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# DEREGULATING NEW GENOMIC TECHNIQUES: THE CHALLENGE OF AMBIGUOUS OBJECTS

Luca Knuth[*] and Ellen Vos[**]

*Abstract**:** Plants derived through new genomic techniques (NGTs) occupy an inherently ambiguous space between genetically modified organisms and conventionally bred plants. Although created through targeted genome editing, many NGT plants are empirically indistinguishable from varieties arising naturally or through traditional breeding. This ambiguity generates corresponding regulatory and epistemic tensions: NGTs do not neatly fit the conceptual architecture that underpins the EU's process-based GMO legislation. The European Commission's 2023 Proposal for a Regulation on NGTs seeks to resolve this tension by introducing two new categories and significantly easing regulatory requirements for NGT plants deemed substantially equivalent to conventional ones. This shift from a precautionary, process-based model toward a product-based approach reflects an attempt to close conceptual uncertainties through legislative boundary-redrawing. Yet, such closure risks conflicting with the precautionary principle, which – while not mandating full authorisation procedures – requires procedural safeguards that keep decisions reversible as new knowledge emerges. Precaution is less a barrier to innovation than an institutional mechanism for learning under conditions of scientific indeterminacy. Scientific expertise itself reflects and reinforces these boundary dynamics. Beyond categorical continuity and blanket exclusion, this article points to a third option: institutionalising productive ambiguity.*

*Keywords: genetically modified organisms, new genomic techniques, risk regulation, EU internal market law, regulatory science, European Food Safety Authority*

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## 1 Introduction

One hundred and seventy stones lined up in rectangular metal boxes arranged into a grid-like structure: Paul Pfarr's installation *Reglement*[1] visualises the result of a slow yet steady process of re-appropriation by nature. Once formed according to industrial norms and standards, the brick/stone surfaces were continuously worn down by the sea's constant friction. These polished, wave-washed remains of industrial production can be read as metaphorical representations of what Hans-Jörg Rheinberger phrased 'outrageous mixtures',[2] being both the product of culture *and* nature, suspended between their increasingly lost, once norm-given cuboid shapes and the sea's steady powers as the forces of the natural.[3]

Outrageous mixtures, such as those described by Rheinberger, find contemporary resonance in the products of new genomic techniques (NGTs), particularly new genomically edited plants. Like Pfarr's bricks/stones, new genomic techniques show a hybridity between biotechnological intervention and the natural. These methods – ranging from targeted mutagenesis to CRISPR-Cas systems to other forms of site-directed nucleases – allow for precise alterations of an organism's genome without necessarily introducing exogenous genetic material. Their products, in the absence of suitable detection methods, may disguise their biotechnological genealogy and, therewith, elude the former distinction between 'naturally bred' and 'genetically modified' plants. These biological artefacts can no longer be comfortably situated on either side of the nature – culture dualism. NGTs produce entities that are both artefact and organism, natural and engineered. They are ambiguous objects. That border blurred by NGTs, though, has always been fuzzy rather than impermeable: plant breeding's long history as a culturalisation technique reveals how humans have continuously intervened in what Enlightenment thought externalised as the non-

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[1] Paul Pfarr, *Reglement* (1991). A picture can be retrieved from the artist's website: <https://paul-pfarr.de/portfolio-item/reglement/> accessed 21 November 2025.

[2] Hans-Jörg Rheinberger, *Iterationen* (Merve 2005) 37. The original German phrase 'unerhörte Mixturen' plays with ambiguity. Whereas a more literal translation could also be 'unheard mixtures', Rheinberger draws on Michel Serres's notion of 'scandalous objects' as developed with a view to the natural contract as a hybrid between legal and socio-biological domains. See Michel Serres, *Le contrat naturel* (Bourin 1990) 14.

[3] For a description of *Reglement*, see Walter Aue, *Orte. Gegenstände. Paul Pfarr* (HM Hauschild 1994) 41. Pointing out the Western, culturally produced and contingent, conceptualisation of the dualism, see Philippe Descola, *Beyond Nature and Culture* (Janet Lloyd tr, University of Chicago Press 2013).

human realm of nature.[4] Through ever more precise interventions in the genome, the processes of wear and tear, appropriation and re-appropriation, as visualised by Paul Pfarr's *Reglement*, reappear on the molecular scale in the shape of insertions and cuts.[5]

Outrageous mixtures challenge categorisation by escaping it. This challenge posed by 'ambiguous objects'[6] may also be a legal challenge and arguably one particularly present in EU internal market regulation. Internal market law is based on the creation of legal categories, establishing 'European objects' as legal constructs that determine which objects are marketable.[7] What these constructs attempt to frame, however, is fluid and changeable. Technological innovations convert existing products and lead to the development of entirely new ones, putting existing legal boundaries to the test.

Thus, EU internal market law must also continuously accommodate changing circumstances, adapt to evolving regulatory subjects, and address new regulatory subjects. This entails conceptual 'boundary work',[8] which often occupies heated political environments:[9] what escapes categories may trigger fears of diffusion. For instance, where

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[4] For a historical overview of plant breeding techniques, see Rolf HJ Schlegel, *History of Plant Breeding* (Routledge 2018).

[5] That promise is, for instance, spelled out by Jennifer A Doudna and Samuel H Sternberg, *A Crack in Creation. The New Power to Control Evolution* (HarperCollins Publishers 2017) xiii.

[6] In the '*objet ambigu*', as coined by Hans Blumenberg, Rheinberger and Serres may find a conceptual predecessor. See Hans Blumenberg, 'Sokrates und das ›objet ambigu‹. Paul Valérys Auseinandersetzung mit der Tradition der Ontologie des ästhetischen Gegenstandes' in Franz Wiedmann (ed), *EPIMELEIA. Die Sorge der Philosophie um den Menschen. Hans Kuhn zum 65. Geburtstag* (Pustet 1964). By contrast, Paul Valéry, 'Eupalinos ou l'Architecte' in *Œuvres,* vol II, Jean Hytier (ed) (Librairie Gallimard 1960) 115 speaks of 'l'objet du monde le plus ambigu', a phrase that may be read as either 'the most ambiguous object' or 'the object of the most ambiguous world'. See Karin Krauthausen, 'Hans Blumenbergs möglicher Valéry' (2012) Zeitschrift für Kunstphilosophie 39–63 at fn 11.

[7] cf Brice Laurent, *European Objects: The Troubled Dreams of Harmonization* (The MIT Press 2022), who sees harmonisation as a legal practice of category-building, which operates through a 'dual disentanglement of European objects from their local ties, on the one hand, and of policy negotiations and the technicalities of market organization, on the other', ibid 44.

[8] The notion is borrowed from Thomas F Gieryn, 'The Demarcation of Science from Non-Science: Strains and Interests in Ideologies of Scientists' (1983) 48 American Sociological Association 781.

[9] cf Viviana Wiegleb and Antje Bruns, 'Working the Boundary: Science–policy Interactions and Uneven Knowledge Politics in IPBES' (2023) 18 Sustainability Science 1069, 1072: 'Boundary work presents a highly political, contextual, and contested process (…)'.

cultivated meat blurs the limits of fresh meat and laboratory products, cultural references to 'Frankenburgers'[10] evoke the horror of techno-sciences turning from an emancipatory project into a threat.[11] GMO regulation in the EU has been particularly marked by such controversies.[12] The strict regulatory requirements under the EU's present GM-specific legislation are seen as hindering innovation and, thus, not doing justice to the particularity of their regulatory subjects.[13] In 2023 and within this context, the European Commission tabled a legislative proposal on plants obtained by new genomic techniques, situating them within a new regulatory framework.[14] Aiming to shift GMO regulation from a process- to a product-centred approach, the proposal envisages two new regulatory categories: one modifying existing rules and one excluding those NGT plants and their derived products from pre-market authorisation requirements. More than two years later, the proposal is still in the legislative process.

This article asks how EU internal market law accommodates the ambiguous figurations of its regulatory objects.[15] Contrasting the

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[10] See Ludivine Petetin, 'Frankenburgers, Risks and Approval' (2014) 5 European Journal of Risk Regulation 168.

[11] Guido Bellenghi and Luca Knuth, 'EU Food Law and the Politics of the Internal Market: The Challenge of Cultivated Meat' (2024) 17 Review of European Administrative Law 39.

[12] Maria Lee, *EU Regulation of GMOs: Law, Decision-Making and New Technology* (Edward Elgar 2008).

[13] For instance, European Academies' Science Advisory Council, 'The Regulation of Genome-edited Plants in the European Union', March 2020, 6 <https://easac.eu/fileadmin/PDF_s/reports_statements/Genome_Editing/EASAC_Genome-Edited_Plants_Web.pdf> accessed 16 December 2025; Sigrid Bratlie and others, 'A Novel Governance Framework for GMO: A Tiered, More Flexible Regulation for GMOs Would Help to Stimulate Innovation and Public Debate' (2019) 20 EMBO Reports, article no 47812.

[14] Commission, '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 (hereinafter: NGT Proposal).

[15] The present analysis will be based on the initial Commission proposal (ibid). Since the publication of the proposal, the European Parliament has adopted proposed amendments (European Parliament, 'Legislative resolution of 24 April 2024 on the 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' [2023] 2023/0226(COD)) and the Council has adopted its negotiating position (Council of the European Union, 'Mandate for negotiations with the European Parliament' (7 March 2025) 6426/25). Only on 4 December 2025, just as this article was being prepared for publication, the European Parliament and the Council reached a provisional agreement. See Council of the European Union, 'New Genomic Techniques: Council and Parliament Strike Deal to Boost the Competitiveness and Sustainability of Our Food Systems' (4 December 2025)

current GMO legislation with those conceptual boundaries envisaged by the Commission proposal (Section 2), it analyses the implications of the present legislative debates for future GMO regulation. Thus, Section 2 reflects on the proposal's compatibility with and implications for the EU's constitutional tenets of precautionary internal market law (Section 3). Turning from a legal-doctrinal to a more theoretical perspective, the role of regulatory science bodies will be considered by drawing on an incident of conflicting views between the GMO Panel of the European Food Safety Authority (EFSA) and the French food authority on the definition of NGTs as a case in point for the intricate role and practices of regulatory science under circumstances of uncertain risk (Section 4). Whilst the Commission evokes scientific necessities for its deregulatory proposal, critiques lament a breach of the precautionary principle. Although law arguably tends to strive for clarity and certainty in its categorical assignments, it will be argued in the concluding Section 5 that there could also be value in temporarily maintaining NGTs plants' precarious state of ambiguity rather than dissolving it.

## 2 From process- to product-based GMO legislation

### *2.1 The current GMO legislative framework*

GMO legislation is crucially based on two conceptual borders. First, it depends on differentiation between what it protects and what it protects against, its regulatory objective and its regulatory object. The central pieces defining these conceptual boundaries for the EU are Directive 2001/18 on the deliberate release into the environment of genetically modified organisms (the GMO Directive)[16] and Regulation 1829/2003 on genetically modified food and feed (the GM Food Regulation).[17] The GMO Directive originates from 1990 and was aimed at regulating the then upcoming use of biotechnology. For this line between GMO legislation's objective and object, at present, the technique of intervention into genetic material is crucial. As shown by the Directive's distinctions

<www.consilium.europa.eu/en/press/press-releases/2025/12/04/new-genomic-techniques-council-and-parliament-strike-deal-to-boost-the-competitiveness-and-sustainability-of-our-food-systems/> accessed 16 December 2025.

[16] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC [2001] OJ L106/1.

[17] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed [2003] OJ L268/1.

between varying techniques, those deemed to result in genetic modification and those deemed not to,[18] such delineation has always been somewhat more complex than the apparent clarity of the nature-culture dualism. Modification is more than intervention of any kind – and necessarily so, given thousands of years of plant cultivation practices that have shaped crops and organisms.[19] Accordingly, the conceptual line between nature to be protected and techniques to be regulated has always been one distinguishing traditional breeding practices and agricultural cultivation, on the one hand, from biotechnological interventions that enable the intentional editing of plants' genetic material, on the other.[20]

The second crucial boundary of GMO legislation results from further differentiation alongside what can be qualified as safe and therefore marketable. Risk is the crucial conceptual gauge to demarcate between those GMOs that may be spread on the fields and processed into products or foods and those that remain banned from release into the environment or placement on the market. Following procedural risk analysis schemes, the current GMO legislation is based on prior approval procedures where approval is largely dependent on the positive outcome of an (environmental) risk assessment.[21] Years of controversy and gridlock have compromised the authority of these authorisation procedures.[22] In particular, some Member States have repeatedly blocked the European Commission's authorisation decisions, bringing comitology to a deadlock.[23] This ultimately led to the insertion of a differentiation mechanism unique within internal market law: pursuant

[18] Art 2(2) GMO Directive read in conjunction with Annex I A thereto.
[19] cf, for instance, as to the interwovenness of the nature-culture-dualism and ultimately pointing to nature itself as a 'hybrid being'. See Rheinberger (n 2) 46ff.
[20] Recital 17 of the GMO Directive, stating that 'techniques of genetic modification which have conventionally been used in a number of applications and have a long safety record' will not fall within its scope.
[21] The lynchpin of GMO legislation: Ludivine Petetin, 'Precaution and Equivalence: The Critical Interplay in EU Biotech Foods' (2017) 42 European Law Review 831, 832. Noting 'technocracy and uncritical Commission compliance with EFSA scientific assessments' in GMO approval procedures turning EFSA into 'the de facto risk manager'. See Marjolein BA van Asselt, Ellen Vos and Bram Rooijackers, 'Science, Knowledge and Uncertainty in EU Risk Regulation' in Michelle Everson and Ellen Vos (eds) *Uncertain Risks Regulated* (Routledge Cavendish 2009) 359, 378.
[22] As to the role of public aversion toward GMOs in the genesis of EU GMO legislation and early (mis-) use of safeguard clauses by Member States to undermine approvals, see Gregory C Shaffer and Mark A Pollack, 'The EU Regulatory System for GMOs' in Michelle Everson and Ellen Vos (eds), *Uncertain Risks Regulated* (Routledge Cavendish 2009) 269, 275–278.
[23] Maria Weimer, 'Risk Regulation and Deliberation in EU Administrative Governance: GMO Regulation and Its Reform' (2015) 21 European Law Journal 622, 627.

to Article 26b of the GMO Directive, Member States may still prohibit the cultivation of genetically modified plants on their territory on the basis of factors other than health or the environment, which may be of a socio-economic nature.[24]

### *2.2 The Commission's proposal*

Not known as such at the time of the adoption of the GMO Directive, NGTs call both of its conceptual borders into question. NGTs refer to targeted mutagenesis techniques which are targeted mutations in the genome without the insertion of foreign genetic material (eg natural, radiation, chemical, as well as CRISPR/CRISPR-Cas9 techniques), and to cisgenesis techniques, whereby genetic material is inserted into a recipient organism from a donor that is sexually compatible with the recipient organism. The adequacy and applicability of the traditional demarcations were first questioned before the European Court of Justice in *Confédération paysanne I*.[25] In its ruling of 2018, the Court confirmed the GMO Directive's applicability to targeted mutagenesis by upholding the distinction between traditional and non-traditional causation of gene mutations.[26] This meant that, in principle,[27] organisms developed through the application of NGTs fall within the scope of the GMO Directive and within the definition of GMOs.[28]

Faced with the *Confédération paysanne I* ruling, the Commission carried out a study at the request of the Council, and concluded that the EU's GMO legislation presented clear challenges for implementation and that there were strong indications that it was not fit for purpose for some NGTs and their products, and that it needed to be adapted to scientific

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[24] As to the genesis of Art 26b of the GMO Directive, see Maria Lee, 'GMOs in the Internal Market: New Legislation on National Flexibility' (2016) 79 The Modern Law Review 317, 319ff.

[25] Case C-528/16 *Confédération paysanne I* ECLI:EU:C:2018:583. For an in-depth analysis, see Hanna Schebesta, 'Confédération paysanne case (C-528/16): Legal Perspective on the GMO Judgment of the European Court of Justice' (2020) Revue européenne de droit de la consommation 369, 372. The ruling was largely confirmed in Case C-688/21 *Confédération paysanne II* ECLI:EU:C:2023:75, paras 43–46.

[26] *Confédération paysanne I* (n 25) para 54.

[27] That applies at least to those NGT organisms developed after the GMO Directive was adopted. See *Confédération paysanne I* (n 25) para 51.

[28] Kai P Purnhagen and others, 'EU Court Casts New Plant Breeding Techniques into Regulatory Limbo' (2018) Nature Biotechnology 799. As to an exception, see *Confédération paysanne II* (n 25) para 64.

and technological progress.[29] Therefore, in its 2023 proposal, the Commission envisions a legislative turnaround from the present, largely process-oriented approach to a (more) result- or product-oriented one. Rather than defining the scope of GM-specific regulation by recourse to the techniques of the genetic modification applied, the result of such modifications should be the decisive factor.[30]

Operating as a *lex specialis* to the existing GMO Directive and the GM Food and Feed Regulation,[31] the Commission's proposal excludes NGT-edited plants as well as products and foods containing them from the scope of the existing frameworks – albeit to a varying extent. It defines NGT plants as any

> genetically modified plant obtained by targeted mutagenesis or cisgenesis, or a combination thereof, on the condition that it does not contain any genetic material originating from outside the breeders' gene pool that temporarily may have been inserted during the development of the NGT plant.[32]

With this proposal, the Commission is re-drawing the boundary between what GMO legislation protects and what it regulates. This re-drawing takes shape through the creation of regulatory categories capturing what it intends to exclude: Category 1 NGT plants (NGT 1) and Category 2 NGT plants (NGT 2) (see Figure 1). NGT 1 plants are plants that fulfil the criteria of equivalence to conventional plants, set out in Annex I of the proposal, or constitute progenies of these NGT plants. This categorical boundary is drawn by a quantitative threshold of no more than 20 genetic modifications of certain types compared to its recipient or parental plant.[33] NGT 2 plants, in turn, are NGT plants other than an NGT 1 plant.[34]

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[29] Commission, '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' SWD(2021) 92 final, 59.
[30] As to the process- versus product-based approach, see Thorben Sprink and others, 'Regulatory Hurdles for Genome Editing: Process- vs Product-based Approaches in Different Regulatory Contexts' (2016) 35 Plant Cell Reports 1494
[31] Arts 5 and 12 of the NGT Proposal. Recital 11 of the NGT Proposal is inconsistent in as much as it indiscriminately refers to all NGT plants and products, whereas Art 5 of the NGT Proposal is plain in its broad wording.
[32] Art 3(2) of the proposal. Targeted mutagenesis and cisgenesis are defined in Art 3(4) and (5) respectively.
[33] Including progeny derived by the crossing of such plants, under the condition that there are no further modifications that would make it subject to Directive 2001/18/EC or Regulation 1829/2003. See Art 3(7) of the proposal.
[34] Art 3(8) of the proposal.

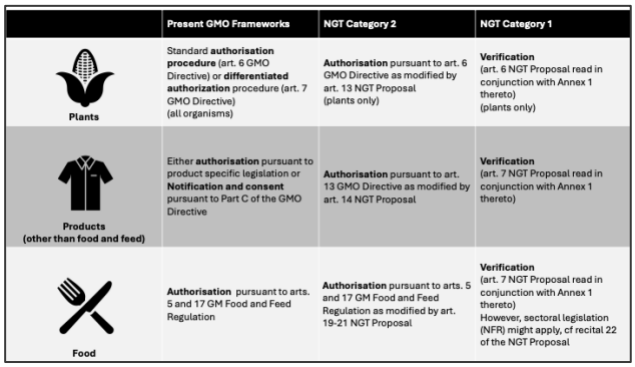

*Figure 1. The Commission's proposal for a regulation on NGTs.*

NGT 2 plants will remain, in principle, subject to the current regimes of the GMO Directive and the GM Food and Feed Regulation, albeit with modifications. Requirements for authorisation or consent prior to deliberate release or marketing for plants[35] and products[36] falling in Category 2, as well as pursuant to the GM Food and Feed Regulation,[37] will remain in place.[38] However, evidentiary requirements concerning the safety of plants and products under Category 2 will be considerably softened and rendered more flexible than existing rules.[39] Whilst Category 2 remains subject to traceability and labelling obligations, the proposal envisages other crucial derogations. In particular, the opt-out mechanism provided for by Article 26b of the GMO Directive would be rendered inapplicable for NGTs, thus eliminating Member States' ability to restrict the cultivation of GMOs within their territory based on compelling grounds, which include socio-economic, environmental, and public policy reasons, despite prior approval having been issued.[40]

In contrast, the proposal aims to almost equate NGT 1 plants and products, including food and feed, with conventionally bred and naturally occurring plants that do not fall under the GMO legislative regime. In particular, NGT 1 plants and products will no longer be

[35] Art 13 of the NGT Proposal provides for derogations from Art 6 of Directive 2001/18/EC.
[36] Art 14 of the NGT Proposal provides for derogations from Art 13 of Directive 2001/18/EC.
[37] Art 19 of the NGT Proposal provides for derogations from Arts 5 and 17 of the GM Food and Feed Regulation.
[38] Art 12 of the NGT Proposal.
[39] cf n 36 and n 37.
[40] Art 25 of the NGT Proposal.

subject to pre-market authorisations.[41] Instead, the proposal stipulates a procedure for verification of their status as Category 1, resulting in a declarative decision.[42] Such a verification procedure is designed as an exclusively technical examination of whether the criteria of Annex 1 are met without any individual, substantive risk assessment.[43] The distinction between Categories 1 and 2 rests essentially[44] on the basis of a quantitative threshold defined as a maximum of 20 substituted or inserted nucleotides.[45] Presumably, this distinction would assign a significant proportion of plants falling within the scope of the NGT Regulation to NGT 1 plants.[46]

### *2.3 Re-drawing boundaries*

By equating NGT 1 plants with conventional plants, the Commission's proposal envisages a re-drawing of the boundary between its subject of protection and its regulatory object, nature and biotechnological intervention, by means of the scope of the legislation. In addition, it also re-draws the line between what is qualified as marketable and what remains banned. It would replace the common mechanism of precautionary European risk regulation by delegating individual risk choices to executive decision-making, whilst tying executive discretion created thereby to procedural, primarily epistemic, limitations, essentially to legislative *a priori* authorisation. Therewith, the proposed NGT Regulation would essentially turn the risk analysis-scheme followed by both the GMO Directive and the GM Food and Feed Regulation on its head.

The Commission invokes a bundle of interconnected arguments in support of its proposal, including environmental, economic, and consumer benefits. Easing regulatory requirements would increase biotechnical innovation,[47] help step-up agricultural production,

[41] Art 5 of the NGT Proposal.
[42] Art 6 of the NGT Proposal.
[43] Recital 20 of the NGT Proposal.
[44] The distinction also depends on other factors listed in Annex I to the NGT Proposal.
[45] Point 1 of Annex I to the NGT Proposal.
[46] Finja Bohle and others, 'Where Does the EU-path on New Genomic Techniques Lead Us?' (2024) Front Genome Ed 6:1377117, especially at 2, identify that of a list of 148 NGT plant applications, of those 85 assigned to fall under the scope envisioned by the NGT proposal, 94% would either clearly fall, or could be assumed to fall, under the scope of NGT Category 1. cf also J Menz and others, 'Genome Edited Crops Touch the Market: A View in the Global Development and Regulatory Environment (2020) Frontiers in Plant Science 11:586027, doi: 10.3389/fpls.2020.586027.
[47] See Recital 10 of the NGT Proposal.

increase consumer choice by offering a wider range of products,[48] and reduce dependence on agri-food imports.[49] Crop resistance, in addition, is expected to foster pest-reduction[50] and improve climate adaptability.[51] Notably, linking the proposal to broader political strategies for a more sustainable, climate-friendly and climate-adaptable agriculture and food system,[52] the Commission also broadens the balancing exercise underlying internal market law. The traditional striking of a balance between free trade on the one hand and health and environmental protection on the other[53] now extends to addressing environmental concerns on both sides, situating it within the broader risk contexts of biodiversity loss and climate change. The actual sustainability benefits of NGT plants, however, remain clouded in uncertainty for now. Moreover, the sustainability incentives foreseen by the proposal remain limited in their reach,[54] while the proposal's de-regulatory effects apply to all NGTs falling within its envisaged scope regardless of their sustainability benefits.

Re-drawing categorial boundaries in a complex system such as the EU internal market GMO regulation inevitably generates numerous follow-up border demarcations, which themselves have political repercussions. Beyond the sustainability aspects, many of the diverse points of contention arise as subsequent problems stemming from the proposal's category formation. Three contentious points have raised particular attention in ongoing legislative debates.

First, excluding the application of the GMO Directive's differentiation mechanism for opt-outs in accordance with its Article 26b, and putting the re-definition of the criteria for NGTs 1 in the Commission's hands, leads to considerable centralisation.[55] Any future adjustment to the criteria defining Category 1 would be subject to the democratically deficient mechanism of the implementing acts.[56]

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[48] NGT Proposal 2, and Recital 38 thereof.
[49] ibid 2, placing the proposal in the context of current geo-political developments.
[50] ibid 4.
[51] ibid 11.
[52] cf Recital 3 of the NGT Proposal.
[53] cf Marjolein BA van Asselt, Michelle Everson, and Ellen Vos, 'Trade Versus Health and the Environment', in Marjolein BA van Asselt, Michelle Everson, and Ellen Vos (eds), *Trade, Health and the Environment: The European Union Put to the Test* (Routledge 2014) 3–8.
[54] Naturally, the incentives foreseen by Art 22 of the proposal apply solely to NGT 2 plants and products.
[55] Art 27(a) of the NGT Proposal.
[56] As to the limited role of the European Parliament within the procedure of adopting implementing acts, see Guido Bellenghi and Ellen Vos, 'Rethinking the Constitutional

Second, a further point of contention concerns the delimitation of conventional and organic farming (so-called 'coexistence'). The ban[57] on the use of genetically modified organisms in organic foods, as foreseen by the proposal, may collide with the absence of traceability provisions for NGT 1 organisms. *De lege lata*, remaining unchanged according to the proposal,[58] any use of genetically modified plants, including NGT plants, in organic farming is prohibited. However, the envisaged labelling of NGT 1 seeds[59] will hardly ensure coexistence in practice. Even where farmers manage to keep plant NGT 1 seeds out of their fields, the problem might sneak in through the backdoor of the food production supply chain. By the time plants are processed into foodstuffs, processors in the subsequent production chain would hardly be able to trace the plants of Category 1 contained therein.[60] The consequence could be a hidden change in what is known as organic food – below the perceptive thresholds of EU law. A similar downstream 'border adjustment' concerns the Novel Food Regulation.[61] While, in principle, NGT 1 food could fall within the scope of the Novel Food Regulation,[62] it is unclear whether food business operators, whom the Regulation tasks to verify whether their product falls within its scope, even know whether they are processing NGT 1 plants given the absence of traceability-requirements.[63]

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Architecture of EU Executive Rulemaking: Treaty Change and Enhance Democracy' (2024) European Journal of Risk Regulation 1, 13–14.

[57] Especially Art 5(f)(iii), 11 Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 [2018] OJ L150/1.

[58] Art 5(2) of the NGT Proposal read in conjunction with Art 5(f)(iii) and 11 of Regulation (EU) 2018/848.

[59]Art 10 of the NGT Proposal.

[60] This argument was, *inter alia*, made in a legal expert opinion commissioned by the German parliamentary group of BÜNDNIS 90/DIE GRÜNEN: Georg Buchholz, Kommissionsvorschlag einer Verordnung über Neue Genomische Techniken (NGT): Zur Verletzung des Vorsorgeprinzips, Gutachten im Auftrag der Bundestagsfraktion Bündnis 90/Die Grünen (Berlin 2023) 38–39 <www.gruene-bundestag.de/fileadmin/dateien/downloads/Weitere_Dokumente/Gruene_im_Bundestag_Gutachten__Vereinbarkeit_des_Kommissionsvorschlags_zu_NGT_mit_dem_Vorsorgeprinzip.pdf> accessed 21 November 2025.

[61] Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 [2015] OJ L327/1 (hereinafter: NFR).

[62] Recital 22 of the NGT Proposal, referring to Art 3 (2)(vii) NFR.

[63] Buchholz (n 60) 32.

Third, the patentability of NGT plants has been a major point of contention in legislative debates. A potential ban on patenting in a future NGT Regulation, arising in the discussion,[64] could run into conflict with the European Patent Convention. Formally, the European Patent Convention is not subject to European Union law and its Convention States would be obliged to respect and enforce patents, whilst such patents would be banned under EU law.

De-regulating NGTs does not dissolve the conceptual boundaries enshrined in the present GMO regulation. Conceptual boundaries reappear in new shapes and forms. The *de facto* deregulation of NGT 1 plants gives rise to subsequent legal demarcation problems, sparking political controversy, where reaching a compromise is particularly difficult and time-consuming. While the proposal secured a favourable vote in the European Parliament in 2024,[65] it took until April 2025 for the Council to finally reach a negotiating agreement,[66] therewith triggering the trilogue process.

## 3 Beyond precaution?

NGT plants and products thus seem to escape categorisation – being both products of biotechnological innovation and substantially equivalent to traditionally bred or naturally occurring plants. However, this ambiguous figuration is called into question from a legal perspective. Re-drawing the boundary between what is to be regulated as a GMO or GM product and what is to be treated as 'traditional' plant or product risks conflicting with the EU's commitment to the precautionary principle as enshrined in international and EU primary law.

### *3.1 Cartagena Protocol*

Excluding NGT Category 1 plants from pre-market authorisation requirements means that these plants could enter European fields, food, and products without ever undergoing a scientific risk assessment.[67] As

[64] Sofia S Manzanaro, 'Why Patents Keep Stalling EU Rules for Gene-edited Crops' (*Euractiv*, 13 March 2025 <www.euractiv.com/news/why-patents-keep-stalling-eu-rules-for-gene-edited-crops/> accessed 16 December 2025.
[65] European Parliament (n 15).
[66] Council of the European Union (n 15).
[67] A potential risk assessment of NGT 1 pursuant to the Novel Food Regulation would, in any case, not satisfy the requirements of the Cartagena Protocol. See Silja Vöneky and others, 'Compatibility of the EU Proposal for a Regulation on Plants Based on Certain New Genomic Techniques with the Cartagena Protocol on Biosafety' (April 2025) 30 <www.bmleh.de/SharedDocs/Downloads/DE/_Landwirtschaft/Gruene-

argued by critics, the absence of any environmental risk assessment prior to release into the environment could constitute a breach of the Cartagena Protocol (CP) on Biosafety to the Convention on Biological Diversity.[68] Following an essentially precautionary approach, according to Annex III(6) of this Protocol, the Convention parties must carry out a risk assessment on a case-by-case basis. Neither a merely technical verification procedure alone nor abstract scientific inquiries prior to the (prospective) adoption of legislative carte blanche de-regulation can meet the Protocol's clear wording.

Yet, a combination of both pre-legislative scientific studies and future verification of their status could be argued to meet the Protocol's requirements.[69] Such an argument presupposes that in pre-legislative studies an abstract scientific finding of equivalence between NGT 1 plants and naturally occurring or traditionally bred plants was made and that the verification procedure applies this finding *in concreto* to individual plants, therewith satisfying the requirement of Annex III(6) of the Cartagena Protocol.[70] As noted by Silja Vöneky and others, such an approach 'carries with it the assertion that the potential adverse effects or risks associated with NGT 1 plants are the same for all intended use cases and for all potential receiving environments, and that any further differentiation is not scientifically necessary'.[71] Whether such an approach meets the requirement of a scientifically sound risk assessment is primarily a matter of science.[72] Legally, as Kahrmann and Leggewie argue, such a line of argument benefits from the Annex's flexible[73] wording.[74]

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Gentechnik/NGT-Gutachten-EU-Vorschlag.pdf?__blob=publicationFile&v=4> accessed 16 December 2025.

[68] Buchholz (n 60) 29–30. For an in-depth analysis of the proposal's compatibility with the Cartagena Protocol, see Vöneky and others (n 67) 30ff, concluding on non-compliance with the Cartagena Protocol, *inter alia*, due to the removal of a notification requirement, ibid 42.

[69] Jens Kahrmann and Georg Leggewie, 'European Commission's Plans for a Special Regulation of Plants Created by New Genomic Techniques' (2024) 9 European Papers 21, 34; Vöneky and others (n 67) 36–37.

[70] ibid.

[71] Vöneky and others (n 67) 36.

[72] ibid.

[73] ibid. According to Annex III(6), the required information may vary and, according to Annex III(8), the elements of a risk assessment apply only 'as appropriate'. This flexibility thus rests on terminological indeterminateness, which itself requires concretisation in a given case. Rather than utilising the leeway granted through the Cartagena Protocol, a combination of abstract pre-legislative risk assessment and subsequent technical verification is a waiver of its use in individual cases.

[74] Kahrmann and Leggewie (n 69) 34.

Regardless of this substantial question, however, it is questionable whether this duty to perform a risk assessment is even applicable. The Protocol applies to 'the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health'.[75] Whilst NGTs undoubtedly qualify as GMOs as defined by EU law,[76] their qualification as living modified organisms within the meaning of the Cartagena Protocol is questioned.[77] Whilst NGTs are clearly both 'biotechnological techniques' and 'modern' in as much as they have not been used in traditional breeding and selection, their capacity to overcome natural physiological reproductive or recombination barriers may be either understood as referring to the result of an individual application of a technique or as referring to the general capacity of a certain technique to achieve such a result.[78] Whereas certain applications of NGTs may not overcome natural physiological reproductive or recombination barriers, NGTs' general potentiality to do so is beyond doubt.[79] The process- versus product-oriented distinction thus reappears as an interpretative question. Excluding NGTs, in part or in total, from the scope of the Protocol would hence require overcoming its originally process-oriented *ratio*.[80]

### *3.2 The precautionary principle*

Yet, regardless of the Cartagena Protocol's applicability, the precautionary principle as a general principle of EU law and an element of its primary law binds the EU legislature.[81] The principle's key function is commonly seen in broadening decision-making discretion where

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[75] Art 4 CP.
[76] See *Confédération paysanne I* (n 25) and Section 2.1 above.
[77] Kahrmann and Leggewie (n 69) 34–35.
[78] A living organism is defined in Art 3(g) of the CP as any living organism 'that possesses a novel combination of genetic material obtained through the use of modern biotechnology'. Modern biotechnology in that sense is defined in Art 3(i) CP as 'the application of', *inter alia*, 'in vitro nucleic acid techniques (…) that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection'. See, in more detail, Vöneky and others (n 67) 30.
[79] See, with further references, F Koller and others, 'The Need for Assessment of Risks Arising from Interactions between NGT Organisms from an EU perspective' (2023) 35(27) Environmental Sciences Europe 1, 4.
[80] Rightly sceptical: Vöneky and others (n 67) 17.
[81] See Art 191(2) TFEU and, in particular, Case T-392/02 *Solvay Pharmaceuticals v Council* EU:T:2003:277, para 121; Joined Cases T-74/00, T-76/00, T-83/00 bis T-85/00, T-132/00, T-137/00 and T-141/00 *Artegodan and others v Commission* ECLI:EU:T:2002:283, paras 183–184.

scientific knowledge as to the existence or extent of a risk remains uncertain, thus serving as a 'shield' to be invoked by the regulator.[82] This way, the precautionary principle provides optionality to interrupt – theoretically infinite – knowledge production in favour of tutioristic decision-making capabilities. Thereby, the principle does not simply abolish the evidence-based mechanism underlying EU risk regulation. It is not simply the 'law of fear' as critics have suggested.[83] Rather, it demands sufficient proof for the persistence of uncertainty[84] and links broadened regulatory discretion to procedural duties, mandating:

> […] first, identification of the potentially negative consequences for health (or the environment) of the proposed use of the substance at issue, and, secondly, a comprehensive risk assessment of the risk to health (or the environment) based on the most reliable scientific data available and the most recent results of international research.[85]

This nexus between discretion and scientific assessments is what gives the precautionary principle its double-headed figuration. On the one hand, it broadens regulatory discretion to adopt decisions in the absence of conclusive scientific evidence and, on the other, restricts this discretion through procedural duties. This proceduralised imperative to gather knowledge is, however, context dependent. Where uncertainties prevail, the principle may allow for cutting assessments short. The regulatory authority is not obliged to wait for anticipated information whatever it takes; an illustrative example can be found in the neonicotinoid case law.[86] Here, the Court emphasised the regulatory

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[82] For the shield-and-sword-metaphor, see Joanne Scott and Ellen Vos, 'The Juridification of Uncertainty: Observations on the Ambivalence of the Precautionary Principle within the EU and the WTO' in Christian Joerges and Renaud Dehousse (eds), G*ood Governance in Europe's Integrated Market* (OUP 2002) 254.

[83] Seminally, see Cass R Sunstein, *Laws of Fear* (CUP 2005). As to the criticism of the precautionary principle with further references, see Kristel de Smedt and Ellen Vos, 'The Application of the Precautionary Principle in the EU' in Harald A Mieg (ed), *The Responsibility of Science* (Springer 2022) 164.

[84] On defining uncertainty, see Anne-May Janssen and Marjolein BA van Asselt, 'The Precautionary Principle in Court: An Analysis of Post-Pfizer Case Law' in Marjolein van Asselt, Esther Versluis, and Ellen Vos (eds), *Balancing between Trade and Risk: Integrating Legal and Social Science Perspectives* (Routledge 2013) 208ff.

[85] See, for instance, Case C-77/09 *Gowan Comércio Internacional e Serviços* ECLI:EU:C:2010:803, para 73.

[86] See Joined Cases T-429/13 and T-451/13 *Bayer CropScience AG and Others v European Commission* ECLI:EU:T:2018:280; and Case C-499/18 P *Bayer CropScience and Bayer v Commission* ECLI:EU:C:2021:367, especially para 121. cf Giulia C Leonelli, 'Balancing Public Health and Environmental Protection and Economic Stakes? Bayer CropScience and the Court's Defence of the EU Socially Acceptable Risk Approach' (2021) 58 Common Market Law Review 1845, especially 1873. For an earlier example, see Case T-70/99 *Alpharma v Council* ECLI:EU:T:2002:210, para 173.

discretion of the Commission to set a deadline for EFSA, precluding consideration of the information applicants were expected to submit only later.[87] However, the duty to improve the information base might then extend beyond the precautionary measure's adoption through monitoring and with a view to the potential revision of such a measure.[88]

The precautionary principle may hence also serve as a 'sword' where a measure or lack thereof is deemed not to be restrictive enough. In the EU's limited judicial fora, contestations of measures not being restrictive enough are rare.[89] Arguably, where the objectives of effective protection of health and environment are assigned primacy through the precautionary principle,[90] a scientific information base underlying a decision not to act in light of uncertainties is equally essential. A rare example of a challenge to a legislative act's validity based on an alleged breach of the precautionary principle is the *Blaise* ruling.[91] The preliminary reference ruling delivered in 2017 found the Plant Protection Products Regulation[92] to be compatible with the principle. The Court recognised the legislature's broad discretion, where it has to 'strike a balance between several objectives and principles, and of the complexity of the application of the relevant criteria' by limiting its review to that of manifest errors.[93] Nevertheless, it derived some basic requirements for the legislative design: the obligation to generate information and knowledge may oblige legislators to make procedural arrangements that enable the 'identification of possible negative consequences' and a 'comprehensive assessment of the risks to health based on the most reliable scientific data available and the most recent results of international research'.[94]

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[87] Joined Cases T-429/13 and T-451/13 *Bayer CropScience AG and Others* (n 86) paras 314 and 500; Case C-499/18 P *Bayer CropScience and Others* (n 86) paras 135–136.
[88] See Commission, 'Communication from the Commission on the precautionary principle' (Communication) COM(2000) 1, 19.
[89] Sabrina Röttger-Wirtz, 'Case C-616/17 *Blaise and Others*: The Precautionary Principle and Its Role in Judicial Review: Glyphosate and the Regulatory Framework for Pesticides' (2020) 27 Maastricht Journal of European and Comparative Law 529, 534.
[90] See *Alpharma v Council* (n 86) para 356.
[91] Case C-616/17 *Blaise* ECLI:EU:C:2019:800.
[92] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC [2009] L309/1 (hereinafter Plant Protection Products Regulation).
[93] *Blaise* (n 91) para 50.
[94] *Blaise* (n 91) para 46.

Transferring such requirements from one legislative area to another comes with uncertainties. In the *Confédération paysanne I* ruling, the Court seemingly presumed the principal risk potential of NGT organisms and a persistent state of uncertainty which justified subjecting them to the GMO Directive's strict pre-market authorisation requirements.[95] The Court even stated that a blanket exclusion of mutagenesis-derived organisms from the scope of the GMO Directive 'would compromise the objective of protection pursued by the directive and would fail to respect the precautionary principle which it seeks to implement'.[96] The *Confédération paysanne I* ruling concerned an interpretative question of the GMO Directive and thus a legislative act expressly adopting a precautionary approach.[97] Scrutinising a potential NGT Regulation, though, would concern its validity in the absence of such a legislative commitment.

Invoking the precautionary principle as a sword against NGT de-regulation would need to draw on its procedural dimension. The proceduralisation of risk choices under the precautionary principle reveals how, from a legal perspective, every risk regulatory decision is always taken from an *ex ante* perspective of limited knowledge about future events. Risk assessment is not a matter of stating the known or expected, but an exercise in generating and evaluating knowledge that is functionally oriented towards testing the *status quo* of that knowledge and putting risk managers in as competent a position as possible.[98] Scientific knowledge is therefore not always an existing resource, but may be generated *ad hoc*.[99] The contexts of application influences the methodologies used. Risk assessment is thus the search for the unknown rather than a reiteration of what is already known.[100] Where legislative frameworks capture whole technological categories,

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[95] *Confédération paysanne I* (n 25) para 48, pointing to the referring court and 'the material before the Court' without specifying it.
[96] *Confédération paysanne I* (n 25) para 53.
[97] cf Art 1 of the GMO Directive.
[98] For instance, Case T-13/99 *Pfizer Animal Health SA v Council* ECLI:EU:T:2002:209, para 158.
[99] Karl-Heinz Ladeur, *Postmoderne Rechtstheorie: Selbstreferenz Selbstorganisation – Prozeduralisierung* (2nd edn, Duncker & Humblot 1995) 209–210. As to a moulding of application and method, see Ino Augsberg, *Informationsverwaltungsrecht* (Mohr Siebeck 2014) 10.
[100] *A fortiori*, risk assessors' tasks are not limited to gathering information of – mostly industrial – notifiers (on the role of economic actors in EU risk regulation, see Marta Morvillo and Maria Weimer, 'Who Shapes the CJEU Regulatory Jurisprudence? On the Epistemic Power of Economic Actors and Ways to Counter it' (2022) 1 European Law Open 510, 514ff) but includes own knowledge gathering and a re-evaluation of studies submitted. cf, with a view to the Plant Protection Products Regulation, Case C-616/17 *Blaise* and Others ECLI:EU:C:2019:190, Opinion of AG Sharpston, para 67.

contingency is inherent in the very categories forged in these legislative acts. NGTs serve as a prime example of how technological innovations craft entities that challenge existing categorisations. Such regulation always attempts to capture what remains inherently fluid.[101] Pre-structuring individualised risk choices through legislative acts is hence a balancing exercise drawing on abstractly identified uncertainties associated with a given regulatory category. Providing for individualised risk assessments is neither a mechanism to bar what is safe nor to reiterate what is known. By demanding knowledge-generation and assigning decision-making responsibilities, the principle commonly operates as a decision-enabler, not a determinant. Where individualised decisions are at stake, it may thus not necessitate intervention but instead broaden discretion. Where legislative frameworks capture whole technologies, it may need to safeguard its own future application by demanding anticipatory mechanisms that allow contingent information bases to be revisited in light of changed circumstances. Excluding NGT 1 from GMO specific requirements arguably threatens to cement a once-made regulatory choice rather than anticipate future invocations of the precautionary principle.

The precautionary principle does not in every case mandate the establishment of pre-market authorisation requirements stipulating full risk assessments.[102] There are other mechanisms to ensure that future, not yet foreseeable, risk may be mitigated. Even where no pre-market authorisation requirements exist, post-market monitoring may serve as a means to allow intervention, where yet unforeseen risks materialise. Where an approval decision is *de facto* irreversible once it has been made,[103] especially in the absence of suitable detection methods, there is nevertheless much to suggest that only anticipatory regulatory intervention can enable knowledge to be generated that allows decision-making by democratically accountable institutions on the basis of the best possible evidence.[104] As illustrated for instance by NGT 2 plants or

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[101] '[V]ery Rapid Development of NGTs in the Recent Years: EFSA, Updated Scientific Opinion on Plants Developed through Cisgenesis and Intragenesis' (2020) 20 EFSA Journal, article no 76211, 15.

[102] Similarly, Gerd Winter, 'The European Union's Deregulation of Plants Obtained from New Genomic Techniques: A Critique and an Alternative Option' (2024) 36 Environmental Sciences Europe, article no 47, 1, 10.

[103] The irreversibility of the release into the environment of GMOs is recognised, for instance, in recital 4 of the GMO Directive. See also *Confédération paysanne I* (n 25) para 49. cf for the CP: Ruth Mackenzie and others 'An Explanatory Guide to the Cartagena Protocol on Biosafety' (IUCN 2003) IUCN Policy and Law Paper No 46, para 52.

[104] As to reversibility as one factor of determining the acceptability of risk levels, see, for example, Joined Cases T-429/13 and T-451/13 *Bayer CropScience* (n 86) para 124.

products, the scope of risk assessments can be rendered largely flexible, allowing assessment duties to be tailored to individual plants and uncertainty profiles. To safeguard its future applicability under not yet foreseeable circumstances, the principle requires legislative anticipation through process design. This implies anticipating processes of knowledge generation and legal bases for future precautionary interventions where such a novel state of knowledge hesitates to do so. In this sense, the precautionary principle may not determine political action toward tutiorism but acts as a tool to ensure that the choice, be it one to act or one not to act in light of uncertainties not yet foreseeable, is vested in politically accountable and legally capable decision-makers.

## 4 Defining NGT 1 plants: a question of boundary work

### *4.1 Diverging opinions*

The precautionary principle is not the only alleged determinant invoked in debates concerning the assignment of NGT plants and products. Whilst the precautionary principle remains remarkably absent in the proposal's text, it contains a seemingly contrasting argument, which presents its de-regulatory shift toward a product-based approach less as a choice but as a matter of necessity. The argument is one of substantial equivalence: subjecting NGT 1 plants to legislative requirements, so the Commission argues, would be disproportionate given their substantially equivalent molecular figuration to the extent of non-detectability.[105] In other words, (substantially) equivalent regulatory subjects should be treated as (substantially) equivalent in regulation.[106] NGTs' de-regulation is presented as a legal necessity triggered through scientific factualities. Being a hybrid between a scientific finding of equivalence and proportionality as a constitutional principle, such an argument presents legislative decisions as mere transpositions from scientific findings rather than a political choice.[107] In the case of NGTs, such transposition lies in the proposal's boundary work determining the crucial distinction between its two categories: the proposal attempts to define science-based criteria delineating NGT 1

[105] See recital 14 of the NGT Proposal.
[106] As to substantial equivalence as both assessment methodology and regulatory strategy, see Petetin (n 21) 834; cf also Les Levidow, Joseph Murphy and Susan Carr, 'Recasting Substantial Equivalence: Transatlantic Governance of GM Food' (2007) 32 Science, Technology and Human Values 26.
[107] Such alignment of legal categories to the non-legal, scientific representations of the regulatory subject can thus be read as an ontologisation, understood as the attempt to align legal categories to alleged external realities.

from NGT 2, thereby establishing what, being substantially equivalent to naturally occurring or traditionally bred plants, is exempted from GM-specific regulatory requirements.

The proposal was welcomed by various scientific associations, with the German Research Foundation, for example, seeing it as 'reflect[ing] the state of the art in science and the environmental and, geopolitical realities'.[108] Yet, even where broad consensus persists, science is hardly a monophonic choir. This holds in particular where risk scenarios are not easily calculable or predictable. Due to the complexity of genomes, their potential release into the environment, and the open-textured technological configuration, GMOs are a prime example of such uncertain risk scenarios.[109] Confronted with naturally limited scientific certitude as to the possibilities and severities of potential hazards, regulators paradoxically tend to resort to science to justify their decisions on these uncertain risks, a mechanism which has been coined as the 'uncertainty paradox'.[110] The Commission's rhetoric in support of the criteria to distinguish between the two categories of NGT plants can be read as an example of the uncertainty paradox at work. Despite the simplicity of the Commission's argumentation and its reliance on scientific studies,[111] the crucial quantitative delineation between the proposal's two categories, ie NGT 1 and NGT 2, in its Annex 1 has encountered some reservations.[112] The French Agency for Food, Environmental and Occupational Health & Safety (ANSES) has, most

[108] See, for instance: The German Research Foundation, 'Keeping Europe Up to Date: A Fit-for-Purpose Regulatory Environment for New Genomic Techniques' (19 July 2023) <www.dfg.de/resource/blob/289576/statement-genomic-techniques.pdf> accessed 21 November 2025.

[109] See, with further references, Marjolein BA van Asselt and Ellen Vos, 'EU Risk Regulation: The Role of Science in Political and Judicial Decision-making' in Hans-Wolfgang Micklitz and Takis Tridimas (eds), *Risk and EU Law* (Edward Elgar 2015) 117, 123; van Asselt, Vos and Rooijackers (n 21) 365–366.

[110] Marjolein BA van Asselt and Ellen Vos, 'The Precautionary Principle and the Uncertainty Paradox' (2006) 9 Journal of Risk Research 313.

[111] These are mentioned, first, in the Commission's impact assessment report. See Commission, 'Commission Staff Working Document, Impact Assessment Report' SWD(2023) 412. The questions concerning the equivalence criteria are then taken up in a Council technical paper: Council, Regulation on new genomic techniques (NGT) – Technical Paper on the rationale for the equivalence criteria in Annex I' (2023) 2023/0226(COD). As rightly pointed out by Vöneky and others (n 67) fn 224, the Commission's proposal mentions neither these documents nor the relevant studies themselves, but quotes EFSA studies, which do not engage with the relevant questions.

[112] More direct criticism is, for instance, expressed by Juliane Mundorf, Samson Simon, Margret Engelhard, 'The European Commission's Regulatory Proposal on New Genomic Techniques in Plants: A Focus on Equivalence, Complexity, and Artificial Intelligence' (2025) 37 Environmental Sciences Europe, article no 143, 1, 7: '(...) not scientifically sound'.

prominently,[113] called into question its suitability.[114] Called upon by the European Parliament, EFSA was asked to address ANSES's concerns.[115] Both ANSES and EFSA have come to seemingly diverging conclusions as to the potential risks and uncertainties associated with NGTs. Divergencies between EFSA's GMO Panel and ANSES concerning, in particular, these criteria from scientific perspectives, may serve as a micro case study to illustrate how not only legislative but also regulatory science practices ultimately resort to boundary work under circumstances of uncertain risks. Despite the Commission's emphasis, this scientific question underpinning the proposal is apparently ambiguous, as varying interpretative positions persist, none of which appears illegitimate at first sight.[116]

At the outset, it is noted that the Commission did not rely on EFSA[117] for the definition of an NGT 1 plant, but relied on a scientific literature

[113] The Dutch advisory Committee on Genetic Modification COGEM did not agree either with the definition in Annex 1 and noted that the criteria in Annex 1 lacked scientific foundation and needed clarification and adjustment, and proposed a new definition. See COGEM, Opinion to revise the criteria in Annex I of the EC proposal for new legislation for NGT plants (2023) CGM/231124-01 <https://cogem.net/app/uploads/2023/11/231124-01-Advice-to-amend-Annex-1-EC-NGT-proposal_ENG.pdf> accessed 21 November 2025.

[114] ANSES, Opinion on the scientific analysis of Annex I of the European Commission's Proposal for a Regulation of 5 July 2023 on new genomic techniques (NGTs) – Review of the proposed equivalence criteria for defining category 1 NGT plants (Internal request No 2023-AUTO-0189) (Maisons-Alfort 2003) <www.anses.fr/en/system/files/BIOT2023AUTO0189EN.pdf> accessed 20 November 2025.

[115] EFSA's response was commissioned as a scientific opinion pursuant to Article 29 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [2002] OJ L31/1, (hereinafter: GFL) by the European Parliament following publication of ANSES's analysis <https://open.efsa.europa.eu/questions/EFSA-Q-2024-00178?search=genomic&sort=lastUpdatedTime> accessed 21 November 2025.

[116] IRGC, 'Introduction to the IRGC Risk Governance Framework' (IRGC 2020) 18, defining: 'Ambiguity results from divergent perspectives on the risk, including the likelihood and severity of potential adverse outcomes'; cf also Ortwin Renn, Andreas Klinke, and Marjolein BA van Asselt, 'Coping with Complexity, Uncertainty and Ambiguity in Risk Governance: A Synthesis' (2011) 40 Ambio 231, 240.

[117] See Arts 22(2), 22(5c) and 23 GFL.

analysis carried out by its own services.[118] In its opinion,[119] EFSA considers the Commission's position to be based on scientific evidence, stating that such changes could also occur in plants with 20 nucleotide modifications, and concluding that 'it is scientifically justified to consider that a plant showing 20 modifications or less compared to its parental could be the result of spontaneous mutations'.[120] This disagreement between ANSES and EFSA shows that different regulatory science actors may respond differently to uncertain risk scenarios. Although, in a nutshell, EFSA's GMO Panel holds the equivalence criteria in the proposal's Annex I to be plausible, its opinion is an exercise in multi-dimensional boundary work, ie the drawing of conceptual boundaries, on at least three different levels.

A first differentiation takes implicit shape in substantial equivalence as a comparative assessment method. Equivalence does not denote equality, but a *substantial* form of equality that already incorporates, at a fundamental level, a difference between the entities compared. It thus does not claim sameness, but rather a negligible dissimilarity. In this sense, equivalence lies in the indeterminacy of the causal pathways leading to a mutation as linguistically reflected in the subjunctive mode used by the EFSA GMO Panel.[121] The notion of equivalence therefore concerns the determination of a hypothetical alternative causality. Equivalent, here, is what can be referred, with somewhat equal plausibility, to the hypothetical possibility of different causal origins. Thus, as a comparative assessment methodology, substantial equivalence does not strive for exactness. Rather, it constitutes an *ad hoc* heuristic for coping with the complexity inherent in non-static objects of inquiry and offers pragmatically oriented balancing between the desire for scientific objectivity and certitude.[122] As a comparative assessment approach, substantial equivalence depends on choices

[118] European Commission Services, Technical Paper Document 14204/23, Rationale for the equivalence criteria in Annex I to the proposal for a Regulation on plants obtained by certain new genomic techniques, (16 October 2023). See Council, Interinstitutional File 2023/0226(COD).
[119] EFSA GMO Panel, 'Scientific Opinion on the ANSES Analysis of Annex I of the EC Proposal COM (2023) 411 (EFSA-Q-2024-00178)' (2027) EFSA Journal 22(7), e8894.
[120] ibid 5.
[121] ibid.
[122] FAO/WHO, 'Safety Aspects of Genetically Modified Foods of Plant Origin: Report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology (World Health Organization 2000) 4; Henry I Miller, 'Substantial Equivalence: Its Uses and Abuses' (1999) 17 Nature Biotechnology 1042: 'a shorthand'.

defining what spatial interactions, and what temporal range, should be considered in the comparative assessment.[123]

Applying substantial equivalence as a scientific method is not value-free but represents an operationalisation of values through judgement that is always based on contingent knowledge preceding the risk assessment.[124] Objectivity and certitude, therefore, should not be conceived as externally given, static properties of scientific knowledge but as results of their operationalisation as values within scientific practice.[125] Hence, choosing alternative heuristics or applying substantial equivalence differently would both remain possible.[126] Relying on substantial equivalence is a regulatory choice that should arguably be taken in full knowledge of those choices made in its application.

Second, at its core, the conclusion drawn from hypothetical alternate causality towards equivalent risk propensity is not a purely descriptive, representational account of an external reality, but a claim about *causal possibilities*. Even if conservative, an estimate remains a valuational, approximative statement. Turning from representational to estimative statements, a temporal discontinuity is introduced, shifting from past to future. Its peculiarity lies in the fact that it is not mere conjecture, but firmative speculation,[127] seeking anchoring in data on past events – a temporal transposition that connects the past observance of mutations and their effects with the projected effects of technological

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[123] As to different scientific cultures visible in ecologists' and microbiologists' definition of these scales, see Stefan Böschen and others, 'Scientific Cultures of Non-Knowledge in the Controversy over Genetically Modified Organisms' (2006) 15 GAIA 294, 296.

[124] See, in general, Nick J Fox, 'Postmodern Reflections on "Risks" and "Life Choices"' in Deborah Lupton (ed), *Risk and Sociocultural Theory* (CUP 1999) 12: 'Inevitably, risk assessment must begin with some prior knowledge about the world, what is "probable" and what "unlikely", what is "serious", what is "trivial" or seemingly "absurd". Such judgements may derive from "scientific" sources, or may depend on "common-sense" or experiential resources; either way, the perception of a hazard's existence will depend on these judgements. How the judgement is made (that is, what is counted as evidence to support the assessment), is relative and culturally contingent'.

[125] For conceptualising objectivity as a historically contingent value, see L Daston and P Galison, *Objectivity* (Zone Books 2010).

[126] eg Koller and others (n 79) 9–10.

[127] For different types of speculative practices, see Susanne Labenicht, 'Cultures of Speculation: Histories of Speculation' in Jeanne Cortiel and others (eds), *Practices of Speculation: Modeling, Embodiment, Figuration* (transcript 2020) 31–48 *passim*; for the difference between firmative and affirmative speculation, see Uncertain Commons, *Speculate this!* (Duke University Press 2013) 27.

intervention.[128] This rupture, from a historically representative to a prognostically approximative dimension of meaning, has dual implications. Both the object of inquiry, ie the 'epistemic thing',[129] and the mode of representation are displaced; the epistemic focus moves from what *is* or *has been* toward what *could be*. Such anticipation is no longer a merely observational practice. It transcends the sphere of statistical description of past events by means of temporal transposition toward a present description of hypothetical futures utilising theoretical assumptions.[130]

The third differentiation in EFSA's opinion is institutional in nature. By raising the question of whether a statement or a regulatory criterion still stands on the secure footings of science, it must demarcate its own territory vis-à-vis the regulator's. Whilst it considers the search for hypothetical, alternative causation of NGT-induced modifications to be scientifically substantiated, the definition of the quantitative threshold is flagged by EFSA as the risk manager's responsibility.[131] Resorting to the threshold of 20 modifications as foreseen in Annex I, according to EFSA's Panel, would be a 'conservative' number supported by scientific studies.[132] Yet, although the Commission's rhetoric relies[133] on a link between equivalence and risk-levels in its proposal, and ANSES's position[134] here, EFSA's Panel avoids engaging with this point, ie whether the substantial equivalence understood as a gene-edit

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[128] Where uncertain risks are concerned, the firmative nature of these speculative practices may reach limits in lacking data availability. Then, scientific risk assessment may increasingly have to operate in affirmative modes by considering not only what is probable but also what is potential. See van Asselt, Vos, and Rooijackers (n 21) 362.

[129] Hans-Jörg Rheinberger, *Toward a History of Epistemic Things: Synthesizing Proteins in the Test Tube* (Stanford University Press 1997) 28ff.

[130] Thus, such a risk statement rather mirrors what Elena Esposito denoted as a 'present future', a contingent prognosis that is to be distinguished from actual 'future presents'. Elena Esposito, *Die Fiktion der wahrscheinlichen Realität* (tr Nicole Reinhardt, Suhrkamp 2007) 50ff.

[131] EFSA GMO Panel (n 119) 5.

[132] ibid.

[133] Recital 13 of the Proposal clearly sets out the risk-based *ratio* underlying the differentiated regulatory approach, which is based on the presumption that NGT 1 plants show a lower degree of risk-propensity than those in Category 2. Moreover, Rec 14 of the Proposal states that NGT 1 'should be treated as plants that have occurred naturally or have been produced by conventional breeding techniques, given that they are equivalent and that their risks are comparable (…)'.

[134] ANSES (n 114) 25–26, noting a 'failure to take account of the relationship between the proposed equivalence criteria and the associated risks', *inter alia,* by rejecting the assumption that the quantitatively determined substantial equivalence would translate into equivalent traits and risk levels for having 'no scientific base' and concluding a 'lack of scientific basis in terms of risk' with a view to the maximum number of modifications set out in Annex I to the Proposal.

remaining below this threshold would serve as a credible indicator of risk potentiality.[135] Instead, by holding that '(…) the proposed limit of 20 modifications for an NGT plant to be considered a Category 1 NGT is a risk management decision (…)', it seeks shelter in deferring this conclusion from substantial equivalence to risk propensity to the risk manager.[136]

### *4.2 Diverging opinions assessed*

Scientifically, neither position needs to be invalid. Conversely, either approach can be read as expressing forms of epistemic humility. ANSES makes the limits in the current state of knowledge transparent by saying what cannot yet be said with certitude. EFSA's opinion restricts what is said to what can be said with sufficient certitude. These approaches have different implications for how the relation between scientific assessment and political choice plays out. ANSES's approach puts regulatory science actors in a position closer to the 'fifth branch',[137] a means of governance through epistemic *ex ante* control that allows for scrutiny by explicating the information base underlying the exercise of public authority – including its limitations. Revealing presumptions and premises underpinning substantial equivalence opens an opportunity for public scrutiny of these choices. Conversely, EFSA's opinion evades any explicit engagement with the remaining uncertainties or the estimative nature of such a conclusion. Rather than explicating the limits in scientific knowledge, EFSA's panel engages in a third dimension of 'boundary work',[138] ie the practice-immanent, rhetorical self-constitution of scientists *vis-à-vis* what was intellectually excluded as non-science.[139] Here, such boundary work operates to shift responsibility for the contentious questions concerning the credibility of the conclusion from substantial equivalence to risk propensity from risk assessors to risk managers. As it has done in the past, EFSA's Panel thereby limits the scope of its own opinion by evading discussions of remaining uncertainties and rendering its opinion an assurance of

[135] EFSA GMO Panel (n 119) 5: 'These equivalence criteria are not meant to define levels of risk but to allow certain NGT plants to be classified as equivalent to conventionally bred plants (recital 14, European Commission Proposal)'.
[136] ibid.
[137] Sheila Jasanoff, *The Fifth Branch: Science Advisors as Policymakers* (Harvard University Press 1998).
[138] The notion of boundary-work was coined by Gieryn (n 8).
[139] ibid 782.

plausibility.[140] Its silence on uncertainties and its only implicit recognition of ambiguity in the questions at stake foster risk managers' ontologising rhetorics and threaten to turn regulatory science bodies into 'active propagators of the uncertainty paradox'.[141]

This points to a more general finding concerning the very boundary worked on by EFSA's Panel. What is a political question and what science can provide answers to, where the realms of science and politics meet and differentiate one another, is ultimately not a fixed line separating the realm of the factual from the valuational, the objectively true from the politically biased. Science's place within risk regulation is thus not a pre-given Archimedean spot, but the result of mutual differentiation practice: on the one hand, the law distances science procedurally and institutionally from political decision-making; on the other hand, scientific practice differentiates itself from the non-scientific. This very boundary work is itself necessarily subject to context-dependent interpretation through the various actors involved and is thus both ambiguous and contingent in its figuration.[142]

Invoking the rhetoric of an objectively mediated scientific reality, and aiming to align regulatory treatment with it, risks obscuring discretion and implicitly inverts the roles of risk assessors and managers.[143] Ultimately, this mechanism may *de facto* shift decision-making capacities from politically accountable to more 'obscure' bodies.[144] Moreover, it also risks misrepresenting the realities of science.[145] Regulatory science does not mechanically mirror reality but operationalises value judgements. Determining the scales underlying substantial equivalence entails judgements of relevance; and drawing prognostic inferences from empirical studies presupposes theoretical

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[140] Uncertainty aversion and boundary work have been shown to be present in past risk assessments performed by EFSA's GMO Panel. See van Asselt, Vos and Rooijackers (n 21) 369ff.
[141] ibid 375.
[142] Gieryn (n 8) 781: 'Thus, "science" is no single thing: its boundaries are drawn and redrawn inflexible, historically changing and sometimes ambiguous ways'. cf also Sheila Jasanoff, 'Contested Boundaries in Policy-relevant Science' (1987) 17(2) Social Studies of Science 195, 224, seeing boundaries' fluidity caused not only by science's indeterminateness, but also the 'politically charged' nature of the differentiations at stake.
[143] Soemni Kasanmoentalib, 'Science and Values in Risk Assessment: The Case of Deliberate Release of Genetically Engineered Organisms' (1996) 9 Journal of Agricultural and Environmental Ethics 42, 45–46.
[144] Vesco Paskalev, 'The Clash of Scientific Assessors: What the Conflict over Glyphosate Carcinogenicity Tells US about the Relationship between Law and Science' (2020) 11(3) European Journal of Risk Regulation 524.
[145] ibid.

assumptions. Even science's boundary work to differentiate itself from politics is not a matter of redrawing a stable line but a context-dependent reiteration of a boundary between non-static categories. Recognising value-operationalisation in regulatory science is not an exercise in debunking. Rather, it allows us to see the perspectivity and ambiguity within scientific practices. Governing biotechnological risks is inextricably bound to the best possible scientific knowledge. Translating such knowledge into political choice and ultimately into legal forms, however, should be based on a vision of science that is aware of its inherent value judgements and limitations. In highlighting underlying premises and making inherent limitations visible to the broader public, regulatory science, understood as a 'fifth branch', finds its true *raison d'être*, rather than in the provision of epistemic authority through proofs of plausibility.

## 5 Concluding remarks: 'without ambiguity, no change, ever'[146]

Boundaries, ultimately, demand assignment. They are filters that include and exclude, that permit or prohibit entrance. But new regulatory subjects may escape categorisation as is the case with NGTs and hence put legal boundaries to the test. In an attempt to accommodate for biotechnological progress and foster innovation, the Commission's proposed NGT Regulation foresees far-reaching legislative boundary work that could fundamentally alter the Union's legislative landscape governing GMOs. Such work involves new boundaries being drawn and established ones being substituted. By creating two new legislative categories, a future NGT Regulation would lower and make more flexible the regulatory burden for its NGT Category 2 whilst providing for deregulation through exclusion from GMO specific regulatory requirements for those plants and products falling within the proposal's Category 1.

Shifting from process- to product-based regulation aims to escape the political, legal, and scientific ambiguities that NGT plants exhibit. Yet, it arguably risks conflicting with the precautionary principle. Although the principle does not imply an obligation that could compel legislators to subject a particular category of technology to preventive authorisation requirements, it nevertheless establishes certain, basic procedural requirements. Its application presupposes anticipation of what remains yet unknown by establishing procedures for generating knowledge and providing legal bases allowing for action in what for the

[146] Paul Feyerabend, *Killing Time. Autobiography.* (Chicago University Press 1995) 179.

moment are unforeseeable circumstances. Instead of anticipating the yet-unknown, the proposal's legislative blanket de-regulation of NGT 1 cements a current state of knowledge through its legislative form. Although the principle may thus demand a legislative design which allows for reversing once-made decisions when new information becomes apparent, it does not provide a determinant for pre-market authorisation schemes. How to regulate NGTs is ultimately a matter of legislative discretion within the confines of EU constitutional law.

Nor can science provide for the NGT disambiguation that risk managers may long for.[147] In a broader sense of the word, ambiguity refers to openness to varying interpretative positions. It thus denotes semantic indeterminacy. As such, ambiguity is not just the persistence of diverging scientific positions. It is the potentiality of interpretative divergency. This ambiguity, arguably, is not a result of science's failure to establish conclusive findings, but a necessary feature of scientific progress. With Rheinberger, ambiguity can be seen as underpinning the operations of experimental practices: 'At the core of science as a process, of science in the making, there is ambiguity. It is ambiguity that incites science to get away from the actual state of the art toward an open future'.[148] Experimental systems are creative exercises of recursive differentiation, providing material arrangements allowing the yet indeterminate epistemic thing to materialise as traces to be transposed into data and assembled into models.[149] Such ambiguity does not vanish in scientific statements intended to inform decision-makers' choices. Given the inherent fluidity of its subject, assessing the uncertainties of NGT plants inevitably involves choices that balance objectivity, certitude, and pragmatic reasons to provide the best possible predictive statements to inform political decision-makers. As the application of substantial equivalence to NGTs illustrates, the practices of regulatory science operationalise value judgements rather than offering value-free, purely mechanical observation. Instead of rubberstamping scientific opinions and shielding behind rhetorical images of scientific conclusiveness, risk managers should actively engage with the choices and limitations inherent in the information they receive. For this to happen, regulatory science bodies need to disclose rather than avoid these limitations. When EFSA's GMO Panel shifts responsibility onto

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[147] Harald A Mieg, 'Science as a Profession: And Its Responsibility' in Harald A Mieg (ed), *The Responsibility of Science* (Springer 2022) 67, 84.
[148] Hans-Jörg Rheinberger, 'On Science and Philosophy' (2018) 5 Crisis & Critique 341, 345. cf Rhein Berger (n 129) 28: '(...) a genuinely polysemic procedure defined by ambiguity, not one just limited by finite precision'.
[149] Tracing these steps, see Hans-Jörg Rheinberger, *Split and Splice: A Phenomenology of Experimentation* (University of Chicago Press 2023) 11ff.

risk managers by resorting to boundary work rather than engaging with controversies and remaining uncertainties, it risks reinforcing the Commission's tendency to hide behind science.

In scientists' operationalisation of ambiguity in their attempts 'to get away from the actual state of the art', one may find a parallel in the arts. Pfarr's installation *Reglement* does not resolve the hybridity of the bricks/stones; it curates it. The arrangement into metal boxes evokes the rational order of regulatory classification — the metal grid as an emblem of law's ambition to systematise, to produce comparability, and to contain. One might read the installation as showing regulation's failure to catch what has already fled its conceptual containers by its fragmentary shape. Yet, one might equally see it as showing the stones' hybrid genealogy: what becomes visible in the space in-between the bricks/stones and their cuboid grid is what has become invisible through marine erosion: the once norm-given, industrial shape reappears as the negative, empty space in-between. Instead of treating ambiguity as a deficit to be overcome, the installation preserves the stone's ambiguous state. Therewith, ambiguity becomes a productive condition for reflection – a site where the boundaries between nature and culture, between object and norm, are continually renegotiated.[150] Hence, scientific and artistic practices are dwelling on, rather than dissolving, ambiguity. This shows how there might be value in provisionally stabilising a state of indeterminacy rather than striving for certainty and finality.[151] From a legal perspective, though, deciding remains inescapable. And the law often strives for clear boundaries to foster legal certainty. Ultimately, NGT plants and products will either have to be granted access to fields and the market or remain barred therefrom. Yet, where regulatory procedures face ambiguity, inclusivity rather than exclusion is crucial.[152] And where knowledge remains inherently provisional, learning remains an indefinite routine rather than a finite process.

Instead of maintaining and visualising NGT's inherent ambiguity, both positions on how to deal with NGT plants and products, their inclusion in GMO legislation's scope or their exclusion through deregulation, seek to stabilise meaning where meaning is in flux. The assumption underpinning the categorical distinction envisaged in the Commission's proposal is that certain genomic alterations, when

[150] cf Aue (n 3).
[151] Mary Shelley's literary image of Frankenstein's monster teaches us that hybridity is not inherently bad; after all, the monster was capable of holding moral values and feeling love.
[152] See Renn and others (n 116) 235 and 237.

technically verifiable as potentially achievable through conventional breeding, may be deemed natural enough to warrant regulatory exemption. In effect, the regulatory *objet ambigu* is then reclassified as a non-object of regulation. What remains is a legal fiction of purity, produced through a technical verification procedure that conceals rather than engages with the entanglement of culture and nature that NGTs embody. The law thus restores its categorical comfort at the price of denying the very ambiguity it is confronted with. The typical precautionary mechanism of pre-market authorisation requirements, in turn, stabilises indeterminacy by providing for proceduralisation rather than legislative assignment *carte blanche*. Risk analysis as a procedural schism underpinning the current GMO legislation reflects science's provisionality and opens *fora* for deliberation that – in principle – may reach beyond more narrow scientific grounds. As defective as the underlying separation of science and policy may be,[153] it does serve as a legally structured site for coordination between scientific and political rationalities.[154] Yet, invoking the precautionary principle as a supra-legislative imperative demanding NGTs assimilation into GMO legislation's established tracks may equally produce closure. Transmuting from precaution to prohibition by establishing evidentiary requirements in excess of the uncertainties at stake, the principle's rigid application could foreclose the exploratory governance that novel biotechnologies require.[155] Insofar as the principle is mobilised to enforce categorical continuity – to treat the novel as if it were already known – it may equally obstruct the very reflexivity that ambiguity calls for. In this sense, reliance on precaution as an imperative for categorical continuance mirrors the tendency to suppress hybridity through de-regulation.

A third option could reside in the border territory between the opposing tendencies of ontological alignment and categorical containment. Exploring this border-territory rather than striving for

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[153] See, for instance, Karl-Heinz Ladeur, 'The Introduction of the Precautionary Principle into EU Law: A Pyrrhic Victory for Environmental Protection? Decision-Making under Circumstances of Complexity in Multi-Level Political Systems' (2003) 40 Common Market Law Review 1455, 1465. In the US context, see Deborah G Mayo and Rachelle D Hollander, *Acceptable Evidence: Science and Values in Risk Assessment* (OUP 1991) xi; Vern R Walker, 'The Myth of Science as a "Neutral Arbiter" for triggering Precautions' (2003) 26 Boston College International and Comparative Law Review 197, 252. With a view to EU GMO regulation, see Kasanmoentalib (n 143) 42.

[154] cf Maria Weimer, 'Risk Regulation and Deliberation in EU Administrative Governance: GMO Regulation and Its Reform' (2015) 21(5) European Law Journal 622, 627.

[155] See Ino Augsberg, *Informationsverwaltungsrecht. Zur kognitiven Dimension der Steuerung von Verwaltungsentscheidungen* (Mohr Siebeck 2014) 60–69.

one-sided assignment could sustain a space of openness where uncertainty and ambiguity are operationalised. This would mean re-inventing the verification procedure foreseen by the NGT proposal[156] to turn it into such an intermediary zone allowing regulatory practice to accommodate gradations of (non-)knowledge, evolving understandings of risk and uncertainty, and societal implications of its regulatory subject. Instead of seeking quantitative assurance, such an extended verification process would need to involve qualitative judgement about the need for further assessment and create a forum for coordination between science and societal preferences. In this sense, regulation could become an exercise in maintaining productive ambiguity – an institutionalised experiment in keeping categories permeable long enough for learning to occur. By widening the boundary rather than policing it, EU law could reflect the dynamic co-production of knowledge and normativity,[157] allowing the governance of NGTs to mirror the contingent, experimental nature of the sciences that risk regulation both depends on and aims to regulate.

[156] Arts 6 and 7 of the NGT Proposal.

[157] As to the conceptual genesis and meaning of co-production, see Brice Laurent, 'Co-production' in Ulrike Felt and Alan Irwin (eds), *Elgar Encyclopedia of Science and Technology Studies* (Elgar 2024) 13–23; For its application to EU internal market law, cf the contributions in Maria Weimer and Anniek De Ruijter (eds), *Regulating Risks in the European Union: The Co-Production of Expert and Executive Power* (Hart Publishing 2017).