Appeal to the European Union:

Do not lower safety standards for releases of genetically engineered microbes into the environment!

In December 2025, the European Commission published a proposal to amend Directive 2001/18/EC regarding the placing on the market of genetically modified micro-organisms (GMMs)[1]. The proposal would **significantly lower existing safety standards** for the environmental release of such microorganisms.

Despite the fact that the EU has no experience with the authorisation and commercial release of GMMs, the proposal would:

- allow fast track approvals for supposedly 'low risk' GMMs including lower standards for risk assessment and monitoring;
- make EU authorisations unlimited in time, thereby waiving the regular renewal needed to review the environmental risk assessment;
- allow releases without analytical detection methods and monitoring.

The Council of Ministers has already adopted its General Approach with only minor amendments.[2] The proposal is now in discussion at the European Parliament.[3]

We call upon you to...

1. Reject the proposal!

The invisibility, mobility, high evolutionary potential, and interaction with complex microbiomes demand urgent enhancement of risk assessment methodologies and post-release monitoring systems. At least, existing protection standards should not be weakened. Therefore, you should not accept fast track releases of genetically engineered microbes. All GMM authorisations must remain time-limited and subject to periodical renewal, methods for the detection have to be made available and case specific monitoring applied in each case.

2. If no majority for rejection of the proposal can be reached, we demand:

2.1 Reduce the scope of the planned deregulation!

Microorganisms which are known to be an essential part of the microbiomes of soils, plants, animals and humans, should be excluded. These microbiomes require the highest level of protection to safeguard human and animal health, the functioning of the ecosystems and food production.

Also, viruses and bacteriophages have to be excluded. The virus families that would enjoy fast track approvals, encompass several virus families that account for several hundred species. These viruses are known to include severe plants pathogens and to kill specific insects. Releasing such genetically engineered viruses cannot be regarded as 'low risk'.

[1] 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 https://health.ec.europa.eu/document/download/34ae693f-9334-4824-b673-38598bae10f4_en?filename=biotech_dir-com2025-1031_act_en.pdf

[2] Council of Ministers, General Approach, document 9805/26 of 8 June 2026 https://data.consilium.europa.eu/doc/document/ST-9805-2026-INIT/en/pdf

[3] https://oeil.europarl.europa.eu/oeil/en/procedure-file?reference=2025/0405(COD)

Microorganisms, that are known to exhibit direct or indirect negative effects on other organisms or have a high likelihood to establish, persist or disseminate in the receiving environment beyond the intended use, should be excluded from the low risk category.

2.2. Improve safety standards!
The Commission has proposed that the status of Qualified Presumption of Safety (QPS) should be considered as part of the environmental risk assessment. The QPS system was originally developed for microbes used in food and feed production. If releases of genetically engineered microbes would be risk assessed by using this system, it would have to be brought in line with the environmental risk assessment as established under Directive 2001/18. The existing data gaps concerning environmental risks have to be closed, before this system could be applied.

2.3. Do not accept losing control and oversight!
All EU GMM authorisations must be subject to renewal on the basis of an updated environmental risk assessment and the latest scientific knowledge. Methods for detection and identification have to enable environmental monitoring, which must remain mandatory in all cases. Where unintended spread cannot be prevented, the release must not be authorised.

Signed by:

AEGILOPS [GR]
Agent Green [RO]
AGROLINK Bulgaria [BG]
Arbeitsgemeinschaft bäuerliche Landwirtschaft (AbL) [DE]
Aurelia-Stiftung [DE]
Beyond GM [UK]
Biodynamic Association Denmark [DK]
Biodynamic Federation Demeter International
Bioland [DE]
Bund Ökologische Lebensmittelwirtschaft (BOELW) [DE]
Bund für Umwelt und Naturschutz (BUND) / Friends of the Earth [DE]
Corporate Europe Observatory (CEO) [BE]
Demeter [De]
Deutscher Imkerbund [DE]
Econexus (UK)
Ekō
Fundacja Strefa Zieleni [PL]
Gen-ethisches Netzwerk (GeN) [DE]
GM Freeze [UK]
GMWatch [UK]
IG Saatgut [DE]
Interessengemeinschaft Nachbau [DE]
Initiative GEN-Klage [DE]
Kokopelli [FR]
Norwegian GMO-nettverket [NO]
NOAH / Friends of the Earth Denmark [DK]
OGM dangers [FR]
Pan-Hellenic Animal Welfare and Environmental Federation [GR]
POLLINIS [FR]
quid est Veritas [SK]
Save Our Seeds! (SOS) [DE]
Schweizer Allianz Gentechfrei [CH]
SITOseeds [GR]
Slovakia Without GMOs [SK]
Testbiotech [DE]
Uniterre [CH]

Annex to the Appeal

Some background to the proposed changes to the EU GMO legislation

1. The Commission has proposed to introduce a category of **Low Risk GMMs** subject to criteria that are problematic:

It is proposed to expand a system called QPS (Qualified Presumption of Safety) that originally was developed for food and feed production to the risk assessment of genetically engineered microbes released into the environment. At present, this 'low risk' category comprises more than 120 species, mostly bacteria (91 species), but also yeasts (18 species), algae (6 species) and 3 virus families representing hundreds of different species. In 2026, this list was opened to also include bacteriophages.

For the approval of products consisting of QPS organisms, larger data gaps are accepted, because these organisms are considered of conferring 'low risks'. According to a staff working document published by the Commission[4], the new regulation would allow to omit key issues of environmental risk assessment if no 'genes of concern' are introduced. These issues comprise toxigenicity, pathogenicity, infectivity, history of use, persistence, invasiveness and selective advantage, horizontal gene transfer, effects on non-target organisms, including humans or animals and the effect on geochemical processes.

Genetically engineered microbes can become more risky without the insertion of additional 'genes of concern': Specific deletions or changed expressions of their own genes can equally give rise to biosafety risks. For example, the above mentioned hazards can be enhanced unintentionally. Therefore, it is not possible to use the concept of 'genes of concern' as the criterion for decision making if a full environmental risk assessment is needed. This qualification may only be taken AFTER a detailed risk assessment, but not before.

2. Currently, all releases of genetically engineered organisms have to undergo **post-market environmental monitoring** to make sure that no risks were overlooked in the environmental risk assessment, and to exclude damage from large-scale and long-term releases. In the future, this requirement can be waived for certain genetically engineered microbes, if they belong to the proposed 'low risk' category.

3. Currently, **market approvals for genetically engineered organisms are limited** for a period of ten years. After that, the approval can be renewed if the risk assessment is updated to the current state of knowledge. In future, market authorisations for genetically engineered microbes will no longer be subject to renewal. The Council has introduced the requirement for only one renewal after ten years.

4. Currently, all market approvals of genetically engineered organisms require notifiers to submit **analytical methods for detection and identification**. Such methods are a prerequisite for environmental monitoring. In future, this requirement may no longer apply for all GMMs, making effective monitoring and traceability after release difficult to achieve.

[4] Commission Staff Working Document accompanying the proposal for a European Biotech Act (C(2026) 3375 final) https://health.ec.europa.eu/publications/commission-staff-working-document-accompanying-proposal-european-biotech-act-c2026-3375-final_en

5. The proposal includes no requirement to **contain the spread of GM microbes** after release. This would damage the legitimate interests of organic and conventional producers who wish to continue producing without the use of GMOs and potentially endanger nature protection areas. The possibility of limiting unintended spread and taking effective remedial measures must be assessed before any release. Where unintended spread cannot be effectively controlled or mitigated, authorisation must not be granted.

In conclusion, the proposal of the EU is based on an outdated understanding of genes and the way how 'concerns' are triggered and risks can be identified. The elimination of mandatory monitoring, the waiver of detection methods, and the removal of the time limit for approvals is not acceptable. These regulatory requirements are indispensable for maintaining the necessary control over risks to humans and the environment and for detecting damage in a timely manner.

Further general arguments

We are concerned about the attempt to reduce safety standards for environmental releases of genetically engineered microbes, due to

- the current very limited knowledge about the number and characteristics of microbial species;
- the complexity of their communities and interactions with the environment;
- the fact that many microorganisms can exchange genetic material within their populations and beyond species;
- the difficulty of controlling the spread of microorganisms and their genetic material once released into the environment;
- the general lack of experience with environmental releases of genetically engineered microbes.

The technical development poses new challenges: In many cases, the outcomes of genetic engineering differs from those of the previous methods, even if no additional genes are inserted; these differences are likely increasing if artificial intelligence (AI) and new genetic engineering (NGT) are included. NGTs, alone and in combination with AI, can be used to manipulate microbial communities directly in the gut and the soil, to redesign whole genomes and to produce microbes with characteristics that are without any reference in natural biodiversity.

In regard to risk assessment of such applications, the current methods and guidance are not sufficient to safeguard health and the environment. Therefore, environmental risk assessment has to be expanded. Already in 2020, EFSA stated[5]: "*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.*" The proposal to lower the standards of Directive 2001/18 EC is largely ignoring the actual situation.

Specific concerns

The current proposal does not sufficiently safeguard against potential risks for the environment, soils, human and animal health. Instead, the application of a "qualified presumption of safety" (QPS) could result in genetically engineered microorganisms being treated as low risk even where

[5]EFSA (2020) Scientific Opinion on the evaluation of existing guidelines for their adequacy for the microbial characterisation and environmental risk assessment of microorganisms obtained through synthetic biology. EFSA J,18(10): 6263. https://doi.org/10.2903/j.efsa.2020.6263

their genetic or phenotypic characteristics, intended uses or environmental exposure differ substantially from those considered in the underlying QPS assessment, or where relevant environmental risk assessment data are lacking.

The proposal would enable fast track marketing of bacteria transformed by new genetic engineering (or new genomic techniques, NGTs) that can be used as biofertilizers, biostimulants, biopesticides, probiotics or for bioremediation. Naturally, many of these species are part of the microbiomes across the domains of life. They can be found in the guts of humans and animals (such as bees and livestock) as well as in the soil and the rhizosphere of plants. Interfering with these microbial communities by introducing genetically engineered microbes cannot simply be presumed to be safe or to exhibit only ‘low risks’. On the contrary, the protection of these natural microbiomes requires the highest level of precaution.

The proposal also includes fast track releases of genetically engineered viruses that are known to be severe pathogens for plants and insects and, in near future, can be used to genetically transform plants and animals outside of laboratories, directly in the environment. Environmental releases of genetically engineered viruses from families that include many plant or animal pathogens cannot be presumed to be safe or to exhibit only ‘low risks’.

In result, the plans of the Commission to lower safety standards for environmental releases of genetically engineered organisms is putting at risks the foundations of our health, food production, biodiversity and the functioning of the ecosystems.

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