European Innovation Council

Report

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The Law and Economics of Regulation of Engineered Living Materials in the EU: Prospects for Investments and Innovation

Expert report for the EIC Pathfinder Portfolio „Engineered Living Materials“

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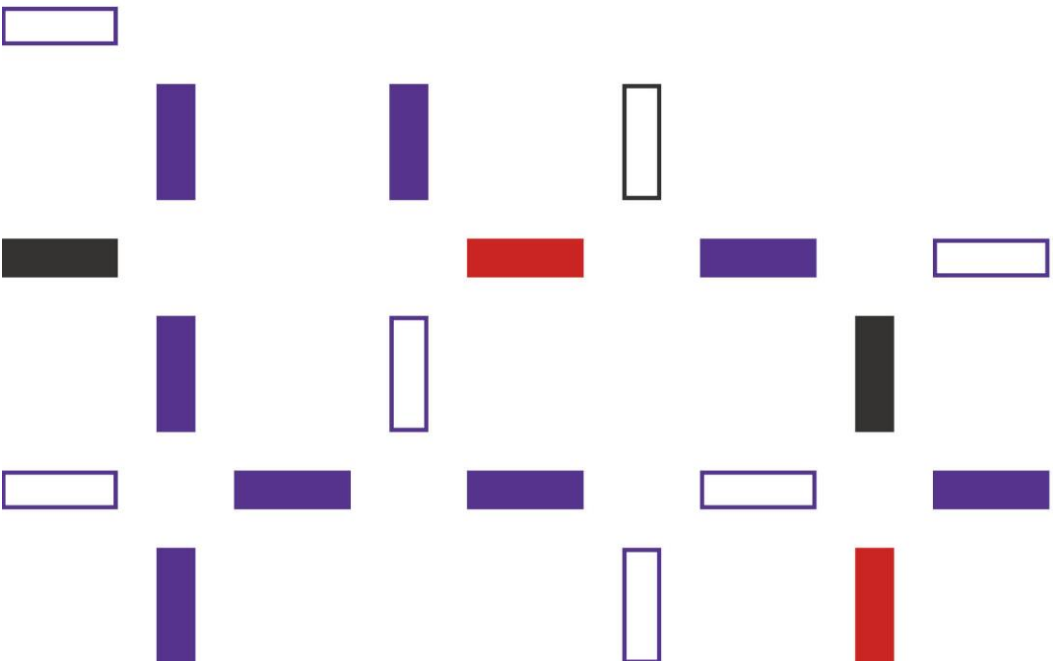

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INTRODUCTION

Over the past decade, national and international stakeholders have shown significant interest in developing Engineered Living materials (ELMs). ELMs represent an emerging technology. They were recognized among the Top 10 Emerging Technologies of 2025 by the World Economic Forum[1] and were included in the OECD's forecasting as a foundational technological development that will reach maturity in the next 5-10 years[2] .ELMs, while not having a strict legal definition in the EU, are used for a wide range of applications.[3] The European Innovation Council (EIC) supports the development of ELMs via its Pathfinder Challenge, aiming "*to seize the opportunity to position strategically Europe at the forefront of the ELMs field, which is still in its infancy.*"[4]

A debate has emerged in the literature and among regulators and stakeholders regarding how best to assess and regulate applications of engineered living materials (ELMs) in a way that ensures market access and fosters innovation, while simultaneously safeguarding human health and the environment. Critical decisions must be made concerning both the anticipated benefits and the potential safety implications of these technologies. Decision-making is further complicated by uncertainties surrounding future risks and benefits.[5]

Many ELMs rely on genetically modified organisms (GMOs), often generated using new genomic techniques (NGTs)[6], either as genetically modified microorganisms (GMMs) for the production of specific compounds or as integral components of the final ELM product.

The question has arisen as to the extent to which ELMs fall within the scope of EU regulations governing GMMs and GMOs, and what implications this may have for current and future investment in ELM technologies.

This report examines the existing EU legal framework for GMOs and GMMs, with a particular focus on the challenges associated with its application to ELMs. It assesses the extent to which these regulations apply to ELMs currently under development, drawing on an analysis of seven projects funded by the EIC. The report then introduces an economic framework designed to evaluate how the regulatory environment influences incentives to invest in ELMs. Finally, it discusses potential regulatory approaches for ELMs and links these to the economic assessment.

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[1] Centre for the Fourth Industrial Revolution, *Top 10 Emerging Technologies of 2025 Flagship Report*, World Economic Forum, June 2025, https://reports.weforum.org/docs/WEF_Top_10_Emerging_Technologies_of_2025.pdf accessed 25. April 2026.

[2] OECD *Synthetic biology in focus' – Policy issues and opportunities in engineering life* (OECD Science, Technology and Industry Working Papers), 24 February 2025 https://www.oecd.org/en/publications/synthetic-biology-in-focus_3e6510cf-en.html accessed 25. April 2026.

[3] Yonatan Chemla, Connor J. Sweeney, Christopher A. Wozniak, Christopher A. Voigt, 'Design and regulation of engineered bacteria for environmental release', (2025) 10 *Nature Microbiology* 281; Erratum (2025) 10 *Nature Microbiology* 1025.

[4] European Innovation Council (EIC), *EIC Pathfinder challenge: Engineered living materials* (EIC 2021), https://eic.ec.europa.eu/eic-funding-opportunities/eic-pathfinder_en, accessed 19 November 2025.

[5] Kai Purnhagen, Justus Wesseler, 'Precaution and the Precautionary Principle: A View on the EU – The Example of Modern Biotechnology', in Alain Marciano and Giovanni Battista Ramello (eds.), *Encyclopedia of Law and Economics* (Springer 2025).

[6] 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.

The authors were granted access to the relevant project proposals of the EIC ELMs Pathfinder Portfolio, and an online session was organised in which the projects were presented. Based on these analyses, the authors provided a first draft of current regulation and future recommendations regarding the future development and regulation of ELMs. This draft was presented to the scientists involved in the EIC programme at an in-person meeting, where the authors discussed the report with stakeholders. In several subsequent feedback sessions authors were provided with in-depth written stakeholder feedback from industry, science, regulative bodies, and investors. Based on this feedback, this report was drafted.

While this report reflects the state-of-the-art at the time of writing in 2025, discussions on changing the regulatory environment of NGTs in the EU and the revision of the pharmaceutical legislation are currently underway, as well as preparation of a European Biotechnology Act, which may have implications on the findings of this report. Where appropriate, we make reference to the documents discussed as they have been publicly available until 15. January 2026.

Research Question

The general question this report investigates is: How does EU GMO and deliberate release legislation intersect with the regulation for different application areas (food, consumer goods, construction, environmental remediation, and health) as exemplified by selected ELMs?

TERMINOLOGY AND METHODOLOGY

Terminological Clarifications

We are using the following terms in the following ways.

Genetically Modified Organisms

When we refer to Genetically Modified Organisms (GMOs), we are referring to the definition of Art. 2 (2) Directive 2001/18. The Directive defines a genetically modified organism (GMO) as "any organism, with the exception of human beings, in which the genetic material has been altered in a manner that does not occur naturally through mating and/or natural recombination." The determination of whether the Directive applies, and whether a given organism qualifies as a GMO, is hence (except for human beings) independent from the type of organism used but based on the techniques employed. Consequently, the term GMO is construed broadly to include animal and plant cells in culture, viruses, viroids, and any other cellular or non-cellular biological entity capable of replication or of transferring genetic material. For example, if ELMs use bacteria, yeast, fungi, algae, bacteriophages, or artificial cells, these are all within the GMOs definition of the Directive in so far as they are using the respective techniques. The use of human cells depends on whether they can be qualified as "human being". Arguably, only the human "body" is exempted from the GMO definition. Once they are isolated from the human body, we would argue that they are not exempted any longer from the GMO definition.

If the GMO law applies depends on the techniques used for modification. The techniques whose use results in the application of the GMO laws are enumerated in Annex IA, Part 1 (techniques resulting in GMOs), Annex IA, Part 2 (techniques not resulting in GMOs), and Annex IB (techniques exempted from the Directive, such as randomly induced mutagenesis and the cell fusion of plant cells from organisms capable of exchanging genetic material through conventional breeding methods). The majority of related legislative instruments (Including e.g. Regulation (EC) No 1829/2003 on GM food and feed and Directive 2009/41/EC[7] on contained use of genetically modified microorganisms)[3] refer back to this definitional framework. Small linguistic differences (for example when the exemptions of Directive 2001/18 are incorporated in the definition such as in Art. 3 Nr. 1 Regulation (EC) No 1830/2003) may have an impact on the legal interpretation. Despite of the mutagenesis exemption, the Court of Justic of the European Union (CJEU)' case law has been interpreted in such a way that organisms obtained through recently developed mutagenesis techniques, such as directed mutagenesis including e.g. CRISRPR Cas 9, fall within the scope of the EU GMO regime under Directive 2001/18/EC because these techniques lack a "long safety record."[8] Under the law, the scientific classification, nomenclature, or technical specifications of a given technique are largely immaterial. Accordingly, for purposes of legal classification, it is immaterial, for example, how extensive the genetic modification is, whether the induced change results in an entirely novel sequence, or whether the sequence previously existed. What is determinative is whether the technique has a long-standing record of safe application. This is normatively legally presumed for all techniques which had been

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[7] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed OJ L 268, 1–23.

[8] Case C-528/16, *Confédération paysanne and Others v Premier ministre and Ministre de l'agriculture, de l'agroalimentaire et de la forêt*, EU:C:2018:583, with comment Kai Purnhagen, 'How to manage the Union's diversity: The regulation of New Plant Breeding Technologies in Confédération paysanne and Others', (2019) 56 *Common Market Law Review* 1379–1396.

in use before 2001, the date Directive 2001/18 came into effect. As a result, organisms derived from conventional mutagenesis methods, such as chemical or radiation-induced mutagenesis, remain excluded under Annex IB of the Directive. This judgment is crucial for the regulation of ELMs, as many of them rely on or make use of methods using recently developed mutagenesis techniques.

Genetically Modified Microorganisms

When we refer to Genetically Modified Microorganisms (GMMs), we are referring to the definition of Art. 2 (b) Directive 2009/41/EC[9] as "a micro-organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination." GMMs are also GMOs in the sense of Art. 2 (1) of Directive 2001/18, hence the respective definitional challenges, in particular regarding human cells, also apply to GMMs. Comparable to the definition of a GMO, the application of the Directive 2009/41/EC is independent from the type of organism used, but based on the techniques employed. As a consequence, the term "micro-organism" is construed broadly to include animal and plant cells in culture, viruses, viroids, and any other cellular or non-cellular biological entity capable of replication or of transferring genetic material. For example, to determine whether the Directive 2009/41/EC applies, it is generally not of relevance if ELMs use bacteria, yeast, fungi, algae, bacteriophages, or certain types of artificial cells because all are part of the definition. It should be noted, however, that the Commission proposed on page 12 of the latest Proposal for a Regulation as regards simplification and strengthening of food and feed safety requirements[10] a distinction that "the reference to GMMs in the definition of 'produced from GMOs' should cover only micro-organisms in the biological sense and exclude animal and plant cells in culture."

Whether the GMO law is applicable depends on the technique used for modification. Consequently, Annex I to the Directive refines this definition by enumerating (i) techniques regarded as inducing genetic modification (Part A) and (ii) techniques excluded from this classification (Part B). Part A covers, inter alia, recombinant nucleic acid techniques creating new combinations of genetic material by inserting nucleic acid molecules produced outside the organism into a vector system for subsequent incorporation into a host organism, as well as techniques involving the direct introduction of heritable material prepared externally into a micro-organism, including by micro-injection, macro-injection, or micro-encapsulation. Part B excludes techniques such as in vitro fertilisation, natural processes (conjugation, transduction, transformation), and polyploidy induction, provided no recombinant nucleic acid molecules or GMMs obtained by non-exempted methods are involved.

Annex II of Directive 2009/41/EC establishes exemptions from the Directive's scope of application, and consequently from its definition of GMMs. Mirroring Annex IB of Directive 2001/18/EC, these exemptions extend to "mutagenesis" in the way the Court interprets this term according to the existence of a "history of safe use" of the respective technique. Although the ECJ judgment interpreting the mutagenesis exemption concerned only Directive 2001/18/EC, the latter is widely regarded as a *de facto* horizontal framework law governing GM products within the European Union.[11] Accordingly, the Court's interpretation may be understood as extending to the mutagenesis exemption under Directive 2009/41/EC, thereby subjecting organisms obtained through recently developed mutagenesis techniques to the regulatory

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[9] Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms OJ L 125, 75–97.

[10] Proposal for a Regulation as regards the simplification and strengthening of food and feed safety requirements COM(2025) 1030 final.

[11] Kai Purnhagen, 'How to manage the Union's diversity: The regulation of New Plant Breeding Technologies in *Confédération paysanne and Others*' (2019) 56 *Common Market Law Review* 1379–1396.

framework established therein.

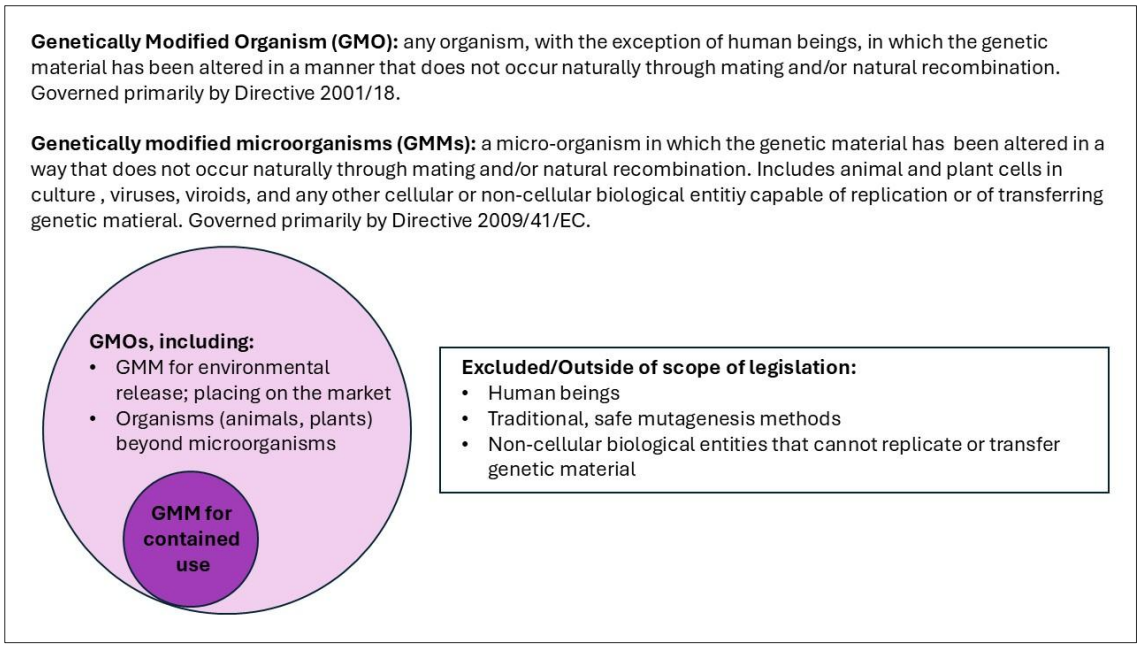

Figure 1. Simplified schematic for the classification of GMOs and GMMs

Food Law

With 'food law' or 'EU food law', we are referring to food law as defined in Article 3 of the General Food Law (GFL):[12] '"food law" means the laws, regulations and administrative provisions governing food in general, and food safety in particular, whether at Community or national level; it covers any stage of production, processing and distribution of food, and also of feed produced for, or fed to, food-producing animals'.

Engineered Living Materials (ELMs)

In the literature, ELMs are rarely defined but described. Rodrigo-Navarro et al, for example, describe ELMs as follows: "Biomaterials have evolved from inert materials that lack interaction with the body to biologically active, instructive materials that host and provide signals to surrounding cells and tissues. Engineered living materials contain living cells (responsive function) and polymeric matrices (scaffolding function) and, thus, can be designed as active and response biomaterials."[13] Wang et al. (2022) describe ELMs as "tak[ing] inspiration from nature and harness[…ing] engineered living systems to produce dynamic and responsive materials with genetically programmable functionalities."[14] Molinari et al. (2021) refer to ELMs as follows: "Biomaterials made by living systems, while very diverse, generally share similar organization: different lineages of cells are precisely patterned within a matrix to create a hierarchically defined structure. This meticulous organization allows for their multifunctional properties, which often exceed those of traditional materials. For these reasons, there is growing interest in creating engineered living materials (ELMs) that

[12] Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety OJ L 31, 1.

[13] Aleixandre Rodrigo-Navarro, Shrikrishnan Sankaran, Matthew J. Dalby *et al.*, 'Engineered living biomaterials' (2021) 6 *Nature Reviews Materials* 1175–1190.

[14] Yanyi Wang, Yi Liu, Jing Li, Yue Chen, Sizhe Liu, Chao Zhong, 'Engineered living materials (ELMs) design: From function allocation to dynamic behavior modulation' (2022) 70 *Current Opinion in Chemical Biology* 102188.

will have capabilities similar to those of natural living materials yet with tailored functions."[15]

The Deutsche Forschungsgemeinschaft defines ELMs as "new materials with programmable and adaptive capabilities [which] will be realized by combining living organisms with materials in a synergistic way."[16]

The Concept note for expert work on ELMs regulatory aspects as delivered to the authors by EISMEA as a basis for this work[17] defines ELMs as "materials that are completely or partially composed of living cells, which have a potentially broad application across different areas, including, for example, health, construction, consumer goods, environmental remediation." In the European Innovation Council Work Programme 2021,[18] the Commission describes ELMs as follows:

"Engineered living materials (ELMs) are composed, either entirely or partly, of living cells. ELMs entirely composed of living cells are called biological ELMs and they self-assemble via a bottom-up process – e.g. synthetic morphogenesis for organoids' production. ELMs only partly composed of living cells are called hybrid living materials (HLMs) and are built with a top-down process with integrated polymers or scaffolds. In both cases, the cellular components extract energy from the environment to form or assemble the material itself, and to adapt its morphology and function to environmental stimuli. This endows these materials with a combination of properties that is not present in any non-living material: self-regeneration, adaptation to environmental clues, longevity and environmental sustainability. By being alive, ELMs represent a fundamental change in materials' production and performance, enabling new, better or similar functionalities, compared to traditional materials but with decreased costs and environmental impact. ELMs have the potential to transform virtually every modern endeavour from healthcare to infrastructures to transportation."[19]

The EIC's definition and explanation of ELMs will serve as a basis for this report. While "engineered" does not favour or exclude any technique, the onus of techniques used to modify living materials would classify as genetic modification. In this report, we will hence focus on this technique.

Advanced Materials

When we are using the term "Advanced Materials" we refer to the OECD Working Party on Manufactured Nanomaterials' Working Description on Advanced Materials (AdMa): "AdMa are understood as materials that are rationally designed to have

- new or enhanced properties, and/or
- targeted or enhanced structural features with the objective to achieve specific or improved functional performance. This includes both new emerging manufactured materials, and materials that are manufactured from traditional materials. This also includes materials from innovative manufacturing processes that enable the creation of targeted structures from starting materials, such as bottom-up approaches. It is acknowledged that what are currently considered as AdMa will change with time."[20]

This definition has been adopted by the European Commission.[21]

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[15] Sara Molinari, Robert F Tesoriero, Caroline M Ajo-Franklin, 'Bottom-up approaches to engineered living materials: Challenges and future directions' (2021) 4 (10) *Matter*, 3095-3120.

[16] Deutsche Forschungsgemeinschaft, *SPP2451 Engineered Living Materials with Adaptive Functions*, "About", https://spp2451.de/about/, accessed 16 November 2025.

[17] On file with authors.

[18] European Commission Decision C(2021) of 17 March 2021.

[19] European Commission Decision C(2021) of 17 March 2021, p. 61.

[20] OECD, *Advanced Materials: Working Description*, Series on the Safety of Manufactured Nanomaterials No. 104, ENV/CBC/MONO(2022)29.

[21] Communication from the Commission, *Advanced Materials for Industrial Leadership*, COM(2024) 98 final.

Methods and Materials

This study represents an interdisciplinary analysis, merging doctrinal legal research with insights from economics and natural sciences.[22] We conducted this analysis with the overall objective to assess the existing regulatory framework for ELMs in the EU and its suitability to attract investments into this market. Doctrinal legal analysis describes the collection and ordering of the available legal material, including legislation, jurisprudence, and legal literature, its syntax, and norms.[23] We conducted such a doctrinal analysis of the existing EU legal order to capture its overarching approach to the regulation of ELMs. For the analysis of this regulatory approach, we employ a real option modelling approach[24] based on Purnhagen and Wesseler[25] and with applications to GMMs.[26] We use the results of the economic model and combine those with the legal analysis to derive possibilities for the regulation of ELMs.

EU Legislation

European legislation and related information were retrieved from EUR-Lex and Curia, using only the most recent consolidated versions of each document. For reasons of brevity, our analysis focused primarily on core aspects of EU life sciences law. Data protection legislation, while potentially applicable in a similar manner, was not included. Intellectual property law was likewise omitted, as the issues it raises are highly context-dependent and amenable to generalisation only to an extent to which it is significant for this study.

Economic Assessment

We employ an economic model that integrates ex-ante regulations and ex-post liability, examining their effects on the economic benefits of investing in products derived from the application of ELMs. The model explicitly considers the uncertainty in the time length of the R&D and approval/authorisation phase. The time length of being able to market the product is also considered, while we include uncertainty about the size of the benefits by considering them to be either high or low. The results of the model allow us to investigate the effect of changes in ex-ante regulations on the value of immediate investment. Parameter calibration enables the provision of insights into the magnitudes of ex-ante regulation on the incentives to invest. The model is also used to discuss the implications of regulatory changes on investment incentives.[27]

Limitations

First, doctrinal legal research predetermines some aspect of coherence of the legal material. Yet, the multilevel character of EU law challenges the assumption of internal coherence: principles such as primacy, conferral, and fundamental rights lack a single constitutional narrative. Second, indeterminate legal concepts—proportionality, subsidiarity, fundamental rights—derive meaning from judicial and political

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[22] Terry Hutchinson, 'The doctrinal method: Incorporating interdisciplinary methods in reforming the law' (2015) 8 *Erasmus Law Review* 130.

[23] Terry Hutchinson, Nigel Duncan, 'Defining and describing what we do: Doctrinal legal research' (2012) 17(1) *Deakin Law Review* 83.

[24] Justus Wesseler, Jinhua Zhao, 'Real Options and Environmental Policies – the Good, the Bad, and the Ugly' (2019) 11 *Annual Review of Resource Economics* 43–58.

[25] Kai Purnhagen, Justus Wesseler, 'Maximum vs minimum harmonization: what to expect from the institutional and legal battles in the EU on gene editing technologies' (2019) 75(9) *Pest Management Science* 2310–2315.

[26] Justus Wesseler, Gijs Kleter, Marthe Meulenbroek, Kai Purnhagen, 'EU regulation of genetically modified microorganisms in light of new policy developments: Possible implications for EU bioeconomy investments' (2023) 45(2) *Applied Economics Perspectives and Policy* 839–859.

[27] Justus Wesseler, Jinhua Zhao, 'Real Options and Environmental Policies – the Good, the Bad, and the Ugly' (2019) 11 *Annual Review of Resource Economics* 43–58.

practice, which doctrinal analysis can describe but not fully explain. Third, the law–fact interface in areas like internal market or environmental law integrates economic modelling and risk assessment; doctrinal methods alone cannot evaluate these empirical foundations. Finally, by focusing on law in the books, doctrinal research often underexposes gaps in implementation across Member States. These limits do not negate doctrinal analysis but mark its epistemic boundaries, highlighting the need for interdisciplinary methods (empirical, economic, or political) to fully capture the EU's evolving legal order.

To cope with some of these limitations in light of the questions of whether these rules impact investments into the EU, we have added an economic analysis to the doctrinal method. Yet, also this analysis has its limits. The exact quantitative effects due to the lack of information are not possible to determine. Implications for international trade are also not explicitly considered. The protection of property rights via patents is only discussed in general, as a complete analysis of the economic implications would go beyond the scope of the current study.

GMOs AND GMMs REGULATION IN THE EU

The regulation of GMOs and GMMs has evolved within a framework of international and EU legal instruments.[28] The first steps toward an international regulatory regime can be traced to the OECD Recommendation on Recombinant DNA Safety Considerations of 1986, which articulated early risk assessment principles such as case-by-case evaluation and the principle of familiarity.[29] Subsequent OECD guidance expanded these principles for the agricultural, industrial, and environmental use of GMOs and food or feed products derived therefrom.[30]

A decisive international development followed with the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, signed in 2000.[31] The Protocol governs the transboundary movement, handling, and use of Living Modified Organisms (LMOs), emphasising the protection of biodiversity and human health. It requires Parties to establish national biosafety frameworks and introduces the Advance Informed Agreement procedure for LMOs destined for environmental release. Importantly, the Protocol embeds the precautionary approach into international biosafety law, building the basis for the EU's precautionary principle.[32]

The GMO and GMMs regulatory frameworks in the EU have mainly been developed with food, feed and agricultural products in mind, and to some minor extent also medical applications. By focusing on the technique employed and not on the organisms or product, however, the scope of application extends to all organisms and products possible. Following this regulatory decision, the regulatory intend has been to capture as many applications of GM as possible in order to assess potential risks stemming from the use of the technique, with the exception of human bodies regardless of the type of organism or product. In this section, we describe the legislative acts and their scope underpinning these regulatory frameworks, and we address whether any aspects of the legislative acts may be applied to GMOs or GMMs products with other applications. In the section "Applications of GMOs and GMMs Legislative Framework to ELMs" we will elaborate further on how these frameworks may apply to the different cases of ELMs.

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[28] Alexandra Molitorisová, Kai Purnhagen, Nils Rostoks, Dennis Eriksson, Martin Wasmer, 'Regulatory Aspects of Plants resulting from New Genomic Techniques in the EU' in Kamel Abd-Elsalam, Aftab Ahmad (eds), *Global Regulatory Outlook for CRISPRized Plants* (Academic Press 2023) 251–279.

[29] Peter W.E. Kearns, Gijs A. Kleter, Hans E.N. Bergmans, Harry A. Kuiper, 'Biotechnology and Biosafety Policy at OECD: Future Trends' (2021) 39(10) *Trends in Biotechnology* 965–969.

[30] OECD Council, Recommendation of the Council concerning "Recombinant DNA Safety Considerations: Safety Considerations for Industrial, Agricultural and Environmental Applications of Organisms Derived by Recombinant DNA Techniques" (OECD 1986).

[31] Cartagena Protocol on Biosafety to the Convention on Biological Diversity (2000) https://treaties.un.org/doc/Treaties/2000/01/20000129%2008-44%20PM/Ch_XXVII_08_ap.pdf, accessed 19 November 2025.

[32] Kai Purnhagen, Justus Wesseler, 'Precaution and the Precautionary Principle: A View on the EU – The Example of Modern Biotechnology' in Alain Marciano, Giovanni Battista Ramello (eds), *Encyclopedia of Law and Economics* (Springer 2025).

GMOs and GMMs Legal Framework

Overview of the EU GMOs and GMMs Legislative Acts

The EU legal framework on GMOs (see Table 1) was developed in parallel yet reflects this international context only to a certain extent.[33] Initial measures such as Directive 90/220/EEC on the deliberate release of GMOs[34] laid the groundwork, while the adoption of the Cartagena Protocol in 2000 triggered substantial legislative reform through Directive 2001/18/EC.[35] This Directive, still central to EU GMO law,[36] distinguishes between deliberate release, deliberate release for research purposes and placing on the EU market. It requires a case-by-case risk assessment, and, despite being an internal market measure, integrates the precautionary principle as a guiding principle.[37]

Specific rules for GMMs predate these reforms in the form of the Contained Use Directive (Directive 90/219/EEC)[38], later replaced by Directive 2009/41/EC[39], regulating GMMs in contained facilities to prevent risks to human health and the environment.

The EU legislative framework further expanded with Regulation (EC) No 1829/2003[40] on genetically modified food and feed and Regulation (EC) No 1830/2003[41] concerning traceability and labelling for GM foods and feed. The establishment of the European Food Safety Authority (EFSA) in 2002 reinforced the role of independent scientific risk assessment at the EU level, particularly under Regulation 1829/2003, while Member State authorities retained significant responsibilities in the initial authorisation phases. This multilayered regime also accommodates national diversity: where harmonisation remains incomplete, Member States may adopt additional measures, reflecting the socio-economic heterogeneity across the Union.[42] In practice, many substances apply simultaneously for authorisation as food and feed and for release into the environment and/or placing on the market, in order to avoid the liability risk if a substance approved for release into the environment or placing on the market ends up unintentionally in food or feed. For this reason, the "one door one key" principle allows to file simultaneously for an authorisation for

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33 For deviations see inter alia Kai Purnhagen, Justus Wesseler, 'Precaution and the Precautionary Principle: A View on the EU – The Example of Modern Biotechnology' in Alain Marciano, Giovanni Battista Ramello (eds), *Encyclopedia of Law and Economics* (Springer 2025).

34 Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms OJ L 117.

35 Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC OJ L 106.

36 Kai Purnhagen, 'How to manage the Union's diversity: The regulation of New Plant Breeding Technologies in *Confédération paysanne and Others*' (2019) 56 *Common Market Law Review* 1379–1396.

37 Kai Purnhagen, 'How to manage the Union's diversity: The regulation of New Plant Breeding Technologies in *Confédération paysanne and Others*' (2019) 56 *Common Market Law Review* 1379–1396.

38 Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms OJ L 117.

39 Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms OJ L 125.

40 Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed OJ L 268.

41 Regulation (EC) No 1830/2003 of the European Parliament and of the Council 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 OJ L 268/24.

42 See for an assessment into this heterogeneity in EU GMO law Kai Purnhagen, 'How to manage the Union's diversity: The regulation of New Plant Breeding Technologies in *Confédération paysanne and Others*' (2019) 56 *Common Market Law Review* 1379–1396.

both, release into the environment and placing on the market of foods or feed.[43]

The cornerstone of the EU's regulatory framework on GMOs remains Directive 2001/18/EC, which defines a GMO in Art. 2 (1) Directive 2001/18/EC as "an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination." Yet, persistent debates concern the scope and precision of the EU definition. A key point of divergence lies in its contrast with the Cartagena Protocol on Biosafety. While the EU refers to genetic material altered "in a way that does not occur naturally," the Protocol defines a Living Modified Organism (LMO) as any organism possessing "a novel combination of genetic material." EU law has also been deviating from the Protocol's precautionary approach with its introduction of precaution as a legal principle and its subsequent more protective interpretation by the EU Courts.[44] It thereby does not only differ from its underlying international legal obligations, it also blurs the lines of the principle that preventive action needs to be taken and the precautionary principle enshrined in EU law.[45] This seemingly technical difference carries major regulatory consequences. As more jurisdictions align with the Protocol's terminology and regulatory approaches, the EU's deviating treatment of risks creates regulatory divergence and trade friction in the global agri-food sector,[46] which are also to be expected for ELMs.

This definitional tension gained urgency with the advent of NGTs such as CRISPR-Cas9, which can induce precise genomic changes difficult to distinguish from conventional breeding outcomes. The CJEU's 2018 judgment in *Confédération Paysanne* (Case C-528/16) has been interpreted in such a manner that it confirmed that organisms obtained by "new" mutagenesis techniques fall within Directive 2001/18/EC unless exempted under Annex IB, thereby subjecting the majority of NGT-derived products to the full GMO regime. In essence, all techniques using mutagenesis for which no record of safe use exist before 2001 fall within the scope of the regulation and are not exempted from its application. The ruling prompted criticism from scientists, regulators, and industry stakeholders, who argued that applying a 20-year-old framework to modern biotechnology stifles innovation without delivering proportional environmental or health safeguards.[47] Responding to these concerns, the European Commission published a 2021 Study on NGTs,

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[43] European Commission, MEMO/04/85, Brussels, 15 April 2004, https://ec.europa.eu/commission/presscorner/detail/en/memo_04_85, accessed 22 December 2025.

[44] Kai Purnhagen, Justus Wesseler, 'Precaution and the Precautionary Principle: A View on the EU – The Example of Modern Biotechnology' in Alain Marciano, Giovanni Battista Ramello (eds), *Encyclopedia of Law and Economics* (Springer 2025); For the European Court of Justice's specific interpretation of the precautionary principle in EU law see Kai Purnhagen, 'You want it extra CRISPERY?: Legal Disruption Through New Plant Breeding Technologies in the EU' (2021) 40 *Yearbook of European Law* 374–397; In the literature, some equate the Protocol's precautionary approach as adopted in international law with a precautionary principle as adopted in some regional regulation, see eg Tomme Young, *'Genetically modified organisms and biosafety: a background paper for decision-makers and others to assist in consideration of GMO issues'* (1 *IUCN Policy and Global Change Series*, 2004) 1–56.

[45] Kai Purnhagen, Justus Wesseler, 'Precaution and the Precautionary Principle: A View on the EU – The Example of Modern Biotechnology' in Alain Marciano, Giovanni Battista Ramello (eds), *Encyclopedia of Law and Economics* (Springer 2025).

[46] Alexandra Molitorisová, Kai Purnhagen, Nils Rostoks, Dennis Eriksson, Martin Wasmer, 'Regulatory Aspects of Plants resulting from New Genomic Techniques in the EU' in Kamel Abd-Elsalam, Aftab Ahmad (eds), *Global Regulatory Outlook for CRISPRized Plants* (Academic Press 2023) 251–279.

[47] See for in-depth analyses of the judgment Felix Beck, 'All about that risk? A (re-)assessment of the CJEU's reasoning in the „genome editing" case' (2019) 17(2) *Europäisches Umwelt- und Planungsrecht* 246–255; Hans-Georg Dederer, 'Genomeditierung ist Gentechnik. Eine kritische Analyse des EuGH-Urteils *Confédération paysanne*' (2019) 17(2) *Europäisches Umwelt- und Planungsrecht* 236–245; Kai Purnhagen, Esther Kok, Gijs Kleter *et al.*, 'The European Union Court's Advocate General's Opinion and new plant breeding techniques' (2018) 36 Nature Biotechnology 573–575; Han Somsen, 'Scientists Edit Genes, Courts Edit Directives. Is the Court of Justice Fighting Uncertain Scientific Risk with Certain Constitutional Risk?' (2018) 9(4) *European Journal of Risk Regulation* 701–718; Kai Purnhagen, 'How to manage the Union's diversity: The regulation of New Plant Breeding Technologies

concluding that current GMO legislation is "not fit for purpose" for plants obtained through targeted mutagenesis and cisgenesis[48] and followed in July 2023 with a proposal for a new Regulation on plants produced by certain new genomic techniques.[49] While its original focus had been on introducing plants into the environment, trilogue discussions also concern a widening of the proposal's scope beyond plants. Accordingly, a scenario exists where the Proposal may also become relevant for ELMs. The legislative proposal introduces a two-tiered system:

Category 1 NGT plants, comparable to conventionally bred varieties, would be exempted from most GMO requirements, subject only to notification and transparency rules;

Category 2 NGT plants, involving more complex modifications, would remain under a proportionate risk assessment and authorisation procedure.

Recent literature has identified this proposal as a part of or a first step from a process-based approach to a product-based approach in EU' GMO legislation.[50]

in *Confédération paysanne and Others*' (2019) 56 *Common Market Law Review* 1379–1396; Juan A. Vives-Vallés, Cécile Collonnier, 'The Judgment of the CJEU of 25 July 2018 on Mutagenesis: Interpretation and Interim Legislative Proposal' (2020) 3(10) *Frontiers in Plant Science* 1813.

[48] European 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, 29 April 2021)

[49] 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.

[50] Vos, E., Knuth, L. 'Deregulating New Genomic Techniques: The Challenge of Ambiguous Objects', (2025) 21 *Croatian Yearbook of European Law and Policies*, 1-30.

Table 1. GMOs EU Legislative Acts' applications and (potential) implications for ELMs.

Legislative act	Basic scope	ELM Relevance
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	Defines GMOs and exemptions, as well as protection goals, etc. Used for the authorisation of GMOs in the EU for cultivation	ELM might be exempted.
+ Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory	+ Provides for the opt-out procedure for member states to restrict or prohibit the cultivation of an EU-authorised GM plant variety	+ MSs might use a similar reasoning for the use of ELMs in their markets
+ Commission Directive (EU) 2018/350 of 8 March 2018 amending Directive 2001/18/EC of the European Parliament and of the Council as regards the environmental risk assessment of genetically modified organisms	+ Updating the Annexes to Directive 2001/18/EC as regards the environmental risk assessment with a view to incorporating and building upon the Scientific opinion establishing guidance on the environmental risk assessment of genetically modified plants	+ Specific requirements for environmental risk assessment for ELMs.
+ Regulation (EU) 2020/1043 of the European Parliament and of the Council of 15 July 2020 on the conduct of clinical trials with and supply of medicinal products for human use containing or consisting of genetically modified organisms intended to treat or prevent coronavirus disease	+ Sets aside the application of certain provisions of Directive 2001/18/EC as regards medicinal products containing or consisting of GMOs that are intended to treat or prevent COVID-19	+ Sets aside the application of certain provisions of Directive 2001/18/EC for specific ELMs

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	Establishes EFSA, sets integrated approach to food and feed safety 'from farm to fork'	Possibility for an authority assessing ELMs, e.g. ELM Safety Authority
Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species	Concerns the acceptance for inclusion in a common catalogue of varieties of agricultural plant species of those varieties of beet, fodder plant, cereal, potato and oil and fibre plant the seed of which may be marketed in the EU.	The same logic may apply to ELMs. If there are concerns about plants, the same can be argued for products derived from similar technologies.
Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on placing on the market of GM food and feed, or food and feed containing, consisting of or derived from GMO	Is used for authorisation in the EU of food and feed consisting of, containing of or produced from GMOs	ELMs may also face specific requirements before being placed on the market.
Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from GMOs, amending the Directive 2001/18/EC	Sets out traceability and labelling requirements for GM food and feed, and establishes a 0.9% labelling threshold of authorised GM products provided that traces are adventitious and technically unavoidable	Labelling and traceability might also be required for ELMs that are used for food or are in contact with food.
Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of GMOs, which regulates the intentional and unintentional movement of GMOs between EU countries and third countries, excluding intentional movements within the EU	Establishes a common system of notification and information for transboundary movements of GMOs and ensures coherent implementation of the provisions of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity	The same is expected to be required for ELMs.
Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (Recast)	Lays down common measures for the contained use of genetically modified micro-organisms with a view to protecting human health and the environment.	Applies to ELMs that use GMMs.
Commission Regulation (EU) No 619/2011 of 24 June 2011 laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorisation procedure is pending or the	Harmonises the implementation of the zero-tolerance policy on non-authorised GM material in feed.	The same is expected to apply for ELMs that have not received authorisation within the EU.

authorisation of which has expired		
Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council of EU, and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006	Provides for more detailed requirements for risk assessment of GM food and feed, which effectively supersede "Guidance for risk assessment of food and feed from genetically modified plants" (EFSA 2011)	Relevant for ELMs entering the food supply chain.
Commission Implementing Decision of 13 June 2013 amending Implementing Decision 2011/884/EU on emergency measures regarding unauthorised genetically modified rice in rice products originating from China	Provides for a series of measures regarding the possible contamination of rice products with unauthorised genetically modified rice lines originating from China.	The same may apply to ELMs that have been authorised outside of the EU but could be of products being imported.
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	Establishes the principles of organic production and lays down the rules concerning organic production, related certification and the use of indications referring to organic production in labelling and advertising, as well as rules on controls.	The differentiation for organic products may also apply to ELMs in the sense that they are not allowed for organic agriculture. This may apply to ELMs as well.
Soft law		
Commission Recommendation of 4 October 2004 on technical guidance on sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003		Provides some insights about what we can expect for ELMs.
Commission Recommendation of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops		Policies for the unintended presence of ELMs in products. This includes liability, insurance, and notification.

Source: Alexandra Molitorisová, Kai Purnhagen, Nils Rostoks, Dennis Eriksson, Martin Wasmer, 'Regulatory Aspects of Plants resulting from New Genomic Techniques in the EU' in Kamel Abd-Elsalam, Aftab Ahmad (eds), *Global Regulatory Outlook for CRISPRized Plants* (Academic Press 2023) 251–279.

Scope of the most relevant GMOs Legislative Acts

As Directive 2001/18 constitutes the de facto framework legislation[51] for EU GMO regulation, the scope of EU GMO law, that means the scope of each one of the EU's GMO legislative instruments, is determined mainly by the Directive's application. The Directive extends to all GMOs that are either deliberately released into the environment or placed on the market within the Union. This means that all ELMs in the EU which still carry traces of a GMO are in principle in the scope of application. If these are used in contained environments, the law on GMMs applies.

+ Processing Aids

With respect to the possible inclusion of new mutagenesis techniques within the Directive's scope, reference is made to our analysis in the Definitions section. It should further be noted that, pursuant to Recital 16 of Regulation (EC) No 1829/2003, the regulation "should cover food and feed produced 'from' a GMO but not food and feed 'with' a GMO." Food and feed produced not from a GMO but with the aid of a genetically modified processing aid fall outside the scope of that Regulation.

'Processing aid' is defined in Art. 3 (2) (b) Regulation (EC) No 1333/2008[52] as "any substance which:

(i) is not consumed as a food by itself;

(ii) is intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing; and

(iii) may result in the unintentional but technically unavoidable presence in the final product of residues of the substance or its derivatives provided they do not present any health risk and do not have any technological effect on the final product."

Scholarly debate has emerged regarding the correct interpretation of Recital 16, specifically as to whether the phrase "transfer of material derived from the genetically modified source" must be understood narrowly as referring solely to the *horizontal transfer* of genetic material possessing reproductive capacity, or whether it extends more broadly to encompass any detectable trace of the GMO employed, irrespective of the trace's molecular size, structural integrity, or replication capacity.[53] The CJEU has decided that this provision must be interpreted to mean that the EU GMO regime applies only to products that contain material derived from GMOs.[54] Where no traces of GMOs cannot be detected in the final product, such a product lies beyond the scope of EU GMO legislation. [55] With a view to the use of GMMs, the Commission has also clarified that "when the GMMs are not removed during the production process, they are not used as processing aids." [56] This fact is particularly noteworthy for ELMs, where the living GMOs/GMMs are removed at the end of the production process. [57] Products that can indeed be entirely freed from GMMs and their remains do not fall within the scope of the special GMO law. However, it is notable to indicate that such removal is increasingly difficult, as detection methods become more effective, thereby increasing the risks for ELMs that employ

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[51] Kai Purnhagen, 'How to manage the Union's diversity: The regulation of New Plant Breeding Technologies in *Confédération paysanne and Others*' (2019) 56 *Common Market Law Review* 1379–1396.

[52] Regulation (EC) No 1333/2008 on food additives, OJ L 354, 31.12.2008, pp. 16-33.

[53] Hans-Georg Dederer, 'rDNA Traces in Fermentation Products Using Genetically Modified Microorganisms (GMMs)' (2021) 18 *Stoffrecht* 135–147.

[54] Case C-442/09, *Bablok and Others v Freistaat Bayern*, EU:C:2011:742, para 86.

[55] Case C-442/09, *Bablok and Others v Freistaat Bayern*, EU:C:2011:742, para 85.

[56] European Commission (2006) Report from the Commission to the Council and the European Parliament on the implementation of Regulation (EC) No 1829/2003 on genetically modified food and feed. COM(2006) 626 final, Sections 10.2 and 10.3.3.

[57] Federica Ronchetti, Laura Springer, Kai Purnhagen, *The Regulatory Landscape in the EU for Dairy Products Derived from Precision Fermentation: An Analysis on the Example of Cheese* (Springer 2024).

such removal practices to comply with a zero-tolerance level in the product to be marketed. This is particularly due to technological advances in synthetic biology and ELMs, especially where living systems are used at the same time as production platforms and as the product itself. As detection methods improve, trace amounts of modified material may be found, creating regulatory ambiguity for ELMs relying on transient or removed GM components. While EU law has not solved the issue of horizontal transfer, the strict wording of the Court's judgment and Commission's recommendation advocates for a view that any detectable trace which leads to the conclusion of the use of GMO, irrespective of its specific features, triggers the application of the EU's GMO legislation.[58] However, from a scientific risk-based perspective, such an interpretation is often presented as lacking a rational basis. Legal clarifications in this area would be welcome.

This ambiguity has been taken in the Commission's latest Proposal for a Regulation as regards simplification and strengthening of food and feed safety requirements[59] in its recital 37:

"Therefore, to ensure the good functioning of the internal market and provide legal certainty to food and feed business operators, food and feed products obtained using a GMM as production strain and from which the GMM has been removed should not fall within the scope of Regulation (EC) No 1829/2003 even if residues of the GMM are present in the food or feed, provided that they are limited to non-viable cells, that the presence thereof is minimized through reasonable attempts to remove them and have no technological effect on the final food or feed. In particular, to ensure that reasonable attempts to remove residues have been made, it should be required that they have been carried out in accordance with good manufacturing practices as those used in similar food and feed products to minimize the presence of residues."

+ Excluded Techniques

The Directive explicitly excludes certain genetic modification techniques from its scope through Art. 3(1) and Annex I B. These exclusions apply provided that the techniques do not involve the use of recombinant nucleic acid molecules or GMOs other than those produced by the listed methods. Pursuant to the CJEU's judgment in Case C-528/16, these exemptions apply exclusively to techniques with a long safety record at the time the Directive entered into force.

The main excluded techniques are traditional methods (e.g., chemical or radiation-induced mutagenesis), fusion of plant cells within the same taxonomic family, provided that the resulting organism could also occur by traditional breeding methods, and some forms of self-cloning (within the same species) and natural genetic exchange processes if they mimic natural recombination events and have a documented safety history. It is worth noting that this is not evident from a layman's reading of the Directive, as the wording does not indicate the exemption's limitation to traditional techniques only. ELMs using non-traditional GM techniques are hence not exempt from the application of this provision.

+ (Partially) Excluded Substances, Medicinal Substances and Compounds

The Directive establishes that Articles 6-11 shall not extend to medicinal products for human use (veterinary use remains within the scope, as long it is not feed) comprising, or containing, GMOs or combinations

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[58] Hans-Georg Dederer, 'rDNA Traces in Fermentation Products Using Genetically Modified Microorganisms (GMMs)' (2021) 18 *Stoffrecht* 135–147; Federica Ronchetti, Laura Springer, Kai Purnhagen, *The Regulatory Landscape in the EU for Dairy Products Derived from Precision Fermentation: An Analysis on the Example of Cheese* (Springer 2024).

[59] Proposal for a Regulation as regards the simplification and strengthening of food and feed safety requirements COM(2025) 1030 final.

thereof, provided that their deliberate release for purposes other than market placement is regulated under Community (now: Union) legislation. Such legislation must mandate the following components: a specific environmental risk assessment pursuant to Annex II, informed by data as outlined in Annex III, without prejudice to supplementary obligations; explicit prior consent for release; a monitoring plan, in accordance with relevant sections of Annex III, for the detection of impacts on human health and the environment; and provisions for handling novel information, ensuring public access, disclosing release outcomes, and facilitating information exchange at least equivalent to that required under this Directive.

Furthermore, environmental risk assessments for such substances and compounds shall be undertaken in coordination with both national and Community authorities referenced in the Directive. The governing legislation must also incorporate procedures guaranteeing conformity of the environmental risk assessment and equivalence with the Directive's provisions, explicitly cross-referencing the Directive itself. This exemption for medicinal products for human use in Directive 2001/18 is closely linked with the existing framework of European pharmaceutical legislation, particularly Directive 2001/83/EC[60] on the Community code relating to medicinal products for human use and Regulation (EC) No 726/2004[61] establishing the centralised authorisation procedure under the European Medicines Agency (EMA). Both legal acts, Directive 2001/83/EC and Regulation (EC) No 726/2004, incorporate requirements for environmental risk assessment of medicinal products containing GMOs. Specifically, Annex I, Part III of Directive 2001/83/EC obliges applicants to submit an environmental risk assessment (ERA) in line with principles comparable to those in Annexes II and III of the GMO Directive, ensuring that the release of GMO-containing medicinal products is not authorised without such evaluation.

The EU's pharmaceutical legislation is currently under revision, and the amendments proposed may have an impact on the pharmaceuticals using or consisting of GMOs. If the required changes will be voted into law, the major changes would result in further harmonization at the EU level, reducing fragmentation of testing at the Member State level.

The requirement for explicit prior consent resonates with the marketing authorisation system under Directive 2001/83/EC and Regulation 726/2004, whereby authorisation may only be granted after a favourable scientific assessment by EMA's Committee for Medicinal Products for Human Use (CHMP) and, in the case of advanced therapies, also the Committee for Advanced Therapies (CAT). For medicinal products containing GMOs, this authorisation is contingent on a parallel GMO-related assessment by competent national authorities, thereby operationalising the Directive's demand for coordination with both national and Community institutions.

Similarly, the monitoring obligations correspond to pharmacovigilance requirements under Regulation 726/2004[62] and Directive 2001/83/EC[63], complemented by post-marketing environmental monitoring obligations under the GMO regime. The emphasis on the treatment of new information, public access, and reporting of release outcomes reflects the general EU principles of transparency (Articles 10 and 11 TFEU)

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60 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use OJ L 311.

61 Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency OJ L 136.

62 Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency OJ L 136.

63 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use OJ L 311.

and specific disclosure obligations under both the pharmaceutical acquis and the GMO framework.[64]

+ Deliberate Release

"Deliberate release" is defined in Art. 2 (3) Directive 2001/18 as "any intentional introduction into the environment of a GMO or a combination of GMOs for which no specific containment measures are used to limit their contact with and to provide a high level of safety for the general population and the environment;" This includes both experimental releases (e.g., tastings or any leaving the lab), cultivation and any other form of circulation by any means, which is not covered by "placing on the market." As the GMO law focuses on the technique only, any organism or product, e.g., medicinal products or devices, textiles, building elements, consumer goods (such as bike helmets,...), or environmental detoxification products (such as filters) are covered by this provision prior to placing on the market.

+ Placing on the Market

"Placing on the market" is defined in Art. 2 (4) Directive 2001/18 as "making available to third parties, whether in return for payment or free of charge;". The term encompasses imports as well as any form of product transfer, irrespective of whether a contractual relationship exists. The definition expressly excludes GMOs made available for activities governed by Directive 2009/41/EC, pursuant to the first indent of Article 2(4); and GMOs intended solely for activities conducted under appropriate stringent containment measures designed to minimise contact with, and ensure a high level of protection for, the general public and the environment, in accordance with the second indent of Article 2(4) Directive 2009/41/EC. It is notable that, unlike the concept of "deliberate release," the term "placing on the market" contains no explicit requirement of intent. Nevertheless, the notion of "making available" implicitly presupposes a degree of volition, such that the act of placing on the market necessarily entails at least some element of intentionality. The CJEU has, in its jurisprudence, accorded this intentionality requirement limited interpretative significance. It stipulated that, contrary to the wording of the law, "the intentional introduction [..., omission by the authors] of a substance [..., omission by the authors] cannot be made into a condition for application of the authorisation scheme".[65] The intention of the regulation would be the prevention of risk to human health, and the existence of such risk is independent from an intentionally or adventitiously introduction of the substance.

In case an ELM, which already had been placed on the market, produces a GMO, which is "placed on the market", it is furthermore questionable who will be responsible for determining the applicable legal system and, eventually, who can be held liable. A similar question arises if an ELM, after placement on the market, undergoes a substantial change. One could hence imagine two scenarios: The material itself will increase in size upon an external stimulus due to the reproduction of the cells to such an extent that one could view this as a new GMO. Or the ELM itself produced non-living materials, which still contain but also could significantly reduce the concentration of GMOs (e.g., the helmet of the EIC ELMs project). The regulations of Directive 2001/18 presuppose a direct link between the action of a company or a private person and the placing on the market of a GMO product. If the placing on the market of an ELM which then produces a GMO product can be attributed to the placing on the market of the initial ELM is not answered in a straightforward manner neither by Directive 2001/18 nor by Regulation (EC) No 1829/2003. Legal clarity with

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[64] There are multiple approved medicinal products on the market, see e.g. for a (possibly incomplete) list Alexandra Lensch et al, 'Safety aspects of microorganisms deliberately released into the environment' (2024) 4 EFB Bioeconomy Journal, 100061.

[65] ECJ, Case C-442/09 *Bablok and Others v Freistaat Bayern* ECR I-07419, para 89.

respect to the responsibilities attached to "placing on the market" of the organism so produced would also help here.

+ Transport

The carriage of GMOs by rail, road, inland waterway, sea or air is also excluded from the application of the Directive (Art. 3 (2) Directive 2001/18). The transport of GMOs falls under a specialized set of EU and international regulations dealing with the safe carriage of dangerous goods and infectious substances. For example, Directive 2008/68/EC governs the inland transport of dangerous goods, and GMOs fall under Class 6.2: Infectious substances or Class 9: Miscellaneous dangerous substances, depending on risk classification.

+ Risk Assessment

Within the Union's regulatory architecture, the European Food Safety Authority (EFSA), acting through its GMO Panel, bears primary responsibility for the risk assessment of genetically modified (GM) food and feed. This assessment is grounded in two sources of information: (i) the scientific literature available at the time of application and (ii) the technical dossier submitted by the applicant, which must adhere to internationally recognised risk assessment standards, in particular those developed under the Codex Alimentarius.[66] The applicable procedural and substantive requirements are codified both in EFSA guidance documents and in Commission Implementing Regulation (EU) No 503/2013.

Risk assessment proceeds on a case-by-case basis, enabling EFSA to require additional data where initial submissions fail to meet the evidentiary threshold. This flexibility, however, has attracted substantial criticism from industry stakeholders, who point to increasingly onerous data requirements, lengthy evaluation timelines, and uncertain regulatory outcomes.[67] The 2013 Implementing Regulation intensified these concerns by introducing, inter alia, a mandatory 90-day rodent feeding trial for toxicological assessment in food and feed applications and by strengthening environmental risk assessment obligations for deliberate release applications. These obligations entail significant compliance costs for applicants[68] and deviate in scope and intensity from risk assessment practices in non-EU jurisdictions.

Under Directive 2001/18/EC, environmental risk assessments (ERAs) fall within the remit of the national competent authorities and must conform to the methodology prescribed in Annex II. This Annex applies to both Part B notifications—concerning deliberate releases for purposes other than placing on the market—and Part C notifications—concerning applications for EU-wide marketing authorisation. Although the information requirements differ between the two, certain general risk assessment principles remain constant. These include the identification of both intended and unintended genetic modifications, as well as the evaluation of potential adverse effects on human health and the environment, taking into account the characteristics of the GMO and the conditions under which it is released.

Given that most authorisation requests for the placing on the market of GM are plants which are submitted under Regulation (EC) No 1829/2003, the EU legislature has largely aligned the information requirements for Part C notifications with those established in Implementing Regulation (EU) No 503/2013.

More recently, EFSA has been mandated to review the adequacy of existing ERA guidelines in light of

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[66] Elisabeth Waigmann, Claudia Paoletti, Howard Davies, Joe Perry, Sirpa Kärenlampi, Harry Kuiper, 'Risk assessment of Genetically Modified Organisms (GMOs)' (2012) 10(10) *EFSA Journal* 1–7.

[67] 'Kicking the can' (2015) 33 *Nature Biotechnology* 111, https://doi.org/10.1038/nbt.3148.

[68] Martin Wasmer, 'Roads Forward for European GMO Policy—Uncertainties in Wake of ECJ Judgment Have to be Mitigated by Regulatory Reform' (2019) 7 *Frontiers in Bioengineering and Biotechnology* 1–12.

synthetic biology applications. As the Convention on Biological Diversity clarifies, synthetic biology involves the de novo synthesis of genetic material and its use in the design of novel biological systems and organisms. Unlike conventional GM techniques, which often target single-trait modifications such as herbicide tolerance, synthetic biology enables the engineering of complex traits, for instance, plants producing nutritionally enhanced compounds, allergenic protein-free crops, or even novel metabolic pathways.

Despite these technological advances, EFSA has concluded that no qualitatively new hazards emerge from synthetic biology compared to conventional GM techniques. Accordingly, the existing risk assessment framework was deemed adequate, albeit with recommendations for targeted updates to address the specificities of synthetic biology applications.[69]

+ Labelling

Food and feed falling within the scope of Regulation (EC) No 1829/2003 are subject to comprehensive labelling and traceability requirements, further elaborated in Regulation (EC) No 1830/2003. These obligations extend even to processed products in which no detectable traces of recombinant DNA or novel protein remain. Additionally, labelling is mandatory for all products placed on the market or their accompanying documents according to Art. 13 (2) lit. f Directive 2001/18.

Recognising the practical difficulties in entirely preventing adventitious or technically unavoidable commingling of genetically modified (GM) and conventional products, the EU legislature introduced thresholds for mandatory labelling. Where a product contains material from EU-authorised GMOs at levels not exceeding 0.9% for food, no labelling requirement applies, provided the presence of GMOs remains unintentional and unavoidable. By contrast, unauthorised GMOs remain subject to a zero-tolerance standard, irrespective of whether the EFSA has previously delivered a positive risk assessment. Certain categories of products are explicitly exempt from labelling obligations. For instance, textiles produced from GM cotton require no GM labelling, nor do animal products such as meat, eggs, or dairy derived from animals fed with GM feed. The foods mentioned are such where the legislator has decided that animal products derived from animals fed with GM feed are not subject to labelling obligations.

As regards "GMO-free" labelling, EU law follows the principle that food and feed should be labelled according to what they contain, rather than what they do not contain.[70] Consequently, while EU legislation neither supports nor explicitly prohibits voluntary "GMO-free" labels[71], such schemes have nonetheless emerged at the initiative of industry actors and certain Member States, leading to a fragmented regulatory landscape in the area of food.[72] There is a small difference when comparing assessments for GMO-free labels on food and assessing those for non-food labels:: For foods, the legal standard is stipulated by Art. 36 Food Information Legislation, while for non-food products the legal threshold is determined by the Directive on Unfair Commercial Practices. As the first one is lex specials to the latter, and the protective

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[69] EFSA Panel on Genetically Modified Organisms (GMO), 'Evaluation of existing guidelines for their adequacy for the molecular characterisation and environmental risk assessment of genetically modified plants obtained through synthetic biology' (2021) 19(2) *EFSA Journal* 6301.

[70] Report by ICF GHK, *State of play in the EU on GM-free food labelling schemes and assessment of the need for possible harmonization* (European Commission 2013).

[71] These labels can be considered "misleading" under the Food Information to Consumers Regulation and the Unfair Commercial Practices Directive.

[72] Elena Castellari, Claudio Soregaroli, Thomas Venus, Justus Wesseler, 'Food processor and retailer non-GMO standards in the US and EU and the driving role of regulations' (2018) 78 *Food Policy* 26–37.

standard in this regard is similar, the authors see no reason why the food-related reasoning should not be applied to non-food products.

+ Risk Management

Within the EU regulatory framework, risk management for GMOs is carried out jointly by the national competent authorities and the European Commission. Risk management obligations arise only after risks have been identified through scientific assessment. Consistent with the Codex Alimentarius principles, any risk management measures for foods and other products derived from modern biotechnology must remain proportionate to the level of risk. Consequently, management strategies are designed based on risk characterisation and anticipated exposure parameters, such as the scale and conditions of release and the degree of scientific uncertainty. These measures aim either to reduce the hazard itself or to limit the extent of exposure and are embedded within the environmental risk assessment framework established under Directive 2001/18/EC.

In practice, however, it is often argued that the European Commission functions as the primary risk manager, given that the final authorisation decision for GMOs lies within its mandate. Yet, despite positive scientific risk assessments for numerous GM applications, the Regulatory Committee under Directive 2001/18/EC- and, in the case of Regulation (EC) No 1829/2003, the Standing Committee on Plants, Animals, Food and Feed-rarely secures the qualified majority necessary in the committee procedure to grant authorisation.[73]

Under the rules governing qualified majority voting, 55% of Member States (currently 15 out of 27) representing at least 65% of the EU population must vote in favour of the Commission's proposal. This threshold reflects the cross-border implications of GMO releases and thus requires a collective political decision at Union level. In practice, however, Member States seldom vote explicitly against draft authorisation proposals; rather, the committees frequently return "no opinion" outcomes, which are then referred to the Appeal Committee under Regulation (EU) No 182/2011, where the stalemate is typically repeated.[74]

To address political deadlock, Directive (EU) 2015/412 granted Member States greater discretion to invoke socio-economic considerations when restricting or prohibiting GMO cultivation at national level, even after EU-wide authorisation. Yet, this reform has not resolved the structural inability to achieve qualified majority decisions at the EU level, nor would that solve the problem in the non-cultivation sector.[75]

Scholars have therefore proposed further reforms aimed at "decentralising" risk management-shifting decision-making authority closer to the Member States, in line with approaches in general food law.[76]

+ Monitoring

EU legislation imposes an obligation to conduct post-market environmental monitoring (PMEM) even where the pre-market environmental risk assessment identifies only negligible risks. Within the Union,

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[73] Richard D. Smart, Matthias Blum, Justus Wesseler, 'EU Member States' Voting for Authorizing Genetically Engineered Crops: a Regulatory Gridlock' (2015) 64(4) *German Journal of Agricultural Economics* 244–262.

[74] Richard D. Smart, Matthias Blum, Justus Wesseler, 'EU Member States' Voting for Authorizing Genetically Engineered Crops: a Regulatory Gridlock' (2015) 64(4) *German Journal of Agricultural Economics* 244–262.

[75] Kai Purnhagen, Justus Wesseler, 'EU Regulation of New Plant Breeding Technologies and Their Possible Economic Implications for the EU and Beyond' (2021) 43(4) *Applied Economic Perspectives and Policy* 1621–1637.

[76] Dennis Eriksson, Tomasz Zimny, 'Critical observations on the French Conseil d'État ruling on plant mutagenesis' (2020) 6 *Nature Plants* 1392–1393.

PMEM has thus far been implemented exclusively for the sole genetically modified (GM) crop authorised for commercial cultivation, namely Bt maize MON810.

Under Directive 2001/18/EC, the applicant must submit a monitoring plan as part of the authorisation dossier, prepared in accordance with Annex IIIA/B and Annex VII. This plan must be designed to detect potential effects on human health and the environment following the GMO's release. Once authorisation has been granted, monitoring and reporting obligations apply under the conditions specified in the consent decision.

Both Part B (deliberate release for experimental purposes) and Part C (placing on the market) notifications require the risk evaluation to identify specific monitoring requirements, which may include, where appropriate, the monitoring of efficacy alongside environmental effects. The monitoring regime thus encompasses both adverse and beneficial effects, although its primary objective remains twofold: To verify the assumptions underpinning the environmental risk assessment, particularly regarding the likelihood and impact of adverse effects, and to identify previously unforeseen risks through so-called case-specific monitoring.

The monitoring reports must be submitted to both the European Commission and the competent national authorities, while the EFSA bears responsibility for evaluating these reports. Certain elements of the monitoring process are also made publicly accessible, thereby contributing to transparency in risk governance.

+ Traceability

The emergence of new gene-editing technologies has intensified debate over the traceability requirement in EU GMO law, with critics increasingly viewing it as both a major obstacle to authorisation and a significant challenge for risk managers.[77] Under the current regime, applicants must provide a unique identifier for each GMO as part of the authorisation process. While this requirement poses no major difficulties for traditional transgenic techniques, it presents considerable challenges for mutations induced by most New Genomic Techniques, where no foreign genetic material is introduced.[78]

In response, the European Network of GMO Laboratories (ENGL) has reviewed existing detection methodologies for site-directed mutagenesis events with a view to find solutions for cultivation.[79] Potential technical solutions under discussion include the development of a unique identification code linked to the specific genomic alteration,[80] and the insertion of an exogenous genetic marker or enzyme to facilitate traceability.[81] The latter approach, however, risks introducing additional genetic modifications that might themselves require separate regulatory authorisation under Directive 2001/18/EC, thereby complicating rather than simplifying compliance. Moreover, all proposed detection and identification methods must still demonstrate technical precision and legal adequacy in practice, with ongoing uncertainties as to whether

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[77] Kai Purnhagen, Justus Wesseler, 'EU Regulation of New Plant Breeding Technologies and Their Possible Economic Implications for the EU and Beyond' (2021) 43(4) *Applied Economic Perspectives and Policy* 1621–1637.

[78] Aleksandra Hubar-Kolodziejczyk, Kai Purnhagen, 'Regulatory requirements for the identification, detection and quantification of gene-edited products in light of the (r)evolution of new genomic techniques' (2025) *European Journal of Risk Regulation* 1375-1391.

[79] European Network of GMO Laboratories (ENGL), *Detection of food and feed plant products obtained by targeted mutagenesis and cisgenesis* (ENGL 2023).

[80] European Network of GMO Laboratories (ENGL), *Detection of food and feed plant products obtained by targeted mutagenesis and cisgenesis* (ENGL 2023) 11.

[81] Patrick Guertler, Steffen Pallarz, Anke Belter *et al.*, 'Detection of Commercialized Plant Products Derived from New Genomic Techniques (NGT) – Practical Examples and Current Perspectives' (2023) 152 *Food Control* 109869, 2.

they would satisfy the evidentiary standards required for EU authorisation.[82] Current EU legislation explicitly demands that identification techniques be analytical in nature—a standard that renders the detection and identification of many genomic alterations as GM-related difficult, if not impossible.[83]

The issue acquires further complexity once gene-edited products begin entering the global chain, particularly from jurisdictions without GMO labelling or traceability requirements. Under current EU law, a zero-tolerance standard applies to imported commodities developed through most New Genomic Techniques.[84] Yet, where genetic alterations are undetectable or analytically indistinguishable from naturally occurring mutations, the practical enforceability of EU import controls remains doubtful and is expected to result in substantial frictions in international trade.[85]

Existing detection techniques have been described as "unsuitable for the routine analysis of commodities",[86] raising concerns over both administrative feasibility and trade disruptions. Suspensions of imports due to suspected low-level presence of unauthorised GMOs could either trigger significant trade conflicts or pressure exporting countries to align with EU regulatory standards, a phenomenon widely known as the "Brussels Effect".[87] Finally, the EU's stringent traceability and zero-tolerance requirements may also face scrutiny under WTO law, particularly under the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)[88]. Indeed, several WTO members formally challenged the EU's regulatory approach to gene-edited organisms before the WTO Committee on SPS Measures as early as 2000.[89]

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[82] Lutz Grohmann, Jens Keilwagen, Nina Duensing et al., 'Detection and Identification of Genome Editing in Plants – Challenges and Opportunities' (2019) 10 *Frontiers in Plant Science* 236.

[83] Aleksandra Hubar-Kolodziejczyk, Kai Purnhagen, 'Regulatory requirements for the identification, detection and quantification of gene-edited products in light of the (r)evolution of new genomic techniques' (2025) *European Journal of Risk Regulation* 1375-1391.

[84] Jenny Teufel, Viviana López Hernández, Anita Greiter et al, 'Strategies for Traceability to Prevent Unauthorised GMOs (Including NGTs) in the EU: State of the Art and Possible Alternative Approaches' (2024) 13 (3) *Foods*, 369.

[85] Vincent Smith, Justus Wesseler, David Zilberman, 'New Plant Breeding Technologies: An Assessment of the Political Economy of the Regulatory Environment and Implications for Sustainability' (2021) 13(7) *Sustainability*, 3687.

[86] Lutz Grohmann, Jens Keilwagen, Nina Duensing and Others, 'Detection and Identification of Genome Editing in Plants: Challenges and Opportunities' (2019) *Frontiers in Plant Science* 236, https://doi.org/10.3389/fpls.2019.00236.

[87] Anu Bradford, 'The Brussels Effect' (2012) 107 (1) Northwestern University *Law Review* 1-68.

[88] World Trade Organization, *Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)* https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm accessed 19 November 2025.

[89] Justus Wesseler, Nicholas Kalaitzandonakes, 'Present and Future EU GMO Policy' in Liesbeth Dries, Wim Heijman, Roel Jongeneel, Kai Purnhagen, Justus Wesseler (eds), *EU Bioeconomy Economics and Policies* (vol II, Palgrave Macmillan 2019) 245–256.

Box 1. What are obligations under Directive 2001/18 (Overview)

Risk assessment:

- EFSA GMO panel bears primary responsibility for risk assessment of GM food and feed; procedual and sustantive requirements are laid out in Commission Implementing Regulation No 503/2013
- The EMA, together with the Member States' competent authorities, is responsible for risk assessment of medicinal products
- Environmental risk assessments (ERAs) fall within remit of national competent authorities

Risk management (only if risk is identified during assessment):

- Carried out jointly by national competent authorities and EC -> but relevant Committees rarely secure the qualified majority: often not due to objection, but „no opinion" -> goes to Appeal Committee

Monitoring: Even if only negligible risks identified

- Requires a monitoring plan, submitted to EFSA as part of authoristation dossier
- If authorisation is granted: monitoring (of both adversal and beneficial effects) and reporting obligations
- Reports must be submitted to EC and national competent authorities; EFSA responsible for monitoring reports

Labelling: applicable if derived from GMO, detection limit of 0.9%/0.1%; certain categories excluded

Overview of GMM Regulation in the EU

Contained Use of GMMs, Scope and Classification

Where an ELM entails the involvement of one or more GMMs, compliance with the requirements set forth in the GMM Directive" becomes mandatory.[90] The Directive pursues the overarching objective of protecting both human health and the environment against potential hazards arising from the handling of GMMs. To this end, it establishes a regulatory framework for the so-called "contained use" of such organisms.

The notion of "contained use" is defined broadly within Directive 2009/41/EC. Art. 2 c) Directive 2009/41/EC stipulates that "'contained use' means any activity in which micro-organisms are genetically modified or in which such GMMs are cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures are used to limit their contact with, and to provide a high level of safety for, the general population and the environment."

It encompasses any operation in which micro-organisms are genetically modified or in which GMMs are cultivated, stored, transported, destroyed, disposed of, or otherwise employed, provided that specific physical, chemical, or biological containment measures are applied to prevent their uncontrolled release and thereby ensure a high level of safety for the general public as well as the environment. Which measure satisfies the "containment" requirement depends on the individual case regarding which containment measures is, given the nature of the product, required to prevent a release into the environment. "Environment" in this sense needs to be understood in light of Art. 2 Directive 2001/18, in particular its Nr. 4, which stipulates that the purpose of these provisions is to limit contact with the general population and the environment. In this respect, a capsule carrying GMOs, which is being swallowed will not classify as containment. Where such a GMO is securely contained in a brick, may only be considered to be classified as "contained" if such a brick is proven to be unbreakable and it would fulfil the criteria for contained use of Directive 2009/41/EC.

As illustrated later, this regulative solution can under certain circumstance create a risk paradox: A modified bacteria/cell culture grown *in vitro* (in a lab) is strictly regulated, while the *identical* modified bacteria/cell produced *in vivo* (in the patient) could potentially escape all GMO regulations. A potential solution could be to introduce the concept of *functional containment* for such situations, whereby engineered biological or genetic safety mechanisms are used to restrict the survival or activity of modified microorganisms to specific physiological conditions. Incorporating this idea could provide a meaningful regulatory and scientific bridge for cases where GMMs operate inside the human body, where the physical containment obligations under Directive 2009/41/EC no longer apply and the exclusion of humans from the GMO definition under Directive 2001/18/EC creates legal uncertainty.

Prior to engaging in any contained use of GMMs, the natural or legal person assuming responsibility for the activity (the "user") is legally obliged to carry out a comprehensive risk assessment. This assessment must evaluate, inter alia, the potential adverse effects on human health and the environment, including the safe management of waste streams and effluents arising from the operation. Based on the outcome of this assessment, the proposed activity is classified into one of four risk categories:

- Class 1: Activities presenting no or negligible risk;

[90] See for a comprehensive assessment Federica Ronchetti, Laura Springer, Kai Purnhagen, *The Regulatory Landscape in the EU for Dairy Products Derived from Precision Fermentation: An Analysis on the Example of Cheese* (Springer, 2024).

- Class 2: Activities presenting low risk;
- Class 3: Activities presenting moderate risk;
- Class 4: Activities presenting high risk.

Where premises are to be employed for the first time for contained use involving GMMs, the user must submit a formal notification to the competent authority of the Member State in which the activity will take place. Such notification must include, at a minimum: (i) the name and contact details of the user; (ii) evidence of the qualifications and training of personnel responsible for supervision and safety; and (iii) a general description of both the premises and the nature of the intended activities.

The procedural requirements differ according to the risk classification. For Class 1 activities, the submission of a complete notification suffices, and the user may proceed without awaiting further authorisation. In the case of Class 2 activities, an extended notification containing additional information is required. Where the premises have already been authorised for Class 2 or higher activities, the user may commence operations immediately upon notification; otherwise, the user must await the competent authority's response. Should the authority fail to issue a refusal within 45 days following submission, the activity may proceed by default under the principle of tacit authorisation.

By contrast, Class 3 and Class 4 activities necessitate *prior* authorisation from the competent authority. The notification must comply fully with the information requirements enumerated in Annex V, Part C of Directive 2009/41/EC. A written decision must be rendered within 45 days for first-time notifications or within 90 days for subsequent notifications concerning the same premises. In both cases, authorisation constitutes a *conditio sine qua non* for the lawful commencement of the activity.

Qualified Presumption of Safety

The Qualified Presumption of Safety (QPS)[91] concept, introduced by EFSA, constitutes a regulatory tool designed to streamline and rationalise the risk assessment of micro-organisms utilised in food and feed production, particularly in the context of applications for market authorisation.

Granting QPS status presupposes that the relevant strain has been extensively characterised in scientific literature, that its taxonomy is well defined, and that its safety has been assessed across several dimensions, including potential adverse effects on human, animal, and environmental health. Micro-organisms meeting these criteria are exempted from undergoing repeated, case-by-case safety evaluations in subsequent authorisation procedures. The presumption of safety is thus qualified in the sense that it is based on cumulative scientific evidence and the absence of identified hazards under specific, well-defined conditions of use.

The authority to confer QPS status lies with EFSA's Panel on Biological Hazards (BIOHAZ Panel). In determining whether a biological agent qualifies, the Panel undertakes a systematic assessment of: (i) the taxonomic identity of the organism; (ii) the extent and reliability of the existing body of knowledge; and (iii) potential safety concerns, including, inter alia, the presence of antimicrobial resistance determinants. The evaluation process is guided by a structured decision tree, which provides the analytical framework for determining suitability for inclusion on the QPS list.

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[91] See for a comprehensive assessment Federica Ronchetti, Laura Springer, Kai Purnhagen, *The Regulatory Landscape in the EU for Dairy Products Derived from Precision Fermentation: An Analysis on the Example of Cheese* (Springer, 2024).

Upon a favourable assessment, the micro-organism is added to the QPS positive list, together with any qualifications or conditions limiting the scope of its presumed safety. This list is subject to periodic revision: the BIOHAZ Panel publishes an updated version every three years.

It bears emphasis, however, that the granting of QPS status operates independently of the mandatory pre-market authorisation procedures required for placing specific products on the market. While the use of a QPS-listed micro-organism may facilitate and expedite regulatory authorisation by obviating the need for a full safety re-assessment, it does not, in itself, confer marketing authorisation. Conversely, micro-organisms lacking QPS status are not prohibited in food production; however, their use necessitates a comprehensive safety evaluation supported by additional data, entailing both greater regulatory scrutiny and increased costs in terms of time and financial resources. While this applies for food and feed, having a QPS for ELMs outside food and feed may streamline the risk assessment and reduce costs.

APPLICATION OF GMOs AND GMMs LEGISLATIVE FRAMEWORK TO ELMs

This section applies the legal framework identified to concrete cases concerning ELMs. Depending on the type of commodity employed, other legal framework not identified above may need to be applied in addition. Following a "law in action" approach,[92] the legal framework will be hypothetically applied to several projects selected by the EIC for the purposes of the study with the aim to illustrate the application of the legal framework in action, identify potential facilitators and barriers for investments and identify potential gaps and uncertainties. It should be noted that each GMO which are not exempted, and even if several are contained in one product, needs to undergo an authorisation procedure. The cases where we apply the legislative framework to are the following:

Table 2. EIC ELMs projects assessed for the report

Project Acronym	Objectives
Bioaction	BIOACTION aims to transform implant-associated bacteria for the production of molecules that support in vivo cell recruitment and tissue regeneration, exploiting engineered liposomes and bacteriophages incorporated into hydrogel scaffolds. BIOACTION will develop advanced biomaterial substrates that can reprogram biofilm towards a beneficial role in supporting the regeneration of target tissues. It will establish a high versatile technology to be used as injectable materials and implant coatings for the treatment of implant-associated infections.
Bio-HhOST	Bio-HhOST is building bio-hybrid materials (organoids) that comprise living & artificial cells, in dynamic communication, such that artificial cells may influence the proliferation, differentiation and function of living cells. This is accomplished by producing precision engineered, microscale, liquid and lipid bilayer-based, chemically compartmentalised artificial cells, co-localised with live cells. The artificial cells can respond to chemical stimuli in the environment to release signalling molecules, on demand, and to regulate the neighbouring living cells, as found in complex biological tissues. The proof of concept is brain organoids for drug development to replace animal models.
Fungateria	The Fungateria project aims to generate an innovative portfolio of ELMs that combine fungi with bacteria. Growing the vegetative part of the mushroom—the mycelium—on different organic substrates is the most common way of producing fungi-based materials. The project will combine the mycelium with engineered bacteria that serve as a chassis for sensor-containing genetic circuits. The resultant ELMs will exhibit advanced functionalities and inducible degradation when no longer needed. Proof of concepts are biodegradable disposable slippers for the hospitality sector, a water filtration system (consumer or in

[92] Roscoe Pound, 'Law in Books and Law in Action' (1910) 44 American *Law Review* 12-36.

	industrial/public settings) and an insulation panel with CO_2 capturing properties for the building sector.
ISOS	ISOS is pioneering the development of a groundbreaking biomedical treatment: an implantable micro-bioreactor, made by genetically engineered probiotic bacteria (GEB) integrated into biomaterials. ISOS GEB are designed to survive within the pathological environment and synthesize the therapeutic molecules in response to specific patient-specific signals such as inflammation or reactive oxygen species. This innovative treatment aims at replacing the repeated injections or other treatments required for chronic diseases, by a single micro-injection, eliminating pain, burden, and costs for the patient. As a proof of concept, ISOS is engineering specific bacteria to treat wet age-related macular degeneration (wAMD).
LoopOfFun	Fungi are amazing factories, producing numerous bioactive metabolites of therapeutic interest. LoopOfFun has recognised their potential in yet another innovative area – as part of engineered living materials (ELMs), with open- and closed-loop control of mechanical and structural properties. The project will identify fungi gifted with superior abilities for materials synthesis and harness them for synthetic biology-based programming. The programming will be accomplished via a novel automatic robotised platform to develop the fungi into ELMs based on iterative design-build-test-learn cycles. The outcomes will then support the rational design of such materials for a filter able to degrade volatile organic compounds and with anti-clogging properties, and for furniture (e.g. stool) with heterogenous stiffness distribution in the same material.
NextSkins	NextSkins is inspired by the structure and function of the many layers of skin. Researchers will mimic the specialised skin arrangement to make two engineered living materials: one is a patch with a therapeutic role to recognise and treat skin diseases and the other one, a sustainable alternative material to plastics or ceramics, with a purpose to be used as a protective garment in sports (e.g. helmet).
PRISM-LT	PRISM-LT will use a hybrid living materials concept to create a flexible platform for living tissue manufacturing. The innovative bio-ink will contain stem cells integrated into a supporting matrix with engineered helper bacteria or yeast cells. The bioprinting process will generate a 3D patterned structure in which stem cells can differentiate into different lineages through controlled stimulation within the cellular microenvironment. The project aims to implement this strategy for the development of two symbiotic materials designed for biomedical (organoids or tissue of bone marrow to be used for drug development as a replacement of animal models) and food applications (marbling meat), respectively.

The following section will apply and assess the regulatory environment of each project, exemplifying the application of the legal framework in action, identify potential facilitators and barriers for investments and identify potential gaps and uncertainties. For this reason, the study will focus on the regulatory aspects that need special attention only and cluster the (part of the) projects which are subject to a comparative regulatory approach.

ELMs for Health application

ELMs as Factory of Medicinal Products in or on the Patient (e.g. Bioaction, ISOS, NextSkins)

The projects aim to develop materials which are in one way or the other designed to cure diseases and are injectable or attachable or brought by other means into the human body. For example, Bioaction seeks to engineer implant-associated bacteria in microfilms to enable the programmable production of defined proteins for in vivo cell recruitment and tissue regeneration. ISOS develops implantable micro-bioreactors which can produce pharmaceuticals inside of the human body, which can replace injections. NextSkin's living material mimics specialised skin arrangements which can be used to treat skin diseases.

These endeavours implicate a range of Union legislative acts governing market access from different regulatory perspectives, raising questions of the applicable law. Insofar as the technologies developed in these projects involves the production of molecules by means of yeast, bacteria, or artificial cells, modified through genetic engineering, which then result in modified cells within the human body, the central issue arises whether the original modified cells (when used as injectable materials or implant coatings) are to be classified as GMOs and as GMMs. Should the genetic modification methods employed fall within the scope of New Genomic Techniques (NGTs), the difficulties in establishing legally compliant identification methods may render it uncertain whether such products can be authorised at all, but less of an issue related to ELMs. Those applications covered here allow not only for detection but also for identification. Still, the identification methods need to be made available and verified.

Applicable Law

As long as the material is being used in a contained environment, the respective contained environment needs to be in line with the requirements of GMM law. Once it is placed on the market, the exact classification determines the applicable law. Materials classified as a medicinal product in accordance with Art. 1 Nr. 2 of Directive 2001/83/EC are subject to a separate authorisation as a medicinal product. In case it classifies as GMO, the relevant provisions would be applicable via this legislative framework. Medicinal products that contain or consist of GMOs constitute a distinct regulatory category by virtue of the reciprocal provisions laid down in Article 12(2) Directive 2001/18/EC and Articles 6(2) and 6(3) Regulation (EC) No 726/2004. In such cases, the marketing authorisation application must additionally include an environmental risk assessment (ERA) conducted in accordance with Annex II of Directive 2001/18/EC. Consequently, the application is required to comprise the complete technical dossier, providing all information mandated under Annexes III and IV of Directive 2001/18/EC.

In some cases, ELMs may also combine elements of medical devices with medicinal products and thus may require not only assessment as a medicinal product under 2001/83/EC, but further need to take into account it's status of medical device. The exact nature and integration of such combinations will impact the classification of the product.

Processing Aid

The regulation of GMOs would only be applicable, if the "medicinal product for human use [would be] containing or consisting of genetically modified organisms within the meaning of Article 2 of Directive 2001/18/EC" (Art. 6 (2) Regulation (EC) No 726/2004). The question arises when a product "contains or consist" of a GMO. In the area of food and feed, a product where processing aid had been used, which cannot be detected in the final product, would not be considered a "GMO". It has so far not been clarified if this categorisation would also extend to non-food GMOs. In all projects, however, the processing aid itself, which has been programmed with the use of GMOs to produce proteins, hormones, or other types

of biologicals, will be injected into the human body or used as tissue on the human body, hence the GMO legislation would be applicable (see below).

GMOs produced in vivo (e.g. as in Bioaction).

The case of Bioaction exemplifies the new regulatory challenges posed by modern medicine. For instance, a bacteriophage or nanoparticle treatment where an ELM is injected into a patient to genetically manipulate implant-associated bacteria. The virus bacteriophage or nanoparticle alters the human symbiotic bacteria, turning those bacteria into GMOs. This scenario raises a critical question: do the Union's GMO laws apply to these newly modified cells produced inside the body? Article 2(2) of Directive 2001/18/EC explicitly excludes human beings from the definition of a GMO. Taken literally, this would imply that GMOs produced in vivo by an ELM integrated into the human body fall outside the scope of the Directive and, consequently, of the Union's GMO regulatory framework. From a practical standpoint, it would in any event be extremely difficult to obtain authorisation for, and to conduct testing on, a product produced in vivo. Yet from a risk perspective, it remains difficult to justify why the very same product should require authorisation when produced in vitro, but not when produced in vivo. This creates a risk paradox, since a modified bacteria/cell culture grown *in vitro* (in a lab) is strictly regulated, while the *identical* modified bacteria/cell produced *in vivo* (in the patient) could potentially escape all GMO regulations. While an ELM introduced into the human body that itself constitutes a GMO would have been subject to prior authorisation, thereby arguably reducing the associated risk, the situation becomes more complex in the case of a processing aid integrated into the body that subsequently produces a GMO in vivo. This illustrates a risk paradox, which may be solved with the concept of functional containment as indicated earlier in the report. It thus remains doubtful whether the exclusion of human beings under Article 2(2) of Directive 2001/18/EC was ever intended to encompass such scenarios. Rather, these cases appear to expose an unresolved lacuna within the current framework of Union GMO law. It is therefore critical for regulators to clarify the scope of Article 2(2).

LMOs reproducing (parts of) the human body in vitro (e.g. Bio-hHOST, PRISM-LT)

A similar observation applies to a living modified organism (LMO) reproducing (parts of) the human body. Article 2(2) of Directive 2001/18/EC explicitly excludes human beings from the definition of a GMO. One begs the question if, when a part of the human body is developed with the help of GMOs, whether the GMO framework is applicable at all and hence the GMO framework would not be applicable. While the legal nature of a "human being", including the beginning and end of "life" has been subject to intensive legal discussion in many legal domains, how "human being" is defined in Article 2(2) of Directive 2001/18/EC has not been discussed.

Additionally, multiple EIC ELM projects cover the usage of human organoids. These 3D tissues may be made from either native or altered cells, which carry potential for therapeutic treatment and may be used in drug development, personalized drug screening or – potentially – human tissue regeneration. For example, the molecular underpinnings of neurological illnesses such as autism are increasingly being modelled using human brain organoids. This technique creates significant regulatory ambiguity as it moves from in vitro research models to direct therapeutic uses, including employing lab-grown, engineered tissues for human tissue regeneration. This application raises serious legal questions that may discourage investment in these next-generation regenerative medicines by directly testing the limits of the "human being" exemption under the existing GMO framework.

Identification and Detection

With the applicability of the GMO legislation, the products would need to go through an authorisation procedure, which includes the submission of the requirements stipulated in Annexes II to IV of Directive 2001/18/EC. Of particular note is the requirement of Annex IIA II Nr. 6 and 7, which requires submission of identification and detection techniques. For foods, Commission Regulation (EC) No 641/2004 qualifies the legal requirements of identification and detection methods as analytical methods.[93] For non-food and feed, no such implementation measures exist at the EU level. However, Directive 2001/18/EC implicitly presupposes the use of analytical methods, as witnessed by the wording of Art. 25 Directive 2001/18/EC.[94] While Member States enjoy discretion with respect to the identification and detection methods, they accept when implementing Directive 2001/18/EC, they are bound to this normative decision when implementing the Directive into national law. In their authorisation dossier, the projects would hence have to produce analytical methods to detect and identify the GMOs in the final product.

ELMs as Foods (e.g. PRISM-LT)

Where foods made from ELMs involve GMMs, but fall outside the categories of additives, enzymes or flavourings, their regulatory status hinges on whether they are deemed produced *from* or *with* a GMO.[95] Under Regulation (EC) No 1829/2003, only products containing material derived from the GMO are included, whereas products made merely *with* a GMO are excluded, as its Recital 16 clarifies. While this recital has been introduced with the view of excluding products obtained from animals fed with GM feed, it is generally accepted in scholarly analysis that this provision also extends to foodstuffs manufactured with the aid of a GM processing aid, provided no recombinant DNA remains in the final product. The Commission's 2006 report[96] confirm that the decisive criterion is whether the GMM is fully removed during production.

In practice, ELMs qualify as processing aid only if no recombinant DNA is detectable. A zero-tolerance approach to DNA traces, however, has been criticised as technologically and economically unworkable.[97] Scholars propose a de minimis threshold,[98] already discussed in EFSA opinions[99], to reconcile regulatory consistency with scientific feasibility. Yet no harmonised standard has been formally adopted.

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[93] Aleksandra Hubar-Kolodziejczyk, Kai Purnhagen, 'Regulatory requirements for the identification, detection and quantification of gene-edited products in light of the (r)evolution of new genomic techniques' (2025) *European Journal of Risk Regulation* 1375-1391.

[94] Aleksandra Hubar-Kolodziejczyk, Kai Purnhagen, 'Regulatory requirements for the identification, detection and quantification of gene-edited products in light of the (r)evolution of new genomic techniques' (2025) *European Journal of Risk Regulation* 1375-1391.

[95] See for details Federica Ronchetti, Laura Springer, Kai Purnhagen, *The Regulatory Landscape in the EU for Dairy Products Derived from Precision Fermentation: An Analysis on the Example of Cheese* (Springer 2024).

[96] Report from the Commission to the Council and the European Parliament on the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed COM(2006) 626 final.

[97] Hans-Georg Dederer, 'rDNA Traces in Fermentation Products Using Genetically Modified Microorganisms (GMMs)' (2021) 18 *Stoffrecht* 135–147; Federica Ronchetti, Laura Springer, Kai Purnhagen, *The Regulatory Landscape in the EU for Dairy Products Derived from Precision Fermentation: An Analysis on the Example of Cheese* (Springer 2024).

[98] Vittorio Silano, José Manuel Barat Baviera, Claudia Bolognesi *et al.*, 'Characterisation of microorganisms used for the production of food enzymes' (2019) 17(6) *EFSA Journal* 5741.

[99] Guido Rychen, Gabriela Aquilina, Giovanna Azimonti *et al.*, 'Guidance on the characterisation of microorganisms used as feed additives or as production organisms' (2018) 16(3) *EFSA Journal* 5206; Vittorio Silano, José Manuel Barat

ELMs in Products Deliberatively Released into the EU Environment (e.g. Fungateria, LoopOfFun, NextSkins, PRISM-LT)

The Fungateria, LoopOfFun and NextSkins projects include as proof of concepts materials to be used for products deliberatively released in the environment. Some of these products are for direct use of citizens while others are for building constructions and environmental remediation.

ELMs composed of GMMs must comply with the requirements set out in the GMM legislation, most notably the obligation to maintain them under contained conditions. Resulting products fall within the scope of EU GMO law only if they contain GMO material. In the food and feed sector, products produced with processing agents that are no longer detectable in the final product are not classified as GMOs. It remains unclear whether this approach extends to non-food GMOs. Since detectability is a prerequisite for authorisation of deliberate release into the environment, undetectable traces cannot reasonably trigger such a requirement. Accordingly, the reasoning of Recital 16 of Regulation (EC) No 726/2004 should be applied by analogy to deliberate release under Directive 2001/18/EC.

Another question concerns the question of unintentional release. According to Art. 2 (2) Directive 2001/18/EC only the "intentional" introduction of GMOs triggers the application of the specific EU GMO regulatory framework. This raises the question of the appropriate legal standard for determining intent. The issue is particularly significant given that GMO material from unauthorised engineered living materials (ELMs) may enter the Union unintentionally, for example, through incidental contact with a structure composed of living cement outside the EU, followed by the inadvertent transfer of GMO material into EU territory. The European Court of Justice (ECJ) has held that "the intentional introduction, into a foodstuff, of a substance [..., omission by the authors] cannot be made into a condition for application of the authorisation scheme provided for by Regulation No 1829/2003, since the risk to human health which that regulation is intended to prevent is independent of whether the substance in question is introduced intentionally or adventitiously."[100] Although the judgment concerned Regulation (EC) No 1829/2003 specifically, its rationale applies equally to Directive 2001/18, given that the relevant provisions of the Regulation explicitly cross-reference the Directive. Subjecting the intentionality requirement to a risk-based interpretation is, at the very least, unexpected, since "intent" constitutes a definitional prerequisite for the concept of "deliberate release." The Court's approach suggests that, despite the clear textual requirement, EU judicial practice affords the "intentional" element limited interpretative weight in the context of GMO regulation. If this would be true and this reasoning would extend to ELMs in other countries unintentionally introduced into the EU by its citizen, this would be of major concern for citizen travel outside of the EU territory.

Baviera, Claudia Bolognesi *et al.*, 'Characterisation of microorganisms used for the production of food enzymes' (2019) 17(6) *EFSA Journal* 5741.

[100] ECJ, Case C-442/09 *Bablok and Others v Freistaat Bayern* ECR I-07419, para 89.

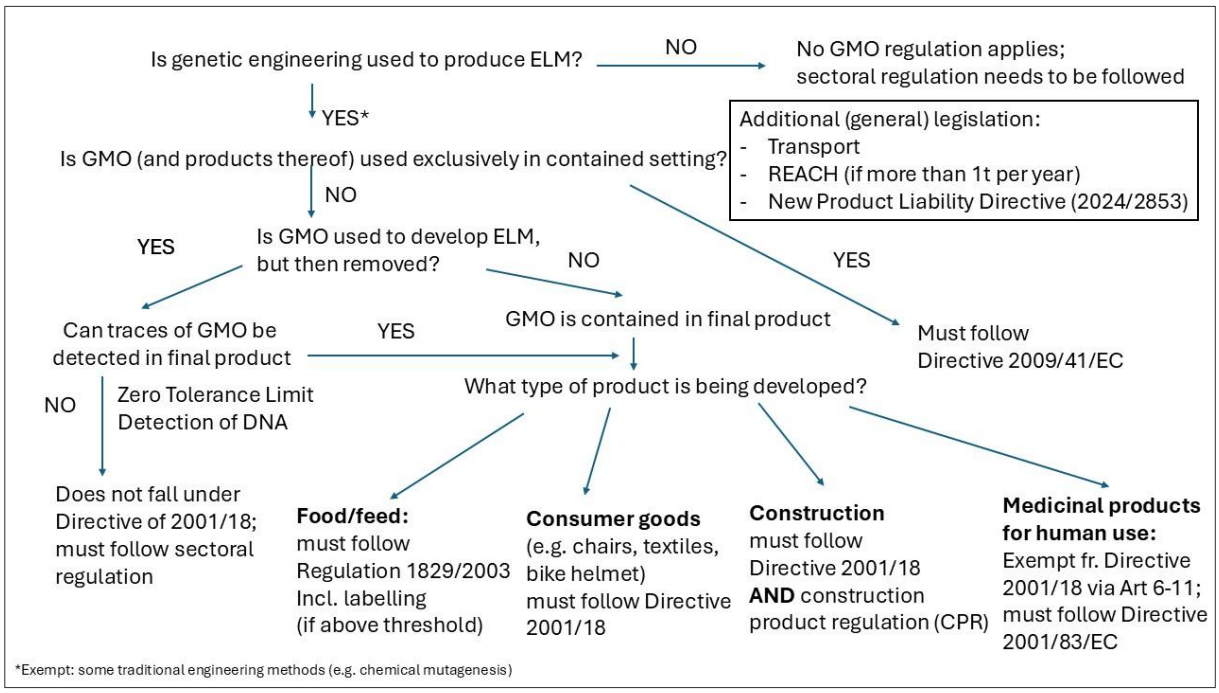

Figure 2. General overview of applicable regulatory considerations for Engineered Living Materials

Umbrella Regulations

Absent inclusion under the GMO legislation, ELMs or products produced from ELMs may fall under other legislative frameworks.

Novel Food Regulation

In cases of ELMs as food or producing foods, the Novel Food Regulation (NFR)[101] may be applicable, notably under categories covering foods produced from microorganisms or novel processes. Several GMM-derived foods, including human milk oligosaccharides, have recently been authorised under the NFR and entered in the Union List. The unresolved tension between the GMO law's exclusion of processing agents and the NFR's broad novelty categories leaves operators navigating significant legal uncertainty.

For projects involving mycelium such as Fungateria or LoopOfFun, in case they would produce foodstuffs, the question remains if the products they develop can be categorised as "novel" at all.[102] Under the NFR, foods lacking significant consumption in the EU prior to 15 May 1997 require authorisation, as they cannot rely on a history of safe use. The Regulation exempts products derived from animals or plants obtained through traditional breeding or propagation practices with such a history, and also products from non-traditional practices where no material compositional changes arise. By contrast, enzymes, additives, flavourings, and extraction solvents remain outside the NFR's scope. For mycelium, the question arises if they are novel, as the fruiting body more often than not has a history of safe use, while the mycelium does

[101] 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 OJ L 327.

[102] See for a comprehensive assessment of the regulation of mycelium products in the EU Alexandra Molitorisová, Alessandro Monaco, Gerald Lackner, Seth Roberts, Kai Purnhagen, *Regulation of Mushroom- and Mycelium-Based Products in the EU* (Springer 2025).

not. It is difficult for food business operators to find a satisfying answer to this question, even more so in the absence of any meaningful consultation possibilities with EFSA.[103] In practice, as the duty to determine the novelty of the products lies with food business operators themselves, scholarly work has proposed a scientific, risk-based, and case-by-case approach, which may be best for consumer protection but is hard to follow up for start-up companies.

Product Safety Regulation

The EU laws on product safety are currently being updated, and the new law will be effective from 9 December 2026. As it is unlikely that products derived from ELM's or ELM's themselves will be placed on the market before 9 December 2026, we take the updated version of EU product safety law, Directive 2024/2853[104], as a basis for our analysis. Most ELMs qualify as a product in the sense of Art. 2 Nr. 1 Directive 2024/2853. In case the ELMs are defective in the sense of Art. 7 Directive 2024/2853, as, for example, they do not comply with the relevant safety requirements of Union law (they are not authorised or do not fulfil other safety requirements under food law or REACH), and this results into a "damage" in the sense of Art. 6 Directive 2024/2853 (that is death or personal injury, including medically recognised damage to psychological health or damage to, or destruction of, any property), the manufacturer may be subject to compensation. In the case of ELMs, a particular legal challenge arises when the damage results from the defect of a product which had been produced by the ELM. Would the "manufacturer" of the ELM then also qualify as "manufacturer" of the final product, produced by the ELM and be liable accordingly?

General Food Law

In the case of foods or feeds produced by ELMs, the food or feed business operator who places the product on the market is responsible "that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met."[105] In the case of food or feed products produced by ELMs, it would be questionable if the food business operator, who placed the ELM on the market, would also be responsible for the product produced by the ELM. Art. 3 Nr. 8 General Food Law presupposes a situation where a food business operator places a food directly on the market. The situation of an ELM producing a food or feed has not been foreseen in this case. Furthermore, as in the case of foods food business operator are tasked with the obligation to comply with food law and verify this compliance, any uncertainty of food operators regarding the legal interpretation is likely to result in risk adverse behaviour, potentially stifling innovation in particular around ELMs.

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[103] Monaco, Alessandro, 'Regulatory Barriers and Incentives for Alternative Proteins in the European Union and Australia-New Zealand' (2025) 127(13) *British Food Journal*, 171-189.

[104] Directive (EU) 2024/2853 of the European Parliament and of the Council of 23 October 2024 on liability for defective products and repealing Council Directive 85/374/EEC, OJ L 2024/2853.

[105] 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 (General Food Law Regulation) OJ L 31, art 17(1).

ETHICAL CONSIDERATIONS

ELMs represent a transformative development in biotechnology, combining the adaptability of living systems with the functional properties of materials. Their potential applications (ranging from self-healing medical implants to environmentally responsive structures) promise significant societal benefits. At the same time, they raise complex ethical and societal questions, particularly concerning responsibility, transparency, and public trust.

A central ethical issue is responsibility. Traditional materials typically pose limited dynamic risks once deployed, but ELMs can grow, adapt, or interact with their environment in ways that may be difficult to foresee. This places a heightened responsibility on researchers, developers, regulators, and users. Responsibility includes not only ensuring that ELMs are safe at the point of release but also taking into account their behaviour over time, potential ecological interactions, and long-term stewardship. Accountability mechanisms must clearly define who is responsible if an engineered living system behaves unexpectedly or causes unintended consequences to producers, distributors, users, or regulators.

Closely linked to responsibility is the need for transparency. Because ELMs are complex and can evoke public concerns similar to those surrounding GMOs or synthetic biology, transparent communication about their design, function, risks, and benefits is essential. Transparency involves more than merely disclosing technical details; it requires genuine clarity about uncertainties, limitations, and the ethical reasoning behind design choices. Openness helps ensure that public discourse is informed rather than driven by speculation or fear, enabling people to understand how living materials work and how risks are managed.

Transparency is also a foundation for public trust, which is indispensable when deploying living materials in health or environmental contexts. Trust cannot be assumed; it must be earned through consistent actions that demonstrate respect for societal values, responsiveness to concerns, and commitment to safety. Public engagement (through participatory dialogues, citizen panels, and co-design processes) can support trust by giving people a meaningful voice in decisions that potentially impact their lives or their environment. Building trust is not only a matter of communication but also of demonstrating that societal welfare and ecological integrity take precedence over commercial or institutional interests.

While legal frameworks define the minimum requirements for safety, authorisation procedures, and liability, they can rarely keep pace with the rapid evolution of emerging technologies. Here, ethical governance can complement the law by providing flexible, anticipatory, and value-driven guidance. Ethical governance mechanisms (such as ethics committees, responsible innovation frameworks, expert advisory boards, and voluntary codes of conduct) allow stakeholders to identify and respond to issues that are not yet codified in regulation. They foster continuous reflection on moral obligations and encourage best practices that exceed legal minima. Importantly, ethical governance can act as a bridge between scientific innovation and public expectations, ensuring that societal values inform the direction of technological development rather than merely reacting to it.

In sum, the responsible development of ELMs requires a combination of robust legal regulation and proactive ethical governance. By integrating responsibility, transparency, and public trust into both scientific practice and policymaking, society can harness the benefits of Engineered Living Materials while ensuring that their use remains aligned with ethical principles and public interests.

ECONOMICS

The design of the regulatory environment has implications for the expected benefits and costs of using ELMs within the EU. In the following section the generic economic model to assess the benefits and costs of investing into ELMs will be presented. The model will be used to combine the legal framework with its economic implications and how this will impact ELMs currently under development.

The design of the regulatory environment affects not only the time length and costs of receiving market authorisation and placing the products on the market but also the research and development costs, as well as the benefits that investors/companies can expect from marketing their products. The research and development costs are driven by the already available knowledge they build on. The advancement of the knowledge frontier often requires investments in additional research equipment and facilities, as well as the necessary human capital. The development phase consists of translating this knowledge into new products. The costs of the R&D phase not only depend on the physical and human capital needed but, depending on the case, on the regulatory environment in which they are happening. The safety requirements for experiments at the laboratory level and product testing can have a substantial impact on costs especially if field trials might be necessary (the costs with plants genetically modified can be in the thousands of EUROs). In addition, field trials may be difficult in Europe for some of the ELMs as is currently practiced for field trials of GMOs where EU member states can "opt-out" of cultivation and field trials. The German Research Foundation (DFG) has highlighted how the use of laboratory equipment in Germany increases costs without yielding additional safety benefits and made several suggestions for improvement.[106]

When comparing the market access of a product, it is imperative to recognize the differences in the regulatory methods. For ELMs, it is essential to differentiate between authorisation (the EU's model) and approval (the model of the USA). Approval means that a regulator has reviewed the product's safety, efficacy, and quality data and has formally approved it for marketing and use.[107] Authorisation means that a regulator has permitted the product to be placed on the market or to be used after demonstrating compliance with predetermined requirements. While for approvals, regulators enjoy a wide margin of discretion as they can also include efficacy reasons, regulatory review during authorisations is tied to predetermined legislative requirements, often providing less flexibility.

The authorisation for ELMs to be placed on the market in the EU differs depending on the specific ELM. The authorisation process involves direct costs, but the length of time also generates additional costs for investors, as this delays market entry and access to financial support. Investors are reluctant to provide financial resources if companies need authorisation, such as via the Novel Food regulation or the GMO regulation, because this step often increases the costs substantially and renders the investments unprofitable.

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[106] Permanent Senate Commission on Genetic Research 'Recommendations on Reducing Bureaucracy and Harmonising the Implementation of Genetic Engineering Legislation in Relation to Genetic Engineering Activities at Safety Level S1' published June 2024. Many of the ELMs under development could benefit from an improvement in the guidelines for the use of laboratory equipment as this can reduce time and money.

[107] Yonatan Chemla, Connor J. Sweeney, Christopher A. Wozniak and Christopher A. Voigt 'Design and regulation of engineered bacteria for environmental release' (2025) 10, Nature Microbiology 281-300.

The regulatory environment also affects the size of the market. Product use can be regionally restricted, for example, according to the geographical regions of the EU that allow them, or differentiated by consumer groups, such as between children and adults.

Even if companies comply with ex-ante regulations, they might be exposed to ex-post liability. Ex-post likability can come in different forms. Companies may be held liable for not having complied with ex-ante regulations and either have to pay a fine or withdraw their product from the market (see e.g. the Amflora case[108], the honey case[109], the Pioneer case[110], the Star Link case[111], or the Viptera case[112]).

Capturing these challenges in an economic model can be done by explicitly modelling the incentives for investing in the development of new ELM products, considering the uncertainty about the time length of the R&D phase, the authorisation phase, and the market phase, and including the ex-post liability as a jump process indicating the probability of being held liable. The results of the incentives to invest will depend on the levels of uncertainty and the relation between reversible and irreversible costs. Reversible costs are those expenditures that are of further use even if the project stops. Examples include the use of laboratory chemicals needed for one experiment but can also be used for another experiment if the other stops. Irreversible costs are those that are not of further use when the experiment stops. This includes experiment-specific equipment. Reversible and irreversible costs also characterize the authorisation phase. The specific dossier to be developed for the application and the costs for developing it can be considered as being irreversible, as it is case-specific. Some of the expenditures made for the authorisation can be used for other purposes as well, similar to expenses for equipment for research and development. In many cases, expenditures for equipment are not necessarily completely irreversible. Equipment that is no longer of use if the experiment stops might be possible to sell. In that case, they are only partially irreversible.

Benefits compensating for the investments made are generated when products are sold on the market. The benefits being generated depend on the size of the market and the respective price of the product. The market size can be EU-wide or regionally constrained. Procurement policies can often play a significant role in determining market size.

The uncertain time length of the different phases can be included by referring to a so-called hazard function. A hazard function is the instantaneous rate of an event occurring at a specific time, given that the event has not yet happened. It measures the likelihood of "failure" (e.g., a patient's death, a machine breaking) at any given moment, conditional on having survived up to that point. In our case, the measure is the likelihood of success, e.g., having developed a product that can be submitted for authorisation, the likelihood of receiving authorisation, and the likelihood that a product disappears from the market. More formally, a hazard rate function can be written as

$$f(\mathrm{k}) = he^{-h\mathrm{k}}, \text{ with } F(\mathrm{k}) = \int_0^{\mathrm{k}} h\, e^{-h\mathrm{k}} d\mathrm{k} = 1 - e^{-h\mathrm{k}}, E[\mathrm{k}] = \frac{1}{h},$$

where *k* is the expected length in time that an event happens, and *h* is the so-called hazard rate. E.g., a hazard rate of 0.1 results in the expected time length for the event to occur of 10. If time is measured in

[108] Case T-240/10, *Hungary v Commission* ECLI:EU:T:2013:645.
[109] Case C-442/09, *Bablok and Others v Freistaat Bayern* ECR I-07419.
[110] Joined Cases 100/80, 101/80, 102/80 and 103/80, *Pioneer v Commission* ECR 1825.
[111] Colin A. Carter, Aaron Smith, 'Estimating the Market Effect of a Food Scare: The Case of Genetically Modified StarLink Corn' (2007) 89(3) *The Review of Economics and Statistics* 522–533.
[112] Thomas P. Redick, 'Liability Prevention for Agricultural Biotechnology' (2017) 22(1) *Drake Journal of Agricultural Law* 31–64.

years, this would be equivalent to 10 years. Alternatively, if we expect the authorisation phase to last approximately 10 years, the equivalent hazard rate has a value of $h = 0.1$.

We can calculate the net present value (NPV) of an immediate investment in a new product by summing up the different phases. See the Figure below illustrating the different phases, where k_i illustrates the different expected time length for phase *i*.

Figure 3. Illustration of the different phases. Please note that the second phase is either called the approval or the authorisation phase. The correct wording depends on the legal environment and tasks and responsibilities of the institutions involved (see text for clarification).

For the R&D phase costs in present value terms, we can write:

$$R\&D_{t=0} = \int_0^{\kappa_1}(R_0 + r_t e^{-\mu t}dt) \quad (1)$$

Where R_0 are the irreversible R&D costs and r_t the average annual reversible R&D costs.

For the authorisation phase in present value terms we can write:

$$AC_{t=0} = Ae^{-\mu\kappa_1} + \int_{\kappa_1}^{\kappa_1+\kappa_2} a_t e^{-\mu t}dt \quad (2)$$

Where A are the irreversible authorisation costs and a_t the average annual reversible authorisation costs.

For the market phase in present value terms, we can write:

$$MP_{t=0} = Me^{-\mu(\kappa_1+\kappa_2)} + \int_{\kappa_1+\kappa_2}^{\kappa_1+\kappa_2+\kappa_3}(b_t - c_t)e^{-\mu t}dt \quad (3)$$

Where MP are the irreversible marketing costs and b_t and c_t the average annual reversible benefits and costs for selling the product.

For the ex-post liability costs in present value terms, we can write:

$$LC_{t=0} = \theta e^{-\mu(\kappa_1+\kappa_2+\kappa_3)} \quad (4)$$

Where q are the probability-weighted liability costs at the end of the market phase, the implicit assumption made is that the marketing of the product will end if liability has occurred.

We can sum those four equations, equations 1 to 4, up, but need to consider that k_i itself follows a distribution from zero until infinity. This can be summarized as follows:

$$NPV_0 = \iiint_0^{\infty}(-R\&D - AC + MP - LC)g(\kappa_1)d\kappa_1 g(\kappa_2)d\kappa_2 g(\kappa_3)d\kappa_3 \quad (5)$$

If the NPV_0 is larger than zero, this would result in an immediate investment. This does not consider that future benefits and costs are uncertain. In particular, the uncertainty with respect to MP is essential, as it is crucial for generating a positive NPV_0. To keep the model simple, we consider that the future MP can be either high or low, depending on the arrival of additional information over one year. In the case that the future MP at t=1 is low, the NPV at t=1 is negative, and in the case that the future MP at t=1 is high, it results

in an NPV at t=1 that is larger than the NPV at t=0. The future high or low MPs occur with a probability of q=1-q=0.5. In this case, the decision of the product developer is not to start the project now or never, but to consider to invest and start now at t=0, or to wait until t=1, for e.g. one year, look at the development of the value for MP, and if MP is high, to invest and start the project, and if MP is low, not to start the project and to further wait. By postponing the decision by t=1, like one year, making losses in case the additional information gathered reveals the benefits during the market phase will be low and result in losses, can be avoided. In the case of postponement, new information arrives over time, and the new information can be used in decision-making. This possibility does not exist if the project is started immediately. The decision problem now becomes to choose the maximum of investing now or later:

$$maxF(NPV_n, NPV_l) \tag{6}$$

Where NPV_n is the net present value of investing immediately, and NPV_l is the value of investing one year from now in today's values.

Considering the model setting, the threshold value for MP when investing now can be identified. This threshold value provides the following:

$$MP_{t=0} > (1 - qe^{-\mu})\left(R + \frac{r+Ah_1}{\mu+h_1} + \frac{ah_1}{(\mu+h_1)(\mu+h_2)} + \frac{\theta h_1 h_2 h_3}{(\mu+h_1)(\mu+h_2)(\mu+h_3)}\right) + qe^{-\mu} MP_{h\ at\ t=1} \tag{7}$$

Where h_i are the hazard rates for the respective k_i and q the probability that MP at t=1 will be high.

Table 3 provides an illustrative example.

Table 3. Illustrative example of the model presented.

Parameters	Now	Later
Fixed research costs R	150	150
Annual research costs r	1	1
Fixed Authorisation costs A	50	50
Annual authorisation costs a	1	1
Expected R&D in years, E[k_1]	10	10
Expected Authorisation in years, E[k_2]	10	10
Expected Market Phase in years, E[k_3]	10	10
Ex-post liability probability	0.001	0.001
Discount rate *m*	0.04	0.04
Probability of future MP high	0.5	0.5
MP_0, high	1508	1457
MP_0, low	-22	0
Ex-post liability costs at t=0	364	350
NPV MP_0 high	946	860
NPV MP_0 low	-584	0
E[$NPVt_{=0}$]	362	430

Note. All values for the net benefits of the market phase (MP) are in present values at t=0. The value of the ex-post liability has been set equal to the market phase value. For the case MP_0 low, it is assumed the project is not successful.

The example in Table 3 is used to illustrate the use of the model. The model can be parameterized to assess the impact of parameter changes. The key insight from the model is that due to uncertainty and flexibility, the economic incentives for postponing investment decisions are extremely high. In the numerical example presented, the ratio of postponed versus immediate investment is 1.19.

The result is a quite complex equation. Still, parameterization of key parameter values of equation 7 allows for gaining some insights on the effects of R&D costs and length, as well as authorisation costs and length. What is of interest are the terms in the bracket. They represent the impacts of the time lengths of the different phases mentioned above. Partial derivatives with respect to h_i can be derived. The results are complex and an explanation about the details goes beyond this report, but they are available upon request from the authors. They are summarized in the following.

The first result, equation 8, with respect to the "hazard rate" of the R&D phase is negative. An increase in h_1, which is equivalent to a decrease in the expected length of the R&D phase, decreases the need for market phase's net benefits justifying immediate investment.

$$\partial MP_{t=0} / \partial h_1 < 0 \tag{8}$$

The same result is obtained for the partial derivative with respect to changes in h_2, indicating the expected length of the authorisation phase, shown in equation 9.

$$\partial MP_{t=0} / \partial h_2 > 0 \tag{9}$$

An increase in h_2, which is equivalent to a decrease in the expected length of the authorisation phase, decreases the need for the market phase's net benefits for justifying immediate investment.

$$\partial MP_{t=0} / \partial h_3 < 0 \tag{10}$$

The marginal effect with respect to the time length of the market phase shown in equation 10 is positive as expected. A decrease in the time length of the market phase decreases the amount of net benefits in the marketing phase and moves the appearance of ex-post liability forward, both increasing the value of postponement.

While the model appears sophisticated, its specification enables the assessment of the regulatory environment's implications for incentives to invest in new products, as discussed in more detail below, taking the legal environment discussed above into consideration.

REGULATORY OPTIONS

We can apply the above equations to a scenario where all ELMs make use of modern biotechnology, including genetically modified microorganisms generated through New Genomic Techniques. This implies they need authorisation at EFSA level as they would be considered a release into the environment, even if they are non-food, as e.g. biological control methods developed by modern biotechnology have to comply with similar safety requirements. At this point in time the specific requirements for receiving EFSA authorisation are not obvious. Specific EFSA guidelines do not exist; still, the general guidelines apply. In addition, depending on the application, authorisation by EMA may also be required, such as for ELMs for health care. At this point in time, it is not obvious to what extent requirements by EMA can serve as alternatives. Providing guidelines for regulatory authorisation can substantially increase the incentives for investing in bringing products to market. They can reduce the costs in the model discussed above, and this has a positive effect on immediate investment, see equations 8 and 9.

At least four options can be foreseen. They have been summarized in Table 4, including the implications for model parameters presented in Section 3 and the cases being considered. The effects on benefits are discussed under the reasonable assumption of having a more substantial impact on immediate than postponed investments, as mentioned in Section 3.

The implications are assessed with respect to an authorisation process that treats ELMs of the investigated cases as GMMs. GMMs are considered to be treated as under the current regulation and receive authorisation for use in the entire EU. This serves as the reference. A similar line of reasoning applies to ELMs that are GMOs. To keep the discussion simple, we refer to GMMs, as they are the most relevant applications among ELMs.

Option 1: ELMs as GMMs are regulated at the EU level (reference option)

Under this option, ELMs are not exempt from GMO law, and the GMO Directive will apply. This also means that the steps that must be taken to obtain authorisation apply. A risk assessment should be undertaken to assess the safety of the product, followed by voting by Member States in the relevant committees. Decisions are reached by majority voting. Taking past cases into account regarding the authorisation of GMOs, reaching a qualified majority in favor of or against a new technology is highly unlikely.[113] The European Commission makes the final decision and usually follows the advice of different authorities, such as the European Food Safety Authority (EFSA) and the European Medicines Agency (EMA). This decision-making process is highly time-consuming.[114] Therefore, the expected authorisation length (κ_2) will be relatively high, decreasing incentives for immediate investment (see equation 9). The market size for products authorised will be the whole of the EU. The probability of being held liable will be reduced as the products have passed

[113] See, e.g. Richard D. Smart, Matthias Blum, Justus Wesseler, 'EU Member States' Voting for Authorizing Genetically Engineered Crops: a Regulatory Gridlock' (2015) 64(4) *German Journal of Agricultural Economics* 244–262.

[114] E.g., Coen Frederiks, Justus Wesseler, 'A Comparison of the EU and US Regulatory Frameworks for the Active Substance Registration of Microbial Biological Control Agents' (2019) 75(1) *Pest Management Science* 87–103; Richard D. Smart, Matthias Blum, Justus Wesseler, 'Trends in Genetically Engineered Crops' Approval Times in the United States and the European Union' (2017) 68(1) *Journal of Agricultural Economics* 182–198.

an EU risk assessment acknowledged by all Member States. Whether products need to be labeled and a tracking and tracing system needs to be in place for non-food items is not obvious at this point in time. If products need to be labelled, tracked, and traced. The costs during the marketing phase increase, and the net benefits of MP will be reduced, providing additional incentives for delaying investments. The case for labelling, tracking, and tracing of applications of NGTs in agriculture in the EU indicates that the additional costs will be prohibitively high. In the case of ELMs, this needs to be further investigated since their applications are not in agriculture and are much more varied (building products, consumer products, environmental safety products, etc.). The examples assessed indicate that the costs might be lower. As the applications are very specific, they might be easier to track and trace.

Option 2: EU develops a general legislative framework but Member States are free how to apply the framework

In this case, the EU develops a general legislative framework that must be voted on by the EU Parliament and the EU Council. As it is a framework, Member States have the freedom to decide how to apply it to their national legislation. GMO regulations were to be "adjusted" to ELMs, or a specific EU-wide synbio/ELM "GMO regulation" was to be introduced. This option can be compared to the EU's General Food Law. Here, the EFSA gives scientific advice and assesses potential risks. However, business operators bear the main responsibility of ensuring that only safe products are placed on the market. Member States are responsible for ensuring that these business operators fulfil the requirements of the Food Law.[115] For ELMs, this would mean that the way Member States deal with the general legislative framework differs. Some Member States will have strict policies, which could mean a ban on specific ELMs, while others apply less strict policies with almost no effect on the investment decisions of ELMs in comparison to current authorisation policies outlined in scenario 1. At the individual Member State level, the costs for R&D and authorisation can be expected to be lower. The market will be limited to the respective Member States, but products can be sold to other markets after they have received authorisation from the competent authority in the other Member States. Communication between competent authorities can facilitate this process and is often observed. Investors can choose which markets they will target, depending on the restrictiveness of the authorisation requirements and costs. The market size in this case will be smaller than under Option 1, but labeling would perhaps not be required, depending on the Member State. This reduces the costs of tracking and tracing. Investors can choose the market they want to serve and avoid markets where labeling is required. The incentives to invest are difficult to model precisely, as they will be dependent on which markets apply more or less strict adoption of the framework. In general, countries that have a larger market to offer, *ceteris paribus*, will be more attractive for investments. Interested readers are referred to Zhu et al. (2025) for more details.

Option 2 is also close to the regulatory system for GMMs in the US, where at the national level an assessment will be done, but business operators face strong liability rules, and Federal States have some degree of freedom in implementing national law.

[115] Tarja Laaninen, *The EU's General Food Law Regulation: An Introduction to the Founding Principles and the Fitness Check* (European Parliamentary Research Service 2017).

Option 3: ELMs as GMMs will be exempted from GMO law and regulations at Member States level apply

In this option, products that are produced using GMMs are exempted from GMO law and will be treated as 'conventional' products. If new products are developed, they will need to be registered. The laws and regulations for these new products at the Member State level apply. If this would be the case, the net benefits of *MP* will be larger, and both κ_1 and κ_2 as well as A and a_t will be lower. The field trials of GMOs and the corresponding fencing and other compliance costs will not apply. Thus, the research costs R and r_t will be lower. If there were zero additional authorisation costs ($A = 0$ and $a_t = 0$), the value of MP justifying immediate investment would substantially decrease. In comparison to Option 2, the costs for R&D can be expected to be the same. The markets can be expected to be larger, as the other Member States have to list the products, but there is no requirement for separate market authorisation in different Member States. This is somewhat similar to the market for "conventional" products, where Member States require different levels of information from suppliers before entering the respective market.

Option 4: ELMs as GMMs are considered GMOs but exempted from GMO law. Member States take action and are free to implement additional regulations

In this case, GMMs are considered GMOs but exempted from GMO law at the EU level. In comparison to Option 2, the use of GMMs is less restrictive. However, Member States are able to implement additional regulations. This means that some Member States can more heavily regulate the use of GMMs than others. It is expected that this view among Member States differs, as is the case for GM crops.[116] This difference can also be seen in the results of Member States at the Standing and Appeal Committee on GMOs. The countries that might be in favour of and countries against the use of GMOs and therefore of GMMs as well can be distinguished. This difference in view among Member States will have implications for the trade in products derived by using GMMs. The net benefits *MP* will reduce, as the technology and products cannot be widely used. Moreover, several applications need to be prepared, as Member States are free to implement additional regulations, and therefore A and a_t are expected to increase.

[116] Richard D. Smart, Matthias Blum, Justus Wesseler, 'EU Member States' Voting for Authorizing Genetically Engineered Crops: a Regulatory Gridlock' (2015) 64(4) *German Journal of Agricultural Economics* 244–262.

Table 4. Harmonization options and potential impact on the incentive to invest (updated and adjusted from Wesseler et al., 2023).

Option	R&D	Authorisation	Market	Ex-post liability
1) New ELMs that are GMMs are regulated at EU level.	High. More information for compliance is to be developed, including unique identification. This resulted in a high κ_1 value.	Lengthy and costly, a	EU market	Medium, due to EU-wide authorisation, but unauthorised events may still appear in supply chains.
Model values	High value of R, r_t, and κ_1	High value of A, a_t, and κ_2	High value of MP	Medium value of θ and low value of κ_3
2) EU develops a general legislative framework for ELMs, but MS are free to decide how to apply the framework	Low in some MS and high in others; there is an incentive to invest in MS with less stringent regulation.	Low in some MS and high in others; there is an incentive to invest in MS with less stringent regulation.	EU market, but with possible limitations depending on MS regulation.	Medium, due to authorisation, but unauthorised events may still appear in supply chains.
Model values	Medium value of R, r_t, and κ_1	Medium value of A, a_t, and κ_2	Medium value of B	Medium-high value of θ and low value of κ_3
3) ELMs that are GMMs will be exempted from the GMO law and regulations at the Member State level apply.	Almost no additional R&D costs resulting in a low κ_1 value.	Low, depending on the member State.	EU market	Low, because the chances of not-authorised GMMs entering the market are low.
Model values	Low value of R, r_t, and κ_1	Low value of A, a_t, and κ_2	Medium to high value of B	Low value of θ and high value of κ_3

Option	R&D	Authorisation	Market	Ex-post liability
4) ELMs that are GMMs are considered as GMOs but are exempted from the GMO law. Member States are free to take action and implement additional regulations.	Almost no additional R&D costs	Low, depending on the member State.	EU market, but restrictions may apply	Low, because of exemptions
Model values	Low value of R, r_t, and κ_1	Low value of A, a_t, and κ_2	Medium to high value of B	Low value of θ and high value of κ_3

Taking the regulatory options together, the development of ELMs will benefit from steps towards better harmonization of the ex-ante authorisation process and ex-post liability law in the EU. Compromising between the need to move fast to ensure competitiveness and legal security, the development of protocols for authorisation can, preliminarily, reduce the costs and time for authorisation. Many of the ELMs under investigation would need assessment from EFSA as well as EMA (if a medical application is foreseen), and face uncertain ex-post liability risks at many levels. A collaboration between both bodies could result in common guidelines that apply to evaluation by both authorities and competent authorities at the Member State level, thereby reducing duplication of work. Further, having an authority supporting applicants in preparing a dossier can reduce the costs of receiving authorisation. Some EU member states have competent authorities that are better equipped than others to provide support to applicants. Centralizing the support for applicants at the EU level has the potential to generate economies of scale. This is a result of the economic model and resonates with the statement of several stakeholders who are developing ELMs, asking for reduced bureaucracy during the authorisation process, as also raised in the Draghi report.[117] As highlighted by several studies, reducing the time length and costs is possible without compromising safety requirements.[118] In the long run, uncertain liability risks and their application in the authorisation process should be addressed through a legislative move to ensure better legal certainty, combined with regulatory learning.

The different options have different effects on the value of the marketing phase. The first option provides the largest market. Under options 2,3, and 54, EU Member States have the possibility to restrict the use of ELMs, which reduces the value of the marketing phase due to a reduction in the size of the potential market. While this is not necessarily the case, the possibility exists.

The marketing phase for new products can be extended by allowing for patents for the products developed. This applies to all options. They protect property rights for 20 years. This will increase the value of the market phase in comparison to a situation where this is not possible.[119] Another important property of patents is that they provide easier access to external financial support from potential investors, as they often value patents as a proof of concept of the product under development.

[117] Mario Draghi, 'The future of European competitiveness – In-depth analysis and recommendations' (European Commission 2024) https://commission.europa.eu/topics/strengtheningeuropeancompetitiveness/eucompetitivenesslookingahead_en accessed 18 November 2025.

[118] Monica Garcia-Alonso, Esteban Alcalde, Ine Criel *et al.*, 'Challenges and opportunities in the regulatory landscape of genetically modified crops in the European Union' (2025) 13 *Frontiers in Bioengineering and Biotechnology* 1709118, 1–8.

[119] Michele Boldrin, David K. Levine, *Against Intellectual Monopoly* (Cambridge University Press 2009).

CONCLUSION

The use of ELMs often results in GMMs that are regulated at the EU level. GMMs can be applied under contained use or be released into the environment. In both cases, applicants need to submit dossiers for authorisation. The EU is no exception from other countries that also regulate the application of ELMs. Most of the ELM applications reviewed result in a release into the environment. While EFSA has developed specific guidelines for GMMs for food, guidelines for GMMs for non-food use are under development. As far as we know, this mainly addresses precision fermentation. Considering the importance of ELMs for the sustainable development of the EU, developing guidelines for ELMs is urgently needed, encompassing both ex ante authorisation and ex post liability. As most ELMs, if not all, use synthetic biology applications, ELMs would hugely benefit from such an update of the guidelines. To date, the guidelines are unfortunately not in line with the requirements of synthetic biology applications.

As ELMs are often used in combination with applications in human health, creating the guidelines together with EMA would be advisable for EFSA. The EU-Innovation Network (EU-IN) Borderline Classification Group (BLCG), which is an informal discussion forum for product classification,[120] should be involved as well.

One of the challenges to be faced is having guidelines that are flexible enough to consider the developments in the applications of ELMs. Modern biotechnology is rapidly evolving, and legislation must include mechanisms for regulatory learning to allow regulatory authorities and market players to be prepared. This will be more difficult in a regulatory system that is more driven by methods than results as in the EU.

[120] European Medicines Agency, *EMA Annual Report 2021: Regulatory Science and Innovation* (EMA 2021) https://www.ema.europa.eu/en/annual-report/2021/regulatory-science-and-innovation.htm accessed 19 November 2021.

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Engineered Living Materials (ELMs) are biotechnology-based advanced materials with versatile use, including, for example, in health, construction, environmental remediation or as consumer goods. ELMs represent an emerging breakthrough technology that was supported at the EIC through a targeted Pathfinder Challenge. The EIC ELMs Pathfinder portfolio consists of 10 projects developing ELM solutions in different application areas.

This expert report examines the applicable regulatory framework in those cases, where ELMs are produced with the use of genetic modification. Using economic modelling, the report also assesses how different regulatory options could impact authorisation time, costs, R&D, and investor returns, and thus overall attractiveness, for bringing ELM-based products to the market.

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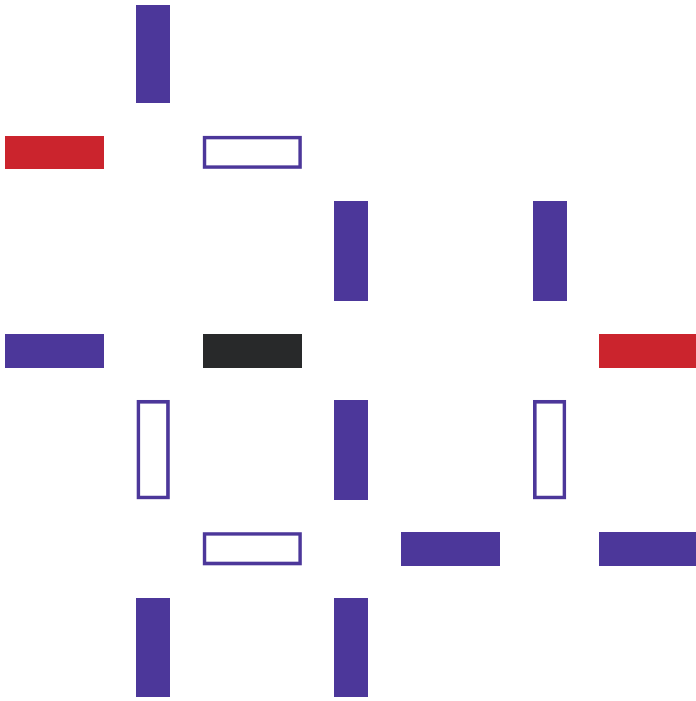

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