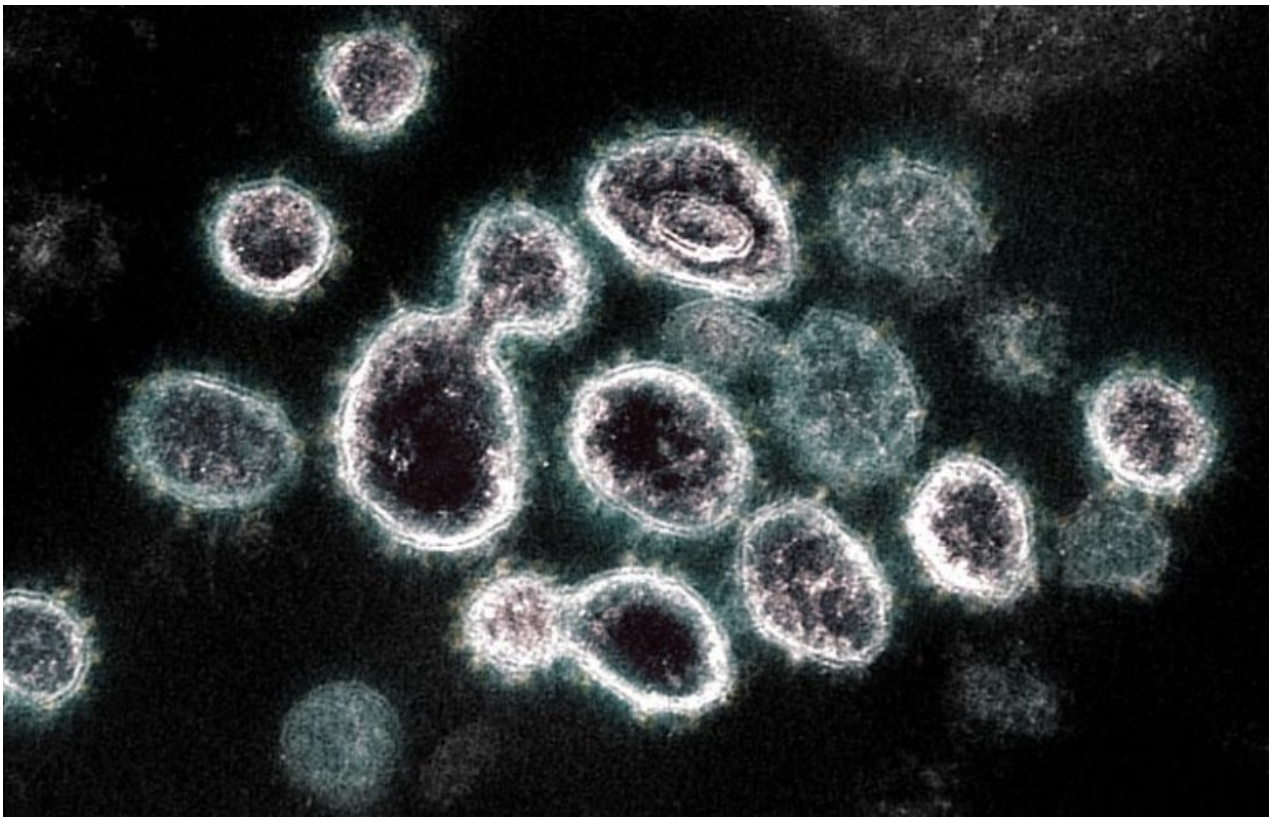
Veille citoyenne d'information sur les OGM et les semences

The European Commission’s proposal to deregulate GMOs does cover some GMO micro-organisms

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In July 2023, the European Commission's proposal to deregulate GMOs was presented and understood as concerning only plants. Micro-organisms, animals and fungi would not be concerned. However, a careful reading will show that, contrary to what the European Parliament seems to have understood, some micro-organisms are indeed concerned... because they are considered to be plants!



Laws are written in words. A truism, one might say... and yet! It is common for everyone to want to give the words in a legal text the meaning that suits them best. Ultimately, if there are different interpretations, only the courts can decide. This situation renders fundamental the understanding of

the words used by a legislator to determine the meaning of a law. Who, for example, could have imagined in 2001 that the '*mutagenesis*' cited in Directive 2001/18 as having an history of safe use also concerned, for the European Commission, some of the '*new*' mutagenesis techniques? Which will force the Court of Justice of the European Union (CJEU) to remind it, in 2018 and then 2023, that this is not the case? Who could have imagined, in 2004, that the Member States themselves would be willing to 'clarify' their own regulatory text adopted a year earlier? They did so in order to decide that additives produced by genetically modified micro-organisms were not covered by the regulations on GMOs adopted in 2003, on the grounds that they were produced with GMOs and not from GMOs. These semantic debates are not without importance. In the last example cited, the change from '*produced from*' to '*produced with*' has enabled the enzyme, colouring agent, vitamin and other additive industry to avoid being labelled '*produced from GMOs*'.

Deregulating plant GMOs, but... which plant GMOs?

In July 2023, when it proposed to deregulate a large number of GMOs, the European Commission wrote that "*this Regulation should be limited to GMOs that are plants,* i.e. *organisms in the taxonomic groups* Archaeplastida *or* Phaeophyceae*, excluding microorganisms, fungi and animals for which the available knowledge is more limited*". Things seem clear: only plants would be concerned. But, as we have already seen in two previous articles[i], plants are not just terrestrial, as marine and freshwater algae are also concerned. The taxonomic groups *Archaeplastida* and *Phaeophyceae* cover land plants as well as so-called '*green*', '*red*' (*Archaeplastida*) and '*brown*' (*Phaeophyceae*) algae, some of which are consumed by humans.

Things become blurred when we realise that algae can be multicellular or unicellular. A unicellular organism is commonly considered to be a micro-organism. European law itself, in Directive 2009/41 on genetically modified micro-organisms, defines a micro-organism as "*any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including viruses, viroids, and animal and plant cells in culture"*. A cellular microbiological entity capable of reproducing or transferring genetic material, that covers unicellular algae.

Are unicellular algae plants affected by the proposed deregulation or are they micro-organisms excluded from this proposal? More generally, are micro-organisms belonging to the taxonomic groups mentioned affected by the proposal because they are '*plants*' or excluded because they are micro-organisms? According to *Inf'OGM*'s information, the wording adopted by the European Commission should be read as covering all organisms belonging to the two taxonomic groups mentioned, whether they are multicellular or unicellular. Micro-organisms belonging to the Archaeplastida and Phaeophyceae groups are therefore affected by the proposed deregulation.

Not all legislators read the same thing

European experts classify certain algae as micro-organisms. In January 2023, in an opinion[ii] on the safety of micro-organisms, the European Food Safety Authority (EFSA) specifically cited certain micro-algae, such as *Chlamydomonas reinhardtii* and *Galdieria sulphuraria*, two unicellular algae belonging to the *Archaeplastida* taxonomic group. *Chlamydomonas reinhardtii* is one of the most studied unicellular algae for genetic modification[iii]. This EFSA letter of January 2023 confirms, if confirmation were needed, that some micro-organisms belong to the two taxonomic groups mentioned.

The MEPs do not seem to have the same understanding of the terms as the European Commission. While retaining the reference to the two taxonomic groups, they modified the proposed wording. On 24 April 2024, the final text voted on first reading by the European

Parliament proposed that "*this Regulation should be limited to GMOs that are plants,* i.e. *organisms in the taxonomic groups* Archaeplastida *or* Phaeophyceae*. Available knowledge on other organisms, such as microorganisms, fungi and animals should be reviewed with a view to future legislative initiatives on them*". Here, micro-organisms as defined by Directive 2009/41 are excluded as such from the proposal. Unicellular algae are therefore not covered by the text voted by the European Parliament. Any other interpretation would be tantamount to making European law say anything and everything.

A non-intuitive definition of micro-organisms…

Outside any legislative framework, the term micro-organism usually refers to microscopic organisms. The french Larousse dictionary defines a micro-organism as "*a microscopic living being such as bacteria, viruses, unicellular fungi (yeasts) and protists*". Historically, however, European legislators have taken what might be described as a '*broader*' view. In 1990, in Directive 90/219[iv] adopted that year on the contained use of genetically modified micro-organisms, the Commission, Parliament and Council of the European Union agreed to define a micro-organism as "*any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material*". This definition was taken up and clarified in 2009 in Directive 2009/41[v], which replaced Directive 90/219 and is still in force. Under this directive, a micro-organism is defined as "*any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including viruses, viroids, and animal and plant cells in culture*".

In the same year, Directive 1107/2009[vi] concerning the placing of plant protection products on the market defined micro-organisms as '*any microbiological entity, including lower fungi and viruses, cellular or non-cellular, capable of replication or of transferring genetic material*'. A final legal definition is provided by Regulation 528/2012[vii], which covers the placing on the market and use of biocidal products. According to this regulation, a micro-organism is defined as '*any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including lower fungi, viruses, bacteria, yeasts, moulds, algae, protozoa and microscopic parasitic helminths*'.

Leaving aside the examples of micro-organisms given in each definition, which may vary from one definition to another, it is clear that, according to European legislation, a micro-organism is "*any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material*". Viruses, bacteria, lower fungi (microscopic), protozoa, etc. are all micro-organisms. So are microscopic algae, which belong to the plant kingdom covered by the two taxonomic groups cited by the European Commission. Finally, both plant cells and animal cells are legally micro-organisms. What remains to be understood here is what a micro-organism could be, defined as a non-cellular microbiological entity. European patent law provides the answer.

...but which overlaps with patent law

For European law, micro-organisms are microbiological entities that are capable of replicating or transferring genetic material. The term '*entity*' suggests that micro-organisms are not necessarily organisms in the eyes of the European legislator.

To understand this, we need to look at patent law as followed by the European Patent Office (EPO). Its guidelines[viii] state that "*he term "*microorganism*" includes bacteria and other generally unicellular organisms with dimensions beneath the limits of vision which can be propagated and manipulated in a laboratory (see T 356/93), including plasmids and viruses and unicellular fungi (including yeasts), algae, protozoa and, moreover, human, animal and plant cells*". In the list of examples provided, the presence of plasmids (circular DNA molecules) makes it clear that micro-

organisms are not necessarily organisms, but can also be molecules.

This definition was clarified in 1995, in a decision that clarified precisely what was covered by the term '*micro-organism*'. The EPO was keen to have a reading of the term which, in patent law, responded to industrial practice, as it noted in specifying that "*this practice [the interpretation of the term micro-organism] takes clearly into account the developments of modern industrial microbiology*"[ix]. This approach enabled the EPO to conclude, as early as 1995, that "*processes [...] carried out on vegetable cells may be defined as "*microbiological processes*" and their products, namely genetically-modified vegetable cells and their cultures, may be defined as "*the products thereof*"*". The conclusion is important because, under patent law, microbiological processes are patentable, unlike essentially biological processes.

A whole commercial field that would escape GMO legislation

The term '*micro-organism*' covers living organisms, isolated cells and molecules such as plasmids. In the case of the proposed deregulation, these micro-organisms, when qualified as '*plants*' and belonging to the two taxonomic groups already mentioned in the GMOs to be deregulated, are indeed concerned, as are multi-cellular organisms such as land plants, trees, algae, etc.

The example of algae speaks for itself, since this market, worth several billion euros a year, is the subject of growing industrial interest[x]. The field of micro-algae, which are among the micro-organisms included in the deregulation proposal, is in fact one of the industrial fields whose potential the European Commission wishes to '*exploit to the full*'…

i Eric Meunier, « GMO algae: a future raw material for industry », *Inf'OGM*, 4 February 2025.
Eric Meunier, « Object of all desire, do GM algae really exist? », *Inf'OGM*, 7 February 2025.

ii EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), Koutsoumanis K. *et al.*, « Scientific Opinion on the update of the list of qualified presumption of safety (QPS) recommended microorganisms intentionally added to food or feed as notified to EFSA », *EFSA Journal*, 2023; 21(1):7747, 23 pp.

iiiS ee the table of the genetic modifications of micro-algae in :
Eric Meunier, « Object of all desire, do GM algae really exist? », *Inf'OGM*, 7 February 2025.

iv « Council Directive 90/220/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms », *Official Journal* L 117 , 08/05/1990, p.0001 - 0014, article 2.

v « DIRECTIVE 2009/41/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 May 2009 on the contained use of genetically modified micro-organisms (recast) », *Official Journal of the European Union* n°L 125/75, article 2, 21 May 2009.

vi « REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC », *Official Journal of the European Union* n°L 309/1, article 3, 24 November 2009.

vii« REGULATION (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 May 2012 concerning the making available on the market and use of biocidal products », Official Journal of the European Union n°L 167/1, article 3, 27 June 2012, https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32012R0528

viii EPO, « Guidelines for Examination in the European Patent Office », version of March 2024, part G, chapitre II-46, point 5.5, Microbiological processes.

ix EPO, « T 0356/93 (Plant cells) 21-02-1995 », 21 February 2025.

x Eric Meunier, « GMO algae: a future raw material for industry », *Inf'OGM*, 4 February 2025. Eric Meunier, « Object of all desire, do GM algae really exist? », *Inf'OGM*, 7 February 2025.

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