

**Opinion on the proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directives 2001/18/EC and 2010/53/EU as regards the placing on the market of genetically modified micro-organisms and the processing of organs**



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## Summary

Genetically engineered bacteria could soon be introduced into to the digestive tracts of cattle, pigs and poultry, added to food, sprayed into the environment as pesticides, or used on farmland as fertilisers. Applications for use in humans are also currently being developed. Many of these uses carry a significant risk potential. Nevertheless, the European Commission intends to substantially lower safety standards.

The Commission proposal aims to create a special category of genetically engineered microorganisms (or more generally GMMOs) and thus facilitate accelerated market access. The exemption from environmental risk assessment is applied to microorganisms such as algae, bacteria, fungi, yeasts and viruses that meet the criteria for a ‘Qualified Presumption of Safety’ (QPS). However these criteria are not sufficient to take decisions on environmental safety of GMMOs.

All authorisations would be valid indefinitely instead of being limited to ten years, and methods of identification would no longer be required in each and every case. In addition, the Commission would also have extensive powers to change the respective criteria in future.

These plans should be rejected.

In recent years, the use of new genetic engineering techniques (or new genomic techniques, NGTs) has substantially expanded the ways in which microorganisms can be engineered. Also due to the convergence of these developments with artificial intelligence, the range of applications is expected

to expand even further. Safety standards should therefore be raised, not lowered. It is not sufficient to take decisions based on presumptions.

Knowledge about microorganisms has increased significantly in recent years. Their characteristics cannot be viewed independently of interactions with other species or the environment. For example, a recent publication shows that bacteria can spread specific resistance genes across the globe and throughout various ecosystems, thus leading to their simultaneous presence in wastewater, estuaries, lakes, terrestrial ecosystems and the human gut.

The risks associated with genetically engineered microbes particularly affect microbiomes, i.e. the complex communities of microorganisms inhabiting the intestines of humans and animals as well as the roots of plants. Despite the European Food Safety Authority (EFSA) has recognised risks and significant uncertainties in this context, it has nevertheless mostly omitted these from its risk assessment guidelines. EFSA has also not developed any guidance for the risk assessment of mixtures of different genetically engineered microbes, even though some companies are already planing the release of such products.

Furthermore, there are procedural concerns. The Commission has neither conducted a consultation nor an impact assessment, arguing with "urgency" without sufficient justification. Moreover, it has bundled the future regulation of GMMOs into a joint directive on the processing of organs. There appears to be no technical reason for combining these very different topics. Testbiotech is demanding that these issues are separated and for a consultation and an impact assessment to be conducted to ensure a proper legislative procedure.

In this context, Testbiotech does not see any need to introduce a new Directive or to change Directive 2001/18/EC. Instead, an implementing regulation on risk assessment of GMMOs within the given legal framework would be much more targeted.

## **Introduction**

The European Commission has proposed a new directive intended to regulate both genetically modified micro-organisms and the processing of organs (European Commission, 2025). There appears to be no technical justification for combining these two very different topics. It is strongly recommended that these topics be addressed in separate proposals to ensure a proper procedure.

The Commission's proposal aims to create a special category for genetically engineered microorganisms, which is intended to facilitate accelerated market access. This exemption from environmental risk assessment is to be based on the classification of the microorganisms in the 'qualified presumption of safety' (QPS) category; furthermore, the organisms must not contain any 'genes of concern'.

All authorisations are to be valid for an indefinite period. Methods for identification are no longer required in every case.

The European Commission is also to be granted extensive powers to amend or adapt the relevant criteria for accelerated market access.

In recent years, the possibilities for genetically engineering microorganisms have been further developed using new genomic engineering (or new genomic techniques, NGTs). This has significantly expanded the range of new traits, potential applications and species involved.

Convergence with developments in artificial intelligence is expected to lead to a substantial expansion of potential applications, posing major challenges in terms of both biosafety and biosecurity (Testbiotech, 2026).

There are a wide range of potential applications here (see, for example, Vogel, 2024): among other things, viable GM bacteria are to be used in the digestive tracts of cattle, pigs and poultry, added to food, sprayed as pesticides in the environment or applied as fertilisers to arable land. Applications in humans are also under development.

To date, there has been little experience in the EU with the release of genetically engineered microorganisms, particularly for purposes such as fertilisers, plant protection, biosensors and decontamination/bioremediation. These and other planned applications could lead to the release of large quantities of living GMMOs.

## **The QPS concept and the example of genetically engineered bacteria**

Most of the microorganisms on the EFSA's QPS list (EFSA 2025a), which is at the center of the Commission proposal, are bacteria. The concept of QPS is a system for categorizing risks, which has so far been used to simplify risk assessment in food production (EFSA, 2005). The recent QPS list that is steadily expanded, includes more than 120 microorganisms. These are considered as being safe, if they do not contain any 'problematic genes'. This refers in particular to new resistance genes against antibiotics.

Knowledge on bacteria has expanded steadily in recent years. It is becoming clear that the characteristics of bacteria can hardly be considered independently of their interactions with other species or their environment. The classification into specific species with genetically fixed characteristics is partially a scientific construct that is being challenged by research. The acquisition, loss and transfer of traits, and the changes associated with frequent cell division, go far beyond what can be observed in eukaryotes or multicellular organisms (De Wit et al., 2022; Arnold et al., 2022; Miklau et al., 2024; Eckerstorfer et al., 2025).

Bacteria are 'social' organisms influenced by interactions within and between populations. The traits of bacteria are also altered by these interactions, such as through the exchange of genes (Arnold et al., 2022; Arnaouteli et al., 2021). A recent publication demonstrates how, for example, certain resistance genes can spread via bacterial 'generalists' across the globe and in various ecosystems, so that they can be detected simultaneously in wastewater, estuaries, lakes, terrestrial ecosystems and the human gut (Kim et al., 2026).

Whilst the new traits of GM bacteria may well be verifiable at a given point in time, their subsequent development in the natural environment is only partially predictable (Grandel et al., 2021; Miklau et al., 2024). This is partly because many of the species with which they interact in various environments are not precisely known and due to the fact that environmental factors influence these interactions in very different ways (Rinke et al., 2013; Gillett et al., 2025).

## The QPS concept is insufficient for assessing environmental risks

The QPS category was developed in the context of food and feed (EFSA, 2005), but not for the large-scale release of GMMOs. The QPS criteria are insufficient for presuming environmental risks. Classification according to QPS is only meaningful if the environmental conditions under which the GMMOs are used can be defined. Furthermore, clear criteria must be established for how the interactions of the GMMOs have to be investigated and assessed. This means that potential interactions with the environment and changes in environmental conditions must be known, assessable and controllable. In reality, however, this is not the case.

Although environmental risks are mentioned in the current EFSA guidance in combination with the QPS concept (EFSA, 2025b), most relevant issues such as the potential impact on microbiomes (soil, plants, gut) are largely excluded.

Already in 2020, EFSA (EFSA, 2020a) identified the following issues as being relevant for risk assessment: *“Altered efficacy can be related to levels of exposure by e.g. 1) increased environmental survival and host colonisation, 2) increased invasiveness and, 3) increased competition in naturally evolved microbial communities due to enhanced fitness, thereby displacing beneficial microorganisms or disrupting, 4) altered metabolism, e.g. by changes in substrate utilisation opening new environmental niches; 5) altered lifestyle, e.g. by energy use (aerobic versus anaerobic) opening new environmental niches.”*

However, this is not dealt with in the EFSA guidance (EFSA,2025b), nor taken into account in QPS criteria. EFSA only concludes that GMMOs that meet the QPS criteria should be considered safe if they and their functions were already present in the microbiomes of the environments into which they are released. However, this assessment is questionable in view of the changes to which these microbiomes are exposed: the properties and composition of natural microbiomes can, for example, change quite significantly under the conditions of climate change (Laine & Leino, 2025). How can the composition of microbiomes and their dynamics under these conditions be assessed accurately prior to release?

The QPS list (as well as the EFSA guidance from 2025) also does not allow for reliable predictions regarding the interactions of different GMMOs when they share a common environment and thus interact with each other. However, current patent applications show that combinations of GMMOs are already intended to be released into the environment as mixtures (WO2020006064, US20250185667 by PivotBio).

Also, the idea that safety of GMMOs could be decided upon the presence or absence of specific ‘genes of concern’ is not a fully valid scientific concept since genetic data may not allow to predict the biological characteristics of the GMMOs. As EFSA stated in 2020 (EFSA, 2020a): *“Even with the complete genetic information of a synthetic micro-organism, it is beyond the capacity of any existent bioinformatic analysis to fully predict the capability of a synthetic organism to survive, colonise and interact with other organisms under natural conditions, given the uncountable diversity of potential microhabitats and their temporal variability.”*

## **Detection methods and time limits on authorisations are essential**

As authorisations for GMMOs are to be granted indefinitely under the present proposal, and detection methods are to be dispensed with, it would be practically impossible to limit, influence or prevent potential damage or undesirable interactions. This also includes the potential emergence of GMMOs that pose a health risk (see, for example, Eckerstorfer et al., 2025). It also could make it practically impossible to provide the necessary information to justify invoking the emergency clause under Article 23 of Directive 2001/18 where required, or to revoke a an approval if necessary.

It follows, that future regulation must allow for the assessment of interactions and the overall environmental impact beyond individual cases. Methods for identification are essential for this purpose (Eckerstorfer et al., 2025). It is also important to have suitable criteria to prevent releases that are not beneficial (e.g. from a sustainability perspective). The revocation of marketing authorisations or the cessation of releases must be legally possible and practically feasible.

## **Lack of data**

The protection of microbiomes must be a high priority, as they form the basis for the survival of humans, animals and plants. However, there are significant gaps in research in this area (see, for example, EFSA, 2020a and 2020b).

As mentioned, in the current EFSA guidance, the microbiome is dealt with only very vaguely (EFSA, 2025b). EFSA foresees a case-by-case risk assessment when GMMOs (or their traits) are introduced into environments or microbiomes in which they were not previously present, however without setting out specific requirements. This highlights the major knowledge gaps regarding these complex risk issues, which concern, for example, the actual composition of the microbiomes and their dynamics at the time of release (see above).

Against this background, accelerated market authorisation for ‘low-risk GMMOs’, combined with a lowering of safety standards and authorisation for an indefinite period, lacks scientific basis. Until sufficient data is available, releases could, at best, serve to conduct basic research. Any releases of GMMOs must be closely monitored and take place under controlled conditions. Among other things, genetic stability, persistence, spread and effects on natural populations and non-target organisms should be investigated.

## **Need for a more comprehensive guidance**

EFSA in its previous opinion (EFSA, 2024) that was performed to develop the final EFSA guidance (EFSA 2025b) did not assess the full range of relevant applications (see Testbiotech, 2024). The opinion and the chosen examples were only applicable in the context of agriculture and food production. Therefore, additional assessment is needed to include other applications such as (i) GMMOs, e. g. for use in biodegradation, waste treatment and bioremediation (see for example Rafeeq et al., 2023); (ii) genetic engineering of micro-organisms that are part of the microbiome of non-domesticated species such as insects (see for example Katac et al., 2023); (iii) potential releases of GMMOs (including viruses) intended to change e. g. the characteristics of non-domesticated plants and animals (see for example Eckerstorfer et al., 2024; Lentzos et al., 2022) or (iv) GMMOs

intended to change the microbiomes of mammals, and thus achieve therapeutic effects (Bai et al., 2023; WO2017087909).

Furthermore, the previous opinion (EFSA, 2024) did not explore the differences between NGT applications in microorganisms in comparison to earlier methods of genetic engineering, conventional mutagenesis or other previous methods. Also in this regard, further assessment is needed, since NGTs may overcome natural mechanisms of genome organisation in microorganisms, thus causing intended or unintended effects that are otherwise unlikely to occur:

- Complex factors in the genome organisation of, e. g. bacteria (but also of archaeae and viruses), are known to make some genetic changes much more likely than others. These are understood as factors in genome organisation which stabilise bacterial genomes in some genomic regions, whilst other regions undergo changes much more frequently (see Lee et al., 2012; Fang et al., 2008; Martincorena et al., 2012).
- For example, essential genes are very often organised in clusters located at greater distances to other regions which have a higher frequency of mutation (Fang et al., 2008; Hosseini & Wagner, 2018). Repair processes which occur more frequently in some genomic regions also seem to play a crucial role in this context (Costantino & Court, 2003; Jee et al., 2016.)
- These effects are also relevant to risk assessment: for example, specific gene deletions may cause bacteria to become more adapted, more virulent or pathogenic under specific environmental conditions (see, for example, Albalat & Cañestro, 2016). At the same time, the frequency of gene deletions is not randomly distributed throughout the genome (Hosseini & Wagner, 2018).
- In this context, empirical data on the phenotypic characteristics of the genetically engineered microorganisms must be taken into account, e. g. in regard to proliferation, horizontal gene transfer, mobility, population dynamics, potential for colonisation, persistence and spread.

Furthermore, the technical potential of NGTs (also in convergence with A.I.) enables various microorganisms with completely novel characteristics to be released into the environment or used in food production, both very quickly and in large quantities. Therefore, the speed of development has to be taken into account for the assessment of cumulative aspects and overall exposure within a given period of time. Consequently, the requirements for EFSA's assessment practices must be further adapted, taking into account systemic effects that go beyond the risks posed by individual GMMOs (Eckerstorfer et al., 2025).

## **Criticism of planned delegated acts and procedural concerns**

There are also serious concerns regarding the planned authorisation of the European Commission, via a delegated act, to amend or adapt the relevant criteria. As can be seen from the present legislative proposal, the European Commission's initiative is primarily driven by the interests of industry. In this context, there is considerable economic pressure due to the rising number of patent applications filed in this sector in recent years (van der Berg et al., 2025). There is therefore concern that the delegated acts could lead to far-reaching deregulation of GMMOs, in which the protection of health and the environment and relevant scientific findings regarding the risks are not sufficiently taken into account.

Furthermore, there are procedural concerns. The Commission has neither conducted a consultation nor an impact assessment, arguing with "urgency" without sufficient justification. Moreover, it has bundled the future regulation of GMMOs into a joint directive on the processing of organs. There appears to be no technical reason for combining these very different topics. Testbiotech is demanding that these issues are separated and for a consultation and an impact assessment to be conducted to ensure a proper legislative procedure.

## Demands

Directive 2001/18/EC provides an adequate legal framework for future regulation of GMMOs. More detailed requirements could be laid down in an implementing regulation that should include the following issues.

### **Molecular characterisation should:**

- require the identification of intended and unintended genetic changes caused by the specific techniques that may otherwise be unlikely to occur.
- take into account the potential presence of artificial guide RNAs that may trigger CRISPR mechanisms that may occur naturally in bacteria.
- include empirical data on potential changes in the biology of the genetically engineered micro-organisms, e. g. in regard to gene expression, proliferation, horizontal gene transfer and population dynamics.

### **Food and feed health risk assessment should:**

- include empirical data on the phenotypic characteristics of genetically engineered micro-organisms, e. g. in regard to proliferation, horizontal gene transfer, mobility, population dynamics, potential for colonisation, persistence and spread;
- require assessment of cumulative effects and potential interactions with other GMMOs present in the food chain;
- consider health risk assessment of GMMOs (or specific nucleotides) that may contaminate the food chain, without being intended for consumption (see for example Fraiture et al., 2024).

### **Environmental risk assessment should:**

- include empirical data on the phenotypic characteristics of genetically engineered micro-organisms, e. g. in regard to proliferation, horizontal gene transfer, mobility, population dynamics, potential for colonisation, persistence and spread.
- specifically require the assessment of potential impacts which changes in symbiotic microbiomes (such as those associated with fungi, lichens, plants, animals, humans, in the soil, above soil or within aquatic systems);
- include the assessment of cumulative effects and potential interactions with other GE organisms sharing the same receiving environment;
- consider risk assessment of GMMOs (or nucleotides) that may contaminate the fields and /or the food chain, but are not meant for food production (see for example Fraiture et al., 2024);
- define cut-off criteria in order to make adequate decisions if too many unknowns and uncertainties emerge (Then et al., 2020).

**Risk management recommendations:** Risk management should not only include monitoring, but also measures and methodologies that allow the control of the overall scale of releases within a given receiving environment. Risk management tools should be established to allow the control of, e. g. the duration of releases, the number of organisms per species, the number of species, the

combination of traits (by parallel releases) and, if required, a reduction in the number and scale of releases.

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