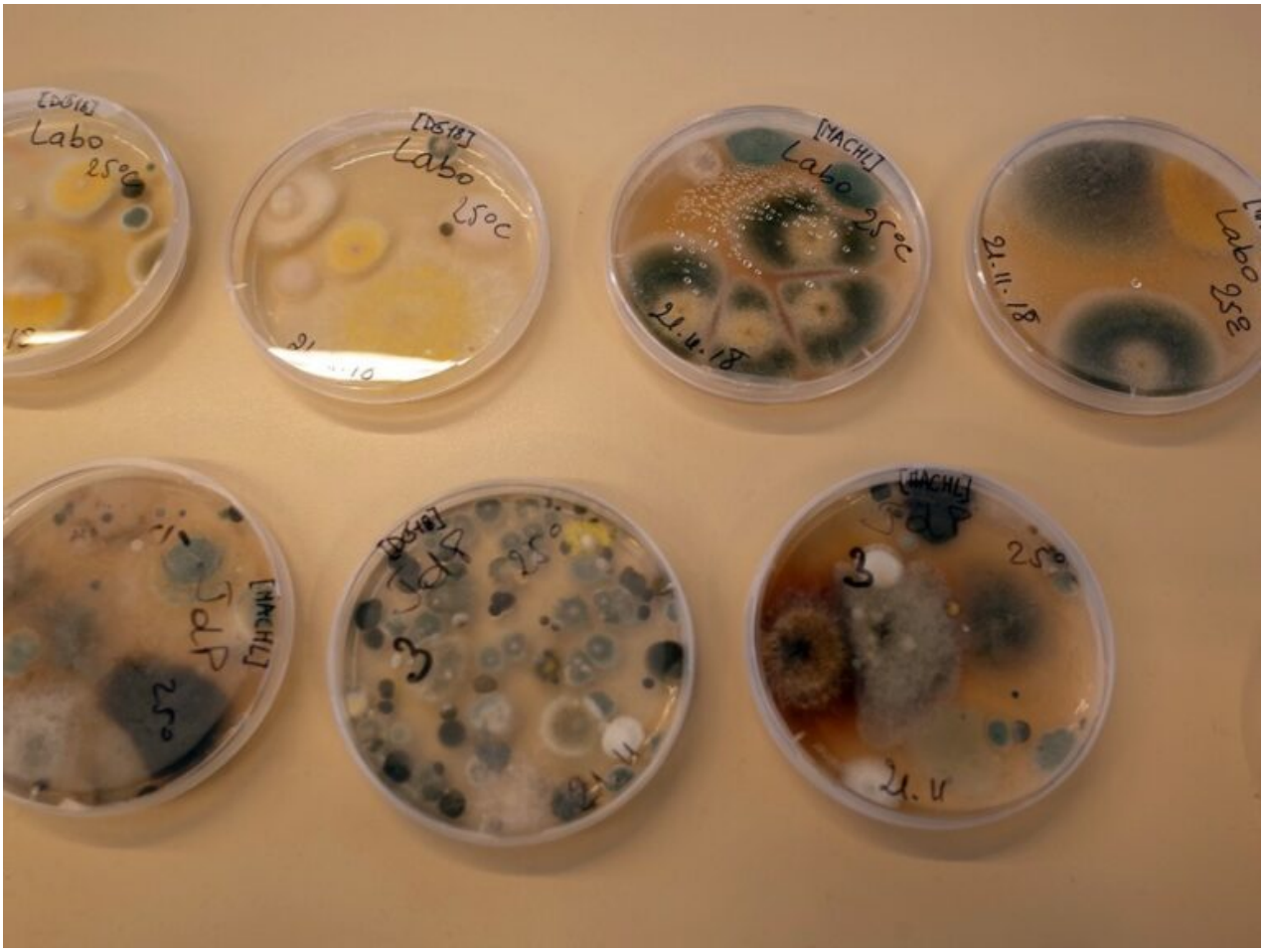
Veille citoyenne d'information sur les OGM et les semences

The European Commission is proposing legislation on biocontrol

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In December 2025, the European Commission proposed a set of measures to amend the regulations governing food and animal consumption, compiled in a document entitled "*Omnibus X*". This document notably proposed the creation of a new legal category: "*biocontrol substances*", described as an alternative to chemical pesticides, whose development and marketing the European Commission aims to promote. However, on June 12, the Council of the EU noted the lack of a qualified majority for this text.



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Inf'OGM *decided to focus on biocontrol once it became clear that the definition currently under discussion at the European level could facilitate the marketing of products derived from biotechnologies. Furthermore, this definition could lead to semantic confusion with products used in organic farming – a confusion we believe it is important to highlight.*

Proposed in December 2025, Omnibus X[1] introduces, for the first time in European law[2], a definition not of biocontrol, but of biocontrol products. It also proposes a streamlined regulatory framework to facilitate their marketing. In its opening remarks, the Commission states that this will "*reduce farmers' dependence on plant protection products containing chemical active substances*" and "*increase the accessibility and availability of sustainable plant protection products, including plant protection products containing biocontrol substances*". Biocontrol thus becomes the showcase for a promise of transition, justifying, for the Commission, a structural easing of controls for a whole range of substances not classified as "*of concern*".

As an introduction, it is important to note that the proposed definition formulated by the European Commission encompasses numerous products: from clay to RNAi sprays and pheromones. This allows for a wide range of interpretations, as biocontrol products can be substances of natural origin or synthetic if they are "*similar*" to the former. Here we find one of the foundational language elements of the deregulation of GMOs/NTGs. This deregulation is supposedly justified by an "*equivalence*" between these GMOs and what nature or conventional breeding does, an equivalence never scientifically explained.

Biological control and biocontrol: a deliberate confusion

The European Commission, supported by the Council, proposes to amend Regulation (EC) No 1107/2009 on "*plant protection products*" (*sic*). They propose to create a new category of "*plant protection products*": the so?called "*biocontrol substances*"[3]. This choice of wording is problematic as it creates confusion. Indeed, it creates an equivalence between "*biological control*" and "*biocontrol products*". Although the etymological relevance of the term "*biocontrol*" can be questioned in itself, *Inf'OGM* will use it here to clearly distinguish the two aforementioned approaches.

The assimilation of the two is far from neutral. It places in a single legal category natural products used in a "*systemic*" approach – *i.e.* an approach that bases plant protection on the ecological balance of agronomic systems – and products with the exact same aim than their synthetic counterparts, which they are supposed to substitute – *i.e.* targeting a "*pest*" species identified as the cause of the unbalance of the agronomic system. The first type of product, identified legally in France as "*low?risk natural preparations*" include ladybirds, nematodes, pheromone traps, Bacillus thuringiensis powders. In the perspective of a systemic approach, they are used to implement a strategy that combines farming practices aimed at slowing down the spread of pathogens and favouring beneficial organisms – such as crop rotations, population varieties and seeds, varietal and species mixtures, hedgerows… By contrast, industrial substitute products target undesirable species once they create issues in the field, and therefore remain firmly within the current paradigm of synthetic pesticides and biotechnologies.

There is another major difference between these two sets of products: some biocontrol products are designed to be covered by patents, whereas natural products and practices used in the context of biological control are not.

Challenging this misleading terminology is crucial. Indeed, as such, it may lead readers to believe that all biocontrol products are biological?control products. Besides, the term "*biocontrol*" may

suggest that these products are compatible with organic agriculture. Yet biocontrol products derived from synthetic chemistry or genetic engineering are not authorised in organic farming. We will further examine the opposition between biocontrol and organic agriculture in a forthcoming article.

Omnibus X defines biocontrol products

The first element of Omnibus X concerns the definition. Article 2 of Regulation 1107/2009 would be revised so that this regulation "*applies to substances, including biocontrol substances [Editor's note: the current regulation states "*including microorganisms*"], which exert a general or specific action on harmful organisms or on plants*".

Omnibus X (Article 3.35) sets out what constitutes a biocontrol product for the European Commission. According to its proposal, it includes:

- microorganisms;
- inorganic substances "*as found in nature*," excluding heavy metals and their salts;
- "*substances of biological origin*" or produced synthetically, but "*functionally identical and structurally similar*" to the former. Here we find the same semantic and conceptual shift as in the transition from Directive 2001/18 (GMO products defined primarily by their method of production) to the new NGT Regulation (products defined by certain characteristics, regardless of their method of production).

First observation: this proposed definition excludes macro-organisms (ladybugs, trichogramma wasps, etc.), which are the epitome of biological control. At the European level, there is no single harmonized authorization procedure for placing beneficial macro-organisms on the market or introducing them. Member States manage, and would therefore continue to manage, the introduction, production, and marketing of these organisms within their territories. France, for example, has included them among biocontrol products.

Let's therefore examine these three categories of biocontrol products.

Microorganisms

Microorganisms (bacteria, fungi, viruses) are already regulated by Regulation 1107/2009 as "*active substances*" in plant protection products. With Omnibus X, they remain within the pesticide category, but this legislation proposes adding another status: that of "*biocontrol products*".

Products consisting of or containing microorganisms have long been used in agriculture, such as powders rich in spores and crystals based on bacteria (*Bacillus thuringiensis* against certain insects, *Bacillus subtilis* against fungal diseases) or fungi (*Trichoderma harzianum* against Fusarium wilt). As of December 31, 2025, the European Food Safety Authority (EFSA) listed 138 microorganisms as *"plant protection products*".

The inclusion of microorganisms in this definition raises the more specific question of genetically modified microorganisms (GMMs). To date, no genetically modified microorganism has been authorized as a pesticide in the European Union. However, several field trials have been conducted. For example, in the Netherlands, the bacterium *Pseudomonas putida* WCS358r, genetically modified to control pathogenic wheat fungi, was field-tested in the late 1990s by Utrecht University[4].

In contrast, several GMMs marketed as "*biocontrol products*" have been authorized in the United States. Let us mention two.
As early as 1996, the bacterium *Bacillus thuringiensis* (Bt), genetically modified to produce several Bt toxins and thus broaden its insecticidal spectrum, was authorized. It is found in Crymax, a "*biopesticide*" (a term equivalent to "*biocontrol product*") marketed by the company Certis Biologicals[5].
Around the same time, the genetically modified bacterium *Agrobacterium radiobacter* K1026, also described as a "*biopesticide*", was used against crown gall. It was marketed by Bio-Care (Australia) under the trade name Nogall.

Omnibus X does not address the issue of GM crops. With Omnibus X, the European Commission is making a major choice. Unlike Chili[6], among others, it has decided not to exclude GM crops from biocontrol. However, as we have seen, microorganisms can be genetically modified for use, for example, as biocontrol substances (even though they are organisms and not substances) or to produce biocontrol substances (such as RNA intended to produce certain biological substances).

Currently, Regulation 1107/2009 (Article 48) specifies that a plant protection product "*containing a*" GMO regulated under Directive 2001/18 "*is subject to an examination concerning genetic modification, in accordance with that Directive*" 2001/18. But the Commission has already proposed another text (Proposal 2025/0405)[7], which amends Directive 2001/18 and explicitly aims to deregulate these GMOs. In genetically modified form, these microorganisms would thus be subject to significantly less stringent regulations for their formal authorization. Secondly, as biocontrol substances, they would be subject to amended Regulation 1107/2009, which aims to simplify their marketing. There would therefore be two regulatory frameworks for GM plants intended as biocontrol products.

Inorganic substances

Inorganic substances include simple mineral salts (potassium bicarbonate, calcium sulfate, certain silicates) used as fungicides or insecticides. They can also include clay, talc, lime, etc. Heavy metals - copper, for example - and their salts are specifically excluded from this definition[8].

Organic or synthetic substances and the problem of "*similarity*"

The third category is conceived in extremely broad terms and defined in a particularly vague manner. It consists of substances "*of natural origin*" or "*synthetically produced that are functionally identical and structurally similar to the former*." "*Synthetic*" is understood to mean "*manufactured by humans in factories using chemical processes*"[9]. These two conditions, "*functionally identical" and "structurally similar*," are never defined, and there is no reference to OECD (Organisation for Economic Co-operation and Development) standards, protocols for analyzing molecular structures, or thresholds of similarity.

This idea of ??equivalence between products derived from nature and those synthesized in the laboratory can only remind us of the political underpinnings of the deregulation of GMOs/NGTs. However, this equivalence is primarily postulated: it has never been systematically demonstrated, neither in the case of biocontrol nor in that of NGTs. This is primarily a political choice, lacking any scientific basis. But, more fundamentally, the idea that the synthetic version can be identical to the "*natural*" one, without providing any criteria to justify this, allows for the alignment of risk assessments between "*natural*" (based on millennia of human experience) and synthetic (recent, and therefore lacking any proven safety evidence), the latter not being inherently riskier[10].

In the recitals of the Omnibus X Regulation, this third category is further defined. It includes, on the one hand, substances emitted by living organisms into the environment that act as so-called "*semiochemical*" signals (pheromones between individuals of the same species or kairomones between different species).

On the other hand, Omnibus X refers to "*biological macromolecules or molecules composed of their components, as well as substances, including those of unknown and variable composition, originating from living organisms or resulting from biological processes*" (extracts of plant products or metabolites produced by microorganisms, for example). With such a definition, Omnibus X is paving the way for a new generation of so-called "*biological*" molecules to enter the market, but which may be synthetic (interfering RNAs, micropeptides), or even synthetic macromolecules "*inspired*" by living organisms.

When the text refers to metabolites produced by microorganisms, it is important to remember that these microorganisms may be genetically modified, like those used to produce ledprona[11], the active substance (RNAi) in calantha. The question then arises as to whether these metabolites are subject only to Regulation 1107/2009 as pesticides or also to Regulation 1829/2003 as products intended for human and animal consumption produced from GMOs.

This question resonates with the fact that, also in Omnibus X, the European Commission proposes amending Regulation 1829/2003 to enshrine in European legislation a practice in place since 2009, namely that metabolites produced by GMOs are not considered "*produced from GMOs*", and therefore subject to GMO legislation, but "*produced using*" GMOs, and thus not subject to this legislation (no labeling is required, in particular).

Biocontrol products, a promising market

According to the company De Sangosse, microorganisms used in biocontrol constituted a $2.5 billion (€2 billion) market in 2021 globally (mainly in North and South America) and are expected to reach $7 billion (€6 billion) in 2029[12].

Biocontrol "*products*" already on the market

We have already mentioned calantha, an RNAi spray produced by GreenLight Bioscience to combat the Colorado potato beetle, which Belgium has provisionally authorized. The European Union has decided to evaluate calantha's active ingredient, ledprona, according to Regulation 1107/2009, even though the existing protocols are poorly suited to this new type of genetic pesticide. We can also mention Micropep's pesticides, based on small peptides derived from plant sequences. Others are in the development phase.

Thus, by stretching the definition somewhat, could the project by researchers at Northeastern University[12] (Boston, USA) to create a synthetic polymer that breaks down the protective layer that bacteria produce around themselves in order to make *Pseudomonas aeruginosa* bacteria more susceptible to conventional antibiotics not be considered a biocontrol substance? These molecules are not organisms: they therefore fall outside the scope of Directive 2001/18 on GMOs, even though they rely on biotechnology. Nor are they chemical pesticides. By broadening the definition of "*substances of biological origin*" to include compounds of "*unknown and variable*" composition, and by accepting synthetic equivalents declared "*functionally identical" and "structurally similar*"

without specifying the criteria for this identity, Omnibus X could pave the way for these new biotechnologies.

What about biostimulants?

The Commission is taking advantage of Omnibus X to explicitly exclude "*biostimulants*" from the scope of the regulation. A new point in Article 3 defines these biostimulants as products that "*stimulate plant nutrition processes*" or improve tolerance to abiotic stress, without acting as a means of controlling harmful organisms. They fall under Regulation (EU) 2019/1009 on fertilizers, and not Regulation (EU) 1107/2009.

The European Commission's proposed definition of biocontrol products is both very broad and very vague. It notably echoes the semantics used in the draft legislation on the deregulation of GMOs/NGTs, referring to synthetic products "*similar*" to those found in nature. However, this equivalence has never been scientifically demonstrated, and no rigorous protocol supports it. As with GMOs/NGTs, the Omnibus X proposal, once this definition is established, aims to propose regulatory relaxations. We will analyze these in a forthcoming article.

The entire Omnibus X text is now in the hands of the EU Council, on the one hand, and the European Parliament, on the other. For the Council, the Cypriot Presidency has shown an impressive willingness to have an amended version of this text accepted by the Member States. Cyprus has thus repeatedly proposed a compromise text, including modifications to the definition of biocontrol products. The country had hoped that the Council, meeting on Friday, June 12, 2026, would express a qualified majority. However, this qualified majority was not reached. According to our information, this was due to opposition from Germany, Spain, and Italy, among others.

- + European Commission, « Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EC) No 999/2001, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 852/2004, (EC) No 853/2004, (EC) No 396/2005, (EC) No 1099/2009, (EC) No 1107/2009, (EU) No 528/2012, (EU) 2017/625 as regards the simplification and strengthening of food and feed safety requirements », 16 December 2025.
  See also the European Commission's working document:
  European Commission, « Simplification Omnibus Package – COMMISSION STAFF WORKING DOCUMENT Accompanying the document « Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EC) No 999/2001, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 852/2004, (EC) No 853/2004, (EC) No 396/2005, (EC) No 1099/2009, (EC) No 1107/2009, (EU) No 528/2012, (EU) 2017/625 as regards the simplification and strengthening of food and feed safety requirements » », 16 December 2025.
- + France had adopted such a definition and framework as early as 2014:
  Christophe Noisette, « Le biocontrôle : un terme récent et problématique », *Inf'OGM, le journal*, n° 177, October/December 2025.
- + Not available on the European Legislative Observatory's website. See the text of the Omnibus X proposal, translated into French, on the National Assembly's website:
  Assemblée nationale, « TEXTE SOUMIS EN APPLICATION DE L'ARTICLE 88-4 DE LA CONSTITUTION PAR LE GOUVERNEMENT, À L'ASSEMBLÉE NATIONALE ET AU SÉNAT – Proposition de RÈGLEMENT DU PARLEMENT EUROPÉEN ET DU CONSEIL modifiant les règlements (CE) nº 999/2001, (CE) nº 1829/2003, (CE) nº 1831/2003, (CE) nº 852/2004, (CE) nº 853/2004, (CE) nº 396/2005, (CE) nº 1099/2009, (CE) nº 1107/2009, (UE) nº 528/2012 et (UE) 2017/625 en ce qui concerne la simplification et le renforcement des exigences en matière de sécurité des denrées alimentaires et des aliments pour animaux », 1st April 2026.
- + Glandorf DC, Verheggen P, Jansen T, Jorritsma JW, Smit E, Leeflang P, Wernars K, Thomashow LS, Laureijs E, Thomas-Oates JE, Bakker PA, van Loon LC, « Effect of genetically modified Pseudomonas putida WCS358r on the fungal rhizosphere microflora of field-grown wheat », *Appl Environ Microbiol.*, août 2001.

- + Certis USA has acquired from Ecogen “*certain assets relating to the Bt biopesticide and insecticidal nematode businesses* ”.
  Certis biologicals, « Certis USA Completes Acquisition of Certain Ecogen, Inc. Assets », 19 July 2022.
- + On 5 May 2026, Chile adopted an amendment to Resolution 1.557/2014 “*which specifies that the simplified authorisation procedure for biocontrol microorganisms is reserved for non-GMO microorganisms*”.
  Ministerio del Interior, « MINISTERIO DE AGRICULTURA / Subsecretaría de Agricultura / Servicio Agrícola y Ganadero / Dirección Nacional MODIFICA RESOLUCIÓN Nº 9.074, DE 2018, Y RESOLUCIÓN Nº 1.557, DE 2014, EN EL SENTIDO DE INCORPORAR Y ACTUALIZAR AUTORIZACIONES ESPECIALES PARA PLAGUICIDAS NATURALES Y SINTÉTICOS », *DIARIO OFICIALDE LA REPUBLICA DE CHILE*, Núm. 44.452, 18 May 2026.
- + « Ongoing european legal initiatives (GMO, patents, DSI, seeds, biotech…) », *Inf'OGM*.
- + The EESC (European Economic and Social Committee), in its opinion of April 2026, wishes to re-include heavy metals and their salts.
- + In Regulation 1107/2009, the adjectives "*natural*" and "*synthetic*" are not defined.
- + It should be noted that, in most cases, a natural molecule and a synthetic molecule do not have the same dextrorotatory or levorotatory structure.
- + Environmental Protection Agency, « Human Health Risk Assessment, Review of Product Characterization and Manufacturing Process for the New end-use product, Calantha », 29 September 2023.
- + Cynthia McCormick Hibbert, « Barnacle-inspired polymers could present new way to design antibiofilm materials, researchers say », *Northeastern Global News*, 9 October 2024.
  Apoorva Vishwakarma, Amal Narayanan, Nityanshu Kumar, Zixi Chen, Francis Dang, Joshua Menefee, Ali Dhinojwala, and Abraham Joy, « Coacervate Dense Phase Displaces Surface-Established *Pseudomonas aeruginosa* Biofilms », *Journal of the American Chemical Society*, Vol. 146, Issue 38, 11 September 2024.

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