Council of the European Union

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NOTE

From:	General Secretariat of the Council
To:	Delegations
Subject:	Study on the Union's situation and options regarding the introduction, production, evaluation, marketing and use of invertebrate biocontrol agents within the territory of the Union - Letter from the European Commission

Delegations will find in Annex the letter of transmission of the Commission Staff Working Document (doc. ST 16317/22) related to the study on the Union's situation and options regarding the introduction, production, evaluation, marketing and use of invertebrate biocontrol agents within the territory of the Union, addressed by the European Commission to the Presidency.

The full report of the external contractor referred to in this letter is available at the Commission's publications website: Study on the Union's situation and options regarding invertebrate biological control agents for the use in plant health and plant protection - Publications Office of the EU (europa.eu)

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EUROPEAN COMMISSION

Maroš Šefčovič
Vice-President

Brussels, 21/12/2022

Dear Minister,

Please find enclosed the Commission's response to Council Decision (EU) 2021/1102 of 28 June 2021, requesting the Commission to submit a study on the Union's situation and options regarding the introduction, production, evaluation, marketing and use of invertebrate biocontrol agents (IBCAs) within the territory of the Union and a proposal, if appropriate, in the view of the outcome of the study.

Yours sincerely,

Maroš Šefčovič

Mr. Jan Lipavský
Minister of Foreign Affairs of the Czech Republic

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Commission's response to Council Decision (EU) 2021/1102 of 28 June 2021, requesting the Commission to submit a study on the Union's situation and options regarding the introduction, production, evaluation, marketing and use of invertebrate biocontrol agents (IBCAs) within the territory of the Union and a proposal, if appropriate, in the view of the outcome of the study

On the basis of Article 241 TFEU, the Council, in its Decision (EU) 2021/1102 of 28 June 2021, requested the Commission to submit, by 31 December 2022, a study on the Union's situation and options regarding the introduction, production, evaluation, marketing and use of invertebrate biocontrol agents (IBCAs) within the territory of the Union and to submit a proposal, if appropriate, in the view of the outcome of the study, or otherwise inform the Council about any possible measures as a follow-up.

The requested study is presented herewith in the form of a Commission Staff Working Document, accompanied by the report of an external contractor. The study is based on field and desk research carried out in 2022, including a comprehensive consultation of all Member States, relevant EU stakeholders and the competent authorities of two non-EU countries (New Zealand and the United States of America). Consulted stakeholders were selected with a view to involving a representative sample of EU-level organisations and associations that could be impacted or have shown interest in policies related to biological pest control. The results of the study were double-checked with respondents during an evaluation workshop.

IBCAs are invertebrate animals, including insects, which can be used to control pests and diseases as well as the vectors of such pests and diseases, and unwanted organisms.

The current small **EU market of IBCAs** is more developed in Member States with an extensive agricultural production, especially in horticultural and protected crops, and the majority of IBCA producers are small and medium-sized enterprises and only a few large companies exist in the EU.

The EU market focuses on augmentative biological control (i.e. mass release *without* intention to establish a stable population) for which a commercially viable business model exists in the EU. This market is expected to grow, whereas a more limited growth is expected for the open-field market.

Introductions of non-native species in the framework of classical biological control (i.e. *with* the intention to establish a stable population) rely mainly on national initiatives, coordinated and led by research. There is a history of about 130 successful introductions of classical biocontrol IBCAs in the territory of the EU. However, the number of introductions considerably dropped since 2010, as no more than twelve introductions were reported by Member States.

Several drivers to fully reflect the possible contribution of IBCAs to meeting the needs of plant protection, have been identified and outlined in the study.

Data on market shares are considered confidential information by industry and data on uses are not systematically collected by the Member States. They were more difficult to obtain than data on regulatory frameworks.

A potential **risk to biodiversity** cannot be excluded where IBCAs are released into the environment. As most of the IBCAs are mobile, they may spread from the territory of one Member State to another. Not all Member States have legislation in place concerning the introduction or release of IBCAs, and considerable differences have been identified amongst regulatory systems where they exist. This may lead to various levels of protection of the environment.

Fourteen Members States have established provisions specifically regulating the introduction, production and/or release of IBCAs in their national legislation, differing mainly in terms of scope, content of the risk assessment and authorisation process.

Five Member States have environmental legislation which prohibits the introduction of all non-native species (in some of these Member States a derogation, however, may be granted).

Seven Member States have neither national (or regional) environmental legislation restricting the introduction of native or non-native species nor specific legislation on IBCAs. The regulatory frameworks of two **non-EU countries**, New Zealand and the USA, have been analysed and practices have been identified that may be further considered in the EU.

Key **regulatory instruments**, like guidance documents or positive/negative lists, are also available at the level of international organisations, such as standards provided on global level by the International Plant Protection Convention (IPPC) of the Food and Agriculture Organization of the United Nations (FAO) and by the European Plant Protection Organization (EPPO). Some Member States have also implemented procedures to assess potential costs and benefits of the use of a specific IBCAs.

As a synthesis of the information collected, the following **criteria** can be identified to ensure balanced regulatory systems:

- develop frameworks that are **proportionate** to the risks, as the risks vary depending on the type of IBCAs used.
- ensure **stability** of the framework over time.

In line with the request from the Council, the Commission study provides a **comprehensive overview** of the status of IBCAs in the EU regarding introduction, evaluation, production, marketing and use. Current problems and underlying drivers have been identified and suggestions for improvement are listed, as collected amongst stakeholders. In describing the **areas for improvement** of the current situation, emphasis was put on the market situation and availability as well as on the safety aspects.

The study provides a detailed overview of the status quo of IBCAs in the EU regarding introduction, evaluation, production, marketing and use. Current problems and underlying drivers have been identified and suggestions for improvement are listed on the basis of stakeholders' suggestions.

There are, however, insufficient quantitative data on the potential market and use of IBCAs in the Member States available to allow a proper analysis of possible impacts of the stakeholder's suggestions and of the possible added value of EU intervention compared to action that could be taken at Member State level. Therefore, a better understanding of the

situation is needed. The study is inconclusive, and the Commission is not in a position at this stage to formulate any appropriate proposal.

As a follow-up of the study, the Commission will share and invite to discuss the results of the study with the European Parliament, the Council, and stakeholders, with a view to defining the possible next steps, and publish the study on its website. This dialogue will allow to better understand the findings of the study and the expectations towards different potential measures and to decide if any further follow up is needed.

The Commission thanks the Member States for their contributions to the study, which have enabled the present a comprehensive overview on the current status of IBCAs across the European Union. The Commission looks forward to further discussions on this topic in the European Parliament, the Council, and with stakeholders.