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EU Biotech Act Open Consultation

This document outlines AMI's response to the EU Biotech Act consultation's proposed amendments to the EU Directive on the Deliberate Release into the Environment of Genetically Modified Microorganisms. Responses spanned a broad spectrum, from conditional support for the policy—subject to the incorporation of the risks, considerations, and mitigation measures discussed below into its development—to serious concern regarding the continued proliferation of novel entities in the environment. Nevertheless, there was consensus that microbes, and consequently genetically modified microorganisms (GMMs), should not be considered in isolation. Rather, their functions within, and the potential impacts of GMMs on, the microbiome—the complex communities of microorganisms that inhabit environments ranging from the human gut to the world's oceans and soils—must be central to policy considerations.

1. Comments on the definition of 'microorganism' within the Directive

The current definition in the draft Directive is scientifically sound, but AMI's members flag several points for consideration in order to strengthen it, future-proof it and reduce legal ambiguity.

The current definition's main strength is consistency: basing it on Directive 2009/41/EC reduces the risk of organisms falling between different definitions. The functional wording, '*any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material*' appropriately covers bacteria, archaea, unicellular eukaryotic microbes and relevant life stages, filamentous fungi, oomycetes, viruses and viroids. It is also broad enough to remain largely scientifically neutral.

However, below are some key points for consideration to strengthen this definition and reduce several risks associated with keeping it the same:

- Some of the higher-level taxonomic terms used, such as 'Protozoa' and 'Chromista', are no longer consistently recognised in modern eukaryotic classification. Although the definition remains workable, these examples could cause confusion or legal uncertainty as classifications continue to change. A definition based mainly on functional criteria, supported by a non-exhaustive list of examples, or a maintained authoritative taxonomy, would be clearer and more durable.

- The definition should be explicitly future-proofed against developments in synthetic biology. Engineered minimal or synthetic cells, cell-free self-replicating systems, and organisms using expanded or xeno-nucleic-acid chemistries may

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test the boundaries of the phrase *'microbiological entity capable of replication*' and could fall into a regulatory grey area.

- The ambiguous phrasing within the proposed definition for 'microorganism' where it refers to the definition used within Directive 2009/41/EC – with the exclusion of 'animal and plant cells in culture' – could be misinterpreted to exclude microalgae and other unicellular eukaryotes, which are microorganisms and should remain within scope.

- The definition does not address self-propagating organisms that do not use DNA or RNA. Prions, for example, do not contain genetic material and do not replicate through conventional genetic processes. Instead, they spread by causing normal proteins to adopt the same abnormal structure. They therefore fall outside traditional regulatory concepts based on replication and genetic material. Although an organism engineered to produce a novel self-templating prion protein would probably still be considered a genetically modified microorganism (GMM), this should be made explicit in the regulatory framework.

- The lack of mention of composite organisms[1] merits consideration. Symbiotic or composite organisms such as lichens raise a scoping question: where the modified partner is the fungal (or cyanobacterial) symbiont, it is unclear whether the current framework adequately captures risks transmitted through the associated partner, and this may warrant clarification beyond the definition itself.

2. Comments on the environmental risk assessment within the Directive

AMI's members flag several considerations and concerns regarding the current proposed environmental risk assessment for GMMs, highlighting an overall omission of the acknowledgement of microbiomes – the communities of microbes that inhabit different environments and their interactions – and an overly narrow focus on microbes as individual organisms, as well as specific weaknesses within the current assessment's parameters and suggestions for where they can be strengthened.

General commentary

AMI's members propose that the proposed amendments to the Directive should recognise the major advances in environmental microbiology and microbial ecology since Directive 2001/18/EC was adopted. Environmental risk assessment should no

[1] Organisms made up of two or more independent organisms living as single functional units.

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longer consider GMMs in isolation. It should also assess their potential effects on resident microbial communities, ecosystem functions, and long-term ecological resilience. Microorganisms and the communities they form – aka microbiomes – underpin vital global processes pertaining to the Earth's atmosphere, soils, oceans, waterways, climate and beyond. They underpin nutrient cycling, ecosystem resilience and broader One Health outcomes, yet their role is not fully reflected in the proposed amendments and accounts for a major omission from this policy. Incorporating microbiome-level endpoints, where scientifically relevant, would provide a more holistic assessment of environmental safety without imposing disproportionate regulatory burdens. Environmental risk assessments should explicitly consider effects on indigenous microbiomes, including changes to community composition, ecological function, resilience and ecosystem services.

Specific recommendations

Annex IIIA's information requirements are less well adapted to GMMs than they are for plants. Several provisions in Section III assume a discrete, open-field release. Concepts such as site size and cultivation method are appropriate for agricultural field trials but are less suitable for applications such as *in situ* bioremediation, wastewater treatment, biosensors, or contained fermentation with unintended environmental emissions. These applications require information on factors such as hydrogeological transport, persistence within existing microbial communities, and interactions with complex environmental matrices. Annex IIIA should be updated to reflect this wider range of application contexts.

Information on survival, persistence, and selective advantage should also be strengthened. While Annex IIIA already considers survival and multiplication, it should place greater emphasis on a GMM's ability to persist in environmental niches or gain a competitive advantage through the introduced trait. This is particularly important for GMMs designed to enhance fitness under specific environmental conditions. Interactions with the abiotic environment, including effects on biogeochemical cycling and nutrient turnover, are also often more relevant for microbial applications than for higher plants and should receive greater attention.

The receiving-environment requirements in Annex IIIB have a similar bias towards plants. They focus on flora, fauna and migratory species, whereas microorganisms can spread through air, water, aerosols and biological vectors. The concept of a clearly defined 'release site' is therefore less appropriate for many microbial applications. Risk assessment should give greater weight to persistence, spread beyond the intended area, and the potential for establishment. For releases into soil or aquatic environments, existing microbial community structure, geochemistry and nutrient

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status are often more relevant than plant-based considerations and should be given equal or greater weight. The impact on the microbiome/s of the receiving environment needs explicit consideration here. Impacts on the microbiome, such as changes to community composition, ecological function and ecosystem services should be incorporated into the environmental risk assessment.

Horizontal gene transfer (HGT) should receive greater emphasis because it is one of the most important differences between microbial and plant risk profiles. In Annex IIIA it is currently treated as one consideration among many, despite its direct relevance to the spread of antimicrobial resistance genes (ARGs), which the proposal identifies as incompatible with low-risk status. This link should be made explicit. HGT and ARG spread should be treated as cross-cutting considerations throughout the general information requirements, rather than only within the low-risk assessment. Environmental risk assessments should evaluate the likelihood of ARG persistence, mobilisation and transfer into clinically or environmentally relevant microbial populations, even where the modified organism is not pathogenic. This approach is consistent with the One Health framework and aligns with OECD and EFSA guidance, which recommends dedicated assessment of HGT risks.

Monitoring requirements need specific adaptation for GMMs. The proposal's use of delegated acts to update Annex III is a practical approach, but the monitoring methods in Section V remain too generic. Monitoring should specifically address gene transfer events, persistence in environmental reservoirs, and changes to microbial community structure, as these are not adequately covered by the current provisions. Experience from monitoring genetically modified microalgae shows that standard methods for detecting horizontal gene transfer to other organisms and assessing acute toxicity are still under development, highlighting the need for updated guidance.

Where scientifically appropriate, validated omics-based approaches, including metagenomics, metatranscriptomics and environmental DNA (eDNA), should complement conventional microbiological methods. These technologies provide a more comprehensive assessment of changes in microbial diversity, functional genes, horizontal gene transfer and ecosystem processes following environmental release. Their inclusion in Annex IIIA would strengthen the detection of indirect, cumulative and delayed environmental effects while remaining consistent with the precautionary principle in Annex II.

3. Comments on the unlimited duration of consents

Though the proposed move to unlimited-duration consents to reduce the administrative burden of periodic renewal given the short product cycles of many GMMs is understood

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and acknowledged by several of AMI's members, the views below additionally express several concerns around this approach. Some suggested amendments to try and safeguard against the identified risks - such as long but finite consent periods with a simplified renewal process, or unlimited-duration consents that remain conditional on ongoing monitoring and clearly defined review triggers - are proposed.

The proposed safeguards to rebalance the regulatory effort towards higher-risk applications are currently trigger-based rather than time-based. The safeguard clause and the obligation to report new information both depend on new evidence being identified and reported, whereas periodic renewal ensures that products are re-examined regardless. This distinction is important for slow-emerging risks, changing scientific knowledge, or the loss of institutional knowledge, for example if a company leaves the market or is acquired. It is particularly relevant for microbial applications, where ecological interactions can be complex and non-linear, and monitoring may not capture all relevant effects.

For several AMI members, the Commission's rationale supports a more proportionate renewal process but does not necessarily justify removing periodic review altogether, although a more averse view of the planet already being outside the bounds of a safe operating space when it comes to novel entities (particularly without a global microbiome-based view to GMMs being held) was also shared. While short product cycles may reduce the commercial lifetime of many products, they do not necessarily reduce the duration of environmental exposure or ecological effects. Previous risk assessments strengthen confidence in the initial authorisation but cannot substitute for periodic review of products that remain on the market indefinitely.

This concern is amplified if unlimited-duration consents are combined with the proposed waiver of monitoring requirements for low-risk GMMs. In that case, both scheduled review and ongoing surveillance would be removed for the same category of organisms. For many of AMI's members who contributed to this response, this risk creates a governance gap for risks that emerge only over time, without a clear scientific basis for assuming that all low-risk GMMs present no long-term ecological concerns.

Environmental effects may persist long after a product's commercial life. Depending on the characteristics and intended use of the GMM, uncertainties may include persistence, dispersal, genetic stability, horizontal gene transfer, interactions with microbial communities, antimicrobial-resistance markers, cumulative exposure, and effects that become apparent only after prolonged or widespread use. Horizontal gene transfer and antimicrobial resistance dissemination are well-established biological processes with potentially significant long-term ecological and public health consequences. As microorganisms can reproduce and evolve, the scientific

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justification for unlimited-duration consent should depend on the specific organism, genetic modification, intended use and receiving environment, rather than on a general assumption that GMM products are short-lived.

As already touched on, a further consideration is the interaction with the proposed low-risk criteria. Low-risk status depends in part on EFSA's Qualified Presumption of Safety (QPS) list, which is reviewed and updated as new evidence emerges. Taxonomic groups may gain or lose QPS status, for example following new evidence relating to antimicrobial resistance. An indefinite consent linked to a scientific assessment that may later change creates a governance gap unless there is a clear mechanism to revisit authorisations. Existing safeguard and reporting provisions provide an important backstop but are reactive and depend on risks being detected, which may be less likely where monitoring is waived or no validated detection method exists.

A scientifically robust approach would retain a proportionate mechanism for periodic review. This could take the form of a long but finite consent period with a simplified renewal process, or unlimited-duration consents that remain conditional on ongoing monitoring and clearly defined review triggers, such as changes to QPS status or other significant scientific developments. Consent duration should be determined on a case-by-case basis, taking account of the organism, the genetic modification, the intended use and the receiving environment. Products involving contained use or well-characterised, non-persistent organisms may justify longer consent periods, whereas products involving environmental release, persistence or antimicrobial-resistance markers would benefit from continued periodic review. This approach is consistent with the precautionary principle and ensures that regulatory oversight remains proportionate to potential risk.

4. Comments on the proposed approach to detection methods

AMI’s members recognise the limitations around detecting the genetic change event but push for focusing on the characteristics of the organism and the associated risk and point out several areas within the Directorate that require further clarification to make the policy more fit-for-purpose. This includes specifying a hierarchy of acceptable alternative approaches, rather than leaving adequacy to be judged case by case, as well as consistent, harmonised application across Member States.

The proposed amendments respond to a genuine technical limitation. Accepting alternative arrangements where event-specific detection of the genetic change, is not technically feasible reflects the current state of scientific knowledge rather than a lowering of regulatory standards. However, these adapted arrangements should remain exceptional, transparent and subject to rigorous assessment.

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For some GMMs produced using new genomic techniques, the genetic change may be very small, may not contain foreign DNA, or may be indistinguishable from changes that could arise naturally or through conventional breeding or mutagenesis. In these cases, the relevant genetic sequence may be detectable, but it may not be possible to determine conclusively whether it originated from the authorised modification. As a result, event-specific identification or reliable quantification may be technically unfeasible.

AMI's members suggest that regulatory requirements should therefore remain proportionate and focus on the characteristics of the organism and the associated risk, rather than solely on the technology used to create it. This recognises that similar genetic outcomes may arise through genome editing, conventional mutagenesis or natural evolutionary processes.

Although sequence-level detection may not always be possible, detection also remains fundamental to several other requirements in Annex IIIA of the Directive. These include environmental monitoring, distinguishing the GMM from parental organisms, detecting horizontal gene transfer where relevant, and supporting emergency response and decontamination measures.

The regulatory framework should therefore clarify several points:

- Detecting the specific genetic modification and detecting/tracking the organism in the environment are distinct problems. Even where a sequence-level signature is absent, phenotypic markers, functional assays or production-level traceability may still support post-release tracking. Implementing acts should specify a hierarchy of acceptable alternative approaches, rather than leaving adequacy to be judged case by case.

- Consistent application across Member States is important. Leaving this judgement to individual competent authorities, with criteria deferred to future implementing acts, risks divergent outcomes for functionally similar notifications. The delegated and implementing acts should establish clear, harmonised criteria for when alternative arrangements are acceptable and what they must achieve in terms of detection sensitivity, specificity, and reliability.

The proposed approach is appropriate provided that adapted arrangements remain exceptional, transparent, and subject to rigorous assessment, and the above clarifications are embedded. The burden of justification should lie with the notifier to demonstrate that a sequence-level detection method is genuinely unfeasible and that the proposed alternative is adequate for its intended regulatory purpose. This ensures that the flexibility granted by the proposed amendments does

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not compromise the core objectives of traceability, monitoring, and risk management that underpin the Directive, while still accommodating the scientific realities of modern genetic modification techniques.

5. Comments on simplified authorisation and 'low risk' GMMs

The majority of AMI's members who contributed to this response support introducing a category of "low-risk GMMs" in principle, as it represents a proportionate, risk-based approach that aligns regulatory effort with actual safety considerations and is appropriate provided that alternative arrangements remain exceptional, transparent and supported by robust scientific justification. However, the proposed criteria, while sound, are not sufficient on their own and require additional safeguards to ensure scientific rigour and consistent application, which are covered below.

The core criteria, taxonomic and molecular characterisation, Qualified Presumption of Safety (QPS) status, and the absence of genes of concern (particularly acquired antimicrobial resistance genes)—provide a scientifically defensible foundation. QPS status is a well-established EFSA mechanism that assesses the body of knowledge, taxonomic identity, and safety of microbial groups, and it can extend to GMMs derived from QPS parental strains where modifications do not raise safety concerns. This effectively leverages existing scientific expertise and reduces the need for duplicative assessments for well-characterised organisms.

However, three additional criteria or safeguards should be explicitly included:

- First, the definition should require demonstrated genetic stability and absence of phenotypic harm, including non-pathogenicity, non-toxigenicity, and non-allergenicity. These are established safety criteria in Directive 2009/41/EC and provide a clear, evidence-based threshold that complements the QPS framework.

- Second, the proposal should address horizontal gene transfer (HGT) potential more explicitly. Even where the organism itself is low-risk, the introduced genetic material should not be self-transmissible or transferable at a frequency that could give rise to harm, particularly concerning antimicrobial resistance genes.

- Third, the environmental context should be part of the low-risk determination—an organism that is low-risk in a contained industrial fermentation may not be low-risk if released into a sensitive ecosystem with different microbial community dynamics. Moreover, persistence, ecological fitness, survivability outside the intended application, potential for HGT,

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interaction with native microbiomes, and effects on ecosystem services such as nutrient cycling, and virulence factors should be considered. Functional ecological characteristics provide a more robust assessment of environmental safety than taxonomy alone.

The burden of proof should rest with the notifier to demonstrate that a sequence-level detection method is genuinely not technically feasible and that the proposed alternative is adequate for its intended regulatory purpose.

This approach is thought to preserve the core objectives of traceability, monitoring and risk management while accommodating the scientific realities of modern genetic modification techniques.

6. Comments on post-market environmental monitoring (PMEM)

Members' views varied considerably. One member considered a legal mechanism that allows the continued accumulation of GMMs without regard for their aggregate effects to be irresponsible, while others argued that general post-market environmental monitoring (PMEM) of GMMs is scientifically challenging and may offer limited value against a highly variable natural microbial background. Nevertheless, the majority of AMI members who contributed to this consultation response agreed that waivers from PMEM should remain exceptional, evidence-based, and decided on a case-by-case basis. They also emphasised that the case for waiving PMEM becomes weaker where several regulatory flexibilities are combined, such as indefinite market consents, the absence of validated detection methods, and the absence of PMEM.

In general it was viewed that a PMEM waiver is scientifically justified only where a comprehensive environmental risk assessment (ERA) demonstrates with a high level of confidence that the specific GMM and its intended use present no plausible pathway to adverse environmental effects.

The ERA should demonstrate that the GMM is well characterised, genetically stable, non-persistent, non-invasive, unlikely to transfer harmful genes, and unlikely to adversely affect non-target organisms or biogeochemical cycles. Waivers are most appropriate for contained or otherwise highly controlled uses rather than open environmental releases and should be supported by a robust body of evidence, including previous environmental exposure or field experience.

EFSA guidance recognises that PMEM may not be necessary where a GMM is shown to be as safe as its conventional counterpart. Qualified Presumption of Safety (QPS) status can contribute to this assessment because it reflects a history of safe use. However, QPS was developed primarily for food and feed safety rather than environmental safety. It should therefore be regarded as necessary but not sufficient

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evidence for low-risk environmental classification and should be complemented by evidence on environmental persistence, dispersal, survival and ecological interactions.

An ERA cannot reliably predict every indirect, delayed or unforeseen environmental effect. These are precisely the types of outcomes that post-market monitoring is intended to detect. Waiving PMEM solely because the ERA identified no concerns risks circular reasoning for the least predictable effects.

This concern becomes greater where several regulatory flexibilities are combined. For example, indefinite market consents, the absence of validated detection methods and the absence of PMEM could together result in very limited post-release oversight of self-replicating organisms.

Rather than complete omission, it is recommended that post-market monitoring should be proportionate to environmental risk. Even low-risk microorganisms may behave differently under environmental conditions than in the laboratory. Where monitoring is reduced or waived, this should be supported by robust scientific evidence from realistic exposure scenarios and previous field experience. For GMMs intended for environmental release, periodic surveillance using molecular methods (e.g. qPCR, metagenomics, or environmental DNA) could provide a cost-effective means of confirming the absence of unexpected ecological effects, while adaptive monitoring frameworks would allow surveillance intensity to reflect demonstrated risk.

Any PMEM waiver should therefore be a transparent, formal decision by the competent authority, explicitly stated in the consent, retained alongside reporting obligations, and subject to review if new scientific evidence emerges. This ensures regulatory resources are focused on higher-risk applications while maintaining appropriate environmental oversight.

7. Comments on the scientific expertise needed to inform future technical requirements

The draft Directive provides flexibility in several areas by allowing technical aspects of the policy to be developed after its adoption. These include the information required for environmental risk assessments, additional criteria for classifying GMMs as 'low risk', and technical requirements for detection methods. The development of these technical requirements—as well as any future amendments or additions to the Directive—requires expert oversight from multiple disciplines to anticipate and prevent unintended adverse consequences.

AMI members state that this should include expertise from across the microbiological sciences. This should include:

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- **Environmental microbiology and microbial ecology** to assess persistence, dispersal, environmental behaviour and interactions with microbial communities.
- **Molecular microbiology** to support detection, characterisation and monitoring.
- **Antimicrobial resistance (AMR) expertise**, given the importance of antimicrobial resistance gene (ARG) mobilisation within the proposed low-risk criteria.
- **Clinical and veterinary microbiology**, together with public health expertise, to provide a One Health perspective on the potential implications for human, animal and environmental health.
- **Virology, mycology and bacteriology** to ensure that the full diversity of microorganisms is considered.
- **Taxonomic expertise** to ensure that regulatory terminology remains consistent with current scientific understanding, particularly as microbial classification continues to evolve and some terminology is already obsolete (such as 'Protozoa' and 'Chromista').

Horizontal gene transfer (HGT) and antimicrobial resistance are cross-cutting issues throughout the proposal and require input across these disciplines to ensure that ecological and One Health considerations are adequately addressed.

In addition, future technical requirements should also draw on expertise from other relevant disciplines, including:

- **Synthetic biology**, to anticipate emerging technologies, including engineered minimal cells, xenobiological systems and cell-free replicating systems, which may challenge existing definitions and risk assessment approaches.
- **Environmental risk assessment**, **bioinformatics** and **aquatic science**, particularly as aquatic environments are important application areas for microbial biotechnology.
- **Analytical chemistry**, working alongside microbiologists to develop alternative detection approaches where event-specific methods are not technically feasible, ensuring they remain scientifically robust and fit for regulatory purposes.
- **Food and feed safety**, alongside environmental expertise, in the development of low-risk criteria, particularly where these rely on Qualified Presumption of Safety (QPS) status, as QPS does not inherently assess environmental behaviour.
- **Environmental monitoring**, **ecosystem functioning**, **industrial biotechnology** and **proportionality assessment**, to ensure that innovation, environmental

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protection and regulatory and economic considerations are appropriately balanced.

AMI members encourage the use of independent scientific panels, transparent evaluation of the evidence base, structured input from learned societies, and periodic review of the technical requirements. This would help ensure that future requirements remain scientifically robust, transparent and responsive to advances in microbiology and biotechnology.

As microbial genomics, synthetic biology and environmental microbiology continue to advance, the regulatory framework needs to remain capable of evolving in response to new scientific evidence.

8. Additional considerations

An AMI member commented on the notable omission in the Directive: the limited consideration of artificial intelligence (AI) and digital environmental surveillance, despite the wider Biotech Act emphasising the role of AI in supporting biotechnology and regulatory innovation.

AI-assisted environmental surveillance, predictive ecological modelling and machine learning could complement existing environmental monitoring by helping to analyse complex datasets generated through metagenomics and long-term monitoring programmes. Used appropriately, these tools could improve the early detection of unexpected ecological effects while increasing the efficiency and consistency of environmental risk assessment.

Another key point, consistently emphasised by all contributors to this consultation response and reflected throughout this document, is the need to recognise that microbes, including GMMs, should not be considered as isolated entities but as components of complex microbial communities (microbiomes). This distinction is fundamental, as the impacts of GMMs across all aspects of One Health, cannot be fully understood without considering their interactions within these communities.

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About Applied Microbiology International

Applied Microbiology International is a charitable, membership-based organisation for those interested in or working in microbiology.

We aim to demonstrate how microbiology can help address global challenges, and our policy work focuses on bringing microbiological evidence and expertise into policy conversations. AMI is solving some of the world's greatest challenges by bringing the applied microbiology community together, across borders and disciplines, to enable meaningful collaboration that delivers scientific impact. With a strong focus on influencing international policy, we are organised around six core UN Sustainable Development Goals and encourage partnership between academia and industry to increase our impact.

This consultation response is the amalgamation of nine member responses. If you have questions on specific points raised, please get in touch and we will put you in touch with the relevant individual/s.