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Could "low-risk criteria" slow down Integrated Pest Management (IPM)?

The Commission's proposals for amending Regulation (EC) 1107/2009 in Omnibus X would ensure safety while scaling up Integrated Pest Management (IPM)

In recent months there has been a lot of discussion of whether acceleration measures for plant protection substances and products in the Food and Feed Safety Omnibus (Omnibus X) should be reserved for substances that meet the criteria in Annex II, point 5 of Regulation (EC) 1107/2009 (the Plant Protection Regulation-PPPR), often referred to as "low-risk criteria." The initial proposal from the European Commission does not use these criteria as the basis for its various suggestions for facilitation measures. Instead, it gives discretion to Member States to grant provisional authorisation, for example, to products composed of biocontrol substances provided that the draft assessment report indicates that the component substances will meet the requirements of Article 4(2) [residues] and Article 4(3) [general efficacy and safety criteria] of the PPPR.

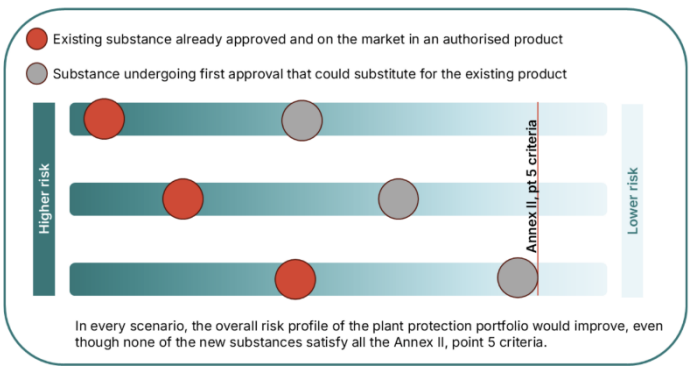
Products composed of biocontrol substances that would be eligible for facilitation measures are not safe because they are biocontrol; they are safe because they satisfy the PPPR's safety criteria in those articles. The Commission's emphasis on biocontrol reflects addressed a major obstacle to Integrated Pest Management (IPM): limited access to biocontrol solutions for many EU farmers. Furthermore, biocontrol substances generally have two other relevant characteristics:

- They have a targeted mode of action that limits non-target effects (but also has implications for the economics of bringing the product to market since a "blockbuster" scenario is unlikely).
- Biocontrol substances are, for the most part, subject to well-known and predictable decomposition pathways.

If a biocontrol substance does not meet the safety requirements in Articles 4(2) and 4(3) or have the two additional characteristics listed above, that would become evident during the preparation of the draft assessment report, and Member States could take informed decisions that might include withholding eligibility for acceleration measures.

Risk exists on a spectrum

The shorthand "low-risk criteria" erroneously gives the impression that substances that do not meet all the criteria in Annex II, point 5 are therefore "high-risk," but this is not true. As the graphic to the right shows, excluding substances that do not meet low-risk criteria from acceleration measures could actually impede IPM, regardless of whether those new substances are biocontrol or conventional.



The criteria in Annex II, point 5 are not suitable for biocontrol products

Part of the problem is that Annex II, point 5 sets hazard-based criteria, which means that they do not consider how mitigation measures can reduce or eliminate risk. As an example, one of the exclusion criteria is "sensitisation," which means that the substance triggers an allergy-like immune response. The risk assessment of biocontrol substances and products already anticipates that sensitisation can be dealt with through the use of Personal Protection Equipment (PPE) during application, while the natural decomposition of biocontrol substances may be sufficient to protect consumers and the environment. In other cases, human and environmental exposure may be limited through the application method, such as when a substance is contained in a trap. This example shows why the Annex II, point 5 criteria should not be used in Omnibus X as a cut-off for determining eligibility for market acceleration measures.

In addition, there is currently a lack of validated methods for testing microorganisms for sensitisation. Because of this, it is impossible to generate data to demonstrate whether a microorganism is sensitising, which means that some Member States exclude them from the "low risk" category by default, not because they are considered to be problematic.

As IFOAM Organics Europe noted when reacting to the Council's General Approach on Omnibus X, reserving facilitation measures only for products containing solely substances that meet the criterial in Annex II, point 5 of Reg (EC) 1107/2009 "will exclude [biocontrol substances] like garlic extract or orange oil…because the criteria and data requirements are not tailored to biocontrol."

The number of biocontrol substances that would be excluded from accelerated access to the market is considerable. According to an analysis that the International Biocontrol Manufacturers Association (IBMA) carried out, **as many as 58% of the biocontrol products that are already on the EU market "may not have been eligible** for an accelerated registration process under the…"low risk" proposal…due to sensitisation issues, or the absence of suitable test methods."

In conclusion, if MEPs want to promote the innovation that will give farmers a robust toolbox while fostering IPM, acceleration measures cannot be limited only to substances that meet the Annex II, point 5 criteria and must include biocontrol substances.

About the Biocontrol Coalition

The Biocontrol Coalition (www.biocontrolcoalition.eu) is a multi-stakeholder platform advocating for the European Union to rethink its framework for agriculture and food, particularly for biocontrol, to enlarge the farmer toolbox while ensuring safety and health and protecting the environment.

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