

Carving a path to regulatory approval for environmental biosolutions: High-level conclusions of UK-EU roundtable, June 2026

Introduction

Genetically modified microorganisms (GMMs) are the workhorses of the bioeconomy. These tiny but powerful biological tools are enabling innovators in the EU and UK to improve plant health and nutrition as well as tackle thorny issues like detecting pollution, decontaminating soil, and removing forever chemicals from water. By working with rather than against nature, biosolutions offer new approaches to lower our dependence on fossil resources and create unique opportunities for both environmental and economic resilience.

However, despite the potential of GMMs, existing regulatory frameworks were largely developed for earlier generations of biotechnology, shaped over time by plant-based applications, and remain poorly suited to environmental applications of GMMs.

With the UK-EU reset negotiations underway, including greater alignment on a Sanitary and Phytosanitary (SPS) Agreement, and the EU Biotech Acts taking shape, there is a significant opportunity to establish a more proportionate, science-based and internationally aligned approach to regulating environmental GMMs. Doing so will be critical to supporting innovation while maintaining high standards of environmental and public health protection.

In June 2026, the UK BioIndustry Association (BIA), EuropaBio, and the UK's Environmental Biotechnology Innovation Centre (EBIC) brought together UK and EU innovators, regulators, academics, and ecosystem enablers to explore how well the regulations governing the release of GMMs into the environment ([Genetically Modified Organisms \(Deliberate Release\) Regulations 2002](#) and [Directive 2001/18/EC](#)) support the development of GMMs designed to be released into the environment. The discussion

aimed to identify concrete, actionable steps toward proportionate and workable regulatory pathways for environmental GMM applications.

Key findings

The discussion identified a set of policy priorities to support a more innovation-friendly regulatory framework for environmental GMMs across Europe. Participants agreed that regulation should continue to be firmly science-led, but that greater investment in evidence generation, improved regulatory tools, and closer UK-EU collaboration will be essential if environmental applications of GMMs are to reach market and provide financially and operationally competitive products and services.

The following priority areas emerged where coordinated action between the UK and EU, and industry and regulators, could deliver meaningful progress:

- Strengthen the scientific evidence base for environmental risk assessment
- Develop proportionate and consistent approaches to environmental risk classification
- Create expedited regulatory pathways for well-understood applications
- Develop specific regulatory guidance for distinct classes of products

Recommendations

Strengthen the scientific evidence base for environmental risk assessment

Participants agreed that additional evidence across a broader range of environmental settings could help further refine risk assessment approaches and support more proportionate regulation. Research on characteristics of the GMMs, such as persistence in the environment, evolutionary stability, horizontal gene transfer and ecological interactions would strengthen the evidence available to regulators and increase confidence in assessment processes.

Further strengthening the regulatory evidence base should become a strategic priority for both the UK and EU. Dedicated funding for fundamental research into the behaviour of

GMM in the environment would provide a robust evidence base to support more risk-proportionate regulation while maintaining high levels of environmental protection. Greater collaboration between regulators, researchers and industry is key to ensuring that research priorities directly address regulatory evidence needs.

Develop proportionate and consistent approaches to environmental risk classification

Participants emphasised that regulatory approaches should better distinguish between different magnitudes and forms of risk. The existing biosafety classifications were primarily designed to assess risk to human health within a confined laboratory context, rather than potential for damage to the wider environment / ecology when released.

The UK and EU should work together to develop expanded biosafety classification approaches that explicitly consider the environmental risks of releasing a GMM alongside existing biosafety considerations. Any future classification system should operate at the GMM strain level, recognising that risk is determined by the characteristics of individual engineered strains rather than the broader microbial species to which they belong.

The EU and UK developing shared approaches would improve consistency between jurisdictions, increase regulatory predictability for developers, and provide regulators with a clearer framework for assessing novel applications.

Create expedited regulatory pathways for well-understood applications

Participants supported the principle that regulatory effort should be proportionate to risk. Where the risks associated with specific strains, genetic modifications or applications are already well understood to be minimal, regulatory procedures should be streamlined without compromising safety.

The EU's proposed [expedited pathway for certain 'low risk' GMMs](#), as part of Biotech Act I, represents an important step in this direction. However, participants highlighted that eligibility criteria, including reliance on the [Qualified Presumption of Safety](#) (QPS) list, should not unintentionally exclude environmental applications where organisms may have well-characterised risk profiles but fall outside traditional food or feed contexts.

The UK should monitor implementation of the EU approach and consider adopting comparable measures where appropriate, particularly in the eventuality that a [SPS deal](#) is not reached later in the year. Participants also noted that regulators could draw lessons from existing simplified assessment procedures for certain GMO medicinal products (i.e. the [Netherlands simplified procedure for adenovirus chassis-based therapies](#)), where extensive scientific evidence has enabled more efficient regulatory processes.

Develop specific regulatory guidance for distinct classes of products

Participants highlighted that different environmental applications require different assessment approaches. For example, biosensors represent a distinct category of environmental GMMs, with risk profiles that differ significantly from microorganisms intended to persist or actively interact with ecosystems. UK and EU regulators should therefore consider working together to develop application-specific guidance where scientific evidence supports differentiated approaches.

Call to action

In order for the UK and EU to reap the benefits of biotechnology and deliver shared environmental goals, more work needs to be done to smooth the regulatory pathway for innovative SMEs developing novel solutions. By implementing these recommendations, the EU and the UK can secure global competitiveness in innovative biosolutions, creating jobs, economic growth and delivering benefits for society and the environment.

Further information:

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

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About BIA

The BioIndustry Association (BIA) is the voice of the innovative life sciences and biotech industry, enabling and connecting the UK ecosystem so that businesses can start, grow and deliver world-changing innovation. With over 600 members spanning human health and non-health biotech, including start-ups, scale-ups and established global companies, our membership encompasses the full UK ecosystem, including non-commercial research institutions and service providers. BIA is a member of the International Council for Biotechnology Associations (ICBA), EuropaBio and the European Biosolutions Coalition (EBC).

About EBIC

Launched in March 2024, EBIC is an Engineering Biology Mission Hub hosted, managed and led by Cranfield University which involves researchers from across 9 academic institutions around the UK and 30 associated partners. Their mission focuses on delivering impactful

research and innovation to solve environmental problems. With a commitment to bridge the gap between discovery and application, EBIC aim to ensure their findings lead to practical solutions that create measurable and meaningful global change. EBIC are currently leading a project: Navigating regulatory approval pathways for EngBio applications in the environment sector ([NAVIREG](#)). In collaboration with Severn Trent and BIA, the project's aim is to better understand the regulatory approval challenges facing environmental engineering biology businesses.

About EuropaBio

EuropaBio is Europe's largest biotechnology industry group, founded in 1996 to represent the interests of the biotechnology ecosystem across sectors. It has the vision to deliver a healthy, sustainable and competitive global Europe through biotechnology innovation applied across industrial sectors. Its mission is to build EU, national and global frameworks through which this critical technology is delivered across sectors. EuropaBio is the key opinion leader for European industrial development, competitiveness and global resilience through biotechnology. Members represent the full industrial ecosystem, from start-ups to global actors, plus the national ecosystems in which they grow.