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BOOK REVIEW

Transnational Narratives and Regulation of GMO Risks

by G.C. Leonelli, Oxford, Hart Publishing, 2021, ISBN 9781509937387, 328 pp.

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At the root of the *Transnational Narratives and Regulation of GMO Risks* by G.C. Leonelli is the question of how to regulate in cases of scientific uncertainty and why different jurisdictions have contrasting regulatory and policy outcomes despite seemingly sharing similar approaches to risks and appreciations of health and the environment. It uses the controversial topic of genetic engineering (GE) or genetically engineered organisms (GEOs) broadly, in the context of agri-food production,[1] as a lens to investigate and tease out the reasoning, frameworks and practices of risk regulation in both the European Union (EU) and the USA, as well as World Trade Organization (WTO) law and beyond.

The book brings the reader on a well-structured journey, introducing key concepts (eg risk, hazards, "sound science", etc) and methodologies (eg the transnational narrative approach) before outlining the approaches in the different jurisdictions (the USA, the EU and internationally), the justifications for these and their relationships with other jurisdictions and actors. At the core throughout is the idea of the transnational narrative, but also the limits thereof or challenges thereto and the significance of context. Transnational legal analysis is developed and used to unpick the narratives and evaluate how they have been socially and politically constructed.

Chapter 1 provides a broad introduction to the field and to the book's overall approach. It outlines the book's three complex, interwoven strands of analysis: methodological, institutional and normative. First, the methodological element (developed further in Chapter 2) entails transnational legal analysis and a transnational narrative approach – moving beyond procedural aspects to encompass also normative aspects. Second, the institutional element relates to the hegemonic and counter-hegemonic narratives regarding GEOs; it thereby considers the ideal types[2] of "evidence-based" approaches (hegemonic) and "socially acceptable risks"[3] (counter-hegemonic). The difference in approach to uncertain risks here is crucial due to the inability of science to provide conclusive evidence of adverse effects (or the absence thereof).[4] Thus, under the

[1] For the purposes of this review, I refer to GE or GEOs in the subsequent discussion as reflecting the book's approach. The sole exception herein is when discussing the EU's approach to new genomic or breeding technologies, where it is necessary to distinguish between the core genetically modified organism (GMO) regime and the legal developments arising regarding these new technologies.

[2] In other words, a pure or abstract version, helpful for analysis, but unlikely to be in existence in this form in practice.

[3] GC Leonelli, *Transnational Narratives and Regulation of GMO Risks* (Oxford, Hart Publishing 2021) p 1.

[4] ibid, 16.

hegemonic approach, "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 contrast, under the counter-hegemonic approach, "risks *should not* be taken unless, in the face of persisting scientific uncertainty, a product or process has been proven to be sufficiently safe".[5] This difference raises factors such as the extent of a prudential approach, the weighting on "sound science" or otherwise and the level of protection pursued.[6] Third, the normative element addresses the potential for an acceptable, "normatively legitimate" solution to "transnational regulatory conflicts".[7] Consideration is given to conflicts law theory and the role of "modern *science-centred* and *procedural deliberative* paradigms to construct normatively legitimate solutions in controversial areas" but, as demonstrated across the book, to little avail.

Chapter 2 is the key to the book's methodology, enabling transnational legal analysis to be used to "deconstruct transnational narratives" regarding GE and their regimes "from within, across and beyond the nation state level".[8] Building on a range of authors including Jessup[9] and Zumbansen,[10] as well as her own earlier work,[11] Leonelli highlights how these transnational elements can be found through extra-territoriality, legal pluralisation and legal hybridisation.

The subsequent chapters (3–6) then outline and evaluate the approaches across different jurisdictions and contexts. Each is valuable for the detailed overview and analysis provided regarding current regulatory approaches to GE, but also for its contribution to the overall consideration of transnational regulatory conflicts. Thus, each chapter outlines and critiques the regimes before identifying the hegemonic or counter-hegemonic narrative, unpicking these and then identifying and evaluating the fundamental underpinnings of the regimes – the raison d'être for the approach and narrative. Needless to say, the chapters address these elements in considerable detail and with nuance that is not capable of being reflected adequately here, but some of the key focus points are outlined below.

Chapter 3 addresses the hegemonic, evidence-based approach in the USA and, for instance, its reliance on cost–benefit analysis, frequent references to "sound science", the role of experts/technicians as decision-makers and rejection of (express) reliance on the precautionary principle. The main focus is on the authorisation system (only "unreasonable risks" are to be regulated) and review processes, but with a brief introduction also provided of the recent developments regarding mandatory labelling. As well as demonstrating a hegemonic narrative (that is then deconstructed), the USA's approach to risk regulation has had considerable extra-territorial impacts, in large part due to globalisation.

Chapter 4 shifts the focus to the EU and the counter-hegemonic approach encompassing socially acceptable risks – where the interplay in this field between the EU institutions, including the Commission and the Court of Justice of the European Union (CJEU) in particular, and the Member States and their regions has proven highly contested and led to

[5] Socially acceptable risks are fundamental to the determination of whether the product or process is "sufficiently safe" and thereby to the counter-hegemonic narrative, as seen at ibid, 12.

[6] ibid, 14–15.

[7] ibid, 2. Similarly, ibid, 30.

[8] ibid, 9, 51–54,

[9] PC Jessup, *Transnational Law, Storrs Lectures in Jurisprudence at Yale Law School* (New Haven, CT, Yale University Press 1956).

[10] Eg 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 and Legal Pluralism* (Cambridge, Cambridge University Press 2015).

[11] Eg GC Leonelli, "The Postmodern Normative Anxiety of Transnational Legal Studies" in P Zumbansen (ed.), *The Oxford Handbook of Transnational Law* (Oxford, Oxford University Press 2021).

unprecedented changes in EU policy and law.[12] This chapter examines and deconstructs the narrative from within the EU, but also across the individual Member States.[13] As with the USA, the EU has significant extra-territorial impacts, but it also demonstrates legal pluralisation. The dominant approaches here include the potential for enhanced levels of protection, a prudential approach (encompassing prior authorisation focused on the process), application of the precautionary principle, political decision-makers and not requiring the cost–benefit analysis to be positive – instead applying an impact assessment with a limited role. Furthermore, (non-scientific) "other legitimate factors" (OLFs) play a significant role in the EU, including in principle in the GE regime. For instance, along with the precautionary principle, they can be considered in EU-level authorisations[14] and have informed national restrictions.[15] However, the introduction of the "opt out" shifts the role of some OLFs more towards the realm of the Member States and further away in practice from the core EU authorisation regime.[16] The effect is arguably to give each individual Member State more control over its own territory (thereby seeking to address internal conflicts) but through restricting the socially acceptable risks approach.[17] Consequently, the approach is somewhat less counter-hegemonic than it might at first appear.

Chapters 5 and 6 turn to the international level, where it might be expected that conflicts between the USA and the EU might be resolved, especially in light of the role of the two jurisdictions in helping to develop and shape international frameworks and rules – but instead we find continued contestation. Chapter 5 examines the WTO, in particular the Sanitary and Phytosanitary Measures (SPS) Agreement and the key cases addressing risk regulation and scientific uncertainties, where the hegemonic narrative plays a key role. The WTO law regime enables considerable impacts across nation states (ie legal pluralisation), akin to the examination of the EU's Member States. Chapter 6 turns then to softer measures – in particular, to the Codex Alimentarius (hegemonic narrative reigns dominant) and to non-governmental organisation standards (counter-hegemonic narrative is central). This chapter's focus clearly extends beyond the nation state, but nonetheless it still examines norms that are set and impact widely. It thereby addresses legal hybridisation. Here, it might have been interesting to reflect further on the role of other private standards (eg those of the agri-food industry), but as always there is simply the issue of practical limitations of the scope of research.

Together, Chapters 3–6 demonstrate that the regulatory approaches to GE vary across the different contexts and jurisdictions. Despite all relying on science and non-scientific factors, their use differs significantly – not just in minor ways, but in their very underpinnings and core values. For instance, the USA's regulatory regime reflects aims of fostering scientific development and individual trade and economic rights, thereby promoting aggregate wealth maximisation and the greatest net beneficial protection of the public health and the environment. In contrast, and despite the significance of the EU's internal market and notions of free movement, the EU's regime enables regulators to

[12] In particular, the potential "opt out" for Member States regarding GMO cultivation is a rare example of partial de-harmonisation in the EU, where progressive harmonisation is the norm – even if not "proper de-harmonisation", as noted by Leonelli, supra, note 3, 174.

[13] ibid, 10.

[14] ibid, 138–44. However, as Leonelli rightly points out in the subsequent pages, there is a significant disconnect between the regime's treatment of OLFs (and scientific uncertainty) on paper and how they are considered in practice.

[15] Eg ibid, 164.

[16] Eg ibid, 173.

[17] ibid, 172–75. See similarly regarding the fragmentation of the authorisation system: L Petetin, "Managing novel food technologies and Member States' interests: shifting more powers towards the Member States?" in M Varju (ed.), *Between Compliance and Particularlism: Member State Interests and European Union Law* (Berlin, Springer 2019). See, however, the current proposals noted in the final paragraph of this review.

choose enhanced levels of protection, have recourse to the precautionary principle and take into account different OLFs when considering the acceptability of uncertain risks – giving greater weight to the public interests (health, environment, social and political). Saying that, although the ideal types are used to analyse the various regimes and each tends to lean towards one more than the other, it is clear that the situation is not black and white in this regard.

Chapter 7 draws the preceding chapters together to highlight the main points discussed and key findings that can be drawn out. Through this, the book makes three major contributions to debates in this field (beyond providing valuable updates across the regimes).

First, the book provides insights as to *why* these divergences exist – where they do. Crucially, the book challenges the prevalent narrative that the divergent approaches to GE are primarily based alternatively in science or policy, instead arguing that they reflect different approaches (and attitudes) to scientific uncertainty and levels of protection. In doing so, Leonelli builds upon authors such as Vogel,[18] Weimer[19] and Wiener,[20] carefully dissecting and analysing each regime.

Thus, the book highlights how scientific uncertainty opens up alternative pathways for decision-makers that vary depending on the surrounding context. This is not to say that they are left with discretion or choice – this may be the case, but it is not a necessary outcome. Instead, scientific uncertainty shifts the focus and weighting of the factors to be considered and approaches to be taken when making a decision.

However, a caveat must be flagged here. As noted throughout the book, GE is contentious, and the standpoints vary considerably across territories and populations. The same is true about other contentious matters – simply think about the COVID-19 pandemic and vaccine hesitancy. So, although the analysis is interesting and provides insights as to the specifics for GE and general considerations for areas of scientific uncertainty, it should not be thought that a similar narrative will exist within the individual jurisdictions for different issues or regimes.[21] Despite Vogel's reference to "ships passing in the night",[22] it is not a simple matter of the EU becoming more precautionary and focusing more on socially acceptable risks (or holding a counter-hegemonic narrative)[23] and the USA shifting away from this, but instead varying approaches can be seen in individual jurisdictions (across different regimes) and are reflected frequently in trade disputes. Consider, for instance, the inverted attitudes towards unpasteurised dairy products. Consequently, it is essential to reflect on the methods and tools that Leonelli utilises so effectively for GE, adapting and applying them elsewhere[24] rather than simply expecting that the outcomes would be replicated across the jurisdiction.

[18] Eg D Vogel, *The Politics of Precaution: Regulating Health, Safety and Environmental Risks in Europe and the United States* (Princeton, NJ, Princeton University Press 2012).

[19] Eg M Weimer, "Applying Precaution in EU Authorisation of Genetically Modified Products – Challenges and Suggestions for Reform" (2010) 16 European Law Journal 624; M Weimer, "Risk Regulation and Deliberation in EU Administrative Governance – GMO Regulation and its Reform" (2015) 21 European Law Journal 622.

[20] Eg JB Wiener, "Whose Precaution After All? A Comment on the Comparison and Evolution of Risk Regulatory Systems" (2003) 12 Duke Journal of Comparative and International Law 207; JB Wiener et al (eds), *The Reality of Precaution. Comparing Risk Regulation in the United States and Europe* (Abingdon, Routledge 2011).

[21] Eg see Leonelli, supra, note 3, 13 and GC Leonelli, "Transatlantic Divergencies in the Regulation of Uncertain Risks: Co-Production, Normative Frames and Ideal Evidence-Based and Socially Acceptable Risk Approaches" (2022) 23 German Law Journal 769, at 777.

[22] D Vogel, "Ships Passing in the Night: GMOS and the Politics of Risk Regulation in Europe and the United States", INSEAD: Centre for the Management of Environmental Resources Working Paper 2002 https://sites.insead.edu/facultyresearch/research/doc.cfm?did=975.

[23] Although, even in the GE context, this is a clear oversimplification, as demonstrated by Leonelli's examination of the opt-out system and the variations across and within the EU.

[24] See supra, note 21.

Second, the book investigates and analyses *the significance of different regulatory approaches* to health and environmental risks in the context of globalisation. It provides insights into both ideal types, as well as the consequences of having transnational regulatory conflicts arise due to jurisdictions pursuing these (eg as reflected in the disputes before the WTO).

However, it should not be thought that health and environmental protection are disavowed or are of little import in jurisdictions such as the USA, and there are advantages and disadvantages to the various regulatory approaches. Yet, there is a different weighting of individual rights and public interests across the jurisdictions and the ideal types – with public interests playing second fiddle to individual rights in the USA and relying, to an extent, on secondary benefits. The regimes reflect fundamental values that might transcend beyond the area of GE. Furthermore, the regimes may impact trust, societal acceptance of decision-making and even accentuate society's perception of that balancing of public versus private interests.[25] This raises a quasi-"chicken or the egg" scenario: is societal, cultural and political change sufficient to produce significant change in regulatory practices and regimes or vice versa? And would such changes be sufficiently fundamental to impact on a widescale basis, or would they merely create a more variegated landscape of regulation within a single jurisdiction?

Third, the book contributes to the debate over *resolution of transnational regulatory conflicts*. However, it should not be thought that this book seeks to identify, evaluate and thereby resolve conflicts. Indeed, although the first two are undertaken, the author expressly states that she considers that conflicts such as those surrounding the EU's and USA's regulatory approaches to GEOs cannot and should not be resolved "at all costs".[26] This may seem an odd conclusion for a lawyer to draw, especially in a globalised world where international trade is taken as the norm – yet, it is an honest, pragmatic and perhaps necessary conclusion, as to do otherwise would be to try to impose social and cultural norms and attitudes in an ineffective, counterproductive manner where conflicts would simply resurface at a later point. A gradual shift might occur, or perhaps some external shock might trigger a more significant change, but legislating, litigation and legal nuance cannot negate the fundamental differences that steer the entire regulatory approach in opposite directions.[27] Indeed, the author notes that procedural approaches, including discourse and deliberation, are typically inadequate where substantive values are in conflict.[28] Instead, the author asks for recognition and understanding of regulatory choices and the reasons for these, with this laying the foundation for (respectful) coexistence.

And, yet, this ask seems like wishful thinking in a globalised world, where trade plays such a significant role. There are clear externalities posed by both restrictions on cultivation, trade and use on the one hand and by the introduction of GE crops and produce on the other – true coexistence of GEOs and non-GEOs in practice is not viable in our current agricultural practices[29] and food chains, with admixture effectively inevitable.[30] Nor does the international trade regime, as currently interpreted and applied by the WTO Dispute Settlement Body, facilitate the coexistence of fundamentally different approaches – with a

[25] Leonelli raises this very issue regarding the approach to the pandemic and vaccine hesitance, conspiracy theorists, etc., in a subsequent journal article: Leonelli, supra, note 21, 798–99.

[26] Leonelli, supra, note 3, 35, 277.

[27] Yet, see the final paragraph below regarding very recent EU legislative proposals.

[28] Eg Leonelli, supra, note 3, 274–75.

[29] M Dobbs, "Co-existence of GMOs in the EU – A Veritable Choice for Whom?" in M Cardwell and J McMahon (eds), *Research Handbook on EU Agriculture Law* (Cheltenham, Edward Elgar 2015).

[30] Eg AG Léger, in his Opinion of 3 March 2005 in Case C-132/03, *Ministero della Salute v Coordinamento delle Associazioni per la Difesa dell'Ambiente e dei Diritti degli Utenti e dei Consumatori (Codacons)* [2005] ECR I-416 at paras 81–82, indicated that the reasonable consumer might expect slight impurities or foreign substances in food, especially as the "contamination of the environment by GMOs is a well known phenomenon".

strong weighting in favour of the hegemonic tradition and a highly restrictive interpretation of the precautionary principle/approach and Article 5.7 SPS in this context, as noted by Leonelli in Chapter 5. Although the EU has changed its approach since the *EC–Biotech* dispute,[31] including emphasising the importance of science and creating the opt-out regime as an incentive for Member States to stop blocking authorisations, it cannot be said that there has been a fundamental shift to the core building blocks,[32] and transatlantic tensions persist. This all supports Leonelli's point of the impracticality and inappropriateness of seeking to resolve such conflicts. But, it also questions whether respectful coexistence is possible between the parties to the *EC–Biotech* dispute (or between jurisdictions more generally), or even if it is enabled by the current international regime.

Furthermore, beyond the more immediate environmental, health and societal concerns flagged within the EU, other longer-term concerns arise due to the potential of patenting and corporate control – especially combined with outcrossing of the GE material into the broader environment.[33] This is an area unfortunately not addressed in any detail by Leonelli, but where there is the real potential for corporations to control the plant genetic resources essential to life across the planet. The intellectual property (IP) implications have not been a priority in the EU to date, presumably due to the very limited presence of GEOs within the territory, as well as the variations in patenting and broader IP regimes. Indeed, this is an issue that has been noted, but not addressed in any substance, in the EU's very recent proposals regarding "new genomic techniques" flagged briefly at the conclusion to this review.[34] However, the impacts have been seen in various countries, including Canada, the USA and Australia, with backlash being observed in countries such as India. Again, the question arises as to whether respectful coexistence is possible between these different approaches.

And yet, even if it proves highly challenging and potentially eventually fruitless in some instances, Leonelli's aim of seeking to foster understanding and respectful coexistence is both worthy and necessary – as a first step to some degree of reconciliation or as the eventual outcome.

In conclusion, the book outlines the regimes with clear and insightful commentary, as well as representing a basis to help predict future developments therein; it does this through identifying key factors influencing the regulation of uncertain risks generally and highlights the challenges for achieving transnational agreements, legitimacy or accord. It becomes apparent that institutional and regulatory arrangements/approaches *and* social values and cultural values are central to what shapes and directs approaches to uncertain risks – where these are not shared but diverge considerably, as in the case of the EU and the USA, then policy divergence rather than convergence may be expected. However, crucially, each may nonetheless still at least use these same tools to help understand the reasoning of the other.

Overall, this book provides valuable contributions to the fields of risk regulation, comparative law and transnational conflicts, as well as to the research on GE/GEOs. Despite the complexity of the field and terminology, it is accessible to those unfamiliar with the area – thanks to the methodical approach and the explanation of key terms and concepts at an early stage. Yet, it also brings valuable new perspectives and contributions to the existing debates and provides a foundation for further research in the field of GE or other

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

[32] Note, however, the developments regarding the related "new genomic techniques" below.

[33] Eg M Dobbs, "Genetically Modified Crops, Agricultural Sustainability and National Opt-Outs – Enclosure as the Loophole?" (2017) 54(4) Common Market Law Review 1093–122.

[34] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625, COM(2023) 411 final, p 8 in the Explanatory Memorandum mentions patenting as an issue of concern for stakeholders.

areas of scientific uncertainty or contestation. However, although the outline and analysis of the GE regimes are valuable resources, the richness truly lies in the theoretical exploration and development.

A final point is worth noting that has largely materialised since the book's publication, which is the current EU proposal for a Regulation on New Genomic Techniques (NGTs).[35] This follows on from the developments by the CJEU regarding "new breeding techniques", discussed by Leonelli,[36] where the CJEU considered that outputs from such techniques would fall within the EU regulatory regime on genetically modified organisms (GMOs).[37] However, the legislative proposal would roll back on this significantly. It indicates an approach to these NGTs that more reflects that taken in the USA, with no mention of the precautionary principle, one category of NGTs being excluded from going through the regulatory approval process and further restrictions on controls (eg on the national or regional "opt outs") by Member States on the second category. There are numerous questions to be raised by this proposal more generally, but in the context of Leonelli's research it does beg the question as to what this indicates about the regulatory choices being made, or whether the proposals are likely to be successful in their current format. Does this indicate some rapprochement in the regulatory conflicts between the EU and the USA surrounding GE more generally,[38] and, if so, does it remain true to the underpinning values in the EU? I look forward to reading more on Leonelli's perspective regarding this development.

Competing interests. The author declares none.

[35] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625, COM(2023) 411 final.

[36] Leonelli, supra, note 3, 127–29.

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

[38] The Commission claims that this does not roll back on their approach to GMOs, as it considers GMOs and outputs from NGTs to be distinct: eg see the Commission's FAQs on the new proposal https://ec.europa.eu/commission/presscorner/detail/en/qanda_23_3568, where the response to Q14 includes the line that "[t]he new rules concern NGTs only, which are distinct from GMOs". However, that is from only one perspective, and there remain considerable similarities and overlaps where one might expect similar regulatory regimes and references to elements such as the precautionary principle.