1.
Introductory Overview: Transnational Narratives, Evidence-Based and Socially Acceptable Risk Approaches, Normative Analysis

An analysis of different approaches to risk regulation and opposed transnational narratives on agricultural biotechnologies and their uncertain risks lies at the heart of this book. Three analytical strands are tied up and set within a unitary framework as the enquiry of the book unfolds: these are methodological, institutional and normative strands of analysis. This introductory chapter provides an overview of these three strands of enquiry. The first section sketches out the broader picture, providing some background on genetically engineered organisms and demarcating the analytical scope of the book. The second section turns to methodological aspects. The methodological framework applied in the book and the relevant analytical implications are then illustrated in greater detail in the second chapter.

The third section, on the other hand, takes a closer look at the institutional strand of enquiry. The book deconstructs the hegemonic and counter-hegemonic transnational narratives on agricultural biotechnologies and their uncertain risks against the backdrop of two ideal approaches to risk regulation: evidence-based and socially acceptable risk models.[1] It examines the two approaches and their specific implications by focusing on relevant governance frameworks, regulatory categories and case law in the field of agricultural biotechnologies. The analysis cross-cuts different legal systems, where the hegemonic and counter-hegemonic narratives on genetically engineered organisms are embedded. The third section explores the rationales, premises and characteristics of these two diametrically opposed ideal regulatory models, anticipating the findings of the book.

Finally, the fourth section focuses on the normative strand of enquiry. From this angle of analysis, the book investigates the extent to which the two opposed transnational narratives and ideal regulatory models may be reconciled, by identifying an agreeable and normatively legitimate solution to transnational regulatory conflicts. The book takes into consideration modern science-centred and legal procedural paradigms, questioning the ability of science and of deliberative practices to generate authentic agreement and build consensus in the face of scientific complexity and intense political and socio-economic controversies. The transnational conundrum of agricultural biotechnologies thus becomes a lens through which irreconcilable perspectives on risk regulation and their broader implications are investigated.

The book draws the conclusion that transnational conflicts on agricultural biotechnologies cannot and should not be solved. Diametrically opposed perspectives on

[1] On "socially acceptable risk" approaches, see GC Leonelli, "The Fine Line between Procedural and Substantive Review in Cases Involving Complex Technical-Scientific Evaluations: Bilbaína" (2018) 55 *CML Rev* 1217; GC Leonelli, "The Glyphosate Saga and the Fading Democratic Legitimacy of EU Risk Regulation" (2018) 25 *Maastricht Journal of European and Comparative Law* 582; and GC Leonelli, "The Perfect Storm: GMO Governance and the EU Technocratic Turn" in M Peeters and M Eliantonio (eds), *Research handbook on EU Environmental Law* (Edward Elgar, 2020). The origins of the terminology of "evidence-based" risk governance are uncertain; for its use, see inter al A Alemanno, annotation of Case C-77/09, *Gowan Comércio Internacional e Servicos Lda* v. *Ministero della Salute*, EU:C:2010:803, (2011) 48 *CML Rev* 1329.

whether, how and why uncertain risks ought to be regulated should merely coexist. Further, the failure of deliberation and legal proceduralisation in the field of agricultural biotechnologies is the starting point for a set of broader considerations. If, as the book suggests, successful *procedural* deliberation largely *results from* specific *substantive* preconditions, notably pre-existing shared perspectives, values and goals, the focus should ultimately shift from modern procedural analysis, which seeks to construct legitimate solutions to increasingly complex regulatory conflicts, to a post-modern substantive deconstruction of regulatory approaches and their underlying premises, goals and impacts.

I. The Broader Picture: Agricultural Biotechnologies and Transnational Controversies

Genetic engineering techniques have evolved considerably since the 1970s, when the first advances in recombinant DNA (rDNA) mediated gene transfer, or genetic modification, took place.[2] Transgenesis, i.e. "traditional" genetic modification by means of inserting foreign DNA, has been largely replaced by different techniques. A whole range of new breeding techniques ("NBTs") inducing genetic mutations has been developed throughout the years. These include both techniques that involve genome editing, such as CRISPR-Cas9 technology, TALENs and Zinc Finger Nucleases technology, and techniques that do not involve genome editing, such as RNAi technology, agroinfiltration, epigenetic approaches and oligonucleotide-directed mutagenesis.[3]

Genetic mutations through NBTs often target the same traits that were selected by means of transgenesis, with a view to achieving the same or similar goals. In this sense, at least at the current stage, the picture has largely remained unchanged; the advantages or disadvantages associated with organisms engineered by means of NBTs are not remarkably different from the ones of "traditional" genetically modified organisms ("GMOs").[4] As to their uncertain public health and environmental risks, the scientific community has acknowledged the increased target precision of NBTs; yet, uncertainty persists as to the potential effects and risks of off-target interferences, unintended mutations, the disruption of different gene sequences and repeated small alterations through the application of one technique or more techniques simultaneously.[5] At a general level, yet again at the current stage of technical-

[2] See the overview in chapter 3, section I.

[3] For a general (pro-biotechnology) overview, see www.geneticliteracyproject.org/ and www.nbtplatform.org/. For a thorough but not entirely up to date overview, see European Scientific Advice Mechanism, High Level Group of Scientific Advisors, *New Techniques in Agricultural Biotechnology* (2017).

[4] See below, in this section.

[5] See inter al European Scientific Advice Mechanism, High Level Group of Scientific Advisors, n 3, at 62 ff; the Statement on New Genetic Modification Techniques of the European Network of Scientists for Social and Environmental Responsibility ("ENSSER"), available at www.ensser.org/publications/ngmt-statement/, and RA Steinbrecher, "Genetic Engineering in Plants and the New Breeding Techniques ("NBTs"): Inherent Risks and the Need to Regulate" (2015) *Econexus Briefing*.

scientific knowledge, the uncertain environmental and public health risks at issue do not appear to be significantly different from the ones at stake in the case of "traditional" GMOs.[6]

Further, the scope of application of genetic engineering techniques has considerably expanded. Throughout the years, these techniques have been used to engineer crops, bacteria and microorganisms, animals, insects or (in a specific and highly controversial case) human beings; genetically engineered crops can be used as food and feed or for industrial or pharmaceutical purposes.[7] NBTs have also been used in the medical field. Taking this complex picture into consideration, it is ultimately unsurprising that different legal systems have varied in their approaches to (old and new) genetic engineering techniques. Different definitions of "genetic modification", "GMOs" or "genetic engineering"[8] and different regulatory categories[9] coexist across different legal systems.

The analytical scope of the book is broader and at the same time more circumscribed than the title might, at first sight, suggest. On the one hand, the book takes into consideration more than "traditional" GMOs; the analysis encompasses recent regulatory developments and reforms relating to products obtained through the application of NBTs. For this reason, while the title refers to the familiar notion of "GMOs", the book uses the more accurate terminology of "genetically engineered" organisms ("GE organisms"). On the other hand, the scope of the analysis is limited to agricultural biotechnologies, with a focus on the cultivation of GE crops and the marketing of GE food and feed varieties. Other applications of GE techniques are not taken into consideration. Further, as the title makes clear and as already mentioned at the beginning of this chapter, the book focuses on the governance of agricultural biotechnologies and their *uncertain risks* from a *risk regulation* perspective. The specific governance approaches, regulatory categories and notions analysed throughout the book belong to the field of risk regulation. Different regulatory aspects or policy debates are only taken into account in so far as they are relevant to the enquiry into transnational narratives on GE organisms and their uncertain risks.

Upon these preliminary clarifications, the rest of this section endeavours to sketch out the broader picture on agricultural biotechnologies and identify the main issues at stake in this complex regulatory area. This paves the way for the threefold analysis of the following sections. The commercialisation of GE products started in the mid-1990s. In 2018, GE crops were grown in 26 countries; the cultivation and marketing of GE organisms is entrenched in several countries, the object of a blanket ban in a few countries, and stringently regulated in

[6] See below, in this section; however, see also the final considerations in chapter 7, highlighting that the overall picture might change as technical-scientific knowledge evolves and the specific applications of these technologies develop.

[7] For further information on different applications, see www.geneticliteracyproject.org/. On the first and highly controversial application of CRISPR-Cas9 to human beings, see the interview to the co-discoverer of CRISPR technology and Nobel Prize winner Professor Jennifer Doudna, at www.issues.org/wp-content/uploads/2020/04/37-39-Doudna-Spring-2020-ISSUES.pdf.

[8] See chapter 3, on the US approach to "traditional" GMOs and to NBTs; chapter 4, on the EU legislative definition of "GMOs" and its broader scope of application to organisms obtained through NBTs; chapter 5, on the 2000 Cartagena Protocol on Biosafety to the Convention on Biological Safety and terminology of living modified organisms ("LMOs"); and chapter 6, on the relevant definitions under the Codex Alimentarius Commission system.

[9] E.g. see chapter 3 for the regulatory categories of "plant pests" and "plant-incorporated protectants", and chapter 4 for reference to "GMOs as or in products" and "GM food and feed".

other jurisdictions.[10] Genetic mutations target specific traits, associated with agronomic or quality characteristics. GE crops have so far been engineered to achieve herbicide or multi-herbicide resistance, pesticidal traits, disease resistance, tolerance to environmental stresses, delayed ripening or bruising, enhanced nutritional qualities or a lack of specific toxins and allergens.[11] In the vast majority of cases, from the origins of transgenesis until nowadays, GE crops have been engineered to be herbicide or multi-herbicide resistant; these are also the most commonly farmed GE varieties.[12]

Like in other highly controversial areas of risk regulation, uncertainties and scientific inconclusiveness primarily surround the existence and nature of specific adverse effects, rather than the characterisation of the relevant risks.[13] Starting with environmental effects, uncertainty surrounds the possibility, extent and potential impacts of hybridisation, crop to crop gene flow and any adverse effects that these could have on biodiversity and specific ecosystems.[14] Similar considerations apply to the impact on non-target organisms of pest-resistant GE crops; in this specific case, the relevant risks are characterised and deemed to be negligible in many jurisdictions.[15] As to the public health adverse effects of GE food, the possibility that GE varieties may trigger allergic reactions has been debated for years.[16] The potential effects of (copiously) spraying herbicide or multi-herbicide resistant GE varieties with the relevant herbicide(s) and other maintenance pesticides have also come under close scrutiny.[17] As explained in the third section of this chapter, persisting uncertainty as to the potential adverse effects posed by GE organisms is evaluated and taken into consideration in different ways under different regulatory models. Different inferences are drawn from the available scientific evidence; further, as the book shows, the very framing of the relevant scientific questions varies considerably. The importance of the public health and environmental interests at issue and the magnitude and pervasiveness of potential indirect or long-term adverse effects makes scientific evaluations in this field even more controversial.

An analysis of the other factors at stake in this field makes the picture increasingly complex. Like in other contentious areas of risk governance, these factors play a prominent role. At a general level, in national and transnational trade circles, GE products are of considerable interest in light of the potential profits to be generated from their market entrenchment. Advocates of agricultural biotechnologies argue that GE organisms yield wide-reaching environmental and social advantages, resulting from an alleged reduction in the use of herbicides and insecticides,[18] an alleged increase in agricultural productivity and a reduction of costs for both farmers and consumers.[19] From this position, by increasing total agricultural

[10] See the data in Brief 54-2018 of the International Service for the Acquisition of Agri-Biotech Applications ("ISAAA"), available at www.isaaa.org/resources/publications/briefs/54/executivesummary/default.asp.
[11] See chapter 3, section IV in particular.
[12] See data available on www.isaaa.org/default.asp.
[13] See below, section III.
[14] For an analysis, see chapters 3 and 4.
[15] See chapter 3.
[16] On the question of allergenicity and other public health risks, see e.g. chapter 4, section V.
[17] Ibid. Herbicide-resistant crops have often been engineered to be resistant to glyphosate-based herbicides; for this reason, the debate on glyphosate and its uncertain public health risks is also connected to the one on agricultural biotechnologies. On glyphosate, see Leonelli, "The Glyphosate Saga and the Fading Democratic Legitimacy of EU Risk Regulation", n 1.
[18] Due to their herbicide resistance and pesticidal traits, respectively.
[19] See www.geneticliteracyproject.org/ and www.isaaa.org/default.asp.

production while lowering costs, GE organisms can serve the purpose of feeding an expanding global population, tackling starvation and achieving food security in developing and less developed countries.[20] Further scientific-technological advances in the field are also portrayed as the way forward to grow nutritionally enhanced or vitamin-fortified GE varieties as well as climate resilient GE crops, which have recently gained increased visibility.[21] On these grounds, to summarise, GE organisms have come to be associated with significant technical-scientific as well as socio-economic opportunities.

This perspective is disputed by different stakeholders in several jurisdictions. These actors consider the cultivation of GE crops to be environmentally unsustainable; in this respect, stakeholders have pointed to increased herbicide resistance of weeds, as a result of the copious spraying of herbicide resistant GE crops,[22] and to the impact on ecosystems of GE crops with pesticidal traits. The contention that agricultural biotechnologies result in increased productivity and greater yields is also disputed, especially in the debate on climate resilient crops.[23] At a broader level, stakeholders and social movements influenced by the food sovereignty philosophy have challenged the argument that agricultural biotechnologies will help achieve food security, emphasising distributional issues and questions of access to food.[24] From a similar perspective, they have argued that nutritionally enhanced or vitamin-fortified GE varieties have failed to deliver on their promises. Ultimately, these constituencies contend that agricultural biotechnologies have only yielded benefits to biotech corporations, which profit from intellectual property law protection.[25]

Yet, there is more to the debate on agricultural biotechnologies. Public opinion, public perception of risk and cultural and ethical considerations have played an important role.[26] The same is true of public interest in high levels of food quality.[27] Coexistence measures, which allow the cultivation of GE, conventional and organic crops alongside each other, are difficult and costly to set in place. Their effectiveness across different geographic areas varies considerably. The limited effectiveness of coexistence measures results in the ubiquitous adventitious presence of GE components in seeds, crops and food.[28] Where the uncertain risks posed by GE varieties are considered too high to be acceptable, stakeholders have then come to indirectly identify a public health and consumer protection dimension in the governance of

[20] For a reference to President GW Bush's famous criticism of the EU precautionary approach to GE organisms on these specific grounds, see M Pollack and G Shaffer, *When Cooperation Fails. The International Law and Politics of Genetically Modified Foods* (OUP, 2009) at 116.
[21] See A Saab, *Narratives of Hunger in International Law. Feeding the World in Times of Climate Change* (CUP, 2019).
[22] See inter al data made available by the Non-GMO Project, www.nongmoproject.org/; GM Watch, www.gmwatch.org/en/; Slow Food International, /www.slowfood.com/; and Greenpeace USA, www.greenpeace.org/usa/. Increased herbicide resistance has resulted in an increased use of herbicides, changes in the specific herbicides used, and the development of multi-herbicide resistant GE crops.
[23] See Saab, n 21.
[24] See chapter 6.
[25] See chapter 6. The same macro-corporations holding patents for GE crops also trade in herbicides to which GE organisms have been engineered to be resistant. On intellectual law property protection, see inter al Saab, n 21.
[26] E.g. see chapter 4, section VI, sub-section C. On this point, see inter al M Echols, "Food Safety Regulation in the European Union and the United States: Different Cultures, Different Laws" (1998) 4 *Columbia Journal of European Law* 525; and D Vogel, *The Politics of Precaution. Regulating Health, Safety and Environmental Risks in Europe and the United States* (Princeton University Press, 2012).
[27] See chapter 6.
[28] See chapter 3.

coexistence, as if these measures were proper risk management measures.[29] Without doubt, ineffective coexistence measures can affect consumer choice and the economic viability of conventional and organic agriculture, due to cross-contamination. All in all, the economic costs of managing coexistence are too often borne by conventional and organic farmers.[30] Thus, the main point of controversy is the impact of the entrenchment of agricultural biotechnologies on different agricultural models.

Against this backdrop, and to draw some conclusions, two aspects in the case of GE organisms are particularly relevant from a risk regulation perspective. The first is that uncertainties and scientific inconclusiveness primarily surround the existence and nature of specific adverse effects, rather than the characterisation of the relevant risks. This makes the scientific dimension of the regulatory conundrum highly contentious. Secondly, the availability of more demonstrably sustainable alternatives to GE organisms, controversies as to the socio-economic advantages that GE products may yield and the clash between different long-term visions for the agricultural and food system make this case even more controversial. These specific dimensions re-surface in the third and fourth sections of this chapter, which respectively focus on the institutional and normative strands of enquiry of the book.

II. The Methodological Framework: Transnational Legal Analysis and Transnational Narratives

The journey of transnational legal studies started with Philip Jessup's famous 1957 Storr Lectures.[31] Since then, transnational law has increasingly come to be associated with *hybrid* standard-setting and norm-making by *non-state actors and bodies* operating *beyond* the nation state level. As chapter two explains, transnational legal theory captures the partial unravelling of the nation state and the shifting balance of power at times of globalisation. As non-state actors are increasingly involved in regulatory governance, new patterns of norm-making are established and the resulting regulatory systems come to interact with both national law and other positive legal regimes. In this sense, transnational law and the socially constructed transnational space are neither public nor private, neither national nor international.[32] Indeed, transnational regulatory governance develops and unfolds across territorial levels and societal forms of organisation, engaging different actors within different sites of norm-making.

On these grounds, transnational legal theorists have traditionally carved out a circumscribed focus of analysis for transnational legal studies. First, a distinction is usually drawn between national law, other positive legal systems, including public international law,

[29] Rather than measures put in place to avoid contamination. See chapter 4, section VI, sub-section B (albeit with reference to the alleged environmental protection dimension of coexistence measures).
[30] See chapter 3. Further problematic aspects, such as herbicide drift associated with the cultivation of herbicide resistant GE crops, may come into play. The recent high profile "Dicamba" litigation in the United States has put this issue in the spotlight; see *National Family Farm Coalition and Others v Environmental Protection Agency*, No 17-70810 (9th Circuit 2020).
[31] PC Jessup, *Transnational Law. Storrs Lectures in Jurisprudence at Yale Law School* (Yale University Press, 1956).
[32] P Zumbansen, "Neither Public Nor Private, National Nor International: Transnational Corporate Governance From a Legal Pluralist Perspective" (2011) 38 *Journal of Law and Society* 50.

and transnational law.[33] Transnational regulatory standards do interact with other legal regimes; the Codex Alimentarius Commission's standards, taken into consideration as a "benchmark" for WTO law purposes under the Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement"), are one of the most famous examples.[34] Further, transnational regulatory standards are "recursively"[35] interpreted, applied and enforced across territorial levels and jurisdictions; to provide an example, transnational standards might be incorporated in contracts concluded at the national level and be interpreted and enforced in national courts. Nonetheless, *hybrid* transnational law is usually distinguished from *positive* (national, international or supra-national) legal regimes. Secondly, transnational law is regarded as a self-standing, albeit hybrid, "field" or "quasi-field" of law; most transnational legal theorists have so far explored the "transnationalisation" of entire areas of law and regulation.[36]

From a "traditional" transnational legal perspective, the "transnational" regulation of the uncertain risks posed by GE organisms would only encompass regulatory standards enacted by market actors, NGOs and agencies operating beyond the nation state level. This book takes a different view and puts forward an alternative understanding of "transnational law" and "transnational legal analysis". For the purposes of the book, "transnational law" is understood as a social reality and a social product of globalisation, rather than as a self-standing "field" or "quasi-field" of law.[37] "Transnational law" is thus defined as the composite and highly complex *regulatory infrastructure* underpinning globalisation flows; a regulatory infrastructure which all legal categories, starting from the traditional notions of "national" and "international" law, fail to capture. Consequently, the "transnational" regulation of GE organisms and their risks is understood as the regulatory infrastructure underpinning the asymmetric globalisation of agricultural biotechnologies. Such regulatory infrastructure results from the coexistence and interaction of transnational discourses on GE organisms and the governance of the uncertain risks that they may pose. More specifically, it is the social product and social reflection of two conflicting, hegemonic and counter-hegemonic transnational narratives.

Clearly, transnational narratives and discourses do not exist in a social vacuum; nor do they emerge out of thin air. They originate from different regulatory sites and are socially and politically constructed *from within*, *across* and *beyond* the nation state level.[38] From this perspective, the regulation of agricultural biotechnologies *within* specific national and regional jurisdictions, or under international or supra-national legal regimes (*across* the nation state level), has been just as relevant to the construction of transnational narratives as hybrid standard-setting by actors operating *beyond* the nation state. National, supra-national and international legal systems coalesce to frame transnational discourses on agricultural

[33] This, however, does not always happen; see chapter 2, part 1.
[34] See chapters 5 and 6.
[35] See inter al TC Halliday, "Recursivity in Global Norm Making: A Socio-Legal Agenda" (2009) 5 *Annual Review of Law and Social Sciences* 263; and TC Halliday and G Shaffer, "Transnational Legal Orders" in TC Halliday and G Shaffer (eds), *Transnational Legal Orders* (CUP, 2015).
[36] See chapter 2, part 1.
[37] See also GC Leonelli, "The Postmodern Normative Anxiety of Transnational Legal Studies" in P Zumbansen (ed), *The Oxford Handbook of Transnational Law* (OUP, 2021).
[38] Ibid. For the use of very similar terminology, albeit in a different theoretical context and with a different meaning, see TC Halliday and G Shaffer, "With, Within and Beyond the Nation State: The Promise and Limits of Transnational Legal Ordering", in P Zumbansen (ed), *The Oxford Handbook of Transnational Law*, n 37.

biotechnologies and feed into the "transnational" regulatory infrastructure. In this sense, the book shows that transnational legal narratives do not necessarily originate beyond the nation state level or beyond positive, formalised systems of law; nor should they be automatically associated with hybrid standard-setting by societal actors, in line with the traditional focus and object of enquiry of transnational legal studies.

As chapter two explains in greater detail, transnational legal analysis is employed in the book as a *methodological framework* to deconstruct transnational narratives on agricultural biotechnologies from within, across and beyond the nation state level. The application of this methodological framework postulates a focus on *transnationally relevant* legal systems; these are the norm-making sites where transnational narratives have originated and where they have been shaped, reshaped, challenged or reinforced. On these grounds, the book uses transnational legal analysis to *interrogate* transnationally relevant regulatory frameworks and case law, with a view to *deconstructing* opposed transnational narratives on GE organisms and risk regulation and uncovering their rationales, policy goals, underlying values and implications.[39] The examination of hegemonic and counter-hegemonic narratives unfolds across three analytical dimensions; these are defined as "extra-territoriality", "legal pluralisation", and "legal hybridisation".[40]

The introductory section in each substantive chapter focuses on the application of the methodological framework, addressing four interconnected questions. The first question relates to the narrative under analysis throughout the specific chapters. The third chapter (US law), fifth chapter (SPS Agreement) and first part of the sixth chapter (Codex Alimentarius Commission) focus on the hegemonic narrative on GE organisms and risk governance. The fourth chapter (EU law) and second part of the sixth chapter (standard-setting by NGO actors), on the other hand, engage with the counter-hegemonic narrative.

The second question focuses on the transnational relevance of the legal systems under analysis throughout the chapters. In other words, it addresses the reasons why these legal systems are the object of analysis and describes how the hegemonic or counter-hegemonic narratives have been constructed, reinforced or challenged within these legal systems. The US system is the legal order where the transnational hegemonic narrative on GE organisms originated. Categories and regulatory notions which were first developed and employed in US risk governance have become a constituent part of hegemonic discourses on risk regulation; thus, US regulatory categories have clear transnational relevance. This reflects the logics of *extra-territoriality* at times of globalisation, whereby national and regional legal systems have unprecedented extra-territorial impact and national or regional legal categories have increased transnational relevance and application. On these grounds, the third chapter deconstructs the hegemonic narrative on GE organisms and risk governance *from within* the US national legal system.

The fourth chapter focuses on EU law. From a methodological perspective, this legal system cuts across the two dimensions of *extra-territoriality* and *legal pluralisation*. First, if analysed as a regional system, the EU legal regime is the site where the counter-hegemonic narrative on GE organisms has been constructed. For this reason, just like in the case of US

[39] See also Leonelli, n 37.
[40] Ibid.

regulation, EU regulation of agricultural biotechnologies has had an important transnational impact. Secondly, as a supra-national system in its own right, the EU legal regime impacts on EU Member States. This adds a further layer of analysis, as the EU and EU Member States have repeatedly clashed on regulatory implementation matters in the field of agricultural biotechnologies. The fourth chapter thus deconstructs the counter-hegemonic narrative on GE organisms and risk governance *from within* the EU regional legal system and *across* the nation state (i.e. EU Member State) level.

The fifth chapter turns to the SPS Agreement. The interpretation and application of the Agreement provisions has had a significant impact on the transnational debate on GE organisms; more specifically, it has considerably strengthened the hegemonic discourse on agricultural biotechnologies and regulation of their uncertain risks. The fifth chapter examines the hegemonic narrative and its far-reaching implications by analysing the WTO law regime, *across* the nation state level (*legal pluralisation*). Finally, the sixth chapter encompasses an analysis of the Codex system and hybrid regulatory standard-setting by non-profit NGO actors (*legal hybridisation*). Both sites of norm-making have transnational relevance. On the one hand, the Codex standard-setting system has strengthened transnational evidence-based discourses on risk governance and agricultural biotechnologies. On the other hand, NGO actors have directly challenged the hegemonic narrative on GE organisms and defended counter-hegemonic discourses. The sixth chapter thus engages in a further deconstruction of the hegemonic and counter-hegemonic narratives, *beyond* the nation state level.

The final questions addressed in each chapter partially overlap. How has the examination of these transnationally relevant legal systems helped deconstruct the hegemonic and counter-hegemonic narratives on GE organisms, casting light on their rationales, underlying value systems, goals and implications? And how has the analysis of these legal systems helped deconstruct transnational discourses on the regulation of uncertain risks, more generally? The answer to these questions is part of the institutional findings of the book, anticipated in the third section of this chapter.

To draw some preliminary considerations on the methodological strand, this book takes a perspective which distinguishes it from other studies on transnational law and transnational legal theory. First, it does not frame transnational law as a discrete and self-contained "field" or "quasi-field" of law. In this sense, for the purposes of the present analysis, the traditional transnational focus on societal actors and standard-setting bodies operating beyond the nation state level is considered insufficient to fully understand socio-legal ordering at times of globalisation. This narrower focus neglects regulatory layers which are integral to the social construction of transnational discourses and fails to capture how they influence the dynamics of transnational juridification.

Secondly, it casts light on the value of transnational legal analysis as a methodological framework. The contextualised analysis of different legal orders does not aim to compare and contrast them; nor is the enquiry anchored to any such legal system. In other words, the legal systems under analysis are not quite relevant in and of themselves. Rather, the analysis shows that elements of these legal orders have transnational relevance and a transnational impact, in so far as legal categories, notions and regulatory approaches embedded in these legal orders have become part of transnational narratives.

Finally, the book transposes "methodological transnationalism"[41] into the practice of legal analysis. By deploying transnational legal analysis as a framework, the analysis cuts across different territorial levels, forms of societal organisation, legal systems and regulatory fields. From this viewpoint, this book applies "methodological transnationalism" to a specific regulatory question within a discrete area of regulatory governance.

III. The Institutional Strand of Analysis: Transnational Narratives on GE Organisms, Ideal Regulatory Models and Different Forms of Uncertainty

The book frames the conundrum of agricultural biotechnologies against the backdrop of two diametrically opposed, hegemonic and counter-hegemonic, transnational legal narratives on GE organisms and uncertain risks. The two narratives are directly connected to two ideal regulatory models in the field of risk governance: evidence-based and socially acceptable risk approaches. The institutional strand of analysis thus deconstructs the characteristics and implications of the hegemonic and counter-hegemonic narratives by conducting an analysis of evidence-based and socially acceptable risk approaches. The enquiry focuses on legal frameworks, regulatory categories and case law, cutting across transnationally relevant legal systems. The book concludes that both hegemonic and counter-hegemonic transnational narratives, and both evidence-based and socially acceptable risk models, are socially and politically constructed. Both pursue specific goals, reflect specific value systems and have specific implications. On these grounds, neither can lay claim to neutrality and objectivity.

Under the hegemonic narrative on risk governance, uncertain risks *must* be taken as long as the potential adverse effects of a product or process have not been conclusively established[42] or in so far as this regulatory choice proves economically cost-benefit effective.[43] Under the counter-hegemonic narrative, risk managers are called upon to make a *convincing case* that uncertain risks are socially acceptable and worth taking, affording due consideration to the intended level of protection in the field, the specific values at stake, the pervasiveness of the potential effects and any relevant other legitimate factors.

The burden of proof shifts under the two narratives. Under the hegemonic narrative, the presumption is that uncertain risks *should* be run unless a product or process has been proven to be unsafe, or to the extent that this choice responds to economic cost-benefit analysis; in the second scenario, risk regulation comes into play where the probability of occurrence of adverse effects and their severity is such that not regulating would not be economically cost-benefit effective. Overall, a product or process should be regulated in so far as this conforms to a cost-

[41] For use of this terminology, see P Zumbansen, "The Incurable Constitutional Itch: Transnational Private Regulatory Governance and the Woes of Legitimacy" in M Helfand (ed), *Negotiating State and Non-State Law. The Challenge of Global and Local Legal Pluralism* (CUP, 2015).

[42] I.e., where uncertainty persists as to the existence of a causal link between the (potentially hazardous) characteristics of a product or process and specific adverse effects, or as to the actual materialisation of a risk. See below, in this section, for a detailed explanation.

[43] I.e., in cases where hazards and risks have been conclusively proven and characterised. See below, in this section, for a detailed explanation.

benefit calculus. Under the counter-hegemonic narrative, risks *should not* be taken unless, in the face of persisting scientific uncertainty, a product or process has been proven to be sufficiently safe. The determination that a product or process is safe enough for any connected risks to be socially acceptable lies at the heart of the counter-hegemonic narrative.

In turn, the two transnational narratives are directly connected to the dichotomy of evidence-based and socially acceptable risk approaches to the governance of uncertain risks.[44] As the following sub-sections illustrate, evidence-based models postulate recourse to a sound science approach to risk assessment, a focus on sound science and reliance on cost-benefit analysis. Conversely, socially acceptable risk approaches postulate a prudential approach to risk assessment and allow regulators margins of manoeuvre to take persisting scientific uncertainty, the pursuit of enhanced levels of protection, the tenets of the precautionary principle and other legitimate factors into account.

Evidence-based and socially acceptable risk approaches are ideal regulatory types, set along a spectrum of differential regulatory implementation.[45] As the book shows, the two ideal types are informed by different rationales and based on the application of different regulatory categories. No national or regional system of risk governance is entirely based on one or the other model across each and every field of regulatory action; nor is each and every regulatory framework perfectly aligned with one or the other paradigm.[46] Further, regulatory implementation may vary considerably. Regulatory frameworks reflecting an evidence-based approach may be implemented in such a way as to accommodate the pursuit of enhanced levels of protection, for instance through recourse to prudential risk assessments, while regulatory frameworks drawing on socially acceptable risk approaches may be implemented in an evidence-based manner.[47] Legal categories and concepts also vary from jurisdiction to jurisdiction, so that at times they can hardly be compared.

However, it is fair to acknowledge that different legal regimes and different regulatory frameworks are largely *informed* by one or the other ideal model. This emerges very clearly from the specific case of GE organisms. Opposed transnational narratives on agricultural biotechnologies, reflecting the clash between evidence-based and socially acceptable risk approaches, have been socially and politically constructed within specific legal systems. In the case of transnational discourses on GE organisms, as the book illustrates, we ultimately witness a polarisation at the two ends of the regulatory spectrum. This reflects a quasi-perfect adherence to the two ideal types.

Under the hegemonic narrative on GE organisms, and in accordance with evidence-based models, the uncertain risks posed by agricultural biotechnologies must be taken. This regulatory choice draws on sound science and is perfectly respondent to cost-benefit analysis.

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[44] See above, n 1.

[45] A specific caveat applies. Borrowing the words used by Fisher in her discussion of procedural Rational-Instrumental and Deliberative-Constitutive paradigms and setting them in the different context of substantive evidence-based and socially acceptable risk approaches, the ideal regulatory models under examination in this book are not "reified and fixed realities"; rather, they represent "polar and incommensurable opposite understandings" of risk governance. See E Fisher, *Risk Regulation and Administrative Constitutionalism* (Hart Publishing, 2007), 27 and 28.

[46] E.g. see chapter 3 for an examination of how different US regulatory agencies follow slightly different approaches in the governance of the uncertain risks posed by GE organisms.

[47] See chapter 4 for the latter scenario.

Reliance on socially acceptable risk approaches, by contrast, has (so far) largely resulted in the determination that the same risks are neither socially acceptable nor worth taking, considering the complex scientific, political and socio-economic picture illustrated in the first section. This determination is reflected in the counter-hegemonic narrative on agricultural biotechnologies. On these grounds, transnational narratives on GE organisms and the contentious issues at stake in this regulatory field provide a unique opportunity to deconstruct the nature and implications of the two ideal regulatory types.

The book argues that the determination of the threshold of *legally relevant* adverse effects, i.e. the threshold which will trigger regulatory intervention, is never a matter of "pure" science.[48] Rather, this determination results from three different factors. The first factor is adherence to more or less prudential approaches to risk assessment.[49] This is a matter of risk assessment policy and impacts on the *evidence base* that regulators draw upon. As acknowledged since the famous 1983 US National Research Council "Red Book", policy judgments are embodied in risk assessment.[50] The selection of specific scientific literature, "hard" data, assumptions and models involves so-called "science-policy choices", which will influence the final results of a risk assessment.[51]

The second factor is the extent to which regulators adhere to sound science, understood in this book as conclusive scientific proof of the existence of hazards and risks, or focus on scientific insufficiency or relevant uncertainties. This aspect concerns the *inferences* that regulators draw from the available scientific evidence, in the face of persisting uncertainty.[52] As expressly recognised by the scientific community, "because all assessments of scientific data are subject to uncertainties and because scientific knowledge is incomplete, it is possible for different analysts to arrive at different interpretations of the same set of data".[53]

The adoption of more or less prudential approaches to risk assessment and the variable extent to which different forms of uncertainty are taken into account, as the book shows, are influenced by specific *normative frames*. Recourse to less prudential (sound science) approaches to risk assessment and adherence to sound science are economically cost-benefit

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[48] For the first suggestion that the determination that a risk exists "cannot be a matter of pure science", developed through an analysis of the logical structure of risk findings and an examination of the logical relationship between available scientific evidence and findings of risk, see V Walker, "The Myth of Science as a 'Neutral Arbiter' for Triggering Precautions" (2003) 26 *Boston College International and Comparative Law Review* 197, at 198 ff; reference to this sentence and terminology is borrowed from this author. On the socially embedded nature of science, and on the co-production of science and social order, see first and foremost S Jasanoff, *The Fifth Branch: Science Advisers as Policy-Makers* (Harvard University Press, 1990); S Jasanoff (ed), *States of Knowledge: the Co-Production of Science and Social Order* (Routledge, 2004); S Jasanoff, *Designs on Nature. Science and Democracy in Europe and the United States* (Princeton University Press, 2005); and S Jasanoff, *Science and Public Reason* (Routledge, 2012).

[49] The terminology of "prudential" risk assessment is borrowed from European Commission, COM(2000)1 Final, *Communication from the Commission on the Precautionary Principle*, at 12, section 5. For a similar focus on different approaches to risk assessment, see also Walker, n 48.

[50] National Research Council, *Risk Assessment in the Federal Government: Managing the Process* (National Academies Press, 1983), the "Red Book", 28 ff. See also Jasanoff, *The Fifth Branch*, n 48; Jasanoff, *Science and Public Reason*, n 48.

[51] National Research Council, *Science and Judgment in Risk Assessment* (National Academies Press, 1994), the "Blue Book", 27 ff; National Research Council, *Science and Decisions: Advancing Risk Assessment* (National Academies Press, 2009), the "Silver Book", 43 to 45.

[52] See also Jasanoff, *Science and Public Reason*, n 48; Walker, n 48.

[53] "Silver Book", n 51, 30.

effective and *indirectly* reflect the pursuit of a cost-benefit effective level of protection. Prudential approaches to risk assessment and regulatory focus on persisting uncertainty, by contrast, are not cost-benefit effective and *indirectly* reflect the pursuit of high(er) levels of protection and consideration of other legitimate factors.

The third and final factor consists in the *level of protection* that regulators are *directly* pursuing. In cases where hazards and risks have been conclusively established, the determination of the threshold of probability of occurrence of adverse effects triggering regulatory intervention will vary in accordance with the intended level of protection. On the one hand, regulators might pursue a cost-benefit effective level of protection, whereby adverse effects should not be "unreasonable" or "excessive" taking into consideration the economic costs of regulation and the economic benefits associated with the relevant (hazardous) product or process. On the other hand, regulators might choose to pursue enhanced levels of protection, taking factors other than economic cost-benefit effectiveness into consideration. These specific aspects are illustrated in greater detail in the following sub-sections.

Against a backdrop of scientific dispute, then, regulatory conflicts in the field of risk governance do not relate to issues of "pure" science; nor are they triggered by allegedly non-scientific precautionary measures. In the face of scientific complexity and multiple uncertainties, sound science will not necessarily yield factually "correct" answers. The same applies to the "best" and "most reliable" science, assuming that it can be identified at all. The boundaries between facts and values thus fade in the field of risk regulation.[54] Even in cases which are relatively uncontroversial in scientific terms, and regardless of how small uncertain risks may be, science can tell us nothing of the acceptability of a risk; the determination that a risk is worth taking and should be taken is always, unavoidably, informed by normative considerations surrounding the intended level of protection and all relevant stakes. Science therefore does not quite lie at the heart of risk regulation disputes. What is truly controversial is recourse to different approaches to risk assessment, the set of inferences that regulators draw from the available scientific evidence, and the level of protection and specific goals that they pursue. These are informed by different normative frames.

Science can be more or less disputed, and uncertainty more or less pervasive. The level of public health and environmental protection pursued in different jurisdictions may vary to a greater or lesser extent. Further, the overarching tenets of the precautionary principle and the relevant social or distributional factors at stake, as opposed to considerations surrounding the cost-benefit effectiveness of risk regulation, may be more or less prominent in specific regulatory fields. This will impact on the level of controversy, when different regulatory approaches are being adhered to. In this sense, each case and each controversy in the field of risk regulation is unique. Yet, different normative frames and perspectives are always, *directly* or *indirectly*, at the centre of disputes in risk governance.

Controversial risk governance cases such as agricultural biotechnologies or residues of hormones in meat, where science cannot provide conclusive proof of specific adverse effects and public opinion, social and distributional factors are prominent, are often analysed through

[54] For a fascinating account, see SO Funtowicz and JR Ravetz, "Science for the Post-Normal Age" (1993) 25 *Futures* 739.

the prism of the "science" versus "politics" dichotomy.[55] These analyses are based on a watertight distinction between technical expertise and politics, objective "facts" and subjective "values". "Science" is usually associated with "sound science", neglecting the reality of scientific pluralism or suggesting that sound science is "better" science. Sound science is then deemed to be the "correct" basis for decision-making. Further, it is considered value-neutral. Clearly, in the face of scientific complexity and persisting uncertainty, the former assumption is open to dispute. As already mentioned, sound science will not necessarily provide factually "correct" answers. As to the latter point, these accounts fail to acknowledge that recourse to sound science approaches and adherence to sound science are not neutral and objective. The assumption that sound science approaches *must* be relied on and that sound science *must* be adhered to is indirectly informed by non-scientific evaluations surrounding the cost-benefit effectiveness of the intended level of protection, if not directly driven by economic imperatives. As the book shows, sound science cannot be equated to "pure" science: facts and values are intertwined in the field of risk governance. On these grounds, as the next sub-sections illustrate in greater detail, the book rejects the "science" versus "politics" dichotomy and reframes risk governance controversies in terms of a clash between evidence-based and socially acceptable risk approaches.

A. Mapping Different Forms of Scientific Uncertainty

The starting point of the analysis is the broader picture of scientific uncertainty in the field of risk regulation. The notion of "risk assessment" refers to the technical-scientific evaluation of uncertain risks, conducted by experts.[56] "Risk management", on the other hand, involves a decision as to whether and how to regulate uncertain risks, weighing alternative policy and regulatory options.[57] The process of risk assessment is divided into different stages: hazard identification, hazard characterisation, exposure assessment and risk characterisation.[58] Uncertainties can surface throughout each and every stage. This book categorises different forms of uncertainty under four broad categories, defining them as *hazard-related*

[55] For a critique of this dichotomy and an acknowledgment that all decision-making unavoidably results from a mix of facts and values, science and politics, see for instance Fisher, n 45, 246. However, Fisher does not set regulatory conflicts against the backdrop of different substantive approaches; rather, from a procedural perspective, she considers that "disputes over standard-setting and risk appraisal in risk regulation are disputes over administrative constitutionalism". See n 45, 5. For a critique of the "illusory separation between values and science" in the field of risk regulation, see also M Lee, "Beyond Safety? The Broadening Scope of Risk Regulation" (2009) 62 *Current Legal Problems* 242; M Lee, *EU Regulation of GMOs* (Edward Elgar, 2008), 39 ff and 80 ff; and M Lee, *EU Environmental Law, Governance and Decision-Making* (Hart Publishing, 2014), 249 ff.

[56] E.g. see Codex Alimentarius Commission, *Procedural Manual*, 27th edn (Joint FAO/WHO Food Standards Programme, 2019), 128.

[57] Ibid. In risk regulation systems informed by socially acceptable risk approaches, risk management functions are usually allocated to political authorities rather than technical regulatory agencies; for more details, see chapters 3 and 4.

[58] Codex Alimentarius Commission, n 56, 128.

uncertainties, *stricto sensu* matters of *scientific uncertainty* and *scientific ignorance*, *risk-related* uncertainties and *methodological* uncertainties.[59]

A "hazard" is defined as a biological, chemical or physical agent with the potential to cause adverse effects.[60] *Hazard-related* uncertainties may surround inconclusive scientific proof of the existence of a causal link between the (potentially hazardous) characteristics of a product or process, on the one hand, and adverse public health or environmental effects, on the other. GE organisms are a good example; hazard-related uncertainties surface in respect of the possibility and potential effects of hybridisation and crop to crop gene flow, the resulting impact on the environment and biodiversity, or potential food safety issues or allergic reactions to GE food. The potential development of antibiotic resistance due to the use of antibiotics as growth promoters in livestock,[61] or inconclusive scientific proof of the adverse public health effects of residues of hormones in meat,[62] are other prominent examples. Confounding factors will often come into play in these cases.[63]

Hazard-related uncertainties may also emerge throughout the hazard characterisation stage; these uncertainties relate to the nature and the severity of the specific hazards at stake. For instance, extrapolations from the findings of animal studies and their applicability to humans are a source of uncertainty.[64] Further, variability will come into play. This may depend on endogenous or exogenous factors and is an "inherent characteristic of a population, inasmuch as people vary substantially in […] their susceptibility to potentially harmful effects […]".[65] Specific constituencies will be more vulnerable than others to the effects of exposure to specific hazards. These forms of uncertainty or variability can be addressed through the application of quantitative uncertainty analysis ("QUA"), safety factors, expert judgment and assumptions.[66] More specifically, "defaults" consist of inference guidelines and scientific assumptions selected among a set of available options.[67]

Stricto sensu matters of *scientific uncertainty* and *scientific ignorance* largely involve hazard identification and hazard characterisation, as well. At their core lies the question of whether persisting uncertainty or scientific ignorance as to the characteristics of a product or process have been dispelled in so far as technically possible. Recourse to comparative assessments, as opposed to all-encompassing risk assessments, exemplifies different

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[59] For different categorisations of forms of scientific uncertainty, see inter al SO Funtowicz and JR Ravetz, *Uncertainty and Quality in Science for Policy* (Kluwer, 1990), 17 ff; Walker, n 48, 105 ff; and A Klinke and O Renn, "A New Approach to Risk Evaluation and Management: Risk-Based, Precaution-Based and Discourse-Based Strategies" (2002) 22 *Risk Analysis* 1071.

[60] Codex Alimentarius Commission, n 56, 128. The definitions enshrined in the Procedural Manual expressly refer to the risk analysis process as relating to food safety issues, in accordance with the Codex Commission's regulatory remit. However, they have broader relevance in that they refer to transnationally established regulatory notions.

[61] In EU case law, for instance, see Case T-13/99, *Pfizer Animal Health SA* v *Council*, EU:T:2002:209, and Case T-70/99, *Alpharma* v *Council*, EU:T:2002:210.

[62] See chapter 5, sections II, III and VIII sub-section A.

[63] Ibid.

[64] "Silver Book", n 51, 43. See below in this section on dose-response assessments and relevant uncertainties.

[65] Ibid, 6.

[66] "Silver Book", n 51, 7 and 32.

[67] Ibid, 99 ff, for an overview of these different strategies.

approaches to stricto sensu matters of scientific uncertainty in the governance of GE organisms.[68]

The next step consists in analysing the notion of a "risk". A "risk" is a function of the probability of occurrence of adverse effects and the severity of these effects, consequential to exposure to a hazard.[69] *Risk-related* uncertainties may emerge at the exposure assessment and risk characterisation stages. The former involves a qualitative or quantitative evaluation of exposures, and is usually fraught with uncertainties. It is undertaken through the development of exposure scenarios; these draw on measured exposures or on modelled estimates. Usually, models play a key role. Risk characterisation, the final stage, consists in the qualitative or quantitative estimation of the probability of occurrence and severity of known or potential adverse effects, as resulting from exposure to a hazard.[70]

Several forms of risk-related uncertainty will emerge. First, these may relate to the qualitative or quantitative evaluation of exposures in real life conditions. The efficacy of relevant risk management measures will also come into play. Pesticidal products offer some good practical examples. Operator exposure to pesticides is affected by the efficacy of risk management measures as well as by climatic, environmental and geomorphological conditions. The same is true for plant or animal exposures to residues of pesticidal products.[71]

Another source of uncertainty stems from multiple exposures. Aggregate effects are the result of exposures to the same substance from different sources, whereas cumulative effects result from exposures to different substances sharing a common mode of action (mechanism of toxicity).[72] Variability (in exposures) will also come into play at the exposure assessment stage; in other words, the range of exposure is variable in different cases, in different contexts and in different population groups. For instance, taking pesticidal products into consideration, dietary exposures to residues of pesticides in food largely vary, on the basis of a plurality of factors. Again, these forms of uncertainty or variability may be addressed through the application of safety factors, expert judgment or specific models.

Turning to the final stage of risk characterisation, available evidence may in some cases be regarded as insufficient for the purposes of a reliable qualitative or quantitative estimation of the probability of occurrence of adverse effects and their severity. Diverging data may also cast doubt on the possibility of adequately characterising risks. This might result in the decision to ban a product, or apply stringent risk management measures.[73] The pathway by which a risk may materialise can also be disputed. For instance, this form of uncertainty emerges from cases relating to the entry, establishment and spread of pests or diseases.[74]

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[68] In this respect, see chapters 3 and 4.
[69] Codex Alimentarius Commission, n 56, 128.
[70] Ibid.
[71] See GC 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 Law Journal* 184.
[72] For a detailed overview, see the "Silver Book", n 51, 213 ff.
[73] On EU case law involving bans or stringent risk management measures in the field of pesticidal active substances, as a result of the regulatory determination that the relevant scientific evidence is insufficient for the purposes of an adequate characterisation of the relevant risks, see GC Leonelli, "Acknowledging the Centrality of the Precautionary Principle in Judicial Review of EU Risk Regulation: Why It Matters" (2020) 57 *CML Rev* 1773.
[74] See chapter 5, sections IV, V and VI. See also chapter 3, for examples in the field of governance of GE organisms.

To conclude, *methodological* uncertainties specifically arise from the application of different casual relationships, methods and models for the purposes of the assessment of hazards and risks. These may yield very different results. For example, the hazardous characteristics of a product may be proven in vitro; however, conclusive proof in vivo may be missing.[75] The relevance of methodological uncertainties emerges very clearly in the field of the regulation of chemicals, where the application of different models can have a remarkable impact on the evaluation of hazards and classification of chemical substances.[76]

Importantly, methodological uncertainties may also surface when dose-response assessments are conducted. A dose-response assessment is the determination "of the relationship between the magnitude of exposure (dose) to a chemical, biological or physical agent and the severity and/or frequency of associated adverse […] effects (response)".[77] Linear or threshold models may be employed; threshold models can also be based on different approaches. Linear models are premised on the assumption that no threshold exists below which adverse effects will not occur. Upon identification of a point of departure ("POD"), the relevant risks are assumed to decrease linearly as the dose decreases.[78] Taking into consideration low doses, regulators will determine the threshold of probability of occurrence of adverse effects which they deem "negligible". Under threshold models, by contrast, the assumption is that a threshold below which effects will not occur (or are very unlikely to occur) may be identified. This is the reference dose (RfD) or reference concentration (RfC) value for a hazardous substance, which may be calculated on the basis of a No-Observed-Adverse-Effect Level ("NOAEL") or, in the majority of cases, on the basis of a Lowest-Observed-Adverse-Effect Level ("LOAEL") or Benchmark-Dose-Lower-Confidence Limit ("BMD").[79] Use of different data, assumptions and safety factors, combined with the application of different models, will yield different results. Bearing this picture in mind, how do evidence-based and socially acceptable risk models approach and frame questions of scientific uncertainty and complexity?

B. The Hegemonic Transnational Narrative and Evidence-Based Paradigms

As anticipated, ideal evidence-based models postulate recourse to a *sound science approach* to risk assessment and regulatory focus on *sound science*. Starting from the latter notion, for the

[75] See chapter 5, section VIII, sub-section A.

[76] For a very clear example in the field of chemicals, see the analysis in Leonelli, "The Fine Line between Procedural and Substantive Review in Cases Involving Complex Technical-Scientific Evaluations: Bilbaína", n 1. For an analysis of the implications of recourse to different models and an argument in favour of greater transparency in the selection and application of specific methods, see P Pascual, W Wagner and E Fisher, "Making Method Visible: Improving the Quality of Science-Based Regulation" (2013) 2 *Michigan Journal of Environmental and Administrative Law* 429. Fisher et al acknowledge that this does not address substantive issues (i.e. "science-policy choices"); see 434 and 435. In this sense, by following a procedural approach and by focusing on questions of transparency, the authors start from the implicit assumption that a "correct" answer (i.e. the application of "better" methods) may be procedurally identified, persisting uncertainty and scientific complexity notwithstanding.

[77] Codex Alimentarius Commission, n 56, 129.

[78] "Silver Book", n 51, 127.

[79] See US Environmental Protection Agency, *Guidelines on Conducting a Human Health Risk Assessment*, available at www.epa.gov.

purposes of the analysis in this book, "sound science" is associated with positive and conclusive scientific proof of the existence of a hazard and pathway for the materialisation of a risk. As the book illustrates, scientific inconclusiveness as to the existence of a hazard and stricto sensu uncertainties are regarded as "theoretical uncertainty" in legal systems informed by the evidence-based paradigm.[80] The same applies to uncertainties surrounding the existence of a risk, when a pathway for its materialisation cannot be positively established.[81]

Symmetrically, adherence to sound science will hardly result in a determination that the available scientific evidence is insufficient for the purposes of an adequate evaluation and characterisation of the relevant risks.[82] In other words, it is irrelevant whether more (or more reliable) evidence and data could be gathered in the future, as technical-scientific knowledge develops; regulatory intervention should be based on what has been positively proven at the current stage of knowledge. In this sense, a presumption of scientific "sufficiency" applies. Nor is the existence of diverging data and bodies of scientific opinion likely to be relevant, in so far as majority opinion is usually taken into account.

The notion of a "sound science approach" to risk assessment is more encompassing in its scope, and relates to specific ways in which risk assessors deal with multiple forms of uncertainty and variability. As already explained, policy judgments are inherent to risk assessment. The selection and application of specific data, models and methods involve "science-policy choices" and will have an impact on the final results of a risk assessment. Reliance on a sound science approach to risk assessment may be reflected in recourse to specific models for hazard identification and for hazard characterisation, specific forms of probabilistic modelling as regards the assessment of potential exposures, the application of specific safety factors to address variability, and reliance on specific defaults, assumptions and forms of expert judgments.

In the face of scientific complexity, it would be useless to try and identify specific pre-determined elements which make a risk assessment "sound", rather than "prudential". Clearly, this will depend on a plurality of factors. Nonetheless, it is important to highlight that sound science approaches to risk assessment reflect a specific understanding of uncertainty and variability; these are considered manageable, objectively quantifiable and reducible.[83] Erring on the side of precaution and potentially over-estimating risks through recourse to prudential approaches is thus unwarranted from an evidence-based perspective.[84] Where regulatory frameworks provide for a streamlined process, limited to an evaluation of data provided by market applicants and excluding a stricto sensu authorisation process, the adoption of prudential approaches to risk assessment is even less likely.[85] At a general level, reliance on "regulatory science", as opposed to "research science",[86] tips the balance in favour of sound science approaches.

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[80] See chapter 3, section VI, sub-section A; and chapter 5, sections II, III, VII and VIII, sub-section A.
[81] See chapter 3, section VI; and chapter 5, sections IV, V and VI.
[82] E.g. see chapter 5, sections V, VI, VII and VIII, sub-section A.
[83] For a similar point, albeit from a procedural perspective and focusing on the "Rational-Instrumental" paradigm, see Fisher, n 45, 29 and 33.
[84] This does not imply that, in the face of persisting uncertainty and variability, such approach is "correct" or "better" than a prudential one; see below, in this section.
[85] See chapter 3, section VI.
[86] Ibid. On the notions of "regulatory science" and "research science" see Jasanoff, *The Fifth Branch*, n 48.

Recourse to sound science approaches to risk assessment and adherence to sound science will result in a specific *evidence base* and specific *inferences* being drawn from the available data. If compared with prudential approaches to risk assessment and regulatory focus on multiple forms of uncertainty, sound scientific approaches and adherence to sound science clearly relieve market actors from regulatory burdens and economic costs. More specifically, as the analysis of the book shows, they *indirectly* respond to the tenets of economic cost-benefit analysis.[87]

In cases where hazards and risks have been conclusively established, then, economic cost-benefit analysis will come into play *directly*. In these cases, it is impossible to determine a point where the probability of occurrence of adverse effects is zero. In many cases, it will also prove impossible to identify a threshold of exposure below which adverse effects are expected to be very unlikely.[88] In this context, how to determine the *legally relevant* threshold of probability of occurrence of adverse effects, and how to decide whether the potential adverse effects and their consequences are "acceptable" or "negligible"? How to decide whether regulatory action should be taken at all, how to devise risk reduction strategies, and how to enact risk mitigation measures?

As an ideal regulatory model, the evidence-based paradigm postulates that risks should only be regulated in so far as this choice is cost-benefit effective. Regulatory measures in the field of risk governance, at a general level, are bound to be cost-benefit effective; in other words, the level of protection pursued by regulators shall be economically cost-benefit effective. Risks should be taken in so far as the economic costs associated with regulatory intervention or the economic benefits of a product or process outweigh the expected environmental or public health benefits of regulation. Risk regulation thus comes into play to the extent that the expected adverse effects, as evaluated in the light of what has been positively proven and established, are "unreasonable" or "excessive"; the legally relevant threshold of adverse effects should be determined through the application of economic cost-benefit analysis.

This goal may be reflected in legislative or regulatory measures, which set out the scope of application of risk governance frameworks and the relevant arrangements.[89] However, it may also emerge directly in the context of product authorisations and risk mitigation measures. In the latter case, the public health and environmental benefits associated with potential

[87] See the analysis in chapter 3, sections VI and VIII. See also how cost-benefit considerations influence the extent to which products, processes and activities are tested: see chapter 3, section VI, sub-section A.

[88] See above, sub-section A; in any case, the determination of any such threshold will still be fraught with uncertainty. Variability will also come into play.

[89] See chapter 3, section VII, for considerations surrounding economic cost-benefit effectiveness in regulatory frameworks in the field of governance of GE organisms. For an example of a legislative provision influenced by evidence-based approaches and considerations surrounding economic cost-benefit effectiveness, see also the stipulation under the US Federal Insecticide, Fungicide and Rodenticide Act that the US Environmental Protection Agency shall register a pesticide if it has, inter al, determined that "[…] (C) it will perform its intended function without *unreasonable adverse effects* on the environment; and (D) when used in accordance with widespread and commonly recognised practice it will not generally cause *unreasonable adverse effects* on the environment" (emphasis added); see 7 USC s 136a(c)(5). For the definition of "unreasonable adverse effects" on the environment, see 7 USC s 136(bb): the term means "(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 resides that result from a use of a pesticide in or on any food inconsistent with the standard under section 346a of Title 21" (emphasis added). Under 21 USC s 346a(b)(2)(A)(ii), the standard is the one of a "reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue […]".

regulatory measures are computed from the results of risk assessment.[90] A full-fledged application of economic cost-benefit analysis does not simply focus on the cost-benefit effectiveness of *alternative risk management measures*, adopted to meet a specific intended level of protection. Rather, it targets the cost-benefit effectiveness of the *level of protection* pursued by regulators,[91] underpinning the identification of a *cost-benefit effective threshold of probability of occurrence of adverse effects*.[92]

Chapters three (US governance of GE organisms), five (SPS Agreement) and six (Codex Alimentarius Commission) explore the regulatory categories, underlying value systems and overarching goals of evidence-based approaches, against the specific backdrop of the transnational controversy on GE organisms; as already explained, evidence-based models are clearly connected to the hegemonic narrative on agricultural biotechnologies. The analysis shows that, in contexts of scientific complexity and scientific pluralism, sound science approaches to risk assessment and adherence to sound science can neither be considered "better" than prudential approaches and a focus on uncertainty, nor "correct" or universally valid. Crucially, evidence-based models cannot lay claim to neutrality and objectivity. Far from being neutral and objective, as the book demonstrates by analysing the governance of GE organisms, the assumption that sound science approaches to risk assessment must be adhered to and sound science must be relied on is informed by non-scientific considerations surrounding the economic cost-benefit effectiveness of risk regulation. And indeed, in regulatory systems influenced by evidence-based paradigms, these non-scientific considerations are expressly taken into account in cases where hazards and risks have been scientifically established.

On these grounds, the book moves on to uncover the specific implications of dominant transnational discourses on the regulation of uncertain risks, highlighting their strengths and weaknesses. First, the deconstruction of US governance of GE organisms shows that evidence-based models are associated with a technocratic approach to risk regulation, wherein both risk assessment and risk management functions are allocated to regulatory agencies. Public opinion and public perception of risk are considered immaterial to "objective" decision-making. Secondly, by relying on a sound scientific evidence base, by focusing on sound science and by employing cost-benefit analysis, regulators will ultimately identify a baseline threshold of safety.[93] For this reason, unlike socially acceptable risk approaches, evidence-based models do not allow the pursuit of enhanced levels of protection. Further, the application of cost-benefit calculus to a sound scientific evidence base, in conditions of scientific uncertainty, is liable to

[90] See for instance the "Silver Book", n 51, at 50.

[91] It is in this spirit, to provide a practical example, that the "Silver Book" recommends the use of linear rather than threshold models. "Because [the reference values identified through 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 risk-benefit comparisons and in risk management […] is limited" (at 8). "[Threshold models] are inadequate for cost-benefit analyses or for comparative risk analyses. [They] do not provide a basis for formally quantifying the magnitude of harm at various exposure levels. […] The approach remains one of defining a [reference value] without any sense of the degree of population risk reduction that would be found in moving from one dose to another dose. A probabilistic approach […] would be much more useful in cost-benefit analysis" (at 133). This perfectly reflects evidence-based approaches and reliance on economic cost-benefit analysis.

[92] If the analysis is conducted through the lens of proportionality, a maximalist application of economic cost-benefit analysis does not simply target the necessity of risk management measures, but their stricto sensu proportionality (i.e. their cost-benefit effectiveness). On the applications of the principle of proportionality in judicial review of EU risk regulation, see Leonelli, n 73.

[93] See the detailed analysis in chapter 3, sections V, VI and VII.

reduce the overall level of public health and environmental protection. This will be particularly problematic in cases where uncertainties are underestimated at the risk assessment stage and reliance on sound science is misplaced.[94]

Finally, other legitimate factors such as the availability of less hazardous alternatives, or a long-term vision for the development of more sustainable approaches in specific sectors, are beyond the radar of evidence-based risk regulation. The same applies to the evaluation of the broader (qualitative) socio-economic advantages and disadvantages of a product or process and the distributional stakes of risk regulation; in other words, consideration of which stakeholders will bear the costs and which constituencies will reap the benefits of the decision to take uncertain risks.[95]

However, evidence-based models also yield benefits. As the analysis of US governance of GE organisms illustrates, adherence to evidence-based risk regulation maximises aggregate wealth by relieving market actors from economic burdens and costs. This facilitates the exercise of individual trade rights and fosters technological-scientific innovation. Similar considerations ensue from the analysis of disputes brought under the SPS Agreement. Chapter five points to the repeated attempts by the WTO Panels and Appellate Body to identify a standard of review within the spectrum from deference to de novo review, taking a closer look at the *EC – Biotech* dispute.[96] In the absence of any objective, self-standing criteria of "pure" science, the evidence-based interpretation of the SPS Agreement provisions and adherence to de novo review draw on the mere acknowledgment that, in the face of ubiquitous uncertainties and scientific pluralism, a deferential reasonableness review would afford Members the opportunity to defend virtually *any* SPS measure. This would be irreconcilable with the rationale and overarching goal of the system: trade liberalisation. In other words, it would undermine any attempt at transnational regulatory convergence in SPS regulation. This casts further light on the implications of the evidence-based narrative on GE organisms, and risk governance more generally. Not only do evidence-based approaches, as illustrated in the third chapter, pursue aggregate wealth maximisation; they are also linked to transnational regulatory convergence and trade liberalisation. This connection is explored in further detail in chapter six.

Evidence-based models thus result in a *double* economic dividend. The exercise of individual (trade-related) rights lies at the core of this ideal regulatory type. On these grounds, the deconstruction of evidence-based models throughout the analysis of US law, the SPS Agreement and the Codex Commission shows what lies underneath the hegemonic narrative on GE organisms and regulation of uncertain risks. As chapter seven concludes, the hegemonic narrative on GE organisms and hegemonic discourses on the governance of uncertain risks are hegemonic *because* they yield a double economic dividend.

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[94] Ibid.

[95] See chapter 3, sections VII and VIII. For sociological accounts on the distributional implications of risk governance, see inter al U Beck, *Risk Society. Towards a New Modernity* (SAGE, 1992); and U Beck, *World at Risk* (Polity Press, 2009).

[96] *EC – Biotech: EC – Measures Affecting the Approval and Marketing of Biotech Products*, Panel Report (adopted 21 November 2006) WT/DS291, WT/DS292, WT/DS293.

C. The Counter-Hegemonic Transnational Narrative and Socially Acceptable Risk Approaches

Socially acceptable risk approaches postulate a *prudential* risk assessment. Further, under this ideal model of risk governance, regulators are *not* bound to adhere to *sound science*. They may take into account uncertainties as to the existence of a causal relationship between the characteristics of a product or process and adverse effects, where the latter effects can neither be conclusively established nor excluded. Uncertainties surrounding the actual materialisation of a risk may also be taken into consideration. In a similar vein, in the face of scientific complexity, regulatory action may be warranted where the available evidence is deemed insufficient for a reliable characterisation of risk.

All in all, uncertainty and variability have a completely different value under evidence-based and socially acceptable risk models; this is reflected in the gap between sound scientific and prudential risk assessments. A prudential risk assessment will expressly disclose uncertainties emerging from each and every stage of the assessment process; these uncertainties should be taken into due consideration for the purposes of drawing any relevant scientific inferences. Further, when "science-policy choices" are required, it will involve the selection and application of prudential models, methods, assumptions and safety factors. These will yield very cautious estimates, usually by taking into consideration worst case scenarios, and may thus over-estimate the relevant risks.[97] Matters of stricto sensu uncertainty and scientific ignorance should also be adequately dealt with. For this purpose, prudential risk assessments should be comprehensive, take into account potential long-term or indirect risks, and strive to dispel scientific uncertainty in so far as is technically possible with the current stage of knowledge.

The allocation of risk management functions and final decision-making powers to political authorities, rather than technical-regulatory agencies, is typical of legal systems informed by socially acceptable risk approaches.[98] This acknowledges that more than (allegedly objective) scientific matters are at stake in risk governance, and that normative frames and judgments play a crucial role in this field. One relevant implication is that political risk managers may disregard the positive results of a risk assessment, reaching the conclusion that uncertain risks are not socially acceptable. This might occur where a risk assessment is perceived as being insufficiently prudential; in this case, political risk managers can refer to alternative studies, assessments and data to substantiate their position. It might also happen where, taking into consideration the available evidence and the level of protection pursued in the field, risk managers draw different inferences as to the acceptability of the relevant risks. For instance, they may point to the scope of persisting uncertainty and the severity of the potential adverse effects, taking the view that the relevant risks are not socially acceptable in the specific field at issue. As already mentioned, disagreements need not stem from reference

[97] See for instance *Communication from the Commission on the Precautionary Principle*, n 49, 28, Annex III. For a more detailed overview, see chapter 4. On prudential safety factors and prudential expert judgment, see for instance the analysis in chapter 5, sections V and VIII, sub-section B.
[98] See chapters 3 and 4.

to a different evidence base. The very same scientific evidence can be differently interpreted and thereby become an object of controversy.

Turning to a more specific analysis of risk management and the extent to which uncertainties may be taken into account, socially acceptable risk approaches postulate that regulators may take *precautionary action*, where warranted. Where uncertainties persist as to the existence and nature of a hazard or the materialisation of a risk, or scientific data is considered insufficient or unreliable, a product may be subject to stringent risk mitigation or may not be authorised at all.[99] Different definitions and understandings of the precautionary principle coexist across legal orders. At a general level, under a baseline understanding, the precautionary principle stipulates that a lack of scientific proof of adverse effects should not prevent regulators from taking action.[100] For the purposes of the analysis of this book, the precautionary principle is analysed within the specific legal orders that are relevant to the deconstruction of transnational narratives on GE organisms.[101] Considerations surrounding the specific values at stake, the pervasiveness of the potential adverse effects or any long-term public health or environmental impacts fall under the scope of the precautionary principle. As the book shows, the determination that uncertain risks may not meet the intended level of protection in a specific field underlies recourse to the precautionary principle.[102]

A prudential approach to risk assessment and a focus on different forms of uncertainty, as opposed to sound science approaches to risk assessment and adherence to sound science, *indirectly* reflect the pursuit of a higher than cost-benefit effective level of protection and consideration of other legitimate factors. And indeed, under socially acceptable risk approaches, regulators may *directly* choose to pursue *enhanced* rather than cost-benefit effective levels of protection, in cases where hazards and risks have been established. For instance, they may decide to minimise exposures to hazardous substances[103] or set a presumption that no safe level of exposure can be determined for highly hazardous

[99] For a plurality of examples, see the analysis in Leonelli, n 73.
[100] For the same understanding, see Fisher, n 45.
[101] See chapter 4 on EU law, and chapter 5 on the SPS Agreement, including an analysis of different references to the precautionary principle under public international law and the 2000 Cartagena Protocol on Biosafety to the Convention on Biological Safety.
[102] See chapters 4 and 5, and Leonelli, n 73.
[103] For an example of a regulatory framework which pursues enhanced levels of protection and aims to minimise exposures, see EU regulation of pesticidal active substances under Regulation (EC) 1107/2009/EC of the European Parliament and of the Council of 21 Oct. 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"). Article 4(2), read in conjunction with Annex II, stipulates that the residues of representative plant protection products (PPPs) containing an active substance, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, must not have *any harmful effects* on human health, animal health and groundwater, and *any unacceptable effects* on the environment. Pursuant to Article 4(3), representative PPPs containing an active substance must not have *any immediate or delayed harmful effects* on human health and animal health, directly or indirectly, *no immediate or delayed effects* on groundwater and *no unacceptable effects* on the environment. This higher threshold as regards the intended level of protection is reflected, inter al, in the identification of Acceptable Operator Exposure Levels ("AOEL") for representative PPPs and Acceptable Daily Intakes ("ADIs") for residues of pesticides in food, under Annex II; these are considerably higher than the transnational baseline, as the aim is to minimise exposures to hazardous pesticidal substances. Further, when Maximum Residue Levels ("MRLs") are set for pesticide residues complying with the ADI, the minimum level of application (and residues) necessary for a PPP to be effective on a crop in accordance with good agricultural practice will be taken into consideration to set the MRLs. This also reflects the pursuit of enhanced levels of protection and the intention to minimise exposures.

substances.[104] At a general level, the pursuit of enhanced rather than cost-benefit effective levels of protection is bound to result in very different regulatory outputs. The threshold is much higher than the one of "unreasonable" or "excessive" adverse effects.[105]

All in all, under socially acceptable risk approaches, economic considerations are only one and not necessarily the most important factor to be taken into account at risk management level. As explained above, regulators may choose to take precautionary action when uncertain risks may not meet the intended level of protection in a specific field; clearly, regulatory focus on persisting uncertainty and recourse to the precautionary principle do not comply with the tenets of cost-benefit analysis. Further, when determining the intended level of protection and threshold of socially acceptable risk in a specific field, regulators may take *other legitimate factors* ("OLFs") into account.[106] OLFs encompass public opinion, considerations as to the availability and practical efficacy of alternative risk management measures, the specific advantages and disadvantages associated with the decision to take uncertain risks, and distributional stakes. Distributional concerns relate to the distribution of (economic and social) costs and benefits across different constituencies, as opposed to the criterion of aggregate wealth maximisation underpinning cost-benefit analysis.

Considerations as to the substitution of products or processes with less hazardous alternatives,[107] a long-term vision for the development of more sustainable approaches in specific sectors[108] and questions surrounding the socio-economic advantages or disadvantages

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[104] For an example, see the EU hazard-based cut-off criteria in regulation of pesticidal active substances. In the case of highly hazardous active substances, a (rebuttable) presumption applies that no safe level of exposure can be determined, and that these active substances shall not be approved at EU level; see Article 4 and Annex II of the PPP Regulation. See also chapter 5, section VIII, sub-section A, on regulation of hormones administered as growth promoters and regulation of genotoxic substances.

[105] For instance, compare US and EU regulation of pesticidal substances and the different "benchmarks" set with reference to the intended level of protection; see n 89, 103 and 104. Even in cases where uncertainties are not salient, reference to enhanced or cost-benefit effective levels of protection will still result in different regulatory outputs, reflecting a different balance between economic and non-economic factors. See also chapter 3, sections VI and VII. It is worth noting that, in cases where hazards and risks have been conclusively proven, systems informed by socially acceptable risk approaches are often alleged to regulate on the grounds of "hazards" rather than "risks"; see e.g. R Lofstedt, "Risk versus Hazard. Regulating in the 21st Century" (2011) 2 *EJRR* 149. In fact, divergences in regulatory standards across different systems stem from reliance on *more or less prudential approaches* to risk assessment, a different focus on persisting *uncertainties*, and the decision in specific legal regimes to minimise exposures and pursue *enhanced* levels of protection, regardless of considerations surrounding economic cost-benefit effectiveness and regardless of whether adverse effects are deemed "negligible" in other jurisdictions. On this point, see Leonelli, n 71.

[106] For references to OLFs and their role in risk management, see inter alia Codex Alimentarius Commission, n 56, 125 (Section IV, Risk Analysis, Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, para 28); Codex Alimentarius Commission, n 56, 245 (Appendix: General Decisions, Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors Are Taken into Account); see also *Communication from the Commission on the Precautionary Principle*, n 49, at 19, sub-section 6.3.4, and the detailed analysis in chapter 4, section III.

[107] For examples of regulatory provisions informed by socially acceptable risk approaches, see the comparative assessment procedure under EU regulation of pesticidal active substances, Article 50(1) of the PPP Regulation; and the substitution principle enshrined in Article 55 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, OJ 2006, L 396/1 (hereafter, "REACH Regulation").

[108] In this respect, see for instance the European Commission's "Farm to Fork" Strategy enacted under the European Green Deal: COM(2020)381 Final, *Communication from the Commission to the European Parliament,*

of a product or process[109] are also part of OLFs. To summarise, the evaluation of OLFs may be defined as the qualitative equivalent of quantitative cost-benefit analysis. OLFs will feed into the determination of the threshold of socially acceptable risk. For instance, the acknowledgment that more sustainable alternatives are available or the conclusion that the socio-economic advantages associated with a product or process are limited will influence the decision as to how high the intended level of protection should be, and how low the corresponding threshold of socially acceptable risk should be.[110]

One further consideration and clarification ensues from this brief overview. Socially acceptable risk models neither aprioristically pursue a zero risk threshold, nor necessarily advocate the lowest possible threshold of risk.[111] Rather, what is distinctive about socially acceptable risk models is that prudential approaches to risk assessment should be followed and more than sound science and cost-benefit analysis *may* be taken into consideration. This means that high risks might be socially acceptable in some instances, while comparatively lower risks might not be acceptable and worth taking in other instances. The other distinctive feature of the approach, as the unfolding of the analysis will show, is that the threshold of acceptable risk must be socially and politically agreeable. The acknowledgment that different risk governance measures reflect different normative perspectives shines through this regulatory model; for this very reason, risk regulation should reflect societal views on the acceptability of uncertain risks.

The counter-hegemonic narrative on the uncertain risks posed by GE organisms clearly reflects transnational discourses on socially acceptable risk. Chapters four (EU law) and six (hybrid regulatory standards) deconstruct the rationale, regulatory categories and broader implications of socially acceptable risk discourses, against the background of the controversy on agricultural biotechnologies. The analysis shows that the attempt to strike a different balance between individual rights and collective interests, and the possibility for the latter dimension to prevail, lies at the heart of socially acceptable risk models. In this sense, the thread is a focus on collective values, including public health, environmental, socio-economic and distributional stakes. Beyond the boundaries of national or regional jurisdictions, adherence to socially acceptable risk approaches goes hand in hand with a defence of legal and value pluralism in the regulation of uncertain risks. As chapter six shows, counter-hegemonic discourses also challenge the assumption that aggregate wealth maximisation, pursued through the application

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the Council, the European Economic and Social Committee and the Committee of the Regions. A Farm to Fork Strategy for a Fair, Healthy and Environmentally-Friendly Food System. See also Directive 2009/128/EC of the European Parliament and of the Council of 21 Oct. 2009 Establishing a Framework for Community Action to Achieve the Sustainable Use of Pesticides, OJ 2009, L 309/1.

[109] For examples of regulatory provisions influenced by consideration of socio-economic OLFs, encompassing more than cost-benefit effectiveness, see e.g. the specific procedure of Article 50(2) of the PPP Regulation, and references to the availability of "suitable alternative substances or technologies" in the socio-economic procedure provided for under Article 60 of the REACH Regulation.

[110] See chapter 4. For an argument in favour of greater consideration of OLFs under risk regulation, see first and foremost Lee, "Beyond Safety? The Broadening Scope of Risk Regulation"; and Lee, *EU Environmental Law, Governance and Decision-Making*, n 55.

[111] For the general assumption that this is bound to occur in regulatory systems where the precautionary principle (or "strong" versions of the principle) may apply, and that the precautionary principle is inherently paralysing and leads in no direction at all, see C Sunstein, "Beyond the Precautionary Principle" (2003) 151 *University of Pennsylvania Law Review* 1003; and C Sunstein, *Laws of Fear. Beyond the Precautionary Principle* (CUP, 2005). For a more recent defence of cost-benefit analysis, see C Sunstein, *The Cost-Benefit Revolution* (MIT Press, 2018).

of economic cost-benefit analysis, results in positive spill-overs and benefits civil society at large.

In this light, just like evidence-based models, socially acceptable risk approaches have strengths and weaknesses. They reinforce political and democratic legitimacy in the field of risk governance, enable regulators to pursue enhanced levels of protection, regardless of whether adverse effects are deemed "negligible" or "acceptable" in other jurisdictions, and account for OLFs. However, they may be economically inefficient and stifle innovation.

Clearly, they are neither value-neutral nor objective. In cases where hazards and risks have not been conclusively proven, the choice to rely on prudential risk assessments and focus on persisting uncertainties incorporates a normative non-scientific component: the pursuit of enhanced levels of protection and consideration of specific OLFs. However, the same is true of the assumption that sound science approaches and sound scientific evidence must be adhered to. This, as already explained, indirectly reflects evaluations on regulatory cost-benefit effectiveness. Symmetrically, in cases where hazards and risks have been established, taking OLFs and enhanced levels of protection into account for the purposes of setting the threshold of acceptable risk entails non-scientific evaluations. Nonetheless, the same is true of the application of economic cost-benefit analysis. To summarise, the pursuit of enhanced levels of protection and the evaluation of OLFs are just as non-scientific as the direct or indirect pursuit of cost-benefit effective levels of protection.

Against this overall backdrop, the deconstruction of socially acceptable risk models throughout the analysis of EU law and regulatory standards enacted by NGO actors sheds light on the counter-hegemonic narrative on GE organisms, counter-hegemonic discourses on the governance of uncertain risks and their specific implications. This sub-section concludes the introductory overview of the institutional strand of enquiry of the book. The next and final section of this chapter turns to the normative aspects of the analysis.

IV. Normative Analysis: Modern Paradigms and Post-Modern Deconstruction of Regulatory Approaches

Deconstructing the hegemonic narrative on the governance of GE organisms casts light on the connections between evidence-based approaches to risk regulation and a double economic dividend. By contrast, an acknowledgment of the value-laden nature of any regulatory choices in the field of risk governance, a defence of legal and value pluralism and the possibility (if not the attempt) to strike a different balance between individual trade rights and collective stakes lie at the heart of socially acceptable risk approaches, which underpin the counter-hegemonic narrative. This is the starting point for a set of normative reflections on the legitimacy of the dynamics of transnational juridification. Here, the ability of *modern* science-centred or procedural deliberative paradigms to identify agreeable solutions to complex regulatory conflicts comes into play.

The normative strand of analysis enquires into the legitimacy of the governance of agricultural biotechnologies at a transnational level. How can regulatory conflicts over GE organisms be solved, reconciling diametrically opposed transnational discourses, and which

normative yardsticks may be relevant to this end? From the transnational angle of analysis, the logics of power and socio-legal ordering at times of globalisation unfold beyond the traditional "inter-governmental" paradigm, which centres on state sovereignty and public international law, and beyond the "trans-governmental" dimension, which focuses on the rise of networks of technical experts. This triggers a set of questions on how to structure a normative enquiry beyond state sovereignty and technocracy.[112]

From a normative theoretical perspective, the Conflicts Law framework[113] offers a way forward towards safeguarding the legitimacy of law at times of globalisation. As explained in detail in chapter two, Conflicts Law theory aims to procedurally construct law's legitimacy by re-coupling law and politics beyond the normative vacuum of transnational legal studies. From this vantage point, it explores the potential for the solution of transnational legal conflicts through *procedural* political deliberation, by *procedurally* balancing regulatory harmonisation and legal and value pluralism, and by *procedurally* re-embedding societal governance and self-governance. As the second part of the second chapter explains, these three dimensions correspond to three constellations of regulatory conflict: horizontal, vertical and diagonal.

The unfolding of the analysis of the book shows that, in the field of agricultural biotechnologies, these transnational conflicts are destined to remain unsolved. The book analyses whether procedural political deliberation might solve the transatlantic horizontal conflict on GE organisms,[114] the failed attempts to solve EU-wide horizontal and vertical regulatory conflicts,[115] the vertical conflict underlying the *EC – Biotech* dispute[116] and conflicts triggered by hybrid standard-setting regimes.[117] None of these regulatory conflicts have been satisfactorily solved. The book thus reaches the conclusion that reconciling the hegemonic and counter-hegemonic narratives on GE organisms through the procedural resolution of transnational regulatory conflicts is an impossible endeavour. Conflicts Law is bound to fail.

This triggers a set of broader considerations on the ability of modern *science-centred* and *procedural deliberative* paradigms to construct normatively legitimate solutions in controversial cases. The analysis is conducted by reference to, and within the specific boundaries of, the field of risk regulation and the controversy on agricultural biotechnologies. Both science-centred and procedural deliberative accounts belong to or are influenced by the modernist tradition. Both are rooted in a rationalist vision of reality. Procedural deliberative paradigms encompass a focus on science, analysing its role in the solution of regulatory conflicts. However, this is set against the broader backdrop of political deliberation, which includes attempts to achieve procedural agreement by reconciling different normative perspectives and political, socio-economic and cultural stakes.[118] Science-centred accounts, in

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[112] See chapter 2, part 2.

[113] For applications of the framework at the transnational level, see inter al C Joerges, PF Kjaer and T Ralli, "Conflicts Law as Constitutional Form in the Post-National Constellation" (2011) 2 *Transnational Legal Theory* 153; and C Joerges, "A New Type of Conflicts Law as the Legal Paradigm of The Post-National Constellation" in C Joerges and J Falke (eds), *Karl Polanyi, Globalisation and The Potential of Law in the Transnational Markets*, eds. Christian Joerges and Joseph Falke (Hart Publishing, 2011). See in detail chapter 2, part 2.

[114] See chapter 3.

[115] See chapter 4.

[116] See chapter 5.

[117] See chapter 6.

[118] Among authors influenced by this tradition, see Fisher, n 45; M Weimer, *Risk Regulation in the Internal Market. Lessons from Agricultural Biotechnology* (OUP, 2019); P Dąbrowska Klosinska, "EU Governance of

contrast, put the accent on technical-scientific elements and postulate that (sound) science provides the means of solving conflicts and disagreements.[119]

Starting from the latter accounts, the book takes the view that science, in and of itself, can hardly generate any form of agreement. Consensus can hardly be built by focusing solely on scientific matters and by seeking to identify the "best" and "most reliable" science. In the face of scientific complexity and persisting uncertainty, the "best" science may not provide factually "correct" answers: as already mentioned, the boundaries between facts and values thus fade in the field of risk governance. Even in cases which are relatively uncontroversial in scientific terms, science can tell us nothing of the acceptability of uncertain risks. Ultimately, science can neither provide a single "valid" answer, nor a universally agreeable one. The modern myth of science's neutrality and objectivity is untenable in the field of risk regulation.[120]

As illustrated in the third section of this chapter, the evidence base that regulators draw upon varies where more or less prudential approaches to risk assessment are being followed. Interpretations of science also vary: regulators may focus on sound science or persisting uncertainties as to the existence and magnitude of hazards and risks, and different inferences will be drawn in light of the underlying normative premises of the actors involved. The level of protection set by regulators also varies. In the face of scientific pluralism, and where different goals are being pursued, neither ideal model can be considered "better" than the other. Thus, where different approaches are being followed, science will be evaluated through different lenses. Normative frames unavoidably come into play, and science cannot square the circle. Nor can any objective and self-standing criteria of "pure" science solve disputes, as the slippery slope of procedural versus substantive review of risk regulation clearly shows.[121] In fact, as the book illustrates through specific examples, the very framings of the relevant scientific questions are hardly reconcilable where different approaches are being adhered to.

Science-centred accounts eschew normative elements from their analysis. Yet, "pure" science is nothing more than an ideal notion in the field of risk regulation.[122] In fact, science-centred accounts usually point to *sound science approaches* to risk assessment and adherence to *sound science* as a way to solve conflicts. This reflects the hegemonic transnational narrative on risk regulation and evidence-based models; however, it does not provide a normatively legitimate solution. Sound science will not necessarily be factually "correct". Nor is recourse to sound science value-neutral or appropriate in controversial regulatory cases.

Finally, making scientific methods more transparent and accessible[123] is often regarded as key to solving risk regulation disputes. Yet, as illustrated in the third section, different approaches to risk assessment may be more or less prudential and yield different results. In

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GMOs: Political Struggles and Experimentalist Solutions?" in CF Sabel and J Zeitlin (eds) *Experimentalist Governance in the European Union* (OUP, 2010).

[119] Among authors influenced by this modernist strand of thought, see inter alia C Sunstein, n 111; M Pollack and G Shaffer, n 20; JB Wiener et al (eds), *The Reality of Precaution. Comparing Risk Regulation in the United States and Europe* (Routledge, 2011); in a similar perspective, albeit not directly dealing with risk regulation issues, see A Alemanno and JB Wiener, "The Future of International Regulatory Cooperation: TTIP as a Learning Process Toward a Global Policy Laboratory" (2016) 78 *Law and Contemporary Problems* 101.

[120] See first and foremost Jasanoff as well as Walker, n 48.

[121] See chapter 5, and Leonelli, n 73.

[122] See Jasanoff as well as Walker, n 48.

[123] See e.g. Pascual, Wagner and Fisher, n 76.

cases of persisting uncertainty and in the face of scientific complexity, different models and diverging bodies of scientific opinion will always coexist. Improved transparency throughout the risk assessment stage will facilitate communication in procedural terms; however, it will not make the choice to employ one model, assumption or safety factor rather than another satisfactory if the final findings are bound to vary. Nor will it make the decision to consider specific data and disregard other evidence satisfactory if hazard-related or risk-related uncertainties persist and the underlying normative premises diverge, or generate any agreement where different levels of protection are being pursued by regulators.[124] As for top-down coordination and convergence in technical-scientific matters, by means of harmonising technical-scientific protocols, this comes with a set of implications. Ultimately, it implies adherence to a specific approach to risk assessment, which could be more or less prudential. Yet again, this is not likely be agreeable to all parties. Nor will it necessarily do justice to a prudential, cautious approach to risk assessment.

On these grounds, science has a limited role to play for the purposes of generating genuine agreement and identifying legitimate solutions in controversial cases. As explained in the third section, regulatory conflicts in the field of risk governance do not relate to issues of "pure" science. Different normative frames are always, directly or indirectly, at the centre of disputes. All in all, reference to scientific matters can only be expected to make a substantial contribution in cases which are uncontroversial. Where uncertainties are very low and scientific agreement very solid, mere reference to scientific matters *may* be sufficient to build consensus.[125]

Procedural deliberative accounts, by contrast, are more encompassing and more nuanced. As anticipated above, they enquire into the ability of actors to identify procedural criteria for the solution of regulatory conflicts by engaging in rational deliberative practices. The relevant criteria will vary in accordance with the specific conflict constellations at stake;[126] however, technical-scientific *as well as* political and socio-economic factors must be taken into due consideration with a view to successfully addressing contentious cases. To put it differently, (authentic) deliberation is structurally different from "technocratic deliberation"[127] and adherence to sound science. Unlike science-centred models, procedural deliberative accounts acknowledge that normative disagreements play a key role in regulatory conflicts, including in the field of risk regulation. Therefore, normative factors must be adequately addressed for the ultimate solution to be legitimate.

As explained in the second part of chapter two, legal proceduralisation lies at the heart of deliberative accounts. The analysis thus consistently focuses on procedural governance arrangements, procedural deliberative dynamics and the margins for a procedural construction of agreeable legal solutions. The book reaches the conclusion that the *procedural* struggle to identify concerted and normatively legitimate solutions through deliberation *can* work. However, it will only work where a set of pre-existing *substantive* conditions are met. Broadly speaking, and having regard to the field of risk regulation, specific scientific preconditions can

[124] See e.g. the analysis in chapter 4, section V.
[125] Even though normative perspectives, values and the specific level of protection pursued by regulators may still result in different determinations as to the acceptability of a risk and different regulatory outputs.
[126] See chapter 2, part 2.
[127] For use of this terminology, see Pollack and Shaffer, n 20.

facilitate procedural agreement; as already mentioned, where uncertainties are very low and scientific agreement is very solid, consensus will generally be easier to build.[128] More importantly, pre-existing and shared substantive perspectives, value systems and goals will facilitate deliberative practices and the identification of legitimate solutions.

Where similar approaches along the spectrum from evidence-based to socially acceptable risk models are being employed, and the same goals are being pursued in a specific regulatory area, reaching an agreement will be possible. Where different regulatory approaches are being followed, yet perspectives, values and goals are shared in the context of a specific regulatory field, agreement will also be possible. In other words, in so far as the normative premises of the relevant actors are similar, different approaches to the governance of uncertain risks can yield similar results at the implementation stage. Other variations could be sketched out, referring to alternative scenarios where a viable intermediate solution might be identified along the regulatory spectrum: for instance, where similar regulatory approaches are employed but the perspectives of the actors involved and the goals pursued partially diverge. In every case, shared substantive perspectives, value systems and objectives will play a crucial role in ensuring that political processes are *truly* deliberative and that they result in the identification of normatively legitimate solutions. Ultimately, shared values and perspectives will result in similar approaches to risk assessment, similar inferences being drawn in a context of disputed science and a similar level of protection being pursued.

In the case of GE organisms, these substantive preconditions are lacking. The two transnational narratives on agricultural biotechnologies and the governance of their uncertain risks are irreconcilable; the polarisation between evidence-based and socially acceptable risk approaches is clearer than in any other case in the field of risk regulation. Scientific disagreements as to the uncertain risks posed by GE organisms are intense; the relevance of stricto sensu uncertainties and hazard-related uncertainties in this regulatory field, where science is often unable to establish a causal link with specific adverse effects, adds a further layer of complexity and controversy. Moreover, OLFs have a unique prominence in this field. The debate on the socio-economic advantages and disadvantages of GE organisms and on the distributional implications of different regulatory approaches has reached unprecedented levels of disagreement.

The failure of procedural deliberation and legal proceduralisation in the field of agricultural biotechnologies thus illustrates the irreconcilable tensions between technocratic evidence-based models of risk governance, the double dividend of aggregate wealth maximisation, transnational regulatory convergence and trade liberalisation, and radically different perspectives on legal pluralism, sustainability and collective and distributional stakes. The book thus draws the conclusion that transnational conflicts on agricultural biotechnologies cannot and should not be solved. Diametrically opposed perspectives on whether, how and why uncertain risks ought to be regulated[129] should merely coexist. It acknowledges that full-fledged transnational conflicts in politically charged fields cannot be completely resolved; nor should they be solved at all costs. To attempt to do so would be counterproductive. Focusing on procedural aspects or pursuing unsatisfactory procedural compromises will either exacerbate

[128] However, see the caveat in n 125.

[129] In this perspective, see Jasanoff, n 48; and M Lee, n 55, with a particular focus on the socio-economic and distributional implications of risk governance.

conflicts or be ineffective. In either case, regulatory conflicts are bound to persist and re-surface.

On these grounds, the book offers an alternative reading of the margins within which a normatively legitimate solution to complex regulatory conflicts can be constructed. Ultimately, it concludes that successful *procedural* deliberation largely *results from* pre-existing shared perspectives, values and goals. These are the *substantive* preconditions mentioned above in this section. In this sense, the success of truly deliberative practices is a procedural reflection of pre-existing substantive factors and conditions; conversely, a failure of deliberation is a procedural reflection of an unbridgeable normative gap. Normative premises, value systems and objectives need not be perfectly aligned for deliberative processes to yield positive results. Yet, a common substantive background and some unity of intent must exist.

Overall, the book suggests that modern procedural deliberative accounts have put too much faith in the ability of *rational communicative processes* to produce shared substantive values and identities and thereby underpin social integration. The book concludes that a different analytical balance should be struck in evaluating the dialectics of substantive vis-à-vis procedural, material vis-à-vis communicative, political and socio-economic vis-à-vis rational-deliberative, and objective vis-à-vis inter-subjective factors.[130] Deliberative and communicative processes do not exist in a political, socio-economic and cultural vacuum;[131] the assumption that any conflict can (and should) be procedurally solved is a legacy of modern, rationalist paradigms.

This has three implications. First, from this perspective, the focus should shift from procedural governance arrangements and procedural dynamics to substantive regulatory approaches and their underlying value systems and goals. This can pave the way for an enquiry into the substantive preconditions for genuine political agreement. In this sense, a modern *construction* of potential solutions by means of procedural practices and interactions should be preceded and complemented by a post-modern *deconstruction* of substantive regulatory patterns. In the book, the latter form of analysis is conducted throughout the institutional strand of enquiry: this part of the analysis deconstructs the nature of the hegemonic and counter-hegemonic narratives, and the specificities of evidence-based and socially acceptable risk approaches, as embedded in the relevant regulatory systems.

Secondly, deconstructing substantive regulatory approaches sheds light on their implications and broader impact, together with the overarching policy goals that they pursue. This deconstruction process helps to pinpoint the relevant issues at stake and what different forms of agreement would entail. As rightly noted, a procedural focus on governance arrangements and deliberative practices can obscure the substantive political and socio-economic issues at stake; in this sense, and in so far as agreement is framed and pursued as a

[130] See also chapter 7. See J Habermas, *Communication and the Evolution of Society* (Beacon Press, 1979), in particular at 106 ff., 111 ff. and 142-142. Ultimately, what underpins long-lasting societal integration or, in Habermasian terms, a "life-world"? Can consciousness and communication underpin effective societal integration, or does social existence determine consciousness and communication? Does societal integration ultimately rely on *material* and *objective* factors, or on *procedural* and *inter-subjective* elements? On these points, see also Leonelli, n 37.

[131] M Everson, "The Limits to the Conflicts Law Approach: Law in Times of Political Turmoil" (2011) 2 *Transnational Legal Theory* 271.

"goal", modern procedural deliberative accounts incorporate a technocratic element.[132] Further, if legal analysis loses track of the relevant values at stake, mere technocratic agreement could end up being mistaken for a successful deliberative outcome.[133]

Thirdly, and finally, the book concludes that modern procedural paradigms face unprecedented challenges in the transnational, post-modern reality. If legal proceduralisation fails to solve transnational legal conflicts and identify normatively legitimate solutions, a turn back to legal materialisation and the construction of substantive normative arguments could then be the only way out of the post-modern normative conundrum.

The next chapter provides a more detailed overview of the methodological framework and normative background of the book. Some final considerations on the institutional, methodological and normative strands of enquiry are then sketched out in the concluding chapter.

[132] Ibid.
[133] See chapter 3, section IX; and chapter 4, sections VIII and IX.