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Novelty, ignorance and the unknown: Uncertain science and the frontiers of science doctrine

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Abstract

This paper examines the historical boundaries of relying upon risk assessment as the bedrock of environmental law. It does so by revisiting a number of historical environmental and public health cases that illustrate the ebbs and flows of judicial and regulatory insights into uncertain science. The paper concludes that the current approach to dealing with scientific uncertainty and doubt based on risk and quantification in environmental law is flawed. A fresh look at the frontiers of science doctrine which developed the link between, novelty, uncertain science and ignorance requires fresh appraisal. Without this key doctrine in place neither a precautionary approach nor the EU's precautionary principle can function as a driver for key environmental protection.

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Novelty, ignorance and the unknown: Uncertain science and the frontiers of science doctrine

Kathleen Garnett

1 Introduction

This is the first of three papers reconfiguring how environmental law manages and controls high-risk, polluting substances marketed and sold by the risk producing industry.[1] The focus of this opening paper is on how novel, Anthropogenic products and processes produced by the risk industry are proving to be highly damaging to the environment. There should be a general presumption in law that novel, untested, Anthropogenic products, processes, and substances are inherently hazardous to the environment and the public interest.[2]

Future market authorisation and use of such high-risk products should be based on a reformed three-step approach to regulation. The first step is to apply the precautionary principle in cases where an entirely novel, Anthropogenic,[3] and synthetic substance, product or process is seeking market authorisation. The second step is to connect the precautionary principle to a frontiers of science doctrine. This doctrine states that environmental risk regulation can identify high risk products and applications by linking environmental hazard to the novelty, inventiveness, industrialisation, and uniformity criteria established in technological intellectual property rights (TIPR).[4] The third step is the creation of narrowly construed exceptions to the general rule based on essential use principles[5] and emergency need derogations. In essence, the reconfiguration of market access for environmentally high-risk products should be caution based on frontier science and necessity. These papers are written within the context of the European Union's Green Deal and its stated objective of, "*...protecting, conserving and enhancing the EU's natural capital, and protecting the health and well-being of citizens from environment-related risks and impacts*".[6]

2 Evidence of harm from novel, synthetic substances

Novel, synthetic, substances, products, and processes invented, marketed, and sold by the risk producing industry have been in use for over a century. This has given mankind sufficient time to assess their overall effect on the environment and biosphere. The evidence is clear. Novel, Anthropogenic, and synthetic substances, products, processes, and mixtures more often than not harm the environment and biosphere even under managed and controlled conditions. It is no longer a question of *if* harm will emerge from such products but a question of when, where and how.

2.1 Evidence of their harmful impact on the biosphere

Two reports prepared by the European Environmental Agency (EEA) in 2001 and 2013 'Late Lessons from Early Warnings'[7] prove that core synthetic products and processes initially assumed 'safe' and authorised for use turned out to be anything but. The novel, manmade products or processes discussed in the EEA report include i.a. benzene, radium, asbestos, GMO's, nanotechnologies, lead in petrol, vinyl chloride, biocide antifoulants, ethinyl oestradiol and seed-dressing insecticides. In the 2013 EEA report Hanson and Tickner[8] conducted an empirical analysis to quantify the number of false positives compared to the number of false negatives in environmental regulation. They show that of the eighty-eight cases selected for research only four cases turned out to be minor risks for which limited regulation was necessary. The remaining eighty-four cases studied were instances where early warnings were raised but no preventative or timely regulatory action was taken to protect the public interest. In over 70% of the cases analysed the authors concluded that the substances under consideration were either real risks, risk-risk trade-offs or the scientific 'jury is still out'.

Unfortunately, the list of novel substances proving to be far more harmful than initially foreseen does not stop with the last of the EEA reports (2013). The evidence keeps mounting. There is no shortage of scholarship warning that our environment is extremely vulnerable in spite of assurances that a risk assessment has the wherewithal to control and manage the

1 Any industry that is currently required by EU law to undergo a risk assessment in public health or environmental law is defined in this paper as a 'risk' producing industry to distinguish them from industries who are not required to perform such risk assessments. The risk producing industry includes the life science, chemical and energy industries. It does not, for the purposes of this paper, include pharmaceuticals.

2 The public interest in this case applying to non-economic interests namely environmental law and public health law in general.

3 The Anthropocene is generally defined as the human-dominated, geological epoch, supplementing the Holocene. Anthropogenic products, therefore, are manmade, engineered, and invented products, processes and applications. See Crutzen, 2002; Lewis and Maslin, 2015; Pattberg and Zelli, 2016.

4 Most notably technological patents and *sui generis* Community Plant Variety Rights (CPVR).

5 A definition derived from the UNEP, 2019.

6 COM (2019) 640, p. 2.

7 European Environment Agency (ed), 2013.

8 Hansen and Tickner, 2013, pp. 17-37.

danger.[9] Hazardous, persistent chemicals such as PFASs are quietly polluting the air, soil, and water and have done so for decades.[10] Biodiversity has plummeted dramatically over the past three decades.[11] Public health diseases particularly cancer remain a matter of high concern.[12] Non-communicable diseases such as diabetes, cardio-vascular disease, obesity, mental health and respiratory problems from air pollution have over-taken communicable diseases as the major cause of human mortality. According to the UN report on Non-Communicable Diseases, these were responsible "…for 41 million of the world's 57 million deaths (71%). Fifteen millions of these deaths were premature (30-70) years." [13]

2.2 Ever more unknown risks

With over 100 000 industrial chemicals sold globally[14] and an increasing number of novel, Anthropogenic products from the life science industry being commercialised and entering both the specialist and consumer market[15] the examples listed above may be just the tip of the iceberg. As the EEA points out assessing risk is a lengthy process, which for the past decade has focused on known risks and on analysing the usual suspects whilst ignoring the big unknowns of the vast majority of lesser studied chemicals.[16] In short and in spite of well-intentioned EU regulation to monitor and control the use of hazardous chemicals for the vast majority of industrial chemicals in use "*we simply do not know how they pass through the environment, whether they are accumulated, dispersed or transformed, and how they affect living organisms at different concentrations".*[17]

Were there exiting methods based on technocratic decision making and risk evaluation a success there would be no need for the EU to propose a third Chemical strategy and promise a "toxic-free" environment for its citizens. Yet again.[18] It should be stressed at this point that novel, untested, and anthropogenic substances are not unique to chemicals but extend equally to the Life Sciences. Unintended consequences of the use of gene technologies intended for human and non-human consumption on public health and the environment remains speculative due to the novelty of this technology and an absence of sufficient knowledge on cause-and-effect relationships when in widespread use. CRISPR Cas-9 technology is only a decade old yet already there are reports of unforeseen risks from altering the DNA of living organisms when applying this novel technology within cells.[19] Must the public interest wait another century as it did with asbestos before exact causal relationships between CRISPR Cas-9 technology and widespread consumer use can be established as was the case with asbestos or PFOAS?[20] A further example of indirect harm from GMO technology is that in spite of initial assurances this agricultural technology would reduce herbicide use the exact opposite is happening. The massive uptake of GMO technology in Argentina[21] has coincided with an exponential increase in the use of synthetic industrial chemicals in agriculture, not a reduction. Total consumption of agricultural synthetic substances in Argentina has increased from 73 to 236 million kg/year over the last decade with glyphosate accounting for 86.8% of total use.[22] This novel technology has not delivered on its promises.

2.3 Indirect risk

Nor should all of the examples noted above be viewed from a purely *direct* toxicological health, and safety/risk assessment perspective. Separate from health and safety risks many of these manmade substances and their mixtures pose serious, *indirect risks* to the public interest.[23] Such indirect risk are practically impossible to foresee, calculate or quantify. The lack of a quantification matric does not make untested substances any less dangerous to long-term civil society. Indirect risks require equal (if not more consideration) from public administrators when assessing whether to authorise these untested technologies for widespread specialist and consumer use. Consider the example of glyphosate use. Over reliance on industrial, manmade and synthetic substances to control pests and/or fertilise soil means

9 Oliver et al, 2021, pp. 152-163; European Environment Agency, 2019.
10 Ritcher et al, 2018; Cousins et al., 2019; SWD(2020)249; Garnett and Van Calster, 2021. The dangers of PFAS have only recently been fully appreciated.
11 It is worth noting that this is the same period in which risk assessment was applied as a method to control hazard and the law permitted the patenting of living organisms both of which date to the early 1980's. For scientific proof of biodiversity loss on a massive scale see Ceballos et al., 2020; IPBES, 2018; Hallmann et al., 2017.
12 World Health Organisation, no date; COM (2021) 44.
13 World Health Organization, 2018, p. 8.
14 European Environment Agency Scientific Committee Seminar, 2017.
15 Martin-Laffon et al., 2019. This report highlights that as of 31 May 2017, 352 patents had been filed for CRISPR Cas-9 gene editing of plants and animals – and these did not include patents which have broadly been described as 'technological improvements' but which relate to gene editing agricultural species – predominantly pigs, cows, buffalo, goats, sheep, chicken, birds and fish and rice for plants but also other plant species.
16 European Environment Agency, 2021, p. 11.
17 European Environment Agency Scientific Committee Seminar, 2017.
18 The first EU Chemical Strategy was set out in the 2001 *White Paper Strategy for a Future Chemical Strategy* COM(2001)88; the second attempt to create a toxic free Europe was in 2013 with the EU's *7th Environmental Action Programme* (EAP), Decision 1386/2013/EU, 20 November 2014, which stated that it was the intention of the EU to create *"…a Union strategy for a non-toxic environment that is conducive to innovation and the development of sustainable substitutes including non-chemical solutions*". None appear to have been particularly effective since in 2020 the EU felt compelled to initiate its third attempt at offering the EU a toxic free environment *Chemical Strategy for Sustainability: Towards a Toxic Free Europe* COM(2020)667.
19 Leibowitz et al, 2021.
20 Bilott, 2020.
21 23.9 million hectares of land there now grow GMO mono crops. See ISAAA, 2018.
22 Sharma et al, 2019.
23 Weiner, 2019, p. 28; Black, 2010; Steele 2004.

valuable traditional knowledge on how to manage both is increasingly side-lined. Traditional, local knowledge built up over generations is fragile. Like biodiversity, it can go extinct within a generation. Where traditional knowledge becomes extinct it leaves future generations uniquely reliant on synthetic, manmade alternatives. The loss of traditional knowledge and what long term effect this may or may not have on future generations is difficult to quantify under a classical NRC risk analysis. Further indirect risks include, *inter alia*, the steep and irreversible decline in edible plant varieties.[24] According to Fowler and Mooney modern plant breeders working out of laboratories are hugely dependant on naturally diverse global regions to find favourable traits from which to develop new, manmade, plant cultivars. Yet the commercialisation of gene edited, Anthropogenic, uniform, and standard-sized plants is the very technology responsible for making natural varieties extinct leaving future generations vulnerable to famine through loss of genetic diversity.[25]

Modern plant breeding techniques are uniquely dependent upon TIPR rights to survive commercially. In TIPR – as my second paper will demonstrate – there is simply no room for tradition, state-of-the-art know-how, or existing knowledge. Only novelty and Anthropogenic priorities. As a result of these stringent TIPR requirements and criteria, agricultural biotechnology encourages a form of mono cultivation, standardisation, and uniformity at a time when the world is in desperate need of more species diversity and less monotony.

Thus, the effect on traditional farming, the importance of local knowledge, the significance of knowledge accumulated over centuries and the ability of future generations to feed themselves with naturally resistant crop varieties[26] barely features on a classical toxicology/risk assessment report prepared by public administrators such as the EFSA, ECHA, FDA or EPA. Yet, the indirect effects of novel plant breeding technologies on the wider public interest may be as damaging to the public interest as the silent poisoning of waterways, soils, and the atmosphere from PFAS and synthetic, manmade chemicals.

Even if risk methodologies are refined and improved the variables are just too big and data collection too lengthy to be meaningful. Collecting sufficient scientific data on cause and effects for all variables can take decades – sometimes even a century to confirm.[27] What Hansen and Tickner's empirical research reveals is that during the period of knowledge acquisition novel, Anthropogenic products morph from the scientific "jury is still out", to risk-risk trade off to "real risk" during which time the hazardous product is still in use. Over this lengthy period it is the public interest which is asked to act as the guinea pig in the risk producing industry's desire for absolute certainty before a product is either restricted or withdrawn from use.

Take glyphosate as an example where "the scientific jury is still out." In 2015 the International Agency for Research on Cancer (IARC) classified glyphosate as 'probably carcinogenic to humans (Group 2A)'.[28] The EFSA and ECHA disagree and concluded glyphosate is "unlikely" to cause cancer.[29] The fear of those living in rural areas where glyphosate is sprayed liberally and frequently is that it will yet prove to be the next asbestos, radium or PFOA crisis. Whilst the public wait for toxicologists and epidemiologists to collect data from which to draw exact causal relationships "the jury" in the words of Hansen and Tickner "is still out." The scientific jury that is. Not a civil jury which may have already come to a different conclusion earlier. The civil jury is more inclined to apply a civil (not scientific) standard of proof and consider glyphosate more likely than not to be carcinogenic. A civil standard being "on the balance of probabilities" with a threshold level of 50% certainty. Yet, current regulatory models require rural communities to wait for a scientific standard of certainty (a level typically described as 95%) before a product such as glyphosate is severely restricted or banned from use.

2.4 The civil jury has come to a verdict

Which brings us to one of the fundamental assertions of this paper. For the sake of protecting the public interest (the stated intention of environmental law) it is no longer useful, even possible to rely on scientifically assessing each and every novel, Anthropogenic chemical or life science patent seeking market authorisation or currently in use. Risk analysis is grinding to a halt through paralysis by analysis and the time has come to reassess its use in environmental law. It is time for the public administrator to step away from this approach and view the problematic substances as a whole not individually. Judging novel products individually based on a certainty level of 95% results in years of doubt and scientific uncertainty. During the period of epistemic data acquisition and whilst the scientific 'jury is still out' waiting the public interest is called upon to act as a huge epidemiological study and the involuntary guinea pigs waiting for date to come to light.

Judging such substances and processes as a whole on the other hand and based on a civil standard of proof

[24] Pearson, 2018; Bundesanstalt für Landwirtschaft und Ernährung, 2018: "*Dabei zeigt sich, dass von 7.000 untersuchten Sorten und Arten 75 Prozent als verschollen angesehen werden müssen.*"

[25] Fowler and Mooney, 1990. See also Fowler, 1993 .

[26] *Ibid*.

[27] See, for example, the challenge of trying to prove exact causal relationships in the case of asbestos in Gee and Greenberg, 2001.

[28] IARC, 2015.

[29] EFSA, 2015; ECHA 2017.

results in a very different conclusion. The case studies considered by the EEA show that on the balance of probabilities, it is more likely than not novel, synthetic, Anthropogenic, products, processes, substances, and their mixtures damage the environment and the biosphere in some form or another if they have not already done so. Over the past century civil society has given the risk producing industry, technical experts, and the administrative state the benefit of the doubt and allowed the individual risk of every new product to be assessed scientifically by toxicologists and risk assessors. This approach has failed and needs to be revised.

With this in mind the second part of my paper will consider how the law has tried to control the use of novel, Anthropogenic substances to protect the public interest and largely failed. It does so by considering the little-known *frontiers of science doctrine* and how this doctrine can assist regulators apply the precautionary principle consistently and efficiently. The paper goes on to consider some salient cases which highlight the link between novelty, an absence of knowledge, risk and how to trigger the first step in the reconfiguration of managing and controlling high-risk environmental products and processes as discussed in the Introduction.

3 Novelty and the frontiers of science doctrine

When confronted with such sobering facts as listed in part one of this paper it is worth considering what all of these hazardous, harmful substances share in common in order to distinguish damaging technological innovation from innovation which benefits the public interest. The one, largely over-looked commonality to all of these hazardous substances is their absolute novelty and the Anthropogenic (manmade) inventive nature of their construction. Precisely because they are a) novel and b) Anthropogenic there is a lack of knowledge with regard to their effects on the natural biosphere when in widespread use. A novel product or process is per definition an untested product or process. Early environmental judicial review cases addressed the challenges of how to regulate in the face of regulating untested, absolute novelty leading to an absence of scientific knowledge. This led to what some US scholars refer to as the 'frontier of science' doctrine,[30] an essential precursor to precaution. Without the frontier of science doctrine in place the precautionary principle makes little to no sense. Decoupling the precautionary principle from frontier science leads some commentators[31] to assume precaution applies to *all* risks rather than a very narrow set of industrial risks only and ones linked to absolute, synthetic novelty in particular.

There is a general assumption in scholarship that the precautionary principle and its link to uncertain science originates in German legislative acts.[32] A strong case can be made, however, that the origin of the principle and its focus on uncertain science lies less in the German *Vorsorgeprinzip* and more in the frontiers of science doctrine which emerged out of early US judicial review cases concerning disputed scientific facts. The US, to recall, was the first developed country to introduce and codify environmental law – at least a decade and a half before the EU.[33] The EU later codified the precautionary principle into primary EU law[34] but in so doing appears to have been unaware of the principle's link to frontier science.

The early cases linked to this doctrine will be discussed in greater detail below but suffice it to say for now the doctrine is of interest to modern environmental lawyers engaged in risk regulation for a number of reasons. First, it establishes in environmental law under what conditions scientific uncertainty and a lack of scientific consensus arises. This condition, the doctrine correctly notes, arises in cases of absolute novelty leading to an absence of scientific knowledge. Second, the doctrine recognises that in the absence of scientific knowledge it is deductively logical and self-evidently true that there is an absolute lack of data from which to extrapolate causal relationships between the product and its effect on either public health or the environment. Since causal relationships cannot be determined, future risk and harm cannot be foreseen and therefore calculated. Third, the doctrine demands that where risks cannot be foreseen due to the novelty/absence of knowledge coupling, independent agencies are required by law to protect public health and the environment. The regulator, therefore, must act with caution and not expose the public interest to unforeseeable risk. This doctrine is a proactive approach to environmental law in that it recognises conditions in which unforeseen danger arises and seeks to prevent the damage from materialising before it actually occurs. As such the frontiers of science doctrine is an essential precursor to precaution. Today the precautionary approach – or

30 Little is written on the frontiers of science doctrine in environmental law or risk regulation. This author first came across the doctrine in, Anderson, 2017, p. 193. See also Shapiro, 1996, who links the term frontiers of science doctrine to patent law but does not elaborate further.

31 Critics of the precautionary principle often assume it applies to all risks rather than a very narrow set of industrial risks linked to novelty and the Anthropocene. Influential writers such as Sunstein and Wiener assume the PP is relied upon in cases of war, everyday risks or standard product liability thus forgetting that the PP is unique to industrial environmental risks. See, generally Sunstein, 2002; Sunstein, 2005; Wiener, 2020; Graham and Wiener (eds), 1995); Wiener et al, (eds), 2001.

32 Sands and Peel, 2019, p. 230; de Sadeleer, 2020, p. 137; Boehmer-Christiansen, 1994, p. 31.

33 Vogel, 2002.

34 Article 191 (2) Treaty of the Functioning of the European Union.

principle – lives on in the EU but the frontiers of science doctrine appears to have withered away and been largely forgotten or ignored in national, regional, and international environmental law.

3.1 Knowledge and the Precautionary Principle

Under its current application the EU's precautionary principle operates within a rigid risk framework.[35] This allows hazardous products onto the open market on the assumption there is sufficient technical knowledge to control the hazardous product once on the market and in widespread use. At the time this appeared to be a sensible solution. However, it has turned out to be a dead-end leading not to scientific certainty but to a morass of confusion and two more decades of pollutants seeping into the environment. A risk approach to environmental hazards may sound reasonable and based on sound, scientific evidence. In reality experts cannot conjure knowledge out of thin air in the case of absolute novelty.

3.2 Knowledge or lack of knowledge in the regulatory process

Much of the confusion over the precautionary principle lies in the very different approaches the regulator and the judiciary have taken towards managing knowledge in an administrative state. Anderson[36] points out that ever since the inception of environmental law in the US five decades ago there has been a marked divide in the US judiciary. On the one hand there are those who favour the classical Weberian model of governance where safety standards are based on *knowledge* and where politics (emotions) do not corrupt the impersonal and universal assertions of science.[37] On the other side are those judges who recognise a more realistic approach to managing risk *in the absence of knowledge* due to the absolute novelty of the technology in use. In 1980 the US Supreme Court in *Industrial Union Department, AFL-CIO v American Petroleum Institute (Benzene)*[38] appeared to favour the former. From 1980 onwards the frontiers of science doctrine (and with it the precautionary approach) were shelved in the US and those who assumed knowledge can be created out of ignorance came to the fore. It was at this juncture that US environmental law changed tack and chose to favour risk above caution. Both the frontier of science doctrine as well as the precautionary approach to regulating novel substances were abandoned in US environmental law. To support the claim that there is always sufficient scientific knowledge available to manage unforeseeable risk the US National Research Council (NRC) published a paper setting out how a quantifiable risk assessment should be utilised in cases of novel, untested substances, processes, and products.[39] The NRC label gave authority to the notion that toxicology, hazard identification and risk assessment as a means to regulate scientific uncertainty is based on hard, verifiable, reproducible results, valorised by rigorous expert peer review and sound science.[40] Henceforward environmental law became enchained to risk assessment as a means to control unforeseeable harm.

The EU chose to keep the precautionary principle but strapped it to an NRC style risk analysis.[41] At the turn of the millennium the EU favoured those clamouring for a risk-based approach to managing environmental law on the false assumption there is always sufficient knowledge in environmental law with which to establish effective safeguard measures. The EU – mistakenly – therefore, chose to set up administrative institutions based largely on the US model of regulating on the basis of knowledge. Quantifiable and calculable environmental risk assessments were assumed – and still are assumed - to be capable of offering the public interest sufficient protection from both direct and indirect unforeseen harm from novel and anthropogenic products produced by the risk industry. In so doing both the US as well as the EU either chose to ignore or were simply unaware of the looming 'elephant in the room' namely how to regulate in cases of ignorance. [42]

3.3 Setting the scene for decades of regulatory confusion

Few stakeholders today dispute the role hazard identification (conducted by toxicologists) and risk assessment (mostly conducted by experts with an economic background) plays in setting preventative environmental standards. There is a strong assumption by all parties involved in environmental law – the legislature, the regulator, the scientific expert, the judiciary, academia, industry, and environmentalists alike - that a quantifiable risk assessment based on toxicological conclusions has the wherewithal to settle disputed science regardless of the conditions under which the uncertainty arises.[43] Yet vehement disagreement between the various stakeholders persists. The risk producing industry lambast the

35 COM (2000)1, p. 2: "*The precautionary principle should be considered within a structured approach to the analysis of risk which comprises three elements: risk assessment, risk management, risk communication. The precautionary principle is particularly relevant to the management of risk.*"

36 Anderson, 2017, p. 193.

37 See section 4 below for how regulation can operate successfully where there is sufficient knowledge with which to draw causal relationships.

38 Industrial Union Department, AFL-CIO v American Petroleum Institute (Benzene), 448 U.S. 607 (1980).

39 National Research Council, 1983.

40 Peel, 2010), p. 113 and 119.

41 COM (2000)1.

42 For challenges to quantifying ignorance within risk see generally, Stirling, 1999; Weimer, 2019, p. 32.

43 It should be noted several legal academics working on environmental risk have raised questions about the efficacy of risk assessment in regulatory science. See de Sadeleer, 2017, pp. 28–32; Scott and Vos, 2002; van Asselt and Vos, 2006.

conclusions of risk assessments for being too cautious. Environmental organisations decry the results of the risk assessment for not being cautious enough. The Life Science industry which is heavily involved in novel, synthetic products and processes is trying to persuade regulators to label their novel, Anthropogenic products as 'natural' and 'conventional' in order to avoid the headache of costly and inconclusive risk assessments.[44] In short, rather than a calm, orderly and consensual approach to science in environmental law bitter disputes emerged between stakeholders. That this would happen, I argue, was inevitable the moment the link between novelty and unforeseeable harm was broken. In such circumstances it is impossible for technical experts to establish facts. Empirical science then becomes more a matter of faith and belief than solid authority. Thus, the main cause of the long-standing tension in environmental law, this paper contends, is the unfortunate abandonment of the frontiers of science doctrine and the recognition that absolute novelty is linked to an absolute absence of knowledge.

To prove this assertion, it is important to establish under what conditions scientific certainty arises in the regulatory process, to contrast it with the conditions which give rise to scientific uncertainty. The next part of the paper, therefore, sets out examples of how science can work effectively in setting regulatory health and safety standards where there is sufficient knowledge. The paper then contextualises how absolute novelty leads to an absence of knowledge and with it the challenge of both toxicology and risk assessors to predict where, when and how harm will emerge. I use the case of the Radium girls, *La Porte v United States Radium Corporation (La Porte)*[45] (1935) as an illustrative example.

4 Finding certainty in existing knowledge and quantification

4.1 Regulating in cases of scientific certainty

Nineteenth century legislators leaned heavily on scientific calculus to determine health and safety standards that offered workers, investors and traders alike protection from foreseeable harm and unnecessary risks. Not only did quantification have the serendipitous effect of protecting workers and the public from harm the promulgation of safety standards did not hinder progress, innovation, or the economy. It was a 'win-win' development for governments looking to offer their citizens prosperity as well as a high level of health and safety protections from the industrial revolution.

4.2 The Merchant Shipping Line

Take, for example, the nineteenth century 'Plimsoll Line' known today as the merchant shipping line. Samuel Plimsoll MP introduced a bill making it a statutory requirement for the merchant shipping fleet to draw a line on all vessels, demarcating safety from hazard. It was common practice at the time of empire building for traders to over-load their vessels with cargo leading to a higher-than-average risk of the vessel sinking at sea. If water roses above the Plimsoll line the vessels was overloaded, and cargo had to be removed. Known today as the shipping load-line it remains a key protection for workers, investors, and the environment from foreseeable and unnecessary risk in merchant shipping.

4.3 The Interstate Commerce Commission and Locomotives

A further example of nineteenth century standard setting is the1888 US Interstate Commerce Commission which was responsible for both the safety inspections of locomotives, as well as the regulation of railroad rates.[46] Either a locomotive "*met the established engineering standard or it did not*".[47] This certainty of outcome, risk and safety based on quantifiable measurements led regulators to assume there were, "*correct technological answers to regulatory questions*".[48] In such cases the risk of a railway bridge collapsing due to incorrect calculation is reasonably foreseeable and can be addressed in the early stages of a project's design by technical experts. Failure to apply the existing knowledge on bridge building can determine liability, fault, and responsibility to a high degree of rational calculus. Civil and mechanical engineering and design, operating in the service of the industrial revolution was and still can offer society as well as public authorities and standardisation bodies the comfort of what Sheila Jasanoff refers to as the "*impersonal and universal assertions of science*".[49] The success of these early reformist statutes and the establishment of independent agencies led the executive as well as the legislature to place their trust in technical experts. According to Anderson the success of independent agencies such as the Interstate Commerce Commission led to US administrative law being largely based on Weberian lines of governance, where power is exercised on the basis of knowledge[50].

In this telling, administration furthers the public good by bringing expertise to bear on the resolution of

44 SWD (2021) 92, p. 3; DEFRA, 2021, in which the suggestion that novel plant breeding techniques are but a continuum of natural, traditional and conventional agricultural domestication.

45 La Porte v United States Radium Corporation, 13 F, 263 (D.N.J.) 1935 Fae. (La Porte).

46 Shapiro, 1996, pp. 1-3.

47 *Ibid*. p. 2.

48 *Ibid*. p. 1.

49 Jasanoff, 1997, p. 25.

50 Anderson, 2017, p. 193.

public policy problems, and it justifies the exercise of executive power by providing a politically neutral basis for the formulation of regulatory policy.[51]

The legacy of the shipping load-line and the Interstate Commerce Commission based on Weberian models of politically neutral decision-making lives on today in the myriad of technical committees that develop product safety standards for novel specialist and consumer products. Civil/mechanical engineering and product design is a branch of the applied sciences general society has most faith in. The fact that so many people ride bicycles, cross bridges, fly aeroplanes and reside in high-rise buildings is testimony to the confidence wider society has in the safety standards developed by technical experts proficient in civil/mechanical engineering and product design.

5 Seeking Certainty, finding Ignorance

The dry, dull but critically important technical committees that meet to establish safety standards for standard product designs rarely, if ever, raise headline news stories such as "*Frankenstein ladder*" of "*Terror hairdryers*".[52] The findings of the product design committees are rarely disputed and there appears to be a general scientific consensus on the conclusions of the health and safety standards designed by technical experts staffing the many standardisation committees worldwide.

Why then is the regulation of health and safety standards in environmental law rife with disputed science and alarmist headlines? Are environmentalists, as some critics have suggested, so deeply attached to conservative tradition they have lost their ability to think rationally and accept the universal assertions of science?[53] The problem of scientific uncertainty, this paper asserts, lies less with conservative thinkers attached to tradition and more with the inability of toxicologists and risk assessors to quantify ignorance. Article 191(3) of the Treaty on the Functioning of the European Union (TFEU) states specifically that when preparing environmental policy, the Union must take account of "*available scientific and technical data*". No credible or legitimate scientist acting in good faith would ever propose that they can offer policy makers available scientific data if there simply is none or very limited data due the absolute novelty of the product under investigation. Thus, what distinguishes certain science from uncertain science lies less in the notion that society is incapable of measuring risk and more in the concept of how to manage risk in the absence of epistemic knowledge arising out of novelty. The 1935 case of *La Port*[54] offers a textbook example of how this challenge arises in cases of absolute novelty.

5.1 The challenge of judging ignorance: The Enlightening tale of Undark

La Porte concerns the death of a factory worker employed by the defendant - US Radium Corporation - to paint a novel paint known as Undark onto watch faces.[55] We now know that Undark was a highly hazardous, toxic mixture of radium-barium carbonate with zinc sulphide and linseed oil which led to a novel form of incurable cancer.[56] The question before the court, therefore, was: could the defendant be held liable for the damage caused to their workers from the use of radium in Undark.

5.2 An empty sheet of paper

Given Undark was designed to light up watch faces in the dark, relying on the usual metaphor of 'shining light into the darkness' to describe empirical scientific research would in this case be an unfortunate analogy. An alternative is that of an empty sheet of paper with the sheet referring to mankind's collective ignorance of an entirely novel product, process or substance's effect on the public interest. There is no image. No markings. No map. No finger pointing towards safety or harm. Markings only begin to appear on the empty sheet of paper the moment a novel substance is in widespread use: this gradually adds pixels to the paper until eventually a sharp, in-focus image appears. It is only at this stage that objective, politically neutral causal relationships can be ascertained, and enough knowledge has been created allowing public administrators to prepare efficient safety regulations. The problem for the regulator is that during the period of data acquisition – as the pixels slowly but steadily accumulate on the paper – the innocent employee, the general public, biodiversity, or the environment are, in effect, acting as the guinea pig. Applying the empty sheet analogy to *La Porte*, a 1921 advert ran by the defendant read: "*Twenty-three years ago radium was unknown. Today, thanks to the constant laboratory work, the power of this most unusual of elements is at your disposal. Through the medium of Undark, radium serves you safely and surely".* Let us examine each claim in turn.

"Twenty-three years ago radium was unknown". We know as a matter of fact that 1898 was the year Marie Curie discovered radium. This date, therefore, marks the scientific frontier between an absence of knowledge and knowledge. The first pixel to appear

51 *Ibid.*

52 Compare that to novel applications of biotechnology where horror headlines are common. See Kaminska, 2021.

53 See Mr Arūnas Vinčiūnas, former Head of Cabinet to Commissioner Vytenis Andriukaitis speaking in 2015, where he stated, that one of the key challenges as a legislator is how to formulate laws, "*in the face of emerging technologies in situations where science appears to be questioned by either deeply-rooted conservative groups, societal opposition or for any other reason*", see Jacobssen, 2015.

54 *La Porte, supra* note 45.

55 Carney, 1983.

56 Lambert, 2001.

on the empty sheet of paper was in 1901 when Henri Becquerele, one of the first persons alongside the Curie's to observe radioactivity, began to report strange burns he received from a vial of radium he carried in his waist pocket.[57] A statistician, however, cannot draw causal relationships and infer general truths from one pixel alone. Shortly after Becquerele's observations, other researchers working on x-rays began to report hair loss and similar, unusual burns on their skin.[58] In 1904 – just six years after radium was discovered Thomas Daly, Edison's x-ray assistant, died of cancer having had both of his arms amputated to try and stop the cancer from spreading.[59] Although pixels were beginning to accumulate on the paper only a shadowy image of random dots was visible. Over the course of time, however, more and more pixels began to accumulate. In 1913 scientific literature showed that radioactive salts introduced in the body would be eliminated in part very slowly.[60] In 1914 a number of articles were published examining the link between external burns of the skin and radium use.[61] It became fairly well established within the scientific community that burns might show late effects in the form of general disturbances or skin changes resulting in cancer.[62] By 1917 a scientific consensus was beginning to emerge that radium was the most active of the elements and possessed an incomprehensible store of energy.[63] In the first two decades of the twentieth century more and more scientific cases – extra pixels on the sheet of paper - were reported exposing the many dangers to the human body from radium which, in certain cases resulted in fatal or dangerous injuries.[64] The few random dots were beginning to cluster into a clear image of danger.

"*Today, thanks to the constant laboratory work, the power of this most unusual of elements is at your disposal."* Unfortunately, an early form of techno-optimism sprayed a fine layer of smoky varnish over the emerging image. Initially there was a huge amount of optimism that radium could prove more beneficial than harmful. Widespread trust in 'science' as a higher authority capable of determining safety is used by the defendant as a means to market their novel product. To be fair, the US Radium Corporation was by no means the only commercial operator using radium as a novel element to add a certain sparkle to commercial products. When Marie Curie discovered radium at the turn of the twentieth century North American and European industry was awash with ideas on how to patent and commercialise what (at the time) was an exciting new discovery. Radium was added to butter, to chicken feed, to cosmetics, to lingerie.[65] In Germany radium was added to chocolate and in Switzerland workers handling radium walked home glowing in the evening dusk. An energy drink 'Raditor' assured consumers they would 'sparkle with energy'.[66] This initial techno-optimism and confidence in radium's safety is reflected in the court papers which note that, "*although there was some suggestion of hazard through the agency of radium, many hailed it as a great boon to humanity, and its internal uses by injection, inhalation, etc., were frequently advocated*", [67] and "*in the early literature, numerous statements were made as to the beneficial effect of radium applied internally*".[68] Although not referring to the empty sheet of paper analogy as such, Judge Foreman relies on similar language when he correctly concludes, "*the learning at the time was so coloured with conjecture and theory, some of which has since been discarded that it is impossible impartially and reliably to rationalize it*".[69]

"Through the medium of Undark, radium serves you safely and surely." Which brings us to the final claim in the marketing of Undark by the defendant – that it serves the consumer "*safely and surely*". The advert dates to 1921 by which time we know that there was a growing body of scientific consensus that radium was harmful and not there 'to serve' consumers 'safely and surely'. To allay increasing fears that radium was harmful experts at the Life Extension Institute wrote to the defendant in 1924, "*that no evidence was disclosed of the influence of any particular metallic poisoning and that the cases, in so far as they went, showed the ordinary range of human troubles and did not reflect any specific occupational influence*".[70] Even the best of scientific and laboratory work was unable to foresee just how dangerous and hazardous radium can be. A blind faith in technological progress then – as now – acts as a smokescreen preventing objective observers from observing the true image that is beginning to emerge from use of novel substance.

Judge Foreman was unable to decide on the disputed scientific claims of safety and harm – nor does he attempt to do so but he does suggest that "*it is doubtful if an accurate picture of the knowledge existing in 1920 concerning radium could be drawn even by experts*". He does, however, give the defendant the benefit of the doubt by suggesting they were "*…utterly ignorant of the harmful effects attendant upon its factory process until 1924*".[71] In this he was partially correct. It was not just the

57 Lambert, 2001, p. 32. See also, Greenwood, 2014.
58 *Ibid*.
59 *Ibid*.
60 *La Porte*, *supra* note 45, p. 268.
61 *Ibid*.
62 *Ibid*.
63 *Ibid*, p. 266.
64 *Ibid*, p. 268.
65 Orci, 2013.
66 Macklis, 1993.
67 *La Porte*, *supra* note 45, p. 271.
68 *Ibid*, p. 268.
69 *Ibid, p.* 268.
70 *Ibid*. p. 269.
71 *Ibid* (emphasis added).

defendant, however, who was utterly ignorant of the harmful effects of radium – mankind was utterly ignorant of its effect given the utter novelty of radium. The defendant, the Life Extension Institute of New York, Miss La Porte, Marie Curie and Henri Becquerele could not possibly have foreseen the damage that did eventually occur. The real tragedy in this case is that early technological optimism clouded the judgement of many scientific experts not least the Curie's.

In the end the claim failed based on the statute of limitation. Judge Forman did finalise his judgement, however, by remarking that judicial *ex post* remedies in tort and nuisance cases had reached their limit. *"The development of the law to meet such contingencies must of necessity lag behind their discovery. Only forward looking, intelligent legislation can protect future situations such as the one here presented*."[72] The closing remarks in *La Porte* are a judicial recognition that the courts had reached the limits of their ability to serve justice to victims of unforeseeable harm in the case of radically new products and processes. Forman is calling on the legislature to pick up the baton to protect the victims of novel, hitherto unknown substances from future harm that no scientist, no matter how brilliant, would ever be able to foresee.

6 Judicial acceptance of scientific ignorance and lack of knowledge: The Frontiers of Science Doctrine

Case such as *La Porte* gave rise to increased public unease over the widespread use of untested, novel, synthetic substances, products, and processes. In 1962 Rachel Carson published 'Silent Spring'[73] detailing the detrimental use of DDT on the natural environment. It gave added urgency for Congress to protect the public interest from unforeseen harm. The regulatory model eventually chosen to prevent future harm from untested novel products, and processes is largely based on the classical Weberian model of governance where safety standards are based on knowledge.[74] Congress felt confident that the relevant safety standards could be promulgated by technical experts in the same way the Interstate Commerce Commission promulgated standards for locomotives where safety did not impede the economic development of the railways.

This ambition was not to materialise. When setting up the independent watch-dog agencies Congress failed to recognise the different conditions that give rise to knowledge (where statutory regulations work well) and conditions that give rise to an absence of knowledge (where statutory regulations are ineffective). The poisoned chalice of distinguishing foreseeable from unforeseeable harm in cases of novelty and absence of knowledge was passed from the courts to congress and from congress onto the independent agencies. Yet the shifting of responsibility did not lessen the toxicity of the poison in the cup.

As a result, the tension over whose science to prioritise is not limited to the twenty-first century. We see similar tensions in environmental review cases dating to the early 1970's shortly after the first environmental acts were passed into law.[75] Judicial dislike of having to review cases based on disputed science is summarised well by Judge McGowan in *Industrial Union Department, AFL-CIO v Hodgson (Hodgson.)* (1974)[76] concerning the promulgation of standards of asbestos dust in industrial workplaces. In his opening statement McGowan implies that the environmental and public health legislation developed by Congress to protect the public interest was neither 'intelligent' nor 'forward thinking' as Judge Foreman in the case of *La Porte* had called for.

"[I]t would have been helpful if there had been some recognition by Congress that the quick answer it gave to a legislative stalemate posed serious problems for a reviewing court, and that there would inevitably have to be some latitude accorded it to surmount those problems consistently with the legislative purposes".[77]

Judge McGowan appears well aware that the poisoned chalice is being passed from the courts to congress, from congress to the administrator and from the administrator back to the courts like a game of 'hot potato'. With an almost audible sigh he, nevertheless, continues: *"The duty remains, in any event, to decide the case before us in accordance with our statutory mandate, however dimly the rationale, if any, underlying it can be perceived."*[78]

The district court judges may have engaged in disputed science cases between industry and the administrator reluctantly. Yet in many respects their understanding of conditions that give rise to uncertain science and how to manage it is sophisticated. Out of the quagmire of disputed scientific facts 'the frontiers of science doctrine' began to emerge. Uncertain science, the doctrine proscribes, arises when science is skirting the frontier between knowledge and ignorance, fact from assertion, science from the occult. Quoting the Foreword to the Legislative History of the Occupational Health and Safety Act (1970) McGowan in *Hodgson* writes: *"Not only are occupational diseases which first came to light at the*

72 *Ibid.* p. 277 (emphasis added).
73 Carson, 1962).
74 Anderson, 2017, p. 193.
75 *Ibid*, pp.195-197.
76 Industrial Union Department, AFL-CIO v Hodgson, 499 F2D 467 (DC Cir 1974). (Hodgson).
77 *Ibid*, p. 469.
78 *Ibid*, p. 470.

beginning of the Industrial Revolution still undermining the health of workers, but new substances, new processes, and new sources of energy are presenting health problems of ever-increasing complexity."[79]

Echoing the analogy to an empty sheet of paper the introduction of 'new substances, new process and new sources of energy' means the image on the paper is decidedly low resolution and as a result: *"[S]ome of the questions involved in the promulgation of these standards are on the frontiers of scientific knowledge, and consequently as to them insufficient data is presently available to make a fully informed factual determination"*.[80]

The inability to determine exact, scientific cause and effect based on limited scientific method and the concept of independent agencies operating on the 'frontiers of science' was reiterated one year later in *Society of the Plastics Industry v OSHA (Society of Plastics)* (1975).[81] This case concerned threshold standards for the vinyl chloride industry. Reiterating McGowan in *Hodgson*, Justice Clark writes: "*[T]he ultimate facts here in dispute are 'on the frontiers of scientific knowledge', the factual finger points, it does not conclude".* [82]

In *Ethyl Corp. v. Environmental Protection Agency (Ethyl Corp)* [83] 1976 Judge Skelly Write remarks: "*Man's ability to alter his environment has developed far more rapidly than his ability to foresee with certainty the effects of his alterations. It is only recently that we have begun to appreciate the danger posed by unregulated modification of the world around us and have created watchdog agencies whose task it is to warn us, and protect us, when technological 'advances' present dangers unappreciated — or unrevealed — by their supporters*."[84]

In seeking to protect the public interest from unappreciated or unrevealed dangers the technical experts staffing the watch-dog agencies are *"unequipped with crystal balls and unable to read the future, [but] are nonetheless charged with evaluating the effects of unprecedented environmental modifications, often made on a massive scale."*[85]

He goes on to note the impossibility of determining risk in the absence of knowledge: *"[H]ow can the Administrator determine that a risk is a significant risk if he cannot assess risks? Surely reliance on 'facts' as contemplated by petitioners will provide little guidance"*.[86]

Having established how and when uncertainty arises and having established the impossibility of technical experts to calculate how, when, where and to what extent harm will emerge the judges go on to consider whether it is appropriate for the watchdog agencies to gaze into the crystal ball and take a speculative bet on the novel substance? At this point the district judges generally conclude that no, the watchdog agencies must not speculate on how, when and whether or even if harm will arise. In *Hodgson*, the judgement notes that where mankind is operating on the frontiers of scientific know-how Decision making must in that circumstance depend to a greater extent upon policy judgments *and less upon purely factual analysis*.[87] Similarly in *Society of Plastics* the judgement reads, under the command of OSHA, it remains the duty of the Secretary to act to protect the workingman, and to act even in circumstances where existing methodology or research is deficient. The Secretary, in extrapolating the MCA study's finding from mouse to man, has chosen to reduce the permissible level to the lowest detectable one. We find no error in this respect.[88]

Skelly Wright could have been writing in 2021 not 1976 in *Ethyl Corp.* when he wrote: *"Technological man has altered his world in ways never before experienced or anticipated. The health effects of such alterations are often unknown, sometimes unknowable. While a concerned Congress has passed legislation providing for protection of the public health against gross environmental modifications, the regulators entrusted with the enforcement of such laws have not thereby been endowed with a prescience that removes all doubt from their decision making. Rather, speculation, conflicts in evidence, and theoretical extrapolation typify their every action. How else can they act, given a mandate to protect the public health but only a slight or non-existent data base upon which to draw? Never before have massive quantities of asbestiform tailings been spewed into the water we drink. Never before have our industrial workers been occupationally exposed to vinyl chloride or to asbestos dust. Never before has the food we eat been permeated with DDT or the pesticides aldrin and dieldrin. And never before have hundreds of thousands of tons of lead emissions been disgorged annually into the air we breathe. Sometimes, of course, relatively certain proof of danger or harm from such modifications can be readily found. But, more commonly, 'reasonable medical concerns' and*

79 *Ibid*, p. 470 (emphasis added).
80 *Ibid*, p. 474.
81 The Society of the Plastics Industry, Inc v OSHA, 509 F2d 1301, 1308 (2d Cir 1975). (Society of Plastics).
82 *Ibid*. p. 1308. Justice Clark clearly understood the question before the court concerned inductive reasoning and may have had Francis Bacon in mind who referred to the "*factual finger points it does not conclude*". See Fara, 2009, p. 137.
83 Ethyl Corp. v. Environmental Protection Agency, 541 F.2d 1 (D.C. Cir. 1976).
84 *Ibid*. p. 6.
85 *Ibid*. p. 6 (emphasis added).
86 *Ibid*. p. 21.
87 *Hodgson*, *supra* note 76, p. 474 (emphasis added).
88 *Society of Plastic, supra* note 81, p. 1308.

theory long precede certainty. Yet the statutes — and common sense — demand regulatory action to prevent harm, even if the regulator is less than certain that harm is otherwise inevitable." [89]

Replace asbestiform tailings, vinyl chloride, DDT and aldrin with PFAS, glyphosate, dicamba and neonicotinoids and the modern environmental lawyer gets the uncanny feeling that we have all been here before and history is repeating itself.

Judge Skelly Wright's opening statement in *Ethyl Corp. v EPA,* is widely regarded as one of the seminal US environmental cases justifying a precautionary approach to the setting of environmental standards. Before the precautionary approach can apply, however, the District Judges recognise the need for the administrator to understand under what conditions scientific uncertainty arises. This is crucial. The precautionary approach could otherwise be used too widely and that was not – indeed is still not – the intention of environmental law. To recall, where there is scientific certainty both the regulator and the law agree scientific expertise is essential in formulating standards that are fit for purpose based on the classical Weberian model of knowledge-based decision-making. The district court judges are not demanding all innovation be halted and the economy return to a mythical past.

What the district judges at the time of the Nixon and Carter administration do recognise is that in the case of *existing knowledge* technical experts are operating in the comforting fold of objective fact where causal relationships can be determined to a high level of scientific certainty. In cases of scientific uncertainty arising out of novelty, on the other hand, technical experts are operating on a scientific frontier separating objective, known fact from subjective speculation. Technical experts responsible for promulgating safety standards in cases of absolute novelty have no choice but to peer over the scientific frontier. As they do so all they see are deep shadows and darkness ahead with no map demarcating safe passage.

The frontiers of science doctrine therefore demands that *in the case of environmental and public health safety standards* where there is an *absence of knowledge due to novelty* the frontier is crossed only with great caution and based on a political choice not a factual one. Judge McGowan, Justice Clark and Judge Skelly Wright may have been in their early years of practice when the tragic case of the radium girls was heard and matured into judges when Rachel Carson published Silent Spring. It would not have been lost on them that in cases when technical experts gazed into their crystal balls to make predictions of safety, more often than not, it ended up in unforeseen and unappreciated, "*danger posed by unregulated modification of the world around us*". In this they were correct.

7 Favouring crystal balls – seeking to quantify the unknown

Hodgson, Society of Plastics and *Ethyl Corp.* were fiercely contested by those who were involved in rapid, technological advances, most notably those in the risk-producing industries - chemicals, synthetic food additives, novel foods, energy, and the then emerging life science industry. The thrust of the risk producing industry's argument was to conflate caution based on frontier science and caution with 'zero risk'. They argued quite correctly that everything in life imposes a risk. No one lives in a zero-risk society.[90] The reasoning beings to fall apart, however, when they suggest that the zero-tolerance approach[91] to regulating uncertain substances is based on irrational fears by a public uneducated in measurable risk. The 'zero-risk' argument of the risk producing industry fails to admit that the regulatory concept of 'zero tolerance' does not refer to all risks but to a very narrow set of unknown risks linked to novel, untested products, processes, and substances only.

Alongside the 'zero-risk' argument the 'assimilation theory' – or the more easily understood 'the poison is in the dosage' approach to toxicology was advocated as a sound, scientific approach to determine causal relationships even in cases where there is a lack of epistemic data. The assimilation theory is based on the idea that the environment (and public health) can assimilate a certain amount of pollution without detrimental changes in the quality of either eco-systems or public health.[92] Those promoting the assimilation theory argue that animal testing was and is sufficiently robust to determine causal relationships. According to Majone: "*[E]xtrapolating from the high doses shown to cause harm in animal experiments or in epidemiological studies, to the much lower exposures normally faced by humans is the essence of quantitative risk assessments"*.[93]

The risk producing industry finally managed to plead the 'zero-risk' and 'assimilation theory' of causal effect in 1980 – not in the district courts – but this time in the Supreme Court case of *Benzene*[94] [95] The facts of *Benzene* (1980) concern the toxicity of the chemical benzene added to petrol. By 1980 there was a high level of scientific, factual certainty and consensus that benzene caused cancer.[96] In light of this, OSHA chose to utilise its Cancer Policy, which

89 *Ethyl Corp*, *supra* note 83.

90 Douglas and Wildavsky, 1983.
91 Sunstein, 2005.
92 Cameron and Abouchar, 1991.
93 Majone, 2002.
94 Benzene, *supra* note 38.
95 Grove 1980, p. 265.
96 Infante, 2001.

was to suppose that no level of exposure to a carcinogenic substance could be considered safe.[97] OSHA felt confident this approach was correct, based on congressional intent and the support of the judiciary's frontiers of science doctrine and precautionary approaches established by the district courts. OSHA, therefore, adopted a standard for air borne benzene of 1 part per million.[98] The American Petroleum Institute (API) objected to this low level, claiming that OSHA had failed to conduct a scientific risk assessment of the threshold level based on the assimilation theory and at what level those thresholds are perceived to entail a risk to the public interest.

Although there was no majority opinion in *Benzene*, the reasoning unclear and the language opaque[99] it is nonetheless regarded as the turning-point in US environmental legislation. *Benzene*, alongside the NRC report into hazard identification and risk assessment was used by the risk producing industry to portray a quantifiable risk analysis based on the assimilation theory in environmental and public health legislation as being equivalent to and on a level with 'sound, evidence-based science' where there is no conjecture, no doubt, no darkness, and no emptiness - only certainty. As the cases discussed above seek to show in this there were and still are wrong.

8 Conclusion

This paper has sought to demonstrate that over the past century mankind has gained sufficient knowledge of the harm novel, Anthropogenic products and processes are doing to the environment and the public interest. Always costly. Often irreversible. Past cases demonstrate that Anthropogenic products marketed by the risk producing industry rarely offer the public interest safe passage through the unknown terrain beyond the scientific frontier. All of the cases discussed in this paper are instances where the frontier separating light from shadowy darkness has been crossed. Witness accounts of the terrain beyond the frontier is not promising. Beyond lies not so much *terra incognita* ready to be safely and productively colonised but *terra pericolosa* with the geography defined by toxic vapours, hazardous fumes and swampy bogs. With that knowledge in mind the precautionary principle should consistently apply the frontiers of science doctrine and determine that the border should be crossed only with extreme caution and prudence. The decision to cross should be a political one. Not a technocratic one.

To conclude, although the objective of the precautionary approach/principle is to protect the public interest from unforeseen harm it cannot do so in the absence of the frontiers of science doctrine which identifies those products and process which are causing the harm to materialise. With the EU committed to a Green Deal, now would be a germane moment for regulatory authorities to rehabilitate the frontiers of science doctrine as a useful precursor to the precautionary principle, and to consider a fresh approach to regulating hazardous novel, Anthropogenic substances based on the three-step approach discussed in the Introduction..

[97] Fed. Reg. 54148 (1977), available here; last accessed 19 February 2021.
[98] Graham, 1987.
[99] Shapiro, 1996, p. 5.

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elni

In many countries lawyers are working on aspects of environmental law, often as part of environmental initiatives and organisations or as legislators. However, they generally have limited contact with other lawyers abroad, in spite of the fact that such contact and communication is vital for the successful and effective implementation of environmental law.

Therefore, a group of lawyers from various countries decided to initiate the Environmental Law Network International (elni) in 1990 to promote international communication and cooperation worldwide. elni is a registered non-profit association under German Law.

elni coordinates a number of different activities in order to facilitate the communication and connections of those interested in environmental law around the world.

Coordinating Bureau

Three organisations currently share the organisational work of the network: Öko-Institut, Technische Hochschule Bingen (TH Bingen) and sofia, the Society for Institutional Analysis, located at the Darmstad University of Applied Sciences. The person of contact is Prof. Dr. Roller at TH Bingen.

elni Review

The elni Review is an English language law review. It publishes articles on environmental law, focussing on European and international environmental law as well as recent developments in the EU Member States. elni encourages its members to submit articles to the elni Review (info@elni.org) in order to support and further the exchange and sharing of experiences with other members.

The first issue of the elni Review was published in 2001. It replaced the elni Newsletter, which was released in 1995 for the first time.

The elni Review is published by Öko-Institut, TH Bingen and sofia.

elni Conferences and Fora

elni conferences and fora are a core element of the network. They provide scientific input and the possibility for discussion on a relevant subject of environmental law and policy for international experts. The aim is to gather together scientists, policy makers and young researches, providing them with the opportunity to exchange views and information as well as to develop new perspectives.

The aim of the elni fora initiative is to bring together, on a convivial basis and in a seminar-sized group, environmental lawyers living or working in the Brussels area, who are interested in sharing and discussing views on specific topics related to environmental law and policies.

Publications series

elni publishes a series of books entitled “Publications of the Environmental Law Network International”. Each volume contains papers by various authors on a particular theme in environmental law and in some cases is based on the proceedings of the annual conference.

elni Website: elni.org

The elni website www.elni.org contains news about the network. The members have the opportunity to submit information on interesting events and recent studies on environmental law issues. An index of articles provides an overview of the elni Review publications. Past issues are downloadable online free of charge.

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