



#### Introduction and context

In 2024, the <u>Strategic Dialogue on the Future of EU Agriculture</u> brought together agri-food stakeholders to develop a shared prospect for farming and food in Europe. Their report addresses the development and use of biocontrol and states that biocontrol can help farmers reduce their pesticide use. Similarly, the <u>Mission Letter to</u> <u>the Commissioner-designate for Health and Animal Welfare</u> indicates that the European Commission will work to improve sustainability of food production, including through organic production and accelerated use of biocontrol.

In the past legislative mandate, biocontrol was addressed with the <u>proposal for the Regulation on the Sustainable</u> <u>Use of plant protection products (SUR)</u>, which intended to define biological control and recognized the need to increase its availability and use.

On 19 February 2025 the European Commission presented a <u>Vision for Agriculture and Food</u>, outlining how to ensure the long-term competitiveness and sustainability of our farming sector within the boundaries of our planet. The Vision announces that it will "provide a definition of biocontrol active substances, introduce the possibility for Member States to grant provisional authorisations for plant protection products containing such biocontrol active substances while their evaluation is still ongoing and create a fast-track procedure for their approval and authorisation." Likewise, it acknowledges that "the European Food Safety Authority (EFSA) will have to be reinforced with additional resources to speed up risk assessment procedures so that it can continue playing a central role in providing timely, transparent and independent scientific advice."

In this political context, IFOAM Organics Europe presents its recommendations on the subject of biocontrol with the present position paper.

Plant health care in organic agriculture relies mainly on preventive and indirect measures, combined into a strategy. Biocontrol is one tool in a farmer's strategy to manage plant health on an organic farm. A healthy crop production system precisely depends on combining several tools into a strategy. These tools include, but are not limited to:

- the use of tools to enhance functional biodiversity (conservation biocontrol): insert landscape elements on the fields and around farms, such as hedges or flower strips that provide a home to natural enemies of pests, like predatory insects and birds;
- crop rotations that avoid repeated planting of crops that are susceptible to the same pests and diseases, thus limiting the chances of these pests and diseases to establish permanently on a field;
- the choice of crop varieties that are resistant or less susceptible to pests and diseases and suitable for the local soil and climate conditions;
- The consistent implementation of all agronomic measures that can help reduce infection pressure from diseases and pests, for example, pruning to remove infestations from crops, improve aeration, and enhance exposure to sunlight, as well as practices like tillage or mulching, or physical management measures such as using nets to protect crops.

Where crops cannot adequately be protected from pests and diseases by the above-mentioned or comparable plant protection measures, biocontrol tools may be used to the extent necessary. Biocontrol tools in organic farming include the use of macrobials and of other permitted biocontrol active substances. In organic fruit growing, for example, azadirachtin is used for the control of the rosy apple aphid, potassium hydrogen carbonate for the control of fungal diseases and a combination of codling moth granulovirus and mating disruption with pheromones is used for codling moth control.

The choice to use biocontrol tools instead of synthetic plant protection pesticides contributes to less pollution at farm level, but also at a much larger environment scale. It is important to consider that biocontrol tools will only work well if the whole system is well-managed and is based on a comprehensive plant health strategy. Biocontrol tools are always part of a combination strategy as described above. In organic farming, in the majority

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of crops, <u>plant health management</u> can be done with little or no use of biocontrol tools, while other crops, such as fruits, grapes and vegetables, will often need the use of such tools.

Farming does not take place in a static world. Regardless of their cultivation method, farmers are increasingly faced with the effects of climate change and globalization. Climate affects the presence of pests and diseases, and the biology of pest/crop interactions. Similarly, farmers have to deal with introduced exotic pests and diseases which are "travelling" to Europe with goods in a world of globalized trade. New pests and diseases, as well as changes in climate, require new solutions, including selective products or natural enemies targeting these pests and diseases.

Due to the increasing dynamics in the emergence of these new problems and the speed of their spread, time becomes a crucial factor. It is essential that appropriate solutions are made available as quickly as possible.

There is an increasing need for specific biocontrol tools that fit in with the combination strategies in organic farming, namely in fruit and winegrowing and in vegetable production. Unlike conventional farmers, organic farmers cannot make use of synthetic pesticides to manage new pests and diseases and are thus more dependent on the availability of biocontrol tools. Nevertheless, these products would be useful not only for organic farmers, but also for conventional farmers to be applied in their IPM strategies.

To contribute to a solution to these problems, IFOAM Organics Europe gives the following recommendations:

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Rue Marie-Thérèse 11 – 1000 Brussels – Belgium – Phone: +32 2 280 12 23 – Email: info@organicseurope.bio

#### Recommendation 1 – Adopt a definition of biocontrol

#### We recommend that a definition of biocontrol should be adopted at EU level.

Biocontrol manages crop health, using organisms and substances from nature, and thus avoids that artificial substances are released into the environment. It is best defined as follows:

'Biocontrol' means the control of organisms harmful to plants or plant products, using:

- 1. living organisms, namely invertebrate macro-organisms or
- 2. living micro-organisms
- 3. semiochemicals (nature-identical)
- 4. natural substances or substances identical to them,<sup>1</sup> such as
- extracts from natural sources such as plants or algae, or from animal origin,
- substances produced from microorganisms or that are constituents of biological organisms
- and inorganic natural substances (mineral origin).

For organic farming, the following restrictions apply for the type of biocontrol tools used:

- Biocontrol used in organic farming must comply with the requirement of being natural or natureidentical.
- Biocontrol used in organic farming must comply with the requirement of being non GMO the organic production rules exclude the use of GMOs, products produced from GMOs, and products produced by GMOs.

# Recommendation 2 - Adjust the approval of biocontrol active substances at EU level, taking into consideration their unique characteristics

Biocontrol active substances must undergo a strict risk assessment to make sure that only those that are safe for human health and the environment are authorised. Regarding the dossier preparation for the approval and registration, we recommend some better adjustments in the approval process that take into account the **specific characteristics of biocontrol** active substances. The approval process needs to be adapted to these substances, especially by taking into account their prior existence in the natural environment, the complexity and variability of their composition and their wider range of uses. This would also ensure that the risk assessment of biocontrol products, including natural substances, is not hampered by technical feasibility.

Here are some important considerations for adjusting the assessment of biocontrol active substances, that are justified by their unique characteristics:

- As discussed in the introduction, biocontrol products consist of substances that are already present in nature (unlike artificially produced synthetic chemicals). Consequently, the background concentration of naturally occurring substances must be considered in calculations of concentrations in soil and water.
- Certain types of substances will already have a use in a different context, such as use as food, or use in fertilizers. This means that humans and the environment are exposed to these substances already. Acknowledging this means that the assessment of such substances must be proportionate to the expected additional impacts of their use in biocontrol on humans and the environment. It should take

Rue Marie-Thérèse 11 - 1000 Brussels - Belgium - Phone: +32 2 280 12 23 - Email: info@organicseurope.bio

<sup>&</sup>lt;sup>1</sup> currently approved basic substances fall into this category

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into consideration already existing regulations, prior experience and studies carried out regarding their safety for uses in other contexts.

- Many biocontrol products do not consist of a single substance or molecule (as is the case for synthetic chemicals). They are multiple substances, for example in the case of plant extracts. Moreover, they might have multiple actions. The assessment process has to recognize this fact and adjust to it.
- Microorganisms should be tested in such a way that adverse effects are not overseen, with test systems
  that are specifically adapted to microorganisms rather than to synthetic substances, where the risks
  posed may be different.

The approval and registration process for biocontrol products must be robust enough to make sure that farmers get safe products that work, and to avoid a market of "grey products". In this context, it is nevertheless important to consider that the process must also be workable and fast enough. This will encourage manufacturers to seek approval of their product as a biocontrol product, ensuring that it will be duly tested and controlled in the process.

As explained in the introduction, biocontrol products will be part of a larger plant health strategy and may be used in combination with other products. For the approval and registration process, it may thus be necessary to define an acceptable level of efficacy and to determine the efficacy of a substance in a combination strategy. These efficacy levels can lie below the levels demanded for synthetic pesticides, as long as the efficacy of the biocontrol product can be proven.

# Recommendation 3 - Better legislation for authorization of biocontrol products at national level and their faster uptake for organic farming

For biocontrol products, we envision an approval and authorization process that considers consequences for safety, while also not giving disadvantages to smaller Member States, and where Member States reciprocally make use of risk assessments carried out. The aim is to have a process that delivers on providing safe biocontrol tools to farmers.

A faster and smoother approval and authorization might be furthered by some of the following scenarios for adjustments to legislation:

- Biocontrol products should have a temporal authorization in Member States for a limited period (for instance, for 3 years), after the active substance has been assessed and approved at EU level. Example: an authorization in one Member State could lead to a temporal authorization in all other Member States, or within the zones defined in reg. 1107/2009. The temporary approval might also be limited in scope, for example only for certain uses. The possibility for opt-outs should be given to Member States. At the end of the temporary period, manufacturers could apply for authorization in each Member State.
  - Advantage: farmers, researchers, manufacturers and competent authorities can develop experience with a product. The authorization of formulated products thus can benefit from the experience gained. The investments into an authorization process can be targeted at those Member States where the product is in demand.
- For biocontrol products, the zonal recognition system for authorizations should be widened to become an EU wide recognition system, encouraging competent authorities to rely on authorization in any Member State, not only within their zone. (This concept is already laid down in regulation 1107/2009, art. 3 (17) for specific uses, for example for the purpose of use in greenhouses and seed treatments and could be expanded to biocontrol products).
  - Advantage: Smaller markets for biocontrol products (i.e. mostly smaller Member States) could benefit from authorization carried out in larger markets where manufacturers are more likely to invest in an authorization, especially if the authorization is for a niche product. For

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Rue Marie-Thérèse 11 – 1000 Brussels – Belgium – Phone: +32 2 280 12 23 – Email: info@organicseurope.bio

manufacturers, this means that it is sufficient to prepare only one dossier, with possible additions for individual Member States if needed.

- A fast-track in approval and authorization for biocontrol products. Dossiers for biocontrol products should be given priority in the process. Their assessment should be preferential and start at the earliest possible moment after the application has been received, allocating them to preferential slots in the assessment process.
  - Advantage: it is often claimed that farmers have no eco-friendly alternatives to the pesticides they are currently using. This fast-track approach could make sure that alternatives will be available soon.
- Re-approval for biocontrol products should be designed differently. For example, data for re-approval after a defined period could be asked by authorities in case of necessity only. This must by no means affect the possibility of withdrawing approval. This scenario would ideally be accompanied by postapproval evaluations for all approved substances.
  - Advantage: This scenario could help to keep approved biocontrol products available for farmers, even when there is no applicant who has an (economic) interest in paying for a re-approval dossier.
- To make a substance available for organic farming, it must be listed in Regulation (EU) 2021/1165. This listing usually follows a recommendation from the EGTOP (<u>Expert Group for Technical Advice on Organic Production</u>). The final decision on dossiers in EGTOP can be a lengthy process, which further slows down the availability of biocontrol products for organic farmers. Consequently, the evaluation of a substance in EGTOP, to assess whether it is in line with the principles and rules of organic production (as laid down in Regulation (EU) 2018/848), could already start before the conclusion of the approval process.
  - Advantage: An earlier start of the EGTOP dossier evaluation would allow for an EGTOP recommendation shortly after the final decision on substance approval.

# Recommendation 4 – Support institutions for better implementation of existing regulations

Besides the recommended adjustments to legislation, there are several ways to make better use of existing provisions. We recommend equipping institutions and competent authorities with the necessary capacities for the implementation of existing legislation.

Currently, institutions and competent authorities have limited capacities to work on dossiers for biocontrol products. We therefore recommend that these institutions are given sufficient public funding, dedicated to biocontrol, to increase the capacities of institutions such as EFSA and competent authorities in Member States. Better funding is justified by the societal interest in providing alternatives to synthetic pesticides.

**Institutions and authorities should have enough capacities to set up working groups of experts dedicated only to biocontrol**. It is important to create forums and networks where biocontrol expert staff from Member State authorities and at EU level can exchange, seek guidance and discuss to look for solutions to recurring scenarios. On a more general level, the approval and authorization of biocontrol products should be accompanied by experts with experience or specialization in biocontrol (e.g. the "green team" of the CTGB in the Netherlands). Often, knowledge in fields such as pharmacology (for expertise in botanicals), microbiology or entomology will be helpful, as well as expertise in ecology for the wider use context of biocontrol tools. We encourage institutionalizing consultations and expert meetings related to biocontrol and there should be further interchange about identified uses for biocontrol substances across Member States (zonal or international "green teams" specialized on the different substance groups).

Likewise, guidance documents for risk assessment of various biocontrol products could be further developed, and they should adequately take into account the specific characteristics of substances coming from nature. Their use should be encouraged, with a view to harmonizing interpretation in Member States.

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Rue Marie-Thérèse 11 – 1000 Brussels – Belgium – Phone: +32 2 280 12 23 – Email: info@organicseurope.bio

Additionally, Member States should be encouraged to make better use of the existing zonal system for the authorization of biocontrol products, in order to avoid situations where farmers in different Member States cannot use the same tools. Currently, the zonal system established by regulation (EC) 1107/2009, providing for a mutual recognition of authorizations, is not being fully implemented as it should. Although the intention with the zonal system is good, companies are often faced with situations where recognition works less smoothly in practice, and where the decisions on applications take well above the 120 days stipulated by the regulation. Finally, as explained in recommendation 3, the listing of a substance for use in organic farming usually follows a

recommendation from the EGTOP (Expert Group for Technical Advice on Organic Production). The evaluation of dossiers in EGTOP can be a lengthy process, but it is a necessary one. To speed this up, EGTOP should be provided with the necessary means to work on their dossiers swiftly. The need of the organic sector for a specific substance should be a criterion that EGTOP should take into consideration when prioritizing and evaluating their dossiers.

#### Recommendation 5 - Facilitate the use of macrobials in Europe

Macrobial biocontrol, or use of invertebrate biocontrol organisms, as natural enemies of pests, is used in Europe in organic and conventional farming. To introduce beneficials, it is relevant to have natural enemies for existing pests, but also to consider that new pests can be introduced, and these might then require new antagonists (i.e. natural enemies).

In many cases, native or naturalized antagonists can be released to help control pests. Sometimes, exotic macrobials are needed and can even be safer, for example in the case of certain invasive pest species.

In the case of exotic macrobials, extensive tests and risk assessments are necessary to decide whether it is safe to release them into the environment. It should, however, be considered whether it makes sense to have very different approaches across Member States, as is the case now, since macrobials will inevitably cross borders within the same biogeographic zones and may consequently appear, and act as biocontrol organisms, in neighbouring Member States.

Since macrobial biocontrol is such an important tool in farming, but also in other areas, we recommend that **Member States should be encouraged to develop provisions for the use of macrobial agents**, if such rules do not yet exist.

Release of native or naturalized species should be possible upon notification and without barriers on their use. Here, it could be helpful to have a harmonized joint understanding of what a native, established or an exotic species is. A whitelist of species that are safe to be used, such as the EPPO list, can give valuable guidance to Member States. Cooperation amongst Member States, that would lead to mutually recognizing dossiers or sections thereof, or to alignment of dossier requirements, could help to reduce administrative burden for use of natural enemies.

For the release of exotic macrobials, we recommend a zonal approach in taking decisions. In order to better exploit the potential that macrobial biocontrol offers, we recommend further investments in research and policies aimed at facilitating the use of macrobials.

# Recommendation 6 – Acknowledge a societal interest for supporting biocontrol

Numerous initiatives have shown that EU citizens wish to move gradually away from the use of synthetic pesticides, which are harmful for human health and the environment and are a major driver of biodiversity loss. One example of such an initiative is the <u>European Citizens' Initiative Save Bees and Farmers</u>.

The final report of the <u>Strategic Dialogue on the future of EU agriculture</u> also states that "urgent, ambitious, and feasible action is needed at all levels to guarantee that the sector operates within planetary boundaries and contributes to the protection and restoration of the climate, ecosystems, and natural resources, including water, soil, air, biodiversity, and landscapes. To advance in this direction, the Strategic Dialogue foresees specific recommendations to promote agrobiodiversity, to reduce external inputs such as mineral fertilizers and pesticides, improve nutrient management, advance in the decarbonization of mineral fertilizers as well as develop

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Rue Marie-Thérèse 11 - 1000 Brussels - Belgium - Phone: +32 2 280 12 23 - Email: info@organicseurope.bio

and use biocontrol. At the same time, the European Commission and Member States need to continue to support organic production as well as agroecological farming practices."

Farmers should not be left alone in the transition. We therefore recommend acknowledging a societal interest in more sustainable ways of farming, by earmarking public funding for supporting farmers who wish to produce according to organic principles or move away from the use of synthetic pesticides towards alternative tools. This includes better funding of the advisory system and information streams for organic farmers to facilitate the uptake of biocontrol tools on farms. As shall be discussed in the following recommendation, market mechanisms are not capable of driving this change towards more sustainable farming practices.

#### Recommendation 7 – Acknowledge weaknesses in market mechanisms and support uptake of biocontrol products

The approval and authorization of plant protection products is currently very lengthy and costly. We are faced with a situation where the market mechanisms do not facilitate the uptake of biocontrol. Manufacturers of plant protection products have an incentive to place products on the market that will meet a large demand. Typically, these will be synthetic pesticides that can be used in major crops against a wider range of pests and diseases.

The economic thresholds for bringing new products to the market are relatively high. The flipside is that huge investments are needed to develop new products and especially to have them authorized. Manufacturers will inevitably seek to place such products on the market that promise good returns on investment, and these are usually broad-spectrum pesticides for major crops. On the other hand, **market access for biocontrol tools**, which are typically niche products for minor uses, is economically difficult and is often denied even if these products are needed most.

Organic farming, with the limits it puts on the type of substances allowed, can be a driver for demand for biocontrol products that are compatible with organic farming. This would, in turn, also be useful in other farming systems that follow an IPM strategy. Organic farming needs substances for niches, and with selective control, in order not to destabilize the self-regulating balances of the ecosystem with its naturally occurring beneficials. For organic farming, it is vital that compatible biocontrol products for essential uses get access to the market and stay on the market. If this is made possible, organic farming can be a first mover that creates a market for more ecofriendly substances, and this will benefit all farmers who are interested in more sustainable methods.

For many biocontrol products, the investments for dossier preparation will not be met with sufficient returns on investment. This failure of the market to promote biocontrol products should be addressed, for the benefit of organic farming and other more sustainable approaches, but also the societal interest to have alternatives to synthetic chemicals available.

For certain substances like plant extracts, the incentive to invest in approval dossier preparation and in the authorization, procedure is even lower. It can be difficult or not possible to patent these substances, which means that traditional uses disappear from the market. The reward for the investment is negligible, since sales will not be exclusive for a manufacturer. This is aggravated by an expensive dossier preparation.

We recommend supporting market access for biocontrol tools by dedicating funds to research, and especially also to dossier preparation, according to the most urgent needs for biocontrol tools identified by the sector. Please refer to our recommendation 8 on identified needs. A lot of research is done on promising substances already, whether active or basic substances, but many of them do not enter the phase of dossier preparation, because the economic interest is limited and there is no public funding. Ideally, policymakers would find solutions to attenuate this threshold and bridge the investment gap when returns from sales are expected to be low. Potentially, there could also be support for "unusual" applicants who are willing to prepare and hand in dossiers for approval, such as producer groups.

In line with the recommendations related to changes in and better use of legislation, as specified above, we believe it is important to create a system where authorization is also economically feasible for manufacturers, and where they are encouraged to place products on the market even in smaller Member States, where total demand may be lower. Here, both fees charged by Member States to applicants for authorization, and the complexity of dossier preparation, can be a lever.

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Rue Marie-Thérèse 11 – 1000 Brussels – Belgium – Phone: +32 2 280 12 23 – Email: info@organicseurope.bio

# Recommendation 8 – Close the gaps identified by the organic sector with research and public funding for biocontrol tools

Public funds should be dedicated to addressing the most urgent needs of the sector in terms of biocontrol. As explained above, beyond a need for funding research, there is a need for public support for dossier preparation when promising biocontrol tools, which would address the identified indications, are not met with a market situation that facilitates private investments in these tools.

We recommend that biocontrol solutions should address indications that have been identified as gaps by the organic farming sector. Specifically, we see a need for investment in biocontrol tools for the following indications. The list below is non-exhaustive and is presented in alphabetical order.

Apple	Apple sawfly (Hoplocampa testudinea)
Apple	Apple scab (Venturia inaequalis)
Apple	Apple proliferation ( <i>Candidatus</i> <i>Phytoplasma mali</i> )
Apple	Codling moth, alternative to CpGV
Apple	Apple woolly aphid (Eriosoma lanigerum)
Apple	Fireblight (Erwinia amylovora)
Apple	Glomerella Leaf Spot GLS (Colletotrichum sp.)
Apple	Brown marmorated stink bug (Halyomorpha halys)
Apricot	powdery mildew of apricot (Podosphaera tridactyla)
Apricot	Monilia sp.
Apricot	Bacterial spot, bacterial diseases (Pseudomonas spp.)
Apricot	Garden chafer (Phyllopertha horticola)
Cherries	Monilia sp.
Cherries	Pseudomonas spp.
Cherries and other fruits and berries	Cherry drosophila (Drosophila suzukii)
Pear	Scab of pear (Venturia pyrina)
Pear	Forest bug (Pentatoma rufipes)
Pear	Pear sawfly (Hoplocampa brevis)
Fruit	Mediterranean fruit fly (Ceratitis capitata)
Grape vine	Downy mildew (Plasmopara viticola)
Grape vine	Esca disease (various pathogens)
Grape vine	Grapevine flavescence dorée phytoplasma
Grape vine	grapevine fanleaf (Nepovirus foliumflabelli)
Lupine	Leaf spot (Alternaria)
Olive	Olive fruit fly (Bactrocera oleae)
Onion	Downy mildew (Peronospora distructor)
Potato	Late blight of potato (Phytophtora infestans)
Sugar beet	Planthopper (Pentastiridius leporinus)
Vegetables	Whiteflies species (Aleyrodidae spp.)
Vegetables, namely outdoor vegetables	Flies, including Delia radicum, Delia antiqua, Delia platura, Contarinia nasturtii
Vegetables, namely Brassicaceae, Asteraceae	Leaf diseases, including <i>Alternaria</i> , <i>Phytophthora</i> , Downy mildew

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IFOAM Organics Europe is the European umbrella organisation for organic food and farming. With almost 200 members in 34 European countries, our work spans the entire organic food chain and beyond: from farmers and processors organisations, retailers, certifiers, consultants, traders, and researchers to environmental and consumer advocacy bodies.



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Rue Marie-Thérèse 11 – 1000 Brussels – Belgium – Phone: +32 2 280 12 23 – Email: info@organicseurope.bio . . . . . . . . . . . . . . . .