 (2015).

36 Activists have attempted to discredit pertinent counter-arguments merely by reference to slogans such as "merchants of doubt" and "the fossil fuel lobby." Cf. Naomi Oreskes, Erik M. Conway, Merchants of Doubt: How a Handful of Scientists Obscured the Truth on Issues from Tobacco Smoke to Global Warming, Bloomsbury Press, 2010. This book argues that "merchants of doubt" claim that there is no "scientific consensus" on an issue, although there is one. See also https://en.wikipedia.org/wiki/Fossil_fuels_lobby

37 "Best Available Science" Defined in Proposed Endangered Species Act Legislation, http://www.martenlaw.com/newsletter/20051221-best-avail-science See also J. Curry, So what is the best available scientific evidence, anyways?, 14 Aug 2013, https://judithcurry.com/2013/08/14/so-what-is-the-best-available-scientific-evidence-anyways/

38 Society of Environmental Toxicology and Chemistry, Sound Science, Technical Issue Paper, 1999. It has also been defined in simple terms as "robustly supported science, confirmed by multiple peer-reviewed studies." http://rationalwiki.org/wiki/Sound_science

39 For a discussion of some of these terms, see L. Bergkamp & L. Kogan, Trade, the Precautionary Principle, and Post-Modern Regulatory Process: Regulatory Convergence in the Transatlantic Trade and Investment Partnership, European Journal of Risk Regulation, 2013/4, pp. 493-507.

## IV. The New Status Quo of the Paris Agreement

The second essay, authored by Rowell and van Zeben, discusses the psychological impact of Paris' 2-degree aspiration. The authors argue that Paris' temperature target may set a new perceived baseline, from which deviations can be measured. Decision-makers may perceive these deviations from the new status quo as "losses." Because politicians will try to avoid such losses, they will be motivated to achieve international norms. As a result, the psychological impacts of the new perceived status quo of climate policy set by the Paris Agreement may prove to be more durable and impactful than its problematic legal status might suggest.

In developing their novel argument, the authors draw on psychology and behavioral studies, referring to the work of Kahneman, Tversky and Thaler on the endowment effect, loss aversion, and status quo bias, as well as that of Samuelson and Zeckhauser on status quo bias in decision making. Under their theory, Paris' aspirational targets may affect states' behavior either directly through politicians' Parisian cognitive biases or indirectly through citizens expressing their cognitively biased preferences. The authors assume that the psychological processes that work at an individual level also work when individuals take actions at the collective and political level.

According to the authors, the Paris Agreement's endowment effect would arise from the creation of "a perceived norm." Does Paris' temperature target effectively establish a "social norm" among signatory countries? As the authors acknowledge, "international law may have to battle against a number of other potential sources (including of domestic law) for forming perceptions of the status quo." They go on to suggest that "[w]here a problem is both global in scope—as climate change is—and where domestic governments and communities have *struggled to develop a meaningful narrative*, international law may be particularly well-positioned to have a significant impact" (emphasis supplied).

Rowell and van Zeben's argument points to a number of questions that merit further analysis. At bottom, one might wonder whether and, if so, how, another reiteration of a six year old[40] abstract global average temperature target in a non-binding international agreement will establish a new *status quo* baseline and create cognitive bias. The relation between global average temperature and any adverse impacts that individuals might experience, is weak, and there is fierce competition with other cognitive sources working in other directions. Further, it is not obvious that psychological processes that work in some settings at the individual level are also at work when the '*body politic*' makes political or policy decisions. According to the authors, the Paris Agreement's endowment effect might arise from the creation of "a perceived norm." If the term 'norm' refers to a standard of proper or acceptable behavior, is the 2-degree objective a norm? This objective is collective, not individualized; it is an abstract ideal, not a concrete, tangible effect. In short, their hypothesis that the Paris target may have a "significant impact" will have to be tested against the '*Realpolitik*' that thus far has governed climate policy-making and resulted in the gap between what politicians say should be done and what they do in fact.[41]

## V. Agriculture and Food Security

In the last essay, Verschuuren presents an insightful overview of the relation between climate change and agriculture/food security, and what impact the Paris Agreement may have on that relationship. This relation is bi-directional, and interactional. Agriculture and farming contribute to greenhouse gas emissions; the IPCC has figured that agriculture, forestry, and other land use, contribute about 25% of total emissions. On the other hand, climate change affects agriculture in both negative and positive ways; Verschuuren states that agriculture is "among the sectors that will suffer the largest negative impacts of climate

40 The 2-degree target was already included a decision made at COP-16 in 2010; this decision also entertains the idea of a "global average temperature rise of 1.5 °C." See Report of the Conference of the Parties on its sixteenth session, held in Cancun from 29 November to 10 December 2010, FCCC/CP/2010/7/Add.1, Decision 1/CP.16 Decision 1/CP.16: The Cancun Agreements: Outcome of the work of the Ad Hoc Working Group on Long-term Cooperative Action under the Convention, 15 March 2011.

41 L. Bergkamp & S. Stone, The Trojan Horse of the Paris Climate Agreement: How Multi-Level, Non-Hierarchical Governance Poses A Threat to Constitutional Government, [2015] Environmental Liability 4, pp. 119-140. A big problem with Paris' collective objective may be that the savvy politicians of individual nations adopt a "progressive" stance if it does not bite, but a "conservative" one where acts require sacrifice. Cf. Oliver Geden, Paris climate deal: the trouble with targetism, The Guardian, 14 December 2015, http://www.theguardian.com/science/political-science/2015/dec/14/the-trouble-with-targetism

change." The relation between climate change and agriculture is even more complex than that. As the author discusses, there also close relations between climate policy and food security, and, again these relations are bi-directional. To meet the growing demands of a growing population, food production needs to increase. Verschuuren points out, however, that, in addition to climate change negatively impacting food production, climate policy will require substantial emissions reductions from food producers. Although feedbacks between emission reduction and food security are not completely understood, this conflict may threaten food security and, thus, make it harder to feed the world's people. There is another threat to food security which Verschuuren identifies: the large-scale production of crop for biofuels, reduces the area of land available for food production and drives up prices. This is an issue that requires serious reconsideration of policies.

Verschuuren shares his disappointment that the Paris Agreement failed to incorporate the EU's proposals to address the key relations between agriculture and food security and climate policy. In the preamble to the Paris Agreement, there is a reference to "the fundamental priority of safeguarding food security," but that exhausts the agreement's focus on agriculture and food. As the author notes, the Paris Agreement, despite its lack of agricultural references, is highly relevant to agriculture and food security. Article 4 of the Agreement, he suggests, "implies that drastic mitigation actions are needed to reduce emissions from agriculture and land use." One might ask, however, whether that is necessarily the case. It would seem to depend on the mix of measures identified and adopted by each nation. In his conclusions, Verschuuren regrets that the Paris Agreement "does not provide a powerful stimulus to adopt and implement climate smart agriculture policies." Yet, what is smart depends on facts and policy judgments. In the area of agriculture and food security, the key issue would appear to be the choice between mitigation and adaptation: a good case could be made for investment in "no regret" adaptation measures that will produce sound returns, irrespective of whether climate change turns out to be a significant or minor problem.

## VI. Conclusions

The essays included in EJRR's mini-special on the Paris Agreement are far from exhaustive. Much more is to be said about the Agreement and its legal nature. EJRR welcomes further contributions on the Paris Agreement, climate policy, and, more generally, legal and risk regulatory issues relating to climate change and policy-making.

If anything, we can be sure that climate change and climate policy-making, including international policy-making pursuant to the Paris Agreement, will be with us for the foreseeable future. The Paris Agreement and, more generally, climate change policy, almost perfectly illustrate the contradictions of the post-modern industrialized *world risk society*,[42] characterized by perceived threats confirmed by politicized science and governed by sub-politics beyond democratic control.[43] Climate change is the ultimate precautionary, distributive justice issue.[44] There is a tendency to subsume all policy issues in the climate change movement, so climate justice can be pursued as holistic, global, social justice. Indeed, climate change is deemed to penetrate all areas of social policy-making, from energy to agriculture, and from immigration to personal choices, such as how to travel and what to eat. After Paris, climate change will remain 'hot'. It is where the money is and will be; pursuant to the COP-21 Decision, developed nations should collectively contribute at least USD 100 billion a year from 2020 to help poorer nations deal with climate change.[45]

The legal and policy issues relating to climate change are diverse, and so are the perspectives on the issues, as the essays in this issue illustrate. I trust that these essays will help move the debate forward.

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42 U. Beck, Risk Society: Towards a New Modernity, London: Sage, 1992. U. Beck, World Risk Society. Cambridge: Polity Press, 1999. U. Beck, World at Risk, Cambridge: Polity Press, 2009.

43 L. Bergkamp, The concept of risk society as a model for risk regulation – its hidden and not so hidden ambitions, side effects, and risks (forthcoming, 2016).

44 See, for instance, Oslo Principles on Global Climate Change Obligations, http://globaljustice.macmillan.yale.edu/news/oslo-principles-global-climate-change-obligations and the critique set out in L. Bergkamp & S. Stone, The Trojan Horse of the Paris Climate Agreement: How Multi-Level, Non-Hierarchical Governance Poses A Threat to Constitutional Government, [2015] Environmental Liability 4, pp. 119-140.

45 COP-21 Decision, under 54.

# The 'Best Available Science' and the Paris Agreement on Climate Change

*Jaap C. Hanekamp and Lucas Bergkamp**

## I. Introduction

Recognising the importance of science to climate policies, the Paris Agreement on Climate Change (the 'Paris Agreement' or 'Agreement') stipulates that 'an effective and progressive response to the urgent threat of climate change' should be based on 'the best available scientific knowledge.'[1] The terms 'best available scientific knowledge' or 'best available science' are used in several places throughout the agreement. The parties should undertake emission reductions and achieve carbon-neutrality (zero net emissions[2]) in the second half of this century in accordance with 'best available science', which seems to accommodate scientific progress.[3] Despite these references to science, the relation between the 'best available science' and the Agreement is ambiguous at best and calamitous at worst.

In the area of climate policy making, there are four interlocking issues that imperil policies' scientific basis. First, the definitions of 'climate change' that circulate within the Paris Agreement's policy and science sphere are inconsistent and apocryphal, which impedes the scientific enterprise of climate research. Second, the predictive ability of climate science is driven by modelling, making all policies reliant on computational projections rather than available empirical knowledge. Third, as a result of these deficiencies, climate science is policy-led instead of climate policy being science-led, as the Paris Agreement seems to require. Finally, under these circumstances, the concept of 'best available science' allows the pursuit of politically convenient policies that interact with the computational projections. These issues are discussed in turn below.

## II. Concepts of Climate, Change, and Default Assumptions

Article 1 of the UN Framework Convention on Climate Change (UNFCCC) defines 'climate change' as 'a change of climate which is attributed directly or indirectly to human activity that alters the composition of the global atmosphere and which is in addition to natural climate variability observed over comparable time periods.'[4] This definition thus centers on *human influences* through anthropogenic greenhouse gases emissions and deforestation. The Intergovernmental Panel on Climate Change (IPCC), conversely, has focused on '*any* change in climate over time, *whether due to natural variability* or as a result of human activity.'[5]

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1 Recital, Paris Agreement, UNFCCC/CP/2015/L.9, http://unfccc.int/resource/docs/2015/cop21/eng/l09.pdf (accessed 18th February 2016). The Agreement is to be distinguished from the Decision of the COP (Conference of Parties, the governing body of the UNFCCC), which precedes it. Pursuant to the UNFCCC, the COP is authorized only to make the 'decisions necessary to promote the effective implementation of the Convention.' Article 7(2), UNFCCC. Thus, the decision that precedes the Agreement may be binding with respect to implementation aspects.

2 The parties aim to 'undertake rapid reductions thereafter in accordance with best available science, so as to achieve a balance between anthropogenic emissions by sources and removals by sinks of greenhouse gases in the second half of this century, on the basis of equity, and in the context of sustainable development and efforts to eradicate poverty.' Article 4(1), Agreement.

3 Article 4(1), Agreement. Gerrard has suggested that this provision, 'when closely read, seems to call for the virtual end of fossil fuel use in this century unless there are major advances in carbon sequestration or air capture technology.' Michael B. Gerrard, Legal Implications of the Paris Agreement for Fossil Fuels, http://blogs.law.columbia.edu/climatechange/2015/12/19/legal-implications-of-the-paris-agreement-for-fossil-fuels/#sthash.OSCkkkfc.dpuf (accessed 18th February 2016).

4 United Nations Framework Convention On Climate Change. 1992, United Nations. See https://unfccc.int/resource/docs/convkp/conveng.pdf (accessed 18th February 2016).

5 IPCC, 2007. Summary for Policymakers. In: "Climate Change 2007: The Physical Science Basis. Contribution of Working Group I to the Fourth Assessment Report of the Intergovernmental Panel on Climate Change." Cambridge University Press, Cambridge, United Kingdom and New York, NY, USA. Emphasis added.

At an operational level, however, the IPCC's role is 'to assess (...) the scientific, technical and socio-economic information relevant to understanding the scientific basis of risk of *human-induced* climate change.'[6]

Scientifically, the Earth's climate system is defined as 'consisting of the atmosphere, hydrosphere, lithosphere, and biosphere, determining the Earth's climate as the result of mutual interactions and responses to external influences (forcing). Physical, chemical, and biological processes are involved in the interactions among the components of the climate system.'[7] No reference to human influence is made here. Of course, such influence is included, but subsumed under the interactions and processes to which the definition refers.

The scientific definition of climate accentuates the peculiarity of the UNFCCC's and IPCC's conceptions of the climate and potential changes thereof. By unduly focussing on human-induced climate change, scientists are compelled to filter out human causes of climate change (anthropogenic greenhouse gas emissions specifically) from the myriad of multi-decadal alterations in one or more physical, chemical and/or biological components of the complex climate system.[8] This emphasis on anthropogenic emissions has had significant consequences for the development and direction of climate science.[9]

To be able to do science relevant to the UNFCCC and IPCC, the actual occurrence and magnitude of human climate influences are simply assumed to be detectable and quantifiable. This postulation has overestimated scientists' potential, however, by way of a series of counterfactuals, it asks scientists to study what the climate would be like *without* some or all of human influences, and compare it to the world *with* human influences. Logically, answers to such questions can be produced *ad infinitum*, but verification and/or falsification is beyond anyone's reach.[10]

In this conundrum, policy makers did not bother to explain how to investigate a world that does not exist. Rather, inspired by the reversal of the burden of proof implicated in the precautionary principle,[11] they included a default assumption of human-induced climate change due to anthropogenic greenhouse gas emissions in the definitions that were codified. Subsequently, scientists simply adhered to these definitions. The Paris Agreement has worsened this problem by further reinforcing the putative causal dominance of greenhouse gas emissions in the etiology of climate change.

## III. Policy-led Science – The Scientism of Climate Change

The analysis in the preceding section raises questions regarding the 'best available science'. The Paris Agreement provides no definition. At a minimum, it includes the IPCC reports, to which the Agreement explicitly refers. COP-21 has invited the IPCC 'to provide a special report in 2018 on the impacts of global warming of 1.5 °C above pre-industrial levels and related global greenhouse gas emission pathways,'[12] and the 'latest IPCC reports' are to be included in the

6 Principles Governing IPCC Work, Approved at the Fourteenth Session (Vienna, 1-3 October 1998) on 1 October 1998, amended at the Twenty-First Session (Vienna, 3 and 6-7 November 2003), the Twenty-Fifth Session (Mauritius, 26-28 April 2006), the Thirty-Fifth Session (Geneva, 6-9 June 2012) and the Thirty-Seventh Session (Batumi, 14-18 October 2013), https://www.ipcc.ch/pdf/ipcc-principles/ipcc-principles.pdf (emphasis supplied; accessed 18th February 2016).

7 National Research Council of the National Academies. *Radiative Forcing of Climate Change. Expanding the Concept and Addressing Uncertainties.* 2005. The National Academies Press. Washington, D.C, p. 15.

8 See https://pielkeclimatesci.wordpress.com/2010/10/04/definitions-of-global-warming-and-climate-change/ (accessed 18th February 2016).

9 R.A. Pielke Jr., "Misdefining ''climate change'': consequences for science and action", 8 *Environmental Science & Policy* 548 – 561 (2005). See also J A Curry, P J Webster and G J Holland 'Mixing politics and science in testing the hypothesis that greenhouse warming is causing a global increase in hurricane intensity' Bulletin of the American Meteorological Society 1025–37 (August 2006).

10 See further W.M. Briggs, Natural Variations In Weather Do Not Explain The 'Pause': Update, With Letter to Nature, Feb. 5, 2015, http://wmbriggs.com/post/15201/ (accessed 18th February 2016).

11 L. Bergkamp & J.C. Hanekamp, "European Food Law and the Precautionary Principle – Paradoxical Effects of the EU's Precautionary Food Policies," In: Kai Purnhagen & Harry Bremmers, Food Law and Economics. Springer Verlag (forthcoming).

12 COP-21 Decision, under 21. According to Hulme, "the UNFCCC's invitation raises the issue of whether the IPCC is in a position to deliver such a report in 2018, and if so, whether its assessment would be useful and robust. More generally, the invitation refocuses attention on the function and status of the IPCC as an institution that mediates between climate science, governance and policy and, more broadly, questions how the interactions between knowledge and values in environmental geopolitics are conceived and navigated." Mike Hulme, 1.5 °C and climate research after the Paris Agreement, Nature Climate Change, Vol. 6, March 2016, pp. 222-224.

'global stocktake.'[13] By the terms of the Agreement, scientific insights and results outside the IPCC's assessment reports are not *a priori* excluded from competing for the label of 'best available science'.

For science to be helpful in the context of the Agreement, however, it should meet the policy makers' expectations.[14] Indeed, the UNFCCC already set as its 'ultimate objective' the '*stabilization of greenhouse gas concentrations* in the atmosphere at a level that would prevent *dangerous atmospheric interference with the climate system*'.[15] Here, the UNFCCC speciously reifies the term 'dangerous', i.e. it defines it as a fixed and unalterable point of reference in reality, whereas the degree to which the climate is (or could become) 'dangerous' differs widely across the globe and further hinges on how different communities appraise security and risk.[16] By promulgating this reification, governments sent a clear message to the scientific community: 'helpful' climate science aids to achieve the ultimate objective. By framing the issue as such, the seeds of climate scientism were sown (see further below).[17]

As one would expect, the Paris Agreement calls on the IPCC to provide the scientific backup for the policy decisions that have already been made.[18] Post-Paris, the IPCC, which is *not* an independent scientific body but a government-led "partnership which is helping to unify the scientific and policy-making communities of the world to lay the foundation for effective, realistic and equitable action on climate change,"[19] will be even less able to avoid bias and resist the mounting political pressure.[20] International policymaking and the related funding opportunities will push scientists further in the direction of 'verifying' that climate change is caused by human activities, and tends to give all climate research one and the same hypothesis for further testing.[21]

Climate policy-making thus imposed serious constraints on scientific enquiry. The political demands on science to detect and attribute climate change to anthropogenic emissions put researchers in a serious bind, divided the scientific community, and, through sticks and carrots,[22] 'converted' many climate scientists to join the camp of 'the helpful.' Any scientific drive towards critical scrutiny and falsification was thereby stifled. Consequently, within the framework of the Paris Agreement, the 'best available science' can only be understood as research that is consistent with the Agreement as drafted. There is hence no need for defining what 'best available science' means. Competing research in the field of climate change has little chance to develop, as adequate funding is hard to obtain.

Essentially, with its reference to science, the Paris Agreement endorses a form of reductionism that is scientistic in nature. Science is expected to be able to *entirely* gauge the climate system, its change with reference to the anthropogenic addition of greenhouse gases to the atmosphere, and the resultant dangers. Once the link between the anthropogenic addition

13 COP-21 Decision, under 100.

14 '[I]t was not until 1995 [i.e. after the UNFCCC and IPCC had been created, JH & LB] that the IPCC 2nd Assessment Report identified a 'discernible' human influence on global climate.' J.A. Curry, "Statement to the Committee on Science, Space and Technology of the United States House of Representatives' Hearing on 'The president's U.N. Climate pledge", (15 April 2015).

15 Article 2, UNFCCC. It provides that '[s]uch a level should be achieved within a time-frame sufficient to allow ecosystems to adapt naturally to climate change, to ensure that food production is not threatened and to enable economic development to proceed in a sustainable manner.' This objective is based on the findings that 'human activities have been substantially increasing the atmospheric concentrations of greenhouse gases, that these increases enhance the natural greenhouse effect, and that this will result on average in an additional warming of the Earth's surface and atmosphere and may adversely affect natural ecosystems and humankind.' Emphasis added.

16 See R. Pielke Jr., *The Climate Fix What Scientists and Politicians Won't Tell You About Global Warming*, Basic Books, New York: 2010.

17 See further: M. Stenmark, *Scientism. Science, Ethics and Religion*, Ashgate Publishing Limited, Aldershot, England: 2001. F.A. Hayek, Scientism and the Study of Society. Part II, 10(37) *Economica New Series*, 34 – 63 (1943). M. Polanyi, The Two Cultures, *Encounter*: 61 – 65 (September 1959).

18 Curry calls this '[t]he 'policy cart' (…) leading the scientific 'horse.'' J.A. Curry, "Statement to the Committee on Science, Space and Technology of the United States House of Representatives' Hearing on 'The president's U.N. Climate pledge' (15 April 2015)". Darwall has argued that 'bias in the IPCC is endemic.' Rubert Darwall, The Age of Global Warming: A History, London: Quartet Books, 2013, p. 348.

19 Report of the Second Session of the Intergovernmental Panel on Climate Change (IPCC), Nairobi, 28 June 1989, https://www.ipcc.ch/meetings/session02/second-session-report.pdf

20 As Beck observes, the IPCC leadership acts 'in an overtly political manner while simultaneously claiming to be disengaged from politics.' She poses the rhetorical question 'why the prevailing form of leadership [is] not openly challenged by participating scientists and governments.' S. Beck, "Between Tribalism and Trust: The IPCC Under the 'Public Microscope,'" 7(2) *Nature and Culture*, Summer 151–173.

21 Pielke, note 9. See further M. Stenmark, *Scientism. Science, Ethics and Religion*, Ashgate Publishing Limited, Aldershot, England: 2001.

22 L. Bergkamp, "Adjudicating scientific disputes in climate science: the limits of judicial competence and the risks of taking sides", 3 *Environmental Liability*, 80-102 (2015).

of greenhouse gases to the atmosphere and climate change is ostensibly established, the Earth's climate is supposed to be understood as a whole, including the detrimental consequences for human life.

The logic contained in this view is that of the 'control panel' metaphor.[23] Within the causal chain of events that is defined as 'climate change' scientistically understood, human activities *lead* to the emission of additional greenhouse gases into the atmosphere, which *leads* to climate change, which *leads* to 'dangerous' negative impacts. So, abating these negative impacts 'simply' requires the reversal of the causal chain, shifting the focus to the reduction of greenhouse gases. Following the causal chain of events backward, the much-trumped mitigation strategy imposes itself, and 'stabilisation' of the climate is more or less warranted. Accordingly, the Earth's climate is deemed to have a greenhouse gases 'thermostat.' Endorsing this logic, the Paris Agreement 'notes with concern' that 'the estimated aggregate greenhouse gas emission levels in 2025 and 2030 resulting from the intended nationally determined contributions do not fall within least-cost 2 °C scenarios but rather lead to a projected level of 55 gigatonnes in 2030, and 'much greater emission reduction efforts will be required than those associated with the intended nationally determined contributions in order to hold the increase in the global average temperature to below 2 °C above pre-industrial levels by reducing emissions to 40 gigatonnes or to 1.5 °C above pre-industrial levels.'

Here, a mischaracterisation of the behaviour of the world's climate system is looming large.[24] The scientistic view holds that climate change is primarily driven by emitted anthropogenic greenhouse gases, and should be remediated through far-reaching policies, in particular mitigation. In addition to greenhouse gas emissions, however, other 'first-order human climate forcings' are important to understanding the future behavior of Earth's climate.[25]

## IV. Virtuality – Climate Model Projections and Reality

Consistent with climate science's long-term perspective, the Paris Agreement stipulates what should happen in the second half of this century. To achieve the Agreement's temperature goal, the signatories are required to 'reach global peaking of greenhouse gas emissions as soon as possible,' and 'undertake rapid reductions thereafter in accordance with best available science, so as to achieve a balance between anthropogenic emissions by sources and removals by sinks of greenhouse gases in the second half of this century.'[26]

These proclamations reflect climate policy-making's need for and trust in long term predictions of global average atmospheric temperature increases as a function of atmospheric greenhouse gas concentrations. To provide the predictions required by the policy makers, climate scientists have developed computer models, which supply the epistemic basis for defining climate communication strategies and regulatory policies. Thus, the merits of the Agreement's policies hinge foremost on the accuracy and reliability of the climate models.[27]

Models, of course, are an accepted and useful method in many areas of science.[28] Like any other method used in science, a model can only be any good if it meets the basic requirements of scientific methodology: (i) it should enable predictions about reality, (ii) these predictions should be sufficiently precise and immediate in time so as to be testable, and (iii) they should correspond to observations or measurements.[29] If a model enables only imprecise

23 Pielke, note 9.

24 J.A. Rial, R.A. Pielke Sr., M. Beniston, M. Claussen, J. Canadell, P. Cox, H. Held, N. de Noblet-Ducoudre, R. Prinn, J. Reynolds, & J.D. Salas, "Nonlinearities, feedbacks and critical thresholds within the Earth's climate system" 65 *Climatic Change*, 11-38 (2004).

25 As Pielke Sr. has stated, '[t]hese forcings are spatially heterogeneous and include the effect of aerosols on clouds and associated precipitation (…), the influence of aerosol deposition (e.g., black carbon (soot) ( …) and reactive nitrogen (…), and the role of changes in land use/land cover (…) Among their effects is their role in altering atmospheric and ocean circulation features away from what they would be in the natural climate system (…) As with $CO_2$, the lengths of time that they affect the climate are estimated to be on multidecadal time scales and longer.' R. Pielke Sr., "Climate Change: The Need to Consider Human Forcings Besides Greenhouse Gases," 90(45) *Eos*, 413-414 (2009).

26 Article 4(1), Paris Agreement.

27 The term "climate models" is used here to refer the full range of models used in connection with climate policy-making, including General Circulation Models and Integrated Assessment Models (the latter are economic models). See generally IPCC, What is a GCM?, http://www.ipcc-data.org/guidelines/pages/gcm_guide.html, and IPCC, Working Group III: Mitigation, 7.6.4 Integrated Assessment Models, http://www.ipcc.ch/ipccreports/tar/wg3/index.php?idp=311.

28 P. Humphreys, *Extending Ourselves: Computational Science, Empiricism, and Scientific Method.* Oxford University Press, Oxford: 2004.

29 R. Feynman, *The Meaning of It All: Thoughts of a Citizen-Scientist.* Perseus Books, Massachusetts, USA: 1998. A.Chalmers, *What is this thing called Science?* UQP, Queensland, Australia: 2013.

predictions, produces two or more inconsistent predictions, or otherwise does not meet these conditions, it is a less than optimal representation of reality. In science, these kinds of issues are part of the standard discourse, and there are methods, standards, and metrics for assessing the performance (validity, reliability, accuracy) and usefulness of models. In this regard, climate models raise questions that are not further addressed here.[30]

In relation to climate policy-making, the key issue associated with climate models is whether they are fit for the purpose of supporting assessments of the 'social cost of carbon,'[31] projecting the timing that the Earth's climate is expected to cross 'dangerous thresholds' (e.g., 3°C), and assessing the impact of $CO_2$ mitigation on the global climate. Substantial uncertainties in the equilibrium climate sensitivity[32] and the growing discrepancy between climate model simulations and observations in the 21st century (e.g. Figure 11.25 in the IPCC AR5[33]) are raising serious questions about whether climate models are suitable for these purposes.

Climate models produce projections of global average atmospheric temperature for different scenarios of atmospheric greenhouse gas concentrations. Actual temperature measurements have created an opportunity to test the climate models empirically, and the models have performed poorly. While the empirical measurements over the last 18 years (roughly since 1998) show little warming at the surface and no warming in the atmosphere, the CMIP5 (*i.e., Coupled Model Intercomparison Project Phase 5, JH/LB*) climate models predicted more substantial temperature increases, resulting in 'over-warming' by a factor of 2.5 to 3.0.[34] According to the IPCC, an 'analysis of the full suite of CMIP5 historical simulations (...) reveals that 111 out of 114 realizations show a GMST trend over 1998–2012 that is higher than the entire HadCRUT4 (*a global temperature dataset, JH/LB*) trend ensemble (...) This difference between simulated and observed trends could be caused by some combination of (a) internal climate variability, (b) missing or incorrect radiative forcing and (c) model response error. These potential sources of the difference (...) are not mutually exclusive.'[35] Other authors have observed that '[i]t is true that there has been a warming hiatus and that the surface of the earth has warmed up much less rapidly since the turn of the millennium than all the relevant climate models had predicted. However, the gap between the calculated and measured warming is not due to systematic errors of the models (...) but because there are always random fluctuations in the Earth's climate.[36] The 'global warming hiatus' debate continues until to date.[37]

The framing of the substantial discrepancy between the models' predictions and actual measurements requires attention: according to the IPCC, the discrepancy would be due to random fluctuations, not systematic errors. If the uncritical adoration of climate modelling is not tempered, there is a risk that in climate science theory trumps reality. This su-

30 For further discusssion, see for instance, Christopher Essex & Ross McKitrick, Taken by Storm: The Troubled Science, Policy, and Politics of Global Warming, Toronto: Key Porter Books, 2008. John Abbot et al., Climate Change: The Facts, Woodsville, NH: Stockade Books, 2015.

31 To assess the economic/social cost of carbon, integrated assessment models have been built. These models receive their inputs from the climate models.

32 N. Lewis, J.A. Curry, "The implications for climate sensitivity of AR5 forcing and heat uptake estimates", 45(3) *Climate Dynamics*, 1009 – 1023.

33 Intergovernmental Panel on Climate Change (IPCC). 2013. *Climate Change 2013: The Physical Science Basis. Working Group I Contribution to the Fifth Assessment Report of the IPCC.* Cambridge University Press, Cambridge, p. 1011.

34 Testimony of John R. Christy, University of Alabama in Huntsville. U.S. House Committee on Science, Space & Technology, 2 Feb 2016. Christy underlined that 'for the global bulk atmosphere, the models overwarm the atmosphere by a factor of about 2.5. … the models over-warm the tropical atmosphere by a factor of approximately 3, (Models +0.265, Satellites +0.095, Balloons +0.073 °C/decade) again indicating the current theory is at odds with the facts.'

35 IPCC, 2013, Note 37, p. 769.

36 *Global warming slowdown: No systematic errors in climate models* (2015, February 2). Retrieved 9 February 2016 from http://phys.org/news/2015-02-global-slowdown-systematic-errors-climate.html. See further: J. Marotzke & P.M. Forster, "Forcing, feedback and internal variability in global temperature trends", 517 *Nature*, 565–570 (2015)

37 Jeff Tollefson, Global warming 'hiatus' debate flares up again: Researchers now argue that slowdown in warming was real, Nature, 24 February 2016, doi:10.1038/nature.2016.19414, http://www.nature.com/news/global-warming-hiatus-debate-flares-up-again-1.19414 ("There is this mismatch between what the climate models are producing and what the observations are showing," quoting John Fyfe). John C. Fyfe et al., Making sense of the early-2000s warming slowdown, Nature Climate Change 2016, 6, pp. 224–228, doi:10.1038/nclimate2938 (published online 24 February 2016) ("It has been claimed that the early-2000s global warming slowdown or hiatus, characterized by a reduced rate of global surface warming, has been overstated, lacks sound scientific basis, or is unsupported by observations. The evidence presented here contradicts these claims.") See also Ronald Bailey, Global Warming Hiatus Is Real, Feb. 24, 2016, http://reason.com/blog/2016/02/24/global-warming-hiatus-is-real ("the fact that global average temperature increases have been considerably slower during the first years of this century than most climate models projected").

premacy of climate theory is prompted by the scientistic fallacy of reification: the models are interpreted to encompass all of climate reality, *including* 'fluctuations in the Earth's climate' as a result of drivers such as the heat content of the oceans,[38] and the reality will eventually 'confess.' The reification of the models involves a curious contradiction, as they did not forecast the 21st century slowdown in global warming.

From a practical perspective, if the models provide inaccurate predictions of temperature increases, how much trust should we have in their ability to predict climate change *and* its adverse impacts? Any errors in the climate models are amplified in the integrated assessment models used to assess the 'social cost of carbon,'[39] which results in inflated estimates. Given the models' deficiencies, should the climate policies of almost all governments in the world, which require huge expenditures over decades to come, be based on such a feeble foundation? To be sure, climate models may be useful for purposes of research, but as long as they do not accurately represent the Earth's climate over time and produce reliable predictions, they should not be the main driver of climate policy making.

The 21st century discrepancy between climate models and observations, and the reaction of some scientists to it, also tell us something about the nature of the climate science discourse. To 'explain away' the discrepancy, scientists have proffered many new theories, some of which are mutually exclusive or conflicting.[40] The 'hiatus revisionism,' to borrow Judith Curry's words,[41] has exposed a deeper problem: the defensive responses reveals a reluctance to review the evidence with an open mind, an *a priori* rejection of the proposition that the climate models may simply be wrong, and an unwillingness to subject them to serious empirical and logical scrutiny.

So far, the empirical challenges to climate modelling have not prompted a fundamental reconsideration of how the climate change problem is conceived, from both a scientific and policy perspective. A science journalist aptly asks: "if the rate of temperature increase continues to remain low, at what point do the models and projections of catastrophic warming get called into question by mainstream researchers?"[42] Such a resistance to change is not uncommon. As Werner Heisenberg observed, when 'new groups of phenomena compel changes of thought (...) even the most eminent of physicists find immense difficulties. Once one has experienced the desperation with which clever and conciliatory men of science react to the demand for a change in the thought pattern, one can only be amazed that such revolutions in science have actually been possible at all.'[43]

If no empirical evidence can be held in opposition to the climate models, modelling itself has become utopian in kind, and the models are held to be impervious to reality as is.[44] That, of course, would render the whole exercise unscientific.

## VI. In conclusion - Science and the Politics of Precaution

Although the Paris Agreement entertains the concept of science-based policy-making, its ability to ensure that policies are accurately informed by science is severely hampered. The Agreement's unspecified concept of 'best available science' allows policy-makers to pursue politically expedient policies supported by climate model projections to their liking.

In an early stage, an activist policy community, operating under the weak democratic controls of the international policy-making system and outside national structures for policy-making and judicial re-

38 G.A. Meehl, J.M. Arblaster, J.T. Fasullo, A. Hu & K.E. Trenberth, "Model-based evidence of deep-ocean heat uptake during surface-temperature hiatus periods", 1 *Nature Climate Change*, 360-364 (2011). H. Douville, A. Voldoire, & O. Geoffroy, "The recent global warming hiatus: What is the role of Pacific variability?", 42 *Geophysical Research Letters*, 880–888 (2015). W. Llovel, J. K. Willis, F. W. Landerer & I. Fukumori, "Deep-ocean contribution to sea level and energy budget not detectable over the past decade", 4 *Nature Climate Change*, 1031–1035 (2014).

39 Such models combine key elements of biophysical and economic systems into one integrated system. See http://www.ipcc.ch/ipccreports/tar/wg3/index.php?idp=311

40 Ronald Bailey, Global Warming Hiatus Is Real, Feb. 24, 2016, http://reason.com/blog/2016/02/24/global-warming-hiatus-is-real ("There have been scores of studies that have tried to explain away this inconvenient fact [of the hiatus].")

41 "I have been expecting to start seeing papers on the 'hiatus is over.' Instead I am seeing papers on 'the hiatus never happened.'" See https://judithcurry.com/2015/09/17/hiatus-revisionism/ (accessed 18th February 2016).

42 Ron Bailey, Global Warming Hiatus Is Real, Feb. 24, 2016, http://reason.com/blog/2016/02/24/global-warming-hiatus-is-real

43 W. Heisenberg, *Across the Frontiers*, Harper and Row, New York, NY: 1974.

44 See I. Berlin, *The Apotheosis of the Romantic Will: The Revolt against the Myth of an Ideal World*. In: *The Crooked Timber of Humanity – Chapters in the History of Ideas*, John Murray (Publishers) Ltd., London: 1990.

view, has set the objective that climate science 'had to' support. Their thinking was driven by the precautionary principle and the reversal of the burden of proof. By implied agreement, the default assumption has been that anthropogenic greenhouse gas emissions cause dangerous climate change, and that the safety of such emissions would have to be proven.[45] Through the use of these default assumptions and predictive models, climate science is able to supply 'helpful' information to policy-makers. Consequently, rather than the policy being science-based, the science has become policy-based.

As the issue of the global temperature 'hiatus' illustrates, the ability of climate science to self-correct and properly inform policy-making is hampered by an inability to reexamine the fundamental assumptions driving the scientific enterprise and its relation to policy-making. Given climate policy's objectives, funding agencies, scientists, and scientific advisors, in turn, are encouraged to provide 'policy-relevant' science supporting the policies pursued by the politicians.

Rather than attempting to reverse this trend, the Paris Agreement aggravates the current problems by reinforcing the scientistic thinking underlying climate policy-making: it codifies the putative causal relations between anthropogenic emissions and global temperature increase, between temperature increase and climate change, and between climate change and adverse impacts. It even intensifies and extends this thinking to make the temperature increase limitation goal more ambitious and to require net zero emissions by the second half of this century.

With the Paris Agreement, the relation between climate policy-making and science has become even more strained and entrenched. As Kuhn observed, the scientist is 'a solver of puzzles, and the puzzles upon which he concentrates are just those which he believes can be both stated and solved within the existing scientific tradition.'[46] Unfortunately, at this juncture, the revolution that is necessary to change the state of affairs requires not only a scientific, but also a political and policy paradigm shift. While the former is already difficult enough to achieve, the Paris Agreement made the latter even harder by increasing the stakes through coupling very substantial financial streams with the dominant hypothesis of human-induced climate change.

None of this will matter, if innovative science comes up with new sources of energy-conversion technologies that will render the issue of human induced climate change moot. Thus, despite the debacle in Paris, there is hope.

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45 See further: W.J. Mckinney & H. Hammer Hill, "Of Sustainability and Precaution: The Logical, Epistemological, and Moral Problems of the Precautionary Principle and Their Implications for Sustainable Development", 5(1) *Ethics and the Environment*, 77 – 87 (2000).

46 T.S. Kuhn, *The Structure of Scientific Revolutions*, The University of Chicago Press, Chicago: 1996.

# A New Status Quo? The Psychological Impact of the Paris Agreement on Climate Change

*Arden Rowell and Josephine van Zeben**

*This brief opinion piece draws upon behavioural and cognitive research to argue that the Paris Agreement's goal of keeping global temperature change below 2 degrees Celsius sets a psychologically powerful baseline against which future policy failures can be measured. When international law successfully triggers perception of a baseline, it can lead decision-makers to perceive deviations from that baseline as "losses." This implicates loss aversion, which provides an additional motivation to achieve international norms. The psychological impacts of this new status quo may end up being more powerful and more durable than either the unusual structure of the document or the domestic implementation questions that have already attracted so much scholarly debate.*

Climate change poses unique challenges to regulators around the world. The international response to these challenges has taken the form of a rich patchwork of international treaty negotiations; an expansive schedule of meetings and working groups tasked with providing a set of norms upon which to build a global response to climate change. In the years after the ratification of the United Nations Framework Convention on Climate Change in 1994, the pressure to reach agreement on a global solution for climate change has continuously compounded.[1] Yet before Paris, the closest negotiators had come to a global agreement was the Kyoto Protocol in 1998, a carefully drafted instrument that mostly imploded after the U.S. refused to ratify it, and which in any case never applied to China, Brazil, India, or other developing countries.[2] As the pressure mounted post-Kyoto, dysfunctions seemed to mount as well, culminating in the disastrous 2009 meetings at Copenhagen.[3]

The most recent meeting of the so-called Conference of the Parties (COP) took place in Paris in December 2015. In the months leading up to the meeting, a number of important foundational steps made observers cautiously optimistic about the chances of a meaningful agreement.[4] The most optimistic observers hoped to see the Agreement articulate a goal of keeping future temperature change below 2°C warmer than pre-industrial levels—the level above which scientists agree changes would reach a catastrophic tipping point.[5] Many commentators, however, considered this aim to be hopelessly naive,[6] as well as politically and practically unattainable.[7]

Against this backdrop, the goals of the Paris Agreement on Climate Change are nothing short of stun-

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1 Full text available on http://unfccc.int/files/essential_background/background_publications_htmlpdf/application/pdf/conveng.pdf.

2 The Protocol's ratification process was fraught with political controversy and did not happen until 2005. See http://unfccc.int/resource/docs/convkp/kpeng.pdf.

3 See, e.g., http://www.theguardian.com/environment/2009/dec/18/copenhagen-deal; see also http://www.bbc.com/news/science-environment-34274461 (suggesting that even the word "Copenhagen" was a "word that dare not be uttered" by anyone at the Paris meeting; a disaster that "still haunts the process six years on").

4 Perhaps most critically, the United States and China entered into a bilateral agreement to reduce emissions, see https://www.whitehouse.gov/the-press-office/2015/09/25/us-china-joint-presidential-statement-climate-change.

5 See most recently the Fifth Report of the Intergovernmental Panel on Climate Change (2014), available at https://www.ipcc.ch/report/ar5/wg3/.

6 See, e.g., Jonathan Katz, Who Wants What in the Final Climate Deal, New Republic, https://newrepublic.com/article/125662/wants-final-climate-deal (December 11, 2015).

7 The practical challenges are recognized even within the decision that adopts the Paris Agreement, see paragraph 17 ("*Notes* with concern […] that much greater emission reduction efforts will be required than those associated with the intended nationally determined contributions in order to hold the increase in the global average temperature to below 2 °C above pre-industrial levels […] or to 1.5 °C above pre-industrial levels […]")

ning.[8] There is now an international agreement that includes all important actors, including the United States and China, and requires a reduction of greenhouse gasses from all of them while recognizing their different stages of economic development.[9] Moreover, the parties agreed to a goal even more ambitious than the 2°C mark that was widely considered infeasible; the Agreement stipulated that the parties intend to "hol[d] the increase in the global average temperature to well below 2 °C above pre-industrial levels and to pursue efforts to limit the temperature increase to 1.5 °C above pre-industrial levels."[10]

This incredibly ambitious goal has already been both lauded and ridiculed. Some have gone so far as to label the agreement "a fraud" and "worthless words."[11] Others have heralded the agreement as "historic," "a diplomatic triumph,"[12] or even "a revolution."[13] Most legal academics have been muted in their praise and their criticism, warning that much of the Agreement's promise is contingent on its implementation, and pointing out that the value of the commitments in the Agreement depends completely on countries' willingness and ability to meet them.[14] And it is worth noting that, even if all countries were completely successful in implementing their domestic commitments at the levels agreed to in the Paris Agreement on Climate Change, the result would still be—conservatively—a 2.7°C rise in temperature.[15]

In the remainder of this short piece, we suggest that an exclusive focus on the feasibility and implementation of the Paris goals could obscure what may end up being one of the most important long-term impacts of the Agreement: namely, the psychological impact that the Agreement may have on the perceived status quo of climate change policy.

Empirical evidence shows that people tend to adjust their own behaviour to conform to what they perceive to be the status quo.[16] Once a state of the world is believed to represent the status quo, people will work both consciously and subconsciously to justify and promote that state of the world.[17] Law can create status quos: when people are given two options and told that one is the default preferred by a (domestic) legal regime, participants treat the default rule as the status quo.[18] We will argue that international legal agreements like the Paris Agreement on Climate Change—and by extension, international law more generally—may present a powerful way to establish a psychological perception of status quo, and that the result may importantly impact the perceived state of the world—and thus the likelihood that the selected state of the world actually comes into being. While nation states are often discussed in international law and policy as if states were autonomous decision makers, states are constructed by individuals who are subject to their own cognitive biases. These biases may affect negotiators and citizens alike, both of which may then influence the state

8 For the concluded Paris Agreement and supporting documentation, please visit http://unfccc.int/meetings/paris_nov_2015/session/9057/php/view/documents.php

9 See e.g. Article 2(2) ("This Agreement will be implemented to reflect equity and the principle of common but differentiated responsibilities and respective capabilities, in the light of different national circumstances.") and Article 4(1) of *ibid* ("In order to achieve the long-term temperature goal set out in Article 2, Parties aim to reach global peaking of greenhouse gas emissions as soon as possible, recognizing that peaking will take longer for developing country Parties, […] on the basis of equity, and in the context of sustainable development and efforts to eradicate poverty.")

10 Article 2(1) Paris Agreement.

11 James Hansen as quoted in http://www.theguardian.com/environment/2015/dec/12/james-hansen-climate-change-paris-talks-fraud.

12 Jeffrey Sachs as quoted in http://www.cbc.ca/news/technology/climate-scientists-paris-1.3366751

13 French President Hollande as quoted by http://www.independent.co.uk/environment/cop21-ministers-keep-the-world-waiting-for-ratification-of-historic-climate-change-target-a6770821.html.

14 The structure of the Paris Agreement is rather idiosyncratic, with the actual Agreement placed in an Annex to a COP decision. For an anticipatory discussion of the Agreement's particular form and its implications, see S. Maljean-Dubois et al, 'The Legal Form of the Paris Climate Agreement: A Comprehensive Assessment of Options' (2015) *Carbon and Climate Law Review* 68.

15 C. Ebinger, 'Transforming the Global Energy Environment', in A. Bhattacharya et al, *COP21 at Paris: What to Expect* (Brookings Institute, 2015) at 34.

16 *See* Dan Kahneman, Jack Knetsch & Richard Thaler, *Anomalies: The Endowment Effect, Loss Aversion, and Status Quo Bias*, 5 J. Econ. Persp. 193 (1991); William Samuelson & Richard Zeckhauser, *Status Quo Bias in Decision Making*, 1 J. Risk & Uncertainty 7 (1988).

17 *See* John T. Jost, Mahzarin R. Banaji & Brian A. Nosek, *A Decade of System Justification Theory: Accumulated Evidence of Conscious and Unconscious Bolstering of the Status Quo*, 25 Pol. Psychol. 881 (2004).

18 *See* Russell Korobkin, Inertia and Preference in Contract Negotiations: The Psychological Power of Default Rules and Form Terms, 51 *Vand. L. Rev.* 1583 (1998) (finding that the substance of legal default rules can create status quo bias in the direction of the legal rule).

as it determines its response to its international obligations.[19]

The mechanism of status quo bias ties in with many of the most fundamental behavioural insights of the past half century, including the endowment effect, a phenomenon whereby people value items in their possession more than items that they do not possess.[20] It also links back to loss aversion and prospect theory: the tendency of people to weight losses more heavily than concomitant gains.[21] These phenomena combine to mean that the effective creation of a status quo has a fundamental psychological impact, in that it identifies an endowment baseline against which subsequent losses (or gains) will be measured. [22]

## I. Status Quo in International Law

The potential implications of status quo bias on international law appear to have been unaccountably neglected.[23] As with domestic law, whenever international law is effective at creating a perceived norm, it may become possible to invoke the power of the endowment effect and loss aversion against diversions from that status quo. For many problems, such as gun violence, the status of women, or the internal distribution of wealth, international law may have to battle against a number of other potential sources (including of domestic law) for forming perceptions of the status quo. Where a problem is global in scope—as climate change is—and where domestic governments and communities have struggled to develop a meaningful narrative, however, international law may be particularly well-positioned to have a significant impact.

Furthermore, the impact of status-quo setting is immune to one of the primary criticisms of international law: its ineffective enforcement.[24] Generally, the lack of an international court with compulsory jurisdiction, or a universal police force that could sanction violating states, is viewed as one of the most disconcerting feature of international law: how can international legal norms matter if no one is there to enforce them?[25] International law scholarship answers this question predominantly through theories of self-interest – a state complies with the law because the law reflects its pre-existing interests[26] – and social norms – the state complies with the law because not doing so would harm its reputation.[27]

19 An interesting question—beyond the scope of this piece—is the extent to which cognitive phenomena affect nation states as a group, as opposed to merely the individual decision-makers within those nation states. At least some empirical research suggests that group-based decision-making can often exacerbate the underlying biases of individuals. *See, e.g.*, Cass Sunstein, *Deliberative Trouble? Why Groups Go to Extremes*, 110 Yale L.J. 71 (2000).

20 *See, e.g.*, Richard H. Thaler, *Toward a Positive Theory of Consumer Choice*, 1 J. Econ. Behav. & Org. 39 (1980) (describing the endowment effect);

21 *See* Daniel Kahneman & Amos Tversky, *Prospect Theory: An Analysis of Decision Under Risk*, 47 Econometrica 263 (1979) (noting that the tendency of people to overweight certain outcomes and underweight probabilistic outcomes may lead people to accept overly high risks in the hopes of avoiding a certain loss); Amos Tversky & Daniel Kahneman, *Loss Aversion and Riskless Choice: A Reference-Dependent Model*, 106 Q. J. Econ. 1039 (1991); *see also* Russell Korobkin, Behavioral Economics, Contract Formation, and Contract Law, in Behavioral Law and Economics at 116 (2000) (describing the perceived relationship between status quo bias and the endowment effect).

22 The combination of these effects underlies most of the most well-known behavioural "nudges" of the past decade. See, e.g., Richard Thaler & Shlomo Benartzi, Save More Tomorrow: Using Behavioral Economics to Increase Employee Saving, 112 J. of Pol. Econ. 164 (2004) (advocating for the use of default rules to take advantage of people's preference for the status quo to encourage additional saving behaviours).

23 Although scholars occasionally mention the status quo in international law, this seems generally to be in the colloquial sense rather than in the psychological sense. See, e.g., Andrew T. Guzman and Timothy L. Meyer, *International Soft Law*, (2010) 2 (1) Journal of Legal Analysis 171-225. We find only one substantive discussion of status quo bias in the international legal literature: an interesting treatment by T. Broude, which focuses on the barriers status quo bias can create in reaching international agreements, and which does not discuss the potential impact of international law on *creating* perceived status quos. See T Broude, Behavioral International Law, (2015) 163 University of Pennsylvania Law Review 1099.

24 For an overview of the literature on this point, see W. Bradford, International Legal Compliance: An Annotated Bibliography, 30(2) North Carolina Journal of International Law (2004) 379-428.

25 For an overview of this puzzle and the presentation of a potential solution, see A. Bradford and O. Ben-Shahar, "Efficient Enforcement in International Law", 12 Chicago Journal of International Law 375 (Winter 2012). See also See e.g. R. Goodman ad D. Jinks, How to Influence States: Socialization and International Human Rights Law, 54 Duke Law Journal (2004), 621 – 703 (on a social theory of state behavior).

26 *See e.g.* Duncan Snidal, "Rational Choice and International Relations" in Walter Carlsnaes, Thomas Risse & Beth A. Simmons, eds, Handbook of International Relations (London, UK: Sage Publications, 2013) 85 and Jack L. Goldsmith and Eric A. Posner, A Theory of Customary International Law, 66 U. Chi. L. Rev 1113 (1999).

27 Martha Finnemore & Kathryn Sikkink, "International Norm Dynamics and Political Change" (1998) 52:4 International Organization 887-917; Ryan Goodman & Derek Jinks, Socializing States. Promoting Human Rights Through International Law (Oxford, UK: Oxford University Press, 2013). See also cf. Anne van Aaken, "To Do Away with International Law? Some Limits to 'The Limits of International Law'" (2006) 17 The European Journal of International Law 289–308 (critiquing Goldsmith and Posner, ibid, and on alternative theories including social norms).

The mechanism of status quo bias offers a different kind of answer to the key question of enforcement. If the norms codified by states through treaty-making effectively establish a psychological status quo baseline against which future action is evaluated, this baseline will trigger the core behavioural phenomenon of loss aversion: failure to meet the new status quo is viewed as a loss, which is psychologically (and thus politically) weighty. The resulting decisions are self-sorting and self-enforcing: status quo bias will apply to anyone who views a norm as having been effectively established as the status quo. This does not, of course, negate differential impacts across countries, groups, or individuals who may perceive an international legal norm as more or less binding: the less binding a norm appears, the less effective it may be at establishing a status quo. The question of how binding a norm appears need not be a purely legal assessment; it may also involve the perceived likelihood of enforcement, the membership of the treaty, the salience of the issue and the domestic support for the norm.[28] Yet where international law is effective at establishing a perceived status quo, psychological phenomena create significant stickiness to that perceived baseline, even without an international police, court, or other entity to enforce it. In sum, viewing international legal norms as status quo baselines provides both a theoretical basis and a potential empirical foundation for claims that norm-setting in international law can affect decision making and thus behavior — even where external enforcement is limited or nonexistent.

## II. The Paris Baseline

A key challenge to climate change policy relates to the difficulty of visualizing both success and failure on the climate change stage. Climate change processes are diffuse, complex, and variable across time and space. As a result, many individuals trying to evaluate climate change still resort to mental shortcuts, like comparing this year's summer temperatures to the baseline of last year's.[29] These ad-hoc baselines are neither accurate indicators of the progression of climate change, nor useful in attempting to limit long-term catastrophic temperature changes. But in the absence of other baselines, they have at least provided some sense of status quo.

Given this backdrop, what role can international law play? Is there reason to think that the 2°C baseline set in the Paris Agreement might in fact constitute a (new) status quo regarding climate change?

There are several reasons to believe that it has, and that it may have done so effectively. First, consider that any international agreement—and particularly international agreements that, like the Paris Agreement, incorporate virtually universal political buy-in—presents the opportunity for setting psychologically powerful norms. Psychological research suggests that unanimity is one of the major factors that tends to affect individuals' tendency to want to conform to communal-set norms.[30] The strong message sent by the unanimous adoption of the Agreement thus strengthens the ability of the Agreement to establish a status quo against which future behaviour can be measured.

Second, and complementarily, the Agreement's choice to select a quantified goal also presents a psychological focal point against which future judgments can be formed. Prior to Paris, climate change agreements were notable for the qualitative nature of their goals. One popular formulation was to attempt to avoid "dangerous anthropogenic change."[31] Negotiators in Paris could easily have chosen to adopt similar language—language that is general enough to leave pre-existing notions of the baseline expectations for international action unmoved. Instead, the Paris Agreement selected identifiable and quantitative targets by which future success—or failure—can be measured: to keep temperature change "well below 2°C above pre-industrial levels [with] efforts to limit the temperature increase to 1.5°C above pre-industrial levels." These goals can be measurably missed: a global increase of 2.7°C will have clearly failed to meet the goals of the Paris Agreement on Climate Change. Whether the same increase would constitute "dangerous anthropogenic change" would at least have been open to further debate. But with a quantitative goal, such hedging is curtailed.

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28 *Ibid*.

29 See Lisa Zaval, Elizabeth Keenan, Eric J. Johnson & Elke Weber, How warm days increase belief in global warming, 4 *Nature Climate Change* 143 (12 June 2013).

30 For a useful summary of psychological research on conformity, see Elliot Aronson, "Conformity," in The Social Animal (2011).

31 See e.g. Article 2 of the UNFCCC.

Even beyond the impact of quantification, the creation of the two-tiered goal may further impact the formation of a status quo in two ways. First, the Paris goals may be understood as establishing both a criterion of "success"—keeping temperature increase to 1.5°C—and of "failure"—failing to keep the increase to less than 2°C. The identification of a metric of failure is likely to be particularly psychologically powerful, as it may trigger loss aversion. Second, and relatedly, the difference between "success" and "failure"—0.5°C—helps create a baseline against which to measure the quantity of deviation from the goal(s) that would constitute success or failure. Compare this to (even a quantified) goal of just keeping temperature change "below 2°C." Is such a goal *failed*—in the loss-aversion sense—if temperature change is kept to 2.2°C? It is at least plausible to think that the psychological impact of such a "failure" might be less than where, as under the Paris Agreement on Climate Change, the 2°C goal is already established as a backstop. This all suggests that the result of the Paris Agreement's unanimous acceptance of a quantitative two-tiered goal of temperature reduction may be that it has now become possible for the world to fail at addressing climate change in a much more psychologically concrete way than was possible before any quantitative baseline was selected.

## III. Conclusions

Our behavioural reading of the Paris Agreement on Climate Change hints at a fundamental psychological impact of international law—an impact that has been missed in widespread dismissals of "soft law" and in concerned abstraction with international enforcement and domestic implementation.[32] In fact, norm-setting in international law may often play a critical psychological function by establishing a status quo baseline from which future actions are evaluated. In this sense, scholarly preoccupation with the agreement's structure, terms, and implementation may miss the most important contribution of the Paris Agreement on Climate Change: the psychological impact of the new status quo that the climate will not warm more than 1.5°C, or at most 2°C. Dismissing aspirational norms, such as those expressed in the Paris Agreement on Climate Change, ignores their fundamental psychological impact and the possible corresponding effect on state compliance under international law.

32 See generally Guzman and Meyer, *supra* note 21.

# The Paris Agreement on Climate Change: Agriculture and Food Security

*Jonathan Verschuuren**

## I. Why Focus on Agriculture and Food Security?

In the coming few decades, the world is facing three related problems.

First, agriculture contributes to climate change to a considerable extent. In its Fifth Assessment Report, the IPCC's Working Group III concludes that the AFOLU sector (agriculture, forestry and other land use) is responsible for just under a quarter (~10 – 12 GtCO2eq/yr) of anthropogenic GHG emissions.[1] Usually, a distinction is made between non-$CO_2$ emissions, in particular methane ($NH_4$) emitted by livestock and rice cultivation, and nitrous oxide ($N_2O$) caused by the use of synthetic fertilizers and the application of manure on soils and pasture. Methane and Nitrous oxide have 25 times and 300 times stronger impact on the climate than $CO_2$ respectively. $CO_2$ emissions from agriculture are mainly caused by deforestation and peatland drainage. Emissions from agriculture have been rising on a yearly basis since 1990, although with important regional differences (they went down in Europe and up in Asia).[2] So far, these emissions have not been addressed under the UNFCCC and the Kyoto Protocol, partly because of a lack of political will, because of fear of negative impact on food production, and because of regulatory difficulties.[3] It is, for example, difficult to measure emissions at the individual farm level since a variety of factors determine the amount of emissions (such as the diet of individual animals, soil composition, weather systems of individual regions, the way in which fertilizer is applied, etc.).[4] In addition to emissions, removals are relevant as well since crops and other vegetation absorb $CO_2$ from the air.

Second, agriculture is also among the sectors that will suffer the largest negative impacts of climate change, for which, consequently, huge adaptation efforts are needed.[5] In its 5th Assessment Report, the IPCC finds that for the major crops in tropical and temperate regions (wheat, rice and maize), climate change without adaptation will negatively impact production with local temperature increases of 2°C or more.[6] In fact, the IPCC finds that climate trends have already negatively affected wheat and maize production for many regions,[7] which has led some to comment that even the Agreement's goal of 1,5°C will be insufficient to stop productivity loss in agri-

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1 P Smith et al., 'Agriculture, Forestry and Other Land Use (AFOLU)' in *Climate Change 2014: Mitigation of Climate Change. Contribution of Working Group III to the Fifth Assessment Report of the Intergovernmental Panel on Climate Change* (Cambridge University Press 2014) 816.

2 Smith et al., above note 2 at 823.

3 See in more detail my chapter 'Climate Change and Agriculture under the United Nations Framework Convention on Climate Change and Related Documents' in: M J Angelo, A DuPlessis (eds.), Research Handbook on Climate and Agricultural Law (Edward Elgar 2016).

4 Hugh Saddler and Helen King, 'Agriculture and Emissions Trading: The impossible dream?' (The Australia Institute Discussion Paper 2008) 102.

5 J R Porter et al., 'Food Security and Food Production Systems' in *Climate Change 2014: Impacts, Adaptation, and Vulnerability. Part A: Global and Sectoral Aspects. Contribution of Working Group II to the Fifth Assessment Report of the Intergovernmental Panel on Climate Change* (Cambridge University Press 2014) 513.

6 Porter et al., above note 6 at 488.

7 Ibid. at 491. In some high-latitude regions, individual locations also benefit from climate change. It is expected that the majority of locations will experience negative impacts while some locations benefit from climate change. Overall, there will be a steady decline of the world's food production because of climate change. Ibid. at 505.

culture.[8] Negative yield impacts for all crops past 3°C of local warming without adaptation are to be expected, even with benefits of higher $CO_2$ and rainfall (both positively affecting plant growth).[9] There is high confidence that irrigation demand will increase significantly in many areas (by more than 40% across Europe, USA, and parts of Asia).[10] A wide range of adaptation measures is considered necessary. According to the IPCC effective adaptation of cropping could be critical in enhancing food security and sustainable livelihoods, especially in developing countries.[11] Adaptation of cropping includes altering cultivation and sowing times, crop cultivars and species, and marketing arrangements.[12] When focusing on water availability, switching to more appropriate crop varieties (drought-resistant, salt-resistant, low water demand), improved irrigation efficiency, reduced demand for irrigation water, and reusing wastewater to irrigate crops are important adaptation measures.[13]

Third, we live in a world that is increasingly food-insecure. Between now and 2050, there will be a sharp increase in the demand for agricultural products. It has been calculated that global food production needs to increase by 40% to meet growing demand, mainly because of population growth (the world's population will grow from 7 billion today to 9 billion in 2050) and because of a rise in global calorie intake by 60% due to greater affluence, particularly in countries like China and India.[14] Climate change negatively impacts food production, so it is expected that the rise in production will be difficult to achieve. It is expected that by 2050, 56% of crops in Sub-Saharan Africa and 21% of crops in Asia will be negatively affected by the consequences of climate change, for instance because of shifts in water availability, temperature shifts and changes in the occurrence of pests.[15] To make things worse, under a business-as-usual scenario, a rise in agricultural production would lead to a further increase of greenhouse gas emissions from agriculture.[16] Roughly in the same period of time, however, global greenhouse gas emissions have to sharply decrease to meet the UNFCCC's goal of a less than 2°C rise of global temperature. Firm mitigation policies could, therefore, negatively affect food production. The IPCC noted that, although feedbacks between greenhouse gas reduction and food security are not completely understood,[17] large-scale biomass supply for energy, or carbon sequestration in the AFOLU sector provide important mitigation measures, but at the same time have potential implications for food security.[18] Research indicates that the large-scale use of bioenergy is threatening food security in Africa because productive lands for sustainable food production are used to produce biofuels.[19] The 2007/2008 global food price spikes are believed to have been partially caused by the rise in biofuel production.[20] Conventional agriculture will also face price increases from emission caps or pricing mechanisms placed upon the use of fuels and fertilizers, as agriculture is a heavily energy dependent sector not only in the developed world, but also increasingly in Latin America and Asia.[21] This shows that climate policies and agricultural policies have to be carefully aligned so as to prevent negative side effects of climate change mitigation on food security and vice versa.

## II. Agriculture in the Paris Agreement on Climate Change

Agriculture was hardly specifically mentioned in the various versions of the Negotiating Text for the Paris Agreement on Climate Change, nor in the final text that was adopted at COP21.[22] The only mention was

8 See, for example, the blogpost by Bruce Campbell, director of the CGIAR Research Program on Climate Change, Agriculture and Food Security, coordinated by the University of Copenhagen: Climate Change: Half a Degree Will Make a World of Difference for the Food We Eat <http://www.huffingtonpost.com/bruce-campbell-phd/climate-change-half-a-deg_b_8756428.html> accessed 1 February 2016.

9 Porter et al, above note 6 at 505.

10 Ibid. at 251.

11 Ibid. at 514.

12 Ibid.

13 Ibid. at 255.

14 Bruce Campbell, Wendy Mann, Ricardo Meléndez-Ortiz, Charlotte Streck and Timm Tennigkeit, *Agriculture and Climate Change: A Scoping Report* (Meridian Institute 2011) 1.

15 Ibid. at 2.

16 Ibid. at 3.

17 Smith et al., above note 2 at 837.

18 Ibid. at 816.

19 Ibid. at 854.

20 ICTSD-IPC Platform on Climate Change, Agriculture and Trade: Considerations for Policymakers (International Centre for Trade and Sustainable Development 2009) 2.

21 Ibid.

22 This section is based upon the negotiating texts and the final agreement, all of which are available through <http://paristext2015.com/> accessed 1 February 2016.

in the provision on mobilizing finance where states are called upon to support the integration of climate objectives into other policy-relevant areas and activities "such as agriculture".[23] In the final Agreement Negotiating Text by the Co-chairs, all references to "agriculture" had disappeared.[24] As a consequence, the Agreement, as adopted at COP21, does not refer to agriculture at all.

In the full text proposals which aimed to set adaptation goals, "maintaining food security" was mentioned,[25] but in the final Agreement Negotiating Text by the Co-chairs, this reference had disappeared, only to reappear in the draft COP Decision's preamble.[26] The latter reference did survive the negotiations in Paris at COP21, so that the preamble to the Paris Agreement on Climate Change now states: "Recognizing the fundamental priority of safeguarding food security and ending hunger, and the particular vulnerabilities of food production systems to the adverse impacts of climate change".

Food production regularly also emerged as a topic in the full Negotiating Texts as a limiting factor to mitigation actions (similar to Art. 2 UNFCCC, see section 2.3 above). In the final version of the Paris Agreement on Climate Change, only one such reference survived. Article 2 has the main objectives of the Agreement, one of which is: "Increasing the ability to adapt to the adverse impacts of climate change and foster climate resilience and low greenhouse gas emissions development, in a manner that does not threaten food production".[27]

Given the contribution of agriculture to climate change and the impact of climate change on agriculture, it is disappointing that so little attention is paid to agriculture in the Paris Agreement on Climate change that sets the tone for the coming years.

The European Union opted for a much firmer approach toward agriculture. In the run-up to the Agreement, the European Commission announced that it would encourage "climate friendly and resilient food production, while optimising the sector's contribution to greenhouse gas mitigation and sequestration."[28] For example, it proposed to include cropland and grazing land management in its policy from 2020, developing instruments to do so before 2020. The EU even proposed to focus its future climate change instruments on all agricultural activities, such as enteric fermentation, manure management, rice cultivation, agricultural soils, prescribed burning of savannahs, field burning of agricultural residues, liming, urea application, other carbon-containing fertilisers, cropland management and grazing land management and "other."[29] As a consequence, the EU proposed to fully include agriculture in the Paris Agreement on Climate Change in two ways: as a source of greenhouse gas emissions, and as a means of $CO_2$ absorption and sequestration. This would mean that the agricultural sector has to undergo a drastic transition from conventional farming to farming using climate smart agricultural practices.

The fact that the Paris Agreement on Climate Change does not pay attention to agriculture, does not mean that the document will not be important for the sector. Article 4 states that a balance needs to be achieved between anthropogenic emissions by sources and removals by sinks of greenhouse gasses in the second half of this century, in order to hold the increase in the global average temperature well below 2 degrees Celsius above pre-industrial levels.[30] Recent research shows that a 1.5 to 2 degree target roughly implies a transition to net zero carbon emissions worldwide to be achieved between 2045 and 2060.[31] This automatically implies that drastic mitigation actions are needed to reduce emissions from agriculture and land use, as this sector is responsible for almost 25% of the global emissions (as was shown above). Many of the provisions on adaptation and finance aim at giving increased support to developing countries to meet their adaptation needs, both through greater emphasis on providing financial re-

23 FCCC/ADP/2015/1, 40 (version 11 June 2015) (under 101bis).

24 Co-chairs, Non-paper of 5 October 2015, <http://unfccc.int/resource/docs/2015/adp2/eng/8infnot.pdf> accessed 1 February 2016.

25 FCCC/ADP/2015/1, 21 (under 50).

26 Co-chairs, above note 25 at 10.

27 Art. 2(1)(b) Paris Agreement on Climate Change.

28 European Commission, 'Commission Staff Working Document. Accompanying the Document Communication from the Commission to the European Parliament and the Council "The Paris Protocol - A Blueprint for Tackling Global Climate Change Beyond 2020"' (SWD 2015) 17 final, 18.

29 European Commission, 'Energy Union Package. Communication from the Commission to the European Parliament and the Council "The Paris Protocol – A Blueprint for Tackling Global Climate Change Beyond 2020"' (COM 2015) 81 final, 16.

30 Art. 4(1) and Art. 2(1)(a) Paris Agreement on Climate Change. Note that the draft texts proposed much stricter end goals, such as zero emissions or full decarbonisation by 2050, FCCC/ADP/2015/1, 9-10 (under 17.2).

31 J Rogelj, G Luderer et al., ' Energy system transformations for limiting end-of-century warming to below 1.5 °C' (2015) 5 *Nature Climate Change* 519.

sources and through the transfer of technology and capacity building.[32] Given the impact of climate change on agriculture and the dependence of developing countries on this sector, it is beyond doubt that implementation of these new provisions will largely focus on agriculture. Another important new instrument may become the National Adaptation Plan (NAP). Under the Agreement, parties are required to engage in adaptation planning processes and building the resilience of socioeconomic systems, which obviously also include agricultural policies.[33] Other pending changes that are relevant for agriculture are a further integration of the various funds under the Financial Mechanism of the Convention, and a strengthening of the role of the Adaptation Committee.[34]

## III. Outlook

Climate change has a profound impact on agriculture and on food security. At the same time agriculture contributes to climate change to a considerable extent. Fortunately there is also much to gain since the agricultural sector holds significant climate change mitigation potential through reductions of greenhouse gas emissions and enhancement of sequestration: "Agriculture offers a wealth of opportunities to deliver simultaneously on improving agricultural resilience to climate change, increasing food production, and lowering emissions. Many of these opportunities use practices, technologies, and systems that are already available and affordable, but need to be tailored to specific contexts and may require incentives from climate finance to ensure adoption. Some interventions also benefit wider environmental services, farming incomes, and agriculture-based economies."[35] A policy aimed at achieving greenhouse gas emission reductions, adaptation to climate change and an increase in productivity is, therefore, very much needed. "Climate smart agriculture" policies are being proposed, but so far remain underdeveloped.

Unfortunately, the Paris Agreement on Climate Change does not provide a powerful stimulus to adopt and implement climate smart agriculture policies. The Agreement, in this respect, does not change the troublesome relationship between agriculture policies and climate policies that we have already witnessed under the UNFCCC and the Kyoto Protocol. Under the UNFCCC, there is little attention to reducing emissions from agriculture. Most attention focuses on adaptation to climate change in rural areas in developing countries, particularly through the various instruments that finance adaptation projects in developing countries. Yet even in that area progress is painfully slow. Much more concrete action is needed to facilitate the transfer of adaptation technologies and adaptation know-how as well as funds to finance adaptation measures in agriculture to developing countries. For the developed countries, the UNFCCC does not make much of a contribution to addressing climate change and food security issues. This is a pity, as the developed country agriculture sector will play an important role in addressing the increasing global demand for food. Fortunately developed countries, including important players such as the EU, do not have to wait for the UNFCCC process. The EU recently announced its intention to implement an ambitious policy aimed at climate friendly and resilient food production, while optimising the agricultural sector's contribution to greenhouse gas mitigation and sequestration. It is of vital importance that this example is followed and implemented across the globe. Hopefully such initiatives will then be picked up by the international community under the UNFCCC process.

32 See for example Articles 7, 9, 10 and 11 of the Paris Agreement on Climate Change.

33 Art. 7(9) Paris Agreement on Climate Change.

34 See the decision that accompanies the Paris Agreement on Climate Change, FCCC/CP/2015/L.9.

35 Campbell et al., above note 15 at 92.

# Opening Editorial

*Jesse L. Reynolds**

Climate change is among the most important and perhaps *the* most challenging problem that global society presently faces, posing serious risks to humans and the environment. The European Union has made climate change one of its top issues. Commission President Jean-Claude Juncker in his agenda (then as president-elect) named "a forward-looking" and "responsible" climate change policy among his ten priorities.[1] The Commission has adopted very aggressive targets for reducing the greenhouse gas emissions that cause climate change, and intends to allocate 20% of the EU's budget for climate-related activities.[2] Furthermore, Europe was at the forefront in crafting the new Paris climate agreement.

Despite these efforts, it is highly likely that the world will surpass the internationally agreed-upon threshold of 2°C warming.[3] In response to insufficient emissions abatement, some scientists and others are increasingly considering proposals that are more drastic. They assert that society should consider "climate engineering" or "geoengineering", "the deliberate large-scale intervention in the Earth's climate system, in order to moderate global warming".[4] Some proposed climate engineering methods presently appear to have the potential to significantly reduce climate risks. However, they also pose environmental and social risks of their own, and are politically contested. Although some form of regulation is warranted, existing legal instruments are insufficient, leaving regulatory gaps.

Climate engineering proposals are diverse. Those in the first of two primary categories seek to remove carbon dioxide—the most important greenhouse gas—from the atmosphere and sequester it for the long term. These methods are relatively slow, expensive, low risk, further developed, and uncontroversial. For example, plants could be grown at large scales—which pulls carbon dioxide from the air—and burnt for energy. The carbon dioxide emitted during burning could be captured and stored. Those in the second primary category would make the planet slightly more reflective in order to counteract climate change. For the most part, such so-called "solar radiation management" are relatively fast-acting, inexpensive, risky, less developed, and controversial. The leading proposal would involve injecting very fine aerosol particles into the upper atmosphere. These particles would spread globally, cooling the planet in a manner similar to the effects of dust emitted by large volcanic eruptions.

Most attention regarding the application of existing legal instruments, and the potential development of new ones, to regulate climate engineering has focused on the international arena. International law will eventually be important, especially for the potential global implementation of solar radiation management. However, European and national law will be relevant in the shorter term. These legal instruments are, compared with international law, more specific, more detailed, and more readily adapted to changing circumstances. Yet there have been few publications regarding national legal environments, and none for Europe.[5]

This is not due to a lack of interest in climate engineering within Europe. The Commission itself has funded two large international climate engineering assessment projects.[6] The Commissioner for Climate

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1 Jean-Claude Juncker, "A New Start for Europe: My Agenda for Jobs, Growth, Fairness and Democratic Change. Political Guidelines for the next European Commission," Opening Statement in the European Parliament, Plenary Session, Strasbourg, 15 July 2014.

2 European Commission, "An EU budget for low-carbon growth," Press Release, 19 November 2013.

3 See e.g. Climate Action Tracker, "2.7°C is not enough – we can get lower," 8 December 2015, available on the Internet at <http://climateactiontracker.org/assets/publications/briefing_papers/CAT_Temp_Update_COP21.pdf> (last accessed 29 January 2016).

4 John Shepherd, Ken Caldeira, Peter Cox, et al., *Geoengineering the Climate: Science, Governance and Uncertainty* (London: The Royal Society, 2009), at p. ix.

5 See e.g. Tracy Hester, "Remaking the World to Save it: Applying U.S. Environmental Laws to Climate Engineering Projects", 38 *Ecology Law Quarterly* (2011), pp. 861 *et sqq*.

6 See Hauke Schmidt, Ulrike Niemeier, Claudia Timmreck, et al., "The FP7 Project IMPLICC Implications And Risks Of Engineering Solar Radiation To Limit Climate Change", available on the Internet at < https://implicc.zmaw.de/fileadmin/user_upload/implicc/other_documents/implicc_final_report_20121130_publishable_summary.pdf> (last accessed 29 January 2016); Stefan Schäfer, Mark Lawrence, Harald Stelzer, et al., "The European Transdisciplinary Assessment of Climate Engineering (EuTRACE): Removing Greenhouse Gases from the Atmosphere and Reflecting Sunlight away from Earth", 2015, available on the Internet at <http://www.iass-potsdam.de/sites/default/files/files/rz_150715_eutrace_digital.pdf> (last accessed 29 January 2016).

Action and Energy clearly indicated that carbon dioxide removal is on the table as a potential additional option.[7] Two of its member states—the United Kingdom and Germany—have been quite active, including providing funding, albeit limited, for research programs.[8]

In order to address the gap in understanding the role of Europe in regulating climate engineering and its risks, Tilburg Law School hosted an international workshop on "Climate Engineering Regulation and European Law" at Tilburg University on 22 and 23 September 2014. The thirteen participants' presentations offered a wide of perspectives. Four of these are printed here as a symposium in the *European Journal of Risk Regulation*.

In the first, *Floor Fleurke* lays a foundation by exploring European Union legislation that could be applicable to climate engineering—especially those legal instruments regarding environmental impact assessment; effects on water, air, and biodiversity; and environmental liability—or that could provide a basis for future regulation specific to climate engineering. Concluding that the EU does, indeed, have competence in this domain, she devotes particular attention to the precautionary principle. Its role, she says, is important but unclear, given the risk-risk tradeoff character of climate engineering.

In the next article, *Anne Therese Gullberg* of the Center for International Climate and Environmental Research Oslo and *Jon Hovi* of the University of Oslo consider the political context of climate engineering in Europe, observing that existing EU processes have the capacity to ensure public participation in decision making regarding climate engineering. However, the low level of public awareness of the issue, particularly that of solar climate engineering, may present challenges to public participation. This will likely have implications for the form and substance of future European climate engineering policy.

The University of Bristol's *Janine Sargoni* takes a more theoretical turn in the third piece of this symposium, examining the importance of legitimacy of potential regulation of solar climate engineering research. She asserts that securing and maintaining legitimacy faces challenges given the high levels of uncertainty in climate engineering and in the relationship between politics and science. Drawing from the literatures of EU risk and science regulation, and of transnational private regulation, Sargoni suggests an innovative "incorporated" approach to risk assessment.

Like at the workshop itself, my colleague *Han Somsen* concludes this printed symposium by placing climate engineering in the broader context of environmental enhancement. Noting that humans are already a dominant influence on the "natural" world, as evidenced by the proposal for an Anthropocene geologic epoch,[9] he contextualizes environmental enhancement in European law. In particular, he turns to the mandate for the EU to base its environmental law in "preserving, protecting and *improving* the quality of the environment".[10] Somsen argues that both European law and the environment itself require acknowledging and pursuing more conscious interventions in the "natural" world.

Hopefully, these articles can provide a robust basis from which the dialogue regarding climate engineering and European law can be broadened and deepened.

I thank the authors, the other workshop participants, the editors of *EJRR*, and Tilburg Law School for making the workshop and this symposium possible.[11]

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7 Miguel Arias Cañete said, "About negative emissions, the [UN Intergovernmental Panel on Climate Change] will say when and how." Arthur Neslen, "EU Says 1.5C Global Warming Target Depends on 'Negative Emissions' Technology", 14 December 2015, *The Guardian*.

8 The United Kingdom's Engineering and Physical Sciences, Natural Environment, Economic and Social, and Arts and Humanities Research Councils supported the projects "Integrated Assessment of Geoengineering Proposals", "Stratospheric Particle Injection for Climate Engineering", and "Climate Geoengineering Governance". The German Research Foundation has a Priority Programme "Research to Evaluate Climate Engineering: Risks, Challenges, Opportunities?". Germany's Helmholtz Association of German Research Centres previously supported a field trial of carbon dioxide removal through ocean iron fertilization.

9 See Colin N. Waters, Jan Zalasiewicz, Colin Summerhayes, et al., "The Anthropocene is Functionally and Stratigraphically Distinct from the Holocene,", 351 *Science* (2016), pp. 137 *et sqq*.

10 TFEU, Article 191.1. Emphasis added.

11 The other participants were Sam Adelman of the University of Warwick; Gareth Davies of VU University Amsterdam; Alexander Proelss of the University of Trier; Rosemary Rayfuse of the University of New South Wales and Lund University; and Sjak Smulders and Jonathan Verschuuren, both from Tilburg University.

# Future Prospects for Climate Engineering within the EU Legal Order

*Floor Fleurke**

## Introduction

This article explores the prospects for the EU to develop a coherent policy regarding climate engineering (CE). To this end, we explore the most significant legal parameters derived from EU law from which such a future EU policy would have to arise. Obviously, in view of the principle of conferral, it must first be established if the EU enjoys competences to initiate a discrete policy on climate engineering. The mere fact that the EU presides over a plethora of climate mitigation and adaptation instruments is not sufficient to conclude that it likewise has competence to initiate a policy of intentional environmental change. Rather, precisely because climate engineering is such a different response to climate change than anything undertaken before, we must establish whether that difference is of a nature so as to rule out a future EU policy on climate engineering.

That question, in turn, requires consideration of secondary EU environmental law that can be expected to impose particularly important constraints on climate engineering. In particular, we propose to focus on environmental impact assessment procedures, impacts on water, air, biodiversity and environmental liability. Ultimately what needs to be clarified is whether the sum total of that body of secondary environmental law mandates, encourages, discourages or prohibits climate engineering.

Finally, climate engineering carries risks unlike any of the previous policy responses to climate change. Even if, as a matter of principle, it would turn out that primary and secondary EU environmental law are permissive as regards climate engineering, for climate engineering to be actually deployed it would need to pass the hurdle of the precautionary principle as well. This article therefore pays particular attention to the operation of that core principle of EU environmental law in risk/risk settings such as these competence to act in this field against the background of the EU's climate policy ambitions. Applied in the realm of climate engineering, precaution is perceived as a double-edged sword. Climate engineering can be framed as a precautionary response against the risks of climate change. Simultaneously, precaution can be perceived as a brake on climate engineering measures, since they carry undeniable uncertain risks that could trigger precautionary constraints. The complexity of such a *risk-risk* trade off will be discussed, focusing on the potential of precaution to make a constructive contribution towards finding ways out of this wicked dilemma.

It will be concluded that, even though the precautionary principle has not been designed to provide direction in risk/risk tradeoff dilemma's, its procedural and organizational functions are equally productive in these novel contexts.

## I. EU's Competences and Climate Engineering

Since climate change shows no sign of slowing down and no substantial progress is achieved at the international political level, new approaches such as climate engineering that offer quick results are being considered by some Member States. There is a great variety in climate engineering techniques, and new techniques are currently being developed. Each form should be evaluated on its own merits, because they differ in numerous important respects, such as cost, risk and scale.[1] However, they are distinguished in two broad categories: carbon dioxide removal (CDR) and solar radiation management (SRM). CDR would collect and sequester greenhouse gasses from the atmosphere. Examples include capturing carbon dioxide from ambient air, fertilizing oceans to increase biological uptake, and enhanced mineral weathering. CDR would address the threat of climate change relatively close to its cause, but would be ex-

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1 Royal Society, *Geoengineering the Climate: Science, Governance and Uncertainty* (2009), at 17-18

pensive and slow.[2] Moreover, given the characteristics of the EU coastal environment, CDR methods such as ocean iron fertilization are unlikely to occur in EU waters; for the remainder of this article the focus will therefore be on SRM.

SRM would increase the planet's reflectiveness counteracting the warming-up of the planet. Examples of SRM include injecting aerosols into the upper atmosphere, spraying seawater to increase clouds' brightness, and injecting microbubbles into the ocean. Contrary to CDR techniques, these proposals promise to be fast and cheap.

Unsurprisingly, there are also constraints for CE initiatives in the EU. Proposals to develop the means to intervene intentionally and on a massive scale in global physical, chemical and biological systems to counterbalance climate change are highly controversial. Like climate change itself, such initiatives pose uncertain risks to the environment and human health. SRM in particular may have significant and unpredictable negative environmental impacts. Global climate patterns and precipitation patterns could change (affecting agricultural practices, for instance), and incoming light would be more diffuse, altering plant productivity and ecosystems. The most widely discussed aerosol substance to be injected into the stratosphere, sulphate particles, may damage the ozone layer.[3]

Considering the extent of both benefits and risks some Member States have expressed increasing interest in climate engineering and its risks, and are currently exploring different CE options in research projects.[4] Taking the perspective of the EU here, the question that first needs to be addressed is if the EU has competence to either constrain or incentivize CE initiatives.[5]

Article 191 of the Treaty on the Functioning of the European Union (TFEU) grants the EU a general competence to act with the aim of preserving, protecting and improving the quality of the environment. In order to meet that objective, environmental policy is based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay. Similarly, Art. 3 of the Treaty on the European Union (TEU) states that the EU shall seek '(...) a high level of protection and improvement of the quality of the environment. For that purpose 'It shall promote scientific and technological advance'.

In addition, the Treaty of Lisbon has introduced new legal foundations that enable the EU to specifically take climate action to combat climate change.[6] Article 191 TFEU has been complemented with the obligation of 'promoting measures at an international level to deal with regional or worldwide environmental problems, and in particular combating climate change'. Similarly, Article 3(5) of the Treaty on the European Union (TEU) states that 'In its relations with the wider world the Union shall uphold and promote its values and interests' that includes the contribution 'to the sustainable development of the Earth'. These new provisions on climate change demonstrate the EU's ambition to be a global leader in the field of climate policy, both within and beyond the borders of EU territory.

Since the late 1990s, the EU has explicitly called upon itself to lead the combat against Climate Change, and has made common action against global warming an important part of its foreign environmental policy.[7] EU leaders agreed on 23 October 2014 the domestic 2030 greenhouse gas reduction target of at least 40% compared to 1990 together with the other main building blocks of the 2030 policy framework for climate and energy.[8] Although the EU is certainly more ambitious than most other developed states, it still falls short of the findings of the Intergovernmental Panel on Climate Change (IPCC) to limit the increase in global temperature of 2 degrees Celsius.[9]

2 Ibid.

3 Royal Society (2009), supra n. 1. M.K. McNutt, et al., *Climate Intervention: Carbon Dioxide Removal and Reliable Sequestration*. (Washington: National Academies Press, 2015); M.K. McNutt, M.K., *Climate Intervention: Reflecting Sunlight to Cool Earth*. (Washington: National Academies Press, 2015).

4 Royal Society (2009), supra n. 1.

5 See on the general regulation of CE J.L. Reynolds, 'The International Framework for Climate Engineering.' Working Paper, Geoengineering Our Climate Working Paper and Opinion Article Series. Available at: http://wp.me/p2zsRk-cw ; J.L. Reynolds, The Regulation of Climate Engineering (2011) 3 *Law, Innovation and Technology* 113. D. Bodansky, 'May We Engineer the Climate?' *Climatic Change* (1996) 33(3), 309-321.

6 M. Lee, 'The Environmental Implications of the Lisbon Treaty', 10 *Envtl. L. Rev*. (2008), 131-8.

7 European Commission, EU Action Against Climate Change: Leading Global Action to 2020 and beyond. Available on the Internet at: http://ec.europa.eu/clima/sites/campaign/pdf/post_2012_en.pdf.

8 Previously, the EU has committed itself to combat climate change in its Climate and Energy package of 2010, in which it pledges a reduction of 20% in greenhouse gases by 2020 relative to a 1990 baseline.

9 The 2 degrees Celsius goal is agreed at the Copenhagen Summit of 2010; See also World Resources Institute, *Comparability of Annex I Emission Reduction Pledges Report.*

The current Climate and Energy package has been translated into a set of legal acts that have been adopted between 2009 and 2012, which were to be implemented from 2013 onwards.[10] Although the EU is on track to achieve this goal, the effectiveness of its climate flagship – the EU emissions trading system (EU ETS) - has been disappointing.[11] The EU ETS has now entered its third trading phase, but so far has achieved only a minor emissions abatement.[12] A cap fixed too liberal, the recession causing reduction in production, 'off-setting' emission reductions abroad and warm weather; the price for CO2 has simply remained too low to press industry into investing in low carbon technology.

To achieve the target of 40% reduction by 2030, the sectors covered by EU ETS would have to reduce their emissions by 43% compared to 2005. Emissions from sectors not covered by the EU ETS would need to be cut by 30% below the 2005 level, to be achieved at Member State level.[13] Member States will seek to diversify their mitigation strategies by exploring new technologies to achieve the target level and counteract climate change. Renewable energy technologies play a key role in this transition, but other technologies in this perspective are also becoming more acceptable as part of the EU's policy on climate change. In this context carbon capture and storage (CCS) forms an interesting case in point.[14] Trapping carbon dioxide emitted from large point sources such as power plants, compressing it, and transporting it to a suitable storage site where it is injected into the ground can be considered the nearest available example of geoengineering.[15] In 2009 the EU has adopted the Directive on geological storage of carbon dioxide in 2009.[16] The objective of the CCS Directive is to establish a legal framework for 'environmentally safe geological storage of CO2 to contribute to the fight against climate change'.'[17] Hence, the Directive is aimed at avoiding health and environment risks, ensuring safety of transport and storage sites, and importantly to incentivize CCS. To this end, the CCS Directive includes a permit requirement, obligations for the operation, closure and post-closure of the storage site as well monitoring and reporting obligations, and liability norms for operator of a storage site. The Directive however leaves full discretion for Member States to determine if any CCS activity is allowed, and if so to what extent.[18] Although distinctive from CE, this example implies that (a) the EU has competence to regulate at least the contours of climate technologies on its territory, and (b) that EU has a keen interest in exploring technology options for achieving their emission reduction targets, particularly considering large reserves of fossil fuels and a high energy demand across the EU.

It is nevertheless important not to overestimate the EU's part in the mitigation of global greenhouse gas emissions. EU GHG emissions represent only 11% of global GHG emissions while still falling.[19] By comparison, emissions from the United States account for 16% and China sets the record with 29% of global GHG emissions, while emissions in Asia, Latin America and the Middle East are growing significantly.[20] EU global initiatives to push forward on global

10 See in this regard also Commission Communication, 'A European Strategic Energy Technology Plan (SET Plan) – Towards a Low Crabon Future, COM(2007) 723 final and [2008] OJ C82/1.

11 See the European Environment Agency Report *Progress towards 2008 – 2012 Kyoto targets in Europe*, October 2014, available on the Internet at: http://www.eea.europa.eu/publications/progress-towards-2008-2012-kyoto.

12 See Sandbag Report*, Drifting Towards Disaster* is Sandbag's 5th annual report on the Environmental Outlook for the EU ETS (2013). Available on the Internet at: http://www.sandbag.org.uk/site_media/pdfs/reports/Drifting_Towards_Disaster.pdf.

13 Directive 2012/27/EU of the European Parliament and of the Council of 25 October 2012 on energy efficiency, amending Directives 2009/125/EC and 2010/30/EU and repealing Directives 2004/8/EC and 2006/32/EC Text with EEA relevance OJ L 315.

14 N. Srivastava, 'Geoengineering and Law: A Case Study of Carbon Capture and Storage in the European Union' *European Energy and Environmental Law Review* (2011), 187-196.

15 The general consensus is that CCS is not a form of geoengineering since CCS modifies emissions and captures CO2 before it enters the atmosphere. See for example Royal Society 2009, supra n.1.

16 Directive 2009/31/EC of the European Parliament and of the Council of 23 April 2009 on the geological storage of carbon dioxide and amending Council Directive 85/337/EEC, European Parliament and Council Directives 2000/60/EC, 2001/80/EC, 2004/35/EC, 2006/12/EC, 2008/1/EC and Regulation (EC) No 1013/2006OJ L 140 (CCS Directive)

17 CCS Directive, Article 1. The Directive requires a permit for storage of CO2 except for research projects of up to 100 kilo tonnes.

18 Ibid., Recital 19.

19 PBL Netherlands Environmental Assessment Agency, *Trends in global CO2 emissions: 2013 Report*. Available on the Internet at: www.pbl.nl/en or edgar.jrc.ec.europa.eu; Although it needs to be noted that the calculation method for GHG emissions is production based rather than consumption based.

20 See also International Energy Agency, *CO2 Emissions from Fuel Combustion* (2014). Available on the Internet at: https://www.iea.org/publications/freepublications/publication/CO2EmissionsFromFuelCombustionHighlights2014.pdf. In 2008 emissions from developing countries for the first time trumped emissions from developed countries.

climate policy, efforts towards emissions abatement are yet unlikely to keep global warming below the 2 degrees Celsius target.[21] Meanwhile, climate change models estimate that global warming could be as much as 4 degrees Celsius by 2100.[22] The international community has yet to find consensus on a new legally binding framework, and it is questionable whether COP 21 of the UNFCCC in Paris will reach a new agreement with some teeth.

In this sense CE should also be viewed against the backdrop of the concept of a climate change 'regime complex'.[23] As Scott and Rajamani explain 'this concept captures the idea that in the absence of a comprehensive multilateral framework for regulating climate change, global action on climate change is emerging in a fragmented manner, on the basis of action by private parties as well as by many national and international organizations, and states'.[24] Since, most CE options are relatively easy and inexpensive to implement it is plausible that the 'regime complex' of climate change will trigger unilateral action (particularly in areas severely affected by climate change), whereby action taken at national level can induce changes at a global scale.[25]

Given the EU's high profile regarding global climate policies, the EU will ultimately have to take a position – internally and externally - on CE as a (risky) policy option. The EU thereby faces the dilemma of a classical risk-risk trade-off: a countervailing risk is generated by deploying a technology that seeks to reduce a target risk, while both risks are not easily compared due to scientific uncertainty.

## II. Climate Engineering and the *Acquis Communautaire*

The European Union has yet to assume a formal position on the governance of CE. The only explicit pointers to EU policy on CE is a statement by the EU Parliament that was inserted into a longer resolution regarding the United Nations Conference on Sustainable Development.[26] In addition, some funding was awarded through FP7 to a research project concerning the implications and risks of engineering solar radiation to limit climate change (IMPLICC project).[27] This paragraph examines in general fashion if current EU environmental law constraints or incentivizes the deployment of CE initiatives focusing on SRM. While there is no specific regulation that deals with CE, there is a patchwork of EU secondary legislation that engages with various aspects of CE. This secondary legislation which can be divided into two categories; (a) horizontal measures such as the Environmental Impact Assessment and Environmental Liability Directive and (b) sectoral measures such in the field of water, air and biodiversity policy.

### 1. Environmental Impact Assessments

The Strategic Environmental Assessment (SEA) Directive, and the Environmental Impact Assessment (EIA) Directive provide a legal framework for conducting environmental impact assessments.[28] It ensures that environmental concerns are considered at the earliest stage of a project or plan and well before a permit is issued. Further, it ensures public involvement during the permit issuing process.

The EIA Directive require that Member States conduct environmental impact assessments for private and public projects.[29] Hence, Member States are required to 'ensure that, before consent is given, projects likely to have significant effects on the environment

21 Intergovernmental Panel on Climate Change, Synthesis Report based on the reports of the three Working Groups of the (IPCC), including relevant Special Reports. Available on the Internet at: https://www.ipcc.ch/pdf/assessment-report/ar5/syr/AR5_SYR_FINAL_SPM.pdf. It provides an integrated view of climate change as the final part of the IPCC's Fifth Assessment Report (AR5).

22 For example R.A. Betts et al., 'When Could Global Warming Reach 4°C? *Philosophical Transactions of the Royal Society A: Mathematical, Physical and Engineering Sciences* (2011) 369, 67.

23 R.O. Keohane and D.G. Victor, 'The Regime Complex for Climate Change' *Perspectives on Politics* (2011) 9, at 7.

24 J. Scott and L. Rajamani, 'EU Climate Change Unilateralism' *The European Journal for International Law* (2012) 23 2, 469-494.

25 Interesting in this regard is the example of a privately financed large scale ocean fertilization project at Haida Gwaii, off the coast of British Columbia, that was justified by one of the First Nation representatives, Old Massett Chief Councilor Ken Rea. He responded to a crowd of protesters by observing; 'On a changing planet, we need to take bold steps and the people of Old Massett believe this is the right step.'

26 European Parliament resolution of 29 September 2011 on developing a common EU position ahead of the United Nations Conference on Sustainable Development (Rio+20), P7_TA(2011)0430.

27 Information on the IMPLICC project has been posted on the project's public website available at: http://implicc.zmaw.de.

28 Directive 85/337 on the assessments of the effects of certain public and private projects on the environment, OJ L 1985 L 175/30 (EIA Directive); Directive 2001/42/EC on the assessments of the effects of certain plans and programmes on the environment, OJ 2001 L 197/30 (SEA Directive).

29 EIA Directive, art. 1(1).

by virtue, inter alia, of their nature, size or location are made subject to a requirement for development consent and an assessment with regard to their effects.'[30] The scope of the concept project is defined in Annex I and II of the EIA Directive; for Annex I projects an environmental assessment is obligatory, whereas for Annex II an environmental assessment is discretionary. Although no form of climate engineering is currently included in Annex I or II, it is likely that once CE becomes viable the Directive will be amended so that it applies to climate engineering initiatives due to the potential environmental impacts of the project. In similar vein, the EIA Directive was amended when the technique of carbon capture storage had become a viable option to geologically storage CO2 as a contribution to the fight against climate change. For that purpose, pipelines for the transport of CO2 streams for the purposes of geological storage, storage sites, installations for the capture of CO2 streams for the purposes of geological storage have been included partly in Annex I, partly in Annex II.[31] It must be emphasized that the EIA is mostly of procedural nature; the Directive only requires that the environmental report and results of the (transboundary) consultations have to be taken into account in the preparation of the decision-making process.

The Strategic Environmental Assessement Directive can however be applicable to CE plans or programmes. This SEA Directive was adopted on the basis that environmental effects for certain actions should be identified in an even earlier stage than required by the EIA Directive. The SEA Directive applies to plans and programmes defined by art. 2(a) as: 'plans and programmes, including those co-financed by the European Community, which are subject to preparation and/or adoption by an authority at national, regional or local level or which are prepared by an authority for adoption, through a legislative procedure by Parliament or Government, and which are required by legislative, regulatory or administrative provisions' According to Article 3(1) all plans and programmes likely to have significant environmental effects are subject to the environmental assessment obligation. Subsequently, Article 3(2) lists two categories for which an environmental assessment is mandatory. In the context of CE, only plans or programmes that fall under the scope of Article 6 or 7 of the Habitats Directive 92/43/EEC require an assessment.[32]

For all other plans and programmes that set the framework for future development consent of projects, and are likely to have significant environmental effects, environmental assessment is optional.[33] Member States have to establish screening mechanisms on the basis of which it will be determined whether or not there is a likelihood of significant environmental effects.[34] Consequently, Member States that view CE as a high-risk activity may require an SEA, while other Member States that do not share similar views may not do so. This can lead to significant legal uncertainty and regulatory differences between the Member States.

If required, the environmental assessment has to be carried out during the preparation of a plan or programme and before its adoption. As a result, an environmental report has to be prepared in which the likely significant effects on the (transboundary) environment and reasonable alternatives are identified, described and evaluated.[35] The Directive requires that the final decisions on the plan or programme are to be communicated to the authorities, the public and the (transboundary) parties in the consultation. Next to that, a summary of how environmental considerations have been 'integrated' needs to be communicated, and the decision needs to be accompanied with a monitoring mechanism in order to identify at an early stage unforeseen adverse effects, and to be able to undertake appropriate remedial action.[36] Failures to integrate environmental impact can be challenged by way of, inter *alia*, judicial review of the planning decision, implying that SEA is more than a mere procedural tool.[37]

## 2. Air

The injection of sulfate aerosols - the most widely considered injection substance for SRM – into the stratosphere may impact both the ozone layer and

30 Ibid., art. 2(1).

31 See for more details points 16, 23 and 24 of Annex I and points 3 (j), 10 (i) of Annex II.

32 See par. 2.4 below.

33 SEA Directive 2001/42. Article 3(4).

34 Ibid., Aricle 3(5); Member States have to use the (non-exhaustive) criteria in Annex II.

35 Ibid., Article 5.

36 Ibid., Article 9 and 10.

37 M. Lee, *EU Environmental Law: Challenges, Change and Decision-making* (Hart Publishing: 2005), at 171.

the atmosphere in general, and it is necessary to examine whether concrete EU legislation regarding these issues could restrict SRM measures. It should however be emphasised that climate change itself is harmful to stratospheric ozone by increasing atmospheric water vapour concentrations, and SRM may be able to reduce this.[38]

The protection of the ozone layer is laid down in Regulation 1005/2009/EC adopted to fulfill the obligations under the Vienna Convention for the Protection of the Ozone Layer and the Montreal Protocol on Substances that Deplete the Ozone Layer.[39] The Regulation applies to 'controlled substances', to new substances and to products and equipment containing or relying on controlled substances.[40] These ozone-depleting substances are added on a 'black list' that can be expanded. Although the Regulation is more stringent in general than the Montreal Protocol, it does not include SO2 as a regulated substance and therefore does not yet impose a restriction on sulfate aerosol injection.

The EU has however established a comprehensive regulatory framework aimed at improving air quality that could be of relevance here. The main instrument in this regard is Directive 2008/50/EC on ambient air quality and cleaner air for Europe.[41] It contains concrete limit values and target values for the protection of human health as well as information and alert thresholds for sulphur dioxide (SO2).[42] However, Article 2 (1) defines 'ambient air' as outdoor air in the troposphere, thus excluding exposition in the stratosphere. Interestingly, the Directive implements The Convention on Long-Range Transboundary Air Pollution (LRTAP Convention) that does not make a distinction between troposphere and stratosphere.[43]

More important here is Directive 2001/81/EC on national emission ceiling for certain atmospheric pollutants (NEC Directive).[44] The NEC Directive aims to limit emissions of acidifying and eutrophying pollutants and ozone precursors in order to protect the environment and human health; primary objective of the Directive is that Member States shall limit their annual emissions of SO2 to amounts not greater than the emission ceiling of Annex I. The NEC Directive covers all emissions from human activity from the territory of the Member States and their exclusive economic zones. International maritime traffic and aircraft emissions beyond the landing and take-off cycle are however excluded from the Directive.[45] The objective of the Directive is to be achieved through the national emissions ceilings and each Member State has to adopt national programmes for the progressive reduction of national emissions.[46] This implies that sulphate aerosol injection is permitted as long as it does not substantially contribute to exceeding the national emission ceiling. Hence, the allowed amount of sulphate to be injected could differ substantially between Member States. It should be noted that the Court of Justice of the European Union (CJEU) has interpreted the obligation to adopt national programmes in order to achieve the aims of the Directive as 'purely programmatic' meaning that exceeding the national emission ceiling could not be taking into account in the individual permitting process.[47]

SO2 and other sulphur compounds are also listed as pollutants for which emission limit values shall be fixed in Directive 2008/1 concerning intergrated pollution prevention and control (IPPC Directive)[48] and the succeeding Industrial Emissions Directive (IE Directive).[49] These Directives are aimed at taking an integrated approach to protecting the environment and

38 K.E. Trenberth and others, 'Observations: Surface and Atmospheric Climate Change' in S. Solomon and others (eds), *Climate Change 2007: Working Group I: The Physical Science Basis* (Cambridge University Press: 2007), at 274-275.

39 OJ 2009 L 286/1 replacing Regulation 2037/2000 OJ 2000 L244/1 as amended by Reg. 1791/2006, OJ 2006 L 363/1.

40 Reg. 1005/2009/EC, Article 2.

41 OJ 2008 L 152/I.

42 Dir. 2008/50/EC, Annex XI and Annex XII.

43 Convention on Long-Range Transboundary Air Pollution (opened for signature 13 November 1979, entered into force 16 March 1983) 1302 UNTS 217 (LRTAP Convention), OJ L 171, 27.6.1981, at 11. See also Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on the Reduction of Emissions or their Transboundary Fluxes by at least 30 per cent (1985); Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on Further Reduction of Sulphur Emissions (1994).

44 OJ 2001 L 309/22. This Directive implements the Gothenburg Protocol to the UNECE Convention on long-range transboundary air pollution to abate acidification, eutrophication and ground-level ozone, and deals with the sources of pollution.

45 Ibid., Article. 2(a)(b). It can be assumed that sulfate aerosol injected from airplanes does not fall under the exception of 'aircraft emissions' and therefore the injection of sulfate aerosols into the stratosphere falls under the scope of the Directive.

46 Ibid., Article 4 and 6.

47 Case C-165/09 and C-167/09 Stichting Natuur en Milieu and Others v. College van Gedeputeerde Staten van Groningen and College van Gedeputeerde Staten van Zuid-Holland, Judgment 26 May 2011, para. 75.

48 OJ 2008 L 24/8.

49 OJ 2010 L 334/17.

are centered on the following concepts: a permit, best available techniques, emission limit values and quality standards.[50] The IE Directives applies to 'industrial activities ', as defined in Chapters II and VI of the Directive. Injection of substances into the atmosphere from planes, ships or from the ground is not listed in the categories of industrial activities set out in the Directive, and therefore this Directive does not cover SRM activities.

## 3. Water

For coastal waters in the European Union, human activities must be carried out in a manner that does not compromise the objective of achieving by 2015 'a good ecological status' as laid down in the framework of the Water Framework Directive.[51] The Water Framework Directive has been complemented by the requirement to achieve by 2020 'good environmental status' of marine waters where Member States exercise jurisdictional rights.[52] Several forms of climate engineering – of which cloud brightening is the most important – are likely to have an impact on these marine waters. It has to be noted though that the relevant secondary EU legislation mentioned here applies only to the coastal and marine waters within the Member States' national jurisdictions and would therefore not be relevant to the high seas.

Similarly, the provisions regulating dumping in international agreements to which the EU is a Party do not establish specific requirements for the high seas.

The main objective of the Marine Strategy Framework Directive is to maintain a good status for marine waters, habitats and resources, delivering an integrated ecosystem-based approach consisting of the development of marine strategies. Similar to the Water Framework Directive a standstill obligation applies according to which Member States must implement the necessary measures to prevent deterioration.[53] The concept of what is 'good status' is specified in a range of indicators listed in Annex I and is to be determined at the level of the marine region or subregion.[54] Member States thus specifically need to prevent and reduce inputs in the marine environment, with a view to phasing out pollution so as to ensure that there are no significant impacts on or risks to marine biodiversity, marine ecosystems, human health or legitimate uses of the sea. Pollution is broadly defined here as comprising: the direct or indirect introduction into the marine environment, as a result of human activity, of substances or energy, including human-induced marine underwater noise, which results or is likely to result in deleterious effects such as harm to living resources and marine ecosystems, including loss of biodiversity, hazards to human health, the hindering of marine activities, including fishing, tourism and recreation and other legitimate uses of the sea, impairment of the quality for use of sea water and reduction of amenities or, in general, impairment of the sustainable use of marine goods and services.[55] In addition, Annex III lists a number of pressures that need to be specifically addressed, such as 'sealing' of marine waters, inputs of fertilisers and other nitrogen — and phosphorus-rich substances (e.g. from point and diffuse sources, including agriculture, aquaculture, atmospheric deposition) and significant changes in thermal regime.[56]

Member States are required to - in respect of each marine region or sub-region- establish a comprehensive set of environmental targets and associated indicators for their marine waters so as to guide progress towards achieving good environmental sta-

50 J.H. Jans and A.H. Vedder, *European Environmental Law* (Groningen: Europa Law Publishing: 2011), at 365.

51 Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy, OJ L 327. Article 4 (1) of the Water Framework Directive require that any adverse changes to the ecological and chemical status of surface waters (this includes coastal waters) must be avoided, and that a good ecological and chemical status must be preserved or attained. Details are contained in Directive 2008/105/EC on environmental quality standards in the field of water policy. The Directive has a programmatic character meaning that Member States have to make (transboundary) management plans including progamme of measures for every river basin within a given timeline.

52 Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy, OJ L 164.

53 Ibid., Article 1(2)(a)(b).

54 For example, human-induced eutrophication is to be minimized, especially adverse effects thereof, such as losses in biodiversity, ecosystem degradation, harmful algae blooms and oxygen deficiency in bottom waters, permanent alteration of hydrographical conditions should not adversely affect marine ecosystems or concentrations of contaminants are at levels not giving rise to pollution effects.

55 Dir. 2008/56/EC, Article 3(8).

56 Most of the human pressures are located on land, within estuaries and along the coastal area but various additional pressures can also be identified for offshore waters, such as a gas storage platform.

tus in the marine environment based upon an assessment.[57] Article 13 requires Member States identify the measures that need to be taken in order to achieve or maintain good environmental status for each sub region in their marine waters. In doing so Member States have to ensure that measures are cost-effective and technically feasible, and shall carry out impact assessments, including cost-benefit analyses, prior to the introduction of any new measure.[58]

A Member State is allowed to invoke some exceptional grounds where the targets or good environmental status cannot be achieved by Member States' measures.[59] One of the reasons listed in the Directive is the 'modifications or alterations to the physical characteristics of marine waters brought about by actions taken for reasons of overriding public interest which outweigh the negative impact on the environment, including any transboundary impact'.[60] It is conceivable that in the future Member States will rely on this provision to justify CE measures to prevent catastrophic effects of climate change.

Within the timeline set out in the Directive, these requirements apply to activities involving the introduction of substances in the relevant waters and therefore to any possible decision to carry out climate engineering that impact the marine waters under the jurisdiction of Member States.[61] In addition to this it has to be noted that a large part of EU coastal areas is designated as protected sites according to the Birds- and Habitats Directives, and are thereby placed under a stricter protection regime (see below).

## 4. Biodiversity

If CE initiatives are considered to constitute a project or plan that is potentially harmful to the conservation of species or habitats and takes place within a designated area it is to be subject to a restrictive authorization scheme according to the Habitats Directive.[62] This Directive in combination with the Birds Directive[63] aims for the maintenance or achievement of a 'favourable conservation status' for the species and the natural habitats it covers, in order to contribute to biodiversity conservation in Europe and to some extent implements the obligations of the Convention on Biological Diversity (CBD) of which the EU is a member.[64] Noteworthy in this context as well is the decision taken by Conference of Parties to the Convention on Biological Diversity on climate engineering. The EU – as a contracting party takes an active part in the adoption of CBD Decisions. It is a non-binding statement of precaution, asking the parties to refrain from climate engineering that may affect biodiversity until there is scientific basis for such work and 'appropriate consideration of the associated risks'.[65] This request is to continue 'in the absence of science based, global, transparent and effective control and regulatory mechanisms'.[66]

As regards to the Birds Directive, avian species mentioned in Annex I and (other) migratory bird species, to the extent that these occur regularly in areas within Member States' jurisdiction, 'shall be the subject of special conservation measures concerning their habitat in order to ensure their survival and reproduction in their area of distribution'.[67] For this purpose, 'the most suitable territories in number and size' for all of these species are to be classified so-called special protected areas (SPAs).[68] Similar measures are to be taken under the Habitats Directive in respect of natural habitat types listed in Annex I and

57 Dir. 2008/56/EC, Article 6 and 9.

58 Ibid., Article 16. It is the Commission assesses whether, in the case of each Member State, the programmes notified constitute an appropriate framework to meet the requirements of this Directive

59 Ibid., Article 14.

60 Ibid., Article 14(1)(d). If this is the case the Member State has to ensure though that the modifications or alterations do not permanently preclude or compromise the achievement of good environmental status at the level of the marine region or subregion concerned or in the marine waters of other Member States.

61 However, similar to the NEC Directive both the Water Framework Directive and the Marine Strategy Framework Directive are programmatic from character and therefore cannot be enforced at the level of the individual permit.

62 Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora [1979] OJ L206/7 (Habitats Directive).

63 Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the Conservation of Wild Birds [2010] OJ L20/7; this is the codified version of Council Directive 79/409/EEC of 2 April 1979 as subsequently modified (Birds Directive).

64 Habitats Directive, Article 2; Birds Directive, Articles 1 and 2. The latter do not contain the words 'favourable conservation status' but are generally understood to imply this purpose for wild birds.

65 Tenth Meeting of the Conference of Parties to the Convention on Biological Diversity, Oct. 18-29, 2010, Decision X/33—Biodiversity and Climate Change 5, U.N. Doc. UN-EP/CBD/COP/DEC/X/33 (2010). Available on the Internet at: https://www.cbd.int/climate/doc/cop-10-dec-33-en.pdf.

66 An exception is made for small-scale scientific activities.

67 Birds Dir., Article 4

68 Ibid.

species listed in Annex II of the Directive, and sites of importance for these habitats and species are to be designated as 'Special Areas of Conservation' (SACs)[69] Together, the SPAs and SACs are to form an ecologically coherent European network of protected sites, denominated 'Natura 2000'.[70]

Subsequently, Article 6 of the Habitats Directive requires the protection of these designated sites.[71] Article 6(1) requires Member States to take 'the necessary conservation measures' which 'correspond to the ecological requirements' of the species involved. In addition, for SPAs, SACs and SCIs[72], Article 6(2) requires Member States to 'take appropriate steps to avoid' any significant 'disturbance' with regard to the listed species concerned, and any deterioration of their habitats. This prescription has repeatedly been interpreted by the Court as an obligation to 'do what it takes.'[73] What the 'appropriate steps' are will depend on the problem at hand, but what ultimately counts is the result.[74] Clearly, effective measures are to be taken before adverse effects occur.[75] Moreover, to meet the requirements of Article 6(2), damage which has already occurred must be undone. For example, the Court has affirmed that 'the protection of SPAs is not to be limited to measures intended to avoid external anthropogenic impairment and disturbance but must also, according to the situation that presents itself, include positive measures to preserve or improve the state of the site.'[76] Significantly, the growing need to help species adapt to climate change could raise the question if CE measures could serve as the implementation of conservation duties under the Birds and Habitats Directives.[77] The answer to this speculative question depends on the effectiveness of CE to protect species and habitats, the causal relationship between implementing CE and protecting certain endangered species and habitats and the availability of alternative less risky measures.

Either way, as mentioned above, any project or plan that is potentially harmful to the conservation of the species within an SAC or SCI, is subject to a restrictive authorization scheme elaborated in Articles 6(3)- (4) of the Directive:

> 3) Any plan or project not directly connected with or necessary to the management of the site but likely to have a significant effect thereon, either individually or in combination with other plans or projects, shall be subject to appropriate assessment of its implications for the site in view of the site's conservation objectives. In light of the conclusions of the assessment of the implications for the site and subject to the provisions of paragraph 4, the competent authorities shall agree to the plan or project only after having ascertained that it will not adversely affect the integrity of the site concerned.
>
> 4) If, in spite of a negative assessment of the implications for the site and in the absence of alternative solutions, a plan or project must nevertheless be carried out for imperative reasons of overriding public interest, including those of a social or economic nature, the Member State shall take all compensatory measures necessary to ensure that the overall coherence of Natura 2000 is protected.

69 Habitats Dir., Article 4.

70 The so-called Natura 2000 network accounts for over 22 000 individual sites and cover almost 17% of EU-25 land area as well as 140 000 km2 of marine area which is of significance for CE activities.

71 According to Article 7, this provision also applies to Birds Directive SPAs.

72 On the basis of preliminary lists of candidate SACs submitted by the member states, the Commission compiles lists of Sites of Community Importance (SCIs), which are then actually designated as SACs by the member states.

73 See F.M. Fleurke and A. Trouwborst, 'European Regional Approaches to Transboundary Conservation of Biodiversity: The Bern Convention and the EU Birds and Habitats Directives' in L. Kotze & T. Marauhn (Eds.), *Transboundary Governance of Biodiversity* (Brill Nijhoff: 2014), 128-163

74 For a particularly clear example, see Case C-117/00 *Commission v Ireland* [2002] ECR I-5335, paras 26-33.

75 See also European Commission, *Managing Natura 2000 Sites: The Provisions of Article 6 of the 'Habitats' Directive 92/43/EEC* (European Commission, 2000), 24.

76 Case C-535/07 *Commission v Austria* [2006] ECR I-2755, para 59; see also Case C-418/04 *Commission v Ireland* [2007] ECR I-10947, para 154.

77 See, *inter alia*, K. Wheeler, 'Bird Protection & Climate Changes: A Challenge for Natura 2000?' (2006) 13 *Tilburg Foreign Law Review* 283; A. Cliquet, C. Backes, J. Harris and P. Howsam, 'Adaptation to Climate Change: Legal Challenges for Protected Areas' *Utrecht Law Review* (2009) 5, at 158; S. Erens, J. Verschuuren and K. Bastmeijer, 'Adaptation to Climate Change to Save Biodiversity: Lessons Learned from African and European Experiences' in B.J. Richardson et al. (eds), *Climate Law and Developing Countries: Legal and Policy Challenges for the World Economy* (Edward Elgar: 2009); A. Trouwborst, 'Conserving European Biodiversity in a Changing Climate: The Bern Convention, the European Union Birds and Habitats Directives and the Adaptation of Nature to Climate Change' *Review of European Community and International Environmental Law* (2011) 20, at 62.

The CJEU has developed an extensive case law explaining these rules, emphasizing the importance of their effectiveness in light of the Directive's objectives.[78] This is illustrated by the *Wadden Sea* judgment, in which the Court determined that under Article 6(3), plans or projects (broadly interpreted) may in principle be authorized only 'where no reasonable scientific doubt remains as to the absence' of harmful impacts.[79] Hence, given this strict precautionary reading of Article 6(3) it is clear that CE initiatives deployed in or near the vicinity of SAC or SCI need to undergo an EIA and, will only be approved if harmful acts are excluded.

There is however a way out. Article 6(4) provides for a specific compensation procedure when authorities want to pursue the plan or project after the negative assessment. There has to be imperative reasons of overriding public interest, including those of a social or economic nature, and the Member State has to take all compensatory measures (e.g. recreating a habitat on a new or enlarged site) necessary to ensure that the overall coherence of Natura 2000 is protected.[80] If the site hosts a priority habitat or species the derogations are only allowed if they are relating to human health or public safety, or to beneficial consequences of primary importance for the environment. On that account, Article 6(4) leaves Member States discretion to take CE measures if there exists imperative reasons of overriding public interest, and under the strict condition that compensatory measures are to be put in place.

## 5. Environmental Liability

The idea of establishing environmental liability is that (private or public) operators of activities or installations that could possibly harm the environment will minimize those chances by taking preventive steps. One of the advantages of liability over regulation is that operators – especially when new technologies are involved – have more knowledge and are therefore better suited to reduce risks.

Directive 2004/35/EC on Environmental Liability (ELD) basically provides for the remediation and restoration of the environment where it has been damaged in a certain way by certain types of activity.[81] The ELD operates on a system of public liability with a competent authority responsible for the functioning of liability. Concrete, this means that in specific cases where operators fail to take preventive or remedial action, or are not identifiable, or have invoked defences, the competent authority may step in and carry out the necessary preventive or remedial measures.

The scope of the ELD is however limited, and is currently of no relevance to CE activities that would cause environmental damage. First, only 'environmental damage' is covered which is defined as damage to protected species and natural habitats (nature), damage to water and damage to land (soil).[82] 'Damage' then means a measurable adverse change in a natural resource or measurable impairment of a natural resource service which may occur directly or indirectly, while liability caused by armed conflicts and natural phenomena are excluded.[83] Considering the risks for environmental damage caused by CE it might be difficult to identify a measurable adverse affect that cannot be also attributed to natural phenomena. The ELD furthermore limits liability to 30 years following the event that caused the damage.

Second, the liable party is in principle the 'operator' - any natural or legal, private or public person - who operates or carries out 'occupational activities'.[84] This latter concept is defined as 'any activity carried out in the course of an economic activity, a business or an undertaking, irrespectively of its private or public, profit or non-profit character'.[85] For CE activities this could mean that they would fall out the scope of the ELD if CE is being deployed by public entities in the field of environmental protection policy.[86] The operator is obliged to take the necessary preventive measures if there is an imminent threat of such dam-

78 See Case C-3/96, Commission *v*. the Netherlands ECR I-03031.

79 Case C-127/02 Landelijke Vereniging tot Behoud van de Waddenzee and Nederlandse Vereniging tot Bescherming van Vogels *v.* Staatssecretaris van Landbouw, Natuurbeheer en Visserij. [2004] I-07405. The Court has borrowed the definition of the concept 'plan or project' from Council Directive85/337/EECon the assessment of the effects of certain public and private projects on the environment, OJ 1985 L 175, at 40.

80 Case C-57/89 *Leybucht* [1991] ECR I-00883; Case C-521/12, T.C. Briels e.a. *v.* Minister van Infrastructuur & Milieu, ECLI:EU:C: 2014:330

81 Directive 2004/35 on environmental liability with regard to the prevention and remedying of environmental damage OJ 2004 L 143/56.

82 Ibid., Article 2(1).

83 For damage regarding species and habitats the ELD refers to the Habitats and Birds Directives; for damage concering water the ELD refers to the Water Framework Directive.

84 Dir. 2004/35, Article 2(6).

85 Ibid., Article 2(7).

86 See e.g. Case C-343/05 Diego Cali &Figli *v*. SEPG [1997] ECR I-1547.

age occurring, and if the damage has occurred to take containment action (and bear the costs).[87]

Third, the ELD importantly distinguishes between two types of liability regimes. Operators who carry out certain inherent dangerous activities to the environment listed in Annex III of the ELD, are strictly liable for environmental damage. They include for example waste management operations, the use of genetically modified organisms and interestingly in the context of CE the operator of a storage sites according to the CCS Directive.[88] For the second category (non Annex III activities) liability only exists for damage to protected species and natural habitats. Moreover, the operator must have been at fault or negligent and for liability arising from pollution of a diffuse character a causal relationship has to be established between the damage and activities of the operators.[89] The ECJ has considered on this point that plausible evidence must be available to reflect their contributions to the pollution.[90]

To be of significance for the prevention and remediation of damage caused by CE activities the ELD would therefore have to be amended as to include CE activities in its Annex III list.

Fourth, even if liability were to be established, operators may rely on certain exceptions (e.g. force majeure) and defenses (e.g. permit defense) allowed by Member States. Particularly relevant here is the possibility to exonerate the operator from the damage caused by 'emission or activity or any manner of using a product in the course of an activity which the operator demonstrates was not considered likely to cause environmental damage according to the state of scientific and technical knowledge at the time when the emission was released or the activity took place'.[91] Recital 20 of the ELD in this context refers to damage that 'could not have been known'. Jans and Vedder assert that this state–of-the-art exception should be interpreted narrowly in light of the precautionary principle.[92] This is especially true when it concerns uncertain risks of new technologies.

## III. Precaution as a Double-edged Sword

As stated CE promise enormous environmental benefits, but they are accompanied by potential catastrophic risks which, like the benefits, remain highly uncertain. A risk trade-off is thus feared, which means a change in the portfolio of risks that occur when a countervailing risk is generated (knowingly or inadvertently) by an intervention to reduce the target risk.[93] When one type of adverse risk is replaced by another adverse risk in the same target population we observe risk substitution.[94] The dilemma for regulators, then, is to choose between a rock and a hard place.[95]

This task is particularly complex if both potential benefits and potential risks remain uncertain as a result of scientific uncertainty or scientific ignorance, while the scale of both problem and response are transboundary, if not global. Scientific uncertainty characterizes a situation in which possible outcomes are known, but the likelihood of those outcomes remains uncertain. In cases of scientific ignorance, both outcomes and likelihoods are uncertain. It is hence fair to say that scientific uncertainty about both the risks and the benefits of new technological development confronts regulators with one of the most difficult challenges of modern times.

Precaution is a tool to deal with uncertain risks and although it is commonly associated with banning certain risky products, activities, substances or technologies, it can also warrant the use of, for example, a new technology or substance to reduce risks. Precaution in the context of CE is however to be perceived as a double-edged sword: it is capable of simultaneously incentivize and discourage the deployment of the technologies.[96]

Hartzell-Nichols, in this regard, argues that climate engineering creates new uncertain, potentially catastrophic risks, and therefore its deployment, and even research should be rejected.[97] Although nobody

87 Dir. 2004/35, Article 5 and 6.

88 Dir. 2004/35, Annex III, point 14.

89 Ibid., Article 4(5).

90 Case C- 378/08 *ERG I* [2010] ECR I-01919, para 57.

91 Dir. 2004/35, Article 8(4).

92 Jans and Vedder (2011), supra n. 50 at 389.

93 As defined by Wiener and Graham *Risk vs. Risk Tradeoffs in Protecting Health and the Environment* (Harvard University Press: 1997), at 23.

94 *Ibid.*

95 R.A. Posner, *Catastrophe* (Oxford University Press: 2004).

96 J. L. Reynolds and F.M. Fleurke 'Climate Engineering Research: A Precautionary Response to Climate Change?' *CCLR* (2) 2013, 101-107.

97 L. Hartzell-Nichols, 'Precaution and Solar Radiation Management'15 *Ethics, Policy & Environment* (2012), 158 et seq, at page 166.

would in theory disagree with this statement to avoid all potential catastrophe, we might not be in position to *prima facie* disregard alternative climate solutions. Consequently, the above statement does not give any direction for policymakers battling the wicked problem of climate change.

What we need is a mechanism that can compare risks of climate change and risks of climate engineering with regard to their *relative* magnitude and scientific uncertainty.[98] Hence, the question is if precaution – as a core principle of EU environmental policy – may provide the EU or its Member States any guidance considering the problem of risk-risk trade offs and potential catastrophes.

As we have seen, Article 191 TFEU instructs that, in preparing its policy EU law shall take account of the available scientific and technical data, advantages and drawbacks, regional factors, and the economic and social development of the EU.[99] The precautionary principle has its origin in Germany and was born out of unease about the functioning of the law, and must be seen as an adjustment to the existing legal system: the precautionary principle seeks to address the disconnection between the law and contemporary technological modernity. The principle has been adopted in countless pieces of secondary legislation.[100] Furthermore, the CJEU has ruled that due to the integration principle of Article 11 TFEU, the principle applies to all EU policies.[101]

Despite its central role in EU environmental policy, the Treaty does not clarify what the principle entails.[102] It is hardly surprising that, left undefined, this crucial principle gives rise to a good deal of confusion and controversy, especially in the international arena. Although numerous articulations of the precautionary principle have been defined, Principle 15 of the Rio Declaration is generally deemed to offer its most accepted meaning:

> 'In order to protect the environment, the precautionary approach shall be widely used by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environ- mental degradation.'[103]

Given its Treaty status the precautionary principle may be perceived as a *regulatory principle*, in the sense that precaution gives rise to a competence to act where, if it were not for precaution, there would not have been such a competence.[104] Thus, where full scientific certainty about risk would normally be necessary to prevent or restrict certain activities, precaution helps lowering this threshold so that regulatory action can be taken on the condition that it is proportional. Moreover, not only is the threshold of proof lowered as a result of precaution, it is also apportioned to the actor (private or public) proposing the activity giving rise to the potential risk.[105]

Arguably the most important element regarding the practical impact of precaution revolves around the qualitative threshold of '*serious or irreversible*

98 J. L. Reynolds and F.M. Fleurke (2013), supra n. 96, at 106; R.A. Posner (2004) supra n. 95; C. R. Sunstein, *Worst-Case Scenario*s (Harvard University Press: 2007).

99 This has also been emphasised by the CJEU. See e.g. Case C-77/09 *Cowan Comércio International e Serviços Lda* v. *Ministero della Salute* [2010] I-13533, para. 71.

100 See for example Dir. 1999/93 on baby food [1999] OJ L 124, p. 8, fourth recital: 'Whereas taking into account the Community's international obligations, in cases where the relevant scientific evidence is insufficient, the precautionary principle allows the Community to provisionally adopt measures on the basis of available pertinent information, pending and additional assessment of risk and a review of the measure within a reasonable period of time'.

101 *Ibid*. See also Case T-74/00 *Artegodan GmbH* v. *Commission* [2002] ECR-II 4945.

102 Article 7 of Reg. (EC) No. 178/2002 contains the first legal definition of the precautionary principle under Community law. It states: *1.* In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment. See also Commission of the European Communities, *Communication from the Commission on the Precautionary Principle*, COM(2000)1 fin. See also the related opinion of the Economic and Social Committee on the 'Use of the Precautionary Principle' 2000/C/268/04. *2.* Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The matters shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.

103 Rio Declaration on Environment and Development 31 *International Legal Materials* (1992), 874 et sqq, Principle 15.

104 H. Somsen, 'Cloning Trojan Horses: Precautionary Regulation of Reproductive Technologies', in R. Brownsword and K. Yeung (eds), *Regulating Technologies: Legal Futures, Regulatory Frames and Technological Fixes* (Hart Publishing: 2008), at 221.

105 F. M. Fleurke, *Unpacking Precaution: a Study on the Application of the Precautionary Principe in Europe* (Edward Elgar, forthcoming). PhD version on file at the University of Amsterdam, 2012, at 34 et seqq.

*damage'*. The concrete operationalization of what is 'serious' or 'irreversible' is ultimately a task for the political realm, and as a rule is further specified in environmental treaties or secondary EU legislation.[106] The precautionary principle implies that scientific uncertainty does not rule out regulatory action to safeguard such qualitative standards.

In the context of climate change the TFEU instructs the EU to take measures combating climate change. At the international level the most important instrument is the UN Framework Convention on Climate Change (UNFCCC), of which the EU is a party, as are all EU Member States in their own right. Here, the qualitative standard to take precautionary measures is to 'prevent or minimize the causes of climate change and mitigate its adverse effects'.[107] Deployment of *environmental technologies* to combat climate change could therefore fall under the scope of the TFEU and the UNFCCC if they effectively seek to mitigate its adverse effect.

At first glance precaution understood as a regulatory principle could at a minimum therefore tilt toward *exploring* the option of CE as a means to combat the catastrophic effects of climate change.[108] If in our thought experiment, CE is perceived as a precautionary response to the threats of climate change, while carrying its own uncertain risks, it logically follows that CE needs to fulfill the conditions for applying precaution itself.[109]

These conditions are in large part developed by the CJEU when judicially reviewing the principle.[110] In fact, the numerous cases of the European courts have disciplined and developed the principle further. The courts have ruled in several cases that the principle constitutes a general principle of EU law, and at the same time the case law has clarified the circumstances under which EU institutions and Member States may enact precautionary measures to engage with risk. Due to the EU's pursuit of a 'high level' of health and environmental protection, laid down in the Treaty the EU courts have granted a relatively broad discretion to EU institutions and Member States to determine the level of protection.[111]

However, this wide margin of discretion left to the political branch has been judicially disciplined in several ways. Most importantly, 'a preventive measure cannot properly be based on a purely hypothetical approach to risk, founded on mere conjecture which has not been scientifically justified.'[112] The Court has emphasized the need to respect procedural requirements and the principle of proportionality before adopting precautionary measures for the protection of the environment and human health under conditions of scientific uncertainty. By insisting on these formal guarantees, it becomes clear that a purely political use of precaution will not be tolerated.[113]

Thus, in cases where the precautionary principle is invoked to justify measures the burden of proof is such that is has to be demonstrated that their risk measures are justified, were based on a risk assessment reflecting the best available scientific evidence, and on the latest (international) research.[114] The courts hence more marginally assess whether authorities have made a manifest error of assessment, misused powers, or manifestly exceeded the limits of their discretion.[115]

Like noted above, secondary law can provide a specific expression of the precautionary principle, for example by virtue of a safeguard clause. In such cases the burden to prove the suspected risk is lower, since the reality of scientific uncertainty has already been explicitly acknowledged by virtue of safeguard clause.[116]

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106 An example of this is the qualitative standard of Article 6(3) of the Habitats Directive as discussed above.

107 UNFCCC 1771 UNTS 107, 9 May 1992, in force 21 March 1994, Article 3.3.

108 Reynolds and Fleurke (2013), supra n. 96 above.

109 Ibid

110 N. de Sadeleer, *Environmental Principles – From Political Slogans to Legal Rules* (Oxford University Press: 2002)., J. Scott, 'The Precautionary Principle before the European Courts' in R. Macrory, *Principles of European Environmental Law* (Europa Law Publishing, 2004), 51-75; J. Peel, Precaution - A matter of principle, approach or process?' *The Melbourne Journal of International Law* (2004) 5, 483-501. F.M.Fleurke (2012), supra n. 73.

111 See e.g. Case C-6/99 *Association Greenpeace France and Others v Ministère de l'Agriculture et de la Pêche and Others* [2000] ECR I-01651; Case C-473/98 *Toolex* [2000] ECR I-5681, paras 46 and 47, Case C-192/01 *Commission* v. *Denmark* [2003] I-9693 and Case C-219/07 *Raad van State, the Nationale Raad van Dierenkwekers en Liefhebbers VZW* [2008] ECR I-4475.

112 Case T-13/99 *Pfizer Animal Health* v. *Council* [2002] ECR II-3305, para. 143; Case C-236/01 *Monsanto*, para. 113; Case C-192/01 *Commission* v. *Denmark*, para. 51.

113 See e.g. Case C-192/01 *Commission* v. *Denmark*, para. 48. The CBD ban mentioned earlier should be viewed rather as an political than a legal expression of the precaution.

114 See for example Case T 74/00 *Artegodan*, paras 199-200.

115 In Case T-13/99 *Pfizer* para. 410, the CFI laid emphasis upon cost-benefit analysis as a 'particular expression' of the proportionality principle

116 An example of this type of regulation is Directive 2001/18/EC on the Deliberate Release of Genetically Modified Organisms [2001] OJ L 106.

In sum, the European courts interpretation of the precautionary principle has resulted in a relatively low risk threshold for taking precautionary measures. However, simultaneously the European courts have elaborated and upheld a set of procedural requirements that constrain and discipline EU institutions and Member States to different degrees.

Precaution is therefore operationalized through these procedural elements instructing the regulator to first take into account 'serious or irreversible harm', acknowledge uncertainty on the basis of a risk assessment to apportion responsibilities to prove safety with regulatees, to respect the principle of proportionality, to ensure provisional nature of measures and lastly to monitor environmental performance.[117]

Viewed in this way, precaution could potentially play a constructive role in situations where it is difficult to balance potential benefits and risks because of scientific uncertainty. Importantly, precaution already fulfills this role in the risk assessment phase where it enables the early identification of uncertain risks and comparable alternatives. Accordingly, precaution does not only have a *regulatory* function; it also has an *organizing* function to deal with uncertain risks.

Through these combined and individual procedural elements, it is this organizing function of precaution that can substantially impact decision-making on CE. Although no pronunciations about the outcome of this exercise can be predicted (since this is the essence of precaution), it is thinkable that - if applied systematically – research into certain forms of CE will be allowed but deployment of those same CE options will be rejected.[118]

## IV. Conclusion

We have conceived climate engineering as a classic case of risk-risk trade off. Climate engineering in confronts policy makers responsible for the future of our planet with a choice between a rock and a hard place. Large-scale intentional interventions in global physical, chemical and biological systems are a highly risky endeavour, but it is also a potentially effective response to equally serious risks that are associated with global warming. The nature and scale of scientific uncertainty surrounding both the effects of climate change itself and climate engineering mean that it is difficult to balance potential benefits and risks. As yet, there exist no concrete EU policy addressing this new environmental technology, but research funding has been provided to explore CE options, and some Member States have shown some interests.

In general it can be concluded EU environmental law does not directly restrict CE initiatives, at least not in so far as such initiatives respect secondary EU environmental law. For example, whether or not a Strategic EI is required is left to the discretion of individual Member States. Secondary legislation engaged by CE does not contain targets that impact specifically on CE, only constrain CE to the extent that it could undermine binding standards unrelated to CE as such (e.g. habitat protection), or is of a programmatic character thus lacking teeth.

Considering both its competence and its ambitions in the field of climate policy it appears likely that the EU will pursue a policy on climate engineering at some stage. It is also clear that precaution will play a pivotal role in the design of such a future policy. Not only does the TFEU instruct that all environmental policy must be based on the precautionary principle, the EU has profiled itself as a *risk regulator* with precaution as its guiding principle. In this role of risk regulator, the EU has not been shy to regulate 'new' environmental technologies (e.g. biotechnology, nanotechnology, chemicals and CCS, but also EURATOM). The general structure of such regulation has been for new risky technology to be authorized, but only after ensuring that considerable risks to the environment or human health have been addressed and, in as far as possible, excluded.

Precaution could not only serves a *regulatory* function here, but also has an *organizational* function; it is implemented in a procedural fashion. It is argued that, even in risk-risk trade off situations for which precaution was not primarily designed, precaution perceived in such a way will indeed play a constructive mediating role in the weighing exercise that must precede any decision about CE proposals.

117 F.M. Fleurke (2012), supra n. 73. In the literature the need for public participation and deliberation is also emphasised, see e.g. E. Fisher, 'Framing Risk Regulation: A Critical Reflection' (2013) 4 *European Journal of Risk Regulation*, 125; M. Weimer, Applying Precaution in EU Authorization of Genetically Modified Products – Challenges and Suggestions for Reform," *European Law Journal* (2010) 16 (5), 624 et seqq.

118 Consider for instance, the well-known termination problem (once a climate engineering measure has been taken (particularly SRM measures) it might be difficult stop) that in violation with the condition that precautionary measures should be provisional as to allow monitoring and re-assessment.

What the precautionary principle cannot do, of course, is to answer the more fundamental question if humankind should reserve the right for themselves to re-engineer our planet, even if this is in response to catastrophic anthropogenic environmental impacts that threaten the continued survival of that same planet.

# Regulating Solar Radiation Management

## The Roles of Public Engagement and Legislative Procedures

*Anne Therese Gullberg* and Jon Hovi*♠

*Climate engineering in general and solar radiation management (SRM) in particular raise profound and complex political, legal, social, and ethical questions that go well beyond technical-feasibility issues. We consider three such questions. First, can existing EU decision-making processes accommodate sufficient public engagement to ensure legitimate decisions on SRM? Second, does politics influence the choice of legislative procedure for SRM regulation? Third, does the choice of legislative procedure influence the likelihood of SRM implementation? Three main conclusions emerge from our analysis. First, existing EU decision-making processes can – given certain conditions – accommodate considerable public engagement and hence ensure legitimate decisions on SRM. Second, politics matters; indeed, the EU's choice of legislative procedure concerning SRM may well become subject to political negotiations. Finally, the choice of legislative procedure may substantially influence the likelihood of SRM implementation.*

## I. Introduction

Despite more than 20 years of climate negotiations and numerous regional, national, and local initiatives to curb greenhouse gas (GHG) emissions, global emissions are higher than ever before. This lack of progress concerning mitigation has spurred political and scholarly interest in alternative responses to climate change, particularly adaptation but also climate engineering.[1]

Climate engineering may be defined as "deliberate large-scale manipulation of the planetary environment to counteract anthropogenic climate change".[2] The International Panel on Climate Change (IPCC) distinguishes between two main types of climate engineering. The first is carbon dioxide removal (CDR), that is, "techniques that aim to remove $CO_2$ directly from the atmosphere by either...increasing natural sinks for carbon or...using chemical engineering to remove the $CO_2$, with the intent of reducing the atmospheric $CO_2$ concentration."[3] The second is solar radiation management (SRM), that is, "intentional modification of the Earth's shortwave radiative budget with the aim to reduce climate change"[4]. SRM includes atmospheric, terrestrial, and space-based approaches. Examples range from sulphur aerosol injection (SAI), marine cloud brightening, to desert reflectivity modification. While CDR reduces atmospheric concentrations of carbon dioxide, SRM reduces the amount of incoming solar energy to the climate system.

The idea of intentionally altering the climate raises profound and complex social, moral, legal and ethical uncertainties that go well beyond issues of technical feasibility.[5] In particular, many scholars consid-

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1 Olivier Boucher et al. "Rethinking climate engineering categorization in the context of climate change mitigation and adaptation." *Wiley Interdisciplinary Reviews: Climate Change* 5(1), (2014), pp. 23-35.

2 John G. Sheperd et al. *Geoengineering the climate: science, governance and uncertainty.* (London: The Royal Society, 2009), at pp. 1.

3 IPCC, 2013: Annex III: Glossary [Planton, S. (ed.)]. In: Climate Change 2013: The Physical Science Basis. Contribution of Working Group I to the Fifth Assessment Report of the Intergovernmental Panel on Climate Change [Stocker, T.F., D. Qin, G.-K. Plattner, M. Tignor, S.K. Allen, J. Boschung, A. Nauels, Y. Xia, V. Bex and P.M. Midgley (eds.)]. Cambridge University Press, Cambridge, United Kingdom and New York, NY, USA, at p. 1449.

4 IPCC (2013). Annex III: Glossary [Planton, S. (ed.)]. In: *Climate Change 2013: The Physical Science Basis. Contribution of Working Group I to the Fifth Assessment Report of the Intergovernmental Panel on Climate Change*. Cambridge: Cambridge University Press, p. 1462.

5 Adam Corner, Nick Pidgeon, and Karen Parkhill. "Perceptions of geoengineering: public attitudes, stakeholder perspectives, and the challenge of 'upstream'engagement." *Wiley Interdisciplinary Reviews: Climate Change,* 3(5), (2012), pp. 451-466.

er that climate engineering in general and SRM in particular pose serious challenges for democratic politics. It is widely held that the public should be engaged in the debate over climate engineering.[6] Moreover, several scholars assume – implicitly or explicitly – that existing decision-making processes cannot produce legitimate decisions in a question as profound and complex as climate engineering. A major concern is lack of public engagement.[7]

We focus on SRM for two reasons. First, because of the moderate implementation costs, SRM could be conducted by a single state or by a single non-state actor.[8] Second, with emissions growth showing few signs of decelerating and with SRM techniques almost ready for field tests, some countries might consider unilateral SRM deployment as a real option.

However, worth noting is that SRM includes several different techniques with varying risks. These techniques vary with regard to effectiveness, costs, side effects, and uncertainty. While space reflectors would be very costly, SAI could quickly (months to a few years) change the climate substantially even at very moderate costs.[9] Experience from volcanic eruptions shows SAI's rapid impact potential.

Some SRM techniques could entail serious side effects, including severe droughts and changes in the monsoon wind. For example, SAI could cause a delay in the ozone layer's recovery,[10] marine cloud brightening might entail changes in the El Niño Southern Oscillation,[11] and increasing desert reflectivity might reduce regional precipitation and monsoon intensity.[12]

Finally, the uncertainties associated with the effectiveness, costs and side effects are high. With regard to SAI, scientists have still not found particles that can be injected without serious side effects, and while some estimate the costs of aircraft injections to be ten times as high as balloon injections[13], others estimate balloon injections to be ten times as high as aircraft injections.[14]

SRM techniques differ substantially in terms of effectiveness, costs, side effects, and uncertainty; however, there is much less variation in possible public engagement procedures. As the focus of this paper is on procedures of public engagement, we therefore focus on SRM *in general*. In doing so, we follow the existing literature on public engagement, which only to a very limited extent distinguishes between different SRM techniques, although several contributions emphasize SAI.

The literature on democratic challenges concerning SRM lacks a common definition of legitimacy; however, most (if not all) previous contributions focus on the need for *public engagement* in the decision-making process. We therefore proceed on the assumption that legitimacy is not only a question of following a predetermined legislative procedure, but also a question of ensuring *deep and broad public engagement* in the decision-making process. In other words, when we talk about the EU "decision-making process", we refer not only to the legislative procedure being used but also to the deliberative and pluralist basis for gathering information and civil-society support for EU policies.

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6 Jonas Anshelm and Anders Hansson. "Battling Promethean dreams and Trojan horses: Revealing the critical discourses of geoengineering." *Energy Research & Social Science* (2) (2014), pp. 135 *et sqq.*; Wylie A. Carr, et al. "Public engagement on solar radiation management and why it needs to happen now." *Climatic change,* 121(3), (2013), pp. 567 *et sqq.*; Marc Poumadère, Raquel Bertoldo, and Jaleh Samadi. "Public perceptions and governance of controversial technologies to tackle climate change: nuclear power, carbon capture and storage, wind, and geoengineering." *Wiley Interdisciplinary Reviews: Climate Change* 2.5 (2011), pp. 712 *et sqq.*; Steve Rayner et al. "The Oxford Principles." *Climatic change,* 121(3), (2013), pp. 499 *et sqq.;* Bronislaw Szerszynski, et al. "Why solar radiation management geoengineering and democracy won't mix." *Environment and Planning A 45*(12), (2013), pp. 2809 *et sqq*.

7 Carr et al., «Public engagement», *supra* note 6, at p. 570. Adam Corner and Nick Pidgeon. "Geoengineering the climate: the social and ethical implications." *Environment: Science and Policy for Sustainable Development,* 52(1), (2010), pp. 24-37. Corner et al., « Perceptions », *supra* note 6; Szerszynski, et al. "Why SRM and democracy won't mix", *supra* note 6.

8 Scott Barrett. "The incredible economics of geoengineering." *Environmental and resource economics* 39(1), (2008), pp. 45-54; David G. Victor. "On the regulation of geoengineering." *Oxford Review of Economic Policy* 24(2), (2008), pp. 322-336.

9 Justin McClellan, David W. Keith, and Jay Apt. "Cost analysis of stratospheric albedo modification delivery systems." *Environmental Research Letters* 7(3), (2012): 034019.

10 Simone Tilmes et al. "Impact of very short-lived halogens on stratospheric ozone abundance and UV radiation in a geoengineered atmosphere." *Atmospheric Chemistry and Physics* 12.22 (2012): 10945 et sqq.

11 C.J. Gabriel and A. Robock. "Stratospheric geoengineering impacts on El Niño/Southern Oscillation." *Atmospheric Chemistry and Physics Discussions* 15.6 (2015): 9173 et sqq.

12 Simone Tilmes et al. The hydrological impact of geoengineering in the Geoengineering Model Intercomparison Project (GeoMIP). *Journal of Geophysical Research: Atmospheres*, *118.22 (2013)*, 11-036.

13 Peter Davidson et al. "Lifting options for stratospheric aerosol geoengineering: advantages of tethered balloon systems." *Philosophical Transactions of the Royal Society A: Mathematical, Physical and Engineering Sciences* 370.1974 (2012): 4263 *et sqq*.

14 McClellan et al. "Cost analysis of SAI", *supra* note 9.

We consider three questions. First, can existing EU decision-making processes accommodate sufficient public engagement to ensure legitimate decisions on SRM? Second, does politics influence the choice of legislative procedure for SRM regulation? Third, does the choice of legislative procedure influence the likelihood of SRM implementation?

To answer these questions, we draw on Rowe and Frewer's typology of public engagement.[15] In particular, we provide an analytical framework to specify and analyze the *depth and breadth* of public engagement required to ensure legitimate decisions on SRM. Moreover, our analytical framework highlights the difference between the existence of a formal right to participate and actual participation.[16]

Climate change and SRM are transnational matters; hence, addressing the prospects for and the legitimacy of international SRM regulation is pertinent. The EU provides a particularly interesting case for studying the democratic challenges posed by SRM. Climate engineering is a contentious issue, and the EU has not (yet) adopted an official policy in this field.[17] However, the EU has been an important player in the international climate-change negotiations since the UN Framework Convention on Climate Change (UNFCCC) was negotiated in Rio de Janeiro in 1992, and has served as a climate-change mitigation frontrunner since the mid-1990s.[18] The UNFCCC's ultimate objective is to achieve 'stabilization of greenhouse gas concentrations in the atmosphere at a level that would prevent dangerous anthropogenic interference with the climate system".[19] The EU later operationalized "dangerous" climate change as a rise in the global mean temperature of more than two degrees Celsius above the preindustrial level (the two degree target was adopted by the UNFCCC under the Conference of the Parties in Cancun in 2010). Having competence in environmental issues (see section 5), the EU has over the last decade developed an integrated energy and climate strategy based on the two degree target. Worth noting is that legal developments at the EU level, not least in the environmental field, have "clear and often very constructive feedbacks into the international processes".[20] This makes the EU an interesting case.

The remainder of the paper is organized as follows. In section 2, we review previous research on public engagement and public acceptance of SRM and climate engineering more generally. In section 3, we outline our analytical framework and discuss existing principles and regulations. In section 4, we consider whether the EU pluralist approach can accommodate sufficient public engagement to ensure legitimate decisions on SRM. In section 5, we address the question of whether politics influence the choice of legislative procedure for SRM regulation. Section 6 concludes.

## II. Previous Research

In this section, we first review the extant literature on public engagement concerning SRM. Next, we provide a brief overview of public perceptions of climate engineering, including SRM.

### 1. Previous Research on Public Engagement Concerning SRM

A diverse literature exists on the democratic legitimacy of climate engineering. Some contributions consider climate engineering as a special case, whereas others emphasize the resemblance between climate engineering and other new, large technologies. While both sets of contributions call for wide public participation, their underlying justification differs. The former contributions base their call in their view of climate engineering as a special case, whereas the latter contributions base their call on a more general desire for public participation in the development of all new, large technologies.

15 Gene Rowe and Lynn J. Frewer. "Public participation methods: A framework for evaluation." *Science, technology & human values* 25(1), (2000), pp. 3 et sqq. Gene Rowe and Lynn J. Frewer. "A typology of public engagement mechanisms." *Science, technology & human values* 30(2), (2005), pp. 251 *et sqq.*

16 Anne Therese Gullberg. "Access to climate policy-making in the European Union and in Norway." *Environmental Politics* 20(4), (2011): 464 *et sqq.*, Anne Therese Gullberg. "Lobbying in Oslo or in Brussels? The case of a European Economic Area country." *Journal of European Public Policy* 22(10), (2015): 1531 *et sqq*.

17 Schäfer, S.et al. *The European Transdisciplinary Assessment of Climate Engineering (EuTRACE): Removing Greenhouse Gases from the Atmosphere and Reflecting Sunlight away from Earth*. (2015)

18 Jakob Skovgaard. "EU climate policy after the crisis." *Environmental Politics* 23(1), (2014), p. 1 *et sqq.*, at p. 3.

19 UNFCCC 1992. United Nations Framework Convention on Climate Change. Available online http://unfccc.int/resource/docs/convkp/conveng.pdf Accessed 17 April 2015.

20 Schäfer et al. EUTRACE, *supra* note 17.

Scholars considering SRM (and climate engineering more generally) as a special case, emphasize different aspects, such as SRM's global impact, challenges related to SRM's uneven regional distribution of impact (including side effects),[21] and SRM's influence on future generations. In contrast, Pidgeon et al. argue that climate engineering raises many of the same questions as other new large technologies.[22] In particular, they refer to characterizations originating in the general literature on climate engineering, such as "potentially unresolvable uncertainties over...global environmental impacts"[23], "profound ethical concerns"[24], and "complex trans-boundary legal and governance issues".[25]

The literature draws different conclusions with regard to public engagement. Several scholars argue that SRM is incompatible with liberal democracy, and that SRM should therefore not be deployed without further assessment of the political implications of such deployment.[26] Arguing that "the traditional institutions and practices of representative democracy may be inadequate to address the global implications of SRM technologies", Carr et al. conclude that representative democracy may struggle to ensure legitimate decisions on large-scale testing and deployment of SRM[27] They suggest a global public engagement process which should be scaled up over time, as research develops.[28]

Szerszinsky et al. go even further, arguing that SRM poses "immense challenges to liberal democratic politics", for four reasons.[29] First, substantial uncertainty combined with unequal distribution of side effects and intended impacts will likely cause conflicts within existing institutions. Second, SRM, and SAI in particular, necessitates autocratic governance.[30] Third, SRM is defined and must be regulated and assessed according to *intent*. However, motivations for SRM deployment will likely be "unstable and open to plural interpretation".[31] For example, whether SAI may be considered as SRM deployment, as research, or as pollution cannot be determined through technical procedures; rather, such determination requires an assessment of intent. Finally, SRM will become conditioned by economic forces, which will pose yet another threat to liberal democratic politics. Szerszinsky et al. conclude that SRM is incompatible with liberal democracy, and that SRM therefore should not be deployed before the political implications are further considered.[32]

Pointing to the "generic difficulties of public engagement", Corner and Pidgeon highlight the challenge of "locating dialogue within existing modes of democratic public representation".[33] According to them, the challenge is not only to organize public-engagement processes but also to ensure that decision-makers receive the results and take them into account.

However, the discussion about democratic legitimacy goes far beyond the issue of climate engineering and SRM; indeed, politicians, media, and scholars have debated the EU's alleged "democratic deficit" for many years.[34] Extending the power of the European Parliament (EP) has been one important way of increasing the EU's democratic legitimacy, another approach has been the European Commission's

21 Szerszynski, et al. "Why SRM and democracy won't mix", *supra* note 6.

22 Nick Pidgeon et al. "Exploring early public responses to geoengineering." *Philosophical Transactions of the Royal Society A: Mathematical, Physical and Engineering Sciences* 370(1974), (2012), pp. 4176 *et sqq*.

23 Corner et al. "Perceptions of geoengineering", W*IRES Climate Change, supra* note 5.

24 Corner and Pidgeon, "Geoengineering the Climate", supra note 7. S.M., Gardiner, "Some early ethics of geoengineering the climate: a commentary on the values of the Royal Society report", 20(2) *Environmental Values (*2011), pp. 163 *et sqq*.

25 Steve Rayner et al. "Draft Principles for the Conduct of Geoengineering Research (the 'Oxford Principles') reproduced in House of Commons Science and Technology Committee." *The Regulation of Geoengineering* (2010): 2009-2010.

26 Bronislaw Szerszynski, et al. "Why SRM and democracy won't mix", *supra* note 6; Phil Macnaghten and Bronislaw Szerszynski. "Living the global social experiment: An analysis of public discourse on solar radiation management and its implications for governance." *Global Environmental Change* 23(2), (2013), pp. 465 et sqq., at p. 465.

27 Carr et al., «Public engagement», *supra* note 6, at p. 575.

28 Carr et al., «Public engagement», *supra* note 6, at p. 574.

29 Szerszynski et al. "Why SRM and democracy won't mix", *supra* note 6, at. p. 2809.

30 Szerszynski et al. "Why SRM and democracy won't mix", *supra* note 6, at. p. 2812.

31 Szerszynski et al. "Why SRM and democracy won't mix", *supra* note 6, at. p. 2813

32 Szerszynski et al. "Why SRM and democracy won't mix", *supra* note 6, at. p. 2809; Macnaghten and Szerszynski. "Living the global social experiment" *supra* note 26, at p. 465.

33 Corner and Pidgeon, «Geoengineering the climate», *supra* note 7, at p. 34.

34 Erik Oddvar Eriksen and John Erik Fossum, eds. *Democracy in the European Union: integration through deliberation?* Psychology Press, 2000. Andreas Follesdal and Simon Hix. "Why there is a democratic deficit in the EU: A response to Majone and Moravcsik." *JCMS: Journal of Common Market Studies* 44(3), (2006), pp. 533-562.Beate Giandomenico Majone. Europe's 'democratic deficit': The question of standards." *European law journal* 4(1), (1998), pp. 5-28.

white paper on good governance (see section 3). Yet another has been public engagement through deliberative democracy.[35] The democratic challenge has also been addressed in the literature on lay-citizen deliberation,[36] and in the debate on public engagement in genetically modified organisms (GMOs).[37] There are many challenges associated with deliberative democracy, not least with regard to deep versus broad participation (see section III).

## 2. Public Acceptance of Climate Engineering

Before turning to how the public's views on SRM might be fed into the EU decision-making process, we turn to the literature on public acceptance and public engagement to see whether the public actually supports or opposes climate engineering.

The literature suggests that low public awareness makes the topic challenging to study.[38] Corner et al. refer to two studies in which about 75% of the respondents reported to know practically nothing about climate engineering.[39]

Mercer et al. present the results of a survey including more than 3.000 respondents in Canada, the United Kingdom, and the United States. While only 8% were familiar with the concept of geoengineering, 45% were familiar with the concept of climate engineering. [40] Wording is always important, but even more so in this issue. Corner et al. find that most respondents, even those reporting to be unfamiliar with geoengineering, do offer an answer. Preference elicitation based on surveys may therefore be highly problematic. [41]

Mercer et al. found high support for allowing *research* on SRM. While 72% expressed somewhat or strong support, only 14% voiced opposition. However, respondents proved less supportive when asked about their views on immediate SRM *deployment* and on future SRM intervention in a climate emergency.[42] This strong support for research would likely decrease if the respondents were informed that large-scale research may in fact be considered as deployment.

Pidgeon et al. found more support for CDR than for SRM, having briefly explained both techniques to the respondents.[43] They also found that "don't know" answers vary systematically across demographic groups. For example, respondents with low formal education and low social status display a comparatively high "don't know" response rate. [44]

Several UK studies suggest a position of conditional public acceptance. In particular, support for *research* on climate engineering may not correlate with support for actual deployment. Moreover, support may be lower for SRM than for CDR, due to concerns about "interference with nature", irreversibility, and limited control.[45] Bellamy et al. report that geoengineering proposals were outperformed by mitigation options and that SAI performed worse than in quantitative studies of public perceptions and in expert-analytic assessments.[46] Moreover, the effect of knowledge is unclear.[47][48]

Another strand of the literature is based on focus groups. Macnaghten and Szerszynski found that par-

35 Grace Skogstad. "Legitimacy and/or policy effectiveness? Network governance and GMO regulation in the European Union." *Journal of European Public Policy* 10(3), (2003), pp. 321 *et sqq.*, at p. 324.

36 John S. Dryzek. *The politics of the earth: Environmental discourses*. Oxford University Press, 2012.

37 Skogstad "Legitimacy and/or policy effectiveness?", *supra* note 35; Marko Ahteensuu and Helena Siipi. "A critical assessment of public consultations on GMOs in the European Union." *Environmental Values* 18(2) (2009), 129 et sqq.

38 Corner et al. "Perceptions of geoengineering", *supra* note 5.

39 Corner et al. "Perceptions of geoengineering", *supra* note 5.

40 Ashley Megan Mercer, David W. Keith, and Jacqueline D. Sharp. "Public understanding of solar radiation management." *Environmental Research Letters* 6(4) (2011), 044006.

41 Corner et al. "Perceptions of geoengineering", *supra* note 5, at p. 456.

42 Mercer et al. "Public perception", *supra* note 40, at p. 8.

43 Pidgeon et al. "Early responses", *supra* note 22, at p. 4176.

44 Pidgeon et al. "Early responses", *supra* note 22, at p. 4187.

45 Macnaghten and Szerszynski. "Living the global social experiment", *supra* note 26. Karen Parkhill and Nick Pidgeon. "Public engagement on geoengineering research: preliminary report on the SPICE deliberative workshops." *Understanding Risk Working (2011–11)* 29 (2011); Nick Pidgeon et al. "Deliberating stratospheric aerosols for climate geoengineering and the SPICE project." *Nature Climate Change,* 3(5), (2013), pp. 451 *et sqq.*

46 Rob Bellamy, Jason Chilvers, and Naomi E. Vaughan. "Deliberative Mapping of options for tackling climate change: Citizens and specialists 'open up'appraisal of geoengineering." *Public Understanding of Science* (2014), 0963662514548628, pp. 1 *et sqq.*, at p. 14.

47 Alexa Spence et al. *Public perceptions of climate change and energy futures in Britain: Summary findings of a survey conducted in January – March 2010*. Technical report (Understanding Risk Working Paper 10-01), (School of Psychology, Cardiff University: Cardiff, 2010).

48 Pidgeon et al. "Deliberating stratospheric aerosols", *supra* note 45.

ticipants "seemed to arrive at more consistently skeptical positions about the prospect of geoengineering than have been reported in earlier research".[49]

Research on public perceptions on climate engineering in Europe is dominated by studies of the UK public. However, a few studies of the German public also exist. Merk et al. found high support for laboratory research on SRM, yet far less support for field research, and little support for deployment.[50] Moreover, in a study based on 98 German participants, Amelung and Funke found that framing climate engineering as a "plan B" increases the likelihood of acceptance, particularly concerning cloud brightening.[51] However, it is not possible to draw any conclusions with regard to differences within Europe. There is still a large gap in the literature on public acceptance of climate engineering in Europe.

The literature first and foremost shows that there is no clear public view on SRM. The results depend on research method (surveys or focus groups), wording, framing, and not at least the alternatives provided (mitigation, adaptation). Eliciting the public´s preferences on SRM is therefore very demanding.

## III. A Deliberative Approach to Legitimacy: How Deep and Broad Public Engagement is Required?

Several EU principles and regulations regarding public engagement already exist. Do these existing principles and regulations ensure deep and broad public engagement?

To answer this question, we draw on an analytical framework based on Rowe and Frewer's typology of public engagement.[52] This typology focuses on the "flow of information" between participants (members of the public) and sponsors (decision-makers or others initiating the process of public engagement).[53] It specifies three types of public engagement. The first is public communication, whereby "information is conveyed from the sponsors of the initiative to the public". The second is public consultation, whereby "information is conveyed from members of the public to the sponsors of the initiative, following a process initiated by the sponsor". Note that public consultation does not imply any formal dialogue; rather, the information elicited is assumed to represent current public opinion. Finally, the third type is public participation, whereby "information is exchanged between members of the public and the sponsors". Hence, public participation involves at least some degree of dialogue and negotiation, both of which are assumed to "transform opinions in the members of both parties (sponsors and public participants)".[54]

In short, Rowe and Frewer's typology distinguishes between pure one-way information from decision-makers to the public, one-way information from the public to decision-makers, and finally, two-way dialogue and negotiations between decision-makers and the public. We will refer to this dimension as the *depth* of engagement. It follows that we consider two-way engagement as deeper than one-way engagement.

Rowe and Frewer also consider the representativeness of the public taking part in public engagement activities. We label this dimension of public engagement as the *breadth* of engagement.

Although researchers might strive to make "mini-publics" such as focus groups, citizens' juries, or citizens' panels representative, Dryzek et al. emphasize that small numbers mean that any claim to representativeness is not statistical. Nor are the participants in mini-publics representative by way of election or by being accountable to the wider public: "Any claim to representativeness comes only in that the range of relevant social characteristics and initial points of view should be substantially present in the mini-public".[55]

Finally, following Gullberg, we distinguish between (1) formal access to decision-making processes on one hand and (2) actual participation in decision-making processes on the other.[56] Broad participation requires not only formal access, but actual and extensive *use* of such access.

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49 Macnaghten and Szerszynski. "Living the global social experiment", *supra* note 26.

50 Christine Merk et al. *Exploring public perception of solar radiation management*. No. 1892. (Kiel: Kiel Working Paper, 2014).

51 Dorothee Amelung and Joachim Funke. "Laypeople's Risky Decisions in the Climate Change Context: Climate Engineering as a Risk-Defusing Strategy?" *Human and Ecological Risk Assessment: An International Journal* 21(2) (2015), pp. 533 *et sqq*.

52 Rowe and Frewer. "Public participation methods", *supra* note 15. Rowe and Frewer. "A typology", supra note 15.

53 Rowe and Frewer. "A typology", *supra* note 15, at p. 254.

54 Rowe and Frewer. "A typology", *supra* note 15, at p. 255-256.

55 John Stanley Dryzek et al. 'Promethean Elites Encounter Precautionary Publics: The Case of GM Foods'." *Science, Technology, and Human Values* (2009), 34, pp. 263 et sqq.

56 Gullberg "Access to climate policy-making", *supra* note 16

The analytical framework is thereby based on two dimensions, following Rowe and Frewer's typology: The first dimension is deep participation. This dimension is arguably at the very core of Rowe and Frewer's typology, which specifies types of public engagement with different "depth" – from one-way communication to two-way dialogue. The second dimension is broad participation, which relates to Rowe and Frewer's term "effectiveness", that is, the extent to which information is being elicited from the relevant population.[57] Here, we distinguish between representative and non-representative (or only partly representative) methods. Attempts to elicit public opinion can be made through representative opinion polls, through more or less representative focus groups, or through non-representative groups.

Within the environmental field, the Aarhus Convention entitles individuals and associations alike to receive environmental information held by public authorities. It also grants them the right to participate in environmental decision-making processes and the right to challenge decisions already made – if the right procedures were not followed.[58] The Aarhus Convention thereby guarantees the public a formal right to *public communication* (one-way information from decision-makers to the public) as well as to *public consultation* (one-way communication from the public to decision-makers). Moreover, it guarantees such rights to the *broad* public; indeed, all citizens are entitled to public consultation. Notably, however, the Aarhus Convention does not require public consultation actually to take place; it only grants the public a *formal right* to such consultation.

In 2001, the European Commission presented a so-called white paper on EU level governance (defined as rules, processes, and behavior that affect the way in which powers are exercised). In particular, the white paper advocates five principles of good governance, emphasizing each principle's importance for establishing *democratic* governance.[59] We concentrate on the first two principles – which are arguably most closely associated with public engagement and democratic legitimacy.

The first of these principles states that the EU should ensure *broad participation* in the policy-making process – from conception to implementation.[60] Furthermore, the EU principles of good governance declare that the EU institutions should work in an *open* manner, no doubt a condition for deep and broad public engagement. Concerning openness, the Commission emphasizes the importance of using language the general public understands, thereby highlighting a main challenge for communicating about climate engineering in general and SRM in particular. While some SRM techniques (such as desert reflectors, space-based reflectors, and roof whitening), are intuitively comprehensible, other techniques (such as cloud-albedo enhancement or stratospheric aerosols) remain challenging. Moreover, SRM techniques are often presented in clusters containing more as well as less comprehensible techniques. Such clustering might provide a barrier for understanding. A related problem, complicating things even further, is that SRM techniques are often presented in tandem with CDR techniques.

The widely endorsed "Oxford principles" on geoengineering state that "those conducting geoengineering research should be required to notify, consult, and ideally obtain the prior informed consent of those affected by the research activities".[61] These principles require one-way *public consultation*, according to Rowe and Frewer's typology. A two-way dialogue is not required. Importantly, the affected parties will vary between different climate-engineering techniques, ranging from local to global publics.[62]

Returning to Rowe and Frewer's typology, we see that existing principles and regulations ensure a right not only to *public communication*, but also to *public consultation*. These principles and regulations do not, however, ensure a right to two-way public participation. And although granting the public a formal right to participation, they do not ensure *actual* participation.

As shown above, the literature on public engagement in SRM calls for two-way public participation. This call is in line with the increasing number of deliberative exercises involving lay people on issues concerning technological risks.[63] Examples include large-scale technologies and genetically modified or-

57 Rowe and Frewer. "A typology", *supra* note 15, at p. 254.

58 European Council Decision of 17 February 2005 on the conclusion, on behalf of the European Community, of the Convention on access to information, public participation in decision-making and access to justice in environmental matters (2005/370/EC).

59 Commission White Paper. European Governance: A White Paper, COM (2001)428.

60 Commission White Paper. European Governance, *supra* note 59.

61 Rayner et al. "Draft Principles", *supra* note 25.

62 Rayner et al. "The 'Oxford Principles", *supra* note 6, at p. 506.

63 Dryzek et al. «Promethean Elites», *supra* note 55, at p. 263.

ganisms (GMO). Despite widespread calls for deeper public engagement, existing principles and regulations seem to concentrate on one-way engagement. For example, EU Directive 2001/18/EC on the deliberate release into the environment of GMOs states that:

> Member States shall (...) consult the public and, where appropriate, groups on the proposed deliberate release. In doing so, Member States shall lay down arrangements for this consultation, including a reasonable time-period, in order to give the public or groups the opportunity to express an opinion.[64]

In terms of Rowe and Frewer's typology, the directive only requires one-way *public consultation*.

The extant literature highlights challenges related to practical conduct of deliberative exercises. Studying public engagement in Finland, Ahteensuu and Siippi find that the GMO consultation exercise did not satisfactorily meet its (many) objectives. These objectives included serving the democracy, informing and educating the public, developing a consensus within the society, enabling better decisions and establishing trust in decision-makers, and experts. The authors conclude that deliberation under less than optimal circumstances can be ineffective at best and counterproductive at worst.[65]

## IV. Can the EU's Pluralist Approach Foster Deep and Broad Public Engagement?

The EU approach to interest group participation may be characterised as pluralist, with open access to participation in stakeholder processes, often through consultative documents ("green papers") and later consultations on legislative proposals.[66] Can this pluralist approach foster deep and broad public engagement? To answer this question, we apply the analytical framework outlined in section three.

A prominent critic has defined pluralism as a system in which a wide range of interest groups representing different societal interests largely offset each other. [67] According to this definition, the basic idea of pluralism is that interest groups compete in their struggle to influence decision makers and therefore tend to *counterbalance* each other. Proponents of this "referee" version of pluralist theory, contend that the government's (or, in the EU's case, the supranational institution's) role is to "lay down the ground rules" for conflict and competition between interest groups and to ensure that no particular interest group benefits disproportionately in an unchecked manner.[68]

A second view on pluralism is the "vector sum" or "give-and-take" theory, according to which the government (or the supranational institution) constitutes a focal point for interest-groups pressures: "The laws issuing from the government are shaped by the manifold forces brought to bear upon the legislators. Ideally, [the government] merely reflects these forces, combining them...into a single social decision".[69]

The Commission's public consultations are in principle open to all interest groups – and thereby allow for *broad* public engagement; however, formal access is hardly a valid indicator of actual participation. Indeed, it is important to distinguish between formal access and actual participation.[70] Although the EU's public consultations are open in principle, actual participation vary considerably across different interest groups. Access is not only a question of open access; it requires resources to make use of these channels.[71]

In other words, formal open access provides no guarantee for broad and balanced participation. Recognizing this problem, the Commission sometimes actively invites environmental organizations to participate in stakeholder processes, aiming to ensure broader representation (e.g., concerning climate policy).[72] In addition, the Commission has helped funding organizations such as the European Environmental Bureau.[73]

Applied to SRM, the doctrine of pluralism presupposes the existence of at least two competing inter-

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64 European Union, Directive 2001/18/EC, Article 9.1.

65 Marko Ahteensuu and Helena Siipi. "A critical assessment", *supra* note 37, at p. 136.

66 Gullberg "Access to climate policy-making", *supra* note 16, at p. 465.

67 Mancur Olson. *The Logic of Collective Action*. (Cambridge, MA.: Harvard University Press, 1965), at p. 111.

68 Robert Paul Wolff. "Beyond tolerance," in Robert Paul Wolff, Barrington Moore Jr. and Herbert Marcuse, *A Critique of Pure Tolerance*. (Boston, MA.: Beacon Press, 1969), pp. 4 *et sqq*.

69 Wolff, "Beyond tolerance," *supra* note 68, at p. 11.

70 Gullberg "Lobbying in Oslo or Brussels", *supra* note 16.

71 Gullberg "Access to climate policy-making", *supra* note 16, at p. 465.

72 Gullberg "Access to climate policy-making" *supra* note 16, at p. 465.

73 Sonia Mazey and Jeremy Richardson. "Shooting where the ducks are: EU lobbying and institutionalized promiscuity" In: *European Union: Power and Policy-Making*, Sonia Mazey and Jeremy Richardson (eds.), 2015, pp. 419 *et sqq*.

est groups – one that supports (regulation of) SRM and one that opposes it. Often, however, only one side is actually represented in EU decision-making processes.[74] In such cases, counterbalancing will unlikely take place.

However, whether the current EU decision-making process are legitimate hinges critically on whether the nature of this process can be said to actually work as pluralist theory prescribes. At least three main lines of critique can be raised against this theory.[75]

The first relates to the theory's "vector-sum" version, according to which the major interest groups in society compete for control over political decisions. The critics argue that new interest groups often find it hard to get acknowledged and to receive their appropriate place in the process. In effect, the critics argue, pluralism has a decelerating effect both on social change and on the regulation of new phenomena.

A second line of critique derives from the theory's "referee" version, which portrays the role of government as one of providing oversight and regulation of the competition between interest groups. The critics argue that governments tend to systematically favor stronger interest groups over weaker ones. By solidifying the position of those groups that already have influence, the government tends to play "a conservative, rather than a neutral, role in society".[76]

Finally, a third line of critique argues that pluralist theory not only discriminates against certain social groups or interests but also against particular types of proposals for problem-solving. Specifically, by focusing on the struggle between different groups and interests, the theory tends to ignore problems having to do with *the common good*.

Are these lines of critique valid for SRM? SRM is obviously a relatively new phenomenon. It concerns climate change, an environmental issue having to do with "the common good". (The first of the Oxford principles actually states that geoengineering should be regulated as a public good.) If the critics of pluralism are right, both properties suggest that (regulation of) climate engineering will likely face difficulties in finding its way onto the political agenda.

These difficulties would seem to be reinforced by the fact that climate engineering might present an "easy way out" for carbon-intensive industries and businesses that would like to avoid costly mitigation measures, while renewable energy industries, although growing, are still not as powerful as traditional carbon-intensive industries.[77] While business belongs to the most powerful interest groups, environmental groups have been portrayed as "poorly trained and therefore weak".[78] Furthermore, business groups have better access to EU decision-makers compared to environmental groups.[79] Still, interest groups lobbying to defend the status quo are more likely to succeed compared to interest groups lobbying to change the status quo.[80] In a pluralist system, SRM would therefore seem to represent a case in which the cards are stacked *against* policy change.

Still, many European countries (e.g., Germany, Austria, and Italy) offer interest groups and civil society organizations a formal, institutionalized part in the policy-making process, which is typically characterized by attempts at reaching a consensus, that is, without generating clear winners or losers. Interest groups thereby not only have direct access to the Commission and to the EP but also indirect access via their national representatives in both legislative institutions.[81] Moreover, although the EU system is a pluralist system, it is also a multi-level system where "no single actor can control a game with so many different players".[82]

As shown above, climate engineering, SRM and SAI have still not reached the public debate and political agenda in most EU member states, with the notable exception of the UK. Both WWF UK and Friends of the Earth in the UK (FOE UK) participate in this debate. Interestingly, FOE UK does not close the door entirely for climate engineering. Their pri-

74 Anne Therese Gullberg. "Lobbying friends and foes in climate policy: The case of business and environmental interest groups in the European Union." *Energy Policy* 36(8), 2008, pp. 2964 et sqq.

75 Wolff, "Beyond tolerance," *supra* note 68, at p. 40.

76 Wolff. "Beyond tolerance." *supra* note 68, at p. 46.

77 Anne Therese Gullberg. "Pressure or information? Lobbying for binding renewable energy targets in the European Union." *Review of Policy Research* 30(6) (2013): 611 *et sqq*.

78 Lars K. Hallstrom, "Eurocratising enlargement? EU elites and NGO participation in European environmental policy." *Environmental Politics* 13(1) (2004), pp. 175 *et sqq*., at p. 179.

79 Gullberg, "Access to climate policy-making", *supra* note 16, at p. 473.

80 Frank R. Baumgartner et al. *Lobbying and policy change: Who wins, who loses, and why*. (University of Chicago Press, 2009).

81 Jonathan P. Doh and Terrence R. Guay. "Corporate Social Responsibility, Public Policy, and NGO Activism in Europe and the United States: An Institutional-Stakeholder Perspective." *Journal of Management Studies* 43.1 (2006), pp. 47 et *sqq*., at p. 51.

82 Richardson, Jeremy. "Government, interest groups and policy change." *Political Studies* 48.5 (2000): 1006-1025.

ority is mitigation and they oppose SAI, but as the two-degree target is out of reach, they are prepared to consider CDR.[83] WWF UK shares this view: They prefer to mitigate but if mitigation fails, CDR could become an option.[84]

Returning to Rowe and Frewer's typology, we see that EU's pluralist approach does not focus on *deep* participation. Stakeholder processes are mainly based on one-way *public consultation*, where stakeholders write position papers. However, there are no formal barriers to deeper participation. Finally, as shown above, several attempts have been made by the Commission to *broaden* participation.

We end this section by suggesting three sets of measures EU decision makers might consider for enhancing public engagement and thus the legitimacy of EU decisions. First, they could narrow the current gap between formal access and actual participation by taking steps for broadening participation (thereby ensuring that all main interests are represented). In particular, they could formalize minimum thresholds for participation in stakeholder processes and stimulate a balanced approach by specifically inviting relevant yet typically underrepresented participants. Ensuring balanced participation by all relevant interest groups – which can be done within existing decision-making procedures – is essential to ensure legitimacy. In this particular case, balanced participation would mean including environmental organizations that support climate engineering as well as environmental organizations that oppose it. Likewise, while some business groups will likely prefer climate engineering over mitigation, the renewable energy sector would likely prefer mitigation through renewable energy over climate engineering. Ensuring balanced participation therefore requires adequate knowledge about different groups' positions.

Stakeholder consultations do not guarantee representativeness. Surveys are therefore a valuable additional tool, although we have already seen that eliciting preferences in the field of SRM through surveys (as well as other methods) are extremely demanding.

Second, concerning good governance rules, broad participation in decision-making processes about climate engineering (SRM as well as CDR) might be enhanced by formalizing openness and by taking steps to ensure that the EU uses language that the general public understands. As we have seen, the extant literature highlights challenges related to the practical conduct of deliberative exercises (section 3). Openness, as defined by the rules of good governance, may contribute to meeting some of those challenges.

Finally, although existing principles do not ensure deep participation, it is certainly possible for the Commission to deepen participation. Environmental organizations have criticized the Commission for its standardized questionnaires in public stakeholder processes on EU climate policies. As a minimum, stakeholder consultation should open for making comments, not only for answering standardized questions. Yet another step would be to include interest groups in the design of stakeholder consultations. Participation could be further deepened by designing stakeholder processes on the basis of results from focus groups that include lay people, and by asking stakeholders to comment not only on the proposals and views of the Commission and organized stakeholders but also on the concerns of lay people. Taking such concerns into account would certainly enhance the legitimacy of stakeholder processes.

## V. Legislative Procedure – A Question of Politics?

Stakeholders' influence on EU decision-making processes depends not only on their participation in the corporate channel; it also hinges on the legislative procedure being used for the issue concerned. In turn, the choice of legislative procedure might influence the legislative outcome. This section considers how politics might influence the legislative procedure for SRM legislation and thereby also the legislative outcome concerning SRM.

EU law cannot be interpreted as generally prohibiting or authorizing climate engineering. However, it structures the decision-making process.[85]

Describing the EU's competence in the field of environment, Article 191 of the Treaty of the Functioning of the European Union (TFEU) states that the Union shall contribute to "preserving, protecting and improving the quality of the environment". It shall

83 Friends of the Earth UK. Geoengineering. Briefing note. November 2009. Available online: http://www.foe.co.uk/sites/default/files/downloads/geoengineering.pdf.

84 Huffington post. Geo-engineering – A tool in the fight to tackle climate change, or a dangerous distraction. September 9, 2012. Available online: http://www.huffingtonpost.co.uk/jon-taylor/geoengineering-climate-change_b_1873231.html.

85 Schäfer et al. EUTRACE, *supra* note 17, at p. 91.

also promote "measures at international level to deal with regional or worldwide environmental problems, and in particular combat climate change." Moreover, EU environmental policy shall be based on the precautionary principle, the preventive action principle, and the polluter pays principle.[86]

According to Article 191, the ordinary legislative procedure applies to environmental matters. This procedure involves both the EP and the Council (as stated in Article 294 in the TFEU).[87] EP decisions are normally taken by simple majority; however, under the ordinary legislative procedure an absolute majority of all EP members is required in the second reading. The Council applies two basic voting rules – unanimity and qualified majority voting (QMV). Both decision rules entail a bias in favor of the status quo.[88]

According to the 2009 Lisbon Treaty, new QMV rules apply from November 2014. The Nice Treaty's triple-majority requirement has been replaced by the double-majority requirement that a decision requires support by at least 72% of the Council members representing member states with at least 65% of the EU population.[89]

Although the European Council (EC) is not part of the ordinary legislative procedure, the 2008 climate and energy package was negotiated by the EC.[90] Moreover, the possibility of moving climate policy up to the EC level is not limited to this particular package; rather, according to the EC conclusions from October 2014, the EC will continue "to give strategic orientations as appropriate, notably with respect to consensus" on climate and energy policies.[91] Thus, the EC has decided to apply consensus instead of (or, formally, in addition to) the ordinary legislative procedure in certain matters of climate policy.

This development enables EU member states to link bargaining over policies to bargaining over institutions: "member state governments do not first settle substantive policy issues and then turn to the selection of institutional arrangements, but have institutional preferences in addition to policy preferences, bargain on policies and institutions at the same time, and make linkages between the two".[92]

Because EU climate policy issues can now be raised to the highest political level, the choice of legislative procedure for such issues might become a matter of political bargaining. Depending on the outcome of this political bargaining, EU decision making concerning SRM regulation could be based either on QMV or on unanimity.

Would QMV make SRM regulation more or less likely than unanimity would? The answer depends on what Scharpf refers to as the "reversion rule",[93] that is, on what will happen if the EU fails to reach a collective choice.

Suppose that absent EU legislation, there will be no regulation of SRM. Use of the unanimity rule would then entail that every member state could veto any EU regulation of SRM. In other words, for such regulation to be adopted, every state would have to be willing to give up its freedom to implement SRM unilaterally. In contrast, use of QMV would entail that SRM regulation could be introduced *without* the consent of the member state(s) least eager to give up this freedom. Thus, with this reversion rule, QMV would make EU regulation of SRM more likely than the unanimity rule would.

Conversely, suppose the point of departure is that SRM is prohibited, so that no EU country can implement SRM unless the EU explicitly permits it. In this case, use of the unanimity rule would enable each member state to veto EU regulation that permits SRM. In contrast, use of QMV would not provide each country with such a veto. Thus, with this reversion rule, QMV would make EU regulation of SRM more likely than the unanimity rule would.

In short, whether use of QMV would make SRM regulation more or less likely than use of the unanimity rule would depends on the reversion rule. So, which reversion rule is most relevant in an SRM context?

As mentioned above, EU law cannot be interpreted as generally prohibiting or authorizing climate en-

86 Consolidated version of the Treaty on the Functioning of the European Union, OJ C 326, 26/10/2012, article 191.

87 TFEU, *supra* note 86, article 294.

88 Tsebelis. *Vetoplayer, supra* 51, at p. 265.

89 TFEU, *supra* note 86, article 238(2).

90 Tora Skodvin, Anne Therese Gullberg, and Stine Aakre. "Target-group influence and political feasibility: the case of climate policy design in Europe." *Journal of European Public Policy* 17(6), (2010), 854-873.

91 European Council 2014. European Council conclusions. Brussels 24 October. EUCO 169/14.

92 Frank Schimmelfenning. Liberal Intergovernmentalism in A. Wiener,and T. Diez (eds.) *European integration theory*. Oxford: Oxford University Press, (2004), pp. 75 *et sqq*.

93 Fritz Scharpf, The Joint-decision Trap: Lessons from German Federalism and European Integration. *Public Administration* 66 (1988): 239-278. See also Jon Hovi and Detlef F. Sprinz, The Limits of the Law of the Least Ambitious Program. *Global Environmental Politics* 6 (2006): 28-42.

gineering.[94] Thus, the answer seems to be that international regulation of climate engineering in general and of SRM in particular is largely lacking. According to Reynolds, we should not expect such regulation anytime soon:

> [O]bservers should be modest in their expectations of climate engineering's international regulation, particularly through binding multilateral agreements. Instead of implying that the international regulation of climate engineering and its research will be entirely lacking, it will more likely be gradual, with a low degree of legalization, and through a plurality of means and institutions.[95]

Assuming Reynolds is right, use of QMV would make EU regulation of climate engineering more likely than use of the unanimity rule would.

Worth noting is that the EU could also leave it for each member state to decide whether to impose a ban. For example, in the case of genetically modified organisms (GMOs), the EU decided that member states may ban GMOs on their own territory, although GMOs are allowed at the EU level.[96]

To summarize, the choice of legislative procedure concerning SRM may become a question of political bargaining. Moreover, the outcome of this bargaining may influence the legislative outcome, depending on the reversion rule. Because international regulation of climate engineering is largely lacking, use of QMV would make EU regulation more likely than use of the unanimity rule would.

## VI. Conclusion

Three main conclusions emerge from this paper.

First, existing EU decision-making processes *can* accommodate considerable public engagement, and hence ensure legitimacy, even for decisions concerning complex issues such as SRM or climate engineering more generally. However, a crucial condition is that EU decision makers ensure openness and participation by all relevant interest groups.

Second, the low level of public awareness concerning climate engineering in general and SRM in particular constitutes a potential barrier for legitimate EU decision making concerning SRM. The EU's pluralist approach permits *broad* participation in the form of one-way inputs from interest groups to decision makers or vice versa. However, while granting the public a formal *right* to participation, it does not ensure *actual* participation, which will likely constitute a considerable challenge concerning SRM regulation. Although *deep* participation in the form of two-way communication is not granted through existing rules, the Commission could open up for deeper participation in its stakeholder consultations.

Finally, politics matters. Indeed, as is also the case for other elements of the EU's climate policy, the choice of legislative procedure concerning SRM may well become subject to political negotiations. The result of these negotiations could be use of the ordinary legislative procedure, which is based on QMV, or that the issue is being raised to the level of the EC, where decision-making is consensus-based. We have argued that given the absence of existing regulation of SRM, QMV would make EU regulation on SRM implementation more likely than the unanimity rule would.

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94 Schäfer et al. EUTRACE, *supra* note 17.

95 Jesse Reynolds. "The International Regulation of Climate Engineering: Lessons from Nuclear Power." *Journal of Environmental Law* (2014), pp. 1 *et sqq.*, at p. 2.

96 European Parliament. «Parliament backs GMO opt-out for EU member states". Press release. 13/01/2015. Available online: http://www.europarl.europa.eu/news/en/news-room/content/20150109IPR06306/html/Parliament-backs-GMO-opt-out-for-EU-member-states.

# The Best of Both Worlds: Maximising the Legitimacy of the EU's Regulation of Geoengineering Research

*Janine Sargoni**

*This paper suggests how the regulation of Solar Radiation Management (SRM) field research in Europe could be designed to maximise the possibility of securing legitimacy. It argues that legitimacy is maximised when regulatory frameworks are legal, and also responsive, flexible, deliberative and inclusive. By adopting an 'incorporated' approach to assessing the risk of Solar Radiation Management (SRM) field research, the EU can import elements of 'directly deliberative polyarchy' into its otherwise orthodox constitutional regulatory approach thereby maximising legitimacy. The argument is new in so far as it juxtaposes two conceptions of procedural legitimacy – one institutional and the other functional – in the context of significant scientific uncertainty in the technocratic regulatory paradigm of the EU. The significance of the work is that it draws on these conceptions of legitimacy to advance a pragmatic model of institutional design which comprises procedures that maximise legitimacy with minimal disruption to the EU's institutional balance of powers.*

## I. Introduction

Back in 2009 the Royal Society's seminal report on Geoengineering the Climate stated that "the greatest challenge to the successful deployment of geoengineering may be the social, ethical, legal and political issues associated with governance, rather than scientific and technical issues".[1] Neither science nor politics can be excluded and both need to be combined in order to provide effective, reliable and legitimate regulation of geoengineering risk in the European context. Given the significant scientific uncertainty of some geoengineering activities, effectiveness and reliability may be more difficult to secure than legitimacy, and so, as far as regulation is concerned, the focus should be upon securing a legitimate process. My contribution seeks to address how this effective, reliable and legitimate regulation can be achieved given the prevailing constitutional framework of the EU. In particular, European regulation of one type of geoengineering research – Solar Radiation Management (SRM) field research – could be designed to maximise the possibility of securing legitimacy.

Geoengineering has been described as "large-scale intervention in the earth's climate system in order to moderate global warming"[2] and can be disaggregated into at least two broad groups of activities:[3] those

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1 John Shepherd et al, *Geoengineering the Climate: Science, Governance and Uncertainty*, (London: Royal Society, 2009), at p. xi.

2 Ibid.

3 There are now a range of different terms used for geoengineering and its component activities, such as 'climate engineering' in Asbjorn Aaheim et al. "The European Transdisciplinary Assessment of Climate Engineering (EuTRACE): Removing Greenhouse Gases from the Atmosphere and Reflecting Sunlight away from Earth." (2015); 'Climate Intervention' in Committee on Geoengineering Climate, *Climate Intervention: Reflecting Sunlight to Cool Earth*. (National Academies Press, 2015), at p. 2. The debate about the classification of geoengineering techniques is ongoing. See Clare Heyward, "Situating and Abandoning Geoengineering: A Typology of Five Responses to Dangerous Climate Change." *46.01 Political Science & Politics* (2013); Olivier Boucher et al., "Rethinking Climate Engineering Categorization in the Context of Climate Change Mitigation and Adaptation", 5 *Clim Change* (2014), pp. 23 et sqq.; Duncan McLaren, "Why We Shouldn't Be in a Hurry To Redefine Climate Engineering", 15th December 2015, available on the internet at http://

that remove or reliably sequester carbon,[4] known as Carbon Dioxide Removal (CDR); and those that reflect sunlight to cool the earth,[5] known as Solar Radiation Management (SRM).

As field research that takes place outdoors beyond the confines of the lab or the computational model, SRM presents huge regulatory challenges both technical and normative. This paper considers how, principally, the latter of two areas of regulatory scholarship – EU regulation of risk and science, and transnational private regulation (TPR) – may contribute to a solution. As "the new body of rules, practices, and processes, created primarily by private actors, firms, NGOs, independent experts like technical standard setters and epistemic communities, either exercising autonomous regulatory power or implementing delegated powers",[6] TPR scholarship offers some potentially useful insights which may also address the reluctance of states to be involved.[7]

Assessing attempts at creating legitimate regulatory frameworks this paper conceives of legitimacy in terms of the 'legality' of 'transnational' regulation, and briefly draws on Weber's 'ideal type' of value-rational action as the basis of consent to the exercise of legal authority.[8] However, legitimacy can also be conceived in functional and procedural terms as the conditions by which normative expectations can be met.[9] Considering four such conditions – responsiveness, flexibility, deliberation and inclusion – this article argues that legitimacy is maximised when regulatory frameworks are both legal *and* responsive, flexible, deliberative and inclusive.

The task of demonstrating *how* a European regulatory framework for SRM field research maximises the possibility of securing legitimacy, by drawing on areas of transnational private regulatory scholarship and EU regulation of science and risk, is challenging, largely on account of the lack of empirical data. In this article I suggest that notwithstanding the germinal state of SRM field research, an embryonic regulatory framework is discernible which can be characterised as nascent transnational private regulation (nTPR) and assumes that, in the EU context, the direction of travel will be from nTPR to more full-blooded EU regulation.

My claim is that where there is significant scientific uncertainty 'incorporated' risk assessments, as opposed to 'isolated' ones, should be used in the EU's regulatory frameworks for SRM field research so that legitimacy can be maximised. An incorporated risk assessment involves science and politics simultaneously and contrasts with the isolated approach – one adopted in the technocratic paradigm – which engages science only in the assessment of risk; politics is consigned to the management of that risk. By adopting an incorporated approach to risk, the EU can maximise legitimacy in three ways: legitimacy as legality, supplementing the conditions for deliberative and inclusive participation in decision-making processes and by transforming a rigid regulatory framework into a flexible and responsive one. This is a novel claim in that it advocates a regulatory mechanism – the incorporated risk assessment – which provides a space for inclusion and deliberation *within* a technocratic regulatory framework.[10]

Three substantive sections of the paper set out more fully the problem posed for legitimacy by SRM field research, the difficulties of the EU's orthodox response to that problem, and finally my alternative response based on the incorporated approach to risk assessment. Section II, A Challenge for Legitimacy, defines SRM 'laboratory' and 'field' research and goes on to suggest that there may be instances when the effects have significant scientific uncertainty. Sig-

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dcgeoconsortium.org/2015/12/15/why-we-shouldnt-be-in-a-hurry-to-redefine-climate-engineering-duncan-mclaren/ (last accessed 6th January 2016).

4 Committee on Geoengineering Climate, *Climate Intervention: Carbon Dioxide Removal and Reliable Sequestration*. (National Academies Press, 2015).

5 Committee on Geoengineering Climate, *Reflecting Sunlight to Cool Earth*, *supra* note 3.

6 Fabrizio Cafaggi, "New Foundations of Transnational Private Regulation", 38(1) *JLS* (2011), pp. 20 et sqq.

7 Ibid, p. 23; K.W. Abbott and Duncan Snidal, "The Governance Triangle: Regulatory Standards Institutions and the Shadow of the State" in W. Mattli and N. Woods (eds), *The Politics of Global Regulation* (Princeton: Princeton University Press, 2009), pp. 44 et sqq.; Gralf-Peter Calliess and Peer Zumbansen, *Rough Consensus and Running Code* (Oxford: Hart Publishing, 2010).

8 Max Weber, *Economy and Society*, Gunter Roth & Claus Wittich (eds) (California: University of California Press, 1978)

9 Jacques Lenoble and Marc Maesschalck, "Renewing the Theory of Public Interest: The Quest for a Reflexive and Learning-based Approach to Governance" in Olivier De Schutter and Jacques Lenoble (eds), *Reflexive Governance: Redefining the Public Interest in a Pluralistic World*, (Oxford: Hart Publishing, 2010), pp. 3-21.

10 The technocratic/deliberative distinction of regulatory paradigms is found in other work, such as the Rational-Instrumental and Deliberative-Constitutive paradigms in Elizabeth Fisher, *Risk Regulation and Administrative Constitutionalism*, (Oxford: Hart Publishing, 2010); Transactional and Political paradigms in Bronwen Morgan, "The North-South Politics of Necessity: Regulating for Basic Rights Between National and International Levels", 29 *J Consum Policy* (2006), pp. 465 et sqq.; and 'private autonomy' and 'collaborative enterprise' in Tony Prosser, *The Regulatory Enterprise*, (Oxford: Oxford University Press, 2010).

nificant scientific uncertainty is defined and the tension between politics and science introduced. The section suggests that the nascent regulation of SRM research, when viewed as transnational private regulation is suffering a legitimacy deficit because the regulating institutions have no formal legal authority to act. Two significant issues arise: the relationship between politics and science in the regulating procedures and institutions, and the ability of individuals to participate directly or be represented in them.

Section III on the EU's response to the challenge for legitimacy argues that the EU's regulation of SRM research is likely to address the challenge for legitimacy in terms of establishing a firm legal basis to regulate. However, the EU's response is problematic, because as identified in section II above, it fixes the relationship between politics and science so that there is little flexibility and makes it difficult for individuals to participate directly in any meaningful way in regulatory institutions. The EU's response is classified typically as technocratic.

In section IV I offer an alternative response, one that maximises the possibility of securing legitimacy. It seeks to make a small yet significant adjustment to legitimacy as conceptualised in formal legal terms by reconfiguring risk-assessments to incorporate elements of a more deliberative, responsive and flexible approach. This mechanism is taken from a conceptualisation of legitimacy associated with directly deliberative polyarchy. In this way the alternative response aims to combine the best of both worlds and maximise the possibility of securing legitimacy.

## II. A challenge for Legitimacy

The effects of SRM field research can be grouped into those that are physical – climatic and environmental – [11] and those that are socio-political[12] or non-physical. [13] In this paper significant scientific uncertainty relates to the physical effects of SRM research; which is not to say that non-physical effects are not significant or do not pose difficulties for legitimacy or do not have implications for SRM governance.[14] I turn to the relationship between physical and non-physical risks in due course.

### 1. Significant Scientific Uncertainty

Uncertainty is a way of describing the limits of our understanding of a subject. It is "an expression of the degree to which a [subject matter][15] – such as the future state of the climate system – is unknown".[16] For SRM field research the subject matters are the physical effects of specific research projects as well as those of the broader SRM research endeavour.[17] All else being equal, as the subject matter becomes more complex, the less likely we are to know this about it. As the limits of our understanding increase so does uncertainty.

It is for scientists to understand the limits of their understanding. In quantifying those limits they make claims about scientific uncertainty. It is scientists, then, that are best placed to determine whether scientific uncertainty is significant or not.[18] An example of when uncertainty is significant is when it is unable to be quantified.

11 Committee on Geoengineering Climate, *Reflecting Sunlight to Cool Earth*, *supra* note 3, p. 47-147.

12 Andy Parker, "Governing Solar Geoengineering Research as it Leaves the Laboratory", *Phil. Trans. R. Soc A* (2014), 2730:20140173; Clive Hamilton. "No, We Should Not Just 'At Least Do the Research'", 496 Nature (2013), pp. 139 et sqq.

13 Stefan Schäfer et al. "Field Tests of Solar Climate Engineering." 3.9 *Nature Climate Change* (2013), pp. 766-766.

14 See papers 10-14 of the Theme Issue 'Climate Engineering: Exploring Nuances and Consequences of Deliberately Altering the Earth's Energy Budget' of *Phil Trans R. Soc.A* 2014: David Morrow, "Ethical Aspects of the Mitigation Obstruction Argument Against Climate Engineering Research." *Phil Trans R. Soc.A* 372.2031 (2014): 20140062; Adam Corner and Nick Pidgeon. "Geoengineering, Climate Change Scepticism and the 'Moral Hazard' Argument: an Experimental Study of UK Public Perceptions" *Phil Trans R. Soc.A* 372.2031 (2014): 20140063; Stefan Schäfer and Sean Low, "Asilomar Moments: Formative Framings in recombinant DNA and Solar Climate Engineering Research." *Phil Trans R. Soc.A* 372.2031 (2014): 20140064.

15 I have replaced the term 'value' with subject matter in order to reduce its ambiguity. In the context of this paper, value is associated with my definition of political activity and used contra science.

16 "Annex II Glossary of Terms" in R.K. Pachauri and A Reisinger (eds), *Climate Change 207: Synthesis Report – An Assessment of the Intergovernmental Panel on Climate Change* (Geneva, Switzerland: 2007), pp. 75-89.

17 Of course, this analysis of uncertainty could apply equally to non-physical effects of SRM research.

18 I use the term 'significant' in its ordinary, not statistical, sense. In this paper the meaning of the word significant is differentiated from its use in statistics because it relates to *scientific* uncertainty rather than *statistical* uncertainty. Scientific uncertainty may or may not be calculated statistically. So, whilst the phrase significant scientific uncertainty could comprise statistical uncertainty, it does not denote it necessarily.

Risk can be differentiated categorically from scientific uncertainty.[19] Risk analysis is meaningful only when the level of uncertainty is low-enough to make reliable statements about the likelihood of events. It is the process of risk analysis that is important not the final outcome. This process is undermined if scientific uncertainty is significant. My focus is on the procedure not the substantive outcome of risk analysis: reference to scientific uncertainty as a means of evaluating field research is not about the safety of those research activities,[20] although clearly the certainty of knowledge feeds into the process of risk analysis and into determinations of safety.

### a. Significant Scientific Uncertainty in the Context of Specific Research Activities

Owing to observations of volcanic activity, some climatic impacts of SRM are relatively 'certain'.[21] Some environmental effects are known also with relative certainty whilst the extent of some effects are less certain.[22] Despite these relative certainties, the National Academy of Sciences concluded that "unambiguous statements about how an intervention by [SRM] would affect the planet are thus not possible".[23] And whilst it might be straightforward to characterise environmental effects such as chemistry, light intensity and precipitation, detecting their impacts on ecosystems could be much more difficult.[24] Moreover, the unknown environmental impacts of SRM and its research are unknown: "there is also of course the possibility of environmental consequences that scientists have not yet identified".[25]

### b. Significant Scientific Uncertainty in the Context of the General SRM Research Endeavour

The unknown unknowns of some SRM research projects raise questions about the broader uncertainty of the entire SRM research endeavour. The Intergovernmental Panel and Climate Change IPCC's 5th Assessment Report (the AR5) of the Working Group I Report quantifies the uncertainty of climate change finding it *extremely likely* (95-100% probability[26]) that the cause of climate change is anthropogenic. It quantifies uncertainty on the basis of underlying scientific understanding and degree of consensus:

> "The degree of certainty in key findings in this assessment is based on the author teams' evaluations of underlying scientific understanding and is expressed as a qualitative level of confidence (from very low to very high) and, when possible, probabilistically with a quantified likelihood (from exceptionally unlikely to virtually certain). Confidence in the validity of a finding is based on the type, amount, quality and consistency of evidence (e.g., data, mechanistic understanding, theory, models, expert judgment) and the degree of agreement. Probabilistic estimates of quantified measures of uncertainty in a finding are based on statistical analysis of observations or model results, or both, and on expert judgment. Where appropriate, findings are also formulated as statements of fact without using uncertainty qualifiers".[27]

There is a high degree of confidence that climate change affects the uncertainty of environmental effects such as flooding, volcanic activity and droughts. For example, there is a *high confidence* level that the "uncertainties about future vulnerability, exposure and responses of interlinked human and natural systems are large".[28] Natural hazards exhib-

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19 Frank H. Knight, *Uncertainty, Risk and Profit*, (London: London School of Economic and Political Science, 1933); For conceptions of uncertainty in the IPCC see Minh Ha-Duong et al. "Uncertainty Management in the IPCC: Agreeing to Disagree." 17.1 *Global Environmental Change* (2007), pp. 8 et sqq.

20 Parker, "Governing Solar Geoengineering Research", *supra* note 12, pp. 3-4.

21 Examples include: the cooling effect of stratospheric sulphate aerosols, Committee on Geoengineering Climate, *Reflecting Sunlight to Cool Earth*, *supra* note 3, pp. 69-71; the delay of ozone recovery, Ibid, p. 86; and changes to precipitation, Ibid., p. 75.

22 Examples include: the reduction of sunlight intensity, Ibid, p. 95; changes to precipitation, Ibid; and acidity of snow and rain, Ibid.

23 Ibid, p. 98.

24 Ibid, p. 95.

25 Ibid.

26 "Summary for Policymakers" in T.F. Stocker, D. Qin, G.-K. Plattner, M. Tignor, S.K. Allen, J. Boschung, A. Nauels, Y. Xia, V. Bex and P.M. Midgley (eds.),. *Climate Change 2013: The Physical Science Basis. Contribution of Working Group I to the Fifth Assessment Report of the Intergovernmental Panel on Climate Change*, (Cambridge: Cambridge University Press, United Kingdom and New York, NY, USA, 2013), at Chapter 1, Box TS1.

27 Ibid, p. 4.

28 "Summary for policymakers" in C.B. Field, V.R. Barros, D.J. Dokken, K.J. Mach, M.D. Mastrandrea, T.E. Bilir, M. Chatterjee, K.L. Ebi, Estrada, R.C. Genova, B. Girma, E.S. Kissel, A.N. Levy, S. MacCracken,P.R. Mastrandrea, and L.L. White (eds.), *Climate Change 2014: Impacts, Adaptation, and Vulnerability. Part A: Global and Sectoral Aspects. Contribution of Working Group II to the Fifth Assessment Report of the Intergovernmental Panel on Climate Change*, (Cambridge University Press, Cambridge, United Kingdom and NewYork, NY, USA, 2014), pp. 1-32, et sqq., at p. 11

it both aleatory and systemic uncertainties "arising both from the inherent unpredictability of the hazard events themselves and from the complex way in which these events interact with their environment and with people".[29] Climate change increases the uncertainty of natural hazard frequency[30] and our exposure and vulnerability to it,[31] yet "it remains unclear whether decreasing the global mean temperature by SRM can reduce the number and intensity of extreme events because of the associated distinct regional pattern in temperature and precipitation changes".[32]

The AR5 is unable to quantify the uncertainty of SRM geoengineering owing to "limited evidence".[33] Clearly only a fraction of climate science research has been on SRM and some uncertainty, although not all, will be reducible through research.[34] It does suggest that "modelling indicates that SRM methods, if realizable, have the potential to substantially offset a global temperature rise, but they would also modify the global water cycle, and would not reduce ocean acidification. ...SRM methods carry side effects and long-term consequences on a global scale".[35]

I am not alone in advocating the use of scientific uncertainty as a basis for making some governance decisions. Among other things, it is suggested by Keith et al[36] as the most appropriate scientific criterion to be taken into account when deciding which field project to pursue.

### c. The Problem of Significant Scientific Uncertainty for Decision-making

In its inaugural edition, the European Journal of Risk Regulation published as its opening article the 'Foundations of Risk Regulation: Science, Decision-Making, Policy Learning and Institutional Reform'[37] by Giandomenico Majone.[38] In the paper Majone refers to 'trans-scientific issues' which are "questions of fact that can be stated in the language of science but are, in practice, unanswerable by science".[39] Frequently these trans-scientific issues arise in relation to the effects of technological activities. To illustrate the point, Majone draws on Weinberg's example of the certainty of determining the effect on health of low level radiation: "It has been calculated that, in order to determine by direct experimentation at the 95% confidence level whether a level of Z-ray radiation of 150 millirems would increase spontaneous mutation in mice by half of one per cent, about 8 billion mice would be required. Time and resource constraints make experiments on such a scale virtually impossible".[40]

Trans-scientific issues raise questions about the basis on which decisions about their use are made and by whom. If scientists are unable to answer questions about the effects of research, what is the role of the scientific assessment in the broader risk analysis process? Majone asks "How does a particular institutional design affect the way scientific uncertainties are resolved? What decision rules are appropriate in situations of high scientific uncertainty".[41] These questions and tensions will be picked up throughout the following sections and lie at the heart of the procedural approach taken in this paper. Decisions about 'who decides and how' point to the question of legitimacy of a regulatory framework and it is to theories of regulation and legitimacy that I now turn.

## 2. Location of Analysis of Significant Scientific Uncertainty in the Context of Existing Broad Regulatory Frameworks

The general position regarding the regulation of environmental and climate-related activities tends to be determined by the existence of physical transbound-

29 Jonathan Rougier, Steve Sparks and Lisa J. Hill, *Risk and Uncertainty Assessment for Natural Hazards*, (Cambridge: Cambridge University Press, 2013), at p. 4.

30 Ibid, at p. 2.

31 Steve Jennings, "Time's Bitter Flood: Trends in the Number of Reported Natural Disasters", 7(1) *Oxfam Policy and Practice: Climate Change and Resilience* (2011).

32 Jana Sillman et al., "Climate Emergencies do not Justify Engineering the Climate" 5 *Nature Climate Change* (2015) pp. 290 et sqq.;Charles L. Curry et al. "A Multimodel Examination of Climate Extremes in an Idealized Geoengineering Experiment." *Journal of Geophysical Research: Atmospheres* 119.7 (2014): 3900-3923.

33 IPCC 2013, *supra* note 26, at p. 29.

34 David Keith et al., "Field Experiments on Solar Geoengineering: Report of a Workshop Exploring a Representative Research portfolio." *Phil. Trans. R. Soc A:*372.2031 (2014): 20140175.

35 Ibid.

36 Ibid.

37 1 *EJRR* (2010), pp. 5 *et sqq*.

38 Emeritus Professor of Public Policy at the European University Institute.

39 Majone, "Foundations of Risk Regulation", *supra* note 37, pp. 5.

40 Ibid.

41 Ibid.

| Broad Regulatory Frameworks by Types of SRM Research | | | | |
|---|---|---|---|---|
| **Type of Research** | Laboratory | Field Research | | Deployment |
| **Physical Effect** | Non-transboundary | Non-transboundary | Transboundary | Transboundary |
| **Examples of Research** | Models, Laboratory tests | Technology Development | Process Studies, Scaling Tests | Climate Response Tests, Deployment |
| **Broad Regulatory Frameworks** | National | | International | |
| | Member State | | EU | |
| | European Union | | | |
| | | Transnational | | |

*Table 1 - Broad Regulatory Frameworks by Types of SRM Research: the group of effects and examples of field research is shaded pale grey; EU and transnational regulatory frameworks (engaged in this paper) are shaded dark grey.*

ary harm. Where the effects are contained within territorial boundaries then national authorities have regulatory jurisdiction. Where the physical effects are transboundary or global then international legal principles or treaties tend to apply. Table 1 sketches this general position in relation to types of SRM research. It is not intended to be used as a detailed typography but rather a simplified depiction of the relationship between regulated activities and their broad regulatory frameworks.[42] It will provide a reference point throughout the rest of the paper. Non-physical effects of SRM research are not included in the transboundary/non-transboundary analysis but are for consideration and determination by democratic political decision-making mechanisms associated with the regulatory frameworks.

The upper row bounded in the heavy border sets out the three different types of SRM research. Laboratory research includes computational modelling and indoor laboratory tests, the physical effects of which are non-transboundary.[43] At the right end of the row is SRM research that constitutes deployment, such as climate response tests, the climatic effects of which are by definition transboundary. There are likely to be transboundary environmental effects also.

In the middle of the upper row is SRM field research. It is a broad category of research that takes place outdoors or 'beyond the laboratory'[44] and which has been sharpened and particularised[45] to include research whose objective is to test hardware,[46] 'bridge gaps across multiple scales' of climate models[47] and to characterise the 'desirable and 'non-de-

42 The transboundary-ness of risks may or may not align with technology development vs. process studies. Likewise, research vs. deployment may or may not align with EU vs. unknown regulation.

43 These may be effects that are localised and minimal, such as increased air-moisture levels resulting from small-scale test of crop-leaf albedo.

44 Parker, "Governing Solar Geoengineering Research", *supra* note 12.

45 Ibid.; Keith et al, "Field Experiments on Solar Geoengineering", *supra* note 34.

46 Ibid.

47 Ibid.

| | SRM Field Research | |
|---|---|---|
| Scale | Non-Transboundary | Transboundary |
| Type of effect | Localised Environmental Effects | Climatic Effects<br>Regional or Global Environmental Effects |
| Example of effect | Localised loss of biodiversity | Climatic (reduced global temperatures)<br>Climatic (delay in ozone recovery)<br>Environmental<br>(variations in precipitation) |

*Table 2 - Transboundary Analysis of SRM Field Research*

sirable' effects of SRM.[48] The category of field research is bifurcated: some research activities such as technology development have effects that are non-transboundary;[49] other activities such as process studies could pose transboundary effects.[50] This paper groups *all* field research together – shaded pale grey – not to be unhelpful[51] but because the focus of this paper is on degrees of scientific uncertainty rather than transboundary harm.

Transboundary effects may or may not be significantly scientifically uncertain. At the start of this section I set out the different levels of certainty for climatic and environmental effects of SRM research. These climatic and environmental effects can represent different scales of physical effects of SRM field research. Clearly climatic effects are most likely to be transboundary. Environmental effects may be transboundary if they cross borders but they may also be contained within a single legal territory such as the UK or the US. Table 2 gives examples of a range of 'transboundaryness' of effects of SRM field research.

Not all transboundary effects of SRM field research are necessarily significantly scientifically uncertain. As we saw at the start of this section, scientists are relatively certain that global average temperatures will drop following SRM deployment/research. Equally, non-transboundary effects of SRM field research may not be significantly scientifically certain. Scientific uncertainty can be determined independently from transboundary effects. Both scientific uncertainty and transboundary effects are likely to shape regulatory frameworks for SRM field research.

Returning to table 1, the lower rows bounded in the heavy border set out three different regulatory frameworks for the three categories of SRM research. The upper row differentiates national and international law on the basis of the transboundary effects of the research activity: national jurisdictions govern research that has non-transboundary effects and international law would govern transboundary effects. The lowest two rows present a more complex view of regulatory frameworks. I suggest that field research may be governed by at least two other regulatory frameworks, which are shaded dark grey in the table. TPR enables public interest functions to be exercised by private organisations comprising highly technical or scientific expertise in relation to activities, such as the development of new technologies[52] and environmental regimes[53] that transcend national boundaries.[54] The EU regulatory framework com-

48 Ibid.

49 An example might be the Stratospheric Particle Injection for Climate Engineering (SPICE) project, details found at http://www.spice.ac.uk/.

50 For example, the proposed SCoPex at Committee on Geoengineering Climate, *Reflecting Sunlight to Cool Earth*, *supra* note 3, p. 161; John A Dykema et al. "Stratospheric Controlled Perturbation Experiment: a Amall-scale Experiment to Improve Understanding of the Risks of Solar Geoengineering." 372.2031 *Phil. Trans. R. Soc. A:* (2014): 20140059.

51 Parker, "Governing Solar Geoengineering Research", *supra* note 12.

52 Cafaggi, "New Foundations", *supra* note 6.

53 Colin Scott, Fabrizio Cafaggi and Linda Senden, "The Conceptual and Constitutional Challenge of Transnational Private Regulation" 38(1) *JLS* (2011).

54 Fabizio Cafaggi, Andrea Renda and Rebecca Schmidt, "Transnational private regulation" in *OECD, International Regulatory Co-Operation: Case Studies, Vol. 3: Transnational Private Regulation and Water Management*, (OECD Publishing, 2013).

| | Non-Transboundary | | Transboundary | |
|---|---|---|---|---|
| **EU** | SSU | Not SSU | SSU | Not SSU |
| **Transnational** | SSU | Not SSU | SSU | Not SSU |

*Table 3 - Introducing Significant Scientific Uncertainty (SSU) Analysis: shaded areas indicate activities that pose difficulties for regulatory frameworks securing legitimacy.*

prises decision-making structures for proper functioning of the internal market as well as the protection of the environment.[55] Whilst they are separated in table 1, transnational and EU regulation need not be disconnected: EU institutions have used the rubric of co-regulation to use fewer resources and regulate more efficiently drawing on private capacity associated with transnational regimes.[56]

There are implications for the regulatory framework of physical effects of SRM field research that are significantly scientifically uncertain. The uncertainty analysis presented in table 3 below, which links the two analyses set out in tables 1 and 2 adds to the earlier analysis based on the scale of effects and type of regulatory framework.

The two columns relate to transboundary characteristics and the two rows to the regulatory frameworks. For both rows there are transboundary and non-transboundary effects which are either significantly scientifically uncertain or not. The shaded areas are characteristics which pose particularly thorny issues for the regulatory frameworks. For both transnational and EU regulatory frameworks, SRM field research effects that are significantly scientifically uncertain pose difficulties. This is important. Both EU and transnational regulatory frameworks are deficient in addressing the issue of legitimacy of SRM field research activities where the effects are significantly scientifically uncertain. The reason for this deficiency stems from the relationship between uncertainty and risk. Whilst uncertainty is a key feature of risk, significant scientific uncertainty means that risk assessments are undermined because scientific information is not concrete or certain enough to provide a reliable assessment. The inability of science to assess risk has implications for the broader analysis of risk which takes into account political and other factors only in the risk management phase. It is for this reason that Majone identifies "arguably the most important question facing political leaders, citizens, and experts ie how to limit regulatory discretion and enforce accountability in policy areas characterised by high uncertainty and cognitive complexity and that are also politically very sensitive?"[57] I return to this point in part III.

The EU is able to rely on orthodox constitutional principles developed in caselaw to safeguard legitimacy for regulating activities that are not significantly scientifically uncertain. By contrast, the transnational regulatory framework faces challenges to its legitimacy *across all four types of effects*: transboundary and non-transboundary and significantly scientifically uncertain or not. It is to this issue that I now turn.

## 3. The Challenge Arising from Nascent Transnational Private Regulation of SRM Field Research

Whilst it has been claimed that there is a gap in the regulation of SRM research particularly at the international level[58] there is evidence of nascent regulation or at least movement towards regulation.[59] Be-

55 Asbjorn Aaheim et al, "EuTRACE 2015, *supra* note 3, pp. 90-92.

56 Scott et al, "The Conceptual and Constitutional Challenge of Transnational Private Regulation", *supra* note 53, at p. 8

57 Majone, "Foundations of Risk Regulation", *supra* note 37, p. 6

58 UK House of Commons Science and Technology Committee 2010, *The Regulation of Geoengineering*, Fifth Report of Session 2009-10 (UK Parliament, HC 221), at pp. 20-21, where the Committee found there to be a "gap in the regulatory framework".

59 Jesse Reynolds, "The Regulation of Climate Engineering" 3(1) *Law, Innovation and Technology* (2011) pp. 113-136, at p. 130; Parker, "Governing Solar Geoengineering Research", *supra* note 12.

ing nascent means that the institutions and procedures governing geoengineering research exist but are difficult to classify. In this section I give an example of how this nascent regulation conceptualised as transnational regulation illustrates the challenges to conceptions of legitimacy posed by SRM field research.

The argument presented here is done so tentatively: there is relatively little SRM research actually taking place,[60] and the research that *is* taking place is doing so in myriad departments and institutions.[61] In short, SRM and its regulation is at an 'upstream' moment of its emergence.[62] The nascent regulation of SRM research can be conceptualised as 'transnational' thereby illustrating challenges to legitimacy understood as the legality of decision-making processes. I take TPR to comprise three elements: regulatory frameworks that "are not constituted through the cooperation of states as reflected in treaties";[63] comprising non-state actors[64] that exercise either "autonomous regulatory power or implementing delegated power";[65] and the development of "new body of rules, practices and processes...primarily by private actors, firms, NGOs, independent experts like technical standard setters and epistemic communities".[66]

## a. Non-state Actors

Solar Radiation Management Governance Initiative (SRMGI) is a "cooperative, international, NGO-driven initiative, co-convened by the Royal Society, Environmental Defence Fund (EDF) and the Academy for the Sciences of the Developing World (TWAS)".[67] It was one of the first governance initiatives for SRM[68] flowing from the Royal Society report of 2009. It is an interesting example of a non-state actor comprising transnational private regulation because of its composition. All three convenors are non-state actors in so far as they have no exclusive legal link to the state. EDF is a leading not-for-profit organisation in the US "linking science, economics, law and innovative private-sector partnerships";[69] the Royal Society is the oldest science academy in continuous existence comprising 1400 outstanding Fellows from all areas of science; and TWAS is an independent international organisation whose principal aim is to "promote scientific capacity and excellence for sustainable development in the South".[70]

SRM companies have yet to become significant actors although this is may change if the commercialisation of research leads to marketable technologies.[71] However, additional financial contributions were made to SRMGI by other non-state actors[72] which aim to tackle climate change through 'entrepreneurial' market-based solutions.[73]

Being a transnational regulatory framework does not preclude the involvement of state actors.[74] What is important is that it is the nonstate - rather than state – that has become the 'key' actor, and that the state has, to some extent withdrawn from the process. In his oral evidence to the select committee, Professor Pidgeon, an influential academic researcher on

60 UK House of Commons Science and Technology Committee 2010, *supra* note 58, pp. 49-52 Conclusions and Recommendations, *et sqq*. Ev27-31 Evidence of Joan Ruddock, Minister for State of Department of Energy and Climate Change.

61 Such as law schools, geography departments, earth science schools and meteorological centres http://www.iagp.ac.uk/ last accessed on 17th May 2015.

62 UK House of Commons Science and Technology Committee 2010, *supra* note 58, at Ev. 31 - Evidence of Pidgeon.

63 Scott et al, "The Conceptual and Constitutional Challenge of Transnational Private Regulation", *supra* note 53, at p. 3.

64 Ibid.

65 Cafaggi, "New Foundations", *supra* note 6, at p. 21.

66 Ibid., at pp. 20-21.

67 Solar Radiation Management Governance Initiative (SRMGI), *Solar Radiation Management: The Governance of Research,* (2012) at p. 12.

68 Others have been the Oxford Geoengineering Programme and then Geoengineering Governance Research.

69 SRMGI 2012, *supra* note 67, at p. 4.

70 Ibid., at p. 4.

71 On the possibility of accruing carbon credits through SRM see Janine Sargoni and Andrew Lockley, "Environment Policy: Solar Radiation Management and the Voluntary Carbon Market." 17(4) *Environmental Law Review* (2015), pp. 266 et sqq.. On commercialisation of geoengineering research and vested interests in using geoengineering research, see SRMGI 2012, *supra* note 67, at p. 17; Steve Rayner et al, "The Oxford Principles", *Climate Change* (2013), pp. 499 *et sqq*, at para. 7.2. For vested interests of SRM research see Jane Long and Dane Scott, "Vested Interests and Geoengineering Research." 29(3) *Issues in Science and Technology* (2013), pp. 45 et sqq.

72 Such as the private global non-profit organisations such as the Carbon War Room, http://www.carbonwarroom.com/ last accessed on 14 May 2015; and Zennstrom Philanthropies http://www.zennstrom.org/ last accessed on 14 May 2015.

73 Such as the Fund for Innovative Climate and Energy Research (FICER), funded by Bill Gates and managed by the University of Calgary.

74 For a typology of actors see Cafaggi et al, "Transnational Private Regulation: OECD", *supra* at note 54.

the human psychology of risk associated with geoengineering recommended that social, political and legal research on governance issues take place alongside scientific research on geoengineering.[75] It is partly on this basis that the Parliamentary committee recommended that the UK government develop a regulatory framework, particularly for SRM techniques that fall outside international agreements,[76] and "carry out research...on the legal, social and ethical implications"[77] of regulation of geoengineering. Rather than adopting these recommendations directly, thereby raising its profile in the area of geoengineering, the government deferred to the SRM governance initiative suggesting an unwillingness to 'commit'. Nonstate actors such as SRMGI have stepped into the regulatory vacuum.

### b. Crystallising Norms and Standard-setting

The development of principles, new bodies of rules or 'standard-setting' processes by private actors is also an illustration of TPR. Regulatory principles or standards have emerged for governing geoengineering research including the Asilomar Principles,[78] and the Oxford Principles which comprise five 'high-level' principles[79] each supported with a short explanatory text.[80] Every principle carries equal weight:[81] principle 1, geoengineering to be regulated as a public good; principle 2, public participation in geoengineering decision-making; principle 3, disclosure of geoengineering research and open publication of results; principle 4, independent assessment of impacts; and principle 5, governance before deployment.

These principles are gaining traction and are prevalent in literature on governance of geoengineering in general. Although it is too soon to tell, they may well crystallise in the process of rule-making or standard setting and thereby further characterise transnational private regulation.[82] As well as being considered by the UK Parliament, the Oxford Principles are considered to "provide a sound foundation for the elaboration of more concrete governance arrangements for research"[83] by the only draft articles to date for geoengineering research.

What we see is that these governance principles have been developed by non-state scientists. By the term 'scientists' I mean researchers that are experts in scientific fields including the natural and social or political scientists. I use the term scientist in the widest sense to differentiate scientific experts from lay persons. For example, the "germ of the idea"[84] of research guidelines was a conversation between two non natural-science academics, Steve Rayner and Tim Kruger, who went on to consult with other experts from a range of disciplines. In this way the Oxford Principles were drafted by an "ad-hoc"[85] group of five academics from British institutions: the Royal Society[86] and the universities of Oxford,[87] Cardiff[88] and London.[89] The academics represent a broad, inclusive range of academic interests including science, law, ethics and psychology. The Oxford Principles illustrate the technical – rather than lay – expertise of rule-making within this transnational regulatory framework. Non-state scientists have also endorsed and developed the Oxford Principles by setting standards taking the form of 'technology-specific research protocols';[90] research guidelines[91] and thresh-

75 UK House of Commons Science and Technology Committee 2010, *supra* note 58, at Ev. 30; http://www.understanding-risk.org last accessed on 14 May 2015.

76 Ibid, p. 25 *et sqq*., para. 55.

77 Ibid, p. 33 *et sqq*., para. 84.

78 Asilomar Scientific Organizing Committee, "The Asilomar Conference Recommendations on Principles for Research into Climate Engineering Techniques." *Washington DC, Climate Institute,* (2010); Margaret Leinen, "The Asilomar International Conference on Climate Intervention Technologies: Background and Overview." *Stanf J Law Sci Policy IV* (2011), pp. et sqq. 1-5; Schäfer and Low, "Asilomar Moments", supra note 13.

79 Rayner et al, "The Oxford Principles", *supra* note 71.

80 Ibid.

81 Ibid. at pp. 502-503.

82 Donal Casey and Colin Scott, "The Crystallisation of Regulatory Norms", 38(1) *JLS* (2011), pp. 76. et sqq.

83 Anna-Maria Hubert and David Reichwein, *'An Exploration of a Code of Conduct for Responsible Scientific Research Involving Geoengineering: Introduction, Draft Articles and Commentaries'* (Potsdam: IASS Working Paper, 2015), p. 6.

84 Tim Kruger, "A Commentary on the Oxford Principles: Opinion Article", *Geoengineering Our Climate? Working Paper and Opinion Article Series*, 2013.

85 Rayner et al, "The Oxford Principles", *supra* note 71, at p. 500.

86 Steve Rayner and Catherine Redgwell.

87 Steve Rayner, Julian Savulescu and Tim Kruger.

88 Nick Pidgeon.

89 Catherine Redgwell, University College London, now at All Souls College, University of Oxford.

90 Rayner et al, "The Oxford Principles", *supra* note 71, at p. 509.

91 Granger Morgan, Robert Nordhaus and Paul Gottlieb, "Needed: Research Guidelines for Solar Radiation Management", *Issues in Science and Technology* (2013) 37-44.

olds[92] and codes of practice.[93] The development of governance principles and implementing standards by non-state actors is significant because it demonstrates a nascent form of autonomous regulatory power which characterises further TPR.

### c. The Legitimacy Deficit

Autonomous regulatory power poses problems for legitimacy as conceptualised by transnational regulatory theory. On the whole, and according to general constitutional principles, national-centred regulation relies on forms of democratic legitimacy for justification.[94] However, as regulation is removed from the state, whether that is in terms of a movement from national to transnational settings or in terms of a movement from public to private actors, the constitutional lines of democratic legitimacy become weaker.[95] A concept of legitimacy that hinges on the legality of the democratic mandate in positive Weberian terms is bound to be reduced in transnational or private regulatory regimes; 'such regimes will necessarily lack legitimacy and any potential for legitimacy, in legal terms'.[96] For this reason, Majone attributes to the regulatory state[97] the problem of securing and maintaining legitimacy as it transfers regulatory functions from state to non-state institutions. This is something to which we return later.

But legitimacy becomes particularly problematic when regulation moves away from the state because the orthodox mechanisms of democratic legitimacy are weakened. Transnational regulation "may end up in a democratic cul-de-sac".[98] Issues of legitimacy are particularly salient for transnational private regulation of public goods,[99] which the Oxford Principles claim SRM research is.

In the preceding section on SRM field research, I suggested that under conditions of significant scientific uncertainty tensions are produced between politics and science in terms of how to justify who makes decisions about its regulation and how. The sketch of the nascent TPR highlights some of those tensions. For example, regulatory principles are being developed and operationalised[100] by predominantly non-state actors such as scientists, with minimal involvement from democratic institutions or lay persons. Whilst this could be seen as a form of 'endogenous' rule-making identified earlier and justified under certain conditions (something to which we return later), viewed as TPR it suffers a legitimacy deficit: there is no formal legal authority from which those non-state institutions can act. Clearly the legitimacy deficit might be considered less relevant as the regulation is merely 'nascent'. But the question of legitimacy becomes more relevant when thinking about how the regulation develops, as set out in part I: from nTPR to TPR; to EU; or to National or International law. This question of legitimacy is likely to increase in significance as the regulatory framework develops. The deficit as conceptualised in formal legal terms could be minimised if a state institution such as the UK Parliament mentioned above, or the EU, were to oversee the regulatory framework thereby formalising the transnational arrangements. It is to the EU that we now turn.

## III. The EU's Response to the Challenge of Legitimacy

There are a number of reasons why the EU would regulate SRM field research: to provide a high level of protection of the environment,[101] public health[102]

92 E. Parson and D. Keith, "End the Deadlock on the Governance of Geoengineering Research" 339 *Policy Forum* (2013) 1278-1279, at p. 1278.

93 Morgan, Nordhaus and Gottlieb 2013, *supra* note 91, at p. 41; UK House of Commons Science and Technology Committee 2010, *supra* note 58, at p. 29.

94 Keith Syrett, *The Foundations of Public Law: Principles and Problems of Power in the British Constitution* (Basingstoke: Palgrave Macmillan 2011); J. Koppell, "Global Governance Organizations: Legitimacy and Authority in Conflict" 18 *Journal of Public Administration Research and Theory* 2008, 177-203, at p. 190.

95 S. Cassese, "Administrative Law Without the State – The Challenge of Global Regulation", *37 New York University Journal of International Law and Policy* (2004) 663.

96 Julia Black, "Constructing and Contesting Legitimacy and Accountability in Polycentric Regulatory Regimes" 2 *Regulation and Governance* (2008) 137-164, at, p. 145.

97 Giandomenico Majone, "The Rise of the Regulatory State in Western Europe" 17 *West European Politics* (1994) 77; Giandomenico Majone, "From Positive toe the Regulatory State: Causes and Consequences of Changes in the Mode of Governance", 17(2) *Journal of Public Policy* (1997) 139-167

98 B. Eberlein and E. Grande, "Beyond Delegation: Transnational Regulatory Regimes and the EU Regulatory State", 12(1) *Journal of European Public Policy* (2005) 89-112, at p. 106.

99 Scott et al, "The Conceptual and Constitutional Challenge of Transnational Private Regulation", *supra* note 53, at p. 6.

100 Hubert and Reichwein, "Draft Articles for Code of Conduct", *supra* note 83.

101 Article 191 TFEU.

102 Article 168 TFEU.

or to ensure the proper functioning of the internal market[103] – were one to emerge – through the approximation of laws. In Table 1 above, I set out the broad position regarding types of regulatory frameworks based on the 'transboundary' scale of effects of the regulated activity: national regulation for SRM research whose physical effects are contained territorially; and international regulation for effects that cross territories. EU regulation was depicted as extending beyond those levels to include regulation of SRM research in the laboratory as well as field research comprising transboundary effects. In practice this means that the EU regulatory framework would govern all SRM field research, even those that do not have transboundary effects. The regulatory framework would apply to specific research proposals as well as the general SRM research endeavour. By comparing briefly the regulation of genetically modified organisms, or agricultural biotechnology, I set out the reasons below.

The EU regulates the process[104] of agricultural biotechnology through a matrix of secondary legislation.[105] The legislation differentiates research that takes place in the laboratory, under the Contained Use Directive,[106] and experimental releases into the environment in the form of crop trials, part B of the Deliberate Release Directive.[107] Non- experimental releases into the environment and the internal market are covered under part C of the Deliberate Release Directive.

Both relevant directives – the Deliberate Release Directive and the Contained Use Directive – demonstrate some of the complexity associated with implementation.[108] For example, the Contained Use Directive effectively allows member states to implement national rules as it chooses whereas part C of the Deliberate Release Directive, relating to the marketing of biotech crops, is implemented at the EU level with member states given very little discretion as to how to make or apply those rules. Part B of the Deliberate Release Directive – regulating experimental releases such as crop trials – is somewhere in between; certain elements are left to member states and others remain with the EU. The extent to which the principle of subsidiarity[109] is applied is linked to the functioning of the internal market.[110] This internal market rationale has been confirmed by policy officers at the Commission; however, in terms of deliberate releases of biotech products, a combination of two other rationales is evident. One pertains to the level of 'containment'[111] of the product: contained use (such as within a laboratory) is highly contained; crop trials are fairly contained; whilst marketing a product for circulation across the EU is uncontained. The other rationale pertains to the territorial 'scale'[112] of potential transboundary harm arising from the release of the product: if the harm is contained to a laboratory or a member state, then discretion is high; if the threatened transboundary harm is to the wider EU community or beyond then discretion in implementation is low. The European Food Safety Authority provides independent scientific advice to the European Commission on applications for release into the environment.[113]

The UK implements part B of the Deliberate Release Directive through the Environmental Protection Act 1990 (EPA) and the Deliberate Release Regulations 2002.[114] Consent to release any biotech product is required by section 111 of the EPA.[115] The specific details of the consent process are set out in the Deliberate Release Regulations, including the information required with an application for consent.[116] The regulations mirror the requirements set out in

103 Article 114 TFEU.

104 By contrast, the US regulates biotechnology through the existing regulations for specific products, eg biotech crops are regulated under the Plant Protection Act which gives the US department of Agriculture and its agency the Animal and Plant Health Inspection Services authority to regulate biotechnology products of plants and plant pests.

105 Details of the relevant legislation can be found at http://ec.europa.eu/food/plant/gmo/legislation/index_en.htm.

106 Directive 2009/41/EC (Recast) [2009] OPJ L125/75

107 Directive 2001/18/EC 90/220/EEC [2002] OJ L106/1

108 For an overview of the regulation of GMOs generally see Maria Lee, '*The EU Regulation of GMOs: Law and Decision-Making for a New Technology*' (Cheltenham: Edward Elgar, 2008)

109 Article 5 TEU.

110 Article 114 TFEU on for the approximation of laws in order to establish the proper functioning of the internal market, is the legislative base of competence of the EU to pass the Deliberate Release Directive, whereas the Contained Use Directive is attributed to article 192 of Title XX on the protection of the environment, rather than exclusively on the functioning of the internal market.

111 Commission Policy Officer Interview.

112 Commission Policy Officer Interview.

113 Regulation 178/2002/EC.

114 The Deliberate Release Regulations were created pursuant to, but also amended, the EPA and repealed the previous 1992 deliberate release regulations, see the Explanatory Note on GMO (Deliberate Release) Regulations 2002/2443.

115 Under section 118 EPA, it is a criminal offence to fail to comply with section 111 EPA.

116 Reg 11 Deliberate Release Regulations.

the Deliberate Release Directive.[117] The Department for the Environment, Food and Rural Affairs (DEFRA) is the competent authority[118] and, amongst other things, is required to examine the application for its conformity with the rules, evaluate the risks of damage and take into account representations[119] prior to its decision to grant consent.[120] However, despite the national authority having competency to regulate, the criteria for conducting environmental risk assessments found in Annex II of the Deliberate Release Directive stand as the test by which experimental releases,[121] as well as those for wider release through marketing,[122] are assessed.[123] So even where member states have competency they must nevertheless comply with standards or processes set at the EU level.

Applying this analysis to the regulation of SRM field research we might expect to see the EU develop a regulatory framework for the process of SRM, that is, the general scientific endeavour, which is able to assess research projects on a case-by-case basis. The regulatory framework could grant regulatory control to member states for contained or laboratory research as well as for non-transboundary field research. However, the EU is likely to reserve for itself control over transboundary research, possibly creating a new European independent scientific advisory committee or by using an existing one. Whilst the impact on the market is not yet significant for SRM, that is not to say that it may not exist in the future or that other products become significant for the research, such as materials to be used for SRM technology research.

Assuming that the EU regulates SRM research, the issues posed by significant scientific uncertainty identified in part II will continue. In the following section I explain how the EU might respond to the legitimacy of decision-making where science is unable to adequately assess risk.

## 1. Attempting to Safeguard Legitimacy

The EU's orthodox response to the question of legitimacy lies with the landmark case of *Meroni*.[124] The case involved a decision by the European Coal and Steel Community's High Authority to require two agencies, known as the Brussels Agencies, to administer a new scrap metal equalisation scheme. *Meroni* was a steel company subject to the scheme and required to contribute to the fund by the High Authority. *Meroni* successfully sought an annulment of the High Authority's decision on the basis, in part, on the misuse of powers. The court enunciated four principles regarding delegation of powers. Firstly, the powers delegated must not be more extensive that the power of the delegator. Secondly, a delegation must be express not implied. Thirdly, only permissible powers can be delegated: only those powers that are 'clearly defined executive powers' rather than discretionary powers can be delegated; the consequences of the delegated power must necessarily be the same as the exercise of delegating power. Lastly, the delegation must not disturb the Community's 'balance of powers'.[125] *Meroni* and subsequent case law has acted as a constitutional limit – the *Meroni* doctrine[126] – to the delegation of discretionary powers by Community institutions.[127]

Regulatory agencies, including independent scientific authorities such as the European Food Safety Authority, remain purely advisory in the light of the *Meroni* doctrine and are not "fully-fledged" regulatory agencies[128] because they lack legislative and executive functions. Technical and scientific assessment of risk undertaken or reviewed by them are commu-

117 Schedules in the Regulations link with appendices in the directive, in so far as they require the same technical information, although differently numbered.

118 Section 126 EPA.

119 Deliberate Release Regulation 20.

120 Deliberate Release Regulation 21.

121 Part B Deliberative Release Directive.

122 Part C Deliberate Release Directive. For marketing biotech products that are not grown in the EU but imported see article 5(5) Food and Feed Regulation, 1829/2003/EC.

123 Some amendments to Annex II have been proposed as General Guidance by EFSA. A differentiated procedure can be used by member state, in which case it will be the ERA confirmed by that member state as approved by the Commission. See Annex A on legal position on ERA in Annex II.

124 C-9/56, Meroni & Co., Industrie Metallurgiche, Spa v High Authority of the European Coal and Steel Community [1957-58] ECR 133.

125 Article 4 of the Treaty of Rome, article 7 EC Treaty, now repealed by article 13 TEU listed Community institutions and that they must act 'within the limits of the powers conferred upon them by this Treaty'.

126 Stefan Griller and Andreas Orator, "Everything Under Control? The "way forward" for European Agencies in the Footsteps of the *Meroni* Doctrine", 35(1) *European Law Review* (2010) 3-35.

127 Majone, Foundations of Risk Regulation 2010, *supra* note 37, at p. 16.

128 Giandomenico Majone, "The new European Agencies: Regulation by Information", 4(2) *Journal of European Public Policy* (1997) 262-275, at p. 262.

nicated to political bodies to manage that risk politically, so that no discretionary political power is delegated. In the Pfizer[129] case and in the context of the precautionary principle, the Court of First Instance reiterated the distinction between the scientific risk assessment and political risk management functions carried out by expert scientific committees and political community institutions respectively. It found that risk assessment constituted a procedural safeguard to the arbitrary exercise of discretion by Community institutions so that "a scientific risk assessment carried out as thoroughly as possible on the basis of scientific advice founded on the principles of excellence, transparency and independence is an important procedural guarantee whose purpose is to ensure the scientific objectivity of the measures adopted and preclude any arbitrary measures".[130]

This quotation is significant. It articulates the basis of the conceptual separation of risk assessment and risk management set out in the US National Research Council's Red Book[131] as being the prevention of biases pandering to public opinion.[132] The separation of risk assessment and risk management is at the heart of the EU's approach to risk analysis. The decision not only articulates this separation but underscores the separation by linking it with the separation of science from politics and links that, in turn, with the safeguarding of the EU's balance of powers. The effect of the court's decision is to confirm that the composition of regulatory institutions is inextricably linked to safeguarding the balance of powers through the process of risk analysis.

### a. Safeguarding Democratic Legitimacy

The *Meroni* doctrine safeguards democratic legitimacy by institutionally retaining political control of decision making for risky activities. The safeguard is effective and appropriate where the scientific uncertainty is not significant, that is, where the science is certain enough to form a reliable basis for assessing risk. In short, science is able to do the 'assessment' part of the risk analysis, which can then be communicated to the political management so that legitimacy is safeguarded.

This analysis of *Meroni* can be applied to the relationship between EU and transnational regulation based on set out in table 3 of part II. You will recall that the shaded areas identified aspects of the regulatory frameworks which posed difficulties for legitimacy. For the EU regulation of field research having non-significantly scientifically uncertain effects – the unshaded areas – legitimacy is not problematic – because *Meroni* is effective at safeguarding democratic legitimacy. For transnational regulation, legitimacy is challenged on two accounts: for the absence of 'input' legitimacy – common for all transnational regulation – and for the challenge posed in the event of significant scientific uncertainty. Drawing on the concept of legitimacy set out in *Meroni* would serve to address the legitimacy deficit for nTPR in some respects but not others; that is, for transboundary effects but not under conditions of significant scientific uncertainty. The shaded areas identifying the legitimacy deficit for non-significant scientific uncertainty would be ameliorated. However, for SRM field research that is significantly scientific uncertain, legitimacy conceptualised as 'legality', would continue. What connects nTPR and EU regulation is that these difficulties remain also for SRM field research regulated by the EU.

### b. Remaining Difficulties for Legitimacy

Whilst the EU's response addresses some of the challenges to legitimacy raised by the conceptualisations of nascent regulation, some significant difficulties remain. Firstly, *institutional* arrangements force science and politics to take place as mutually exclusive activities when risk is analysed. The *Meroni* doctrine ensures that legitimacy is retained only by the political – risk management – institutions which are thereby able to differentiate and distance themselves from 'independent' scientific – risk assessment – institutions. Following this doctrine, the institutions for the analysis of risk of SRM research are likely to be bifurcated into the political and scientific; each addressing in turn separate parts of the process of risk analysis. In so doing the EU is situated squarely in Fisher's rational-instrumental paradigm of risk reg-

129 T-13/99, Pfizer Animal Health SA v Council of the European Union [2002] ECR II-03305

130 Ibid. at para. 7.

131 National Research Council, *Risk Assessment in the Federal Government: Managing the Process*, (Washington DC: National Academic 1983), available on the internet at http://www.nap.edu/read/366/chapter/1 (last accessed 14 May 2015).

132 S. Gabbi, "The Interaction between Risk Assessors and Risk Managers: The Case of the European Commission and of the European Food Safety Authority", 3 *European Food and Feed Law Review* (2007) 126-135.


*Figure 1 - Institutional Separation of Science from Politics and the Regulatory 'Lock' into Isolated Risk Assessments.*

ulation: the administration of risk "is understood...to identify and assess a specific risk as well as assess the possible consequences of possibly regulatory actions to manage that risk. This should involve a collection of all the information available and an assessment of that information by experts".[133]

Secondly, the institutional separation of science from politics necessarily leads to a regulatory principle underpinning risk analysis which I call 'isolated' risk assessments. The role of science in assessments of risk is isolated so that risk is to be ascertained by scientific expertise alone. The institutional arrangements – the 'administrative constitution' - do not allow there to be any other information upon which risk is assessed (only 'managed'). Figure 1 depicts the relationship between the *Meroni* doctrine, the institutional separation and the lock into isolated risk assessments.

The regulatory lock applies to risk assessments only. I am not suggesting that risk analysis, which includes the political management, communication and scientific assessment elements, is bereft of any political or value-laden consideration. Clearly values are included in analyses of risk at the management stage. The lock applies to assessments of risk that can take place solely by scientific institutions and can only ever be based on scientific information alone. Majone claims that the institutional separation of risk assessment from risk management is counterproductive because "while the two functions are conceptually distinct, in practice they are closely intertwined".[134] Whilst this lock may be appropriate where science is certain enough to formulate meaningful risk assessments, I suggest that the lock is inappropriate where there is significant scientific uncertainty because assessments on scientific information alone are likely to be meaningless.

The regulatory 'lock' into isolated assessments marks a return to a point foreshadowed in the introduction, namely that the EU's regulatory structure for risky activities tends to be rigid and technocratic. The principle of isolated risk assessments is rigid because it is unable to apply different types of risk assessment such as the incorporated risk assessment. It prevents the regulatory framework from responding appropriately to differing levels of scientific uncertainty posed by different activities. It is unable to respond to the high level of scientific uncertainty characterising trans-scientific issues[135] such as significant scientific uncertain SRM field research. In short the EU's response as articulated in the *Meroni* doctrine is counterproductive in maximising legitimacy because of the assumption it makes about the ability of science to assess the risk of SRM and its research. So the legitimacy deficit of nTPR might be ameliorated through the EU's formalisation and commitment to *Meroni*'s principle of non-delegation but the resulting framework might also be unresponsive, inflexible, exclusive and technocratic.

## IV. An alternative Approach

This is the story so far: SRM field research is a trans-scientific issue when its effects are significantly scientifically uncertain thereby raising challenges for legitimate decision-making. Conceptualising the regulation of SRM research as nTPR allows us to view those legitimacy challenges in terms of the legality of decision-making institutions and processes. The EU's response to the challenge of legitimacy is focused on the legal constitutional principle of non-delegation, thereby safeguarding the EU's institutional balance of powers. In so doing the EU safeguards le-

133 Fisher, *Risk Regulation*, *supra* note 10, at p. 28.

134 Majone, "Foundations of Risk Regulation", *supra* note 37, at p. 18.

135 Ibid.

gitimacy as conceptualised by the transnational approach but results in inflexible, unresponsive, exclusive and technocratic frameworks. To ameliorate these problems, we can turn to an alternative conceptualisation of regulation and concomitant views of legitimacy.

There are three parts to this final section in which I set out an alternative response to regulating SRM field research that is better able to maximise the possibility of securing legitimacy. Firstly, I illustrate the conceptualisation of regulation as 'directly deliberative polyarchy' through the example of responsible research and innovation. I use this functional approach to identify other significant aspects of legitimacy – responsiveness, flexibility, deliberation and inclusion. Secondly, I suggest that an incorporated approach to risk assessment can promote elements of deliberation and inclusion within the existing EU regulatory paradigm. Finally, in looking at the implications of adopting the incorporated risk assessments, I suggest that the EU will be required to take the counter-intuitive response to safeguarding legitimacy by departing on occasion from its strict non-delegation position, but in so doing a more flexible, responsive framework can emerge that is better able to maximise the possibility of securing legitimacy.

## 1. Illustrating an Alternative Conceptualisation of Regulation and Legitimacy

What follows is an illustration of how the regulation of one type of SRM field experiment helps us think about alternative conceptualisations of legitimacy and the degree to which they are able to address the deficiencies presented by legitimacy as 'legality' under the conditions of significant scientific uncertainty.

### a. SPICE – An Example of 'Responsible Research and Innovation'

The Stratospheric Particle Injection for Climate Engineering (SPICE) project[136] investigated the effectiveness of SRM by exploring how the mimicking of natural processes of volcanic eruptions by injecting sulphate particles into the stratosphere might lower average global temperatures. There were three working packages which aimed to evaluate candidate particles, test delivery systems and model climate impacts.

SPICE is an example of SRM field research because the second of its working packages aimed to investigate "the feasibility of putting particles into the stratosphere in order to affect global temperatures".[137] This part of the project was to take place outdoors in order to explore potential delivery systems of the particles into the stratosphere[138] by studying a large balloon tethered by a 25km length of pipe to a pump on the ground. Unlike other proposed tests whose effects could be transboundary[139] it was unlikely that this technology development test[140] would generate transboundary effects. It falls under non-transboundary SRM field research of table 1. SPICE is an appropriate example because it was more than only a proposed test; it commenced and was subject to regulation. It provides a site in which to consider different conceptualisations of regulation and legitimacy.

The progress of SPICE's second working package is an example of the governance framework called 'responsible innovation', which I suggest can be classified as a type of reflexive governance. One of SPICE's funders[141] was the Engineering and Physical Sciences Research Council (EPSRC) which is committed to responsible innovation. Working Package 2 of SPICE was required to pass through a 'stage-gate': "a decision point where [the EPSRC] considers whether to continue an activity, add additional resource based on progress achieved, or reduce or stop funding. Stage-gating also allows major changes in direction to be agreed, guided by the results obtained to date".[142] In October 2011, EPSRC's Societal Issues Panel postponed the field trial for six months and in

136 http://www.spice.ac.uk/ (last accessed 12th May 2015).

137 http://www.spice.ac.uk/project/about-the-project/ (last accessed 12th May 2015).

138 Working Packages 1 and 3 are laboratory based, but Working Package 2 takes place outdoors.

139 *Supra* note 55.

140 For example, process studies, scaling tests and climate response tests in Keith et al, "Field Experiments on Solar Geoengineering", *supra* note 34.

141 Two other funders are Natural Environment Research Council (NERC) and the Science and Technology Facilities Council (STFC) which all comprise part of group of Research Councils in the UK (RCUK).

142 http://www.epsrc.ac.uk/about/plans/implementingdeliveryplan/transchange/research/stagegating/Pages/stagegating.aspx last accessed on 17th April 2014.

May 2012 cancelled it altogether[143] for reasons relating to its governance, intellectual property and insufficient deliberation and stakeholder participation.[144] The stage-gate provides an opportunity to evaluate the extent and nature of stakeholder deliberation and direction of the research prior to allocation of subsequent tranches of research funding.

Since that time the principles of responsible innovation have become more common-place.[145] The European Commission has identified similar initiatives in other member states which it calls 'Responsible Research and Innovation', recommending a 'comprehensive approach to achieve...improved alignment'.[146] It might now be argued that it has developed into a framework[147] – although not formally part of EU policy – exhibiting four dimensions: anticipation; reflexivity; inclusion; and responsiveness.[148]

### b. An Illustration of 'Directly Deliberative Polyarchy'

Despite lacking conceptual weight,[149] responsible research and innovation can be viewed as a new governance of science[150] that is redolent in a number of ways of a broader regulatory theory such as Sabel and Zeitlin's democratic experimentalism.[151] Democratic experimentalism is an approach to regulating "intractable problems that cannot be resolved by a simple appeal to 'the facts'"[152] characterised by processes of co-design, benchmarking and monitoring.[153] Drawing on regulation as democratic experimentalism to think about legitimacy for regulating SRM field research is appropriate for numerous reasons. Firstly, it is appropriate for the regulation of highly complex problems and solutions[154] under conditions of strategic uncertainty.[155] For the purposes of this paper, in situations where the physical effects of SRM field research are significant, scientific uncertainty is indicative of an intractable scientific problem that cannot be resolved by science alone. And whilst Sabel and Zeitlin refer to strategic uncertainty as "meaning that policy makers recognise that they cannot rely on their strategic dispositions...to guide action in a particular domain"[156] there is clearly the possibility that a parallel could be drawn with scientific uncertainty.

Sabel and Zeitlin call this new form of governance 'directly deliberative polyarchy': "It is deliberative because it uses argument to dis-entrench settled practices and open for reconsideration the definitions of group, institutional, and even national interest associated with them. It is directly deliberative because it uses the concrete experience of actors' differing reactions to current problems to generate novel possibilities for consideration...It is polyarchic because it is a system in which the local units learn from, discipline and set goals for each other".[157]

Responsible research and innovation views itself as experimentalist to the degree that it promotes social learning and democratisation[158] in much the same way as Sabel and Zeitlin's directly deliberative polyarchy. Both are procedural. Directly deliberative polyarchy, characterised as a form of reflexive gover-

143 http://www.guardian.co.uk/environment/2012/may/16/geoengineering-experiment-cancelled and https://www.newscientist.com/article/dn21840-controversial-geoengineering-field-test-cancelled/.

144 http://thereluctantgeoengineer.blogspot.co.uk/2012/05/testbed-news.html.

145 IAPG, "The Public and Other Stakeholder Perception of Geoengineering: Facilitating Responsible Innovation" Briefing Note 2, available on the internet at: http://iagp.ac.uk/sites/default/files/IAGP_Briefing_Note_2.pdf (last accessed on 14 May 2015).

146 European Commission DG for Research and Innovation Science in Society "Options for Strengthening Responsible Research and Innovation" EUR25766 (2013), at p. 3.

147 Jack Stilgoe, Richard Owen and Phil Macnaghten, "Developing a Framework for Responsible Innovation", 42 *Research Policy* (2013) 1568-1580; Rene Von Shomberg "Prospects for Technology Assessment in a Framework of Responsible Research and Innovation", in M. Dusseldorp and R. Beecroft (eds), Technikfolgen Abschätzen Lehren (VS Verlag für Sozialwissenschaften, 2012)

148 Ibid.

149 Ibid p. 1570.

150 Ibid p. 1577.

151 Charles, F. Sabel and Jonathan Zeitlin, "Learning from Difference: The New Architecture of Experimentalist Governance in the EU" 14(3) *European Law Journal* (2008) 271-327

152 Olivier De Schutter and Jacques Lenoble (eds), *Reflexive Governance: Redefining the Public Interest in a Pluralistic World*, (Oxford: Hart Publishing, 2010), pp. xix.

153 Charles F Sabel and Jonathan Zeitlin, "Experimentalist Governance", in David Levi-Faur (ed.), *The Oxford Handbook of Governance,* ( Oxford: Oxford University Press, 2012), pp. 169 *et sqq*.

154 Joshua Cohen and Charles Sabel, "Directly-Deliberative Polyarchy" 3(4) *European Law Journal* (1997), pp. 313 et sqq.

155 Sabel and Zeitlin, "Learning from Difference", *supra* note 151

156 Ibid., p. 280.

157 Ibid., p.. 276.

158 Stilgoe, Owen, Macnaghten, Developing a Framework 2013, *supra* note 147, at p. 1577.

nance[159] is a dynamic, functional regulatory process that aims to maximise its members' normative expectations through conditions of collective action[160] in the same way that responsible innovation is "a transparent, interactive process by which societal actors and innovators become mutually responsive to each other".[161]

Legitimacy as conceptualised in directly deliberative polyarchy can be characterised as inclusive and deliberative. It is the normative expectation of *members* that are met, not solely groups of scientific experts or politicians. Technocratic forms of authority are *dis-entrenched* through the democratising destabilisation[162] of directly deliberate polyarchy. And it is the *concrete experience of actors' differing reactions to current problems* which generates new innovated solutions. SRM research community members, university ethics committees, research councils etc. are able to participate in transformative politico-scientific decision-making processes through stage-gate processes, inclusively composed committees, and other procedures.

Legitimacy as conceptualised as directly deliberative polyarchy can also be characterised as responsive and flexible. It is the responsiveness and flexibility of the regulatory framework which is significant here. So the framework that comprises institutions and procedures that enable members to interact, learn from and mutually respond to one other will be more legitimate than a framework that does not. Being flexible marks a regulatory framework as capable of change; of disturbing settled practices; of facilitating change through learning.

## 2. Incorporated Risk Assessments

Thus far the focus of SRM field research has been on its physical effects and the problem for legitimacy raised under the conditions of significant scientific uncertainty. SRM field research is, as Majone calls it, a 'trans-scientific' issue when its effects are significantly scientifically uncertain, for which science alone is unable to assess risk owing to the 'inherently unpredictable'[163] outcome of action. This section marks a return to an issue touched upon earlier, namely the non-physical impacts of SRM research; the different types of sensitivities aroused by SRM research which relate to political, moral, ethical, as well as scientific issues. I suggest an alternative approach to regulating risk which accounts for non-physical effects of SRM field research in assessments of risk where there is significant scientific uncertainty.

This alternative approach is one based on what I call an 'incorporated' approach to risk assessment. An incorporated approach is more inclusive and deliberative and better able to meet members' normative expectations. There are two elements to incorporated risk assessments which link to inclusive and deliberative regulatory mechanisms. Firstly, they allow for science and politics to be considered simultaneously *during the risk assessment phase*. To this extent, risk can be 'co-assessed' just as it is 'co-produced'.[164] Thus, rather than politics being consigned to representative interests in democratic institutions such as in the legislature through formal processes such as law-making, political involvement is able to take place in the administration of regulation at the point of assessment of risk. It is incoherent to use science as the basis for assessing risk where scientific uncertainty is significant, and as a result something *more* is needed. By incorporating other bases for its assessment risk can be constructed in ways that reflect members' values rather than on incomplete scientific data.

Secondly, incorporated risk assessments are spaces in which individuals can participate directly should they choose. There are formal opportunities for individuals to participate in decision-making processes such as in the form of written comments on proposals as well as in attending meetings. Direct individual participation means that it may be possible for lay knowledge to be included in decision-making processes on the basis that the participation is

159 Jacques Lenoble and Marc Maesschalck, "Renewing the Theory of Public Interest: The Quest for a Reflexive and Learning-based Approach to Governance" in Olivier De Schutter and Jacques Lenoble (eds), *Reflexive Governance: Redefining the Public Interest in a Pluralistic World*, (Oxford: Hart Publishing, 2010), pp. 3-21.

160 Ibid; De Schutter and Lenoble, *Reflexive Governance*, *supra* note 152; Part of the Sixth European Framework Programme for Research and Development REFGOV papers found on the interest at: http://sites.uclouvain.be/cpdr-refgov/ (last accessed 14 May 2015).

161 Von Shomberg, Prospects for Technology Assessment, *supra* note 147.

162 Sabel and Zeitlin, Learning from Difference 2008, *supra* note 151, at p. 277.

163 Fisher, *Risk Regulation*, *supra* note 10, at p. 7.

164 Cass Sunstein, *Designing Democracy: What Constitutions Do* (New York, Oxford University Press, 2001).

deliberative. Participation does not dispense with expertise but includes all "generally reliable knowledge, subject to methodological and epistemological limits".[165] Risk is assessed through a process of deliberation with participation by lay persons and through interest group representatives.

It is arguable that deliberation and inclusion by different interest group representatives should take place in *all* risk assessments, based on the politically contingent nature of science itself. This is accepted. But as I set out in the introduction, the intention of this paper is not to critique the orthodox epistemology of science nor to call for a wholesale shift from the technocratic to the deliberative paradigm. My approach is pragmatic instead: only where there is a significant degree of scientific uncertainty should incorporated approach to risk be facilitated. In so doing my aim is to minimise the disruption to the 'constitutional administration' of the regulation of SRM research.

I am not alone in advancing a risk-incorporated approach. Pidgeon et al[166] report the results of one of the first public engagement studies into acceptability and ethics of the feasibility test in SPICE; the test bed for the pumping of water into the sky using a one-kilometre pipe. The findings from the public engagement research are very interesting. They include the imperative for international governance based on consensus; concerns over the unintended consequences of science; knowledge limitation and the links between 'subscale and transboundary effects', and communication between politicians and researchers. The most significant finding is developed into the discussion of the paper where Pidgeon et al refer to the 'intertwining' of epistemological, societal and institutional ambivalences with the strictly technical and scientific question which, they claim, "will pose the greatest challenge"[167] for future governance research.

My suggestion is that where scientific uncertainty is significant there is an intertwining of the scientific, the social and the political, which evidences the need for a risk-incorporated approach to risk assessment. It is the significance of scientific uncertainty that triggers the need for a risk-incorporated approach so that the scientific, the social and the political can intertwine.

As I suggested above, taking an incorporated approach to risk assessment makes it more inclusive and deliberative by providing opportunities for lay persons to be directly involved in assessments of significantly scientifically uncertain SRM field research. There are other notable advantages for the EU: employing an incorporated approach to risk assessment would to develop a regulatory framework in the EU that is more flexible and responsive, and therefore better able to maximise legitimacy. It is to these last characteristics that we now turn.

## 3. Implications for the EU

In section III this paper suggested that the EU's response to safeguarding legitimacy was based on the principle of non-delegation. The case of *Meroni* illustrated the EU's preservation of the institutional balance of powers, which in turn preserves the institutional separation of science and politics in the assessment and management of risk respectively. I suggested that the *Meroni* doctrine – this regulatory procedure – 'locks' the EU's regulatory framework into one specific type of risk analysis. It is less able to respond to different types of activities because change can only take place pursuant to treaty revisions. In short the framework is rigid, not flexible and unresponsive. As a result it is less able to maximise legitimacy as conceptualised by directly deliberative polyarchy because it cannot respond to members' normative expectations.

My suggestion is that a risk-incorporated approach is better able to maximise the possibility of securing legitimacy for a regulatory framework in the context of highly scientifically uncertain SRM field research by being more flexible, preventing regulatory lock-ins and facilitating participation in decision-making processes. By adopting a pragmatic stance, elements of directly deliberative polyarchy can be incorporated into the administrative constitutionalism of the EU.

However, as the EU stands, there is little possibility of creating the space for an incorporated approach to assessing risk because the principle of non-delegation set out in *Meroni* precludes the delegation of po-

165 Fisher, *Risk Regulation*, *supra* note 10, at p. 33.

166 Nick Pidgeon, Karen Parkhill, Adam Corner and Naomi Vaughan, "Deliberating Stratospheric Aerosols for Climate Geoengineering and the SPICE Project", 3 *Nature Climate Change* (2013), pp. 451-457.

167 Ibid, at p. 454.

litical powers to scientific institutions. The implications for the EU of developing a regulatory framework that maximises the possibility of securing legitimacy by being flexible is that it will be required to take the counter-intuitive step to delegate decision-making authority in certain circumstances to politically and scientifically composed regulatory bodies. Changing the approach set out in *Meroni* will prevent the lock-in of institutionally separating risk from politics and can allow institutions to evaluate risk by incorporating, rather than separating, politics and science.

The step is counter-intuitive precisely because that delegation will be seen to disturb the constitutional balance of powers that has ties to democratic legitimacy as its core. Moreover, in the context of decision-making around scientifically uncertain activities, the *Meroni* doctrine safeguards against otherwise scientific decision-making on the grounds of efficiency.

It is arguable that these disturbances would reduce formal legal legitimacy. But the disturbance can be minimised in three ways. Firstly, the delegation can be controlled; it can be subject to procedural safeguards such as those set out in the Administrative Procedure Act[168] in the US. Safeguards include participatory procedures for decision-making, such as the Notice and Comment procedure[169] and requirements for transparency and accountability of committee reporting under the Government in the Sunshine Act.[170] Secondly, the composition of committees would have to be inclusive so that delegated decisions would not be made by scientists solely. The institutions co-assessing risk would necessarily be required to be both political and scientific and the composition would reflect that. So, for example, committees would be inclusive and comprise lay members as required by the Federal Advisory Committee Act.[171] Lastly, strict conditions will be imposed on when the delegation can take place. In the context of SRM field research this will be when a threshold of scientific uncertainty is significant.

The threshold for significant scientific uncertainty is noteworthy because it is the point at which a move from the isolated to incorporate risk assessment is triggered. Who decides this threshold? I suggest that it be agreed by political institutions on advice from scientists as a 'framework threshold' in much the same way as 'framework goals' such as 'good water status' comprise part of the EU's experimentalist architecture identified by Sable and Zeitlin. By contrast, the decision as to whether SRM field research actually falls within the threshold and therefore classifiable as significantly scientifically uncertain rests with scientists themselves. Again, this poses difficulties. There may be problems about whether scientists are likely to be biased and want to preserve for themselves their own autonomous space. There is also the charge that the decision to use the risk incorporated mechanism thereby triggering a delegation of decision-making power has simply replaced the scientific assessment of risk: the decision about risk has been shifted further up the line to question of whether the technology is scientifically uncertain or not.

These problems are valid but not insurmountable. The pragmatic stance accepts that decisions about scientific uncertainty need to be taken somewhere and by someone. Climate scientists are able to quantify uncertainty; such quantifications from the basis of IPCC AR reports. In the past significant scientific uncertainty has led to scientists calling for governance arrangements. The Berg letter of 1974 announced the limits of scientific understanding associated with the development of biotechnology. The Royal Society's own 2009 report is an example of the scientific community announcing the discipline's concerns over levels of certainty. Moreover, the US National Academy of Science Committee on Geoengineering the Climate recommended a 'serious deliberative process' to decide governance issues[172] as well as natural scientists and engineers suggesting governance thresholds for SRM field experiments.[173] It is arguable then that scientists are capable and willing to make decisions about uncertainty even if that means triggering rules for constraining the scientific enterprise.

The call to 'mellow' the *Meroni* doctrine[174] and permit delegation subject to strict safeguards is, to some

168 5 U.S.C. § 551.

169 5 U.S.C. § 533.

170 5 U.S.C. § 552b(e)(3).

171 5 U.S.C.

172 Committee on Geoengineering Climate, *Reflecting Sunlight to Cool Earth*, *supra* note 3, at p. 190.

173 Keith et al, "Field Experiments on Solar Geoengineering", *supra* note 34.

174 Jacques Pelkmans and Marta Simoncini, "Mellowing *Meroni*: How ESMA can help build the Single Market" *Centre for European Policy Studies: Commentary 18th February 2014* (2014), pp. 1-5.

extent, pushing at an open door. The UK failed recently in its attempt to have annulled by the EU Court of Justice based on *Meroni*'s principle of non-delegation a discretionary power conferred to the European Securities and Markets Authority (ESMA) by the Council and European Parliament.[175] Article 28 of the 'short-selling' regulation[176] gives ESMA the power to adopt intervening measures to ban short-selling 'in exceptional circumstances' where there is a threat to the proper functioning of the financial markets. The Court rejected the UK's plea that the power entails 'a very large measure of discretion'[177] on the basis that they are amenable to judicial review[178] and therefore suitably circumscribed.[179]

The judgment does not undermine the constitutional principle set out in *Meroni* and the necessity of the balance of powers. The ESMA case is situated in a different context to that of scientific uncertainty in this paper and adopts a different basis of legitimacy, arguably output legitimacy[180] but it does place greater weight on the conditions of delegation and the availability of judicial review, which arguably have changed since *Meroni*. The overall point is that *Meroni* has not been applied strictly to preclude regulatory measures by ESMA and my suggestion that delegation take place subject to strict safeguards is not entirely unprecedented.

The pragmatic stance and incorporated risk assessment advanced in this paper balances the need of objective certainty from science (as opposed to decision made on politically arbitrary public opinion or other criteria) with the understanding that under certain conditions alternative constructions of risk should be recognised. My approach differs from Fisher's deliberative-constitutive paradigm in which a shift from one paradigm to another requires a substantial change to the administrative constitution. The pragmatic stance accepts that whilst there may be desirable elements of the deliberative paradigm, there need not take place a wholesale change in the administrative constitution away from the technocratic paradigm. The pragmatic stance minimises the disturbance of the EU's constitutional balance of powers, and as such may be considered an improvement on a regulatory framework located in the deliberative paradigm alone.

## V. Conclusion

Claims about the legitimate regulation of SRM field research are easy to make but difficult to substantiate. Firstly, the current absence of a formal regulatory or legal framework for SRM field research makes it difficult to suggest improvements that strengthen its legitimacy. Secondly, the significant scientific uncertainty of SRM field research and its effects link to questions of risk and the relationship between science, politics and other value-systems. Thirdly, there is no certainty about what kind of regulatory framework will emerge, leading to similar uncertainty about the conceptions of legitimacy that will be relied upon. In trying to suggest mechanisms to maximise the possibility of securing legitimacy, this paper has engaged with many variables: what sort of regulatory framework will emerge; how can risk be regulated; and what concept of legitimacy will be employed? It is within the context of these significant variables that the paper's central claim has been made.

The paper suggested how the EU regulation of SRM field research could be designed to maximise the possibility of securing legitimacy. Under conditions of significant scientific uncertainty, SRM field research poses challenges for its legitimate regulation. The EU's orthodox response to the challenge of legitimacy is to ensure the institutional 'balance of powers'. This response is deficient because it entrenches a risk analysis approach that is inappropriate for significantly scientifically uncertain SRM technology. My suggestion is a pragmatic one. It is to institutionalise an incorporated approach to risk which provides space for deliberative and inclusive decision-making in the technocratic paradigm as part of a responsive and flexible framework whilst retaining the general institutional balance of the EU. In doing so, the EU develops spaces for more directly deliberative polyarchy without jettisoning its orthodox constitutional approach.

175 Case C-270/12 United Kingdom of Great Britain and Northern Ireland v European Parliament and Council of the European Union [2014]

176 European Parliament and Council Regulation (EU) No 236/2012 on short-selling and certain aspects of credit default swaps, OJ 2012 L 86.

177 Ibid., at para. 54.

178 Ibid, at para. 53.

179 Ibid, at para. 45.

180 Ibid, at para 35: ESMA's measures "require a high level of technical and economic expertise and information".

In the introduction I explained why the paper engages with two substantial areas of regulatory scholarship: EU regulation of risk and transnational private regulation. In exploring the relationships between conceptualisations of legitimacy and their respective regulatory frameworks, this paper is not situated firmly in the literature on transnational private regulation or in EU regulatory scholarship. Instead it spans both. The aim has not been to contribute solely to one or other area of scholarship but to evaluate how each views legitimacy and then apply it in the context of the regulation of SRM field research. The paper is intended to be of interest to both audiences because it provides an opportunity to apply the concept of legitimacy beyond the terms ordinarily expected of each respective regulatory theory. In so doing the paper endeavours to provide a theoretical opening in which both audiences are able to think about how to govern SRM field research that best maximises the possibility of securing legitimacy.

# Towards a Law of the Mammoth? Climate Engineering in Contemporary EU Environmental Law

*Han Somsen**

## I. Outline of the General Idea

In an article that made waves when it was first published in 1996, judge Easterbrook scorned the idea that the technological reality of cyberspace justified talk about or a need for 'Cyber Law'.[1] Just as there is no need for a 'Law of the Horse' merely because horses give rise to legal claims, he argued, conventional legal principles and reasoning are sufficiently accommodating to absorb new legal challenges that arise in the wake of cyberspace. We may likewise doubt the need for a 'Law of the Mammoth', even though technologies emerge that harbour the prospect of bringing back the woolly mammoth from extinction, reversing climate change, and creating new life forms. Cyber Law is now firmly established, of course, and Easterbrook also appears to have lost the academic debate from the likes of Lawrence Lessig.[2] That fact notwithstanding, the onus to show that the time has come for a Law of the Mammoth clearly is on those staking the claim.

The purpose of this short article essentially is to prepare the ground for that argument, with particular but by no means exclusive reference to climate engineering. Instead of framing the question as one of a confrontation between environmental law and climate engineering, a multitude of technologies instrumental in intentionally enhancing the environment suggests that it is appropriate more generically to consider the introduction of a novel concept in environmental law that captures the essence of such efforts. In the same vein as 'human enhancement' has come to be distinguished from 'medical therapy', in view of novel environmental policy uses of technologies it is submitted that we should consider the virtues of distinguishing environmental 'enhancement' from environmental 'improvement'. Whereas the mere prospect of *human* enhancement has spurned profound academic and public debate about core principles and base-lines that can serve the purpose of regulating human enhancement,[3] the phenomenon of *environmental* enhancement has done little more than to unleash a flood of publications regurgitating the possible environmental and health risks of practices such as genetic modification, nanotechnology and synthetic biology. In fact, the term 'environmental enhancement' does not feature in the vocabulary of environmental scholars or generate hits in search-engines, at least not until this essay finds its way to cyberspace. Yet, just as there is at least conceptual mileage in distinguishing human enhancement from medical therapy, there undoubtedly is value in differentiating between 'improving the environment' as mandated by Article 191(1) of the Treaty on the Functioning of the European Union (TFEU), and 'enhancing the environment', for which environmental law currently offers few principled constraints other than risk. Water purification projects aimed at improving environmental quality to levels that are supportive of animal species such as salmon that have long disappeared from many of our rivers (improvement), may be a qualitatively different intervention in the natural environment from genetically engineering salmon so as to allow them to survive rising water temperatures (environmental enhancement). Bringing back the Pyrenean ibex after its extinction in 2000 somehow feels different from doing the same for the woolly mammoth that also disappeared due to human activities, but some 6.000 years ago. Dyeing the oceans to counteract the greenhouse effect seems more radi-

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1 Frank H. Easterbrook, Cyberspace and the Law of the Horse, (1996) *U. CHI. LEGAL F.* 207–16

2 See L. Lessig, 'The Law of the Horse: what cyberlaw may teach', (1999) 113 *Harvard Law Review* 501-45.

3 For a useful attempt to introduce a taxonomy of human enhancement see G. Cohen, 'What (if anything) is wrong with human enhancement? What (if anything) is right with it?' (2013) 49 *Tulsa Law Review*, 645.

cal than assisted migration of species to colder climates in aid of their survival. Cooling down the planet to pre-industrial revolution levels is an altogether different ambition than endeavouring to replicate prehistoric climates.

Somewhere along the line, if only instinctively, we feel that these are differences that ought to matter, and this is so even despite the fact that none of these examples should arouse feelings of potential catastrophic risk. Although those differences almost certainly cannot be caught in simple dichotomies or couched exclusively in legal terms,[4] the ambition of this article indeed extends not much further than to argue that (i) the environmental improvement/environmental enhancement dichotomy is productive, and (ii) the arrival of a plethora of enhancement technologies implies a need for a fundamental overhaul of environmental law, to the extent even that it calls for a Law of the Mammoth.

Paramount in that assessment must the realization that environmental enhancement more often than not is in pursuit of agreed environmental and health goals. The important implication of that observation is that 'risk' in itself cannot serve as a useful divider between acceptable and unacceptable environmental enhancement policies, at least not when conventional policy alternatives pose equal or greater risks of compromising those imperatives. Recently, for example, successful large scale open field trials were conducted with genetically modified male *Aedes Aegypti* mosquitoes, offering prospects to control dengue fever in realization of the right to health.[5] This purposeful enhancement of the living environment in pursuit of health goals undoubtedly carries (uncertain) risks, but those are understandably deemed inferior to proven health risks associated with dengue fever.

Yet, the preoccupation in the literature remains squarely with risk and risk governance and the question of principle whether enhancement initiatives such as climate engineering more fundamentally fit the paradigm informing conventional environmental law is mostly ignored. Scholarly fixation on risk is premature, however, for as long as there remains doubt whether, more fundamentally, environmental enhancement policies are compatible with the values and principles codified in the law. All things considered, it is as unfortunate as it is baffling that to this day this high-order question of principle has been allowed to remain obfuscated by the dominance of the risk paradigm.

To engage the question if environmental enhancement initiatives, including climate engineering, can be productively assessed and regulated within the confines of the prevailing logic of conventional environmental law, what we need is a deontological framework transcending risk. To this end, it is necessary to strip environmental law of its paraphernalia, including risk, until only its constitutive paradigm remains. If we engage in such an exercise, it will be shown, what emerges is a simple trilogy of state duties to 'preserve, protect and improve' the environment. The negative duty, first, is to refrain from compromising the integrity of environments that satisfy pre-agreed standards (duty to preserve). Second, states have positive duties to protect environments against external threats (duty to protect) and to remedy any damage that has been allowed to materialize (duty to improve). On the basis of this three-tiered system, climate engineering may be simultaneously perceived as *prohibited* by virtue of duties to preserve and protect, or *mandated* by duties to improve. That legal muddle of course is little short of existential, which would suggests that contemporary environmental law may be unfit to respond to climate engineering. In short, it appears that humankind is embarking on an unprecedented project to enhance the planet, and beyond the highly ambiguous precautionary principle addressing 'risk' en-

4 For an ethical approach, see S.M. Gardiner, 'Some Early Ethics of Geoengineering the Climate: A Commentary on the Values of the Royal Society Report', (2011) 20 *Environmental Values* 163–88; S.M. Gardiner, "Is Arming the Future" with Geoengineering Really the Lesser Evil? Some Doubts about the Ethics of Intentionally Manipulating the Climate System, Policy Responses to Climate Change in S.M. Gardiner et al (Eds.) *Climate Ethics* (Oxford: Oxford University Press, 2010), 284 -312. For a legal approach towards adaptation see R.K. Craig, '"Stationarity is dead " – Long live transformation: five principles for climate adaptation law', (2010) 34 *Harvard Environmental Law Review*, 10-73. P.G. Harris, *World Ethics and Climate Change: From International to Global Justice* (Edinburgh: Edinburgh University Press, 2010); T. Hayward, 'Human Rights Versus Emissions Rights: Climate Justice and the Equitable Distribution of Ecological Space' (2007) 21 *Ethics & International Affairs*, 431-50; E. Posner and D. Weisbach, *Climate Change Justice* (Princeton: Princeton University Press, 2010); P.E. Taylor, 'From Environmental to Ecological Human Rights: A New Dynamic in International Law?', 10 (1997) *Geo. Int'l Envtl. L. Rev.*, 309-98.

5 See the deliberate release in the Cayman Islands, Malaysia, and Brazil of genetically modified mosquitos in attempts to put an end to dengue fever without recourse to hazardous pesticides, with promising results. http://www.theatlantic.com/health/archive/2014/09/engineering-mosquitoes-to-stop-disease/379247/.

vironmental law is at a loss as to how to respond to this reality.

Whilst I am not optimistic about the chances to prove the case for a Law of the Mammoth in this short contribution, let alone about articulating its guiding principles, at the very least it should become clear that climate engineering and other enhancement technologies should set in motion fundamental legal change.

## II. Regenesis and Current EU Environmental Law

Our analysis is legally situated within the confines of Articles 191-194 TFEU. In conjunction with international law binding the EU, these provisions articulate the outer-limits of what is currently constitutionally imaginable in terms of environmental policy.[6] For the sake of avoiding possible misunderstandings: even as an EU law scholar I do not sufficiently lack in humility to suggest that the future of climate engineering - let alone humankind's future on our planet - should hinge on legal interpretations of four provisions in the TFEU. Clearly, man-made legal obstacles should not stand in the way of the right thing to do, regardless of what that means in the context of climate change, and if Articles 191-194 TFEU turn out to be such obstacles then a Law of the Mammoth may have to be constructed. Nonetheless, these provisions are formal and authoritative expressions of European values regarding humans' relationship with the environment, and for climate engineering initiatives to pass muster they must fit the mould these provisions cast.[7]

The toughest and most fundamental legal challenge of environmental enhancement appears to reside in the absence of base-lines that clarify the point in time when it must be resorted to, and to which level it must be deployed. In essence, current EU environmental law operates on the basis of a trilogy of conditional state duties 'to preserve, protect and improve' the environment. The duties are conditional, because a specific prior act is needed for them to be triggered and operationalized. Crucially, EU environmental law hence does not operate on the basis of a single overarching ecological standstill principle, related to a specific moment fixed in the past and on the basis of which states must preserve, protect and improve the environment. Instead, the point of departure is that humans are free to manipulate the environment unless a specific prior act has established a base-line for protection. The radical consequence is that Member States are free to enhance all those aspects of the environment that are not covered by specific legal acts (e.g. the colour of the oceans and skies, cloud formations, micro-organisms etc.). It is true that in actual fact the European environment is densely regulated, and also that this corpus of EU environmental law includes horizontal measures such as, in particular, environmental impact assessment.[8] This means that an answer to the question if and to what extent EU environmental law leaves room for environmental enhancement requires a detailed analysis of secondary EU environmental law, which is an endeavour that quite obviously cannot be undertaken in this short article. After a brief exploration of primary EU environmental law to determine the scope for environmental enhancement measures, instead we focus on Directive 92/43/EEC on the Conservation of Natural Habitats and of Wild Fauna and Flora.[9] That Directive set up a protective regime impacting on almost every aspect of the living and non-living environment and hence appears an ideal case study for our purposes.

### 1. Environmental Enhancement in Primary EU Environmental Law

Article 191(1) TFEU provides that EU environmental policy must contribute to: (1) preserving, protecting and improving the environment, (2) protecting human health, (3) prudent and rational utilisation of natural resources, and (4) promoting measures at international level to deal with regional or worldwide

6 Regarding the compatibility with international environmental law, see J. Reynolds, 'Climate Engineering Field Research: The Favorable Setting of International Environmental Law' (2014) 5 ***Washington and Lee Journal of Energy, Climate, and the Environment*** 417-86.

7 See A. Williams, *The Ethos of Europe: Values, Law and Justice in the EU* (Cambridge: Cambridge University Press, 2010)

8 Dir. 2014/52/EU amending Directive 2011/92/EU on the assessment of the effects of certain public and private projects on the environment, OJ [2014] L 124/1.

9 Dir. 92/43/EEC on the conservation of natural habitats and of wild fauna and flora, OJ [1992] L 206/7.

environmental problems, and in particular combating climate change.[10]

Whereas no hierarchy is readily discernible from Article 191(1) TFEU, there are sound legal arguments in favour of the preposition that, in common with global articulations of environmental law, the backbone of EU environmental law consists of instructions to 'preserve, protect and improve' the environment. In particular, both 'energy' (Title XI) and 'health' (Title XVI) constitute discrete EU policies in their own right. In view of the principle of conferral articulated in Articles 4 and 5 of the Treaty on European Union (TEU), in conjunction with the 'centre of gravity' approach employed by the Court of Justice of the European Union (CJEU) for determining the boundaries between policies, this means that Title XX confers powers to pursue environmental goals. To be sure, concerns about 'health' and 'prudent and rational utilization of resources' (e.g. energy) can trigger environmental policy, but environmental policy cannot be used as a disguise for health or energy policies. To do so would upset the institutional balance pertaining to those policies, and would undoubtedly lead the CJEU to invalidate such measures.[11]

This conclusion is significant for our purposes, as it means that enhancement measures primarily targeting human health, as is the case with the genetically engineered *Aedes Aegypti* mosquitoes, cannot be based on Article 192 TFEU as a matter of environmental policy. For that purpose Article 168(5) TFEU specifically exists, which in all likelihood leads to the conclusion that the EU possesses no such powers.[12]

One might argue that climate engineering, likewise, amounts to health policy rather than environmental policy, which hence also cannot be pursued as a matter of EU environmental policy. Fact of the matter is that Article 191(1) TFEU explicitly mentions climate change, and that EU climate policy thus far has often been based on the predecessor of Article 191 TFEU, Article 175 EU.[13] The well-established centre of gravity principle therefore does not rule out climate engineering as a matter of EU environmental law. Since it is uncontroversial to regard climate engineering as part of climate policy in the same way as current mitigation and adaptation policies are, we can conclude that climate engineering techniques that satisfy the conditions set forth in Articles 191-194 TFEU are legally acceptable manifestations of EU environmental policy. Significantly of course, the same conclusion applies to any other environmental enhancement initiative that falls within the ambit of EU environmental law, such as genetically modified salmon and the regenesis of mammoths. This means

10 Article 191 TFEU provides:
1. Union policy on the environment shall contribute to pursuit of the following objectives:
– preserving, protecting and improving the quality of the environment, (emphases added)
– protecting human health,
– prudent and rational utilisation of natural resources,
– promoting measures at international level to deal with regional or worldwide environmental
problems, and in particular combating climate change.
2. Union policy on the environment shall aim at a high level of protection taking into account
the diversity of situations in the various regions of the Union. It shall be based on the precautionary
principle and on the principles that preventive action should be taken, that environmental damage
should as a priority be rectified at source and that the polluter should pay.
In this context, harmonisation measures answering environmental protection requirements shall
include, where appropriate, a safeguard clause allowing Member States to take provisional
measures, for non-economic environmental reasons, subject to a procedure of inspection by
the Union.
3. In preparing its policy on the environment, the Union shall take account of:
– available scientific and technical data,
– environmental conditions in the various regions of the Union,
– the potential benefits and costs of action or lack of action,
– the economic and social development of the Union as a whole and the balanced development of its regions.
4. Within their respective spheres of competence, the Union and the Member States shall cooperate with third countries and with the competent international organisations. The arrangements for Union cooperation may be the subject of agreements between the Union and the third parties concerned.
The previous subparagraph shall be without prejudice to Member States' competence to negotiate in
international bodies and to conclude international agreements.

11 Most recently, the centre of gravity test was applied in Case C-81/13 *United Kingdom* v *Council* (judgment of 18 Dec. 2014, not yet reported). The Court repeated that '[a]ccording to settled case-law, the choice of the legal basis for a European Union measure must rest on objective factors amenable to judicial review, which include in particular the aim and content of the measure.' (Para. 35).

12 Article 168(5) TFEU provides:The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, may also adopt incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health, and measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol, excluding any harmonisation of the laws and regulations of the Member States.

13 See for example Dir 2009/29/EC amending Directive 2003/87/EC so as to improve and extend the greenhouse gas emission allowance trading scheme of the Community, [2009] OJ L 240/63.

that we can now turn to a more substantive analysis of the potential for environmental enhancement in regulated spaces, for which we turn to Directive 92/43/EEC on the Conservation of Natural Habitats and of Wild Fauna and Flora.[14]

## 2. Environmental Enhancement in Regulated Spheres: The Example of the Habitat Directive

As observed, the single most important instruction flowing from EU environmental law is that the EU and its Member States have assumed duties 'to preserve, improve and protect' the environment. Yet and surprisingly, EU environmental law scholarship thus far has attached little or no significance to the difference between 'preservation' 'protection' and 'improvement'.[15] In the age of environmental enhancement this may turn out to amount to a serious oversight. The fundamental importance of this trilogy for environmental enhancement initiatives can be usefully illustrated by a cursory analysis of Directive 92/43/EEC on the Conservation of Natural Habitats and of Wild Fauna and Flora.[16]

The general purpose of the Directive, according to Article 2, is 'to maintain or restore, at favourable conservation status, natural habitats and species of wild fauna and flora of Community interest.' The duties to preserve and protect (in the language of the Directive reduced to the single concept of 'to maintain'), as always, are conditional. What is needed to trigger the duties is an act that designates a specific Special Area of Conservation (SAC), which at the same time determines the substantive and temporal scope of those duties.[17] Notwithstanding the fact that the CJEU and Commission have attempted to curtail the discretion to designate, it is this discretionary act from which duties flow.[18]

Article 6 of the Directive articulates the three levels of duties that are triggered by the designation of a SAC. In tandem with a general obligation of surveillance,[19] the first paragraph engages the duty to preserve, by obliging Member States to establish the necessary conservation measures and appropriate statutory, administrative or contractual measures which correspond to the ecological requirements of the natural habitat type. Environmental enhancement, i.e. an intentional technological intervention in the SAC in pursuit of human interests, needs or rights that transcend agreed environmental base-lines at first sight would appear to have no role to play in the context of Article 6(1), and in fact would seem to amount to a breach of the duty to preserve. However, that conclusion may be premature in light of the way in which the Directive constructs the duty' to protect'.

The duty to protect a SAC is generically worded in Article 6(2), and implores Member States proactively to take appropriate steps to avoid the deterioration of natural habitats and the habitats of species as well as disturbance of the species for which the areas have been designated, *in so far as such disturbance could be significant in relation to the objectives of this Directive* (emphasis by the author). This general obligation is further specified, *inter alia*, in Article 12 for the animal species listed in Annex IV(a), in Article 13 for plant species featuring on Annex IV(b), and in Article 14 for animal and plant species appearing in Annex V. Room for environmental enhancement appears to exist, at least to the extent this causes no disturbance which is 'significant' in relation to the objectives of the Directive. Hence, if animals featuring on Annex IV(a) are not affected by the colour of the ocean, then dyeing the ocean white is not prima facie incompatible with the Directive. Moreover and significantly, Article 16 contains a broadly worded derogation which allows Member States to derogate from Articles 12-15. This they can do in so far it is not detrimental to the maintenance of the populations of the species concerned at a favourable conservation status in their natural range:

> (a) in the interest of protecting wild fauna and flora and conserving natural habitats;
>
> (b) to prevent serious damage, in particular to crops, livestock, forests, fisheries and water and other types of property;
>
> (c) in the interests of public health and public safety, or for other imperative reasons of overriding public interest, including those of a social or eco-

14 N. 9 above

15 The most detailed analysis is probably still by L. Kramer, *EC Treaty and Environmental Law* (London: Sweet & Maxwell, 1998).

16 N. 9 above.

17 See Art. 4 Dir. 92/43/EEC, ibid.

18 See Commission Note on the Designation of Special Areas of Conservation (SACs) Final Version of 14 May 2012, published on the internet at https://circabc.europa.eu/sd/a/eaab0066-5360-4ec2-8a04-c180475634fc/Commission%20note%20on%20SAC%20designation.pdf.

19 Art. 11 Dir. 92/43/EEC, n. 9 above.

> nomic nature and beneficial consequences of primary importance for the environment;
> (d) for the purpose of research and education, of repopulating and re-introducing these species and for the breedings operations necessary for these purposes, including the artificial propagation of plants;
> (e) to allow, under strictly supervised conditions, on a selective basis and to a limited extent, the taking or keeping of certain specimens of the species listed in Annex IV in limited numbers specified by the competent national authorities.

Surprisingly and counter-intuitively, even within the confines of duties to protect a SAC, environmental enhancement appears permitted as long as it is in support of the wide-ranging and broadly worded imperatives listed in Article 16. Moreover, the precautionary principle in Article 191(2) empowers the EU to take proactive action even before causal linkages between (private) activities and threats of environmental harm can be established beyond scientific doubt. Precaution in that sense blurs the divide between the duty to preserve and the duty to protect, and serves to migrate enhancement measures to the realm of preservation.

A duty 'to improve' a SAC, finally, arises if damage to the area has occurred because derogations to duties have to preserve and protect have been granted for imperative reasons of overriding public interest. In this vein Article 6(4) of the Habitats Directive provides:

> If, in spite of a negative assessment of the implications for the site and in the absence of alternative solutions, a plan or project must nevertheless be carried out for imperative reasons of overriding public interest, including those of a social or economic nature, *the Member State shall take all compensatory measures necessary to ensure that the overall coherence of Natura 2000 is protected.* It shall inform the Commission of the compensatory measures adopted.
> Where the site concerned hosts a priority natural habitat type and/or a priority species, the only considerations which may be raised are those relating to human health or public safety, to beneficial consequences of primary importance for the environment or, further to an opinion from the Commission, to other imperative reasons of overriding public interest. (author's emphasis)

As with the duty to protect, there is a possible role for environmental enhancement, as long as those measures are to ensure the overall coherence of Natura 2000, are mandated by human health or public safety, have beneficial consequences of primary importance for the environment, or answer imperative reasons of overriding public interest. Climate engineering, for example, could rather easily be justified on any the basis of most of these counts.

Important for the future of the mammoth, finally, is Article 22 which concerns the deliberate re-introduction or introduction of species. Article 22(b) provides that Member States must ensure that the deliberate introduction into the wild of any species which is not native to their territory is regulated so as not to prejudice natural habitats within their natural range or the wild native fauna and flora and, if they consider it necessary, prohibit such introduction. As a matter of principle, there is nothing that stands in the way of reintroducing the mammoth or other genetically enhanced species, provided these species comply with relevant secondary EU law, such as Directive 2001/18/EC on the Deliberate Release on Genetically Modified Organisms,[20] and do not prejudice natural habitats within their natural range or the wild native fauna and flora.

The sympathetic stance of EU nature conservation law vis-à-vis environmental enhancement applies *a fortiori* to anthropocentric environmental law such as Directive 98/83/EC on the Quality of Water Intended for Human Consumption.[21] Thus, Member States must ensure that 'the measures taken to implement the Directive in no circumstances have the effect of allowing, directly or indirectly, either any deterioration of the present quality of water intended for human consumption so far as that is relevant for the protection of human health or any increase in the pollution of waters used for the production of drinking water' (duty to preserve).[22] They must take all measures necessary to ensure that the water available to consumers meets the requirements of the Directive (duty to protect),[23] and must take remedial action soon as possible to restore its quality if it no

20 [2001] OJ No. L 106/1.

21 [1998] OJ No. L 330/32.

22 Ibid., Art. 4(2).

23 Ibid., Art. 7(1).

longer satisfies those requirements (duty to improve).[24] Environmental enhancement, in all likelihood, is permitted in so far as it does not impinge on the primary purpose of the Directive, which is to secure a minimum quality of water intended for human consumption.

In summary, we tentatively conclude that even eco-centric EU environmental law as epitomized by Directive 92/43/EEC on the Conservation of Natural Habitats and of Wild Fauna and Flora leaves ample room for environmental enhancement. This, for those who cherish what Michael Sandel has termed 'respect for the given',[25] will come as an unpleasant surprise.

Some might retort that, if there is anything we should learn from the notion of the Anthropocene it is surely that humankind has been engineering the environment from the moment it laid hands on technologies.[26] Whilst this is true, the crucial point is that those anthropogenic impacts have been predominantly collateral, unplanned and deleterious, and it is in in that respect that climate engineering is so fundamentally and crucially different. Recent examples of environmental engineering involve (a) *intentional* efforts (b) *directly* to engineer the living or non-living environment (c) in pursuit *human* ambitions, needs or rights and, crucially as a separator from conventional environmental improvement, (d) *divorced* from any benchmark or standard derived from the past.

To illustrate the difference between conventional environmental law and environmental enhancement, imagine the excavation of the remains of a Shakespearean theatre built around 1600 to premier Shakespeare's plays. The theatre is a jumble of numerous (often ill-conceived) modifications made over the decades, reflecting different uses and architectural styles. A post of curator is advertised, and two candidates are invited to present their vision.

Mrs Green proposes that a law be adopted that grants her powers to preserve the site by protecting it against souvenir hunters and as far as possible against climatological impacts, and instigate whatever restoration projects are necessary to repair damage occurred since the excavation. Any intentional change to the ruin, she insists, amounts to an act of state sponsored cultural vandalism. Mrs Red argues that the time has come and that technologies are available to set in motion a cultural renaissance. Her proposal envisages a new multi-storey virtual reality experience at the location where the ruins have been found, and in which visitors can actually feel, smell and hear what it was like to participate in a Shakespearean play in different periods. Mrs Red finishes her presentation imploring that preserving the ruins of an ancient architecturally compromised temple of cultural life will not turn the tide of unprecedented cultural nihilism and consumerism that has turned creative critical minds into shallow obedient zombies.

Mrs Green's vision is consistent with a conventional 'preserve, protect, improve' paradigm. Mrs Red, whilst guided by the same cultural imperatives as Mrs Green, does not accept the constraints imposed by the ruin, and proposes a technology-driven experience that generates greater benefit, and by implication accepts that the integrity of the ruin, which in any event has been violated by successive 'improvements', is not of primary importance.

In order to instil further structure in our thinking about the fit of visions such as those of Mrs Red with the prevailing 'preserve, protect, improve' paradigm, it is helpful to consider the fate of a particular European species of wild goat.

## 3. The Return of the Pyrenean Ibix: The Fuzzy Divide between 'Improvement' and 'Enhancement'

In 2009, a team of Spanish scientists used reproductive cloning techniques in efforts to bring back the Pyrenean ibex, a species of mountain goat that became extinct in 2000. This involved inserting the cell nuclei of the ibex's skin cells into egg cells of domestic goats which had their own cell nuclei removed, resulting in seven pregnancies. Although due to lung deformities the only clone carried to term died seven minutes after birth, the event remains monumen-

24 Ibid., Art. 8(2).

25 See M. Sandel, *The Case Against Perfection*, (Cambridge (MA), Harvard University Press: 2009). But see the response by G. Kahane ' Designing Children and Respect for the Given', Proceedings of the 2012 Uehiro-Carnegie-Oxford Ethics Conference published on the Internet at http://www.practicalethics.ox.ac.uk/__data/assets/pdf_file/0006/29733/Kahane.pdf. See also G. Kahane: 'Mastery without mystery: Why there is no Promethean sin in enhancement', (2011) 28 *Journal of Applied Philosophy* 355–68.

26 L. Lewis and M. Maslin, 'Defining the Anthropocene' (2015) 519 *Nature* 171..

tal. As illustrated by table 1, the significance of the story of the Pyrenean ibex resides in the fact that it marks a new phase in environmental policy in which technology-driven remedial (regenesis) policies are triggered once preventive (nature conservation laws) have failed.[27]

*Table 1: Regenesis of animal species under conventional environmental law*

| Duty to Preserve → | Duty to Protect → | **Duty to Improve** |
|---|---|---|
| Designate SAC, list Pyrenean Ibex as protected | Protect SAC and Pyrenean Ibex threats | Reintroduce species, assist migration, *de-extinction of Pyrenean Ibex* |

Although the suggestion that states may find themselves under a duty to bring back species from extinction using cloning techniques is bound to raise eyebrows, table 1 suggests that de-extinction policies still fit the conventional 'preserve protect improve', trilogy as long as they are in support of and ancillary to specific pre-agreed standards articulated in conventional environmental law. Indeed, our brief analysis of Directive 92/43/EEC on the Conservation of Natural Habitats and of Wild Fauna and Flora, and in particular Article, 22 did not reveal a prima facie inconsistency with such a claim. This is not to downplay the fundamental temporal and substantive questions that arise. Temporal questions emerge, for example, because regenesis need not be confined to species that have become extinct during the recent era of conservation laws. Efforts to bring back the woolly mammoth thousands of years after its demise and which have produced first significant results prove that point.[28] Should we distinguish between the Pyrenean ibex (a species that featured on Annex IV(a) of Directive 92/43/EEC), the passenger pigeon (extinct prior to adoption of the Directive in 1914), and the woolly mammoth?[29] As for the scope of the duties, presuming we possess the technological capabilities, does de-extinction imply corollary duties to re-engineer habitats and climates in support of the survival of such species?

Climate policy likewise is at the brink of an era in which climate adaptation initiatives address shortcomings of climate mitigation policies, and climate engineering initiatives compensate for the limits of climate adaptation.

*Table 2: Regenesis of the climate under conventional environmental law*

| Duty to Preserve → | Duty to Protect → | Duty to Improve → |
|---|---|---|
| Climate Mitigation | Climate Adaptation | Climate Engineering in support of agreed temperature reduction targets |

Unlike duties to improve the environment (e.g. climate adaptation), the temporal and substantive scope of which can be determined with reference to whatever it is that states have committed themselves to preserve and protect, the question at what point and to what end climate engineering must or may be deployed is harder to answer. Tentatively and inspired by the return of the Pyrenean ibex, however, we might suggest that climate engineering deployed to realize agreed temperature reduction targets in support of (ineffective) mitigation and adaption measures is consistent with duties to improve.

Hard and troubling as these questions are, however, some may still concur with judge Easterbrook that

27 See 'Cloned goat dies after attempt to bring species back from extinction' *The Independent* 2 Feb. 2009. Available on the internet at http://www.independent.co.uk/news/science/cloned-goat-dies-after-attempt-to-bring-species-back-from-extinction-1522974.html (last visited 24 Feb. 2015). Attempts to bring back the Pyrenean ibex from extinction are ongoing.

28 See 'The Mammoth Cometh', *The New York Times* 24 Feb. 2014. Available on the internet at http://www.nytimes.com/2014/03/02/magazine/the-mammoth-cometh.html?_r=0 (last visited 24 Feb. 2015). On candidates for de-extinction see http://longnow.org/revive/ (last visited 24 Feb 2015).

29 Article 22 of of Directive 92/43/EEC on the Conservation of Natural Habitats and of Wild Fauna and Flora (see n. 8 above) answers that question as follows: In implementing the provisions of this Directive, Member States shall:'(a) study the desirability of re-introducing species in Annex IV that are native to their territory where this might contribute to their conservation, provided that an investigation, also taking into account experience in other Member States or elsewhere, has established that such re-introduction contributes effectively to re-establishing these species at a favourable conservation status and that it takes place only after proper consultation of the public concerned;(b) ensure that the deliberate introduction into the wild of any species which is not native to their territory is regulated so as not to prejudice natural habitats within their natural range or the wild native fauna and flora and, if they consider it necessary, prohibit such introduction. The results of the assessment undertaken shall be forwarded to the committee for information (…).'

*Table 3: Genesis of the living and non-living environment and the Law of the Mammoth*

| Duty to Preserve → | Duty to Protect → | Duty to Improve → | Duty to Enhance |
|---|---|---|---|
| Climate mitigation | Climate adaptation | Climate engineering in support of pre-agreed temperature reduction targets | Climate engineering outside the realm of pre-agreed targets |

they are still not so fundamentally different from similar questions that have begun to trouble the minds of nature conservation scholars as to call for a Law of the Mammoth.[30] However, as the ubiquitous practice of agricultural biotechnology shows, our efforts to engineer the environment are not constrained by the traits that evolution has bestowed on present or even past animal and plant life. In terms of technological prowess, almost literally, the sky is the limit. And it is not just the living environment that has become the target of human ambitions fundamentally to redesign the environment, climate engineering proving that point. Astounding examples of such enhancement ambitions can be derived from the past. In fact, we must go back more than 2.5 billion years to find a natural event that has changed the global nitrogen cycle as fundamentally as the Haber-Bosch process, through which atmospheric nitrogen is converted into ammonia on a massive scale for the production of agricultural fertilizer. Patented by Fritz Haber in 1908 and earning him the Nobel Prize in Chemistry, nitrogen fixation has changed the planet for ever.[31]

The preceding analysis suggests that current EU environmental law is positively inclined towards these ambitions to alter the living and non-living environment. The example of the Habitat Directive shows that this is so even if those ambitions go beyond preserving, protecting and improving environments relative to pre-agreed base-lines derived from the environmental status quo or status quo ante. A crucial follow-up question is whether Member States may have *duties* not just to preserve, protect and improve the environment but at some point may be mandated to 'enhance' the environment in those cases when mere 'improvement' will no longer do. Although that question cannot be fully discussed here, if such a duty were to exist or to arise, it is submitted, a Law of Mammoth would be called for along the lines depicted by Table 3.

It is proper at this point to introduce the forceful 'planetary boundaries' discourse, which appears to contain seeds of answers to that critical question.[32] Intimately related to the notion of the Anthropocene and embraced by the United Nations High-Level Panel on Global Sustainability, the Planetary Boundaries Hypothesis posits that there are nine critical, global biophysical thresholds to human development, and further claims that crossing these boundaries has catastrophic consequences for human welfare.[33] Some of these boundaries arguably already have been transgressed: the amount of $CO_2$ in the air is higher than in the past 2.5 million years and a new record of 400 ppm of $CO_2$ - triggering a glut of media attention - was recorded in 2014.[34] Morally and politically, it is not hard to argue the case that states are duty-bound pro-actively to steer clear of such critical thresholds that threaten human survival, if necessary by deploying environmental enhancement technologies. There is little room for arguing the logic that, when broadly conceived risks of unintentional climate change significantly exceed those of intentional climate change, the right thing to do is to turn to engineering the climate intentionally. A priori preferences for the status quo (i.e. unintentional and ill-considered anthropogenic environmental change) over risks from intentional and considered change

30 On the problem of hybrids on nature conservation law, for example, see A. Trouwborst, 'Exploring the Legal Status of Wolf-Dog Hybrids and Other Dubious Animals: International and EU Law and the Wildlife Conservation Problem of Hybridization with Domestic and Alien Species', in: (2014) 23 *Review of European, Comparative & International Environmental Law*, 111-24.

31 See J.W. Erisman *et al.*, 'How a Century of Amonia Synthesis Changed The World', (2008) 1 *Nature Geoscience* 636-39.

32 J. Rockström *et a.l*, 'A Safe Operating Space for Humanity,' *Nature* 461, no. 24 (Sept. 24, 2009).

33 These are land-use change, biodiversity loss, nitrogen and phosphorous levels, freshwater use, ocean acidification, climate change, ozone depletion, aerosol loading, and chemical pollution.

34 Up to date information is available on the Internet at http://www.esrl.noaa.gov/gmd/ccgg/trends/. In February 2014 the level stood at 400.26.

indeed are irrational, but consistent with what psychologists and economists have taught us about biases favouring the status quo over change.[35] It appears that whilst we have resigned ourselves to the inevitability of unintentional unplanned human interventions in complex earth systems notwithstanding risks, the prospect of wilfully assuming the immense responsibilities that come with intentional and considered interventions in such earth systems simply is too daunting to bear.[36] However, we may not be in a position to avoid cutting the Gordian knot much longer. Either we address potentially catastrophic risks of anthropogenic climate change engineered intentionally, or finally seriously engage similar risks of continued reliance on international mitigation and adaptation regimes that have allowed the consequences of unintentionally engineered anthropogenic climate change to become uncomfortably close to catastrophic.[37] Unless we find some categorical imperative instructing that risks of oblivion due to intentional climate engineering *ipso facto* outweigh those resulting from unintentional climate change, regulators hence might be duty-bound to decide in favour of pursuing intentional change by means of a well-considered climate engineering policy.

At present, the multitude of risks (environmental, moral, health, geo-political etc.) of different forms of climate engineering remains highly uncertain, of course, and the scientific basis to make that dramatic call therefore for the time being is grossly insufficient. Nor, for that matter, are risks of climate change resulting from business as usual scenarios (i.e. continued efforts to curb unintentional climate change through 'radical' cuts in greenhouse gas emissions coupled to adaptation measures) all that much better understood. Addressing those uncertainties, then, is a necessary if insufficient step on the road to informed policies aimed at steering humankind clear of climate disaster. This calls for multi-disciplinary research answering the highest standards of scientific and academic excellence, which may then pave the way for well-conceived public debates and, finally, a political decision-making process enjoying both input and output legitimacy.[38] As recent experience with (ultra-) hazardous technologies shows, that road is a treacherous and long one, demanding a combination of massive investment of resources, political leadership and perseverance in the face of inevitable setbacks.

## III. Concluding Remarks: The Case for a Law of the Mammoth

Climate engineering is a radical technological response to anthropogenic climate change and will most probably be resorted to only when it is near certain that current mitigation and adaptation policies cannot avert climate catastrophe. Should that point arrive, it is not altogether implausible to expect that states will be duty-bound to deploy climate engineering techniques, for example in order to fulfil the socio-economic right to health and environment. Climate engineering is radical especially in terms of the nature and scale of the risks involved, its institutional and global governance implications, and a host of other legal, ethical and policy concerns arising from the absence of agreed benchmarks as to what constitutes a desirable re-engineered climate.

The central question this article asked is whether conventional EU environmental law is fit to take on the challenges that arise from the large-scale deployment of a host of enhancement technologies. To equate that question with 'risk' is to dodge the issue of principle, and moreover fails to acknowledge the message implied in the Planetary Boundaries Hypothesis that conventional less effective policy responses carry equal or greater risk. We have therefore attempted to uncover the central tenet of conventional EU environmental law, which we argued

35 See, for example, D. Kahnemann and A. Tversky, 'Prospect Theory: An Analysis of Decision under Risk', (1979) 47 *Econometria* 263-92.

36 The term 'ecological anxiety disorder' has been coined to denote the state of paralysis that has ensued among conservation biologists, restoration ecologists and the like, because of the rapid loss of 'environmental baselines, grounded and normal conditions from which to make objective assessments for advocating interventions in the world.' See P. Robbins and S.A. Moore, 'Ecological Anxiety Disorder: Diagnosing the Politics of the Anthropocene', (2013) 20 *Cultural Geographies*, 3-19.

37 For qualitative challenges ot 'climate law' and more generally 'adaptation law' see J.B. Ruhl and J. Salzman 'Climate Change Meets the Law of the Horse' (2013) 62 *Duke Law Review* p. 975 et seq. See also J.D. Graham and J.B. Wiener, *Risk vs. Risk Tradeoffs in Protecting Health and the Environment* (Cambridge: Harvard University Press, 1997).

38 Input legitimacy is derived from participation by citizens and measured by the degree of responsiveness to their concerns. Output legitimacy is judged on the basis of the effectiveness of policies in furthering the interests of citizens. Throughput legitimacy refers to the efficacy, transparency and openness of the EU's governance process as such. See V.A. Schmidt, 'Democracy and Legitimacy in the European Union Revisited: Input, Output and 'Throughput'', (2013) 61 *Political Studies* 2-22. See also S. Borrás, C. Koutalakis and F. Wendler, 'European Agencies and Input Legitimacy EFSA, EMeA and EPO in the Post-Delegation Phase' (2007) 29 *Journal of European Integration* 583-600.

is to preserve, protect and improve the environment. De-extinction projects, which may be viewed as an equivalent of what climate engineering endeavours to achieve for the non-living environment, give rise to difficult and new questions of a temporal and substantive nature (should we bring back the woolly mammoth or confine our efforts to species that are victims of unsuccessful conservation policies, and should we engineer a habitat that supports mammoths?). They also serve to illustrate the fluidity of the divide between 'improvement' and 'enhancement'. We have tentatively suggested that technological interventions in the environment that aim to attain pre-agreed targets can be argued to be ramifications of the duty to improve the environment. This indeed is a big claim that perhaps needs further corroboration, as it means that the Pyrenean ibex must be cloned because it featured on Annex IV(a) of the Habitat Directive, and climate engineering must be deployed (again taking risk out of the equation) to realize agreed temperature reductions.

Environmental enhancement, then, is an intentional technological intervention in the environment in pursuit of human interests, needs or rights which takes place outside the confines of such pre-agreed environmental base-lines. The return of the mammoth is an example of environmental enhancement, as is climate engineering deployed to recreate climates that are colder than what has been internationally agreed as a target, the genetic manipulation of the *Aedes Aegypti* mosquito also enhances the environment, etc.

Can EU environmental law cope with environmental enhancement? It is suggested that the answer is in the negative. Crucially, EU environmental law does not include a general ecological standstill principle, but base-lines must be purposefully established by legal or administrative acts that assign environments a particular status. For example, SACs must be designated, binding ambient or aquatic quality objectives articulated, limit values for point-source emissions fixed, etc. With only very few exceptions, the protection of environments or the control of substances and industrial processes hinges on such prior constitutive acts.[39] Cloud formations have become famous by the Dutch masters of the Golden Age and are much loved today, but there is nothing that protects them until an act has been adopted establishing that cloud formations are worthy of protection. Similarly, *Aedes Aegypti* mosquito is outlawed until the day that the is explicitly protected. If dyeing the oceans white to combat climate change sounds like a good idea, then the good news is that colouring the ocean is permitted until it is prohibited.

In those instances where base-lines have been established, moreover, they dictate that environments must not deteriorate relative to that base-line (duties to preserve and protect) but do not rule out that states decide to enhance the environment provided that isolated legal 'no go-areas' are respected (in the context of the Habitat Directive Article 22 would not appear to rule out the return of the woolly mammoth). In short, and remembering that we have intentionally left risk out of the equation, environmental enhancement essentially is permitted unless it is prohibited.

Even though EU environmental law is of relatively recent origin (the first environmental action program dates from 1973), the drafters of course could never have fathomed that, within their lifetimes, we would be seriously discussing enhancing the climate and every single aspect of the living environment. For that reason alone there is ample reason urgently to consider the outlines of a Law of the Mammoth that reflects this new reality. A blank prohibition on environmental enhancement is most probably unrealistic, as the example of the *Aedes Aegypti* mosquito illustrates. Nor is it necessarily desirable, given the dire situation humankind has engineered itself into. At present however, due to the absence of a generic ecological standstill principle, EU environmental law effectively operates on a 'yes unless' basis. With hindsight that paradigm perhaps has never had much going for it, with foresight it seems crucial to instigate a fundamental overhaul of environmental law in ways that afford protection to the many different values intrinsic in the environment, regardless whether they have been explicated in legal acts acknowledging those values.

39 The REACH regulation implements an important innovation in this respect. Reversing preceding chemicals legislation, it stipulates that unless producers of chemicals can show a substance to be safe the substance cannot be marketed. See F.M. Fleurke and H. Somsen, 'Precautionary Regulation of Chemical Risk: How REACH Confronts the Regulatory Challenges of Scale, Uncertainty, Complexity and Innovation, (2011) 48 *Common Market Law Review*, 357-93.

# Cultivation Restrictions for Genetically Modified Plants

## On Variety of Risk Governance in European and International Trade Law

*Gerd Winter**

*Directive (EU) 2015/412*[1] *allows Member States to restrict the cultivation of genetically modified seed or propagating material, although their placing on the market has been authorized. This so-called opt-out is meant to resolve the current Member States' conflict about gene technology by facilitating differences of states concerning cultivation regulations. The concept has at the same time the potential to pioneer a general reorientation of European and even global principles of free trade. Whereas trade restrictions on grounds of health and environmental protection could thus far only be justified on a strict scientific basis, a variety of risk perceptions and evaluations are now made acceptable. The article explores what grounds may justify cultivation restrictions beyond those identified in a concrete environmental risk assessment. Two categories are suggested: general environmental concerns weighing systemic effects and uncertainty, and trans-environmental concerns such as the use-value of genetically modified plants, the avoidance of costs resulting from policies of coexistence with conventional plants, the halting of agricultural industrialisation, and ethical considerations. It is further examined if cultivation restrictions based on such grounds are compatible with the EU rules of free movement of goods and relevant WTO agreements. The pertinent report of a WTO-Panel on genetically modified plants is scrutinized for this purpose and a dissenting interpretation developed.*

## I. Preliminary Considerations

### 1. The Trajectory of Regulating Genetic Engineering

Since its emergence, genetic engineering has triggered significant controversy, which became manifest in society, economy, academia and politics alike. This has not only played out at the domestic level, but also within the EU and on a global scale. In a first phase, compromises were sought for the development of a generally binding framework; in a second phase, when it became obvious that differences were irreconcilable, compromises were sought enabling the coexistence of genetic engineering and conventional or organic agriculture respectively.[2]

The first phase can itself be divided into four stages:

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1 Directive (EU) 2015/412 of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory, OJ L68, p. 1.

2 See for a similar analysis N. de Sadeleer, Marketing and cultivation of GMOs in the EU. An uncertain balance between centrifugal and centripetal forces, 4/2015 EJRR, pp. 532-558. What would be required in the near future is that an entirely new and broader approach is developed for the regulation of modern biotechnology. This would encompass techniques of highly invasive breeding and of synthetic biology; at the same time, the genetic engineering law—itself in need of revision—would be merged with such an approach. See G. Winter, P. Knoepfel, H.-P. Fricker, *The biotechnical utilisation of genetic resources and its regulation. An integrative approach*. Bienne (sanu durabilitas) 2014 (http://www.sanudurabilitas.ch/uploads/downloads/5/Durabilitas_2014_Genetic_resources.pdf

(1) The controversy over the introduction of genetic engineering in the late 1980s led to national and European legislation that removed genetic engineering from coverage by the more general environmental law on industrial emissions and toxic products, and regulated it separately, especially in the Directives 90/218/EEC and 90/220/EEC and corresponding national laws, such as the German *Gentechnikgesetz* (GenTG [Genetic Engineering Act]) of 1990.

(2) A new controversy at the end of the 1990s, fanned among other things by the BSE crisis, led to a more restrictive regime with regard to the release and placing on the market of GMOs; it entailed especially a stricter risk assessment and an emphasis on the precautionary principle. The cornerstone of this development was Directive 2001/18/EC[3].

(3) The controversy found continuation in diverging risk perceptions and policy among Member States (MS). This prompted the adoption of Regulation (EC) 1829/2003[4] for genetically modified (GM) food- and feedstuff which transferred authorization to the European level.

(4) The impasse between supportive and rejecting Member States remained both being unable to achieve a qualified majority for or against authorization. Under prevalent competence rules the decision-making powers fell to the Commission, which however was reluctant to use them. To the extent that it did use them approvingly, rejecting Member States reacted with cultivation bans, which were based on the powers to introduce additional measures (Art. 95 EC-Treaty, now Art. 114 Treaty on the Functioning of the European Union (TFEU)) or on the safeguard clause of Art. 23 Directive 2001/18/EC.

The second phase brought about a move away from the concept of a fully harmonized seeds regime. Consensus for the market authorisation was now attempted to be reached through enabling divergence of cultivation practices. Two steps can be distinguished:

(5) So-called coexistence measures were accepted. Member States should be able to separate the cultivation, processing and storage of GM and unmodified plants thus allowing both to be handled side by side.[5]

(6) Because such measures are difficult to organize and anyway hardly effective, coexistence policy did not change majorities between Member States. This finally led to the recent more fundamental solution: the introduction through Directive (EU) 2015/412 of an opt-out clause into Directive 2001/18/EC. Member States should retain powers to restrict[6] the cultivation of GM plants at larger scale, and even country-wide.

In conclusion, the opt-out model is a radical solution to a long-running controversy. Taking recourse to the principle of subsidiarity[7], it enables a variety of regulatory practices of Member States.

## 2. The Uneven Constitutionalisation of Economic and Social/Environmental Interests

The concept of an opt-out is an innovative move also in the broader context of what can be called the secular economization of societal life of which the ever more technical design of food is a case in point. Opting out allows to position cultural difference in this fundamental trend, a trend that has been grasped by a variety of categories including (sociologically) the formal-rational bureaucracy in economy and state forcing the citizen into a "Gehäuse der Hörigkeit" (shell of bondage) (M. Weber[8]), (philosophically) the invasion of the instrumental systems-

3 Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC - Commission Declaration, OJ L 106, 17.4.2001, p. 1. Latest consolidated version http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02001L0018-20150402

4 Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (Text with EEA relevance), OJ L 268, 18.10.2003, p. 1. Latest consolidated version http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02003R1829-20080410 According to the - rather dubious - prevailing interpretation food- and feedstuff also encompasses seeds as being "a source material for the production of food" (Art. 2(no. 8) Reg 1829/2003/EC). Cf. Recital 34 and Art. 6(3)(c) of the same Regulation.

5 See Art. 26a Directive 2001/18 which was introduced by Art. 43 Reg 1829/2003.

6 In this text, the term cultivation restriction encompasses the prohibition of cultivation in contrast to the aforementioned Directive, which uses 'restriction' and 'prohibition' separately.

7 Cf. Recital 8 of Directive (EU) 2015/412: "In that context, it appears appropriate to grant Member States, in accordance with the principle of subsidiarity, more flexibility to decide whether or not they wish to cultivate GMOs on their territory without affecting the risk assessment provided in the system of Union authorisations of GMOs, [...]".

8 G. Roth, C. Wittich (eds.) *Max Weber, Economy and Society*, Berkeley (University of California Press) 1978, p. 1402.

world into the communicative life-world (J. Habermas[9]), or (ecologically) the preponderance of the economical over the social and environmental spheres[10]. This development has been legally supported through buttressing economic interests with constitutional protection against governmental regulation, and even granting them subjective rights of stronger build tham those of societal interests. Significant steps in this trajectory were the following:

(1) The fundamental rights to property and profession stipulated in national constitutions, which originally aimed at the liberties of the individual person, were extended to any economic enterprise.[11] Whether the cobbler in his corner shop or the multinational corporation, all could similarly claim protection of their property and occupational freedom. This meant that any economic regulation that was previously considered to belong to the political sphere was now conceived as an intrusion into basic rights and in consequence became a candidate for review by constitutional oversight.[12]

(2) The free movement of goods was stipulated in the wording of the European Treaties only as an objective principle addressed to the Member States[13], but was construed as implying subjective rights.[14] In interplay with the Dassonville-formula, which extended the principle of free trade to any product regulation whether it treated foreign goods differently or not from domestic goods, corporations were entitled to subject any restrictions to international trade to review at the European courts. Furthermore, the free movement of goods became the yardstick under primary law for EU secondary legislation—also in the form of a subjective right for corporations.[15]

(3) By dint of case law, the ECJ developed a fundamental right of entrepreneurial freedom, which comes without the individual person as anchor point and positions itself against any European regulation of economic activity. It was codified in the Charter of Fundamental Rights (CFR) as the general freedom to conduct a business (Art. 16) standing apart from the personal freedom to choose an occupation (Art. 15).

(4) International investment treaties and arbitration have given investments of transnational corporations the status of property and thus subjected interventionist state regulation to scrutiny in terms of compensation for indirect expropriation.[16] International trade law although still being law between states often has its effect in serving trade interests of large enterprises such as producers of asbestos, of cigarettes, of bananas, of genetically modified plants (to name a few at stake in famous dispute settlements).[17]

This constitutionalisation and at the same time subjectivisation of economic interests has not been paralleled by an equal constitutional status of social and even less so of environmental interests. Persons who are not individually and seriously affected have hard-

9 J. Habermas, *The theory of communicative action*, Cambridge (Polity Press) 2006, vol. II, chap. VI.2.

10 Cf. G. Winter, A Fundament and Two Pillars. The Concept of Sustainable Development 20 Years after the Brundtland Report, in: H.-C. Bugge and C. Voigt (eds.) *Sustainable Development in International and National Law*, Groningen (Europa Law Publishing) 2008, pp. 25 - 45

11 Taking Germany as an example the extension of the right to property to business corporations had already been prepared by the Supreme Court of the German Reich (Reichsgericht) and was continued by the Federal Court of Justice (Bundesgerichtshof - BGH). Cf. H. Rittstieg, *Eigentum als Verfassungsproblem*, Darmstadt (Wiss. Buchgesellschaft) 1975, pp. 252-271. Concerning the right to profession the Federal Constitutional Court (Bundesverfassungsgericht – BVerfG) detached its protective scope from traditional vocation profiles and included also any "atypical (but permissible) activities freely chosen by individuals" (BVerfGE 7, 377 (397). While in the fine-tuning of the protective intensity the court still somewhat privileged the personal aspect of a vocation, this context has meanwhile been lost almost completely (cf. BVerfGE 68, 193 ff. (206); remnants in BVerfGE 95, 220 et seq. (242) and BVerfGE 99, 367et seq. (389)).

12 For this development and its criticism, which has faded away nowadays, cf. H. Ehmke, *Wirtschaft und Verfassung*, Karlsruhe (C. F. Müller) 1961, pp. 7 ff., 56 ff. For a late yet somewhat farcical case of this problematique see BVerfGE 80, 137 ff., where the court declared horse riding in forests as protected by the basic right to developing one's personality, Judge Grimm dissenting pp. 164 et seq.

13 Art. 12 and 13 EECT, now Art. 34 and 35 TFEU.

14 ECJ Case 26/62 (van Gend & Loos), Slg. 1963, pp. 25 f.; ECJ Case 8/74 (Dassonville) paras. 7/9.

15 ECJ Case 15/83 (Denkavit), para 15. See also fn. 67 below.

16 O. Fauchald, Property and environmental protection in investor-state arbitration, in: G. Winter (ed.) *Property and environmental protection in Europe*, Groningen (Europa Law Publishing) 2016, pp. 77-92.

17 Recent discourses on bringing human rights in into trade disputes (cf E.-U. Petersmann, *International economic law in the 21st century*, Oxford (Hart Publishing) 2012, chapters IV and VII) are under risk to finally end up with even more strengthening economic property rights. As an example see Petersmann himself, op. cit. p. 469: "By giving private investors directly enforceable rights to challenge governmental investment restrictions [...] international investment law offers private citizens legal and judicial remedies that tend to be more effective in most other areas of international law, including human rights law and international trade law". The statement is true but for the obtuse equating of investors' rights and human rights.

ly any possibility to take legal action in request for better social or environmental protection. Association actions do have developed instead but only in certain sectors and depending on restrictive procedural preconditions.[18] Hence, the protection of social and environmental interests largely depends on the political path, i.e. ultimately the willingness of governments to engage themselves.

As a requirement of the constitutionalisation of economic rights such political will must be justified by a public interest and abide by the principle of proportionality. In this way, public interests triggering restrictions on economic freedoms are in a defensive position from the outset. They are pressed in a higher-ranking constitutional and international legal framework and thereby become depoliticized, meaning that the political discretion of the regulator is not anymore solely based on the government's democratic basis but "conceded" by the now responsible courts.

Such concession, or judicial self-restraint, has been more or less generous depending on the national traditions and international contexts of courts.[19] But in relation to health and environmental protection policy the general mood has been to ask for scientific proof of adverse effects or – where the precautionary approach is accepted – at least scientific indication of risk.[20]

This reliance on science has largely hemmed courts, both European and international, to acknowledge cultural differences in the perception and evaluation of risks.[21] Cultural traditions affect concerns about the environment and human health, in particular insofar as adverse effects escape scientific proof.[22] Of course, cultural traditions also induce attitudes beyond the health and environmental realm. For instance, they influence visions about life styles ("do we want meat from cloned pigs?"), agricultural practices ("do we want lifeless villages and dreary landscapes?"), technological progress ("do we want dequalifying high-tech?"), etc. Cultural traditions are rooted in the history of nations and states and are therefore difficult to harmonize. As for the thematic genetically modified plants, cultural traditions allow to explain why GM agriculture is seen rather critically, for instance, in Germany, while attitudes are rather more positive, for instance, in Spain.[23] The opt-out concept now opens a door for accepting such variety, both in relation to broader environmental and trans-environmental concerns. We will see how the two can be defined and stand the test of court review in terms of the constitutionalised principles of free trade.

## II. The Opt-Out Concept

Directive (EU) 2015/412 modifies Directive 2001/18/EC by, among others, adding the new Art. 26b on opting out. This article sets out the procedure and substance of opt-out measures, their legitimate grounds, and further requirements.

### 1. Procedures and the Substance of Measures

Two possible procedures are introduced:

(1) In an authorization procedure for GM seeds, a Member State can in a statement vis-à-vis the Commission demand to restrict the geographical scope of the authorization. The applicant can adjust the application accordingly, but is not obliged to do so.[24]

18 For an account of subjective rights and locus standi in environmental matters see the contributions in J. H. Jans, R. Macrory, A. M. Moreno Molina (eds.) *National courts and EU environmental law*, Groningen (Europa Law Publishing) 2013, on EU law, and P. Birnie, A. Boyle, C. Redgwell, *International law and the environment*, Oxford University Press 3rd ed. 2009, pp. 268-315 on international and comparative law.

19 For an elaborate discussion see P. Craig, *UK, EU and global administrative law*, Cambridge (CUP) 2015, pp. 236-260, 477-487.

20 For the EU see the landmark decision CFI T-13/99 (Pfizer). Cf. Craig, op. cit. pp. 478-487. For the WTO see analysis below, chapter IV..

21 M. Kritikos, Traditional risk analysis and releases of GMOs into the European Union: Space for non-scientific factors? *European Law Review* 2009, pp. 405 – 432; D. Chalmers, G. Davies, G. Monti, *European Union Law*, Cambridge (CUP) 2nd ed. 2010, pp. 902-905; P. Lamy, The Emergence of collective preferences in international trade: implications for regulating globalisation. Speech at the Conference on "Collective preferences and global governance: what future for the multilateral trading system", Brussels, 15 September 2004, available at http://europa.eu/rapid/press-release_SPEECH-04-400_en.htm?locale=en (8.01.2016). See further on the WTO dispute settlement practices infra ch. IV.

22 See further O. Renn, B. Rohrmann (eds.) *Cross-cultural risk perceptions. A survey of empirical studies*, Dordrecht (Kluwer) 2000.

23 In Germany explanations may be considered that lead back to German romanticism, to holistic conceptions of science and philosophy, to societal learning from the horrific effect of Nazi racial ideology, and others more. Cf. P. Watson, *The German genius*, New York (HarperCollins) 2010.

24 Art. 26b(1) Directive 2001/18/EC.

(2) If the applicant insists in an unrestricted authorization and the latter is granted accordingly, the Member State may itself adopt measures restricting cultivation, after it has given the Commission the opportunity to "make any comments it considers appropriate".[25]

The restriction of cultivation can relate to agricultural practices or entail the entire banning of cultivation of a GMO. It can be limited to specific areas (such as a single nature protection area), categories of areas (such as all Natura 2000 areas) or extend to the entire territory of a state.[26]

## 2. Grounds in Summary and Proportionality of Measures

The cultivation restrictions must be based on grounds determined by Art. 26b (2) Directive 2001/18/EC, including:

a) environmental policy objectives; b) town and country planning; c) land use; d) socioeconomic impacts; e) avoidance of GMO presence in other products; f) agricultural policy objectives; g) public policy.

Since these grounds are only listed as examples, additional grounds can become relevant.

Measures based on these grounds (or, reading grounds as objectives, measures persuing such objectives) need to be proportional.[27] This means according to EU and Member State jurisprudence that the measure must in view of the objective be appropriate, necessary and proportionate *strictu sensu*.[28]

When applying this scheme four qualifications should be considered.

First, the core rational of the directive must be brought to *effet utile*[29], namely to enable and not to prevent a pluralism of cultivation regulations among the Member States.

Second, both the environmental and the trans-environmental grounds for measures must be acknowledged as legitimate objectives because they are offered by EU legal act.

Third, corresponding to its democratic accountability the regulator has broad discretion to determine what objective to choose, and what measure is appropriate, necessary and proportionate. It has been observed that the ECJ developed differential standards when checking EU legal acts or MS legal acts under EU primary law. Its judicial self-restraint usually is greater in relation to EU action than in relation to MS action.[30] In the present context we are confronted with a hybrid situation: While it is MS action that is to be checked this action is directed by EU secondary law which intentionally provides the MS with margins of discretion. This means that the standard check would be whether the action was "manifestly inappropriate".[31] In terms of necessity of means the more demanding and general the policy objective is, the greater the scope of potential alternatives becomes and the more deference of the courts to the choice of the democratically legitimated rule-maker should apply.

A fourth consideration may be added which hardly appears in the CJEU jurisdiction[32] but more so in pertinent case law of German courts: Proportionality should be checked differently in relation to individual administrative decisions and general legal norms.[33] In relation to the first any affected individual person must be treated proportionally. However, if general legal norms are concerned, not any individual but the average affected person is taken as reference. According to the BVerfG "the abstract possibility of goal attainment suffices".[34] In our case of a general regulation, for instance, when the ground for restricting cultivation is to maintain GM-free status of valuable ecosystems, and a ban is generally established for all nature reserves, it is not necessary to go through the individual nature reserves and to con-

25 Art. 26b(4)(c) Directive 2001/18/EC.

26 Art. 26b(3)(cl. 1) Directive 2001/18/EC.

27 Art. 26b(3)(1) Directive 2001/18/EC.

28 See for an authoritative formulation of the doctrine ECJ C-331/88 (Fedesa), para. 14.

29 *Effet utile* is an interpretation guidance often used by the CJEU to enhance the effectiveness of EU law. See D. Chalmers, G. Davies, G. Monti, *European Union Law*, Cambridge (CUP) 2nd ed. 2010, p. 1015.

30 Chalmers/Davies/Monti, op. cit. p. 368.

31 ECJ C-331/88 (Fedesa), para. 14.

32 Cf. P. Craig, *EU Administrative Law*, Oxford (OUP) 2006, chap. 17 and 18.

33 For an example in the ECJ jurisdiction see ECJ C-594/10 (van Laarhoven) para. 33 concerning tax law, where the court held that a flat rate method of calculating taxes is allowed if proportional to its aim.

34 BVerfGE 67, 157 (175). In German police law the doctrine was developed that normative acts may be based on an "abstract danger" ("abstrakte Gefahr") while the precondition for individual acts is a "concrete danger" ("konkrete Gefahr"). Cf. C. Gusy, *Polizeirecht*, Tübingen (Mohr Siebeck) 5th ed. 2003, p. 407.

sider, whether they would be damaged. Or else, when the ground given is uncertainty about the predicted impact of a specific GMO and a nationwide ban on cultivation is established for this GMO, then it is not necessary to require that the uncertainty is determined for each individual site of cultivation.

## 3. The Major Grounds in Detail

### a) Environmental Policy Objectives

Environmental policy objectives open up a wide field of regulation, which is, however, limited by the proviso that the measures shall not conflict with the environmental risk assessment (ERA) carried out as part of the procedure authorizing the bringing on the market of the GM seed.[35] The ERA is designed to proceed in 6 steps including an assessment of

1) the hazardous characteristics of the GMO
2) the magnitude of adverse effects
3) the likelihood of their occurrence
4) the risk understood as the combination of magnitude and likelihood
5) the mitigation effects of risk management strategies
6) the resulting overall risk.[36]

In order to determine the latitude available to the Member States, it is advisable to distinguish two intellectual operations in the process of risk regulation, namely the scientific study and appreciation of risks, and the evaluation – or weighing – of risks. In my conception, the study and appreciation of risk is the substance of what is called risk assessment, while the weighing of risk is part of the so-called risk management, which also encompasses the selection and design of appropriate instruments (see the following table 1).[37] One may distinguish between an "internal" and "external" weighing of risks.[38] The weighing of risks is also the place for determining the level of protection which in some legal orders is marked as an important step of policy choice.[39]

*Table 1: Suggested structure for risk analysis in the EU*

| risk assessment | | risk management | |
|---|---|---|---|
| study of risks | appreciation of risks | weighing of risks (internal and external); choice of level of protection | selection and design of instruments |

*aa) The Scientific Study and Appreciation of Risks*

In the given context, the study of risks generates scientific statements especially about the characteristics and effects of GMOs. Risk assessment inextricably also includes judgmental appreciation, which still belongs to the realm of science and is open to scientific reasoning.[40] This is important to note against naive perceptions which assume that science is perfectly value free. Such appreciation includes, for instance: the choice of representative paths of impact to be tested, the interpolation from a path of impact to a similar other one, the assessment of the validity and reliability of a test or of a propagation model, the calculation of a safety factor when conclusions need to be drawn from test animals to protected organisms, the determination of the degree of uncertainty, etc.

If a Member State considers that within an ERA a statement of fact is wrong or that a scientific appreciation is erroneous, it is not allowed to simply deviate, because it would then act contrary to the ERA, which is as said prohibited. Of course, the Member State remains free to take legal action against the allegedly unlawful authorisation.[41]

This is however different, if the ERA concerning a specific GMO does not address certain aspects, especially if certain effects (such as on non-target organisms) are not investigated, although this would be permissible or even necessary according to the

35 Art. 26b(3)(2)(2nd subcl.) Directive (EU) 2015/412.

36 Annex II C. to Directive 2001/18 (EC).

37 See for an elaborate concept of the relationship between risk assessment and management the procedural manual of the Codex Alimentarius Commission. Both operations are to be conducted by separate but interacting authorities. The risk manager and not the risk assessor is responsible for drawing conclusions from situations of uncertainty (CAC Procedural Manual, 32rd ed. No. 25, 28 (pp. 112 f.). Available at ftp://ftp.fao.org/codex/Publications/ProcManuals/Manual_23e.pdf 2015 (8.01.2016).

38 See further below sub bb).

39 Cf. Art. 114 (3) TFEU; for the WTO agreements see infra ch. IV 1 c) aa).

40 Similarly A. Stirling, *On science and precaution in the management of technological risk*, EC Joint Research Center, May 1999, pp. 19. ff. (http://ftp.jrc.es/EURdoc/eur19056en.pdf (8.01.2016).

41 Such action would fall under the jurisdiction of the ECJ, see Art. 51(a) ECJ Statute.

general rules for ERAs. Member States can scrutinize such effects in a complementary effort; newly gained findings can then be used as basis for their measures. The reason for this is that the ban of conflict according to Art. 26b Directive 2001/18/EC refers to the actually conducted ERA, but not to the general rules of risk assessment as stated in Annex II of Directive 2001/18/EC and the Guidance Paper of the European Food Safety Authority (EFSA)[42]. The respective Member States must conduct an ERA according to established methodology in this case.

*bb) Risk Weighing*

One needs to separate scientific statements and appreciation of fact from general evaluations emanating from environmental policy. Such evaluation may take a narrow scientific view and suggest that regulatory measures shall always be based on scientific proof of risks. It may however as well take a more cautious stance concerning the capacity of science, one significant aspect being the treatment of systemic effects and the related unavoidable uncertainty, in other words risks from complex interactions and indirect effects that escape firm scientific evidence.[43] In this vein risks must be weighed. Of course, conclusions from such weighing may not be purely speculative. They must find ground in and be substantiated by the risk assessment.

As proposed above, the weighing can be "internal" and "external". While the "external" weighing would compare the risks with the expected agro-ecological or other benefits of the GM plant, the "internal" weighing would concentrate on the characteristics of the risks themselves and evaluate them, for instance, in terms of

- a policy of keeping areas free with a view to preserve the self-organization of evolutionary dynamics
- a policy of preserving biodiversity in valuable agro-biotopes
- a cautious take on the problem of uncertainty
- a shift of the onus of proof on the users of gene technology
- a critical view of the choice of comparators with a GMO, such as parental lines
- a particularly cautious stance concerning the likelihood and consequences of a horizontal gene transfer[44]
- an emphasis on the irreversibility of releasing propagating GMOs
- a longer-term perspective on the emergence of adverse effects
- a particular awareness of epigenetic effects[45]
- a more cautious assessment of indirect agro-ecological effects of herbicide-resistant and insecticidal GM plants[46]
- the aim to avoid climate effects caused by the industrialization of agriculture fostered by GMO cultivation
- a focus on systemic objects of protection like biocenoses, ecosystems and biodiversity

It is true that such precautionary and holistic evaluation is partially seen as a task of the ERA in the market authorisation procedure. This poses the question of whether the prohibition of a conflict with the ERA also encompasses such evaluation. Thus, Annex II of the Directive 2001/18/EC laying down the ERA methodology refers under point D 2, inter alia, to subsequent direct and indirect interactions of the GM plant in ecosystems as well as to subsequent direct and indirect effects on agricultural techniques. However, though such more complex effects are frequently touched upon in the practice of ERAs, they commonly rest on weak empirical evidence, for instance, when based on very few studies the conclusion is drawn that "no evidence" of risks exists, or when it is suggested to reduce assumed risks by appropriate

42 EFSA Panel on Genetically Modified Organisms (GMO), Guidance on the environmental risk assessment of genetically modified plants. EFSA Journal 2010;8(11):1879. [111 pp.]. doi:10.2903/j.efsa.2010.1879. Available at http://www.efsa.europa.eu/en/efsajournal/pub/1879.htm.

43 A rich analysis of the possibilities and limitations of the scientific study and assessment of different risks can be found in the *Umweltgutachten 1987 des Sachverständigenrats für Umweltfragen* (SRU), BT Drs. 11/1568. For the gaps regarding ecotoxicology, see especially No. 3.1.3.2.

44 For the state of the dispute, see Statement of EFSA on the consolidated presentation of opinions on the use of antibiotic resistance genes as marker genes in genetically modified plants, The EFSA Journal (2009) 1108, pp. 1-8.

45 This includes the silencing of genes (gene silencing), position effects in the molecular context of the introduced transgene, und pleiotropic effects, i.e. the simultaneous effect on several characteristics. Cf. *Moch* et al., *Epigenetische Effekte bei transgenen Pflanzen: Auswirkungen auf die Risikobewertung*. BfN-Skripten Bd.187, 2006, pp. 20 et seq. http://www.bfn.de/fileadmin/MDB/documents/service/Skript187_gesamt.pdf (8.01.2016).

46 As with herbicide-resistant seeds that trigger the application of broad spectrum herbicides, which in turn threatens biodiversity (M. S. Heard et al., Weeds in fields with contrasting conventional and genetically modified herbicide-tolerant crops. I. Effects on abundance and diversity. Phil. Trans. R. Soc. Lond. B 358/2003, pp. 1819-1832), or as with insecticidal seeds that release toxins into the soil, cause new resistances, etc.

cultivation management.[47] Such remarks transcend what an ERA is meant to do, namely to establish what effects are possible, what their likelihood is, and what degree of uncertainty is involved. To the extent that ERA documents include rough evaluations of indirect effects, the acceptability of risks or even recommended actions, they move into the argumentative realm of risk weighing and the choice of instruments, i.e. the realm of risk management.

The extent to which a risk weighing is apposite depends on the legal provisions applicable in the given case, and especially on the latitude granted to the responsible authority. The wording of Art. 7(1) and Art. 19(1) Regulation (EC) 1829/2003 is open ("consider"), refers to "any relevant provisions" of the entire EU law as yardstick and allows "other legitimate factors"[48]; hence, discretion is given. In my opinion, risk weighing can be accommodated by this discretionary scope; it can encompass "other legitimate factors", and their anchoring in Art. 26b Directive 2001/18/EC turns them also into "relevant provisions of Community law".

In summary, Art. 26b Directive 2001/18/EC while prohibiting a conflict with the scientific assessment of risk does not exclude different views about the overall risk evaluation. Although the market authorization cannot be questioned, leeway is given with regard to cultivation; here, risk weighing can take place and general environmental policy evaluations can have an impact. Put bluntly, Member States can base their cultivation regulations on those grounds that the Commission is allowed to invoke in its risk management and go beyond a straightforward scientific risk assessment. This applies even to those grounds the Commission has in fact not invoked in a given case.

### b) Socio-economic Impacts

The consideration of socio-economic effects that could result from the cultivation of GMOs allows to reflect on a wide field of consequences. To substantiate them, European and international expert committees compiled some reports, which however do not offer more than general classifications for the steps of analysis and the assessment dimensions.[49] In general, there is a lack of data on socio-economic effects. Most readily available are studies on profitability of GM and non-GM agriculture as well as on consumer readiness to buy GM products.[50] However, assertions cannot only be drawn from empirically proven facts but also from forecasts based on plausible indicators.[51] Likewise, the concept of socio-economic impact encompasses not only monetarily measurable effects but also effects that can only be described and assessed qualitatively.[52] As socio-economic effects one can consider: the costs of coexistence, the lack of benefit, and consumer protection.

#### *aa) Costs of Coexistence*

Recital 15 of Directive (EU) 2015/412 mentions as a socio-economic impact the high costs or the impracticability of coexistence measures. Coexistence costs are to be expected

- for GM-free agriculture insofar as it has to finance studies on whether its products are GMO-free;
- for GM agriculture insofar as it must comply with isolation distances, must keep separate GM and

47 See, for instance, the argumentation in Scientific Opinion on GM insect resistant and herbicide tolerant maize MON 88017 for cultivation, EFSA Journal 2011;9(11):2428 regarding the effect on non-target organisms and herbicide management.

48 This formulation matches the one used by the Codex Alimentarius Commission, according to which in risk management "decisions should be based on risk assessment, and taking into account, where appropriate, other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade [...]" (CAC Procedural Manual, 32rd ed.).ftp://ftp.fao.org/codex/Publications/ProcManuals/Manual_23e.pdf (8.01.2016).

49 European Commission, "Framework for the socio-economic analysis of the cultivation of genetically modified crops. First Reference Document, third Draft, 02 July 2014", Available at http://ec.europa.eu/dgs/health_food-safety/dgs_consultations/docs/ag/sum_20141212_pres_4_en.pdf (8.01.2016); CBD Secretariat, Report of the Ad hoc Technical Expert Group on Socioeconomic Considerations. Annex: Elements of a framework for conceptual clarity on socio-economic considerations UNEP/CBD/BS/AHTEG-SEC/1/3. 2014. Available at https://www.cbd.int/doc/meetings/bs/bs-ahteg-sec-01/official/bs-ahteg-sec-01-03-en.pdf (8.01.2016).

50 See, however, the rather superficial Commission report, European Commission, Report from the Commission to the European Parliament and the Council on socio-economic implications of GMO cultivation on the basis of Member States contributions, as requested by the Conclusions of the Environment Council of December 2008. SANCO/10715/2011 Rev. 5 (POOL/E1/2011/10715/10715R5-EN.doc).http://ec.europa.eu/food/plant/docs/plant_gmo-socio-economic_considerations-socio_economic_report_gmo_en.pdf (8.01.2016).

51 Similar M. Herdegen in H.-G. Dederer, M. Herdegen, *Anbauverbote für gentechnisch veränderte Organismen(„Opt-Out"),* Berlin (LIT Verlag) 2015, at fn. 62.

52 The European Commission ignores this in its draft of a Framework for the socio-economic analysis of the cultivation of genetically modified crops (above fn. 49).

GM-free products and must process them separately;
- for cultivators and producers of non-GM seeds insofar as they must pay attention to varietal purity and introduce the respective protective measures and investigations;
- for cultivators and producers of GM seeds insofar as they must separate from each other their GM and GM-free facilities and activities;
- for those processing and retailing food insofar as they must separate from each other GM-free and GM plant processing and placing on the market;
- for official monitoring, especially when different regulations apply from MS to MS, region to region and site to site;
- from the destruction of contaminated products and from compensating the damages of affected farmers.

Coexistence measures are particularly impracticable in regions of small-scale agriculture, where no sufficient puffer zones can be established. If one were to significantly expand the required puffer zones in response to recent studies into the distances pollen travels[53], cultivation would also be impeded in other regions.

*bb) Lack of Benefit*

Another dimension of the socio-economic impact is the benefit of GM plants that may be considered as such or weighed against environmental risks. In the latter case the socio-economic ground would overlap with the ("external") risk weighing suggested as element of environmental policy. In terms of benefit, it might for instance be doubted whether the use-value of some GM products is better than that of conventional or organic products.[54]

In principle, though, it is constitutionally not permissible that the state decides on use-values and thus determines whether a product is needed; such decisions are the domain of the market.[55] Nonetheless, this is different, when benefits are considered in order to weigh risks. Thus, for example, it is established that in the authorization of pesticides[56] risks are weighed against the use-value of a product. § 16(1)(no. 3) of the German Genetic Engineering Law (GenTG) also entails such a weighing up. It is likely that risk-benefit analyses are also a, yet implicit, part of the European Commission's practice of authorizing GMOs, when, for instance, an overall risk evaluation concludes that a risk was "acceptable" or "negligible". In such cases the underlying consideration appears to be that the risk is offset by a larger advantage. Hence, when things turn out vice versa, i.e. the risk outweighs the advantage, one could speak of a "needless risk".

The consideration of use-value is, for example, apposite when GM crops are discussed that have an increased content of certain substances, such as vitamin A in a variety of potato. A Member State may decide that this does not increase the use value significantly—consumers might after all also eat carrots—to justify accepting the residual risk of genetic modification. Or it could decide that an increased starch content of potatoes is not desirable, because the scarce agricultural area of potato cultivation was to be reserved for the production of foodstuff. The same would be conceivable with regard to the change of maize for the purpose of better yield when used for energy production.

The benefit can also be assessed in terms of agricultural production method. In this vein, a Member State can follow the argument that a herbicide-resistant plant leads to the application of more broadband herbicides than typically used in conventional agriculture. It could also be argued that an insecticidal property is not necessary in some regions, because the type of pest being addressed did not occur there; the GM seed would therefore be "needless".

*cc) Consumer Protection*

Art. 38 CFREU reads: "Union policies shall ensure a high level of consumer protection." The question is whether this article allows to derive that Member States may restrict the cultivation of GMOs, if a majority of their consumers reject GMO cultivation. Art. 38 applies primarily to the institutions of the EU, but must also be observed by the Member States according to Art. 51(1) CFREU. Consumer protection serves, inter alia, consumer choice. The latter is

53 F. Hofmann, M. Otto, W. Wosniok, Maize pollen deposition in relation to distance from the nearest pollen source under common cultivation - results of 10 years of monitoring (2001 to 2010), in: *Environmental Sciences Europe* 2014, pp. 24 et seq.

54 See also *Umweltgutachten 2004 des Sachverständigenrates für Umweltfragen*, Baden-Baden (Nomos) 2004, No. 10.2.5.

55 Consistent case-law of the BVerfG since BVerfG 7, 377 ff. (407 f.) and the ECJ, see, for instance, ECJ C-203/96. (Dusseldorp) para. 44.

56 Cf. Art. 4(3) Reg (EC) 1107/2009.

threatened if no non-GMO products could be consumed anymore due to the unavoidable contamination of the production chain by GMOs. Such reasoning would therefore be legitimate. But it would have to be weighed against the freedom of choice of those consumers who prefer GM products.

### c) Agricultural Policy Objectives

The protection of agricultural ecosystems, the preservation of small-farm agriculture and the promotion of organic agriculture may, inter alia, qualify as agricultural policy objectives. They can partially also be categorized as environmental or socio-economic objectives. This overlap can be explained by the fact that agriculture is dependent on functioning ecosystems, economic livelihood and social embedding. The overlap is acceptable because different grounds can be listed cumulatively.[57]

#### *aa) Protection of Agricultural Ecosystems*

The protection of agricultural ecosystems may, for instance, aim at providing GM-free status of area types in order to preserve biodiversity in valuable agricultural habitats, or at the prevention of indirect agro-ecological effects of herbicide-resistant and insecticidal GM plants.

#### *bb) Agriculture Paysanne*

A Member State could aim to foster a mode of agriculture that detracts from the current trend towards industrialisation. This trend is also fed by gene technology. The question is whether such ground would justify the restriction of GMO cultivation. The *leitbild* pursued could be what is called "*bäuerliche Landwirtschaft*" in Germany[58] (peasant-based agriculture, *agriculture paysanne*), or "local learning agricultural knowledge, science and technology (AKST)" as suggested as an option by the World Agriculture Report of 2009.[59] Under European Union law as well as international trade law a protection of products from (as I will call it) *agriculture paysanne* against competition from industrialised agriculture might be considered to be a protectionist measure. Indeed, if one focuses solely on the profitability of the individual farm, the use of GM seeds may prove to be more efficient than conventional seeds. This effect would become particularly significant in large-scale operations, because genetic engineering allows for further rationalization.

However, the preservation of *agriculture paysanne* aims at more than just the survival of a (supposedly) inefficient form of economic activity. With it, there is a broader variety of seeds, more diversity of taste and content of the products, more regional markets, more jobs and more social and cultural exchange in villages, which today often degenerate into mere dormitory places. *Agriculture paysanne* is, hence, also about the social dimension of sustainability. Art. 26b Directive 2001/18 could be the trigger and vehicle to overcome this social blindness of commercial law.[60]

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57 Art. 26b(3)(2)(1st sub-cl.) Directive 2001/18/EC.

58 Cf. the description by the Arbeitsgemeinschaft Bäuerliche Landwirtschaft e.V.: "'*Bäuerlichkeit*'—small-farm life, mindset and economic activity—means a bond with farm, nature and home, responsibility for animals, soil and plants, largely self-directed work, mindset in terms of generations and circuits, work related to the family or other close social relationships. The aim of rural economic activity is of course the best possible income, but always in the context of preserving the work place and farm—and not short-term maximum capital return without regard to the content and location of production. This stands in stark contrast to an agro-industrial orientation." (available at http://www.abl-ev.de/fileadmin/Dokumente/AbL_ev/Agrarpolitik/15-03-Beilage_Bauernstimme-kl.pdf (8.01.2016) (author's translation).

59 Local learning AKST is the most promising and workable among four options of agricultural development described in Agriculture at the Crossroads, International Assessment of Agricultural Knowledge, Science and Technology, vol. IV: North America and Europe, 2009 (available at http://www.weltagrarbericht.de/reports/NAE/NAE_full_report.pdf (8.01.2016), p. 200: "Local learning AKST is regionally focused and proactive in meeting local development and sustainability goals. It is a well coordinated multi-actor system that successfully integrates the different goals at regional and local levels. It successfully contributes to the goals of enhancing livelihoods, equity and social capital and environmental sustainability. Nutrition and human health are improved through knowledge-based sustainable, fresh and safe local diets and a reduction in meat consumption. Balanced regional economic development and stewardship of natural resources are promoted by keeping the added value and employment of input production, processing, transportation and marketing in the region and through investments in quality growth and welfare services. Due to the local orientation, there is little exportation of products or knowledge outside of NAE, but more resources of low-income countries are left untouched by NAE so they can serve other purposes including the provision of food, fiber and fuel for their own consumption. Nevertheless, many technologies developed for NAE could be appropriate for resource-poor rural communities also in low-income countries."

60 Mind that according to Art. 42 sec. 1 TFEU the chapter on competition is only applicable to agricultural production insofar as the European Parliament and the Council so determine respecting the more complex goals of EU agricultural policy. For the WTO see the preamble of the Agreement on Agriculture which prescribes to "have regard to non-trade concerns, including food security and the need to protect the environment."

One can draw on the Cartagena Protocol[61] to support such interpretation. Art. 26 of the Protocol entitled "socio-economic considerations" reads:

> "(1) The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, *socio-economic considerations* arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to *indigenous and local communities*.
> (2) The Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities." (author's emphasis)

There is no indication that the mention of "local communities" only refers to those in developing countries and not also to those in industrialized countries.

*cc) Organic Farming*

As additional, specific agricultural policy ground, one can especially add the protection and promotion of organic agriculture. Thus a Member State could designate areas in which predominantly organic agriculture is to develop and be preserved, and prohibit the cultivation of GM crops altogether in such areas. A Member State may also decide that it wants to gradually convert conventional agriculture entirely into organic production, and therefore to close its territory for the cultivation of GM seeds.

### d) Ethics and Democracy

As mentioned, Art. 26b(3) Directive 2001/18/EC lists grounds only as examples and therefore does not rule out other grounds. This may include ethical grounds and those of a democratic public.

*aa) Ethical Grounds*

Ethical grounds could be, among others:

- respect for "nature", i.e. what emerges, what lives
- confidence in the learning capacity of evolution's trial and error
- recognition of a plant's genuine character (*Eigenart*)[62]
- reverence for the Creation.

With its opening clause ("for example"), the directive provides Member States with political latitude. Before the backdrop of the above-mentioned intended pluralisation, this needs to be taken seriously. However, the given leeway needs to conform to primary law, and in particular the principle of the free movement of goods.

Important for those ethical grounds is the judgment of the ECJ in the infringement proceedings against the Republic of Poland, which excluded GM seeds from the catalogue of seed varieties and thus from placing them on the market. Poland had argued[63]:

> "In the present case, the adoption of the contested national provisions was inspired by the Christian and Humanist ethical principles adhered to by the majority of the Polish people.
> In that connection, the Republic of Poland goes on to put forward a Christian conception of life which is opposed to the manipulation and transformation of living organisms created by God into material objects which are the subject of intellectual property rights; a Christian and Humanist conception of progress and development which urges respect for creation and a quest for harmony between Man and Nature; and, lastly, Christian and Humanist social principles, the reduction of living organisms to the level of products for purely commercial ends being likely, inter alia, to undermine the foundations of society."

According to Poland's opinion, its ethic-based restriction on GMOs fell outside the scope of application of Directive 2001/18/EC, since this Directive (to be sure: its version before introduction of the opt out clause) only pursues the purpose of health and environmental protection.

The ECJ does not specify whether trade related measures based on ethical grounds are excluded in

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61 Cartagena Protocol on Biosafety to the Convention on Biological Diversity, adopted 2000.

62 Under Art. 8 of the Swiss Gene Technology Act, it is a fundamental duty to honour the dignity of living beings: "In animals and plants, modification of the genetic material by gene technology must not impair the dignity of living beings. In particular, impairment is deemed to have occurred if such modification substantially harms species-specific properties, functions or habits, unless this is justified by overriding legitimate interests. In evaluating the harm, the difference between animals and plants must be taken into consideration."

63 ECJ C-165/08 (Commission v Poland) paras. 30 f.

the scope of the Directive, and if so, whether such grounds can be recognized as a justification for trade restrictions in accordance with Art. 28/30 EC Treaty (now Art. 34/36 TFEU). In any case Poland would insofar need to carry the burden of proof for a justifiable ground, but the court found it did not meet this obligation. Poland had raised ethical concerns not as an independent ground but coincided with reasons of health and environmental protection.[64] It had even not invoked ethical grounds at all when adopting its restriction measures.

If Poland could therefore not argue to have taken a justifiable measure outside Directive 2001/18/EC, the only avenue open would be the application of this very directive, and especially—after a narrowing down of the matter in dispute by the Court—its Art. 22 (free circulation) and Art. 23 (safeguard clause). However, the safeguard clause could be invoked only in the specific situations listed there. These do not include general ethical grounds.

Given the new opt out clause one can conclude from this judgment that the ECJ remains open for the recognition of ethical grounds both under Art. 26b Directive 2001/18 and Art. 34/36 TFEU. However, it establishes almost unrealizable demands on the burden of proof, for ethical reasons cannot be stated equally precise as health or environmental risks. They are inherently general. Nevertheless, in case of a renewed referral of the question of ethical grounds to the ECJ, better substantiation of ethical concerns may persuade the court to approve them.

*bb) Democratic Values*

A Member State could try to justify the restricting of cultivation also with reference to the fact that a majority of the population rejects GM foods and wishes domestically produced foods to be GM-free. Such reasoning would in turn have to be tested for its compliance with primary law.

Since Poland had also raised this argument in the aforementioned proceedings, the reply of the ECJ is significant. It argued as far as Poland pointed to majority public opinion that a Member State may in accordance with consistent case-law

> "not plead difficulties of implementation which emerge at the stage when a Community measure is put into effect, such as difficulties relating to opposition on the part of certain individuals, to justify a failure to comply with obligations and time-limits laid down by Community law (see Case C-121/07 Commission v France [2008] ECR I-0000, paragraph 72)."[65]

The "obligations" refer to the European fundamental freedoms. In the referenced judgment C-121/07, which dealt with obstructions to the release of GMOs, the ECJ could have referred to the freedom of association under Art. 12 CFREU. In its judgment on Poland, the Court could also have considered the principles of democracy and participation according to Art. 10 and 11 TEU. Other judgments have been much more explicit in pointing to such political fundamental rights as counter-principles to the free movement of goods.[66]

This is not the point to engage with these aspects in more detail. However, it should be noted that a mere majority opinion of consumers determined in surveys does not constitute a legitimate ground for a corresponding government decision. Democracy relies on argument and political controversy. So it depends on what arguments prevail in the procedures provided for participation and decision-making. Accordingly, only substantive grounds are valid grounds such as those discussed above. However, they gain soundness if politically desired by a majority of citizens and consumers.[67]

### e) Combination of Grounds

Grounds can be combined. This means that two self-standing grounds can be cumulated, and that one ground can be complemented if it would not carry a measure alone. To give an example, for an herbicide-resistant rapeseed the following grounds might—either in cumulation or in complement—justify a nationwide cultivation ban:

– environmental policy objectives: the grounds to exclude that the GM property spreads to a wild variety; that more herbicides are applied as previously; that the herbicides used eliminate an unnecessarily wide range of plants; and that plants

64 ECJ C-165/08 paras. 54 f.

65 ECJ C-165/08 para. 56.

66 See especially ECJ C-112/00 (Schmidberger), paras. 65 ff., which concerned traffic-obstructing demonstrations against air pollution by heavy goods vehicle traffic on the Brenner motorway.

67 Similar D. H. Kahan, Cultural cognition as a conception of the cultural theory of risk, in: S. Roeser, R. Hillerbrand, P. Sandin, M. Peterson (eds.) *Handbook of risk theory*, Springer 2012, pp. 725-759.

develop resistances to the herbicide tolerated by the crop plant;
- socio-economic impacts: the ground that the advantage of saving farming costs is outweighed by the environmental risk;
- agricultural policy objectives: the ground that the industrialization of agriculture should be slowed down and *agriculture paysanne* should be promoted; the ground to exclude that seed purity is compromised and that crop variety is diminished;
- other grounds: the respect for a plant-intrinsic "Eigenart" shaped by nature's evolution.

## III. The Compatibility of Measures with the EU principle of free movement of goods

Art. 26b contains the additional proviso that the measures must be in accordance with European Union law. I will concentrate on whether the principle of free movement of goods (Art. 34/36 TFEU) and a principle of coherence of measures (provided it exists at all) may be breached.[68]

### 1. Art. 34/36 TFEU

The ECJ disclaims recourse to Art. 34/36 TFEU if the secondary legal act contains an exhaustive regulation.[69] We have hence to ask if Art. 26b Directive 2001/18/EC fully harmonises the possibilities and limitations of opt-out measures. The Directive does in fact not aim at harmonisation but at a pluralisation offering different options for measures. It both facilitates and limits options by specifying the allowable grounds and asking for proportionality of measures. The allowable grounds specify the general public interests recognized as legitimating trade restrictions according to Art. 36 TFEU and related court jurisdiction. In a paradoxical formulation, one could speak of a fully harmonized non-harmonization, or, less paradoxical, with the exhaustive structuring of pluralistic solutions.[70]

This means that those Member States that use the opt-out solution operate entirely under the Directive itself. They present no additional grounds that would need to be assessed against the standard of Art. 36 TFEU and other grounds formulated in Community law; they rather utilize grounds that are expressly provided for in Union law.[71]

In an alternative assessment, it may be assumed that the Directive does not exhaust the matter. It must then be asked if cultivation restrictions affect the international trade in goods. Cultivation restrictions are not restrictions on the placing on the market of seeds. GM seeds can still be traded without impediment. The ECJ has, however, regarded restrictions on the use of products to be trade-relevant when they "have the effect of preventing users [...] from using them for the specific and inherent purposes for which they were intended or of greatly restricting their use".[72]

It is certainly a "specific and inherent purpose" of seeds to be sown. This however would imply that any regulation of cultivation, or, more generally, any use regulation of any product, were subject of a review for the violation of the free movement of goods. The

68 I leave out the test of compatibility of cultivation restrictions with fundamental rights to enterprise and private property of national constitutions and of the CFREU. Neither do I discuss whether Art. 26b Directive 2001/18/EC itself is compatible with the principle of free movement of goods (cf. in that regard ECJ C-15/83 (Denkavit) para. 15). The test is about the same on all of these levels asking whether the public interest is legitimate and the measure proportional. It should be noted that not only the fundamental rights of GM but also that of conventional and organic farming are affected; in sum, this is about balancing multipolar relationships for which the legislator and regulator possesses broad discretion.

69 ECJ C-573/12 – Aaland Vindkraft AB – para. 57: "In that regard, it should be noted that the Court has consistently held that, where a matter has been the subject of exhaustive harmonisation at EU level, any national measure relating thereto must be assessed in the light of the provisions of that harmonising measure and not in the light of primary law."

70 Alternatively one might consider the unspecified grounds enabled by the term "for instance" in Art. 26b Directive 2001/18 as not being harmonized. In that case a partial harmonization would be given. For the possibility of partial harmonization, see ECJ C-402/03 (Skov Aer) paras 22 et seq. It needs to be noted that the entire problematique of Member States introducing additional measures would not have emerged, if the approval of seed had been based on Art. 175 ECT (now Art. 192 TFEU) instead of Art. 95 ECT (now Art. 114 TFEU). This legal foundation is more apposite, since seed is meant to be used stationary, similar to an industrial plant. It would have provided Member States with the latitude of Art. 176 (now Art. 193 TFEU). (I owe this consideration to Ludwig Krämer).

71 On the parallel question of the compatibility of coexistence measures in the realm of Art. 26a Directive 2001/18/EC cf. the statement in ECJ C-36/11 (Pioneer) paras. 70 f. that "a prohibition or restriction on the cultivation of those products may be adopted by a Member State in the situations expressly provided for in European Union law. (71) Those exceptions include [...] the coexistence measures adopted under Article 26a of Directive 2001/18."

72 ECJ C-142/05 (Mickelsson and Roos), para. 28. Also ECJ C-110/05 (Commission v Italy) paras. 56 f.

present article is not the place to discuss in detail such undue extension of the free movement of goods.[73] After all, the ECJ restrictively examines whether the regulation of use impedes the chances of use greatly, leaving customers to hardly wish to buy this product. It noted in the case of water scooters, for instance, that the actual opportunities to use this device in Sweden were "merely marginal" anymore.[74] One can assume that the court has a certain threshold of relevance in mind. In the present context, this means that only such a cultivation restriction would enter the scope of Art. 34 TFEU which covers the entire agricultural area of the state territory and which contains a ban and not only certain cultivation requirements.

Assuming that such a nationwide cultivation ban would for a particular GMO be established it would be necessary to consider, whether the trade restriction can be justified. Since the ban would apply to foreign and domestic products alike, the grounds of Art. 36 and other justifiable public interests could be considered.[75] This endeavour would succeed without great difficulty, given the openness of the concept of Union public interests and the accepted latitude of Member States. General environmental policy evaluations can be based on the provision of precaution under Art. 191(2)(2) TFEU, agricultural grounds on the social objectives of agricultural policy under Art. 39(2) TFEU, socio-economic grounds among others on the consideration clause of Art. 191(3)(3) and (4) TFEU, and ethical grounds among others on the principles of pluralism and tolerance under Art. 2 TFEU.[76]

Next, the proportionality of the measure would need to be justified. However, since this is already required by Art. 26b Directive 2001/18/EC, it has to be already reviewed when this very article is applied. A review under Art. 34 TFEU would only repeat this step and is therefore redundant.

## 2. A Requirement of Coherence?

Dederer and Herdegen in their book on opt-out measures assume a requirement that Member State measures need to be coherent. They argue this requirement would be breached, if for reasons of an agricultural policy aiming at inhibiting the further industrialization of agriculture the cultivation of GM seeds was restricted while conventional agriculture which is also in a process of industrialization is left untouched.[77]

The authors rightly situate the coherence requirement within the principle of proportionality, but ascribe it a fundamental importance it does not deserve. The ECJ so far demands consistency only in the limited sense of excluding the manifest internal inconsistency of specific measures but not in the broad sense of the coherence of entire regulatory policies. In judgments justifying a state monopoly on betting, it argued, for example, that this is not a suitable means to reduce incentives to gamble, if Member States at the same time advertise betting to increase government revenue.[78] Coherence is therefore indeed to be assessed, when it comes to the question of whether a measure is appropriate in achieving a specific policy objective, but not in the sense of consistency with other policies.[79] For measures at the EU level, the ECJ in contrast stressed that political institutions are free to initially only intervene partially when pursuing a policy objective and to tackle other cases later, even though they are probably also in need of regulation. In one case, a producer of hydrochlorofluorocarbons claimed that the marketing ban on these substances violated Art. 130r EC Treaty (now Art. 191 TFEU), because it did not cover halons, although halons were even more dangerous. In this

73 One should note that within the "inherent nature" the ideology of the free movement of goods is reified into a kind of entelechy of the product. Is the inherent nature of a sports car not also hampered, when a state opts for a general speed limit of 120 km/h? Will the manufacturer bring France soon before the ECJ in order to attack the French general speed limit of 120 km/h? One should not object that at the stage of justification certainly many possible grounds could be accepted. Functionally, this is about a further step towards the dominance of the freedoms of business enterprises vis-à-vis societal interests noted above ch. I. 2. In the future, the ECJ will not only decide which items must be purchasable, but what use society has to make of products. Take the example of the sports car: The ECJ would then be able to decide that it is inappropriate and unnecessary to limit traffic speed, when there is little traffic, it is night, there are six lanes, etc. For a similarly critical assessment, see *Epiney/Waldmann/Oeschger/Heuck, Die Ausscheidung von gentechnikfreien Gebieten in der Schweiz de lege lata et de lege ferenda*, Zürich (Dike Verlag) 2011, p. 27.

74 ECJ C-142/05 para. 25.

75 The ECJ seems to have definitely given up the differentiation of possible grounds with regard to the equal or unequal treatment of foreign and domestic products. Cf. ECJ C-573/12 (Alands Vindcraft AB), para. 76.

76 See further the reference to Art. 34/36 TFEU above II. 3. d).

77 Dederer/ Herdegen, op. cit., at fn. 32 and 163.

78 ECJ C-243/01 (Gambelli) para. 67. Also ECJ C-316/07 (Stoß) para. 103.

79 In a similar vein ECJ C-171/07, 172/07 (Apothekerkammer des Saarlands) para. 42; C-137/09 (Marc Michel Josemans) para. 70.

matter, the ECJ found that the Treaty does not require "the Community legislature, whenever it adopts measures to preserve, protect and improve the environment in order to deal with a specific environmental problem, to adopt at the same time measures relating to the environment as a whole." The Treaty "authorises the adoption of measures relating solely to certain specified aspects of the environment".[80]

If there is no stringent requirement of coherence that would ask for a mandatory equal treatment of GMO-based and conventional agriculture, Dederer and Herdegen have nevertheless highlighted a sore point in the policy of GMO cultivation restrictions. One could capture this in a legally more open form, drawing on the requirement of a concept (*Konzeptgebot*) suggested by the German BVerwG in comparable cases. The emitters of sulphur dioxide had argued that the best available technology and the corresponding emission limits were disproportionate in geographical areas not exceeding the pollution limits, suggesting that the reduction of their emissions would not contribute to achieving the policy objective. The Court rejected this by arguing that the objective of pollution control was not the small-scale local pollution situation but the management of a national problem of excessive load, which could only be solved with an overall concept that would also encompass such emission sources whose effects are not identifiable individually.[81]

This approach is also applicable to cultivation restrictions, which pursue more general environmental or agricultural policy objectives. What would be required is a "concept" that serves the realization of the chosen general regulatory objective. For example, if a cultivation restriction for GM plants aims at counteracting the industrialization of agriculture, then this has to be embedded in a wider policy of promoting *agriculture paysanne* and biological agriculture.

## IV. The Compatibility of Measures with International Trade Law

Cultivation restrictions must also comply with international trade law of which the WTO Agreements on Sanitary and Phytosanitary Measures (SPS Agreement), on Technical Barriers to Trade (TBT Agreement) and on Tariffs and Trade (GATT) are pertinent. The obligations under these agreements must be respected both by EU and Member State regulators.[82] I only discuss the sublegal cultivation regulations by Member States, because they ultimately cause the trade restriction, while higher-ranking norms only enable such regulations but do not stipulate them conclusively. When checking compatibility it is important to note the difference between measures based on environmental and/or on trans-environmental grounds.

### 1. SPS Agreement

#### a) Principles of Interpretation

When applying the SPS Agreement to regulatory measures, it should be kept in mind that there is a link between the scope and the requirements of the agreement. It would be inconsistent if the scope was extended very far and measures were then subjected to a requirement profile that was created for a narrower scope. Following Annex A (4) of the Agreement and its interpretation by the dispute settlement body[83], the assessment of the risk that shall be avoided aims at examining scientifically provable causalities. This is appropriate, if the objective of the measure - the environmental endpoint that shall be protected – and the alleged causal factor are precisely determined, such as certain non-target organisms that may be poisoned by the cultivation of a GM plant. Then it makes sense to assess whether the alleged causal relationship between the GM plant and the endpoint is given in fact. Causality becomes blurred, however, if holistic entities like ecosystems shall figure as endpoints and various organisms activating diverse causal chains shall be examined. When the scope of the agreement is construed to apply to measures that regulate such complex interrelations, the regulator is trapped in an impasse because precise causal patterns would have to be asserted and proven. The way out of this trap can only be

80 ECJ C-284/95 (Safety Hi-Tech Srl) paras. 44, 45.

81 BVerwGE 69, 37 (45 f.).

82 Cf. Art. 216(2) TFEU.

83 European Communities — Measures Concerning Meat and Meat Products, WT/DS26/AB/R, WT/DS48/AB/R 1998, No. 186 f., 200 (in the following cited as EC-Meat Products); European Communities — Measures Affecting the Approval and Marketing of Biotech Products, WT/DS291/R, WT/DS292/R, WT/DS293/R 2006, No. 7.3240 (In the following cited as EC-Biotech Products).

to either exclude measures based on systemic reasons from the scope of the SPS Agreement or to open up the methodology of the risk assessment for systemic cognition.

### b) Scope

*aa) Legal Basis*

The scope of the Agreement covers sanitary and phytosanitary measures. These are defined in Annex A (1). They comprise measures applied to prevent (a) health risks for animals and plants arising from pests or pathogens; (b) health risks for humans and animals arising from harmful chemicals or pathogens in food or feed; (c) health risks for humans arising from diseases carried by animals or plants or pests; and (d) other damage caused by pests. Measures of this kind are generally held to be legitimate, but subjected to certain conditions that shall prevent protectionist abuse. In our context, where effects of GMOs on the environment are at stake, lit. (a) and (d) are particularly relevant.

*bb) The Interpretation of the Panel in EC-Biotech Products*

In the case EC-Biotech Products a Panel was set up on application of the US, Canada and Australia to consider the compatibility with WTO agreements of the authorization proceedings for GM plants of the EC and of trade and use restrictions for GM plants of certain EC Member States.[84] In its conclusion the Panel did indeed lay the trap: It widened the scope of the Agreement significantly and kept the requirements for measures narrow. In the pending case, this was not at the expense of the charged EC, as the Panel so far only administered justice procedurally and determined that the delay of proceedings was an illegal moratorium. By contrast, it used a precise yardstick of a scientific nature against Member States that had restricted the placing on the market or use via the safeguard clause, and largely determined violations.[85] The scope is extended both in relation to Annex (1) (a) and (d).

• *Measures Protecting from Risks to Animals and Plants Caused by Pests (Annex A (1) (a))*

The Panel extends the scope of measures in three directions: the objects of protection, the relevant harm-causing organisms, and the relevant causal processes.

Firstly, the objects of protection—the life and health of animals and plants according to Annex A (1) (a) —are extended by the Panel to any imaginable components and interactions in the physical world. It takes the generalising view that "animals" are part of the "fauna" and extends "fauna" to "micro-fauna"; similarly it takes "plants" to be a part of the "flora" and extends "flora" to "microflora". Its references can be found in footnote 4 to Annex A of the SPS Agreement, which however has a different purpose[86], and "*The Shorter Oxford English Dictionary*, L. Brown (ed.) (Oxford University Press, 2002), vol. 1, p. 931".[87] In this way, the Panel broadens "textually"[88], i.e. without considering meaning and purpose, the scope of the Agreement considerably. Similarly, it also includes biogeochemical components and cycles as well as population dynamics and genetic diversity.[89] Thus, the Panel blows the rather concrete objects of protection - plants and animals – up to the "environment" in general.

Secondly, the Panel extends the definition of the causal organism, in this case the "pest". It is already difficult to see GM plants as a pest because they are actually designed against pests, such as the insecticidal plant against insects and the herbicide-resistant plant (indirectly) against weeds. Even if one accepts that such GM plants when they harm pests are, so to speak, pests of pests, the question arises which GM plants fall into this category. Although the relevant International Standard for Phytosanitary Measures of the Food and Agriculture Organisation (FAO) defines "pests" as "injurious"[90], the Panel expands the concept to plants that are just "troublesome or annoying".[91] This basically includes all GM plants, also, for example, those that do not produce toxins like insecticidal plants, but have certain growth advan-

84 EC-Biotech Products, No. 7.3240.

85 EC-Biotech Products, No. 7.3240 and section F (pp. 868 et seq.).

86 Fauna and Flora are mentioned in fn. 5 to Annex A, but the inclusion of the micro level is not intended there. It is rather only concerned with adding wild species to agrarian animals and plants.

87 EC-Biotech Products, No. 7.219.

88 EC-Biotech Products, No. 7.219, 3rd sentence.

89 EC-Biotech Products, No. 7.285 and 7.286.

90 International Standard for Phytosanitary Measure No. 11, Pest Risk Analysis for Quarantine Pests Including Analysis of Environmental Risks, FAO, Rome, 2004 (adopted April 2004), Annex 1, p. 34, quoted in EC-Biotech Products, No. 7.235.

91 EC-Biotech Products No. 7.240.

tages[92], such as an acceleration of growth, yield improvement, drought resistance, etc. or grow where they are undesired through pollination.[93]

Thirdly, with regard to the adverse causal processes from pests to animals and plants, the Panel does not concentrate on scientifically provable connections but includes indirect and delayed effects thus extending the scope of the SPS-requirements to measures aiming at controlling those complex causalities. This is done by referring to Annex II Directive 2001/18/EC in which direct, indirect, immediate and delayed effects are mentioned.[94] It is already dubious that the Panel draws on the tested EU provision for interpreting the applicable international standard rather than construing the standard independently of the tested provision. Moreover, when the Panel—very formally—adds that

> "there is nothing in Annex A(1)(a) which indicates that potential risks to animal or plant life or health must necessarily be the direct or immediate result of, e.g., the spread of a pest"[95],

one could counter, in a similarly formal manner, that there are also no arguments for the opposite. What would be required is a view that takes into account the "object and purpose"[96] of what sanitary controls aim at and of when they are abused for protectionist purposes. If a contracting state decides to prohibit the cultivation of GMOs because of those systemic effects, then this does not aim at protecting against specific causal processes but against potential yet hitherto indeterminate processes. In my opinion, such decisions of a general environmental policy nature exceed the horizon of sanitary and phytosanitary measures in the sense of the SPS agreement.

• *Measures Preventing Other Damage Caused by Pests (Annex A (1) (d)*

The Panel also interprets the concept of prevention of "other damages" caused by pests, which according to Annex A No. 1(d) supplements the safety objectives of the letters a) to c) (life and health of humans, animals and plants), in a very broad sense. The Panel takes this to include any damage to property, an economic damage under the condition of coexistence, an impact on biogeochemical cycles and even harm to biodiversity.[97] It is unclear if the Panel would include also adverse social, ecological, economic, and ethical effects tackled by measures of agricultural, socio-economic or ethical policy. I believe such boundless expansion would leave the realm of the meaningful, given that the purpose of the SPS Agreement is to protect real animals and plants against pests and diseases. Rightly, the "other damages" should be construed to address only those effects in which the specific harmfulness of pests, here a GMO, has become effective, and where the damage is causally related to health risks to humans, animals or plants.[98] Economic costs under the condition of coexistence and the social costs of an industrialized agriculture lie outside of this reading, because they do not result out of the potential harmfulness of the pest.

*cc) Résumé*

In the proceedings EC-Biotech Products, the EC presented detailed reasons against the mentioned extensions of scope, which it summarized as follows:

> "The issues arising out of the existence of GMOs go far beyond the risks envisaged and regulated by the SPS Agreement. A rigorous interpretation of the definitions in Annex A.1 of the SPS Agreement unequivocally shows that measures addressing issues such as antibiotic resistance or changes in the ecological balance are not among the measures that the SPS Agreement intends to discipline. Since the European Communities, through its actions, aims at the fulfilment of objectives that go beyond the specific situations that determine the applicability of the SPS Agreement, such Agreement does not provide a sufficient legal framework for the examination of the European Communities' behaviour."[99]

I find this to be a reasonable position. However, it does, as stated, not correspond with the view of the Panel. Unfortunately, the EC did not submit the Panel report to the Appellate Body. Therefore, there is still no conclusive WTO case law on genetic engineer-

92 In EC-Biotech Products, they are called "GM plants growing where they are undesired", see No. 7.243-7.247.

93 EC-Biotech Products, No. 7.464.

94 Directive 2001/18/EC Annex II D 2. Cf. EC-Biotech Products, No. 7.285 and 7.286.

95 EC-Biotech Products, No. 7.226.

96 Cf. Art. 31(1) Vienna Convention on the Law of Treaties.

97 EC-Biotech Products, No. 7.369-7.373. No. 7.370 even mentions a reputational damage.

98 Similar Dederer in: Herdegen/Dederer, op. cit., fn. 236.

99 EC-Biotech Products, No. 4.355.

ing. In my opinion, it is doubtful whether the Appellate Body would have supported the almost limitless extension of the scope of the SPS Agreement. It is quite possible that GMO-critical EU Member States could have more success in a new dispute settlement proceeding, among others because awareness has grown that the WTO must open itself up for more general environmental policy reasons that justify trade restrictions.[100]

In sum, in my opinion

- the scope of the SPS Agreement only encompasses those grounds that refer to the effects of intrinsically harmful GMOs (i.e., especially insecticide plants) on the health of animals and plants;
- those measures lie outside of the scope that are based on risk weighing, especially those based on fundamental evaluations regarding uncertainties and systemic effects;
- completely outside of the scope are measures aiming at non-environmental objectives.

### c) Requirements for SPS Measures

As far as measures fall under the scope of the SPS Agreement, they must follow certain substantive and methodological requirements. In an alternative approach I will in the following assume the position of the Panel so that measures based on general environmental considerations are also included in the analysis. Measures based on trans-environmental grounds are however not further reviewed, since it seems farfetched to assume that they fall under the SPS Agreement.

*aa) Legal Basis*

Art. 2.1 SPS Agreement recognizes the contracting states' right to take measures "necessary for the protection of human, animal or plant life or health".[101] The determination of the level of protection, the choice of measures and the risk assessment basis should be distinguished. It is common ground that the level of protection directs the choice of measures.[102]

• *Level of Protection*

In determining the level of protection contracting states are largely free.[103] Hence, latitude exists that could also legitimize measures resulting from the weighing of risks. In doing so, members have however to "take into account the objective of minimizing negative trade effects."[104] Therefore, when weighing risks trade effects of measures must be considered.

• *Choice of Measures*

The contracting states must ensure that a measure "is applied only to the extent necessary to protect human, animal or plant life or health [...]".[105] In other words measures must be proportional to their objectives. This is understood as a three pronged test requiring that an alternative measure is reasonably available, achieves the envisaged level of protection and is significantly less restrictive.[106] As a qualification, I submit that only generalised alternatives in the sense of normative proportionality[107] are to be tested.

• *Risk Assessment*

SPS measures must be based on a risk assessment carried out in accordance with internationally recognized methods.[108] When assessing risks, the available scientific evidence as well as the relevant ecological and environmental conditions need to be considered.[109] Measures must be "based on scientific principles".[110]

This scientific orientation has led the dispute settlement bodies to review risk assessments in detail.[111] In my opinion, the contracting states howev-

100 Cf. above ch. I. 2.

101 Art. 2.1 SPS Agreement.

102 Australia — Measures Affecting Importation of Salmon, WT/DS18/AB/R 1998, No. 523 (In the following cited as Australia-Salmon).

103 Cf. Art. 3.2 SPS Agreement. Clearly pointed out in Australia-Salmon, No. 199: "The determination of the appropriate level of protection, a notion defined in paragraph 5 of Annex A, as "the level of protection deemed appropriate by the Member establishing a sanitary … measure", is a prerogative of the Member concerned and not of a panel or of the Appellate Body." Cf. P. C. Mavroidis, *Trade in goods. The GATT and the other WTO agreements regulating trade in goods*, Oxford (OUP) 2012, pp. 721, 725.

104 Art. 5.4 SPS Agreement.

105 Art. 2.2, similar Art. 5.6 SPS Agreement.

106 Australia-Salmon No. 194.

107 See ch. II. 2 above.

108 Art. 5.1 SPS Agreement. Cf. EC-Meat Products, No. 180: "Article 2.2 informs Articles 5.1: the elements that define the basic obligation set out in Article 2.2 impart meaning to Article 5.1."

109 Art. 5.2 SPS Agreement.

110 Art. 2.2 SPS Agreement. It is striking that this requirement is not established for determining the level of protection, except the latter is more stringent than aimed for in international standards (cf. Art. 3.3. SPS Agreement).

111 See for an in-depth analysis Mavroidis, op. cit. pp. 713-723.

er possess a margin of judgment. Different reasons support this argument: The protection of health and the environment is not an exception to the fundamental principle of free trade but at least an equivalent principle;[112] the contracting states are better equipped to resolve scientific questions than the dispute settlement bodies[113]; and the decisions of the WTO dispute settlement bodies possess a lower degree of democratic legitimation than the regulations established by contracting states.[114]

• *Precautionary Approach*

In cases where "relevant scientific evidence is insufficient", measures may be "provisionally adopt[ed] [...] on the basis of available pertinent information" including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other contracting states.[115] The interpretation of this clause allows bringing to bear the precautionary approach. That is why the dispute settlement bodies deemed it hitherto unnecessary to decide whether the precautionary principle is already customary international law.[116]

*bb) Application to Opt-out Measures*

Applying the above profile of requirements two situations – one for science and one for weighing of risks – should be distinguished.

Cultivation restrictions that are based on a scientific study and appreciation have to follow the recognized risk assessment rules. For instance if a Member State bases its restriction measure on the alleged impact of the GM plant on a specific non-target organism that was not investigated in the ERA it needs to complement the ERA by related scientific study. This should not pose particular difficulties, since the methods of ERA recognized in the EU match international risk assessment standards.

The situation is different when it comes to measures (alternatively assumed that they fall under the SPS Agreement) that are based on general environmental policy evaluations and the weighing of risk. Such evaluation and weighing should be seen as part of determining the level of protection in the sense of Art. 3.2 SPS Agreement and is hence at the discretion of the contracting state.[117] If a Member State intends, for instance, to avoid the eco-systemic effects of GMO cultivation, it chooses a higher level of protection than in a case in which it merely intends to avoid harm to particular non-target organisms.

Also for measures that shall realise a high level of protection, a risk assessment needs to be conducted. However, one of the strictly scientific kind can in my opinion not be demanded, since, as mentioned earlier, it is based on linear causalities and neglects the complex interconnections within ecosystems.[118] Rather it must suffice that the risk is substantiated according to the state of the art and that the weighing of risk is motivated.

Contrastingly, the Panel in the EC-Biotech Products case did insist that "a risk assessment must evaluate the likelihood or probability of particular risks".[119] It held that the assessment of a Member State that an impact was "uncertain", "possible" or "non-conclusive" would not meet this requirement and would thus not justify a restriction.[120] Since in the given case it found the risk assessment not being adequate it concluded that Art. 5.1 SPS Agreement was violated. It however suggested to test Art. 5.7 SPS Agreement.

A precondition of this provision is that the "relevant scientific evidence is insufficient". The EU Member States that had established a cultivation ban had argued that the required scientific evidence depended upon the chosen level of protection, that was high, and that it could not and need not be proven on a hard scientific basis.[121] The Panel rejected this claim referring to an opinion of a scientific committee, the EU Scientific Committee on Plants (SCP), that had examined the matter drawing on quite a number of existing studies. The Panel found this to be "sufficient evidence" so that Art. 5.7 SPS Agreement could not be invoked.[122] It said the information required

112 Cf. the preamble to the WTO Agreement.

113 This justification for judicial self-restraint has been suggested by the German Federal Administrative Court, most significantly in BVerwGE 72, 300 (316 f.).

114 Cf. G. Winter, Regimekonflikte im globalisierten Recht: Erscheinungsformen und Lösungen, in: 20/4 *GAIA*, (2011), pp. 248 – 255.

115 Art. 5.7. SPS Agreement.

116 Cf. EC-Biotech Products, No. 7.89.

117 It should be noted that the SPS Agreement only knows the term risk assessment but not risk management, because the differentiation only appeared after its adoption. Cf. EC-Meat Products, No. 181.

118 See above ch. II. 3. a) bb).

119 See EC-Biotech Products, No. 7.982-7.984 in connection with the review of the Austrian regulation of maize T 25.

120 Ibidem.

121 EC-Biotech Products, No. 7.1129.

122 EC-Biotech Products, No. 7.952.

for a risk assessment had to be determined in a purely scientific manner, while the level of protection comes only into play when, as a second step, the acceptability of the risk is assessed.[123]

Thus, in the opinion of the Panel the 'normal' risk assessment under Art. 5.1 required scientific proof which the defendants failed to provide, while the precautionary risk assessment under Art. 5.7 was not applicable because it presupposed uncertainty which the Panel found was not given. The Panel closed its eyes for the possibility of a holistic risk assessment that looks at complex causal interrelationships. It departs from the somewhat naive assumption that risk assessment can be scientifically value-free and definite.[124] Rather, to what extent scientific rigour is appropriate depends on the chosen level of protection. If the chosen level of protection requires, for instance, the safe exclusion of damage to soil organisms and there is insufficient information available for such a conclusion, it cannot simply be demanded that the probability of damages must nevertheless be determined. A substantiation of risks must suffice in such cases.

My proposal to allow a risk assessment adapted to the level of protection, which possibly only substantiates the risk and justifies its weighing, finds resonance in Art. 5.2 SPS Agreement, according to which a number of other factors can be taken into account, including even the "relevant ecological and environmental conditions".[125] Some formulations of the Appellate Body point into the same direction, accepting assessments of a qualitative nature[126] and those of more complex causal relationships[127]. The following often-quoted sentence points to risks as a matter of life praxis:

> "It is essential to bear in mind that the risk that is to be evaluated in a risk assessment under Article 5.1 is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die."[128]

The risk assessment must not necessarily come to a "monolithic conclusion", and it can instead of having to follow the scientific mainstream, rather be based on "a divergent opinion from a qualified and respected source".[129]

The opening up of the risk assessment becomes particularly obvious in the following statement:

> "Although the definition of a risk assessment does not require WTO Members to establish a minimum magnitude of risk, it is nevertheless difficult to understand the concept of risk as being devoid of any indication of potentiality. A risk assessment is intended to identify adverse effects and evaluate the possibility that such adverse effects might arise. This distinguishes an ascertainable risk from theoretical uncertainty. However, the assessment of risk need not be expressed in numerical terms or as a minimum quantification of the level of risk."[130]

According to this, it is not required to quantify the level of damage and likelihood of occurrence. Required are indications for risks, while a mere theoretical uncertainty is not apposite.

Should there be a new dispute settlement proceeding on GM plants, the odds are therefore not all bad that the competent bodies come to an extended understanding of risk assessment.

## 2. Agreement on Technical Barriers to Trade (TBT Agreement)

As far as the measures fall within the scope of the SPS Agreement and meet its requirements, they are not to be assessed against the TBT Agreement also, because the SPS Agreement has priority.[131] As explained, this does not include measures that aim at

123 EC-Biotech Products, No. 7.1131 - 7.1134.

124 The very definition of risk assessment in Annex A of the SPS Agreement knows both the probability and the potentiality of adveres effects. See EC-Meat Products No. 183-4 and Mavroidis, op. cit. p. 718.

125 Cf. the respective reference in EC-Meat Products, No. 187.

126 European Communities – Measures Prohibiting the Importation and Marketing of Seals Products, WT/DS400/AB/R, WT/DS401/AB/R, No. 5.198.

127 Cf. United States — Continued Suspension of Obligations in the EC – Hormones Dispute, WT/DS320/AB/R 2008, No. 562.

128 EC-Meat Products, No. 187. Also quoted in Appellate Body Report, US – Continued Suspension of Obligations in the EC – Hormones Dispute, WT/DS320/AB/R 2008, No. 527.

129 EC-Meat Products, No. 194. Also quoted in United States — Continued Suspension of Obligations in the EC – Hormones Dispute, WT/DS320/R 2008, No. 529.

130 United States — Continued Suspension of Obligations in the EC – Hormones Dispute, WT/DS320/AB/R 2008, No. 569.

131 Art. 2.5 TBT Agreement.

general environmental policy objectives or at trans-environmental policy reasons; it needs therefore to be assessed whether such measures fall within the scope of the TBT Agreement. The TBT Agreement differs from the GATT with regard to the question of whether only measures that treat foreign and domestic products differently (so-called discriminatory measures) are in need of justification or also measures that do not treat them differently (so-called non-discriminatory measures). The TBT Agreement (as well as the SPS Agreement) covers both categories and the GATT only discriminatory measures.[132] This means that the GATT only aims at preventing protectionist discrimination, while the TBT Agreement claims to discipline the general trade policies of its Members.

Decisive for the scope of the TBT Agreement are its Art. 2.1 and 2.2 the first paragraph prohibiting discriminatory measures and the second both discriminatory and non-discriminatory ones. In any case the measure must be a technical regulation which is defined as a

> "Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory [...]."[133]

Cultivation restrictions refer to the characteristic of seeds, namely—positively—to its feature as genetically modified or—negatively—as genetically unmodified.

It is questionable, however, whether a document "lays down" this feature.[134] An abstract definition of characteristics, such as in the form of "it is hereby determined that a seed is genetically modified" would be meaningless. Feature descriptions always occur in a particular context of action. This is meant by the phrase in Annex I "For the purpose of this Agreement, however, the following definitions shall apply". As the Appellate Body emphasizes, "a determination of whether a measure constitutes a technical regulation 'must be made in the light of the characteristics of the measure at issue and the circumstances of the case'".[135]

The purpose of the agreement is the liberalization of the trade in products. For this trade, rules and mandatory provisions could be imagined, which state that products with the characteristic "genetically modified" cannot at all or can only under certain conditions be placed on the market. Cultivation restrictions or bans do just not prescribe this. They refer to cultivation. The producer remains free to place the cultivation-restricted products on the market.

One might consider whether the cultivation-related technical regulation affects trade indirectly, because sales opportunities are reduced. But this implies a significant extension of the scope of the TBT Agreement, for which the dispute settlement bodies were hardly legitimated. They would then embark on a similar move to the one pursued by the ECJ in its judgments Mickelsson and Commission v Italy.[136] At the European level, this is already doubtful but, given the degree of integration within the EU, may be acceptable, if appropriately designed. In the global dimension of the TBT Agreement, this would in my opinion constitute an action taken *ultra vires*.

As a result, it should be noted that the TBT Agreement is not applicable to cultivation restrictions.

## 3. General Agreement on Tariffs and Trade (GATT)

What remains then is an assessment with regard to Art. III.4 GATT which reads:

> "The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less favourable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use."

This provision is explicitly also applicable to the regulation of product use, hence also to cultivation restrictions. However, it is presupposed that these regulations must treat foreign products less favourable than like domestic products. Both de iure and de facto differential treatment is considered to breach Art.

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132 This is not the place to discuss, whether this corresponds to the original intention of the Agreements.

133 Annex 1(1) TBT Agreement.

134 The term "mandatory" is not significant here, since it points to the difference to international standards.

135 EC – Measures Prohibiting the Importation and Marketing of Seal Products, WT/DS400/AB/R no. 5.60.

136 Cf. Above ch. III. 1.

III.4 GATT. However, "there must be in every case a genuine relationship between the measure at issue and its adverse impact on competitive opportunities for imported versus like domestic products to support a finding that imported products are treated less favourably."[137] This is not the case here, because all GM plants are subject to precisely the same cultivation restrictions.[138]

In the alternative, it may be assumed to extend the scope of Art. III.4 GATT to cases where foreign products hold – and loose – more market share than domestic ones, as it may be in our case with foreign in relation to domestic GM seed. Then a justification under Art. XX GATT of the differential effects of measures is to be considered. Art. XX (g) GATT ("relating to the conservation of exhaustible genetic resources") could be invoked but the term "exhaustible natural resources" even if broadly understood[139] can hardly be extended to include systemic interrelations of nature. Measures reflecting general environmental concerns and risk weighing could rather be based on Art. XX (b) ("necessary to protect human, animal or plant life or health") if the term "animal or plant life or health" were broadly interpreted like the Panel in EC-Biotech Products did concerning the same terms in Annex A to the SPS Agreement.[140] I objected against this broad reading so that it might appear contradictory that I defend the same in the context of Art. XX GATT. But the difference can be explained. Concerning the SPS Agreement the term disciplines the scope of application of the agreement which should be narrow in order to cope with the narrow concept of risk assessment. Concerning Art. XX GATT the term opens up grounds for justifying trade restrictions and should be broadly understood as a corollary to an assumed extension of the scope of application of Art. III.4 GATT.[141]

Concerning the trans-environmental grounds it appears that the ethical concerns about cultivation of GMOs[142] are covered as "public morals" according to Art. XX (a). Panels and the Appellate Body have interpreted this term flexibly allowing also for some scope for contracting states to define and apply it.[143] However, the grounds of socio-economic impact and agricultural policy are hard to subsume. Insofar as they are interrelated with environmental concerns (such as when benefits are weighed against risks, or when agricultural ecosystems shall be protected) they may pass as grounds under Art. XX (b) GATT. For the rest (such as coexistence costs and social and regional concerns of *agriculture paysanne*) Art. XX GATT does not seem to provide a justification. This warns against extending the scope of Art. III.4 GATT to non-discriminatory measures.

In a more theoretical perspective the logical gap observed in relation to the SPS Agreement reappears in relation to the GATT: Widening the scope of application causes inconsistencies with the narrow reading of grounds for trade restrictions. Either the scope must be kept narrow or the justifying grounds must be extended. Or, in methodological terms: if teleological interpretation is employed in the widening of the scope the same must be done to extend the realm of legitimate restrictions, and vice versa.[144]

Considering the underdevelopment of the relevant doctrines my conclusion is that cultivation restrictions treating foreign and domestic GM products equally do not violate the principle of national treatment under Art. III.4 GATT. Grounds under Art. XX GATT need not be invoked.

## VI. Findings

The opt-out concept introduced by Directive (EU) 2015/412 radicalizes the approach of the coexistence between GM, conventional and organic plant culti-

137 US – Measures Affecting the Production and Sale of Clove Cigarettes, WT/DS406/AB/R, No. 201. EC - Measures Affecting Asbestos and Products Containing Asbestos, WT/DS135/AB/R. 2001, No. 100. Dominican Republic - Measures Affecting the Importation and Internal Sale of Cigarettes, WT/DS302/AB/R, at IV 8.

138 A case of discrimination could be assumed, if one did not compare genetically modified seeds from abroad and home, but genetically modified seeds from abroad with domestic conventional seeds. The former would be limited in regard to cultivation, the latter not. For such a comparison, both product groups would have to be "like" products. This is not the case, because both products vary in their physical properties as well as in the perception and in the behaviour of consumers.

139 See for such extension covering renewable resources US – Import Prohibition of Certain Shrimp and Shrimp Products, WT/DS58/AB/R. 1998, No. 131.

140 See above ch. IV 1 b).

141 Cf. the parallel development concerning Art. 36 TFEU the justifiable grounds of which have been flanked by additional grounds in case of non-discriminatory measures. See above fn. 74.

142 Above ch. II 3 d).

143 EC – Measures Prohibiting the Importation and Marketing of Seal Products, no. 5.199, quoting the Panel in US – Gambling, no. 6.465, that "the term 'public morals' denotes 'standards of right and wrong conduct maintained by or on behalf of a community or nation". For a support of this understanding see Mavroidis, op. cit. pp. 332-334.

144 See further on this problem Mavroidis, op. cit. pp. 326-337.

vation. It aims at resolving the Member States' conflict about gene technology by facilitating the pluralisation of cultivation regulations. In its application, the directive must be granted *effet utile*. The concept is at the same time an example for a reorientation of European and possibly global principles of free trade. Whereas trade restrictions on grounds of health and environmental protection could thus far only be justified on a strict scientific basis, now a variety of risk perceptions and cultures of response are accepted.

Two types of grounds can be distinguished that go beyond those environmental risks which can be proven by science in a narrow sense[145]:

- Grounds of general environmental policy: They must not conflict with scientific statements and assessments of the EIA, but may be based on independent fundamental evaluations about uncertainty, indirect and long-term effects, systemic effects and the holistic protection of nature. One needs therefore to distinguish between the scientific study and appreciation of risk, which are the subject of the so-called risk assessment, and the weighing of risk, which (in addition to the choice of instruments) is the subject of risk management.
- Trans-environmental grounds including
- socio-economic grounds: They can aim at avoiding the economic costs associated with small-scale coexistence rules, carry out a weighing of residual risks with the benefits of GMOs and/ or accommodate consumer preferences.
- grounds of agricultural policy: They can aim at protecting agricultural habitats; more generally, they can be directed against the industrialization of agriculture and for promoting conventional *agriculture paysanne* or organic agriculture.
- ethical grounds: they can rely on the wisdom of the trial and error processes of evolution, protect the inherent characteristics of all living creatures or aim at expressing reverence for the Creation.

The measures based on those grounds may be designed with a local, regional or national scope and consist of mere restrictions or the complete ban of the cultivation of particular GM plants. They must be proportionate. Since restrictions are not imposed by individual acts but by general norms, the test of available alternatives must not refer to the circumstances of each concerned individual but to those concerned in general. Concerning different treatment of GM and other agriculture a strict requirement of coherent strategies cannot be assumed. Nevertheless, if for instance a cultivation ban on GMOs is meant to prevent the further industrialization of agriculture, a political concept should exist that provides for like measures concerning conventional agriculture.

Regarding the compatibility of opt-out measures with the EU principle of free movement of goods, it is submitted that the Directive establishes an exhaustive regulation that supersedes the test under Arts. 34/36 TFEU. In the alternative, the grounds for cultivation restrictions can be based on recognized public interests of the Union.

As far as the compatibility with the SPS Agreement is concerned, a thorough analysis of its scope is required. The Panel in the EC-Biotech Products case overstretches the relevant terms – risks to animals and plants from pests – in three directions, i.e. the endpoints, the factors and the causal chains. Thus measures based on general environmental policy grounds and a weighing of risks would be covered, possibly even measures that are based on trans-environmental grounds. In contrast, a more appropriate reading would confine the scope to measures aiming at the protection of concrete adverse effects.

In contrast to the wide range of scope of the SPS Agreement, the Panel takes the required risk assessment to be a narrowly science-related one. This creates a logical gap, for general environmental evaluations of risk weighing cannot be subjected to a precise inquiry into the seriousness and probability of damage. Such gap must be avoided. Either the scope of applicability must be kept narrow, or the requirement of risk assessment must be opened up to allow for a mere substantiation of risk if the measure is based on more general environmental evaluations and risk weighing. It is true that this suggestion deviates from the Panel's opinion but indications exist that a Panel or the Appellate Body would in future proceedings come to a different conclusion.

Concerning the compatibility with the TBT Agreement it is submitted that this agreement is not applicable because cultivation restrictions relate to the use of products and therefore are not technical regulations of trade.

Finally, Art. III.4 of the GATT is not breached because cultivation restrictions would not treat foreign

145 It should be noted that the two types do not have sharp contours but may overlap depending on specification.

products less favourable than internal products. In the alternative, if a less favourable treatment were assumed to cover de facto differentials due to different market shares, the legitimate grounds for restrictions under Art. XX GATT would have to be widened to include environmental policy in general as well as trans-environmental considerations short of protectionist intentions.

# Handling Uncertain Risks: An Inconsistent Application of Standards?

## The Precautionary Principle in Court Revisited

*Anne-May J.P. Janssen* and Nele F. Rosenstock***

*The problematic application of the precautionary principle by the European Courts has led Janssen and Van Asselt to identify patterns and inconsistencies in the Courts' use of the principle. As a consequence, the principle runs the risk of becoming an empty tool. This paper examines new case law to determine whether these patterns have continued in the rulings of the Courts and discusses what can be done to stop the degradation of the precautionary principle.*

## I. Introduction

In the past technologies were simple, and so were the risks, making it relatively easy to determine the safety of a product. Nowadays, new technologies and their risks are often extremely complex. The precautionary principle was established for policy makers to deal with these new and complex risks. Article 15 of the Rio Declaration holds the most widely known explanation of the principle stating that "[w]here there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."[1]

According to Van Asselt and Vos, the precautionary principle is not applicable to every type of risk.[2] There are situations where "there are serious reasons to believe that there may be danger, but the scientific evidence is neither sufficient to substantiate that danger nor to refute suspicions of that danger arising."[3] These situations create uncertain risks. In contrast to quantifiable simple risks, uncertain risks are not quantifiable and therefore uncontrollable.[4] Situations of uncertain risks are marked by "suspected, possible hazards, which are usually associated with complex causalities, large-scale, long-term and transborder processes, and which are generally difficult to control."[5] Remarkably, uncertain risks also exist in situations of high knowledge and information. If adding new information could just erase uncertain risks, they would not exist per se.[6] In such cases the precautionary principle is a tool to deal with these uncertain risks.

Before becoming a general principle of EU law, the precautionary principle was developed through case law and the European Commission's Communica-

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1 Report of the United Nations Conference on Environment and Development, Annex 1 Rio Declaration on Environment and Development, Principle 15, UN Doc. A/CONF.151/26 (Vol. I), 12 August 1992, available on the Internet at: <http://www.un.org/documents/ga/conf151/aconf15126-1annex1.htm> (last accessed 10 October 2013).

2 Marjolein B.A. Van Asselt and Ellen Vos, "The Precautionary Principle and the Uncertainty Paradox", 9 *Journal of Risk Research* (2006), pp. 313 *et sqq.*; Marjolein B.A. Van Asselt, and Ellen Vos, "Wrestling with uncertain risks: EU regulation of GMOs and the uncertainty paradox", 11 *Journal of Risk Research*, pp. 281 *et sqq*.

3 Anne-May Janssen and Marjolein B.A. Van Asselt, "The Precautionary Principle in Court – An Analysis of Post-Pfizer Case Law", in Marjolein B.A. Van Asselt, Esther Versluis and Ellen Vos (eds.), *Balancing between trade and risk: Integrating legal and social science perspectives* (London, UK: Routledge, 2013), pp. 197 *et sqq*., at p. 197.

4 Marjolein B.A. Van Asselt, Ellen Vos and Bram Rooijackers, "Science, Knowledge and Uncertainty in EU Risk Regulation", in Michelle Everson and Ellen Vos (eds.), *Uncertain Risks Regulated: Facing the Unknown in National, EU and International Law* (London and New York: Routledge, 2009), pp. 1 *et sqq.*; For an elaborate analysis of the differences between 'risks' and 'uncertain risks', see Van Asselt, Vos and Rooijackers, 2009, *supra* note 6, at p. 360-365.

5 Van Asselt, Vos and Rooijackers, "Science, Knowledge and Uncertainty in EU Risk Regulation", *supra* note 4, at p. 359.

6 Van Asselt and Vos, "The Precautionary Principle and the Uncertainty Paradox", *supra* note 2, at p. 313-336.

tion on the precautionary principle (hereafter: Communication).[7] Nevertheless, there is yet no legally binding definition of the principle. Crucial terms such as "scientific uncertainty" and the criteria that justify the application of the principle were left undefined.[8] As a result, "[c]ritics have argued that the lack of a clear definition inhibits any sound application of the principle"[9] and made the principle arbitrary.[10]

The Communication holds that a risk assessment requires "*reliable scientific data* and logical reasoning, leading to a conclusion, which expresses the possibility of occurrence and the severity of a hazard's impact" (emphasis added).[11] The Commission refers to the definition of simple risks, and expects it to be possible for scientists (in situations of uncertainty) to provide reliable data and to indicate the probability and impact of the risk. This requirement is described as the uncertainty paradox[12]: although uncertainty is acknowledged, decision-makers still demand scientists and experts to present conclusive data to establish certainty.[13]

This ambiguity of the Communication left room for the European Courts (Court of Justice of the European Union (CJEU) and the Court of First Instance (CFI)) to develop their own definitions of the terms and procedures of the precautionary principle.[14] The leverage the Courts have (taken) in applying this principle has been noticed by scholars[15]: The Courts' role in assessing the application of the precautionary principle is usually to review the procedural steps, however, in the milestone case *Pfizer*[16], the Courts became more proactive.[17] From their mere judicial position as an "informational catalyst", the Courts departed towards the role of a super-expert and risk assessor.[18] In *Pfizer*, the ruling of the CFI was problematic as it constructed its own definition of uncertainty. Janssen and Van Asselt examined post-*Pfizer* case law to determine whether the problematic ruling of the CFI in *Pfizer* had set a precedent.[19] They identified several tensions and inconsistencies in the Court's ruling. Based on these findings we continued our research into more recent case law to establish whether these tensions and inconsistencies still remain.

We first summarise Janssen's and Van Asselt's findings.[20] Hereafter, four cases that were reviewed by the CJEU or the CFI are discussed. The analysis follows where we examine established and new patterns and tensions in dealing with uncertainty. We argue not only that the new evidence substantiates the pattern and tensions as defined by Janssen and

7 Communication from the Commission on the Precautionary Principle, COM(2000)1 final.

8 Elizabeth C. Fisher and Ronnie Harding, "The precautionary principle and administrative constitutionalism: the development of frameworks for applying the precautionary principle", in Elizabeth C. Fisher, Judith Jones and René von Schomberg (eds.), *Implementing the precautionary principle* (Cornwall: Edward Elgar Publishing Limited, 2006), at pp. 113-137.

9 Janssen and Van Asselt, "The Precautionary Principle in Court - An Analysis of Post-Pfizer Case Law", *supra* note 3.

10 Robert V. Percival, "'Who's afraid of the Precautionary Principle?'", 23 *Pace Environmental Law Review* (2005), p. 1 *et sqq*.; Per Sandin, "The Precautionary Principle and Food Safety", 1 *Journal of Consumer Protection and Food Safety* (2006), at pp. 2-4.

11 Communication on the Precautionary Principle, *supra* note 7, at p. 14.

12 For an elaborate argumentation see: Van Asselt and Vos, "The Precautionary Principle and the Uncertainty Paradox", *supra* note 2.

13 Ibid.

14 Alberto Alemanno, "The Shaping of the Precautionary Principle by European Courts: From Scientific Uncertainty to Legal Certainty", in Lorenzo Cuocolo and Luca Luparia (eds), *Valori Costituzionale e Nuovo Politiche Del Diritto, Cahiers Européens, Halley*, Bocconi Legal Studies Research Paper (2007) 1007404, at p. 13.

15 Van Asselt and Vos, "The Precautionary Principle and the Uncertainty Paradox", *supra* note 2; Janssen and Van Asselt, "The Precautionary Principle in Court - An Analysis of Post-Pfizer Case Law", *supra* note 5; Alberto Alemanno, "The Shaping of European Risk Regulation by Community Courts" 18/08 *Jean Monnet Working Paper* (2008), pp. 1 *et sqq*., available on the Internet at <http://ssrn.com/abstract=1325770> (last accessed on 2 March 2013); Alberto Alemanno, "Case C-79/09, Gowan Comércio Internacional e Servicos Lda v. Ministero della Salute, Judgment of the Court (Second Chamber) of 22 December 2010", 48 *Common Market Law Review* (2011), pp. 1329 *et sqq*.

16 Case T-13/99, Pfizer Animal Health SA v. Council of the European Union [2002], ECR II-03305.

17 Alemanno, "Case C-79/09, Gowan Comércio Internacional e Servicos Lda v. Ministero della Salute, Judgment of the Court (Second Chamber) of 22 December 2010", *supra* note 15; Van Asselt and Vos, "The Precautionary Principle and the Uncertainty Paradox", *supra* note 2; Michael D. Rogers, "Risk management and the record of the precautionary principle in EU case law", 14 *Journal of Risk Research* (2011), pp. 467 *et sqq*.; Ellen Vos, "EU risk regulation reviewed by the European Courts" in Marjolein B.A. van Asselt, Michelle Everson and Ellen Vos (eds.), *Trade, Health and the Environment: The European Union Put to the Test* (New York, Routledge, 2014), p. 213 *et sqq*.

18 Vos, "EU risk regulation reviewed by the European Courts", *supra* note 17, at p. 219

19 Janssen and Van Asselt, "The Precautionary Principle in Court - An Analysis of Post-Pfizer Case Law", *supra* note 3.

20 Ibid.

Van Asselt, but also that these newly discovered patterns reaffirm the Court's lack of vision on how to deal with uncertainty and precaution.

## II. Tension and Patterns Identified by Janssen and Van Asselt[21]

The initial role of the Courts is to judge the rightfulness of the procedural steps that resulted in the application of the precautionary principle. Yet this role is changing, as Chalmers, Davies and Monti argued. Currently there is a "scientification" of the judicial review, meaning the Courts "increasingly moved towards a proceduralist test of whether a sufficiently rigorous risk assessment has been carried out".[22] By "increasingly pay[ing] attention to the science underlying the decision-making"[23], instead of "engag[ing] in normatively motivated and accountable inquiry"[24], the Courts have adopted a new role. Observing how *Pfizer* set a precedent [25], Janssen and Van Asselt reveal even more problematic tensions and inconsistencies in subsequent case law.[26]

### 1. Uncertainty as Contrasting Scientific Opinions

The CFI has used scientific dissension as a way to construct uncertainty about the risk in question. The Court very clearly referred to diverging opinions between the experts, which was subsequently used to legitimise the application of the precautionary principle.[27] This is an unfortunate precedent, because in virtually all cases of uncertain risks, a dissident opinion can be found. It could undermine "the meaningful use of the precautionary principle as a risk management tool."[28]

### 2. Uncertainty through Analogical Handclapping

In two cases (on substances belonging to the group of antibiotics and nitrofurans), there were no risk assessments performed on the specific substances. The Court, however, ruled that "all antibiotics and all nitrofurans have similar characteristics and should be treated in the same way."[29] This argumentation entails that "substance-specific characteristics are no longer needed in the risk assessment and commonalities suffice."[30] "[W]hen uncertainty has been established for one specific substance, there is a general claim of uncertainty"[31] and the application of the precautionary principle follows for all comparable substances. This way the precautionary principle can easily become a tool to prohibit marketing of products.

### 3. Uncertainty Equals the Absence of Full Safety

In previous case law the Court defined risk assessment as a procedure, which it had to evaluate.[32] Recently, however, "risk assessment [in different cases] is lacking," meaning "there is either no SCAN[33] opinion present or SCAN could not perform a full risk assessment."[34] In several cases the Court did not repri-

21 For an elaborate analysis of the tensions and patterns see Janssen and Van Asselt, "The Precautionary Principle in Court - An Analysis of Post-Pfizer Case Law", *supra* note 3.

22 Damian Chalmers, Giorgio Monti and Gareth Davies, *European Union Law: Cases and Materials*, (2nd, rev. ed.), (Cambridge: Cambridge University Press, 2010), at p. 898; Vos, "EU risk regulation reviewed by the European Courts", *supra* note 17.

23 Ibid., at p. 214.

24 Vos, "EU risk regulation reviewed by the European Courts", *supra* note 17, at p. 226, see also: Scott and Sturm, "Courts as catalysts: Rethinking the judicial role in new governance", 13 *Columbia Journal of European Law* (2006), at p. 571 and at p. 593.

25 Janssen and Van Asselt, "The Precautionary Principle in Court - An Analysis of Post-Pfizer Case Law", *supra* note 3; Vos, EU risk regulation reviewed by the European Courts, *supra* note 17; Alemanno, "The Shaping of European Risk Regulation by Community Courts", *supra* note 15; Michael D. Rogers, "Risk management and the record of the precautionary principle in EU case law", *supra* note 17.

26 Janssen and Van Asselt, "The Precautionary Principle in Court - An Analysis of Post-Pfizer Case Law, *supra* note 3; Case T-74/00, Artegodan GmbH v. Commission of the European Communities [2002] ECR II-04945.

27 Janssen and Van Asselt, "The Precautionary Principle in Court - An Analysis of Post-Pfizer Case Law", *supra* note 3.

28 Ibid.

29 Janssen and Van Asselt, "The Precautionary Principle in Court - An Analysis of Post-Pfizer Case Law", *supra* note 3, at p. 207.

30 Ibid.

31 Ibid.

32 Alemanno, "The Shaping of European Risk Regulation by Community Courts", *supra* note 15.

33 Scientific Committee on Animal Nutrition

34 Janssen and Van Asselt, "The Precautionary Principle in Court - An Analysis of Post-Pfizer Case Law, *supra* note 3, at p. 213.

mand the Commission or the Council, for not performing a risk assessment. Instead, the Court "acted as a super risk assessor"[35], while it ought to determine whether the risk manager conducted a risk assessment and if this had been done according to the procedural requirements. In its place, the Court constructed uncertainty as the absence of full safety.

### 4. The Temporary Nature of Precautionary Measures

In some cases the Court has ignored the temporary nature of precautionary measures. They should be reviewed whenever new scientific evidence is available. Such re-evaluations are necessary to prevent precautionary measures to become permanent.[36] Instead of demanding a substantive review of the latest scientific findings, "the Court found [...] that an administrative review is sufficient when deciding on precautionary measures."[37] Consequently, "by not insisting on a new risk assessment of the substances, the Court disregards the temporary character of the precautionary principle."[38]

Due to the lack of standards concerning minimum requirements for a risk assessment, all cases demonstrate varying levels of uncertainty as a basis for precautionary action. Janssen and Van Asselt argue that these patterns evolved because of deeper tensions in the regulatory scheme of the principle.[39] These tensions rose from the uncertainty paradox, the tendency to equate uncertainty with risk, and the (im)possibility of performing a risk assessment.

## III. Case Law on the Precautionary Principle

The Courts have been inconsistent in dealing with the relationship between uncertainty and the precautionary principle. Most of the patterns and inconsistencies revealed by Janssen and Van Asselt are also visible in more recent cases.[40] This research also discloses new inconsistencies in the Courts' rulings. First the cases are introduced, where after the analysis of the tensions is discussed.

### 1. Gowan[41] – Challenging the Validity of Restrictions on Fenarimol

*Gowan* concerned restrictions on fenarimol, an active substance used in Plant Protection Products (PPP). After inclusion in Annex I of Directive 91/414, a substance may be marketed within a period of ten years under certain conditions. The inclusion of fenarimol was preceded by a risk assessment, conducted by the UK. Gowan, the UK, and the Standing Committee on the Food Chain and Animal Health (SCFCAH) concluded from the study that "the use of fenarimol was acceptable without any further analysis or risk management."[42] A similar assessment on risks of endocrine disruption in plants by the Scientific Committee on Plants reached the same conclusion of "no convincing evidence" in these studies for human risk.[43]

Although the procedure for inclusion was closed in 2004, the "risk management measures were [continuously] discussed in the "legislation" working group of the [SCFCAH]."[44] The group's recommendation to restrict the use of fenarimol and to limit its period of authorisation in addition to the concerns of some Member States, led the Commission to conduct extensive consultations with (national) experts. The adopted proposal limited the authorisation to 18 months and the uses of fenarimol (Directive 2006/134/EC).[45] The justification was "the risk of endocrine disruption"[46] and the lack of OECD test guidelines to assess "potential endocrine disrupting properties."[47] According to the Advocate General, in cases of non-existing "established and undisputed

35 Ibid.

36 Janssen and Van Asselt, "The Precautionary Principle in Court - An Analysis of Post-Pfizer Case Law, *supra* note 3, at p. 213.

37 Ibid.

38 Ibid.

39 Ibid.

40 Janssen and Van Asselt, "The Precautionary Principle in Court - An Analysis of Post-Pfizer Case Law", *supra* note 3.

41 Case C-77/09, Gowan Comércio Internacional e Serviços Lda v. Ministero della Salute [2010] ECR I-13533.

42 Case C-77/09, Gowan Comércio, *supra* note 41, at para. 34.

43 Ibid., paras. 34-36.

44 Ibid., at para. 37.

45 Commission Directive 2006/134/EC of 11 December 2006 amending Council Directive 91/414/EEC to include fenarimol as active substance Text with EEA relevance, OJ L 349, p. 32–36; Case C-77/09, Gowan Comércio, *supra* note 41, at para 43.

46 Ibid., paras. 34, 38, 62.

47 Ibid., at para. 41.

methodolog[ies]", the "analysis necessarily entails choices of a political and social nature which are for the Commission to make."[48] Gowan challenged the validity of this Directive and in 2010, the CJEU ruled in favour of the Commission upholding the limited time of inclusion and uses of fenarimol.

## 2. Afton[49] – Challenging the Validity of Directive 2009/30

Methylcyclopentadienyl-manganese-tricarbonyl (MMT) is a chemical substance, which is commercially used as a metallic additive to fuel. It raises "the octane level in unleaded fuel and/or to protect against valve damage in vehicles running on lead replacement petrol."[50] Many vehicle manufacturers disapprove the use of fuel containing metallic additives, as this may invalidate vehicle warranties. Moreover, fuel with MMT "might raise the risk of damage to human health."[51] To avoid these risks the Commission is to develop test methodologies as "an assessment of the risks for health and the environment."[52] Meanwhile, through Directive 2009/30[53], an insertion to Directive 98/70[54], the use of MMT was increasingly restricted and labelling requirements had been established. These restrictions will only be changed in accordance to the yet to be developed test methodologies, meaning that while a lift of the restrictions is possible, a ban is possible as well. Afton Chemical Limited, however, considered this insertion as unlawful, as prior to it there were no limit and no labelling requirements, neither for MMT nor for any other metallic additives.[55] Consequently, the Administrative Court of the UK brought the case to the CJEU, claiming unlawfulness.[56] The Court, however, rejected Afton's claim.

## 3. S.P.C.M.[57] – Registration of Monomer Substances

"Polymer" is the term used for all substances "consisting of molecules characterised by the sequence of one or more types of monomer units."[58] A polymer consists of "a simple weight majority of molecules containing at least three monomer units."[59] Polymers are nearly everywhere in daily life, as they are part of plastics. The REACH Regulation prescribes that all chemical substances need to be registered by importers, manufacturers and downstream users with the goal to "ensure a high level of protection of human health and the environment as well as the free movement of substances."[60] Those who need to register chemical substances have to use the data to "assess the risks related to these substances and to develop and recommend appropriate risk management measures."[61] This concerns mainly monomer sub-

48 Opinion of Advocate General Jääskinen in Case-77/09 Gowan Comércio Internacional e Serviços Lda v. Ministero della Salute [2010], ECR I-13533, available on the Internet at: <http://curia.europa.eu/juris/document/document.jsf;jsessionid=9ea7d2dc30db6150ae1f124b4c058521df228d168146.e34KaxiLc3qMb40Rch0SaxuLaxr0?text=&docid=78679&pageIndex=0&doclang=en&mode=lst&dir=&occ=first&part=1&cid=3469612> (last accessed on 5 May 2013), at para. 71.

49 Case C-343/09, Afton Chemical Limited v Secretary of State for Transport [2010] ECR I-07027.

50 Case C-343/09, Afton Chemical, *supra* note 49, at para. 6.

51 Ibid., at para. 3.

52 Ibid., at para. 4.

53 Directive 2009/30/EC of the European Parliament and of the Council of 23 April 2009 amending Directive 98/70/EC as regards the specification of petrol, diesel and gas-oil and introducing a mechanism to monitor and reduce greenhouse gas emissions and amending Council Directive 1999/32/EC as regards the specification of fuel used by inland waterway vessels and repealing Directive 93/12/EEC, OJ L 140, at pp. 88 *et sqq*.

54 Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels and amending Council Directive 93/12/EEC, OJ L 350, at p. 58 *et sqq*.

55 Case C-343/09, Afton Chemical, *supra* note 49, at para. 7.

56 Ibid., at para. 9.

57 Case 558/07, The Queen, on the application of S.P.C.M. SA, C.H. Erbslöh KG, Lake Chemicals and Minerals Ltd and Hercules Inc. v Secretary of State for the Environment, Food and Rural Affairs [2009] ECR I-05783.

58 Case C-558/07, S.P.C.M., *supra* note 57, at para. 9.

59 Ibid.

60 Ibid., paras. 3-4, see also: Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, at Recital 1.

61 Ibid., at para. 5, see also: Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Text with EEA relevance), at para. 19.

stances of which polymers consists. Whereas monomer substances have "individual chemical characteristics", polymers "are generally stable and safe."[62]

The issue in *S.P.C.M.* was that polymers are exempted from registration as their diversity renders registration very costly and time-consuming. Subsequently, the applicants brought the case in front of the Court to clarify the definition of monomer substances and whether polymers needed to be registered. It ruled that manufacturers, importers and downstream users need to register their substances and that the "concept of "monomer substances" in Article 6(3) of the REACH Regulation relates only to reacted monomers, which are integrated in polymers"[63] and therefore rejected the case.

### 4. Bayer CropScience[64] Challenge on the Non-inclusion of Endosulfan

This case dealt with the active substance endosulfan, which is used in Plant Protection Products (PPPs). Endosulfan "acts as a contact poison on a wide variety of insects and mites on many crops, including cotton and many varieties of fruit and vegetables."[65] The "good plant protection practice" (GAP) rules apply to endosulfan. These rules must "be complied with in planting and the manner of cultivation so as to optimise agricultural production, while reducing the risks to human beings and the environment."[66] All active substances must be included into Annex I to Directive 91/414[67] – as this inclusion shows that the GAP rules are applied to. Since the producers and users of endosulfan, among them Bayer CropScience, were unable to prove the harmlessness of endosulfan[68], it was not included into Annex I. Moreover, the inclusion of endosulfan was hindered as it was not possible to show that metabolites of metabolites to which endosulfan is a parent substance are not "potentially harmful."[69] As consequence to non-inclusion Member States were not allowed to authorise any PPPs containing endosulfan to the market.[70]

In accordance with the Commission, BayerCropScience had prepared information for endosulfan to be included in the Annex, when doubts arose whether endosulfan, or rather the metabolites of metabolites are safe.[71] Although the Commission firstly adopted a decision on the possible inclusion of the substance[72] and the applicants added new data on the formulation of endosulfan as to "dispel some of the doubts already expressed by the Kingdom of Spain,"[73] the decision for inclusion was postponed again and again. After continuous forth and back between Commission, rapporteur state Spain and the applicants, the Commission announced that it was preparing to not include endosulfan.[74] While the applicants tried to submit new data, the Commission's decision on non-inclusion was final.[75] Ultimately the case was brought to the CFI, mainly as an action for failure to act[76], which the Court judged to be non-existent.[77] The Court also decided not to let "certain experts appear before it" as "those measures would serve no useful purpose."[78]

## IV. Do the New Findings Support the Identified Patterns?

In the following we discuss in how far problematic tensions and inconsistencies as identified by Janssen and Van Asselt have continued.

### 1. Lack of Risk Assessment and the Court as Risk Assessor

In *Afton*, the Commission did not conduct a risk assessment to determine the negative impact of MMT

62 Ibid., at para. 16.

63 Ibid., at para. 38.

64 Case T-75/06, Bayer CropScience AG, Makhteshim-Agan Holding BV, Alfa Georgika Efodia AEVE and Aragonesas Agro, SA v Commission of the European Communities [2008] ECR II-02081.

65 Case T-75/06, Bayer CropScience AG, *supra* note 64, at para. 23.

66 Ibid., at para. 171.

67 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market, OJ L 230, p. 1-32.

68 Case T-75/06, Bayer CropScience AG, *supra* note 64, paras. 126-128, 228.

69 Ibid., at para. 126.

70 Ibid., paras. 3-4.

71 Ibid., at para. 24.

72 Ibid., at para. 30.

73 Ibid., at para. 31.

74 Ibid., at para. 35.

75 Ibid., at para. 39.

76 Ibid., at para. 40.

77 Ibid., at para. 259.

78 Ibid.

on pollution abatement technologies. The Court excused the lack, stating that "the state of scientific knowledge meant that the development of test methodologies was difficult or impossible."[79] Interestingly, however, there were many studies on MMT. Yet, as the scientific studies were conducted by two opposing industries, the Court argued that they were not reliable as the "widely disparate conclusions"[80] only showed the different interests of the industries. Nevertheless, if industries are able to conduct studies, the Court should have insisted on a risk assessment by a (independent) national or European institution.

In the same case, the Court did not criticise the Commission for wrongly basing its claim on health whereas "it expressly ruled out an appraisal of the health risks of MMT."[81] When Afton found no evidence of harm to health in the scientific documents, the Court referred to the documents of the Member States, instead of reprimanding the Commission for, arguably, a manifest error.

In *Bayer CropScience,* there was also no risk assessment performed on the substance in question. Although the Court acknowledged this absence, it excused it by stating, that

> the consultation with experts from the Member States and the possibility for notifiers to submit additional data and studies on the basis of meetings and discussions with the various parties involved in the evaluation procedure, are *clearly* a response to the concern regarding compliance with the procedural guarantees as established in *Pfizer*[82] (emphasis added).

This is consistent with Janssen's and Van Asselt's findings that the Court sometimes held expert consultation "to be sufficient as a risk assessment."[83] This is a weak risk assessment at best. The applicants attempted several times to submit additional information, but the Commission chose to discard the new information by referring to expired deadlines. The Commission even requested Spain to ignore the new data too. This action clearly goes against the rules and the spirit of the precautionary principle, as precautionary measures must always be based on the latest scientific evidence.

In *S.P.C.M.*, the Court argued that it is acceptable to market substances even though there are no studies on them. Additionally, it consents that certain substances (dangerous or not) do not need to be registered, when there are no "cost-efficient" methods to do so yet.[84]

> Polymers should be exempted from registration and evaluation until those that need to be registered due to the risks posed to human health or the environment can be selected in a practicable and cost-efficient way on the basis of sound technical and valid scientific criteria.[85]

It is striking, that in *Afton* the possibility of a risk is enough to justify the application of the precautionary principle (the Court stated that the MMT *might* entail risk), whereas in *S.P.C.M.* the Court states that the polymers that pose risks to human health only need to be registered when there is a cost-efficient way to do it.

In *Gowan*, the Commission first agreed with the SCFCAH report stating that there was no risk in using fenarimol. It then changed its stance, based on consultations with Member States' experts and a recommendation of a legislative Working Group. The Court argued that the assessment by the UK was not binding for either the Commission or the Council, and that these actors are entitled "to adopt different risk management measures from those proposed by the rapporteur Member State."[86] Consultations with Member States' experts and a recommendation of a legislative Working Group do not, in our view, constitute a sufficient risk assessment. Additionally, a legislative Working Group is not qualified to make the decision that, contrary to the findings of the SCFCAH report, there is a risk of endocrine disruption. Instead, the experts should formulate an opinion regarding fenarimol, where after this opinion should be included in the risk assessment.

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79 Case C-343/09, Afton Chemical, *supra* note 49, paras. 44, 51.

80 Ibid., at para. 58.

81 Opinion Advocate General Kokott in Case C-558/07 The Queen, on the application of Afton Chemical Limited v Secretary of State for Transport [2009] ECR I-05783. Available on the Internet at http://curia.europa.eu/juris/document/document_print.jsf?doclang=EN&text=&pageIndex=0&part=1&mode=DOC&docid=77516&occ=first&dir=&cid=765456 (last accessed on 5 May 2013), at para. 38.

82 Case T-75/06, Bayer CropScience AG, *supra* note 64, at para. 257.

83 Janssen and Van Asselt, "The Precautionary Principle in Court - An Analysis of Post-Pfizer Case Law, *supra* note 3, at p. 208.

84 Case C-558/07, S.P.C.M., *supra* note 57, paras. 50-51.

85 Ibid., para. 6

86 Case C-77/09, Gowan Comércio, *supra* note 41, para 60.

These acceptances of lacking risk assessments are low thresholds for precautionary measures showing that the Courts are at liberty to define the requirements for a risk assessment.

## 2. Constructing Uncertainty

In *Afton,* two competing industries had conducted scientific assessments reaching opposing results. The Court described that the EU legislature faced "serious doubts, in the absence of adequate and reliable scientific data, ... whether MMT was harmless for health and the environment."[87] Although the research was arguably biased, it does demonstrate that it was possible to do a risk assessment. Instead of demanding the scientific assessment of an institution such as the Scientific Committee on Health and Environmental Risks (SCHER), the risk managers continued with the two existing assessments and thus "created" uncertainty. The Court consequently argued that "no public body or independent entity had undertaken a scientific assessment of the effects of MMT on health ... it follows that the ... legislature was faced with serious doubts."[88] Still, the Court did not insist on such an assessment and did not reprimand the Commission for failing to perform one but rather accepted the constructed uncertainty.

Considering the precautionary measures, the CJEU stated that "the fact that the use of that substance *might* entail risks for human health and *might* cause damage to vehicle engines [...]" (emphasis added) validated the measures.[89] As the precautionary measure is only temporary and can be lifted in the future, a measure amounting to a *de facto* ban is acceptable while test guidelines are developed.[90] The Court clearly equates uncertainty with risk. The CJEU concluded that the precautionary principle is rightly applied if the *likelihood* of risks exists, though due to "the insufficiency, inconclusiveness or imprecision of the results of studies conducted"[91] no final conclusion could be drawn.

In *Bayer CropScience* too, the decision not to include endosulfan into the Annex was "based on the absence of sufficient information to show that there were no risks"– here uncertainty is created by the expectation that sufficient information would show zero risks.[92] However, as the uncertainty paradox demonstrates, it is impossible to scientifically establish zero risk in a situation of uncertainty. Moreover, uncertain risks often exist in high knowledge situations. Adding more information does not necessarily decrease or eliminate the uncertain risk. The Commission based its decision of non-inclusion "on a lack of information rather than on identified risks."[93] The Commission and the Court equate the absence of information with uncertainty, and in turn, uncertainty equals risk. The Court rejected the applicants' claim stating "the Commission wished to have evidence of a safe use" and that therefore the "behaviour of the metabolite of endosulfan sulfate" had to be understood.[94]

Additionally, in *Gowan*, the Commission created uncertainty by labelling fenarimol as "hazardous", referring to the impossibility "to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted."[95] Remarkably, none of the conducted studies had referred to fenarimol neither as a hazardous substance nor as unacceptably risky. The Court, as in *Pfizer*, defined uncertainty as differing scientific opinions.

## 3. Analogical Handclapping

In *Gowan*, the Commission referred to scientific studies that were performed on substances that were similar to fenarimol.[96] The Court consequently ruled that the Commission had rightly applied the precautionary principle, "in the light of this evidence which *tends* to demonstrate that there was still some scientific uncertainty regarding the assessment of the effects on the endocrine system of *substances such as* fenarimol"(emphasis added).[97] Using probabilistic language, the Court accepted all risk management

87 Case C-343/09, Afton Chemical, supra note 49, para. 59.

88 Ibid., paras. 58-59.

89 Ibid., at para. 48.

90 Ibid., at paras. 48-53.

91 Ibid., at para. 61.

92 Case T-75/06, Bayer CropScience AG, *supra* note 64, at para. 228.

93 Ibid., at para. 128.

94 Case T-75/06, Bayer CropScience AG, *supra* note 64, at para. 128.

95 Case C-77/09, Gowan Comércio, *supra* note 41, at para. 76.

96 Case C-77/09, Gowan Comércio, *supra* note 41, at para. 78.

97 Ibid., at para. 79.

measures neglecting whether the provision of only "similar" assessments was consistent with the usual procedure. Using analogical handclapping, the Court excused the Commission for not performing a risk assessment.

In *Bayer CropScience* the applicants requested a risk assessment, as the Commission "cannot assess the safety of endosulfan on the basis of data results which relate to another substance."[98] Although confirming the necessity of excellent scientific review, the Court concluded that the Commission had not committed an error of assessment, especially as it had considered the views of experts and the notifier. The Court added, the "applicants confuse compliance with procedural guarantees with the possibility of differing views on the substance."[99] The CFI discarded a lack of a proper risk assessment by asserting that instead of a separate assessment of endosulfan, the Commission "assess[ed] the safety of endosulfan on the basis of data results which relate to another substance – endosulfan sulphate and/or other unknown metabolites."[100] Furthermore, the Court ruled that the Community institutions have broad discretion to employ precautionary measures in the interest of human health.[101] These findings demonstrate that the Courts based precautionary measures on analogy.

## V. New Tensions

New tensions further underline the Courts' struggle when dealing with uncertainty and the precautionary principle. Thus, more case law is not the way to further develop the principle.[102]

### 1. Discretion of the EU Legislature

By ignoring "self-established boundaries and rules, [and] allowing the Commission and the Council to do the same,"[103] the Court created a new tension. This is particularly visible in the far-reaching discretion of the Commission to adopt risk measures, and the undefined link between risk assessment and risk management. Not only does the Community legislature have broad discretion regarding the (legality of the risk measure[104], "technical and scientific assessment[s]," political, social and economic choices,"[105] and in finding the basic facts.[106] In all previous judgments the Commission's broad discretion[107] is continuously emphasised making it look like the Courts just rubberstamped the Commission's decisions.

In *Gowan*, though studies had demonstrated that there were no "unacceptable risks" arising from fenarimol, the Commission created uncertainty based on the concerns of some Member States and through analogical handclapping. The CJEU reiterated the Commission's considerable discretion and its own restriction to check the procedural steps. Arguing that the UK assessment was not binding for either the Commission or the Council, and that these actors may choose a risk measure freely.[108] *Gowan* is therefore one of the cases questioning "whether and under which conditions European Courts can depart from the outcome of risk assessment while adopting risk management measures,"[109] and also: how broad should be the Commission"s discretion? Alemanno reasons that "by failing to counterweight the broadening of EU discretionary powers stemming from the invocation of precaution with an effective judicial scrutiny, the Court seems ready to surrender its function of gatekeeper of precautionary action."[110] The Court arguably "de-intensif[ies] the stringency of judicial review over the legality of its action."[111] It seems that the Courts excused the lack of risk assessments and begun to "content [themselves] to identify some evidence of scientific uncertainty without engaging into a procedural check aimed at identifying the procedural steps leading to determination of

98 Case T-75/06, Bayer CropScience AG, *supra* note 64, at para. 247.

99 Ibid., at para. 257.

100 Ibid., at para. 247.

101 Ibid., para. 256.

102 Janssen and Van Asselt, "The Precautionary Principle in Court - An Analysis of Post-Pfizer Case Law, supra note 5, at p. 216.

103 Janssen and Van Asselt, "The Precautionary Principle in Court - An Analysis of Post-Pfizer Case Law, supra note 3, at p. 216.

104 Case C-558/07, S.P.C.M., *supra* note 57, at para. 2.

105 Ibid., para. 42; also: Case C-343/09, Afton Chemical, *supra* note 49, at para. 46, also: Case C-77/09, Gowan Comércio, *supra* note 41, at para. 82.

106 Case C-343/09, Afton Chemical, *supra* note 49, at para. 33.

107 Ibid., paras. 28, 33, 46; see also: Case C-558/07, S.P.C.M., *supra* note 57, paras. 2, 42; also: Case T-75/06, Bayer CropScience AG, *supra* note 64, paras. 82, 88, 108, 196, 224.

108 Case C-77/09, Gowan Comércio, *supra* note 41, paras. 3, 46 - 62.

109 Alemanno, "Case C-79/09, Gowan Comércio Internacional e Servicos Lda v. Ministero della Salute, Judgment of the Court (Second Chamber) of 22 December 2010", *supra* note 15, at p. 1330.

110 Ibid., at p. 1329.

111 Ibid., at p. 1344.

scientific uncertainty."[112] These are very problematic developments, because if the Courts do not check the Commission, then who will? This tension arguably underlies the following problematic patterns.

## 2. Introduction of New Scientific Evidence

In the *IQV* case[113] the Court ruled that "the Commission cannot rely on time-limits as the sole ground for refusing to consider the new data submitted by the applicants."[114] In two of our cases, it is clear that the Court does not adhere to its own ruling: In *Afton* and *Bayer CropScience*, the Commission rejected new scientific evidence because the submission deadline had already expired or because the study was published too late.[115] Notifiers of an active substance, as in *Bayer CropScience*, had to demonstrate a "situation of *force majeure* which prevented them from complying with procedural time-limits for the submission of additional information."[116] Failing to prove a situation of *force majeure* as a reason for their late submission, neither the Commission nor the Court considered alternative measures to the *de facto* ban.[117] The Court accepted this, arguing "that an indefinite postponement of the deadline for evaluating an active substance would be contrary to the aim pursued."[118] In *Afton*, conversely, the CJEU highlighted the Commission's discretion to accept new scientific evidence during the proceedings.[119] This in combination with the Commission's refusal to consider the UK's risk assessment in *Gowan*, raises the suspicion that in the current framework, rejection or acceptance of evidence is in the hands of the Commission. Strict adherence to deadlines contrasts the precautionary principle and its temporary nature.

## 3. Proportionality of Precautionary Measures

In all cases, the Court accepted risk measures amounting to *de facto* bans. The Communication, however, stated that albeit a "risk can rarely [be] reduced to zero ... a total ban may not be a proportional response to a potential risk in all cases."[120] Moreover, previous case law established that "when there is choice between several appropriate measures, recourse must be had to the least onerous."[121] Even though the applicants in *Gowan* and *Bayer CropScience*[122] offered various safe options to the use of the substance, a ban was issued.

As there were no undisputed test methodologies in *Afton* yet, the Court argued that "a restrictive measure such as a limitation"[123] leading to a ban was proportionate.[124] The Court justified the ban by stating that "the substance *might* entail risks ... and *might* cause damage" (emphasis added).[125] Here again the Court equates uncertainty with risk. Similarly, in *Gowan*, the Commission changed its first positive opinion on the substance due to concerns of the Member States. The Court then ruled the ban to be proportionate, though this uncertainty was based on analogy and a lack of risk assessments.[126] It is strange that a substance that initially was described as possessing no unacceptable risks, eventually was banned from usage altogether. In both cases the Court acted as a super-expert in risk assessment.

# VI. Discussion and Conclusion

Our findings have demonstrated that the Courts are deviating further from their judicial role. How far have the Courts departed from their previously established rules for risk assessments[127] and how have

112 Ibid., at p. 1345.

113 C-326/05 P *Industrias Químicas del Vallés* v *Commission* [2007], Judgement of 18 July 2007, ECR I-6557.

114 *Case T-75/06,* Bayer CropScience AG*, supra* note 64*,* at para. 219.

115 Case C-343/09, Afton Chemical, *supra* note 49, paras. 36, 60; CFI, Case T-75/06, Bayer CropScience AG, *supra* note 64, at para. 226.

116 Case T-75/06, Bayer CropScience AG, *supra* note 64, at para. 226.

117 Ibid., paras. 149-152, 159-192.

118 Ibid., at para. 86.

119 Case C-343/09, Afton Chemical, *supra* note 49, at para. 41.

120 Communication on the Precautionary Principle, *supra* note 7, at p. 4

121 Case C-174/05 *Zuid-Hollandse Milieufederatie and Natuur en Milieu* [2006] ECR I-2443, para. 28 and the case-law cited.

122 Case C-77/09, Gowan Comércio, *supra* note 41, paras. 38, 69-71; see also: Case T-75/06, Bayer CropScience AG, *supra* note 64, paras. 31, 237.

123 Case C-343/09, Afton Chemical, *supra* note 49, at para. 55.

124 Ibid., at para. 68.

125 Ibid., paras. 3, 48, 87.

126 Case C-77/09, Gowan Comércio, *supra* note 41, paras. 62-64.

127 Elen Stokes, "The EC courts' contribution to refining the parameters of precaution", 11(4) *Journal of Risk Research,* pp. 491 *et sqq.,* at pp. 498 - 499.

they accepted lesser forms of it? In line with Stokes, we argue that it is still unclear what a risk assessment should look like.[128] The framework of the precautionary principle does not sufficiently address the complexities of uncertain risks, the role of the Courts and of the Commission therein.

The Communication demands a comprehensive scientific evaluation, and an identification of the scientific uncertainty at stake.[129] The risk measure must be consistent with the principle of proportionality, based on a cost-benefit analysis and established on the most recent scientific data. These requirements, however, are difficult to fulfil in situations of scientific uncertainty. The identification of the already established and new tensions and inconsistencies demonstrates that the Courts still "lack a clear vision of how to rule on uncertainty and precaution."[130]

The inconsistencies of the Court in dealing with uncertain risks, has led to several problematic patterns which are effectively crippling the precautionary principle as a tool of risk management. Our research has demonstrated that the Courts further expanded their efforts in constructing uncertainty. It continues to be defined as contrasting scientific opinions, or the lack of consensus between experts. This development opens the door for protectionism, as in virtually all-uncertain risk cases a divergent opinion can be found. Moreover, the Courts have defined uncertainty as the absence of full safety. They ruled that the possibility of a risk, the absence of zero risk, or the lack of information establishes uncertainty and risk, and is therefore sufficient legal basis for precautionary measures. These are very low thresholds for precautionary measures, as uncertain risks always have a possibility of risk. Also, scientists are not unable to prove zero risk, nor does more information reduce the risk. The Courts are clearly acting as a super risk assessor, determining what constitutes risk.

We also demonstrated that the Courts continued to accept inadequate risk assessments. Moreover, to various extents in the different cases no risk assessments were performed by independent bodies, risk assessments were ignored, analogy between substances and consultations with experts were deemed to be enough. The Courts also disregarded the temporary nature of risk measures by failing to insist on new risk assessments or ignoring new information, while each case must be reviewed based on the latest scientific evidence available. These risk assessments are obviously not consistent with the standards of excellence and transparency the CFI set itself in *Pfizer*.

Another development that gives reason for concern is the tendency of the Courts to allow the Commission to disregard the proportionality of precautionary measures accepting a *de facto* ban in all analysed cases. This seems to be an extreme measures, especially because the Communication states that bans are not the appropriate measure in response to a risk.[131] Particularly worrying is the amount of leverage the Commission has gained under the argument of protecting human health. The willingness of the Courts to rubberstamp the Commission's risk measures and their refusal to demand proper risk assessments confirms Alemanno's view that "the Court [the CJEU in *Gowan*] seems ready to surrender its function of gatekeeper of precautionary action,"[132] thereby relinquishing more power to the Commission.

We agree with Alemanno who holds that "EU Courts should not hesitate to assert control not only on the techno-scientific process preceding the adoption of risk decisions but also on the relationship existing between the outcome of that process and the final risk management decision."[133] At the same time we wonder, "whether the Court should even have to deal with such cases of scientific complexity."[134] The solution by Janssen and Van Asselt seems appropriate: a new and revised Communication "to "save" the precautionary principle as a tool for risk management."[135] In the revised version, terms should be defined more clearly, the link between risk assessment and risk management should be re-thought and the Commission's discretion clearly defined.

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128 Stokes, "The EC courts' contribution to refining the parameters of precaution", *supra* note 127, at p. 503 - 504.

129 Alemanno, "The Shaping of European Risk Regulation by Community Courts", *supra* note 15.

130 Janssen and Van Asselt, "The Precautionary Principle in Court - An Analysis of Post-Pfizer Case Law", *supra* note 3, at p. 216.

131 Communication on the Precautionary Principle, *supra* note 7, p. 4.

132 Alemanno, "Case C-79/09, Gowan Comércio Internacional e Servicos Lda v. Ministero della Salute, Judgment of the Court (Second Chamber) of 22 December 2010", *supra* note 15, p. 1330.

133 Ibid., at p. 1335.

134 Janssen and Van Asselt, "The Precautionary Principle in Court - An Analysis of Post-Pfizer Case Law, *supra* note 3, at p. 210.

135 Ibid, at p. 214.

# The Definition of Nudge and Libertarian Paternalism: Does the Hand Fit the Glove?

*Pelle Guldborg Hansen**

*In recent years the concepts of 'nudge' and 'libertarian paternalism' have become popular theoretical as well as practical concepts inside as well as outside academia. But in spite of the widespread interest, confusion reigns as to what exactly is to be regarded as a nudge and how the underlying approach to behaviour change relates to libertarian paternalism. This article sets out to improve the clarity and value of the definition of nudge by reconciling it with its theoretical foundations in behavioural economics. In doing so it not only explicates the relationship between nudges and libertarian paternalism, but also clarifies how nudges relate to incentives and information, and may even be consistent with the removal of certain types of choices. In the end we are left with a revised definition of the concept of nudge that allows for consistently categorising behaviour change interventions as such and that places them relative to libertarian paternalism.*

## I. Introduction

> "... 'Soft Paternalism' would refer to *actions of government that attempt to improve people's welfare by influencing their choices without imposing material costs on those choices... We can understand soft paternalism, thus defined, as including nudges, and I will use the terms interchangeably here."* (Cass Sunstein *Why Nudge? The Politics of Libertarian Paternalism* 2014, p. 58).
>
> "It is important to recognise that behavioural economics and so-called 'nudges' are distinct. The former is a scientific subdiscipline; the latter is a particular way to apply its findings to policy, which holds that policy makers should avoid regulations that limit choice (bans, caps, etc.) but can use behavioural science to direct people towards better choices." (*Regulatory Policy and Behavioural Economics*, (Lunn 2014), OECD report)

Since the publication of Thaler and Sunstein's *Nudge: Improving Decisions about Health, Wealth and Happiness*[1] the concepts of *nudge* and their particular version of soft paternalism called '*libertarian paternalism*' have become concepts of increasing interest and debate among public policy makers and academics alike.[2,3,4,5,6] However, ensuing discussions[7] concerned with particular applications, the im-

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1 Richard H. Thaler and Cass R. Sunstein, *Nudge: Improving Decisions about Health, Wealth, and Happiness*, Revised and Expanded Edition (New York: Penguin Books, 2009).

2 Sarah Conly, *Against Autonomy: Justifying Coercive Paternalism* (New York: Cambridge University Press, 2012), at p. 29.

3 Daniel Kahneman, "Foreword", in Eldar Shafir (ed.), *The Behavioral Foundations of Public Policy*, (Princeton NJ: Princeton University Press, 2012), pp. VII *et sqq*., at p. VIII.

4 Pete Lunn, *Regulatory Policy and Behavioural Economics* (OECD Publishing, 2014).

5 Barry Schwartz, "Why not nudge? A Review of Cass Sunstein's Why Nudge", 17 April 2014, available on the internet at: <http://thepsychreport.com/essays-discussion/nudge-review-cass-sunsteins-why-nudge/> (last accessed on 17 April 2014).

6 Cass R. Sunstein, *Why Nudge?: The Politics of Libertarian Paternalism* (New Haven: Yale University Press, 2014).

7 See e.g. Ryan Calo, "Code, Nudge, or Notice", 99(2) *Iowa Law Review* (2014), pp. 773 *et sqq*; Henry Farrell and Cosma Shalizi, "Nudge No More", New Scientist, 26 November 2011: <http://www.slate.com/articles/health_and_science/new_scientist/2011/11/does_nudge_policy_work_a_critique_of_sunstein_and_thaler_.html> (last accessed on 26 November 2014); Lunn, *Regulatory Policy and Behavioural Economics*, *supra* note 4; Thomas Ploug, Søren Holm and John Brodersen, "To nudge or not to nudge: cancer screening programmes and the limits", 66(12) *Journal of Epidemiology and Community Health* (2012), pp. 1193 *et sqq*; Anthony Randazzo, "The Case Against Libertarian Paternalism", 23 April 2013, available on the internet: <http://reason.com/archives/2013/04/23/the-case-against-libertarian-paternalism> (last accessed 26 November 2014); Mark D. White, *The Manipulation of Choice: Ethics and Libertarian Paternalism* (New York: Palgrave Macmillian, 2013); Mark D. White, "The richness of personal interests: A neglected aspect of the nudge debate", 23

plications and the acceptability of nudges in public policy and their relationship to libertarian paternalism have paid very little attention to a series of disagreements and ambiguities with regard to the way that the concept of nudge has been defined and how it relates to that of libertarian paternalism.

The confusion exists even amongst researchers. For instance, nudges and libertarian paternalism are often discussed as synonymous, as indicated by the two quotes above.[8] At the same time it is said that supermarkets, restaurants, and cafeterias are nudging consumers all the time whether they recognise this or not.[9] Yet it seems that the choice architects of supermarkets, restaurants and cafeterias can hardly be said to be libertarian paternalists (whether they recognise this or not, or whether the references to them as choice architects who nudges are intended as such). So *are* nudges always acts of libertarian paternalism, and are libertarian paternalists *always* nudging by definition? Researchers seem to be confused.

An extension of this confusion is that the application and acceptability of nudges are usually discussed without determining or being sufficiently clear about whether certain requirements apply to the motives of the choice architect for an intervention to count as a nudge.[10] That is, does a nudge have to be rooted in the mind-set of libertarian paternalism? Is it only truly a nudge if applied with this mind-set? That is, is it true, as it is often held by critics, that any proponent of nudge interventions is also necessarily suggesting the doctrine that policy makers should avoid regulations that limit choice?

In addition, a series of conceptual specifics are underdetermined in the current literature. For instance, it is often unclear what the exact relation between nudges and incentives is.[11] According to Sunstein and Thaler it depends on whether the material or "cognitive" costs are low enough to make a nudge easy or cheap to avoid.[12] Yet, as illustrated by discussions such as in Mongin and Cozic 2014[13], that easily becomes a little too vague to be useful in any practical discussion. For instance, while imposing a tax is said not to be a nudge[14], and the same goes for placing candy in an obscure place in the supermarket[15], choosing a charm price or asking costumers to pay 5 cents for plastic bags both count as nudges.[16] But, as someone with philosophical inclinations might ask, where is the objective point of difference to be found between the nudge provided by a 5-cent tax on plastic bags or placing candy at eye height, and a non-nudge of a 5-dollar tax on plastic bags or placing candy behind the counter? Is there a strict line between nudges and other interventions, is it a continuum, or can an intervention be both a nudge and not a nudge at the same time (especially since cognitive costs seem relative to the individual cognitive capabilities of those nudged)? All of this is currently not clear from the literature.

Besides the confusion on incentives, it also remains in the shadows whether and under what conditions the addition or removal of choice options may count as a nudge and if so whether it should also be regarded as a policy based on libertarian paternalism.[17] On the one hand, the definition of nudge provided by Thaler and Sunstein does not exclude adding choices. On the other, the removal of choice options barred by the definition may, as we shall see, in some cases seem to qualify as nudges. This vagueness and its consequences became clearly illustrated

October 2013, available on the internet at: <http://blogs.lse.ac.uk/politicsandpolicy/the-richness-of-personal-interests-a-neglected-aspect-of-the-nudge-debate/> (last accessed 26 November 2014); Paula Zoido-Oses, "The problem with nudge policies is that threaten our freedom to choose to act well", 9 July 2014, available on the internet at: <http://blogs.lse.ac.uk/politicsandpolicy/the-problem-with-nudge-policies-freedom-to-choose/#Author> (last accessed on 26 November 2014).

8 See also Calo, "Code, Nudge, or Notice", *supra* note 7, at p. 773, 775, 783, 785, 786, and 795; Conly, *Against Autonomy*, *supra* note 2, at p. 29-31; Lunn, *Regulatory Policy and Behavioural Economics*, *supra* note 4; Farrell and Shalizi, "Nudge No More", *supra* note 7; Ploug, Holm and Brodersen, "To nudge or not to nudge", *supra* note 7; Sunstein, *Why Nudge?*, *supra* note 6, at p. 58.

9 See e.g. Thaler and Sunstein, *Nudge*, *supra* note 1, at p. 3; and Alberto Salazar, "Libertarian Paternalism and the Dangers of Nudging Consumers", 23(1) *King's Law Journal* (2012), pp. 51 *et sqq*.

10 See e.g. Salazar, "Libertarian Paternalism and the Dangers of Nudging Consumers", *supra* note 9; and Pierre Schlag, "Nudge, Choice Architecture, and Libertarian Paternalism", 108(6) *Michigan Law Review* (2010), pp. 913 *et sqq*.

11 See e.g. the debate concerning user financial incentives as nudges around Adam Oliver, "A nudge too far? A nudge at all? On paying people to be healthy", 12(4) *Healthcare Papers* (2012), pp. 8 *et sqq*.

12 Sunstein and Thaler, *Nudge*, *supra* note 1, at p. 8 *footnote*.

13 Philippe Mongin and Cozic Mikaël, "Rethinking Nudges", (HEC Paris Research Paper No. ECO/SCD-2014-1067, 2014).

14 Thaler and Sunstein, *Nudge*, *supra* note 1, at p. 8.

15 Thaler and Sunstein, *Nudge*, (Ibid).

16 Sunstein, *Why Nudge*, *supra* note 6, at p. 64-65.

17 Mongin and Cozic, "Rethinking Nudges", *supra* note 13, at p. 6 and Schlag, "Nudge, Choice Architecture, and Libertarian Paternalism", *supra* note 10, at p. 917.

by the debate caused by former New York City Mayor Michael Bloomberg's Big Gulp Ban.[18] While Mayor Bloomberg referred to it as a nudge, Richard Thaler quickly tweeted "To state the obvious: a BAN is not a NUDGE. The opposite in fact. So don't blame Bloomberg's ban on large soda cups on us."[19] However, commentators were not convinced on theoretical grounds by Thaler's disclaimer.[20]

Finally, as we shall see, confusion is widespread even as to how nudges may be properly separated, if at all, from trivial standard measures such as the mere provision of information and rational persuasion.[21] Such trivial interventions are obviously true measures of libertarian paternalism and qualify as nudges on the original definition presented by Thaler and Sunstein. But if they are nudges, then the question arises: what is new about nudging, if anything at all?

Although these disagreements and ambiguities may seem 'just theoretical' they actually pose serious problems for the on-going efforts to apply behavioural science to public policy and other pro-social domains. Without clear and consistent foundational concepts the new policy-paradigm of applied behavioural science may easily come to seem ill founded, leaving the concept of nudge as well as the ideology of libertarian paternalism vulnerable to accusations of slippery-slopes, claims of conceptual inconsistency, and warnings that nudges may quickly turn into shoves and so forth. It also renders current efforts vulnerable to a misuse or the dilution of the underlying ideas. Any kind of intervention may easily seem to qualify as a nudge, making any practitioner claim that there is little new to the nudge approach and that he or she has always been nudging; and any objection pertaining to libertarian paternalism may seem to concern the use of nudges as well, and *vice versa*.

However, the prevailing confusion about the nudge concept and its relation to libertarian paternalism is quite understandable. As pointed out by Hausman and Welch,[22] the explicit definition of nudge provided by Thaler and Sunstein in *Nudge* only provides two *negative* conditions (that is conditions saying what nudges are not), a couple of heuristics for determining what counts as such, and a vast series of examples distributed throughout the book.[23]

Yet, to the person well versed in behavioural science, one of these heuristics provides a fundamental theoretical principle for defining nudges based upon the discipline of behavioural economics. This is the heuristic saying that "... a nudge is any factor that significantly alters the behavior of Humans, even though it would be ignored by Econs".[24] In their paper "Debate: To Nudge or Not to Nudge" Hausman and Welch at one point revise Thaler and Sunstein's definition of nudge for reasons of consistency with this principle so as to exclude incentives broadly conceived. In their paper "Nudge and the Manipulation of Choice" Hansen and Jespersen revise the definition even further so as to separate the concept of nudges from mere accidental influences in order to accommodate ethically relevant considerations, and in this process they note the principle as a foundational one as well.[25] In the paper "Rethinking Nudges" Mongin and Cozic semantically distinguishes this heuristic as a concept of nudge separate from that provided in the original definition.[26]

In this paper I argue, based on this principle, for revising Thaler and Sunstein's original definition of 'a nudge' on a series of important points. That is, distinct from Mongin and Cozic I do not treat it as a separate concept of nudge, but as the primary sense of it. The aim is to arrive at a more viable definition to guide the discussion of applications of nudges as well

18 Michael M. Grynbaum, "Health panel approves the restriction on sale of large sugary drinks", New York Times, 13 September 2012.

19 Richard Thaler, Tweet on Twitter, 31 May 2012, available on the internet: <https://twitter.com/R_Thaler/status/208273339507150849> (last accessed on 27 December 2014).

20 See e.g. Oliver Burkeman, "'How Bloomberg's soda ban is a classic example of 'choice architecture'', Blog on The Guardian, 10 July 2012, available on the internet at: <http://www.theguardian.com/commentisfree/oliver-burkemans-blog/2012/jul/10/bloomberg-soda-ban-new-york-freedom> (last accessed 26 December 2014) and Pelle Guldborg Hansen, "The 'Big Gulp Ban' – a nudge or not?", 8 October 2012, available on the internet: <http://inudgeyou.com/the-big-gulp-ban-a-nudge-or-not/> (last accessed 26 December, 2014).

21 Mongin and Cozic, "Rethinking Nudges", *supra* note 13; and Sunstein, *Why Nudge*, *supra* note 6, at p. 58.

22 Daniel Hausman and Brynn Welch, "Debate: To Nudge or Not to Nudge", 18 Journal of Political Philosophy (2010), pp. 123 *et sqq*.

23 See Thaler and Sunstein, *Nudge*, *supra* note 1, at p. 6.

24 Thaler and Sunstein, *Nudge*, *supra* note 1, at p. 8.

25 Pelle Guldborg Hansen and Andreas Maaløe Jespersen, "Nudge and the Manipulation of Choice: A Framework for the Responsible Use of the Nudge Approach to Behaviour Change in Public Policy", 1 *European Journal of Risk Regulation* (2013), pp. 3 *et sqq*, at p. 6.

26 Mongin and Cozic, "Rethinking Nudges", *supra* note 13.

as to explicate the relationship between the concept of nudge and that of libertarian paternalism as understood by Thaler and Sunstein. In the process I clarify how nudges relate to and differ from other interventions such as the provision of factual information and rational persuasion as well as how nudges may incorporate incentives while even being consistent with the removal of certain types of choice. Ultimately I put forward the following definition of what a nudge is:

> A nudge is a function of (I) any attempt at influencing people's judgment, choice or behaviour in a predictable way (1) that is made possible because of cognitive boundaries, biases, routines and habits in individual and social decision-making posing barriers for people to perform rationally in their own declared self-interests and which (2) works by making use of those boundaries, biases, routines, and habits as integral parts of such attempts.

I also conclude that in so far as a nudge serves the declared self-interests of those being nudged, it may further be referred to as *libertarian paternalism* since the revised definition of nudge implies that people's behaviour is influenced in ways that work independently of (i) forbidding or adding any rationally relevant choice options, or (ii) changing incentives, whether regarded in terms of time, trouble, social sanctions, economic incentives and so forth. In addition, this definition also implies that libertarian paternalism goes beyond nudging since it follows from it that nudges (iii) work independently of the provision of factual information and rational argumentation, that fall squarely within libertarian paternalism.

## II. The Two Concepts

### 1. Libertarian Paternalism

Richard Thaler and Cass Sunstein originally introduced the concept of 'libertarian paternalism' in their 2003 essay of the same name published in *The American Economic Review*.[27] Here they defined a policy as *'paternalistic'* "if it is selected with the goal of influencing the choices of affected parties in a way that will make those parties better off",[28] where they intend by "better off" that this be "measured as objectively as possible"[29] (and not always equating revealed preference with welfare). According to Thaler and Sunstein, while many economists believe the term paternalistic to be derogatory because they think paternalism always involves some kind of coercion, this is not necessarily the case.[30] Policies may be selected with the goal of influencing the choices of affected parties in a way that will make those parties better off, but where there is no coercion involved.[31] They refer to this kind of paternalism as *libertarian paternalism* and ultimately define it as

> "... an approach that preserves freedom of choice but authorizes both private and public institutions to steer people in directions that will promote their welfare."[32]

According to Thaler and Sunstein an approach like that of libertarian paternalism "should be acceptable to even the most ardent libertarian".[33] Of course, many critics have pointed out that Thaler and Sunstein's notion of libertarian paternalism is neither truly 'libertarian', nor truly 'paternalistic',[34] and that it is a contradiction in terms[35]. However, those discussions will not concern us here, as it is the concept of nudge and its relation to libertarian paternalism that are in focus.

In their best-selling book *Nudge* the notion of libertarian paternalism is further refined. It is described as a "movement" or "strategy" recapturing common sense from dogmatists.[36] The *libertarian* aspect of the strategy is said to lie in "the straightforward insistence that, in general, people should be free to do what they like – and to opt out of undesirable arrangements if they want to do so".[37] Borrowing a

27 Richard H. Thaler and Cass R. Sunstein, "Libertarian Paternalism", 93(2) *American Economic Review* (2003), pp. 175 *et sqq*.

28 Thaler and Sunstein, "Libertarian Paternalism", *supra* note 27, at p. 175.

29 Ibid.

30 Ibid.

31 Ibid.

32 Ibid, at p. 179.

33 Ibid, at p. 175.

34 See e.g. Hausman and Welch, "Debate: To Nudge or Not to Nudge", *supra* note 22.

35 Gregory Mitchell, "Libertarian paternalism is an oxymoron", 99 *Northwestern University Law Review* (2005), pp. 1245, *et sqq*.

36 Thaler and Sunstein, *Nudge*, *supra* note 1, at p. 5.

37 Ibid.

term from Friedman, Thaler and Sunstein say that "libertarian paternalists urge that people should be 'free to choose'" and strive to "design policies that maintain or increase freedom of choice." [38] In particular, Thaler and Sunstein say that by modifying the term *paternalism* with *libertarian* they simply mean *liberty preserving*, adding that "Libertarian paternalists want to make it easy for people to go their own way; they do not want to burden those who want to exercise their freedom."[39] According to Thaler and Sunstein the *paternalistic* aspect lies in the claim that "it is legitimate for choice architects to try to influence people's behaviour in order to make their lives longer, healthier, and better."[40] Hence they argue for a self-conscious effort by institutions "to steer people's choices in directions that will improve their lives."[41] However, they also modify their understanding of paternalism compared with their 2003 paper, now - referring to Van De Veer[42] – holding that, "a policy is 'paternalistic' if it tries to influence choices in a way that will make choosers better off, *as judged by themselves*"[43], rather than interpreting "better off" as earlier to be "measured as objectively as possible"[44].

According to Thaler and Sunstein "libertarian paternalism is a relatively weak, soft, and nonintrusive type of paternalism because choices are not blocked, fenced off, or significantly burdened."[45] Yet, it does count as paternalism, or 'soft paternalism' because "private and public choice architects are not merely trying to track or to implement people's anticipated choices. Rather, they are self-consciously attempting to move people in directions that will make their lives better."[46] In particular, Thaler and Sunstein say that by doing this "They nudge."[47]

## 2. Nudge

But what do Thaler and Sunstein mean when saying that libertarian paternalist 'nudge'? The concept was originally suggested by the first editor approached by Thaler and Sunstein, an editor who ultimately declined to publish the book that later became a best-seller titled *Nudge: Improving Decisions About Health, Wealth, and Happiness*. Beforehand most famous from Monty Python's sketch "nudge, nudge, wink, wink" the concept of 'nudge' has now become a term closely tied – if not almost synonymous with – Thaler and Sunstein's concept of 'libertarian paternalism'.[48] But what does 'nudge' mean and how does the concept fit together with that of libertarian paternalism?

In *Nudge* Thaler and Sunstein define a nudge as follows:

> "A nudge, as we will use the term, is any aspect of the choice architecture that alters people's behavior in a predictable way without forbidding any options or significantly changing their economic incentives. To count as a mere nudge, the intervention must be easy and cheap to avoid. Nudges are not mandates. Putting fruit at eye level counts as a nudge. Banning junk food does not."[49]

The concept of nudge thus seems to fit like hand in glove with that of libertarian paternalism. Libertarian paternalism is an approach that authorises both private and public institutions to steer people in directions that will promote their welfare; a nudge alters people's behaviour in a predictable way. Libertarian paternalism is an approach that preserves freedom of choice; a nudge works without forbidding any options or significantly changing economic incentives. Finally, libertarian paternalists nudge.

But does that mean that nudges are always libertarian paternalistic by definition? As noted in the introduction this has been a tacit assumption by many commentators. It is thus often assumed that interventions based on nudges and the strategy of libertarian paternalism are the same. That is, that nudges are libertarian and paternalistic, and that libertarian paternalistic measures are nudges. But is this the case? In order to answer that question and resolve

38 Ibid.

39 Ibid.

40 Ibid.

41 Ibid.

42 Donald Van De Veer, *Paternalistic Intervention: The Moral Bounds on Benevolence*, (Princeton: Princeton University Press, 1986).

43 Thaler and Sunstein, *Nudge*, *supra* note 1, at p. 5.

44 Thaler and Sunstein, "Libertarian Paternalism", *supra* note 27, at p. 175.

45 Ibid.

46 Thaler and Sunstein, *Nudge*, *supra* note 1, at p. 6.

47 Ibid.

48 See *supra* note 8.

49 Thaler and Sunstein, *Nudge*, *supra* note 1, at p. 6.

the resulting confusion and ambiguities, we need to look more closely into the concept and the theoretical foundations underpinning it.

## III. Nudge by Definition

It is often said that the concept of nudge is ill defined[50] and may lead to slippery slopes[51]. Such observations easily lead to critiques headed "When nudge comes to shove" or something like it.[52] However, given Thaler and Sunstein's definition quoted above, such critiques may seem to misfire. In fact, by rearranging the original definition provided by Thaler and Sunstein a bit, it seems that they provide a quite clear-cut definition saying that:

> A nudge is any aspect of the choice architecture that alters people's behaviour in a predictable way without
> 1) forbidding any options or
> 2) significantly changing their economic incentives.

Still, definitions are not all of one kind. They serve a variety of functions. Thus e.g. some definitions are descriptive, while others are stipulative. That is, some definitions try to *describe* or capture the actual usage of the term, while others *stipulate* or impart a meaning to the defined term and thus involve no commitment that the assigned meaning agrees with prior uses (if any) of the term.[53] For this latter type, "ill defined" can only mean that a definition fails to provide the wanted conceptual clarity and consistency needed for it to work within its intended area of application.

Obviously, Thaler and Sunstein's original definition is a *stipulative* one, and one that has since then been broadly adopted. However, as this paper will show, it is not always true for Thaler and Sunstein's definition of nudge that it provides the intended clarity and consistency. In particular it fails to serve its function relative to its theoretical foundations in behavioural economics and its relation to the concept of libertarian paternalism. Of course, that does not imply that the concept is fundamentally flawed or necessarily will lead to slippery slopes. Rather it implies that it can be improved upon. Throughout this section I thus offer an *explication* of the definition of nudge resulting in what I see as an absolute improvement of an existing, imperfect concept.

### 1. Econs and Humans

To explicate the definition of 'nudge' we first need to understand the purpose intended to be served by its introduction and to which it should be aligned. In *Nudge* Thaler and Sunstein explicitly motivates its introduction with the findings of four decades of behavioural economics.[54] This is not surprising since Thaler is one of the world's leading behavioural economists and Cass Sunstein is, amongst many other things, a pioneer and leading scholar in Behavioural Law, a movement explicitly rooted in behavioural economics and the Biases and Heuristics programme of Kahneman and Tversky. This background becomes particularly obvious in Thaler and Sunstein's section in *Nudge* titled 'Humans and Econs: Why Nudges Can Help"[55] that follows directly after their section 'Libertarian Paternalism'[56] that ends by providing the original and explicit definition of nudge quoted above.

The distinction between *Econs* and *Humans* introduced by Thaler and Sunstein is a distinction contrasting traditional conceptions of human behaviours as derivatives of axioms of reason and rationality with the insights into human behaviours emerging from cognitive psychology and behavioural economics in the last four decades. Reason and rationality have been analysed most intensely in philosophy

50 See e.g. Mongin and Cozic, "Rethinking Nudges", *supra* note 13; and House of Commons, *Public Health: Twelfth Report of Session 2010-12, Vol. 1: Report. Together with Formal Minutes* (Great Britain: Parliament: House of Commons: Health Committee 2011), at p. 84.

51 See e.g. Mario J. Rizzo and Douglas Glen Whitman, "Little Brother Is Watching You: New Paternalism on the Slippery Slopes", 51 *Arizona Law Review* 2009, pp. 685 *et sqq*; and Adam C. Smith and Todd J. Zywicki, "Behavior, Paternalism, and Policy: Evaluating Consumer Financial Protection", George Mason Law & Economics Research Paper No. 14-05 (2014), at p. 12.

52 See e.g. Tim Adams, "Nudge economics: has push come to shove for a fashionable theory?", The Guardian, 1 June 2014, available on the internet at <http://www.theguardian.com/science/2014/jun/01/nudge-economics-freakonomics-daniel-kahneman-debunked> (last accessed on 27 December 2014); John Tierney, "A Nudge (or Is it a Shove?) To the Unwise", New York Times, 24 March 2008, available on the internet at <http://tierneylab.blogs.nytimes.com/2008/03/24/a-nudge-or-is-it-a-shove-to-the-unwise/> (last accessed on 27 December 2014).

53 See Anil Gupta, "Definitions", in Edward N. Zalta (ed.), *The Stanford Encyclopedia of Philosophy*, (Fall 2014 Edition), available on the internet <http://plato.stanford.edu/archives/fall2014/entries/definitions/> last accessed (28 December 2014).

54 Thaler and Sunstein, *Nudge*, *supra* note 1, at p. 6-8.

55 Ibid.

56 Thaler and Sunstein, *Nudge*, *supra* note 1, p. 4-6.

and economics in a movement that ultimately led to neo-classical axiomatisations of rational or economic behaviour. According to these axiomatisations, behaviour is epitomised by *rational choice* or *decision-making* based upon individual agents reasoning their way by deduction to appropriate actions based on their desires or *preferences* together with their *beliefs* and information about the world. Keeping it simple, options, preferences, and beliefs are thus all that influence the behaviours and actions of a rational agent.[57]

In passing it may be noted that in the neo-classical view of decisions and behaviour there is no room for nudges and no reason for libertarian paternalism. This is perhaps most clear from the adoption of Revealed Preference Theory (RPT) in the neo-classical economic analysis of real world behaviour. RPT assumes that the preferences of consumers are revealed by their purchasing habits. If a consumer chooses a particular item it is inferred that this outcome is observed as a result of the consumer's preference for that item above others given her available information. This means that the intention-action gap that motivates the libertarian paternalist strategy and, as we shall see, within which the nudge approach to behaviour change works, is ruled out *a priori*.

However, as pointed out by Thaler and Sunstein,[58] during the last four or five decades the disciplines of behavioural economics, cognitive, and social psychology have provided ample evidence or *behavioural insights* that much of our behaviours and choices cannot be explained convincingly as being consistent with the neo-classical axioms of rational behaviour. For instance, behavioural economics has shown that human behaviour and choice exhibit *bounded rationality*, *bounded self-interest*, and *bounded willpower*.[59] This helps explain not only why people often fail to reason their way to the right conclusions, but also why we often fail to act upon these conclusions when reached, causing the gap between our good intentions and our actual behaviour - the gap that motivates the doctrine of libertarian paternalism.

Now, to some, "bounded" may seem to carry the connotation that we are merely *limited* in our cognitive skills at exerting rationality, self-interest, and willpower. That is not the case. Behavioural economics runs on experimental evidence pioneered in cognitive and social psychology, showing that much of our individual and social behaviour is due to our brains processing information in ways that are not only bounded but also cognitively biased, where a cognitive bias is a systematic pattern of deviation in judgment or decision-making. Implicit in this concept is a "pattern of deviation" from a baseline or standard of comparison.[60] In this case the baseline is made up by the bundle of neo-classical assumptions and their derivatives giving rise to the rational agent *Homo Economicus* - or as Thaler and Sunstein dub them in plural: *Econs*.

Of course, the empirical evidence and theoretical constructs of biases invoked to explain our behaviours only make up a consistent alternative to neo-classical economics and its derivatives such as RPT, if an alternative theory exists that not only predicts, but better explains the facts. Here, like others, Thaler and Sunstein rely on *Dual Process Cognitive Theories* (DPTs), especially as portrayed by Kahneman[61] as a result of Kahneman and Tversky's work on the Biases and Heuristics programme.

DPTs assert that the human brain functions in ways that invite a distinction between two kinds of thinking: one, which is intuitive and automatic, and another, which is reflective and rational. Kahneman dubs these ways of thinking System 1 and System 2, respectively; we choose, however, to follow the lead of Thaler and Sunstein when referring to these modes of thinking as automatic thinking and reflective thinking. Automatic thinking is characterised by being fast, intuitive, and usually not associated with experiences that one would describe as thinking. Reflective thinking is associated with the deliberate and conscious processing of information. It is slow, effortful, and dependent on concentration. It is associ-

57 See also Thomas Gilovich and Dale Griffin, "Introduction - Heuristics and Biases: Then and Now", in Thomas Gilovich, Dale Griffin and Daniel Kahneman (eds.), *Heuristics and Biases: The Psychology of Intuitive Judgment* (Cambridge: Cambridge University Press, 2002), pp. 1 *et sqq*; Martin Peterson, *An Introduction to Decision Theory*, (Cambridge: Cambridge University Press, 2009).

58 Thaler and Sunstein, Nudge, supra note 1, p. 7.

59 See also Christine Jolls, Cass R. Sunstein and Richard Thaler, "A Behavioral Approach to Law and Economics", 50(5) *Stanford Law Review* (1998), pp. 1471 *et sqq*.

60 Gilovich and Griffin, "Introduction - Heuristics and Biases", *supra* note 57.

61 See e.g. Daniel Kahneman, "Maps of Bounded Rationality: Psychology for Behavioral Economics", 93(5) *The American Economic Review* (2003), pp. 1449; and Daniel Kahneman, *Thinking, Fast and Slow*, (London: Allen Lane 2011).

| Automatic thinking | Reflective thinking |
|---|---|
| Uncontrolled | Controlled |
| Effortless | Effortful |
| Associative | Deductive |
| Fast | Slow |
| Unconscious | Self-aware |
| Skilled | Rule following |

*Table 1.1*

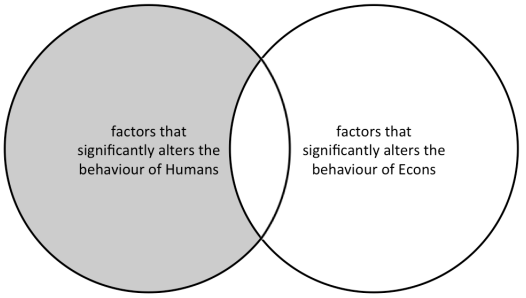


*Figure 1*

ated with self-awareness, the experience of agency, autonomy, and volition. The key features of each system are shown in Table 1.1.

DPTs explain why we – being *Humans* rather than *Econs* – not only fall short of rational decision-making, but actually may systematically *deviate* from its normative prescriptions (even in our reflected decisions at times) due to our behaviour and decisions being biased by seemingly irrelevant factors and aspects of decision-making and behavioural contexts. At its most general, the concept of nudge is devised to capture the fact that human decision-making and behaviour are influenced by cognitive boundaries and biases in ways that may be utilised for promoting particular behaviours - and Thaler and Sunstein's original definition is their attempt to capture this insight.

## 2. The Principle from Behavioural Economics

However, the discussion of Human and Econs ultimately leads Thaler and Sunstein to state a corollary of their original definition that I will refer to as *the principle from behavioural economics*. This says:

> "In accordance with our definition, a nudge is any factor that significantly alters the behavior of Humans, even though it would be ignored by Econs."[62]

This principle of behavioural economics, I believe, although misleadingly stated as a *derivative* of the explicit definition[63], is what provides us with the clear-cut and foundational criterion of what should count as a nudge. In accordance with the general gist of Thaler and Sunstein's book, its adoption takes the Biases and Heuristics programme as the core motivation for devising a concept of nudge for referring to any contextual feature causing Humans to deviate from the prescriptions of normative rationality. As a criterion it states that if we know what behaviour or choice would count as rational in a given situation provided agents' preferences and information, and we observe judgment, choice, or behaviour deviating from this prediction, then the contextual feature responsible for such deviation should be categorised as a nudge. If accepted as a foundational criterion, it thus follows that any viable definition of a nudge should be aligned with it. See Figure 1.

Granted the criterion as a fundamental one, the concept of *nudge* is thus devised to refer to features that influence behaviour in ways not in accordance with that of economic rationality. Since economic rationality follows from the dictates of principled reason, one could add that nudges work in ways that should not work in principle, or in ways that 'ought' not influence us. That is, in principle a nudge shouldn't influence behaviour, but in practice it does. In particular, it is obvious that condition (1) and (2) of Thaler and Sunstein's original definition are intended to exclude those features that influence the behaviour, not only of humans, but also of rational agents. Hence, it seems that it is conditions (1) and (2) of the original definition that are derivatives of the principle, rather than *vice versa*. Of course, the acceptability of this proposed hypothesis about the foundations of the concept of nudge, rests on the ability of the principle from Behavioural Economics to

62 Thaler and Sunstein, *Nudge*, *supra* note 1, at p. 8.

63 Thaler and Sunstein, *Nudge*, *supra* note 1, at p. 6.

provide a consistent and clear framework for a more viable definition of the concept than that provided by Thaler and Sunstein's explicit definition. I believe it does, and the remainder of this paper provides the argument for this. However, instead of constructing a definition anew from the foundational principle from Behavioural Economics, I will start in *medias res* and revise the original definition so as to reconcile this with the principle.

## IV. Reconciling the Definition of Nudge with the Principle from Behavioural Economics

### 1. Adding some Positive Conditions

As a first step to reconcile Thaler and Sunstein's definition of nudge with the principle from Behavioural Economics, we may notice that Thaler and Sunstein's original definition of a nudge says nothing about cognitive boundaries and biases (Humans) or the baseline from neo-classical economics (Econs). It only says what a nudge is not. But given what has just been explained about DPTs and the Biases and Heuristics programme, we can now see why Daniel Hausman and Brynn Welch in a later article add the "positive" condition to the definition of a nudge saying that:

> "They [nudges] are called for because of flaws in individual decision-making, and work by making use of those flaws".[64]

In fact, being a conjunctive sentence, this addition contains two positive conditions. One of function or *motivation* – that "nudges are called for because of..." and a second condition, which explicates the underlying principle by specifying that nudges "work by making use of those flaws". That is:

> (i) They [nudges] are called for because of flaws in individual decision-making, and (ii) work by making use of those flaws.

Thus, as a first step to reconcile the definition of nudge with the principle from Behavioural Economics, we may integrate Hausman and Welch's positive conditions into the former. But rather than calling biases "flaws", I prefer calling them by their proper name: *cognitive bias*. Also, it should be added that biases do not necessarily only pertain to individual decision making, but also may be argued to pertain to *social* decision making, i.e. when aggregate group behaviour deviates from the interests of each individual group member.[65] In addition, it is not only biases, but also cognitive *boundaries*, *habits* and *routines* that may systematically lead Humans to deviate from the behaviour of Econs.[66] Finally, we should be a bit more specific than Hausman and Welch are, so instead of saying "making use of those flaws", we specify that biases should be an *integral part of the choice architecture*.

Given these adjustments the positive conditions may be added to the original definition so that we now have a definition with four conditions:

> A nudge is any aspect of the choice architecture that alters people's behavior in a predictable way without
> (1) forbidding any options or
> (2) significantly changing their economic incentives.
> (3) Nudges are called for because of cognitive boundaries, biases, routines, and habits in individual and social decision-making, and (4) work by making use of those boundaries, biases, routines, and habits as integral parts of the choice architecture.

### 2. Incentives (Condition (2))

Still, more work needs to be done to reconcile the definition of nudge with its theoretical underpinnings. As noted above, the fundamental principle for determining if something is a nudge is by determining whether it alters the behaviour of Humans but would be ignored by Econs.[67] Fundamental to Econs is that their preferences may be captured by a suitable utility-function. As a fundamental construct in economic theory it is not surprising that a utility function is

64 Hausman and Welch, "Debate: To Nudge or Not to Nudge", *supra* note 22, at p. 126.

65 See e.g. Vincent F. Hendricks and Pelle Guldborg Hansen, *Infostorms: How to Take Information Punches and Save Democracy* (New York: Springer, Copernicus, 2014); and Cass R. Sunstein *Infotopia: How Many Minds Produce Knowledge* (New York: Oxford University Press, 2006).

66 See e.g. Judith A. Oullette and Wendy Wood, "Habit and Intention in Everyday Life: The Multiple Processes by Which Past Behavior Predicts Future Behavior", 124(1) *Psychological Bulletin* (1998), pp. 54 *et sqq*.

67 Thaler and Sunstein, *Nudge*, *supra* note 1, at p. 9.

sensitive to *economic* incentives – hence, Thaler and Sunstein's condition (2) saying that a nudge influences behaviour without "significantly changing [people's] economic incentives".

Yet, as pointed out by Hausman and Welch,[68] rational agents are not only responsive to economic incentives. For instance, the utility-function of a rational agent is determined by the prospect of pain as well as penalties. This is not captured by the definition as it stands since, if taken at face value, the definition would render a 10.000 voltage electroshock, or a public beating to count as a 'nudge.' Because this would be a rather uncharitable interpretation of what Thaler and Sunstein mean by a nudge, as well as not in accordance with the principle from Behavioural Economics, it is only reasonable to follow Hausman and Welch's suggestion of broadening the definition so as to encompass all other types of incentives affecting a rational utility function as well.

Thus, we may revise the definition of a nudge as follows:

> A nudge is any aspect of the choice architecture that alters people's behaviour in a predictable way without
> (1) forbidding any options or
> (2) significantly changing **incentives, whether regarded in terms of time, trouble, social sanctions, economic and so forth.**
> (3) Nudges are called for because of cognitive boundaries, biases, routines, and habits in individual and social decision-making, and (4) work by making use of those boundaries, biases, routines, and habits as integral parts of the choice architecture.

### a. "Significantly" Changing Incentives

Still, one may ask why the original condition (2) says "significantly" (as well as why Hausman and Welch restates this as "appreciably"). To the best of my judgment this is done to accommodate insights from Behavioural Economics about how changing incentives may be used to influence behaviour of Humans in ways that do not affect Econs.

Let me give three examples of how this may happen.

1. Lotteries. First, disproportionally large behavioural effects on Humans may be obtained by making small, in principle insignificant changes in incentives that wouldn't have an effect on Econs (at least not to the same extent). Say for instance you want to conduct a survey amongst 500 people. To get people to respond you consider giving them some proper incentive. But your budget is only $500. One possibility is to offer each potential respondent $1 to complete the survey. Another possibility is to offer each potential respondent a ticket for a lottery draw where the prize is an iPad. Now, to a rational agent this should make no difference since the expected utility in both scenarios would be $1. However, for Humans it makes a world of difference. Being offered a lottery ticket increases our tendency to participate since we tend to overestimate small probabilities because of, amongst other factors, the availability heuristic, anchoring on arbitrary priors, and a tendency to be more sensitive to probability changes close to 0 than to probability changes away from 0.[69] In addition one may also argue that Humans often perceive direct payment differently than they perceive lottery tickets (usually regarding the latter as more like a gift, thereby activating norms of reciprocity, contrary to the former which we regard as impersonal payment, possibly with some suspicion and comparison to alternative activities and the profit gained by the payer).
2. A second example is that of rearranging incentives in ways that shouldn't have any effect on us if we were Econs, but does affect us, as we are Humans. For instance, to an Econ it shouldn't affect consumption patterns whether a tax payback is given as a lump sum or distributed in a series over time. However, due to what is called *mental accounting*, there is a tendency for humans to treat a lump sum payment very differently.[70] For instance, we may regard it as house-money, or decide to use it for larger investments, such as travelling, rather than integrate it into our everyday consumption. In addition, incentives may be distributed over time

68 Hausman and Welch, "Debate: To Nudge or Not to Nudge", *supra* note 22, at p. 123-136.

69 Zach Burns, Andrew Chiu and George Wu, "Overweighting of small probabilities", in James J. Cochran (ed), *Wiley Encyclopedia of Operations Research and Management Science* (New York: Wiley, 2010).

70 Shefrin, H. and Richard Thaler, "The behavioral life-cycle hypothesis", 26 *Economic Inquiry* (1988), pp. 609 *et sqq*; Richard H. Thaler, "Mental Accounting Matters", 12 *Journal of Behavioral Decision Making* (1999), pp. 183 *et sqq*.

causing so-called present-bias, where Humans discount valuations hyperbolically rather than exponentially, that is, where valuations fall very rapidly for small delay periods, but then fall slowly for longer delay periods, rather than being discounted at a constant rate.[71]

3. A third example is that of "charm prices", e.g. advertising a price of $0.99 rather than $1 thereby utilising the 'left-digit-right-digit' effect. This price change shouldn't lead to the significant changes in consumer behaviour that we actually observe.[72]

Effects like these three are not reconcilable with the standard economic model of Econs. Yet, all do seem to involve changing incentives. However, looks may be deceiving. Being more precise we may point out that example 1 is not really about *changing* incentives, but rather about *restructuring* incentives in terms of a lottery in ways that would not affect Econs. Likewise example 2 is about *rearranging* incentives, rather than changing them. But what about example 3 – is this not obviously about changing incentives? Well, in a sense changing incentives does create the behavioural effect. Yet, the behavioural effect is not credibly derivable from an agent's utility function alone. The incentives are not changed significantly in creating a significant effect. The nudge is identified by *the deviation* from the predictions of the standard model from observed behaviour – a deviation caused in this case by the *salience effect* - and not the full behaviour change as such.

It is most likely in order to allow such insights from behavioural economics of how *insignificant* change in incentives may create effects beyond what may be explained as rational that Thaler and Sunstein adopt the qualification "significantly" in the 2nd condition. However, if we substitute "work without" with "that works independently of" we can retain this point without the need of this qualification that has sometimes confused commentators. Also, to emphasise more clearly that it is not the full intervention or choice architecture as such that is evaluated as a nudge - e.g. it is not the incentive as such, but the structuring of an incentive as a lottery - we may substitute the somewhat vague term 'aspect' with that of 'function' which is also a more standard term in the behavioural sciences. Hence, we may say:

> A nudge is a **function** of the choice architecture that alters people's behaviour in a predictable way **that works independently** of
> (1) forbidding any options or
> (2) changing their incentives, whether regarded in terms of time, trouble, social sanctions, economic and so forth.
> (3) Nudges are called for because of cognitive boundaries, biases, routines, and habits in individual and social decision-making, and (4) work by making use of those boundaries, biases, routines, and habits as integral parts of the choice architecture.

## 3. Choices (Condition (1))

So far the only part of the original definition that we have not revised is that concerned with the ruling out or forbidding of options, i.e. condition (1). Obviously, this condition has a strong affinity with the idea of libertarian paternalism. That is, its formulation seems primarily intended to target this complex of ideas, and only secondarily at capturing the underlying principle of a nudge as expressed by the revised definition. In particular, by emphasising that a nudge works without forbidding any options it follows that nudging neither involves bans or mandates, which is a basic characteristic of libertarian paternalism. In practice such a ban or mandate may often be reduced to a positive or negative incentive coupled with a symbolic dimension of social disapproval.

From a conceptual point of view, however, condition (1) turns out to be incomplete along several dimensions. For instance, it does not say anything about whether one may add options to the choice set. This raises the question of whether *adding choices* may qualify as a nudge?

### a. Adding Choices: Predictively Rational

To investigate this, assume that Marge wants to influence Homer in a way so as to stop him from eating all that cake. Also assume that in the status quo Homer has the options or choice-set *A* comprising *a*:

71 Edward Cartwright, *Behavioral Economics* (New York: Routledge Advanced Texts in Economics and Finance, 2011), p. 143-147.

72 Manoj Thomas and Vicki Morwitz, "Penny Wise and Pound Foolish: The Left-Digit Effect in Price Cognition", 32(1) *Journal of Consumer Research* (2005), pp. 55 *et sqq*.

"not eating cake" and *b*: "eating cake". Finally we also assume that Homer prefers *b* to *a*. That is,

$A_h = (a, b)$, $a <_h b$.

Next, assume that Marge in order to influence Homer decides to serve a bunch of sandwiches - i.e., she adds *c:* "eat sandwiches" to the choice-set - knowing that Homer prefers sandwiches to cake. Thus we have that,

$A_h = (a, b, c)$, $a <_h b <_h c$.

The question is whether Marge's addition of sandwiches to the choice-set should be regarded as a nudge.

Obviously, Marge attempts to influence Homer's behaviour in a predictable way. Also, she is not forbidding any options. Hence (1) is not violated. Nor is she significantly changing the incentives so (2) is respected as well. Thus, based on the original part of the definition Marge's addition would seem to qualify as a nudge.

However, it is obvious that Homer's preferences are rational in the sense that he is consistent in preferring sandwiches to cake. Hence, the intervention would not only influence Humans - or Homer in this case - but also Econs. This is because the influence is not made possible because of cognitive boundaries or bias in individual and social decision-making, or routines or habits, posing a barrier for Homer to perform rationally. Instead, the influence is made possible by Homer's rational capacities. Also, it does not work by making use of those boundaries and biases as an integral part of Marge's attempt at creating behaviour change. In conclusion, Marge's attempt is not a nudge since it does not satisfy conditions (3) and (4) that have been explicated on the basis of the principle from behavioural economics.

### b. Adding Choices: Predictively Irrational

But does that mean that we always have to rule out the addition of choice options as a nudge? No, because one may also add choices to the existing choice-set so as to influence people in a "predictively irrational" way. Various decoy effects violating the independence of irrelevant alternatives axiom of decision theory reveal this. Decoy effects are one family of biases in which the asymmetric dominance effect and the compromise effect resulting from extremeness aversion have been shown to be among the most stable.[73]

To illustrate the asymmetric dominance effect, imagine that you are faced with the choice between two laptops that vary in price and storage:

*Choice-set 1*

| | A | B |
|---|---|---|
| Price | $400 | $300 |
| Storage | 300 GB | 200GB |

Given this choice set, you may either prefer *A* for its greater storage capacity or *B* for its lower price. Now, suppose that a new laptop, *C*, is added to the choice set, where *C* is more expensive than both A and B and has more storage capacity than *B*, but less than *A*:

*Choice-set 2*

| | A | B | C |
|---|---|---|---|
| Price | $400 | $300 | $450 |
| Storage | 300 GB | 200 GB | 250 GB |

If you are like most other people, the addition of *C* to the choice-set will make you become more attracted to *A*. This is because, while you are likely to avoid *C* since you can get laptop A with more storage for a lower price, *C* affects your preferences by acting as a basis of comparison for *A* and *B*. Because *A* is better than *C* in both respects, while *B* is only partially better than *C*, more consumers will prefer *A* now than did before. *C* is therefore a decoy whose sole purpose is to increase sales of *A*. This is what is called the asymmetric dominance effect.

The asymmetric dominance effect can also be used to influence your preferences so that you come to prefer laptop B. Imagine that instead of introducing laptop C, a laptop D is introduced into the choice-set with the attributes shown in Choice-set 3:

73 See Joel Huber, John W. Payne and Christopher Puto, "Adding Asymmetrically Dominated Alternatives: Violations of Regularity and the Similarity Hypothesis", 9(1) *Journal of Consumer Research* (1982), pp. 90 *et sqq;* Itamar Simonson and Amos Tversky, "Choice in context: Tradeoff contrast and extremeness aversion", 29 *Journal of Marketing Research* (1992), pp. 281 *et sqq*.

*Choice-set 3*

| | A | B | D |
|---|---|---|---|
| Price | $400 | $300 | $350 |
| Storage | 300 GB | 200 GB | 150 GB |

Faced with this set of choices the asymmetric dominance effect is likely to influence your preferences such that while you will disregard *D*, you will now find *B* more attractive than A.

So is the asymmetric dominance effect to be considered a nudge? The effect is not one that may be reconciled with the rational preferences of Econs.[74] That is, the effect of adding an, in principle, irrelevant choice option does not affect Econs. Still, it does affect experimental subjects and hence Humans. According to the principle from behavioural economics, then, it counts as a nudge.

But does our revised definition of nudge align with this conclusion? Obviously the addition of an irrelevant choice option does not rule out or forbid any options from the original choice-set. Hence (1) is not violated. Nor does it significantly change the incentives and hence (2) is respected as well. Instead the influence is made possible because of cognitive bias in individual decision-making. This means that condition (3) is satisfied. Finally, the addition of the irrelevant choice option is an intervention that works by making use of those biases. That is, it is not a case of merely de-biasing choice and thus condition (4) is satisfied.

Accordingly, relative to our revised definition, adding choices in this way is a case of a nudge – not only because it is stipulated so, but because it is consistent with the underlying principle saying that a nudge is any factor that significantly alters or influence the behaviour of Humans, even though it would be ignored by Econs. However, before revising the definition so as to allow for the addition of rationally irrelevant choice options and bar the addition of relevant ones, we will address an interesting issue.

### c. Nudging by Removal of Irrelevant Alternatives

If one may nudge by *adding* an irrelevant choice, then it seems reasonable that the same may be the case by *removing* such an irrelevant choice. For instance, going back to the asymmetric dominance effect: if three laptops are available in the status quo as in choice-set 2 and 3, and we then remove the choice-option *C* and *D*, respectively, are these interventions then instances of nudges?

To answer this question we should, according to the definition, first ask whether the removal of a rationally irrelevant choice option like this significantly alters the behaviour of Humans, even though Econs would ignore it. To determine this we may look at the examples above in reverse. Of course, since some of the experiments on the asymmetric dominance effect are *between-subjects* design, the effect of removing the rational irrelevant options is the reverse of that observed when adding it. But even for within-subjects designs the effect occurs.[75] We then ask whether these behaviour-changes would be consistent with the standard rationality axioms from which the behaviour of Econs is derived – the answer, of course, is no.

To be precise, according to the standard axiom of decision theory referred to as the *independence axiom*,[76] rational choices should be independent of irrelevant alternatives. This axiom is sometimes also referred to as *Sen's property* stating that:[77]

> if an alternative *x* chosen from a set *T*, and *x* is also an element of a subset *S* of *T*, then *x* must be chosen from *S*.

That is, eliminating some of the unchosen alternatives should not affect the selection of *x* as the best option. In our case of the asymmetric dominance effect the independence axiom implies that Econs should be unaffected by the removal of *C* and *D*. Yet, as the evidence for the asymmetric dominance effect and other decoy effects shows, Humans *are* influenced by this removal. Hence, in such cases, removal of irrelevant choice options would qualify as nudges according to the principle from behavioural economics.

It is in light of this conclusion that the definition of a nudge above needs to be further refined so that

74 Huber, Payne and Puto, "Adding Asymmetrically Dominated Alternatives", *supra* note 73; Simonson and Tversky, "Choice in context", *supra* note 73.

75 See e.g. Huber, Payne and Puto, "Adding Asymmetrically Dominated Alternatives", *supra* note 73.

76 Peterson, *An Introduction to Decision Theory*, *supra* note 57, at p. 99.

77 Amartya Sen, *Collective Choice and Social Welfare* (San Francisco: Holden Day, Inc., 1970), at p. 17.

besides barring only the addition of relevant options, it also allows for the removal of rationally irrelevant ones. While the removal of irrelevant choices as a nudge has no bearing on the other conditions, it calls for revising condition (1) by adding the qualification of *relevancy*, such that:

> A nudge is a function of the choice architecture that alters people's behaviour in a predictable way that works independently of
> (1) forbidding **or adding** any **rationally relevant choice** options or
> (2) changing their incentives, whether regarded in terms of time, trouble, social sanctions, economic and so forth.
> (3) Nudges are called for because of cognitive boundaries, biases, routines, and habits in individual and social decision-making, and (4) work by making use of those boundaries, biases, routines, and habits as integral parts of the choice architecture.

## 4. Information

Earlier it was mentioned that only three basic elements influence the behaviour of an Econ. Choice options, preferences over the outcomes associated with these, and information or beliefs. So far we have revised the definition relative to choice options and preferences. But what about information? Just like it was the case for the addition of choice options, the original definition of a nudge provided by Thaler and Sunstein says nothing about this. So do information and various forms of communication count as nudges?

### a. The Provision of Factual Information

Beginning with the mere *provision of factual information* we may observe that in his recent book *Why Nudge?* Sunstein is quite straightforward on this point:

> "Provision of information is certainly a nudge, but it may or may not qualify as paternalistic..."[78]

But is Sunstein right in this? Obviously in the sense targeted here, the provision of factual information is usually intended to influence behaviour without forbidding or adding any relevant choice options or significantly changing incentives. Hence, the provision of factual information would seem to qualify as a nudge given Thaler and Sunstein's original definition taken at face value. In addition, if offered as well intended advice it should definitely also count as both libertarian and paternalistic.

However, if we look to the principle from behavioural economics saying, "a nudge is any factor that significantly alters the behaviour of Humans, even though it would be ignored by Econs" it becomes clear that, despite Sunstein's assertion to the contrary, the provision of factual information should usually not qualify as a nudge. This becomes even clearer if we look at the two final conditions of the definition that captures this principle:

(3) Nudges are called for because of cognitive boundaries, biases, routines, and habits in individual and social decision-making, and (4) work by making use of those boundaries, biases, routines, and habits as integral parts of the choice architecture.

For one, the provision of factual information would not necessarily be called for because of cognitive boundaries and biases. It would merely be motivated by a person's limited information. Second, under normal circumstances it would be intended to work in a way that would seek to influence Econs as well as Humans. So while it is possible that the provision of factual information may qualify as a case of libertarian paternalism, it does not qualify as a nudge.

Perhaps a reason why nudges and the provision of information may sometimes be confused is because information may be provided in ways that are not intended as the provision of pure factual information that one did not have access to beforehand. Take *reminding* someone of something, say, that I have an appointment with my dentist as in studies like that of Altman and Traxler[79]. Here, conditions (1) – (3) would be satisfied. It would be an attempt to influence my behaviour in a predictable way without forbidding or adding any rationally relevant choice options or changing my incentives, whether regarded in terms of time, trouble, social sanctions, economic and so forth. The reminder would be called for because of my *limited memory*, which in turn may be conceived of as the result of cognitive boundaries given Econs are assumed to have perfect memory –

78 Sunstein, *Why Nudge?*, *supra* note 6, at p. 55

79 Steffen Altmann and Christian Traxler, "Nudges at the Dentist", (IZA Discussion Papers 6699, Institute for the Study of Labor, 2012).

hence an Econ would never need a reminder. But would condition (4) be satisfied? That is, would the reminder be an attempt at influencing my behaviour in a predictable way intended to work by making use of cognitive boundaries, biases, routines or habits as an integral part of that attempt? That is, am I not just being reminded in a way that could be described as 'de-biasing'? Following Sunstein reminding does satisfy condition (4) since it makes use of *salience*.[80] That is, it is not the information as such that causes the behavioural effect or function, but that of making the information salient as a means of memory retrieval. Thus, as with the structuring of incentives, the intervention consists of two components - an informational component and a behavioural function in terms of salience. In fact, this means that the whole so-called *notice paradigm* as described by Ryan Calo qualifies as nudging.[81] This includes the infamous "fly in the urinal" which also satisfies condition 4 by making use of salience; although it is called for due to another cognitive boundary *viz.* limited attention, rather than limited memory. In general, such notice-tactics are part of the nudge approach, although they may often seem like mere provision of information. Still, the general conclusion holds: the provision of factual information in and by itself does not count as a nudge.

### b. Arguments and Fallacies

Another tactic that is likely to give rise to similar confusion is that of *rational persuasion* or argument. Does this qualify as a nudge? Well, the answer is evident given the term "rational". For rational persuasion and logical argumentation (1) and (2) will be satisfied as well as perhaps (3); though (3) will not be satisfied because of 'limited memory', but perhaps rather because of 'limited processing capacity' in connecting the facts. However, condition (4) will not be satisfied: rational persuasion or argument is not intended to work by making use of cognitive bias as part of the attempt at influencing people's behaviour in a predictable way. In so far as rational persuasion works – not by providing new premises by means of the provision of factual information, but by connecting these premises into a conclusion – it should at most be considered as a de-biasing strategy.

However, the reason to pick up the subject of arguments here is that not all persuasion is rational. One could make use of *logical fallacies* in order to persuade. So would that qualify as a nudge? Obviously, the use of such fallacies would not convince a perfectly rational agent, that is an Econ. Yet, as is well documented, fallacies are often used to convince and mislead Humans. Hence the use of fallacies to persuade ultimately qualifies as nudging when considering the principle from behavioural economics.

The same conclusion is also reached by applying the revised definition. The use of logical fallacies satisfies conditions (1) and (2) as the intervention would be intended to influence behaviour, broadly conceived of, without forbidding or adding any rationally relevant choice options or changing incentives. Likewise conditions (3) and (4) are met since persuading someone by means of a logical fallacy would only be possible due to cognitive boundaries and biases and would work by making use of those biases and boundaries as an integral part of the attempt to persuade. Hence, the use of logical fallacies qualifies as a nudge on this definition as well.

Given the conclusions reached in this discussion of information and fallacies, we may now revise the definition of nudge as follows:

> A nudge is a function of the choice architecture that alters people's behavior in a predictable way that works independently of
> (1) forbidding or adding any rationally relevant choice options**,**
> (2) changing their incentives, whether regarded in terms of time, trouble, social sanctions, economic and so forth, **or**
> (5) the provision of factual information or rational argumentation.
> (3) Nudges are called for because of cognitive boundaries, biases, routines, and habits in individual and social decision-making, and (4) work by making use of those boundaries, biases, routines, and habits as integral parts of the choice architecture.

## 5. Conclusion: Minimal Definition of Nudge

To reconcile the definition of nudge provided by Thaler and Sunstein with the principle from behavioural economics we have revised most elements of

80 Sunstein, *Why Nudge?*, *supra* note 6, at p. 39-44.

81 Calo, "Code, Nudge, or Notice", *supra* note 7.

the definition. However, at this point one may have noticed that the negative conditions concerning options, preferences, and information are derivatives from this principle, rather than *vice versa*. To emphasise this as well as pre-empt the possibility that even further negative conditions may be identified, I suggest the following re-arrangement of what I put forward as the *minimal definition* of a nudge:

> Minimal Definition
>
> A nudge is a function of the choice architecture that alters people's behaviour in a predictable way (1) that is called for because of cognitive boundaries, biases, routines, and habits in individual and social decision-making and which (2) works by making use of those boundaries, biases, routines, and habits as integral parts of the choice architecture.
>
> Thus a nudge amongst other things works independently of:
>
> (i) forbidding or adding any rational relevant choice options,
>
> (ii) changing incentives, whether regarded in terms of time, trouble,
>
> social sanctions, economic and so forth, or
>
> (iii) the provision of factual information or rational argumentation.

## V. Nudge and Libertarian Paternalism

Despite having reached a minimal definition of nudge, it is not yet possible to determine the exact relationship between nudge and libertarian paternalism. Obviously a clear overlap exists between these two concepts as it follows from the definition of a nudge that nudges work independently of (i) - (iii). However, the question remains whether any particular motivation, if any motivation at all, is to be tied to nudges and how to deal with this conceptually in order to achieve the wanted clarity and consistency. The purpose of this section is to examine that question.

### 1. Intentionality (A Nudge, or "to Nudge")

A first answer to the question is found in the discussion about whether the concept of nudge should be treated as a *noun* or a *verb*.[82] Initially, this may seem a ridiculous point to make, but it turns out to have some important bearings when one turns to theoretical issues as well as discussions of the ethics of nudge.

In Thaler and Sunstein's original definition, the concept of 'nudge' is treated as a noun referring to "any *aspect* of the choice architecture" (my emphasis). Thaler and Sunstein's formulation of the principle from behavioural economics takes the same stance since, there, a nudge is referred to as "any *factor* that significantly alters the behavior of Humans, even though it would be ignored by Econs" (my emphasis).

However, as in the Monty Python sketch, a "nudge" usually serves as a verb designating an action. Hence, "to nudge" is an action intended by a subject. This also makes it possible to say, "*nudging* the ball" just as you would say, "hitting the ball". Likewise, as Thaler and Sunstein say, libertarian paternalists nudge, meaning that a libertarian paternalist may be nudging. Of course, using the term nudge in this way does not exclude derivative uses implying a lack of intentionality, such as "he *hit* the wall" in the more unfortunate sense. But notice, using the term this way would be *derivative* and not primary (like when we say that "she unintentionally poisoned him", we do not mean that she actually *poisoned* him). Also, intentionality does not imply that when someone "nudges" he necessarily does so with this concept in mind whether in *sensu composito* or in *sensu diviso*. You don't need the concept of 'bragging' to actually do this, nor do you need to intend to 'brag' in individual instances in order to do it.

From the title of their paper "Debate: To Nudge or Not to Nudge"[83] Hausman and Welch actually seem to take the "verb" approach to the question. However, on a closer read, it turns out that they oscillate between treating "nudge" as a verb and as a noun. In general they treat nudges as "factors".[84] Yet, in their summary they refer to nudges as "*ways* of influencing choice". This formulation may in turn be understood as a noun referring to systematic relations (bias, boundaries, etc.) in an objective world (as when saying "*ways* in which gravity affects the earth"), or as a verb describing the use of systematic competences

82 See Hansen and Jespersen, "Nudge and the Manipulation of Choice", *supra* note 25.

83 Hausman and Welch, "Debate: To Nudge or Not to Nudge", *supra* note 22.

84 See e.g. Ibid, at p. 126.

involving some kind of intentionality. Either way, as they point out by the end of their paper there remains an important difference between choices that are intentionally influenced by a third party, and choices that are not.[85]

It is for reasons resulting from this last point that Hansen and Jespersen argue for consistently treating the concept of nudge as a verb:

> ... there seems to be a clear and important distinction to be made between a given context that accidentally influences behaviour in a predictable way, and someone – a choice architect – intentionally trying to alter behaviour by fiddling with such contexts.[86]

The reason why Hansen and Jespersen make this point is that in matters of normative justification one simply cannot dispense with the issue of intentionality and, by extension, agency. Intentionality is a conceptual precondition of normative evaluation. Ignoring it would render the notion of responsibility superfluous. Unfortunately, as Hansen and Jespersen also point out, this is exactly what is often indicated when treating the concept of "nudge" as a noun, rather than as a verb. Such a conceptual move blurs a crucial distinction at the heart of normative justification as to the notion of responsibility. Hence the seemingly ridiculous question of whether to treat the concept of "nudge" as a noun or a verb makes a crucial difference because it introduces intentionality and thus the normative dimension of responsibility into the debate about the nudge approach to behaviour change.

For this reason Hansen and Jespersen argue for stipulating the definition of nudge as being one of a verb in order to ensure that this important distinction is not lost.

> Thus, we suggest that a nudge henceforth is best understood as the intentional attempt at influencing choice, while it is accepted that the settings of any given decision-making context may accidentally influence choice and behaviour in predictable ways as well. ... The notion of "nudge" then, should only apply when someone intentionally tries to influence our behaviour without the use of regulation or fiddling around with incentives.[87]

So returning to the revised definition we may now follow Hansen and Jespersen 2013 by integrating a more precise and viable condition substituting the passive aspect of "choice architecture" with condition (I) stipulating that a nudge is a function of any (*intentional*) *attempt* at influencing people's behaviour. While modifying this part of the definition we may also note that it may be beneficial to make explicit what is implicitly contained in the concept of behaviour - namely judgment, choice as well as overt behaviour - in order to avoid confusions on that point.

> A nudge is a function of (I) any **attempt at influencing** people's **judgment, choice or** behaviour in a predictable way (1) that is called for because of cognitive boundaries, biases, routines, and habits in individual and social decision-making, and which (2) works by making use of those boundaries, biases, routines, and habits as integral parts of **such attempts**.
>
> Thus a nudge amongst other things works independently of:
>
> (i) forbidding or adding any rationally relevant choice options,
>
> (ii) changing incentives, whether regarded in terms of time, trouble,
>
> social sanctions, economic and so forth, or
>
> (iii) the provision of factual information or rational argumentation.

As we will see below, this at the same time clarifies why the terms nudge and bias are not logically equivalent and this hence precludes a logical substitution that otherwise would make for a conceptual oddity.

## 2. Who's Calling? Or, Why Nudge?

So far we have determined that a nudge is an intentional attempt at influencing people's behaviours in a predictable way under certain constraints. However, this raises the next question of whether a special motivation for forming this intention is required as well in order for such an act to qualify as a nudge. For instance, is a libertarian paternalistic motive required, or could other motives do as well? The addition by means of condition (1) in the revised definition adopted might indicate so by stating that

85 Ibid, at p. 133.

86 Hansen and Jespersen, "Nudge and the Manipulation of Choice", *supra* note 25, at p. 10.

87 Ibid.

"nudges are called for" – but what position on this provides consistency and clarity?

Hausman and Welch's formulation "nudges are called for" definitely seems to invite an interpretation in terms of the *motivation* behind the nudge. That is, it seems to refer to someone's reason for intervening – the motive behind the (I) attempt at nudging. For this reason we may revise condition (1) so that it says:

> (1) that is **motivated** because of cognitive boundaries, biases, routines, and habits in individual and social decision-making

But what kind of motive, if any, is required by the definition? Here, Hausman & Welch's attempt at a definition says that nudges are called for "because of flaws in individual decision-making".[88] This means that condition (1) may be read as identifying a *precondition* for when a nudge is called for: *given* cognitive boundaries, biases (recall that we dropped the concept of 'flaws'), routines, and habits in individual and social decision-making, nudges are called for. But why would that be? One possible and very likely reason would be that since boundaries, bias, routines, and habits may prevent one from acting according to the standards of rationality *then* nudges "are called for" because these biases pose barriers for people to perform (act, judge, evaluate) rationally. If we follow this interpretation we might thus consider revising condition (1) such that we get:

> (1) that is motivated because of cognitive boundaries, biases, routines, and habits in individual and social decision-making **posing barriers for people to perform rationally in their own declared self-interest.**

Now this addition explicates the notion of cognitive boundaries and biases, as well as certain routines, and habits. But why does the occurrence of cognitive boundaries, biases, routines, and habits result in a reason to nudge? That is, who or what is calling for the need to nudge? As it turns out, a lot hangs on the interpretation of this subtlety only implicit even in Hausman and Welch's attempt at explicating the definition provided by Thaler and Sunstein. I find that two possible interpretations are readily available.

### a. Nudging as Libertarian Paternalism

First, we may interpret the definition as requiring that the motive be *paternalistic*. That is, because of cognitive boundaries and biases in individual and social decision-making, the nudged agent is prevented from acting rationally according to his own interest as judged by the one nudging or as judged by himself – and this may be taken to *call* for a paternalistic intervention, which as a matter of definition is done in the interest of the people nudged (as judged by the one nudging or as judged by himself). This is the position taken by Sunstein in his recent *Why Nudge?*[89] If this interpretation is chosen, we have that:

> A nudge is a function of (I) any attempt at influencing people's judgment, choice or behaviour in a predictable way **according to their own self-declared interests** (1) that is motivated because of cognitive boundaries, biases, routines, and habits in individual and social decision-making posing barriers for people to perform rationally **in their own self-declared interests**, and which (2) works by making use of those boundaries, biases, routines, and habits as integral parts of such attempts. Thus a nudge amongst other things works independently of:
> (i) forbidding or adding any rationally relevant choice options,
> (ii) changing incentives, whether regarded in terms of time, trouble,
> social sanctions, economic and so forth, or
> (iii) the provision of factual information or rational argumentation.

If choosing this interpretation of the motive in (1) we essentially marry the concept of nudge to that of libertarian paternalism. Hence we may refer to this definition as *the LP-definition*. Under this definition nudges are a subset of libertarian paternalism. See Figure 2.

### b. Nudging in the Technical Sense

Alternatively we may interpret the definition as not making any specific requirements as to the motive, other than that the motive is dependent on or made possible by the fact that cognitive boundaries, biases, routines, and habits in individual and social decision-making pose barriers for people to perform ra-

88 Hausman and Welch, "Debate: To Nudge or Not to Nudge", *supra* note 22, at p. 126.

89 Sunstein, *Why Nudge?*, *supra* note 6.

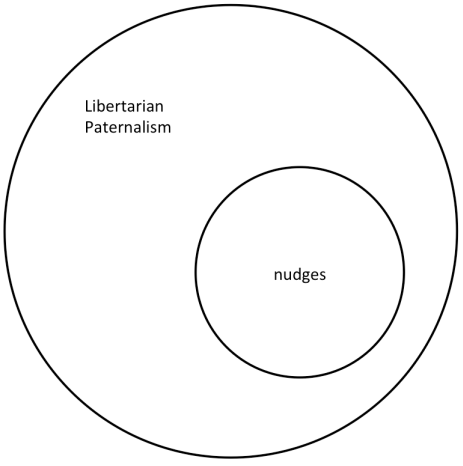


*Figure 2*

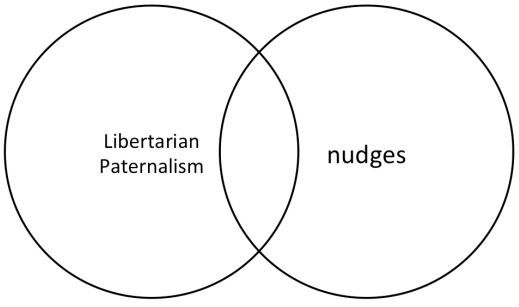


*Figure 3*

tionally. If we choose this strictly *technical* interpretation we get a definition saying that:

> A nudge is a function of (I) any attempt at influencing people's judgment, choice, or behaviour in a predictable way that is (1) made possible because of cognitive boundaries, biases, routines, and habits in individual and social decision-making posing barriers for people to perform rationally **in their own self-declared interests**, and which (2) works by making use of those biases, routines, and habits as integral parts of such attempts.
>
> Thus nudges amongst other things work independently of:
>
> (i) forbidding or adding any rationally relevant choice options,
> (ii) changing incentives, whether regarded in terms of time, trouble,
> social sanctions, economic and so forth, or
> (iii) the provision of factual information or rational argumentation.

Obviously, "made possible" is weaker than "called for" and thus, different from the LP-definition, the technical definition is not married to the notion of libertarian paternalism. Hence we refer to it as the *technical*, or the *neutral* definition. Under this definition the set of nudges overlaps with that of libertarian paternalism, but is not contained in the latter. See Figure 3.

Now, to decide which definition to prefer, one could turn exegetic. However, in my opinion, re-reading what has been written by Thaler and Sunstein about nudges to search for clues in one or the other direction would not lead to any decisive conclusions. Whether they favour the LP-definition or the technical definition does not decide the question of which stipulative definition we should opt for. However, as I have argued elsewhere there is one set of exegetic readings that lend evidence to the technical definition as the best *stipulative* definition of the concept of nudge given the way that this concept has come to be adopted in discussions surrounding the nudge approach to behaviour change.[90]

### c. "Nudge for Good"

First, the technical definition is consistent with certain central comments made by Thaler and Sunstein.

In general Thaler signs copies of *Nudge* with the slogan "nudge for good". This precautionary call clearly indicates that the notion of 'nudge' is not necessarily married to that of 'libertarian paternalism', but may instead be cast in terms of the technical definition – because if this weren't the case, Thaler's phrase would be nothing more than a tautology. Something similar goes for the title of Sunstein's recent book *Why Nudge?* After all, if the LP-motive were part of the definition of a nudge, then one would not have to answer the question of 'why nudge?' – one would only have to define the term. In addition one may observe that when Sunstein says that the "Provision of information is certainly a nudge, but it may or may not qualify as paternalistic...",[91] this seems to reveal

90 Pelle G. Hansen, "Nudge for good", Policy Options, 3 Jun 2013, pp. 22-23 *et sqq*.

91 Sunstein, *Why Nudge?*, *supra* note 6, at p. 55.

that nudges that fall outside the scope of libertarian paternalism exist and hence the set of nudges cannot be a subset of libertarian paternalistic measures. These considerations support the adoption of the technical definition.

Second, the technical definition is consistent with points about nudges and marketing consistently made by commentaries. If we opt for the technical definition it makes sense to refer to the many marketing tricks used to fool us into buying things we don't need as nudges as well. That is, the technical definition recognises that it is possible to nudge "for bad" or "for profit" as well as "for good". This observation is both in line with many comments made in the general literature and mentioned here in the introduction as well as many formulations in the work of Thaler and Sunstein themselves.

Thirdly, when the nudge approach to behaviour change is regarded as a sub-branch of libertarian paternalism or as synonymous with this, there is a danger that anyone in favour of the former must also be in favour of the latter. That is, if one sees nudges as valuable measures for creating behaviour change, one is often taken as favouring the political ideology of libertarian paternalism - an ideology that by some is said to hold that policy makers should avoid regulations that limit choice (bans, caps, etc.) but can use behavioural science to direct people towards better choices. However, this is not necessarily so on the technical definition. Here one may adopt nudges as valuable measures to behaviour change without adopting a particular political ideology.

There are probably other reasons for sticking with the technical definition of nudge. However, I will accept the three mentioned above as sufficient as they lend evidence to the technical definition as the best *stipulative* definition of the concept of nudge, refining what has come to be standard usage in the reception of *Nudge*. That is, while one may choose either one as one's favourite definition, it seems that there is a conceptual need for adopting the technical one since it is better at providing clarity when discussing applications of behavioural economics and other behavioural sciences with the aim of creating behaviour change. For this reason I conclude that the most suitable definition of nudge is as follows:

> A nudge is a function of (I) any attempt at influencing people's judgment, choice or behaviour in a predictable way, that is (1) made possible because of cognitive boundaries, biases, routines, and habits in individual and social decision-making posing barriers for people to perform rationally in their own self-declared interests, and which (2) works by making use of those boundaries, biases, routines, and habits as integral parts of such attempts.
>
> Thus a nudge amongst other things works independently of:
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>
> (ii) changing incentives, whether regarded in terms of time, trouble,
>
> social sanctions, economic and so forth, or
>
> (iii) the provision of factual information and rational argumentation.

In so far as a nudge serves the self-declared interest of those being nudged, it may further be referred to as *libertarian paternalism* since the general definition of nudge implies that people's judgment, choice, or behaviour is influenced in ways that work independently of (i) forbidding or adding any rationally relevant choice options, (ii) changing incentives, whether regarded in terms of time, trouble, social sanctions, economic incentives and so forth. In addition, this definition also implies that libertarian paternalism goes beyond nudging since it follows from it that nudges work independently of (iii) the provision of factual information and rational argumentation, which fall squarely within libertarian paternalism.

# Causal Inference in Law: An Epidemiological Perspective

*Bob Siegerink, Wouter den Hollander, Maurice Zeegers and Rutger Middelburg**

## I. Introduction

Causal inference lies at the heart of many legal questions. Yet in the context of complicated disease litigation, in particular, the causal inquiry is beset with difficulties due to gaps in scientific knowledge concerning the precise biological processes underlying such diseases. Civil courts across the globe, faced with increased litigation on such matters, struggle to adhere to their judicial fact-finding and decision-making role in the face of such scientific uncertainty. An important difficulty in drawing evidentially sound causal inferences is the binary format of the traditional legal test for factual causation, being the 'but for' test, which is based on the *condicio-sine-qua-non* principle.[1] To the question 'would the damage have occurred in the absence of the defendant's wrongful behaviour' the 'but for' test requires a simple yes or no answer. This is increasingly deemed unsatisfactory in cases in which, given the state of science, true causation cannot possibly be determined with certainty. Given the general rule that the burden of proof in principle lies with the claimant, the 'but for' test passes on the uncertainty to the claimant entirely. Such is not only felt to be at odds with fairness, but is also unsatisfactorily from an epidemiological perspective, given the binary format of the 'but for' test on the one hand and the fact that most diseases are multi-causal and cannot be ascribed to a single factor only on the other hand.

In this article, we will elaborate this epidemiological perspective and from that perspective discuss the problem of causal inference in law in general and scrutinize one new legal concept dealing with this problem in particular. This is the concept of the so-called proportional liability, as accepted by the Dutch Supreme Court in the Nefalit-case. The Supreme Court agreed with the lower courts, assuming liability of employer Nefalit, in proportion to the reasoned estimation of the chance that the lung cancer Karamus suffered from was caused by asbestos exposure during the work for his employer Nefalit (55%). We will argue that although such proportional liability adheres to the epidemiological concept of multi-causality, and in that respect, is not without merit, epidemiological measurements *on a population level* should not be taken to calculate the probability that the employers' wrongful conduct has actually caused the disease in an *individual*. We propose a different approach in two stages, making proportional liability more truly proportional to the defendant's relative contribution in the known causal mechanism underlying the damage in question and, by that, more fair for both parties, even though our approach is not flawless either.

We will set out some important concepts from the field of epidemiology with respect to causal inference first. A thorough understanding of these concepts will help to further strengthen and inform legal principles of causation. Epidemiology, where probabilistic concepts are applied to address causal questions in individuals, could in particular aid in the understanding of multi-causality and its possible links to proportional liability as a legal concept. Epidemiology studies the distribution and determinants of disease frequency in human populations. It contrasts with daily medical practice which focuses on individuals. We will elaborate the difference in concepts of causal inference between groups and individuals, with a link to the *condicio-sine-qua-non* principle and the concept of multi-causality. We will then discuss

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1 See for instance Deakin, S., Johnston, A., Markesinis, B. *Markesinis and Deakin's Tort Law* (7th ed.), Oxford: Clarendon Press 2013, pp. 218-256.

how causation can be quantified in a single number and how these numbers compare to the legal concept of proportional liability as accepted in the Nefalit-case. Ultimately, we will try to reconcile the impossibility to know the exact causal mechanism of a disease in an individual to the *condicio-sine-qua-non* principle and the application of proportional liability to come to a fair reimbursement of damages in complex disease litigation.

## II. Causal Inference in Medicine and Epidemiology

In clinical medicine, doctors are confronted with questions of causality on a daily basis. Will this medical treatment cause the cure of a patient? And will the benefits outweigh the side-effects caused by this treatment? For example, when a patient suffers from an ischaemic stroke caused by a blood clot in the brain that is preventing the flow of oxygenated blood, a decision can be made to start treatment targeted to resolve the blood clot and restore blood flow. This treatment is called thrombolysis and restores blood flow in 43% of treated cases.[2] However, thrombolysis also causes bleedings, which in itself can also be a cause of morbidity and mortality.[3] Thrombolysis can only be applied in the first 3-4,5 hours after the onset of symptoms, because only in this time period the benefits of treatment, which declines over time, outweigh the negative consequences of this treatment on a population level.

Treating a patient is not restricted to addressing the acute symptoms of a certain cause, but also includes the removal of possible causes to prevent a possible recurrence of the disease. For example, the physician confronted with a patient suffering from an ischaemic stroke will not only apply thrombolysis, but will also target the smoking habit and the increased cholesterol levels of that particular patient to prevent another case of ischaemic stroke in the long run. The decision to target these risk factors is based on studies that *on a population level* these factors area cause of the disease. Targeting these risk factors in an *individual* is therefore thought to lower the risk of recurrence.[4,5] But how can the physician, based on epidemiological studies, be certain that the smoking habit and high cholesterol levels were causal in the mechanism leading to the ischaemic stroke in *this* particular patient? The unsettling answer is that he is not certain, neither can he ever be.

## III. The Counterfactual Ideal

Theoretically, we can only be certain on the causal nature of a risk factor if we observe the outcome when the patient is exposed to this risk factor and compare that to the situation when we go back in time, and see what happens if the patient is unexposed, but all other factors are kept constant.[6] Because this hypothetical situation is contrary to fact, this concept is sometimes referred to as the counterfactual or potential outcome model.[7,8] If we could go back in time, and manipulate only one certain factor we could determine in each individual patient whether an individual risk factor was indeed a cause of the observed disease.

This counterfactual model is comparable to the *condicio-sine-qua-non*-test in law. The risk that describes this relationship between exposure and disease for one individual is binary, being 1 (for the disease is caused by the exposure) or 0 (for the disease is not caused by the exposure). However, since the counterfactual outcome cannot be observed, we cannot determine the causal mechanism in an individual. The counterfactual ideal can be approached, though, in the comparison of different populations under certain conditions. For example, if two groups are similar except for the presence of the risk factor of interest, a difference in disease frequency can be ascribed to the sole difference between these groups,

2 Joung, H. Rha, & Saver, L.J., 'The Impact of Recanalization on Ischaemic Stroke Outcome: a Meta-Analysis', *Stroke* 38 (2007), pp. 967–73.

3 Lansberg, M.G. *et al.*, 'Antithrombotic and Thrombolytic Therapy for Ischaemic Stroke: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines', *Chest* 141 (2012), e601S–36S.

4 Goya Wannamethee, S. *et al.*, 'Smoking Cessation and the Risk of Stroke in Middle-Aged Men', *JAMA* 274 (1995), pp. 155–60.

5 Milionis, H.J. *et al.*, 'Statin Therapy after First Stroke Reduces 10-year Stroke Recurrence and Improves Survival', *Neurology* 72 (2009), pp. 1816-22.

6 For more background reading on the theory of causation, please refer to: Pearl, J., Causality: Models, Reasoning, and Inference, Cambridge University Press, 2000; 2nd edition, 2009.

7 Rothman, K.J. *et al.*, 'Causation and Causal Inference in Epidemiology', *Am. J. Public Health* 95 (2005) Suppl. 1, pp. S144-50.

8 Rothman, K.J., Greenland, S., Lash, T.L., *Modern Epidemiology* (third revised edition), Lippincott Williams & Wilkins 2008.

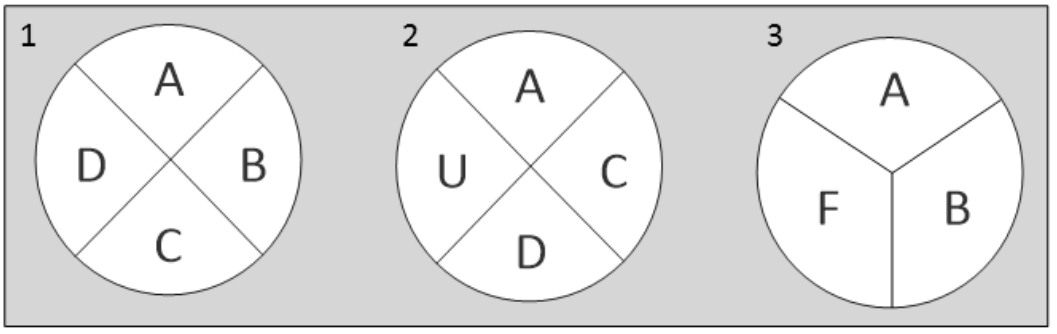


*Figure 1 - Three sufficient causes*

being the risk factor of interest. This comparison does not allow to establish the causal mechanism within an individual. However, these group comparisons do allow us to estimate the causal relationship between the exposure and the outcome to be quantified in terms of probability.

## IV. From One Cause to the concept of Multi-causality

Before we describe how causal relationships can be quantified, we first have to focus on the definition of a causal mechanism. Often, the cause in a causal mechanism is thought to be a single factor in a cause-consequence sequence. However, a consequence can have multiple causes: several factors, as a combination, cause an effect. This concept is known as multi-causality and is important in epidemiological thinking on causality, for it provides a way to think about causal mechanisms instead of single cause-consequence sequences. To avoid confusion, multi-causality should be distinguished from the situation in which a single factor, such as smoking, can cause different diseases.

In epidemiological theory, the concept of multi-causality has gained ground since it was formalized by K.J. Rothman in 1976.[9] The concept distinguishes and describes the implications of *necessary*, *sufficient* and *component causes* and is further explained with the use of figure 1.

Let there be three possible causal mechanisms that lead to a certain disease. Figure 1 depicts these three causal mechanisms as three *sufficient causes*, all comprising multiple *component causes*. In this example we assume that these three sufficient mechanisms are the only three possible causal mechanisms that lead to an event, which can be a disease, injury or anything similar. The frequency of the disease normally is a direct function of the frequency of – a combination of – the different component causes. We also assume that all component causes are equally present in the population and that the presence of each component cause is independent from the others (i.e. no confounding causes, see below).

Important to note is that sometimes component causes are present in all sufficient causes, making them *necessary component causes* (A in our example). In theory, removal of a necessary component cause from the population will lead to complete eradication of the disease. It is not necessary for all sufficient causes to have an equal number of component causes, nor is it needed to name all component causes in detail. A component cause can even be unknown (often depicted as 'U', as is done in the middle sufficient cause in figure 1).

A component cause can be present long before the sufficient cause is completed. For example, a genetic variation in a certain gene is present from before birth, but other component causes are needed to complete a sufficient cause. The completion of a sufficient cause equals the biologic onset of the disease, which is not necessarily the time of diagnosis. These concepts are illustrated in an example where genetic variations are part of the causal mechanism leading to ischaemic stroke: genetic variations in the APOE gene are known to cause blood cholesterol levels to rise. These genetic variations are present from before birth, but this small increase in blood cholesterol alone is in itself insufficient and additional car-

9 Rothman, K.J., 'Causes', *Am. J. Epidemiol* 104 (1976), pp, 587-92.

diovascular risk factors are needed in order to cause an ischaemic stroke. Together with such factors (e.g. smoking), increased blood cholesterol might result in an atherosclerotic plaque. Sometimes, these plaques rupture and a thrombus is formed, which subsequently blocks the flow of blood to the brain. Also, the moment of diagnosis of the ischaemic stroke or even the first symptoms can be hours later than the actual blockage of the cerebral artery.

Since component causes accumulate over time, the incidence of many diseases rises sharply with age. The time between the first presence of a component cause and the completion of the sufficient cause is referred to as the induction time. In our example, the alphabetical order of the components refers to the order in which they occur. It is important to note that the length of the induction does not necessarily reduce the importance of a particular component cause. The component cause that completes the sufficient cause has an induction time of zero and is therefore easily identified as a cause. Component causes with little to no induction time are in layman's terms for that reason sometimes erroneously referred to as *the* cause of the disease.

Nonetheless, the order of component causes is of importance: a person who is only exposed to component causes A and B has no sufficient cause. Subsequent exposure to the two components causes C and D will complete a sufficient cause. When this person is not exposed to C or D, he will not develop the disease at that particular point in time. However, when this same person at a later moment is exposed to component cause F, a sufficient cause has formed and the person still develops the disease, albeit somewhat later in time.

The sufficient cause model adheres to the counterfactual ideal. When we consider the sufficient cause 1 depicted in figure 1, we can see that A, B, C and D are the component causes for this particular sufficient cause. If we think of the counterfactual situation that this particular individual was not exposed to component cause A and all other things equal, this disease would not have occurred. The same goes for the common causes B, C and D. We can even broaden our view and see what happens with the whole population: if necessary component cause A were to be eliminated from the population, 100% of all sufficient causes cannot be formed anymore and the disease would have been eradicated from the population.

We can also see that 2/3 of the sufficient causes comprise component cause D. Removing D from our population would however not necessarily reduce the number of diseased in our population by this same number. After all, persons with sufficient cause 1 are now only exposed to component cause A, B and C and therefore still at risk of developing the disease for example when exposed to component cause F later in time. If in the extreme case each individual exposed to component cause D is also, at some later time, exposed to component cause F, sufficient cause three would be formed in half of the people for whom the sufficient cause otherwise included D (half since half of those people – sufficient cause 2 – is not exposed to component cause B). In this example we can see that only 1/3 of the diseased can be attributed to component cause D (known as the *attributable fraction*), even though it is present in 2/3 sufficient causes (known as the *aetiologic fraction*). Please notice that this observation can be at odds with the interpretation of the *condicio-sine-qua-non* test that is applied in different judicial systems, for this principle does not necessarily provide the right mind-set to handle the possibility that a different causal mechanism leading to the same consequence could arise.

Although neither the counterfactual nor the sufficient cause of an individual can be observed, this conceptual framework does provide useful insight in the idea of causation and multi-causality.

## V. Study Designs

The counterfactual ideal can be approached in several study designs, as long as several assumptions are made. Although uncommon, sometimes the counterfactual is undisputed and direct causal inferences can be made. For example, certain forms of brain injury can induce massive swelling of the brain which leads to increased intracranial pressure and subsequently the death of almost all patients with this condition.[10] Any intervention that reduces the intracranial pressure and prevents death in all patients, for example by drilling a hole in the skull so that the swollen brain can extent outward, will be re-

10 Zuurbier, S.M. *et al.*, 'Decompressive Hemicraniectomy in Severe Cerebral Venous Thrombosis: a Prospective Case Series', *Journal of. Neurology* 259 (2012), pp. 1099-105.

garded as causal in the prevention of death of these patients.

There will hardly be any discussion about the causal claim made in such a scenario, so we will not focus on this type of studies. We will focus on scenarios which are much more unclear. Since most, if not all, diseases can be regarded as multi-causal, the composition of sufficient cause of individual patients cannot be known, making it impossible to determine causal mechanisms in individuals. We can only quantify the effect of component causes in probabilistic terms.[11] Often this is done by comparing the risk of those who are exposed to the factor of interest to the risk of those who are not exposed, for example by the ratio of the respective probabilities of disease. This ratio is also known as the *relative risk*.

The study design that approaches the counterfactual ideal as close as possible is the crossover trial. In this design patients are assigned to two subsequent treatment strategies, of which one can be a placebo treatment, and the outcome of the patient (e.g. blood pressure) is measured directly after each treatment (e.g. antihypertensive medication vs. placebo). This way the same patient is observed both with and without the exposure, as prescribed by the counterfactual ideal. It is important that the patient has to return to his 'original state' from before his first treatment, before receiving his second treatment. Otherwise such a comparison will not result in correct causal inference. This problem can be countered by tweaking the experimental design, for example introducing a wash-out period between the two treatment periods, but also severely limits the applicability of this design.[12] Another study design that approaches the counterfactual ideal is the case-crossover design. In this design the exposure status of a patient is determined on two moments: acutely before the onset of the disease and in a control period some time before the onset of the disease. If the exposure of interest is indeed a cause of the disease it is likely to be more present just before the acute onset of the disease than in the control period. This can only be done when the information needed to determine exposure status can be reliably obtained after the patients are identified. Another disadvantage of this design is that it can only investigate triggers of diseases with an acute onset, which are the component causes with no or little induction time. An example of this study design is a study that investigated potential triggers of sub arachnoid bleeding, which showed that short but distinctive exposures such as coffee consumption and sexual intercourse can indeed be the trigger of this type of haemorrhagic stroke.[13,14]

Although these two study designs approach the counterfactual ideal, these can only be applied to situations in which an exposure is variable within one person and the effect is either acute or reversible. Many research questions do not adhere to these conditions (e.g. genetic exposures are not variable within a person, cancer has no acute onset and death is not reversible) thus leaving one or both of these crossover designs inappropriate. Other study designs do not suffer from these restrictions, but need more assumptions to justify causal inferences. Randomized trials can be used to study the effect of different treatment strategies by applying the treatments to different groups of persons and observe whether there is a difference in the frequency of the outcome of interest. This study design relies heavily on the assumption that the two groups would have a similar risk of the outcome if these were left untreated, a situation in which the counterfactual ideal clearly resonates. This situation is created by the randomization principle: the likelihood of receiving a certain treatment is independent from other causes of the outcome. Randomized trials are a powerful tool in the discovery of intended effects of modifiable exposures, being treatments targeted at reducing the risk of the outcome, as is the case in a clinical trial that compares two treatments to prevent cardiovascular disease. Also, data from randomized trials can provide more insight in the side effects of new drugs.

However, the use of randomized trials to identify causes of a disease is in many cases ethically undesirable. Additionally, many exposures cannot be modified (e.g. genetic variations) and therefore a large proportion of causal questions cannot be answered by experimental studies. In such cases observational studies must be applied to estimate the causal relationship between the exposure and the

11 Rothman, K.J., Greenland, S., Lash, T.L., *Modern Epidemiology* (third revised edition), Lippincott Williams & Wilkins 2008.

12 Senn, S., *Crossover-trials in clinical research*, Wiley 1993.

13 Maclure, M. *et al*, 'Should we use a case-crossover design?', *Annual Review of Public Health* (2000), pp. 193-221.

14 Vlak, M.H.M. *et al.*, 'Trigger Factors and Their Attributable Risk for Rupture of Intracranial Aneurysms: a Case-crossover Study', *Stroke* 42 (2011), pp. 1878–82.

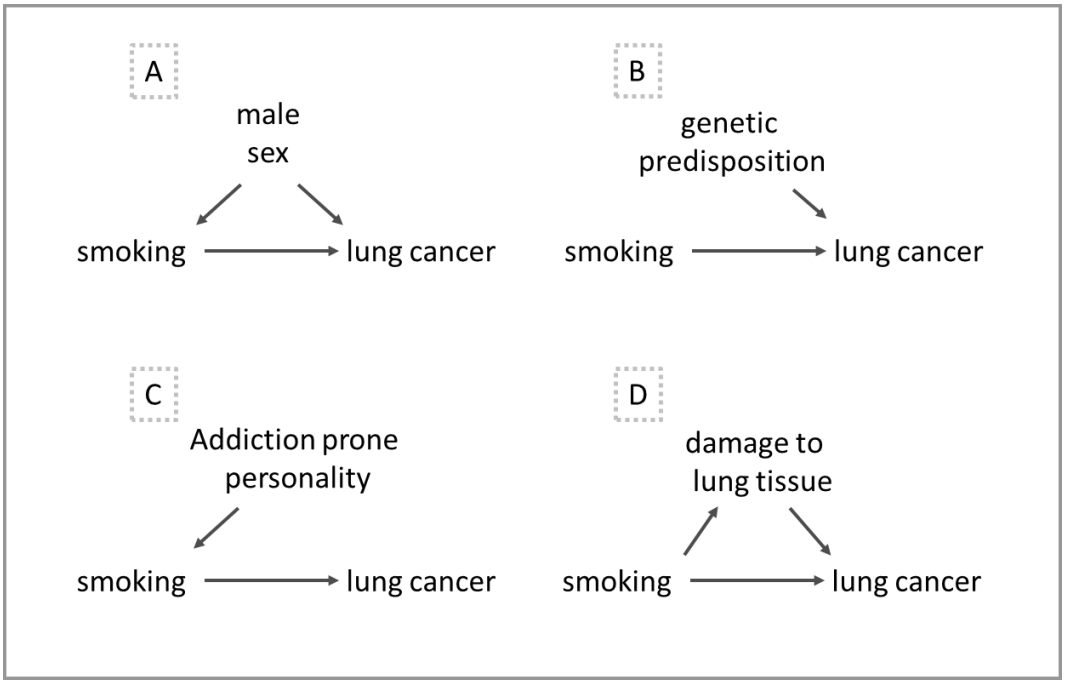


*Figure 2*

outcome of interest. The observational study designs can be categorised in two groups, being the cohort studies and the case-control study, each with their own merits. Like experimental study designs, observational study designs rely on certain assumptions to allow estimation of the causal effect. These designs, their merits and pitfalls as well as the assumptions needed for causal inference are too complex to describe here in detail and are discussed at great length in several textbooks and we limit ourselves to a general description of the concept of bias.[15]

## VI. Bias

One major assumption in causal inference from epidemiological studies is the absence of bias, which introduces an incomparability into the study. We will discuss three major forms of bias with regard to the causal relationship between smoking and lung cancer. The first is *information bias* in which data are collected incorrectly and bias the result in a particular direction. For example when data about smoking habits are collected in a different fashion (for example more rigorously or through different types of questionnaires) in lung cancer patients than in healthy subjects. A comparison of those data would not only reflect the effect of smoking on the risk of developing lung cancer, but undesirably also reflects the differences in data collection. Another form of bias is *selection bias* in which study participation is dependent on the exposure and/or the outcome. For example, when lung cancer patients are compared to a group of healthy volunteers who are not reflective of the population from which the lung cancer patients arose, but are instead (indirectly) selected for being non-smokers, results of the comparison of these groups would not reflect the effect of smoking on the risk of developing lung cancer. It will undesirably be reflective of the differences between the two separate populations from which the patients and control group were sampled. A third form of bias is *confounding bias* in which the increase in risk of the exposure of interest is mixed with the risk of another cause of the disease of interest. This happens when the exposure of interest shares a common cause with the outcome of interest, as is discussed in figure 2.

15 Rothman, K.J., Greenland, S., Lash, T.L., *Modern Epidemiology* (third revised edition), Lippincott Williams & Wilkins 2008.

This figure contains four graphs that describe the causal relationship between smoking and lung cancer, but also include a third factor. These graphs are examples of four different classes of factors that are statistically associated to the risk of lung cancer, which could impede causal inference. It is important to differentiate between these classes because the nature of such a variable determines whether it should be taken into account to ensure valid estimation of the causal effect between smoking and lung cancer development.

**A|** A common cause of the exposure and outcome is considered a confounder. This example shows that men are more likely to smoke, but also that men intrinsically have a higher risk of lung cancer. The smoking-lung cancer association is said to be confounded and 'male sex' needs to be taken into account in order to ensure valid causal inference. Confounding can be a source of fallacious 'post hoc ergo propter hoc' conclusions.

**B|** Another cause of lung cancer, e.g. a genetic predisposition, which is independent of smoking is not considered a confounder. Therefore, the additional risk of some individuals will not confound the smoking-lung cancer association.

**C|** Causes of the exposure which are not a cause of the outcome other than via the exposure of interest are not confounders. In this example, an addiction prone personality is a causal factor in the development of a smoking habit. However, it is not a cause of lung cancer by itself. These causes are part of the causal mechanism of lung cancer, but do not confound the smoking-lung cancer association.

**D|** A direct consequence of the exposure which ultimately leads to the outcome of interest is not considered to be a confounder. In this example, smoking increases the risk of lung cancer because it causes damage to lung tissue. This intermediate cause is said to lie 'in the causal pathway'. Therefore, there is no confounding present.

The presence of confounding can lead to a fallacious 'post hoc ergo propter hoc' conclusion: even when an exposure of interest is not a cause of the disease, it is still possible that exposed individuals are more likely to develop the disease. This increase in risk, which is in fact a spurious relationship, can then be explained by other causes of disease that are found more often amongst exposed individuals leading to *confounding bias*. When confounding is not taken into account the disease develops more often in those with a certain exposure, it seems as if the exposure is in fact the cause. If sources of confounding are identified before the start of the study, confounding can be addressed and accounted for in the study design or statistical analyses.[16] However, when confounding is not sufficiently addressed, its presence may lead to erroneous causal statements.

All study designs are subject to bias, but different study designs suffer from different forms of bias and to a different extent. There are some classifications that categorise studies according to their 'level of evidence'.[17] This practice can be useful, as long as this practice does not preclude critical thinking. For example, many researchers believe that the randomized clinical trial is the only study design in which causal relationships can be studied. This is however an outdated point of view, since observational studies can be as credible as randomized trials under certain conditions.[18] The randomized controlled trial study design remains however the unbeatable golden standard if one wants to study the beneficial effects of a new drug. The randomization procedure breaks the link between the prescription of the new drug and the probability of the outcome. Observational studies do not break this link, which could severely bias the results (i.e. confounding by indication). However, these biases are less severe when one wants to study drug side effects or identify causes of a disease. This makes observational studies suitable to investigate causal mechanisms, in case biases can be accounted for.

## VII. Causal Inference: More than One Study

So can we draw definite conclusions on the probabilistic relationship of a cause and its consequence based on a single study? It is advisable to use multiple studies for several reasons. First, it is possible that

16 For more background information on the statistical approaches that can be applied to investigate causal relationships, please refer to Berzuini, C., Dawid, S., Bernadinell, L., (editors), *'Causality: Statistical Perspectives and Applications',* (Wiley, 2012)

17 See for example the website of the Centre for evidence based medicine with the title 'Levels of evidence', <http://www.cebm.net/index.aspx?o=1025> (21 July 2014).

18 Vandenbroucke, J.P., 'When are observational studies as credible as randomised trials?', *Lancet* 363 (2004), pp. 1728–31.

just by chance the effect estimate from a single study is very different from the true effect. By combining the result of multiple studies into a so-called 'meta-analysis' the statistical power increases and the effect estimate is more precise. Second, all studies are subject to bias and some studies are more prone to particular forms of bias. Therefore, a lot can be learned from comparing the results of studies with different study designs. But even in the unlikely scenario that bias is thought to be completely absent and that the effect of the presumed cause is measured with sufficient statistical power, more information is needed to draw firm inferences on the causal relationship between the exposure and outcome of interest. This knowledge must focus on the plausibility of the proposed causal claim. Are other plausible factors present that could explain our results? Is the proposed mechanism in line with our current knowledge?

Therefore, part of causal inference in medicine lies outside the reach of a single study or even outside the realm of epidemiology. This concept is in line with the crossword analogy of science philosopher Susan Haack.[19,20] Several factors are of importance when filling out a crossword: the clue, the already entered answers, the possibility of alternative answers, and the level of completion of the crossword. A new answer cannot be at odds with already existing entries without rethinking previous answers. Causal inference can be regarded in a similar fashion: one single result is not likely to justify causal claims. But several results, from various research groups, backed by previous knowledge, not likely to be explained by alternative scenarios such as bias or chance could justify cautious causal claims about the quantification of the cause and effect estimate of interest.

Some have tried to codify all aspects that need to be considered before a relation can be regarded as causal. For example, Sir Austin Bradford Hill noted nine aspects of causality that might be considered when talking about causality in epidemiology.[21] Hill noted in his original address to the Royal Society that these factors are not to be considered as criteria. Only one, 'temporality', is a true criterion, that is that the cause must be present or act before its effect. The other eight aspects are not criteria and can be regarded as aspects that might be discussed when one wants to come to a causal judgement. However, despite the warnings by Hill and others, some researchers have misused these nine conditions as a checklist for causal claims. Such practice prohibits a critical appraisal of all evidence and should be abandoned. Unfortunately, this not the case.[22, 23]

## VIII. Causal Claims in Law

It is easy to see that it is not straightforward to transfer epidemiological knowledge obtained from populations to individual legal claims. We will discuss these difficulties by discussing the Dutch Nefalit-case.[24] In this case, Karamus attributed his disease to his long-term exposure to asbestos, suffered in the factory where he worked, for which he held his former employer Nefalit liable. Nefalit had failed to take the necessary precautionary measures and was therefore, in the view of Karamus, to compensate all damages related to his disease. Nefalit responded, however, that the lung cancer could also have been caused by Karamus' long time smoking habit, by other factors or a combination of these. It is indeed known from epidemiological evidence as well as laboratory studies that both exposures are known to increase the risk of this particular type of lung cancer, often in combination with others causes. Therefore it is not possible, given the state of science and the idea of multi-causality, to determine the single cause of Karamus' disease and his damages. Lower courts, with the consent of the Dutch Supreme Court, acknowledged that applying the *condicio-sine-qua-non* test would mean passing on this uncertainty to Karamus entirely, as his claim would have to be dismissed on the ground that causation could not be estab-

19 Haack, S., *Manifesto of a Passionate Moderate*, Chicago: University of Chicago Press 1998.

20 Vandenbroucke, J.P., 'Alternative Medicine: A "Mirror Image" for Scientific Reasoning in Conventional Medicine', *Annals of Internal Medicine* 135 (2001), pp. 507-511.

21 Hill refers to these nine points as 'aspects of …(an) association' that should be considered before deciding on the interpretation of causation. These points are: strength, consistency, specificity, temporality, biological gradient, plausibility, coherence, experiment and analogy. See also Hill, A.B., 'The Environment and Disease: Association or Causation?', *Proceedings of the Royal Society of Medicine* (1965), pp. 295-300.

22 Morabia, A., 'On the Origin of Hill's Causal Criteria', *Epidemiology* 2 (1991), pp. 367-369.

23 Phillips, C.V. *et al.*, 'The Missed Lessons of Sir Austin Bradford Hill', *Epidemiology Perspectives and Innovations* 1 (2004), p. 3.

24 Hoge Raad 31 March 2006, ECLI:NL:HR:2006:AU6092, reachable through <http://uitspraken.rechtspraak.nl/#ljn/AU6092> (in Dutch; 9 December 2014).

*Equation* 1

$$attributable\ fraction\ (AF) = \frac{Relative\ Risk - 1}{Relative\ Risk}$$

lished. Therefore these courts applied the concept of so-called proportional liability, ruling that Nefalit was liable for only a proportion of Karamus' damages, based on expert testimony and epidemiological publications about the chances that his lung cancer was indeed caused by the asbestos exposure (55%).[25]

It was a matter of fairness, the Supreme Court indicated, not to pass on this uncertainty to the claimant entirely, by dismissing Karamus' claim altogether, given that in this case the chance that the lung cancer was indeed caused by asbestos, was neither very small nor very large. In such cases, courts are allowed to make a reasoned estimate, if necessary on the basis of expert testimony. It is important to note that the Supreme Court justified the application of this so-called 'proportional liability' in part by stating that there was uncertainty whether it was the asbestos exposure, the claimant's smoking habits, genetics or other additional external factors that caused the lung cancer, alone or in combination.

We will discuss later whether the 55%-ruling is justified in light of this motivation given by the Dutch Supreme Court. First, it is important to understand how the 55% came about. This number was obtained by calculating the *attributable fraction*, as discussed in section IV, which is defined as the fraction of cases in which the exposure of interest is a component cause of the sufficient cause leading to the disease. A second related measure is the *probability of causation*, which is a direct function of another fraction: the *aetiological fraction*. This fraction describes the probability that the factor of interest is a component cause in a sufficient cause, in a case randomly drawn from a patient population. In theory, these concepts can be very helpful in liability cases, because they provide a way to link a population measure to a single case. However, we have already argued that the aetiological fraction cannot be observed directly or calculated without strong additional assumptions, which cannot be empirically verified.

However, the *attributable fraction*, the fraction of the diseases among the exposed that can be ascribed to the exposure of interest, on the contrary can be calculated in a cohort study as (see Equation 1), where the relative risk is the risk of the outcome amongst the exposed divided by the risk in the unexposed. Once calculated the attributable fraction should directly be interpreted as the aetiological fraction: the aetiologic fraction is always similar or higher, but never lower than the attributable fraction.[26]

Some points have to be emphasized to ensure correct interpretation of these numbers. Both the aetiologic and attributable fraction are calculated for component causes, which implies that the sum of all fractions do not necessarily equal, but is likely to be higher than 100%, due to the multi-causal nature of complex diseases. In fact, the sum of these fractions could be both higher or lower, and basically depends largely on the number of causes that have been identified for a specific disease. Therefore, these fractions should never be interpreted as the probability that a certain factor of interest is *the single cause* of the disease in a particular case, since there is no such thing as a *single cause*. Some have proposed this wrong definition in order to use the effect size as a measure of causality. In line with this wrong notion a relative risk greater than 2, which equals an attributable fraction of > 50% (AF = (2-1) / 2), has sometimes even been abused as cut off point for 'causality-proven vs.

25 Hoge Raad 31 maart 2006, ECLI:NL:HR:2006:AU6092. See also, more recently, Hoge Raad 14 december 2012, ECLI:NL:HR:2012:BX8349. On these cases, see Castermans, A.G. & Hollander, P.W. den, 'Omgaan met onzekerheid. Proportionele aansprakelijkheid, artikel 6:101 BW en de leer van de kansschade', *NTBR* 2013, pp. 185-195 (in Dutch).

26 The situation under which the attributable fraction can be interpreted as the aetiological fraction are described in Kenneth J. Rothman, Sander Greenland, Timothy L. Lash. *Modern Epidemiology,* third revised edition, (Lippincott Williams & Wilkins, 2008)

*Equation* 2

$$aetiological\ fraction = \frac{number\ of\ \textbf{sufficient causes}\ that\ include\ the\ component\ cause\ of\ interest}{all\ possible\ \textbf{sufficient causes}\ leading\ to\ this\ disease}$$

*Equation* 3

$$proportional\ liability = \frac{number\ of\ \textbf{component causes}\ that\ are\ the\ responsibility\ of\ the\ defendant}{total\ number\ of\ \textbf{component causes}\ in\ the\ sufficient\ cause\ of\ the\ claimant}$$

causality not proven'.[27] This misuse of the attributable fraction precludes any form of critical thinking about the causal mechanism underlying events and should be abandoned.

Another possible misinterpretation of both the aetiologic and attributable fraction lies in the direct translation of the attributable fraction to the proportion of the claims that should be reimbursed, with the idea that on average both the plaintiff as well as the defendants are treated satisfactorily. However, by coupling the attributable fraction to the proportion that should be reimbursed, the court forgets a crucial characteristic of the attributable risk, which again is that the sum of the attributable fraction can exceed 100%. In contrast, the shares in proportional liability in one particular case should not. Consider again our example in figure 1, in which 100% of cases (3/3) was 'caused by A' and 66% of all cases (2/3) was 'caused by B'. If a claimant with this particular disease would theoretically hold both 'A' and 'B' liable in separate law suits, this approach would yield a total of 166% of the claimed sum, which does not adhere to the fairness principle. The misconception that the aetiologic or attributable fraction can directly be applied as an allocation instrument for proportional liability as a legal concept thus lies in erroneously applying a population measure to an individual probability estimation. This can also be appreciated when we compare the formula for the aetiological fraction (see Equation 2) to the concept that uses proportional liability to adhere to the fairness principle (see Equation 3).

So what to think then of the use of proportional liability in the case of Nefalit and Karamus? During the hearings, an expert motivated that there was a 125% increase in risk due to asbestos exposure, which corresponds to a relative risk of 2.25 and an attributable fraction of 55% (the AF = (2.25-1)/2.25= 55.56%, the lower court mentions 55% in its ruling). The Dutch Supreme Court motivated the use of proportional liability, including this figure, and thereby implicitly the use of the attributable fraction in its ruling with the observation that there was uncertainty whether asbestos was indeed the cause. However, the court went further by coupling this number as the fraction of the damages that employer Nefalit should reimburse as a matter of fairness. At first glance, the motivation of the Supreme Court sounds fair, but we have already showed in our example above that linking the attributable fraction to the fraction that should be reimbursed by the defendant does not always adhere to the matter of fairness. Therefore, the ruling by the Supreme Court could lead to unfair reimbursements and, perhaps unknowingly and unwantedly, sets a precedent with possibly unwanted consequences.

We will continue with the Nefalit-case to illustrate this. Let say that besides smoking and asbestos exposure the claimant was also subjected to another risk factor 'X' due to negligence of another employer. Again, it is uncertain whether indeed it was 'X' that was the cause of his disease. Let us state that 'X' increases the risk of lung cancer by 178% and therefore has an attributable fraction of 64% (i.e. a relative risk = 2.78 and AF = (2.78-1)/2.78). Following the same line of reasoning as the court did when it came to asbestos exposure (i.e. there is uncertainty about the causal claim and therefore only a part of the claim should be reimbursed), in theory 64% of the claim

27 Greenland, S., 'Relation of Probability of Causation to Relative Risk and Doubling Dose: a Methodologic Error That Has Become a Social Problem', *American Journal of Public Health* 89 (1999), pp. 1166–9.

should be reimbursed by the second employer. This makes the received amount to theoretically supersede the original claim.

When a court wants to directly couple the aetiological faction to a 'fair' distribution of the damages the court has to know the true underlying causal mechanism of each individual liability claim. In a sense, the court has to be certain about all the component causes that make up the sufficient cause in this particular individual. However, the exact sufficient cause cannot be observed in an individual case, an uncertainty that the Supreme Court used to motivate its ruling. So, when a court is willing to assume proportional liability, it should be well motivated. Even more, when a court is uncertain whether the defendant is indeed responsible for one of the component causes in this particular case, it is even more difficult to understand how it can be justified to link the proportional liability to the aetiological fraction, its derivatives and approximations.

Based on these points, it is already highly questionable whether proportional liability should be directly linked to epidemiological population measures such as the unobservable aetiological fraction or the attributable fraction as its derivative. But the most important objection of this direct coupling is the fact that the sum of these numbers are not restricted to, and is even very likely to supersede, 100%. We do see the merit of proportional liability, especially given the multi-causal nature of most diseases, and we would therefore like to propose a different approach that links these two concepts without the aforementioned problems. For this, we will use the component cause concept in combination with the *condicio-sine-qua-non*-principle in a two-stages approach.

## IX. Proportional Liability in Two Stages

The approach we would like to propose is a two-stages-approach, linking the concepts of proportional liability and multi-causality. This approach makes use of the *condicio-sine-qua-non*-test and thus provides equal weights to all possible causes. This is in line with the notion of both the sufficient cause model and the counterfactual model.

During the first stage of this approach, the court has to decide whether the defendant's wrongful behaviour indeed played a role in the causal mechanism. The court should motivate its decision on evidence and expert witnesses. Once decided whether the defendant indeed played a role in the causal mechanism (i.e. is responsible for one or more component causes of the sufficient cause), the defendant can advocate proportional liability in the second stage. The defendant does so by providing a list of possible other component causes to the court, of which it has to determine whether these also played a role in this particular case. This way, the court can determine the fraction of component causes part of the presumed sufficient cause, that are the responsibility of the defendant. This fraction could be used to determine proportional liability (cf. equation 2). For example, when there are six possible causes, of which four might play a role in the case at hand and one of these four can be attributed to the defendant, the defendant would have to compensate 25% of the claim.

This two-stages-approach is not flawless, for it could overestimate the number of component causes that play a role in the sufficient cause and thereby underestimate the liability of the defendant. Also, new component causes could be identified after the court has decided. If this would lead to a new liability claim with a new defendant, our example could be summarised as follows. With the discovery of a new cause that is relevant to our case, there are now seven component causes of which five are applicable to the case at hand. If one of those component causes can be attributed to the second defendant, then he would have to pay 20% of the original claim. This way, the total sum of all claims, 40% in our example, will never supersede 100% of the original claim, but approaches this number asymptotically. Receiving this 20% of the second defendant should be conditional on the reimbursement of the excess 5% that was paid by the first defendant.

Another problematic aspect of this two-stage-method is that all possible component causes are considered equally important and are given the same weight in this approach. Although this is in line with the component cause model, it does result in some practical problems. For example, there can be numerous component causes which might be listed that indeed are component causes in the most strict definition, but lack relevance when it comes to proportional liability (e.g. one has to have lungs in order to develop lung cancer). Also, evidence might suggest that some component causes cannot be discarded, but are certainly less relevant to the case in question then others. In that case, a weighted approach could be

*Box 1 - Take home messages*

- Causal claims should always be considered in the light of multi-causality: there is never *the* cause, but a set of component causes that make up a sufficient cause.
- Causality in epidemiology relies on more than just one study: different studies, the effect of possible biases and additional evidence, even outside the realm of epidemiology, should all be taken into account before cautious claims can be made.
- The aetiological fraction and the probability of causation as its derivative are both epidemiological measures which cannot be calculated. They can only be approached, under certain assumptions, by calculating the attributable fraction.
- Linking the concept of proportional liability to the attributable fraction is wrong, especially because the sum of all attributable fractions is likely to exceed 100%.

considered. All in all, it is up to the court, with the aid of experts and scientists, to rule which possible component causes are relevant to the question of liability.

## X. Conclusion

Causality research in epidemiology is largely embedded in the concept of the counterfactual model, which resembles the legal *condicio-sine-qua-non*-test. By definition, the counterfactual cannot be observed and the sufficient cause in a single person cannot be known. Therefore, it is not possible to know the exact causal mechanism leading to the disease in an individual person. However, epidemiological studies can be used to study the effect of a presumed cause on the risk of disease at the population level. Results from multiple and reliable studies, considering multi-causality, combined with prior biological knowledge can result in cautious causal claims. Although the aetiologic fraction can never be known, the attributable fraction can be calculated and gives insight in the relation between cause and effect on a group level.

This population measure cannot directly be applied to individual cases without relying on untestable assumptions (see Box 1).

Linking the concept of proportional liability to the attributable fraction is thus wrong. In addition, the sum of the attributable aetiological fractions is likely to exceed 100%, which could lead to unfair reimbursements. We have therefore proposed a two-stage-approach for a court to apply the concept of proportional liability, by first deciding on liability and then on the proportion. This links proportional liability to the concept of multi-causality, while also and firstly adhering to the *condicio-sine-qua-non*-test. In this process, the court should consult scientist and experts, but ultimately, the decision remains a normative judgment for the court itself to make.

# Reports

This part of the EJRR hosts reports in which our correspondents keep readers up to date on the most recent developments in different areas of risk regulation. Our aim is to fuel the debate and trigger future research on cutting-edge risk subjects. The Reports are organised under different policy sections. Further sections will be added at regular intervals. If you are interested in contributing to any of the existing sections, please contact the Reports Editor at enrico.bonadio.1@city.ac.uk

## Biotechnology

*This section aims to update readers on decisions related to marketing products of modern biotechnology (e.g., GMOs, animal clones) at EU level and on national measures concerning their production. Special attention is devoted to problems of competence between Member States and the EU in regulating biotechnology issues; the institutional dynamics of decision making regarding products derived from modern biotechnology; the relationship between the EFSA and the EU institutions on green biotech-related issues; the evolution of EU regulatory framework and of national attitudes towards the risks and benefits of biotechnology derived products and their production. This section will also delve into the interaction between the EU legislation and WTO law regarding advances in the application of biotechnology within the agri-food value chain.*

## The European Commission's GMO Opt-out for Member States: A WTO Perspective

*Blanca Salas Ferer**

### I. Introduction

In April 2015, the European Commission (hereinafter, Commission) adopted a package on the authorisation of genetically modified organisms (hereinafter, GMOs) as food and feed in the EU. The package, which derives from the Political Guidelines presented to the European Parliament in July 2014 on the basis of which the current Commission was elected,[1] consists of a Communication (titled *Reviewing the decision-making process on genetically modified organisms*)[2] and a legislative draft (i.e., *Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1829/2003 as regards the possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory*, and hereinafter, the Proposal).[3]

GMOs are organisms whose genetic characteristics have undergone artificial modification. The EU has a legal framework in place that concerns the authorisation, traceability and labelling of GMOs, which is (in relevant part) found in *Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed*[4] and *Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC*.[5] The Proposal seeks to amend the former instrument, which covers food, food ingredients and feed containing or consisting of GMOs (i.e., GM food and feed). Conversely, the lat-

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1 *A New Start for Europe: My Agenda for Jobs, Growth, Fairness and Democratic Change*; July 2014.

2 COM (2015) 176 final.

3 COM (2015) 177 final.

4 OJ 2003 L 268/1.

5 OJ 2001 L 106/1.

ter instrument concerns GMOs for uses other than food and feed (notably, cultivation).

## II. Background

In essence, the Proposal seeks to allow EU Member States to decide whether a GM food or feed that has been authorised at the EU level is to be authorised on their national markets. It intends to bring to an end the trend where, over the years, a large number of safeguard and emergency measures has been adopted by EU Member States against GM food and feed previously authorised by the EU.

Under the current framework, an application for GM food and feed must be first submitted to the competent authority in an EU Member State, which forwards it to the European Food Safety Authority (hereinafter, EFSA) for a scientific risk assessment. Within three months of EFSA's opinion, the Commission prepares a draft implementing act granting or refusing the authorisation of the given GM for food or feed. Although the Commission is not bound by EFSA's opinion, it must justify its position if it diverges from it. The Commission's draft implementing act is then voted on by EU Member States, as gathered at the committee (and, possibly, appeal committee) level, under a qualified majority rule. If EU Member States fail to adopt the decision (i.e., if the result of the vote is "no opinion"), the applicable rules compel the Commission to adopt it within a given timeframe.[6] Since the entry into force of this framework, mostly due to societal concerns in certain parts of the EU, EU Member States have been systematically unable to reach the necessary majority to adopt any such draft act. Therefore, approval by the Commission, despite the result of the vote, has become the general rule in GM food and feed authorisations.

In this context, the Proposal seeks to address the discrepancies between EU Member States' will and the Commission's obligation to ultimately grant the authorisations. In fact, the approach embodied in the Proposal mirrors the recently adopted scheme for GMO cultivation, which it extends to GM food and feed. In that case, *Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC*[7] allows individual EU Member States to restrict or prohibit the cultivation of GMOs in their territory.

## III. Comment

The Proposal (which does not apply to food and feed with a GM content below the required threshold for labelling, nor to GMOs for cultivation) foresees that EU Member States be able to restrict or prohibit the use, in all or part of their territory, of GM food and feed authorised at the EU level. EU Member States may adopt "opt-out" measures on the basis of criteria other than the GMOs' effects on health and/or the environment, which have already been addressed by EFSA's risk assessment. In addition, such measures must be reasoned, based on compelling grounds in accordance with EU law,[8] proportional and non-discriminatory. The Proposal foresees that any EU Member State "opting-out" from the EU authorisation will need to provide a justification and consider comments submitted by other EU Member States and the Commission. In addition, the Proposal provides for the exhaustion of stocks if the affected GM food or feed was already on the market.

"Opt-out" measures must comply with Article 34 of the Treaty on the Functioning of the European Union (i.e., TFEU), which prohibits quantitative restrictions and measures having an equivalent effect. Such measures need to be justifiable under Article 36 of the TFEU, which provides for an exception to the prohibition of quantitative restrictions on specific grounds if said restrictions do not constitute a means of arbitrary discrimination or a disguised restriction on trade. This provision foresees that measures be justified on grounds of, inter alia, public morality, public policy and public security.

Additionally, the scheme embodied by the Proposal, as well as any potential restriction that EU Member States may adopt pursuant to it, will need to comply with the relevant international obligations, including those stemming from the World Trade Organization (WTO). In this regard, the language of the exception captured in Article 36 of the TFEU largely recalls the wording of Article XX of the General Agreement on Tariffs and Trade (GATT). Under the

6 Regulation (EC) No 1829/20023, read in light of Article 41 of the Charter of Fundamental Rights and relevant case-law of the Court of Justice of the EU, notably case C-390/99, *Canal Satélite Digital SL* [2002] ECRI—607, para. 41.

7 OJ 2015 L 68/1.

8 The relevant case-law of the Court of Justice of the EU on overriding reasons of public interest is also factored-in.

"General Exceptions" clause, WTO Members may adopt measures that would otherwise be GATT-inconsistent (including inconsistent with Article XI of the GATT, which outlaws import prohibitions or restrictions), provided that they are justified on specific grounds and that they do not constitute a means of arbitrary or unjustifiable discrimination or a disguised restriction on international trade. Inter alia, Article XX of the GATT covers measures "necessary to protect public morals" and "relating to the conservation of exhaustible natural resources".

Considering the reasons under which the Proposal foresees that national "opt-out" measures be based (i.e., on grounds "which shall, in no case, conflict with the risk assessment"), it cannot be ruled-out that the EU may invoke Article XX of the GATT to justify the relevant measures. In fact, documents produced by the Commission, the European Parliament and the Council in the context of the legislative procedure of the scheme allowing EU Member States to "opt-out" from GMO cultivation, suggested that Article XX of the GATT (in particular, subparagraph (a) thereof, concerning the protection of public morals) could provide grounds to defend the WTO-compatibility of national restrictions.[9]

The EU's GMO regime was already assessed against the backdrop of WTO law more than a decade ago, when the panel found the relevant framework to be inconsistent with WTO law. In 2003, the EC – Biotech dispute[10] was triggered when the United States, Canada and Argentina challenged the system for the approval of GM products in the EU and the safeguard measures imposed by several EU Member States affecting the importation and marketing of certain products. In relevant part, the panel found that the EU (at that time, European Communities) was in violation of the WTO Agreement on Sanitary and Phytosanitary Measures (SPS Agreement), insofar as it applied a de facto moratorium leading to undue delays on the approval of biotech products. The panel also found that certain Member States' safeguard measures were not based on a risk assessment within the meaning of Article 5.1 of the SPS Agreement, breaching also Article 2.2 of the same agreement.[11]

Despite the significant differences between the framework in force at that time and the framework that has been recently proposed, the findings of the panel in EC – Biotech provide useful guidance when anticipating issues that could be raised in the context of a potential WTO challenge against the EU's proposed rules (when – and if adopted). An important issue concerns the applicability of the SPS Agreement to the several measures at stake. In EC – Biotech, the panel found that the EU's decision to apply a de facto moratorium did not constitute a SPS measure in itself, inasmuch as it was "a decision concerning the application, or operation, of procedures" and "as such, it did not provide for 'requirements [or] procedures' within the meaning of Annex A(1) [of the SPS Agreement]".[12] Accordingly, the panel dismissed the claims against the EU's decision to apply a moratorium. Nonetheless, the panel established that, as a result of the moratorium's application, the EU contravened Annex C (and, thereby, Article 8)[13] of the SPS Agreement. In particular, the panel ruled that the moratorium led to "undue delays" in the completion of the approval procedures for specific GMOs, which it had found constituted SPS measures.[14]

Arguably, a potential panel examining the WTO-consistency of the EU's proposed framework could apply a similar reasoning and find that the EU-wide measure, despite not being a SPS measure, could still, as a result of its application, violate the SPS Agreement. If in line with the Proposal, the possible national restrictions will not be based on risks for health or the environment and, accordingly, appear likely to fall outside the scope of the SPS Agreement. In EC – Biotech, the panel found that safeguard measures imposed by EU Member States were covered by the SPS Agreement but, unlike under the proposed framework, in that case such measures were typically based on grounds related to human health or the environment. Should the SPS Agreement not be applicable, the relevant measures could be assessed un-

9 See, in particular, documents 15696/10 (Opinion of the Council of the European Union's Legal Service of 5 November 2010), SJ-0630/10 (Legal Opinion of the European Parliament's Legal Service of 17 November 2010), SEC(2010) 1454 final (Commission staff working document of 19 November 2010) and SEC(2011) 551 final (Commission staff working document of 29 April of 2011).

10 DS291, DS292 and DS293; European Communities – Measures Affecting the Approval and Marketing of Biotech Products (EC – Biotech).

11 Panel Reports, EC – Biotech, WT/DS291/R, Add.1 to Add.9 and Corr.1 / WT/DS292/R, Add.1 to Add.9 and Corr.1 / WT/DS293/R, Add.1 to Add.9 and Corr.1, adopted 21 November 2006, DSR 2006:III, p. 847.

12 Panel Report, EC – Biotech, para. 7.1383.

13 Concerning control, inspection and approval procedures.

14 Panel Report, EC – Biotech, para. 7.1569.

der the WTO Agreement on Technical Barriers to Trade (TBT Agreement), which mandates, in relevant part, that technical regulations not be more trade-restrictive than necessary to fulfil a legitimate objective.

Apart from observing its international obligations, the EU will also need to ensure that any measure it adopts does not run counter to its own domestic principles. The Proposal claims to pursue a high level of protection throughout the EU, while protecting individual EU Member States' views. However, it is undeniable that further and, possibly, unwanted effects may be created if restrictions are put in place in national jurisdictions (aggravated by the fact that they may vary from one EU Member State to another). In particular, the proposed measures could result in a fragmentation of the EU's internal market and create related obstacles to trade, such as costs and logistical problems arising from the need to segregate imports. This may ultimately produce effects such as discouraging companies from submitting applications for GM food and feed in the EU, and thereby negatively affect an important market that is highly dependent on international trade. It is noted that, concerning feed, the EU needs more than 36 million tonnes of equivalent soybean annually to feed its livestock, but it only produces 1.4 million tonnes domestically.[15]

## IV. Conclusion

Soon after the adoption of the package on GMO food and feed, the United States Trade Representative indicated that the Proposal "seems at odds with the EU's goal of deepening the internal market" and that it "appears hard to reconcile with the EU's international obligations".[16] Other important trading partners also expressed their concerns in relation to the proposed scheme in the context of the WTO, including within the Dispute Settlement Body, where at least the United States raised this issue.[17] In addition, within the TBT Committee, Argentina and Paraguay, in addition to the United States, Canada, Brazil and Chile, also raised their concerns about the scheme,[18] which they deemed to be, in relevant part, arbitrary, unnecessary and not proportional, as well as a pathway to legal uncertainty both in the EU's internal market and on the international trade arena. A number of WTO Members also indicated that the measure should be examined in light of the SPS Agreement.

These concerns appear to be shared in certain EU instances. From the beginning, the tabling of the Commission's Proposal received a cool welcome from the majority of EU Member States, which appeared to be concerned that the proposed scheme would formally shift the responsibility of authorising GM products to the national instances, while not granting them the necessary tools to implement it in line with EU rules.[19] In addition, in a legal opinion circulated to EU Member States in December 2015, the Legal Service of the Council noted that it had "serious doubts" as to the compatibility of the Commission's Proposal with the EU internal market and WTO law.

Although the Proposal has undergone several stages of the legislative procedure (including a rejection by the Parliament at first reading), EU Member States appear to have little appetite to further discuss and potentially agreeing on it, which arguably gives margin to interested parties to seek expert advice on the potential implications of the proposed framework and maintain regular communications with the relevant authorities. It remains to be seen how, in light of the dissenting voices within the EU and the views of the EU's trading partners, the procedure will progress. It will also be interesting to see whether those views will ultimately result in litigation, possibly before the WTO.

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15 "Questions and Answers on EU's policies on GMOs", European Commission Fact Sheet, 22 April 2015.

16 "USTR Concerned by EU GMO Proposal", United States Trade Representative Press Release, 22 April 2015.

17 "Statements by the United States at the Meeting of the WTO Dispute Settlement Body", 19 June 2015. Available on the Internet at https://geneva.usmission.gov/wp-content/uploads/2015/06/Jun19.DSB_.Stmt_.as-delivered.Public.pdf (last accessed on 20 February 2016).

18 "Toy safety and genetically modified organisms top WTO standards committee agenda", WTO press release, 15-18 June 2015.

19 Peter Teffer, "EU states prefer to 'blame Brussels' on GMOs", EU Observer, 9 June 2015.

# Food

*This section aims at updating readers on the latest developments of risk-related aspects of food law at the EU level, giving information on legislation and case law on various matters, such as food safety, new diseases, animal health and welfare and food labelling.*

## Food intended for Sportspeople: The EU's Regulatory Framework after 20 July 2016

*Ignacio Carreño and Tobias Dolle**

### I. Introduction

On 20 July 2016, a new legal framework comes into effect for the so-called "food for specific groups", established by Regulation (EU) No. 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control[1] (hereinafter, FSG Regulation). The FSG Regulation repeals Directive 2009/39/EC on foodstuffs intended for particular nutritional uses[2] (hereinafter, the PARNUTS Directive). Food intended for sportspeople placed on the market will be affected by the repeal of the PARNUTS Directive as such food has not been included in the FSG Regulation's scope and will have to comply with general EU food law from 20 July 2016. This has a major impact on compositional requirements, product names and claims made on such food. Inter alia, the possibility to make so-called "suitability statements" on food intended for sportspeople, which currently does give manufacturers some margin to make statements that some consider as something similar to claims, is likely to be controversial without the PARNUTS Directive.

### II. Background

The PARNUTS Directive[3] and its predecessor[4] indicate that specific rules will be established by EU legislation to cover foods intended to meet the expenditure of intense muscular effort, especially for sportspeople, which never occurred. The majority of the substantive provisions laid down in the PARNUTS Directive date back to 1977.[5] The proposal of the European Commission (hereinafter, Commission), which led to the FSG Directive,[6] suggested to leave foods intended for sportspeople out of the scope of the proposed FSG Regulation and to have them covered exclusively by general food legislation (and in particular the Regulation (EC) No. 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on foods,[7] hereinafter, NHCR) and Regulation (EC) No. 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods (the Fortified Foods Regulation). The European Parliament agreed with the Commission that these products should fall outside the scope of the FSG Regulation, but called on

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1 Regulation (EU) No. 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No. 41/2009 and (EC) No. 953/2009, OJ 2013 L 181/35.

2 Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses, OJ 2009, L 124/21.

3 In Annex I A No. 5.

4 Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses, OJ 1989 L 186/27.

5 Council Directive 77/94/EEC of 21 December 1976 on the approximation of the laws of the Member States relating to foodstuffs for particular nutritional uses, OJ 1977 L 26/55.

6 Commission Proposal of 16 January 2008 for a Directive of the European Parliament and of the Council on foodstuffs intended for particular nutritional uses (Recast), COM (2008) 3.

7 OJ 2006 L 404/9.

the Commission to assess the need to review general food law in this regard. The Council agreed in its position to leave these products out of the scope of the proposed FSG Regulation, but introduced amendments requiring the Commission to draft a report on the necessity, if any, of specific rules for these products with the possibility to accompany this report with a legislative proposal. The Council's request for a report was seen as a compromise. Therefore, the FSG Regulation provides that, for food intended to meet the expenditure of intense muscular effort, especially for sportspeople, no successful conclusion could be reached as regards the development of specific provisions due to widely diverging views among the EU Member States and stakeholders concerning the scope of specific legislation, the number of subcategories of food to be included, the criteria for establishing compositional requirements and the potential impact on innovation in product development[8].

## III. Comment

The FSG Regulation does not define "food intended for sportspeople". Similarly, the PARNUTS Directive did not define "food intended to meet the expenditure of intense muscular effort". The concept of such food (hereinafter, referred to as "food intended for sportspeople"), interpreted in the broadest manner, covers food specifically produced for and marketed to people doing any kind of sport-related activity (from professional sportsmen to amateur sportsmen and people undertaking occasional exercise)[9]. The concept also covers certain foods that, even if not specifically produced and marketed as such, would satisfy the specific nutritional or physiological requirements of people in the context of sport-related activity and are, therefore, consumed by them.[10] Some sectors of the respective industry define such food more narrowly as products specifically designed, formulated and marketed in relation to physical activity, physical performance and/or post-exercise recovery[11]. However, other sectors of the respective industry do not see the need for such a definition and rather consider such products as normal food.[12]

The category of food intended for sportspeople may include food, drinks and food supplements. The FSG Regulation repeals, in particular, the PARNUTS Directive (also known as "Dietetic foods Directive"), including the specific directives for certain dietetic foods adopted under its framework (although no specific directive has been established for food intended for sportspeople) and replaces it with a new framework covering only food for certain vulnerable groups of consumers, for which specific composition and information rules are deemed justified (i.e., food intended for infants and young children, food for special medical purposes and total diet replacement for weight control). After the entry into effect of the FSG Regulation and the repeal of the PARNUTS Directive on 20 July 2016, food intended for sportspeople may thus no longer be classified as dietetic food, but as food for normal consumption governed by relevant horizontal rules of EU food law. Already today, food intended for sportspeople needs to comply with Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law[13] (the so-called General Food Law, or GFL).

Different views exist as to whether additional rules (to the GFL and horizontal rules) are needed to ensure adequate protection of consumers of food intended for sportspeople. In this regard, Article 13 of the FSG Regulation required the Commission to present a report to the European Parliament and to the Council, by 20 July 2015, after consulting the European Food Safety Authority (hereinafter, EFSA), on the necessity, if any, of provisions for food intended for sportspeople. The publication of this report appears to be imminent.[14] Extensive discussions with

8 Recital 32 of the FSG Regulation.

9 European Commission, Study "SANCO/2014/E4/027 on foods intended for sportspeople", Ref. Ares(2014)3016865 - 15/09/2014. Available on the Internet at: http://ec.europa.eu/food/safety/docs/labelling_nutrition-special_groups_food-sportspeople-tor_2014_027_en.pdf (last visited on 3 February 2016).

10 Idem.

11 Specialised Nutrition Europe (SNE), Questions & Answers - Foods intended to sportspeople, 9 June 2015. Available on the Internet at: http://www.specialisednutritioneurope.eu/uploads/content/2015315finalsneqaonsportsfoodsjune2015.pdf (last visited on 3 February 2016).

12 Such as the European Specialist Sports Nutrition Alliance (ESSNA) and the Union of European Soft Drinks Associations (UNESDA).

13 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ 2002 L 31/1.

14 Not published before 23 February 2015.

stakeholders took place at the end of 2015 and EFSA provided scientific assistance regarding food intended for sportspeople on 29 September 2015.[15] EFSA compiled existing scientific advice in the area of nutrition and health claims and dietary reference values for adults, that are relevant to sportspeople, and informed the Commission that the recommendations of the report of the Scientific Committee on Food (SCF) adopted in 2001 on the composition and specification of food intended for sportspeople[16], and the subsequent scientific advice provided by EFSA, is still fully valid.

One question to address is why the repeal of the PARNUTS Directive has such an impact on the marketing and the composition of food intended for sportspeople. Although no specific rules have been established regarding food intended for sportspeople under the PARNUTS Directive, its general rules for dietetic food to ensure product safety, suitability and appropriate consumer information apply. In its Article 1(2), it defines foodstuffs for particular nutritional uses as "foodstuffs which, owing to their special composition or manufacturing process, are clearly distinguishable from foodstuffs for normal consumption, which are suitable for their claimed nutritional purposes and which are marketed in such a way as to indicate such suitability". Article 1(3)(b) of the PARNUTS Directive states that "a particular nutritional use shall fulfil the particular nutritional requirements of certain categories of persons who are in a special physiological condition and who are therefore able to obtain special benefit from controlled consumption of certain substances in foodstuffs".

The imminent repeal of the PARNUTS Directive does not allow for sufficient time to adopt new legislative measures on food intended for sportspeople. Current mandatory requirements for such ("dietetic") food will be repealed. It currently appears that no specific legislation will be introduced and that certain products may be at risk of incompliance with, inter alia, the requirements of the following horizontal food law legislation: (i) the NHCR; (ii) the Fortified Foods Regulation; (iii) Regulation (EU) No. 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers (hereinafter, the FIR); and (iv) Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements[17] (the Food Supplements Directive). On 20 July 2016, the PARNUTS Directive will be repealed and the concept of "dietetic food" will disappear, and food intended for sportspeople will have to comply with the existing relevant rules of EU food law.

Currently, information on the particular nutritional characteristics of food intended for sportspeople and its beneficial health effects can arguably be provided either under Article 9 of the PARNUTS Directive, as a mandatory requirement if the food intended for sportspeople is classified as food intended for particular nutritional use, or as an authorised claim under the NHCR, if such food is classified as food for normal consumption and governed by horizontal rules of food law. On the basis of requests submitted by food business operators, related claims for such food have been considered for authorisation in accordance with the NHCR.[18] The PARNUTS Directive requires, in addition to the indication of the particular nutritional characteristics, that foods covered by its scope be intended for the particular nutritional uses and be clearly distinguishable from foodstuffs for normal consumption. In the absence of specific provisions after 20 July 2016, denomination and instructions for use on sports food will be governed only by the NHCR and the FIR. Article 17 of the FIR lays down provisions on the name of the food and Article 9(1)(j) on the instructions of use, which shall be indicated in such a way as to enable appropriate use to be made of the food. The possibility to make so-called "suitability statements" on food intended for sportspeople, which currently arguably does give manufacturers some margin to make statements that some consider as something like claims, is likely to disappear without the PARNUTS Directive. In this context, EU

15 EFSA Scientific and technical assistance on food intended for sportspeople, 29 September 2015. Available on the Internet at: http://www.efsa.europa.eu/en/supporting/pub/871e (last visited on 3 February 2016).

16 Scientific Committee on Food. Report of the Scientific Committee on Food on composition and specification of food intended to meet the expenditure of intense muscular effort, especially for sportsmen SCF/CS/NUT/SPORT/5 Final (corrected) of 28 February 2001.

17 OJ 2002 L 183/ 51.

18 So far, seven health claims targeting sportspeople have been authorised and some additional may be considered relevant for them. There are substances for which claims were not authorised, sometimes despite a positive assessment of EFSA regarding the beneficial effect for sportspeople of the product concerned, because the claim was considered as non-beneficial for the general population from the health policy point of view (e.g., "high in sodium"). Commission Staff Working Document of 10 December 2015 on food intended for sportspeople.

Member States have reported that the legislation on dietetic foods is being used by some operators to circumvent the rules of subsequent legislation, distorting the notion of a food for particular nutritional uses, and resulting, in certain cases, in confusion over its application that creates unfair competition between businesses. In other words, it appears that some operators notify under the dietetic food legislation a "normal" food in order to be able to use a "dietetic" suitability statement (mandatory according to the dietetic food legislation) instead of the equivalent voluntary claim and therefore avoid the requirements of the NHCR.[19] However, such statements do seem to be important for manufacturers and sportspeople as consumers alike. According to the Commission, with respect to the marketing techniques for foods intended for sportspeople, information on the label was identified by operators as one of the most significant marketing techniques. Information on the label can relate to the: (i) sale denomination: clear description of the function of the products (e.g., energy bars); (ii) brand and packaging (e.g., the use of photos of sportspeople); (iii) clear instructions for use (e.g., during or after physical activity); (iv) composition and ingredients; (v) use of information such as "high energy" and "source of glucose" used as mandatory indications, as required by the PARNUTS Directive; and (vi) use of health claims authorised under the NHCR.[20]

With respect to the use of claims, information falling under the definition of nutrition and health claims provided for food intended for sportspeople on a voluntary basis will have to comply with the NHCR. Consequently, only nutrition and health claims authorised pursuant to the strict framework of the NHCR will be allowed for use on foods intended for sportspeople after 20 July 2016. In this context, the Commission has informally underlined that in the case of health claims, when operators submit an application, from the scientific point of view, it is important that the evidence on which the claim is based is provided for the target group. This is the only way to assure that an authorised health claim can refer to the target group of sportspeople[21].

Regarding the compositional aspects relevant to food intended for sportspeople, in the absence of specific provisions after 20 July 2016, such foods would most probably be considered, as the case may be, under the Food Supplements Directive or under the Fortified Foods Regulation. Consequently, food intended for sportspeople would need to comply with the relevant compositional requirements set out in this legislation. In this context, consideration should be given to Article 6(6) of the Fortified Foods Regulation, which requires that vitamins and minerals, if added to the food, should be present at least in a significant amount as defined in the FIR. However, in food intended for sportspeople, vitamins and minerals are sometimes added at lower level than that significant amount, to ensure that the composition of the product best addresses the requirements of the body when carrying out sports activity. Although it has never been used up to now, the Fortified Foods Regulation provides in the second sentence of Article 6(6) for the possibility of granting a derogation to the requirement of the "significant amount" in justified cases for certain categories of food.[22] It must also be noted that Article 20(3) of the FSG Regulation establishes that products on the market, or labelled before 20 July 2016, can be sold until stocks are exhausted.

While it appears that the majority of EU Member States believe that the existing horizontal rules are suitable to regulate food intended for sportspeople, other EU Member States have recognised the need for specific rules to address this issue.[23] In fact, there are currently national rules or guidelines in place in some countries, including France. In the absence of any specific rules at the EU level, EU Member States may have their own rules on foods intended for sportspeople. In Case C-107/97 Rombi and Arkopharma,[24] the Court of Justice of the EU (hereinafter, CJEU) dismissed that certain rules in force in France on food intended for sportspeople were contrary to EU legislation. The CJEU concluded this on the fact that no specific EU legislation had been established with respect to such food for particular nutritional uses.[25]

19 Commission Staff Working Paper - Impact Assessment accompanying the document "Proposal for a Regulation of the European Parliament and of the Council on food intended for infants and young children and on food for special medical purposes.

20 Commission Staff Working Document of 10 December 2015 on food intended for sportspeople.

21 Summery Record, European Commission Working Group of the Advisory Group on the Food Chain and Animal and Plant Health on 21 December 2015.

22 Idem.

23 Supra at note 20.

24 Judgment of 18 May 2000, Case C-107/97 Rombi and Arkopharma, ECR 2000 I-03367.

25 Idem, para 59-60.

Food business operators appear to be divided on the question of whether specific legislation is necessary for food intended for sportspeople or whether such food should be governed by existing horizontal EU food law. Some are in favour of specific legislation and believe that, under horizontal rules of food law, the quality of the products and the communication on food intended for sportspeople cannot be guaranteed, in particular in relation to product claims. Other industry groups appear to consider that the applicable horizontal rules are sufficient to govern the different aspects (e.g., food safety, composition, and information). However, all industry groups acknowledge that some specific aspects, in particular the use of claims for food intended for sportspeople,[26] are not adequately addressed under the horizontal rules on food law, and they should therefore be adapted. Amending EU food labelling legislation may be desirable to better inform sportspeople about the particular nutritional characteristics and instructions of use regarding foods that are not covered under the FIR. The NHCR addresses nutrition and health effects in the general populations and may need to account for the specific needs of sportspeople, narrowing down the target population. Some of the communications currently made on food for sportspeople may be difficult to make under the FIR and the NHCR, which essentially do not allow for the information that consumers may need or expect on food for sportspeople.

According to the Commission, the EU-wide market for sports nutrition and drinks was worth EUR 3.07 billion (retail value) in 2014 and approximately 30,000 sports food products were identified. The highest number of sport food products can be found in the category of protein-based sports food. However, from the market value point of view, sports drinks can be considered as the most important category, followed by (protein-based) muscle strengthening, bodybuilding and post-exercise recovery products.[27] Reportedly, consumer demand is growing and the market for sports nutrition products, which previously supplied mainly athletes and body builders, increasingly attracts a young non-athlete consumer group.[28] To meet the requirement of an expanded consumer base, manufacturers need to invest in new product development. Arguably, foods intended for sportspeople are, therefore, not specialist products or the preserve of a small group, but ones widely used by the public.

Another aspect is that food intended for sportspeople is not always perceived well by the general public. Many people associate it with non-compliant and unsafe products for bodybuilders and other athletes, which are distributed via the Internet and are imported from outside the EU. Contaminated or inadvertent supplement use appears to be the most common defence offered by athletes with positive doping controls, although this defence rarely succeeds, especially with manufacturers having quality assurance procedures in place. But the reputation of the industry is often harmed and it seems as though it is often becoming a common scapegoat with respect to doping and in relation to safety incidents that are suffered by athletes. Over the last years, some EU Member States have, in fact, issued warning messages in relation to prohibited substances in foods for sportspeople.[29] The Commission's Working Document does not address safety or doping aspects related to foods intended for sportspeople. The use of doping substances falling under the definition of food could only be considered, in the context of the food safety legislation, under the angle of their safety as food. Indeed, the GFL lays down the requirement that food placed on the market needs to be safe (i.e. not injurious to health and fit for human consumption). But the use of a substance considered safe according to the food safety legislation, but prohibited by the rules applicable to sport competition, is not relevant to the food safety legislation.[30] This is one reason why adequate information on the products, be it the product's name, instructions for use and claims, is so important.

## IV. Conclusion

The existing market for food intended for sportspeople is already highly fragmented as EU Member

26 In particular for not yet authorised (and controversial) nutrition claims which set out product properties, such as high energy, high carbohydrates.

27 Supra at note 20.

28 Annie-Rose Harrison-Dunn, Sports food expected to outpace sports drinks in 2015 – 2020, Nutraingredients.com, 14 December 2015. Available on the Internet at: http://www.nutraingredients.com/Markets-and-Trends/Sports-food-expected-to-outpace-sports-drinks-in-2015-2020 (last visited on 3 February 2016).

29 See https://webgate.ec.europa.eu/rasff-window/portal/.

30 Supra at note 21.

States have adopted distinctive approaches, which obstruct trade in the EU's internal market,[31] as well as innovation. Currently, diverging national rules often make it difficult to commercialise a single sport food product across the entire EU. Depending on its composition, food intended for sportspeople may even fall under legislation for medicines (e.g., for products presented as having properties for treating or preventing disease in human beings or products containing substances having the effect of restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action). There is, in fact, no functioning single market of food intended for sportspeople across the EU. This causes problems to manufacturers when they formulate and/or advertise their products.

After the repeal of the PARNUTS Directive and in the absence of specific legislation at the national level, if some elements are not fully harmonised at the EU level, EU Member States retain some manoeuvrability to regulate food intended for sportspeople in the future, subject to the general rules of the Treaty on the Functioning of the EU (hereinafter, TFEU). In particular, the introduction of national rules needs to be justified on the basis of Article 36 of the TFEU and EU Member States have to notify the Commission, which assesses the rules in light of the TFEU and of the case law of the CJEU.

A delayed repeal of the current PARNUTS Directive (inasmuch it relates to food intended for sportspeople), so as to consider appropriate legal avenues, either adopting a separate legal framework for food for sportspeople or adjusting the existing horizontal EU food law, appears difficult to achieve. However, discussions with EU Member States need to be carried-out after the adoption of the Commission's report on food intended for sportspeople in order to ensure uniform interpretation of the legislation. There appears to be a need for the urgent implementation of guidelines in order to clarify aspects related to the future legal status of food intended for sportspeople, its composition and marketing. The possibility for operators to request the application of Article 6(6) of the Fortified Foods Regulation in relation to significant amount of vitamins and minerals appears to be an important step. The next steps taken in the EU on food intended for sportspeople (in particular the report and eventual legislative proposals put forward by the Commission) should be monitored and stakeholders should be prepared to participate in shaping potentially upcoming EU legislation or guidelines by interacting with relevant EU institutions, trade associations and affected stakeholders, seeking expert legal advice where necessary.

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31 The principle of mutual recognition stemming from Regulation (EC) No. 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State (OJ 2008 L 218/21) which defines the rights and obligations for public authorities and enterprises that wish to market their products in another EU country, does not appear to work for such products. The Regulation also defines how a country can deny mutual recognition of a product.

# Food Fraud in the EU

*Francesco Montanari, Cesare Varallo and Daniele Pisanello*

## Introduction

By making the headlines in the major European newspapers in 2013, the horsemeat scandal impaired consumer confidence in the transparency of the European food chain to a significant extent. In spite of its negative economic impact on the European Union (EU) market, the scandal in question has stimulated an unprecedented reflection in the area of food fraud by the EU institutions, national authorities, other stakeholders as well as by members of academia and the legal profession in general.

On an EU level, the European Commission swiftly responded to the scandal with the adoption of a wide-ranging action plan consisting of targeted policy, legislative and enforcement measures. The latter included, among others, the establishment of a dedicated Food Fraud Network (FFN) gathering national enforcement authorities, the adoption of stricter rules for horse identification,[1] the integration of anti-fraud provisions in the Commission's proposal reviewing the EU framework for official controls[2] and the organisation of EU-wide coordinated control plans.[3]

Although satisfied with the Commission's reaction to the horsemeat scandal, early in 2014 the European Parliament called for additional measures to counteract fraudulent practices along the food chain, namely, the establishment of a definition of food fraud, the infliction of heavier sanctions and the introduction of a legal obligation for food business operators to report fraud cases to competent authorities.[4]

Lastly, by the end of 2014 the Council of the EU adopted its own conclusions on food crime,[5] with the term 'food crime' referring to fraudulent schemes orchestrated by organised networks as opposed to misgivings attributable to individual business operators. In this context, the Council asked for an increased level of cooperation between enforcement authorities to tackle organised crime relating to food across the EU, greater involvement of EU agencies such as EUROPOL and EUROJUST and, finally, the adoption of a European convention on food crime under the auspices of the Council of Europe.

Against this background, three food lawyers express their own views with regard to some of the most critical aspects of the policy and legal scenario related to food fraud that is steadily taking shape at the EU level.

## I. Francesco Montanari*

### Regulatory vs. Non-Regulatory Approach: Does the EU need a regulatory action to fight against food fraud? What would be the major critical points in opting for a mandatory approach instead of a voluntary one when it comes to fighting food fraud?

The core body of law that currently governs the EU food chain - notably the General Food Law[6] and Reg-

1 Commission Implementing Regulation (EU) 2015/262 of 17 February 2015 laying down rules pursuant to Council Directives 90/427/EEC and 2009/156/EC as regards the methods for the identification of equidae (Equine Passport Regulation), in OJ 2015 L 59/1.

2 Proposal for a Regulation of the European Parliament and of the Council on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health, plant reproductive material, plant protection products, COM (2013) 265, 6 May 2013.

3 Commission Recommendation 2013/99/EU of 19 February 2013 on a coordinated control plan with a view to establish the prevalence of fraudulent practices in the marketing of certain foods, in OJ 2013 L 48/28 and Commission Recommendation 2014/180/EU of 27 March 2014 on a second coordinated control plan with a view to establishing the prevalence of fraudulent practices in the marketing of certain foods, in OJ 2014 L 95/64.

4 Report of the European Parliament of 14 January 2014 on the food crisis, fraud in the food chain and the control thereof, A7-0434/2013, PE519.759v03-00.

5 Council Conclusions on the role of law enforcement cooperation in combating food crime, 4.12.2014, 15623/14, ENFOPOL 369, AGRI 709, DENLEG 173.

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6 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ 2002 31/1.

ulation (EC) No 882/2004 [7] - has been developed having primarily in mind food safety rather than food fraud. Hence, few are the provisions enshrined in the EU legislation under consideration that make direct or indirect reference to such practices.

Conversely, EU legislation regulating specific areas of food law (e.g. labelling and food information to consumers) or specific sectors or product categories (e.g. fish, olive oil, and geographical indications) contain a relatively broad range of provisions designed to prevent business operators from engaging in illegal sourcing, production and/or marketing practices. Regulation No (EU) 1169/2011 on the provision of food information to consumers[8] - also known as 'FIC Regulation'- sets out several requirements that may well serve to exemplify the previous statement. For instance, Article 8 para. 4 of the Regulation requires any operator of the food chain, within the business under its control, to refrain from modifying the information accompanying a food whenever such a modification might result in the consumer being misled or in the impairment of his/her capacity to perform an informed choice. In addition to that, Annex VI lists a number of situations where the name of a food must be coupled with further information in order to avoid misleading the consumer about the true nature of his/her purchase. These include, for instance, the addition to meat and fishery products of protein of a different animal origin or of water amounting to more than 5% of the weight of the finished product.

Whether provisions such as those now recalled contribute to preventing fraudulent practices in the food chain to a significant degree - notably, by reducing their prevalence within the EU - is something difficult to ascertain in practice due, also, to the lack of structured data collection in this area. Moreover, stakeholders tend to have diverging views on the real benefits of regulatory requirements aimed at preventing fraudulent practices, with industry generally asserting that their first undesired effect is to make food prices soar.

Beyond these general considerations, it is worth noting that the codification of specific anti-fraud provisions in EU food law appears to follow, in most cases, from the detection of widespread fraudulent practices by enforcement authorities on the EU market. Following the horsemeat scandal, however, a merely reactive approach as the one just described no longer suffices to address food fraud at the EU level. Indeed, EU legislation can hardly keep pace with a phenomenon that has attained unprecedented levels of sophistication, often with no impact on food safety or on the product itself, e.g. through forgery of certificates and invoices, and which is, thus, extremely difficult to detect by means of traditional investigative techniques. Furthermore, the horsemeat scandal as well as other recent national incidents would indicate that criminal groups are increasingly behind food fraud, especially when high-value products, i.e. organic products, wine, spirits, fish, olive oil, but also plant protection products, are at stake.

Based on the above, one may conclude that legislative and regulatory measures, standing alone, cannot provide a solution to food fraud. Regulatory measures must thus necessarily operate in conjunction with non-regulatory measures, which, because of their flexible nature, can be easily adjusted to evolving circumstances or scenarios such as those that food fraud seems also to be experiencing. Better enforcement, the setting of multidisciplinary food fraud teams by public authorities, major investments in the development of laboratory capacity in the area of food authenticity, and vulnerability assessment schemes voluntarily implemented by food operators are just some of the measures that could flank and support EU regulatory action in this area.

## Intentionality vs Negligence: from the private sector point of view, how can food business operators build reliable internal procedures allowing them to face a food fraud-related criminal prosecution successfully? How to bridge best practices and legal liability?

As known, EU Member States (MS)' criminal laws are harmonised to a limited extent. As a result, food fraud may be framed differently at the national level (e.g. as a sanitary and/or commercial fraud, coun-

7 Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, OJ 2004 L 165/1.

8 Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, OJ 2011 L 304/18.

terfeiting or forgery) and, thus, subject to different criminal liability regimes and sanctions. In this context, intentionality is generally a qualifying criterion to determine whether any given conduct is tantamount to a criminal offence. However, the legal orders of some MS (e.g. Belgium, Finland, Slovenia, and Portugal) also consider gross or mere negligence as legally relevant subjective elements on which criminal prosecutions may be based.

Since today's food chain is complex and potentially entails several stages of production, processing and distribution, it is essential that any food business operator not only scrutinises the activities under his/her own direct control, but is also vigilant against his/her suppliers. It is in this context that such schemes aimed at food fraud prevention come into play. Developed in the wake of the horsemeat scandal as purely voluntary tools, vulnerability assessment schemes are meant to help food business operators in identifying the vulnerabilities that are relevant to the specific activities they perform. Some schemes (e.g. SSAFE) have been developed in conjunction with industry-led organisations based on the advice of leading food chain experts, are freely available on the internet and usable by all business operators, irrespective of the size of their business and geographical location.

Although the schemes in question cannot guarantee food business operators full immunity from investigations launched by enforcement authorities and criminal proceedings, strict adherence to them may contribute to proving that they have acted with the required professional diligence.

## What is the state of play of whistleblowing as a tool to fight fraud and food fraud in particular?

In its report on food fraud the European Parliament has recognised the added value that whistleblowers play in unveiling fraudulent practices in the food chain together with the need of guaranteeing their protection from any possible retaliation. Besides that, it has called for the introduction at the EU level of a legal obligation requiring food business operators to share information on fraudulent practices of which they may have had knowledge with competent authorities.

The views expressed by the European institution need to be considered in a broader context. Over the last years, in fact, whistleblowing has received a lot of attention both at the international and national levels, though not always in relation to the food sector.

Starting with the Council of Europe, this pan-European international organisation adopted in 2014 a recommendation addressed to its Member States on this very subject.[9] In the recommendation, the Council of Europe views whistleblowing as a mean to fight fraud and corruption by ensuring transparency and democratic accountability in the private as well as in the public sector. A whistleblower is there defined as '*any person who reports or discloses information on a threat or harm to the public interest in the context of their work-based relationship, whether it be in the public or private sector*'.

In addition, a recent report (2013) issued by the non-governmental organisation Transparency International and financed by the European Commission indicated that only a few EU MS (e.g. Luxembourg, Slovenia, and the United Kingdom) would currently provide those who blow the whistle in the workplace with a sufficiently advanced set of legal rights.[10]

Finally, the attention raised by the horsemeat scandal has then pushed some national authorities to regulate whistleblowing with regard to the food sector, in particular. This is the case, for instance, of the United Kingdom where the provisions of the Public Interest Disclosure Act 1998 have been extended to employees of the food sector, thereby encouraging them to refer situations that may involve conduct of criminal relevance or an endangerment of public health or the environment.[11] On top of that, food business operators may now share information with competent authorities on suspected frauds of which they may have become aware through their trade associations, which, acting as a filter, can ensure sensitive data are handled safely and anonymously. As for other MS, whilst some are discussing the adoption of dedicated legal frameworks in this area (e.g. Denmark), others seem more oriented towards the devel-

9 Recommendation CM/Rec(2014)7 adopted by the Committee of Ministers of the Council of Europe on 30 April 2014.

10 *Whistleblowing in Europe – Legal protections for whistleblowers in the EU*, Transparency International, 2013.

11 https://www.food.gov.uk/enforcement/the-national-food-crime-unit/foodfraud/whistleblowing

opment of ad hoc administrative practices (e.g. Portugal). The experience that some EU MS are acquiring by developing or implementing whistleblowing policies at the national level will be essential to gain a better understanding of this practice, its constraints and implications for the food sector. Only with this knowledge, it will be possible then to consider whether there is any need or benefit in EU food law regulating this area.

## How can the system of official controls on food and feed contribute to fighting food fraud? To what extent does the Commission's proposal reviewing the applicable EU acquis in this area address this issue?

Official controls that MS competent authorities perform to verify compliance of food and feed are a key tool to ensure that the EU food chain is subject to independent monitoring and regularly tested. Several food fraud cases originate from inspections and checks carried out in this context. For this reason, it is not surprising that the European Commission has seized the opportunity offered by the revision of Regulation (EC) No 882/2004 to include a set of provisions aimed at stepping up EU and MS capability to detect and counteract food fraud.

Whilst the Commission's proposal is still undergoing inter-institutional negotiations at the EU level and it is thus difficult to predict its outcome, some of its provisions are nevertheless noteworthy because, if adopted, they may impact the way food fraud enforcement is currently performed within the EU.

In the first place, the Commission's proposal foresees the inclusion of anti-fraud checks within the Multi-Annual National Control Plans that MS must draw pursuant to Article 41 Regulation (EC) No 882/2004[12]. It is not entirely clear at this stage what kind of activities the anti-fraud checks above referred should entail. Nevertheless, this requirement might contribute, in the long term, to bridging the gap between those Member States for which fighting against food fraud is clearly a political priority (e.g. Italy, France and Spain) and those where this issue enjoys a lower place in the national enforcement agenda at present. Moreover, the Commission has already started working ahead of time to ensure that awareness about fraudulent practices in the food chain is raised and existing disparities in national enforcement are minimised by sponsoring EU trainings for MS staff involved in official controls.

Secondly, the proposal turns the possibility that the European Commission has to 'recommend' to MSs the execution of EU-wide coordinated control plans into a fully-fledged binding legal obligation.[13] As targeted control plans across the EU territory have proven to be successful in the context of the investigations that followed the horsemeat scandal, the Commission is likely to resort to such plans quite regularly in the future. However, in order to maximise their potential in the detection of food fraud, they should be, insofar as it is possible, planned and carried out without fraudsters having prior warning or knowledge of them.

Thirdly, the Commission's proposal envisions an increase in the level of sanctions to apply to intentional violations of food law. In particular, sanctions should at least offset the economic or financial gain sought through the fraud, as opposed to the current situation where national sanctions must merely be proportionate, effective and dissuasive.[14] Indeed, the principle whereby sanctions are to be determined taking into account the amount of the profit earned by the fraudsters seems to be present only in a few MS (e.g. Czech Republic, France, Greece, and Portugal), though subject to varying conditions and application criteria. From this perspective, the Commission's attempt at ensuring a minimum common denominator between national sanctions regimes for food fraud is to be welcome. It remains to be seen whether the European Parliament will try to impose its own views on this point, having called for sanctions that outweigh fraudsters' gains. In this respect, it is worth noting that there would be precedents in EU law supporting the Parliament's request. For instance, for the most serious infringements of its legal framework, Regulation (EC) No 1005/2008 on illegal, unregulated and unreported fishing requires

12 Articles 8 para. 2 and 108 of the Commission's proposal above cited.

13 Article 111 of the Commission's proposal above cited as opposed to Article 53 Regulation (EC) No 882/2004.

14 Article 136 para.2 of the Commission's proposal cited above as opposed to Article 55 Regulation (EC) No 882/2004.

MS to inflict penalties that are at least five times the value of the catch illegally captured.[15]

There are, however, some areas in which the Commission's proposal might have been more ambitious, the most important, in my view, being laboratory capacity. Whilst the draft text foresees the establishment of EU Reference Laboratories for animal welfare and plant health, there is no similar provision for food authenticity. An EU Reference Laboratory in this area could have propelled the establishment of a network of National Reference and official laboratories across the EU territory, thereby laying the foundations for the development and sharing of that technical knowledge that is key to ensuring food integrity.

## II. Cesare Varallo♣

### Regulatory vs. Non-Regulatory Approach: Does the EU need a regulatory action to fight against food fraud? What would be the major critical points in opting for a mandatory approach instead of a voluntary one when it comes to fighting food fraud?

The current EU regulatory framework relating fraudulent or deceptive practices towards consumers is overall robust. Regulation (EU) No 1169/2011 on the provision of food information to consumers[16] - also known as 'FIC Regulation'- provides general and specific requirements that could greatly help detect common fraudulent practices on the market.

Namely, Article 7 on fair information practices establishes that consumers shall not be mislead, particularly referring to: *'(a) [...] the characteristics of the food and, in particular, as to* ***its nature, identity, properties, composition, quantity, durability, country of origin or place of provenance, method of manufacture or production****; (b) by attributing to the food effects or properties which it does not possess; (c) by suggesting that the food possesses special characteristics when in fact all similar foods possess such characteristics, in particular by specifically* ***emphasising the presence or absence of certain ingredients and/or nutrients****; (d) by suggesting, by means of the appearance, the description or pictorial representations, the presence of a particular food or an ingredient, while in reality a component naturally present or an ingredient normally used in that food* ***has been substituted*** *with a different component or a different ingredient.'*

While point a) is quite similar in wording to many definitions of commercial frauds present on the EU territory (e.g. art. 515 of the Italian Criminal Code) and applicable to all goods, points c) and d) are interesting examples of practices widely spread and that could be easily considered *'food frauds'* in their most serious expression (e.g. crab claws made by undeclared formed fish).

Moreover, Annex VI FIC Regulation provides more specific obligations: the foods where an ingredient normally used or naturally present has been substituted have to bear a specific declaration, the formed fish and meat have to be named as such, the added proteins of animal origin have to be declared in the name of the food, as well as the added water in case of meat products, meat preparations and fishery products, if it makes up more than 5 % of the weight of the finished product.

Another regulatory option that competent authorities often neglect – because it is not provided with autonomous sanctions – is Article 8 Regulation (EC) No 178/2002[17] – also known as General Food Law – which specifies that the Regulation shall aim at the prevention of *'(a) fraudulent or deceptive practices; (b) the adulteration of food; and (c) any other practices which may mislead the consumer'*.

Additionally, all the sectors most exposed to fraudulent practices have specific rules in place strengthening traceability or requiring more detailed information to be passed along the supply chain (e.g. olive oil, organic, fishery, meat, honey, etc.). While framing a regulatory approach to food fraud, it is essential to bear in mind that laying down further and stricter obligations has not stopped the phenomenon.

15 In particular, Article 44 Council Regulation (EC) No 1005/2008 of 29 September 2008 establishing a Community system to prevent, deter and eliminate illegal, unreported and unregulated fishing, OJ 2008 L 286/1.

♣ Food lawyer in Italy, founder of foodlawlatest.com, Vice President Business and Regulatory Affairs EU at Inscatech.

16 Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, OJ 2011 L 304/18.

17 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ 2002 31/1.

On the contrary, the additional burden placed on food business operators causes higher prices and, thus, higher incentives for organised criminal groups willing to orchestrate fraudulent schemes. It is not by chance that most of food fraud cases concerned those sectors.

In conclusion, in order to ensure a strong regulatory framework at the EU level, a more comprehensive approach to the problem has to be considered. Regulatory measures should be accompanied by administrative support, better trained and equipped multidisciplinary enforcement authorities, increased testing capacity by private and public laboratories and more cooperation with the police forces – which have more specific powers to contrast organised crime (i.e. confiscation of goods, access to all relevant records and computers, etc.).

## Intentionality vs Negligence: from the private sector point of view, how can food business operators build reliable internal procedures allowing them to face a food fraud-related criminal prosecution successfully? How to bridge best practices and legal liability?

The answer cannot be unique, since in the EU we face the coexistence of several different legal systems and the food fraud liability could be determined in accordance with the principle of strict liability as well as on gross negligence.

What is certain is that when a food business operator faces litigation, either on the criminal or civil side, he/she has to prove his/her own diligence, and records are the only way. Often companies with sound records and procedures can avoid criminal liability, if they can demonstrate that all reasonable care was taken. That, basically, could be the role of the vulnerability assessment schemes and it could be very important for the companies to have effectively implemented one of them when the next scandal will break. But a vulnerability assessment scheme is not is the solution of the problem: most of the biggest conglomerates – but also the small and medium companies – know exactly which are the commodities and/or the ingredient at higher risk just by looking at the prices, at the country of origin or at what are the particular conditions on the market. Therefore, they need to create as much visibility as possible throughout their supply chain. *'One step back, one step forward'* is not enough when you suspect fraudulent practices; therefore, intelligence gathering is fundamental.

## What is the state of play of whistleblowing as a tool to fight fraud and food fraud in particular?

First of all, it is necessary to define what whistleblowing is because the mechanism is not well known in the food sector.

A whistleblower is primarily a person who reports information on a threat or harm to the public interest in the context of his work-based relationship. Therefore, we could primarily imagine whistleblowing as involving an employee bringing to light his/her employer's wrongdoing. However, a competitor or another food business operator along the same supply chain can also be a whistleblower. All of these situations should be considered.

A whistleblowing mechanism should grant the person who reports information the immunity from any consequence on his life or career: in essence, the legal framework should offer whistleblowers to remain completely anonymous and enjoy a preferential channel to disclose confidential issues.

This instrument proved itself well in the financial sector, where both private companies - internally and on voluntary basis - and several enforcement authorities largely implemented it. There is no reason not to think that it could be the same in the food sector. Based on my professional experience most of the food fraud cases that are detected are denounced by subjects acting in the supply chain. It is crystal clear that we cannot think to shape an effective strategy without considering a whistleblowing protection system.

If at the moment a few EU MSs (e.g. Luxembourg, Slovenia, and the United Kingdom) have in place such a system, other MSs like Denmark and Ireland are actively working on it. If the matter will not be considered at the EU level, soon we will have a bunch of different schemes and that could not be beneficial for business and the smooth functioning of the supply chain. Moreover, whistleblowing could also be a terrific self-regulatory mechanism of the market because it will ensure that wrongdoings promptly emerge. It is in the same interest of the companies

that similar schemes are regulated and effectively implemented.

The main issues in this area are clearly related to confidentiality: a set of rules that determine how to filter and handle this information is absolutely necessary.

### How can the system of official controls on food and feed contribute to fighting food fraud? To what extent does the Commission's proposal reviewing the applicable EU acquis in this area address this issue?

The current revision of Regulation (EC) No 882/2004[18] is the perfect opportunity to introduce in the official control system some key elements for delivering better enforcement.

First of all, despite the fact that most of the MSs have a definition of commercial fraud in place, a common definition of food fraud could help the MSs to rethink their internal competences, identify the competent authorities involved in fighting against the phenomenon and ensure greater cooperation between health authorities and police forces. Although it is still unclear what would be the timing and outcome of the current review, it could be the right place to insert such a definition.

The Commission also included anti-fraud checks within the Multi-Annual National Control Plans drawn by the MSs pursuant to Article 41 Regulation (EC) No 882/2004 and the chance to recommend to MSs binding EU-wide coordinated control plans: the hope is to see more specifically targeted plans in the future, since they proved to be extremely efficient following the horsemeat scandal.

What has probably not been completely addressed is the testing capacity of the EU and MSs' laboratories on authenticity: adequate funding and the capacity of the public laboratories are prerequisites for any action, as well as the specific training of all the people involved in the official controls. On this side, anyway, the Commission has made a great effort, and it realized a Better Training for Safer Food (BTSF) program on innovative investigative techniques for food frauds.

Finally, what should be absolutely addressed in the final proposed Regulation are the sanctions imposed on fraudsters. The actual discussion focuses on the amount of the sanctions, which should be equal, or greater (as requested by the MEPs), to the economic profit made by the fraudsters. However, in my opinion, a more deep reflection must be made. Food frauds are as old as ancient civilization. We cannot change this fact though we can try to minimise the incentives for fraudsters. If organised criminal groups moved to the food sector because of the lack of sanctions and high profits, a comprehensive strategy is the only way to drive them away. We should not think just in terms of profit, but shape a response that also considers all the ancillary sanctions that could be imposed, and often are more dissuasive than a mere fine, especially if it is not paid because the fraudster vanished and cannot be prosecuted. Closing of premises, withdrawal of licences and authorisations, as well as *'naming and shaming'* techniques or the institution of a register of legal or natural persons convicted for fraud in the food sector could help considerably to build a more effective fighting strategy.

## III. Daniele Pisanello♠

### Regulatory vs Non Regulatory: Does the European Food Market need a Regulatory Action to fight food frauds? What major critical points would be necessary to enforce a mandatory or a voluntary approach in fighting food crimes?

Food fraud has always been there. The Municipal Statutes of ancient Italian authorities, or those of London and Paris, are full of rules designed to thwart counterfeiting of food. In the past, the fight against fraud, be it agrarian or in the grocery store, was then a problem of supply (security). Nowadays, the fight against food fraud consists of a crisis in the "perception of quality" and lack of "trust" in the agro-industrial system. Further, if until after World War II the fraud concerned essentially "maverick" cases and,

18 Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, OJ 2004 L 165/1.

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therefore, fraudsters, with dangerous levels of isolated phenomena, today the interconnections between organised crime and international markets make the agri-food sector a target for high profits for criminal organisations with high levels of financial and technical capabilities.

In order to respond to such a serious problem we must start by considering that the food fraud phenomenon is a byproduct of the food and the Mafia interrelation. That said, it seems to me that the recent case of the horsemeat scandal proves that more regulation does not necessarily guarantee greater commercial fairness. The horsemeat case implicated the beef industry, thus one of the alimentary sectors with the most advanced food standards and regulations including its traceability! More generally, it is worrying that a fraud so widespread was committed using products of animal origin, as well as manufacturing plants supervised by official veterinarians. In short, there is enough concern so as to question the effectiveness of regulation only. Perhaps the regulatory efforts in recent years have forced the official control of foodstuffs to center more on paperwork surveillance than on actual site inspection?

It seems to me, therefore, that the problem is not actually changing rules within the food market. If the phenomenon of Economically Motivated Adulteration (EMA) is one of transborder criminality, then the judicial enforcement authorities' investigatory tools need to be strengthened. For example, in recent years, Italian investigations in the sector of olive oil became possible thanks to an ad hoc law. It allowed performing a series of in-depth investigation tools (for example, the obligation to declare the origin of the olives and oils entering Italian soil, or continuous monitoring of sales prices) and the review of the code of criminal procedure, permitting broader terms of investigation by authorizing even wiretaps and other activities. They also established the immediate forfeiture of money and other turnout of which the accused were unable to justify a provenance. A previous law had worked in the same direction, but limited to counterfeit phenomena on PDO and PGI products.

Finally, investment should be aimed at strengthening ordinary and extraordinary enforcement control, i.e. the investigative capacities (technical, financial and human) of the supervisory authorities and their cooperation with the counterparts of other EU States, as with the Judiciary, at cooperation between national courts (European and beyond), and at upgrading investigative tools.

## Intentional vs Negligence: from the private sector's point of view, how can FBOs build reliable internal procedures allowing the company to successfully face criminal food fraud prosecution? How to bridge best practices and legal liability?

Apart from the differences between national legal systems, the crime of fraud requires intention (malice). It is also true that, when a health hazard's involved, simple negligence usually justifies a criminal indictment. The case of food fraud should be considered as a risk, and as such approached accordingly, similar to that of HACCP. The latest BRC edition contains references to food defence. There may be different approaches, but there is no doubt that, from both the private and public point of view, the EMA faces a specific control booth, apt only to deal with actual concrete cases/markets.

## What is the state of play of whistle blowing as a tool to fight frauds and food fraud in particular?

Whistle blowing, as a voluntary instrument, may constitute an element for actual monitoring, but it is clear that its concrete practice requires a serious rethinking of the company's organization as well as effective sanction of the way to act in case of unqualified and potentially alarming news.

## How the System of Official Control for Food may contribute to fight food frauds? Does the draft of a new regulation on official controls, currently under discussion at the PE, address new provisions on these grounds?

As already discussed, the Official Control System is the first *cordon sanitaire* against the phenomena of non-compliance, be it fraudulent or not. Let us not

forget that the Irish national authorities, as part of a voluntary program of market monitoring, were the ones who investigated and effectively located the rotten horsemeat. Looking at the work of amending the General Regulation on official controls, the picture does not look promising, even as regards the theme of the fight against food fraud. Particularly worrisome is that despite high-minded declarations, such as those contained in the *European Parliament resolution of 14 January 2014 on the food crisis, fraud in the food chain and the control thereof*, they were not followed by any concrete action or reflection on one of the most suitable formats, the reform of the framework regulation on official controls of foodstuffs. It is embarrassing that on the EMA front, no serious consideration is paid to the analytical capacity of the official controls. It is a fact that conventional testing is unsuitable for detecting food adulteration problems. To cover the widest range of adulterants usually requires sophisticated analytical equipment such as mass spectrometry. Secondly, I do not see any change in the current situation, anchored to the logic of passive surveillance. I think, instead, that food policy should move towards incorporating food fraud methodology into certification standards, supply chain assurance and product verification. Predicting types of adulterants and ways of manipulation can be carried out using the *Rational Choice Theory* (assuming those who commit fraud make rational choices, which may not be the case) or indeed in terms of food bioterrorism where irrational behaviour may well underpin the behaviours that occur. Inspection protocols and product testing programmes should be developed through a risk assessment process that might only be undertaken on an annual basis and such attacks may occur much more frequently. Databases and risk assessment measures as well as predictive modelling and intelligence gathering will be undertaken in order to identify the potential for EMA and food crime. None of the above mentioned measures seem to be under discussion at the houses of Parliament.

## Intellectual Property

*This section is devoted to giving readers an inside view of the crossing point between intellectual property (IP) law and risk regulation. In addition to updating readers on the latest developments in IP law and policies in technological fields (including chemicals, pharmaceuticals, biotechnology, agriculture and foodstuffs), the section aims at verifying whether such laws and policies really stimulate scientific and technical progress and are capable of minimising the risks posed by on-going industrial developments to individuals' health and safety, inter alia.*

# Economic Analysis of the Risks Associated with Seeking a Preliminary Injunction

*Richard P. Rozek**

*An issue that may arise for both the plaintiff and defendant in a patent dispute involving pharmaceutical technology concerns the risks associated with selling an allegedly infringing product prior to the dispute being resolved. The plaintiff has the option to seek a preliminary injunction. Deciding whether to grant an injunction involves fact specific analysis. The economic components in such an analysis, which are addressed in this report, are: assessing whether the plaintiff will suffer irreparable harm without an injunction, measuring the balance of harms to the plaintiff and defendant, and evaluating whether the public interest will be served by an injunction.*

## I. Introduction

In litigation involving a defendant seeking to sell a generic version of a pharmaceutical product covered by a patent, the defendant (alleged infringer or imitator) may be faced with the decision to launch a bioequivalent version of the product covered by the patent prior to the litigation being resolved. The corresponding issue for the plaintiff (patent holder or pioneer) is whether to seek a preliminary injunction (PI) to block entry by the alleged infringer. Both parties must assess the risks and rewards of their respective options. Most importantly, a PI allows the patent holder to keep the alleged infringer from selling a competing product. If the patent holder subsequently losses the patent case on the merits, the alleged infringer may seek damages for delayed entry.

These issues arise in both European and U.S. legal proceedings. The ability to obtain a PI in European courts is codified in Article 9 of the IP Enforcement Directive (2004/48/EC).[1] In the U.S., Courts also consider requests for PIs. For example, if certain pharmaceutical patent disputes between pioneer companies and imitators are not resolved in 30 months, the imitator may launch its product assuming the U.S. Food and Drug Administration (FDA) has approved the imitator's product for sale in the U.S. The pioneer company may seek a PI to prevent the launch until the litigation is resolved.[2] A request for a PI also arose in connection with a matter involving a pioneer large molecule product and a

* Ph.D, Independent Consultant, Alexandria, VA, USA. The analysis in this paper is based on my experiences testifying on behalf of pharmaceutical and medical device companies in U.S. patent disputes involving requests for injunctions.

1 See Huw Evans and Pam Taak, "Preliminary Injunctions Alive and Well – A View from Europe," *IP Federation*, December 16, 2011, https://www.google.be/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKEwjh3q6myMfLAhVEYQ8KHWpzAHkQFggcMAA&url=http%3A%2F%2Fwww.ipfederation.com%2Fdocument_download.php%3Fid%3D909&usg=AFQjCNGz0RZUYkXVt5zTk8P0EjO6utSG5A&cad=rja. This article also states that a PI may be referred to as an interim or interlocutory injunction in Europe.

2 Such situations arise in the U.S. as a result of provisions in the Drug Price Competition and Patent Term Restoration Act of 1984 (U.S. Public Law 98-417), which is referred to as the Hatch-Waxman Act.

biosimilar product.[3] The economic issues are generally similar in Europe and the U.S. However, there are slight differences in standards and timing across the National Courts in Europe, which raises risks and costs for plaintiffs and defendants.[4] Given the diversity across Europe, I will focus explicitly on the U.S. standards and not address the specific risks due to country-by-country differences. In the U.S., the four standards for a PI are: the patent holder must demonstrate likelihood of prevailing on the merits of the case, the patent holder will be irreparably harmed without a PI,[5] the balance of harms favors the patent holder, and the public interest will not be harmed by a PI.[6] The last three standards have economic components and will be the focus of in this paper.

Based on my experience testifying in matters involving PIs, my conclusions are:

a) While it may be possible to measure certain elements of harm to a patent holder, there are some elements of harm that are difficult to measure and other elements of harm that are impossible to quantify in monetary terms to a reasonable degree of certainty.
   i) Calculating certain elements of harm in terms of lost profits, reasonable royalties, and/or convoyed sales are regularly addressed in the damages phase of a patent dispute.
   ii) Measuring elements of harm such as the harm to the patent holder for lost sales after the date of the Court's decision that the patent is valid and infringed is difficult or impossible.
   iii) Other elements of harm are impossible to quantify in monetary terms to a reasonable degree of certainty including lost profits on lost opportunities, and harm to the patent holder's reputation.

b) Without an injunction, the patent holder will likely suffer lost sales and/or lost profits from the lost opportunities to sell other health care products it currently markets or launches in the future at the same levels had there been no infringing sales by the imitator. If it is ultimately determined that the patent at issue is valid and infringed,[7] it will be nearly impossible to restore the patent holder's sales and profits on these other products to the appropriate levels. These lost profits are impossible to quantify in monetary terms to a reasonable degree of certainty.

c) Loss of sales and profits from the products covered by the patent will reduce the resources available to fund the patent holder's research and development ("R&D") for new or improved products across therapeutic areas. Reducing R&D will likely result in additional lost sales and profits in the future since fewer new products will be developed and fewer new uses for existing products will be identified. To quantify in monetary terms to a reasonable degree of certainty the patent holder's total lost profits from lost R&D opportunities is impossible. Even if the patent holder could divert financial resources from other uses to fund R&D, such a strategy would not necessarily maximize shareholder value.

d) There will be harm to the patent holder's reputation as an innovator in discovering and developing products that provide health care advances among patients, physicians including key opinion leaders ("KOLs"), pharmacists, and payers. It is impossible to quantify in monetary terms to a reasonable degree of certainty the full extent of this element of harm.

e) As a result of developing and selling the innovative patented product, the patent holder has assembled and retained talented scientific and commercial professionals in the field of improving health care. It will likely reassign or lose some of these employees with valuable expertise if the potentially infringing products are sold prior to the patent dispute being resolved. The patent holder may not be able to reassemble this professional team after the legal process concludes, which will

3 See Susan Decker, "Amgen, Novartis Battle in U.S. Court over Neupogen Copycat," *Bloomberg Business*, June 3, 2015, http://www.bloomberg.com/news/articles/2015-06-03/amgen-novartis-battle-in-court-on-copycat-version-of-neupogen. Biosimilar products are covered by the Affordable Care Act of 2010 (U.S. Public Law 111-148).

4 See, for example, Simon Holzer, "Requirement of Irreparable Harm: Swiss Federal Supreme Court Puts Spokes in Appellants' Wheels in Appeals against Decisions in Summary Proceedings", *Kluwer Patent Blog*, April 3, 2015, http://kluwerpatentblog.com/2015/04/03/requirement-of-irreparable-harm-swiss-federal-supreme-court-puts-spokes-in-appellants-wheels-in-appeals-against-decisions-in-summary-proceedings/.

5 By irreparable harm, I mean harm that cannot be remedied by the payment of monetary damages at the time of trial.

6 See Kevin Noonan, "Utah Judge Denies Myriad's Preliminary Injunction Motion", *Patent Docs*, March 11, 2014, http://www.patentdocs.org/2014/03/utah-judge-denies-myriads-preliminary-injunction-motion.html.

7 For ease of exposition, I assume a single patent is at issue. The analysis is similar when a patent dispute involves multiple patents.

harm its reputation in recruiting and retaining top talent. The resulting harm to the patent holder in terms of developing and selling future products cannot be quantified in monetary terms to a reasonable degree of certainty.

f) The imitator will not be irreparably harmed if it is prohibited from marketing and selling the product. Such companies often already sell other pharmaceutical products that do not infringe the patent at issue. It likely has an established position among patients, physicians, pharmacists, and payers. Given the number of pioneer pharmaceutical products with expiring patents, the imitator also has other opportunities to generate sales and profits.

g) The public interest will be served by prohibiting the imitator from marketing and selling the alleged infringing products. Patients will have access to the technology embodied in the patent since the pioneer's products will be available. The incentives for companies to devote resources to R&D and launch new products will be preserved.

I will explain the basis for these conclusions in the remainder of this paper.

## II. Irreparable Harm to the Patent Holder

### 1. Traditional Patent Damages

If the imitator continues to market and sell a competing product and the Court determines that the patent at issue is valid and infringed, the patent holder will be entitled to damages.[8] In my experience, damages in patent disputes usually involve measuring lost profits on lost sales of the plaintiff's product that embody the patent at issue, price erosion for the product due to competition from the infringer, reasonable royalties determined following the *Georgia Pacific* factors,[9] and lost profits on convoyed sales. For example, measurable damages would include the extent to which the patent holder has to reduce prices for the product covered by the patent at issue as well as increase its costs absent a preliminary injunction.[10] Generally, it is possible to calculate the patent holder's damages in the form of lost profits including price erosion and higher costs as well as reasonable royalties applied to any market expansion resulting from the imitator's sales of a competing product.

The patent holder's damages from its lost sales of the product covered by the patent at issue are an element of harm that can be calculated. However, there may be some factors associated with calculating damages such as measuring the extent to which physicians would switch back to the Product covered by the patent at issue, other pharmaceutical products, or non-pharmaceutical treatments if the imitator's product is withdrawn from commercial sale that may be difficult to measure. In addition, damages to the patent holder's sales and profits from the product covered by the patent at issue may extend beyond the date of the Court decision.[11] Removing the imitator's competing product after the Court decision would not necessarily return the patent holder to the same market position as before the infringement. The patent holder will have lost its leadership momentum in the area of treating a particular medical problem and correspondingly the sales of the product covered by the patent at issue that result.[12] Measuring the extent of the gap in sales and the time (if ever) for the patent holder to recover the market position it would have had absent infringement is another difficult problem. It may actually not be possible to quantify these elements of damages to a reasonable degree of certainty.

### 2. Lost Opportunities and Diminished Reputation

The harm to the patent holder resulting from the imitator marketing and selling competing products goes beyond its damages from lost sales of the product covered by the patent at issue. These other elements

8 Documents obtained in discovery in which the imitator and the patent holder identify the product covered by the patent at issue and the imitator's product as competitive alternatives are helpful.

9 *Georgia-Pacific Corp vs. United States Plywood Corp.*, 318 F Supp. 1116, 1120 (S.D.N.Y. 1970).

10 Documents in which the patent holder identifies increasing promotional activities as a strategy for managing risk factors such as increased pricing pressure and intense competition from entry by the imitator are helpful.

11 The patent owner may not recover all the costs associated with patent infringement litigation (e.g., the opportunity costs of management time due to focusing on the litigation).

12 The patent holder may be the leader in the area of treating a particular medical problem due to the product covered by the patent at issue. The patent holder's overall strategy for the product covered by the patent at issue may be to leverage its reputation to other therapeutic areas.

of harm to the patent holder cannot be quantified in monetary terms to a reasonable degree of certainty. The imitator may either dismiss the significance of some of these other elements of harm or fails to identify these other elements of harm altogether. It is precisely these other elements of harm to the patent holder that are irreparable. I divided the other elements of harm to the patent holder that I have identified into two categories: lost profits on lost opportunities and diminished reputation. These additional elements of harm cannot be quantified in monetary terms to a reasonable degree of certainty.

### a. Opportunities

*Sales and Profits from Other Products*

Given that the leadership momentum gained through selling the product covered by the patent at issue provide the patent holder access to patients, physicians, pharmacists and payers,[13] the patent holder will have less access to the health care marketplace for the patent holder's product if it is competing with the imitator's product.[14] The product covered by the patent at issue is an introduction or starting point for the patent holder open dialogs with patients, physicians, pharmacists, and payers. During these interactions, the sales representatives also discuss other products sold by the patent holder. The patent holder's innovative efforts embodied in the product covered by the patent at issue provide the patent holder access to health care providers that allows the representatives to share additional information about these other products. The patent holder will not be able to generate the same level of sales and profits for its other products given this decreased access to health care providers.[15] It would be impossible to quantify the total amount of harm in monetary terms from the lost sales and profits of these other products. That is, it would be impossible to measure accurately the levels of sales and profits the patent holder would derive from these other products but for the imitator marketing and selling the alleged infringing product.

*R&D Activities*

Investing in R&D for pharmaceutical projects is time-consuming, risky, and expensive.[16] A recent study by economists affiliated with Tufts University determined (in 2013 dollars) that "developing a new prescription medicine that gains marketing approval, a process often lasting longer than a decade, is estimated to cost $2,558 million ... [as follows] ... Average out-of-pocket cost of $1,395 million ... [and] ... Time costs (expected returns that investors forego while a drug is in development) of $1,163 million."[17] Given the specialized skills and substantial capital required to discover and develop a technology that results in a medical device being approved by the FDA for commercial sale, companies seek protection of the underlying intellectual property that guarantees the exclusive right for a period of time to make, use, and sell the device embodying the intellectual property. This protection available through patents allows the innovator the opportunity to earn a return on its investment in developing the technology. Research based pharmaceutical companies consider patents and trademarks to be material to their businesses and use available means to seek protection of their intellectual property.[18] Undermining those incentives to develop new technologies for pharmaceutical products will weaken the incentives to invest in innovative activities at the patent holder and result in fewer new products for patients.

The patent holder identifies strategies including R&D activities to maximize shareholder value. Management makes decisions regarding the amount of R&D spending and capital investments in the pharmaceutical area on the assumption that the patent at issue would provide exclusivity through the date the patent expires. It considered relying on the retained earnings from the sales of the product covered by the

13 The patent holder's activities in the form of direct-to-consumer advertising, direct contact of health care providers by sales representatives, journal advertising, sponsoring medical symposia or other activities geared toward disseminating information about its products will be restricted.

14 The types of products that are not related to the product covered by the patent at issue would likely not be captured in the analysis of convoyed sales.

15 I understand that the patent holder will be able to recover damages only on lost sales of products functionally related to the product covered by the patent at issue.

16 In general, only one project out of every 10 that begins as an idea results in a commercial product. However, there is no guarantee that the product will be successful once available for sale.

17 Joseph DiMasi, Henry Grabowski, and Ronald Hansen, "Cost to Develop and Win Marketing Approval for a New Drug is $2.6 Billion" (press release), Tufts Center for the Study of Drug Development, November 18, 2014, http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study.

18 Richard Levin, Alvin Klevorick, Richard Nelson, and Sidney Winter, "Appropriating the Returns from Industrial Research and Development", *Brookings Papers on Economic Activity*, Volume 3, 1987, pp. 783-820, http://www.brookings.edu/~/media/projects/bpea/1987%203/1987c_bpea_levin_klevorick_nelson_winter_gilbert_griliches.

patent to invest across therapeutic areas. If management had expected competition from the imitator's product prior to the expiration of the patent at issue, it likely would have made different strategic decisions regarding allocation its R&D and capital investments, possibly outside of health care.

The success of the patent holder's current and future R&D projects hinges on its ability to maintain funding for future R&D activities. The patent holder funds its ongoing R&D projects from existing sales. Research based pharmaceutical companies spend billions of dollars annually on R&D activities.[19] Loss of sales from the product covered by the patent at issue if the imitator sells a competing product will reduce resources available for the patent holder to fund its portion of pharmaceutical R&D activities. If the patent holder has fewer sales to devote to R&D due to lost sales from the product covered by the patent at issue, other pharmaceutical technologies may not be evaluated, fewer new improvements to other products may be identified, and fewer new products for patients in other therapeutic areas may be developed. Merely suggesting that the patent holder shift revenue from other uses such as paying dividends to shareholders to fund R&D will not maximize shareholder value. The imitator continuing to market and sell a competing product will reduce the expected benefits of the patent holder investing in R&D.

To address the magnitude of this problem in an actual litigation, it is helpful to examine the patent holder's R&D pipeline for pharmaceutical and other technologies including the timetable for the expected dates for regulatory approvals of the projects. Without a preliminary injunction, the patent holder with an active R&D program will likely experience a disruption in its planned orderly progress for its other R&D projects through the clinical, regulatory, and marketing planning processes. This disruption may mean it will incur higher costs, achieve lower sales for some or all of its new products, or refocus R&D efforts. The total harm to the patent holder is impossible to quantify in monetary terms with a reasonable degree of certainty.[20]

## b. Reputation

*Patients, Physicians, Pharmacists, and Payers*

To the extent that the patent holder invested in establishing a leadership reputation as an innovator in discovering and developing products, there will be harm to the patent holder's reputation among patients, physicians, pharmacists, and payers if its leadership is challenged by the imitator infringing the patent at issue through actual marketing and selling a competing product. Many health care providers may be unaware of the circumstances underlying the imitator's marketing and selling activities. They may view the imitator's actions as signaling the patent holder's innovation is not as important as initially claimed. The harm to the patent holder's reputation will make it more difficult to develop and sell pharmaceutical products. If the patent holder does not have the leadership momentum in the marketplace, KOLs will be less interested in working with the patent holder to expand awareness of its product covered by the patent at issue and to develop the next generation of products for unmet medical needs. It is impossible to quantify in monetary terms to a reasonable degree of certainty the full extent of this element of harm.

*Talented Employees*

The patent holder that has assembled a talented group of scientific and commercial employees with expertise in health care may lose these employees to competitors or be forced to reassign them to other therapeutic areas within the company. Its reputation with respect to being the leader it developed with the product covered by the patent at issue will be harmed if it loses key scientific and commercial employees. Research based pharmaceutical companies routinely recruit employees with relevant expertise from other companies identified as the leaders in a particular area. If the imitator continues to market and sell a competing product so that the patent holder no longer has its leadership momentum, other companies may seek to recruit employees currently working at the patent holder. The patent holder may lose its scientific and commercial employees with expertise in the therapeutic area covered by the patent at

19 Most research based pharmaceutical companies are members of the Pharmaceutical Research and Manufacturers of America (PhRMA). In 2014, PhRMA member companies invested $51.2 million in biopharmaceutical R&D. Andrew Powaleny, "Fact Check Friday: The Truth about Industry's Role in R&D", *The Catalyst*, PhRMA, October 23, 2015, http://catalyst.phrma.org/fact-check-friday-the-truth-about-industrys-role-in-r-and-d. Research based pharmaceutical companies usually fund R&D from current revenues.

20 At the extremes, the foregone research may have identified the cure for cancer or failed to generate any useful scientific information.

issue to competitors because it will not be able to offer these employees challenging work assignments. For the employees not lost to competitors, the patent holder may have to reassign part of these people to other therapeutic areas or layoff some current employees. If the remaining scientific and commercial employees are reassigned to other therapeutic areas where they have less expertise than in the area covered by the patent at issue, they will be less productive and effective. It is impossible to quantify in monetary terms to a reasonable degree of certainty the total losses to the patent holder due to employees leaving the company or the lost productivity among the remaining employees reassigned to other therapeutic areas.

## III. Balance of Harms Supports Prohibiting The imitator from Selling Competing Products prior to Resolving the Patent Dispute

The balance of harms from not granting a preliminary injunction in a pharmaceutical patent dispute between a research based pharmaceutical company and a generic or imitator company generally favors the research based pharmaceutical company. The opportunities available to the imitator suggests that it will not be irreparably harmed if it is prohibited from marketing and selling the competing product. Most imitator companies sell a portfolio of generic products. They have established positions in the marketplace among patients, physicians, pharmacists, and payers. There are other patented products with expiring patents that provide opportunities for a generic company to continue adding to its product portfolio. "Between 2013 and 2017, more than $78 billion in annual brand drug sales are at risk for losing patent protection."[21] The generic company can replace its sales of a competing product to the product covered by the patent at issue with sales of the other generic products. If a preliminary injunction is granted but it is later determined the imitator's competing product does not infringe the patent at issue, the imitator can leverage its existing relationships from sales of its other generic products to reintroduce the competing product into the marketplace. Given the breadth of generic products most imitators provide, an alleged infringer will be able to maintain its existing sales force and overall market presence regardless of the decision on the request for a preliminary injunction.

## IV. The Public Interest Is Served by Prohibiting The imitator from Marketing and Selling a Competing Product

Patients, physicians, pharmacists, and payers typically benefit from the contribution that the patent holder makes by disseminating information about the product covered by the patent at issue and the associated therapeutic area. Research based pharmaceutical companies also have patient assistance programs to provide patients unable to pay for a pharmaceutical product with the product at no out-of-pocket cost. Generic pharmaceutical companies generally do not have such programs. Allowing the imitator to sell a competing product before the patent dispute is resolved with reduce the incentives of the patent holder to disseminate information and sponsor patient assistance programs. There may be long term adverse health outcomes for patients. The product covered by the patent at issue will continue to be available to patients and physicians after the preliminary injunction. The patent holder has the capability to manufacture sufficient quantities of the product covered by the patent at issue to meet patient needs.

## V. Conclusion

A preliminary injunction allowing the patent holder to maintain the exclusivity provided by the patent at issue will preserve the incentives for innovators to devote resources to R&D. A preliminary injunction will facilitate entry into marketing and selling innovative products for medical problems. Public policy that encourages investment in biomedical R&D and competition will help to create new products to address unmet medical needs. Consumer welfare analysis should consider these long term benefits to prohibiting infringers from entering markets.

21 "Issues Document: Patent Expirations (2013-2017)", *Emerging Therapeutics*, Express Scripts Holding Company, updated May 6, 2013, http://www.centerlighthealthcare.org/images/uploads/Brand_Name_Drugs_with_Patent_Expirations_2013_-_2017.pdf.

In considering whether to seek a PI in a pharmaceutical patent dispute, it is necessary to address the full extent of the harm to the patent holder from allowing the imitator to market and sell a competing product. I have identified some elements of harm in pharmaceutical disputes in which the patent holder will incur irreparable harm without a PI. Examining whether these elements of harm exist in a particular dispute is a fact specific inquiry. Granting a preliminary injunction will usually not create insurmountable problems for the imitator and will likely be in the public interest.

# Risk Communication

*This section discusses issues related to risk communication across a range of publicly perceived high risk industries (such as pharmaceuticals, nuclear, oil, etc.). It reports critically and provides analysis on risk communication as an outcome of risk research within these industries. Contributions are intended to include methods working towards the advancement of risk perception research and describe any lessons learned for successfully communicating to the public about risk.*

## Performativity in Action: How Risk Communication Interacts in Risk Regulation

*P. Marijn Poortvliet, Martijn Duineveld and Kai Purnhagen**

*In order to better understand the effects of risk communication on regulatory preferences, and vice versa, it is necessary to think beyond the objective/perceived distinction that is often made in risk studies, policies and practices. As an alternative we introduce the concept of risk hybrid, which can be the result of communications of objectified risks and perceived risks. Risk communication, we argue, is not just a representation of the calculated or perceived risks in risk assessment, which subsequently informs risk regulation processes. Instead, it often contributes to the construction of risk conceptualizations and objects in risk assessment and risk management, which in turn are part of larger discourses that enable and constrain regulatory action. We propose the concept of performativity as an explanatory mechanism to analyse the relation between risk communication and risk regulation. We show how performativity can explain the entanglements between risk communication and risk regulation, and close by pointing out implications for understanding and coordinating risk regulation practices.*

### I. Introduction

Examples abound of highly politicized instances of risk controversies, such as the climate debate, counterterrorism, and the commercialization of genetically modified organisms (GMOs). Numerous reasons, such as divergent perspectives, ways of communication, and interests, explain why involved actors often find themselves locked in a controversy.

For instance, in the GMO debates environmental politicians, NGOs, industrial parties, consumers, and GMO scientists have exerted very distinct ways of communication, resulting in a highly polarized and contested gene-risk landscape.[1] As a consequence, some industrial players have left or terminated R&D activities in the EU, while other scientists escape the gaze of EU-regulations and started experimenting in places with a different approach to GMO regulation and control.

Evidently the type and modality of risk communication is pivotal in how risk debates develop. A key conceptual distinction made within such debates, among academics, in the literatures, and in wider society, is one between *perceived or subjective* risks on the one hand, and *factual or objective* risks on the other. This distinction is mainly established and reinforced by academic literatures in which much work

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1 See on the bias-driven regulation in GMO communication on the example of the precautionary principle Kai Purnhagen, The Behavioural Law and Economics of the Precautionary Principle in the EU and Its Impact on Internal Market Regulation, 37 *Journal of Consumer Policy*, 2014, 459-460.

has been conducted on the role of *perceived* risk in risk attitude formation and risk behaviour, and its role in understanding risk-related decision-making. Likewise, procedures for *objective* risk assessment have been optimized and are presented over the years as increasingly accurate. We refer to these as the distinction between *risk as perception* and *risk as analysis*[2]. This distinction has been transferred into risk regulation as a strict dogma to distinguish the trias of (allegedly objective) risk assessment, (allegedly subjective) risk management and risk communication. In the ideal world of risk regulation, all three of which need to be distinguished in order to keep science free from politics, inform politics with (allegedly) neutral science and then communicate the outcome of such politicized scientific insights.[3]

We argue that although this 'classic' distinction serves a purpose of an idealistic categorization of research schools or regulatory domains, it does not prove to be a useful distinction to analyse and understand risk communications, the discourses which they are embedded in, and ways they affect the realities of risk regulation, including risk assessment and risk management. Objectified and perceived risks will be difficult – if not sometimes impossible – to separate in practice. As an alternative we introduce the concept of *risk hybrids*, which combines objectified risk (how the risk is represented in the risk analysis) and a perceived risk and nullifies the a-priory made distinction between the two. This concept will enable us to re-conceptualize risk beyond the dichotomy of objective and subjective risks and allows us to understand how risk communication influences risk assessment and risk management. By observing how different risk communications perform different risk hybrids in the various contexts in which they emerge, we show how the concept of risk hybrids can offer a richer understanding of risk communication practices. In risk regulation, understanding risk hybrids can inform which "other factors legitimate to the matter under consideration" (Art. 6 (3) General Food Law) shall be taken into account during risk management. Before deepening our theoretical understanding of risk hybrids as objects of performative discourses, we will first offer a brief review of research on risk assessment, risk management and risk perception. We close this contribution by pointing at some concrete avenues for how this notion could be taken forward within the realm of risk regulation.

## II. Risk Assessments, Risk Management, Risk Perceptions, and Claims of Objectivity

Within many disciplines, making calculations and estimates of the nature and magnitude of risks is essential. In economics and natural sciences, for instance, risks are studied in order to accurately predict potential negative outcomes, such as financial loss, the chance of flooding, or toxicity of chemical substances. In many fields of EU risk regulation such as food law, chemical law and pharmaceutical law, risk assessment is a necessary precondition for regulatory intervention. Risk-related predictions are deemed vital for the viability of businesses, such as the insurance industry and for governments to deliver "good" regulation. Insurance premiums are based on a combination of the chance and the size of a risk event – plus the insurer's operational costs. Poor risk assessment puts the competiveness of the insurance company at stake, and eventually also the interests of its customers. Governmental interventions based on risk are grounded in scientific estimations of threshold levels with a view of protecting consumers' health and safety. Poor risk assessment provides political decision makers with poor data, which likely results in suboptimal, in the worst case, life-threating regulation for consumers. In risk assessment many different conceptualizations of risk and uncertainty can be used. Examples of risk concepts include risk as an expected value, as a probability distribution, as an expected disutility, as an epistemic or stochastic uncertainty, as a simple threshold level for when a substance is deemed to be hazardous and so forth[4]. What all of these approaches have in common is the striving to objectify risk. The risk calculation that is derived from the variety of available risk assessment procedures can subsequently be used to take protection measures against a risk, if deemed

2 P. Slovic, M.L. Finucane, E. Peters, and D.G. MacGregor. Risk as analysis and risk as feelings: Some thoughts about affect, reason, risk, and rationality. 24 *Risk Analysis*, 2004, 311-322. See also G.F. Loewenstein, E.U. Weber, C.K. Hsee, and N. Welch. Risk as feelings. 127 *Psychological Bulletin*, 2001, 267-286.

3 See e.g. Art. 3 No 10, Art. 6 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety OJ L 031 2002 p. 1 – 24 (General Food Law).

4 For a comprehensive overview see Terje Aven, Misconceptions of Risk (Chichester, Wiley, 2009).

necessary, such as establishing proper risk management procedures.

The objectification of risk has obvious strong merits, and is a vital part of the operational reality within many regulatory institutions, scientific fields, societal domains, industries, and commercial enterprises. Not surprisingly, the fact-driven nature of risk assessment functions as a golden standard, and appeals to the adage of rational decision making. However, as many scholars in social sciences have argued the method of risk as analysis has certain limits. For one thing, on philosophical and methodological grounds the existence of 'objective knowledge' or 'facts', independent of observation can be contested. Secondly, the behavioural sciences have contributed much to our understanding of human decision making within contexts of risk and uncertainty and have stressed that not only objectified risks but also perceived risks make a difference in these processes. Most notably, research on risk perception shows that people can worry deeply about risks that may objectively be very slim, especially when compared to (much bigger) risks that most people willingly accept[5]. For example, some travellers are quite worried about the safety of taking a plane but not even consider the – statistically much greater – risk of driving to the airport. Furthermore, recent research showed that the combination of the extent of perceiving a hazard to be risky and the extent to which people felt uncertain about a certain hazard predicted the degree to which members of the general public demanded regulatory action about the hazard.[6] As such, demand for risk regulation is sometimes entirely driven by perceptual processes, not by technical analysis of the particular hazard.

The act of risk as analysis has proven to be important to harvest factual risk figures that can inform decision making, risk management, policy development and risk regulation. Also, risk as perception helps us to understand how people psychologically engage with risks that are relevant to them[7]. These approaches each have important merits and it makes little sense to value any of the two approaches over the other, since both enable and constrain regulatory action and impact decision-making.[8] Because a priory to a practice of regulatory action and decision making it is impossible to predict which risk communication will be most influential, in actual risk communications practice they can both contribute to the creation of risk objects such as 'a dangerous gene' or 'a risky hedge fund'. Because risk objects can be the result of combining elements from objective and subjective risk assessment we will call them *risk hybrids.* To deepen our understanding of how risk hybrids emerge and how they can become embedded in different risk discourse we will continue by introducing performativity theory, which will serve as a conceptual lens.

## III. Performativity Theory

Performativity theory is developed in constructivist and post-structuralist frameworks, which depart from the epistemological premise that everything we observe is constructed by the observer (yet not unrelated to the constraints set by the social and material world under observation) and therefore contingent. Risk or risk objects do not exist before they are observed or conceptualized as such.

In line with this way of thinking it can be argued that risk communication is embedded in discourses, which can be defined as 'a structured set of concepts that enables access to a certain part or aspect of reality, while simultaneously veiling other parts or aspects'.[9] Risk discourses, like any other discourse, can become performative, they can sort all kinds of unsuspected (or anticipated) reality effects. Simply put: 'Performative means that discourses constitute the objects of which they speak.'[10] One of the first authors who coined the term was the philosopher J.L Austin.[11] For him "a performative utterance was a specific kind of statement or expression that estab-

5 P. Slovic. Trust, emotion, sex, politics, and science: Surveying the risk-assessment battlefield. 19 *Risk Analysis*, 1999, 689-701.

6 P. Marijn Poortvliet and Anne Marike Lokhorst. The key role of experiential uncertainty when dealing with risks: Its relationships with demand for regulation and institutional trust. *Risk Analysis* (in press).

7 For an example in the context of GMO risks see B.C. Mulder, P.M. Poortvliet, P. Lugtig, and M. de Bruin. Explaining end-users' intentions to use innovative medical and food biotechnology products. 9 *Biotechnology Journal*, 2014, 997-999.

8 See on this point Micklitz and Tridimas.

9 Kristof Van Assche, Raoul Beunen, and Martijn Duineveld, Evolutionary Governance Theory: An Introduction (Heidelberg, Springer, 2014).

10 L. Bialasiewicz, D. Campbell, S. Elden, S. Graham, A. Jeffrey, and A.J. Williams, "Performing Security: The Imaginative Geographies of Current US Strategy", *26 Political Geography* (2007), 405-422.

11 J.L. Austin, How to Do Things with Words (London, Clarendon Press, 1962).

lishes its referent through the very act of uttering.[12] In saying, for instance, "I apologize," I am not reporting on an already existing state of affairs. I am bringing that state of affairs into being: to say "I apologize" is to make an apology. "I apologize" is, thus, a performative utterance.[13] Later this theory was further developed by Pierre Bourdieu,[14] Judith Butler,[15] and recently within Evolutionary Governance Theory.[16]

By stating that risk communications, can have 'reality effects', we do not mean to introduce a naïve distinction between discourse as 'just' a social construction and material reality as the real world. It does not naively imply that there are no material realities, that there are no bodies or trees or risky rock formations on the verge of collapse, it implies that things (objects and subjects) appear to be truth because of the emergence and evolvement of discourses.[17] Reality effects occur when risk communications shape the discourses in which they emerge or other discourses or when they mould material 'realities', like fences to keep the enemy out, CCTV cameras to increase (or erode) the feeling of safety or a sign on a product declaring it GMO free.

## IV. Making up Risk Hybrids

If a risk communication renders real – whether it is performative – can only be observed empirically. Sometimes risk communication will have effects, sometimes not. Some risk communications will render real on the short-term and sometimes it takes longer, sometimes it only renders real in a very specific place or context, sometimes it gets widespread in society.

Risk communications perform risk objects; these are the objects that are constituted according to the distinction as risk/no risk. If and how a risk communication performs a risk hybrid cannot be predicted. A risk hybrid that is the result of a scientific risk analysis has a higher chance to make a difference in the on-going communication within the sciences, it could for example be picked up by other researchers for further investigation. Yet, whether this risk communication will make a difference outside of the scientific discourses cannot be predicted. It will depend on the logic of the other discourses, if it will be communicated and if this communication will make a difference. For example, whether the media picks up a risk hybrid constructed by the sciences and how they frame this risk cannot be determined by the sciences. It depends on the logic of the media discourses: Does it relate to a societal debate on that risk? Is it newsworthy for our readers? Is it fashionable? Do we need an attractive headline for the cover? Does the scientific risk coincide with our moral standards? Therefore risk hybrids are not fixed objects that can just travel unchanged from one discourse to another. Since discourses are differently structured, an unaffected transgression of a risk hybrid from discourse to discourse is an illusion. This is due to the self-referential nature of discourse. Self-referentially means that a discourse reproduces itself based on previous communications within that discourse, every observation of its environment (i.e. other discourses, the material world) will always be communicated account to the internal logic a specific discourse. Media discourses for example will only reproduce communications that observed by the media as news. Whether something is news or not does not make a difference in legal discourses. The legal system will communicate according to the distinction: legal vs illegal. For the legal system a risk will only make a difference if it is framed in the legal/illegal code.

A risk hybrid therefore can be the result of different risk communications, by academics, worried citizens, media coverage and so on. Sometimes these communications can complement each other and sometimes they conflict, sometimes enforce each other and could also attenuate the risk hybrid[18].

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12 Ibid.

13 D. Mackenzie, F. Muniesa, and L. Siu (eds.), Do Economists Make Markets? On the Performativity of Economics (Princeton, Princeton University Press, 2007).

14 P. Bourdieu, Language and Symbolic Power (Cambridge, Polity, 1991).

15 J. Butler, Excitable Speech: A Politics of the Performative (New York, Routledge, 1997).

16 Kristof Van Assche, Raoul Beunen, and Martijn Duineveld, "Performing Failure and Success: Dutch Planning Experiences", *90 Public Administration* (2012), 567–581. See also Kristof Van Assche, Raoul Beunen, and Martijn Duineveld, Evolutionary Governance Theory: An Introduction (Heidelberg, Springer, 2014).

17 J. Butler, Excitable Speech: A Politics of the Performative (New York, Routledge, 1997). See also D. Mackenzie, F. Muniesa, and L. Siu (eds.), Do Economists Make Markets? On the Performativity of Economics (Princeton, Princeton University Press, 2007).

18 R.E. Kasperson, O. Renn, P. Slovic, H.S. Brown, J. Emel, R. Goble, J.X. Kasperson, and S. Ratick. The social amplification of risk: A conceptual framework. 8 *Risk Analysis*, 1988, 177-187.

## V. Ways forward

We propose to study the construction, relations and dependencies between risk, risk hybrids, risk assessment, and risk regulation processes in risk discourses. Within these discourses some risks are labelled as objective, some as subjective, depending on the inner logic the respective discourses, not on the quality of the research, the toughness of the methods and methodologies used. What is constituted as 'real' risk in one discourse could be observed as a danger in another – and non-existent in a third. Some risks might come into existence after thorough risk analysis and labelled as objective in the first place but when new insights emerge, new models of measuring and calculation are replacing the old, they could be re-conceptualized as a misunderstanding. Meanwhile these 'misunderstandings' could remain persistently 'real' and alive in public discourse for years.

To deepen our understanding of the performativity of risk communication we call for studying the multiple ways in which a risk hybrid can gradually become the object of risk regulation and the ways risk hybrid gains a more enduring and formalized character in legal discourses and politics and policy. The performative effects of risk communications and the emergence and evolvement of risk hybrids can be understood if we start to analyse the different self-referential discourses and their couplings contributing to their emergence and reproduction. Then we can observe if and how a risk communication has effects. We thus argue for a novel next step in risk research in which we pay attention to and study the emergence of and interactions between risk hybrids and risk regulations.

Thus, we believe the presented perspective can help to understand, for example, why some risks and risk hybrids – which emerged from years of scientific research – still lack media attention. We can then observe why a risk object performed by an international network of worried citizens might be debunked by scientists, while making it to the headlines and strengthened by the media, becomes a seemingly objective risk for many, triggering political actions and informing risk regulation.

It is risk communication, the way it emerges in different self-referential discourses and the ways it 'travels' from discourse to discourse and adopt to the internal logic of a discourse, that forms our interest. We assume that if we follow risk communications within discourses and the interdependencies between discourses we will observe that claims in terms of the objectivity/subjectivity divide are not stable over time and not stable between discourses. Risk hybrids are performed in multiple sites, following different pathways of emergence and leading to different outcomes that should be observed empirically. Departing the analysis from an a-priory assumption of the well established and taken-for granted difference between *perceived or subjective* risks on the one hand, and *factual or objective* risks on the other, will only obscure how risk hybrids really come into existence.

A final thought pertaining to the fluid nature of risk hybrids is that formalized risk regulation procedures can also inform risk hybrids. That is, just as the composites of objective and subjective risk have performative effects in creating risk regulation, risk regulation as a phenomenon can perform risk hybrids too. A stringent regulation of a particular nature, such as the ban on carrying certain amounts of cosmetics or fluids during air travel, may make seemingly trivial behaviours salient and can evoke feelings of risk. In that way, risk regulation procedures that were installed to make air travel safer may make, by intrusive screening of all passengers, actually instil feelings of uncertainty and risk in them.

# Case Notes

## Minimum Unit Pricing for Alcohol May Not be a Proportionate Public Health Intervention

*Oliver Bartlett**

*Case C-333/14 Scotch Whisky Association and Others v Lord Advocate and Advocate General for Scotland [2015] ECLI:EU:C:2015:845*

### I. Background to the Case

Setting a minimum unit price for the sale of alcoholic beverages has been on the agenda of the Scottish government for many years. As far back as 1999 the then newly formed Scottish Government decided to review data on the use of alcohol[1] that revealed trends in Scottish alcohol consumption such as the fact that in the two decades following 1994 alcohol sales went from being split equally between the on-trade and off-trade to the off-trade comprising around 70 per cent of sales.[2] Further studies reveal that the affordability of alcohol throughout the whole United Kingdom increased steadily between 1987 and 2007, with duty increases frequently short of inflation, and with supermarkets continuing to use alcohol as a loss-leader.[3] The result has been an increase in the affordability of wines and beers by 129% and 153% respectively.[4]

Another study focussing on alcohol related admissions to a hospital in Edinburgh found that 'this patient population purchases alcohol units on average at £0.29 less per unit than that paid on average by the general Scottish population',[5] and that 'of these patients, those who pay the lowest prices per unit tend to consume the greatest number of units'.[6] A Sheffield University Study that is consistently referred to by the Scottish Government furthermore found that setting a minimum unit price for alcohol of £0.50 may lead to a 5.7% reduction in population alcohol consumption,[7] mostly attributable to reductions in 'the consumption of heavier drinkers'.[8] An evidence base comprised of empirical findings such as these has been the driving force behind efforts to reduce the harm caused in Scotland by the consumption of alcoholic beverages that are low in price but high in alcoholic strength (LPHS alcohol), which are favoured by the heaviest and most hazardous drinkers.

The Scottish Parliament rejected minimum pricing in 2010,[9] however after the UK general election returned a majority Scottish National Party government in Scotland, plans for minimum unit pricing were reintroduced into the Scottish Parliament,[10] and

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1 Peter Rice, Why do health professions want Minimum Unit Price in Scotland' (*Scotland the Brave! Alcohol Policy in Scotland, 5th September 2014, Brussels*), available on the Internet at <http://www.epha.org/IMG/pdf/mup-event-summary.pdf> (last accessed on 16 February 2016), at p. 2.

2 *ibid*, at p. 2.

3 Petra Meier, 'Polarized drinking patterns and alcohol deregulation' 27 (5) Nordic Studies on Alcohol and Drugs (2010), pp. 383 *et seqq*., at p. 395.

4 *ibid*, at p. 396.

5 Heather Black et al, "The price of a drink: levels of consumption an price paidper unit of alcohol by Edinburgh's ill drinkers with a comparison to wider alcohol sales in Scotland" 106 Addiction (2010), pp. 729 *et seqq*., at p. 733.

6 *ibid*, at p. 734.

7 Petra Meier et al, Model-based appraisal of alcohol minimum pricing and off-licenced trade discount bans in Scotland using the Sheffield alcohol policy model (v2): - second update based on newly available data (University of Sheffield, 2012) available on the internet at <http://www.shef.ac.uk/polopoly_fs/1.156503!/file/scotlandjan.pdf> at p. 5.

8 *ibid*.

9 BBC News, 'MSPs pass Alcohol Bill without minimum drink pricing' (*BBC News,* 10 November 2010) available on the internet at <http://www.bbc.co.uk/news/mobile/uk-scotland-11719594> (last accessed 16 February 2016)

10 BBC News, 'Scottish government reintroduces alcohol pricing bill' (*BBC News*, 1 November 2011) available on the internet at <http://www.bbc.co.uk/news/uk-scotland-scotland-politics-15525950> (last accessed 16 February 2016)

were successfully voted through on 24 May 2012 in the form of the Alcohol (Minimum Pricing)(Scotland) Act 2012 (the Act).

Section 1(2) of the Act amends schedule 3 of the Licensing (Scotland) Act 2005 to ensure that in all licensed premises, 'alcohol must not be sold on the premises at a price below its minimum price'. The Act stipulates that the formula to be used in calculating the minimum unit price is the minimum price per unit given in pounds, multiplied by the strength of the alcohol given in ABV percentage, multiplied by the volume of alcohol given in litres, multiplied by 100 – or MUP x S x V x 100. Section 2 of the Draft Alcohol (Minimum Price per Unit)(Scotland ) Order has provisionally set the minimum price per unit as £0.50. By way of example, under the Act a bottle of wine of 12% ABV would be 0.50 x 0.12 x 0.75 x 100 = £4.50.

When the Act was introduced, it attracted substantial criticism from industry operators and several Member States,[11] as well as the European Commission, who issued a Detailed Opinion which argued that the Scottish measure unlawfully restricted trade within the internal market.[12] Opposition culminated in a consortium of alcohol producers, led by the Scotch Whisky Association, petitioning for judicial review of the Act. The grounds of petition relating to EU law were incompatibility with Article 34 TFEU, inability for justification under Article 36 TFEU, and incompatibility with the common organisation of the market in wine. This challenge was initially dismissed by Lord Doherty in the Outer House of the Court of Session, where his Lordship held that there was 'objective justification for the conclusion that the alternative measures would be likely to be less effective in achieving the legitimate aims which the minimum pricing measures pursue'.[13] Upon appeal to the Inner House a preliminary reference was made to the Court of Justice of the European Union (the Court), comprised of six questions on the application of EU law.[14] The next section of this piece analyses the Court's response.

## II. Judgement of the Court

Following an Advocate General's Opinion that was generally cautious on the legality of minimum unit pricing for alcohol (MUP),[15] the Court delivered its judgement on 23 December 2015. It can be summarised as a disappointment for public health advocates but not necessarily the end of MUP in Europe. The Court noted that the answer to all questions posed, including the single question on the common organisation of the market in wine, 'specifically concerns the analysis of the proportionality of [the] legislation',[16] and thus an analysis of proportionality constituted the bulk of the judgement.

The Court began by applying the classic case law on Articles 34 (prohibition of quantitate restrictions on imports) and 36 TFEU (circumstances in which derogation from Article 34 is justified). Since MUP erases competitive advantages arising from lower production costs it hinders trade within the meaning of *Dassonville*[17] and is therefore caught by Article 34.[18] In line with case law including *ANNETT*,[19] MUP may be justified under Article 36 on grounds of protection of health and life of humans, but only if appropriate and necessary for achieving the objective pursued.[20] Finally, in line with case law including *Rosengren*,[21] Member States can decide the degree of public health protection they wish to pursue, including whether to implement measures such as MUP, as long as they remain within the limits of the Treaties.[22]

The Court then turned its attention to the proportionality of MUP. The Court first noted that 'it is apparent from the Explanatory Notes that accompanied the draft of the 2012 Act ... and from a recent study entitled "Business and Regulatory Impact Assess-

11 For further detail on the objections raised, see: Oliver Bartlett, 'Distilling prospects: reflections of the proportionality of minimum unit pricing under EU law' 1 European Journal of Risk Regulation [2014], pp. 73 *et seqq*.

12 Commission Communication SG (2012) D/52513.

13 *The Scotch Whisky Association & Ors* [2013] CSOH 70, para 81.

14 See: Aidan Robertson, 'Minimum unit pricing for alcohol in the Court of Justice' 4 European Journal of Risk Regulation [2014], pp. 459 *et seqq*.

15 Opinion of Advocate General Bot, delivered on 3 September 2015, in Case C-333/14 *The Scotch Whisky Association and Others* [2015] ECLI:EU:C:2015:527.

16 Case C-333/14 *The Scotch Whisky Association and Others* [2015] ECLI:EU:C:2015:845, para 28

17 Case C-8/74 *Procureur du Roi v Dassonville* [1974] ECLI:EU:C:1974:82

18 note 16, at paras 31-32

19 Case C-456/10 *ANETT* [2012] ECLI:EU:C:2012:241.

20 note 13, at para 33

21 Case C-2170/04 *Rosengren and Others v Riksåklagaren* [2007] ECLI:EU:C:2007:313

22 note 16, at para 35

ment", that that legislation pursues a twofold objective',[23] namely of reducing harmful and hazardous consumption specifically and population consumption generally – a twofold objective that the Lord Advocate confirmed in the hearing.[24] The framing of the Act's objectives was crucial. The Scottish Government allowed the Court to misinterpret the targeting of the Act and assume that reducing consumption specifically and generally were equal objectives, when in reality MUP targets hazardous and harmful drinkers while incidentally reducing population consumption.

On the question of appropriateness, the Court held that it was not unreasonable to consider that MUP, 'the very specific aim of which is to increase the price of cheap alcoholic drinks, is capable of reducing the consumption of alcohol, in general and the hazardous or harmful consumption of alcohol, in particular'.[25] Thus, the appropriateness of MUP in achieving both general and specific objectives of public health protection was not in doubt for the Court.

On the question of necessity, the Court started by pointing out that tax, a measure that is less trade restrictive than MUP, is an important tool for discouraging alcohol consumption, and that raising the price of alcoholic beverages to a high level 'can adequately be pursued by their increased taxation, since increases in excise duties must sooner or later be reflected in increased retail selling prices, without impinging on the free formation of prices'.[26] This is questionable reasoning. The Court cannot know with certainty that industries *will* pass on tax rises in full to the consumer,[27] and therefore that taxation will be effective as intended.

The Court continued to factor misunderstandings of public health practice into its proportionality analysis. The Court supported its reasoning on the general effectiveness of taxation with case law on tobacco taxation, but then held that:

> 'the fact that the case law cited in the preceding paragraph concerns tobacco products does not mean that it is inapplicable to the main proceedings, which concern the trade in alcoholic drinks. In the context of national measures which have as their objective the protection of human life and health, and irrespective of the particular characteristics of each product, an increase in the prices of alcoholic drinks can be achieved, as was the case with respect to tobacco products by increased taxation'.[28]

This reasoning is unsatisfactory from a public health viewpoint – the particular characteristics of products are crucial when determining the desirability of public health measures, including taxation. Tobacco-containing products always cause harm when consumed, and are relatively homogenous in terms of the purpose they fulfill for the consumer. Alcoholic beverages do not always cause harm, are an extremely heterogeneous product, and serve a variety of consumption desires. Raising the price of tobacco in order to discourage consumption is desirable in every circumstance. However this is not the case for alcohol, since even tax increases within certain categories of beverage cannot effectively discriminate between the variety of products and the ways in which they are consumed – some of which do not need to be discouraged. A large increase in tax of the kind envisaged by the Court would be liable to raise the price of beverages for which discouragement of consumption is not necessary, warranted or likely to occur, such as with respect to more expensive, non-mass market and bespoke products.

It is submitted that the Court was misguided in applying the case law on the public health effects of tobacco taxation to alcohol taxation without question. The Court's subsequent implication that MUP is unnecessary for securing general and specific price rises on alcoholic beverages due to the availability of a less trade restrictive measure such as taxation was therefore a disappointing one, in view of the questionable effectiveness of a blunt measure such as taxation in securing specific objectives of reducing LPHS alcohol consumption.FUßNOTE 300 NICHT GEFUNDEN This is especially so in view of the Court's later statement that governments are not under an obligation to 'prove, positively, that no other conceivable measure could enable the legitimate objective pursued to be attained under the same conditions'.[30]

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23 note 16, at para 34

24 note 16, at para 34

25 note 16, at para 36.

26 note 16, at para 44

27 Jenny Chalmers et al, 'Real or perceived impediments to minimum pricing of alcohol in Australia: public opinion, the industry and the law' 24(6) International Journal of Drug Policy (2013), pp. 517 *et seqq*.

28 note 16, at para 45

30 note 16, at para 55

Mistaken or not in its conclusion that taxation is an equally effective public health tool whatever the product, the Court then proceeded to state that the fact that increased taxation affects harmful and moderate drinkers alike 'does not appear, in the light of the twofold objective pursued by the national legislation at issue in the main proceedings ... to lead to the conclusion that such increased taxation is less effective than the measure chosen'.[31] The additional benefits offered by taxation of contributing to general objectives 'not only cannot constitute a reason to reject such a measure, but is in fact a factor to support that measure being preferred'.[32] This led the Court to the inexorable conclusion that 'Articles 34 TFEU and 36 TFEU must be interpreted as precluding ... the option of legislation ... which imposes an MPU ... and rejecting a measure ... that may be less restrictive of trade and competition'.[33] This conclusion feels distinctly unsatisfactory from a public health perspective.

However from a legal perspective this decision was somewhat inevitable. By telling the Court that there is a general, albeit secondary, objective pursued by the Act, the Scottish government led the Court to frame its analysis in terms of a twofold objective. The Court's analyses in alcohol control cases have tended to be economically oriented,[34] and this case is no exception. If price rises constitute an effective public health tool in general, and taxation raises the price of drinks consumed by the specific and general target populations without being as restrictive of trade as MUP, and the stated objective of intervention is both specific and general, it was not surprising that the application of an economically oriented internal market analysis led to the conclusion that MUP is a potentially disproportionate restriction on trade when taxation is also available.

Despite this, there may yet be hope for the Scottish government. At the brink of an outright declaration that MUP is disproportionate, the Court stayed true to its *Gourmet*[35] judgement and declared that 'it is however for the referring court, which alone has available to it all the matters of fact and law pertaining to the circumstances of the main proceedings, to determine whether ... [taxation] is capable of protecting human life and health as effectively [as MUP] ... while being less restrictive of trade'.[36] The Court confirms that it is, in the end, the national court who must decide whether the summary of the law given by the Court is actually applicable to the Scottish circumstances specifically. This may throw a lifeline to the Scottish Government, who now have a second chance to present all of the evidence on MUP with maximum clarity, and to emphasise the targeting of the 2012 Act to the Court of Session – provided the Court of Session can be persuaded, of course.

## III. Implications for Alcohol Control Policy

The judgement of the Court in *Scotch Whisky* is good and bad news for public health advocates. The bad news is that the judgment clearly demonstrates the CJEU's lack of understanding of the comparative effectiveness of public health interventions, and its conviction that taxation should be preferred if price measures are desirable for public health protection. There was an air of ambivalence towards MUP in the Court's analysis, the Court being clear that internal market principles would be breached if MUP is adopted in the face of equally effective and less trade-restrictive measures. The Court also demonstrated a willingness to prioritise the protection of economic freedoms over protection of public health in this case. There is nothing to suggest that the Court would change this economic approach when confronted with other ambitious public health strategies. From this judgement we can gather that either the Court is happy to pay little attention to the public health imperatives that interact with internal market imperatives in national decisions to adopt laws that might restrict trade – or that national governments are still not particularly competent at leveraging public health imperatives to argue for the proportionality of their laws.

Disheartening though the Court's decision in *Scotch Whisky* may be at first, public health advocates might still take solace from the judgement. It is possible to compare this case to the infamous *To-*

31 note 16, at para 47

32 note 16, at para 47

33 note 16, at para 50

34 Ben Baumberg and Peter Anderson, 'Health, alcohol and EU law: understanding the impact of European single market law on alcohol policies' 19(4) European Journal of Public Health (2008), pp. 392 *et seqq*.

35 Case C-405/98 *Konsumentombudsmannen v Gourmet International Products* [2001] ECLI:EU:C:2001:135.

36 note 16, at para 49

*bacco Advertising 1*[37] judgement, with respect to the mechanical reasoning employed. The Court essentially held in *Scotch Whisky* that if a twofold objective is pursued, MUP is a disproportionate response. The implication beneath the surface of the judgement is relatively clear – pursuit of a targeted objective *only* may result in MUP being proportionate. In similar fashion to *Tobacco Advertising 1*, the Court did not particularly dispute the public health credentials of MUP, merely how it was mapped onto the stated objectives. Thus, it might be tentatively concluded that if another, more closely targeted MUP measure were to be brought before the Court, the conclusion on its proportionality may be more favorable. This possibility is encouraging for other governments that are considering implementing a minimum unit price for alcohol – if they were to rigorously ensure that the targeting of their measure is clearly and specifically concerned with harmful and hazardous drinkers *only*, the *Scotch Whisky* judgement might actually build bridges for those governments, rather than burn them.

37 Case C-376/98 *Germany v Parliament and Council* [2000] ECLI:EU:C:2000:544

# Another Step towards a Definition of 'Implementing Measures'?

*Camilla Buchanan and Luca Bolzonello**

*Case T-397/13, Tilly Sabco v Commission, Judgment of the General Court (Fifth Chamber) of 14 January 2016, ECLI:EU:T:2016:8*

*Article 263 TFEU allows applicants to challenge regulatory acts which are of direct concern to them and do not entail implementing measures. In this judgment the General Court held effectively that the implementing measure cannot be hypothetical but must follow-on naturally from the underlying regulatory act. This note discusses the significance of this seemingly new element in the meaning of 'entail implementing measures' and its potential consequences.*

## I. Introduction

Article 263, paragraph 4, TFEU, introduced by the Lisbon Treaty, allows natural and legal persons to challenge regulatory acts which are of direct concern to them and do not entail implementing measures, without the need to establish individual concern. The EU Courts have been gradually interpreting the new provision.[1]

The present writers have recently commented on the judgment of the Court in *T&L Sugars*, which clarified that the degree of discretion afforded to implementing authorities is irrelevant when determining the existence of implementing measures.[2] This case note follows on from that commentary with a short analysis of the judgment from the General Court of 14 January 2016 in *Tilly Sabco v Commission*. The General Court has now added a further dimension to the definition of 'entail implementing measures': in order to qualify as such, implementing measures must be adopted by the relevant authority 'during the normal course of affairs' and follow 'naturally' from the underlying regulatory act. After a summary of the judgment, this note discusses what it contributes to the admissibility requirements for actions directed against regulatory acts.

## II. Facts

Tilly-Sabco is a French company which exports frozen chicken to the Middle East. On 6 August 2013, it brought an action for annulment before the General Court challenging a measure adopted by the Commission in the context of the EU rules for the common organisation of agricultural markets, namely export refunds for poultry meat.[3] It also requested interim relief, which it did not obtain.

Under the Single CMO Regulation,[4] certain agricultural products can benefit from export refunds

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1 Most notably, the Court defined the concept of '*regulatory act*' in Case C-583/11 P, *Inuit Tapiriit Kanatami and Others v Parliament and Council*, EU:C:2013:625, at para. 61. The question of what are '*implementing measures*' has also been broached in several cases, see e.g. Case T-262/10, *Microban International Ltd and Microban (Europe) Ltd v Commission*, EU:T:2011:623; Case C-274/12 P, *Telefónica v Commission*, EU:C:2013:852; Case C-456/13 P, *T&L Sugars Ltd and Sidul Acúcares v Commission*, EU:C:2015:284.

2 C. Buchanan and L. Bolzonello, *Towards a definition of implementing measures under Article 263, paragraph 4, TFEU*, 2015 EJRR 6(4), p. 671-676.

3 The French company Doux SA intervened in support of Tilly-Sabco in this case and also brought its own similar action in Case T-434/13, *Doux v Commission*, EU:T:2016:7. Notably France also brought an action for annulment against the Commission on the same matter in Case T-549/13, *France v Commission*, EU:T:2016:6.

4 Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation), OJ L 299, 16.11.2007, p. 1.

covering differences between global and EU market prices. In July 2013, the Commission adopted Implementing Regulation (EU) No 689/2013[5] which set the export refund to zero for certain categories of poultrymeat with regard to a number of destinations, including whole frozen chicken exports to particular countries in the Middle East. This was the latest in a series of reductions of the export refund which had previously been set at 40 €/100kg and then at 10.85 €/100kg.[6]

The applicant raised five pleas in law against the contested Regulation alleging inter alia procedural irregularities in the adoption of the act, errors of assessment, inadequacy of the statement of reasons and infringement of legitimate expectations. The Commission questioned the admissibility of the action and argued it should be dismissed as unfounded.

The General Court declared the action admissible but dismissed it on the merits. At the time of writing it is not yet known if an appeal will be lodged. The following discussion is limited to the assessment of the admissibility of the case by the General Court.

## III. Judgment of the General Court (Fifth Chamber)

The applicant argued that it had standing to bring the case under the third limb of Article 263, paragraph 4, TFEU (in the alternative, it argued it was directly and individually concerned by the act, in accordance with the second limb of that provision).

The Court started its assessment by holding that the contested act was indeed a regulatory act under the (by now) settled case-law, since it was an act of general application but not a legislative act.[7] The Commission had not disputed that point.

Next, the Court explicitly confirmed that the concept of direct concern has the same meaning under both the second and third limbs of Article 263, paragraph 4, TFEU.[8] It therefore applied the long-standing test for direct concern.[9] As the contested Regulation set the export refund at zero, in contrast to the previous level of 10,85 €/100kg, the General Court held that it directly affected the applicant's legal situation. Moreover, the contested Regulation left no margin of discretion to the national authorities responsible for refunds, as any refund would be zero with no possibility for them to grant more. Accordingly, the Court held that, as the Commission had also conceded, the applicant was directly concerned.[10]

The judgment takes a more interesting turn on the issue of whether the contested Regulation 'entail[s]' implementing measures'. The Court first recalled the reason for the introduction of this condition, namely access to justice. It also recalled that in relation to assessing the existence of those implementing measures, it is only the position of the applicant that matters.[11]

It then stated, somewhat intriguingly, that while the concept of regulatory acts not entailing implementing measures must be interpreted in light of the objective of access to justice, as per existing case law, that this does not mean that the concept must be exclusively examined from such a perspective.[12]

The Court then proceeded to focus on the term 'entail' in the third limb of Article 263, paragraph 4, TFEU. It held that the word 'entail' means that only measures that the authorities (Union or national) adopt during the 'normal course of affairs' can be considered as implementing measures within the meaning of the third limb of Article 263, paragraph 4, TFEU. If no such measures are ordinarily adopted to implement the act and give effect to its consequences ('*concrétiser ses consequences*') for the concerned entities, then the regulatory act in question does not 'entail' implementing measures.[13] The Court

5 Commission Implementing Regulation (EU) No 689/2013 of 18 July 2013 fixing the export refunds on poultrymeat, OJ L 196, 19.7.2013, p. 13 (henceforth the 'contested Regulation').

6 See Case T-397/13, *Tilly Sabco v Commission,* EU:T:2016:8, para. 8-9.

7 *Tilly-Sabco*, *supra,* note 6, para. 30-32; citing *Inuit Tapiriit Kanatami*, note 1 *supra* , para. 61; Case T-18/10, *Inuit Tapiriit Kanatami and Others v Parliament and Council*, EU:T:2011:419, para. 56; and *Microban*, note 1 *supra*, para 21.

8 *Tilly-Sabco*, note 6 *supra*, para. 34.

9 *Tilly-Sabco*, *supra,* note 6, para. 35.

10 *Tilly-Sabco*, *supra,* note 6, para. 36-38.

11 *Tilly-Sabco, supra,* note 6, para. 41, citing *Telefónica*, *supra* note 1, para. 30-31.

12 *Tilly-Sabco*, *supra,* note 6, para. 42.

13 *Tilly-Sabco*, *supra,* note 6, para. 43. The judgment is only available in French at the time of writing (the language of the case). The French text states: *« Cela signifie que peuvent seulement constituer des mesures d'exécution au sens de cette disposition des mesures que les organes ou organismes de l'Union ou les autorités nationales adoptent dans le cours normal des affaires. Si, dans le cours normal des affaires, les organes ou organismes de l'Union et les autorités nationales n'adoptent aucune mesure pour mettre en œuvre l'acte réglementaire et pour concrétiser ses conséquences pour chacun des opérateurs concernés, cet acte réglementaire ne « comporte » pas de mesures d'exécution* ».

then underlined that according to the wording of the third limb of Article 263, paragraph 4, TFEU it is not sufficient that an act 'could entail' implementing measures, rather that it must so do.[14]

With reference to various language versions of the provision, the Court held that the wording implies that in order for a regulatory act to 'entail' implementing measures those implementing measures must 'naturally follow the regulatory act'. It is not sufficient that an operator has the possibility to oblige, in an artificial way, the administration to adopt a challengeable measure, since such a measure is not one which the regulatory act entails.[15]

On that basis, the General Court proceeded to examine whether, during the normal course of affairs, national authorities would adopt measures to implement the contested Regulation. It considered that economic operators wishing to export agricultural products not benefitting from a refund were not obliged to present an export certificate and to request a refund amounting to zero. The Commission also essentially conceded that economic operators did not usually do so. In other words, during the 'normal course of affairs' national authorities would adopt no measures to implement the contested Regulation, which therefore entailed no implementing measures. The Court considered, in particular, that it would be 'artificial' to require the operators concerned to request the payment of a refund amounting to zero simply in order to be able to obtain a challengeable measure.[16]

Finally, the Court dismissed the Commission's argument that it would be paradoxical to find that parties can have standing to challenge a regulatory act such as the one in question when it sets the refund to zero, while a positive refund would entail implementing measures. The Court recalled that, according to case-law, when assessing the existence of implementing measures it is the position of the applicant that matters, and that it is irrelevant whether there are implementing measures affecting other persons.[17] *A fortiori*, the General Court considered that it is entirely possible that a regulation setting the amount of refunds to zero would not entail implementing measures, while a 'similar' regulation fixing positive refunds would.[18]

The action was therefore found to be admissible. The applicant, however, lost on the merits. While interesting from the perspective of administrative law, a discussion on the merits of this case would go beyond the remit of this case note.

## IV. Comments

It is helpful at this point to recall some of the main tenets of the existing case-law on the phrase 'entail implementing measures'.

The case-law has developed certain tests to determine whether a regulatory act entails implementing measures. First, it is only the position of the applicant that matters, it being irrelevant whether there are implementing measures affecting other persons.[19] Secondly, the degree of discretion available to the authorities responsible for the implementing measures is irrelevant.[20] Thirdly, reference should be made exclusively to the subject matter of the action such that in an action for partial annulment it is solely an implementing measure which that part of the act may entail that can be taken into consideration.[21]

The General Court has now added a new element: only measures adopted by the EU or by the Member States during the 'normal course of affairs' can constitute implementing measures within the meaning of Article 263 TFEU. If the Union and national authorities do not ordinarily adopt any measure to implement the regulatory act and to give effect to it vis-

14 *Tilly-Sabco*, *supra,* note 6, para. 43-44

15 *Tilly-Sabco*, *supra,* note 6, para. 45: *« [I]l doit s'agir de mesures qui suivent naturellement l'acte réglementaire. Il n'est pas suffisant qu'un opérateur ait la possibilité d'obliger, de manière artificielle, l'administration à adopter une mesure susceptible de recours, car une telle mesure ne constitue pas une mesure que l'acte réglementaire « comporte ». »*

16 *Tilly-Sabco, supra,* note 6, para. 59 -62

17 *Tilly-Sabco, supra* note 6, para. 65; see also *Telefónica*, note 1 *supra*, para. 65.

18 *Tilly-Sabco*, *supra,* note 8, para. 65: *« À plus forte raison, il n'est pas exclu qu'un règlement fixant à zéro le montant de restitutions ne comporte pas de mesures d'exécution, tandis qu'un règlement « similaire » fixant des restitutions à un montant positif en comporte. »*

19 *Tilly-Sabco*, *supra,* note 6, para. 41-42, citing *Telefónica*, *supra*, note 1, para. 30-31. See also *T&L Sugars*, *supra,* note 1, para. 32, and Case C-132/12 P, *Stichting Woonpunt and Others* v *Commission*, EU:C:2014:100, para. 50.

20 See C. Buchanan and L. Bolzonello, *Towards a definition of implementing measures under Article 263, paragraph 4, TFEU*, 2015 EJRR 6(4), p. 671-676; see also Case T-279/11, *T&L Sugars Ltd and Sidul Açúcares v Commission*, EU:T:2013:299, para. 49-50; cf. *Tilly-Sabco*, *supra,* note 8, para. 43.

21 Case C-84/14 P, *Forgital v Council*, EU:C:2015:517, para. 52.

à-vis each concerned operator, the regulatory act in question does not 'entail' implementing measures.[22]

It would be artificial for a concerned operator to make a request to the relevant authority to pay a refund amounting to zero only for the purpose of obtaining a challengeable act, therefore the granting of that request (which would be obligatory for the authority) would not happen in the normal course of affairs.[23] In so holding, the Court built on the principle that the concept of entailing implementing measures must be looked at from the view of the applicant. However its reasons for so doing are not entirely clear from the judgment and therefore it remains to be seen if, and how, this approach will be developed in future.

The Commission's argument that it is 'paradoxical' to allow direct actions when the refund is zero, but to require national action when the refund is positive, was briefly dismissed by the General Court on the basis of the fact that the existence of implementing measures must be assessed with reference to the position of the applicant.[24] The case was therefore declared admissible despite the fact that the forum in which the relevant regulatory act can be challenged may thus come to depend on the level of the refund.

This curious situation may be due to the fact that this case regards the lowering of an entitlement to zero, rather than the placing of obligations on an economic operator which would more readily give rise to an implementing measure, such as in the case of custom duties.[25]

Overall, the finding of the General Court on admissibility in this case hinges on a literal reading of the term 'entail' and may raise mixed feelings. On the one hand, requiring an assessment of whether a certain implementing act would follow-on naturally from a regulatory act can be viewed as introducing a further and unnecessary element of complexity in Article 263, paragraph 4, TFEU. On the other hand it can be viewed as a victory for common sense.

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22 *Tilly-Sabco*, *supra,* note 6, para. 43.

23 *Tilly-Sabco*, *supra,* note 6, para. 62.

24 *Tilly-Sabco*, *supra,* note 6, para. 64-65.

25 See for example C-552/14 P, *Canon v Commission*, EU:C:2015:804, paras. 50-51.

# Book Reviews

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*EU Chemicals Regulation: New Governance, Hybridity and REACH*
by Steven Vaughan
Cheltenham: Edward Elgar Publishing, 2015, 259 pp.
€ 123,06

*Apolline Roger**

The first thing I would like to say about this book might seem frivolous - but it is not. Steven Vaughan has mastered the art of storytelling. Such a skill makes one very popular around a campfire. It is also extremely handy when one ambitions to write a detailed *and* easily readable book on the EU Chemical Regulation 'REACH'. The '*and*' should not be underestimated. Do not get me wrong, REACH (which stands for Registration, Evaluation, Authorisation and Restriction of Chemicals) is a fascinating regulation. Toxic pollution is one of the most important environmental and health issues of our time, and the extent of our 'toxic ignorance' is puzzling. REACH was a courageous regulatory innovation, adopted at the end of entrenched battles involving powerful industry lobbies from the EU and the US, as well as the US government and NGOs. Under REACH, an entity manufacturing or importing more than one tonne/year of a chemical substance has to register it to be allowed to access the European market. The heart of REACH, at least on paper, is therefore the production and diffusion of data on the intrinsic properties of chemical substances. It also sets out the procedures to limit the use of a given substance ('Authorisation') or to ban it ('Restriction') when it poses an unacceptable risk.

However fascinating, REACH is dry, extremely long, complex and technical. REACH has been discussed by academics, but very few venture inside the beast even though, as is often the case, the devil lies in the detail[1]. Furthermore, and this is the whole focus of Steven Vaughan's ambitious book, REACH has a life which extends far beyond the provisions of the regulation. The European Chemical Agency (ECHA) and several other actors are adopting a daunting amount of implementing guidance documents. This post-legislative soft law production has been mainly ignored by academics.

Steven Vaughan had the courage to analyse these numerous and lengthy (as he reiterates many times, citing the number of pages and words involved) documents. He digested them and, without minimising or hiding the true complexity of the matter, explained the normative system they create in an insightful, engaging and simple way.

## I. Objectives

The objectives of the book are twofold. The first is to offer an explanation of the REACH regulation enriched by a detailed understanding of the soft law adopted to guide its implementation. Such an understanding is rare, and the book is of unprecedented depth on the topic. The book usefully unveils the practicalities of the implementation of REACH, a reality truly difficult to uncover considering the number and length of guidance documents. It is an example of rigour and clarity. This book will certainly be a stepping stone for other studies of the REACH norms constellations, not least to answer the multiple and fascinating questions sign-posted by the author.

The second objective of the book is to analyse to what extent REACH guidance documents, as a case

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1 Two recent volumes are however all about the details – see Lucas Bergkamp (ed.) *The European Union REACH Regulation for Chemicals: Law and Practice* (Oxford: Oxford University Press, 2013) and Dieter Drohmann and Matthew Townsend (ed.) *Best Practice Guide to Regulation (EC) No 1907/2006* (Oxford: C.H. Beck/Hart/ Nomos, 2013).

study of post-legislative soft law, confirms and/or challenges the existing 'new governance' scholarship. The author sets out, in particular, a classification of REACH post-legislative soft law according to several criteria (authorship, forms, addressees, acceptance, function, genesis, review, impact, coverage). The main contribution to the new governance scholarship is the elaboration of a more nuanced taxonomy of the functions of post-legislative soft law. Four are identified:

– 'Amplification' (guidance goes beyond but respects the text of the regulation);
– 'Standardisation', a subset of amplification (the guidance prescribes a behaviour not specifically set in the regulation);
– 'Translation' (the guidance contradicts a clear provision of the regulation); and
– 'Extrapolation' (the author aims at filling a gap he/she/it identified in the regulation).

These functions are usefully employed throughout the book to classify and clarify the analysed guidance documents. However, the terminology could offer a more immediate comprehension of what each function covers. 'Amplification' is used to describe a situation where optional advice is offered (in contrast with 'standardisation', which concerns the prescription of a precisely described behaviour). A term other than 'Amplification' might have given a more intuitive and immediate comprehension of the reality it designates and of how it differs from 'standardisation'. More importantly, the word 'Translation' can be misleading when used to describe a soft law document which contradicts a clear provision of the hard law it is supposed to help implement. This is especially the case when the author of the guidance document is not the author of the regulation it aims to implement and might not have the power to amend it. Public authorities adopting soft law often tend to be strategically quite vocal on its lack of binding effect, maybe to detract attention from the fact that they adopt influent acts without adequate accountability mechanisms and transparency. A translation is innocuous; it respects the meaning of the main text. Using this term may not be the most efficient way to shine light on a contentious practice.

However, finding an adequate label is a deeply difficult exercise. And in the same way that 'a rose by any other name...', my disagreement is only with the labelling. The differentiation itself, between these four functions, is a precious tool for future new governance studies. It helps better understand the potential impact of soft law in practice and the intention of its authors. Last but not least, it reveals the variety of relationships between hard law and soft law when they are 'yoked', i.e. so deeply bound that a 'hybrid' is created.

The main strength of the book, and what I am sure must have made it a seriously difficult project to complete, is that each contribution to the new governance theory is deeply grounded in a rigorous, detailed, skilful and informed analysis of the practice. The structure of the volume reflects this methodology.

## II. Structure and Content

As advised by Steven Vaughan, Chapters 2 and 3 can be skipped by readers already accustomed to REACH and more generally to the chemical policy debate. However, they will be indispensable for others. Chapter 2 presents the scientific and political background of REACH. By doing so it emphasizes why reducing our 'toxic ignorance' - REACH's aim - is a truly ambitious and complex enterprise. Our knowledge of the characteristics and impacts of chemicals is still limited, as is our capacity to gather adequate data. Furthermore, even when data is actually available, REACH has yet to find a way to standardise the format of the data and diffuse it in a way which would make the information useful for public authorities, consumers, downstream users, etc. Building on this background, Chapter 3 draws REACH's landscape. It gives an overview of the institutions and of the main obligations REACH creates, which are studied in-depth in the following chapters.

Chapter 4 is the first of five chapters eviscerating the complexities of REACH's institutional and normative architecture. After detailing the functioning of the European Chemical Agency, it explains who is involved in the adoption of REACH post-legislative soft law as well as the scope and variety of this production. A useful typology of the different acts of post-legislative soft law is provided on p. 78-79. Having observed that the procedures for guidance production and amendment lack public participation and transparency, the chapter logically ends with a reflection on accountability. The author confirms

what can be observed in other areas where EU soft law flourishes: the disconnection between the perception of guidance documents by EU Courts and the importance and variety of their practical effects. The data collected will, without doubt, be useful to people interested in the impact of the growing use of soft law on access to justice, public participation and accountability in environmental law.

REACH mandates the sharing of certain data between those manufacturers and importers intending to register the same substance. When they need to do so, they come together in groupings called 'Substance Information Exchange Fora' (SIEFs). Informed by practice and academic reflection, Chapter 5 is a brilliant piece to obtain a concrete understanding of SIEFs and the theoretical significance of this peculiar structure of cooperation between enterprises. It identifies the gaps in the main regulation that the guidance either tries to fill, effectively fills or ignores – even when guidance would have supported a better functioning of the system. Steven Vaughan therefore identifies the contours of the enterprises' margin of appreciation and reveals the nature and impact of ECHA normative strategy.

Chapter 6 is an extremely rich analysis of the very heart of REACH: the obligations related to the creation, registration and dissemination of information. It addresses a fundamental question: is REACH able to effectively reduce toxic ignorance or will it become a box ticking exercise with little impact on both the capacity of public authorities to identify dangerous substances and of the public to better control their exposure? More than ever, the deep analysis of the guidance opens a window on what is really required from companies. What the analysis reveals is that ECHA focuses on data creation rather than dissemination, on information flows between companies rather than between companies and employees/consumers/the public. REACH's heart, the creation of information, is not beating as it should to drastically reduce toxic ignorance. As brilliantly evidenced by Steven Vaughan, the information is presented in a format that is difficult to exploit and is often of very poor quality. The guidance document and enforcement procedures set by REACH do not seem to be able to address this issue.

Chapter 7 highlights what might be the main weakness of REACH: the disconnection between information generation and regulatory action. Only 5% of the registration dossiers are checked; the registrants have no obligation to notify the authority when they identify an unreasonable risk; and the quality and format of the information are a barrier to an easy review for regulatory action. The registration could be, but is not, used as a tool to gather toxic knowledge to ground decisions to restrict harmful chemicals. Steven Vaughan rightly qualifies the situation as 'worrying, and a waste of regulatory effort' (p. 163). Chapter 7 exposes the practical issues in the Authorisation and Restriction processes. It also points out evidence of the significant influence of ECHA guidance, which shapes, usefully but not always for the best, the Authorisation and Restriction processes.

Chapter 8 demonstrates that surprisingly little guidance has been developed at EU level on the enforcement of REACH by the Member States. Despite some effort of harmonisation and the existence of an enforcement cooperation forum, it is not clear whether the mechanisms developed under REACH will effectively support the creation of a level playing field for chemical manufactures and importers. A study of the UK enforcement system further illustrates the complexity of ensuring an effective, multi-level implementation.

Chapters 9 and 10 build on the data collected in the previous chapters to draw together the lessons learned from the analysis of REACH as a 'hybrid' for the new governance scholarship. REACH soft law assumes multiple forms. It deals more comfortably with obligations of enterprises (or of the Member States) than with the rights of the general public, which it tends to ignore. Most of the soft law aims at extrapolating the hard law obligations or standardising the ways in which they are implemented. However, ECHA has adopted guidance which contradicts the main regulation to shape essential aspects of implementation.

In addition, the author highlights the ways in which REACH post-legislative soft law challenges some aspects of the new governance scholarship. Is REACH peculiar? Or is the extent of the soft law adopted to support its implementation the reason why more variety can be identified? Whatever the reason, REACH shows that if private persons are involved, soft law production remains mostly in the hands of public authorities which defies the common 'privatisation' observed in new governance case studies. Even more interestingly, REACH hybridity challenges several of the 'positive' assumptions frequent-

ly underlying the analysis of the new governance phenomenon. First, an increase in transparency is not a by-product of new governance. It is a basic requirement of good governance, but is far from being systematically respected. Second, instruments of new governance are not necessarily more consensual and non-hierarchical. REACH shows the exact opposite. Some documents contain an explicit waiver informing of the absence of consensus and a hierarchy exists between the different forms of soft law. Last but not least, seeing new governance as a solution to the limits of traditional EU law might be misleading. REACH post-legislative guidance often mirrors hard law provisions in everything but their binding effect. It does not embed an innovative method of action; it simply ensures that what was not specified by the legislator can be detailed downstream. Steven Vaughan rightly qualifies this as a necessity, but is soft law the best media for this endeavour? This important question becomes essential when looking at the lack of justiciability, of transparency, of public participation and the on-going debate on the legitimacy of soft law. Another question is the legality of the guidance. The author notes that 'one might question whether there is an element of competence creep in ECHA's approach' and 'whether the Agency has overstepped its generic mandate' (p. 232). Unfortunately this question is raised but left unanswered, which seems problematic given that the book evidenced the adoption of guidance contradicting the main regulation. The Treaties have been interpreted by the Court as opposing a fundamental limit to the power of EU Agencies[2]. This question is essential as it comes down to whether EU authorities can escape the procedural and substantive limitations framing the adoption of hard law by simply giving to a very prescriptive document the label of 'guidance'. For the same reasons, the discussion of the legitimacy of REACH post-legislative guidance (p. 243-246) could have been usefully developed further. However, not everything can be done in a reasonably sized volume and these remarks are a compliment: it is only because the analysis is so good that the reader wants more.

Finally, the author suggests avenues for further research (p. 233-234) – which I have no doubt will gain a lot from using this volume as an example of excellent methodology, as a collection of insightful findings and as an ambitious contribution to the new governance scholarship.

*Deference in International Courts and Tribunals - Standard of Review and Margin of Appreciation*
Edited by Lukasz Gruszczynski and Wouter Werner
Oxford: OUP, 2014, 464 pp.
£70 GBP

*Filippo Fontanelli**

States must comply with international obligations. When an international court or tribunal has competence to do so, it reviews State acts to determine their legality under international norms. Reviewing State acts is a delicate affair: international adjudication's effectiveness depends on its legitimacy. Legitimacy, in turn, depends on the perception that international bodies ensure compliance with international norms, rather than interfering with State policies and annulling them at will.

In brief, international tribunals must be concerned to display a respectful stance towards States, lest the latter be tempted to consider withdrawing from their jurisdiction. Since jurisdiction by consent is the rule, the prospect is not merely hypothetical. Venezuela's withdrawal from the ICSID Convention and the ongoing debate about the UK abandoning the European Convention of Human Rights show this much clearly. When States dislike how international justice is administered, exit is a realistic option, alongside voice, loyalty and the unlikely tool of neglect.[1]

The spectacle of international judges tiptoeing deferentially around State sovereignty is understandable. One aphorism illustrates it exhaustively:

> Leopards break into the temple and drink the sacrificial pitchers dry; this repeats over and over again; finally it can be calculated in advance and becomes part of the ceremony.[2]

The priests run the temple, but cannot dare to bother the leopards. The result is a ceremony hardwired with deferential rituals. ***Gruszczynski*** and

2 Case 9/56 Meroni v. High Authority [1957/1958] ECR 133; Case 98/80 Romano v. Inami, [1981] ECR 1241, Case C-270/12 UK v. Parliament and Council EU:C:2014:18.

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1 Albert O. Hirschman, *Exit, voice, and loyalty: Responses to decline in firms, organizations, and states* (Harvard university press, 1970).

2 Franz Kafka, *The Zürau aphorisms* [1946] (2006), 20 (our translation).

***Werner*** edited a comprehensive overview of these rituals in international adjudication and arbitration.

***Petersmann*** provides a majestic overview of the topic. Standards of review in different regimes are a function of different norms, practice and circumstances. For instance, the formulation of certain BIT clauses, inherently subject to balancing constructions, makes the review of State measures in investment arbitration different from that carried out by WTO Panels. Nevertheless, insofar as both investment tribunals and WTO bodies administer a 'cosmopolitan legal system'[3] for the management of public goods, their review should always be informed by higher considerations of justice, and the standard should adjust accordingly. ***Cheyne*** zooms in on the EU, WTO and investment fields, tracing a set of recurring techniques used to review States' invocation of public policy exceptions. Deference, generally, is inversely proportional to the degree of institutionalisation of the legal context (in increasing order: investment arbitration, WTO disputes, EU review of MS acts). However, the tools used to dose deference are similar across the systems. The author lists five of them: a presumption that deference is not unlimited, the merits review of public policy, a *de minimis* control, evidentiary and procedural devices.[4] ***Pirker*** zooms back out, exploring the rationale of the review of State action. He posits that the standard depends on the reviewer's ability 'to monitor and review the reconciliation of values found by a first-level decision-maker'[5] and that the chosen standard requires justification along such lines. When, in the domestic process, all interests are represented adequately, the intrusion of the international level is less justified. The author uses John Ely's doctrine of procedural democracy[6] to suggest that international tribunals look into the measure that is up for review, assess whether it represents adequately the values of the underlying community and opt for more incisive review when that is not the case. ***Mamolea***'s chapter takes issue with a specific element of review, that is, the analysis of a State's good faith. Whereas bad faith is normally not an essential element of wrongfulness, it can assist the tribunal's analysis and therefore is often scrutinised. The author laments the lack of legal tools available to tribunals which tread the area of States' intentions: whereas practice generates deference in certain instances (tribunals normally afford States a presumption of good faith, and pay little attention to propensity evidence and adverse inferences) in other cases the review into the facts establishing States' intent is full. The unregulated review of intentions is liable to displease States, and therefore undermine the tribunals' authority.[7]

***Ioannidis*** discusses the deference displayed by WTO panels and Appellate Body. He correctly starts by saying that, outside the field of antidumping, all review of WTO-legality is carried out according to the generic standard centred on the 'objective assessment of facts'.[8] This under-defined standard harbours several techniques of deference (or lack thereof), which are singled out and analysed. The author praises the review of the procedural quality of national decisions, mainly in terms of participation and due process.[9] He goes as far as suggesting that national measures that take into account foreign interests should typically resist review, even if it is acknowledged that the selection of the relevant interests would be arduous. ***Henckels*** embarks on a similar analysis of a different regime, that of investor-State arbitration. In the absence of statutory instructions, only casuistry accounts can illustrate the relevance of deference. NAFTA tribunals appear on average to afford more deference, possibly for systemic reasons, whereas the record of non-NAFTA tribunals is mixed, as the diverse approach towards Argentina's conduct during the financial crisis shows. The author engages in a comparative study of international judiciaries to identify some trends of deference. The overview reveals certain recurring rationales for deference to State authorities, hinging on considerations of regulatory autonomy, proximity and expertise.[10]

***Leonhardsen*** discusses the treaty-change that States undertake to react to intrusive standards of review. By inserting exceptions and narrowly worded obligations in their investment treaties, States increasingly seek to reduce the intensity of the review

3 37.

4 41.

5 59.

6 John Hart Ely, *Democracy and distrust: A theory of judicial review* (Harvard University Press, 1980).

7 87.

8 *Appellate Body Report, United States* – Continued Suspension of Obligations in the EC – Hormones Dispute, WT/DS320/AB/R, adopted 14 November 2008, para 177.

9 110.

10 134.

exercised by tribunals. States, through these clauses, try to benefit from the epistemic deference[11] that, for instance, the European Court of Human Rights affords to domestic decisions reached through responsible decision-making procedures. Interestingly, how these provisions should operate is shown through past arbitral decisions (issued applying old-style investment instruments), which seems to suggest that the changes might be redundant, or inserted just for greater certainty. In their chapter, ***Gruszczynski*** and ***Vadi*** address the international review of scientific determinations of domestic actors. The authors negotiate the terminological limbo evinced in the previous chapters: WTO bodies and investment tribunals use undefined degrees of deference. The difficulty increases when the authors challenge the express characterisation of the reviewers: in the WTO *Apples* cases (against Japan and Australia), for example, the authors claim that *de novo* review was carried out,[12] despite panels and AB's express reassurances to the contrary. This divergence creates terminological fuzziness: whereas the AB is said to endorse a 'relative intrusive'[13] review, it is then stated that the WTO rejects 'the idea of an intrusive *de novo* review'.[14] Only experienced readers can grasp the relevance of the various shades of review mentioned and appreciate the authors' findings. The chapter concludes that investment tribunals, which focus their review on the procedural integrity of decision-making, do a better job than WTO bodies, which scrutinise its correctness. **Dąbrowska-Kłosińska** picks up the baton and analyses the same topic, but from the Luxembourg's perspective. She explains that the Court of Justice of the EU claims to limit its review to the plausibility of the evidence presented by domestic authorities and to its procedural integrity. However, this limited review often encroaches on the factual findings, therefore intruding on the determinations made by domestic authorities.[15]

***Van Cleynenbreugel***'s chapter observes the standard of review used by the Court of Justice of the EU to assess whether domestic procedural rules (which States can design autonomously) breach EU law. Four degrees of review intensity are identified,[16] each with a different structure and widely different implications, which accurately illustrate how the Court modulates its mandate to override domestic law when States fail to sustain 'the process of European integration'.[17] As the conclusion notes,[18] however, nothing in the different standards allows predicting which applies in a given case. ***Herwig*** and ***Serdarevic*** draw a comparison between the use of necessity and proportionality in WTO law and in EU law, limitedly to the application the exceptions to free trade provisions. The Court of Justice declines these devices with different intensity when reviewing domestic measures (more stringent) or EU measures (more deferent). The analysis of WTO case law is conscientious if restricted to a handful of Art. XX GATT cases. The authors' conclusion is that the deference afforded to EU acts should extend to State acts, especially over questions of factual and normative uncertainty.

The section on human rights opens with ***Ambrus***'s analysis of the ECtHR's case-law on the margin of appreciation and the attending evidentiary standards. She notes that the Court's review is consistently strict when assessing State's attempts to justify a restriction of Articles 2 and 3 (which contain no express exception). Instead, in cases hinging on Articles 8 to 11, the case-law is difficult to navigate and different standards apply. The author contends that the relative precision of the applicable norms is a plausible predictor of the intensity of the scrutiny in specific cases,[19] but finds that the inconsistencies prejudice the fairness of the Court's jurisprudence. ***Belavusau***'s study assesses the relative deference that the ECtHR pays to domestic judgments in hate speech cases, and the opinions of the experts retained by the domestic tribunals. He notes that only once did the ECtHR question the domestic court's reliance on an expert opinion (case *Balsytė-Lideikienė v. Lithuania*), and that, in general, the Court uses a 'low-to-intermediary' standard of proof for States[20] in these cases, hence offering them a considerable margin of action. The doctrine of equivalent protection (cfr the *Solange* cases, or *Bosphorus*) is explored by ***Bílková***. She gives a diligent account of the emergence of this doctrine

11 146.
12 158.
13 165.
14 169.
15 205.
16 185.
17 191.
18 Ibid.
19 252.
20 268.

up to the *Bosphorus* and *MSS* cases before the Strasbourg court, to then assess the applicable standard of review in the ECtHR's determination of whether other international systems, and the EU in particular, guarantee a 'comparable' level of protection of human rights. The chapter also asks whether the *Bosphorus* presumption could be maintained after the EU's accession to the ECHR. The chapter's timing is unfortunate not just because it cannot discuss the implications of Opinion 2/13, but also because it misses the chance to analyse those cases in which the *Bosphorus* presumption was lifted (e.g., *Nada*, *Al Dulimi*, *Michaud*, *Dhahbi*). ***Duhaime*** shifts the focus on the Inter-American system, and notes that the Inter-American Court has been hesitant to afford deference to domestic authorities. Whereas it has refrained from serving as 'fourth instance' chamber (therefore granting deference to the determinations of impartial domestic courts),[21] it has generally applied the Convention with rigour. This relative intrusiveness, it is argued, depends on the context of systemic violations occurring in the region, which hardly aligns with the notion of appreciation and its link with consensus.

***Ragni***'s analysis delves on the International Court of Justice. After a detour on the reviewability of the acts of the Security Council, she focuses on the review of State acts. A discussion of the cases *Nicaragua*, *Oil Platforms* and *Gabčíkovo–Nagymaros* leads to conclude that the Court affords some deference to States invoking exceptions to escape their obligations, but will review the existence of the attending conditions.[22] This review allows an inquiry into the good faith of the State and prevents abuses of self-judging clauses. ***Rayfuse*** tackles instead the judicial review of the International Tribunal for the Law of the Sea in prompt release cases. Under review can only be the reasonableness of the bond required for release by domestic authorities, which shall be attested against international standards, using domestic rules and findings only as relevant facts. The Tribunal's practice to lower the bond requested by coastal States has raised doubts to the appropriateness of the intrusive standard adopted.[23] The International Criminal Court's approach to admissibility challenges is discussed by ***Wirczynska***. Admissibility of cases to the Court requires a determination of States' inability or unwillingness to carry out prosecutions (under the complementarity paradigm). Up for review are the identity of the prosecuted persons, conduct and charges across the domestic and international level, and the genuineness of the domestic proceedings. The author praised the Court's tendency to loosen some admissibility criteria over time,[24] to afford more deference to State action (for instance, shifting from a 'same conduct' test to one of 'substantially same conduct'). ***Bernard***'s chapter expands on the application of complementarity, with specific attention to the standards of due process that domestic proceedings must satisfy to fall under Art. 17 ICC and stop the ICC from hearing a case. These requirements interact with the conditions of unwillingness and inability, and present the ICC with the delicate question of whether the interest of combating impunity can supersede the deference towards procedurally imperfect domestic decisions.

The format of this collection, inevitably, lends itself to repetition and perhaps this book is best consumed in targeted chapter-reading than cover to cover. What is striking is less the occurrence of repetitions than the relative lack thereof. With many authors engaging into the treatment of topics that are often identical, at least in part, it is revealing and somewhat frustrating that a unitary approach eludes these competent attempts. Therefore, this book might be disorienting for the non-experts, faced with different but equally plausible approaches to the same ideas – which diverge also in their outcomes without falsifying each other. Conversely, those with some knowledge of the WTO, EU, ECHR and investment legal regimes are in for a real treat, and will find here a veritable banquet of food for thought. Even if this collection cannot benefit from the substantive and methodologic cohesion of a monograph, it serves its readers well, providing a disciplined and learned brain-storming over an intrinsically volatile subject of inquiry. The chapters on ICJ, ITLOS and ICC are a bit out of context but are certainly valid if taken on their own merits.

The editors are to praise for taming, to the extent practicable, an intractable topic. The predictable effect of this effort is that, at times, the chapters highlight the fuzziness of the tantalizing notions studied, instead of clarifying their nature.

21 291.

22 326.

23 353.

24 365.

# REACH CONFERENCE

## Prague-Pruhonice, Czech Republic, May 16-17, 2016

### In cooperation with the Ministry of Environment of the Czech Republic

Lead organizer:

Ekotoxikologické centrum CZ s.r.o.
www.reachconference.eu;
conference@ekotox.eu

In cooperation with:

**REACH Conference Prague 2016** is organized for the ninth time combining lecturers and participants from different sectors of industry, authorities, experts and other stakeholders. REACH registration 2018 deadline is coming closure and authorisation process is getting on full speed. Subsequent duties for downstream users in the supply chain are under implementation. Exposure scenarios and e-SDSs are of challenge for all of involved.

Further restrictions are applied by revision of Annex XVII. Corap for REACH Regulation is proposing further activities for REACH players...

**Overlap with other legislation will be a matter of further development where different directorates and sectors are involved. Difficulties as well as good practices will be discussed.**

**We focus also on REACH and CLP implementation in Small and Medium Enterprices (SMEs).**

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**During the Conference the most important topics will be discussed:**

- **REACH 2018 REGISTRATION DEADLINE**
- **Authorisation**
- **REACH & Articles**
- **SDS / E-SDS and Exposure Scenarios**
- **Downstream Users Duties & Communication**
- **REACH Legislation Enforcement**

The REACH Conference Prague in year 2016 will include a session focused on REACH enforcement and a block of practical presentations in the area of automotive industry, metals industry, chemicals distributors and downstream users and tools for REACH and CLP compliance...results of Exchange Network on Exposure Scenarios (ENES) meeting...

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ISSN: 1867-299X