



IBMA POSITION
on potential harmonisation of regulation
of Invertebrate Biological Control Agents
in the European Union





EXECUTIVE SUMMARY

Following the discussion on harmonisation of approaches proposed by the EU council in 2021 The International Biocontrol Manufacturers Association (IBMA) wishes to put forward the position that it fully supports a harmonised approach to procedures with regards to use and release of Invertebrate Biocontrol Agents (IBCA's) in the EU.

IBCA's will make a critical contribution in the realisation of the EU's overarching Farm to Fork and Green Deal policy goals, such as the 50% reduction of pesticide use and risk by 2030 and the 25% share of organic farming. Maintaining a proportionate regulatory framework that encourages innovation and entrepreneurial initiative while also ensuring trust in environmental safety is essential for the invertebrate biocontrol producers to contribute to their full potential.

IBMA considers existing regulation to be sufficient but does recognise there is scope for more consistency between national legislations of different EU countries.

This should be fit for purpose and focused on the goal of creating opportunities for BCA use by farmers at competitive costs, while maintaining high standards of safety and hygiene. No additional hurdles to market entry that do not add to the safety of humans or the environment should be imposed.

National legislation inspired and guided by the existing EPPO standard PM6 would be valuable:

- EPPO guidance maintains an appropriate distinction between classical and augmentative biocontrol.
- EPPO guidelines also address aspects of identity and purity of the material, thus providing effective, safe and sustainable solutions to growers.

Thus, IBMA advocates that all the 27 member states should adopt legislations strictly aligned with EPPO guidance. This would meet the objective of protecting biodiversity without creating excessive hurdles that would stand in the way of the biocontrol industry delivering sustainable solutions to farmers.

IBMA further encourages that member states should mutually recognise each other's Risk Assessment dossiers on non-native species used in augmentative biocontrol in order to avoid duplication of work, provided that relevant climatic conditions are sufficiently similar.

IBMA is available to provide further input and information in support of the process at any time based on unique expertise and decades of experience.





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INTRODUCTION

During its presidency of the EU council in 2021, the Portuguese launched a discussion on the potential benefits of greater harmonisation of approaches with regards to use and release of IBCA's in the EU.

The International Biocontrol Manufacturers Association (IBMA) fully supports a harmonised approach to procedures which is fit for purpose and focused on the goal of creating opportunities for BCA use by farmers. IBMA does not see a need to add extra regulation on European level and would be more in favour of having the existing EPPO criteria and guidelines implemented at national level in all the member states. Indeed, regulation by a European expert panel is in place, the rules are harmonised and many EU member states already use the information for a rapid mutual recognition.

With this position paper IBMA aims to:

- provide initial high-level input in connection with the study detailed below.
- highlight key principles which it believes should underpin any proposal to be brought forward as a result thereof.



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BACKGROUND

IBMA is the long-standing and experienced voice of the biocontrol industry, representing 236 members around the globe. The majority of members are EU based with a strong representation of SME's (75% of 165 EU based members). The association deals with four categories of products defined as biocontrol products. One of these product categories is Invertebrate Biocontrol Agents (IBCA's).

Following the aforementioned discussion, a questionnaire was sent out in January 2021 and answered by all member states.

This led to council decision (EU) 2021/1102 of 28 June 2021, to request the Commission

“to submit a study on the situation regarding introduction, production, evaluation, marketing and use of invertebrate Biological Control Agents (BCAs) within the territory of the Union. The possibilities for the harmonisation of procedures throughout the territory of the Union should also be evaluated, so as to facilitate the promotion of the deployment of, and market access to BCAs, to support investment and innovation in, and contribute to the safe use of BCAs, including where they are needed for quarantine pest control as imposed by plant health authorities”.



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KEY PRINCIPLES AS ADVOCATED BY IBMA

The background note provided by the PT presidency states:

“A harmonised approach should be fit for purpose and focus on the goal of creating opportunities for BCA use by farmers, while maintaining high standards of safety and hygiene, so no additional hurdles to market entry that do not add to the safety of humans or the environment should be imposed.”

IBMA fully supports a harmonised approach which is fit for purpose and focused on the goal of creating opportunities for BCA use by farmers, and therefore makes the following recommendations with a view to ensure that future initiatives remain in line with this stated goal.

1. Criteria for use and release of IBCA's in EU member states should focus on environmental risk assessment of non-native species.
2. The goal of harmonisation could best be reached by implementation of existing EPPO standard PM6 as the base for national regulation.

Key principle 3.1 Criteria for use and release of IBCA's in EU member states should focus on environmental risk assessment of non-native species.

The initiative launched by the Portuguese presidency was inspired by a specific case related to the introduction of a parasitoid from South-Africa to control *Trioza erythrae*, a vector of citrus greening. This is a textbook case of "classical biocontrol" defined as "the intentional introduction of an exotic, usually co-evolved, biological control agent for permanent establishment and long-term control of invasive pests" (based on Ris and Malausa, 2011).

Since it typically involves releases of an exotic and hence non-native organism in the environment, IBMA fully recognises the need for an appropriate environmental risk analysis prior to any novel release.

Augmentative biological control predominantly uses native natural enemies to control native and/or invasive pests. The impact on population ecology is very limited in time and space and does not differ from the usual fluctuations in pest-enemy population dynamics that occur in nature. It helps re-establish the balance between (crop) plants, pests and natural enemies when this is temporarily disturbed during pest outbreaks. In order to speed up much needed access of biocontrol agents to growers, **IBMA is of the opinion that regulation should not require risk assessment for the augmentation of native species.**

The IBCA industry, including through coordination efforts from IBMA and organisations such as IOBC (International Organisation for Biological Control) which has a long-standing working group on Mass Rearing and Quality Assurance, has developed internal guidelines and codes that are fit for purpose to ensure that growers have access to efficacious, high-quality products (van Lenteren, 2003). Additionally, the EPPO guidelines also address aspects of identity and purity of the material, thus providing effective, safe and sustainable solutions to growers.

IBMA believes that any regulation requiring environmental risk assessment for native species would create additional hurdles to market entry that do not add to the safety of humans or the environment.

Key principle 3.2 The goal of harmonisation could best be reached by implementation of existing EPPO standard PM6 as the base for national regulation.

In the EU council's request for the Commission study, the suggestion is made that a harmonised EU regulation could facilitate and promote the use of IBCA's. IBMA does recognise there is scope for more consistency between national legislations of different EU countries. National legislation inspired and guided by the existing EPPO standard PM6 would be valuable.

The framework referred to above was co-developed by EPPO, IOBC and IBMA experts under the umbrella of the REBECA EU Scientific Support to Policy Action SSPE-22709 (Ehlers, 2011) and is now adopted as standard by the European and Mediterranean Plant Protection Organisation (EPPO standards PM 6). A joint EPPO/IOBC panel is in charge of continuously developing and revising these standards

EPPO guidance maintains **an appropriate distinction between classical and augmentative biocontrol.**

Concerning the introduction of non-native species, EPPO has published standard PM 6/1(1): First import of exotic biological control agents for research under contained conditions and PM 6/2(2): Import and release of non-indigenous biological control agents. The standards are based on an extensive body of scientific research (e.g., studies already conducted by IOBC, ERBIC and REBECA in REBECA final reports, Van Lenteren, 2006; Bale, JS 2011). The framework clearly defines when a Risk Assessment is required and provides proper Risk Assessment methodologies. EPPO is committed to evolving its recommendations as science progresses. IOBC and IBMA are equally committed to provide input to this process.

Several EU Member states have fully implemented the EPPO guidelines, resulting in an effective procedure that only requires full risk assessment for species which are not listed in EPPO standard PM 6/3 or for non-native species. For native species (or in some cases species listed in EPPO standard PM 6/3) a short dossier or simply a notification suffices. Examples are the Netherlands, Finland and Latvia. In case a non-native species is proposed for application in augmentative biocontrol, EPPO standard 6/2 can be used to assess what information is required for proper evaluation of the species (see Appendix).

In summary, IBMA believes EU harmonisation discussions should not result in “reinventing or duplicating the REBECA wheel” and welcomes an outcome which would result in EU member state legislations being closely aligned with EPPO guidance.

Thus, IBMA advocates that all the 27 member states should adopt legislations strictly aligned with EPPO guidance. This would meet the objective of protecting biodiversity without creating excessive hurdles that would stand in the way of the biocontrol industry delivering sustainable solutions to farmers.

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FURTHER SPECIFIC RECOMMENDATIONS

IBMA recommends the constitution of an Expert Group in Europe, consisting of independent experts on biological control. This group can be an invaluable resource, which can be consulted both by national authorities and applicants for evaluation of a new IBCA. The International Organisation of Biocontrol (IOBC) is one organisation that brings together individual scientists, governmental and scientific organisations that are expert in the field of biocontrol; experts that could provide the basis of an Expert Group, albeit this group is voluntary and lacks resources to provide regular input. In recognition of the lack of expert resources available, EPPO developed a decision support scheme (EPPO standard PM 6/4) to provide advice to national authorities.

IBMA further encourages that member states should mutually recognise each other's Risk Assessment dossiers on non-native species used in augmentative biocontrol in order to avoid duplication of work, provided that relevant climatic conditions are sufficiently similar. Unless specific ecological reasons for border constraint would apply, as could be the case with islands, the use of invertebrates in multiple countries will speed up the availability of these biocontrol agents to farmers. A mutual recognition of Risk Assessment files will help ensure that regulatory costs

are kept under control and do not become a disincentive with regard to the development of new products based on IBCA's. This is particularly important for biocontrol industry where companies are SME's which provide innovative and specific solutions for crop protection. Indeed over 75% of IBMA's 165 European members are SME's.

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IBCA'S AND OVERARCHING EU POLICY OBJECTIVES

IBCA's will make a critical contribution in the realisation of the EU's overarching Farm to Fork and Green Deal policy goals, such as the 50% reduction of pesticide use and risk by 2030 and the 25% share of organic farming. Maintaining a proportionate regulatory framework that encourages innovation and entrepreneurial initiative while also ensuring trust in environmental safety is essential for the invertebrate biocontrol producers to contribute to their full potential.



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CONCLUSION

IBMA does recognise the need for harmonisation of procedures for invertebrate biocontrol in Europe, however IBMA believes that regulation and harmonisation of guidelines is already in place with the function of the EPPO/IOBC panel. Member States can participate by sending their experts to the panel and adopt their recommendations. The panel has never identified risks justifying the evaluation of native species, there is no need to further evaluate risks of these species. Furthermore, we don't think that regulation at European level is the best way to reach the goals of the Green Deal. We would recommend the encouragement of uptake of regulation at a national level following EPPO standard PM 6. EPPO guidance was co-developed by the EU (REBECA), EPPO, IOBC and IBMA and in the opinion of IBMA remains valid today. It forms the basis of many of the national regulatory frameworks in place for invertebrate biocontrol agents. Particularly effective examples of implementation can be seen in the Netherlands, Finland and Latvia. The EPPO standards are based on extensive research studies conducted over several years and provide for a scientific basis for harmonised environmental risk assessments of non-native species and decision support schemes.

IBMA is available to provide further input and information in support of execution of the study at any time based on unique expertise and decades of experience.



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