Veille citoyenne d'information sur les OGM et les semences

The deregulation of GMO microorganisms is underway

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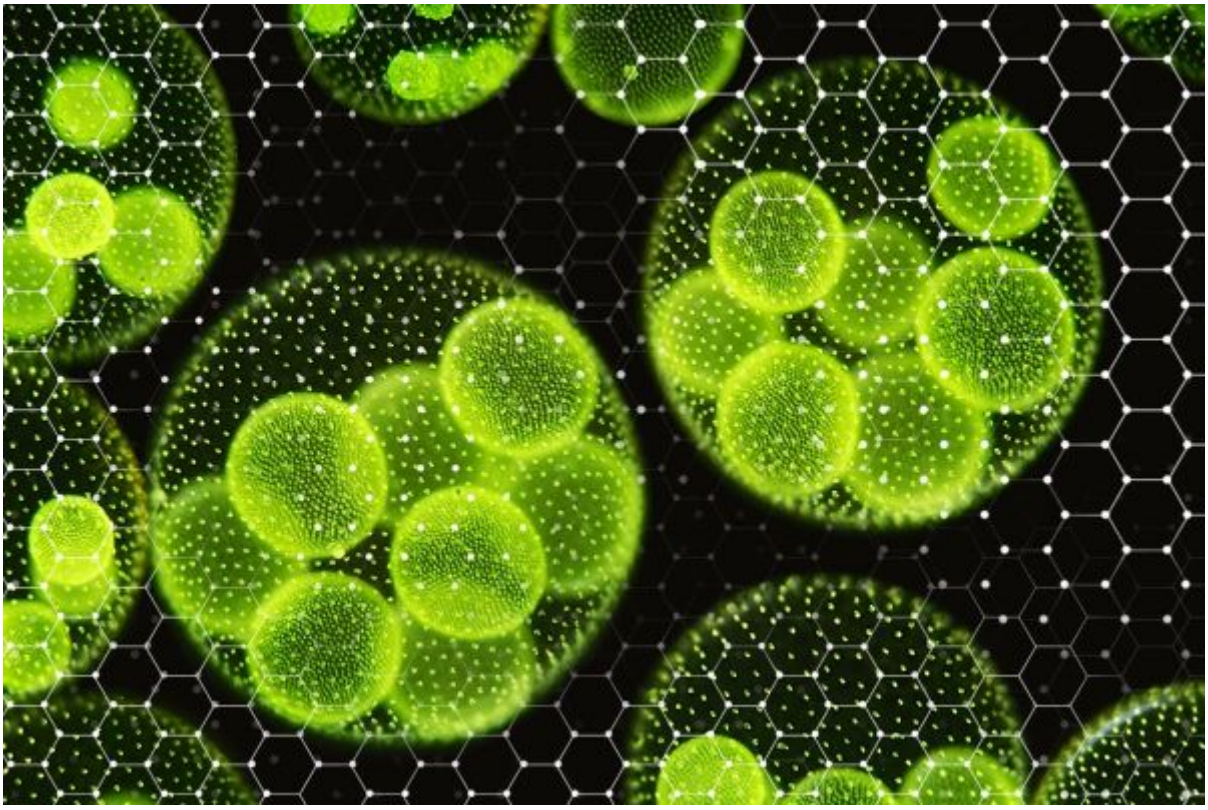
A proposal for a directive made by the European Commission on 16 December 2025 calls on Member States and the European Parliament to deregulate the marketing of genetically modified bacteria, yeasts, viruses and other micro-organisms, including transgenics. According to the Commission, the aim would be to allow companies to market these GMO microorganisms (GMMs) under lighter or even no rules. This would involve an "*adapted*" health and environmental risk assessment, an end to traceability, an end to environmental monitoring... Following the plants, the deregulation of GMOs is therefore continuing, this time with microorganisms, with perhaps the animals next in line in 2026.



Micro-organismes et virus génétiquement modifiés

In 2023, the European Commission openly proposed deregulating plants and microalgae genetically modified using new techniques of genetic modification (NGT). While discussions

between European authorities on this issue are still ongoing in early 2026[i], the Commission seems to have decided that following the same path for microorganisms would be too risky. Thus, rather than putting a proposal for a new regulation on the table for legislators, on 16 December 2025 the Commission chose to propose an amendment to an existing directive, 2001/18. Arguing that there was an "*urgency*" to table this proposal for a directive[ii], the Commission used arguments that are sometimes misleading, just as it failed to provide all the documents supporting its proposal, even though this was mandatory. *Inf'OGM* will return to this situation at a later date, after describing the content of the proposal in this article.

Reducing the regulation of all GMMs, including transgenic organisms

The amendments to Directive 2001/18 contained in the Commission's proposal are few in number but effective in achieving the deregulation of GMMs. The Commission proposes, as a first step, to define GMMs as "*any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including viruses, viroids*" and "*in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination*", with the exception of plant and animal cell cultures. Although Directive 2001/18 already defines organisms, including therefore micro-organisms, introducing this definition allows the Commission to propose the inclusion in Directive 2001/18 of articles devoted entirely to micro-organisms.

The Commission therefore proposes adding a complete chapter dedicated to GMMs to Part C, which deals with the placing on the market of GMOs or their products (Part B deals with experimental releases into the environment). The proposed chapter contains three proposals for the addition of articles on the risk assessment of GMMs, their traceability and the duration of authorisations issued. Mechanically, it is essential to note here that these proposals concern all GMMs, *i.e.* both transgenic microorganisms and genetically modified microorganisms that supposedly do not contain transgenes in the final product.

"*Adapted*" risk assessment, unlimited authorisation period, etc.

Contrary to the provisions of Directive 2001/18, the Commission is initially proposing to the Council and the European Parliament that it alone should decide on the content of authorisation applications to be submitted in the EU in order to market GMMs or products thereof. It justifies this proposal by the need to adapt the list of information required from a company to "*scientific and technical progress*". This information should be provided in each authorisation application file (known as a “*notification*”). The Commission wishes to be able to amend Annex 3 to Directive 2001/18, which lists the “*information requiredin the notification*”, on its own, by means of delegated acts. Currently, this annex requires information to be provided on the description of the organism, the genetic modification method(s) used, the description of the desired and undesired genetic modifications, the assessment of risks to health and the environment, and plans for environmental monitoring after commercial release. Having been committed for several years to simplifying the management of GMOs[iii], or even deregulating them, it is reasonable to assume that the European Commission intends to reduce the amount of information required rather than maintain it.

The second proposal is summarised in a few lines. This time, it involves amending Directive 2001/18 so that authorisations for the marketing of GMMs are issued for an unlimited period. Currently, the directive sets a maximum period of ten years, after which a renewal application must be obtained in order to continue marketing a GMO. The main consequence of such a measure is that there would be no reassessment of potential risks, as is currently the case. If a risk were to be discovered after an authorisation had been granted, it would therefore not be taken into account, by definition.

No traceability method required

A third proposal is to allow companies to be exempt from providing methods for detecting, identifying and quantifying GMMs or their commercialised products if they duly justify that it is "*not possible to provide amethods*". This last measure would therefore blind the EU and other economic operators (from farmers to consumers) to any contamination or illegal commercialisation on its territory. Above all, as is the case with plants and microalgae, this would open the door even wider to patents held by private actors on GMMs, but also on non-modified micro-organisms, constituting a definitive obstacle for all actors using "*wild*" microorganisms.

At this stage, the European Commission is therefore proposing that the marketing of bacteria, yeasts, viruses or any other GMMs, whether transgenic or not, be authorised for an unlimited period. This authorisation would be based on dossiers (including risk assessments) whose content could only be decided by the European Commission, without the company having to provide a method for detecting and tracing GMMs and their products.

Total deregulation of GMMs obtained by NGT

The fourth proposed measure appears to be the one containing, as for plants modified by NGT, an even more complete deregulation of GMMs. This time, the aim is to distinguish GMMs from other GMMs which would be described as "*low risk*". While the former would be subject to the requirements of Directive 2001/18, which would have been greatly reduced, if not eliminated, as we have just seen, the latter would be virtually deregulated.

Based on a July 2024 opinion from the EFSA stating, with regard to the assessment of risks associated with micro-organisms, that "*on a case-by-case basis for specific [micro-organisms modified by "*new genomic techniques*"] fewer requirements may be needed*"[iv], the Commission proposes that GMMs could be declared "*low risk*". This declaration would be made if they are "*taxonomically and molecularly well characterised*", if they belong to a group of micro-organisms whose supposed safety has already been established and, crucially, if they do "*not contain genes of concern which are not naturally present in the parental organism, in particular acquired antimicrobial resistance genes*". Put more simply, "*low-risk*" GMOs would be all GMOs that do not contain transgenes.

In addition to proposing that it alone should be able to supplement these "*low-risk*" classification criteria by means of delegated acts, the Commission also proposes that the risk assessment provided for in Directive 2001/18 should be "*adapted*" for these GMMs. Similarly, the post-marketing environmental monitoring provided for in Directive 2001/18 could be waived if the company considers that such monitoring is "*not needed*".

Submitted to the European authorities on 16 December 2025, the European Commission's proposal will now go through the same procedure as that followed for plants in 2023. The Member States, meeting within the Council of the EU, will examine it and, if they reach an agreement, will issue their version of the text. For its part, the European Parliament will do the same as part of a process that is expected to begin in 2026.

i Eric Meunier, « Qualified majority in the Council of the European Union to deregulate numerous GMOs », *Inf'OGM*, 24 December 2025.

ii It is a proposal for a new Directive modifying existing Directive 2001/18, a proposal made under procedure reference 2025/0405, « Placing on the market of genetically modified micro-organisms and the processing of organs ».

[iii] Eric Meunier, « OGM dans l'UE : une directive progressivement allégée », *Inf'OGM, le journal*, n°165, October/December 2021.

[iv] EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Mullins, E., Bresson, J.-L., Dewhurst, I. C. *et al.*, « New developments in biotechnology applied to microorganisms », *EFSA Journal*, 22(7), e8895, 22 July 2024.
