Veille citoyenne d'information sur les OGM et les semences

Biocontrol: European Commission seeks lighter regulation

Par Christophe NOISETTE

Publié le 02/07/2026, modifié le 15/09/2026

Presented as an alternative to chemical pesticides, biocontrol operates on a logic of substitution that allows the pesticide industry to "*green*" its operations. Worse still, biocontrol products could overshadow beneficial approaches such as peasant agroecology or biological pest control. To facilitate the marketing of biocontrol substances, the European Commission proposed a definition and simplified regulations in the draft Omnibus X regulation in December 2025.

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.*

According to the European Commission, biocontrol substances include microorganisms (bacteria, fungi, viruses), inorganic substances (potassium bicarbonate, clay), semiochemicals (pheromones, kairomones), and substances of natural origin or those "*produced synthetically that are functionally identical and structurally similar to the former*". As we noted in a previous article[i], this latter category could allow a new generation of synthetic pesticides - such as molecules produced *via* genetic engineering (*e.g.*, interfering RNA or micropeptides) or synthetic macromolecules "*inspired*" by biological systems - to be classified as biocontrol products. Once authorized, a biocontrol substance would be designated as such on the list of authorized active substances maintained by the European Commission[ii]. The "*biocontrol*" label - which evokes "*biological*" and carries a more positive connotation than "*pesticide*" or "*plant protection product*" - would facilitate social acceptance.

Biocontrol substances eligible for "*low-risk*" designation

Omnibus X[iii] aims to introduce major simplifications for these biocontrol substances without directly tackling the issue of the assessment process itself. To achieve this, the proposed text would allow many biocontrol substances to be classified as "*low-risk*" active substances. Work by the European Food Safety Authority (EFSA) and ongoing discussions regarding this text are already moving in this direction. A biocontrol substance would be subject to the active substance assessment criteria defined in Annex II of Regulation 1107/2009, unless it is also designated as "*low-risk*."

Currently, Regulation 1107/2009 governs so-called "*active*" substances that serve a "*plant protection*" function; these can be either chemical or "*biological*" in nature. These active substances may also be classified as "*low-risk*" if they meet the criteria set out in Annex II of the regulation (see sidebar). In practical terms, Omnibus X paves the way for biocontrol substances to qualify as "*low-risk*" by establishing a definition of biocontrol substances that largely overlaps with products already designated as "*low-risk*" (such as certain microorganisms like *Bacillus amyloliquefaciens* - sold under the name Taegro[iv] - pheromones, certain mineral substances, plant extracts, etc.). The regulation leverages the established reputation of staples like Bt or pheromone traps - which have been authorized for organic farming for decades - to promote products derived from genetic or chemical synthesis, such as RNAi sprays or micropeptides[v].

Omnibus simplifies regulations for "*low-risk*" substances

Low-risk substances are already subject to a less rigorous assessment process than other active substances. EFSA considers that an active substance (whether chemical, mineral, or biological - excluding microorganisms, which are treated and assessed differently) can qualify as a "*low-risk substance*" if it is not carcinogenic, mutagenic, or toxic to reproduction (CMR); is neither persistent nor bioaccumulative (PBT); is not an endocrine disruptor; and shows no neurotoxic or immunotoxic effects.

Since 2022 - following the adoption of four implementing regulations amending Regulation (EC) No 1107/2009 - microorganisms have been assessed under a specific regime. A microbial strain can be approved as a low-risk active substance if it meets general safety criteria. These criteria include the absence of pathogenicity for humans and non-target organisms, the absence of toxins or hazardous metabolites, the absence of identified virulence factors, and the absence of a significant risk of gene transfer to other microorganisms. Furthermore, the EFSA assessment must

demonstrate that the microorganism does not possess functional, transferable genes conferring resistance to antimicrobials used in human or veterinary medicine, nor characteristics of persistence or uncontrolled multiplication incompatible with "*low-risk*" status.

Whether dealing with chemical molecules or microorganisms, the authorization process for low-risk substances is thus significantly streamlined.

Omnibus X also proposes that "*low-risk*" status be applied retroactively to chemical or biocontrol active substances that have already been authorized.

Finally, to determine whether a product is low-risk, Omnibus X proposes relying solely on the intrinsic properties of the active substance (hazard, theoretical exposure profile). Article 22 of Regulation 1107/2009, which defines the criteria for a low-risk active substance, is being revised under Omnibus X. Currently, for an active substance to qualify as low-risk, it must be shown that it is "*foreseeable that plant protection products containing that substance will present only a low risk to human health, animal health and the environment, in accordance with Article 47(1)*". Omnibus X proposes removing this condition, noting that its implementation "*has proved difficult in practice, given that at the time of approval or renewal of approval of active substances, it is generally unknown whether or not the product-related criteria set out in Article 47 can be met*". However, Article 47 itself is retained under Omnibus X: a low-risk product must be composed exclusively of low-risk molecules (including co-formulants such as safeners and synergists).

"*Priority*" treatment

In practical terms, what does Omnibus X propose to facilitate the marketing of biocontrol products as such? First, the European Commission calls for the assessment of biocontrol substances to be prioritized over that of other "*plant protection substances*". In its view, these substances support sustainable agriculture by potentially reducing the use of controversial chemical pesticides.

Are Member States being sidelined in the risk assessment process?

Under Regulation 1107/2009, a Member State acts as the rapporteur for the assessment of an active substance. Omnibus X introduces the possibility for EFSA to assume this role directly for biocontrol substances, on the grounds that their assessment "requires specific technical expertise" that some Member States might lack (an argument championed by multinationals and adopted by the European Commission[vi]). To justify this proposal, the European Commission points to Member States with limited resources that would be unable to handle such dossiers. However, this move would primarily serve to bypass national agencies that are deemed overly critical - such as Anses (which is also facing attacks in France from the FNSEA) or the Federal Agency for Nature Conservation in Germany. In practice, this would shift the assessment process to the European level, where conflicts of interest[vii] have already been exposed and the relationship with the public is more distant. Omnibus X also proposes increasing EFSA's budget if necessary[viii].

Authorizations granted for 25 years

A highly significant measure within Omnibus X concerns all plant protection products (whether chemical or "*biological*"). The European Commission proposes granting authorizations for an indefinite period, subject to certain conditions that could apply to a large number of substances. Re-evaluations would not be eliminated; however, they would be triggered solely at the Commission's initiative when it deems "*new scientific knowledge*" necessitates them, rather than occurring on the regular basis currently required by every authorization renewal application every

10 years. Omnibus X includes an exception for substances explicitly classified as being "*of concern* ". In its opinion published in April 2026, the European Economic and Social Committee (EESC)[ix] stated that "*the European Food Safety Authority (EFSA) should be empowered to flag the need for targeted re-evaluations of active substances approved for an indefinite period [...]. This matter should not fall solely within the remit of the Commission and the Member States*"ix. Will the Commission take this opinion into account? And how will "*new scientific knowledge*" be assessed?

Provisional authorizations

Currently, Article 30 of Regulation 1107/2009 allows a Member State to issue a provisional market authorization - valid for a maximum of three years - for a plant protection product containing an active substance that has not yet been authorized. Omnibus X proposes restricting this procedure to biocontrol substances.

The European Commission justifies this change, once again, by the need to make biocontrol substances "*more quickly accessible and available to farmers*". In practical terms, a provisional authorization - now valid for a maximum of five years - could be granted by a Member State that has, firstly, completed its assessment report and, secondly, concluded that all active substances in the plant protection product meet the criteria defining a "*low-risk*" substance or, failing that, can be considered "*biocontrol active substances*". Thus, a plant protection product containing biocontrol substances could be granted provisional authorization without waiting for a formal decision at the European Union level.

This five-year period is presented as the time needed to finalize the comprehensive assessment and formal authorization of the active substance. Indeed, "*to avoid unnecessary administrative procedures*", the Commission proposes that "*once the new biocontrol substance is authorized […], it should be possible to convert these provisional authorizations into regular authorizations without the need for a new assessment, unless the conditions established in the approval require a modification of the conditions set out in the provisional authorizations*". Currently, once the active substance has been assessed by EFSA and approved by the Commission, the holder must submit a new, complete application for market authorization (MA) to the Member State. This will no longer be necessary. Once the active substance is authorized at the European level, the Member State can convert the provisional authorization for the final product into a definitive authorization (MA). In effect, this aligns the validation of the substance with the validation of the product, thereby greatly facilitating market access for biocontrol substances under the guise of administrative "*simplification* ".

Derogations for emergency situations

Regulation 1107/2009, in its current version, provides for the granting of derogations in cases of " *emergency situations regarding plant protection*". Article 4 allows a Member State to obtain a derogation for an active substance in the event of a "*serious danger to plant health*". The Omnibus X proposal seeks to add "*a danger to plant production*" (which need not be characterized as " *serious*") to the criteria for obtaining this emergency derogation. In a memo regarding Omnibus X, the organization Générations Futures[x] explains that "*this means the derogation could be invoked to approve highly hazardous substances when production levels (yields) for a specific crop are deemed to be under threat*". The implementation details for this provision are particularly vague. There is legitimate concern that these derogations might be granted solely on the basis of strict yield comparisons focusing exclusively on immediate output, without regard for the broader context of long-term soil health, biodiversity, overall farm resilience, and food security. This derogation regime could pave the way for multiple exemptions, allowing the recurring use of substances

normally prohibited under the regulation’s criteria.

Another proposal involves ending the requirement for Member States - when granting such derogations - to draw up "*a phase-out plan aimed at controlling the serious danger by other means, including non-chemical methods, and to submit this plan to the Commission without delay*".

Regulation 1107/2009 also allows Member States (under Article 53) to grant emergency derogations for a plant protection product (comprising an active substance, co-formulants, and synergists) "*in special circumstances*", for a maximum period of 120 days and for "*limited and controlled*" use. Such a derogation is permitted only if there is "*no other reasonable means*" of controlling the phytosanitary threat. This is how Calantha, an RNAi spray, received provisional authorization in Belgium to combat Colorado potato beetles[xi]. The Omnibus Regulation does not alter Article 53. However, through the amendment to Article 4 discussed earlier, the European Commission is extending the scope of emergency derogations: they will now apply not only in cases of danger to "*plant health*" but also in cases of "*threats to plant production*".

Authorizations valid everywhere?

Omnibus X would radically overhaul the geography of authorizations. It proposes treating the Union as a single zone for products containing only biocontrol substances (amended Articles 3 and 33). If adopted, an authorization in one Member State would be *de facto* valid across the entire EU - unlike the current situation, where distinct "*zones*" may have different characteristics requiring tailored approaches. If a national authority fails to rule on a mutual recognition request within the prescribed timeframe, the authorization would be deemed granted (amended Article 67). Silence implies consent - a principle widely recognized as unfair.

Finally, Omnibus X would eliminate a tool essential for post-market monitoring. The European Commission proposes exempting products containing only biocontrol substances from record-keeping obligations (Article 67) in the name of reducing the administrative burden on farmers.

Multinationals are rejoicing

Omnibus X therefore aims to facilitate the marketing of biocontrol products - or at least to introduce greater flexibility - notably by allowing them to be classified as "*low-risk active substances*". Consequently, industry associations advocating for industrial biocontrol (such as IBMA and Alliance Biocontrôle) welcome the prospect - should the Omnibus X proposal be adopted in its entirety - of a common definition, a single European zone, the possibility of provisional authorizations, 25-year authorizations, and so on[xii]. Conversely, for NGOs like Générations Futures or Pollinis, the assessment is more ambiguous: under the guise of "*unleashing*" biocontrol, Omnibus X establishes a streamlined regulatory regime that would benefit - far beyond ladybugs, pheromones, and *Bacillus thuringiensis* - microorganisms (whether genetically modified or not) as well as new synthetic products that are nonetheless "*similar*" to those produced by nature[xiii].

Ultimately, Omnibus X does not create a "*green label*" for biocontrol products - at least not yet - but it paves the way for such a concept. It does not formally alter the scientific principles of risk assessment already established by Regulation 1107/2009. Instead, it operates in other areas: timing (extended authorization periods, provisional authorizations), geography (single zone, tacit recognition), and traceability (simplified usage record-keeping).

This proposal is currently under discussion within the Council of the EU. Since January 2026, the Cypriot presidency has put forward several compromise texts, with certain amendments addressing

the "*biocontrol*" component. When asked by *Inf'OGM*, the Council of the EU's press office indicated on May 27, 2026, that "*the Council Presidency […] remains optimistic that an agreement among Member States on a common Council position (a '*negotiating mandate*' with the European Parliament) can be reached in the coming weeks*". However, an initial review of Member State positions on June 12, 2026, revealed that, as it stands, the Omnibus X text was not acceptable to a majority of states. Consequently, to date, the Council of the EU has not adopted a mandate to negotiate with the European Parliament. As for the European Parliament, the Agriculture and Environment Committees are spearheading the process through a joint committee. Amendments must be submitted to this committee by July 13, 2026, with a view to presenting and adopting a report in the autumn, before the full text is debated by MEPs in a plenary session.

i Christophe Noisette, "The European Commission is proposing legislation on biocontrol", *Inf'OGM*, 8 July 2026.

ii Article 7 of Omnibus X, amending Article 13(4) of Regulation (EC) No 1107/2009.

iii 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.

iv Corder asbl, « Des produits phytopharmaceutiques dits « *à faible risque* » existent en Belgique » .

v Christophe Noisette, "The European Commission is proposing legislation on biocontrol", *Inf'OGM*, 8 July 2026.

vi See the introductory remarks of the European Commission's Omnibus X proposal, page 1.

vii Martin Pigeon, « L'AESA : une indépendance sous influence », *Inf'OGM, le journal*, n°116, mai/juin 2012.
Eric Meunier, « UE – OGM : l'AESA, objet d'une plainte pour conflit d'intérêts », *Inf'OGM*, 29 août 2012.
« Efsa : la moitié des scientifiques seraient en situation de conflit d'intérêts », *franceinfo* et *Brut*, 20 June 2017.

viii "*The proposed initiative is expected to result in an increase of €15.073 million in the subsidy paid by the Commission to the Authority for the 2028–2034 period*". This figure represents the total increase resulting from all the amendments introduced by Omnibus X. Source: 2025/0410 (COD), p. 19.
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.

ix EESC, « Food and feed safety simplification omnibus », 29 April 2026.

x Générations Futures, « OMNIBUS X – SECURITÉ ALIMENTAIRE ET ALIMENTATION ANIMALE – LE DÉMANTÈLEMENT SOUS COUVERT DE SIMPLIFICATION », 19 March 2026.

xi Phytoweb, « CALANTHA ».

[xii] IBMA, « IBMA welcomes the publication of the Proposal for the Simplification Package Omnibus », 17 December 2025.
Alliance Biocontrôle, « Projet de règlement « omnibus sécurité alimentaire » : une avancée majeure pour libérer l'innovation en solutions de biocontrôle », 17 December 2025.

[xiii] Pollinis, « Les pesticides génétiques ARNi, nouvelle arme de l'agrochimie contre le Vivant ».
Générations Futures, « OMNIBUS X – SECURITÉ ALIMENTAIRE ET ALIMENTATION ANIMALE – LE DÉMANTÈLEMENT SOUS COUVERT DE SIMPLIFICATION », 19 March 2026.
