German Law Journal (2022), **23**, pp. 769–799
doi:10.1017/glj.2022.47

CAMBRIDGE UNIVERSITY PRESS

ARTICLE

Transatlantic Divergencies in the Regulation of Uncertain Risks: Co-Production, Normative Frames and Ideal Evidence-Based and Socially Acceptable Risk Approaches

Giulia Claudia Leonelli[1]

[1]Department of Law, Birbeck College, University of London, London, United Kingdom
Corresponding author: g.leonelli@bbk.ac.uk

(Received 06 December 2021; accepted 16 March 2022)

Abstract
This article analyses the US and the EU systems of risk regulation through the lens of two ideal models: evidence-based and socially acceptable risk approaches. The examination is conducted against the backdrop of these ideal regulatory paradigms, which broadly inform US and EU risk governance. The article employs an analysis of transatlantic divergencies in the regulation of pesticides and agricultural biotechnologies to illustrate that neither approach can lay claim to neutrality and objectivity; non-scientific normative frames are always at stake in the field of risk regulation. Through these case studies, the article thus challenges the narrative that transatlantic divergencies result from a focus on "risks" or "hazards," "science" or "politics." The US and the EU systems reflect different approaches to scientific uncertainty, the pursuit of different levels of protection, and consideration of different non-scientific factors. They also have very different implications. The conclusive section of the article sketches out some final considerations on the strategic vision of the Biden administration. Environmental and public health protection are high on President Biden's agenda; further, public interest litigation is thriving in the US. Will this be sufficient to break regulatory path dependency and lay the foundations for a paradigm shift in US risk governance?

Keywords: Co-production Theory; Agricultural Biotechnologies; Pesticides; US Law; EU Risk Regulation

A. Introduction

This article analyses the US and the EU systems of risk regulation through the lens of two ideal models: evidence-based and socially acceptable risk approaches.[1] The examination is conducted against the backdrop of these ideal regulatory paradigms, which broadly inform US and EU risk governance. While influenced by co-production theory and post-modern accounts of risk regulation,[2] the conceptual framework developed in this article puts forward a specific categorization of the relevant regulatory notions and systematizes them under the umbrella of evidence-based and socially acceptable risk approaches.

[1]For a detailed overview of these ideal models and an application in the context of the transnational conundrum of agricultural biotechnologies, see GIULIA CLAUDIA LEONELLI, TRANSNATIONAL NARRATIVES AND REGULATION OF GMO RISKS (2021).

[2]On the notion of co-production, see Sheila Jasanoff (ed), STATES OF KNOWLEDGE: THE CO-PRODUCTION OF SCIENCE AND SOCIAL ORDER (2004).

The article employs two case studies, governance of pesticidal products and governance of genetically engineered organisms ("GE organisms"), to uncover the rationales and the far-reaching implications of the two ideal models: these are largely reflected in the US and the EU regulatory frameworks in these fields. More specifically, the article challenges two recurrent criticisms raised against EU risk regulation. The first is the assumption that EU risk regulation focuses on "hazards", rather than "risks."[3] This is addressed in the case study on pesticidal products. The second is the narrative on the "politics" versus "science" dichotomy and the EU "politicized" approach to risk regulation.[4] This aspect is under examination in the case study on GE organisms.

The article challenges these framings. From a completely different perspective, it aims to demonstrate that ideal evidence-based and socially acceptable risk approaches, and US and EU risk regulation, reflect different value systems and pursue different goals. Neither approach can lay claim to neutrality or objectivity; rather, they are informed by different normative frames. Nor can any of the two models be considered "better" than the other. Rather, they have very different implications.[5]

As the article concludes, ideal evidence-based models seek to achieve aggregate wealth maximization and the greatest net beneficial protection of public health and the environment. These goals are largely reflected in the US system of risk governance. Under ideal socially acceptable risk approaches, by contrast, regulators may choose to pursue enhanced levels of protection, may have recourse to the precautionary principle, or may take other legitimate factors into consideration when setting the threshold of acceptable risk. This paradigm informs the institutional architecture of EU risk regulation. Non-scientific normative frames are inherent to both approaches, and to both the US and the EU systems.

Sections B, C and D set the stage for the examination, illustrating the conceptual background of the enquiry, the specific characteristics of ideal evidence-based and socially acceptable risk models, and the reasons why the US and EU risk regulation systems are broadly informed by these paradigms. Section E focuses on the first case study, governance of pesticidal products. The analysis of US and EU regulation of pesticides through the lens of evidence-based and socially acceptable risk models sheds some light on the gap between the two jurisdictions in this field, challenging the myth that EU regulation focuses on "hazards". Section F turns to an analysis of governance of GE organisms, undertaking the same form of examination and challenging the "politics" versus "science" dichotomy.

The final section of the article pulls together the threads of the enquiry and highlights the implications of the two opposed ideal approaches. It also sketches out some final considerations on the environmental and public health protection agenda of the Biden administration, and the crucial role played by public interest litigation in Federal and State Courts. Will this be enough to break regulatory path dependency in the US? Will the Biden administration's approach set the foundations for a long-lasting paradigm shift in the US system of governance of uncertain risks, or is it a mere temporary deviation from the well-entrenched US focus on regulatory cost-benefit effectiveness?

B. Hazards, Risks and Different Forms of Scientific Uncertainty

The first and critical distinction in the field of risk regulation is the one between "hazard" and "risk." A "hazard" is defined as a biological, chemical or physical agent with the potential to cause adverse effects.[6] A "risk," on the other hand, is technically defined as a function of the probability of occurrence of adverse effects and the severity of these effects, consequential to

[3]*See, e.g.,* Ragnar Löfstedt, *Risk versus Hazard. Regulating in the 21st Century*, 2 Eur. J. Risk Regulation 149 (2011); Ragnar Löfstedt, Risk Management in Post-Trust Societies (2009).

[4]Examples are Cass Sunstein, Risk and Reason. Safety, Law and the Environment (2002); Cass Sunstein, Laws of Fear. Beyond the Precautionary Principle (2005); Mark Pollack & Gregory Shaffer, When Cooperation Fails. The International Law and Politics of Genetically Modified Foods (2009).

[5]For an in-depth account, see Leonelli, *supra* note 1.

[6]*See* Codex Alimentarius Commission, 27 Procedural Manual 128 (Joint FAO/WHO Food Standards Programme, 2019).

https://doi.org/10.1017/glj.2022.47 Published online by Cambridge University Press

exposure to a hazard.[7] The "risk assessment" stage involves an identification and characterization of hazards and risks, conducted by technical-scientific experts. "Risk management," by contrast, entails weighing and balancing all interests at stake with a view to deciding whether and how to regulate uncertain risks.[8] The first step to define and examine ideal evidence-based and socially acceptable risk approaches consists in an analysis of different forms of scientific uncertainty. Unsurprisingly, uncertainties are ubiquitous in the field of risk governance and may emerge at every step of the risk assessment process. They may be broadly categorized as *hazard-related*, *risk-related* and *methodological* uncertainties.[9]

Hazard-related uncertainties may surround inconclusive scientific proof of a direct causal link between the—potentially hazardous—properties of a product or process and adverse public health or environmental effects. GE organisms offer an example; hybridization and crop to crop gene flow may produce adverse environmental effects and threaten biodiversity and specific ecosystems, yet scientific uncertainty persists in this regard. The potential allergenicity of GE foods and the potential public health risks posed by crops engineered to be herbicide or multi-herbicide resistant also come into play. Another prominent example is scientific controversy as to the potential public health effects associated with residues of hormones—administered for growth promotion purposes—in meat.

Hazard-related uncertainties may also relate to the nature and the severity of the specific hazards at stake, as evaluated throughout the hazard characterization stage; this is defined as the "qualitative and/or quantitative evaluation of the nature of the adverse . . . effects associated with biological, chemical and physical agents . . . ."[10] Different confounding factors and variability will come into play. The latter notion refers to the varying extent to which different constituencies will be vulnerable to the effects of exposure to specific hazards and susceptible to the relevant harmful impacts.[11]

Risk-related uncertainties, on the other hand, emerge at the exposure assessment and risk characterization stages.[12] Factors such as exposures in real life conditions, the efficacy of specific risk management measures or multiple exposures come into play. Pesticidal products offer some good practical examples. Operator exposure to pesticides is affected by the efficacy of the risk management measures in place as well as specific real life—for instance, climatic, environmental and geomorphological—conditions. The same applies to the environmental adverse effects of pesticides. Further, the issue of multiple exposures, their adequate evaluation by risk assessors and the assessment of the relevant adverse effects is at stake in the governance of maximum residue levels ("MRLs") of pesticides in food.

At a more general level, the available scientific evidence may be regarded as insufficient for the purposes of a reliable qualitative or quantitative evaluation of the probability of occurrence of adverse effects and their severity. Diverging data may also cast doubts on the possibility to adequately characterize risks. Further, the specific pathway by which a risk may materialize can be disputed.[13] In all these cases, specific forms of risk-related uncertainty come into play.

[7] *Id.*

[8] *Id.*

[9] For this categorization see Leonelli, *supra* note 1. For other categorizations of different forms of scientific uncertainty, *see, e.g.*, Silvio Funtowicz & Jerome Ravetz, Uncertainty and Quality in Science for Policy 17 (1990); Vern Walker, *The Myth of Science as a 'Neutral Arbiter' for Triggering Precautions*, 26 B. C. Int'l and Compar. L. Rev. 197 (2003).

[10] Codex, *supra* note 6, at 137.

[11] National Research Council, Science and Decisions: Advancing Risk Assessment 6 (2009) ("the Silver Book").

[12] Exposure assessment aims to qualitatively and/or quantitatively evaluate potential exposures to the relevant hazard. Risk characterization is the final stage of the process; it involves a qualitative and/or quantitative evaluation of the probability of occurrence of adverse effects, as resulting from (predicted) exposures to a hazard.

[13] For example, uncertainties surrounding the pathway by which a risk may materialize emerge in the assessment of the risks posed the potential entry, establishment and spread of a pest or disease.

https://doi.org/10.1017/glj.2022.47 Published online by Cambridge University Press

Finally, methodological uncertainties arise from the application of different causal relationships, models, safety factors, forms of expert judgment or default assumptions. To give some examples, specific hazardous properties may be proven *in vitro*; however, there may be no conclusive proof of the same hazards *in vivo*. Dose-response assessments, namely the "determination of the relationship between the magnitude of exposure (dose) to a . . . [hazard] and the severity and/or frequency of associated adverse health effects (response),"[14] may be based on linear or threshold models. Threshold models are premised on the identification of a threshold value below which adverse effects are not expected to occur, or are expected to be unlikely to occur. The relevant threshold may be calculated on the basis of a No-Observed-Adverse-Effect Level ("NOAEL") or, in the majority of cases, by reference to a Lowest-Observed-Adverse-Effect Level ("LOAEL") or mathematical Benchmark-Dose-Lower-Confidence Limit ("BMDL").[15] Linear models, by contrast, postulate that the probability of occurrence of adverse effects linearly decreases as the dose decreases. At a more general level, reliance on different methods and models can yield (very) different results, resulting in different findings on hazards[16] or risks.

Ubiquitous uncertainties are the starting point for an analysis of evidence-based and socially acceptable risk approaches; indeed, uncertainty and variability are differently addressed under the two paradigms. The next section thus takes a closer look at the two ideal regulatory models and their distinctive features.

C. From the Co-Production of Facts and Values to Ideal Evidence-Based and Socially Acceptable Risk Approaches

More than thirty years have elapsed since the publication of Sheila Jasanoff's pathbreaking account of the "fifth branch."[17] Ever since then, the notion of the co-production of facts and values, cognitive and normative dimensions, science and social order has been highly influential for all post-modern enquiries into the regulation of uncertain risks.[18] The conceptual framework employed in this article draws on co-production theory and is indebted to Jasanoff's pioneering work in science and technology studies.[19] More specifically, it aims to contribute to post-modern accounts in this field by pushing the analysis further in three directions.

First, the theorization of ideal evidence-based and socially acceptable risk approaches elaborates further on the notion of co-production by taking the *continuum* of *risk assessment* and *risk management* into consideration as its object of enquiry. In this sense, the conceptual framework employed in this article broadens the scope of analysis. The co-production and mutually constitutive nature of facts and values is inherent to the dichotomy of evidence-based and socially acceptable risk approaches. Rather than focusing on the risk assessment stage and the "socially embedded" nature of science,[20] however, the conceptualization of evidence-based and socially

[14]Codex, *supra* note 6, at 136.

[15]*See* United States Environmental Protection Agency, *Guidelines on Conducting a Human Health Risk Assessment*, https://www.epa.gov/risk/conducting-human-health-risk-assessment.

[16]For a clear example in the field of EU regulation of chemicals, see the analysis in Giulia Claudia Leonelli, *The Fine Line between Procedural and Substantive Review in Cases Involving Complex Technical-Scientific Evaluations: Bilbaína*, 55 Common Market L. Rev. 1217 (2018).

[17]Sheila Jasanoff, The Fifth Branch: Science Advisers as Policy-Makers (1990).

[18]Jasanoff, *supra* note 2. For a post-modern account of "post-normal" science, see Silvio Funtowicz & Jerome Ravetz, *Science for the Post-Normal Age*, 25 Futures 739 (1993). For a critique of the "illusory separation between values and science" in the field of risk regulation, *see* Maria Lee, *Beyond Safety? The Broadening Scope of Risk Regulation*, 62 Current Legal Problems 242 (2009).

[19]*See* Sheila Jasanoff, Gerald Markle, James Petersen and Trevor Pinch (eds), Handbook of Science and Technology Studies (2001); Sheila Jasanoff, *A Field of Its Own: The Emergence of Science and Technology Studies*, *in The* Oxford Handbook of Interdisciplinarity (Robert Frodeman ed., 2017).

[20]Jasanoff, *supra* notes 2, 17.

https://doi.org/10.1017/glj.2022.47 Published online by Cambridge University Press

acceptable risk approaches aims to identify the normative frames which underlie the entire risk regulation process.

Second, it takes a distinctive *legal* perspective. The conceptual framework developed in this article puts forward a specific categorization of the relevant regulatory notions, and systematizes them under the umbrella of ideal evidence-based and socially acceptable risk approaches.

Finally, in accordance with its post-modern foundations, this framework provides a toolbox to *deconstruct* the goals, underlying value systems and far-reaching implications of different regulatory approaches. Evidence-based and socially acceptable risk models offer a conceptual apparatus to explain the causes of regulatory divergencies and conflicts; in this respect, they bear some resemblance to ideal Rational-Instrumental and Deliberative-Constitutive models.[21] Unlike *modern* Rational-Instrumental and Deliberative-Constitutive paradigms, however, *post-modern* evidence-based and socially acceptable risk approaches do not lay emphasis on *procedural* aspects and different models of administrative constitutionalism. From a completely different perspective, they focus on different *substantive* regulatory categories, goals, and normative frames.

Under ideal evidence-based paradigms, a *sound science approach* to risk assessment must be adhered to and *sound science* must be relied on. For the purposes of the present analysis, the notion of "sound science" is associated with positive and conclusive scientific proof of the existence of a hazard and pathway for the materialization of a risk. In cases where science cannot establish a causal link between the properties or characteristics of a product or process, on the one hand, and adverse effects, on the other, hazard-related uncertainties are regarded as "theoretical uncertainty". The same applies to risk-related uncertainties, in cases where the pathway for the materialization of a risk has not been positively established.[22] In a similar vein, adherence to sound science implies that the evidence base which is available at the current stage of technical-scientific knowledge will hardly be regarded as insufficient for the purposes of decision-making. The evolutionary nature of science or the perceived unreliability of the available data are not considered a valid justification for the adoption of stringent risk management measures.[23] Nor is the coexistence of different bodies of scientific opinion relevant, in so far as evidence-based models largely involve adherence to majority opinion.

The notion of a "sound science approach" to risk assessment is broader than the one of "sound science."[24] It encompasses recourse to specific "science-policy choices" and reflects specific policy judgments; this form of judgments are always inherent to the risk assessment stage.[25] Reliance on a sound science approach to risk assessment may be reflected in the adoption of specific models for hazard identification and for hazard characterization, specific probabilistic models for the assessment of potential exposures, the application of specific safety factors to address variability, and reliance on specific forms of expert judgments and default assumptions. At a general level, a "sound science approach" to risk assessment reflects a specific framing and understanding of the notions of uncertainty and variability: these are ultimately considered to be predictable, objectively quantifiable and manageable.[26] Having recourse to prudential approaches and worst-case

[21]*See* Elizabeth Fisher, Risk Regulation and Administrative Constitutionalism (2007).

[22]For an analysis of both scenarios, see *infra*, Section D.

[23]See *infra*, Section D.

[24]The question of regulatory focus on "sound science" or "uncertainty" is distinct from the issue of recourse to "sound scientific" or "prudential" approaches to risk assessment. First, the "sound science" versus "uncertainty" dichotomy does not center on scientific methodological questions pertaining to the risk assessment stage, but on the interpretation of the available data by regulators. Second, it encompasses a focus on the different ways in which the "same" evidence base may be differently interpreted by different regulators. Third, in cases where hazards and risks have been conclusively established, the former dimension (recourse to "sound scientific" or "prudential" approaches) may result in regulatory divergencies; the latter dimension ("sound science" versus "uncertainty"), by contrast, will not come into play.

[25]National Research Council, Risk Assessment in the Federal Government: Managing the Process 28 (1983) (the "Red Book"); Silver Book, *supra* note 11, 43–45. *See also* Jasanoff, *supra* note 17.

[26]For the same view, set against the different theoretical backdrop of procedural Rational-Instrumental paradigms, see Fisher, *supra* note 21.

https://doi.org/10.1017/glj.2022.47 Published online by Cambridge University Press

scenarios and potentially over-estimating risks is thus unwarranted, from an evidence-based perspective.

In the face of scientific pluralism, high levels of complexity and multiple uncertainties, there is ultimately no guarantee that sound scientific risk assessments and sound science will provide factually "correct" answers. The boundaries between "objective" facts and "subjective" values thus fade in the field of risk regulation. Far from being neutral and objective, the assumption that sound science approaches to risk assessment *must* be adhered to and that sound science *must* be relied on is *indirectly* informed by a normative frame: the pursuit of an *economically cost-benefit effective level of protection*. Clearly, sound science approaches and a focus on sound science relieve market actors from the regulatory burdens and economic costs associated with a focus on scientific uncertainty.[27]

Indeed, in cases where hazards and risks have been conclusively proven, evidence-based models expressly rely on the application of economic cost-benefit analysis and postulate that regulation should only be enacted in so far as the relevant public health and environmental benefits outweigh the economic costs associated with risk regulation. The legally relevant threshold of probability of occurrence of adverse effects and their severity, that is, the threshold triggering regulation, is determined through the application of cost-benefit analysis: the adverse effects of a product or process should not be "excessive", taking into account the economic benefits associated with the relevant product or process and the economic costs of regulation. The level of protection pursued by regulators is bound to be the one which is *cost-benefit effective*;[28] the relevant normative frame thus emerges *directly* in these cases. This sheds some light on ideal evidence-based paradigms and their constituent elements and regulatory categories. As this brief analysis has illustrated, sound science approaches to risk assessment, adherence to sound science and recourse to cost-benefit analysis are *co-produced*.

From a diametrically opposed perspective, ideal socially acceptable risk approaches postulate that due consideration should be given to uncertainty and variability, as a matter of risk assessment policy. A *prudential* risk assessment should highlight uncertainties emerging from each step of the assessment process and take long-term, indirect and cumulative effects into due account. Further, risk assessments should be comprehensive and dispel persisting uncertainties in so far as technically possible at the current stage of scientific knowledge. Prudential safety factors, prudential probability modelling and prudential forms of expert judgment should be employed to address uncertainties surrounding hazard characterization, exposures and variability.

Unlike under ideal evidence-based models, regulators do not have to adhere to sound science; *persisting uncertainty* as to the existence of a hazard or the actual materialization of a risk do not prevent them from taking action. Equally, risk assessors or regulators may conclude that the available scientific evidence is insufficient for the purposes of an adequate characterization of the relevant risks. This could result in a decision to refrain from authorizing a product, or in the enactment of stringent risk management measures.

Recourse to prudential approaches to risk assessment and the possibility for regulators to focus on persisting uncertainty *indirectly* reflect the pursuit of a *higher than cost-benefit effective* level of protection, and consideration of *other legitimate factors*; these are the normative frames through which science is assessed and evaluated under socially acceptable risk approaches. And indeed, in

[27]In cases where hazards and risks have been conclusively established, as explained below in this section, the normative frame underlying the evidence-based regulatory process comes into play *directly*. In cases where hazards and risks are not conclusively proven, by contrast, the normative frame (that is, the pursuit of cost-benefit effective levels of protection) only comes into play *indirectly*; in other words, it informs the assessment of uncertain risks ("sound science approaches") and the evaluation of scientific evidence ("sound science").

[28]If analyzed through the prism of proportionality, this would correspond to stricto sensu proportionality (cost-benefit effectiveness of the level of protection) rather than necessity (cost-benefit effectiveness of the risk management measures enacted to comply with the specific intended level of protection). See *infra*, Section D.

https://doi.org/10.1017/glj.2022.47 Published online by Cambridge University Press

cases where hazards and risks have been conclusively established, the intended level of protection pursued by regulators is not bound to be the one which is cost-benefit effective.

First, regulators may pursue *enhanced* levels of public health or environmental protection. For instance, they may decide to minimize exposures to hazardous substances, regardless of whether the relevant risks are deemed "negligible" or "acceptable" in other jurisdictions. Further, they may set a regulatory presumption that no safe level of exposure can be determined for highly hazardous substances.[29] Even in cases where uncertainties are not salient, the pursuit of enhanced rather than cost-benefit effective levels of protection is bound to result in (very) different regulatory outputs.

Second, regulators may have recourse to the *precautionary principle* where scientific uncertainty persists and a risk is considered too high to be acceptable.[30] Third, when determining the intended level of protection and setting the threshold of acceptable risk, regulators may take a range of other legitimate factors ("*OLFs*") into account. These include public opinion, a consideration of the availability and efficacy of alternative risk management measures, an evaluation of the social advantages and disadvantages associated with the relevant product or process, an analysis of the distributional implications of risk regulation, considerations as to the potential substitution of products or processes with less hazardous alternatives, and a long-term vision for the development of more sustainable approaches in specific sectors.[31]

Clearly, evidence-based and socially acceptable risk approaches are two sides of the same coin. Prudential approaches to risk assessment, regulatory focus on persisting uncertainty, the pursuit of higher than cost-benefit effective levels of protection and consideration of qualitative OLFs are also *co-produced*. This does not mean that socially acceptable risk approaches will always result in an application of the precautionary principle, the enactment of stringent risk management measures, or consideration of specific OLFs. Nor does it mean that they will always result in the pursuit of enhanced levels of protection. Rather, it means that more than sound science and economic cost-benefit effectiveness *may* be taken into account by regulators. For this reason, a higher level of protection than that achievable under evidence-based approaches may be pursued, or precautionary action may be taken. Equally, OLFs which are beyond the radar of evidence-based paradigms may be taken into consideration.

This overview triggers some considerations. First, as the next sections endeavor to illustrate in practice, the determination of the *legally relevant* threshold of probability of occurrence of adverse effects is never a matter of "pure" science.[32] Rather, it results from three factors. The first factor consists in recourse to more or less prudential approaches to risk assessment. This affects the *evidence base* that the regulators draw upon. The second factor is the extent to which regulators focus on sound science, as opposed to persisting uncertainties on hazards and risks or the perceived insufficiency of the available evidence. This affects the *inferences* that regulators draw from the available evidence.[33] The third factor is the (cost-benefit effective or enhanced) level of protection pursued by regulators and the specific non-scientific factors that they take into account for the purposes of their decision. These are the *normative frames* which *directly* or *indirectly* inform the entire risk regulation process, and which result in the identification of a different threshold of acceptable risk.

Second, neither evidence-based nor socially acceptable risk approaches can lay claim to neutrality or objectivity. To begin with, sound scientific approaches do not reflect scientific

[29]See *infra* Section E, sub-section II, for some practical examples.

[30]Different definitions of the principle coexist across legal systems; see *infra*, Section D, for an analysis of the EU law understanding.

[31]On the relevance of OLFs in the governance of uncertain risks, see Lee, *supra* note 18.

[32]Leonelli, *supra* note 1. The sentence/terminology is borrowed from Walker, *supra* note 9.

[33]*See supra* note 24 for a clarification regarding the distinction between "sound scientific" and "prudential" approaches to risk assessment, on the one hand, and regulatory focus on "sound science" or "uncertainty", on the other hand.

https://doi.org/10.1017/glj.2022.47 Published online by Cambridge University Press

certainty or universal scientific consensus. Sound science, or even the "best" science, will not always and not necessarily yield any factually "correct" answers; the linkage between the assumption that sound science *must* be adhered to and regulatory cost-benefit effectiveness thus becomes apparent.

Even in cases which are relatively uncontroversial in scientific terms, there is no value-free way out of the *acceptability* of a risk, regardless of how "small" or "uncertain" it may be. The assumption that the results of a sound risk assessment are all that matters to determine whether a risk should be taken is informed by considerations surrounding the cost-benefit effectiveness of risk regulation. Equally, the assumption that political or social OLFs are irrelevant to establish the acceptability of "small" or "big", "unlikely" or "likely" risks is no more than an artificial discourse: yet again, a discourse informed by economic considerations.[34] In this specific respect, the systematization of regulatory categories under the umbrella of evidence-based and socially acceptable risk approaches helps overcome the long-standing compartmentalization between "scientific" evaluations and "political" considerations pertaining to OLFs. Far from being value-neutral and objective, the narrative on "political" OLFs and the idea that they cannot be taken into consideration for the purposes of establishing the threshold of acceptable risk is influenced by the tenets of economic cost-benefit effectiveness; scientific and non-scientific evaluations are structurally intertwined in the field of risk regulation.

Further, it is worth stressing again that in cases where hazards and risks have been conclusively proven, regulators will always and necessarily draw on non-scientific factors to set the threshold of legally relevant adverse effects. This also confirms that the determination that a specific risk is "acceptable" or "negligible" unavoidably draws on normative evaluations.

To conclude, the conceptual apparatus of evidence-based and socially acceptable risk approaches also helps overcome the dichotomy of "sound science" and "precaution". This is important for at least three reasons. First, the "sound science" versus "precaution" dichotomy fails to capture the normative frames underlying the risk regulation process. It tells us nothing of the reasons why experts follow different approaches to risk assessment, and regulators draw different inferences from the available evidence base. Second, in cases which are relatively uncontroversial in scientific terms, this dichotomy cannot explain different determinations as to the acceptability of a risk. In so far as it fails to encompass *non-scientific* economic considerations and *non-scientific* OLFs, a focus on "sound science" and "precaution" is too narrow to account for the complexities of risk regulation. Finally, in cases where hazards and risks have been conclusively established, the dichotomy of "sound science" and "precaution" is largely irrelevant. In these cases, as already explained, non-scientific considerations surrounding the determination of the intended level of protection will come into play directly; ultimately, regulators will have to strike a balance between economic and non-economic interests.

The next section briefly illustrates how the US and the EU risk regulation systems are broadly informed by the two opposed ideal paradigms of risk governance. While a set of specific caveats apply, the next section aims to demonstrate that the regulatory philosophy of the two regimes is structurally different.

[34]For instance, this is revealed by a comparison between the treatment of so-called "lifestyle" risks, on the one hand, and the narrative that uncertain risks to public health and the environment *must* be taken unless conclusively established or as long as this regulatory choice proves cost-benefit effective, on the other. In the latter case, the consideration of OLFs is erroneously considered to result in a "politicization" of regulatory choices. In the case of "lifestyle" risks, by contrast, normative questions surrounding the acceptability of a risk, regardless of how "small" or "uncertain" it may be, are perceived as central to decision-making. The difference in the treatment of these categories of risk confirms that the narrative that OLFs cannot be taken into account to establish the acceptability of uncertain risks is indirectly informed by economic considerations.

https://doi.org/10.1017/glj.2022.47 Published online by Cambridge University Press

D. US and EU Risk Governance: How They are Broadly Informed by the Two Ideal Regulatory Models

Evidence-based and socially acceptable risk approaches are ideal paradigms, set along a spectrum of differential regulatory implementation. Borrowing the words used in the discussion of Rational-Instrumental and Deliberative-Constitutive paradigms, these models represent "polar and incommensurable opposite understandings" of risk governance.[35] Neither the US nor the EU risk regulation systems are entirely or perfectly aligned to these models, across every area in the field of risk governance. In other words, the extent to which US and EU *regulatory frameworks* conform to the ideal models varies. Equally, *regulatory implementation* may vary considerably. Regulatory frameworks reflecting socially acceptable risk approaches may then be implemented in an evidence-based manner; the opposite may also occur.[36]

Nonetheless, it is fair to acknowledge that the US and the EU risk governance systems are broadly informed by the two opposite ideal models. Reference to the two paradigms and their underlying conceptual apparatus allows sufficient flexibility to overcome the long-standing debate on the "reality of precaution" and the extent to which US risk regulation is less "precautionary" than EU risk regulation.[37] From a different perspective, an analysis through the conceptual dichotomy of evidence-based and socially acceptable risk approaches demonstrates that US and EU risk governance are influenced by different regulatory philosophies. In other words, important elements of the two ideal models are reflected in the US and the EU regulatory systems and find expression in regulatory practice in these jurisdictions. The extent to which the two regimes conform to the ideal models in discrete areas of regulation must then be assessed in practice, on a case-by-case basis, and at a given point in time.

US risk governance is strongly influenced by ideal sound science approaches to risk assessment and by the tenet of adherence to sound science. References to "sound science" and "sound scientific standards" are ubiquitous in policy documents.[38] Uncertainty and variability are afforded a different value than in the context of prudential risk assessments and prudential "science-policies." With specific regard to the notion of "sound science," uncertainties surrounding the existence of a hazard or the actual materialization of a risk are usually deemed irrelevant.[39] In accordance with the general US regulatory philosophy, hazards and risks must be conclusively proven for a product to be the object of specific *risk management measures*. Further, in many cases, hazards and risks must be conclusively proven for a product to be the object of *regulation* and of specific *authorization procedures*.[40]

The US has consistently advocated and actively sought to export this approach, claiming that regulatory focus on scientific uncertainty or insufficiency and recourse to the precautionary principle are non-scientific.[41] Risk assessments conducted by US agencies may of course be cautious and prudential. This is liable to result in stringent regulatory standards. Equally, US agencies may

[35]Fisher, *supra* note 21.

[36]*See infra* Section F (on the regulatory implementation of the EU framework for the governance of GE organisms) & Section G (on President Biden's agenda and the evolving approach of the US Environmental Protection Agency).

[37]*See* John Graham, *Saving Lives through Administrative Law and Economics*, 157 U. Pa. L. Rev. 395 (2008); JB Wiener, *Whose Precaution After All? A Comment on the Comparison and Evolution of Risk Regulatory Systems*, 12 Duke J. Comp. Int'l L. 207 (2003); Jonathan B. Wiener, Michael D. Rodgers, James K. Hammitt, Peter H. Sand, The Reality of Precaution. Comparing Risk Regulation in the United States and Europe (2011); David Vogel, The Politics of Precaution. Regulating Health, Safety and Environmental Risks in Europe and the United States (2012).

[38]For a famous example, *see* Executive Office of the US President, Office of Science and Technology Policy, *Coordinated Framework for the Regulation of Biotechnology*, June 26, 1986.

[39]As regards the existence of a hazard, *see e.g.* the factual background in *EC – Hormones*, Panel Report (adopted 13 February 1998) WT/DS26/R/USA; and *EC – Biotech*, Panel Report (adopted 21 November 2006) WT/DS291, WT/DS292, WT/DS293. As regards the materialization of a risk, see for instance the background in *Japan – Agricultural Products II*, Panel Report (adopted 19 March 1999) WT/DS76/R; and *Japan – Apples*, Panel Report (adopted 10 December 2003) WT/DS245/R.

[40]For a clear example in the context of US governance of GE organisms, see *infra* Section F, sub-section II.

[41]*Supra* note 39.

https://doi.org/10.1017/glj.2022.47 Published online by Cambridge University Press

pursue higher than cost-benefit effective levels of protection, in cases where hazards and risks have been established. This is also liable to result in stringent regulatory standards. Nonetheless, sound scientific proof of the existence of a hazard and materialization of a risk is required for regulators to take action. In this sense, the precautionary principle "stricto sensu" does not apply in the US system of risk regulation; nor is there any evidence of regulatory recourse to it.[42] Conclusive scientific proof of hazards and risks is needed for regulatory purposes.

Turning to the cases where hazards and risks have been conclusively established, the US system relies heavily on the application of cost-benefit analysis with a view to determining to what extent and how to regulate risks. A fully-fledged application of cost-benefit analysis models does not merely aim to identify cost-benefit effective *risk management measures*, which are enacted to comply with the intended level of protection. In a different vein, it aims to identify the cost-benefit effective threshold of probability of occurrence of adverse effects. This is the point where, taking into consideration the probability of occurrence of adverse effects, the benefits of regulating will outweigh all relevant economic costs.[43] Thus, the *intended level of protection* pursued is meant to be the one which is cost-benefit effective. The application of economic cost-benefit analysis to the regulatory process has been entrenched in the US since the years of the Reagan presidency, and was revamped under the Trump presidency.[44] However, it is worth clarifying two points.

First, as documented throughout the years, US regulators will be bound to pursue higher than cost-benefit effective levels of protection and will omit to weigh and balance economic costs and benefits where a statute so provides.[45] Second, the regulatory treatment of cost-benefit analysis has evolved throughout the years. Executive Order 12291 of 1981 instructed agencies to conduct a full cost-benefit analysis prior to taking regulatory action. Regulation could not be enacted unless the relevant benefits *outweighed* the economic costs associated with all regulatory burdens.[46] By adopting Executive Order 12886 of 1993, President Clinton amended the relevant applicable criteria and administrative processes. Pursuant to this Order, agencies are under a duty to "assess both the costs and the benefits of intended regulation and [. . .] propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation *justify* its costs."[47] This has marked a shift towards a softer approach to the (stricto sensu) cost-benefit effectiveness of the level of protection pursued by regulators. Nonetheless, the Order still mandates a close focus on the cost-benefit effectiveness ("necessity") of the regulatory measures selected to achieve the relevant goals.[48]

"Significant regulatory actions" by executive agencies are subject to a centralized review process conducted by the Office of Information and Regulatory Affairs ("OIRA"); a cost-benefit analysis shall be submitted for review.[49] In the case of "significant regulatory actions" with specific annual effects on the US economy, a fully-fledged regulatory impact analysis is required.[50] The Executive Orders adopted under the Obama Presidency have further softened regulatory applications of cost-benefit analysis, broadening the margins of maneuver. Qualitative measures of costs and

[42]Intuitively, the reason is that in the absence of scientific proof of the existence of a hazard or materialization of a risk, or in so far as the available evidence is sufficient for technical-scientific experts to conduct a risk assessment, "stricto sensu" precautionary measures could not possibly be cost-benefit effective in economic terms. In other words, recourse to the precautionary principle does not respond to the tenets of economic cost-benefit analysis.

[43]*See infra* Section F, sub-sections I & III. *See also supra* note 28.

[44]*See* Exec. Order No. 13,771, 82 Fed. Reg. 9339-9341 (Jan. 30, 2017). The 2017 Order has been revoked by President Biden in 2021. *See* Exec. Order No. 13,992, 86 Fed. Reg. 7049-7050, (Jan. 20, 2021).

[45]For a detailed analysis, *see* Cass Sunstein, *Cost-Benefit Analysis and Arbitrariness Review*, 41 HARV. ENVTL. L. J. 1 (2017).

[46]*See* Exec. Order No. 12,291, 46 Fed. Reg. 13193-13198 (Feb. 17, 1981).

[47]*See* Exec. Order No. 12,866, 58 Fed. Reg. 51735-51835, § 1(b)(6), (Sept. 30, 1993) (emphasis added).

[48]*Id.* at §§ 1(b)(5); 1(b)(11).

[49]*Id.* at § 6(a)(3)(A).

[50]*Id.* at §§ 6(a)(3)(B)-(C).

https://doi.org/10.1017/glj.2022.47 Published online by Cambridge University Press

benefits may be included where quantification would be too complex, and distributive impacts and equity may be taken into account when choosing alternative regulatory approaches.[51]

This brief overview triggers the question whether changes in the regulatory treatment of cost-benefit analysis have gone hand in hand with significant changes in regulatory applications of cost-benefit analysis in the field of risk governance. Have these changes in the regulatory arrangements translated into a (very) different approach at the regulatory implementation stage? Providing a straightforward answer to this question is impossible. The extent to which specific measures conform to stricto sensu cost-benefit effectiveness and necessity or incorporate OLFs such as distributive impacts and equity is very difficult to gauge. In this sense, references to express statutory criteria provide a more reliable indicator of the approach that US agencies (are bound to) follow.[52] Nonetheless, it is fair to suggest that discourses on regulatory cost-benefit effectiveness still play a prominent role within the US risk governance system. Conversely, as the following sections illustrate, qualitative OLFs are largely excluded from the determination of the intended level of protection and selection of risk management measures.[53] It is difficult to tell whether this results from institutional regulatory factors, including the prominence of economic cost-benefit effectiveness criteria in statutory frameworks, or from the normative orientations and policy preferences of (politically and non-politically appointed) officers.[54]

Against this background, to draw a summary, the US approach to risk governance largely reflects ideal evidence-based models. In a diametrically opposite vein, the EU approach is informed by socially acceptable risk models. First, this is broadly confirmed by the allocation of risk management functions to political authorities. These authorities determine the legally relevant threshold of adverse effects by reference to the EU intended level of protection and by taking all relevant factors into account. Had sound science and economic cost-benefit effectiveness been all that regulators had to take into account, technical-scientific agencies would have been perfectly fit for the task, as occurs in regulatory systems drawing on evidence-based approaches.[55] Risk managers are not bound by the positive results of a risk assessment. They may refer to an alternative (i.e. more prudential) evidence base, or draw different inferences as to the acceptability of the relevant risks. Ultimate authority thus rests with political decision-makers.[56] This is an acknowledgment that more than allegedly neutral and objective matters of "pure" science are bound to be at stake in risk governance, and that risk regulation always entails value-laden, political and social determinations.

Second, adherence to a prudential approach to risk assessment and consideration of persisting uncertainties are uncontroversial as a matter of EU risk assessment and risk management policy.[57] Third, the EU level of public health and environmental protection is not bound to be cost-benefit effective. Regulators may thus refer to enhanced levels of protection in specific fields, may seek to minimize exposures,[58] or may start from the assumption that no safe level of exposure can be determined in case of highly hazardous products or processes.[59] Fourth, regulators may have recourse to the precautionary principle when scientific evidence is *incomplete*, *inconclusive* or

[51] *Id.* at § 1(a). *See also* Exec. Order No. 13,563, 76 Fed. Reg. 3821-3823 (Jan. 18, 2011); Exec. Order No. 13,579, 76 Fed. Reg. 41587-41588, (July 18, 2011).

[52] See for instance the analysis by Sunstein, *supra* note 45.

[53] *See infra* Section F, sub-sections I and III.

[54] For a detailed analysis of the "institutional design" versus "cultural factors" conundrum, see the analysis in Vogel, *supra* note 37.

[55] *See* Giulia Claudia Leonelli, *Judicial Review of Compliance with the Precautionary Principle from* Paraquat *to* Blaise*: Quantitative Thresholds, Risk Assessment and the Gap between Regulation and Regulatory Implementation* (2021) 22 German L. J. 184.

[56] *See e.g. Pfizer* case; Case T-13/99, *Pfizer Animal Health SA* v *Council*, EU:T:2002:209, para 149.

[57] Indeed, the terminology of "prudential" approaches to risk assessment is borrowed from European Commission, COM(2000)1 Final, *Communication from the Commission on the Precautionary Principle*, at 12, § 5.

[58] *See infra* Section E, sub-section II.

[59] *Id.*

https://doi.org/10.1017/glj.2022.47 Published online by Cambridge University Press

insufficient and uncertain risks may not meet the *EU intended level of protection*.[60] This acknowledges that society may be willing to pay a high price for the protection of an interest to which it attaches priority.[61] The principle that a high level of protection should be attained and the precautionary principle are enshrined in the Treaties and in every regulatory framework in the field of EU risk governance.[62]

What is remarkably more controversial, on the other hand, is consideration of OLFs. Under ideal socially acceptable risk models, OLFs feed into the determination of the intended level of protection and threshold of socially acceptable risk, making them higher or lower in accordance with the specific circumstances of the case and informing the final decision as to whether a risk is worth taking. High risks might be considered acceptable and worth running, taking all relevant OLFs into account, while comparatively lower risks in different regulatory fields might not be. The role of OLFs is explicitly and implicitly recognized in EU risk regulation.[63] The reluctance to acknowledge their value and relevance in the risk regulation process builds on the recognition that these factors are non-scientific in nature. This is undoubtedly true. Nonetheless, this disregards the point that quantitative considerations surrounding the economic cost-benefit effectiveness of risk governance are just as *non-scientific* as the evaluation of qualitative OLFs. Normative frames are always, *directly* or *indirectly*, at stake in the field of risk regulation.

This section concludes the preliminary overview of the conceptual frame applied in this article. It is against this overall backdrop that the next sections examine US and EU governance of pesticidal products and agricultural biotechnologies, challenging the false dichotomy of "hazard" versus "risk" and "politics" versus "science." Pesticides and GE organisms are very important regulatory areas in the field of risk governance; this is one of the reasons why they have been selected as case studies.[64] Further, while the usual caveats apply, US and EU regulations and regulatory practice in these areas exemplify broader trends in the US and EU systems of risk governance.[65] In this sense, an analysis of US and EU governance of pesticidal products and agricultural

[60]*Communication from the Commission on the Precautionary Principle*, *supra* note 57, at 9 § 3, 12 § 5.

[61]*Id.* at 19 § 6.3.4.

[62]The principle that a high level of protection shall be pursued in the Union is enshrined in a plurality of Articles of the Treaty on the Functioning of the European Union ("TFEU"), starting from Articles 114(3) and 191(2). The precautionary principle is enshrined in Article 191(2) TFEU. In legislative acts, see for instance Recital (8) and Articles 1(4) and 13(2) of Regulation (EC) 1107/2009/EC of the European Parliament and of the Council of 21 October 2009, Concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, OJ 2009 L 309/1 ("PPP Regulation"); Recital (21) and Articles 6(3) and 7(1) of Regulation (EC) 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 ("General Food Law"); Recital (8) and Articles 1(1) and 4(1) of 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, OJ 2001, L106/1 ("Deliberate Release Directive"); and Recitals (9) and (69) and Article 1(3) of Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), Establishing a European Chemicals Agency (ECHA), amending Directive 1999/45/EC and repealing Council Regulation (EEC) 793/93 and Commission Regulation (EC) 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, O.J. 2006, L 396/1 ("REACH").

[63]In legislative acts, see for instance Recital (19) and Articles 3(12), 5(1), 6(3) and 7(2) of the GFL; Article 13(2) of the PPP Regulation; Recitals (9), (57), (58) and (62) and Article 31(7)(d) of the Deliberate Release Directive; and Recital (32) and Articles 4(1) and 7(1) of Regulation (EC) 1829/2003 of the European Parliament and of the Council of 22 September 2003 on Genetically Modified Foods O.J. 2003, L 268/1 ("GM Food and Feed Regulation"). *See also* the *Communication from the Commission on the Precautionary Principle*, *supra* note 57, at 19, sub-section 6.3.4. *See* Leonelli, *supra* note 1 (providing an analysis of how OLFs find indirect/implicit reflection in EU regulatory frameworks.)

[64]The article and all relevant arguments focus on the field of risk regulation stricto sensu: from an environmental and public health protection perspective, this encompasses the regulation of chemicals, pesticidal products, GE organisms, food safety, and pharmaceuticals.

[65]*See* the caveats in this section: the extent to which the US and EU regimes conform to ideal evidence-based or socially acceptable risk models in discrete areas must be assessed in practice, on a case-by-case basis, and at a given point in time.

https://doi.org/10.1017/glj.2022.47 Published online by Cambridge University Press

biotechnologies helps explain why and how the US and the EU regimes are respectively informed by ideal evidence-based and socially acceptable risk models.

E. Governance of Pesticides in the US and the EU: Sound Science and "Unreasonable Adverse Effects" versus Uncertainties and Enhanced Levels of Protection

According to empirical research, 692 pesticidal active ingredients are approved for use in the US, as opposed to 468 pesticidal active substances authorized in the EU. Around 9,000 pesticidal formulations are registered with the US Environmental Protection Agency ("EPA"), as opposed to 2,900 pesticides authorized across the EU.[66]

Seven active substances which are acknowledged to cause severe human health adverse effects are authorized in the US; none of them is authorized in the EU.[67] This includes paraquat, which has been at the center of recent, high-profile public interest litigation in the US.[68] Before August 2021, chlorpyrifos was also authorized for use by the EPA; a recent decision by the Court of Appeal for the Ninth Circuit has resulted in the EPA's revocation of all maximum residue levels ("tolerances") for chlorpyrifos residues in food, the cancelation of all registered food uses of chlorpyrifos, and a review of the registration of this active substance.[69] Both paraquat and chlorpyrifos have come under the spotlight due to their long-term developmental neurotoxic effects. The highly controversial active substance glyphosate is also approved for use by the EPA.[70] Further, all neonicotinoids are approved in the US, with the exception of nitenpyram; none of them are authorized in the EU other than for use in glass houses.[71] Neonicotinoids are associated with severe adverse effects on pollinators.

Data shows that US tolerances for pesticidal residues are also significantly higher than the MRLs provided for under EU law. In many cases, the gap ranges from a (x2) value to a remarkable (x300), (x400) or (x1,000) value.[72] At a general level, as also confirmed by available data, EU MRLs are considerably lower (that is, more stringent) than the transnational baseline set by the Codex Alimentarius Commission standards.[73] US and EU regulatory standards thus significantly diverge in the field of governance of pesticides and pesticide residues.

This section conducts an analysis of US and EU governance of pesticides through the lens of evidence-based and socially acceptable risk approaches, illustrating how the two ideal models and their constituent elements are reflected in the US and EU regulatory systems. Examining US and EU regulation of pesticides against the backdrop of this conceptual framework helps pinpoint the origins and causes of regulatory divergences in this field, together with the underlying regulatory

[66] Sustain & Emily Lydgate, Toxic Trade: Comprehensive and Progressive Agreement for Trans-Pacific Partnership, 22 (Pesticide Action Network UK, 2021).

[67] *Id.*, at 24.

[68] For an overview of paraquat litigation and of the "Paraquat papers", see U.S. Right to Know, *Paraquat Papers – Updates to U.S. litigation*, (last visited Apr. 11, 2022), https://usrtk.org/paraquat-papers.

[69] *See* Pesticide Action Network North America and Others v. EPA, No 19-71979 (9th Cir., 2021). The Court of Appeals for the Ninth Circuit found that the EPA should either produce evidence that consumer exposures to residues of pesticides containing chlorpyriphos in foods are safe under the reasonable certainty criterion (*see infra* sub-section I), or take action. As regards the EPA's decision, *see* United States Environmental Protection Agency, *EPA Takes Action to Address Risk from Chlorpyrifos and Protect Children's Health*, (last visited Apr. 11, 2022) https://epa.gov/newsreleases/epa-takes-action-address-risk-chlorpyrifos-and-protect-childrens-health.

[70] For information on glyphosate litigation and of the "Monsanto papers", see U.S. Right to Know, *Monsanto Papers*, (last visited Apr. 11, 2022), https://usrtk.org/monsanto-papers/.

[71] Further, the approvals for clothianidin and thiamethoxam have recently expired without a request for re-approval.

[72] *Toxic Trade*, *supra* note 66, at 15-18.

[73] *Id.* The Codex Alimentarius Commission international standard-setting body was established in 1963 under the auspices of the Food and Agriculture Organization ("FAO") and the World Health Organization ("WHO"). Its standards are employed as a "benchmark" under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures. For more details, see Leonelli, *supra* note 1.

https://doi.org/10.1017/glj.2022.47 Published online by Cambridge University Press

rationale. The third sub-section thus summarizes the findings of the analysis, challenging the false dichotomy of "hazard" versus "risk"-based regulation and providing a different account of transatlantic regulatory divergencies in this area.

I. Governance of Pesticides in the US: The Evidence-Based Rationale

The United States EPA is in charge for regulating pesticides.[74] Pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"),[75] pesticides may not be distributed or sold in any State unless they have been registered with the EPA.[76] A distinction is drawn between active substances —that is, the main active component(s) in pesticidal formulations—[77] and inert ingredients; the latter, residual category includes any other substances which are present in pesticidal formulations.[78] All relevant active and inert ingredients must be approved by the EPA, in order to register a pesticidal formulation containing them.[79]

Under the registration procedure, applicants shall file a statement including information on the pesticidal formulation and a full description of all relevant tests, results and scientific literature.[80] Specific data requirements are enshrined in the Code of Federal Regulations ("CFR").[81] Nonetheless, the FIFRA takes a flexible approach to the duty of data production.[82] The EPA enjoys very broad discretionary powers throughout the registration procedure. It may at any stage waive data and test results for specific pesticidal products.[83] Further, the FIFRA expressly stipulates that the EPA shall "consider the *economic factors* of potential national volume of use, extent of distribution, and the *impact of the cost* of meeting the requirements on the incentives for any potential registrant to undertake the development of the required data."[84]

The key provision of the entire regulatory framework pertains to the risk management stage. Under the FIFRA, the EPA shall register a pesticide if it determines that, taking into consideration the applicable risk mitigation measures, the pesticidal product's composition is such as to warrant the applicant's claims, the relevant labelling and associated requirements comply with the FIFRA, the pesticidal product will perform its intended function *without unreasonable adverse effects on the environment*, and when used in accordance with widespread and commonly recognized practice it will *not generally* cause *unreasonable adverse effects on the environment*. Lack of essentiality is not a criterion for denying registration; where two products meet FIFRA's requirements, neither of the two should be registered in preference to the other.[85] "Unreasonable adverse effects" are defined as "(1) any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from use of a pesticide in or on any food inconsistent with the standard under section 346a of title 21."[86] As

[74]For the complete definition, *see* 7 U.S.C. § 136(u).

[75]7 U.S.C. § 136 ff.

[76]States may authorize additional uses (for example, on specific crops) of pesticides which are registered with the EPA, as long as all relevant tolerances have been established (see *infra* in this sub-section) and the EPA has not dissented. States are also involved in enforcement. *See* 7 U.S.C. §§ 136u, 136, 136w-i.

[77]7 U.S.C. § 136(a).

[78]7 U.S.C. § 136(n). The Code of Federal Regulations ("CFR") provides further and more detailed definitions. *See* 40 C.F.R. §§ 152.3, 152.15 (2008) (providing the definition of substances used for pesticidal purposes).

[79]*See* Environmental Protection Agency, Pesticide Registration Manual, Ch. 8, (2022) www.epa.gov.

[80]7 U.S.C. § 136a(c)(1). *See also* 40 C.F.R. § 152.50 (2008).

[81]40 C.F.R. § 158(D) (describing product chemistry); 40 C.F.R. § 158(F) (describing toxicology); 40 C.F.R. §158(G) (2008) (describing ecological effects); 40 C.F.R. § 158(K) (2008) (on human exposure); 40 C.F.R. § 158(L) (2008) (describing spray drift); 40 C.F.R. § 158(N) (2008)(describing environmental fate); 40 C.F.R. § 158(O) (2008) (describing residue chemistry).

[82]7 U.S.C. §§ 136a(c)(2)(A), 136a(c)(2)(E) (providing information on minor use waivers).

[83]40 C.F.R. § 158.30 (2008). *See also* 40 C.F.R. § 152.91 (2008); 40 C.F.R. §§ 158.45, 158.75 (2008).

[84]*Id* (emphasis added).

[85]7 U.S.C. § 136a(c)(5).

[86]7 U.S.C. § 136(bb). *See also* 7 U.S.C. § 136(x).

https://doi.org/10.1017/glj.2022.47 Published online by Cambridge University Press

explained below in this sub-section, the second part of the definition cross-references provisions in the Federal Food, Drug and Cosmetic Act ("FFDCA"), as amended by the Food Quality Production Act ("FQPA").[87]

The "unreasonable adverse effects" criterion sets a *baseline* threshold of safety and reflects the pursuit of *cost-benefit effective* levels of protection. The US framework does not aim to minimize exposures or pursue enhanced levels of protection. Rather, the benchmark is the one of "unreasonable" or "excessive" adverse effects, taking into consideration the benefits associated with pesticidal products and the costs of regulation. This reflects considerations surrounding economic cost-benefit effectiveness; and indeed, references to risk-benefit evaluations, economic benefits, and economic costs are ubiquitous in the regulatory framework.[88] Notably, under the CFR, use of pesticidal products should only be restricted to certified applicators or persons under their direct supervision or be the object of further restrictions where the decrease in *risks* as a result of the restrictions *exceeds* the decrease in *benefits*.[89]

The statutory text of the FIFRA and the additional regulatory arrangements of the CFR thus clearly reflect the rationale of evidence-based approaches. Regulatory applications of cost-benefit analysis by the EPA, with a view to identifying an economically cost-benefit effective threshold of probability of occurrence of adverse effects, have then been further strengthened throughout the years. If any doubts persisted surrounding the extent to which cost-benefit analysis models have been employed in product authorizations, these would be dispelled by the 2009 Silver Book and recommendations to the EPA.

According to the Silver Book, the utility of risk assessment to evaluate the merits of different risk management strategies must be improved. Thus, "the questions posed [in the context of risk assessment policy should] arise from early and careful planning of the types of assessments (including risks, costs and technical feasibility) and the required level of scientific depth that are needed to evaluate the relative merits of the options being considered."[90] Notably, as regards product authorizations, the Silver Book recommends the use of linear rather than threshold models at the hazard characterization stage. The express aim is to enable risk managers to take into consideration the respective *economic costs* and *economic benefits* associated with different levels of probability of occurrence of adverse effects and different thresholds for regulatory intervention.[91] According to the Silver Book, because the reference values identified in threshold models "do not quantify risk for different magnitudes of exposure but rather provide a bright line between possible harm and safety, their use in risk-risk and cost-benefit comparisons and in risk management decision-making is limited."[92] Linear models, by contrast, help identify "a risk-specific dose that provides information on the percentage of the population that can be expected to be above or below a defined [. . .] risk [. . .], [allowing] risk managers to weigh *alternative risk options* with respect to that *percentage of the population* [and permitting] a *quantitative estimate of benefits* for different risk management options."[93] This illustrates how, as anticipated in the previous sections, cost-benefit analysis models are not simply employed to select the least trade restrictive risk management measures which will comply with the intended level of protection. Rather, they underpin the identification of a cost-benefit effective level of protection and threshold of probability of occurrence of adverse effects.

[87]21 U.S.C. § 321(ff).

[88]7 U.S.C. §§ 136(bb), 136a(c)(7), 136a(c)(8), 136a(h)(3)(a)(ii), 136w-8(a). *See also* 40 C.F.R. §§ 158.1(a), 158.45, 158.110(a)-(c) (2008).

[89]40 C.F.R. §§ 152.170(a)(4), 152.171(b) (2008).

[90]Silver Book, *supra* note 11, at 12.

[91]For instance, when considering different potential operator exposure levels or different daily intakes of residues of pesticides.

[92]Silver Book, *supra* note 11, at 8-9.

[93]*Id.* at 12 (emphasis added).

https://doi.org/10.1017/glj.2022.47 Published online by Cambridge University Press

The EPA's discretionary power to grant either unconditional or conditional registration is also an expression of considerations surrounding economic cost-benefit effectiveness. The EPA may grant conditional registrations where the data submitted by the applicant are incomplete or insufficient for the agency to determine that all requirements have been met, but the registration is unlikely to lead to the materialization of "unreasonable" adverse effects.[94] Conditional registrations may also be granted in cases involving pesticides which contain unregistered active ingredients.[95]

The last relevant considerations pertain to the tolerances set for pesticides applied to crops which will be used as food or feed. Pursuant to the FFDCA, a food shall be deemed to be adulterated if, inter alia, it bears or contains a chemical residue that is unsafe within the meaning of section 346a(a) of title 21 of the United States Code.[96] The FFDCA, as amended by the FQPA, stipulates that any pesticide residues in or on food shall be deemed unsafe unless a tolerance or an exemption from the requirement of a tolerance is in place for such residues in or on such food.[97]

Factors to be taken into account by the EPA when setting tolerances include dietary consumption patterns, aggregate exposures, cumulative effects and variability. As a general rule, the safety standard is the one of a "reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information."[98] However, specific rules are laid out for "eligible pesticide chemical residues"; these include cases where the EPA is not able to identify a threshold, i.e. a level of exposure at which the residue will *not* contribute to adverse effects.[99] Therefore, exceptions exist to the general criterion of "reasonable certainty of no harm" and economic evaluations may play a role.[100]

As this sub-section has endeavoured to show, the US system for the governance of pesticides is largely informed by ideal evidence-based approaches. The next sub-section conducts the same form of analysis, setting the EU system for regulation of pesticidal products against the broader backdrop of socially acceptable risk approaches.

II. Governance of Pesticides in the EU: Socially Acceptable Risk Approaches

Pesticidal products are regulated in the EU in accordance with the multi-level arrangements of the Plant Protection Products ("PPP") Regulation.[101] Active substances are approved and regulated at the EU level.[102] Specific PPPs, containing one or more active substances and different co-constituents, are authorized and regulated at the national level.[103] The EU-wide approval of active substances involves different technical-scientific and political authorities at the EU and the Member State level.[104] These procedural arrangements thus maximise the chances for stakeholders to challenge the approval of active substances. Further, the authorization of specific PPPs containing the active substance at the national level provides further opportunities for an assessment of the risks posed by the interactions between the active substance and relevant co-constituents in different pesticidal formulations.[105]

[94]40 C.F.R. § 152.111 (2021).

[95]*See* 7 U.S.C. §§ 136a(c)(7)(A), (B), (C); *see also* 40 C.F.R. §§ 152.113–15 for the specific conditions.

[96]*See* 21 U.S.C. § 342(a)(2)(B).

[97]*See* 21 U.S.C. § 346a(a)(1).

[98]*See* 21 U.S.C. § 346a(b)(2)(A)(ii).

[99]*See* 21 U.S.C. §§ 346a(b)(2)(B)(ii), (iv).

[100]*See* Pesticide Action Network, *supra* note 69, and the introductory section, as regards the case of the pre-existing (now revoked) EPA's tolerances for chlorpyrifos.

[101]Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

[102]See *id.* at Ch. II, Section 1 (Active Substances), Arts. 4–24. Safeners and synergists are also regulated at EU level.

[103]*See id.* at Ch. III (Plant Protection Products), Arts. 28–57; *see also* Annex I.

[104]See *id.* at Arts. 7–13.

[105]For an analysis, *see* Leonelli, *supra* note 55.

https://doi.org/10.1017/glj.2022.47 Published online by Cambridge University Press

Regulation 546/2011 and Regulation 283/2013 lay out uniform principles for the evaluation and authorization of active substances.[106] They both mandate *prudential* and thorough risk assessments, highlighting that uncertainties should be taken into due consideration in the analysis of potential hazards and in the determination and characterization of risks. The procedure for the authorization of PPPs at Member State level largely replicates the criteria to be met for the purposes of EU approvals of active substances.

When the European Commission enacts its draft proposal on an active substance, it is bound to take into consideration the risk assessments conducted at the EU and the Member State level, any other legitimate factors, and the precautionary principle.[107] By contrast impact assessment, the EU nuanced version of cost-benefit analysis, has played a marginal role in EU governance of pesticides.[108] Member States can also have recourse to the precautionary principle and decide not to authorize PPPs, despite the approval of the relevant active substance(s) at EU level.[109]

Turning to a more specific analysis of the "benchmark" level of protection set within the PPP Regulation, three aspects deserve particular attention. First, a number of hazard-based cut-off criteria apply to the assessment of active substances. In other words, in the case of highly hazardous active substances, a (rebuttable) presumption applies that no safe level of exposure can be determined. This does *not* reflect a focus on *hazards*, *but* an acknowledgment of the *magnitude of the risks* ensuing from exposure to the most hazardous categories of active substances.[110] These cut-off criteria thus reflect a presumption that the risks posed by these substances are *too high* to be *acceptable*, taking the pursuit of enhanced levels of protection into account.

If an active substance meets the cut-off criteria, it will be tested for compliance with the requirements of Article 4. Article 4(5) and point 2.1 of Annex II to the PPP Regulation clarify that the approval criteria are met when authorization in at least one Member State is expected to be possible for at least one PPP containing that active substance for at least one representative use. Active substances are the main active components of pesticidal products; they are not used on their own, but in pesticidal formulations. For this reason, an assessment of the risks posed by indicative uses of representative PPPs containing the specific active substance is necessary for that active substance to be authorized at EU level; testing the active substance, as such, would not make any sense in scientific terms. This holds true despite the fact that specific PPP formulations containing the active substance will be authorized at Member State level.

The criteria are quite detailed and highly protective. Articles 4(2) and 4(3) lay out specific conditions for the *residues of the PPPs*, and the *relevant PPPs*. Any cumulative and synergistic effects resulting from the interactions of active substances and co-constituents must be taken into due consideration. The benchmark level of protection is lower for environmental effects ("no unacceptable effects") than for public health effects ("no immediate or delayed harmful effects, directly or through drinking water, food, feed, air and consequences in the workplace"). However, it is still considerably higher than the cost-benefit effective baseline of "unreasonable" adverse effects. The requirements of Article 4(2) and (3) are then implemented through the setting of specific

[106] *See* Commission Regulation (EU) No. 546/2011 of 10 June 2011 Implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards Uniform Principles for Evaluation and Authorization of Plant Protection Products, O.J. 2011, L 155; *see also* Commission Regulation (EU) No. 283/2013 of 1 March 2013 setting out the Data Requirements for Active Substances, in Accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards Uniform Principles for Evaluation and Authorization of Plant Protection Products, O.J. 2013, L 93.

[107] *See generally id.* at Art. 13(2).

[108] *See*, *e.g.*, Case T-429/13, *Bayer CropScience v Commission* EU:T:2018:280; Case C-499/18 P, *Bayer CropScience and Bayer v Commission* EU:C:2021:367. For a detailed analysis, *see* Giulia Claudia Leonelli, *Balancing Public Health and Environmental Protection and Economic Stakes? Bayer CropScience and the Court's Defence of the EU Socially Acceptable Risk Approach*, 58 Common Mkt. L. Rev. 1845 (2021).

[109] *See* Commission Regulation (EU) No. 546/2011 of 10 June 2011, *supra* note 106, Recital 8 and Article 1(4).

[110] *See id.* at Annex II, points 3.6.2–4, 3.7. If these criteria are satisfied, compliance with the criteria of points 2 and 3 must be checked. The presumption is rebuttable, if the predicted exposures are such that the adverse effects would be excluded; *see id.* at Art. 4(7).

https://doi.org/10.1017/glj.2022.47 Published online by Cambridge University Press

Acceptable Operator Exposure Level ("AOEL") and Acceptable Daily Intake ("ADI") values. These are also considerably lower (more stringent) than the transnational baseline, and reflect the attempt to identify a point where exposure to the PPP is *not* likely to have *any* adverse effects.

PPPs approved at Member State level are associated with specific Maximum Residue Levels ("MRLs"), if the pesticides are applied to agricultural products used as food or feed. MRLs are laid out in Regulation 396/2005, as regularly amended and updated by the EU institutions.[111] As occurs in the authorization of active substances, the system in place to set or modify MRLs involves technical-scientific and political authorities at the EU and the Member State levels.

An application for MRLs should provide all relevant information on the toxicity of the PPP(s), the use of the PPP(s) on specific crops in accordance with good agricultural practice ("GAP"), and the residues which are expected to be on the crop after application of the PPP(s) in accordance with the GAP. The Member States and the European Food Safety Authority will assess the intake of residues through all foods to which the PPP(s) may be applied vis-à-vis the ADI.[112] If the expected residues of the PPP(s) comply with the ADI, MRLs will be set; as Regulation 396/2005 expressly provides, MRLs will be set at the *minimum, lowest* level which is necessary for the PPP to be effective on a crop in accordance with good agricultural practice.[113] In the majority of cases, the residues remaining after application of a PPP will be lower than the ADI. However, MRLs are *not* set to merely comply with the safety threshold of the ADI, *but* to minimise consumer exposures to all pesticide residues to the greatest possible extent. This reflects the pursuit of *enhanced levels* of public health protection. Further, it gives due consideration to the need to protect vulnerable consumers[114] and aims to take account of risk-related uncertainties; most importantly, exposures in real life conditions, multiple exposures, and confounding factors.[115] Progress has been made and work is underway to assess the cumulative impact of residues of pesticides whose modes of action are dissimilar, but which might still result in joint/cumulative toxic effects.

The final considerations relate to recourse to the precautionary principle and any relevant OLFs. References to the *precautionary principle* are ubiquitous in the PPP Regulation;[116] as briefly mentioned above, both the Commission and national authorities may take precautionary action within their regulatory remit. At the EU level, the precautionary principle may come into play when compliance with the AOEL, ADI or conditions regarding environmental protection are being checked. In *Paraquat*, for instance, the Kingdom of Sweden challenged the authorization of this active substance and alleged a breach of the precautionary principle and of the principle that a high level of protection must be safeguarded. Sweden relied, inter alia, on data and scientific studies which cast serious doubts on the Commission's finding that the AOEL would be met when operators used pesticides containing paraquat. The action was successful.[117]

To conclude, it is worth stressing that *OLFs* such as the promotion of sustainable agricultural and food production systems and the development and use of less hazardous pesticidal alternatives (substitution principle) are inherent to EU governance of pesticides. The comparative assessment procedure, for instance, enables the EU institutions to categorize the most hazardous active substances approved for use at the EU level as "candidates for substitution."[118] Pursuant to Article 50 of the PPP Regulation, the Member States shall then perform a comparative assessment of pesticides containing these active substances and different PPPs; whenever a less hazardous

[111]Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on Maximum Residue Levels of Pesticides in or on Food and Feed of Plant and Animal Origin and Amending Council Directive 91/414/EEC, OJ 2005, L 70.

[112]*See id.* at Arts. 3(2)(i), 3(2)(j).

[113]*See id.* at Recital (5); *see also id.* at Art. 3(2)(a).

[114]*See id.* at Art. 3(2)(d).

[115]*See id.* at Recital (6).

[116]*See* Commission Regulation (EU) No. 546/2011 of 10 June 2011, *supra* note 106.

[117]For an in-depth analysis, *see* Leonelli, *supra* note 55.

[118]*See* Commission Regulation (EU) No. 546/2011 of 10 June 2011, *supra* note 106, at Annex II, point 4, and Annex IV.

https://doi.org/10.1017/glj.2022.47 Published online by Cambridge University Press

alternative to the former pesticides is available, the Member States shall not authorize them or shall restrict their use.[119]

To draw a summary, EU regulation of pesticides is clearly informed by ideal socially acceptable risk approaches. This concludes the overview of US and EU governance of pesticidal products. It is against the backdrop of this analysis that the next sub-section draws all relevant preliminary conclusions.

III. Preliminary Conclusions. Beyond the Myth of "Hazard" versus "Risk"

The assumption that the EU follows a "hazard-based" approach to risk governance, as opposed to the US "risk-based" approach, is widespread.[120] This assumption has been consistently applied in analyses of governance of pesticides. The EU alleged "hazard-based" approach is portrayed as irrational and inefficient. This framing misses the entire point and fails to capture the causes of regulatory divergence. Far from being influenced by alleged "hazard-based" or "risk-based" models, US and EU frameworks and regulatory implementation are characterized by different approaches to risk assessment, a different focus on sound science or persisting uncertainty and scientific insufficiency, and the pursuit of different levels of protection. In other words, they are informed by evidence-based and socially acceptable risk approaches.

In accordance with the broader architecture of US risk regulation, the EPA is likely to conduct *sound scientific* risk assessments; for instance, the safety factors and the models applied in the context of hazard characterization or appraisal of exposures are likely to be different from the prudential ones applied in the EU. The EPA is also highly likely to focus on *sound science*; if uncertainties relating to the existence of specific hazards or the specific pathways by which risks may materialize persist, the relevant margins of uncertainty are unlikely to be taken into account. Turning to risk management, as illustrated in the first sub-section, the FIFRA stipulates that pesticides should not pose *unreasonable* adverse effects, taking the risk/benefit balance into due consideration. As already explained, this reflects the pursuit of a baseline level of protection. The standard for setting tolerances is higher, at least on its face; yet, as the analysis has shown, a considerable gap exists vis-à-vis other jurisdictions.

Conversely, the EU regulatory framework pursues *enhanced* levels of public health and environmental protection, aims to *minimise exposures*, and allows for recourse to the *precautionary principle* and consideration of *OLFs*. The regulatory framework provides for a *prudential* approach to risk assessment. As explained in the second sub-section, the hazard-based cut-off criteria set a rebuttable presumption that the risks posed by exposures to highly hazardous active substances are not acceptable; they are an expression of the pursuit of higher than cost-benefit effective levels of protection, rather than the foundation of allegedly "hazard-based" regulatory arrangements. When setting AOELs and ADIs, the agencies involved will also pursue higher than baseline levels of protection. On these grounds, even if uncertainties were not salient and US and EU regulators were looking at the "same" science, they would still reach different conclusions as to whether adverse effects are "acceptable" and set different reference values. In a similar vein, as explained in the second sub-section, it is common practice in the EU to set MRLs at the lowest possible level, regardless of the specific ADIs. Further, uncertainties as to whether the relevant reference values will be met are taken into account for the purposes of decision-making; regulators may then have recourse to the precautionary principle.

[119] *See id.* at Art. 50. In specific cases, the procedure may also apply to PPPs containing active substances which are not candidates for substitution.

[120] For some examples, *see* Löfstedt, *supra* note 3; the Specific Trade Concerns raised by WTO Members within the Technical Barriers to Trade and the Sanitary and Phytosanitary Measures Information Management Systems, WORLD TRADE ORGANIZATION, *Technical Barriers to Trade and the Sanitary and Phytosanitary Measures Information Management Systems* http://tbtims.wto.org/ andhttp://spsims.wto.org/ (accessed March 2022); and even *Toxic Trade*, *supra* note 66.

https://doi.org/10.1017/glj.2022.47 Published online by Cambridge University Press

Against this backdrop, transatlantic regulatory divergences in this field result from adherence to evidence-based and socially acceptable risk approaches. The US and the EU regulatory frameworks reflect a very different value afforded to scientific uncertainty, and a very different understanding of "negligible," "acceptable" or "unacceptable" adverse effects. This account opens up a different perspective on the divergences between US and EU regulation of pesticides, beyond the myth of "hazard-based" and "risk-based" approaches.

F. The Transatlantic Conundrum of Agricultural Biotechnologies: A Matter of "Pure" Science?

The cultivation of GE crops has been entrenched in several jurisdictions since the Nineties. The greatest majority of commercially marketed GE varieties are engineered to be herbicide (or multi-herbicide) resistant or pest-resistant.[121] In the last few years, new GE crop varieties have been developed through the application of new breeding techniques ("NBTs").[122] These may or may not involve genome editing, but no longer involve the insertion of foreign DNA (traditional "transgenesis").

Scientific research has cast light on the increasing reliability and target precision of NBTs. Part of the scientific community has advocated deregulating these new GE crop varieties, claiming that the relevant modifications could have occurred in conventional breeding. By contrast, other parts of the scientific community and different societal stakeholders are taking a prudential approach to the uncertain risks posed by the application of NBTs. These actors have laid particular emphasis on the question of potential off-target alterations, and the effects of repeated small alterations of the genome through the application of one or more techniques.[123] As regards the advantages connected with these new GE varieties, applications of NBTs are portrayed as the way forward to develop climate resilient GE crops. According to the advocates of agricultural biotechnology, these crops will increase yields and help tackle food insecurity at times of climate change. This construction is fiercely disputed by different constituencies.[124] The debate on NBTs thus perpetuates the clash between opposed narratives on the *uncertain risks* posed by agricultural biotechnologies, their *advantages* and *disadvantages*, and the *balance* to be struck between individual trade rights and collective interests. Different approaches to risk assessment, different scientific inferences, the pursuit of different levels of protection and consideration of different (economic or political and social) factors come into play and influence regulatory outputs.

As of July 2018, the Animal and Plant Health Inspection Service ("APHIS") within the United States Department of Agriculture ("USDA") had issued more than 19,500 authorizations for the environmental release of GE crops, 14,000 authorizations for importation, and around 12,000 authorizations for inter-state movement.[125] As of March 2020, it had approved 128 petitions for the deregulation of previously regulated GE crops.[126] This, however, does not give the full picture of the number of GE crop varieties cultivated in the US. To begin with, the pre-existing authorization (notification or permit) procedures only applied to some GE varieties. Second, the

[121]See generally ISAAA, Inc., www.isaaa.org/default.asp (accessed March, 2022).

[122]Most importantly, CRISPR technology. For an overview, see Leonelli, *supra* note 1.

[123]*See*, *e.g ENSSER Statement on New Genetic Modification Techniques*, European Network of Scientists for Social and Environmental Responsibility, www.ensser.org/publications/ngmt-statement/ (accessed March, 2022); *see also* Ricarda A. Steinbrecher, *Genetic Engineering in Plants and the New Breeding Techniques ("NBTs"): Inherent Risks and the Need to Regulate*, Econexus Briefing (2015).

[124]*See* the analysis in Anne Saab, Narratives of Hunger in International Law. Feeding the World in Times of Climate Change (2019).

[125]See 84 FR 26514-26541, Docket No APHIS-2018-0034, June 6, 2019, Proposed Rules, *Movement of Certain Genetically Engineered Organisms* (hereafter, "2019 APHIS Proposal"), at 26515.

[126]*See generally Petitions for Determination of Nonregulated Status*, United States Department of Agriculture, www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status (accessed March, 2022).

https://doi.org/10.1017/glj.2022.47 Published online by Cambridge University Press

system has been the object of reform and (further) deregulation in 2020. Third, pest-resistant varieties are regulated by the EPA. As regards GE foods, in June 2020 the US Food and Drugs Administration ("FDA") had conducted consultations and cleared the way for the marketing of 186 GE food and feed varieties.[127] An analysis of GE organisms in the EU offers a completely different picture. As of June 2020, 73 GE varieties had been authorized for use as food or feed in the EU; the vast majority of these varieties are used as animal feed.[128] There is only one GE crop authorized for cultivation at EU level. The system is likely to be the object of reform over the next years; however, the direction of future reforms is still unclear.

This section conducts an examination of US and EU governance of GE organisms through the lens of evidence-based and socially acceptable risk approaches. The analysis illustrates how the two ideal models and their regulatory categories are reflected in the US and EU systems. Taking stock of this examination, the third sub-section challenges the false dichotomy of "politics" and "science" and provides a different account of transatlantic regulatory divergencies in this area. This sub-section illuminates the connections between recourse to a *sound scientific approach* to risk assessment, the centrality of *sound science* in *regulatory frameworks* and *product authorizations*, and considerations surrounding *economic cost-benefit effectiveness*. On these grounds, it emphasizes that neither evidence-based nor socially acceptable risk approaches can lay claim to neutrality and objectivity. Rather, they are informed by different normative frames. Scientific evaluations and normative considerations are co-produced in the field of risk regulation.

I. Governance of Agricultural Biotechnologies and their Uncertain Risks in the US: When Sound Science is Cost-Benefit Effective

Ever since the adoption of the 1986 Coordinated Framework for the Regulation of Biotechnology,[129] the US regulatory system has been grounded on a product-based approach to the governance of GE organisms. GE organisms, as a class, are presumed to be substantially equivalent to their conventional counterparts in so far as the genetic engineering process has not altered specific features of the *products*. Symmetrically, a regulatory presumption applies that bio-engineering techniques, understood as *processes*, do not pose any inherent risks.

By implication, the US regulatory frameworks provide for an authorization process only in so far as GE varieties have specific characteristics which increase their "risk profile." In all other cases, the varieties are simply presumed to be equivalent to their conventional counterparts.[130] Alternatively, informal consultations may take place and focus on a comparative assessment of the GE product vis-à-vis its conventional counterpart. This is not tantamount to a formal authorization process.[131] Nor can a comparative assessment, unlike an all-encompassing risk assessment, provide an overview of any potential (environmental or public health) hazards and risks posed by GE varieties.[132]

The US approach draws on the absence of sound scientific proof of any hazards associated with genetic engineering processes *and* specific considerations surrounding regulatory cost-benefit effectiveness. In the words of the Coordinated Framework, regulatory "oversight will be exercised *only* where the risk . . . is *unreasonable*."[133] Thus, adherence to a sound scientific, rather than a

[127]A number of GE varieties obtained through NBTs are also included. For more information, see *New Plant Variety Consultations*, United States Food & Drug Administration, https://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=Biocon&sort=FDA_Letter_Dt&order=DESC&startrow=1&type=basic&search= (accessed March, 2022).

[128]The (MON810) maize variety is currently the only variety authorized for cultivation.

[129]Executive Office of the US President, *supra* note 38.

[130]Specifically, this applies in the case of GE crops – see *infra* in this sub-section.

[131]This applies in the case of GE foods – see *infra* in this sub-section.

[132]*See* the acknowledgment in the Codex Guidelines: CAC/GL 45-2003, Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants, 13.

[133]*Supra* note 38 (emphasis added).

https://doi.org/10.1017/glj.2022.47 Published online by Cambridge University Press

prudential, approach at the regulatory level is not based on scientific "certainty" and neutral and objective matters of "pure" science; it is grounded on a consideration of the balance between the *economic costs* of over-testing GE organisms, and the relevant *public health and environmental benefits*. Indeed, the discourse on the economic benefits of agricultural biotechnologies, their societal advantages, and the economic costs associated with precaution surfaces very clearly from US policy documents and regulatory acts.[134]

The APHIS is in charge of protecting agriculture from pests and diseases.[135] Accordingly, it regulates GE varieties which may act as direct or indirect plant pests. The pre-2020 regime, as laid out in the old version of Title 7—Agriculture—, part 340 of the U.S. CFR, was already informed by a focus on sound science and cost-benefit analysis. The old version of section 340.1 CFR provided a twofold definition of "regulated articles": any varieties engineered through specific plant pest components and any products with the ability to act as a plant pest fell within this definition. All other GE crops were non-regulated, tout court. Since 2011, developers had the choice to submit a request under the "Am I Regulated?" ("AIR") screening process; this preliminary review by the APHIS resulted in a mere finding of regulated or non-regulated status. However, this streamlined review did not involve a comprehensive analysis of potential changes in plant pest impacts, impacts on non-target organisms, and propensity for increased weediness.[136] Therefore, over the years, GE varieties which should have been "regulated articles" may have slipped through the cracks.

Prior to 2020, "regulated articles" would have to go through either the fast-track "notification" process or the "permit" procedure. Both involved field trials. In 2005, the USDA's Office of Inspector General ("OIG") called for a reform of the notification procedure and the adoption of specific protocols to be followed in that context.[137] The APHIS never implemented the recommendations, claiming that this two-pronged authorization process met cost-benefit effectiveness requirements.[138] In a similar vein, the OIG called on the APHIS to maintain post-market monitoring of GE varieties; yet again, this recommendation was never implemented. Finally, under the pre-2020 framework, a biotech firm could have recourse to a petition for non-regulated status after conducting field trials. Where a petition was approved, the formerly regulated variety was deemed not to pose any greater plant pest risks than its conventional counterpart. As a result, the APHIS no longer had any monitoring or oversight role. Similarly, a previous petition could be invoked by an applicant to obtain an extension of non-regulated status to a different GE variety with similar characteristics.[139]

As this concise analysis has shown, the pre-2020 framework was heavily influenced by sound scientific approaches and economic cost-benefit analysis. This is all the more true for the 2020 APHIS reform. The new system reverses the regulatory presumption that field trials must precede *deregulation*, where potential plant pest risks might exist, and embraces the opposite perspective; a preliminary assessment should precede any form of *regulation* by the APHIS.

Rather than providing a definition of "regulated articles", the new text of section 340.1 starts by setting out two very broad exemptions. Under section 340.1(b), the regulations do not apply to plants which have been engineered through specific NBTs in such a way that the specific genetic modification could have been achieved through conventional breeding. Under paragraph (b)(4), the APHIS may also exempt plants with additional modifications "based on what could be achieved through conventional breeding."[140] The rationale of this exemption is that "where

[134]*See e.g.* Exec. Order No. 13874, 84 Fed. Reg. 27899 (June 11, 2019).

[135]*See* Animal & Plant Health Inspection Services U.S. Department of Agriculture https://www.aphis.usda.gov/aphis/home/ (accessed Mar. 2022) (giving further information on the APHIS's role and remit).

[136]*See* the 2019 APHIS Proposal, *supra* note 125, at 26520.

[137]*Id.* at 26515.

[138]*Id.* at 26528.

[139]7 C.F.R. § 340.6(e) (1997).

[140]7 C.F.R. §340.1(b) (2020).

https://doi.org/10.1017/glj.2022.47 Published online by Cambridge University Press

genetic modifications are similar in kind to those modifications made through traditional breeding, the plant pest risks *should* also be similar."[141]

Further, under the new text of section 340.1(c)(1) and (2), the regulations do not apply to GE crops with a plant-trait mechanism of action ("MOA")[142] which has previously been the object of an assessment by the APHIS—namely, the object of an AIR request, petition, or extension of non-regulated status. The new focus on the MOA has marked a shift towards a less prudential approach to risk assessment. The APHIS previously followed an event-by-event approach, whereby each transformation event was assessed separately where plant pest risks might exist.[143] This drew on an acknowledgment that "the locus of insertion, which varies from one transformation event to another, even using identical DNA constructs and host plant genotypes, may give rise to different inserted gene expression patterns, gene product levels and perhaps affect other features as well."[144] After the reform, this approach has been abandoned.

Developers of GE varieties falling under one of these broad exemptions may request confirmation of non-regulated status to the APHIS;[145] however, they are supposed to use a self-determination mechanism to certify that their varieties are non-regulated.[146] Where a GE variety does not fall within one of the exemptions, a new regulatory status review will apply. This, however, will not involve field trials; it has been described by the APHIS as similar to the streamlined AIR scheme.[147] Experimental data are expressly *not* required for the purposes of a review.[148] Further, it is only where the APHIS identifies a plausible pathway by which the GE plant would pose an increased plant pest risk, compared to the conventional counterpart, that the variety will be considered a regulated article.[149] This means that, in order for an article to be regulated, the APHIS will have to provide conclusive proof of the *hazardous*—plant pest—*properties* of a variety and positively establish a *plausible pathway* for the *materialization* of the relevant *risks*. The "plausible pathway" threshold sets the bar quite high, and persisting uncertainties appear to be largely irrelevant in this context. Even where plant pest risks are identified, field trials may not be mandated; although the requestor shall in that case apply for a permit, the APHIS is no longer under an obligation to request field trials.[150]

Against this overall backdrop, the 2020 reform is clearly informed by adherence to *sound science*. Conclusive scientific proof of the *unsafety* of a GE variety is required for any form of regulation and oversight to apply. Reliance on a sound scientific approach is not based on scientific "certainty" as to the absolute safety of GE organisms, or neutral and objective matters of "pure" science; this is perhaps most apparent in the specific case of NBTs. The role played by considerations surrounding *cost-benefit effectiveness* is clear; the regulatory arrangements aim to target *unreasonable* risks. Indeed, the centrality of economic cost-benefit analysis emerges very clearly from the 2019 APHIS proposal for reform, with its focus on the compliance costs of regulation and the opportunity costs of delayed innovation, as well as from the APHIS's regulatory impact assessment.[151] As expressly acknowledged, the reform draws on the guiding principle that limited federal oversight resources ought to be applied where they will accomplish the greatest *net beneficial protection* of

[141] 2019 APHIS Proposal, *supra* note 125, at 26516, 26517 (emphasis added).

[142] *Id.* 26517, 26526 (explaining that a specific trait might be achieved through different MOAs).

[143] *Id.* 26517.

[144] Alan McHughen & Stuart Smith, *Regulation of Genetically Modified Crops in USA and Canada: American Overview*, *in* REGULATION OF AGRICULTURAL BIOTECHNOLOGY: THE UNITED STATES AND CANADA 42 (Chris A. Wozniak & A McHughen eds. 2012).

[145] 7 C.F.R. § 340.1(e).

[146] 2019 APHIS Proposal, *supra* note 125, at 26517.

[147] *Id.* at 26525.

[148] 7 C.F.R. § 340.4.

[149] 7 C.F.R. § 340.4(b)(2).

[150] 7 C.F.R. § 340.4(b)(3)(i).

[151] 2019 APHIS Proposal, *supra* note 125, at 26535.

https://doi.org/10.1017/glj.2022.47 Published online by Cambridge University Press

public health and the environment.[152] The 2020 regulations are currently under challenge in the context of public interest litigation brought by non-governmental organizations.[153]

An analysis of the FDA's approach to GE food and feed triggers similar considerations on the "linkage" between adherence to *sound science* and the pursuit of *cost-benefit effective* levels of protection. Under sections 409(a) and (b) of the FFDCA, the FDA would have the authority to formally approve the transferred genetic material and the intended expression products of GE organisms as food additives.[154] However, it has refrained from doing so by resorting to the "Generally Recognized as Safe" ("GRAS") presumption.[155] In recent years, as new proteins are developed which do not meet the substantial equivalence test and which have never before been assessed, the FDA has still chosen to conduct streamlined biotechnology consultations rather than mandating authorizations. These consultations involve the submission of dossiers by developers of GE food and feed varieties. Developers do not have to produce any experimental data; nor do they have to conduct a thorough risk assessment. The results of a comparative assessment and the absence of sound scientific proof that a GE variety is unsafe are sufficient for the FDA to close the consultations; a further streamlining of the process has been recently proposed.[156] This perfectly conforms to *sound science* and the overarching tenets of *cost-benefit analysis*. The lack of any authorization or post-market monitoring of GE food varieties saves federal resources; this combines with the economic savings associated with the absence of any comprehensive risk assessment and reliance on summary dossiers by market actors, and with the economic benefits for biotechnology firms. These regulatory arrangements thus respond to the principle of aggregate wealth maximization. As this concise overview has endeavored to show, the US approach to the governance of GE organisms is strongly influenced by evidence-based models.

II. Governance of Agricultural Biotechnologies and Their Uncertain Risks in the EU: At the Heart of Socially Acceptable Risk

Much has been written throughout the years on EU governance of GE organisms. This sub-section provides a very brief overview of the regulatory framework, focusing on the main specificities of the system. Directive 2001/18/EC applies to GE organisms "as [products] or in products" and regulates the deliberate release into the environment of GE organisms.[157] It was amended in 2015.[158] Regulation (EC) No. 1829/2003, on the other hand, regulates GE organisms falling in the category of GE "[human] food or [animal] feed."[159] Both regulatory frameworks draw on

[152]*Id.* (citing the 1986 Coordinated Framework).

[153]In July 2021, the National Family Farm Coalition, the Center for Food Safety, Pesticide Action Network North America, the Center for Environmental Health, Friends of the Earth, and the Center for Biological Diversity have lodged a complaint for declaratory and equitable relief, challenging the APHIS's 2020 reform. Compl. for Declaratory & Equitable Relief at 1, Nat'l Fam. Farm Coal. v. Vilsack, No. 21-5695 (N.D.C.A. July 26, 2021).

[154]*See also* 21 U.S.C. §§ 348(b) and (c))(defining "safety" as "a reasonable certainty . . . that the substance is not harmful under the intended conditions of use."); 21 U.S.C 321(u) (using "safety" to refer to public—human and animal—health).

[155]*See* Leonelli, *supra* note 1 (giving a more detailed overview of the FDA's regulatory practice).

[156]Food & Drug Admin., *Plant and Animal Biotechnology Innovation Action Plan* (2019) https://www.fda.gov/media/119882/download.

[157]Directive 2001/18, *supra* note 62; Regulation 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the Transparency and Sustainability of the EU Risk Assessment in the Food Chain and Amending Regulations (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC, 2019 O.J. (L 231) 1 (amending articles 1, 6, 13, 25, and 28 of the Directive with an aim to enhance the publicity and transparency of the risk assessment process).

[158]Directive 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the Possibility for Member States to Restrict or Prohibit the Cultivation of Genetically Modified Organisms (GMOs) in their Territory, 2016 O.J. (L 68).

[159]Regulation 1829/2003, *supra* note 62; Regulation 1381/2019, *supra* note 156 (amending Articles 5(3), 6(7), 10(1), 11(2), 17(3), 18(7), 22(1), 23(2), 29(1)–(2) and 30 of Regulation 1829/2003 have with an aim to enhance the publicity and transparency of the risk assessment process).

https://doi.org/10.1017/glj.2022.47 Published online by Cambridge University Press

a *process*-based model; the presumption of substantial equivalence of GE organisms—as a class—and their conventional counterparts does not apply in the EU. Consequently, each and every GE variety is the object of a thorough *risk* assessment and of a mandatory pre-market *authorization* process. Both legislative instruments provide for multi-level regulatory arrangements, involving technical-scientific and political authorities at the EU and the Member State level. These arrangements maximize opportunities for scrutiny and debate across the EU.

EU governance of GE organisms draws on a *prudential* approach to the evaluation of the uncertain risks posed by agricultural biotechnologies. At the regulatory level, this is reflected in adherence to process-based models and the requirement that every variety shall go through an ad hoc authorization process. At the current stage, the multi-level authorization procedure laid out in the 2001 Directive and 2003 Regulation also applies to all organisms obtained through NBTs. This extension of the GMO regulatory regime to different GE organisms has resulted from a preliminary ruling delivered by the European Court of Justice ("ECJ") in Case C-528/16, *Confédération Paysanne*.[160]

Pursuant to Article 3(1) of the 2001 Directive, the Directive's provisions shall *not* apply to organisms obtained through the techniques of genetic modification listed in Annex I B. This Annex includes mutagenesis; however, it obviously refers to *old* mutagenesis techniques, which were known back in 2001. NBTs are not mentioned in the Annex. The questions referred to the ECJ in *Confédération Paysanne* related to herbicide-tolerant rape varieties obtained through *new* mutagenesis techniques—an NBT. The referring court sought to ascertain whether new mutagenesis techniques were excluded from the scope of application of the legislative framework, due to the express "mutagenesis exemption" of Article 3(1) and Annex I B. In this crucial preliminary ruling, the ECJ took a dynamic and evolutionary perspective[161] and answered the questions by interpreting the relevant provisions in light of the precautionary principle.[162] It thus concluded that the mutagenesis exemption "must be interpreted as meaning that only organisms obtained by means of techniques/methods of mutagenesis which have conventionally been used in a number of applications and have a long safety record are excluded from the scope of that Directive."[163] The ECJ's interpretation of the relevant provisions in the light of the precautionary principle, in a case where an express legislative exemption was laid out, has opened up spaces for the application of the GMO legislative framework to any organisms obtained through NBTs. The Commission has announced that it will propose a new regulatory regime for NBTs; at the current stage, however, the Commission's approach is still unclear.

As this concise overview has shown, the EU *regulatory frameworks* draw on a highly prudential approach. At the *regulatory implementation* stage, this prudential approach finds expression in the form of risk assessments conducted by the national authorities and the European Food Safety Authority. Comprehensive, case-by-case environmental risk assessments must be carried out prior to authorizing GE crops; these should take into consideration factors such as indirect, cumulative, and long-term effects on biodiversity and ecosystems, as well as the intended scale of release or use of the crop, the potential receiving environment and the interactions between them.[164] Post-market monitoring—as well as traceability—obligations apply. Thorough risk assessments must also be conducted before the authorization of GE food and feed varieties; in accordance with process-based models, the comparative assessment stage is understood as a necessary but not sufficient condition for the purposes of a risk assessment. The 2003 Regulation expressly mentions that

[160]Case C-528/16, *Confédération Paysanne and Others v Premier Ministre and Ministre de l'Agriculture, de l'Agroalimentaire et de la Forêt*, EU:C:2018:583.

[161]*Id.* at ¶¶ 41–54.

[162]*Id.* at ¶ 52.

[163]*Id.* at ¶¶ 51, 54.

[164]*See* Directive 2001/18, *supra* note 62, at Annex II, part B.

https://doi.org/10.1017/glj.2022.47 Published online by Cambridge University Press

"whilst substantial equivalence is a key step in the procedure for assessment of the safety of [GE foods], it is not a safety assessment in itself."[165]

Turning to risk management, the *precautionary principle* and references to *OLFs* are enshrined in the 2001 Directive as well as the 2003 Regulation.[166] A rich literature exists on the troubled implementation of the EU framework. National authorities and the European Food Safety Authority have repeatedly clashed on technical-scientific matters of risk assessment. Further, the EU committee system involving Member State representatives—"comitology"—has been plagued by dissent; deadlock at committee level has resulted in all authorizations being single-handedly pushed through by the European Commission. Only one GE crop—a "GMO"—is currently approved for cultivation in the EU. Further, the afore mentioned 2015 reform has repatriated consideration of a range of OLFs to the national level; while the authorization—i.e. risk regulation—process is still harmonized at EU level, Member States can opt-out from cultivation of GE crops with the biotech firm applicant's consent or on the basis of a range of OLFs.[167]

The EU controversy on GE organisms can be analyzed through the lens of evidence-based and socially acceptable risk approaches.[168] EU stakeholders and a majority of EU Member States have repeatedly made the case that the uncertain risks posed by GE organisms are neither socially acceptable nor worth running, taking persisting uncertainty, the overarching tenets of the precautionary principle and all relevant OLFs into due consideration. Absence of sound scientific proof of hazards and risks, on the other hand, is all that the European Commission has ever taken into consideration in its proposals for authorization. EU stakeholders and Member States have thus challenged the assumption that uncertain risks *must* be run as long as the adverse effects of a product or process have not been conclusively established.

These actors have pointed to persisting uncertainty as to hybridization and crop to crop gene flow, and emphasized the risks posed by pest-resistant GE crops to non-target species. Further, the public health risks posed by herbicide—or multi-herbicide—resistant GE varieties, copiously sprayed with herbicides and other maintenance pesticides, have come under the spotlight. In this respect, EU Member States and civil society have invoked the precautionary principle and striven to pursue enhanced levels of protection.

OLFs have also fed into the process, making the intended level of protection in this field *very high* and the threshold of socially acceptable risk *correspondingly low*. Stakeholders have stressed that GE crops are environmentally unsustainable, in so far as they have resulted in increased herbicide resistance, an increased use of herbicides, and increased pest resistance. As widely documented throughout the years, coexistence measures are difficult and costly to implement; the relevant regulatory burdens and compliance costs have been disproportionately borne by conventional and organic farmers. Moreover, widespread cultivation of GE crops unavoidably results in the adventitious presence of GE components in seeds, food, and feed; this threatens the viability of different agricultural models and affects consumer choice.[169] Public opinion and food quality issues also come into play. Nor have GE products, according to the denigrators of agricultural

[165]Regulation 1829/2003, *supra* note 62, at recital 6.

[166]*See id.* at art. 7(1), Directive 2001/18, *supra* note 62, at recital (8), art. 1(1), 4(1) (discussing the precautionary principal); *see also* Directive 2001/18, *supra* note 62, at recitals (9), (57), (58), (62), art. 31(7)(d), Regulation 1829/2003, *supra* note 62, at recital (32), art. 4(1), 7(1) (discussing OLFs).

[167]*See* Maria Lee, *GMOs in the Internal Market: New Legislation on National Flexibility*, 79 MOD. L. R. 317 (2016), (emphasizing the increasing separation of "facts" and "values" in EU governance of GE organisms after the 2015 reform).

[168]*See generally* Leonelli, *supra* note 1; Giulia Claudia Leonelli, *The Perfect Storm: GMO Governance and the EU Technocratic Turn*, *in* RESEARCH HANDBOOK ON EU ENVIRONMENTAL LAW (Marjan Peeters & Mariolina Eliantonio eds., 2020), MARIA WEIMER, RISK REGULATION IN THE INTERNAL MARKET. LESSONS FROM AGRICULTURAL BIOTECHNOLOGIES (2019) (giving a different account of the GMO controversy, set against the backdrop of procedural paradigms).

[169]*See* Maria Lee, *The Governance of Coexistence Between GMOs and Other Forms of Agriculture: A Purely Economic Issue?*, 20 J. ENV. L. 193 (2008) (giving an in-depth analysis of the issue of coexistence).

https://doi.org/10.1017/glj.2022.47 Published online by Cambridge University Press

biotechnologies, yielded any benefits to civil society in developing and least developed countries. Rather, transnational corporations have profited from their patenting and sale.

Against this overall backdrop, by taking persisting uncertainty, enhanced levels of protection and non-scientific OLFs into account, these stakeholders have disputed the assumption that uncertain risks *must* be run in the light of *sound science* and *non-scientific economic considerations*. While EU institutions have hardly made justice to these claims at the regulatory implementation stage, it is worth underlining that recourse to the precautionary principle and consideration of OLFs *belong to* the field of EU governance of GE organisms, as a matter of regulation. For this reason, as illustrated in this sub-section, the EU regulatory system is informed by socially acceptable risk models.

III. Preliminary Conclusions. Beyond the Myth of "Politics" Versus "Science"

This section has explored US and EU governance of GE organisms through the lens of opposed evidence-based and socially acceptable risk approaches. The analysis has illustrated that the US regulatory frameworks draw on a *sound scientific* approach; this conforms to the tenets of ideal evidence-based approaches. Symmetrically, the regulatory decisions of US agencies on specific GE varieties are based on *sound science*—that is, they focus on the absence of conclusive scientific proof of the existence of hazards and/or the materialization of specific risks.

By contrast, EU legislative frameworks reflect ideal socially acceptable risk approaches. The regulatory arrangements mandate a *prudential* (process-based) approach to the assessment of the uncertain risks posed by GE varieties and aim to achieve *enhanced* levels of public health and environmental protection. At the regulatory implementation—product authorization—stage, the overarching tenets of the *precautionary principle* and the *OLFs* at stake in this field may be taken into consideration by EU risk managers to decide whether the uncertain risks of GE organisms are acceptable and worth taking.

Crucially, an analysis through the lens of evidence-based and socially acceptable risk models shows that neither approach can lay claim to neutrality and objectivity. The connection between sound science approaches to risk assessment, adherence to sound science and regulatory focus on cost-benefit analysis illustrates that evidence-based approaches are informed by non-scientific normative frames: more specifically, the pursuit of an economically cost-benefit effective level of protection. Equally, a normative component is inherent to socially acceptable risk approaches; these afford regulators margins of maneuver to take enhanced levels of protection and qualitative OLFs into account.

Adherence to a sound scientific approach and reliance on sound science are *not* based on scientific "certainty" as to the absolute safety of GE organisms, or neutral and objective matters of "pure" science. This is most apparent in the specific case of NBTs. Even in cases which are less controversial in scientific terms, such as the governance of "traditional" GMOs obtained through transgenesis, there is no value-free way out of the *acceptability* of a risk. The very assumption that "negligible" risks *must* be taken and that the results of sound risk assessments should be the *only* basis for decision-making is informed by considerations surrounding the economic cost-benefit effectiveness of risk regulation.

Ultimately, evidence-based approaches embody the assumption that uncertain risks *must* be taken in the light of *sound science* and *non-scientific*—economic—considerations. By contrast, under socially acceptable risk approaches, risks should only be taken in so far as they are considered socially acceptable; *persisting uncertainty*, the pursuit of *enhanced protection* and *non-scientific*—political and socio-economic—*OLFs* may be taken into account by regulators. Facts and values, scientific and non-scientific considerations are co-produced under both models. Non-scientific normative frames are inherent to both approaches. The myth that different regulatory responses are informed by "politics" or "science" thus collapses; this account opens up a different perspective on the divergences between US and EU regulation of GE organisms.

https://doi.org/10.1017/glj.2022.47 Published online by Cambridge University Press

G. Conclusions: The Implications of the Two Ideal Approaches and the Trajectory of US and EU Risk Regulation

This article has analyzed US and EU risk regulation through the lens of ideal evidence-based and socially acceptable risk approaches. Sections E and F have employed an examination of transatlantic divergencies to challenge the false dichotomies of "hazard" versus "risk" and "politics" versus "science". The analysis has emphasized the different value afforded to scientific uncertainty in the two jurisdictions, the different levels of protection pursued, and the different extent to which US and EU regulators take non-scientific—economic or social and political—factors into consideration. As the enquiry has illustrated, these elements are structurally intertwined.

Section E has focused on governance of pesticidal products. In this regulatory area, hazards and risks are positively established; the normative frames informing the regulatory process thus come into play *directly*. Far from being influenced by a focus on "hazards" or "risks," EU and US regulatory practices reflect a different consideration of multiple uncertainties and the pursuit of different levels of protection. Overall, transatlantic divergencies boil down to different approaches to risk assessment and the pursuit of cost-benefit effective—baseline—or higher than cost-benefit effective levels of protection.

Section F has turned to governance of GE organisms. In this field, hazards and risks are not conclusively established; the normative frames informing the regulatory process thus come into play *indirectly*. The analysis has demonstrated that the transatlantic conundrum of biotechnologies should not be interpreted against the backdrop of the "science" versus "politics" dichotomy. In the face of scientific complexity and multiple forms of uncertainty, science cannot provide a single "correct," "valid" and universally agreeable answer. The assumption that sound science must be adhered to, and that it is the only relevant element for the purposes of decision-making, is informed by considerations surrounding regulatory cost-benefit effectiveness. Prudential approaches to risk assessment and a focus on persisting uncertainty, by contrast, reflect consideration of qualitative OLFs and the pursuit of enhanced levels of protection. The divergencies in US and EU approaches thus reflect different perspectives on multiple uncertainties, the pursuit of different levels of protection, and consideration of different non-scientific factors.

Non-scientific normative frames may come into play directly or indirectly. Nonetheless, they are always at stake in the field of risk regulation. Through adherence to sound science and reliance on cost-benefit analysis models, evidence-based approaches seek to achieve *aggregate wealth maximization* and the greatest *net beneficial protection* of public health and the environment. These goals are largely reflected in the US system of risk governance. Fostering technological-scientific developments and the exercise of *individual* trade rights is the twofold overarching aim of this approach; the assumption is that both elements will result in positive spill-overs and benefit society at large. This approach yields considerable economic benefits.

The EU system, by contrast, is informed by socially acceptable risk approaches. The assumption that aggregate wealth maximization and the greatest net beneficial protection must be pursued does not apply; nor are technological-scientific developments and market freedoms necessarily associated with the "common good." Regulators may choose to pursue enhanced levels of protection; equally, they make have recourse to the precautionary principle and take different OLFs into account when deciding whether uncertain risks are acceptable and worth taking. This reflects a different balance between *individual* —economic and trade—rights and *collective*—public health, environmental, social, and political—interests.

Both approaches are also associated with specific disadvantages.[170] Socially acceptable risk approaches are likely to be economically inefficient. The threshold of acceptable risk should always be politically and socially agreeable, and reflect the intended level of protection and consideration of all OLFs. Economic rights, however, are likely to take second place. This does not

[170]*See* Leonelli, *supra* note 1 (discussing an in-depth analysis of these points).

https://doi.org/10.1017/glj.2022.47 Published online by Cambridge University Press

respond to the tenets of aggregate wealth maximization and can easily stifle technological and scientific innovation. By moving out of the realm of quantitative cost-benefit analysis and by giving expression to public perception of risk, socially acceptable risk approaches are also liable to misallocate economic resources which could be used to target more or more salient risks.[171]

Finally, under specific circumstances, recourse to the precautionary principle in situations involving risk-risk trade-offs may turn out to be counter-productive and detrimental to public health and environmental protection. Nonetheless, the traditional argument surrounding the "irrational" nature of the precautionary principle fails to address several points.[172] According to this argument, based on behavioral economics, precautionary approaches rely on cognitive biases and cognitive mistakes which are typical of the individual dimension.[173] Particular emphasis has been placed on the notions of trade-off neglect and risk-risk trade-offs. In this specific respect, recourse to the precautionary principle has been alleged to expand risks in other fields; by way of example, a precautionary approach to agricultural biotechnologies is alleged to increase the risks of food insecurity. While the points on trade-off neglect and risk-risk trade-offs are important, these accounts fail to demonstrate that socially acceptable risk approaches are bound to increase the overall levels of risk. The reason is that this argument neglects several elements which are typical of socially acceptable risk approaches, including the overarching tenets of the substitution principle and regulatory focus on a long-term vision for the development of more sustainable approaches. For instance, a precautionary approach to GE organisms will not increase the risks of food insecurity if adequate alternative strategies—for example policies to promote and enhance the productivity of small-scale conventional and organic agriculture—are devised and implemented. On these grounds, the point regarding the counter-productive effects of recourse to the precautionary principle should be nuanced and circumscribed to cases where alternative strategies are either highly ineffective, or unavailable in the short and in the long term.

Evidence-based models have different shortcomings. First, the identification of a *baseline* level of safety and *baseline* threshold of adverse effects may be irreconcilable with the value that society attaches to the protection of public health and environmental interests. Indeed, the pursuit of economically cost-benefit effective levels of protection does not enable regulators to provide for enhanced protection. Second, this model can hardly allow for consideration of qualitative OLF; these, as the article has illustrated, are beyond the radar of evidence-based approaches.

Third, and crucially, the application of economic cost-benefit analysis in conditions of scientific uncertainty is liable to underestimate risks and undermine public health and environmental protection.[174] To begin with, methodological questions surrounding the selection and quantification of economic "costs" and "benefits" arise. This aspect has been extensively covered in the literature.[175] Further, in the face of persisting uncertainty, the application of cost-benefit analysis models to a "sound" scientific evidence base may result in an—additional—underestimation of risks. This may have severe consequences where hazards have not been identified or have been incorrectly characterized, for instance due to confounding factors; equally, it will undermine public

[171]Giandomenico Majone, *Foundations of Risk Regulation: Science, Decision-Making, Policy Learning and Institutional Reform* 1 EUR. J. RISK REGUL. 5, 14 (2010).

[172]*See* Sunstein, *Laws of Fear*, *supra* note 4; Cass R. Sunstein, *Precautions Against What? Perceptions, Heuristics and Culture*, *in* THE REALITY OF PRECAUTION, *supra* note 37, at 492.

[173]These encompass loss aversion, entailing disregard of the potential benefits associated with the decision to take a risk; the myth of a benevolent nature; availability heuristics, focusing on the cognitive distinction between lay people and experts; probability neglect; system neglect, including the potential misallocation of resources which could be more efficiently allocated to reduce other risks; and trade-off neglect. *See* Sunstein, *supra* note 172; Sunstein, *Risk and Reason*, *supra* note 4; Sunstein, *Laws of Fear*, *supra* note 4.

[174]*See* Leonelli, *supra* note 1 (giving a detailed analysis of this point).

[175]*See generally* Steven Kelman, *Cost-Benefit Analysis: An Ethical Critique*, AM. ENTER. INST. (1981) https://www.aei.org/articles/cost-benefit-analysis-an-ethical-critique/; Frank Ackerman & Lisa Heinzerling, *Pricing the Priceless: Cost-Benefit Analysis of Environmental Protection*, (2002) 150 UNIV. PENN. L. R. 1553; FRANK ACKERMAN & LISA HEINZERLING, PRICELESS: ON KNOWING THE PRICE OF EVERYTHING AND THE VALUE OF NOTHING 1 (2004).

https://doi.org/10.1017/glj.2022.47 Published online by Cambridge University Press

health and environmental protection if a risk assessment has failed to capture exposures in real life conditions or multiple exposures. Finally, the pursuit of *net beneficial protection* is liable to reduce the final level of public health and environmental protection considerably. Most importantly, considerations surrounding variability and non-discernible, non-fatal or long-term effects will hardly be captured and taken into due consideration. This is all the more likely to occur in cases where the economic stakes are high; the more a product or process is economically beneficial, the more severe or "unreasonable" the relevant adverse effects will have to be for risk regulation to be enacted.

Against this overall backdrop, as anticipated in section C, ideal evidence-based and socially acceptable risk models offer a toolbox to deconstruct the goals, underlying value systems and far-reaching implications of different regulatory approaches. Further, they offer a conceptual apparatus to explain the causes of regulatory divergencies and conflicts. A reading through the lens of this framework may also trigger reflections on different aspects of risk governance, including different societal responses to the materialization of uncertain risks. In times of pandemic, for instance, it may be worth asking whether transatlantic divergencies in US and EU regulatory approaches could help explain the different reception of COVID vaccines by US and EU civil society. Has the US traditionally close focus on sound science and regulatory cost-benefit effectiveness increased public skepticism over the safety of COVID vaccines? Has the presumption that uncertain risks must be run in so far as they have not been conclusively established and the traditional US pursuit of net beneficial protection increased public anxiety? Have these factors undermined the US vaccination campaigns, and have evidence-based approaches backfired? Or should we interpret societal responses to COVID vaccines in the light of the balance struck between individual and collective rights in different jurisdictions? Does the approach of large parts of US civil society reflect the superiority of individual rights and of self-determination, vis-à-vis collective interests and the attempt to protect vulnerable constituencies from COVID?

The last relevant considerations regard the future of the US and EU risk regulation systems. As the US President Biden and the President of the European Commission Von der Leyen pioneer new forms of transatlantic cooperation,[176] the question whether the US and the EU may gradually converge in their approaches to risk regulation has remained an open one.

As mentioned throughout sections E and F, strategic environmental and public health litigation is flourishing in the US. Further, environmental and public health protection are very high on the agenda of the Biden administration. President Biden has taken significant steps to dismantle his predecessor's policies.[177] At the same time, the Biden era-EPA has already made several U-turns; the EPA's "new" vision is characterized by a more prudential approach to risk assessment and the promotion of higher levels of environmental and public health protection. The EPA's revocation of tolerances for chlorpyrifos and its current attempts to tackle the US "forever chemicals" ("PFAS") crisis are significant examples of this new approach.[178]

[176]For instance, the COP26 commitments taken on by the US and the EU as regards reducing methane emissions and tackling deforestation. BRIT. BROAD. CORP., *COP26: US and EU announce global pledge to slash methane* (Nov. 2, 2021) https://www.bbc.com/news/world-59137828#:~:text=EU%20Commission%20chief%20Ursula%20von,30%25%20compared%20with%202020%20levels. Further, the US and the EU have announced their intention to negotiate the first sectoral arrangement for the promotion of low carbon steel and aluminum. *Questions and Answers: EU-US negotiation ono trade on steel and aluminum,* EUR. COMM'N https://ec.europa.eu/commission/presscorner/detail/en/QANDA_21_5722 (accessed Mar. 2022).

[177]President Biden's decision to re-join the Paris Agreement and the "Build Back Better" agenda are perhaps the most famous examples. However, other changes have taken place; some have a specific impact in the field of risk regulation *stricto sensu*. In January 2021, President Biden revoked Executive Order 13771 of 30 January 2017, on the reduction of regulation and regulatory costs. *see supra* note 44. At the time of writing, the controversial reform of regulatory oversight of animals developed using genetic engineering, involving transfer of authority from the FDA to the APHIS, has also been stalled.

[178]For more information on the PFAS "crisis" in the US and the measures that the EPA is taking. ENVIR. PROTECTION AGENCY, *EPA Actions to Address PFAS* https://www.epa.gov/pfas/epa-actions-address-pfas (accessed Mar. 2022); *see also supra* note 69 (discussing the EPA's decision regarding chlorpyrifos).

https://doi.org/10.1017/glj.2022.47 Published online by Cambridge University Press

As this article has endeavored to illustrate, US societal groups and the Biden administration are confronting a rather well-entrenched approach to the regulation of uncertain risks. Will they succeed in striking a different balance between economic interests and environmental and public health protection? Will their efforts be sufficient to break regulatory path dependency? Will the Biden administration's approach set the foundations and pave the way for a long-lasting paradigm shift in US risk regulation? These points bring us back to the question of the relationship and interactions between institutional and regulatory arrangements vis-à-vis social values and cultural factors. Would regulatory changes produce lasting results in US regulatory practice in the field of risk governance? Would any such change result from institutional and regulatory factors, or from an evolution in societal perspectives and value systems? There is no easy answer to any of these questions; nor is it possible to address them meaningfully at the current stage. Nonetheless, an analysis through the lens of evidence-based and socially acceptable risk approaches may help provide an answer in the near future.

Cite this article: Leonelli GC (2022). Transatlantic Divergencies in the Regulation of Uncertain Risks: Co-Production, Normative Frames and Ideal Evidence-Based and Socially Acceptable Risk Approaches. *German Law Journal* **23**, 769–799. https://doi.org/10.1017/glj.2022.47