EuropaBio Position on targeted amendments of Directive 2001/18/EC: Unlocking the potential of genetically modified microbial products in Europe (July 2026)

Genetically modified microbial products represent a strategic asset for Europe's sustainability, food security and climate objectives, and for its industrial competitiveness and economic growth. They offer significant potential across a range of applications[1], including agriculture, environmental remediation, and industrial processes, and can play a key role in reducing reliance on fossil-based inputs. Genetically modified microorganisms (GMMs) can be optimised to degrade specific pollutants in soil or water, providing targeted and less energy-intensive alternatives to conventional remediation methods, and enhance nutrient availability and soil functionality, reducing reliance on synthetic fertilisers. These microbial products enable precise, function-specific interventions with limited impact on non-target aspects.

EuropaBio supports the objective of ensuring a high level of safety for human health and the environment while stimulating and advancing innovation, competitiveness and legal certainty. The European Commission has recognised that the current EU regulatory framework for products of biotechnology, in particular Directive 2001/18/EC[2], developed at the end of the 1980s and shaped over time by plant-based applications, has not been significantly updated since and is not fit for purpose[3]. The existing framework remains predominantly process based, limiting the uptake of new and emerging scientific knowledge and technology (like CRISPR/CAS) in the research and development of new innovative microbial products/solutions.

As a result, no genetically modified microbial products beyond those used in medicinal applications are currently authorised on the EU market, while other regions have enabled their use in a broader range of applications including as fertilisers[4]. The legislative gap undermines Europe's economic and sustainability ambitions; hampers progress towards reducing fossil fuel dependency at a time where the urgency of reducing strategic dependencies is reinforced and places the EU at a competitive disadvantage in a rapidly evolving world where beneficial microbial innovation develops at pace.

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[1] Alexandra Lensch, Hanna Abbas Lindfors, Elke Duwenig, Tobias Fleischmann, Carsten Hjort, Sirpa O. Kärenlampi, Lucie McMurtry, Emily-Denise Melton, Mikael Rørdam Andersen, Ryan Skinner, Markus Wyss, Richard van Kranenburg, Safety aspects of microorganisms deliberately released into the environment, EFB Bioeconomy Journal, Volume 4, 2024, 100061, ISSN 2667-0410, https://doi.org/10.1016/j.bioeco.2023.100061.

[2] 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, 17.4.2001, p. 1)

[3] Commission Staff Working Document, 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, Brussels, 29.4.2021

[4] See 1

While **EuropaBio welcomes the introduction of targeted improvements in the Directive, these require further refinements now** to ensure their effectiveness in practice.

Furthermore, **to address the structural limitations of the current GMO framework and deliver meaningful impact however, EuropaBio calls for the adoption of a dedicated regulatory framework for microorganisms** under the forthcoming Biotech Act II.

Biotech Act I as a first step towards unlocking the potential of microbial innovation

EuropaBio sees the proposed introduction of a low risk GMM category as a first step towards recognising the specificities of microorganisms, as well as a progressive move towards a more pragmatic, streamlined, and product focused regulatory approach enabling delivery of safe innovation to the market. At the same time, EuropaBio cautions that the low-risk GMM concept requires careful consideration to avoid inadvertently stigmatising GMMs that fall outside this category as inherently high-risk.

Therefore, to ensure this approach delivers its full potential further adjustments are needed. Directive 2001/18/EC applies transversally across applications and is cross referenced in other legislative texts as the basis for risk assessment. In this context, divergence on restrictions with regards to food and feed in the scope creates legal incoherence and should be addressed to ensure regulatory consistency.

Moreover, the framework should better support the full range of deliberate release applications of GMMs, beyond plant protection products. While reliance on the narrow "Qualified Presumption of Safety (QPS) status" as an eligibility criterion provides strong safety assurances, it restricts eligibility largely to plant protection uses, thereby excluding other beneficial applications such as remediation and fertilisers. Introducing risk Group 1 as an alternative eligibility criterion would expand eligibility to a broader range of deliberate-release applications, while maintaining robust safeguards, as Group 1 covers microorganisms with intrinsically low hazard recognised internationally as an established biosafety concept.

Finally, while remaining within a process based legislative framework, greater coherence is needed between provisions governing contained use and deliberate release of GMMs. The treatment of genetic modification techniques should be aligned across the two legislations for example. Introducing an additional provision to explicitly ensure such coherence would improve legal clarity and operational consistency.

The core shortcoming of the proposal and of the current GM framework remains reliance on a process based regulatory approach that is unable to reflect scientific progress and limits Europe's competitiveness, innovation capacity, and ability to fully harness the sustainability benefits of microbial biotechnology. This structural limitation highlights the need to move beyond incremental adjustments towards an ambitious, future-proof and product-centric enabling regulatory framework for microorganisms.

A dedicated microorganisms framework under the Biotech Act II as a future-proof enabler of innovation and competitiveness

EuropaBio calls for the adoption of a dedicated horizontal regulation on Microorganisms as part of the upcoming Biotech Act II, that would place the EU on an equivalent industrial framework as other

major biomanufacturing regions, whilst preserving the current high safety standards expected by consumers and innovators. It would also enable predictable biomanufacturing innovation, market access and scale, with the result that investment can increase at all TRL stages.

This framework would apply across sectors (incl. food/feed and environmental applications but excluding advanced therapies in health) and covering both the deliberate release and contained use of microorganisms. The safety assessment under this Regulation should be based on a science-based classification of microorganisms reflecting existing knowledge and the state of the art of scientific development, and regulatory requirements should be proportionate to safety risks, with streamlined procedures for biotechnology applications presenting low safety risks.

The framework would cover all types of microorganisms, and structured around 3 microorganisms categories.

<table>
<tr><th></th><th>CATEGORY 0</th><th>CATEGORY 1</th><th>CATEGORY 2</th></tr>
<tr><td>DESCRIPTION</td><td>Microbial wild-type strain or microbial strain mutated using conventional methods (excluded from GMO legislation)</td><td>Genetically modified microbial strain without (functional*) foreign DNA**

Examples of modifications leading to Category 1 microorganisms are point mutations, an increase in the number of gene copies or a promoter exchange.</td><td>Genetically modified microbial strain in which (functional*) foreign DNA** has been introduced or reconstructed</td></tr>
<tr><td rowspan="2">STATUS PATHWAY FOR ASSESSMENT & APPROVAL</td><td rowspan="2">RA & EC approval under sectoral product legislation</td><td rowspan="2">RA & EC approval under sectoral product legislation
or
Notification to EU MS relevant body and entry into an EU registry when placing on the market not subject to sectoral product legislation</td><td>Contained use
RA & EC approval under sectoral product legislation</td></tr>
<tr><td>Placing on the market (MO part of product)
RA & EC approval under GMO legislation
+
under sectoral product legislation</td></tr>
<tr><td rowspan="2">LABELLING OF COMMERCIAL/FINAL PRODUCT</td><td colspan="2" rowspan="2">No GMO labelling</td><td>Contained use
No GMO labelling</td></tr>
<tr><td>Placing on the market (MO part of product)
GMO labelling</td></tr>
</table>

**functional DNA = DNA that is intact and capable of being expressed or transferred in a biologically meaningful way. This functionality is typically characterised by key attributes, including the presence of a complete or near-complete gene, appropriate regulatory elements (e.g. promoters and terminators), and sufficient structural integrity to enable transcription, translation, and/or transfer to another microorganism where it can be expressed.*

***foreign DNA = DNA sequences not present in the pangenome of the subject species, or originating from a species that the subject species could not conceivably exchange genetic material with.*

The proposed framework introduces a comprehensive, science-based and risk-proportionate approach to the regulation of GMMs anchored in:

- A product and risk-based categorisation of microorganisms aligned across EU legislation, under which regulatory requirements are adapted proportionately, based on:
    - the type of genetic modification, and
    - the intended use of the product (placing on the market vs. contained use).

  The definitions and references to genetic modification within the different classes should continue to rely on the existing GMM definition under Directive 2009/41/EC[5]. The newly introduced categorization would determine the scope and effort for registration, authorisation, requirements, and labelling obligations.
- Streamlined procedures for Category 1 microorganisms, based on a standardised notification system to Member States, supported by defined data requirements, clear timelines and potential inclusion in an EU register.
- Targeted simplification for contained uses of Category 2 microorganisms.
- Transparency and legal certainty mechanisms, notably through the establishment of a central EU register covering notified and authorised microorganisms.
- Risk-proportionate labelling and traceability requirements, ensuring that obligations are aligned with the level of risk and focused primarily on Category 2 microorganisms.

In addition to a dedicated microorganisms framework, sectoral legislation must also unlock microbial applications, including those involving GMMs, by removing restrictive provisions such as the restriction linked to the intentional addition of GMMs in the new Regulation 2026/405 on Detergents and surfactants.

[5] 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, 21.5.2009, pp. 75–97)