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Sustainability in regulating biotechnology: A new form of knowledge in regulatory co-production?

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Abstract

We analyse the extent to which sustainable development influences the co-production of regulations that target new technologies in the European Union (EU). We start by identifying the conventional forms of knowledge that serve as inputs into that co-productive process, namely scientific, societal and legal knowledge. We show that sustainability-related propositions have gained considerable traction in the regulation of genetic modification (GM) in the EU. Furthermore, the analysis reveals that sustainability cannot be reduced to scientific or societal knowledge. As far as the overlap between sustainability knowledge and legal knowledge is concerned, it is undeniable that sustainable development is deeply embedded into EU regulation; however, treating sustainable development solely as an element of the law does not capture the material influence that it exerts on society and technology, not to speak of its evolutionary flexibility. It follows that it would be best to treat sustainability as a separate input into the co-creation process.

1 | INTRODUCTION

Sustainable development has become the lynchpin of contemporary European Union (EU) policy. The EU is seeking to make Europe the first climate-neutral continent, and it has adopted flagship policies have sustainable practices at their core, such as the Green Deal and the Farm to Fork (F2F) Strategy.[1] Traditionally, the concept of sustainable development has been defined as 'development that meets the needs of the present without comprising the ability of future generations to meet their own needs'.[2] This general aspiration has since been distilled into other international policy documents where three main dimensions—economic, social and environmental—should be balanced in the adoption of public policies.[3] Moreover, the 2030 Agenda for Sustainable Development led to the adoption of Sustainable Development Goals (SDGs), which contain precise targets that can inform day-to-day policymaking.[4] It is in its SDG form that sustainable development features in the Green Deal and the F2F Strategy. However, if one examines the idea of sustainable development separately from its manifestations in policy, one soon discovers that it has multiple meanings, many forms, many applications and many contexts.[5]

[1]Commission (EU) 'The European Green Deal (Communication)' COM(2019) 640 final, 11 December 2019 (EU Green Deal); Commission (EU) 'Farm to Fork Strategy' (Communication) COM(2020) 380 final, 20 May 2020 (F2F Strategy).

[2]'Report of the World Commission on Environment and Development: Our Common Future' UN Doc. A/42/427 (20 March 1987) 16.

[3]See, e.g., Rio Declaration on Environment and Development in 'Report of the United Nations Conference on Environment and Development' UN Doc A/CONF.151/26 (12 August 1992) Annex I; UNGA 'Programme for the Further Implementation of Agenda 21' UN Doc A/RES/S-19/2 (28 June 1997); Johannesburg Declaration on Sustainable Development in 'Report of the World Summit on Sustainable Development' UN Doc A/CONF.199/20 (4 September 2002). Please note that the degree to which the various dimensions of sustainable development are emphasised varies in each international policy document.

[4]UNGA 'Transforming Our World: The 2030 Agenda for Sustainable Development' UN Doc A/RES/70/1 (21 October 2015).

[5]V Barral, 'Sustainable Development in International Law: Nature and Operation of an Evolutive Legal Norm' (2012) 23 European Journal of International Law 377.

The present article is not an attempt to solve *all* of the analytical problems to which this multiplicity gives rise. It focuses exclusively on how sustainable development relates to the regulation of technology in the EU. In both the Green Deal and the F2F Strategy, technology is seen as a key driver of sustainable development.[6] Nowadays, the emergence of any new technology is bound to be accompanied by calls for regulation. We draw an analogy between the creation of regulation and co-production. The co-production of (technology) regulation requires inputs, in the form of knowledge,[7] and it yields outputs, in the form of information products such as laws, regulations, guidance documents, best practices and so on.[8] The focus of this article is chiefly on the inputs into this co-productive process. Ordinarily, these inputs take three forms: scientific knowledge, societal knowledge and legal knowledge. Our argument is that knowledge about sustainable development, which will be named 'sustainability knowledge',[9] should be added to this list.

We use the regulation of genetic modification (GM) as an example. In the EU, that domain of law has long been deadlocked—the legal procedure under which authorisation decisions are made is geared towards an enhanced role for scientific information inputs, but Member States commonly withhold authorisations on account of the societal knowledge which they claim to possess. We will explore whether the ascent of sustainable development and reliance on sustainability knowledge can help break that deadlock.

The remainder of this article is structured as follows: Section 2 outlines the different knowledge inputs in regulatory co-production; those forms of knowledge have been identified in the literature on science and technology studies, as well as law.[10] Section 3 describes the background to GM regulation in the EU. Section 4 zooms into the inputs into its co-production. Section 5 develops our principal theoretical argument, namely, that sustainable development should be treated as an independent knowledge input in that co-productive process. Section 6 concludes.

2 | THREE DIFFERENT FORMS OF KNOWLEDGE IN REGULATORY CO-PRODUCTION

Co-production has recently become a popular conceptual framework in a wide range of disciplines, including public administration and science and technology studies. In essence, the term 'co-production' denotes the process by which multiple producers design and administer a government service or product.[11] Under this framework, regulation is conceptualised as an information product. Specifically, those who are charged with the design of regulation leverage several inputs, that is, several types of knowledge, to produce their regulatory output.[12] In short, regulation is the by-product of interdependent forms of knowledge that come together.

The framework has been applied to a wide range of government services. [13] Most importantly, for the purposes of this article, its proponents have long striven to identify the individual forms of knowledge that governments use to decide how to regulate new technologies.[14] Scientific knowledge is evidently one of those inputs:[15] Scientific experts can inform the regulator about the most recent developments in biology, GM, artificial intelligence and so on, and those developments obviously shape the government's responses to innovation. Somewhat less obviously, the regulator can also use scientific knowledge to decide whether to regulate a new technology in the same way as an old one or whether to regulate anew. This point is far from banal because a finding that the new technology is analogous to an old one will usually be terminal to the entire co-productive process. Thus, scientific knowledge, which we take to include all knowledge about the technical aspects of a technology, is key to the co-productive dynamics that underlie regulation.

As Faulkner and Poort showed, scientific knowledge is not the only form of knowledge that matters for regulation. Returning to the decision *whether* to regulate, societal and legal knowledge can also call for, or even require, a regulatory response to the emergence of a new technology.[16] The term 'societal knowledge' denotes knowledge about matters such as ethics, which can only be distilled from evidence on the values that a society holds dear and about the concerns that trouble its members. These values and concerns matter in debates about new technologies, and they influence the degree to which a new technology will command acceptance among the public. The notion of societal knowledge also includes information about the economic drivers of societal development and about the context in which that development occurs.[17] These types of knowledge are also inputs into regulation:[18] They may cause a new technology, whatever

[6]For example, F2F Strategy (n 1) 7 and 10.

[7]C Wyborn et al, 'Co-producing Sustainability: Reordering the Governance of Science, Policy, and Practice' (2019) 44 Annual Review of Environment and Resources 319, 320; M Innes et al, 'How Co-production Regulates' (2019) 28 Social and Legal Studies 370, 372.

[8]D Demortain, 'Expertise, Regulatory Science and the Evaluation of Technology and Risk: Introduction to the Special Issue' (2017) 55 Minerva 139; A Faulkner and LM Poort 'Stretching and Challenging the Boundaries of Law: Regulatory Connection and Regulatory Knowledge in Biotechnologies' (2017) 55 Minerva 209.

[9]In the literature, the meanings that are attributed to the terms 'sustainable development' and 'sustainability' do not coincide completely. Nevertheless, we employ the phrase 'sustainability knowledge' to avoid repeating the more cumbersome 'knowledge about sustainable development'.

[10]See, e.g., S Jasanoff, '(No?) Accounting for Expertise' (2003) 30 Science and Public Policy 157; A Liberatore and S Funtowicz, '"Democratising" Expertise, "Expertising" Democracy: What Does that Mean, and Why Bother?' (2003) 30 Science and Public Policy 146; W van der Burg and FWA Brom, 'Legislation on Ethical Issues: Towards and Interactive Paradigm' (2000) 3 Ethical Theory and Moral Practice 57.

[11]CA Miller and C Wyborn, 'Co-production in Global Sustainability: Histories and Theories' (2020) 113 Environmental Science and Policy 88, 90.

[12]S Jasanoff and SH Kim (eds), *Dreamscapes of Modernity: Sociotechnical Imaginaries and the Fabrication of Power* (University of Chicago Press 2015).

[13]E Ostrom and G Whitaker, 'Does Local Community Control of Police Make a Difference? Some Preliminary Findings' (1973) 17 American Journal of Political Science 48; G Whitaker 'Coproduction: Citizen Participation in Service Delivery' (1980) 40 Public Administration Review 240; D Boyle and M Harris, *The Challenge of Coproduction: How Equal Partnerships Between Professionals and the Public are Crucial to Improving Public Services* (Nesta 2009); C Durose and L Richardson (eds), *Designing Public Policy for Co-production: Theory, Practice and Change* (Policy Press 2016).

[14]Demortain (n 8).

[15]ibid.

[16]Faulkner and Poort (n 8).

[17]ibid.

[18]M Hisschemöller and R Hoppe, 'Coping with Intractable Controversies: The Case for Problem Structuring in Policy Design and Analysis' (1995) 8 International Journal of Knowledge Transfer and Utilization 40.

its technical attributes, to be seen as so different from the old that additions to the existing regulatory framework become warranted.

According to Faulkner and Poort, legal knowledge is the third input into regulation.[19] Legal knowledge is knowledge about the legal order, the legal system and its procedures, legal taxonomy, legal principles and the (historical) background to the law.[20] A deep understanding of the legal system is increasingly necessary for the design of regulation, as well as for the identification of technological developments that can be accommodated into the existing law. For instance, studies have shown that the choice of legal actor[21] and legal form has sizable implications for the success and failure of regulatory programmes.[22] That the regulator's failure to account for the technical particularities of the legal system in which regulation is embedded can lead to the collapse of the entire regulatory enterprise suggests strongly that legal knowledge is a distinct input into the process of regulatory co-production.

In short, the existing literature has shown that at least three different forms of knowledge shape the co-production of regulations for new technologies. These inputs are scientific knowledge, societal knowledge and legal knowledge. The three forms of knowledge can be obstructive or mutually reinforcing in their interactions, and the co-production of government regulation can be described as the process by which they are synthesised. The precise contours of this synthetic process vary widely across regulatory domains, institutional settings and times. Since our concern here is primarily with the integration of sustainability-related ideas into the regulation of biotechnology in the EU, we propose to begin by describing the manner in which the three knowledge inputs have been synthesised into regulation in that field.

3 | THE REGULATION OF GENETIC MODIFICATION IN THE EU

The F2F Strategy places a strong emphasis on the idea that new genomic techniques (NGTs) such as CRISPR-Cas[23] can improve the sustainability of EU agriculture, for example, by reducing dependency on pesticides. NGTs also contribute to seed security and diversity, which means that they can enable the sector to adapt to the escalating pressures of climate change.[24] However, for European agriculture to benefit from easy access to NGTs, it would be necessary for the Union to revise its regulation of GM.[25]

On 5 July 2023, the European Commission presented a new proposal for the use NGTs in agriculture: the NGT Regulation. On 7 February 2024, the European Parliament adopted amendments to the proposed Regulation. Those amendments cover plants that are obtained through certain NGTs and their use in food and feed. The European Parliament then referred the Regulation back to the responsible Committee.[26] With the new NGT Regulation, the Commission aims to maintain a high level of protection for human health and the environment while also contributing to the innovation and sustainable development objectives of the European Green Deal and the F2F Strategy. It intends to attain those goals by lowering regulatory hurdles for NGTs.[27] In the amended Regulation, plants that are obtained through NGTs are exempted from the regulations on GM under certain conditions, provided that they do not have a negative effect on sustainable development. NGTs are defined as 'techniques that are capable of altering the genetic material of an organism and that have merged or have been developed since 2001'.[28]

The NGT Regulation is the output of a long co-productive process.[29] For decades, the regulation of GM was deadlocked because the Member States could not reach majority decisions on the authorisation of GM crops for the market. Authorisation decisions are based on risk assessments, which are scientific in nature. However, the Member tates would vote against authorisation for other reasons, none of which are mentioned in Directive 2001/18.[30] The Commission tried to break this stalemate through additional regulations, such as Directive 2015/412 on the cultivation of genetically modified crops. That Directive allows Member States to ban the cultivation of genetically modified crops on their territories for non-safety reasons.[31] Insofar as it was an attempt to break the impasse, it was unsuccessful.[32]

GM technology evolved considerably during this deadlock. NGTs such as CRISPR-Cas pose challenges to the current framework,[33] which does not appear to be facilitating technological development and innovation.[34] In 2018, the Court of Justice of the EU (CJEU) had to rule on the question of whether new mutagenesis techniques fall under the scope of Directive 2001/18 on the deliberate release of genetically modified organisms (GMOs).[35] The CJEU held that the techniques in question do fall under the scope of the Directive but are not covered

[19]Demortain (n 8); Faulkner and Poort (n 8).
[20]Faulkner and Poort (n 8) 225, 227.
[21]MK Kołacz et al, 'Who Should Regulate Disruptive Technology?' (2019) 10 European Journal of Risk Regulation 4.
[22]A Quintavalla and O Yalnazov, 'Regulating Eco-innovation in the European Union' (2024 fc) Journal of Environmental Planning and Management.
[23]CRISPR-Cas is a modern gene-editing technique that can easily change an organism's DNA. By use of a template, it detects a certain piece of the DNA which it then replaces, deletes or substitutes.
[24]F2F Strategy (n 1) 7 and 10.
[25]These promises have not yet been proved. Until now, only a few applications are placed on the market. See Commissie Genetische Modificatie (COGEM) and Gezondheidsraad, 'Trendanalyse biotechnologie 2023, Tijd voor een integrale visie' (COGEM 2023).
[26]Commission (EU) 'Proposal for a Regulation on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation' COM(2023) 411 final, 5 July 2023.
[27]ibid.
[28]Commission (EU) 'Study on the Status of New Genomic Techniques under Union Law and in Light of the Court of Justice Ruling in Case C-528/16' (Staff Working Document) SWD(2021) 92 final, 29 April 2021.
[29]R Mampuys, 'The Deadlock in European GM Crop Authorisation as a Wicked Problem by Design: A Need for Repoliticisation of the Decision-making Process' (PhD Thesis, Erasmus University Rotterdam 2021) 23, 106 and 112–114.
[30]See also P Macnaghten and M Habets 'Breaking the Impasse: Towards a Forward-looking Governance Framework for Gene Editing with Plants' (2020) 2 Plant, People, Planet 353.
[31]R Mampuys and LM Poort, 'Controversy First: Factors Limiting the Success of Directive (EU) 2015/412 for National Decision-making on the Cultivation of GM Crops' (2019) 11 Law, Innovation and Technology 175.
[32]ibid.
[33]Mampuys (n 29) 234–235.
[34]LM Poort and F Coman-Kund, 'The EU GM Regulatory Framework on Green Biotechnology under Revision' (Dutch Ministry Infrastructure and Water Management 2023).
[35]Case C-528/16, *Confédération paysanne and Others v Premier ministre and Ministre de l'agriculture, de l'agroalimentaire et de la forêt*, ECLI:EU:C:2018:583.

by the exemption for mutagenesis techniques (Article of 3 Directive 2001/18). The ruling prompted a study of the status of NGTs. Its results provided the spur for the most recent revision of the GM regime.[36]

In that regime, the main regulations for GM plants are Directive 2009/41 [37] and Directive 2001/18.[38] Directive 2009/41 regulates the contained use of genetically modified organisms.[39] Directive 2001/18 lays down authorisation procedures for two different scenarios: (1) the deliberate release of GMOs into the environment (Part B) and (2) the placing of GMOs on the market (Part C).

The 'contained use' and 'deliberate release' of GMOs fall under the jurisdiction of national competent authorities because, in both cases, the use of GMOs is restricted to the territory of a single Member State. The 'placing of GMOs on the market' is subject to an authorisation procedure that is conducted on the EU level. Since all Member States have a say on licensing, placing GMOs on the market is subject to more intensive scrutiny than their 'contained use' or 'deliberate release'. Once an environmental risk assessment (ERA) has been conducted, all subsequent procedures depend on authorisation decisions by national competent authorities. The authorisation procedure for placing GMOs on the market contains an additional step, in which all Member States vote on authorisation (comitology). Prior to the vote, the European Food Safety Authority (EFSA) delivers an ERA. The EFSA accounts for the previous findings of the national competent authorities in its conclusions. The Commission then drafts a proposal on which the Member States vote. That proposal is based on the EFSA ERA. Decisions on authorisation are made by qualified-majority voting. If no agreement can be reached in this way, the Commission has a mandate to make a final decision. This procedure seems straightforward, and one might expect that the proposals of the Commission would be followed by the Member States. After all, those proposals are based on an ERA that is conducted by an authoritative body with scientific expertise, the EFSA. In reality, however, the Member States do not vote in line with Commission proposals or EFSA advice. Despite the sensitivity of Directive 2001/18 to risk, Member States hold opposing views on the cultivation of GM crops in the EU, partially because they question the potential risks and disagree on the optimal level of safety—how safe is safe enough?—and partially for other reasons. The co-existence of crops, concerns about biodiversity and the importance of freedom of choice, divergent understandings of the food system and heterogeneous cultural values dominate socio-economic debates about the use of GM in agriculture. Although these values and concerns are not accommodated in the ERA that is issued prior to voting, they are reflected in the voting process that the Member States follow informally.[40] Other GM regulations in the EU may account for such inputs. For example, freedom of choice is safeguarded by the provisions on mandatory labelling, which apply even to products that are considered to be safe (Regulation 1830/2003 on traceability and labelling of GMOs[41]). As noted previously, the Commission tried to break the voting impasse through the introduction of Directive 2015/412, amending Directive 2001/18, which enabled the Member States to restrict or prohibit the cultivation of GMOs on their territories. That Directive does refer to non-safety considerations and was seen as a viable solution. However, voting behaviour did not change.[42] The Directive provides now for an opt-out; it does not regulate *debates* about non-safety considerations. It did not solve the problem; it merely skirted it.

Under the comitology procedure, if no qualified majority can be reached, the Commission decides. The Commission is reluctant to force decisions on authorisation for cultivation. Formally, it must formulate a proposal and put it to a vote within 3 months of receiving EFSA's advice. However, between 2011 and 2013, the average approval period for GM food or feed products was 19 months.[43] As a result, authorisation procedures have stagnated, as has the development of GMOs, and concerns have begun to mount about the EU falling behind other polities, such as the United States, Canada and Argentina, in terms of technological innovation.[44]

Scientists have argued that NGTs should no longer be considered GM techniques—the term 'gene-editing methods' appears to be preferred.[45] The modification of genes entails the insertion of foreign DNA into an organism, while 'gene editing' refers to the replacement, deletion or insertion of strands from the organism's own DNA.[46] According to the scientists who have made the argument for gene editing, NGTs are cheaper, easier to apply and more accurate than the 'old' GM techniques and conventional breeding techniques. In agriculture, NGTs such as CRISPR-Cas can be used to develop plants with specific traits. The procedure is much more precise than conventional breeding, and the products that result from it are indistinguishable from products that occur naturally and from those that are obtained through conventional breeding. Accordingly, scientists have cast doubts on the supposed safety risks of the use of NGTs. In their view, NGT products are no longer GMOs.[47]

On 29 April 2021, the Commission published a study on NGTs. The study pointed to various factors that indicate that the current regulatory framework cannot accommodate them adequately.[48] The Commission emphasised that a follow-up study would be required to determine how the regulatory framework can be future-proofed. It also made clear its intention to simplify the assessment procedures for NGTs, which it claims are particularly useful in attempts to meet the sustainable development objectives of the Green Deal. For example, NGTs might be helpful in the development of crops that require less water or pesticides.[49]

[36]Commission (EU) (n 28).
[37]Directive 2009/41/EC of 6 May 2009 on the contained use of genetically modified micro-organisms [2009] OJ L 125/75.
[38]Directive 2001/18/EC of 12 March 2001 on the deliberate release into the environment of genetically modified organisms [2001] OJ L 106/1.
[39]For further explanation of the legal framework see Poort and Coman-Kund (n 34) 7.
[40]Macnaghten and Habets (n 30); Mampuys and Poort (n 31).
[41]Regulation 1830/2003/EC of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC [2003] OJ L268/24.
[42]Mampuys and Poort (n 31).
[43]Mampuys (n 29) 179.
[44]COGEM, 'Rode Draden in de GGO-Vergunningverlening. De positie van genetische modificatie in een IenM-breed afwegingskader veiligheid' (COGEM 2015) 29.
[45]Commission (EU) (n 28); K Purnhagen and J Wesseler, 'Regulation of New Plant Breeding Technologies and Their Possible Economic Implications for the EU and Beyond' (2020) 43 Applied Economic Perspectives and Policy 1621.
[46]C Bain et al, 'Emerging Sociotechnical Imaginaries for Gene Edited Crops for Foods in the United States: Implications for Governance' (2020) 37 Agriculture and Human Values 266.
[47]Commission (EU) (n 28).
[48]ibid.
[49]ibid.

The study that the Commission produced and its intention to reduce regulatory hurdles were met with criticism from several stakeholders. Those stakeholders doubted the promise of NGTs and expressed concerns about the potential risks that they pose to human health and the environment. Their critiques focused on the acceptable level of safety and the existence of potential risks. Specifically, the concerned stakeholders were opposed to the idea of assimilating conventional breeding and NGTs fully. In doing so, they questioned the consequences for freedom of choice, biodiversity and for upholding their cultural values.[50]

In light of these concerns, the Commission revised its regulation of GMOs thoroughly. On 5 July 2023, it presented the NGT proposal. That proposal distinguishes between two types of NGT plants: Category 1 and Category 2. Category-1 NGT plants are defined as plants that 'could also occur naturally or be produced by conventional breeding' and do 'not harbour traits that can have a negative impact on sustainability'.[51] Plants that fulfil these criteria are subject to a notification procedure, but not to risk assessment or authorisation. All other NGT plants require authorisation, but the information that is required for risk assessment differs from case to case. Furthermore, the proposal states that regulatory incentives should be offered when Category-2 NGT plants exhibit traits that contribute to the sustainability of the agri-food system.[52] The examples of such traits include tolerance or resistance to biotic and abiotic stresses, improved nutritional characteristics and increased yield.[53] On 7 February 2024, the European Parliament adopted the new regulation, with some amendments, and referred it back to the responsible Committee. The amendments only concern mandatory labelling and the ban on all patents.[54] In general, the members of the European Parliament (MEPs) supported a simpler procedure for NGT plants. A majority of MEPs emphasised the need to devise a food system that is more sustainable and resilient.[55]

4 | CO-PRODUCTION DYNAMICS IN CONTEXT

4.1 | Scientific, societal and legal knowledge in biotechnology regulation

A common strategy for coping with innovative biotechnologies is to involve scientific experts in regulatory decision making.[56] It is often argued that scientific experts know more about the technology and the uncertainties that are associated with it than the regulator, which justifies their substantive role in regulatory processes. The robust scientific knowledge that scientists provide injects a degree of neutrality and rationality into the co-production process.[57] According to Poort and Bovenkerk, when innovative biotechnologies are being regulated, scientific experts are highly accountable, and much reliance is placed on their input.[58] Insights from science and technology studies indicate that the opposite may be true—the neutrality of scientific facts has often been questioned. Science is only a part of the issues that are at stake.[59] Sarewitz showed the complexity of knowledge claims by elaborating on the diverse disciplinary lenses that can be used to examine nature. He argued that these disciplinary lenses inevitably incorporate diverse normative perspectives on the interpretation of facts.[60] Furthermore, in science and technology studies, the relevance of societal values and experiential knowledge is emphasised.[61] Several social scientists have argued for a broader assessment of the use of GMOs.[62] The content of regulation also depends on what the public want and experience, that is, on what we defined as societal knowledge in Section 2. Societal knowledge is relevant to regulatory co-production.[63] In addition, when new technological developments are being introduced into existing legal frameworks, it is possible that technical juridical challenges will arise. Legal knowledge contributes to understanding and addressing these regulatory challenges.[64]

Unsurprisingly, the development of the regulatory regime for GM in the EU has so far strongly depended on scientific expertise. The first attempt to devise a regulatory framework can be traced back to the Asilomar debate in 1975, in which scientists gathered to discuss the potential risks of GMOs for human health.[65] These potential risks eventually triggered the development of a novel regulatory regime that was based on risk assessment. Other factors did not have a role in the regulatory framework, but they did set the scene. For example, social considerations such as naturalness and the importance of freedom of choice often find expression in debates about GM. This said, scientific knowledge was the dominant influence in the initial stages of the development of regulation.[66]

As noted in Section 3, as far as the use of GM in agriculture is concerned, regulatory practice has been in a state of deadlock. Closer scrutiny reveals that the Member States have been voting against licensing on the basis of considerations other than safety, that is, on account of their societal knowledge. Those considerations do not have a clear role in the licensing procedure for the placement of

[50]Biodynamic Federation Demeter, 'Biased from the Outset: The EU Commission's "Working Document" on New GM Techniques Fails to Uphold Environmental and Consumer Protection Standards (September 2021) <https://demeter.net/wp-content/uploads/2021/09/Open-Letter_Biased-from-the-outsets_20210906.pdf> 13.
[51]Commission (EU) (n 26) recitals 13 and 16.
[52]ibid recitals 26–28 and 19.
[53]ibid recital 31.
[54]ibid. Banning all patents on NGT plants is an important issue in balancing between striving for a sustainable food system and the stimulation of innovation. Banning patents makes innovation less profitable, but also contributes to a rapid growth of sustainable crops in agriculture.
[55]See European Parliament, 'New Genomic Techniques: MEPs Back Rules to Support Green Transition of Farmers' Press Release (7 February 2024) <https://www.europarl.europa.eu/news/en/press-room/20240202IPR17320/new-genomic-techniques-meps-back-rules-to-support-green-transition-of-farmers>.
[56]Faulkner and Poort (n 8) 211.
[57]LM Poort and B Bovenkerk, 'Changing Expectations of Experts: The Symbolic Role of Ethics Committees' in B van Klink et al (eds), *Symbolic Legislation Theory and Developments in Biolaw* (Springer 2016) 272.
[58]ibid.
[59]LM Poort et al, 'Restore Politics in Societal Debates on New Genomic Techniques' (2022) 39 Agriculture and Human Values 1207.
[60]D Sarewitz, 'How Science Makes Environmental Controversies Worse' (2004) 7 Environmental Science and Policy 385.
[61]Liberatore and Funtowicz (n 10).
[62]See for example R Helliwell et al, 'NGO Perspective on the Social and Ethical dimensions of Plant Genome Editing' (2019) 36 Agriculture and Human Values 779; and Macnaghten and Habets (n 30).
[63]Faulkner and Poort (n 8) 227.
[64]ibid 213.
[65]B Bergmans et al, 'Analyse van de Europese Wet- en regelgeving over genetisch gemodificeerde organismen' (COGEM 2016) 18–19.
[66]ibid 18.

GMOs on the market.[67] Additional regulations, such as mandatory labelling (to ensure freedom of choice; Regulation 1830/2003) and the opt-out for cultivation on the territory of a Member State (Directive 2015/412), have not prevented non-safety considerations from affecting voting behaviour.

The crisis in GM regulation cannot be explained solely by the tension between the scientific facts that the proponents of GM emphasise and the societal concerns that its opponents claim to voice. The crisis is more complicated. For example, the proponents of GM also highlight its economic benefits, its advantages for food security and its potential to increase the availability of healthy food.[68] Beyond the controversies about the definitions of safety and potential risks, it has been argued that GM has not lived up to its promise and thus to the expectations of the public.[69]

It may be desirable to describe the role that each form of knowledge has played in addressing the challenges that are associated with the regulation of NGTs. In the early 1970s and 1990s, the potential risks of GM served as incentives for the development of a new legal framework. Interestingly, in the current NGT debate, scientific knowledge discharges a different function. Nowadays, scientists argue that NGTs no longer differ from conventional breeding methods. Therefore, the argument runs, there is no scientific reason to place these techniques within the scope of GM regulation. The question is not whether the new technology is too different from those that the existing legal framework is intended to regulate. Instead, the issue is whether innovation has narrowed a difference that was previously thought to be fundamental.

Scientific knowledge dominates this debate as well. The opponents of GM continue to question the promises of scientists and their appraisals of risk levels. They also argue that exempting NGTs from GM regulation would endanger freedom of choice, co-existence between conventional plants and GM-plants, biodiversity and cultural values. Regulations on labelling cannot overcome freedom-of-choice and co-existence objections because new NGTs make it difficult to distinguish between plants that have been obtained through the use of GM techniques and plants that have been obtained through conventional breeding. Therefore, the opponents argue that NGTs should remain within the scope of the GMO regulation and that assessments should even be expanded to account for non-safety considerations.[70] Focusing on the scientific debate about the use of GM obscures the existence of diverging opinions about its role in the food system and the weight that is attributed to socio-economic considerations in practice.

The deadlock in GM regulation is also partially procedural, which is why legal knowledge is relevant to it. GM regulation is part of EU environmental law and therefore strongly depends on the functioning of that larger regulatory complex. There, the precautionary principle plays a significant role as the environmental risk assessment strongly relies on it.[71] Pursuant to the judgement of the CJEU in Case C-528/16, the precautionary principle should be interpreted narrowly, focusing on avoiding risks.[72] Consequently, the framework for the regulation of GM translated into environmental risk assessment does not accommodate societal concerns; at best, it pays lip service to them.[73]

In short, the three forms of knowledge that we mapped in Section 2 affect the regulation of GM in the EU. Beyond scientific knowledge, societal and legal knowledge have influenced efforts to amend the regulatory framework. These forms of knowledge do not seem to be mutually reinforcing; instead, they are often used by the competing factions that are seeking to shape EU regulation.

4.2 | The role played by sustainable development in biotechnology regulation

Let us now turn to the position that sustainable development occupies in this co-production exercise. Sustainable development has come to permeate discourse about GM law. Its ascent appears to have accelerated regulatory change. The Commission announced its Green Deal in December 2019 as part of its efforts to combat global warming. In the Green Deal, sustainable development is associated with three sets of objectives: environmental, social and economic goals.[74] Likewise, in the F2F Strategy, the use of GM has been brought to the fore as a means of achieving a *sustainable* food system.[75] Accordingly, the concept of sustainable development has begun to assume greater prominence in debates about the revision of EU regulations on GM, in both policymaking and academic circles.

When it revises existing legal frameworks to accommodate new developments in green biotechnology, the Commission focuses on the contribution that GM can make to the pursuit of sustainable development. In the F2F Strategy, it states that 'new innovative techniques, including biotechnology and the development of bio-based products, may play a role in increasing sustainability, provided that they are safe for consumers and the environment while bringing benefits for society as a whole'.[76] Thus, sustainability plays a critical role in the revision of EU regulations on green biotechnology.[77] All of the various stakeholders in GM regulation have interpreted sustainable development objectives in ways that advance their stances on GM in agriculture. On the one hand, scientists and industry representatives have emphasised the environmental and economic benefits of a sustainable food system—in line with the F2F Strategy—and consequently pleaded for lower regulatory hurdles. On the other hand, those who criticise GM have emphasised societal knowledge and advocated for a broader assessment framework. The latter stance is also in line with the F2F Strategy.[78] For example, Bratlie and colleagues argued for a more flexible, tiered regulation of GMOs. In their view, innovation should be

[67] See also Macnaghten and Habets (n 30).
[68] Bain et al (n 46) 270 and 272–273.
[69] Poort and Coman-Kund (n 34) 3.
[70] ibid 55.
[71] Directive 2001/18/EC (n 31) recital 8.
[72] Case C-528/16 (n 35).
[73] Mampuys (n 29) 106–107 and 177–180.
[74] EU Green Deal (n 1).
[75] Commission (EU) (n 25).
[76] ibid 10.
[77] ibid; EU Green Deal (n 1).
[78] See, e.g., Macnaghten and Habets (n 30).

stimulated, but not at the expense of public debate.[79] Similarly, Purnhagen and colleagues pointed to the conflicting goals of the parts of the F2F Strategy that pertain to NGTs, sustainability and the promotion of organic farming.[80]

Beyond the F2F Strategy, claims about sustainability have also emerged in the discussion of Regulation 2018/848, which stipulates that organic farming is not compatible with GMOs.[81] Purnhagen and colleagues called for legal reform that would make organic farming and innovation of NGTs comprehensive, 'allowing the use of modern biotechnology and novel breeding techniques in organic production'.[82] The same authors claimed that organic farming will take up vast expanses of land, which may threaten natural biodiversity. This development could jeopardise the sustainability goals. GM can enable these threats to be addressed through the introduction of innovative breeding techniques.[83] Furthermore, according to Purnhagen and colleagues, from a scientific perspective, the distinction that the legal system draws between 'organic', 'conventional' and 'genetically modified' organisms is no longer credible. Without change, therefore, the legal system may actually obstruct the pursuit of sustainable development.[84]

It is in this context that the co-productive dynamics of the EU regulatory framework for GM have begun to absorb the concept of sustainable development. Its newly acquired prominence is exemplified by the explicit references to sustainable development in the F2F Strategy and a growing awareness of the need for sustainability-oriented legal reform. At the same time, it should not be forgotten that when issues are framed along sustainability lines, there is often a serious risk of the ambiguity of the concept being exploited strategically. While the notion of sustainable development is substantiated by the three pillars of environmental, social and economic development, it remains open to divergent interpretations. As we showed previously, in the practice of regulating GMOs, the meanings that industry and the scientific community attribute to the term 'sustainable food system' differ from those that are favoured by consumers, environmental activists and organic farmers.[85] This divergence may lead to the same concept being deployed to different ends, with the attendant risk of regulatory paralysis.

Kuhlman and Farrington explained this risk by analysing a hypothetical project that scores well on the environmental dimension but poorly on the social and the economic ones. In this scenario, a policy-maker might decide that it would be best to abandon the project because its socio-economic drawbacks outweigh its environmental benefits. In this three-dimensional approach, the environment is afforded too little weight.[86] As Kuhlmann and Farrington wrote, 'since socio-economic aspects are mostly about the well-being of the present generation and environmental ones are about caring for the future, this means the former become twice as important as the latter'.[87] They sought to remedy this analytical problem by proposing that the social and economic dimensions of sustainable development be corralled into a distinct concept. Accordingly, they maintained that sustainable development is primarily about environmental goals, which led them to argue for a two-dimensional approach in which sustainability is balanced against a socio-economic policy objective.[88]

To conclude, sustainable development is of considerable import to the regulation of GM. One potential implication of this elevated importance is that the findings from sustainability analyses, that is, sustainability knowledge, may be used to complement scientific, societal and legal knowledge. In the next section, we inquire whether this hypothesis is logically coherent and whether it is supported by the evidence.

5 | SUSTAINABILITY AS A SEPARATE FORM OF KNOWLEDGE?

Should sustainability knowledge be placed on an equal footing with scientific, societal and legal knowledge? Logically, the veracity of this proposition depends on whether the information that comprises sustainability knowledge can be subsumed into any of the other three forms of knowledge that we described in Section 2. In this section, we will argue that no deconstruction of sustainability knowledge into scientific and societal knowledge can do justice to the content of the former term; the same also holds true of any attempt to incorporate sustainability fully into a legal principle or norm. If our argument is correct, then sustainability should be accepted as a self-standing form of knowledge in regulatory co-production.

We readily concede that many elements of sustainable development can be described as scientific or societal knowledge. This point emerges easily even from the most perfunctory analysis of the SDGs. The contribution that NGTs can make to the emergence of a sustainable food system can be understood as scientific knowledge. More generally, the notion of sustainable development is embedded into technological development and into all analyses of the risks of NGTs. Likewise, NGTs can accelerate progress towards various societal goals, such as ensuring a (healthy) future for our progeny and intergenerational equity more broadly. Here, sustainable development is embedded into economic and social concerns.

Now, as previously indicated, one of the main uses of knowledge in the co-production of technological regulations has to do with the identification of innovations that merit the imposition of new measures, as opposed to technologies that can be governed through measures that are analogous to those that have been applied to technologies in the past. If one approaches the status of sustainable

[79]S Bratlie et al, 'A Novel Governance Framework for GMO' (2019) 20 Science and Society e47812.
[80]KP Purnhagen et al, 'Europe's Farm to Fork Strategy and Its Commitment to Biotechnology and Organic Farming: Conflicting or Complementary Goals? (2021) 26 Trends in Plants Science 600.
[81]Regulation (EU) 2018/848 of 30 May 2018 on organic production and labelling of organic products [2018] OJ L150/1 art 11.
[82]Purnhagen et al (n 80) 606.
[83]ibid 604.
[84]ibid 601–602.
[85]IFOAM Organics Europe, 'Sustainability in Organic Breeding Improving the Entire System or Adjusting Some Genes?' (November 2023).
[86]T Kuhlman and J Farrington, 'What is Sustainability' (2010) 2 Sustainability 3439.
[87]ibid 3439.
[88]ibid 3440.

development from this angle, it soon becomes apparent that treating it as subordinate to other forms of knowledge is counterproductive. We may point to two issues. First, sustainability is more than the aggregation of several interconnected issues, and its deconstruction would inevitably cause regulators to overlook its comprehensiveness. For instance, the value of the SDGs lies in the clarity of the policy goals that they engender. Sustainable development enhances that value because it is integrated into *all* of the SDGs.[89] Second, and relatedly, the concept of sustainable development has strong normative implications. Its deconstruction would cause those implications to be absorbed into non-sustainability discourses. As a consequence, the normative implications in question would lose much of their force in practice.[90]

Let us now turn to the possibility that sustainability knowledge can be absorbed into the concept of 'legal knowledge'. After all, EU law sets the context in which regulations on GM can be revised, and sustainable development has become a policy objective of the EU.[91] This is also the case for the GM regulation in light of the recently adopted Green Deal and the F2F Strategy.[92] Would the foregoing suffice to allow us to embed *all* sustainability knowledge into the concept of legal knowledge? Theoretically, this is unproblematic—sustainable development is a legal principle that guides regulatory change. However, in practice, treating all sustainability-related propositions as instantiations of a legal principle would disrupt the co-productive dynamics of regulation in the Union: Such a development would raise the serious risk of different stakeholders interpreting sustainable development in different ways, rendering the principle unusable in legal practice.

This problem has not gone unnoticed in the literature. Lowe was writing on this issue when he emphasised the importance of sustainable development for judicial reasoning.[93] He understood sustainable development as a meta-law that colours the interpretation of other rules and principles.[94] Lowe considered sustainable development to be an interstitial norm and highlighted its hermeneutical function. Barral also acknowledged the significance of this hermeneutical function, arguing that it 'would be a purely hermeneutical judicial tool, empty of any binding content purporting to regulate legal subjects' conduct'.[95] Sustainable development may be a powerful tool in the hands of judges, but not all disputes are brought to court. Barral focused on the evolutive nature of sustainable development and its strength, writing that 'to be able to function, the contents of sustainable development must evolve, the specificities of each situation and each set of circumstances must be taken into account, and this inherent malleability is not an obstacle to sustainable development's legal classification'.[96] She argued that its flexible but nevertheless identifiable material content makes it a primary norm-guiding principle for States.[97] According to her, then, sustainable development is legal knowledge, in the sense in which we use that term. The same appears to be true of Lowe, who sees it as a meta-law.

We do not deny that both arguments are coherent and, to a certain degree, compelling. However, it can be argued that the view that sustainable development is more than a judicial hermeneutical tool because of its material content, which is at its most developed in Barral's writings, leads to a different conclusion. Although sustainable development may affect the interpretation and drafting of laws and is thus akin to a legal principle, its material content is such that it also influences the regulation surrounding technology and the way in which the needs of society are met. If we treat sustainability considerations *solely* as a form of legal knowledge, we would have to ignore or even repress the latter influences. Furthermore, the tensions between the various SDGs, that is, the various instantiations of sustainable development, are significant, and they are resolved differently in different places, by different institutions and at different times. The concept of a legal principle does not capture this flexibility as soon as a norm assumes the function of a principle in a given corpus of law, its scope becomes limited to the legal framework in which it has been embedded.[98]

Hence, it would be undesirable to deconstruct sustainable development into societal and scientific knowledge, and it would be equally problematic to treat it exclusively as a form of legal knowledge. A possible solution would be to elevate sustainability to the position of a self-standing form of knowledge fulling play to its role in the co-creation of regulation. Beyond its hermeneutical function, it can and should moderate debates about whether and how to regulate a technology. If this is correct, then sustainability knowledge ought to be accepted as a distinct input into the co-production of regulation. It is only by treating it in this way that the regulator can harness the comprehensiveness and the flexibility of the concept.

6 | CONCLUSION

To recapitulate, we set out to analyse the extent to which sustainable development influences the co-production of regulations that target new technologies in the EU. We began by identifying the conventional forms of knowledge that serve as inputs into that co-productive process, namely scientific, societal and legal knowledge. Thereafter, we showed that sustainability-related propositions have gained much traction in the regulation of GM in the EU. It emerged that sustainable development has been so prominent in that regulatory domain that it may be treated as a self-standing form of knowledge. We then proceeded to inquire whether sustainable development *should* be elevated to that status. Our analysis revealed that sustainability cannot

[89]RE Kim, 'The Nexus between International Law and the Sustainable Development Goals' (2016) 25 Review of European Community and International Environmental Law 15.
[90]Kuhlman and Farrington (n 86) 3439.
[91]See, e.g., Treaty of the European Union (consolidated version) [2016] OJ C202/1 arts 3 and 20. See also Treaty of the Functioning of the European Union (consolidated version) [2016] OJ C202/1 art 11.
[92]EU Green Deal (n 1); F2F Strategy (n 1).
[93]V Lowe, 'Sustainable Development and Unsustainable Arguments' in A Boyle and D Freestone (eds), *International Law and Sustainable Development: Past Achievements and Future Challenges* (Oxford University Press 1999) 19.
[94]ibid 31.
[95]Barral (n 5) 389.
[96]ibid 383.
[97]ibid 389–390 and 397–399.
[98]S Perry, 'Two Models of Legal Principles' (1997) 82 Iowa Law Review 787.

be reduced to scientific or societal knowledge. As far as the overlap between sustainability knowledge and legal knowledge is concerned, it is undeniable that sustainability is deeply embedded in EU regulation. However, treating sustainable development solely as an element of the law does not capture the material influence that it exerts on society and technology, not to speak of its evolutionary flexibility. It follows that it would be best to treat sustainability concerns as a separate input into the co-creation process.

These conclusions are based on our observations about the revisions of the GM regulation and the development of the regulatory treatment of NGTs. In these domains, sustainable development caused regulatory change to seem more urgent to regulators. The F2F Strategy and the Green Deal set the scene for the revision of GM regulation. Lawmakers learned that, if the SDGs are to be attained, the regulatory framework must come to accommodate innovations in green biotechnology. Prior to that realisation, efforts to revise GM regulation had been ongoing for decades; it was sustainable development that provided the spur that ultimately brought this process to its conclusion.

Beyond theory, treating sustainable development as a separate input into the co-production of regulation would have important practical benefits. For instance, it may lead to a more profound understanding of various impediments to regulatory change, thereby yielding more effective regulations. Similarly, the interactions between different forms of knowledge, be they desirable or undesirable, would become more transparent. It would also be easier to identify the specific knowledge inputs that are needed for a particular co-production exercise to attain a given objective.[99] At present, many, if not most, of those regulatory processes revolve around sustainability concerns, a trend that shows no signs of abating. Therefore, the elevation of sustainability to the status of a distinct input into the co-production of regulation is likely to prove key to the implementation of the policies that will shape the regulation of technology in Europe.

[99] Poort et al (n 59).

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no datasets were generated or analysed during the current study.

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