Study on the Union's situation and options regarding invertebrate biological control agents for the use in plant health and plant protection

Final report

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Contents

Executive Summary

Introduction / overview

The Council adopted on 22 June 2021 a Decision (EU) 2021/1102 requesting 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".

In this context, the Commission requested EY to undertake a study aiming to provide input in analysing the Union's current situation (extent of use of IBCAs, potential for further development, state of regulations at Member State level), to identify the main problems, and to support the preparatory work for the design of a possible initiative that addresses these shortcomings.

In line with the evaluation criteria required by the Better Regulation Guidelines, this study relied both on quantitative data and a qualitative consultation: national competent authorities from the EU Member States; key representatives from relevant European stakeholders: intergovernmental, scientific and civil society organisations; and industry and user associations.

Key findings

Current IBCA market, uses, and potential for development

Market

IBCAs in Europe are a growing market (estimated between 300 and 350 million euros per year), representing around 30% of the European biocontrol market (around 1bn€). Although this growth is significant (103% increase between 2016 and 2020), it remains slower than the global market for biological control.

This market is expected to be more developed in Member States with an extensive agricultural production, especially in horticultural and protected crops. According to representatives of the IBCA industry, biological control has reached significant critical mass, especially in the protected crop segment, which is seen as mature: 80% of commercially used IBCAs are used in greenhouses, and 20% in field crops (mainly for maize and some specialty crops).

Production of IBCAs relies on a few large companies and a base of SMEs, contrary to the chemical industry that mostly relies on large international companies. Several countries have few or no implanted producers and rely mostly on imported organisms from neighbouring countries.

Uses

Uses of IBCAs firstly depend on the type of biological control considered. The European market focuses on augmentative biological control. It corresponds to the periodic release of natural enemies to control a recurring pest and is a commercially viable business model. It is generally used by growers, on a crop-to-crop basis. This market is expected to continue growing, with more limited expected growth on the open-field market (although a few success stories exist, such as *Trichogramma,* parasitoid wasps against corn borers in maize).

Classical biological control on the other hand aims at controlling pests more permanently, by introducing and establishing a permanent population of their natural enemies, which are not yet present in the field. Introduction programs rely mainly on national initiatives, coordinated and led by research. The use of Sterile Insect Technique (SIT) relies on the same logic as it requires large technical facilities for research and production. Commercial perspectives are completely different from those of augmentative biological control as there is no business model replicable from one year to another. These strategies may, however, become activities handled by other types of private actors, with risk-taking and investments shared between growers, food chain value actors and public bodies.

Classical biological control introductions used to be frequent during the last century. However, recent restrictive regulations have set directions for the evaluation of their safety with respect to biodiversity but reduced their number: less than 20 classical biological control programs were identified in the study since the 2000s. Biological control of animal pests is more advanced, whilst other biological control (especially of plants or fungi) would require some more development.

The use of IBCAs varies significantly across the Member States. Some species are widely authorised and some only used in a restricted number of Member States. More generally, the following drivers and parameters shape the use of IBCAs and the potential for development:

- ***The type of agriculture or horticulture that prevails in a given Member State****:* Member States with sophisticated horticulture and substantial areas of protected cropping have adopted a much larger number of uses.
- ***The general public policy approach of a Member State:*** Member States that focus strongly on Integrated Pest Management (IPM) through policy initiatives, dedicated R&D and industry engagements have a much better chance to increase familiarity with the newest methods and IBCA use, and finally in broader scale adoption.
- ***The agricultural approach of growers:*** IBCA use is frequent among organic growers and growers who follow IPM principles, as well as in some horticultural crops where pesticide use is limited (e.g. crops that depend on bumblebees for pollination).

- ***The efficacy of IBCA, especially in outdoor crops:*** Adoption by farmers, especially in outdoor use, is hampered by the lower immediate efficacy of IBCAs that is often behind that of plant protection products. Efficacy is however a concept linked to the *modus operandi* of chemical PPPs and is not well-adapted to biological control, which often relies on pest population regulation (rather than eradication), and whose impacts may be observed after several seasons.
- ***The high costs of the IBCA solutions:*** The technicity of IBCA development, shipment, and application, can lead to high costs, especially where large quantities of IBCAs are required. Transport and storage can be challenging, and the field-delivery is often manual, and thus labour intensive. These costs can limit the use of IBCAs.
- ***The demand on the final consumers' side:*** Concerns regarding the environment, biodiversity and the use of chemical PPPs are increasing. Communication on the benefits of IBCAs (returns on investment, higher sustainability), collective organisations and sharing (through associations and cooperatives) are success factors in IBCA uptake.
- ***The lack of knowledge on IBCAs:*** On the side of farmers and advisors, lack of knowledge or expertise may lead to no use or the misuse of IBCAs, which may be counterproductive in the adoption of this solution in farmers' practices. IBCAs can also have a bad reputation on the public's side.

Although the use of some IBCAs is sometimes claimed to be compatible with the use of pesticides (especially selective ones), this combination is rarely an efficient approach. The replacement of PPPs by IBCAs in systems developed for chemical pesticide use (which rely on the immediate curative effect of pesticides and very little on preventive measures and pest regulating agroecosystem services that are suppressed by pesticides) leads to biocontrol failures and a sense among growers that biocontrol is not effective or efficient. Profound system changes in cropping approaches are very likely much more efficient in speeding up the development of biocontrol.

Regulatory frameworks

At European level

IBCAs are not covered by the current European regulation for the placing into the market of PPPs[1]. (Regulation (EC) No 1107/2009). However, they fall under the scope of two European regulations to ensure protection of biodiversity (Regulation (EU) No 1143/2014) and plants[2].

[1] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market

[2] Regulation (EU) No 1143/2014 of the European Parliament and of the Council of 22 October 2014 on the prevention and management of the introduction and spread of invasive alien species and Regulation (EU)

(Regulation (EU) 2016/2031). At international level, there are however several guideline-setting organisations, whose work is often informally considered in the different regulation systems developed by European Member States. This is mainly the work undertaken by the IPPC (global level) and EPPO (regional level), in developing standards on importation for research, for release into the environment, on safely used species, and on guidelines for authorisation and risk-assessment.

At Member State level

14 Members States have established provisions specifically regulating the introduction, production and/or release of IBCAs in their national legislation, while three more Member States are currently developing such provisions. They are almost systematically different from those applied to PPPs.

- **The 14 Member States with specific regulations for IBCAs** have regulatory frameworks that differ depending on whether they cover all IBCAs (11 Member States) or only non-native ones (three Member States).
- **The 13 Member States without a specific national or regional regulation** often have a limited use of IBCAs. Among the Member States without specific regulations for IBCAs, five (and two regions in Belgium) have environmental regulations which prohibit the introduction of non-native species (specific derogations can be provided in some Member States). The remaining seven Member States (and one region in Belgium) do not have specific national (or regional) regulations restricting the introduction of native or non-native species.

The scope of these regulations is also heterogeneous: some Member States treat release and introduction differently, and may regulate one and not the other. Transport is regulated in only one Member State, and production in five Member States.

Authorisation processes related to IBCAs also take different shapes, and can cover a specific IBCA (species, strain, source), a specific plant protection product (containing one or more specific IBCA organisms), and specific uses (research, commercial, indoors, outdoors). Finally, most Member States do not distinguish between augmentative and classical biocontrol. Two factors may however *de facto* implicitly distinguish between classical and augmentative biocontrol: (i) the distinction between native and non-native species, as classical biocontrol only relies on non-native species; and (ii) the risk assessment, where the impact on biodiversity and the potential of the IBCA to become invasive is considered.

The risk-assessment processes are also heterogeneous. Among the Member States who carry out a formal risk-assessment (not all

2016/2031 of the European Parliament of the Council of 26 October 2016 on protective measures against pests of plants

countries who have a regulation), the requirements also vary according to the status of the species: native (sometimes to the strain level), non-native, in an EPPO list, authorised in another Member State. The contents of these assessments also vary, and the procedures may focus most frequently on the risks of unintended spread, risks for plant health and biodiversity. Risks to human and animal health are less frequently assessed. Finally, some Member States also carry out an analysis of benefits: they cover mostly plant protection/phytosanitary effects, benefits to local biodiversity, and environmental benefits. Most dossiers are approved by the authorities. Obtaining the right data is however a recurrent challenge for Member States, and it make take years for companies to elaborate a dossier ready to be formally submitted, and its examination by authorities may also take 6 to 9 months on average.

Several data gaps were identified by the Member States:

- Establishment potential for non-native organisms
- Unclear description of the intended use, especially in terms of territories, target organism, dose rate, stage of development, and product formulation
- Identity, origin, history and distribution of the organism in the national territory, variations within species and possible effects on genetic diversity
- Practical effectiveness and unintended effects, including on non-target organisms, host range, and contamination risks
- General lack of data and literature

The risk for the environment is particularly difficult to evaluate, as some topics are not covered by existing research**.**

This legal heterogeneity also takes place at the **monitoring** level: the registration of IBCA producers and retailers (nine Member States register both, one Member State only registers producers), quality control (rarely included in the regulations), and post-release monitoring. The latter is rarely conducted: current strategies at the national level rely on the submission of a report or alert if an unexpected effect is identified. However, the identification of such effects requires a strong and expensive scientific monitoring, which is rarely performed. Few Member States mentioned undesirable impacts of IBCAs after release (the only reported cases of undesirable impacts concerned *Harmonia axyridis*, *Cales noacki* and *Lysiphlebus testaceipes*, which have been removed from the EPPO safely used list), as well as *Nesidiocoris tenuis* (reported by Finland and also the target for control in Belgium and France, although it is used without negative consequences in some other Member States).

Concerning the administrative process and support to the applicants, publicly available guidance is often available, although sometimes only in the national language, and a limited number of Member States offers regularly informal pre-submission meetings. Areas

of improvement of the procedures revolve around the facilitation of administrative and organizational processes, the internalization of expertise and specific training regarding IBCAs, the scope of the legislation (e.g., lack of inclusion of environmental effects, no provisions for SIT, etc.). Overall, representatives from the industry underlined that their main needs are Member States with clear frameworks and simple procedures for naturally occurring species.

Research and innovation projects and knowledge transfer

The availability of IBCAs depends heavily on research and development to develop effective solutions and ensure that they do not pose a risk to the environment. Inversely, even if some IBCA research programs have shown results and interest from farmers, there could be a lack of industrial interest due to limited commercial perspectives (for minor crops and/or minor target pests).

The knowledge of professional users regarding IBCAs stems mainly from general information provided by authorities as well as industry advisory services. Amateur users or users who often buy products from third parties or on the internet may be considerably less knowledgeable. Finally, on the administrative side, there is a **wide discrepancy between Member States with regard to availability of biocontrol experts**, and the specialisation of public officials on biocontrol and more specifically IBCAs.

Strategic approaches at national level

Member States have different approaches regarding their national strategy to support the development and use of IBCAs. Some of the Member States may also have developed specific financial incentives. The extent of support is, overall, proportionate to the investment from the private sector (via programmes financing public-private projects, public projects with likely transfers to the existing industry, tax credits for companies carrying out R&D). Given the small size of IBCA markets, resources available to IBCA R&D remain very modest, even in the most active Member States. However, the study identified specific provisions for IBCAs in only two national CAP plans.

The analysis of the framework of two third countries, New Zealand and the USA, showed different approaches. In New Zealand, few incentives are given to develop the use of IBCAs, which are principally classical biological control uses. The framework regulates the introduction, release, commercialisation, quality control and transport of all new organisms that were not present in New Zealand before 29 July 1998. Procedural costs are much higher than in Europe (25 thousand dollars), but most dossiers are approved thanks to an open informal feedback channel between the authority and the petitioners. In the USA, the

framework is federal and regulates all aspects of IBCA use with State-specific permits. IBCAs are the subject of federal funding of research.

Instruments to bridge gaps

The study outlines that key instruments already exist in a few countries or at the level of international organisations: Member States authorities and EPPO display the capacity to provide guidance documents, providing positive and/or negative lists of IBCAs. Some Member States have also implemented more or less detailed risk analysis procedures. Hence, most of the raw material to implement a regulation framework at the EU level is already available (except for post-release monitoring strategies).

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

- **Develop frameworks that are proportionate to the risks**. As mentioned above, the risks vary depending on the type of IBCAs used. Thus, adapting processes depending on the level of risk ensures a balanced regulatory system. In addition, the risk assessment should also put in balance the benefits of the use of IBCAs in comparison to chemical solutions.
- **Ensure stability of the framework over time**. As in all authorisation processes, changes in the rules that apply may have important consequences on the applicants and private sector. It is especially true for IBCAs where the development of new products takes several years and is performed by SMEs with limited economic capacity.

Regulatory instruments to foster innovation may be classified within two categories: (i) innovation push (e.g., supports to research & development at the national or EU level) or (ii) innovation pull, which the study recommends focussing on. Innovation pull would foster transitions to agrosystems more favourable to IBCAs, greater co-innovation dynamics between the biocontrol industry and actors of the agrifood value chain, as well as specific instruments for classical biological control.

Main potential options for an EU intervention

Two main consequences of observing the status quo were identified during the study:

- Insufficient development and use of IBCAs as an alternative to chemical pesticides in the control of plant pests, which will limit their role in achieving the objectives of the Farm to Fork strategy;
- Potential negative consequences on biodiversity, as risks on biodiversity are managed differently across Member States.

Several options were identified to address these problems, with the objective to foster market access, increase the availability of effective

(existing and new) solutions and ensure the safe development and use of IBCAs:

- **Options related to the harmonisation of the legal framework between Member States** to ensure that farmers have access to safe IBCAs in all Member States due to authorisation and that the analysis of risks for biodiversity are homogeneously covered in the European Union. **These options can be designed with different scenarios for centralisation:**
    - The systematic integration of IBCAs as an alternative of chemical pesticides in the initiatives and other documents of the European Commission,
    - The harmonisation of definitions of native, exotic and/or established species, the establishment of whitelist(s) of safe IBCAs,
    - The harmonisation of the content of risk assessment and consequences of the analysis (especially mitigation measures)
    - The existence of processes to ensure that IBCAs can be authorized after proper risk assessment in all the Member States

  Scenarios have been developed which reflect different levels of centralisation: a voluntary scheme based on the use of data from EPPO; a two-level procedure to find a balance between homogenization and freedom of action of Member States; centralized risk analysis managed by an EU organisation with expertise on IBCAs, and finally a completely centralized process, from risk assessments to decision-making.
- **Options related to the production, recording and monitoring of IBCA data** to ensure that knowledge continues to be gained in the European Union regarding the effects of using IBCAs (especially negative and positive effects on biodiversity). They include the registration of European producers as well as data on their sales, the monitoring of IBCA use through indicators aggregated at EU level, processes to share information on risk-assessment between the Member States, and a working group at EU level on post-release assessment.
- **Options related to fostering research and development** for the development of new or more effective solutions (innovation push through EU-wide funding programmes, specific efforts focused on the strategies that display the highest cost-benefit ratios for farmers, generate data and references about impacts, and co-innovation projects).
- **Options related to fostering training, knowledge transfer and behavioural changes along the agrifood value chains (innovation pull).** These options include developing a specific platform / working group supported by the European Union in order to share information

between the stakeholders and Member States regarding the use of IBCAs (or more generally biocontrol solutions) in redesigned agroecosystems; strongly engaging downstream industries and retailers in initiatives promoting sustainable cropping systems and food chains; supporting farmers through financial support and training; supporting the monitoring and data collection and its availability at EU level; training public authorities; and emphasizing communication and success stories, through forums or demonstration farms for example.

Acronyms

BCA	Biological control agents
CAP	Common Agricultural Policy
CBA	Cost-benefit analysis
EC	European Commission
EPPO	European and Mediterranean Plant Protection Organization
EFSA	European Food Safety Authority
EU	European Union
FAO	Food and Agriculture Organisation
F2F	Farm to Fork Strategy
IAS	Invasive alien species
IBCA	Invertebrate Biological Control Agents
IBMA	International Biocontrol Manufacturers Association
IFOAM	International Federation of Organic Agriculture Movements
IOBC-WPRS	International Organisation for Biological and Integrated Control – West Palaearctic Regional Section
IPM	Integrated Pest Management
IPPC	International Plant Protection Convention
MRLs	Maximum Residue Levels
MS	Member State
NCA	National Competent Authority
NPPO	National Plant Protection Organization
OECD	Organisation for Economic Co-operation and Development
PAN	Pesticide Action Network
PPP	Plant Protection Products
SIT	Sterile Insect Technique
SUD	Sustainable Use of Pesticides Directive
ToRs	Terms of Reference
USA	United States of America

1 Background, objectives and scope of the Study

1.1 Objectives

The Council adopted on 22 June 2021 Decision (EU) 2021/1102 requesting 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 (IBCA) within the territory of the Union".

In this context, the Commission has requested EY to undertake a study aiming to support and provide input in analysing the Union's situation and establishing options regarding the introduction, production, evaluation, marketing and use of IBCAs within the territory of the Union and support the preparatory work for the design of a possible initiative that address shortcomings of the existing system in place. Provided inputs shall be part of further considerations towards future policy options to foster the development and use of IBCAs and address existing gaps in terms of managing risks and ensuring access to safe and sustainable products and services.

More specifically, the Study aims to:

- Allow a comprehensive description of the current situations of IBCAs in the Union, including an analysis of the current extent of use of IBCAs, the potential for further development and the state of regulations at Member State level;
- Identify problems of the current system in different MS and underlying drivers;
- Identify objectives and policy options, which will involve identifying and listing instruments that may address problems, as well as possible elements for policy options;
- Assess potential positive or negative effects/impact, e.g. identify and assess (mainly from a qualitative perspective, but also where possible through a quantitative cost-benefit analysis approach) pros and cons, e.g. positive of negative consequences which may be expected from the implementation of different policy options.

1.2 Scope

Content:

The study focuses on **Invertebrate Biological Control Agents** such as insects, including male sterile insects, mite, and nematode species (IBCAs). As mentioned in the ToRs, only uses which are linked to the intentional release of IBCAs shall be considered. Furthermore, only IBCAs shall be

considered which are intended to protect plants or plant products, ("plants" and "plant products" as defined in Article 2 of Regulation 2016/203111), including those to control invasive plants.

Further inputs regarding definitions and the scope of the Study are provided under Annex 1 of this final report.

Territory:

In terms of geographical scope, the study covers the territory of the Union. Most analyses cover all EU Member States, with some specific questions focusing on a more limited sample of 7 Member States that are representative of the composition of the Union. **Selected 7 Member States for this study are Austria, France, Hungary, the Netherlands, Portugal, Spain, and Sweden.**

In addition, the study aims to analyse the situation and alternative approaches in two third countries. In agreement with DG SANTE, the selected third countries were **New Zealand and the USA.**

Timeline:

The Study is both retrospective and prospective. Its retrospective component mainly focuses on analysing the current situation and current regulation, thus establishing current existing problems. The prospective component includes projections for the next 5 to 10 years.

1.3 Overview of Study questions

The Study aims to answer the following **questions** as defined in the ToRs:

- 1. What is the **current market** of IBCAs on the level of Member States and how can it be further developed?
- 2. What **(regulatory) systems** are in place in relation to introduction, production and/or release of IBCAs in the different Member States?
- 3. What are the **characteristic elements of the regulatory approaches** in force towards the introduction, evaluation, production, marketing and use of IBCAs in Member States?
- 4. Which of the **regulatory instruments below** are used and in which Member States? How can they be used more effectively? Have additional instruments been mentioned by stakeholders and which are they?
  - Internationally agreed guidance documents
  - Research projects & funding of product development
  - Knowledge transfer
  - Economic and financial incentives
  - Training activities

- Mechanisms to collect feedback from extension and advisory services

- 5. Which successful alternative approaches exist in **countries outside the Union** and how can they be characterised?
- 6. Which complementary instruments exist that are complementary to regulatory provisions in place and what are their expected effects?

Sub-questions and their specific scope are listed in annex 3.

Considering these Study questions as guiding elements, the report is structured as follows:

- Chapter 2 provides an overview of the methodological approach followed by the Study, and highlights existing limitations in terms of data gaps and completeness of findings and conclusions; in addition to this chapter a synopsis report is provided in Annex 5;
- Chapter 3 provides detailed answers to each Study question;
- Chapter 4, which is based on the findings presented in Chapter 3, summarizes existing problems and suggests potential actions to be taken at an EU level to address them. It also integrates an analysis of the pros and cons of the identified options considering the issues identified with the current situation.

2 Methodological approach, timeline, and data collection

2.1 Overview of the approach

The methodological approach for this Study has been divided into three phases and four main tasks (study design, consultation, analysis, synthesis and reporting) as follows:

Table 1 - Phases, tasks and timeline of the Study

PHASES	TASKS	DELIVERABLES & MEETINGS
Phase 1: inception phase	**Study design** (Task 1 as per ToRs): ► Exploratory interviews with identified and approved stakeholders ► Desk research ► Elaboration of the draft Intervention logic ► Development of the draft methodological approach and consultation strategy	Kick off meeting: ***11 March 2022*** Draft Inception Report: *25 April 2022* (revised version sent on *16 May 2022*) Steering committee meeting No 2: ***29 April 2022***
Phase 2: consultation and preliminary analysis phase	Consultation activities *(Task 2 as per ToRs):* ► Collection of feedback and inputs from relevant stakeholders through interviews, surveys, and desk research **Analysis** (Task 3 as per ToRs): ► Preliminary answers to Study questions leading to a revised/ completed problem definition ► Initial identification of objectives and potential policy options and instruments that may address problems, and analysis of their potential positive or negative effects/ impact	Progress meeting: ***15 June 2022*** Draft Interim Report: *8 July 2022* (revised version sent on *29 August 2022*) Steering committee meeting No 3: ***12 July 2022***

PHASES	TASKS	DELIVERABLES & MEETINGS
Phase 3: final analysis, synthesis, and reporting	Continuation of consultation activities *(Task 2 as per ToRs):* ► Finalisation of collection of feedback and inputs from relevant stakeholders **Final analysis** (Task 3 as per ToRs): ► Triangulation of both quantitative and qualitative data to provide evidence-based answers to all Study questions, propose policy options and analyse their consequences (pros and cons) Synthesis and reporting *(Task 4 as per ToRs):* ► Completion of analyses ► Validation workshop ► Final conclusions	Validation workshop: ***30-31 August 2022*** Draft Final report: *9 September 2022* Steering committee meeting No 4: ***23rd September 2022*** Final report: 30 September 2022

2.2 Summary of data collection activities

2.2.1 Inception (phase 1)

Phase 1 aimed at refining the background and scope of the Study and detailing the work programme and methodological approach of the study. It included:

- **7 scoping interviews** were conducted with:
  - the Commission (DG SANTE, DG AGRI),
  - EU agencies (the European Food Safety Authority (EFSA))
  - organisations representing users (IFOAM), the industry (IBMA), and scientific organisations (IAEA-FAO and EPPO).

  During these interviews, the study was presented to the stakeholders, as well as the main needs for data and key issues to be dealt with. An open discussion was organised to give the stakeholders the opportunity to describe their view of the topics addressed and the main pros and cons they foresee in terms of implementation of public policies at the EU level. The stakeholders were also invited to make suggestions of institutions to be contacted for the various issues to address and to gather data needed for the study. These interviews allowed the team to get a

clearer overview of their respective role and responsibilities, collect their expectations on the study, and estimate their degree of involvement and knowledge regarding IBCAs, and which data could be obtained in the later steps of the study.

- **Initial desk research and preliminary analysis.** These tasks included desk research at an EU and national level (in selected MS only) to provide initial input to the Study questions, better identify existing data gaps and define how to address these gaps through consultations and additional documentary review. The documentary review mainly focus on:
  - Official documents (legal texts and websites) to complement the consultation, or to address gaps in the consultation (Malta and the region of Wallonia). These documents include for example the lists of species available for use and/or authorised in some Member States, legal provisions for data requirements and risk assessments
  - A literature review to anchor the analysis in the existing scientific findings. The list of documents consulted is provided in Annex 2.
  - Databases: Eurostat (pesticide sales, agricultural output in the EU-Member States, and crop production in EU standard humidity)[3], 2021 and 2022 IBMA market studies, lists of approved or commercially available species in the Member States, databases on the uses of IBCAs in the Member States
- **Preparation of the consultation programme.** Based on the scoping interviews and preliminary analyses, several types of stakeholders have been identified as targets to gather data and information. For each, questionnaires or interview guidelines have been developed. A plan to contact and interview each category has been defined.

2.2.2 Consultation activities (phase 2)

Stakeholders consulted

Stakeholders were pre-identified in the Terms of Reference of the Study by the European Commission and validated with the study team. The choice was made to keep the stakeholder consultation at European level. The following categories of stakeholders have been contacted for the assignment:

- European Institutions;
- Relevant national competent authorities in all 27 Member States, e.g., authorities in charge of Plant Health, Plant Protection and Environmental protection. As requested by the ToRs, "the contractor

[3] Annual pesticide sales per Member State in kilograms Statistics | Eurostat (europa.eu)
Economic accounts for agriculture - values at current prices Statistics | Eurostat (europa.eu)
Crop production in EU standard humidity Statistics | Eurostat (europa.eu)

shall limit its contacts to the authority being in the lead for the national process for the production and release of IBCAs, respectively".

- Third countries: competent authorities in 2 non-EU countries to compare and identify alternative approaches. New Zealand was chosen for its historical approach to the regulation of IBCAs, while the United States of America were selected as a relevant case study on how the federal level can be articulated with State independence and decision-making power.
- Organisations other than public entities, which includes:
  - 3 Intergovernmental organisations on biological control
  - 2 International and EU Industry associations representing the interests of manufacturers and retailers of IBCAs
  - 3 Farmers', forestry and home gardeners' associations at EU and international level;
  - 3 Civil society organisations (environmental NGOs);
  - 2 Scientific organisations.

Consultation tools

Stakeholders and National Competent Authorities were consulted through two main data collection tools that were implemented in a sequential manner. Each tool enabled to collect evidence that complements desk research by providing additional qualitative and quantitative inputs which are not available in official documentation. These tools are the following:

- **Surveys**, by the mean of structured questionnaires sent to NCAs and other stakeholders. Questionnaires were developed during phase 1 to collect as much information as possible to answer questions of the Study and feed into the problem definition and the identification of possible options for an EU initiative. Starting with written questionnaires (before interviews) left more time to targeted stakeholders to collect relevant documentation and consult with other authorities, where needed, to provide useful and as exhaustive as possible answers. The goal was to consult all 27 Member States and the 12 other stakeholders, as well as one relevant authority from a third country. In total, 26 questionnaires were received, corresponding to 24 different Member States. One of the third countries sent a detailed questionnaire, while the other opted for selective e-mail responses. 3 questionnaires were collected from stakeholders, who generally preferred to provide input during the interviews rather than sending written answers..
- **Targeted interviews** that aim to confirm the problem definition and collect additional views and data to measure the impact of the different options and identify main pros and cons of policy options. They were led with Member States to better refine and complement

the questionnaires, and sometimes were proposed to replace the questionnaire to accommodate NCAs (this was the case for 2 Member States and one regional authority). Stakeholders were also proposed this option, to ensure maximum contribution, and this proved to be their preferred consultation tool. The goal was to lead 20 interviews with a representative sample of stakeholders, including at least 7 Member States, at least one non-EU country and 1-2 representatives of each other stakeholder category. In total, 23 interviews were organised: 13 with the Member States (in two cases to replace the questionnaire), 8 with the stakeholders, and finally 2 with both non-EU countries.

Both consultation tools were implemented in a sequential manner. The survey was launched at the end of May, and interviews were conducted from June to August 2022. This allowed to consult the following stakeholders:

Table 2 - Consulted stakeholders

Type of stakeholders	Surveys	Interviews
27 Member State "national competent authorities", e.g. contact points identified within each national authority in charge of IBCA in their respective country.	√ Additional and complementary questions were asked in the form of interviews and emails	Interviews were led with authorities from Belgium (Brussels region), Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, the Netherlands, Portugal, Spain and Sweden
Intergovernmental organisations	√ EPPO	√ EPPO, IAEA-FAO CABI Europe
Industry associations representing the interests of manufacturers and retailers of IBCAs:	√ IBMA No response from other contacted association	√ IBMA,
Farmers', forestry and home gardener's associations:	All stakeholders opted for interviews	√ COPA-COGECA, EUSTAFOR

Type of stakeholders	Surveys	Interviews
Environmental NGOs	No response from contacted organisations	√ PAN Europe
Scientific organisations	√ IOBC-WPRS	√ EFSA
National competent authorities from third countries	√ New Zealand, the USA	√ New Zealand, the USA

Focus on the consultation with National Competent Authorities

NCAs were mainly consulted through a structured questionnaire, complemented with a series of interviews.

Several follow up tasks were undertaken to support NCAs and ensure a high response rate to the questionnaire, and ensure better quality of the responses:

- Phone calls and frequent reminders by email, to ensure that data is collected and at least get in touch with each stakeholder to ensure to receive feedbacks (including negative ones).
- Series of follow-up interviews and email exchanges with stakeholders who are not able to provide written answers as well as with stakeholders with answers not sufficiently detailed or which required clarification.
- Review of relevant national documentation, either transmitted by national competent authorities or available online, to fill the data gap.
- Documentary review for Member States who did not reply.
- Literature review of scientific evidence to support and refine the elements transmitted by the different stakeholders and Member States, when possible.

Detailed inputs could be obtained for 25 Member States (all Member States except Malta). In total 26 questionnaires were received (including 3 questionnaires covering the regional level in Belgium), corresponding to 24 different Member States. 2 more Member States (Luxembourg and Portugal) were interviewed (although no questionnaire was received, these interviews enabled to complete the questionnaire). Finally, an additional documentary review was led for Malta, which confirmed the absence of a regulatory system. As a result, the survey covers all Member States, except for Malta and the region of Wallonia in Belgium, with a response rate of 28 responses out of the 30 solicited.

A detailed overview of Member States' participation in the consultation activities is available in section 5.5.3.1.

2.2.3 Validation workshop (phase 3)

An online validation workshop was organized on August 30th and 31st 2022.

This workshop aimed to present the results of the study, validate the main findings, and discuss over some more challenging topics identified. It was opened for participation to representatives of key stakeholders concerned by IBCAs at European level, e.g., the national competent authorities of each Member State, representatives of business operators (producers and users), representatives of NGOs, as well as recognised experts in IBCAs. Overall, participation was high, with 60 people (including the EC and the study team) present on the 30th and 56 people on the 31st.

Table 3 - Number of participations per stakeholder group and overall target

Type of stakeholders	Number of participations per stakeholder groups	Target number of participations per group
Member States	17	27
Intergovernmental organisations	2	3
Industry associations representing the interests of manufacturers and retailers of IBCAs	1	2
Farmers', forestry and home gardener's associations	1	2
Environmental NGOs	0	3
Scientific organisations	2	2

Alongside the data collection, the workshop's outputs were included in the report.

2.3 Robustness of the data and of the analysis

The content of the report has been developed in compliance with the Better regulation guidelines which define a six-step approach to construct robust evidence base: understanding, mapping, collection, analysis, interpretation

and presentation[4]. Regarding the analysis step more specifically, it has mainly involved: (i) Survey data consolidation, cleansing and processing, (2) documentary review and analysis, (3) combination and cross-analysis of collected data as well as triangulation to describe the situation of IBCAs across the EU, inform on existing problems and assess potential impact of an EU action.

Although the quality of data collected, especially at Member States level, is mixed (see below), the triangulation of several sources ensures the robustness of the analysis. Main findings of the Study were presented and discussed with representatives of the Member States and key experts during a validation workshop.

The level of details and the quality of data collected at Member State level are mixed:

- Survey's sections about the regulatory framework have been thoroughly completed for Member States which have a regulation. Member States currently developing one have also provided certain details on their future regulations. The sections on the legal aspect of IBCAs are therefore robust.
- Sections on the use of IBCAs were more unequally completed. Generally, the number of uses (as in one solution for one crop) is seldom if ever collected in the Member States. When available, the number of authorized IBCAs was communicated, and the desk research allowed to form a database of the species that are either authorised or available for use, without hindsight into the actual use of these organisms. And pesticide use and distribution among crops was also rarely provided. Crop type granularity was available only in a few cases. As such, the analysis of the uses relies more on converging qualitative data obtained through interviews and questionnaires. While this analysis is quite robust, it is missing to some extent the point of view of users (farmers, foresters, gardeners, etc.), that was not thoroughly detailed and available at the level of European organisations. Indeed, the users consider IBCAs as one of the existing alternatives to chemical pesticides and were able to provide the main needs and issues encountered with biological controls. They apply to IBCAs and have been considered in the conclusions. However, they were rarely able to provide specific insights regarding IBCAs. Thus, the analysis consolidates these general concerns on the demand and use side with more specific data and challenges raised in other interviews and relevant studies.
- Similarly, data on the market was difficult to obtain, except for a few Member States which collect indicative information from

[4] Better Regulation Toolbox, tool #4

industry associations. Some interviews allowed for more qualitative but less precise descriptions of the market.

- Perspectives were generally expressed in a very concise way. A few Member States left the section empty. A hypothesis for this response behaviour is that some respondents might think they were not at the right decision or political level to reply. Other Member States provided very detailed and exhaustive answers. Ample room was however given to the stakeholders to express their views, through the questionnaires, interviews and the workshop: while not all expressed their view, it can be reasonably thought that not all had views to express given the technicality of the subject, and that the analysis is not limited by this factor.

2.4 Difficulties and limitations of the Study and related mitigation measures

Based on the data collection and assessment of the quantitative and qualitative data available, several limitations could be underlined:

- **Important lack of data regarding the market and current use of IBCAs:**
  - Very few Member States were able to provide data regarding the current uses of IBCAs on their territory and none of them have data regarding the market of IBCAs at national level. There is no monitoring strategy in place in the Member States leading to very little knowledge on the current situation within NCAs.
  - IBMA conducts annual surveys at European level regarding the market of BCAs. However, few data were available from the 2022 survey and important delays in the publication of the results were encountered. In particular, due to some technical issues, the information regarding the market at Member States level is not available. All available data have been integrated in the report.
  - Considering the lack of available data, we have proposed in this report an assessment of the current market based on the available data and a qualitative assessment of the structuration of the market in Europe to describe the main producers and the main characteristics of the market. A typology of the types of use has also been proposed, reflecting the main drivers identified during the study and confirmed during the workshop, e.g. Member States' agricultural scenarios, and public policies in place with regards to IBCA authorisation, research, and incentivisation.
- **Difficulty to establish projections at this stage:**

The potential for development of IBCAs has proved challenging to assess by the consulted stakeholders, both in the questionnaires and in the interviews. Especially, information on the product pipeline specific to IBCAs

was not available to IBMA. An estimation of the cost breakdown of new products was however provided by IBMA, as well as the market value of their members' yearly sales, and the estimation of their representativity in the overall European biocontrol market. These estimations were used for the projection of the total IBCA market. Finally, projections related to the impact on pesticide use relied on Eurostat data on pesticide use and on market projections for the evolution of biocontrol. Additional information regarding methodology used for quantitative projections are provided in the section detailing the baseline scenario (section 4.1.2.1).

- **Challenges when assessing the impact on substituting chemical pesticides and contributing to achieving the F2F targets:**

Some of the study questions tend to assume that current chemical pesticides' uses can be substituted by IBCA uses one by one, with no further consequences. However, the differences in the type of products (chemical substance versus living organisms) made this analysis very difficult to perform. The findings of the study have showed that IBCAs are generally included in a more global strategy (IPM especially) with the aim of regulating pests by favouring natural enemies (conservation biological control), introducing additional predators and parasitoids to the pests in specific context to regulate the pest population (augmentative biological control), and sometimes alongside chemical biological control. However, it relies on more long-term strategy with potential higher effects on the crop production in comparison to pesticides where one chemical product is used as a specific solution to one problem. The projections regarding IBCAs were therefore based on the estimation of the total potential of development of non-chemical alternatives and the specific contribution of IBCAs estimates based on the feedbacks from the stakeholders and internal expertise.

- **Challenges concerning the analysis of the various regulatory instruments on innovation:**

No quantitative or scientifically sound impact study of various regulatory instruments on innovation could be surveyed in this study. Moreover, very little input was proposed by Member States within the questionnaires, although two Member States mentioned possible systems of subsidies or obligations to use biocontrol strategies. To address this shortcoming, discussions had to rely on qualitative evaluations, discussions, opinions of experts and NCAs, and scientific publications providing data on innovation trends.

3 Findings of the study

3.1 Q1: What is the current market of IBCAs on the level of Member States and how can it be further developed?

This question aims to develop a clear understanding of the current and potential future market of IBCAs in the 27 Member States of the European Union. It especially provides information on the following elements:

- Market value and market share, especially in comparison to that of chemical pesticides as well as to current production (location, volumes, market destination, etc.) and demand (type of users, unmet needs, gaps in terms of available products or IBCA solutions, etc.)
- Uses: current uses, scenarios of uses (types of crops, types of users, association with chemical pesticides, etc.), potential for new uses (based on unmet needs as well as on the potential for developing new IBCAs), proportion in relation to authorised chemical pesticide uses, etc. Specific focuses are placed on the factors that shape differently the patterns of uses across the Member States, as well as on the different types of invertebrate biological control (augmentative and classical).
- Potential for development of new solutions and products
- Expected benefits on the Farm to Fork objectives, as well as biodiversity and food safety (as defined in the Terms of Reference)

3.1.1 Availability of data on market share and uses of IBCAs

One major objective of the Study is to provide an overview of the data available at the European and national level regarding the market share and the use of IBCAs.

Availability of data at the national level

Data collection tasks undertaken during the Study have revealed that there is little to no data available at the Member State level regarding IBCA market value, use and production, albeit some data on the authorised species. An overview of the data collected and/or available in the NCAs is provided in Annex 4.

- Data on the market and on the industry

Little information is available at the level of the National Competent Authorities. Some NCAs were able to either transmit data collected from national industry associations, or provide an estimate of the market value. Some Member States require the sellers to communicate data, but they have not been able to communicate market value numbers specific to the IBCA market (our working hypotheses are that they are either not consolidated at the national level, or that the IBCA segmentation of the biocontrol market is not available). Finally, a proportion of the IBCAs used

in the Member States is imported (from other European MS or from third countries). As such, IBCA market data remains largely invisible to the National Competent Authorities (NCAs).

Contrary to chemical pesticides, there is no data on the volume of IBCAs produced and sold. On the other hand, there exists some available data on the IBCA sales collected by industry associations; this information is not available for chemical pesticides.

- Data on authorised species

16 Member States have provided information on the number of species that are authorised and accessible for purchase in their territory. In some Member States with an authorization system, the number of authorized species is also not known (implicit authorization, for example in the Czech Republic).

While in some cases, the number of authorized uses is available, it does not necessarily reflect the number of actual uses (including those who are not subject to authorization).

- Data on the actual uses

Only a few countries have been able to communicate precise data on the actual uses and their repartition by crop type and aim (France, the Netherlands, Slovenia and Sweden). The most developed tool among the different Member States can be found in the Netherlands: the open data website StatLine[5] provides very precise data collected in agricultural censuses[6] on the uses of various beneficials, combining crop types and couples of target pests and IBCAs. However, only two censuses have been made so far, for the years 2012 and 2016. Austria has also developed a website[7] for the authorized plant products which includes IBCAs, and gives information on the field of use, the target pest and the type of crop, although no specific search is possible for IBCAs.

No data is collected at the national level in Member states with no regulation. The National Competent Authorities were therefore not able to communicate the number of actual uses. In many countries with a regulation, the regulation does not include any provision related to the monitoring of the uses of IBCAs, and thus no generation nor consolidation of IBCA-related data. As a result, the collected data is insufficient and heterogeneous across Europe, which does not allow for any consolidation or comparison between Member States.

Despite this lack of data, most NCAs have been able to qualitatively describe the main uses in their territory and provide some examples and best practices.

[5] https://opendata.cbs.nl/statline/#/CBS/nl/dataset/84008NED/table?ts=1656676963062
[6] Use of pesticides in agriculture (cbs.nl)
[7] Pflanzenschutzmittel-Register (baes.gv.at)

Availability of data at the European level

The data produced by companies is not consolidated at the European level. However, IBMA conducts a market study on their member base (which represents around 90% of the European biological control market) on an annual basis. However, due to confidentiality challenges, the data is aggregated at the European level by an external contractor and does not give any insight into the national biological control markets. In this report, the representativity of the data provided (market share of surveyed companies) is not known. Furthermore, at this stage, most of the newest data from the 2022 IBMA market survey remains unavailable. As such, data from the 2021 market study was also used to complement the most recent figures.

At EU and international levels, there are lists available on the use of species across Member States. EPPO PM 6/3 contains a list of safely used species (although its scope goes beyond the territory of the European Union). Studies also look at the species used at the international level[8], and especially by van Lenteren, and their repartition by invertebrate and crop types, and were utilised in the analysis.

3.1.2 Current market of invertebrate biological control agents

IBCAs are a growing market, representing around 30% of the European biocontrol market

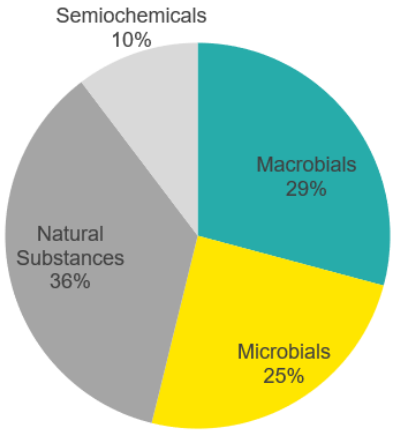
According to IBMA, the international biocontrol market represented around €3bn in 2020[9], and the European biocontrol market around €1bn (30% of the global biocontrol market). IBMA estimates that **invertebrates (also named macrobials) represent around 30% of the European biocontrol market (between 300 and 350 million euros)**[10].

[8] https://link.springer.com/chapter/10.1007/978-3-030-22304-5_16

[9] Sources: Dunham Trimmer and HIS Markit

[10] IBMA 2022 – EY projection: detailed data rely on extrapolation based on data covering 43% of the market

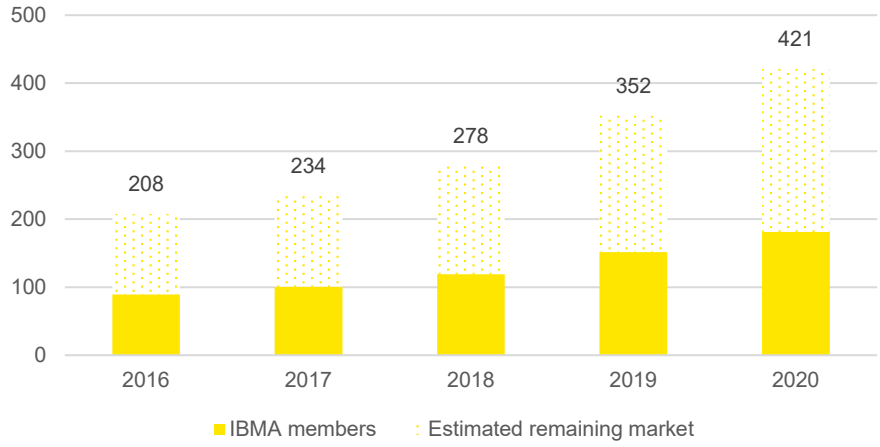
Figure 1 – Distribution of market value of biocontrol market categories in Europe in 2020



Source: IBMA Market survey 2022

The market for IBCAs has steadily increased over the last years. According to the data received from IBMA through their annual market survey (which covers between 40 and 50% of the market), the market share of invertebrate biocontrol agents has increased by 103% between 2016 and 2020 from €89 million to €180 million while the year 2019 to 2022 saw a 22% increase.

Figure 2 - Evolution of the market of IBCAs in Europe (in € millions)



Source: Analysis based on IBMA Market surveys 2021 and 2022

The IBCA market is still limited in comparison with chemical pesticides

IBCAs represent less than 3% of the current European crop protection market.

Although the growth of the IBCA market is significant, it remains slower than the global market for biological control which had increased by 188% between 2016 and 2020 (+20% between 2018 and 2019). In the same period, the market value of microbials increased by 228% while natural substances and semiochemicals increased by 182% and 110% respectively (with a stable market between 2018 and 2019). Company sales information is commercially sensitive, but IBMA estimates that price increases since 2016 are mostly linked to inflation and would represent 15 to 20% of the total increase in market value. The remaining increase, upwards of 80%, can be thought to be due to increased volumes.

Very little data is available on the current IBCAs market in the Member States

Very few Member States have information on the national market value of IBCAs. Only four reported estimated figures of the annual sales of IBCAs used in their territory:

Table 4 - Estimated market value for IBCA per Member State based on available information

Member States	Annual sales	Indicative share of the EU IBCA market
France	23,6 million euros	7,9%
Finland	4,5 million euros	1,5%
Sweden	< 2,6 million euros	< 0,9%
Slovenia	0,3 million euros	0,1%
Croatia	0,25 million euros	0,1%

Source: IBMA France and questionnaires to NCAs

This data shows that gross IBCA sales and trends are probably very different from one Member State to another, with different levels of uses across Europe.

Box 1: Evolution of IBCAs sales in France

Consolidation of data from IBMA France (representing >90% of the national biocontrol market) since 2015 reveals a growth of IBCA sales which reached approximately 45% between 2016 and 2020 (below the EU estimated average), with a growing proportion within the national crop protection market; it amounted to 1.2% in 2020, still below the EU estimate average of 3%.

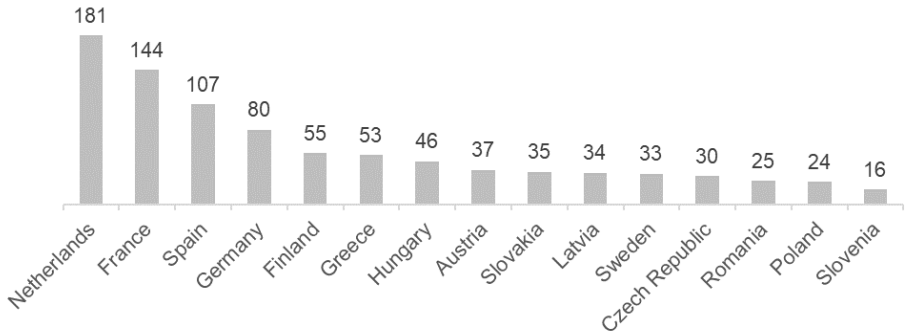
Table 5 - Evolution of IBCAs sales in France

Year	Sales (M€)	% of crop protection market
2016	16.5	0.8%
2017	19.6	0.8%
2018	18.7	0.9%
2019	21.7	1.1%
2020	23.6	1.2%

Given the scarcity of available information on the current market, another approach had to be used to give an overview of the current development of IBCAs in the Member States. The number of IBCAs authorized is one of the main data available in the Member States. The following assumption can be considered: the number of species authorized in the Member States is correlated with the number of actual uses and the development of IBCAs[11].

The following graph presents the number of authorized species in the Member States based on data transmitted in the questionnaire.

Figure 3 - Number of authorised species in the Member States



Source: Questionnaire to NCAs

[11] For the Member States who transmitted information on their national IBCA market, this assumption is consistent with the number of authorized uses

This data shows important differences regarding the number of species authorized as IBCAs: from more than 100 in Spain, France and Netherlands to less than 20 species in Slovenia.

However, it should be noted that in Slovakia and the Czech Republic, some species can be introduced based on mutual recognition (when it is authorized in another Member States), thus the number of species can be higher than the number reported.

The current IBCAs market is mostly concentrated in the main EU crop producers and in Member States with substantial area under protected cropping

The market of IBCAs is more developed in Member States with an extensive agricultural production, especially horticultural and under protected cropping. Biological control has reached significant critical mass, especially in the protected crop segment, which is seen as mature by representatives of the industry. 80% of commercially used IBCAs are used in greenhouses, and 20% on field crops (arable and specialty crops shows the higher potential for expansion)[12].

The European crop market is very segmented, with four countries leading production (France, Italy, Spain and Germany) with crop outputs above 25 000 million euro in 2020, distorting the European average by Member Sate to around 8 127 million euro in 2020. A second group (crop outputs between 5 000 and 15 000 million euros) is formed by the Netherlands, Poland, Romania, and Greece. The remaining 19 Member States have crop outputs below 5 000 million euro, around the median (3 303 million euros).

A study in 2012[13] shows that in the European Union, between 2006 and 2010, the average utilized agricultural area (UAA), was 165 493 thousand hectares, of which 0,09% (146,7 thousand hectares) were crops under greenhouses. Utilised agricultural area (UAA) includes arable land, permanent grassland, fruit crops, crops under glass, and hardy nursery stock. The leading countries with regards to indoor crops production are similarly ranked: the largest production under protected cropping is in Spain (65 thousand hectares on average between 2006 and 2010, representing 0,26% of the UAA, then comes Italy (33,8 thousand hectares, 0,24% of Italy's UAA), the Netherlands (10,8 thousand hectares, 0,53%) and France (7,8 thousand hectares, 0,03%).

Eurostat data is available for some of the main crops under protected conditions (lettuce, peppers, tomatoes, cucumber, and strawberries)[14]. In 2010 they represented 86,1 thousand hectares in the European Union and

[12] van Lenteren, J.C., Bolckmans, K., Köhl, J. *et al.* Biological control using invertebrates and microorganisms: plenty of new opportunities. *BioControl* **63**, 39–59 (2018). https://doi.org/10.1007/s10526-017-9801-4

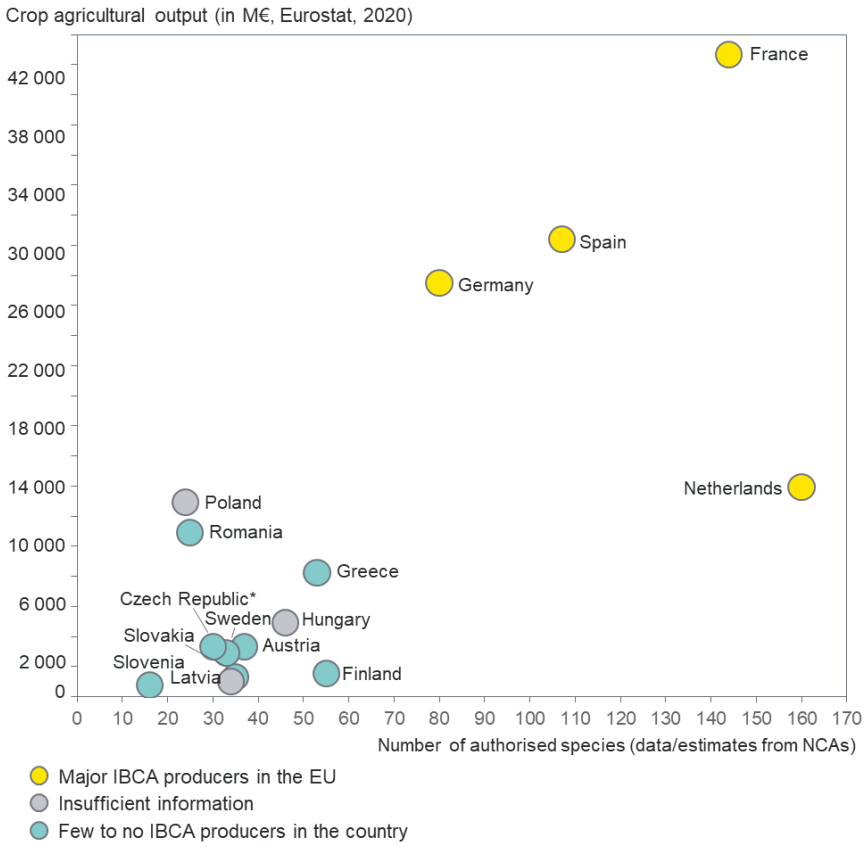
[13] Pierre Hucorne, 2012, EPPO website https://www.eppo.int/media/uploaded_images/ACTIVITIES/plant_protect_products/zonal_assessment/Hucorne_2012_crop_distribution.pdf

[14] Crop production in EU standard humidity Statistics | Eurostat (europa.eu)

in 2021 they represent 104 thousand hectares. For these crops, the major producing Member States are also Spain, Italy, France and the Netherlands. Greece and Poland have also become leading countries in terms of protected cropping on these specific crops, with levels of production similar to respectively France and the Netherlands.

Top crop producers are also Member States with the highest pesticides sales[15]: Spain (22% of pesticide sales in Europe in 2020 according to Eurostat data), France (19%), Italy (16%), Germany (14%) and Poland (7%). Consistently with their agricultural crop output, these five countries are thus the highest consumers of pesticides, making up 70% of the 345 508 tonnes of pesticides sold in 2020. It should be noted that, between 2016 and 2020, the quantity of pesticides sales in Europe had decreased from 370 000 tonnes in 2016 to 333 418 tonnes in 2019 (-10%). However, even considering this decrease in sales volumes in the last years, the estimated annual growth rate of the pesticide market for 2021-2026 is an expected 4,1%. [16]

Figure 4 - Crop agricultural output and authorised IBCA species across EU Member States



Sources: Questionnaires sent to Member States; IBMA, Eurostat

[15] Annual pesticide sales per Member State in kilograms Statistics | Eurostat (europa.eu)
[16] IMPACT ASSESSMENT REPORT_ Proposal for a Regulation on the sustainable use of PPP 1 / June 2022 citing Europe Biopesticides Market | 2021 - 26 | Industry Share, Size, Growth - Mordor Intelligence

Production of IBCAs relies on some big companies and a strong involvement of SMEs

The production of IBCAs relies on:

- Some large companies that have production sites in several Member States (mainly France, Belgium, Netherlands, and Spain) and sell IBCAs in the Member States that use IBCAs most;
- A large number of SMEs: in 2019, SMEs made up 61% of biocontrol (all categories included) sales value, and 87% of biocontrol products sales.[17] For example, Germany relies mainly on SMEs (7 companies identified) to produce IBCAs.

Thus, IBCAs and, more generally, biocontrol industry, differs greatly from the structure of the chemical industry, which relies mostly on international big companies with thousands of employees. In comparison, a study in 2011 reported that in Europe, around 20 "large" commercial producers (companies of more than 10 people) were active (two thirds of producers worldwide), of which less than five employed more than 50 people. The largest employed 600 people[18]. Worldwide, in 2017 there were around 500 commercial producers of IBCAs, employing for most of them less than 10 people. Several countries (such as Sweden, Portugal Czech Republic, Romania), have no, or very few, implanted producers and rely mostly on imported organisms from neighbouring countries. For example, Portugal does not produce IBCAs, so the farmers mainly rely on importation from Spain where the production is well developed. Similarly, Sweden, or smaller countries like Luxembourg, have no national production and rely exclusively on imports from other Member States.

Finally, it should be noted that some of the companies who produce IBCAs within the European Union also have productions sites just outside the European Union, such as Morocco and Turkey.

The graph below summarizes the number of companies with a production site identified in the Member States based on information transmitted by the Member States and IBMA.

[17] IBMA Market survey 2021

[18] Joop C. van Lenteren 2011, The state of commercial augmentative biological control: plenty of natural enemies, but a frustrating lack of uptake, BioControl (2012) 57:1–20, DOI 10.1007/s10526-011-9395-1

Figure 5 - Number of known companies with a production site in EU Member States

Source: IBMA, input from Member States

Production in augmentative biological control is usually linked to recurring pests for which the solutions already exist as commercial products. Supply is very responsive to the needs: the industry works on very limited timeframes, as shelf life of the IBCAs is very short (the products are generally to be used within 2 to 3 days), but their generation times can vary. Species that take one week to be generated are much easier to scale up and to supply quickly than species who require one month.

The IBCA producing companies have developed planning systems that allow anticipation of the growers' needs. There is an element of predictability with regard to the resurgence of known pests (e.g. when white flies / aphids are supposed to appear). However, IBMA acknowledges that they are subject to climate variation. In the event of a shortage in one supplier, there were alleged cases of suppliers supplying each other. The supply chains have been refined, with air transport, and truck transport within Europe. Therefore, the industry estimates that there is limited risk of supply break in the EU. It should however be noted that "while hundreds of companies sell beneficial insects, mites and nematodes, fewer than 30 trade internationally"[19], as the complexity of logistical and regulatory requirements is a deterrent for smaller producers. Indeed, the smaller size of most IBCA producers also limits their capacity to develop effective production techniques and transport processes. Thus, availability of

[19] E. Vila, F. Wäckers & J. Klapwijk, Shipping augmentative biocontrol agents

products is still a limiting factor for some growers, for instance when they have to supply themselves in other countries.

3.1.3 Uses of invertebrate biological control agents in Europe

Uses of invertebrate biological control agents first depend on the type of biological control considered. Augmentative biological control is a commercially viable business model, as shown by the growing segment of macro-organism biocontrol (which is centred on augmentative releases) in the IBCA market and aims at the periodic release of natural enemies to control a recurring pest. It is generally used by growers, on a crop-to-crop basis. Classical biological control on the other hand aims at controlling pests more globally, by introducing and establishing a permanent population of natural enemies, which are not yet present on the field. Introduction programs rely mainly on national initiatives, coordinated and led by research.

While the Sterile Insect Technique (SIT) also relies on the periodic mass-release of invertebrates. This approach is also more publicly funded and operates on a wider geographical scale.

In addition, the use of IBCAs varies significantly across the Member States. Some species are widely authorised in the Member States, such as some native nematodes (*Heterorhabditis bacteriophora) or* non-native species *(*such as *Eretmocerus eremicus*, a whitefly parasite used for prevention and control whiteflies). On the contrary some species are authorised only in a restricted number of Member States, even if the pest occurs in a larger number of Member States (such as *Coccophagus scutellaris* that parasitizes small soft scales, which is only authorized in France, the Netherlands and Slovenia).

The next section provides an overview of the main factors that differentiate the use patterns across the Member States. A description of the current uses for augmentative and classical biological control are provided afterwards.

3.1.3.1 Main factors that differentiate the use patterns across the Member States

The consultation activities as well as the documentary research allowed the identification of several drivers and blocking factors for the use of IBCAs in the European Union.

The type of agriculture or horticulture that prevails in a given Member State.

Countries with sophisticated horticulture and substantial areas under protected cropping have adopted a much larger number of uses. Indeed, protected cropping is more favourable to current use of IBCAs because of

reduced vulnerability to weather variations. In 2008, augmentative biological control was estimated to be used on 10% of protected cropping[20]. As such, representatives of the IBCA industry indicated during the consultation that "apart from several open field crops (maize, several orchards) where massive releases of IBCA are performed, the major markets where IBCAs are most widely used are protected crops (glasshouses, plastic houses, walk-in plastic tunnels and multi-span structures)". Within protected cropping, use also varies depending on the crop type: IBCAs are used much more intensively in fruit vegetables (tomato, cucumber, peppers, aubergine…) than in leafy vegetables or ornamental greenhouse crops. Finally, IBCA uses are more developed in high added-value crops.

Agriculture systems with high IPM expertise and low pesticide use increase IBCA adoption (in particular crops dependent on pollination by insects).

Inversely, there are several phytosanitary scenarios that limit IBCA use. According to the IBCA industry, scenarios which have limited potential for IBCA portfolios include crops that cannot tolerate insect vectored diseases (such as seed potatoes needing to be 100% virus free), or crops exported to countries where plant protection services reject or destroy any plant material on which a quarantine species is detected. Finally, systems where the use of conventional pesticides remain high may be incompatible with IBCA use (on the short term: chemical residues that are toxic to natural enemies can remain for months on the crops). The International Organization for Biological Control (IOBC) side-effects database includes pesticides of different toxicity classes to natural enemies. Selective pesticides identified in this database could be used together with IBCAs. However, even fungicides, which are not directly toxic to IBCAs, can have negative indirect effects, leading to lower IBCA populations in fungicide treated fields (Ioriatti et al. 1992)[21]. The shape of the agriculture may also limit the need to use IBCAs. Luxembourg reported limited use of IBCAs in horticulture due to insect pests are not perceived as being a critical issue in the country (unlike fungi and diseases).

The national policy approach regarding chemical pesticides, biocontrol and IBCAs

Member States that focus strongly on IPM through policy initiatives, dedicated R&D and industry engagements (grower bodies, etc.) have a much higher chance of increasing their familiarity with new methods and IBCA use, ultimately leading to broader scale adoption. With regard to chemical pesticides, the ban or restriction of some chemical products leads

[20] Bale J.S, van Lenteren J.C and Bigler F 2008 Biological control and sustainable food production Phil. Trans. R. Soc. B363761–776 http://doi.org/10.1098/rstb.2007.2182

[21] Ioriatti C., Pasqualini E., Toniolli A. (1992) Effects of the fungicides mancozed and dithianon on mortality and reproduction of the predatory mite Amblyseius andersoni. Experimental & Applied Acarology 15:109-116. DOI: 10.1007/BF01275521.

to an increased use of IBCAs. One case in Spain showed that this replacement can also happen when pesticides cannot be used: between 2004 and 2007 in the Almeria region, isofenphos-methyl had to be substituted by augmentative biological control so that exports to Germany could resume[22]. Encouragement of non-chemical alternatives makes IBCA adoption by farmers more likely, especially when it takes the form of direct subsidies for the use of IBCA. For example, in Germany, the use of *Trichogramma brassicae* against European Corn Borer or the use of IBCA in greenhouses is supported as an agri-environmental measure within the second pillar of the CAP-scheme.

Fostering the research and development of new solutions and new technologies: technological improvements (e.g., with regard to storage, transport and field delivery)[23] are also expected to make solutions more attractive and enable larger deployment (facilitating the use in greenhouse and enabling access to non-protected crops). At the European level, a main driver of biocontrol and biodiversity improvement can be EU subsidies in the Common Agricultural Policy (CAP) for greening.

On the other hand, the regulation may become an obstacle for the use of IBCAs. There are instances where an IBCA solution exists but is not approved by the Member State, or where the registration/authorisation process is lengthy and generates administrative costs on the manufacturer or retail side. When it comes to the development and authorisation of a new IBCA in response to a new emerging pest, the time needed in the regulatory processes may become a limiting factor to the efficacy before the new pest becomes invasive.

A lack of knowledge of the environmental impact and of the unintended effects of IBCAs may be another barrier or limitation, as it can lead to incomplete or unsatisfactory dossiers for risk evaluations. Still, in most Member States that have a regulation in place, the submitted request for the release of an organism is often approved. Many Member States take into account, when conducting their risk assessments, the EPPO-IOBC Panel on biological control "positive list", which relies on field evidence, and few undesirable impacts have been recorded.

Finally, the national listing of native species can also be a limiting factor (lack of recording of species in a Member State can lead to native species not being known or identified if they later expand their geographical range).

[22] Product-country image and crises in the Spanish horticultural sector: Classification and impact on the market M. Mar Serrano-Arcos, Juan Carlos Pérez-Mesa, Raquel Sánchez-Fernández https://doi.org/10.7201/earn.2018.01.05.
Green Pest Management Revolution: An Opportunity That Arose from a Food Safety Alert (mdpi.com)

[23] For example, the transportation framework can be streamlined (e.g industry paper Streamlining cross-border shipping of live invertebrates), field delivery can be improved by drone aerial spraying, etc.

The agricultural approach of growers

This factor is key in IBCA use, which is more frequent among organic growers and growers who follow IPM principles, as well as in some horticultural crops where growers depend on bumblebees for pollination and cannot use pesticides.

According to IBCA manufacturers, and consistently with farmers' representatives' input, there is demand on the growers' side for more alternative options against pests. One of the drivers behind demand is the need for a response to the apparition of invasive new pests, which normally enter a country through unrelated imports: IBCA species can be identified, developed and commercially produced to answer these needs. Most classical biological control programs (for example T*orynus sinensis* against *Dryocosmus kuriphilus*[24]) are examples of needs that arose from the emergence of new invasive pests (see 3.1.3.2). In augmentative biological control, *Trichogramma achaeae* against *Tuta absoluta* is an example of a successfully developed commercial IBCA against a new pest (*T. absoluta* is a pest from South America that was first spotted in the European Union in 2006). A recent example of new needs that do not have clearly effective IBCA available yet is *Drosophila suzukii*, a significant pest of berries and fruits (research is underway). Pre-emptive biological control actions also may drive demand and public health programmes, to identify and answer to new emerging pests.

On the grower side, options are sought after for uses where no, chemical PPPs are available (they may either have been banned, or pests often develop resistance against conventional pesticides). Further, accreditations such as GlobalGap[25] and other retailer-affiliated (private) standards put pressure on growers with regard to pesticide residues and Maximum Residue Levels (MRLs). This leads growers towards measures which have no inherent risk for pesticide residues in the crop. In Spanish horticulture, in the years 2000-2010, a significant shift from chemicals to the use of IBCAs took place after media attention in several member states on high residue levels on agricultural products (see also 3.1.3.4).

Several types of growers were identified by the industry:

- Growers of **high-value crops** represent the large majority of the European IBCA market.

The use of IPM in high value crops such as fruits, vegetables and flowers is now the norm, according to IBMA. Many growers of high value crops incorporate IBCA's into their mix of IPM tools, sometimes simultaneously with chemical products. IBCA use by growers of high-value crops is particularly widespread in protected crops. In some horticultural crops,

[24] https://www.inrae.fr/actualites/combattre-guepe-guepe-succes-torymus-sinensis-lutte-contre-cynips-du-chataignier
[25] https://www.globalgap.org/uk_en/for-producers/index.html

growers are dependent on IBCAs when pollination goes by bumblebees, for example on tomatoes, cucumbers and sweet peppers.

- Non-organic growers are also users of IBCAs, without necessarily prioritizing their use in their agricultural practices

For a broad range of reasons (willingness to decrease their environmental/health impact, incentives from public policies or downstream industry, resistance of pests to chemical pesticides, pollination by bees, etc) growers commonly use IBCAs even if their production is not organic. However, some of them also revert to the use of pesticides e.g. when new chemistry becomes available or in case of a pest outbreak[26] or because of the introduction of a new exotic pest for which no biocontrol solution is available yet (e.g. *Tuta absoluta*).

- Organic growers are, logically, users of IBCA, although their limited numbers make them a relatively small market for IBCAs

IBCAs are of particular importance for organic growers given their limited options (only a few low-risk chemical pesticides are accepted for organic production). IBMA members see the organic market as a place for "innovation setting" for IBCA companies, since organic growers – in contrast to IPM growers – cannot rely on chemical pesticides as a backup solution and IBCA companies are hence motivated to find new ways to "stretch" the application of IBCA's beyond what is typically done in an IPM setting. This in turn may lead to new practices that are later adopted in IPM production.

Source: IBMA, EY analysis

The efficacy of IBCA

Efficacy of IBCAs is the subject of a conceptual shift from chemical PPPs, as it often relies on pest population regulation (rather than eradication), and impacts may be observed after several seasons. Efficient use is possible only in favourable systems, i.e. ensuring high regulation of pests (resistant varieties, management of functional biodiversity, etc.) and compatibility with the use of IBCAs. This is the case in many protected crops where systems tend to implement most IPM levers and successfully integrate IBCAs.

Adoption by farmers, especially in outdoor uses, is hampered by the lower immediate efficacy of IBCA that is often behind that of plant protection products. Representatives of the farmers estimate that about 3% of farmers in arable crops in the EU manage to use biocontrol effectively, especially due to weather conditions; an abundance of rain or high humidity may compromise IBCA use. Nematodes are easier to apply but are only

[26] Of the one targeted by the IBCA or another one that would need another IBCA – that may not always be available – but that can be controlled using chemical pesticides

used by few farmers, e.g. against codling moth (*Cydia pomonella*) to complement potential resistance to viruses (biopesticides). Effective utilization implies wide changes of agricultural systems, including the management of crops, resistant varieties, soil fertilization, agroecological principles to sustain and boost functional biodiversity etc. However, for the latter, it is possible to obtain EU subsidies. The current concept of efficacy in itself is hampering the use of IBCAs, as IBCA use does not bring immediate efficacy, but rather longer-term and more sustainable pest control.

For already developed and approved organisms, the timescale needed for the solution to operate is estimated by manufacturers to be no critical issue. Through thorough monitoring growers can predict pest outbreaks well and take timely action. Unexpected events occur that may lead to reliance on chemical pesticides as IBCAs may be insufficient to provide a quick 'knock down'.

High costs of the IBCA solutions

According to the consulted farmers' organisations, farmers do not feel that the use of IBCAs is available and affordable. Due to the technical nature of IBCA development, shipment, and application, costs can be high and become blocking factors, especially where large quantities of IBCAs are required (outdoor uses, systems which are less favourable to the growth of IBCA populations). Transport and storage can be challenging, and the field-delivery is often manual, and thus labour intensive.

Studies on the cost of biological control estimate the direct cost of application to range from 175€ to 350€ (although this includes micro-organism biological control). SIT for controlling the onion fly would cost approximately 400€ per hectare and nematode application around 600€ per hectare[27]. Trichogramma use may be lower. Finding comparable information for the direct application cost of chemical pesticides is more difficult. By way of indication, a study carried out in France in 2008 found that typical pesticide expenditures range between 152€ per hectare for low-pesticide use technologies to 220€ per hectare for high-pesticide usage technologies[28]. Pesticide expenditure for crop mixes including vegetables, wheat (durum) and corn ranged from 191€ to 257€ per hectare. However, one should take into account the longer-term benefits of biocontrol application in crops (less pest resurgence, longer persistence of beneficials in the crops, etc.), as well as social and environmental costs and benefits[29].

[27] Cost of crop protection measures – Panel for the Future of Science and Technology (2021)
[28] (PDF) Exploring cost dominance between high and low pesticide use in French crop farming systems by varying scale and output mix (researchgate.net)
[29] https://www.ars.usda.gov/ARSUserFiles/4056/Naranjo%20et%20al.%20IPMEconomicsBookChapter.pdf

The demand on the final consumer's side

Concerns of citizens regarding environment, biodiversity and the use of chemical pesticides are increasing[30]. This drives the market and farmers towards more sustainable agricultural practices. Communication on the benefits of IBCAs (returns on investment, higher sustainability), and collective organisations and sharing (through associations and cooperatives) may further improve IBCA uptake in farmers' agricultural practices.

The development of organic farming and the effect it has on the demand for IBCA is also linked to consumer willingness to pay for quality food[31]. Industry associations pointed out that a Member States' sovereign wealth and consumers' spending capacities play a major role in the demand for higher quality food products. Consumer opinions on the 'goodness' of organic food are not equally aligned with actual purchase decisions, which largely depend on disposable income[32]. High disposable income means that consumers are more likely to afford more sustainable and high-quality food products. This in turn may push for more biological or organic production and therefore support more restrictive policies for chemical pesticides. The food market however remains volatile and the recent inflation across the EU and globally, also have an impact on consumer choice. This may factor into the augmentation of IBCA uses, even if most IBCA uses are within conventional production, often alongside chemical pesticides.

The lack of knowledge on IBCAs

On the side of farmers and advisors, lack of knowledge or expertise may lead to no use or the misuse of IBCAs, which may be counterproductive in the adoption of this solution in farmers' practices. For example, a study in 2020 showed that cider-apple farmers in Spain underestimate the importance of biological control and have misconceptions and knowledge gaps related to the interactions between natural enemies (especially arachnids and insects, with the exception of ladybugs) and pests. Developing farmers' knowledge regarding biological control and natural enemies would promote biological control in cider-apple orchards[33]. As for the general public, some Member States reported that public opinion and thus demand may be negatively impacted by the image of invertebrates on crops, and by the negative publicity of *H. axydiris*.

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[30] See for example European Citizens Initiatives "Save Bees and Farmers", "Ban glyphosate and protect people and the environment from toxic pesticides", PAN resources on the impacts of pesticides on children

[31] Li Shanshan, Kallas Zein, 2021, Meta-Analysis of Consumers' Willingness to Pay for Sustainable Food Products http://dx.doi.org/10.22004/ag.econ.314970

[32] Household income positively influences consumers' likelihood of buying organic food: Rimal, A.P., Moon, W. and Balasubramanian, S. (2005), "Agro-biotechnology and organic food purchase in the United Kingdom", British Food Journal, Vol. 107 No. 2, pp. 84-97. https://doi.org/10.1108/00070700510579162

[33] Martinez-Sastre et al., 2020, Farmers' perceptions and knowledge of natural enemies as providers of biological control in cider apple orchards https://doi.org/10.1016/j.jenvman.2020.110589

3.1.3.2 Focus on augmentative biological control

Augmentative biological control refers to the large-scale release or inoculation of natural enemies (parasitoids, predators or micro-organisms) that can be native or non-native species. With the use of non-native species, it does not aim to establish these species in the long run. Several techniques exist[34]:

- **Inundative biocontrol**: short-term release for crops with a short production cycle (e.g. nematodes, SIT).
- **Seasonal inoculative biocontrol**: for crops with a longer production cycle, establishment is made impossible by the natural climatic conditions (for instance for species that cannot survive winter), or by the removal in greenhouses of all possible natural habitat for the natural enemy at the end of a production cycle[35].

The European market focuses on augmentative biological control, which is a viable business model with companies selling mainly species native to the European Union

The EPPO Positive list (standard PM 6/03) counts 112 species that are considered "safe" and used in the EPPO region for augmentative biocontrol across countries (87 insect species, 17 arachnid species and 8 nematode species). This list refers to commercially available or officially used IBCAs that are either:

- Indigenous and widespread in part of, or the whole of, the EPPO region; or
- Established and widespread in part of, or the whole of, the EPPO region; or
- Used for at least 5 years in at least 5 EPPO countries (exceptionally fewer, if relevant crops, target pests or plants are present in <5 countries);
- And for which no adverse effects or only acceptable adverse effects have been reported.

In 2016, almost 40% of the income of the European companies originates from invertebrate biological control agents sold for control of thrips, another 30% for control of whitefly, 12% for control of spider mites, 8% for control of aphids, and the remaining 10% for control of various other pests[36].

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[34] van Lenteren, J.C., Bolckmans, K., Köhl, J. et al. Biological control using invertebrates and microorganisms: plenty of new opportunities. BioControl 63, 39–59. 2018. https://link.springer.com/article/10.1007/s10526-017-9801-4

[35] Marieke Busson, Julien Chetty, Marie-Hélène Robin, Jean-Noël Aubertot. 2019. Biocontrol : Definition. Dictionnaire d'Agroecologie, https://dicoagroecologie.fr/en/encyclopedia/biocontrol/

[36] van Lenteren, J.C., Bolckmans, K., Köhl, J. *et al.* Biological control using invertebrates and microorganisms: plenty of new opportunities. *BioControl* **63**, 39–59 (2018) https://link.springer.com/article/10.1007/s10526-017-9801-4#:~:text=Almost%2040%25%20of%20the%20income,other%20pests%20(Bolckmans%20K%2C%20personal

So far, most of the IBCA market corresponds to the use of insects and mites to control insect or mite pests in protected crops, i.e. vegetables, fruits and ornamentals grown under greenhouses. This is due to extensive environment control in greenhouses and the high incentive to use plant protection solutions which do not interfere with the use of hymenopteran pollinators. Most IBCAs used are predators (e.g. Predatory mites to control mites, whiteflies and thrips, or miridae to control thrips, whiteflies, aphids) or parasitoid wasps (van Lenteren 2000, 2012; van Lenteren et al. 2018). A few nematodes are also used in Europe, e. g. against a range of coleopteran and dipteran larvae and slugs.

A notable exception is the relatively large use of the micro-wasps of the genus *Trichogramma* to control the European corn borer *Ostrinia nubilalis* in maize (up to 25% of surfaces affected by this pest in France, i.e., 150,000 to 250,000 Ha).

Overall, IBCA use is characterized by a large number of products available but a low uptake of most of them. Only a few products have reached large market value and a use of a substantial proportion of crop surfaces. Some examples of the main IBCAs (in terms of market value) in Europe are provided in the table below:

Table 6 - Widely used organisms across the EU and intended targets

Biocontrol agent	Target
Aphidius & *Aphelinus* hymenopteran parasitoids	Aphids
Predatory mites (e.g. Amblyseius, Typhlodromus, Hypoaspis, Neoseiulus, Phytoseiulus)	Mites, thrips, whiteflies, flies
Parasitoid wasps (e.g. *Aphytis*)	Scale insects
Predatory Neuroptera (e.g. *Chrysoperla*)	Aphids
Predatory ladybirds (e.g. *Cryptolaemus, Adalia*)	Scale insects, Aphids
Predatory mirids and anthocorids (*Macrolophus, Orius*)	Whiteflies, thrips, Lepidoptera
Encarsia & *Eretmocerus* Hymenopteran parasitoids	Whiteflies
Trichogramma Hymenopteran parasitoids	Lepidoptera
Nematodes (Heterorhabditis, Steinernema)	Coleoptera, Diptera, slugs

All IBCAs cited in this table are used under protected conditions, except for *Trichogramma* which are used outdoors, on maize, and for a few marginal uses of *Chrysoperla* in other outdoor crops.

With regard to augmentative biological control of forest pests, augmentative releases of natural enemies to forests are very uncommon. This is more due to the low efficiency of this method in forests than prohibitive regulations. However, augmentative biological control is sometimes used to combat pests in forest nurseries.

Specific use of SIT

The insects used in the sterile insect technique (SIT), are not considered as part of the biocontrol market by IBMA. Their status is somewhat similar to that of classical biocontrol programmes, as they cannot be considered as simple commercial products and their use rely on business models mixing service and products. Initial exchanges with IAEA-FAO suggest that the use of SIT, although responding to an augmentative biocontrol logic, stands alone in terms of use and regulations. It is highly species-specific, using indigenous species (i.e. sterile individuals of the pest to be controlled), and presents a low risk of establishment of new strains (sterilization is not 100% effective, and a limited possibility of gene introgression remains). Release objectives can include eradication, containment (by establishing barriers of SIT to prevent their spread), prevention, and as part of suppression programs.

Insects are sterilized by γ-radiation with a dose that does not significantly impair the ability of the sterile males to fly, mate, and transfer sperm to wild females. As such, and with a sufficient sterilized-to-wild ratios, the proportion of fertile mating decreases. Therefore, SIT is best used at low population density of pests, and over entire ecosystems rather than specific crops (or herds of animals). This "area-wide approach" necessitates coordination over wide geographical areas, which sets conditions rarely met in Europe. SIT is currently very little used in the EU (uses were identified in only four Member States, see below).

The Valencia region (Spain) is one of the rare agricultural areas with large-scale farming activities in Europe where SIT is efficiently used. Some uses have been recorded in Croatia, who imports *Ceratitis capitata* from Spain and Israel since 2010 in support of an eradication program[37].

Production facilities in Europe are located in[38]:

- Spain: *Ceratitis capitata*, or Mediterranean fruit fly. Production capacity of 500 million insects per week, currently working at half-capacity
- The Netherlands: *Delia antiqua*, or onion maggot. Small production used to treat 5000 ha of onion.
- Other production facilities related to non-plant health use are located in Spain, Italy (production of Asian tiger mosquitoes, combined

[37] DIR-SIT - IAEA - HISTORY OF TRANSBOUNDARY SHIPMENTS OF STERILE INSECTS
[38] Directory of SIT facilities (IAEA) Site Pages - Default (iaea.org)

capacity of 1,25 million per week) and Slovakia (tsetse flies for export, capacity of 0,3 million insects per week)

- France has also started several programmes to test SIT strategies against the codling moth *Cydia pomonella* and mosquitoes and supports R&D of new SIT techniques against the invasive fruit fly *Drosophila suzukii*.

The main identified uses are reported below:

Table 7 - Overview of the main recent uses of SIT for plant protection in the European Member States

	Cyprus	France	The Netherlands	Spain
Ceratitis capitata	X	X		X
Cydia pomonella		X		
Bactrocera dorsalis		X		
Delia antiqua			X	

While some examples do exist, the use of SIT is still extremely low in terms of proportion of crop surfaces covered in Europe. This is due to the fact that this technique needs to be used in complementarity with other control methods, can only be used in very specific conditions, and faces specific challenges in comparison to other types of invertebrate biological control:

- Technical feasibility: as the sterile insects belong to the pest population, the selected species need to be released at a mature but not damaging stage of growth. Production and use of SIT is also very technical (definition of spatial and temporal ecological parameters of the target population, insect quality, rearing of mainly male insects, establishing genetic sexing strains, etc.).
- Economic feasibility: the technique is costly and necessitates significant investments in research and development. In Europe, this has impacted production structures, which are generally publicly owned research centres (Centro Agricoltura Ambiente "Giorgio Nicoli" in Italy, Bioplanta de Insectos Estériles in Spain). Development of SIT and commercial production will necessitate to globally harmonize quality control procedures for production, processes, and products.

3.1.3.3 Focus on classical biological control

Classical biological control refers to the intentional introduction and permanent establishment of an exotic biological agent for long-term pest management[39]. The species introduced is a non-native species with the capacity to regulate the pest targeted. It is often used when an exotic pest has been imported without its natural enemies, to introduce this natural enemy in the territory and control the pest. In case of neoclassical biological control, the introduction is based on a novel association of the pest and a natural enemy species (with no previous coevolutionary interaction).

As the aim is to establish a new species in a specific territory, this might require a long process of research, selection, risk-assessment, quarantining, release methodology, etc. This type of biological control is more generally state-funded and thought to be less commercially viable.

Classical biological control introductions used to be frequent, but restrictive regulations have reduced the number of introductions.

For classical biological control, a retrospective approach can be adopted to better understand the main successes of the establishment of new species in Europe. In the past, the introduction and establishment of classical biological control strongly relied on public research and development. No products are currently commercially available and commercial perspectives are lower than for augmentative biological control as there is no business model replicable from one year to another (once the species is established in the environment, there will be no further sale of IBCAs).

EPPO also lists 42 insect species safely used for classical biocontrol in Europe. It gathers information on IBCAs for classical biological control, which is found at least 5 years after release, to be successfully established in part of, or the whole of, the EPPO region.

In total, around 650 introductions of biocontrol agents can be identified in the EU. Italy, France, Spain and Greece account for more than 50% of these introductions. Out of these 650 introductions, around 200 resulted in the establishment of the agent, and 130 significantly impacted the targeted pests[40] . Although the number of introductions has drastically decreased since the 2000's, recent successes have been obtained in Europe using this strategy. For example, the Asian parasitoid *Torymus sinensis* has been used in the last 10 years against the invasive chestnut gall wasp and successfully managed its damages (see section on forestry below).

Several classical biological control programs were reported by the national competent authorities surveyed, and are listed below:

[39] OCDE Guidance for Information Requirements for Regulation of Invertebrates as Biological Control Agents (IBCAs) (researchgate.net)

[40] Base de données BIOCAT, analysed dans Seehausen ML, Afonso C, Jactel H, Kenis M. 2021. Classical biological control against insect pests in Europe, North Africa, and the Middle East: What influences its success? NeoBiota 65: 169–191. doi: 10.3897/neobiota.65.66276

Table 8 - Classical biological control programs reported by National Competent Authorities

Year	Country	Biocontrol agent	Target species and crop
2006-2008	France	Cibdela janthina	*Rubus alceifolius* (invasive weed of forest edges and open areas in La Réunion)
2012-2015	Greece	Neodryinus typhlocybae	*Metcalfa pruinosa* (various crops, mainly Actinidia chinensis)
2012	The Netherlands	Stenopelmus rufinasus	Azolla filliculoides (aquatic systems)
Since 2012	Slovenia	Aphidoletes aphidimyza, Aphidius matricariae	Aphididae, pepper
		Neoseiulus cucumeris	Thysanoptera, pepper
		Encarsia formosa, Macrolophus pygmaeus	Trialeurodes vaporariorum, tomato
		Steinernema kraussei, Heterorhabditis bacteriophora, Steinernema carpocapsae	Otiorhynchus sulcatus, ornamentals
		Steinernema carpocapsae and Steinernema feltiae	Steinernema carpocapsae and Steinernema feltiae
		Steinernema feltiae	Sciaridae, ornamentals
		Heterorhabditis bacteriophora	*Melolontha*, *Amphimallon solstitiale* - greens, parks, golf courses
2014	France	Allotropa burelli	*Pseudococcus comstocki,* apple orchards, ornamental trees
2010-2011	France	Torymus sinensis	

Year	Country	Biocontrol agent	Target species and crop
2014-2017	Croatia		Chestnut wasp Dryocosmus kuriphilus (Yasumastu) - chestnut
2018-2022	Greece		
before legislation change	Italy		
2018	Spain	Tamarixia dryi	Trioza erytreae, Citrus
2019	The Netherlands	Aphelara itadori	Fallopia japonica, ornamentals
2020-2022	Italy	Trissolcus japonicus	Halyomorpha halys, orchards
2021-2022	Italy	Ganaspis brasiliensis	Drosophila suzukii, berries
To be launched in 2022	France	Mastrus ridens	Cydia pomonella, apple
To be launched in 2022	France	Ganapsis brasiliensis	*Drosophila* suzukii, berries

Classical biological control in forestry

Forests within the EU and around the world are increasingly affected by exotic pests that sometimes become invasive. Outside of the EU, such exotic pests are often combated using classical biological control, as this type of biocontrol is especially suited for perennial systems where introduced IBCAs have better opportunities to establish and contribute to permanent pest control than in annual systems. In fact, at the global scale, the majority of all classical biocontrol initiatives have been recorded from forest systems (Reviewed by Kenis et al. 2017). In this perspective, the EU stands out with remarkably few cases of classical biological control.

The best-known European examples of classical biological control of forest pests include releases of the monospecific predatory beetle *Rhizophagus grandis* to control the great spruce bark beetle (*Dendroctonus micans*) in France (Grégoire et al. 1984) and the UK (Fielding and Evans 1997). The populations of the bark beetles normally drop below the economic injury level within 10 years after *R. grandis* releases (Fielding & Evans 1997) indicating that the biocontrol is effective.

A more recent example is the release of the Asian parasitoid *Torymus sinensis* to control the invasive chestnut gall wasp (*Dryocosmus kuriphilus*).

This parasitoid was released in Italy in 2005 (Quacchia et al. 2008), France 2011 (Borowiec et al. 2014) and Croatia, Hungary, and Slovenia 2014 (Matošević et al. 2015). The releases of the parasitoid are considered rather successful, showing that classical biological control can be a useful tool in forest systems, although negative effects on biodiversity have been recorded[41].

Classical biological control of weeds is mostly under development outside of the Union

Many examples show that classical biological control can be used to control exotic weeds. However, almost all of these examples are from non-EU regions.

The only known example of intentional introduction of exotic IBCAs to combat weeds in the EU is from Portugal, where the gall-forming wasp *Trichilogaster acaciaelongifoliae* (endemic to Australia) was released in 2015 to control the environmental weed *Acacia longifolia* (Marchante et al. 2017). If this attempt is successful in Portugal, we are likely to see initiatives to release the same wasp in other Mediterranean Member States where *Acacia longifolia* is a problematic weed.

In addition, some exotic IBCAs have been accidentally introduced and established in the EU – for example, the azolla weevil *Stenopelmus rufinasus* (from Florida) was unintentionally introduced in the 1920s together with its weed host plant *Azolla filiculoides* to Belgium and Italy and has since spread over parts of central and southern Europe (Shaw et al. 2004). Likewise, the ragweed leaf beetle *Ophraella communa* was accidentally introduced in Italy and shows strong potential to control the common ragweed *Ambrosia artemisiifolia*.

Shaw et al. (2016) highlight a positive change in attitude towards these exotic IBCAs within the EU, arguing that the future of classical biological control of weeds within the EU is probably bright, despite current regulations. Sheppard et al. (2006) argued that the most important factors obstructing classical biological control of weeds in the EU are the legislative and regulatory framework for biocontrol as well as a lack of financial resources. The same authors further proposed 13 weed species that would be particularly suitable for classical biocontrol in the EU.

Table 9 - 13 environmental weed species proposed by Sheppard et al. (2006) to be suitable for classical biological control using exotic IBCAs. Some of these IBCAs have already been reported as accidentally introduced to some parts of the EU.

Common weed name	Latin name	Exotic IBCAs
Butterfly bush	*Buddleja davidii*	*Cleopus japonicus*

[41] https://planthealthportal.defra.gov.uk/assets/uploads/Risk-Analysis-T.-sinensis.pdf

Common weed name	Latin name	Exotic IBCAs
		Mecyslobus erro
Japanese knotweed	*Fallopia japonica*	*Lixus* sp.
		Aphalara sp.
Silver wattle	*Acacia dealbata*	*Trichilogaster acaciaelongifoliae*
Tree of heaven	*Ailanthus altissima*	*Eucryptorrhynchus brandti*
		Cryptorhynchus chinensis
		Orthopagus lunulifer
Water fern	*Azolla filiculoides*	*Stenopelmus rufinasus*
		Pseudolampsis guttata
Black locust	*Robinia pseudoacacia*	*Phyllonorycter robiniella*
		Obolodiplosis robiniae
		Megacyllene robiniae
Common ragweed	*Ambrosia artemisiifolia*	*Zygogramma suturalis*
		Epiblema strenuana
Silverleaf nightshade	*Solanum elaeagnifolium*	*Leptinotarsa texana*
		Leptinotarsa defecta
		Orrina phyllobia
Groundsel-bush	*Baccharis halimifolia*	*Hellinsia balanotes*
		Megacyllene mellyi
		Rhopalomyia californica
		Trirhabda bacharidis
Floating pennywort	*Hydrocotyle ranunculoides*	*Listronotus elongatus*
Water primrose	*Ludwigia grandiflora*	*Lysathia ludoviciana*
Parrot's feather	*Myriophyllum aquaticum*	*Lysathia* sp.
		Listronotus marginicollis
Canadian goldenrod	*Solidago canadensis*	*Eurosta solidaginis*
		Gnorimoschema gallaesolidaginis
		Phaneta formosana
		Epiblema scudderiana

3.1.3.4 Use of IBCAs in combination or substitution of (chemical/ non-chemical) pesticides

Substitution may be possible in some cases

Current pesticide uses targeting emerging exotic pests in EU (but also pre-emptive biocontrol actions) as well as low-threshold pests in crops e.g. like ornamentals, or when in need to control certain insect vectors of plant viruses, could be substituted by IBCAs. IBCAs are often already considered as substitutes to pesticides in the Member States: 13 Member States (and one regional authority in Belgium) consider IBCAs as "non-chemical alternatives" in the Comparative Assessment conducted at national level (Art. 50 of Regulation 1107/2009). Only 3 Member States do not, and 12 Member States did not have information on the question.

Evidence is accumulating that IPM strategies relying on IBCAs can ensure production under greenhouse with little or no use of chemical pesticides.

Data from Spain following isofenphos-methyl crisis[42] in 2006 triggered a rapid shift to biocontrol. Surfaces using biocontrol increased from 129 ha in 2005 to 17,000 ha in 2009[43] and now reach approximately 26,000 ha[44]. Qualitative discussions with MS reveal that the common use of IBCAs under greenhouse has reached most parts of Europe. Although the relative use of IBCAs and pesticides is difficult to estimate under greenhouse throughout the EU, most if not all greenhouse surfaces use at least a few IBCAs.

The biocontrol industry views the main pros and cons of IBCAs as follows:

Table 10 - Summary of the pros and cons of chemical pesticide use vs. IBCA use

	Pros	Cons
IBCA use	▸ Self-regulating, once the pest is controlled the IBCA populations drop back to natural levels or disappear ▸ Populations can be built up using food supplements ▸ Bio-control organisms are often specific in their action ▸ Safe for users ▸ Popular among consumers ▸ Mostly safe for crops ▸ Residue free ▸ No PHI – so harvesting can be done daily within greenhouse optimising produce quality	▸ Specific conditions required ▸ Application requirements ▸ Often preventive use, which requires to anticipate
Pesticide use	▸ Often quick action ▸ Ease of use ▸ Efficacy	▸ Residues ▸ Phytotoxic effects on crop (photosynthesis reduction)

[42] See also 3.1.3.1 Main factors that differentiate the use patterns across the Member States, or the paper "Green Pest Management Revolution: An Opportunity That Arose from a Food Safety Alert" (mdpi.com)
[43] Lozano et al. 2010. Evolution of the phytosanitary control system in the intensive horticulture model of high yield in Almería (2005-2008). Journal of Food, Agriculture & Environment Vol.8: 330-338.;
[44] https://www.juntadeandalucia.es/organismos/agriculturaganaderiapescaydesarrollosostenible/servicios/actualidad/noticias/detalle/284551.html

	Pros	Cons
		▸ Contamination of soil and water ▸ Persistence (often for decades) ▸ Pests may become resistant to PPPs ▸ Side-effects to beneficial organisms such as pollinators, predators and parasitoids ▸ Re-entry periods/ post-harvest intervals ▸ Requirement for operator safety measures and training

Source: IBMA Global

Combination can also be an option…

In many agricultural scenarios, predominantly in IPM managed crops, both IBCAs and authorized pesticide uses (chemical, but also microorganisms, semiochemicals, plant products) co-exist, alongside other types of biological control (conservation biological control). The combined use of IBCAs and pesticides requires a specialized understanding of the ecological system of the crop to make the different control methods work synergistically and/or sequentially. Growers have to be trained and will often require advice from the companies producing either of both natural enemies and other pesticides. Quite often these companies offer a pack for the farmer: Representatives of scientific organisations pointed that IBCA producing companies and their advisory services have recommendations ready for combined use of IBCAs and authorized pesticides, mainly for protected crops, vineyards, orchards and field vegetables.

An example of IBCAs and pesticides combination exists in citrus plantations: the use of paraffin oils and/or pheromone traps for the control of the red scale *Aonidiella aurantii* can be made compatible with the releases of the parasitoid wasp *Aphytis melinus*. Likewise, the use of sterile males of the medfly *Ceratitis capitata*, which is combined with other control methods (pesticide applications, mass-trapping, conservation biological control in different fruit crops (including citrus). The compatibility relies on separation, either spatially or in time[45].

[45] IOBC-WPRS survey

Compatibility is yet challenging

However, compatibility between IBCAs and chemical pesticides is very low and selective chemicals are not often available. For instance, whitefly control in glasshouse tomatoes can be reached through a combination of many IBCAs: *Macrolophus pygmaeus*, *Encarsia formosa*, *Eretmocerus eremicus*, *Amblyseius swirskii*, *Amblyseius montdorensis*. However, farmers may use chemical control to prevent other pests from inhabiting the crop (e.g. the invasive leaf miner *Tuta absoluta*), leading to adverse effects on IBCAs targeting whiteflies (e.g. sublethal effects, see Desneux et al. 2007, Annu Rev Entomol) and thus leading to failure in whitefly control by released IBCAs.

As the use of chemical products is mostly reduced when a product is banned, or when a pest develops resistance, an approach to substitution on a use-by-use basis will be limited. Still, a few empty uses have been identified, for which IBCA solutions are currently being developed, or are starting to arrive on the market:

- In Cyprus, *Cales noacki* was introduced in 1998 to control the woolly whitefly *Aleurothrixus floccosus,* for which currently no phytosanitary solution exists. However, this species has been removed from the EPPO list due to reported non-target effects. Today, *C. noacki* is not reared but every few years a survey is conducted to record its presence in citrus areas infested with whiteflies. In Germany, the Julius Kühn-Institute for Biological Control, is currently involved in the EUPHRESCO-project "Preparedness in biological control of priority biosecurity threats". Within this project, potential IBCAs of priority quarantine pests are considered (e.g. *Bactrocera* sp., *Popilia japonica*, *Agrilus planipennis*, *Anoplophora* spp. and others) and decision support schemes for risk assessments are developed.
- The *Halyomorpha halys* issue is an example of a phytosanitary problem that has not been able to be solved with treatments with insecticides or with other systems including insect nets, for which the path of biological control has become mandatory. R&D is ongoing, based on the use of egg parasitoids of the genera *Trissolcus* and *Anastatus (among those, Anastatus bifasciatus* is currently on the market).[46].
- Control of aphids is a challenge in many crops. Hoverflies and lacewings are among the naturally present IBCAs of aphids in the field. Modification of the habitats, active release of flies and manipulation of fly behaviour might increase the efficacy of hoverfly application.
- Long-legged flies are the most important natural enemies of spruce-forest damaging bark beetles. Better knowledge on the presence,

[46] https://doi.org/10.3390/insects12050464

identity, and behaviour of the flies are key for their exploitations as IBCAs and is facilitated through the development of an attractant.

- Slugs are an increasing problem in agriculture and their chemical control is costly. Nematodes are potential IBCAs of slugs (the nematode Phasmarhabditis is on the market) but better knowledge of their establishment and new innovative ways of application might increase the efficiency of their control.

Replacement of pesticides by integrating IBCAs in systems developed for the use of chemical pesticides is not the right approach

Overall, and despite previous works to study compatibilities between pesticides and IBCAs (summarized and updated by IOBC), there is consensus among the experts involved in this study that research on pesticide substitution with IBCAs, in order to integrate IBCAs in cropping systems, is likely to be a good idea only at first sight: it actually implicitly encourages the integration of IBCAs in systems that have been created and developed for the use of chemical pesticides, with little mobilization of agroecological levers that enable pest prevention and regulation. It leads to situations where practitioners try to integrate IBCAs in systems that are mostly unfavourable to their wide and efficient use, and ultimately contributes to the apparent inefficacy or inefficiency of IBCAs. It seems that the best examples of IPM packages successfully including IBCAs are found in systems in which chemical pesticides could not be used (following a ban or following pesticides having become inefficient) and where new systems had to be designed (e.g. the situation observed in Almeria greenhouses in the 2000's).

In terms of trajectories used to foster the use of IBCAs, transitions aiming at decreasing the use of chemical pesticides by introducing progressively IBCAs and other agroecological levers are not the right approach. Civil society organisations also insisted that a reimagination of cropping systems and profound system changes will likely be more efficient in speeding up the development of biocontrol.

3.1.4 Potential for development of the IBCA market

Uses regarding augmentative biological control should continue to grow in high-value systems

Representatives of the industry highlighted that companies consistently invest in the R&D of high-value systems such as greenhouses (now, the industry estimated that one to three new IBCAs enter the market in the European Union each year). To reflect the dynamism of R&D within the industries, it can be highlighted that in 2019 in Europe, 208 biological control products (not differentiating macrobials, microbials, semiochemicals and natural substances) were in the IBMA companies'

pipeline, with half having been submitted for registration (IBMA 2021 Market Survey). Aside from the development of new products, R&D also happens at the level of public and private partnerships, and the development of solutions to facilitate IBCA use (e.g., drone aerial spraying[47], which is faster and less labor-intensive than manual application).

The number of uses should continue to increase within the next years, answering the demand from the market of alternatives to chemical pesticides (as mentioned before). As for the current uses, the development and R&D of IBCAs is also strongly stimulated by the ban of some active substances at European level or the arrival of new pests in Europe. Products will also continue to be accompanied by services (advice, monitoring, decision-support tools) that should take profit from technological advances in the fields of digital tools, diagnostic capacities, etc. Pre-emptive biocontrol actions may also rise (identification, selection, risk assessment and potential pre-approval for release of selected IBCAs prior to the arrival of the target pest in a given new area, or inundative biocontrol for known pests referred to as "standing army" biological control by the industry). This will strengthen the position of IBCAs in greenhouse systems, which will progressively help decrease the use of pesticides that are currently still used.

Outside of greenhouses, specific situations of high-value crops grown in open field, such as vineyards, may also host new IBCA uses, for example *Trichogramma* against *Lobesia botrana* or, a mite genus new to biocontrol which proves able to suppress mildew.

Finally, concerns regarding intellectual property seem to be minor for the industry: while species cannot be patented, the *use* of species in particular processes, or techniques linked to production processes can be patented. Representatives from the industry reported an increase in such intellectual property applications by IBCA-rearing and selling companies.

Experts have limited expectations towards IBCAs in non-protected crops although a few exceptions may continue to punctually create success-stories.

In cash crops or open-field vegetables and fruit orchards, perspective of a massive increase of uses is considered unlikely by experts. Successes are expected to remain exceptions, like *Trichogramma brassicae* on maize (or *Trichogramma* and *Cotesia* on sugarcane in Brazil), but such exceptions may prove to be stimulating success stories. The reason for this comes down to the incompatibility of IBCA mass-rearing costs when compared to the quantities of IBCA individuals that would be necessary to achieve pest control in open-field systems and the crop protection financial capacities of growers in these crop sectors. In addition, most application methods of

[47] https://www.uaviq.com/en/biocontrol/

IBCAs are costly, which further reduces competitiveness of IBCAs over chemical pesticides (that are easily sprayed). Game changers may be next-generation diagnostic and decision-support tools that boost the efficacy and efficiency of inoculative introductions (although this may be hindered by strong dispersal capacity of IBCAs released, this implying release plans at large scales for being effective). However, to our knowledge, short- or mid-term perspectives of research advances are not expected to specifically target IBCAs, although they will have a positive impact on their uses. For instance, possible IBCA developments showing the highest potential involve the management and/or manipulation of farmland habitats (e.g. development of temporary ecological structures) that enable IBCAs to sustain their populations while pests are absent or at low densities. These could be coupled with the development of IBCA release systems to increase further biocontrol services provided by IBCAs in open field systems.

Classical biological control and conservation biological control development perspectives are limited as business models but can develop through public-private partnerships.

Industries and most public bodies in MS tend to restrict market analyses and perspectives to augmentation biological control. This is likely because most, if not all, industrial players in Europe generate sales by selling IBCAs as commercial products using business models that look like that of chemical pesticides (although services associated to products are often more important in the biocontrol sector) and favour organisms to be used in the closest possible way to a pesticide: in the largest possible quantity and with the fastest possible action against the target (while most IBCAs are costly to produce and display the potential to regulate pest populations over time, but more rarely at short term).

As discussed in the augmentation section, it is likely that such intended use of IBCAs will continue to grow slowly in most cropping systems because the intrinsic features of IBCAs clearly depart from those of chemical pesticides.

By contrast, it is likely that industries and policy makers will neglect the potential of conservation biocontrol (that may favour resident IBCAs but also the ones used in augmentation biocontrol) and classical biocontrol. From a scientific point of view, this presents a paradox because conservation biocontrol and classical biocontrol display a remarkable history of success in relation to their often-outstanding cost–benefit ratios (e.g., from 1:50 to > 1:3000 for classical biocontrol programs performed in New Zealand and Australia in the past few decades) (Page et al. 2006; Hardwick et al. 2016). Fear-related risks implied by the use of exotic organisms in classical biocontrol may be an explanatory factor but it is probably not the only one, as conservation biological control is not much more developed in terms of explicit implementation. A hypothesis accounting for this situation is that these strategies using IBCAs do not have established and recognized business models, especially in Europe.

Biocontrol industries see conservation and classical biocontrol as economically unviable activities that should be handled by the public sector, because these activities do not rely on inputs that can be recurrently sold to farmers in large areas. These strategies may however become activities handled by other types of private actors, with risk-taking and investments shared between growers, food chain value actors and public bodies. Success stories already exist (e.g. the Coöperatie Collectief Hoeksche Waard in the south of Rotterdam that implemented a conservation biocontrol programme allowing a consistent 90% decrease in insecticide use in potatoes and wheat). Public efforts should foster the exploration of possible business models and organizational innovations that will enable the emergence of a private sector exploiting conservation and classical biocontrol, as these would be an enormous source of IBCA uses for a wide range of crop sectors.

Autocidal control (including SIT) is not highly prioritized, but contains perspectives for development

Perspectives of uses of autocidal control methods, such as the Sterile Insect technique, probably fall in between the situation of augmentation and conservation/classical biocontrol. SIT is known to generate recurrent sales and rely on massive releases of IBCAs. In that sense, it attracts more interest from the industry. However, business models applicable to SIT remain very different to that of augmentation biocontrol and in many cases, SIT has been considered as an activity to be handled by public organisations. Consequently, its use across Europe is mostly limited; the use of SIT has been identified only in four Member States: Croatia, France, the Netherlands and Spain.

Recently, French research institutes, extension services and public authorities (notably within the Ecophyto Plan) have launched several programmes attempting to produce proofs of concept on new uses of SIT (*Cydia pomonella*, *Ceratitis capitata* and *Bactrocera dorsalis* in orchards, *Drosophila suzukii* in strawberry and orchards). If successful, and if sustainable business models can be implemented, SIT may also be a source of new uses outside greenhouses for IBCAs.

Development of IBCAs within holistic IPM strategies

IBCAs are typically developed as stand-alone elements in plant protection. However, optimal IPM strategies ideally combine multiple plant protection elements which synergistically improve each other's function (Stenberg 2017 [48]). Efforts to optimise biocontrol within broader IPM strategies are so far mainly developed for resident IBCAs (conservation biological control) in arable fields and forests, while the progress for added IBCAs (augmentation

[48] Stenberg 2017, A conceptual framework for integrated pest management. Trends in Plant Science 22: 759-769

and classical biocontrol) still is limited in this respect. Thus, there is still room for considerable development of augmentation biocontrol in this area.

Most examples of holistic IPM strategies where IBCAs constitute one element within a bouquet of many elements are based on efforts to maximise biodiversity to improve resilience. High biodiversity can be obtained at the level of forests, landscapes, or individual fields using *e.g.*, crop rotation (Rusch et al., 2013)[49], mixed forests (Klapwijk and Björkman 2018), intercropping (Brandmeier et al. 2020)[50], hedge rows (Gontijo 2019)[51], flower strips (Cahenzli et al. 2019)[52], and cultivar mixing (Dahlin *et al.*, 2018; Musaqaf *et al.*, 2022). Such efforts often have direct negative effects on pests, while at the same time promoting IBCAs and pollinators.

Another rapidly growing approach involves breeding for plant resistance traits that are compatible with biocontrol (Peterson *et al.*, 2016)[53]. Recent research shows that forest trees, grain crops, and horticultural crops typically have resistance traits that either promote IBCAs or are disadvantageous to IBCAs. Breeding efforts to optimise those plant traits to promote (or at least not disfavour) IBCAs are ongoing for *e.g.*, willow trees, strawberry, and barley.

Unfortunately, the research fields underlying the development of resident and added IBCAs have developed separately from one another for many decades. Much of the advances made for resident IBCAs (conservation biological control) in these areas could be implemented for added IBCAs (mainly augmentation biocontrol). Mutual cross-fertilization of these areas holds strong potential to improve the development of IBCAs

The Nagoya Protocol may negatively impact the R&D and the introduction of new products

The Nagoya Protocol, a supplementary agreement to the Convention on Biological Diversity, came into force on 12 October 2014. Its goal is to provide a framework for the effective implementation of the fair and equitable sharing of benefits (ABS) arising out of the utilization of genetic resources, which includes biological control agents. Countries have sovereign rights over the genetic resources in their territory and access to these resources can be regulated by mutual agreements, covering the fair sharing of the benefits that arise from this biological material. This may negatively affect commercial uptake of IBCAs: 58f58s additional step in the research and development of new IBCAs could hinder the development of the sector in the European Union.

The IOBC considers that the main benefit that arises from the use of genetic material for invertebrate biological control is the reduced use of pesticides

[49] https://doi.org/10.1111/1365-2664.12055
[50] https://doi.org/10.1016/j.baae.2021.02.011
[51] https://doi.org/10.1016/j.biocontrol.2018.10.014
[52] https://doi.org/10.1016/j.agee.2019.03.011
[53] Knowledge sharing, cooperative research in source countries and transfer of production technology to

for the benefit of farmers and consumers, especially when exotic species are mostly used for classical biological control, sustained by governments and universities. A guide for best practices for the use and exchange of invertebrate biological control genetic resources was subsequently developed by the IOBC: it includes knowledge sharing, collaborative research with source countries and production technology transfer to source countries [54]. Additionally, common efforts could be made at the European level to harmonize access and benefit sharing agreements with third countries.

3.1.5 Expected benefits and negative impacts on biodiversity and food safety

NB: the potential impact on the quantitative targets for the reduction of use of pesticides outlined in the F2F strategy is analysed under section 4.2.2.1

Benefits of biological control agents are well-established

Between 20-40% of global crop production are lost to pests annually and each year, plant diseases cost the global economy around US$220 billion, and invasive insects cost around US$70 billion[55]. Controlling pest and diseases on crops is a necessity in economic terms and for food security. Chemical pesticides can reduce crop losses; however, they may cause important damage to the environment and human health.

In comparison to chemical products, pest control with IBCAs presents various advantages:

- They are more environmentally friendly as they cause no pollution (no chemical residues) and affect only specific species, thus limiting the impacts on biodiversity especially in comparison to non-specific chemical insecticides for example (some risks for biodiversity could however still exist and are described in the next section); when biocontrol with IBCAs is successful, it may be beneficial for native species. In 2010, a review of 70 cases of classical biological control showed that biological control often has positive effects on the protection of biodiversity in 98% of the projects, and classical biological control against insects (21 projects) provided benefits to protection of biodiversity in 81% of the projects in the meta-analysis[56].
- IBCAs also present a low likelihood of resistance-building amongst targeted organisms and decrease the risk to conduct to failures in pest control;

[54] Mason, P.G., Cock, M.J.W., Barratt, B.I.P. *et al.* Best practices for the use and exchange of invertebrate biological control genetic resources relevant for food and agriculture. *BioControl* **63**, 149–154 (2018). https://doi.org/10.1007/s10526-017-9810-3

[55] Food and Agriculture Organisation, 21: https://www.fao.org/news/story/en/item/1402920/icode/

[56] R.G. Van Driesche et al. / Biological Control 54 (2010) S2–S33

- They will reduce the risk of plant protection on human health in comparison to the negative impacts on the health of users (farmers and field workers) as well as of consumers following the presence of chemical residues in food products;
- IBCAs could be a solution where no other alternatives are available, especially in organic farming or to support the development of Integrated Pest management strategies;
- They may be, in certain situations and when commercial products are well established, cost-effective. In addition, for classical biological control, it is self-perpetuating or self-sustaining and therefore permanent.

Potential theoretical negative impacts on biodiversity (risk of damage to surrounding ecosystems and established organism relationships) are real, although they have so far remained limited

Directly affecting species on the same trophic level, IBCAs may increase competition between invertebrate predators, causing displacement or interferences within established food webs, which may decrease the amount of biodiversity within an environment[57]. Historically, the use of generalist biocontrol agent species has generated a few but famous cases of unintended impacts. The most recent case is the ladybird *Harmonia axyridis*, initially introduced for classical biocontrol in the USA, and then sold worldwide as an augmentative biocontrol product. It later became a worldwide invader, and which has been suspected to be involved in decreases in the abundance of certain native ladybirds (including in Europe). According to EPPO, the species is currently recognised as damaging for European biodiversity as it has a wide host range across many taxonomic groups with a strong capacity for natural spread, and is known to attack non-target prey, including some beneficial species. This is mainly due to the nature of the ladybug: its feeding habits, climatic adaptability, high degree of phenotypic plasticity, effective chemical and physical defence strategies and good dispersal abilities contribute to its high establishment potential (van Lenteren et al. 2008). An article in the journal BioControl titled, "Intraguild predation involving *Harmonia axyridis*: a review of current knowledge and future perspectives"[58], describes the success of this insect, along with the threat that *H. axyridis* poses to biodiversity. The authors of this study describe how *H. axyridis* served as an effective biocontrol agent against aphids and other hemipteran pests, evidence suggests that the introduction of this invertebrate in 2004 caused the decline of some native coccinellid species due to their, "superior competitive ability and status as an intraguild predator". Replacement of native coccinellid species in the EPPO region could thus be expected.

[57] Barratt, B. "Assessing safety of biological control introductions." Perspectives in Agriculture, Veterinary Science, Nutrition and Natural Resources 6.042 (2011)

[58] Pell, J.K., Baverstock, J., Roy, H.E. et al. "Intraguild predation involving Harmonia axyridis: a review of current knowledge and future perspectives." BioControl 53, 147–168 (2008). https://doi.org/10.1007/s10526-007-9125-x

Furthermore, this article introduces the concept of guild diversity, which is the diversity within the group of species that utilizes the same kinds of resources in comparable ways. The authors state that, "Declines in guild diversity as a result of introduction of *H. axyridis* could, therefore, reduce the resilience of pest suppression in the long term.". Formerly listed as a successfully introduced classical biological control agent, *Harmonia axyridis* has been removed from the EPPO list PM 6/3.The case of *H. axyridis* is the most salient example of recorded negative consequences on biodiversity following the introduction of an IBCA on biodiversity and was mentioned by several Member States in the consultation. However, based on the scientific information available, this did not lead to the disappearance of any local species.

Some cases of negative impacts on plant health were also reported but are not as consistent across Europe. For example the predatory bug *Nesidiocoris tenuis,* although successfully used as an IBCA in several Member States (for example Spain, Greece, Belgium or Hungary), negatively affected the tomato greenhouses in the Finnish Osthrobotnia region. *N. tenuis* is an arthropod that predates pests but also feeds from the plant. Plant feeding behaviour in this species is variable. This species is generally highly beneficial, but it was shown in Finland to cause significant losses of tomato yield. It even led to the use chemical pesticides to control its populations, threatening IPM programmes[59]. The problem was more important in year-round tomato greenhouses because *N. tenuis* could install on the long term as its reproductive cycle was not broken in wintertime in greenhouses. This led to the establishment of a regulatory system in Finland and the use of this organism is now forbidden.

Negative side effects of the introduced parasitoid *Lysiphlebus testaceipes* were also reported[60], which led to the removal of the species from the safely used list (Appendix 3 of EPPO PM6/3).

Apart from the example of *Harmonia axyridis*, the introduction of IBCAs seems to have rarely led to negative consequences for biodiversity. A study by van Lenteren et al. in 2006 reviewed over 5000 introductions over the past 120 years of 2000 exotic arthropod agents for control of arthropod pests in 196 countries or islands and showed rare negative environmental effects: Less than 1% appears to have caused population-level effects in nontargets species (0,5% for classical biological control against insects and 0,7% against weeds), and only 3% to 5% may have caused some smaller

[59] https://onlinelibrary.wiley.com/doi/abs/10.1111/jen.12789

[60] Lumbierres B., Starý P., Pons X., 2007. Seasonal parasitism of cereal aphids in a Mediterranean arable crop system. Journal of Pest Science, 80: 125-130.
Pons X., Lumbierres B., Starý P., 2004. Expansión de Lysiphlebus testaceipes (Cresson) (Hym., Braconidae, Aphidiinae) en el Noreste dela Península Ibérica. Boletín de Sanidad Vegetal. Plagas, 30: 547-552.34
Starý P., Lumbierres B., Pons, X., 2004. Opportunistic changes in the host range of Lysiphlebus testaceipes (Cr.), an exotic aphid parasitoids expanding in the Iberian Peninsula. Journal of Pest Science, 77: 139-144

effects. Augmentative biological control had no population effects in non-target species, but higher percentage of smaller effects[61].

However, it should be underlined that:

- Theoretical risk for biodiversity remains high, knowing that only one case of uncontrolled introduction of a species is sufficient to disrupt ecosystems;
- In addition, the available data regarding post-release monitoring are limited (see section 3.2.1). More and more methods for assessing the impact of the release of species are being developed and may reveal blind spots in anterior research.

Expected impacts on food safety are very positive

Although the literature suggests that the introduction of non-native invertebrates can be detrimental to biodiversity, IBCAs have clear benefits in terms of food safety. In a journal article from the journal of BioControl titled, ""Biological control using invertebrates and microorganisms: plenty of new opportunities" the authors describe the multiple facets of augmentative biological control, and its potential as an alternative to conventional farming. The authors stated that augmentative biological control is not only healthier for farm workers and for people living in farming communities, but also resulted in "a healthier product and reduced pesticide residues [well below the legal Maximum Residue Levels (MRLs)]" (van Lenteren et al.). This same article describes some accomplishments within augmentative biological control. For example, in greenhouses in Spain, augmentative biological control allowed for the "virtually complete replacement of chemical pesticides by predators (mites and hemipterans) to control thrips and whiteflies on sweet peppers" (van Lenteren et al).

This also has impacts on the internal market; the excessive use of chemical pesticides and the resulting high levels of residues in sweet peppers had caused a collapse in the export of peppers to Germany by 40% between 2004 and 2007. Widespread implementation of augmentative biocontrol in 2006/2007 allowed for a full recovery of the sector, leading to a 200% increase since 2012 (IBMA[62]).

Although this example may demonstrate how invertebrate biological control agents can operate within modern agriculture, closed areas may not serve as accurate representations of how IBCAs may affect open-air environments.

[61] ASSESSING RISKS OF RELEASING EXOTIC BIOLOGICAL CONTROL AGENTS OF ARTHROPOD PESTS
J.C. van Lenteren, J. Bale, F. Bigler, H.M.T. Hokkanen, A.J.M. Loomans, Annual Review of Entomology 2006 51:1, 609-634 https://www.annualreviews.org/doi/10.1146/annurev.ento.51.110104.151129

[62] Widespread implementation of augmentative biocontrol in 2006/2007 allowed for a full recovery of the sector, leading to a 200% increase since 2012

Expected impacts on international trade

IBCAs can complicate international trade when they are present in consignments and are intercepted during inspections. Some countries may consider certain categories of IBCAs (e.g., non-native species with a potential environmental impact, plant-feeding IBCAs with potential a plant health impact) as a biosecurity concern and when those are intercepted, this may lead to consignments being stopped or having to be treated. For example, in Australia, the 2019 Final Pest Risk Analysis for Cut Flower and Foliage Imports notably mentions intercepting the IBCA mite *Neoseiulus californicus*, with a yearly average of between 10 and 50 events per year. While it is not a quarantine pest for Australia, two other species intercepted in this genus, *N. bicaudus* and *N. longisiphonulus*, are quarantine pests for Australia. The Dutch administration also reported that consignments of plants/plant materials are regularly refused by New Zealand biosecurity services when any live natural enemies are found.

3.2 Q2: What (regulatory) systems are in place in relation to introduction, production and/or release of IBCAs in the different Member States?

This question aims at providing a comprehensive overview of the regulatory systems in place in EU-27 Member States regarding the introduction of the organisms in the territory (in a contained or non-contained environment), production of IBCAs, and release of IBCAs in the environment (including the placement on the market and marketing). The analysis will especially focus on:

- The current **regulatory frameworks** in place: how IBCAs are currently covered by the national regulations (specific to BCAs, specific to IBCAs, included in pesticide regulation, etc.), the legal provisions applied to their use and production, processes for authorization (when relevant), the link made with international guidelines (EPPO guidelines especially), authorities in charge, etc.
- The processes for **risk assessment** before the introduction, production and/or release of IBCAs (elements analysed, authorities in charge or involvement of third parties, mobilisation of experts, mitigation measures for the release of IBCAs, etc.)
- The other legal requirements regarding the introduction of IBCAs

3.2.1 Introduction: EU legal framework for BCAs (and IBCAs)

IBCAs are not covered by the current European regulation that regulate the placing into the market of pesticides…

IBCAs are not specifically referred to in any EU strategy and regulation.

First there are no common EU rules on the production, use and placing on the market of IBCAs. Existing legal instruments regulate **the placing of "Plant Protection Products" (PPP) on the market**, but do not include IBCAs in their scope as IBCAs do not fall into the definition of PPPs in existing EU texts[63]. **Regulation (EC) No 1107/2009**[64], which aims to "ensure a high level of protection of both human and animal health and the environment and to improve the functioning of the internal market through the harmonization of the rules on the placing on the market of plant protection products", applies to substances (chemical elements and their compounds) including micro-organisms having general or specific action against harmful organisms or on plants, parts of plants or plant products, referred to as "active substances and define specific requirements for authorisation and market access". IBCAs are outside the scope of this Regulation; however, it follows the principles of integrated pest management (and based on the principle of subsidiarity) set out in the

[63] This EU definition differs from other existing definitions, such as OECD's definition which defines Plant Protection Products as chemical or biological products used in agriculture to protect plants; OECD definition of biological pesticides also explicitly includes invertebrates/macrobials.(https://www.oecd.org/chemicalsafety/pesticides-biocides/biological-pesticides.htm)

[64] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32009R1107

Sustainable Use Directive 2009/128[65]. Protecting and enhancing important beneficial organisms is one of these principles. According to this regulation, Member States should give priority in their National Action Plan wherever possible to non-chemical methods of plant protection and pest and crop management (without any explicit reference to IBCAs).

…but IBCAs fall under the scope of two European regulations to ensure protection of biodiversity and plants

However, IBCAs (as well as micro-organisms used for biological control, insofar as they are non-native living organisms) fall within the scope of two European regulations in place to ensure protection of biodiversity and protection of plants:

- **Regulation (EU) No 1143/2014** [66]on the prevention and management of the introduction and spread of invasive alien species provides specific requirements to prevent, minimize and mitigate the adverse impact on biodiversity of the introduction and spread within the Union, both intentional and unintentional, of invasive alien species. It relies on a list of exotic alien species regularly updated by the European Commission. As "alien species" are defined as any live specimen of a species, subspecies or lower taxon of animals, plants, fungi, or microorganisms introduced outside its natural range, non-indigenous IBCAs can be considered as 'alien species'.
- **Regulation (EU) 2016/2031** [67]on protective measures against pests of plants establishes protective measures against the introduction into the Member States from other Member States or third countries of organisms which are harmful to plants or plant products. It defines specific controls and requirements for these types of organisms considered as pests in the European Union. It relies on a list containing the plants, plant products and other objects which are prohibited from being introduced into the territory of the Union as well as a list with special requirements, or equivalent requirements for their introduction. This may be relevant to omnivorous and herbivorous IBCAs, which can cause unintended damage to crop and other plants, such as *Nesidiocoris tenuis* in some specific conditions.

In case of negative impacts on biodiversity or plant health, IBCAs could be added to the above-mentioned lists, conducting to restrictions for their introduction in Europe. It prevents the introduction of already known threads on biodiversity or plant health in Europe and the management of the current species with negative impacts. These lists are regularly revised, and Member States are engaged in the identification of new species to be added on those lists when risk assessments are performed for example.

[65] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32009L0128
[66] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32014R1143
[67] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32016R2031

In addition, the article 22 of the Council Directive 92 /43 /EEC of 21 May 1992 [68]on the conservation of natural habitats and of wild fauna and flora established that the Member States should "ensure that the deliberate introduction into the wild of any species which is not native to their territory is regulated so as not to prejudice natural habitats within their natural range or the wild native fauna and flora and, if they consider it necessary, prohibit such introduction. The results of the assessment undertaken shall be forwarded to the committee for information."

In addition, the European Commission is engaged in the reduction of the use of chemical pesticides through the European Green Deal objectives and the support to the Integrated pest management.

The Farm to Fork Strategy (F2F), a comprehensive 10-year plan adopted by the European Commission to drive the transition to a fair, healthy, and environmentally friendly food system in Europe, is at the heart of the "European Green Deal" and stands in line with the Sustainable Development Goals (SDGs) since it touches upon many sectors from agriculture to food labelling. Among its ambitious targets, it aims to "***enhance provisions on integrated pest management***" and to "***achieve a reduction by 50% of the use and risk of chemical pesticides, and the use of more hazardous pesticides by 50% by 2030***". Other objectives also include a reduction of nutrient losses by at least 50% while ensuring that there is no deterioration in soil fertility; a reduction of overall EU sales of antimicrobials for farmed animals and aquaculture of 50% by 2030; and reaching 25% of agricultural land under organic farming by 2030. These targets cannot be achieved without developing, producing, and providing alternative tools for farmers.

The Sustainable Use Directive (Directive 2009/128/EC[69]) is currently under revision. The Commission proposal for a Regulation of the European Parliament and of the Council on the sustainable use of plant protection products and amending Regulation (EU) 2021/2115 [70]has been published in June 2022. It established a specific definition of biological control (specifically mentioning IBCAs) and mentions biological control as one of the general principles for IPM in Annex. It also strengthens the trainings and information to pesticide users on Integrated Pest Management (IPM), in particular by establishing advisory services in each Member State. The proposal also refers to the current study to define what could be a future EU intervention in this area.

Finally, **the EU's new Biodiversity Strategy for 2030**[71] contains a vision of ecologically sustainable farming. Target 3 of the EU Biodiversity Strategy aims at achieving more sustainable agriculture and forestry, to preserve species and their habitats. As part of the European Green Deal, it aims to build European resilience to future threats such as the impacts of climate

[68] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A31992L0043
[69] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009L0128-20190726
[70] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021R2115
[71] https://environment.ec.europa.eu/strategy/biodiversity-strategy-2030_en

change, fires, food insecurity, and disease outbreaks. It recalls the economic benefits of biodiversity, especially including restoration of carbon-rich habitats and climate-friendly agriculture, and the need to "provide space for wild animals, plants, pollinators and natural pest regulators", with the objective of bringing back at least **10% of agricultural area under high-diversity landscape features**. It states the need to reduce pollution, in particular coming from pesticides, circulating back to the Farm to Fork Strategy.

Thus, this framework establishes a favourable context and clear support of the European Commission for the development of the use of the IBCAs in alternative to chemical pesticides. However, IBCAs are not explicitly and systematically referred in these strategies.

3.2.2 Existence of national regulations in Member States

IBCAs are an alternative to chemical products, which has high benefits for pest management. However, they can also present risks for plant health (especially for other species than the one targeted, when the IBCAs are herbivorous) as well as for biodiversity. Thus, even if no regulatory framework has been developed at European level, some Member States have adopted legal provisions that specifically regulate the introduction, production and/or release of IBCAs on their national territories.

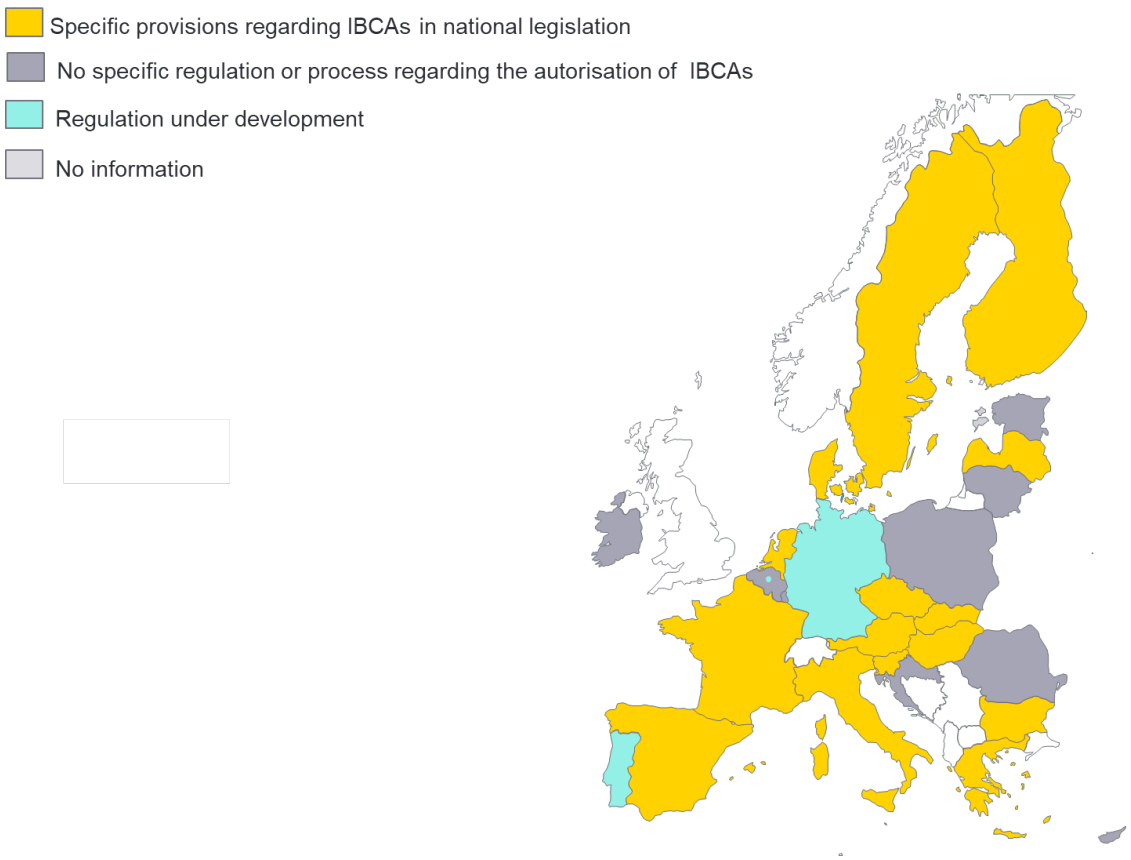
15 Members States have established provisions specifically regulating the introduction, production and/or release of IBCAs in their national legislations, whilst three more MS are currently developing such provisions

Project REBECA[72], which was conducted in 2006 and 2007, aimed at accelerating "*the market introduction of environmentally safe BCAs*", through acceleration of their registration process, cost reduction, and preservation of safety. The outputs of the project included a review of EU legislation, and of risk assessment strategies tailored to each BCA subgroup (microbials, macrobials, semiochemicals and plant extracts). It also analysed risk-benefits of existing regulation, and proposed measures to accelerate registration of BCA products. At this time, several Member States had already developed regulations and administrative procedures covering IBCAs (Austria, Czech Republic, Denmark, Hungary, Sweden), six countries were still working on the design and implementation of a regulation system (Finland, Germany, Ireland, Netherlands, Slovenia, Spain). The remainder Member States had no regulation implemented.

[72] REBECA Final Activity Report v4.doc (europa.eu)

Since then, an increasing number of Member States have adopted dedicated regulations over the years or revised their regulation. The situation at the date of this Study across 26 Member States is as follows[73]:

Figure 6 - Status of adoption of regulatory frameworks for IBCAs in EU Member States



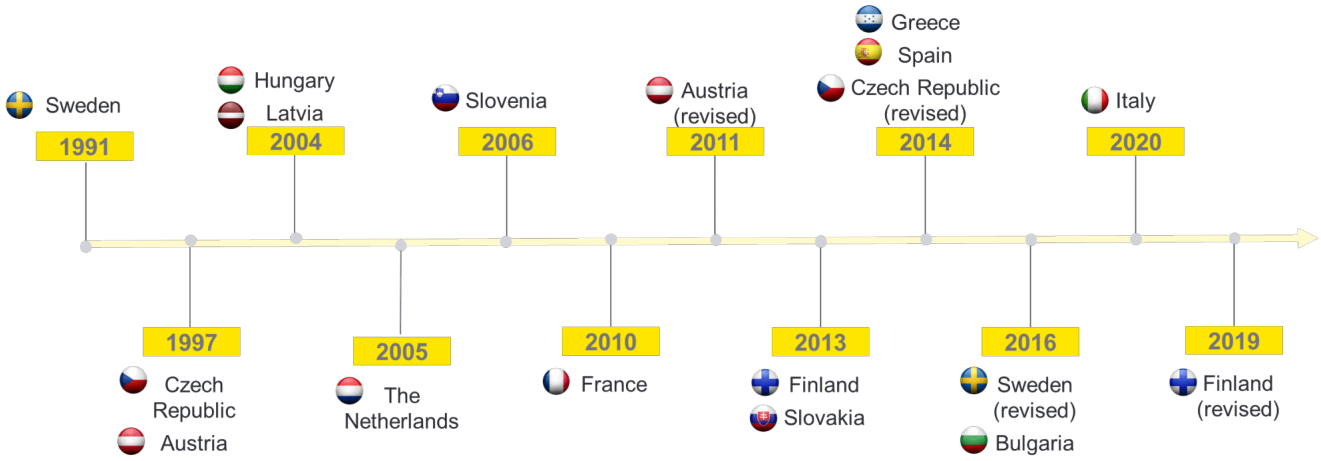
Source: EY, based on questionnaires, documentary research and interviews

- **15 Member States have introduced specific provisions regarding IBCAs** in their national legislation that govern a process for permitting IBCAs (involving environmental risk assessment and other review criteria for decision-making). These include 5 Member States already identified by the REBECA project (Austria, Czech Republic, Denmark, Hungary, Sweden), and 10 additional countries (Bulgaria, Finland, France, Greece, Italy, Latvia, the Netherlands, Slovakia, Slovenia, and Spain). Sweden and Austria, which were the first Member States having adopted dedicated regulations respectively in 1991 and 1997, have updated them in the recent years. In Sweden for instance, the revised 2016 national regulation aimed to reduce the cost of IBCAs' application and registration incurred by companies as costs were identified as a main obstacle

[73] Information is not available regarding the current situation in Bulgaria.

for the development towards more available IBCAs. These MS have either developed specific IBCA-dedicated regulations or have integrated specific IBCAs' provisions in their national regulation on plant protection products, except Denmark. In Denmark, specific IBCAs' provisions have been introduced in the national environmental regulation.

Figure 7 - Dates of adoption of regulatory frameworks for IBCAs in EU Member States



Source: Responses to the questionnaires sent to NCAs, EY elaboration

- **3 Member States are currently developing regulatory provisions specific to IBCAs,** at national level in Germany[74] and in Portugal, and at regional level in Belgium (in the region of Flanders and Brussels[75]). For these three cases, although there is currently no specific regulation in force that governs a process for permitting IBCAs, the release into the environment of non-native animals requires a permit considering the interests of species conservation, which is regulated by national environmental/ nature conservation regulations.
- **The remaining 9 Member States do not have any specific process governing the use of IBCAs:** Belgium – region of Wallonia, Croatia, Cyprus, Estonia, Ireland, Lithuania, Luxembourg, Poland, Malta, and Romania. Croatia does not have a regulation; however, the country has a specific procedure linked to the use of a SIT biological control program of *Ceratitis capitata,* and *Torymus*

[74] According to the German Plant Protection Act, the Ministry of Agriculture (BMEL) is legitimated to establish a regulatory framework for regulation of import, marketing and use/release of invertebrate biological control agents. A draft for such a regulation is currently under development

[75] In Belgium the introduction of species is regulated at regional level and rules varied in the three regions.

sinensis has also been used for biological control program implemented during the 2014-2017 period for forestry.

3.2.3 Scope of national regulations in Member States

Regulatory frameworks in Member States are defined by a corpus of several layers of regulations: European regulation, national environmental regulation, and specific processes for the authorisation of IBCAs, which can fall under the plant protection regulation or consist in derogations to the environmental regulation. This framework defines the degree of restrictiveness towards the use of IBCAs, and notably towards non-native species. The different configurations are summarized in figure 9.

Among the countries without specific regulations for IBCAs, 6 countries have environmental regulations which prohibit the introduction of unauthorised non-native species (*top right of figure 9*). They however differ regarding the restrictiveness of their regulation:

- Croatia, Estonia, Brussels region in Belgium and Portugal are very restrictive and do not allow derogations for IBCAs. Non-native IBCAs are not specifically targeted by the regulations but are almost always prohibited.
- The Flanders region in Belgium, Denmark, and Germany are less restrictive and can provide derogations for non-native species.

Among the countries **with specific regulations for IBCAs** (*middle of figure 9*), two main categories can be identified. Their regulatory frameworks differ depending on **whether they cover all IBCAs or only non-native species**:

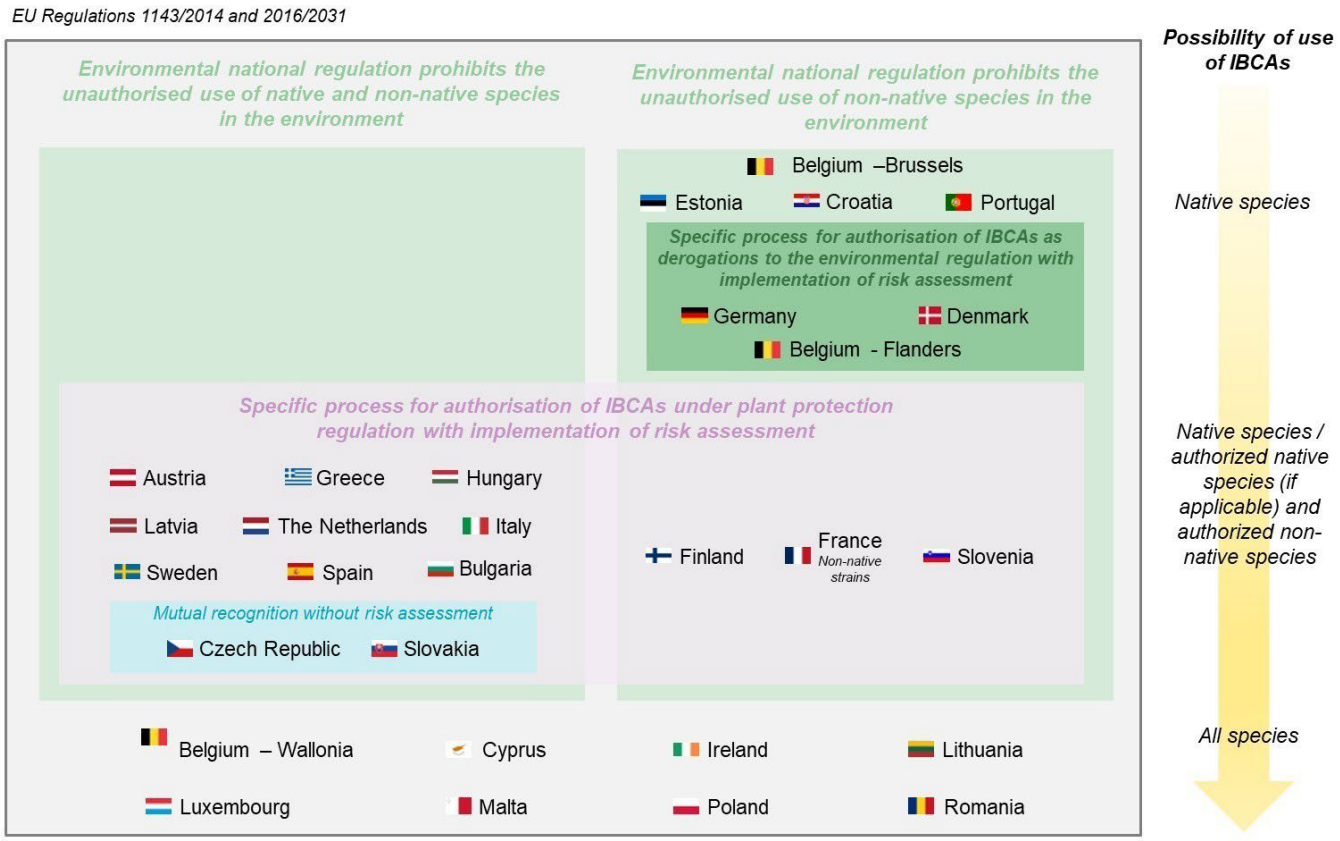
- In Finland, France, and Slovenia, environmental regulations prohibit the introduction of exotic species, while native species are allowed. Specific regulations for IBCAs cover only non-native IBCAs, for which an authorisation process is required[76].
- In 10 countries (Austria, Czech Republic, Greece, Italy, Hungary, Latvia, the Netherlands, Slovakia, Spain, Sweden), environmental regulations are stricter and native species also require an authorisation. As a result, IBCA regulations cover all species.

Two of these countries, Czech Republic and Slovakia, however, have *de facto* more permissive regulations, as they implement mutual recognition without risk assessment. For these two countries, IBCA regulation doesn't cover species imported and authorised in other European countries, nor species introduced for non-commercial purposes; it only applies to species which are first commercialized on their national territory.

[76] It should be underlined that Slovenia indicated that an authorisation process is in place for exotic species but it does not seem to be effective as all current uses are native IBCAs

Finally, 8 countries or regions (the Wallonia region in Belgium, Cyprus, Ireland, Lithuania, Luxembourg, Malta, Poland, Romania; *bottom of figure 9*) don't have specific national (or regional) regulations restricting the introduction of native or non-native species. They however refer to the European lists for invasive species and quarantine pests. These countries often have a limited use of IBCAs, which may explain the absence of specific regulation.

Figure 8 - Typology of the different regulatory settings for IBCAs in Member States



When IBCA regulation is integrated in the environmental regulation, it is **almost systematically different from that applied to pesticides**. In some countries, IBCA and pesticide regulations are similar for specific points; for instance, in Sweden the same regulation applies for supervision (but not for approvals and registration). The regulation which is currently being developed in the Brussels region could be an exception as it will cover both pesticides and IBCAs within a comprehensive framework on ecological management of green infrastructure and integrated pest management[77].

The regulation applies to the introduction stage for almost all Member States which have specific processes for IBCAs; Hungary, Latvia and Slovakia are exceptions as they don't regulate the introduction but the

[77] Source: interview with the NCA from the Brussels region

release/commercialisation of IBCAs. France regulates both introduction and commercialisation/release, while the Italian legislation applies to introduction, production and release. Denmark, Greece, Italy, the Netherlands and Slovenia also cover the stage of production.[78] Transport is only covered in Italy. The regulation in Bulgaria also covers all fields, as their regulation prohibits import, introduction, movement and use of biological control agents unless they have been approved and published to a list of biological agents maintained by the regulating authority. Companies have to formally notify the Regional/District Food Safety Directorate.

Authorisation processes differ depending on the kind of IBCA (taxonomy, origin…)

While some Member States regulations set out different provisions according to whether the IBCA is indigenous or not[79]**[80]**, it should be noted that the definitions of native and non-native species are not homogenous, which introduces additional differences between national regulations. While some countries align their considerations on EPPO's framework, others use national definitions. For Denmark, the Nature Conservation Act (Section 31) sets apart animals that do not occur naturally in the wild in Denmark, which does not only include non-native species, but also species which are native but have been absent from Denmark for a period of time. In Finland, invasive alien species definition is based on species which have been introduced after 1850.

In most Member States such as Austria, Finland, France, Greece, and Latvia, authorisation is granted for a specific IBCA (species, strain, source) or for a specific plant protection product (containing a specific IBCA organism) for specific uses. In other MS such as Bulgaria, Hungary, Latvia, the Netherlands, Sweden and Spain, the authorisation process is carried out for specific species or organisms. France gives authorisation for a combination of a specific species, origin, and applicant. In Italy, the level of analysis (species or strain) is determined by the information on the diffusion of the ICBA and its differentiation in relation to the geographic diffusion in the area of origin and the specialization on different hosts.

Safe or low risk lists exist in Austria, the Netherlands, and Spain, which are often aligned or coherent with the EPPO safe list (Standard PM 6/3).

For some Member States, authorisation processes also differ depending on the use of the IBCA

The process can differ depending on whether the IBCA is used for research or commercial purpose:

- For Denmark, Germany, the incoming regulation of the Brussels region, and Spain, the same process applies. For France, while the same process

[78] To be confirmed at the next stage of the study
[79] The existence of list of native species will be further assessed during the study
[80] Source: Responses to the questionnaire to NCAs – Question 4b

generally applies, adaptations can be made in case of strict confinement of IBCAs.

- For Austria, Czech Republic, Hungary, Italy Latvia, Slovakia and Sweden, processes are different. For Austria, IBCAs used for research purpose don't need an authorisation unless trials are intended. Information on ability to survive outside is asked in the case of non-native species; the same applies for Hungary. In Czech Republic, a notification must be sent to the regulator in case of experimental use. In Italy, requests from scientific institutions follow a different process and are examined by the National Phytosanitary Committee. In Slovakia, IBCAs for research are subject to a specific authorisation. For Slovenia, some exotic organisms may be allowed only for research intentions.

Countries with specific processes for authorisation of IBCAs differ depending on whether they authorize SIT:

- **The use of SIT is generally not authorized**, as 12 of these countries (Austria, Bulgaria, Czech Republic, Denmark, Finland, Germany, Hungary, Italy, Latvia, the Netherlands Slovakia, Slovenia)**, don't cover it in specific provisions**. In Italy for instance, IBCA regulation does not allow the release of pests; the authorisation process only covers their natural antagonists.
- **SIT is authorised in a minority of countries (France, Greece, Spain and Sweden)**. In France, SIT must follow the regulation established for non-indigenous species. In Greece, while SIT is included in the definition of IBCA and therefore covered by IBCA specific provisions, it has been left out of the ministerial decision that followed, and the required data required for the use of such insects lacks clarity; no specific authorisation request has been presented so far. In the Brussels region, the text currently being developed includes specific provisions for SIT as a special case of biological control.

Most Member States do not distinguish between classical and augmentative biocontrol[81]. This distinction can however emerge as a factor in risk assessments, when the impact on biodiversity and the potential of the IBCA to become invasive is considered: this is the case for Austria. The Netherlands seems to be an exception in conducting risk assessments differently when IBCAs are used for classical or augmentative biocontrol.

The same regime generally applies regardless of where the IBCA is produced in EU countries or in other countries. For Czech Republic and Slovakia, however, the application of the mutual recognition principle implies that IBCAs which are produced in other EU countries will be automatically authorised.[82]

[81] Source: Responses to the questionnaire to NCAs – Question 4a

[82] Czech Republic applies the Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March on the mutual recognition of goods lawfully marketed in another Member State is applicable

Regarding the profile of user of the IBCAs, the same rules generally apply. Czech Republic is the only country which mentions different rules for amateur users, who don't have to submit an application[83].

Example of a national regulatory framework for IBCAs: the case of Sweden

Sweden adopted its first regulation for IBCAs in 1991 and updated it in 2016. Before 2016, IBCAs were registered in the same way as microbials: the products were registered by the Swedish Chemicals Agency, and companies bore costs for the application as well as yearly costs for registration. The costs were however identified as an important obstacle for the development for IBCAs. With the aim to increase the number of available IBCAs in Sweden, a new regulation came in place in 2016[84], and the Swedish Environmental Protection Agency (SEPA) became the responsible authority for authorization of IBCAs.

The current authorization process focuses on organisms, not products. The Swedish state funds the evaluation of all species on EPPOs list of biological control agents safely used in the EPPO region[85]. To register other IBCAs, applicants incur a cost to register IBCAs (8000 SEK, or 746 €). Once an IBCA is approved, it can be imported and marketed in Sweden by anyone. It is also possible to apply for non-authorized IBCAs for R&D projects, for 3000 SEK, or 279 €.

To be approved, IBCAs have to undergo a risk assessment focusing on several factors: health, environment, and effects on biodiversity. Factors such as the purpose of use, or its effectiveness, are not considered. Approval may be subject to special conditions related to origin, strain, area of use, if it is motivated from a health or environmental perspective.

Once an IBCA has been approved, stakeholders who import or market IBCAs have the obligation to notify the Swedish Environmental Protection Agency if adverse effects on human health or the environment are detected. SEPA can reconsider approval decisions if necessary, on the ground of new information regarding adverse effects.

3.2.4 Organisation and processes

Although Member States with a regulatory framework all have a legislation which is distinct from that for pesticides[86], some similarities and mutualization can be noted in terms of organisation and processes. In Sweden, for supervision, the same regulation is applied to all chemical products and biotechnical organisms. In Czech Republic, inspection

[83] Source: Responses to the questionnaire to NCAs – Question 9
[84] Regulation 2016:402
[85] EPPO Standard PM 6/3, Appendix I, the "Positive List"
[86] Source: Responses to the questionnaire to NCAs – Question 27

authorities are similar for IBCAs and pesticides, and the obligations in place for professional pesticides users are applied on IBCAs as well.

The implementation of the regulatory framework is performed at the State level[87] and sometimes at a more decentralized level or with more specialized stakeholders. Several authorities are involved[88]: Ministries dedicated to Agriculture or Rural Development, authorities related to health, food and product safety, environment protection agencies, and specialized institutes. As the implementation of the regulatory framework includes several dimensions (risk assessment process, monitoring, importation, production, and release), it sometimes includes several of these stakeholders. In Greece, the Benaki Phytopathological Institute is responsible for the risk assessment and monitoring process, while the Directorate of Plant Produce Protection at the Ministry of Rural Development and Food is responsible for importation, production and release. Regional authorities are not involved, with two exceptions: Belgium, a federal state in which regulations are being developed in the regions of Brussels and Flanders, and Italy, where a National Phytosanitary Committee is responsible for importation and production, while regional phytosanitary services are responsible for monitoring.

3.2.5 Risk assessment

A risk assessment is a formal process where researchers or scientists examine the data, review literature, and provide the legislative body that oversees insect introductions with a document or proposition.

Almost all Member States that do regulate IBCAs carry out a formal risk assessment. Some exceptions have to be underlined:

- In Belgium – Flanders, there is no specific process for new application or risk assessment process in place. Only some specific derogations have been provided for native species or species listed in EPPO list.
- In Hungary, there is no proper risk assessment in place. However, the opinion of the nature conservation authority is required for non-native species.
- In Germany, the risk assessment is not adapted to IBCAs as it relies on the requirements of the Federal Nature Conservation Act that prohibit any risks to ecosystems, biotopes or species. However, some permits have been granted for non-native species.

The scope of application of the risk assessment and its content vary across the Member States depending on the type of organisms concerned (native or non-native mainly), the integration of the organisms in the EPPO list or when the IBCA is already authorised in another Member State. In Czech Republic and Slovakia, mutual recognition is in place for

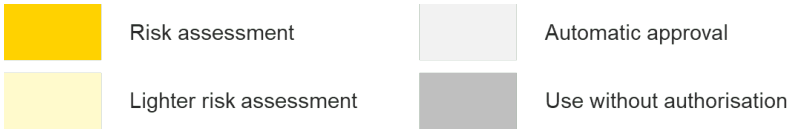
[87] Source: Responses to the questionnaire to NCAs – Question 37
[88] Source: Responses to the questionnaire to NCAs – Question 38

IBCAs authorised in other Member States without additional risk assessment at national level.

The table below provides an overview of the scope of risk assessment in the Member States.

Figure 9 - Scope of risk assessments according to national IBCAs' regulations

Member States	Native organism	Non-native organism	IBCA of the EPPO list	IBCA authorised in another Member State
Austria	Risk assessment (no environmental risk assessment required)	Risk assessment	If listed in EPPO PM 6/3, no efficacy assessment required	Risk assessment
Bulgaria	Risk assessment			
Czech Republic	Risk assessment	Risk assessment	Risk assessment	Automatic mutual recognition without notification
Denmark	Use without authorisation	Risk assessment		
Finland	Notification	Risk assessment	Automatic approval	Risk assessment
France	Use without authorisation	Risk assessment		
Greece	Risk assessment restricted to efficacy, environment and health	Risk assessment (detailed)	Risk assessment	Risk assessment
Italy	Use without authorisation	Risk assessment	Risk assessment	Risk assessment
Latvia	Risk assessment	Risk assessment (detailed)	Risk assessment	Risk assessment
The Netherlands	Risk assessment		Automatic approval	Risk assessment
Slovakia	Risk assessment		Risk assessment	Automatic mutual recognition
Slovenia	Use without authorisation	Risk assessment	Risk assessment	Risk assessment
Spain	Use without authorisation	Risk assessment	Risk assessment	Risk assessment
Sweden	Risk assessment		Risk assessment financed by the State	Risk assessment



Source: Responses to the questionnaire sent to NCAs and interviews with NCAs

Risk assessments are carried out for non-native IBCAs in all Member States. For native IBCAs, the situation differs depending on the restrictiveness of the environmental regulation:

- Native IBCAs can be used without authorisation in Denmark, France, Italy, Slovenia and Spain; for Finland, only a notification is required.
- A risk assessment is still required in Latvia, the Netherlands, Slovakia, and Sweden.

- The risk assessment is lighter in Austria, where no environmental risk assessment is performed, and Greece, where it is restricted to efficacy, environment and health.

IBCAs included in the EPPO list PM6/3 are automatically approved in Finland and the Netherlands. Other countries still carry out risk assessments for these IBCAs, although being on the list is considered as a significant advantage and can lead to a lighter risk assessment (Austria) or a fully financed process (Sweden).

The content and analysis conducted during risk assessment are also heterogeneous among the Member States

Risk assessments usually start with the identification of the organism concerned. The authorisation is provided at species level in all Member States apart from France where it is required at strain level. However, in some other Member States, specific issues at strain level could be analysed during the risk assessment:

- In Austria, for single predatory mites and nematodes the strain level may be considered if corresponding information is provided by the applicant;
- In Italy, the level of analysis regarding species or strain is determined by the information on the diffusion of the ICBA and its differentiation in relation to the geographic diffusion in the area of origin and the specialization on different hosts;
- In Slovenia, it is conducted at both levels.

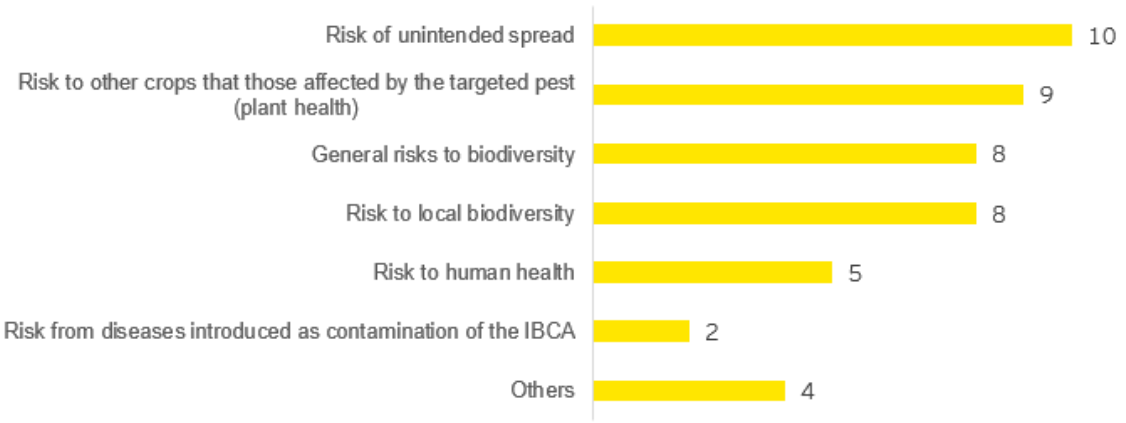
Risk assessment in France

A sharper risk assessment in place is in France. It includes requested detailed identification information on the IBCA, both at morphology and molecular levels, as well as characterization at the level of the strain; such focus on identification of actual IBCA to assess is related to the potential differences in biological characteristics exhibited by various strains belonging to a same species. Voucher specimens should be sent to a dedicated ANSES lab. Details should be given on the planned uses and targets of the IBCA, its mass rearing, product composition, and planned packaging, and precaution regarding IBCA usage. In addition, detailed assessment of both **benefits** and **risks** associated with the release of the IBCA should be provided; notably, the applicants should provide an assessment of the probability IBCA establishment in the environment, of its dispersal, and its potential risks to human and/or animal health, plant health, and non-target organisms (including risk of competition or hybridization with other species).

All this information should be supported by data generated by the applicants (including field data when dealing with effectiveness of the IBCA planned to be released) as well as by data from the literature when available.

In addition, the risks considered during the assessments are different depending on the Member States. The assessments focus most frequently on the risks of unintended spread, risks for plant health and biodiversity. Risks to human health and risks from diseases are less frequently assessed.

Figure 10 - Question to Member States: What are the possible unintended impacts that are evaluated?



Source: Responses to questionnaires sent to NCAs, EY Elaboration. The question has been answered by 13 Member States with specific processes for IBCAs and which perform risk assessments (Austria, Czech Republic, Denmark, Finland, France, Greece, Italy, Latvia, Lithuania, the Netherlands, Slovenia, Spain and Sweden). Bulgaria, Hungary and Slovakia are not included as they have not provided a detailed answer.

More specific risks include genetic diversity and risks from pathogens or endosymbiotic bacteria (Sweden), risks of hybridization (Spain), and phytotoxicity (Austria).

Risk regarding cross-border spread

Unintended cross-border spread has already been a cause for concern in the EU and its neighbours, particularly between Switzerland and Italy, with the release of an IBCA close to the common border of these two countries. Five countries currently consider cross-border spread as a potential safety issue in the assessment of risks: Austria, France, Italy, Slovenia, Spain. For Austria, it is considered indirectly. Countries which apply mitigation measures (Denmark, Greece, Italy, Netherlands, Sweden) don't seem to include specific measures related to cross-border issues. However, countries mention general rules related to unintended spread which can indirectly apply to cases of cross-border spread. For instance, Swedish regulation (20016:402) notes that anyone spreading IBCAs should take measures to prevent the organism from spreading outside the intended spreading area.

An ecoregion can be defined as "a physical region that is defined by its ecology, which includes meteorological factors, elevation, plant and animal speciation, landscape position and soils". The ecoregion concept can predict the spread of IBCAs: "Alien species that are suited to Europe north of the Mediterranean region can be expected to spread throughout mainland Europe with little hindrance from natural barriers". For example, the horse chestnut leafminer and the western corn rootworm have crossed the English Channel and have been reported in the UK, likely due to trade and human movement. Based on this information, one can conclude that introduced IBCAs established in one area in Europe could spread extensively within their preferred ecological limits over a few years[89]. Within the same book, the authors of explain, "Although dispersal distance is potentially a species-specific trait, as it is dependent upon longevity and power of flight, there is often an overriding influence of the abiotic and biotic characteristics of the surrounding landscape" These characteristics are important to note when conducting risk assessments and evaluations of IBCAs.

Some Member States also carry out an analysis of benefits: they cover mostly plant protection/phytosanitary effects (13 Member States), benefits to local biodiversity (Bulgaria, Denmark, France, Latvia, Slovenia), and environmental benefits (Bulgaria, France, Greece, Italy, the Netherlands, Slovenia). In Italy, the economic, social and environmental impacts, including the reduction in the use of insecticides, are also assessed. Efficacy, which is assessed by several Member States, can also be included among benefits.

Variation in the scope of the regulation leads to differences in the number of risk assessments conducted each year in the Member States. However, the number of applications received remains low and the majority of

[89] https://www.researchgate.net/profile/Barbara-Barratt/publication/233390234_Assessing_safety_of_biological_control_introductions/links/00463518d9348ed2b3000000/Assessing-safety-of-biological-control-introductions.pdf

applications are approved. The table below summarizes the number of assessments, approvals and rejections in the last years among the Member States which carry out risk assessments.

Table 11 - Summary of assessments, approvals and rejections in the Member States

Member States	Number of assessments	Approbations	Rejections	Period
Austria				
Czech Republic	0	0	0	2020-2022
Denmark	36	28 (2022 applications still pending)	0	2020-2022
Finland	0-10	9	1	Yearly average
France	14	17	1	2020-2021
Greece	22	18	0	Yearly average over 2016-2021
Italy	2	2	0	2020-2022
Latvia	5.5	5.5	0	Yearly average over 2014-2021
The Netherlands	10	9.5	0.5	Yearly average over the last 10 years
Slovakia				
Slovenia	1			Since 2006
Spain	43	33	10	2012-2021
Sweden	8	5	0 (with a few pending applications)	Yearly overage 2017-2022

Source: *Responses to the q*uestionnaire sent to NCAs, EY elaboration. Question 22.

While applications are rarely rejected, some Member States (Austria, Denmark, France, Finland, Greece, Italy, Slovenia and Sweden) impose risk mitigation measures related to IBCA releases.

- In Austria, Denmark, France and Sweden, the approval can be conditioned to specific conditions of use, for instance restricted to greenhouses or controlled conditions, to limit the risk of dissemination and contact with the national population; in Sweden, there can also be restrictions related to origin (to minimize risk of hybridization) or to specific strains (limit risk of establishment). For France, specific risk management measures may be established if needed at the stage of authorization. The risks addressed relate to unintended spread, hybridization, plant health, decreased efficacy of beneficial insects when mixed with synthetic/biologic insecticides.
- In Finland, specific support from the Ministry of Agriculture can be provided to determine how to mitigate risks in the case of adverse effects on plant health
- In Austria, an additional labelling for risk on health (wear protective gloves, may produce allergic reactions) is mandatory

3.2.6 Other legal requirements regarding introduction, production or marketing of IBCAs

In addition to the authorisation of IBCAs, 9 Member States are providing specific authorisation and registration of producers and/or retailers

Nine Member States register IBCA producers and retailers: for France, this only applies to producers and introducers of non-native IBCAs, and not for retailers. In Latvia, the IBCAs are considered as plant protection products and special permits are required for distribution.

Quality control requirements are not included in national frameworks

Very few requirements have been identified in the Member States regarding quality control of IBCA products, and they do not consist in strong quality control process:

- In France, the applicants are asked to describe measures that will be implemented to ensure the sanitary quality of the population to be introduced. It is analysed during the risk assessment.
- In Greece, some controls are performed on domestic unit manufacturing to ensure they comply with standard operating procedures.
- In addition, the Netherlands conducts specific controls on quality only in the case of export to third countries when an export permit is required.

Recording and monitoring measures vary across Member States

Only Denmark, France, Italy and Slovenia have established a monitoring framework for the release of IBCAs into the environment. For Denmark, this applies when a derogation is granted for the release of a non-native species; in that case, a written report must be submitted on whether the derogation has been used. In Slovenia, professionals must keep a record concerning the quantities of beneficial organisms that have been cultivated, introduced, sold or disposed to a third person.

In several countries, even in the absence of a monitoring framework consolidated at the national level, users of IBCAs are obliged to keep record of the IBCAs they use (Austria, Denmark, Finland, Greece, Italy, Latvia, Slovakia, Slovenia), and/or store (Czech Republic, Denmark, Italy, Latvia and Slovenia), with some countries making also record of purchase mandatory (Czech Republic, Latvia, Slovakia).

Data is recorded for post-release monitoring in several Member States. In Austria and Greece, all effects have to be reported to the authority. France, Italy, the Netherlands, and Spain mention recording the following elements:

- Negative or positive impacts on biodiversity
- The duration of the occurrence of the IBCAs in the environment
- Interactions with naturally occurring populations of plants or animals
- Efficacy in terms of pest/weed/pathogen control (which is recorded by Slovenia as well).

Only France records specifically effects on human health. In France, the applicants also have to send to the national authority all information related to post-release monitoring that are susceptible to change the initial evaluation. The data is consolidated at the national level in Finland, France and Italy. In Greece, while there is no systematic monitoring system in general, the installation of the insect *Torymus sinensis*, which was released for the first time in 2018 with a program of the Ministry of Rural Development and Food, is monitored by annual sampling.

The authorities in charge of the collection and maintenance of the monitoring system are generally the ones already involved in IBCA regulation in their respective countries.

3.3 Q3: What are the characteristic elements of the regulatory approaches in force towards the introduction, evaluation, production, marketing and use of IBCAs in Member States?

This question aims at providing additional information on the characteristics of the regulatory approach in the different Member States (key data requested in applications, most common data gaps). It will also focus on the implementation of the existing legal frameworks, their challenges, and consider views from the users of IBCAs and other non-institutional stakeholders.

3.3.1 Key data requested in applications and most common data gaps

The risk assessments mainly rely on the data provided directly by the applicants as well as documentary review (scientific publications or available risk assessment).

The data requested and main issues encountered in the implementation of risk assessment were merely analysed in the 7 Member States identified as case studies: Austria, France, Hungary, the Netherlands, Portugal, Spain and Sweden. **While a large part of the data required is similar in all 7 Member States, the format of the application is not homogenous and specific requirements differ from country to country**, such as the assessment of efficacy (Austria), of expected benefits (France), suggestions to include information on other restrictions in other countries (Hungary), or taxonomic and contamination risks, e.g. confusion with similar species (Sweden). For the Netherlands, the request of key data is aligned on EPPO PM 6/2; this is also mostly the case for Spain.

A table presenting the content of the EPPO PM6/2 standards and the content of the risk assessment at national level is provided in Annex for the Member States for which the information was transmitted (section 5.5.6)

Austria requires a description of the product (including the organism species), and Good Agricultural Practice (GAP) tables. Several risk assessments are then performed which require specific data:

- An efficacy assessment. When the organism is not listed in EPPO PM 6/3, data on efficacy is required. Non-GEP trials and publications can be used in the assessment.
- An environmental risk assessment. For this assessment, data on the geographical home range is used to determine if the species is indigenous or not. If the species is not indigenous, additional data is required:
  - Potential of an exotic species to establish (survival and ability for reproduction at low temperatures, potential of hibernation, ability for diapause)
  - Potential of dispersal (mechanism of dispersal, life-span, habitat conditions)

  - Host range/specifity and direct effects on non-target organisms
  - Indirect effects of released species on non-target-organisms.
  - Will the exotic macro-organism provide better pest control than native species?
- A human health risk assessment. For this assessment, data for co-formulants is required, such as transport material or storage material.

In the case of Hungary, the data requested falls within 8 categories:

1. General data on the formulation containing macro-organisms
2. Biological properties
3. Biological activity of the product containing the macro-organism
4. Toxicological data of the macro-organisms concerning pesticides and other chemicals and micro-organisms (IOBC risk scale 1-4)
5. Environmental data of the macro-organism
6. Food hygienic aspects of the use of products containing macro-organisms, occurrence of macro-organisms and their non-viable residues on the crop at harvest
7. Other information (including possible restrictions of the product in other countries)
8. Annexes

For France, the assessment process seeks to evaluate the probability of establishment and dispersal, the risk of adverse effect to human, animal, plant health, and the risk to adverse effect on other non-target organisms. This dossier is noticeably close to the EPPO standard PM 6/2. To this effect, the following data is required:

- Proof of the organism's identity (morphological and/or molecular identification)
- Origin of the claimed strain
- Data related to the biology and ecology of the species
- Data on measures implemented to ensure the sanitary quality of the population to be introduced (contaminants and others).
- Data related to the benefits of introducing organisms into the environment

Obtaining the right data is a recurrent challenge for Member States, especially for risk assessments[90].

One of the main challenges identified during the study is related to the lack of available data regarding the impacts of IBCAs.

[90] Source: Responses to the questionnaire to NCAs – Question 26 for case studies

Obtaining the necessary data to meet the application requirements can prove challenging, and a large part of the work relies on applicants. Assembling data may take about a year, but if there is not much known about the IBCA, this process could take longer. A biocontrol program from the beginning to the release can take over a decade depending on the complexity of the organism. Best practices and methodologies to perform a complete environmental risk assessment entail[91]:

- "Identification and evaluation of potential risk of releasing a natural enemy,"
- "A plan to minimize risk and mitigate unwanted effects of biological control agents," and,
- "A risk/benefit analysis of the proposed release of the natural enemy, together with risk/benefit analyses of current and alternative pest management methods", that may at the same time prevent serious mistakes without making biological control unfeasible[92]

A negative impact on an ecosystem can be defined as something that can be, "named and measured, such as direct and indirect negative effects on non-target organisms and negative effects on the environment."[93]

Risk assessments and pre-release tests are performed in a laboratory setting, in order to complete host specificity screening for the pest if it is a plant. There are specific and established regulations and tests required for herbivorous insects, such as the standardization for screening of biocontrol agents from the International Organization for Biological Control (IOBC), but much less regulation for predators and parasitoids[94]. Pre-release tests are different for herbivore, predator, and parasitoid species, and therefore, one single test cannot be applied to all three categories of invertebrates.

For each target, scientists analyse relationships through exposure tests, taxonomically, investigating relationships between predator and prey or preferred plants. One test performed is "no-choice," in which the invertebrate is given only one food source, and thus would have no choice but to consume what is given or not. Scientists can also perform "two-choice" or "multiple choice" with the same concept but with two or more food sources to determine what the insect is likely to consume. However, performing tests within greenhouses can produce inaccurate results because insects in a closed space will likely try plants within the greenhouse that they would not eat in the field because they have limited food sources. This would be the same for parasitoids and predators.

[91] Environmental Impact of Invertebrates for Biological Control of Arthropods: Methods and Risk Assessment, chapter 15: "Environmental Risk Assessment: Methods for Comprehensive Evaluation and Quick Scan,", (van Lenteren and Loomans 256)

[92] De Clercq, Patrick, Peter G. Mason, and Dirk Babendreier. "Benefits and risks of exotic biological control agents." BioControl 56.4 (2011): 681-698.7

[93] Environmental Impact of Invertebrates for Biological Control of Arthropods: Methods and Risk Assessment Chapter 15 Environmental risk assessment: methods for comprehensive evaluation and quick scan (van Lenteren and Loomans)

[94] Interview with Bernd Blossey, co- author of "Post-release Evaluation of Non-target Effects of Biological Control Agents" and professor at Cornell University

Thus, the Member States identified several data gaps when the risk assessments are implemented:

- Data gaps concerning theoretically available information:
- Unclear description of the intended use (Austria and France), especially in terms of territories (France), target organism, dose rate, stage of development, and product formulation
- Identity, origin, history and distribution of the organism in the national territory (Austria, France), and more specifically variations within species
- General lack of data and literature (France, Sweden)
- Data gaps concerning information that is either unavailable or difficult to obtain
  - Establishment potential for non-native organisms (Austria, Sweden)
  - Practical effectiveness (France)
  - Unintended effects (Austria, France, Sweden), including on non-targets organisms and risks due to pathogens and endosymbiotic organisms, genetic diversity. Respondents from Austria and Sweden underlined the difficulty to evaluate the risk to the environment as some topics are not covered by existing research.
  - Host range and prey preference in the case of polyphagous species

Regulators have to balance the need to perform a comprehensive assessment to mitigate risks effectively, with the cost incurred for the administration and the applicant, which may hinder the adoption of IBCAs[95]. The type of authorisation process used has an impact on the precision of the data required: authorisation systems which consider the specificity of the demand at the product level can be more demanding data-wise than authorisation systems which base their considerations on the type of organism. Overcoming current data challenges may require finding the right level of detail required for the authorisation process, engaging in further training applicants and sustaining research and development efforts in the field of IBCAs:

Risk anticipation is difficult, as there are almost always risks within biocontrol, but **the level of risk of biocontrol could be compared with**

[95] In this regard, IBMA questions the need to carry out several dimensions of the authorisation and risk assessment process, including local efficacy trials, requiring that the IBCA has been collected on the national territory, rather than on the broader European ecological zone, and considering distinctions between indigenous and non-native species at the country level rather than at the European level, on the ground that these dimensions of the assessment represent a significant cost compared to their value added.

the risks of continuing with current practices, or "doing nothing.", and be taken into account when performing the risk analysis.

In addition to the issue regarding data used for risk assessment, the post release monitoring is also facing the same challenges leading to very little available knowledge regarding the negative and positive impacts of IBCAs on biodiversity.

The current post release monitoring strategies implemented in the Member States rely on the submission of a report or alert if an unexpected effect is identified. However, the identification of such effect requires a strong scientific monitoring in place (which could be expensive).

There are various ways of monitoring IBCA populations, including mark-release-recapture (MRR)[96] which, "has been the most widely used approach in the analysis of dispersal and has been applied to insects of all sizes" (Mills et al. 116). This strategy is predominantly used for quantifying movement and spread of IBCAs within the ecosystem. Several strategies can determine the effect that IBCAs have on natural ecosystems[97], specifically taking field samples of the target pest habitat, to analyse if the IBCAs attack any non-target species and to determine the proportion of non-target species being attacked. Field samples include gut analysis (done in the field or in a laboratory) and should be performed on IBCAs to determine if non-target species are being consumed. Finally, when analysing what the IBCAs consume, one must examine the demography of not only the target pest, but also native species and potential non-target species[98].

Introduction of herbivore IBCAs for the control of weeds may cause risks to existing plants (both crops and other plants), that may also be eaten by the herbivores, analysing an insect's impact on non-target species relies mostly on the examination of demography, how the population changes over time. The study of possible decline in population of native species along with other non-target species after the IBCA is released allows to determine the impact of the introduced herbivore species on the ecosystem.

Furthermore, the authors of "Post release evaluation of non-target effects of biological control agents" recommend creating a predictive model of the IBCA population's impact before they are released, and once completed, a life-table analysis post release should be done to demonstrate how the predictive models compare to the post release evaluation. A life table analysis would examine the mortality, birth, and reproductive rates of

[96] Environmental Impact of Invertebrates for Biological Control of Arthropods: Methods and Risk Assessment, chapter 7: "Methods for Monitoring the Dispersal of Natural Enemies from Point Source Releases Associated with Augmentative Biological Control"

[97] Environmental Impact of Invertebrates for Biological Control of Arthropods: Methods and Risk Assessment, chapter 10: "Post release evaluation of non-target effects of biological control agents"

[98] Interview with Dr. Bernd Blossey

organisms, along with hazard and survival rates of the population over a certain time period[99].

Scientists who work with predatory IBCAs cannot always conduct very sophisticated post release tests because it is complex and measuring demography is difficult and expensive. The scale of the project further impacts the cost of monitoring: the time necessary to complete post release monitoring may take between five to twenty years, as biocontrol is usually slow.

3.3.2 Facilitation of the administrative process and support to the applicants

Generally, all Member States who have a regulation on IBCAs also have some level of facilitation of the administrative process and support to the applicants. Only exceptions are Germany (who is in the process of reviewing the existing regulation), Slovakia and Slovenia.

7 Member States reported having publicly available guidance: Austria, Denmark, Finland, Greece, the Netherlands, Spain and Sweden. In Austria, this is included in guidance and pre-submission meetings available to all kinds of plant protection products. Romania also has measures for plant protection products and fertilizers, but none are specific to IBCAs. In Sweden, a web-based application system with guidance is planned. More generally, the competent authorities specified that some level of guidance is included in the application forms.

5 Member States can offer pre-submission meetings to applicants, although this can take several forms: in France this is informal assistance in the pre-constitution of dossiers prior to their submission to Anses, in Latvia these meetings are available on request of the applicant. In Sweden, SEPA has ongoing contact with companies that wish to have new IBCAs approved.

Several Member States also have internal facilitation of the administrative process. Specifically in Italy, where the subject of IBCA is regional matter, the National Phytosanitary Committee sets up specific National Technical Groups on specific biocontrol problems in which scientific institutions and stakeholders also participate.

3.3.3 Shortcoming and challenges identified by the Member States regarding the implementation of their national regulatory framework

Several Member States are rather satisfied with the current functioning of their regulatory frameworks and mention few to no problems[100] (Latvia,

[99] Hintze, Jerry L. (2007) "Life-Table Analysis." *NCSS User's Guide III.* https://ncss-wpengine.netdna-ssl.com/wp-content/themes/ncss/pdf/Procedures/NCSS/Life-Table_Analysis.pdf (570-1, 570-2, 570-3)

[100] Source: Questionnaire to NCAs – Question 41

Netherlands, Spain, Sweden). Some Member States would rather mention challenges or share good practices (like Sweden). Several areas of improvement and challenges have been identified by the Member States::

- Organisational and administrative issues (e.g. Slovenia, Italy, Bulgaria, Germany, France) may impact the length of authorisation procedures: different administrations and administrative perimeters may be involved in the process and generate time-consuming back-and-forth between administrations. Human resources (human capacity but also internal expertise) may also be lacking and insufficiently trained to make adequately informed decisions on IBCAs without relying on external expertise.
- Legislative issues (Finland, Sweden, Bulgaria, Greece) may arise from a scope that is too limited. For example, the lack of inclusion of environmental effects in the legislation, the absence of clear definitions for native and non-native species, the lack of inclusion of SIT, or the lack of an effective and efficient monitoring system are all issues that have been reported by Member States.
- Application processes and data gaps (Netherlands, Austria, Sweden): the national application processes may not be to applicants, which hinders the quality of applications. Lack of experience of applicants in drafting a dossier is also frequent, and producers are small and medium enterprises have difficulties in drafting applications and shouldering application costs. Finally, producing new knowledge once information gaps have been identified remains a challenge.

Several good practices have sometimes been established to overcome the identified shortcomings:

- In Sweden, the change from product to organism authorization has been positive with respect to increasing the number of available IBCAs and lowering the cost and administrative work required. Organism-based authorization systems however come with their own challenges, in that the monitoring of the products used and not registered in Sweden is more difficult, for example, if there is need to follow up possible side-effects in the field.
- In Sweden as well, to try and bridge the knowledge gaps, information gaps are acknowledged in evaluations performed on the initiative of SEPA. The Swedish Environmental Protection Agency communicates knowledge gaps continuously to universities and research centres (such as the Swedish Agricultural University), which has resulted in both master theses, analyses, and experimental studies (some with funding from SEPA).

3.4 Q4: Which of the regulatory instruments below are used and in which Member States? How can they be used more effectively? Have additional instruments been mentioned by stakeholders and which are they?

This question aims at identifying the main regulatory or other instruments used in the Member States to promote and foster the development of IBCAs. In addition to national strategies, the answer to this question relies on the analysis of the current use of specific instruments to support the development and the use of IBCAs, especially:

- Use and role of internationally agreed guidance documents and especially EPPO standards in the current regulatory process or other commercial activities;
- Organisation, role and support provided to research and development;
- Knowledge transfer organization and support, training activities for national authorities, private advisers, industry and users;
- Economic and financial incentives such as tax relief for industry and/or users, fast track procedures in administrative processes, financial instruments to increase uptake of IBCAs at user level, etc.).
- Perception from stakeholders of the different approaches to regulation in the Member States

3.4.1 Role of internationally agreed guidance documents

The main international organisation relevant to biological control of plant pests is the International Plant Protection Convention (IPPC), which has designed frameworks regarding the import and release of exotic biological control agents

Even if there is no specific framework at the European Union level, there are some international standards with specific guidelines and risk assessment of products.

The IPPC/FAO ISPM-3 Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms are the main international framework for IBCA regulation. They were first adopted in 1995 and later revised in 2005 and 2017. They define standards that list the related responsibilities of contracting parties to the IPPC, national plant protection organizations (NPPOs) or other responsible authorities, importers and exporters: "*The standard addresses biological control agents capable of self-replication (including parasitoids, predators, parasites, nematodes, phytophagous organisms, and pathogens such as fungi, bacteria and viruses), as well as sterile insects and other beneficial organisms (such as mycorrhizae and pollinators) and includes those packaged or formulated as commercial products*. *Provisions are also*

included for import for research in quarantine stations of non-indigenous biological control agents and other beneficial organisms."

Exporters and importers are encouraged to ensure the safe transportation of these products, along with proper documentation to provide to the national authorities. NPPOs and / or the relevant designated contracting authorities are encouraged to:

- carry out pest risk analysis of biological control agents and other beneficial organisms prior to import or prior to release
- ensure, when certifying exports, that the phytosanitary import requirements of importing contracting parties are complied with
- obtain, provide and assess documentation as appropriate, relevant to the export, shipment, import or release of biological control agents and other beneficial organisms
- ensure that biological control agents and other beneficial organisms are taken either directly to designated quarantine stations or mass-rearing facilities or, if appropriate, passed directly for release into the environment
- encourage monitoring of release of biological control agents or beneficial organisms in order to assess impact on target and non-target organisms.

The IPPC subsection relevant to Europe is the European and Mediterranean Plant Protection Organisation (EPPO), although its scope is broader than the European Union, with 52 members

Nine regional plant protection organizations (RPPOs) work to facilitate the implementation of the IPPC among its 180 contracting parties. The relevant RPPO at the European level is **EPPO (European and Mediterranean Plant Protection Organisation)**. All EU-Member States are adherents to EPPO, although its geographical scope is wider. EPPO established in 1996 a **Panel on biological control agents**, which operates along the lines set out by the IPPC, strongly focusing on invertebrates, and occasionally including microbials.

EPPO works conjointly with the International Organisation for Biological and Integrated Control – West Palaearctic Regional Section (IOBC-WPRS in a Panel, to consider all aspects of the assessment and regulation of the import and release of biological control agents for use in plant protection and assists the EPPO Secretariat and Working Parties in preparing guidance for use by member countries and the biological control industry. Since then, the Panel has developed four Standards, intended to be used by the relevant authorities at national level in their overseeing and, if appropriate, regulating of the introduction and use of biological agents.

The **EPPO standard series PM 6 – 'Safe use of biological control'** provides information concerning import and release of invertebrates, as well as a decision-making scheme and a list of IBCAs which are widely used in several EPPO countries. Although these standards are not legally binding, they are useful instruments for a National Authority (i.e. National Plant Protection Organisations) to structure the facilitation, implementation and need for information requirements for risk assessment of IBCAs.

Providing general guidelines for risk assessment and reduction of biocontrol agents, the Standards make a framework intended to be "as light as practically possible" as not to hamper the growth of BCA use.

- PM 6/1(1) 'First import of exotic biological control agents for research under contained conditions';
- PM 6/2 (3) 'Import and release of non-indigenous biological control agents'. These Guidelines for the completion of an application form for import and release of BCAs in EPPO countries are available on the EPPO website. They cover four main categories:
- Part 1. Application information (information on the applicant, purpose of the application and use)
- Part 2. Information for indigenous and non-indigenous BCAs (taxonomy and origin, product information)
- Part 3. Information requirements for intentional release of a non-indigenous BCA with reference to: Biology and ecology, and assessment of risks and benefits (Establishment, Host specificity, Dispersal, Non-target effects)
- Part 4. Submission of forms and signature (Submission details, agreement: safeguards and signature)
- PM 6/3(5) 'List of biological control agents widely used in the EPPO region- 2021 version'. This list is amended on a yearly basis (except between 2002 and 2008), approved by the EPPO Working Party for Phytosanitary Regulations, and represents a register of BCAs for which EPPO recommends its member countries to use a simplified procedure for import and releases. Criterion for inclusion include
- For **augmentative BCAs** (appendix 1): they must have been marketed and officially used, and be widespread in the EPPO region or parts thereof (either indigenous or established), or have been used by at least 5 EPPO countries for at least 5 years and in any of these cases with no reported adverse effects, or with acceptable adverse effects
- For **classical BCAs** (appendix 2): successfully established BCAs 5 years after their introduction
- Appendix 3 includes BCAs which previously were on the above-mentioned lists, but removed as there were reports of adverse effects; these species need to be re-assessed before introduction

- PM 6/4(1) 'Decision-support scheme for import and release of biological control agents of plant pests. It **can be used by a national competent authority** to assess whether to authorize the import and release of a non-indigenous BCA.

EPPO has also developed Guidelines on Pest Risk Analysis (standard PM 5/1(1)) with a checklist of information required for risk-assessment. It is currently under revision and brought 'in line' with ISPM 11– IPPC, but yet has to be adopted for IBCAs specifically. These guidelines aim to facilitate procedures for a proper risk-assessment, but they do not yet provide working instructions for the risk-assessment itself.

Nevertheless, these standards are not sufficient to create a level playing field between Member States, as clearly stated in the recitals to Council Decision (EU) No 2021/1102, which requests the Commission to assess the potential for harmonisation within this study.

The available guidance is often informally considered in the different regulation systems developed by European Member States

Most MS have used the IPPC/EPPO standards when developing their regulations (with or without referencing them explicitly) or have integrated them to some extent. The other standards mentioned by NCAs in their questionnaires are the International Standards for Phytosanitary Measures (ISPM) for Italy, and the Organisation for Economic Co-operation and Development (OECD), EFSA and IOBC for other Member States.

Regarding EPPO guidelines, some Member States rely on the use of these guidelines to authorize the use of IBCAs.

The most frequently used guideline is the EPPO PM 6/3 "safely used" list: 11 Member States (Austria, Czech Republic, Finland, France, Greece, Hungary, Italy, Latvia, the Netherlands, Spain, and Sweden) declared that they take this standard into account when reviewing risk assessment in the applications. As indicated by Sweden, "The fact that an IBCA has been assessed and included on the positive-list is of course an advantage in the risk assessment". Most Members States however still carry out their own risk assessment, but in some Member States, the IBCAs listed in the EPPO positive lists are concerned only by simplified procedures (in Spain, they are considered native and subject to fast-track authorisation processes). Belgium (the regions of Brussels and Flanders), Germany and Portugal also indicated that in their future regulations, the EPPO standard PM 6/3 will also be included.

In line with this general alignment, the data requested in application processes seem mostly consistent with EPPO standards, which are often adapted into the regulations. Specifically, the Netherlands indicated strong participation within the EPPO-IOBC Panel and the development of the standards. As a consequence, the regulation in the Netherlands is aligned

quite strictly to these standards (with the standards PM 6/1 and PM6/2 being applied to non-indigenous BCAs only) and is expected to evolve taking into account the newer standards. The national whitelist in the Netherlands was set up in 2017 but is different from the safely used EPPO list. Its upcoming revision is also expected to include information from the EPPO list.

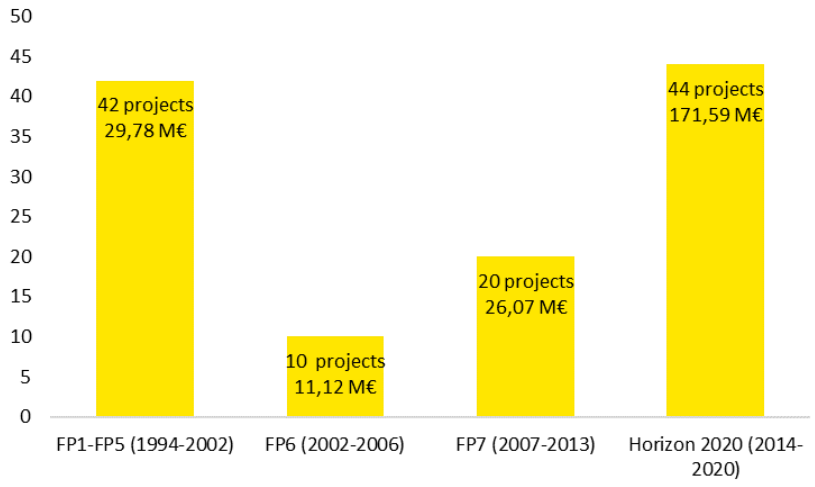
Explicit mention of international guidance documents within the regulatory texts is rarer. In Italy, the Ministerial Decree mentions the ISPM 3, and the FAO code of conduct for the import and release of exotic biological control agents.

3.4.2 Contribution of research projects and funding of product development to availability and usability of IBCAs

The availability of IBCAs strongly relies on research and development to develop effective solutions and ensure that they do not present risks for the environment. Inversely, even if some IBCAs research programs have shown results and interest from farmers, there could be a lack of industrial interest due to limited commercial perspectives (for minor crops and/or minor target pests).

At European level, around 129 projects can be identified in the EU database Cordis in the last 20 years through a search with key word "biocontrol"[101]. The number of projects supported by the European Union tends to increase above years, thus, from the selection of 129 projects:

Figure 11 - Number of research projects on biocontrol supported by the European Commission



Source: EY based on Cordis database

From the Horizon 2020 projects, the projects mainly concerned the mobility of researchers and their training and exchange of knowledge, support

[101] Exploring the benefits of biocontrol for sustainable agriculture (ibma-global.org)

public-private partnerships to developing near-to-the-market prototypes of biological agents and increase technology readiness levels of the solutions and finally support collaborative research projects to support the development of specific guidelines or foster the development of products.

A national level, the organisation of research and development is strongly related to the potential for commercial development of IBCAs. Thus, research and development for classical biological control and development of SIT are mainly supported by public authorities as it requires important costs of development, longer timeframe, and limited commercial perspectives. Indeed, the aim of classical biological control is to establish the IBCAs in the environment in the long term so little to no repetitive commercial activity could be envisaged. For SIT, it seems that the process is highly technical and use effective when it concerns geographical area of a certain size, so the decision to use this technique is mostly not made at individual grower level.

For the most part, commercial perspectives rely on augmentative biocontrol, where a part of the research and development is supported by private companies, or through public-private partnerships (in Spain for instance). The industry, through supplier field agents and crop consultants, is in constant contact with growers; advising on cultivation (incl. pest management practices). During these on farm visits, IBCA producer consultants obtain first-hand 'needs-knowledge' of growers. This information is fed back to R&D and business intelligence structures at IBCA producers and Business Cases for new emerging or reoccurring pests are developed. Local growers' associations, research and academic institutions survey pest incidence and prioritize R&D needs. Much of the latter is often done in collaboration with private IBCA producer businesses in order to also consider later stage commercialization.

Success stories

Thanks to the research and development work carried out by public and private organizations, the improvement of breeding and packaging techniques have allowed the development of diffusers that contain *Trichogramma* at different stages of development to ensure staggered releases and cover the entire egg-laying period of the borer. This is one of the main successes of the IBCAs spread in the agricultural sector

Some of the very first research projects in the Netherlands are examples of R&D success stories. In the Netherlands, the use of *Encarsia formosa* against greenhouse whiteflies in the 1980's is a good example. Collaboration between academics (Wageningen UR) and growers was essential. More recent examples of such collaborations between producers and academics include the use of predatory mites.

Industries, generic public research financing and dedicated national or regional funding programmes (e.g. aiming at promoting IPM, Agroecology or biocontrol) consistently finance research and development in Member State organisations. However, most investments are of small size (when compared to that on pesticides or other biocontrol categories).

The size of the R&D public or private community is relatively small, with teams well identified in each MS and experts involved in the main biocontrol networks or associations (IOBC). Overall, R&D activities result in 1-3 new IBCAs per year for augmentation and 1 or 2 ongoing classical biocontrol programmes (i.e. one programme starting every 4-5 years and lasting 4-7 years).

3.4.3 Knowledge transfer and training on the use of IBCAs usually takes place at the industry-to-grower level

The knowledge of professional users regarding IBCAs stems mainly from general information provided by authorities as well as industry advisory services

Having an important understanding of the correct use of IBCAs and the main stakes surrounding them is particularly important. This is due to the specific nature of IBCAs: contrary to conventional pesticides that are simply applied to control a pest, IBCAs need to be considered in a broader perspective, at the ecosystem level: an understanding of the targeted pest and IBCA life cycles, their interaction and timing in order to apply the most appropriate management strategy. This ecosystem perspective also integrates natural conservation strategies, which are a factor to invertebrate biological control success. In Spain, a tool has been designed to advise growers how to establish the right functional biodiversity surrounding the greenhouses[102]. One of the companies producing IBCAs is also already providing information to the growers about how to design margins and islands of vegetation inside the crops that favour the native populations of natural enemies, as well as providing commercially the mixtures of native plant species to create these ecological infrastructures.

In the countries selected for the case studies, general information is available to all users[103]. A formal training is not required to use IBCAs in the Member States. In Hungary, the information which is considered as necessary for the use is provided through the authorisation certificate, and no qualification or license are required for the purchase and use of the product. In Sweden, written information is also available from the Swedish Board of Agriculture and can be accessed online[104]. The effective knowledge of users however depends on the accessibility of the information, and therefore on the dissemination strategy, rather than on its mere existence.

For professional users, more detailed information is often be provided by the IBCA industry and the users' technical staff[105]. In Austria, basic use information is provided by use tables and supporting label

[102] https://www.arc2020.eu/wp-content/uploads/2017/06/WackersVanRijn-Gurr2012-Ch9.pdf ; www.diseñen.es
[103] Source: Responses to the questionnaire to NCAs – Question 45 for case studies
[104] www.jordbruksverket.se
[105] Source: Responses to the questionnaire to NCAs – Question 45 for case studies

warnings/advice, and specific support is usually provided by authorization holders, through instructions of use, according to the questionnaire. Similarly, in the Netherlands, according to the questionnaire, informing and training users about product application is considered as the responsibility of the producer and not that of the authority.

The degree of knowledge may therefore differ depending on the status of the users:

- **Users of IBCAs in the professional field are generally sufficiently informed**, according to IBMA. Technical support is often part of the service provided by companies, on top of products. Season-long contracts are often made for biological crop protection during the growing season. Furthermore, suppliers of IBCAs may be incentivized to inform farmers, so that their products are used correctly to increase the farmers' confidence in the products. The degree of knowledge may however differ depending on the profile of the user and on the country. Data from Sweden confirm this positive outlook on farmers' general knowledge regarding IBCAs, for the case of Sweden: according to the questionnaire, most of professional growers have a basic education regarding plant protection products, apart from a number of organic growers, and information about the legal framework, including that for the IBCAs, is included in this education. Some information about the use of specific IBCAs is also included in the education for use of pesticides in greenhouse production. It should be noted that according to Directive 2009/128, all professional users of pesticides in the EU must follow training or undergo similar measures on, amongst others, IPM strategies and techniques and on biological pest control methods. According to a 2019 report by the Swedish Plant Protection Council[106], there is a good knowledge on IBCAs among users, as they often work closely with their advisor (wholesale IBCA companies). The report suggests that advisory, information and communication initiatives would be useful to increase the use of IBCAs among those who don't use them. Most States also have specific measures in place to facilitate the administrative process. Several factors may however limit the knowledge available to professional users at the European level, such as formal training on IBCAs is currently limited in curricula from agricultural schools and universities.
- **Amateur users, or more generally users who** often buy products from third parties or on the internet **may be considerably less knowledgeable than professional users** who receive advice and training from biological control companies.

[106] Jordbruks verket (2019), *Hinder för ökad användning av alternativa bekämpningsmedel,* retrieved from: Hinder för ökad användning av alternativa bekämpningsmedel (jordbruksverket.se)

The industry estimates that there is a **wide discrepancy between Member States with regards to availability of biocontrol experts**, who not only have experience in the subjects of Entomology, Nematology or Acarology and crop production, but also **understand the integration into grower needs**. As a result, regulatory personnel in national competent authorities often lack understanding of IBCA application in IPM strategies, in particular in the field (covered crop and open field). During the consultation, IBMA suggested that an expert panel or group constituted of IBMA / EPPO / IOBC experts could deliver regular "training" to competent national authorities, especially to raise awareness in the use of IBCAs in IPM strategies.

From the side of public research experts, the opinion is that intensity and quality of knowledge transfer and training are correlated to the size of the IBCA markets and intensity of IBCA uses. For example, the professional communities (producers, advisors, groups of producers, etc.) working on greenhouse crops display high level of expertise on IBCAs and knowledge transfer is ensured via multiple canals: companies, extension services, research projects increasingly involving local stakeholders (for co-design and transfer). In areas with high usage of biocontrol (e.g. in the regions of Almeria or Valencia in Spain), a rich landscape of public to private organisations are involved on knowledge transfer and training and are supported by regional public bodies). However, in crop sectors where no or little IBCA use exists (e.g. cash crops), level of expertise is low and involvement of public and private organisations is close to inexistent.

Concerning knowledge transfer and training towards end users, public authorities could develop more positive communications, workshops, and more incentives for the use, sanctuarizing and focusing on IBCA as a sustainable tool, especially in IPM programs. In Austria, the national agency for health and food safety (AGES - Österreichische Agentur für Gesundheit und Ernährungssicherheit) sees the submission of an application, which includes in its data requirements detailed instructions of use as part of the submitted data, to be a form of knowledge transfer. According to IBMA, on the academia side, there is limited focus on IBCA in curricula from agricultural schools and universities. The industry estimates that universities and research institutions could be stimulated to transfer their knowledge to growers through extension programs. However, this could also be led to a lack of knowledge and diffusion of the existing materials and training to the farmers.

Finally, to counter **limited funding regarding independent advisory services and knowledge dissemination,** supporting the development of demonstration farms could contribute to disseminating knowledge, as it has been identified as an important tool for raising awareness and changing attitudes to alternative pesticides in general. Forums for exchanging experiences and disseminating information should also be encouraged, and even harmonized at European level.

Good practices regarding knowledge transfer and training: France and Sweden

Sweden

The Swedish Board of Agriculture provides education for advisors about IPM and the use of IBCAs. Written information that can be used by advisors and users is directly available on the web-site: Växtskyddsåtgärder i din odling - Jordbruksverket.se. There are also regular meetings organized by for example The Federation of Swedish Farmers (LRF) or The Rural Economy and Agricultural Societies, - with advisors, industry and users, at national, region and association level, in which information about IBCAs is included in the information about IPM strategies.

France

Knowledge transfer

In France, the "biocontrol" consortium, launched in 2016, aims to promote the use of biocontrol and support the deployment of biocontrol in France. The about 50 private and public members of the consortium work jointly on scientific and technical programme of collective interest. The consortium's strategy is to focus its efforts on pre-competitive research and actions aimed at increasing the expertise and know-how of the Research-Development-Innovation community. It is not specifically focused on IBCAs but on all biocontrol alternatives to chemical pesticides.

At regional scale, competitiveness clusters are also working closely with industrials and institutes to bring together research and innovation and allow the transfer from academia to industries. Five clusters are oriented toward biosolutions, included IBCAs.

France regularly launches calls for projects open to biocontrol manufacturers. The selected projects generally involve public laboratories, technical institutes and private organisations.

Sporadic training activities

Although there is no coordination of technical trainings at national level by the French authorities, the French Ministry for agriculture and Food participates to workshops and trainings to present the French regulation of IBCAs. They are delivered to professionals, regional authorities, competitive clusters, university, institutes…

3.4.4 Strategic approaches in different Member States regarding the development and use of IBCAs

Member States have different approaches regarding their national strategy to support the development and use of IBCAs. Some of the Member States have also developed specific financial incentives to support the implementation of this strategy.

For instance, France adopted an action plan in 2008 regarding plant protection products and the support to an agriculture less dependent to chemical products ("Ecophyto" Plan). One of the priorities of this action plan aims to increase the research and development of alternatives to chemical products and their use by farmers. More specifically, the objectives are to:

- Reinforce research and development activities of sustainable solutions
- Support the development of biocontrol through the support of innovation in SMEs and the improvement of the current national authorization process (reduction of delays) as well by encouraging the European Commission to recognize biocontrol products in regulation 1107/2009
- Facilitate the access to natural preparations of low concern
- Support farmers in the adoption of existing alternatives and favour collective approaches

Since 2020, it has been accompanied by a strategy for the deployment of biocontrol (2020-2025) that plans specific actions related to research and development, training, communication, and public policies fostering the development and use of biocontrol solutions. In this frame, a large R&D programme specific to biocontrol, supported by public financing of about 40 M€ over 5 years, is under preparation. Specific provisions have been put in place to encourage retailers of plant protection products to promote the use of various alternative methods to chemical pesticides through a regulatory system called "certificats d'économie de produits phytopharmaceutiques (CEPP)". IBCAs are part of these alternative techniques since 2019.

However, in France and other countries where public financing supports R&D on IBCAs, the extent of support is, overall, proportional to the investment from the private sector (via programmes financing public-private projects, public projects with likely transfers to the existing industry, tax credits for companies carrying out R&D). Seen the small size of IBCA markets, resources available to IBCA R&D remains very modest, even in the most active MS (e.g. France, The Netherlands, Spain). For example, consolidated data from public financing of R&D projects in France (2017-2021) reveals that direct subvention to IBCA research and development is between 1 and 2 million € per year (which is consistent with the idea that R&D efforts of private actors is approximately 10% of their sales – approx. 15-20 M€ / year – and that there is a balanced effort between the public and private sector in France). This tight link between public and private investment also accounts for the relatively low support of conservation/classical biocontrol and autocidal control for which the industry currently does not allocate efforts.

IBCA are also included in some MS strategies. In Austria, the strategy process "Zukunft Pflanzenbau" ("Future Plant Production") of the Austrian Ministry of Agriculture, Regions and Tourism includes regular round table

meetings called "Dialog Zukunft Pflanzenbau" of experts and stakeholders. Amongst others, the use of beneficials as plant protection products was discussed (2017). In the Netherlands, such programmes also exist: there are different funding programmes for research where companies may be involved. These funding bodies are versatile. National programmes include NWO, Dutch Research Council, PPS, an example of a dedicated international programme is the BINGO-ITN framework of the Marie Curie Grants.

IBCAs are also included in several CAP plans: in Germany, IBCA use is subsidized in the case of *Trichogramma brassicae* against European Corn Borer. The use of IBCA in greenhouses is supported as agri-environmental measure within the second pillar of CAP-scheme. In France, IBCAs are also included in the CAP plan.

3.4.5 Perception from the industry of the different regulatory systems

Knowledge regarding the current regulatory systems in place in the Member States is very scarce, only the industry had a sufficient knowledge to give a comparative perception of the current frameworks.

The average time needed for the assessment and approval of products in the different Member States is very variable, with 3 to 24 months between renewal and new registration and a median of 6 to 9 months. For example, in Spain the commercialization is allowed from the moment the communication (for native species) is sent, and in Finland, IBCAs on the EPPO list are typically approved within two weeks (industry data). In the case of France, approval of commercialization can take up to 24 months (industry data).

The costs for these procedures for biological control companies are estimated and reported below (based on IBMA data):

Application and registration costs	▸ Finland, Belgium, UK, France: no fees for applicants ▸ Latvia: 284€ ▸ Sweden: 747€ ▸ The Netherlands: 800€ ▸ Austria: around 2300€ ▸ Spain: Communication of commercialization of native IBCAs: 223,92€, Request of authorisation of exotic IBCAs: 746,36 €

Source: IBMA, questionnaire to NCAs

For the industry, putting a new product on the market also entails internal direct and indirect costs, referred to as "Market Access expenditure". In addition to the application and registration costs presented above, it also entails documentation fees (legalization, translation, postage, consultant),

trademark maintenance, time and human resources, and were estimated at around 25 000€ per product. Additional record keeping costs linked to the frequent actualization of dossiers (related both to Market Access costs and R&D trials and confirmations) are also incurred by the development of products and their authorization and estimated at around 5 000€ per product.

Some Member States are recognized as having clear frameworks and procedures by the industries:

Concerning industry perception of the different regulatory systems, **Finland**, **France**, and **Spain** are seen as having very clear regulations and procedures, based on native status and environmental risk assessment. Spain was highlighted by the industry for its regulation on naturally occurring species, as only a communication sent to the Plant Health DG of the Ministry of Agriculture, Fisheries and Environment (MAPA) suffices to obtain the registration of the product. This communication, at the moment it is sent, also allows commercialization to start.

Denmark regulations are also well appreciated by the Danish IBCA manufacturers who were interviewed during the collection phase, especially with regards to IBCAs on the EPPO list, that can easily be imported and produced without complex, costly, or time-consuming registration processes.

The Netherlands has a process that is also rated as clear and simple, as native and widely used beneficials are exempt from regulation/registration requirements. Newly discovered natives or imported IBCAs can be applied for based on a risk assessment with the RVO, where the latter process is highly transparent with open interaction with the case officer.

Hungary was described as having a clear procedure, with case-by-case exception for pest of significant economic importance. Hungary recognizes neighbouring Member State decisions in support of an environmental risk assessment for the approval of IBCAs native to other EU countries.

On the contrary, some Member States are seen as having developed restrictive frameworks for importation and release of IBCAs. The Finnish producer of IBCAs mentioned Austria, Germany and Sweden as extremely difficult MS to export to. Larger companies may have the resources needed, but smaller companies find it is very difficult to get their biocontrol products approved and registered. This shows that complex legislations can also have an impact on the competitivity and integration of the IBCA market.

3.5 Q5: Which successful alternative approaches exist in countries outside the Union and how can they be characterised?

In order to provide experience and examples from countries outside the European Union, New Zealand and the USA were chosen to provide inputs on their national frameworks. The goal was to understand the type of organisation and regulation adopted as well as ensure a global international coherence on this subject.

3.5.1 New Zealand

Uses and market

Few information is available on the uses, as neither the Environmental Protection Authority (EPA) nor the Ministry for agriculture and forestry (MAF) focus on IBCA as a separate category.

Most of the time, BCA releases are used to control weeds and invasive insects in classical biological control programs outside of the agricultural sector. In particular, biological control is mainly used for weeds that are hard to reach out (weeds far in the forest or high in the mountain). Successful examples are showcased on the EPA biological control online page[107].

In parallel, New Zealand is one of the countries that uses most pesticides and herbicides in the world, and the primary sector is very important. The growers community tend to use pesticides to treat their crops more than biological control agents. The mindset is reported to be changing slowly, but there are no financial incentives to support the use of biological control agents in crops.

Regulatory framework

Public authorities have long-term established regulatory processes for the use of IBCAs. The regulation process for the introduction of new biological control agents in New Zealand is described in the 1996 Hazardous Substances and New Organisms Act (HSNO Act), which came into force in 1998 for new organisms, and 2001 for hazardous substances. It was formerly managed by the Environmental Risk Management Authority (ERMA). In 2011 the responsibilities of this government agency have been transferred to a new public body, the Environmental Protection Authority (EPA).

This framework regulates the introduction, release / commercialisation, quality control and transport of all new organisms that were not present in New Zealand before 29 July 1998 (when the HSNO came into force for new organisms), and an indicative list is available in the Ministry for Agriculture and Forestry's Biosecurity Index. "New organisms" include any species of any animal, plant, bacterium, virus and genetically modified organisms[108].

[107] https://www.epa.govt.nz/industry-areas/new-organisms/biological-control-agents/
[108] https://environment.govt.nz/assets/Publications/Files/guide-to-hsno-act-jul01.pdf

It distinguishes between biological control agents (both macro and micro-organisms) and other organisms (such as tropical plants or pollinators). In some cases where the environmental risk is low such as the importation in contained environments like laboratories, or for SIT, rapid pathways exist (25 working days). Although the assessment is typically done at species level, the EPA can decide to approve an organism at the strain level.

Since 1998, 39 biological control agents have been approved by the EPA. They include both micro and macro-organisms, and are used to control insects (11 BCAs) and weeds (28 BCAs).

Binding deadlines require a quick decision of public authorities after the filing of an authorization request.

The fees associated with the formal application are 25 000$ for biological control agents, and 35 000$ for other organisms. In practice, many applications go through a sometimes long pre-application stage, where drafts can be submitted by the future applicant, and reviewed and commented by the EPA, free of charge. Potential rejections are usually identified before the formal receipt of the application and withdrawn, leading to on average 2 formal applications per year. Once the application is formally submitted, the EPA has 100 working days to assess it. The breakdown is as follows:

- 10 working days to make a rapid assessment of the application and publicly notify the application[109]. This includes making a list of stakeholders that may be interested, contacting them, and
- 30 working days to collect submissions from the open consultation (Maori consultation should typically be done before the application is formally received)
- 30 working days to organize a hearing (if requested by a stakeholder or a member of the civil society). A report should be publicly available 10 days before the hearing.

After this consideration period, the EPA meets with the committee and submits their assessment report and recommendation.

Once the EPA has released their assessment, the applicant can obtain the permit for release from the HSNO Committee. Although a feedback form at the end of each process is sent to the applicant and submitters, the EPA's role does not exceed this recommendation for approval and does not regard effects after actual release. This lack of post-release impact consideration is identified by the EPA as the main shortcoming of the regulatory approaches in force. In the future, the Authority's role might evolve to include this.

The assessment process is based on a risk–cost–benefit (RCB) analysis

The 1998 HSNO Act principles stipulate that if the benefits of a new introduction are higher than potential adverse impacts, it should be

[109] https://www.epa.govt.nz/public-consultations/

allowed. This approach is radically different from the one focusing on the quantum of risk, without analysing the potential benefits. In practice, the EPA follows guidelines describing the positive and adverse effects (risks and costs are generally regarded as being adverse (or negative) effects, and benefits as being positive). Most information is provided by the applicant, but the EPA also conducts a literature review and, from time to time, hires a consultant expert in a specific domain.

Regarding risks, cost and benefits, the EPA considers both the likelihood of occurrence (probability) and the potential magnitude of the consequences, as well as at distribution effects (who bears the costs, benefits and risks). The risks and benefits that are considered are the following:

- Environmental (e.g. could the organism cause any significant displacement of any native species within its natural habitat, cause any significant deterioration of natural habitats or cause significant adverse effect to New Zealand's inherent genetic diversity,
- Plant health (is the organism likely to cause disease, be parasitic, or become a vector for animal or plant disease? Risk to other crops)
- Human health and safety
- The relationship of Māori to the environment, the principles of the Treaty of Waitangi, society and the community
- The market economy
- New Zealand's international obligations.

Risk of unintended spread is not considered, as the regulation does not differentiate between classical and augmentative biocontrol. Due to the latitude of the island, many species have the potential to establish (for example, the winter season is not cold enough) and are treated as such. It is also relevant to point out that in the application, the described use is not specific to a crop: the EPA only considers the couple targeted pest / biocontrol agent. A list is available on the EPA website.

Facilitated access to EPA advisors and clear online communication allow for detailed applications

Due to the pre-approval period, most applicants have detailed enough applications (although Māori consultation was identified as the most common data deficit). The quality of applications is variable depending on whether the applicant has experience with the process and the EPA's information needs. Even with experience, in the pre-approval period a lot of back-and-forth can happen.

The EPA pages on biological control also include some positive communication[110] on the benefits and relevance of biological control.

[110] https://www.epa.govt.nz/industry-areas/new-organisms/biological-control-agents/

Best practices identified in New Zealand:

- The **informal open-communication canal** between applicants and the EPA, which improves the quality of formal applications
- The short and clearly paced timeframe for processing applications
- The open consultation procedure
- The inclusion of **benefits to the market economy** in the risk assessment requirements

3.5.2 The United States of America

The situation in the USA concerning "commercial" biological control agents is similar to that of the European Union: little information is available at the level of the National Competent Authorities, and most of the information comes from the industry. However, patterns of use seem to be similar to European Union: a large percentage of commercial biological control agents are used in greenhouses. The use in crops under field conditions is also significant (e.g., strawberries and cannabis).

In the USA, federal regulatory system covers the importation, interstate transportation, transit through the United States of America, and a list of indigenous or established species that can be moved Interstate without a permit

In **the USA**, the federal context implies the construction of a harmonized regulatory system. The overarching regulations relevant to IBCAs is the Plant Protection Act (2000)[111]. This act, and more specifically the rule 330, which explicitly prohibits the unauthorized importation, interstate movement, transit through the US, and release of biological control organisms and pests into the environment. It also sets exceptions and requirements for packaging. It should be noted that rule 330 also covers plant pests, pathogens, and organisms under study as biostimulants until their mode of action is elucidated and ultimate jurisdiction determined (transfer to the Environmental Protection Authority if relevant).

The authorization process is led by a federal administration within the U.S. Department of Agriculture, the Animal and Plant Health Inspection Service (APHIS), department of Plant Protection and Quarantine (PPQ). There are no legal fees. APHIS issues permits specific to each scenario: importation, transportation, release… Export however is not limited in any way, except for protected and endangered species.

This regulation includes a framework for the entirety of the United States, as well as its Territories and Possessions, with one centralized authorization system that includes State-specific consultation when appropriate, and a permitting system for movement to all US States and includes an exempted

[111] https://www.ecfr.gov/current/title-7/subtitle-B/chapter-III/part-330#330.200

list for the movement of naturally occurring organisms in the continental US[112].

Importation and release of a new organism

When a lab or company wishes to introduce or use a non-native species in the USA, they must first be imported under a specific USDA-APHIS permit into an APHIS-certified quarantine containment facility for further evaluation[113] (APHIS may request inspections of sites and facilities to assess the dissemination or dispersal of invertebrates, generally inspections are led every three-years by field agents who work conjointly with state Plant Health authorities). Mitigation procedures are in place in case of a containment breach. If the results are satisfactory this may lead to a request ("Petition") for release into the environment.

This petition must address the nature and impact of the pest target, the taxonomy and biology of the natural enemy, information on its effectiveness against the target, and anticipated non-target impacts and mitigations (if any). Usually, the petitions are reviewed by APHIS before they are formally submitted. The reviewing process of applications is as follows:

- Once the application is formally received, it is sent by APHIS:
    - If it is a petition for the control of an invertebrate: to an *ad hoc* biocontrol review committee to obtain their recommendation[114]. The committee chair sends the petition to outside reviewers, often a dozen or so, to obtain a range of opinions. The reviewers are generally scientists and regulators working in biocontrol, pest management, invasive species and environmental management, or related areas. The reviews may recommend granting the petition or ask for revisions including more data that address their questions, or rejection. APHIS generally accepts the committee's recommendation but is not required to do so.[115]
    - If it is a petition for the control of weeds: to the Technical Advisory Group (TAG), with the same process.
- If the dossier in satisfactory, then assessments are carried out:
    - If it is a petition for the control of an invertebrate: an environmental assessment is carried out to determine if there may be an impact on the endangered arthropod and insect species in the US. This list is relatively small.
    - If it is a petition for the control of weeds: a formal biological assessment needs to be prepared within APHIS. It evaluates

[112] USDA APHIS | APHIS Revises the Regulations for the Movement of Plant Pests and Biocontrol Agents
[113] United States, as well as its Territories and Possessions
[114] While the committee is not specifically NAPPO, it attempts to have representation of Canada and Mexico.
[115] Interview with researchers with expertise on the US system

(with the data provided by the petitioner) the potential impact on the over 1600+ endangered species in the US. This is then shared with the U.S. Fish and Wildlife Service (part of the U.S. Department of the Interior) as part of an informal consultation with experts at their regional field offices. A Letter of Concurrence with the proposal to release a novel biological control agent generally necessary to continue with the process.

- Then an assessment is also carried out to determine if the species has potential to have negative impacts on other areas of value, including to crops, plants of cultural importance and also the potential to be a nuisance pest – all possible impacts on human condition.
- The petition is then shared with tribal authorities for consultation, and if the comments are positive, it is published in the Federal register and public comments are open for 30 days to anyone in the targeted area. In most cases this area encompasses the 48 continuous States, in other cases it might be only for Alaska or Hawaii. Any State can comment as part of this process. They are also often brought into the TAG. The comments are addressed and added in an appendix in the environmental impact.
- If the process is successful, then the Plant Health official will sign a "finding of no significant impact", which opens the possibility to import the organism or to remove it from containment. APHIS is the regulatory authority, but each State may review the permit application for their State.

Petitions for the release of novel biocontrol organisms in the U.S. happen on an annual basis, almost entirely for classical biocontrol agents of arthropods or weeds. Regarding petitions for specific agents as part of classical biocontrol programs, the approval rate might approach 50%, however the time over which they are evaluated can be lengthy (2 years at minimum). Generalist biocontrol agents for commercial use are rarely applied for, typically because they are not always specific to a particular pest or weed, which makes it difficult for petitioners to prove that they are "no-risk".

Permits come with requirements: usually the post-release monitoring is kept to the recording of specific releases.

Movement of an organism through the United States

Moving a resident or native beneficial organism from one state where it occurs to another where it does not naturally occur requires a permit: native species found uniquely in one US region that do not occur in other parts of the US are in effect treated as exotic species when it comes to inter-state transportation and introduction. Commercial biocontrol producers are usually selling species approved across the contiguous U.S., however, if they would like to sell a species of unknown distribution,

obtaining details of that distribution would be required as part of the permitting process.

When determining the distribution of a potential commercial biocontrol agent for permitting, the required information will notably include a study of natural distribution across the US. Not all States are required to be positive, it's more about common sense and general distribution. For instance, if an organism is found in a sufficient number of south-eastern states, it would be approved for the entire zone. The zones are not formally fixed, but there are usually geographical distinctions across natural demarcations (such as the Rocky Mountains). In any case, States have a say in the permit for transportation. Certain biological control organisms are subject to exceptions, when they are considered to be established throughout their geographical or ecological range in the continental United States and are determined not to present any additional plant pest risk to plants or plant products. APHIS maintains this list of biological control organisms which are well-known, widely used natural enemies that are exempted from **transport permit** requirements within the U.S. due to their long and widespread use in North America and which are generally accepted as safe for use with no significant non-target impacts (on the PPQ Permits and Certifications website). Importation of these species still requires a permit, however subsequent movement within the U.S. can be done without additional permit. The initial list was approved through a national public consultation process, in which the States could raise objections. As such, if an organism is authorised in a specific State and on that list, it does not require further permits.

This list may be expanded upon request to APHIS by a petitioner with a dossier containing evidence that the organism is indigenous or established (on the taxon level) or is present in a limited area and has limited to no potential to establish (augmentative biological control), based on field study data (sampling for direct and indirect impacts), and a literary scientific review. A process is being developed by APHIS for adding organisms to the various lists (biological control agents of arthropods, of weeds, and plant pests) of organisms that can be moved without a permit. This process is completely different from approving a novel biological control agent for release in the U.S. Importation of these species still requires a permit, however subsequent movement within the U.S. can be done without additional permit. At this point, APHIS is beginning to get new requests for organisms to be included on these lists, but no organisms have yet been either approved, or rejected. As for the initial lists, the petition would then be published on the Federal register, and open for national consultation. Similarly, organisms may be removed from the list when previously unknown evidence emerges. Some individual states may have their own permit processes (California for example). A few may be stricter than APHIS national policies, others less, and some may simply accept the recommendation of APHIS.

Information is regularly shared for stakeholders on the APHIS website[116].

Common research and development projects are supported at federal level

- The USDA-APHIS (Animal and Plant Health Inspection Service) also supports many types of biological control activities, at the APHIS Center Plant Health Science and Technology laboratories, or through cooperative agreements with Universities and other State and federal agencies. Activities are funded by APHIS under several programs and coordinated by a cross-functional working group. Some projects are funded under the Plant Protection Act 7721[117]. This covers projects linked to the investigation and evaluation of potential new agents against plant pests or noxious weeds
- Some projects are funded through more related to field operations, especially in developing techniques to enable successful establishment, implementing the release and distribution of these agents, and conducting post release monitoring and evaluation.
- APHIS also funds CABI to assist with a variety of biological control programs against weeds.

The "**Biocontrol Target Pest Canvassing and Evaluation**" process is conducted every 5 years and relies on the State Plant Health Directors. Input is solicited from agencies, universities, weed management districts, to identify important exotic insects and weeds that can be considered as possible targets for cooperative biological control program.

The biological control of weeds in particular is the subject of a **Technical Advisory Group (TAG)**, why was established due to the perception of greater risks for weed biological control agents in relation to potential non-target impacts on Threatened or Endangered (T&E) Species or habitats, or to plants of economic or cultural importance. This committee includes:

- USDA, APHIS, National Biological Control Institute
- USDA, Agricultural Research Service
- USDA, Cooperative State Research, Education, and Extension Service
- USDA, Forest Service
- USDA, Natural Resources Conservation Service
- USDI, Bureau of Land Management
- USDI, Bureau of Reclamation
- USDI, U.S. Fish and Wildlife Service
- USDI, National Park Service
- USDI, U.S. Geological Survey

116 https://www.aphis.usda.gov/aphis/newsroom/stakeholder-info

117 https://www.aphis.usda.gov/aphis/ourfocus/planthealth/ppa-ppdmdpp

- USDI, Bureau of Indian Affairs
- US Environmental Protection Agency
- DOD, US Army Corps of Engineers
- The National Plant Board
- The Weed Science Society of America
- ARS Biological Control Documentation Center
- Other Federal agencies expressing interest in participating

The goal is to review petitions from the agency's perspective, evaluate risks to agriculture, human health, the environment, and compare them to the expected benefits. Experts are consulted as part of the process, and APHIS considers TAG recommendations carefully. APHIS works with researchers in the process of collecting information for petitions and if after a petition is reviewed, additional information is required; APHIS will maintain a dialogue with the petitioner to assist them in ensuring the information collected is appropriate. Additionally, TAG may conduct training workshops.

Best practices identified in the USA

- A **federally harmonised assessment procedure** for importation in confined environments and release, leaning on the **consultation** of States, and other relevant stakeholders
- Specialised **expert bodies** responsible for this assessment
- A system of **permits for the movement of species** across the USA that allows US States to authorise species themselves if they wish, leaning on a **list of exempted species**
- State-wide needs assessment and inventory procedures for research projects

3.6 Q6: Prospective question - Which instruments could complement the regulatory provisions in place and what are their expected effects?

T*his question aims to analyse the range of improvement of the current situation regarding IBCAs based on the answers and data collected during the interviews and through the questionnaires. It focuses especially on the potential for developing a harmonized framework at the European level and identifying the perception of the stakeholders and willingness of the Member States to adopt these new frameworks. Impacts of complementary implementation modalities such as voluntary schemes or European guidelines are also analysed and discussed. In addition, the potential evolution in the roles of actors (e.g., responsible authorities, etc.) and other stakeholders is also analysed, especially the implication of current actors like EFSA, and EPPO.*

The detailed questions are listed below:

a) What is the scope for the better implementation of existing instruments, taking into account the differences between the Member States, as identified during the study?

b) What are expected benefits of more engagement by EFSA into the process and what level is most appropriate (guidance documents, scientific opinions, risk assessments)? Are there concerns raised by Member States or other stakeholders towards this approach and what are these concerns?

c) In which ways could a more harmonized decision-making be achieved?

d) What are the expected effects of a centralized assessment of IBCAs before import on the market and/or use? How do they compare to the expected effects of a centralized decision-making structure?

e) What are the benefits and limits of voluntary schemes? How can efficiency be assured? Which of the shortcomings and problems identified are not expected to be solved in such system?

f) Which regulatory instruments are expected to be the most efficient to foster innovation?

3.6.1 Scope for the better implementation of existing instruments and for achieving a more harmonised decision-making between Member States

The study has revealed important differences between the policies in different MS, from no specific instrument applying on IBCAs (Ireland, Estonia, etc.) to impact assessments and authorization processes that include the potential impact of biological variability among populations within a same IBCA species (such as France). In other cases, national

regulation may still apply to IBCAs but only considering them at the level of the species, and in which detailed analyses are performed only when such species cannot be considered native.

The study also outlines that key instruments already exist in a few countries or at the level of international organisations; Member States' authorities and EPPO display the capacity to prepare guidance documents, providing positive and/or negative lists of IBCAs. Some Member States have also implemented more detailed risk-assessment procedures. This is to say that most of the raw material to implement a harmonised framework at the EU level is already available. A key exception is the absence of clearly planned post-release monitoring strategies, likely because of their (potentially high) costs when compared to the size of the market and industry.

Regarding the implementation of existing instruments, the main findings can be seen in the answers provided by the National Competent Authorities:

- Member States that already have a regulation in place have expressed that they are very reluctant to change their processes; they consider themselves satisfied with the functioning of both public authorities and entities submitting authorization demands in this regard.
- They further insisted on the fact that Member States should retain their ability to decide how they wish to manage biodiversity on their territory, hence making the option of a completely centralised process unable to reach a possible consensus (in current regulatory situation).

However, the option for a more harmonised and centralized framework appears possible for the MS authorities who were contacted.

Some of the Member States that do not rely on strong national framework and/or did not develop a process for the implementation of risk assessments are more open to the possibility of conducting risk assessments at the EU level because they do not have the competencies to perform these analyses at the national level.

Hence, the study indicates that there is space for a homogenization of procedures at the EU level, provided that Member States retain a sufficient level of freedom at the national or regional level.

A consensual approach would likely combine several levels of instruments:

- A package of guidance documents (scientific and regulatory) and species lists available to all MS with existing national regulatory processes applying to IBCAs.
- A centralized procedure available to MS with no national regulation on IBCAs,
- A few provisions and principles applying to all countries.

Some of the main potential scenarios have been identified on this basis and in consideration of the other findings of the study. They are presented in the next section.

As a synthesis of the information collected, several 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. Thus, having adapted processes according to the risk level will ensure a balanced regulatory system. In addition, the risk assessment should also weigh the benefits of IBCAs in comparison to chemical solutions.
- **Ensure stability of the framework over time**. As in all authorisation processes, changes in the rules that apply may have important consequences on the applicants and other private sector actors. This is true especially for IBCAs where the development of new products takes several years and is performed by SMEs with limited economic capacity.
- **Ensure that the applicants are well informed on the process and data required,** and that they have open communication channels with the competent authority. This point was especially mentioned by the USA and New Zealand.

3.6.2 Expected benefits of more engagement by EFSA into the process

The main benefits of an increased engagement from EFSA identified via the questionnaires and interviews are the following:

- An increased independence of the material (guidance documents, lists, etc.), analysis work or decisions when compared to what can be provided by voluntary networks or associations like EPPO.
- More consistent data quality if verified and curated by a dedicated service of EFSA,
- An increased level of mutual recognition among countries that services or agencies could rely on data and lists published by EFSA, strengthened by its independence and its quality procedures.

On the possible role of EFSA, we observed a clear contrast between the positions of the public bodies and the industrial stakeholders represented by IBMA:

Overall, public bodies positively saw a role of EFSA. There was relative consensus on the interest of having EFSA involved in the production of guidance documents and organisation of expert panels and opinions (out of the 15 Member States that expressed an opinion on the involvement of EFSA, 13 were positive and 2 negative). The possibility of making EFSA in charge of risk assessments was more contentious (10 positive, 5 negative) and would be dependent on two conditions:

- (i) the impact assessments do not interfere with existing national procedures, but rather facilitate the work performed at national level thanks to preliminary advice at the species level, with the creation of a 'negative' and 'positive' list to which Member States may refer in their own analysis and decision, and if EFSA can compile data to define if the species are already resident or not in each of the MS.
- (ii) if the involvement of EFSA does not add a significant administrative burden and unnecessary delays to the processes already in place.

IBMA argues for the simplest possible process at the EU-level, corresponding to the strict application of the EPPO guidance documents and lists (while seeing an interest in improving these documents and lists). A possible involvement of EFSA is seen as a risk; as EFSA oversees the analysis for the pesticides, it is seen as a 'non-relevant' merging of IBCAs with pesticides by a large share of stakeholders. However, from an IBMA perspective, this risk did not seem as critical as the risk of a proliferation of national regulations imposing different criteria and involving analyses at the intraspecific levels, virtually obliging the commercialisation of different strains in different countries, which would eventually render the production and distribution of most IBCA economically unviable.

3.6.3 Expected effects of a centralised assessment and decision-making of IBCAs

In total, 14 Member States provided an analysis on the hypothesis of centralisation of the assessment of IBCAs. Of these, 4 MS were positive, 4 negative, and 6 held an intermediate position.

A centralised impact-assessment would bring several benefits according to the Member States:

- It would ensure a unique process throughout the EU for all entities, with maximum clarity on the process, ensuring higher attractivity of the EU market for companies.
- It would enable the homogenisation of the processes of all Member States, with minimum safety standards for all countries, including those with no current regulation. This is seen as a guarantee of better biodiversity protection by several MS (including issues related to transboundary risks).
- It would enable access to a large panel of experts at the international level.

However, some drawbacks were also identified:

- Member States expressed their concern about possible additional administrative burden and slow processes when compared to national processes. In particular, this view was expressed by the countries with an existing regulation (or setting up a regulation).

- Such a scheme may be confronted to critical difficulties due to large differences in the expectations of MS in terms of analysis depth required during the assessments and enabling to reach authorisation decisions. For example, France will request the consideration of intraspecific variations while such a level of complexity would be considered an unacceptable administrative burden for other MS. The inverse is also true: an impact assessment conducted at the level species as implemented by some MS (e.g., Spain) would appear less safe to Member States like France, who would ask to carry out their own national impact-assessment.
- A centralised impact-assessment may also be excessively complex and costly because the benefits and risks would have to be evaluated in all Member States' biological contexts (including specificities related to island systems, ultramarine systems for some Member States, or other specific ecological systems) while commercialisation may sometimes be intended in some specific areas only. One option, however, would consist of carrying out an assessment for a list of specific areas for which an authorisation is requested by the petitioning entity.

Regarding the possibility of developing a **centralised decision-making framework**, of the 15 Member States that expressed themselves on this subject, 7 were clearly negative, none were positive, and 8 had intermediate positions. A central decision-making framework would have the advantage of homogenising and simplifying the process at the EU level, and would provide an option to the MS that do not have a regulation system for IBCAs or do not wish to carry out decision-making at the national level. However, the majority of Member States were heavily critical of a centralized decision-making framework. They argued that authorities of each MS should keep their decision-making capacity to ensure that their own territorial, ecological and political context is always taken into account.

3.6.4 Benefits and limits of voluntary schemes

Voluntary schemes are instruments that are supported by the industry because of their simplicity. Out of the 14 Member States that expressed themselves about voluntary schemes, 7 were negative, 4 were positive, and 3 had intermediate positions.

The most cited voluntary scheme would rely on EPPO standards PM6. However, several Member States expressed concerns regarding EPPO data and procedures. This criticism is related to (i) the composition of the EPPO-IOBC Panel on Biological Control Agents with regard to the industry and (ii) the processes used by the EPPO-IOBC Panel to define their lists, which may benefit from more details and depth. For example, the use of a given species can be considered safe provided it has been introduced in a country for a few years without reported negative impact, even if there was no or no scientifically sound post-release monitoring of possible impacts.

Another concern is the lack of impact of such schemes: they are not considered to be binding enough, the level of implementation remains low, and it does not make significant changes to the current situation, with a set of countries strongly relying on EPPO lists (e.g. The Netherlands, Latvia, Greece, Finland, and Slovenia),□a set of countries with a national process little influenced by EPPO documents, and countries with no regulation.

Such voluntary schemes may also be too flexible and fail to limit the emergence of a range of contrasting instruments in the Member States, which would defeat the purpose of harmonising the regulations, pose risks to the protection of the environment, and may eventually become a problem for the industry (multiplying the human resources involved in the application processes).

The questionnaires and interviews did not enable the elaboration of precise measures that would ensure the efficiency of such scheme. However, a few elements were discussed, such as a directive or common guidelines and timescales to provide key principles and basic rules. Another proposal was to create a hybrid network of experts within a perimeter set by EFSA to ensure independence and the creation of EFSA-validated material (documents, lists) using data and information shared between EPPO and EFSA.

3.6.5 Regulatory instruments to foster innovation

Regulatory instruments may be classified within two categories, according to their intended effect. They may indeed foster innovation via (i) innovation push or (ii) innovation pull.

No quantitative or scientifically sound impact study of various regulatory instruments on innovation were identified as part of the literature research. There was very little Member States input in the questionnaires, although two Member States mentioned possible systems of subsidies or obligations to use biocontrol strategies. Hence, the discussions below are based on qualitative evaluations, discussions, opinions of experts and NCAs, as well as scientific publications providing data on innovation trends.

Retrospective descriptions of innovation dynamics on IBCAs (see for example articles from Van Lenteren from 1988 to 2022) all converge to the same trends, whatever the continent considered. A first set of innovations and peaks of use were first observed before and soon after the second world war. This period gave birth to major biocontrol innovations (e.g., the development of *Trichogramma* products). Innovations from these periods reached a plateau in terms of market penetration during the late 1990s and early 2000s. Since then, IBCAs grew slowly, following a continuous trend punctuated by rapid and strong increase in specific systems (e.g., in greenhouses after specific scandals related to pollution by pesticides in the 2000s or after 2019 France after the "Loi Labbé" prohibited the use of chemical pesticides in public areas and gardens).

This trend of overall slow growth in terms of new products and market sizes reveals that strategies to push innovation, implemented by France for example, via the Ecophyto Plan 2008-2018 or the "Credit Impot Recherche" (a tax credit proportional to R&D investment by companies), have likely had little impact on the growth of IBCA innovation and its markets. Moreover, funding available for innovation push in the industry (support to private R&D) is recurrently underused. Sudden and fast growth of innovation activities were rather triggered by events affecting the phytosanitary markets and creating very strong innovation pull (e.g., scandals and pesticides bans). Dominant systems, in which chemical pesticides are cornerstones ensuring short-term economic benefits, locked innovation pull in most crop systems, and eventually decreased the strength (proportional to R&D investment, which is itself proportional to sales) and the effects of innovation push instruments.

The importance of the interplay between innovation on IBCAs and the evolution of the agricultural and agrifood value chains and markets is further underlined by recent research works. Most recent instruments fostering innovation in France have been redirected towards more innovation pull. For example, the CEPP instruments (certificates for economy of chemical pesticides) promote the use of alternative strategies (with approx. 30% of strategies relying on biocontrol) via a credit system applying to agricultural input distributors. An increasing number of innovation support actions also focus on co-innovation initiatives at the level of territories or value chains, to stimulate innovation pull.

In light of the brief analysis presented above, our recommendation is, without neglecting instruments fostering innovation push (e.g., supports to research & development at the national or EU level), to focus on new instruments fostering innovation pull.

Innovation pull would seek to:

- **Foster transitions to agrosystems that are more favourable to IBCAs** (e.g. relying on prevention and resistance rather than the systematic use of chemical pesticides), be it in terms of biological/technical compatibility (most IBCAs are strongly impacted by chemical pesticides or their action is seen as insufficient in agrosystems where natural regulations are absent or decreased by the effects of chemical pesticides) or economic competition (chemical pesticides are economically beneficial at short term and dominate all alternative strategies whenever their price does not include their hidden costs related to impacts on biodiversity and health. Moreover, chemical pesticides are produced at large scale and benefit from all of the agrifood infrastructure (distributors, agri-equipment) that has been designed for their use). Such measures may include **pro-active programmes of progressive exclusion or additional taxation of chemical pesticides** whenever biocontrol methods or alternative strategies are available or close to being so (leave them space for production at larger scale, decrease of costs, etc.). Such

measures may be relevant particularly if the timeframe of the programme is set to create a strong boost to R&D investment of all actors while allowing enough time for innovation to support the crop sector facing the progressive/partial loss of agrochemical tools. A future example will likely be the incoming ban of neonicotinoids in sugar beet in France, that is currently accompanied by a massive public-private innovation investment.

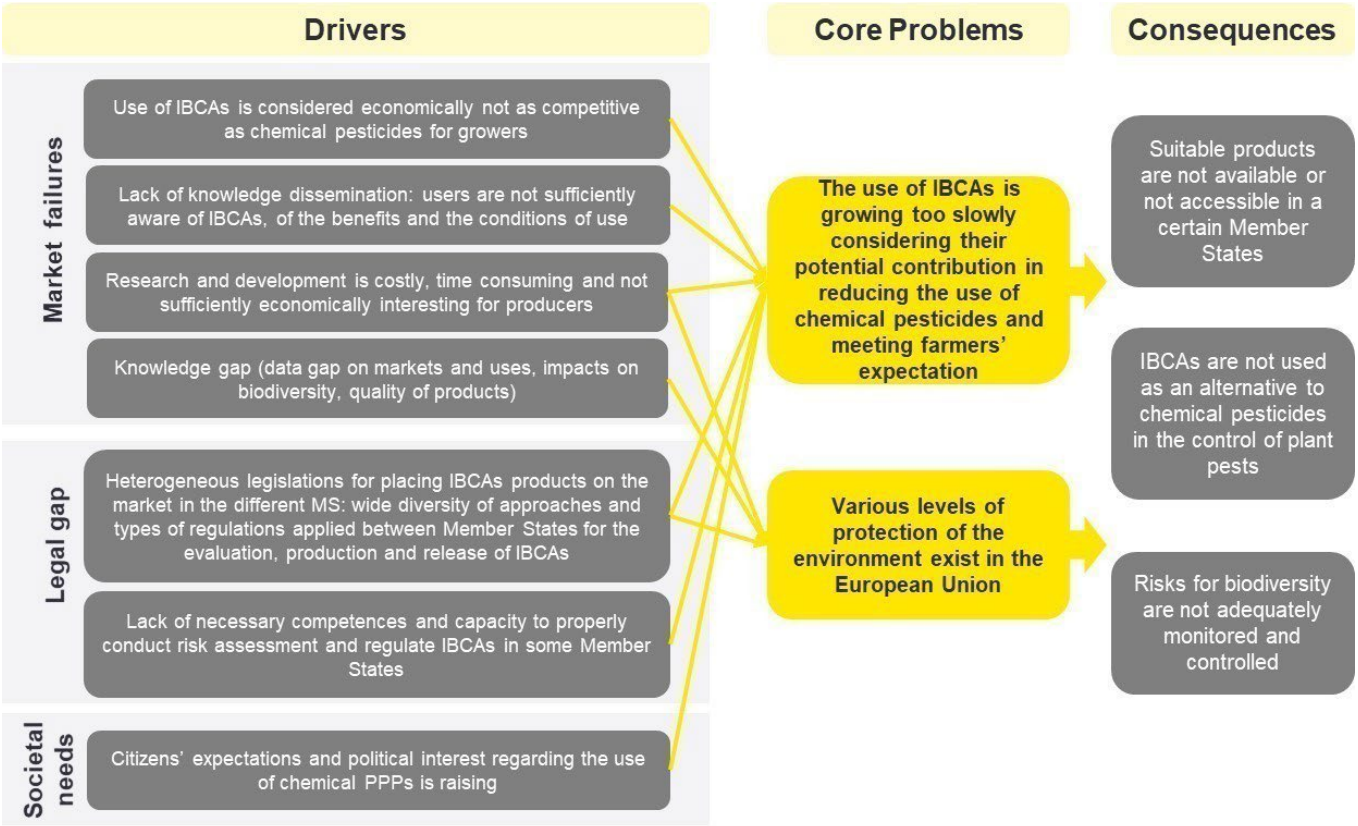
- Fostering co-innovation dynamics between the biocontrol industry and actors of the agrifood value chain. This would, for example, involve fostering dialogue and co-design of innovation strategies with a view to integrate product specifications, including the use of agroecological measures (including biocontrol) at the level of cooperatives, food transformation or retail. Other instruments may foster the development of an insurance system against any losses caused by pests that would be based on the adequate use of IBCAs to replace chemical pesticides. These insurances may be inserted into contracts between agrifood actors (cooperatives, food processing industry) and their providers (farmers). In all cases, instruments fostering pull by downstream actors that ultimately add value to growers engaged in sustainable practices involving the use of IBCAs should be favoured. This added value will enhance risk-taking, boost the adoption of new methods, increase market size and lead to a virtuous loop sustained by increased investments on innovation, supported by mechanisms already in place for innovation push (that will be increasingly used by IBCA R&D actors).
- Another important element to consider is **the risk of focusing excessively on IBCAs corresponding to products similar to classical inputs**. The most indispensable IBCA services to agriculture are probably not the ones provided by the introduced products, but rather the ones provided by populations well established providing free and extensive pest regulation throughout the seasons. This biocontrol activity falls into the specific categories of conservation biocontrol and classical biocontrol. However, new business models that rely increasingly on services and the intelligent use of inoculation (be it of innocuous exotic organisms associated to an invasive pest or of native organisms temporarily in insufficient density) should be fostered. **Classical biocontrol would require specific instruments for its safe use** (with specific resources and guidance to produce comprehensive data for risk assessment and post-release monitoring) and more balanced partnerships between public and private investment from agrifood actors (classical biocontrol is excessively relying on public funding in Europe). Business models specific to activities falling in between inoculation biocontrol and conservation biocontrol should also be fostered.

4 Synthesis of the problem definition and analysis of the main potential options for an EU intervention

4.1 Problem definition

The current situation regarding IBCAs in the European Union presented in the previous sections, conducts to several issues and challenges that are presented below.

Figure 12 - Problem tree



4.1.1 Problems and their drivers

Core problems

Two main problems emerge from available data and analyses:

- The use of IBCAs is growing too slowly considering their potential contribution to reducing the use of chemical pesticides and meeting farmers' expectation of finding alternative methods.
- **Divergent levels of environmental protection exist in the European Union.** The use of IBCAs could also present some risks for environment and biodiversity, especially where non-native species are used and considering that IBCAs can spread beyond the borders. The frameworks developed in the Member States are based on different perceptions. The differentiated way of taking

this risk into consideration of leads to various levels of protection of the environment: some Member States are conducting little to no risk assessment for the use of IBCAs in their territory where some have developed a protective framework.

Main drivers

Several related causes and drivers can be listed, which are obstacles for the further development and use of safe, reliable, and effective IBCAs:

Market failures:

The use of IBCAs is often considered economically not as competitive as chemical pesticides for growers. The use of IBCAs is often considered in the context of a substitution for chemical pesticides. However, in comparison to chemical pesticides, the cost of IBCAs remains high for farmers (2 or 3 times higher, as stated in section 3.1.3). They can also be considered as less efficient than chemical products as they often rely more on controlling the pest than total eradication.

In addition, farmers do not have sufficient knowledge regarding IBCAs' solutions and their potential benefits. The use of IBCAs must be integrated into global biocontrol strategies at the farm level, which may be very technical to implement for farmers. For instance:

The use of IBCAs can be integrated into biological control programs that may involve up to 15-20 different species of naturel enemies to be effective[118]

The use of other (especially chemical) products can lead to the eradication of the IBCAs.

Application methods of IBCAs are different from chemical pesticides and climatic conditions may have highest consequences on their effectiveness in outdoor crops.[119]

Thus, the use of IBCAs requires specific training for farmers to support them in the reduction of the use of pesticides and ensure that the IBCAs are used appropriately. In addition, despite the European and national strategies, the incentives for farmers are not always sufficient to conduct to a global change of practices at farm level.

The development and commercialisation of IBCAs is not sufficiently economically interesting for producers. Regarding augmentative biological control, the cost and time required to develop new solutions remain high as new species need to be captured, studied, cultured, etc[120]. to know if they may be used as IBCAs. Mos the existing solutions concerned high value crops in greenhouses system where the economic viability can

[118] 841 Lenteren et al ABC Plenty of Ops BiCo 2017.pdf (boerenlandvogels.nl)
[119] 841 Lenteren et al ABC Plenty of Ops BiCo 2017.pdf (boerenlandvogels.nl)
[120]https://www.researchgate.net/publication/316251091_Best_practices_for_the_use_and_exchange_of_invertebrate_biological_control_genetic_resources_relevant_for_food_and_agriculture

be reached. The issue of intellectual property could further erode economic interest, thus impeding the development of new solutions, because the "classic" patents cannot be applied to natural species. The industry however makes an increased use of patents concerning processes and techniques. In addition, many producers of IBCAs in Europe are small-scale SMEs with lack of professionalisation, which encounter difficulties to develop effective production techniques, transport of IBCAs, etc.

In addition, some of the IBCAs are used for classical biological control, which is not economically interesting for businesses as it is based on the establishment of a new species in the environment that does not lead to long term business model. It mainly relies on public research and support with limited capacity of funding.

Important knowledge gaps exist regarding both:

- The current IBCAs market and the use of IBCAs in the European Union; these gaps do not allow for any monitoring or clear identification of necessary actions to accelerate the take-off of IBCA market. Indeed, it does not give sufficient information for public authorities to make informed decisions on which kinds of needs, uses or segments of the market would most benefit from public funding.
- The long-term effects of *some* IBCAs, especially on biodiversity (positive and negative effects). Knowledge and data gaps have also been identified by the Member States during the implementation of risk assessment. It should also be underlined that the current regulations in place do not integrate any system for monitoring the use and potential side-effects of the use of IBCAs, which further limits the production of data to assess the impact of IBCA on biodiversity. Thus, the current data gaps in the long-term effects on biodiversity lead to some risks regarding the protection of the environment.

Legal gap:

The different approaches of Member States to authorising the introduction, production and/or release of IBCAs can lead to **potential adverse effects on biodiversity** as risks concerning biodiversity are managed differently across Member States. While some are implementing specific risk assessments, some other Member States do not assess the risk and do not regulate the use of IBCAs. Moreover, invertebrates are able to spread and cross borders, and an IBCA used and authorised in one Member States may be harmful in another MS due to different local conditions.

Some Member States, regardless of whether they have a legislation in place or not, have reported **lacking the necessary competences and capacity to properly conduct risk assessments and regulate IBCAs**. Member States frequently face a lack of sufficient data to provide a decision based on comprehensive scientific evidence (for instance, Sweden underlined the lack of available data regarding the potential of

establishment of exotic species or the consequences with respect to genetic diversity of native species).

The different provisions in Member States around risk assessments and the placing on the market of IBCAs also cause **competition and market-related issues due to uncertainty and additional administrative burden for IBCA producing companies**. The different regulations among European countries cause serious problems to the biocontrol industry because dossiers must respect the various national requirements and criteria in countries where regulation is in place. This makes applications more time consuming and costly and can deter a company from developing a new product if the estimated market potential is low in comparison to its development costs. In addition, some Member States rely on the EPPO positive list PM 6/3 to authorise (or not) a species on their territory. However, non-native species products need to have been on the market for several years to be included in the EPPO list, thus this is not adapted for new products and species coming in the market.

Societal needs

The (too) limited development of IBCAs is becoming a growing issue. The slower the use of IBCAs develops, the less they can contribute to a reduction in the use of chemical plant protection methods. Citizens' expectations and political scrutiny regarding the use of pesticides is raising for various reasons. These reasons include:

- The use of chemical pesticides has very negative impacts on human health, especially children's development[121];
- The use of chemical pesticides leads to declines in biodiversity, especially for pollinators;
- The estimated cost of chemical pest control in Europe (€2,3 billion) is considerably higher than its benefits (€0,9 billion), according to the firm BASIC[122] .

Citizen's concerns continue to be raised regarding the use of chemical pesticides. For example, two European Citizens Initiatives have been launched and were largely supported:

- European Citizens Initiative "Stop Glyphosate"[123] in 2017 calls for a ban on glyphosate (an herbicide), to reform the pesticide approval procedure, and to set EU-wide mandatory reduction targets for pesticide use
- More recently, European Citizens Initiative "Save Bees and Farmers"[124] calls on the Commission and European Parliament to act to gradually reduce the use of synthetic pesticides by 80% in EU agriculture by 2030 and to phase it out completely by 2035.

[121] https://www.pan-europe.info/issues/health/children
[122] https://eeb.org/wp-content/uploads/2022/02/SUD-Joint-Statement.pdf
[123] https://europa.eu/citizens-initiative/ban-glyphosate-and-protect-people-and-environment-toxic-pesticides_en
[124] https://www.savebeesandfarmers.eu/eng

4.1.2 Baseline scenario

An analysis of the evolution of the problems identified and their likely evolution is provided below. Two main consequences have been identified during the study:

- Insufficient development and use of IBCAs as an alternative to chemical pesticides in the control of plant pests, which will limit their role in contributing to the reduction of the use of chemical pesticides and achieving the objectives of the Farm to Fork strategy;
- Potential negative consequences on biodiversity, as risks on biodiversity are managed differently across Member States. While some are implementing specific risk assessments, other Member States are not assessing the risks and do not regulate the use of IBCAs. Despite the potential economic and ecological benefits of biological control as a pest control strategy, there are growing concerns about the risks associated with the use of non-native natural enemies for plant protection.

4.1.2.1 Slow development and use of IBCAs

The consequences in terms of market development, which may be slower than expected, are analysed in terms of potential impact on the quantitative targets for the reduction of use of pesticides outlined in the F2F strategy.

Estimation of the total potential of IBCAs development

The assumption and conclusion were presented during the workshop organised in the framework of this study.

A set of a few assumptions were established to reach quantitative estimates:

- IBCAs mostly target insects and mites. Although the company Biobest claims the development of a predatory mite targeting both pests and fungi (mildew), this currently remains an exception and it is difficult to estimate the extent to which this type of IBCA can be generalized in the future. Augmentatively released IBCAs are not expected to play an important role in the control of weeds, but resident ones could contribute to their control.
- The global relative uses of fungicides, herbicides and insecticides will remain similar at 45%, 35% and 15% of total pesticide quantities respectively (data in 2020 from Eurostat).

- Reduction of pesticide use will not be reached by substituting each current PPP use by an IBCA use. On the contrary, pesticide use will be decreased by the implementation of new and more resistant agrosystems that enable the combination of levers, including the use of IBCAs. Hence, estimating the rate of substitution of pesticides by IBCA is likely not a relevant method.
- Classical biological control will likely be vital for the response to biological invasions of exotic pests. It may also have a small impact on pests currently triggering pesticide use (e.g., *Cydia pomonella*, *Drosophila suzukii*, etc.).
- Conservation biological control fostering the activity of resident IBCAs is probably the most important tool to reduce pesticide use. It may act on all crop sectors and enable the use of most other agroecological levers.
- Augmentation biological control and SIT have the potential to enable pesticide free production under greenhouse and have strong focused impacts in other systems (e.g., against Lepidoptera and Tephritid flies in compatible cropping sectors).

In the long term, assuming a concrete transition to agroecology where pesticides are used in extremely small quantities, **the potential impact of IBCA is likely capped at -10% of pesticide use**. Indeed, IBCAs and semiochemicals, together with other levers of agroecology (resistant varieties, agronomic practices), have the potential to enable crop production without chemical insecticides (-15% of current pesticides based on the current share of insecticides in chemical pesticides use) and to decrease the use of a few fungicides (estimation at -1%) and herbicides (-2%). With a scenario where semiochemicals and IBCA remain equally important in biocontrol against arthropods (the trend observed within the last ten years), the possible impacts of IBCAs can be estimated to (-15% / 2) – 1% - 2% = -10.5%.

This corresponds to the long-term potential total impact of IBCAs.

The analysis of the current situation shows that, as a baseline, the IBCA market will continue to develop during the next 5 to 10 years.

The possible growth rate of the IBCA market is high: a recent report specifically dealing with IBCAs (the Global Beneficial Insects Companies Market Report) estimates the global IBCA market to be US$ 633 Million in 2020 and projects it to reach more than USD $ 1.4 bn by 2028, thus an increase of 220%. Applying this growth rate to the European IBCA market, it could be estimated that IBCAs will represent around 3-4% of the European crop protection market by 2030. Thus, it can be considered that IBCAs will contribute to a reduction in chemical pesticide use of 1 to 2% in the European Union from now until 2030.

4.1.2.2 Possible negative consequences on biodiversity

There have been very few reports of adverse non-target effects[125] despite the over 5000 introductions of over 2000 species of arthropod biological control agents over the past 100 years. This can be explained by the limited number of scientific publications on the subject as well as by the limited establishment of the species in the environment (only 5 species of biological control agents were removed from the EPPO positive lists).

EPPO has identified the risks related to invasive alien species, including the following: crossbreeding, competition for resources with native species, predation, and parasitism, as well as apparent competition. In addition, the risks related to the propagation, reproduction and perhaps modification of the intrinsic nature of the genetic heritage of the native species of the ecosystems, close to the introduced species, seem real.

Some examples of negative impacts of some species used as IBCAs could be reported (see also section 3.1.5):

- The main known example is ***Harmonia axyridis***, also known as the harlequin ladybird, or Asian ladybeetle. Originally used for both classical and augmentative uses over the world and in Europe, this species is currently recognised as damaging for European biodiversity as it has a wide host range across many taxonomic groups with a strong capacity for natural spread. Formerly listed by EPPO as a successfully introduced classical biological control agent, *Harmonia axyridis* has been removed from the EPPO list PM 6/3.
- ***Cales noacki*** is a hymenopteran parasitoid that was used for biological control of *Aleurothrixus floccosus (a* whitefly). It was introduced in Mediterranean countries in the 70s. However, it has been removed from the EPPO list in 2008 as "commercial releases may lead to establishment in non-target habitats in certain areas. Outdoor releases have shown a wide host range that extends beyond the Hemiptera order and in some areas, out competes indigenous natural enemies."

With the expected development of the use of IBCAs, especially in arable crops, the risk for biodiversity should be carefully analysed before their release and be monitored to ensure that their use does not negatively impact ecosystems.

4.2 Objectives to be considered

Based on the analysis of the problem definition, two main objectives have been identified:

[125] A critical evaluation of augmentative biological control, Timothy Colliera and Robert Van Steenwyk

- Foster market access and increase the availability of effective IBCAs in the territory of the European Union (existing and new solutions);
- Ensure the safe development and use of IBCAs across the European Union

4.3 Options and scenarios to be considered

Considering the drivers identified during the analysis of the problem definition, several options have been identified to answer to the problems described above.

These options are covering four main topics:

- **Options related to the harmonisation of the legal framework and/or risk assessment between Member States**. This is to both ensure that farmers have access to safe IBCAs in all Member States thanks to authorization and that the analysis of risks for biodiversity are homogeneously covered in the European Union.
- **Options related to the production, recording and monitoring of IBCA data** for the continued accumulation of knowledge in the European Union regarding the effects of using IBCAs (especially negative and positive effects on biodiversity).
- **Options related to fostering research and development** for the development of new and more effective solutions, without being limited by high costs for research and development.
- Options related to fostering training and knowledge transfer.

A first analysis of the pros and cons of these options is provided in the tables in each section. It aims to underline the extent of the effects they will have on:

- The evolution of the main problems identified and how these options will address the two main issues identified:
  - Regarding the slow development of the use of IBCAs, the pros and cons of the options are assessed against two criteria: the availability of IBCAs and the time needed to market new products.
  - Regarding the potential negative effects on biodiversity, the pros and cons of the options regarding environmental safety are provided.
- In addition, the pros and cons are analysed regarding the feasibility of the options as well as the economic sustainability of their implementation.

4.3.1 Options related to the harmonisation of the legal framework and/or risk assessment between Member States

Based on the analysis of the main issues identified through the findings of the study and the analysis of the problem identified, the Study identified several options regarding the possible harmonization of the legal framework between Member States:

- **Systematically integrate IBCAs as an alternative to chemical pesticides the initiatives and other documents of the European Commission** including as a candidate for substitution in a comparative assessment conducted at the national level according to Art. 50 of Regulation 1107/2009
- **Harmonized definitions of native, exotic and/or established species** can be provided at the European level
- **The establishment of whitelist(s) of safe IBCAs could be systematized**. It could be implemented by requiring the Member States to establish national lists of native and established species which can be used as IBCAs, establishing a whitelist of IBCAs that can be used safely at the European level (native and/or non-native species) or using the EPPO list PM6/3 as a common whitelist at the EU level.
- **The content of risk assessment and consequences of the analysis (especially mitigation measures)** could be harmonized. Several options have been identified to ensure that the content of the risk assessments performed takes account of the main risks, and that the same risks are analysed across the Member States. It also aims to ensure that the risk assessments are adapted to the species and types of organisms in order to limit any administrative burden. The main options are the following:
    - Use of EPPO guidelines in all Member States as a minimum common basis;
    - Increased homogenization of guidelines, standards, and form templates at the European level to be used by the Member States (including required data);
    - Adaptation of guidelines and forms to fit all IBCA uses (classical or augmentative biological control, native or non-native species, SIT, type of organism) in a flexible way;
    - Analysis of risk-benefits (and not only risks)
    - Analysis at species level only or analysis at the level of subspecies/strain, i.e., taking into account intraspecific variability
    - Distinction between demands for research and commercialisation: the authorisation process can be lightened

for research under certain specific conditions (confined space especially)

- Use of process with several steps: importation, introduction, commercialization to ensure that the analysis of the risk is adapted to the specific challenges of each step
- Definition of risk mitigation measures or plans as a result of the risk assessments in the Member States and control of their implementation

- **The existence of processes to ensure that IBCAs can be authorized after proper risk assessment in all the Member States.** Several options have been identified depending on the level of centralization and the involvement of third parties:
  - Requirement of Risk-Assessment performed by Member States
  - Risk-Assessment performed by EFSA. It can be the only authority in charge of the risk assessments in the European Union but can also be considered as a complementary option to conduct risk assessment in addition to the process in place in the Member States. In that case, several possibilities exist regarding the scope of the geographical coverage of the risk assessment: at the European level, considering the specific oversea/island zones, for specific zones required by the applicant, etc.
  - Centralized decision-making at the European level
  - Decision-making by each Member State
  - Mutual recognition between Member States

Options	Availability of IBCAs	Environmental safety	Time to market new products	Economic sustainability of the approach	Feasibility
Systematically integrate IBCAs as an alternative of chemical pesticides in the publication of the European Union and policy frameworks	+ This would encourage the use of IBCAs when a solution exists	-	-	-	- It should be ensured that the benefit-risk assessments are well adapted to consider IBCAs
Definition and list of species					
Harmonized definition of native, exotic and/or established species	-	-	-	-	- Would require negotiations among MS and among stakeholders
List of native and established species for each Member State	+ This would facilitate and speed up risk-assessment procedures as risks to analyse are low for native species + Native species listed will be available for farmers	-	-	-	-

Options	Availability of IBCAs	Environmental safety	Time to market new products	Economic sustainability of the approach	Feasibility
Establishment of EU-wide harmonized whitelist of IBCAs	+ Speed up regulatory process in the Member States where the process will be lighter for the IBCAs on the whitelist + Ensure a minimum list of authorised IBCAs in all Member States	- Review performed at the EU level will need to ensure that all the specificities of Member States are covered (crops, climate conditions, etc.)	-	- Would require review work to establish this list	- Would require negotiations among the Member States and among the stakeholders to establish the list
Use EPPO list as a common whitelist at EU level	+ Speed up regulatory process in the Member States where process will be light for the IBCAs on the whitelist + Ensure a minimum list of authorised IBCAs in all Member States	- The list should be adapted to each geographical zone to ensure coverage of variety of climate conditions and ecosystem - There is no information available regarding the risk assessment or	-	-	-

Options	Availability of IBCAs	Environmental safety	Time to market new products	Economic sustainability of the approach	Feasibility
		mitigation measures to be implemented			
Content and consequences of risk assessments					
Use of EPPO guidelines in all Member States	Stakeholders already know the procedures.				+ No impact for the Member States with a regulation in place
Increased homogenization of guidelines, standards and forms templates (including required data)	-	+ Would ensure that a minimum framework in all the Member States regarding risk on biodiversity	+ Facilitates the implementation for petitioners and experts	-	- Decrease flexibility at the level of each MS
Adaptation of guidelines and forms to fit all IBCA uses (classical or augmentative biological control, native or non-native species, SIT, type of organism) in a flexible way	- Would enable the use of the same procedures and forms for all types of IBCA uses, based on a smart use of specific subsections if needed.	-	-	- Analyses of dossiers would require additional expertise and flexibility	- Might complicate processes for individual MS with regulation separating the different uses.

Options	Availability of IBCAs	Environmental safety	Time to market new products	Economic sustainability of the approach	Feasibility
Analysis of risk-benefits (and not only risks)	-	+ Enables balanced analyses that account for both the risks the and benefits for MS biodiversity.	-	- Increased costs of gathering sound data on efficacy and efficiency of crop protection	+ Better fits most current Member State regulatory frameworks.
Analysis at species level only	-	- May overlook specificities of strains or other taxa within a so-called species (see below).	-	-	+ Prevents complication induced by considering subspecific aspects, and consequently easier to handle.
Analysis at the level of subspecies/strain, i.e. taking into account intraspecific variability	-	+ Different strains may carry different pathogens that should be specifically analysed during the risk assessment	- Requires precise data that the petitioner may not be able to produce. - Gathering the required data may be costly and would slow down R&D	- Accounting for intraspecific variability requires high expertise and high flexibility and adaptability when analysing the dossiers.	- There may be misidentification in complexes of species, leading to irrelevant assessments.

Options	Availability of IBCAs	Environmental safety	Time to market new products	Economic sustainability of the approach	Feasibility
		+ Strains may be very different at the phenotypic level (case of strains improved or modified for their use as IBCAs, or subjected to genetic drift in rearing), it will ensure that the different existing strains continue to exist.		- Different MS may develop strict or contrasting regulations preventing the industry from selling an IBCA species using the same strain throughout the EU. This would be a severe lock to most current business models based on economy of scale.	
Distinction between demands for research and commercialisation: the authorisation process can be lightened for research under certain specific	-	-	+ Speed up research and development	-	-

Options	Availability of IBCAs	Environmental safety	Time to market new products	Economic sustainability of the approach	Feasibility
conditions (confined space especially)					
Processes with several steps: importation, introduction, commercialisation	-	-	+ Enables parsimony in the efforts asked to petitioners at early steps of R&I processes	- Increased number of interactions and dossiers between petitioners and competent risk analysis services	-
Ensure that risk mitigation measures or plans are used and implemented in the Member States	-	+ Ensure that risk identified are monitor and manage	-	- Implementation of control will be necessary	-
Level of centralisation and third-party involvement					
Requirement of Risk-Assessment performed by Member States	Possible unavailability of IBCAs in Member States without adequate procedures, services or expertise.	Different MS may develop strict or contrasting regulations preventing the industry from selling an IBCA species using the same strain throughout the	-	- Redundant work in several MS - Lack of knowledge and capacity in some Member States to conduct theses risk assessment	+ Acceptable for MS with a regulation in place

Options	Availability of IBCAs	Environmental safety	Time to market new products	Economic sustainability of the approach	Feasibility
		EU. This would be a severe lock to most current business models based on economy of scale. Local officials have the necessary competence on local habitats, subspecies, populations			
Risk-Assessment performed by EFSA	- Risk of increase of the time needed for authorization of IBCAs + Increase access to authorised IBCAs in all the Member States	+ Ensures high standards of quality and independence. - Risk assessment should consider variety of conditions between the Member States	-	- New procedures to be set up, with additional resources to EFSA and an EC portal to submit dossiers - Additional resource and investment: An EC portal used as entry point transmitting to EFSA is required.	-

Options	Availability of IBCAs	Environmental safety	Time to market new products	Economic sustainability of the approach	Feasibility
				Additional resources must be planned to make sure EFSA can perform risk-assessment within short times + Avoid reductant work between Member States	
Centralized decision-making	+ IBCAs will be available at European level	- Does not let MS authorities to decide their own principles of biodiversity protection and risk-management	-	+ One procedure for multiple Member States	-
Decision-making by each MS	-	+ Let the Member States decide according to its own risk-management strategy and its own specificities (local biodiversity,	-	- Redundancy of procedures with up to 27 Member States conducing decision making	-

Options	Availability of IBCAs	Environmental safety	Time to market new products	Economic sustainability of the approach	Feasibility
		cropping systems, etc.)			
Mutual recognition between Member States	+ Facilitate the authorisation and availability of IBCAs	- Some regional / local specificities have to be considered regarding risk on biodiversity	-	+ Limit the redundancy between Member States	-

Four types of scenarios have been defined by combining the different options in order to provide some examples of the possible frameworks that can be developed at the European Level within a gradient from voluntary scheme to a completely centralised assessment and centralised decision-making. These scenarios have been discussed during interviews with NCAs and other main stakeholders as well as during the workshop. They are described below, and the main pros and cons identified are summarised for each of them:

Scenario 1: Voluntary scheme based on the use of data from EPPO

The simplest voluntary scheme may rely on the production by EPPO of a set of guidance documents and positive/negative lists including the native/exotic status of species in each Member States (if known). Member States or groups of Member States could then agree to use these documents and lists as directly usable criteria to provide authorisation of importation/use of IBCAs or as a mere source of information to feed their own regulatory processes. This system may then be more or less constrained in so far is it can impose quality or reliability criteria on the data published by EPPO, with different possible extents of intended harmonization.

The pros and cons of this scenario (and that of scenario 2 below) were discussed precisely during the validation workshop on 31st of August. The outcomes of this discussion are summarized in the table below.

Pros	Cons
▸ Industry already knows how to work under this scenario ▸ Little administrative burden. ▸ Flexible in terms of use by the MS.	▸ Not binding enough to ensure availability and safety throughout the EU ▸ Not enough homogenization at EU level ▸ No consideration of cross border issues ▸ Requires that all MS have a regulation ▸ Risk assessment would require a higher level of independence vs stakeholders and formal management of conflict of interest ▸ Difficulty for small companies to handle many different national frameworks

	▸ Lot of work for all MS ▸ Not suitable for MS without national regulation ▸ Disruption of free movement of goods

Scenario 2: A two-levels procedure to find a balance between homogenization and freedom of action of Member States

Here, EFSA (or another EU organisation with expertise on IBCAs) would play a major role by being responsible for (i) an impact assessment for any species to be produced/used/commercialised and not previously listed in the EU, and (ii) the publication of guidance documents, negative and positive lists, and lists detailing the exotic/resident status of species in Member States (referring to the data produced by EPPO if relevant). The work at the EU level will only concern assessment and studies at the species level. The only obligation for all Member States would be to automatically prohibit the use of species on the negative list produced at the European level. Then, the Member States would be able to choose between several options: (i) Member States may use EU documents and lists as a source of information to implement their own national processes for the authorisation of products on their territory (e.g. reliable data from EFSA would be appreciated in Spain and France that already set their national regulations); (ii) Member States with no national regulation on IBCAs or no impact assessment process may use the impact assessments and existing lists to reach their conclusions regarding authorisations (or may even delegate additional specific assessment regarding strains or specific geographical area or the authorisation decision to EFSA). In addition, some voluntary mutual recognition schemes could also be integrated for groups of Member States by specific zones.

Pros	Cons
▸ The initial centralized risk assessment performed once for any new (exotic or previously not assessed) IBCA ensures safety for all MS. ▸ The two-step process combines safety for all MS and flexibility/freedom for MS in terms of implementation ▸ A competent EU risk assessment body is involved in the	▸ Risk of duplication of work between centralized and national risk-assessments ▸ Longer timelines involved by a formal EU-level procedure and involvement an EU agency. ▸ Risk of redundancy between EFSA and EPPO ▸ If the centralized risk-assessment is performed for the

assessment of new (exotic or previously not assessed) IBCAs. ▸ Higher level of homogenization ▸ Whitelist and negative lists help with decision making ▸ Sharing of information and resources ▸ Close cooperation between EFSA and EPPO	entire EU zone, this is a challenging work ▸ Longer time to set up the new framework

Scenario 3. A centralized impact-assessment managed by EFSA (or another EU organisation with expertise on IBCAs).

Under this scenario, EFSA would handle the demands from all entities and perform impact assessments. Decision-making would be left to the government services of each Member States on the basis of the results of the European analysis (unless decision making is delegated to EFSA by the Member State authorities).).

Pros	Cons
▸ Simple process, one entry point	▸ Limited freedom/flexibility for MS at the national level for risk-assessment

Scenario 4: A completely centralized process, from assessments to decision-making.

Under this scenario, EFSA (or another EU organisation with expertise on IBCAs) would handle the whole process, from assessment to decisions of authorizations of importation/production/commercialisation in Europe.

Pros	Cons
▸ Simplest process, one entry point and one decision-making procedure	▸ Exclusion of the MS authorities from the risk-assessment and decision-making processes

Each of the scenarios based on a high level of centralisation (3 and 4) would then have to be split into two sub-scenarios: (i) with impact-assessments at the species level only and (ii) with impact assessments taking into account intraspecific variations (e.g., as it is currently implemented in France). The rationale behind the choice to deal with intraspecific variations is that very different subspecies or differentiated populations can be found within a same so-called species and may display very different phenotypes

and contrasting risks and benefits in terms of use as biocontrol agent; these risks and benefits may also differ according to the release environment: ecological zone, island, etc.

On the relevance of accounting for intraspecific variations in IBCAs, from a scientific point of view, IBCA populations may display significant differences in terms of phenotypes affecting the risks they can pose on biodiversity and the benefits they can provide to crop protection. IBCA populations display a gradient of genetic differentiation that ranges from local variations to genetic differentiation. This can cause reproductive isolation. There is no clear boundary to set at which populations can be considered differentiated populations, subspecies, sibling species, different species, etc. In theory, accounting for intraspecific variations is relevant, because assessments may be biased by the occurrence of intraspecific differences which, in turn, may affect the risks and benefits.

In practice, however, data about genetic structure of IBCA populations are extremely scarce and data about genetic structure impacting functional diversity (i.e., impacting phenotypic traits important for biocontrol features; which by the way are not clearly set in the scientific literature) are, to our knowledge, not available. Hence, the risks of misinterpreting intraspecific data and creating a high administrative burden due to assessments based on poor quality data or inadequate interpretation of data in an evolutionary and ecological perspective are very high. Obliging petitioners to produce scientifically sound intraspecific data would also be unrealistic: most companies do not have the resources to do so (particularly with regard to running analyses at the level of functional genetic diversity) and the costs would be unreasonably high when compared to the possible accessible markets. It could be underlined that there is only one entry in the EPPO positive list that goes to strain level (only the non-diapausing strain of *Neoseiulus californicus* is accepted in the positive list of commercially available IBCAs).

On the definition (or absence of definition) of zones relevant to the risk-benefit assessment. One issue is the difficulty in agreeing to the zones that ought to be considered separately when assessing risks and benefits. Member States currently use at least political borders (which is not making sense in a scientific point of view), and they sometimes delineate zones within their borders (in islands and in ultramarine territories, for instance). Some experts and stakeholders argue that Europe can be considered as a single zone or that several zones could be delineated according to a range of criteria: (i) using the same zones (South, North, Centre) as those used in the regulation applying to pesticides, (ii) zones delineated by barriers (mountains, sea, etc.) relevant to dispersal capacities of IBCAs, (iii) zones delineated by pedoclimatic features, (iv) zones delineated by crop sector features, (v) "ecoregions"[126], etc. Choices may also be influenced by the type of regulatory framework to be adopted. The more the processes are

[126] https://www.cabdirect.org/cabdirect/abstract/20063106175

centralized, the more relevant the discussions about the delineation of zones when assessing risks and benefits will be.

4.3.2 Options related to the production of data, recording and monitoring of IBCAs

As identified during the study, little data is available regarding the current market of IBCAs in the EU and the use of IBCAs by the Member States (including the long-term effects of the release of IBCAs). The following options aim at improving the current situation regarding the production of data and the recording and monitoring of the use of IBCAs:

Options	Availability of IBCAs	Environ-mental safety	Time to market new products	Economic sustain-nability of the approach	Feasibi-lity
Require the registration of European producers and volume of sales	+ Increase understanding of the mean of production available in Europe and the evolution of the market	-	-	-	-
Monitor the use of IBCAs through the definition of common indicators to be reported at EU level (i.e. number of species authorised, number of products, etc.)	+ Facilitate sharing of knowledge and return of experience regarding the use of IBCAs	+ Deepen knowledge on where and which IBCAs are used to ensure monitoring of the situation and react faster in case of detection of unintended effects	-	- Additional administrative burden for Member States and European Commission	-
Develop the process to	-	-	+ Speed up the risk	-	- Some issues

Options	Availability of IBCAs	Environ-mental safety	Time to market new products	Economic sustain-nability of the approach	Feasibi-lity
increase the share of information on risk assessment between the Member States			assessment in Member States		may be encountered regarding private property
Set up a working group at EU level to conduct specific work on post release assessment (and especially positive and negative impacts of IBCAs)	-	+ Increase of knowledge on post-release effects of IBCAs	-	- Need of financial support to conduct large scale scientific projects on a long-term basis (effects should be monitor on several years)	-

4.3.3 Options related to innovation fostering

As previously mentioned; the effort to support the research and development of IBCAs could be increased. This push for innovation could be supported by several national and/or European initiatives:

- Several financial schemes exist at the European level that support public and private stakeholders (and public-private partnerships): Horizon programme, CAP (through EARDF), ERDF, etc.
    - BTSF program could be mobilized to increase the expertise of both risk analysis specialists and BCA users. It is funded by the EC with specific training sessions to improve the capacity of the expert work with microorganisms. There are specific sessions for technicians which could be extended for BCAs, not only to train technicians on BCAs, but extend them to NCAs.
    - EIP Agri projects

  - Generally, EU-funded projects in Horizon Europe are large, but there are also smaller programs, also related to knowledge dissemination (Ex RELAX, under which some field trials are funded). They are also a very important part of the practical information transfer to farmers.

- Specific **efforts should be focused on the strategies with the highest cost-benefit ratios for farmers**, i.e. coupling conservation biocontrol, establishment biocontrol and inoculation augmentation biocontrol, and establishing non-academic players working on their routine implementation with stakeholders (cooperatives, farmers' groups, etc.). So far, IBMA does not include companies that proved able to create an economically viable activity from conservation biocontrol for example, because the suitable business models, that strongly depart from the classical "input producer" model, have not been put into practice.
- Specific programs focused on generating data and references about impacts (environmental, economic, social) of IBCAs, including life-cycle analyses, could be beneficial to remove constraints to development and use. **Horizon Europe calls may specifically target this objective of producing data on biocontrol sustainability** (including that of IBCAs) over the coming years.
- **Encouraging co-innovation projects** among different stakeholders (**until downstream industries** that create added value for food produced via more agroecological methods) could help foster innovation. This is currently encouraged in most EU calls, but not always put into practice and rarely (or never) performed specifically on co-innovation regarding biocontrol methods. This could be fostered both at the levels of Member states and Horizon Europe.
- Financial incentives could be given to farmers for the use of IBCAs to support the demand of products (it could also be integrated in CAP strategic plans, as it is the case in France)

The pros and cons of these options are summarized in the table below.

Options	Availability of IBCAs	Environ-mental safety	Time to market new products	Economic sustain-nability of the approach	Feasibi-lity
Using financial schemes at the EU level to support public and	+ This would make more solutions available on the market	+ This could help build capacity to assess environmental safety	+ This would speed up the production and	-	-

Options	Availability of IBCAs	Environ-mental safety	Time to market new products	Economic sustain-nability of the approach	Feasibi-lity
private stakeholders: Horizon programme, CAP (through EARDF), ERDF, etc.			commercia-lisation of new products		
Leveraging EU and national programs focused on assessing impacts	-	+ This would make more solutions available on the market	-	-	-
Encouraging co-innovation projects involving local stakeholders, growers, industry	+ This would make more solutions available on the market	+ Involving different stakeholders could help increase IBCA acceptability + This could increase capacity to assess environmental risks locally	+ This would speed up the production and commercia-lisation of new products	-	- Involving different stake-holders in a co-innovation project may be complicated from a practical point of view
Requiring national strategies regarding the development and use of IBCAs	+ This would make more solutions available on the market	+ This could encourage considerations related to environmental risk assessment and monitoring at the national level	+ Reducing the time to market new products could be an objective of national strategies	- Some Member States may not have the capacity of feel the need to provide significant financing	- Some Member States may not have the capacity or willingness to design and implement such a strategy

Options	Availability of IBCAs	Environ-mental safety	Time to market new products	Economic sustain-nability of the approach	Feasibi-lity
				for the strategy	
Setting financial incentives to support the demand of IBCA products among farmers	-	+ This could help decrease the use of insecticides among farmers	-	- This would require additional financial expenses at the EU or national level	-

4.3.4 Options related to training, knowledge transfer and behavioural changes along the agrifood value chains

Knowledge of IBCAs among growers has been identified by the study as a key driver for the adoption of IBCAs. As mentioned above, knowledge transfer currently happens foremost between industry advisors and growers. Other sources of knowledge could be reinforced, such as education, public communication, industry associations, etc. Several means exist to support training and knowledge transfer:

- Developing a specific platform / working group supported by the European Union to share information between the stakeholders and Member States regarding the use of IBCAs (or more generally biocontrol solutions). In particular, it would ensure that specific contacts are identified in each Member State and in charge of the subject. At the EU scale, this could be fostered through programmes like the Circular Bio-based Europe Joint Undertaking (CBE JU)[127].
- Supporting farmers' capacity development and share experience, from financial support to training on the subject.
- Supporting the monitoring and data collection regarding the use of IBCAs in the Member States and encourage the sharing of this data at European level.
- Fostering communication and success stories in which IBCAs are successfully integrated into place-based and collective agroecological initiatives. Communication among Member states should be

[127] Circular Bio-based Europe Joint Undertaking (CBE JU).

emphasized. Several national programmes exist but they rarely engage stakeholders from other Member States.

Knowledge is not only lacking among growers, but also among NCAs, specifically on risk assessment. Several initiatives could help improve the situation:

Providing additional guidelines and tools for Member States to develop their own framework

- Providing training regarding risk assessments

The pros and cons of these options are summarized in the table below:

Options	Availability of IBCAs	Environ-mental safety	Time to market new products	Economic sustain-nability of the approach	Feasibi-lity
For growers					
Developing a specific platform / working group supported by the European Union in order to share information between the stakeholders	+ This would promote the adoption of IBCAs	+ This could help increase knowledge on the environmental safety of IBCAs	-	-	- This working group should complement /improve existing networks and not duplicate them
Supporting farmers capacity development through financial support to training on this subject and sharing of experience	+ This would promote the adoption of IBCAs	+ This could help increase knowledge on the environmental safety of IBCAs	-	- This would require additional financing	- Communicati on on these initiatives is important for their success, especially in Member States in which the use of IBCAs is limited

Options	Availability of IBCAs	Environ-mental safety	Time to market new products	Economic sustain-nability of the approach	Feasibi-lity
For growers					
Supporting the monitoring and data collection and ensuring accessibility to this data in the European Union	-	+ This could help increase knowledge on the environmental safety of IBCAs	+ This could speed up risk assessments and therefore the process of marketing new IBCAs	-	- This would require significant effort as data requirements and whether data is consolidated at the national level differ across Member States
Fostering communication and success stories in which IBCAs are successfully integrated into place-based and collective agroecological initiatives	+ This would promote the adoption of IBCAs	+ This could help increase knowledge on the environmental safety of IBCAs	-	-	-
For Member States					
Providing additional guidelines and tools for Member States to develop their	+ This would promote the adoption of IBCAs	+ This could help increase knowledge on the environmental	+ This could help disseminate good regulatory practices which		- As different Member States have different approaches to

Options	Availability of IBCAs	Environ-mental safety	Time to market new products	Economic sustain-nability of the approach	Feasibi-lity
For growers					
own framework		safety of IBCAs	would speed up the authorisation process		regulations and different perceptions of risk, guidelines should be careful not to suggest a unique model
Providing training regarding risk assessments	+ This would promote the adoption of IBCAs	+ This could help increase knowledge on the environmental safety of IBCAs	+ This could help disseminate good regulatory practices which would speed up the authorisation process		- As different Member States have different approaches to regulations and different perceptions of risk, guidelines should be careful not to suggest a unique model

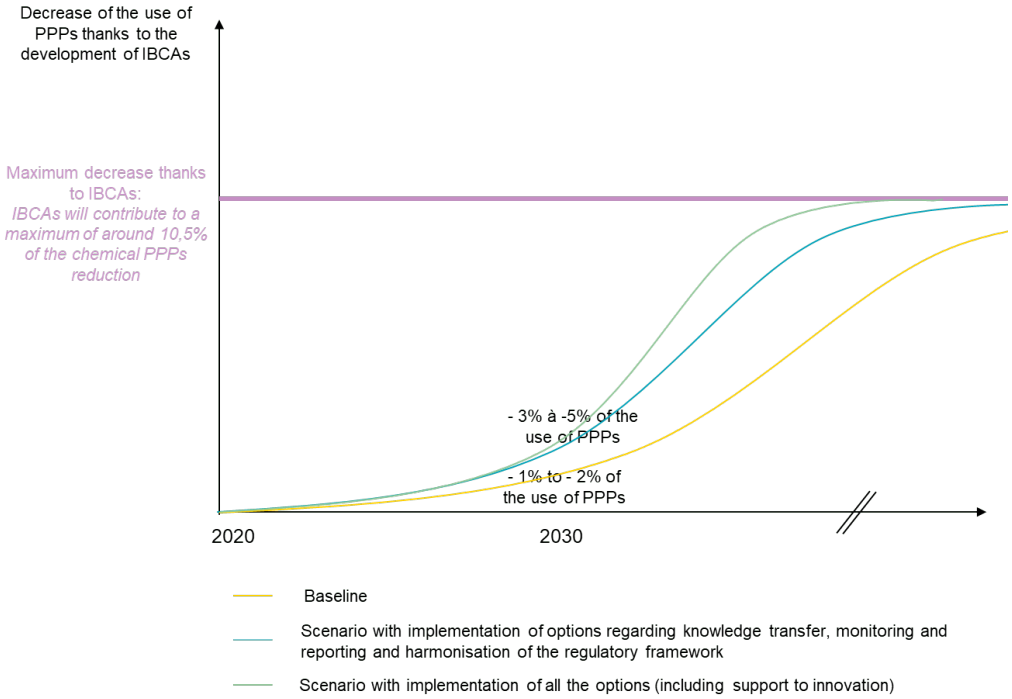
Preliminary inputs regarding the impacts of the implementation of the option on the achievement of the objectives of reduction of the use of chemical pesticides of the Farm to Fork Strategy.

As mentioned in the analysis of the pros and cons of the different options, these options will have various impacts on the development and use of IBCAs and thus, on the achievement of the objectives of the Farm to Fork Strategy.

Within the next 10 years in the frame of the Farm-to-Fork strategy, assuming (i) strong policy measures to increase market penetration of augmentative biocontrol and SIT, and (ii) above all, concrete actions to professionalize the management of conservation biocontrol, IBCAs may contribute to a reduction of -3% to -5% of pesticide use in 2030, given that the timeframe is very limited (7 years to 2030). Thus, an additional reduction of -2% to -4% of pesticides in comparison to the baseline.

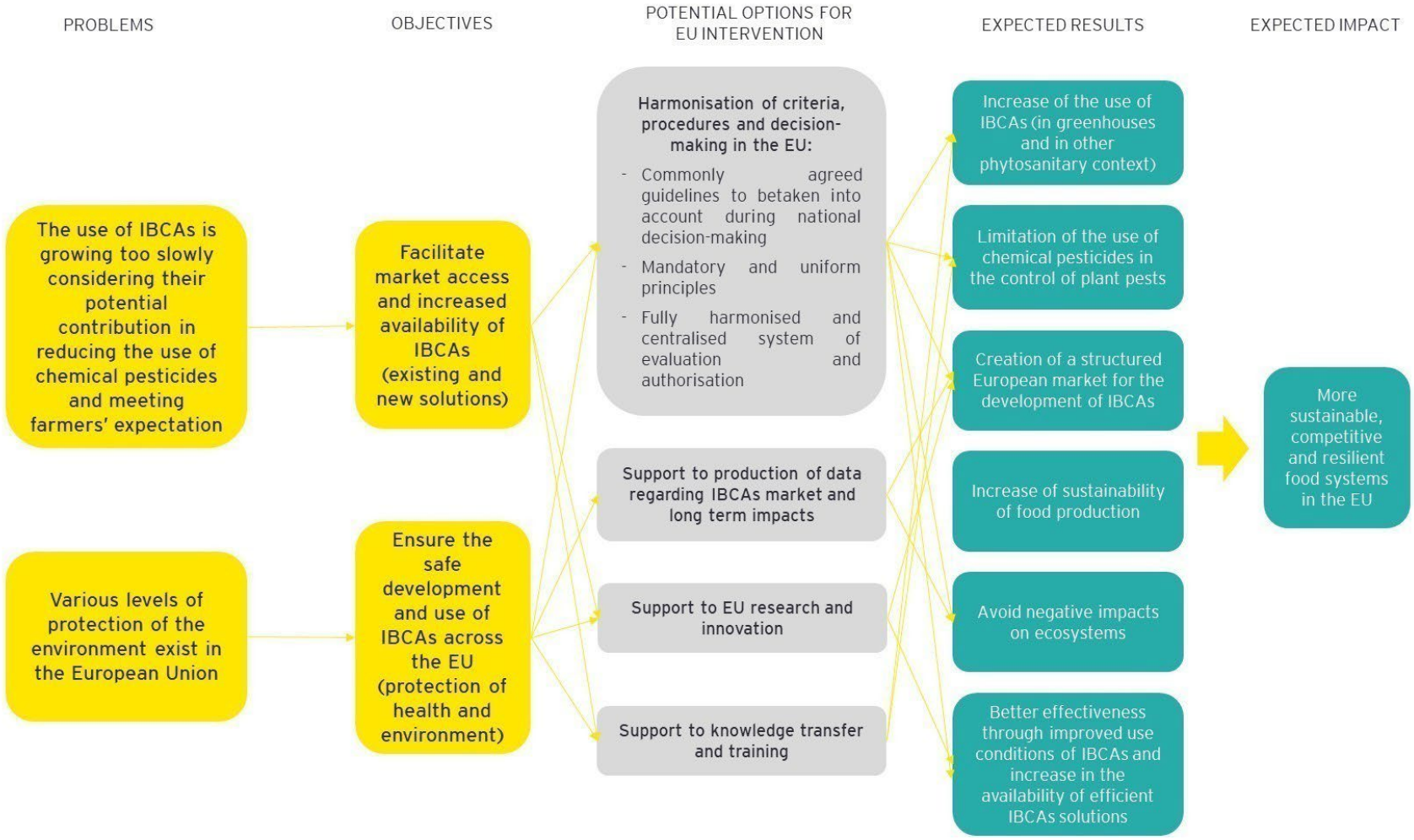
Knowing that impacts from starting research are generally reached after 15-20 years and that, as a consequence, only results of already started and identified R&D activities will be able to impact in 2030. However, from a longer-term perspective, the support to innovation may ensure that the maximum potential for the reduction of the use of chemical pesticides thanks to IBCAs is reached faster.

Figure 13 - Schematic view of the potential of decrease of the use of chemical pesticides through the development of IBCAs



The impacts of the options would need to be further assess in case of the implementation of the various options by the European Commission.

4.4 Intervention logic



5 Annexes

5.1 Annex 1 - Key definitions regarding IBCAs

BCAs

Biological control is a concept in plant protection and plant health defined by the OECD as a "pest management strategy making use of living natural enemies, antagonists or competitors and other self-replicating biotic entities"[128]. However, this definition is still controversial among researchers[129].

Biological control mainly relies on the agents and substances used to control plant pests and invasive alien plants. The OECD programme on biological pesticides identifies four groups of **biological control agents (BCAs)**: (i) plant extracts/botanicals, (ii) semiochemicals, (iii) microbials, and (iv) macrobials/invertebrates. This classification is presented below:

Table 12: classification of biocontrol agents into 4 groups

Groups of BCAs	Biocontrol agents	Examples
Plant extracts / natural products[130]	Natural biocides or pesticides	Extracts of onion, garlic, eucalyptus, tobacco, ground and dried flowers, essential oils…
Semiochemicals[131]	Species-specific organic compounds used by insects to convey specific chemical messages that modify behaviour or physiology. Biocontrol management strategies include monitoring, mass trapping, mating disruption, attract-and-kill, and push–pull	Pheromones, allochemicals (allomones, kairomones, synomones, apneumones)
Microbials	Micro-organisms (mainly viruses, bacteria, and fungi) which can be used to control pests, pathogens, and weeds. Most micro-organisms used against pests and weeds are pathogens, while modes of action to control other micro-organisms can be via direct or indirect antagonism (parasitism, competition, etc.).	Bacteria, algae, fungi, protozoans, viruses

[128]OECD (PDF) Guidance for Information Requirements for Regulation of Invertebrates as Biological Control Agents (IBCAs) (researchgate.net)

[129] https://doi.org/10.1023/A:1014193329979 ; https://doi.org/10.1017/9781139029117 ; https://dx.doi.org/10.1007/s10340-021-01354-7

[130] van Lenteren, J.C., Bolckmans, K., Köhl, J. *et al.* Biological control using invertebrates and microorganisms: plenty of new opportunities. *BioControl* **63,** 39–59 (2018). https://doi.org/10.1007/s10526-017-9801-4

[131] Anamika Sharma, Ramandeep Kaur Sandhi, and Gadi V. P. Reddy https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6955951/

	**Macrobials / invertebrates**	Invertebrate animals which can be used to control pests and diseases as well as vectors of such pests and diseases, unwanted organisms and weeds.	Insects, mites, nematodes

IBCAs

Invertebrate biological control agents (IBCAs), also called macrobials, are invertebrate animals which can be used to control pests and diseases as well as vectors of such pests and diseases, and unwanted organisms. They can act as predators, parasitoids, parasites, competitors for common resources, or otherwise inhibit their population growth or spread:

Table 13: types of IBCAs (or macrobials) species

Category	Mode of action	Examples
Predators	Predators kill and feed other organisms Specific advantages for biological control: smaller range of prey species, shorter life cycles allow for predator population density to fluctuate in response to changes in the density of their prey	Spiders, predatory mites, lady beetles, ground beetles, lacewings, nematodes, etc.
Parasites	Organisms that live in or on other organisms, without killing them	Nematodes, mites …
Parasitoids	Insects parasitic only in their immature stages, killing its host in the process of its development, and free living as an adult[132]. High host specialization Sterile insect techniques are being developed to release sterile parasitoids that still kill their hosts, but have lesser impact on non-target organisms[133]	Hymenoptera (parasitoid wasps), Diptera (parasitoid flies)
Competitors	For common resources (honeydew, plant nectar or pollen) For common mates: Sterile Insect Technique (SIT) involving the mass-rearing and release of sterilised insects to disrupt fecundity	SIT
Phytophages	Herbivorous invertebrates used to control weeds. Classified according to what they consume (roots, stems, leaves, flowers, seeds, fruits), and by how they feed (sucking, chewing, leaf or stem mining, root boring). Some herbivores can be vertebrates (goats, fishes…) but are outside the scope of this study	Herbivorous invertebrates

Invertebrates used for biological control can be either:

[132]□OCDE (PDF) Guidance for Information Requirements for Regulation of Invertebrates as Biological Control Agents (IBCAs) (researchgate.net)

[133] Horrocks, Kiran & Avila, Gonzalo & Holwell, Gregory & Suckling, David. (2021). Irradiation-induced sterility in an egg parasitoid and possible implications for the use of biological control in insect eradication. Scientific Reports. 11. 10.1038/s41598-021-91935-4. https://www.researchgate.net/publication/352287980_Irradiation-induced_sterility_in_an_egg_parasitoid_and_possible_implications_for_the_use_of_biological_control_in_insect_eradication

- **Native species** (also called indigenous) species, meaning that they originate from and have evolved in a local area over a long period of time. Species that are native are described in terms of their geographic origin: this could lead to specific challenges as in a same specific Member State, a species can be considered as a native one in a specific region but not in another area (this is especially the case for Member States with outermost regions). This will be further investigated through survey and interviews with NCAs to better understand the definition applied at national levels.
- **Non-native species** (also called exotic or alien species), that on the contrary refer to organisms that have evolved in a different area of the world and are now present elsewhere or may occur elsewhere. **Non-native species are called introduced** species when they were introduced either intentionally or accidentally in environments in which they were not native. **Non-native species are called "established"** when they do not need human help to reproduce and maintain themselves over time in an area where they are not native.

Member States may have their own definition of the scope of IBCAs, especially with regards to what is considered as native or non-native. Thus, some Member States may not consider SIT as being part of the scope in their legislation, or not consider native species as they only regulate non-native ones.

Biocontrol mechanisms

The use of BCAs (including IBCAs) in pest management relies on different strategies. Traditionally, biological control can be achieved through four different mechanisms which refer to different introduction methods of the agent, different origins, and/or different types of biological control agent(s) used in the process. The four categories of biocontrol are briefly presented below[134]:

[134] Eilenberg J, Hajek A, Lomer C. 2001. Suggestions for unifying the terminology in biological control. BioControl 46:387-400 DOI:10.1023/A:1014193329979

Table 14: types of biological control mechanisms / strategies

Types of biological control	
Natural biological control[135]	Natural biological control refers to the natural functioning of ecosystems where pest organisms are reduced by naturally occurring beneficial organisms. This occurs in all the world's ecosystems **without any human intervention**
Conservation biological control of existing natural enemies[136]	Conservation biological control refers to the protection, promotion, and attraction of native beneficial organisms by: Providing or restoring habitat and resources for natural enemies (other sources of nectar and pollen, shelter, substitute prey and hosts…) Reduction of pesticide use (to preserve highly pesticide-sensitive natural enemies), selection of pesticides impacting them less, application of these pesticide in a manner more likely to affect the pest more than the beneficial organism Attracting of natural enemies by semiochemicals
Classical biological control: introduction and establishment of a new species	The intentional introduction and permanent establishment of an exotic biological agent for long-term pest management[137]. The species introduced is a non-native species that present capacities to regulate the pest targeted. It is often used when an exotic pest has been imported without its natural enemies, to introduce this natural enemy in the territory and control the pest. In case of neoclassical biological control, the introduction is based on a novel association of the pest and a natural enemy species (with no previous coevolutionary interaction). As the aim is to establish a new species in a specific territory, this might require a long process of research, selection, risk-assessment, quarantining, release methodology, etc.
Augmentative biological control: periodic release	Augmentative biological control refers to the large-scale release or inoculation of natural enemies (parasitoids, predators or micro-organisms) that can be native or non-native species. In case of the use of non-native species it does not aim to establish these species on the long term. Several techniques exist[138]: **Inundative biocontrol**: short-term release for crops with a short production cycle (e.g. nematodes, SIT, microbials) **Seasonal inoculative biocontrol**: longer term production cycle. Ex: appropriate for natural enemies who cannot survive winter, for

[135] van Lenteren, J.C., Bolckmans, K., Köhl, J. *et al.* Biological control using invertebrates and microorganisms: plenty of new opportunities. *BioControl* **63,** 39–59 (2018). https://doi.org/10.1007/s10526-017-9801-4

[136] Alissia Rousseaux, Lorie Seychal, Jean-Pierre Sarthou. 2018. Conservation biological control : Definition. Dictionnaire d'Agroecologie, https://dicoagroecologie.fr/en/encyclopedia/conservation-biological-control/

[137] OCDE Guidance for Information Requirements for Regulation of Invertebrates as Biological Control Agents (IBCAs) (researchgate.net)

[138] van Lenteren, J.C., Bolckmans, K., Köhl, J. et al. Biological control using invertebrates and microorganisms: plenty of new opportunities. BioControl 63, 39–59. 2018. https://link.springer.com/article/10.1007/s10526-017-9801-4

	greenhouses where all possible natural habitat for the natural enemy at the end of a production cycle is removed[139]

The study will focus on **classical and augmentative biocontrol** using invertebrates (including SIT), which target the deliberate production, release, and marketing of macrobial organisms. The **distinction between these two types of biocontrol will be key**, as they follow different logics: classical biocontrol aims at establishing a new species with a long-term perspective, whereas augmentative biocontrol focuses on shorter-term release of organisms. As such, the study questions may apply most directly to one type or the other.

Other relevant definitions linked to IBCAs

- ***Biological diversity / Biodiversity:*** The variety of life on Earth. It includes all organisms, species, and populations; the genetic variation among these; and their complex assemblages of communities and ecosystems. It also refers to the interrelatedness of genes, species, and ecosystems and in turn, their interactions with the environment[140]. (Definition adopted by The United Nations Environment Programme (UNEP). In the present document, biodiversity more specifically relates to the variety of organisms in specific geographical area.
- ***Integrated Pest Management (IPM)****:* Integrated Pest Management (IPM) means the careful consideration of all available pest control techniques and subsequent integration of appropriate measures that discourage the development of pest populations and keep pesticides and other interventions to levels that are economically justified and reduce or minimize risks to human and animal health and the environment. IPM emphasizes the growth of a healthy crop with the least possible disruption to agro-ecosystems and encourages natural pest control mechanisms (Definition adopted by FAO).
- ***Invasive alien species (IAS):*** Species whose introduction and/or spread outside their natural past or present distribution threatens biological diversity and related ecosystem services[141]. (IUCN)
- ***Plant pest:*** "Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products" (IPPC)

[139] Marieke Busson, Julien Chetty, Marie-Hélène Robin, Jean-Noël Aubertot. 2019. Biocontrol : Definition. Dictionnaire d'Agroecologie, https://dicoagroecologie.fr/en/encyclopedia/biocontrol/
[140] https://www.unep.org/unep-and-biodiversity
[141] UNEP - Convention on Biological diversity. 2018. https://www.cbd.int/doc/c/0c6f/7a35/eb8815eff54c3bc4a02139fd/cop-14-inf-09-en.pdf

- ***Quarantine plant pest:*** "A pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled" (IPPC)

Other relevant definitions for the purpose of the Study

For the use of this study, the following terms are used:

- Introduction of IBCAs refers to the import and entry of IBCAs in the territory of the Union;
- Production of IBCAs refers to the breeding of invertebrates to obtain sufficient number of individuals (mass-rearing);
- Release of IBCAs refers to the actual use of IBCAs (in a contained or non-contained environment);
- Marketing of IBCAs refers to the placement of a product on the market.

5.2 Annex 2 - Documentary review

Guidance documents

OECD & van Lenteren. 2004. Guidance for Information Requirements for Regulation of Invertebrates as Biological Control Agents (IBCAs) : //www.researchgate.net/publication/40123759_Guidance_for_Information_Requirements_for_Regulation_of_Invertebrates_as_Biological_Control_Agents_IBCAs

OECD - Biolocigal pesticides https://www.oecd.org/chemicalsafety/pesticides-biocides/biological-pesticides.htm

EFSA PLH Panel (EFSA Panel on Plant Health), 2015. Statement on the assessment of the risk posed to plant health in the EU territory by the intentional release of biological control agents of invasive alien plant species. EFSA Journal 2015;13(6):4134, 12 pp. https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2015.4134

EFSA PLH Panel (EFSA Panel on Plant Health), 2015. Risk to plant health in the EU territory of the intentional release of the bud-galling wasp Trichilogaster acaciaelongifoliae for the control of the invasive alien plant Acacia longifolia https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2015.4079

IPPC Secretariat. 2017. Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms. International Standard for Phytosanitary Measures No.3. Rome. FAO on behalf of the Secretariat of the International Plant Protection Convention https://www.fao.org/3/j5365e/J5365E.pdf

Legislative texts

Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009L0128-20190726

Regulation 1107/2009 (EC) of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32009R1107&from=fr#d1e583-1-1

Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02012R0528-20220415

Council Decision (EU) 2021/1102 requesting the Commission to submit a study on the Union's situation and options regarding the introduction, evaluation, production, marketing and use of invertebrate biological control agents within the territory of the Union and a proposal, if appropriate in view of the outcomes of the study. OJ L 238, 6.7.2021, p.81 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32021D1102

Regulation (EU) 2016/2031 of the European Parliament and of the Council on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 2000/29/EC, 2006/91/EC and 2007/33/EC. OJ L 317, 23.11.2016, p.4. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R2031

Regulation (EU) 1143/2014 of the European Parliament and of the Council on the prevention and management of the introduction and spread of invasive alien species. OJ L 317, 4.11.2014, p.35. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02014R1143-20191214

Commission Directive (EU) 2019/782 of 15 May 2019 amending Directive 2009/128/EC of the European Parliament and of the Council as regards the establishment of harmonised risk indicators. OJ L 127, 16.5.2019, p.4. https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32019L0782

Non-legislative texts published by the Commission

BIOLOGICAL CONTROL CONFERENCE, Lisbon, 28 April 2021, Presentation of BCA MS survey https://www.dgav.pt/wp-content/uploads/2021/05/DGAV_-conferencia_BCA.pdf

European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system. COM/2020/381

final. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0381

Scientific studies & Research projects

REBECA (Registration of Biological Control Agents) Final activity report https://cordis.europa.eu/docs/results/22/22709/123869671-6_en.pdf

Anamika Sharma, Ramandeep Kaur Sandhi, and Gadi V. P. Reddy. 2019. A Review of Interactions between Insect Biological Control Agents and Semiochemicals https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6955951/

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Venter, J. Invasive species and the Working for Water programme in South Africa https://www.fao.org/3/y5968e/y5968e13.htm

Sterile Insect Technique (Hendrichs & Robinson) IAEA-FAO

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R. Hill, D. Campbell, L. Hayes, S. Corin and S. Fowler, Why the New Zealand Regulatory System for Introducing New Biological Control Agents Works, International Symposium on Biological Control of Weeds, 2011

https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwiV8pHT86_3AhXCh_0HHYV9BzMQFnoECAQQAQ&url=https%3A%2F%2Fwww.invasive.org%2Fproceedings%2Fpdfs%2Fhill.pdf&usg=AOvVaw02Jewl0cwAh1ckR8QjYFcn

J. Brodeur, P.K. Abram, G.E. Heimpel and R.H. Messing Biocontrol, 63 (1) (2018), pp. 11-26

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Crowder, D.W., Northfield, T.D., Strand, M.R., Snyder, W.E., 2010. Organic agriculture promotes evenness and natural pest control. Nature 466, 109–112

Others

Alissia Rousseaux, Lorie Seychal, Jean-Pierre Sarthou. 2018. Conservation biological control : Definition. Dictionnaire d'Agroecologie, https://dicoagroecologie.fr/en/encyclopedia/conservation-biological-control/ https://dicoagroecologie.fr/en/encyclopedia/conservation-biological-control/

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UNEP and Biodiversity https://www.unep.org/unep-and-biodiversity

UNEP - Convention on Biological diversity. 2018. https://www.cbd.int/doc/c/0c6f/7a35/eb8815eff54c3bc4a02139fd/cop-14-inf-09-en.pdf

IBMA Black Box Market Survey 2021 https://ibma-global.org/wp-content/uploads/2021/10/IBMA-Membership-Appraisal-Black-Box-Survey-2021_summary.pdf

DIR-SIT - HISTORY OF TRANSBOUNDARY SHIPMENTS OF STERILE INSECTS (iaea.org) https://nucleus.iaea.org/sites/naipc/dirsit/SitePages/HISTORY%20OF%20TRANSBOUNDARY%20SHIPMENTS%20OF%20STERILE%20INSECTS.aspx?WikiPageMode=Edit&InitialTabId=Ribbon%2EEditingTools%2ECPEditTab&VisibilityContext=WSSWikiPage

Directory of SIT facilities (IAEA) https://nucleus.iaea.org/sites/naipc/dirsit/SitePages/All%20Facilities.aspx

"Hulot, J.F. and Hiller, N. (2021) 'Exploring the benefits of biocontrol for sustainable agriculture – A literature review on biocontrol in light of the European Green Deal', Institute for European Environmental Policy." https://ibma-global.org/wp-content/uploads/2021/06/IEEP-Exploring-the-benefits-of-biocontrol-for-sustainable-agriculture-2021.pdf

Joint EPPO / COST-SMARTER Workshop on the Evaluation and Regulation of the use of Biological Control Agents in the EPPO Region, Budapest, 2015-11-23/24 https://www.eppo.int/MEETINGS/2015_meetings/wk_biocontrol

"IBMA - Position paper on the interpretation of 'native' in invertebrate biocontrol agent regulations" https://ibma-global.org/wp-content/uploads/2020/12/positionpaperlocalpopulationsvotedabim2015adoptiononwebsite20161213.pdf

5.3 Annex 3 - Study grids and sources

5.3.1 Question 1: What is the current market of IBCAs on the level of Member States and how can it be further developed?

Sub-questions & Coverage		Types of analysis	Data to be collected and data sources
a. **Which information is available** on the market value of IBCAs used in different Member States?	7 MS	Data to be collected: Number of IBCAs subject to commercial activities, sales of IBCAs (in euros), market destination (internal/EU/global) (in euros), native/non-native species Question to IBMA (and NCAs in each of the 7 MS): do they collect data on IBCA market value? how? What factors determine the availability and quality of existing information: existence of national umbrella organisation, directly from industry members…? How reliable is that information? What are existing challenges? Is that information sufficiently detailed to be able to compare IBCAs with BCAs in general, and with PPP? If no comparable data: review of existing data as provided by IBMA or NCAs, and analysis of their specific scope and how they are produced and collected by the data provider. If possible, the Study team will process collected data in order to have comparable information In case no data is available to certain Member States: The Study team will rely on other sources of information as far as possible such as representatives of IBMA at national level or research publications.	▸ IBMA market survey 2022 ▸ Questionnaire sent to NCAs ▸ Interviews with 7 MS
What is their **market share** in comparison to PPP?	7 MS	Analysis based on: - Data collected for question a)	▸ Questionnaire sent to NCAs

Sub-questions & Coverage		Types of analysis	Data to be collected and data sources
		- Data on PPP sales (euros) and available studies - Complementary data from NCAs on PPP market at national level	▸ Survey and interviews with industry associations representing the interests of manufacturers and retailers of IBCAs
b. What is the proportion of IBCA uses in relation to authorised PPP uses?	All	Analysis based on the lists of uses at European level and in each Member States Specific analysis for pests where both alternatives are existing (examples to be identified during interviews)	▸ Eurostat ▸ EPPO list of uses ▸ Questionnaire sent to NCAs ▸ Interviews with NCAs ▸ Survey and interviews with industry associations representing the interests of manufacturers and retailers of IBCAs
c. In which cropping or phytosanitary scenarios (e.g. greenhouse, specialty crops ('minor uses'), major crops,…) are IBCAs currently used? How are these use patterns distributed	All	Number of IBCAs for commercial activities, Surface of application of IBCAs in the main different scenarios on the basis of a typology of uses. Typology will rely on the types of IBCAs used, the targeted crop / forest, the conditions of use (greenhouse especially), minor/major use, use in association	▸ Questionnaire sent to NCAs ▸ Targeted interviews with industry associations representin

Sub-questions & Coverage		Types of analysis	Data to be collected and data sources
or replicated over the Union: are the patterns similar across all Member States or do specific national patterns exist and how do they look like?		with PPP, conventional or organic farming, etc. Identification of IBCAs used for classical biocontrol agents and established in Member States, targeted crops and pests, etc. Mapping of existing uses across MS Comparison across MS, with an identification of some groups of MS with similar patterns Identification of factors that explain these use patterns	g the interests of manufacturers and retailers of IBCAs,farmers associations and scientific organisations
d. What is the potential for development of IBCAs over the coming 10 years in terms of new uses, additional cropping and phytosanitary scenarios as well as of market value in the different areas considered under point (c)? How many of these uses are currently empty (i.e. no phytosanitary solution exists)? How many uses of chemical PPP are likely to be substituted and what will be the quantitative impact on the Harmonised Risk Indicators defined under Directive 128/2009/EU? e. On the opposite: for which uses and cropping/	All	Analysis will rely on data collected in questions c), f) and g) as well as some additional data to cover all MS: Development of a model considering different scenarios and assumptions: - Existing gaps based on current/ future demand and available products - Potential products available in the short/ middle term (depending on their development stage, time to develop new products…) - Other assumptions depending on potential initiatives at EU level: stronger incentives to develop new products, marketing authorisations… It will be crucial to consider the point of view of experts, researchers, producers and users. Specific analysis to feed into the model assumptions: - Analysis of historical trends for the development of the products and time of research	▸ Questionnaire sent to NCAs ▸ Targeted interviews with industry representatives, farmers associations and scientific organisations

Sub-questions & Coverage		Types of analysis	Data to be collected and data sources
phytosanitary scenarios is there little or no potential to develop an IBCA solution within a reasonable timeframe? What are the reasons?		required / number of products entering the market per year - Analysis of farmer's needs and current orphan uses - Analysis of existing public and private research activities (to be linked with existing instruments of incentives in question 4) Analysis of the quantitative impact on the Harmonised Risk Indicators defined under Directive 128/2009/EU: - Identification of the pesticides that could be substitute by IBCAs in the coming 10 years - Application of the methodology to calculate Harmonised Risk Indicators	
f. In which Member States are IBCAs produced, how significant is the production (compared to the overall production in the Union and globally) and for which markets are they produced (domestic/EU/global)? How many new IBCAs are under development and how many newly enter the market per year?	7 MS	Analysis will rely on data collected in question a), in addition the following data will be collected: - Overall production of IBCAs in Europe and globally - Number of IBCAs under development (public and private) - Number of IBCAs entering the market per year (historical data)	▸ Data from industry associations representing the interests of manufacturers and retailers of IBCAs ▸ Questionnaire sent to NCAs ▸ Targeted interviews with scientific organisations

Sub-questions & Coverage		Types of analysis	Data to be collected and data sources
g. What are the demands from the side of users (agriculture, forestry, plant quarantine) for new IBCAs/new uses of existing IBCAs to be developed?	7 MS	Identification of current orphan uses, farmer's need as well as current experiments under implementation	▸ Targeted interviews with representatives of farmer's, and forestry associations
h. What are expected benefits from the use of IBCAs for the ability to control additional plant pests as a substitute to chemical PPP and hence how will this impact the quantitative targets for the reduction of use of PPP outlined in the Farm to Fork strategy (quantify)?	All	Qualitative descriptions of the expected benefits Different projections depending on potential initiatives to be taken to foster the development of new IBCAs and/to better regulate and control related risks. Model to establish the quantity of PPP that could be substitute with the development of IBCAs (based on the research trends) and the development of IBCAs to fight new pests rather than the development of new PPPs	▸ Survey and Targeted interviews with industry associations representing the interests of manufacturers and retailers of IBCAs, farmers associations and scientific organisations ▸ Questionnaire sent to NCAs
What are the expected effects on biodiversity?		General description of the potential effects on biodiversity and ecosystems Identification of the different types of effects (direct / indirect, reversible / irreversible, etc.) Identification of the biological mechanisms that might impact natural biodiversity (competition,	▸ Questionnaire sent to NCAs ▸ Interviews with representatives of civil society organisations

Sub-questions & Coverage		Types of analysis	Data to be collected and data sources
		parasitism, predation, crossbreeding, etc.) Analysis based on literature review as well as interviews of stakeholders	
What are the expected effects on food safety?	All	Qualitative analysis of positive and negative impacts on food safety: decrease of PPP residues on products, possible increase of toxins, etc. Illustrations from examples with previous experience of IBCAs	▸ Targeted interviews with Industry associations representing the interests of manufacturers and retailers of IBCAs, farmers associations and scientific organisations

5.3.2 Question 2: What (regulatory) systems are in place in relation to introduction, production and/or release of IBCAs in the different Member States?

Sub-questions & Coverage		Types of analysis	Data to be collected and data sources
a. Which Member States do not regulate at all the introduction, production and/or release of IBCAs and are IBCAs used in these Member States?	All	Identification of the Member States where introduction, production and/or release IBCAs are not covered by national regulation	▸ Questionnaire sent to NCAs
b. Of the Member States that do regulate IBCAs, which authorities are involved in the regulatory process	All	Scope of application of the regulatory system in place in the Member States regarding the introduction, production and release of IBCAs:	▸ Questionnaire sent to NCAs

Sub-questions & Coverage		Types of analysis	Data to be collected and data sources
and the decision making for the release of IBCAs for agricultural, forestry and phytosanitary purposes? Which administrative levels (state, regions, municipalities) are involved in this process in the different Member States? Is the same regime applied to IBCAs imported from outside the EU, from other Member States and produced domestically? Do the same rules apply to amateur and professional users?		- Legal statues of IBCAs: plant protection products / specific statues / not defined - Scope of application of the framework(s) depending on products and use: classical / augmentative biocontrol, native / Non-native species, Agricultural / forestry / phytosanitary purposes, SIT, invasive plant species, etc. - Geographical scope of application (national level, importation and exportation from other EU MS or from third countries) - Scope of application regarding users: amateur and professionals' users Content of the regulatory system: - Description of the regulatory process and decision making for the introduction, production and release of IBCAs - Existence of lists of products that can be used at Member States level (content of the lists) - Process for the introduction, production and release of a new product - In what consist the regulatory framework (law, directives, guidelines, etc.) Description of the authorities involved: - Administrative level of implementation of the framework (state, regions, municipalities) - Role of the different authorities in the implementation of the framework	
c. Which Member States carry out a formal risk assessment before introduction, production and/or	All	Content of risk assessment process - Scope of application - Responsible authority - Source of data used for the assessment (industry, other)	▸ Questionnaire sent to NCAs

Sub-questions & Coverage		Types of analysis	Data to be collected and data sources
release within their territory is permitted and what are the elements within that risk assessment (e.g. risk to local biodiversity, risk to non-target plants, risk of unintended spread)? Which Member States rely on third-party assessments in their decision-making (e.g. using the list from EPPO PM 6/3(4)) and to which extent?		- Stage of application of the risk assessment (before first introduction, before commercial use, etc.) - Impacts considered during the assessment (risk to local biodiversity, risk to non-target plants, risk of unintended spread, etc.) - Geographic scope of the analysis of the impacts - Use of EPPO list (PM 6/3) Description of the decision-making process - Implication of third-party - How are benefits and risks assessed, and decision taken Number of assessments conducted each year and results (approbation or rejection of products)	
d. Which Member States apply the same or similar regulatory approach to IBCAs compared to PPP (i.e. pre-marketing authorisation based on scientific risk assessment)?	All	Analysis of the answers to question b and c Identification of Member States where IBCAs are considered as plant protection products	▸ Questionnaire sent to NCAs
e. In which Member States is the introduction, production or marketing of IBCAs subject to legal requirements (e.g. registration of producers or retailers, rules regarding quality control) and what are the legal	All	Description of other legal requirements for the introduction, production or marketing of IBCAs: - Registration of producers and retailers - Rules regarding quality control - Other? (Transport requirements for example)	▸ Questionnaire sent to NCAs

Sub-questions & Coverage		Types of analysis	Data to be collected and data sources
provisions and procedures in place?			
f. In which Member States are users of IBCAs legally obliged to keep record of the IBCAs they purchase, store and/or use? Is the system independent from the corresponding obligations regarding PPP? Is a system in place to record negative impacts and possible harm by IBCAs (e.g. lack of efficacy, undesired longevity of the IBCA in the environment, interference with naturally occuring populations of plants or animals)? Is the information collected systematically by the competent authorities or merely kept available at farmer's level?	All	Description of monitoring and recording process in place: - Identification of Member States where the record of IBCAs, purchase, store and use in mandatory as well as during transport - Comparison and differences from the PPP system Description of data and information that are recorded: - Negative impacts on biodiversity: o Undesired longevity of the IBCAs in the environment o Interference with naturally occurring populations of plants or animals - Efficacy of products Description of the process to collect data information - Responsible of the data collection - Control in place - Consolidation at national level (or kept available at farmer's level)	▸ Questionnaire sent to NCAs
g. Which Member States impose risk mitigation measures in connection to the release of IBCAs? Which risks are addressed (e.g. risk to local biodiversity, risk of unintended spread) and which	All	Description of the risk mitigation measures defined at Member States level before the release of IBCAs: - Risks covered - Content of the risk mitigation measures - Process to ensure the enforcement of the measures (controls, authorities in charge, monitoring, etc.)	▸ Questionnaire sent to NCAs

Sub-questions & Coverage		Types of analysis	Data to be collected and data sources
measures are in place? How are these measures being enforced?			
h. Does a "safe" or "low risk" list exist that requires no regulatory input?	7 MS	Existence of "safe" or "low risk" list at Member States level Comparison of this list between Member States and with the list of EPPO	▸ Interviews with NCAs
i. Are there quality control procedures in place for the production of IBCAs?	7 MS	Description of quality control procedures in place: - Types of indicators used to measure quality of the products - Process for reporting and controls - Authorities involved	▸ Interviews with NCAs ▸ Survey and Targeted interviews with industry associations representing the interests of manufacturers and retailers of IBCAs, and scientific organisations
j. Are there monitoring strategies in place to identify changes in natural ecosystems?	7 MS	State of the art of monitoring strategies to identify changes in the ecosystems structure and species Critical review of existing approaches to monitor the changes (duration, frequency, targeted species and / or ecosystems components, etc.)	▸ Interviews with NCAs

5.3.3 Question 3: What are the characteristic elements of the regulatory approaches in force towards the introduction, evaluation, production, marketing and use of IBCAs in Member States?

Sub-questions & Coverage		Types of analysis	Data to be collected and data sources
a. What are the key data requested by Member States for authorising the release of IBCAs? What are the most common data deficits in applications for release?	7 MS	▸ Identification of the data used during authorisation process, source and indicators used ▸ Identification of the most common data lacking in the applications and the data that are the most difficult to obtain ▸ Identification of potential other challenges (reliability of data, capacity of analysis of data provided, etc.)	▸ Interviews with NCAs ▸ Targeted interviews and surveys with Industry associations representing the interests of manufacturers and retailers of IBCAs
b. Are there measures in place to facilitate the administrative processes (e.g. specific, updated and publicly available guidance, pre-submission meetings for dossier submitters) in the different Member States? What are these measures and how do industry and public authorities rate their fitness?	All	▸ Identification of measures in place to facilitate administrative process ▸ Perception of industry and public authorities regarding the relevance and effectiveness of the existing measures and identification of gaps and current difficulties encountered to meet the expectations	▸ Questionnaires to NCAs ▸ Interviews with NCAs ▸ Targeted interviews with Industry associations representing the interests of manufacturers and retailers of IBCAs,

Sub-questions & Coverage		Types of analysis	Data to be collected and data sources
			farmers associations and scientific organisations
c. Are the users of IBCAs sufficiently informed and trained and which measures are considered to be useful in improving the situation from their point of view?	7 MS	▸ Perception of the stakeholders regarding the level of knowledge and training of users (farmers, technical advisor from industry, from extension, etc.)	▸ Interviews with NCAS ▸ Interviews with representatives of the users (farmers mainly)
d. Which Member States and stakeholders consider cross-border spread as a potential safety issue? In which Member States is a potential cross-border spread of IBCAs after release part of the risk assessment and where so, which mitigation measures are imposed? Are these measures considered realistic, affordable and sufficient by the different stakeholders?	All	▸ Identification of the Member States and stakeholders considering cross-border spread as a potential safety issue ▸ Existence of specific risk management process towards cross-border spread risk ▸ Existence of specific mitigation measure	▸ Questionnaire to NCAs ▸ Targeted interviews with, farmers associations and representatives of the environmental NGOs
e. Are there sufficient production capacities for IBCAs and how can it be assured that there is a sufficient supply with IBCAs over the season (taking into account that outbreaks may occur at differing points in time)? How will producers have sufficient IBCAs available for the case of an unexpected pest outbreak?	7 MS	▸ Market organisations: number of producers, capacities of production ▸ Existence of supply break over the season ▸ Existence of stocks of IBCAs ▸ Time for production in case of pest outbreak ▸	▸ Interviews with NCAs ▸ Questionnaire to NCAs ▸ Targeted interviews with Industry associations

Sub-questions & Coverage		Types of analysis	Data to be collected and data sources
			representing the interests of manufacturers and retailers of IBCAs, farmers associations
f. Which cases of undesirable impacts of the release of IBCAs (e.g. on non-targeted species, ecosystems and biodiversity in general) have been reported so far? If yes, which and what was done to mitigate them? Which Member States provide for the systematic accompanying monitoring for the release of IBCAs into the environment and how is that monitoring structured?	All	▸ Identification of negative impacts on biodiversity reported within the EU members ▸ Identification of possible records of problems or issues on biodiversity related to specific IBCAs species ▸ Identification of the mitigation approach adopted by the EU members ▸ Existence of a systematic monitoring of the effects of IBCAs on biodiversity after the release within the EU members ▸ Nature and approach of such monitoring (methodology, species targeted, duration, frequency, etc.), especially regarding the IBCAs that can persist over the years	▸ Interviews with NCAs ▸ Questionnaire to NCAs ▸ Targeted interviews with Industry associations representing the interests of manufacturers and retailers of IBCAs, farmers associations and scientific organisations and representative of environmental NGOs

Sub-questions & Coverage		Types of analysis	Data to be collected and data sources
g. Are there negative effects expected from remnants of IBCAs in exported goods for the international trade of goods?	7 MS	▸ Same approach as for question f.	▸ Interviews with NCAs ▸ Questionnaire to NCAs ▸ Targeted interviews with Industry associations representing the interests of manufacturers and retailers of IBCAs, farmers associations and scientific organisations and representative of environmental NGOs
h. What are the main shortcomings under the regulatory approaches in force in Member States current practice? What are the drivers behind?	All	▸ Identification of the main shortcomings of the current regulatory approach in place in the Member States, the challenges resulting from differences in regulation and rules in place	▸ Questionnaires and Interviews with representatives of users and producers

5.3.4 Question 4: Which of the regulatory instruments below are used and in which Member States? How can they be used more effectively? Have additional instruments been mentioned by stakeholders and which are they?

Sub-questions & Coverage		Types of analysis	Data to be collected and data sources
a. What is the role of internationally agreed guidance documents? Which documents are used?	7 MS	▸ Use of positive lists of EPPO ▸ Integration of the guidelines of EPPO in the approval and risk assessment in the regulation ▸ Use of guidelines for the importation of IBCAs	▸ Interviews with 7 MS ▸ Questionnaires and interviews with EPPO, IPPC, IAEA-FAO, EFSA ▸ Targeted interviews and questionnaire with intergovernmental organisations
b. How do research projects and (public or private) funding of product development contribute to availability and usability of IBCAs? Which success stories exist? Where did the use of ICBAs fail and what are the reasons?	7 MS	▸ Distribution of public and private research and main characteristics (difference between augmentative and classical biological control) ▸ Impacts on research and development on the availability of IBCAs (difference of needs of research depending on native or non-native species for example) ▸ Examples of success stories of research projects ▸ Examples of failure of research projects and causes	▸ Documentary review / scientific papers ▸ Interviews with 7 MS, ▸ Targeted interviews with industry associations representing the interests of manufacturers and retailers of IBCAs, farmers associations and representatives of environmental NGOs
c. Is there a knowledge transfer academia – industry – users in the Member States? How is it organised	7 MS	▸ Description of the knowledge transfer organisation, the main stakeholders involved ▸ Capacity developed by the Member States to	▸ Interviews with 7 MS ▸ Targeted interviews with industry associations representing the

Sub-questions & Coverage		Types of analysis	Data to be collected and data sources
and how does it look like?		support knowledge transfer	interests of manufacturers and retailers of IBCAs and representatives of environmental NGOs
d. Are there any economic or financial incentives (tax relief for industry and/or users, fast track procedure in administrative processes, financial instruments to increase uptake of IBCAs at user level) applied in the Member States? What are the effects and what are the costs?	7 MS	▸ Identification of the existing financial incentives in the member States ▸ Impact of these incentives on research and development and use of IBCAs ▸ Cost of the financial incentives	▸ Interviews with 7 MS ▸ Targeted interviews with industry associations representing the interests of manufacturers and retailers of IBCAs and representatives of environmental NGOs
e. In which form are regular or sporadic training activities concerning IBCAs for national authorities and private advisers (e.g. awareness), industry (e.g. regulatory aspects) and/or users (e.g. use) organised, by whom and on which level (Member State, region, association)? Where do training strategies exist?	7 MS	▸ Review of the training strategies of Member States ▸ Description of the current training activities for the different groups of stakeholders	▸ Documentary review of documents transmitted by NCAs ▸ Interviews with 7 MS ▸ Targeted interviews with industry associations representing the interests of manufacturers and retailers of IBCAs, farmers associations and representatives of environmental NGOs
f. Which Member States have mechanisms in place to collect feedback from	7 MS	▸ Documentary review of the collected feedbacks from extension and advisory services	▸ Documentary review of documents transmitted by MS

Sub-questions & Coverage		Types of analysis	Data to be collected and data sources
extension and advisory services (public and private)? Which are examples for improvements due to such feedback? How is efficiency of the regulatory process rated by Member States and stakeholders and how could the different approaches be improved?		▸ Identification of range for improvements of the use of IBCAs ▸ Perception of stakeholders regarding the regulatory process and possible improvements	▸ Interviews with 7 MS ▸ Targeted interviews with industry associations representing the interests of manufacturers and retailers of IBCAs

5.4 Annex 4 - Templates of the surveys and interview guides used during the study

Note: The data collection tools were adapted to each stakeholder consulted during the study. Thus, the next sections presented one example of questionnaire (sent to National Competent Authorities) and one example of interview guide (used with representatives of industry/business operators).

5.4.1 Questionnaire to National Competent Authorities

Our consortium has been mandated by the European Commission – DG SANTE to carry out a study on the Union's situation regarding invertebrate biological control agents (IBCAs) for the use in plant health and plant protection. The objective is to provide input to the Commission regarding the introduction, production, evaluation, marketing and use of invertebrate biological control agents within the territory of the Union, including an overview of the existing regulations in each MS (if any) and an analysis of the potential for further development of IBCAs.

In this framework, the following **questionnaire** has been developed to collect data and relevant information from each national competent authority within the European Union. It is structured as follows:

- **Section 1** seeks to collect information on **national regulation applying to IBCAs** in your country (scope, content, processes, authorities involved, etc.);
- **Section 2** seeks to collect information on the **market of IBCAs in your country** and the current uses;
- **Section 3** focuses on the main perspectives, on ways to fostering the development and use of IBCAs and potential options for developing initiatives and addressing existing problems at EU level;
- **Annexes** seeks to collect additional information on the current market and use of PPPs (for comparison with IBCAs market and the potential for development of IBCAs)

The questionnaire is integrating both some questions to be answered by Yes or No (tick boxes) and some open questions (please use the open cells in light yellow).

Could you please send the questionnaire completed **before the 17th June 2022.** We are aware that this timeframe is short, but this is unfortunately due to strained Commission schedules.

To facilitate the process, please note the following:

- We would like to schedule an exchange about this survey in the coming days to define how to support you in the collection of

expected information. Could you please propose several timeslots for this meeting (45 minutes approximately)?

- Please feel free to send partial responses along the way/ step by step. You may send us each section as soon as it is completed to the best of your knowledge, and redirect other sections to other contributors at national level;
- **Priority question** questions are indicated **in bold**: you may first focus on these questions and we can discuss further how to collect any missing information;
- In addition to the completion of the questionnaire, please do not hesitate to send us all additional documents that could be relevant for the study (in national language if needed): regulatory framework, assessment grids, additional lists of species, national studies, etc.

In case you need additional information, or you have specific questions on the content of the questionnaire, please do not hesitate to contact us through the following email address: *EY email address was provided*

We thank you in advance for your answer and information provided,

Best regards,

The Study team

Preamble: Focus on the scope of the following Study questions

Please note that this study will focus only on **Invertebrate Biological Control Agents** such as insects, including male sterile insects, mite, and nematode species (IBCAs). Only uses which are linked to the intentional release of IBCAs shall be considered. Furthermore, only IBCAs shall be considered which are intended to protect plants or plant products, ("plants" and "plant products" as defined in Article 2 of Regulation 2016/203111), including those to control invasive plants. Insects purely used for pollination are outside of the scope of the study.

In addition, the definition of plant protection products (PPP) is the one of Article 2 of Regulation (EC) No 1107/2009 referring to substances (chemical elements and their compounds) including micro-organisms.

Thus, we thank you to apply this scope and definition for the completion of the questionnaire.

➔ If available data does not fit with the scope of the study, please clearly explain the scope and types of products covered by the data provided and, if possible, provide an estimation in accordance with the scope of IBCAs considered by this study.

Section 1 - Regulation applying to IBCAs in your country

1. **In your country, <u>is there a regulatory framework in place applying to IBCAs</u> (augmentation, inundation/inoculation, introduction/classical biocontrol, autocidal control/SIT)?**

   ☐ Yes, adopted since … (please specify)

   ☐ Yes, under development but not adopted yet

   ☐ No

Please send us documents describing the regulatory framework, or the regulation itself

2. ***IF NO, please answer to this question and go directly to section 2:* Do you identify a lack of regulatory framework in your country? If relevant, what are the main challenges you identify regarding IBCAs (for instance, low use of IBCAs, poor research and development, introduction of species without assessment of the potential risks, etc.)?**

text

If YES: please provide additional information by answering following questions (sections 1.1, 1.2, 1.3 and 1.4)

Section 1.1: Scope and content of regulation (whether existing or under development)

3. ***W*hich of following aspects are covered by IBCA framework (existing or under development)?** Please select all that apply and indicate the reference to the legislation, when applicable.

	Yes	No	In development
Regulation for the <u>introduction</u> of IBCAs	☐	☐	☐
If 'Yes', please specify/ add reference	Text (please specify if the regulation relies on an authorization system or not)		
Regulation for the <u>production</u> of IBCAs	☐	☐	☐
If 'Yes', please specify/ add reference	Text (please specify if the regulation relies on an authorization system or not)		
Regulation for the <u>release/ commercialisation</u> of IBCAs	☐	☐	☐
If 'Yes', please specify/ add reference	Text (please specify if the regulation relies on an authorization system or not)		

Registration of IBCA producers and retailers	☐	☐	☐
If 'Yes', please specify/ add reference	Text		
Quality control (at the time of production, storage, during transportation, etc.)	☐	☐	☐
If 'Yes', please specify/ add reference	Text		
Transport of IBCAs	☐	☐	☐
If 'Yes', please specify/ add reference	Text		

4. **Regarding the scope of IBCA, does the national regulatory framework:**

   a. Provide a distinction between classical and augmentative biocontrol?

text

   b. Provide a distinction between native and non-native species (if any), and in that case what is the scope/definition applied to native species?

text

   c. Integrate sterile insects (SIT) releases?

text

5. **Is authorisation granted either for a specific function or for a specific IBCA organism (species, strains, etc.) (where applicable)?**

text

6. **What is the role of internationally agreed documents (IPPC / EPPO standards, OECD, EFSA, IOBC, etc.) within this national legal framework? Is the regulation consistent with these frameworks? To what extent are these standards integrated in existing regulation?**

text

7. **Is the same regime applied to IBCAs imported from outside the EU, from other Member States and produced domestically?**

   ☐ Yes

   ☐ No

Text – Add precisions if needed

8. Is the same regime applied to IBCA used for augmentation biocontrol, classical (introduction/acclimatation) biocontrol and autocidal control (Sterile Insect Technique)?

☐ Yes

☐ No

Text – Add precisions if needed

9. Do the same rules apply to amateur and professional users?

☐ Yes

☐ No

Text – Add precisions if needed

10. Is the same regime applied to IBCA used for research and for commercial purposes?

☐ Yes

☐ No

Text – Add precisions if needed

11. If necessary, could you provide any additional description of the Regulatory framework in place in your country to clarify its scope, content and specificities?

Text

Section 1.2: Focus on risk assessment processes

12. Is a risk assessment conducted for IBCAs in your country?

☐ Yes

☐ No

13. *If yes*, at which stage(s) is the risk assessment conducted:

☐ Before importation

☐ Before first introduction outside confined spaces, e.g. for research purposes☐

☐ Before commercial use

☐ Other? Please specify:

14. Does a "safe" or "low risk" list or a similar concept (e.g. qualified presumption of safety) exist that requires no regulatory input?

☐ Yes

☐ No

In that case could you provide this list or documentation describing the concept?

text

15. What are the key data requested for the assessment and authorisation of the release of IBCAs?

text

16. What are the sources of data used for the assessment?

☐ Applicants

☐ Third parties

☐ Others (e.g. open literature, please specify)

text

17. What are the possible unintended impacts that are evaluated?

☐ Risk to local biodiversity

☐ General risks to biodiversity

☐ Risk to other crops than those affected by the targeted pest (plant health)

☐ Risk of unintended spread

☐ Risk to human health

☐ Risk from diseases introduced as contamination of the IBCA

☐ Others (please specify)

text

18. What are the evaluated possible benefits?

☐ Plant protection /phytosanitary effects

☐ Environmental benefits

☐ Risk to local biodiversity

☐ Others (please specify)

text

19. What is the geographical scope considered for the analysis of the impacts (local, national, regional, European, worldwide, etc.)?

text

20. Is cross-border spread considered as a potential safety issue in the assessments?

☐ Yes

☐ No

21. Do the analyses take into account the possible negative effects of remnants of IBCAs in exported goods for the international trade of goods?

text

22. Is the assessment conducted at species or strains level (or other)?

text

23. Are mitigation measures imposed in your country?

☐ Yes

☐ No

If 'Yes', which of them relate to related to cross-border issues?

text

24. Does the process rely on third-party assessments in their decision-making (e.g. using the "Positive" list from EPPO PM 6/3(4))?

☐ Yes, EPPO PM 6/3(4)

☐ Yes, other☐ No

25. What is the number of assessments conducted each year and results (approbation or rejection of dossiers)?

Total number of assessments per year		
Approbation of dossiers per year	[average number per year]	[please indicate the period over which this data was collected]
Rejection of dossiers per year	[average number per year]	[please indicate the period over which this data was collected]

26. What is the number of assessments relying on third-party assessments:

Number (average per year)	[please indicate the period over which this data was collected]

27. What are the most common data deficits in application? For the analysis of the impacts?

text

Section 1.3: Focus on record and monitoring measures

28. Does the regulation framework of your country establish a systematic monitoring for the release of IBCAs into the environment?

☐ Yes

☐ No

29. If 'Yes', how is that monitoring structured?

Text

30. Are users of IBCAs legally obliged to keep record of the IBCAs they:

☐ purchase

☐ store

☐ use

31. Is the regulatory system applied to IBCAs independent from that applied to PPPs?

☐ Yes

☐ No

Please add some additional information, if appropriate

text

32. Is there data recorded regarding to post-release monitoring about:

☐ Negative or positive impacts on biodiversity

☐ The duration of the occurrence of the IBCAs in the environment

☐ Interactions with naturally occurring populations of plants or animals

☐ Efficacy in terms of pest/weed/pathogen control

☐ Effects on human health

☐ Others (please specify)

text

33. Are the data consolidated at the national level?

☐ Yes

☐ No

34. If yes, who are the authorities or stakeholders in charge of the collection and maintenance of these data?

text

35. Does your country impose risk mitigation measures in connection to IBCA releases?

☐ Yes

☐ No

36. If yes, what are the risks addressed by these mitigation measures?

text

37. Are there processes to ensure the enforcement of the measures?

☐ Yes

☐ No

38. If so, what are these processes (controls, authorities in charge, monitoring, etc.).

text

39. Have the authorities ever detected undesirable impacts of IBCAs in your country?

☐ Yes

☐ No

40. If Yes, please briefly describe the case, the mitigation measures taken and the result

text

Section 1.4: Focus on organisation, processes and evaluation

41. Which administrative levels are involved in the implementation of the regulatory framework?

☐ State

☐ Other(s), please specify

text

42. Could you please list the name(s) of authority/authorities currently involved in the implementation of the regulatory framework ? Please indicate which authority is responsible on the following:

	Name of Authority
Authority responsible for the risk assessment process (if applicable)	*[Text]*
Authority responsible for the monitoring process (if applicable)	*[Text]*
Authority responsible for the final decision on the importation of IBCAs	*[Text]*
Authority responsible for the final decision on the production of IBCAs	*[Text]*
Authority responsible for the final decision on the release of IBCAs	*[Text]*

Other (if any)	*[Text]*

43. **Are there any specific measures in place to facilitate the administrative process (specific, updated and publicly available guidance, pre-submission meetings for dossier submitters) in your country?**

☐ Publicly available procedural guidance

☐ Pre-submission meetings for dossier submitters

☐ Other (please specify)

text

44. Are there any measures to assess the adequacy and effectiveness of the legal framework in place for the introduction, production, evaluation, marketing and use of IBCAs ?

text

45. Are the users sufficiently informed and trained to use IBCAs and which measures are considered to be useful in improving the situation from your point of view?

text

46. In your opinion, what are the main shortcomings of the regulatory approaches in force in your country (for instance, administrative burden, lack of data to conduct risk assessment, non-coverage of some risks, etc.)? What are the drivers behind?

Text

47. How could the regulatory instruments in your country be better implemented? Which elements are missing?

text

48. How is efficiency of the regulatory process rated by national services and stakeholders and how could the different approaches be improved?

Text

Section 2 - Current uses and markets

49. Is there any specific data and information regarding <u>IBCA</u> market value, use and production in your country?

☐ Yes

☐ No

50. If so, what kind of information (sales only or more data) is available? What is the source of these information, how it is collected and who is in charge

of the consolidation? Do you consider existing information and data is sufficiently reliable?

text

Please complete this section with as much information as possible. When exact numbers are not available, you may instead provide estimates based on your knowledge or you may refer to documents where some information can be available.

Please send us any existing documents or data that can provide additional inputs.

Use of IBCAs in your country

51. **What is the number of IBCA uses in your country?** *For this question we define a use as the combination of 1 crop, 1 issue and 1 solution. Please define what is considered a use if you have a different definition.*

number

Are all uses available to professional and amateur users at the same time (if 'No', please explain)?

☐ Yes

☐ No

text

52. What is the number of species/strains used as IBCAs in your country?

number

53. What percentage of these species/strains uses as IBCAs are native and non-native?

percentage of native species

54. What is the number of authorised PPP uses in your country? Could you specify the total of PPPs uses, insecticides and acaricides, fungicides, herbicides, others)?

number

55. If possible, could you please fill out the table below to depict the use of IBCAs in the main plant production systems in your country? If not, do you have some relevant documents that could provide some of the information?

	Greenhouse (crops & ornamentals)	Orchards	Vegetables	Vineyards	Maize	Other arable crops	Forests (including short rotation and nurseries)	Amenity	Specialty crops	Invasive plants	Other
Total surface in your country (approx)											
% of surface covered by at least one IBCA use (approx.)											
% of total surface covered by IBCA use in organic farming (approx.) *= Surface in organic farming covered by IBCA / total surface in your country (organic and non-organic)*											
Insecticides and Acaricides											
Herbicides											
Fungicides											
Molluscicides											
Nematicides											
Description of the main scenarios of use (targeted species, name of invertebrate, use in complement with PPP, etc.)											

56. Could you please list the classical biological control programmes that have been implemented in your country within the last 10 years (last 20 years if possible)?

Approximate period (year range)	Target species and crop concerned	Biocontrol agent(s) released (name(s) of species)

57. Could you please list the past and current programmes based on the Sterile Insect Technique (SIT) used in your country for plant protection purpose (not biocide) within the last 10 years (last 20 years if possible)?

Approximate period (year range)	Target species and crop concerned	Type of sterilisation technique used

Market value (imports and exports)

58. What is the market value for IBCA products used in your country per year (in € - Exchange rate as per 1st January 2022)? If the exact number is not available could you please provide an estimation based on your knowledge of the sector?

number

59. Among the IBCAs used in your country, could you indicate an estimate of the IBCAs:

Produced in the country:	[% - market value estimation]
Produced in another country in the EU:	[% - market value estimation]
Produced outside the EU:	[% - market value estimation]

60. For IBCAs produced in your country, are these IBCAs commercialised:

- For a domestic use in your country: [% - market value estimation]
- In the EU: [% - market value estimation]
- Outside the EU: [% - market value estimation]

National production of IBCAs in your country

61. Does your IBCA national industry have sufficient production capabilities to ensure the production of IBCAs all over the season?

text

62. What are the strategies of the industry to ensure that sufficient quantities of IBCAs are available for the case of an unexpected pest outbreak?

text

63. Could you provide with the list of authorised companies approved or registered for the production and sell of IBCAs in your Member States?

text

Comparison with the use of Plant Protection Products (PPPs)

64. What is the market value for PPPs products in your country (in €)? Could you precise the total of PPPs uses, insecticides and acaricides, fungicides, herbicides, others?

text

65. Are IBCAs considered as "non-chemical alternatives" in the Comparative Assessment conducted at national level according to Art. 50 of Regulation 1107/2009?

☐ Yes

☐ No

Section 3 - Policies fostering the development and use of IBCAs and perspectives

Policies fostering the development of IBCAs (7 MS only)

66. What is the average duration of the process authorisation of a new IBCA?

Text

67. **Could you provide with an estimation of the number of FTEs involved in the process of evaluation, authorisation and monitoring of IBCAs (public administration and other technical organisations, external companies, etc.)?**

text

68. How do research projects and (public or private) funding of product development contribute to availability and usability of IBCAs in your country?

text

69. **Which success stories exist regarding research and development? Where did the use of ICBAs fail and what are the reasons?**

text

70. Is there a knowledge transfer academia – industry – users in your country? How is it organised and how does it look like?

text

71. **Are there any economic or financial incentives (tax relief for industry and/or users, fast track procedure in administrative processes, financial instruments to increase uptake of IBCAs at user level) applied in your country?**

text

72. **Is there a system in place to monitor the effects of the financial incentives?**

☐ Yes

☐ No

73. If yes, what are the effects and what are the costs of these economic/financial incentives?

text

74. In which form are regular or sporadic training activities concerning IBCAs for national authorities and private advisers (e.g. awareness), industry (e.g. regulatory aspects) and/or users (e.g. use) organised, by whom and on which level (national, region, association)? Where do training strategies exist?

text

75. In your country, are there mechanisms in place to collect feedback from extension and advisory services (public and private)?

☐ Yes

☐ No

76. If so, could you briefly list these mechanisms?

text

77. Which are examples for improvements due to such feedback?

text

78. Do you foresee to specifically support the development of IBCAs through the next strategic plan? Through which measures?

text

Potential for the development of IBCAs

79. Are there public and private research and development on IBCA in your country?

☐ Yes

☐ No

☐ I do not know

80. If yes, what are the main current IBCA public and private research and development projects implemented in your country and what are the current stage of development?

text

81. If relevant, can you provide a list of the IBCA developments targeting a phytosanitary need for which currently no phytosanitary solution exists ('empty use')?

- Text
- ...
- ...

82. What are the main current obstacles for the development and use of new IBCAs that you identify in your country? (Intellectual property, cost of development and marketing, legislative framework, etc.)

text

Recommendations for potential actions at an EU level

83. Do you consider that the absence of a harmonised regulatory framework across the European Union on IBCAs is an issue? Why?

text

84. From your point of view, is there a need/ potential for developing actions at an EU level in order to increase innovation and safe use of biological control agents?

a. Potential for harmonising criteria, procedures and decision-making,

text

b. Potential for coordinating effort to foster research, innovation and knowledge dissemination,

text

c. Potential for a reinforced cooperation with international organisations and the support of investment,

text

d. Other types of actions

text

85. To what extent do you consider that a harmonised framework at European level would be of benefit? Can you explain why you consider this would be relevant or not?

text

86. In your opinion, in which ways could a more harmonised decision-making be achieved?

text

87. Do you expect benefits from a stronger involvement of EFSA on the issues related to IBCAs?

☐ Yes

☐ No

88. If yes, should EFSA become more strongly involved:

☐ Into drafting Guidance documents

☐ Developing scientific opinions on individual questions

☐ Carrying out risk assessments?

☐ Others? (please specify)

text

Centralised assessment / decision-making for IBCAs at European level

89. Which positive impact (economic, environmental, social effects) would you expect from an EU *centralised assessment* of IBCAs before import, commercialisation and use?

Text

90. Would you expect any negative impact from an EU *centralised assessment* of IBCAs before import, commercialisation and use (increase of time needed to authorised the products, administrative burden, etc.) ?

Text

91. Which positive impacts would you expect from an EU-centralised *decision-making*?

text

92. Which negative impacts would you expect from a centralised *decision-making*?

text

Voluntary scheme

93. Do you consider that a voluntary scheme (submission of national scheme to the European level to demonstrate compliance with common criteria and guidelines and ensure mutual recognition between the European countries) would be relevant?

text

94. What benefits would you expect from voluntary schemes?

text

95. What limits would you expect from voluntary schemes?

text

96. What measures would you recommend to ensure the efficiency of such scheme?

text

97. Do you identify shortcomings and problems not to be solved in such system?

text

Other regulatory instruments

98. In your opinion, which regulatory instruments may foster innovation on IBCAs?

text

99. Do you identify some other instruments at European level that may be implemented to support the development, production and use of IBCAs?

text

5.4.2 Interview guide

Our consortium has been mandated by the European Commission – DG SANTE to carry out a study on the Union's situation regarding invertebrate biological control agents (IBCAs) for the use in plant health and plant protection. The objective is to provide input to the Commission regarding the introduction, production, evaluation, marketing and use of invertebrate biological control agents within the territory of the Union, including an overview of the existing regulations in each MS (if any) and an analysis of the potential for further development of IBCAs.

In this framework, the attached questionnaire has been developed to collect data and relevant information from the main stakeholders at European or international level. It would be completed by some interviews where relevant.

It is structured as follows:

- **Section 1** seeks to collect information on the **market of IBCAs** and the current uses;
- **Section 2** seeks to collect information on your perception of **national regulations applying to IBCAs**;
- Section 3 focuses on the main perspectives and options to fostering the development and use of IBCAs.

The questionnaire integrates both questions to be answered by Yes or No (tick boxes) and open questions (please use the open cells).

Could you please send the questionnaire completed **before the 17th June 2022.** We are aware that this timeframe is short, but this is unfortunately due to strained Commission schedules.

To facilitate the process, please note the following:

- We can schedule an exchange about this survey in the coming days to define how to support you in the collection of expected information. Could you please propose several timeslots for this meeting (45 minutes approximately)?
- Please feel free to send partial responses along the way / step by step. You may send us each section as soon as it is completed to the best of your knowledge, and redirect other sections to other contributors as you see fit;
- **Priority question** questions are indicated **in bold**: you may first focus on these questions and we can discuss further how to collect any missing information;
- In addition to the completion of the questionnaire, please do not hesitate to send us all additional documents that could be relevant for the study (in national language if needed): regulatory framework, assessment grids, additional lists of species, national studies, etc.

In case you need additional information, or you have specific questions on the content of the questionnaire, please do not hesitate to contact us through the following email address: *EY email address was provided*

We thank you in advance for your answer and information provided,

Best regards,

The Study team

Preamble: Focus on the scope of the following Study questions

Please note that this study will focus only on **<u>Invertebrate</u> Biological Control Agents** such as insects, including male sterile insects, mite, and nematode species (IBCAs). Only uses which are linked to the intentional release of IBCAs shall be considered. Furthermore, only IBCAs shall be considered which are intended to protect plants or plant products, ("plants" and "plant products" as defined in Article 2 of Regulation 2016/203111), including those to control invasive plants. Insects purely used for pollination are outside of the scope of the study.

In addition, the definition of plant protection products (PPP) is the one of Article 2 of Regulation (EC) No 1107/2009 referring to substances (chemical elements and their compounds) including micro-organisms.

Thus, we thank you to apply this scope and definition for the completion of the questionnaire.

➔ If available data does not fit with the scope of the study, please clearly explain the scope and types of products covered by the data provided and, if possible, provide an estimation in accordance with the scope of IBCAs considered by this study.

Section 1 - Current uses, markets and potential for development

Uses

1. What are the main current patterns of use of IBCAs? What are the main differences between Member States and why?

2. Where are IBCA most widely used? By whom and for which uses?

3. What are the current main obstacles to the use of existing IBCAs?

4. Do you have examples of pests where both IBCA use and authorized PPP uses co-exist? What are the main pros and cons of both existing solutions?

Markets

5. Could you provide information you have on the market share of IBCAs, quantities of products of IBCAs in the European Union

6. How is the current market structured? Where are located the main producers / main capacity of production? More specifically:
   a) Are there issues of supply break over the season?
   b) Are there some risks of supply break?
   c) Are some stocks available in the Member States?
   d) What would be the time required for the production of IBCAs in case of a pest outbreak?

7. How many IBCAs are currently under development in the European Union? What is the number of new IBCAs entering the market each year?

8. What is the state of imports and exports of IBCA, both in the EU-market and outside the EU-market?

Potential for development

9. What is the potential for development of IBCAs in the European Union over the coming 10 years in terms of:
   a. New uses (in greenhouses or arable crops, forestry, major crops or minor uses, etc.)
   b. Additional cropping and phytosanitary scenarios (in greenhouses or arable crops, internal landscaping, forestry, major crops or minor uses, organic farming or not, etc.)
   c. Market value (% of growth) at EU level

10. What could be the main differences between Member States? For what reasons?

11. What are the current main obstacles for the development of IBCAs (Intellectual property, cost of development and marketing, availability of access to and benefit sharing of effective IBCAs legislative framework, etc.)

12. What are the demands from the side of the farmers for new IBCAs or new uses? How does the industry answer these demands?

13. For which uses and cropping/phytosanitary scenarios do you consider that there is little or no potential to develop an IBCA solution within a reasonable timeframe? What are the reasons?

14. From your point of view, what will be the main positive and negative impacts on biodiversity of the development of IBCAs? Could you illustrate with examples or do you have available data to quantify these impacts?

15. From your point of view, what will be the main positive impacts on food safety of the development of IBCAs? Main negative impacts? Could you illustrate with examples or do you have available data to quantify these impacts?

Section 2 - Regulatory systems in place for the introduction, production and release of IBCAs and characteristics elements

16. Are the provisions, regulatory framework and processes clear, comprehensive and transparent in the Member States? Can you give details?

17. What are the measures in place to facilitate the administrative process in the different Member States (available guidance, pre-submission meetings for dossier submitters)? Do you identify relevant best practices implemented by some Member States that could be spread across the EU?

18. How well do these measures answer to your needs?

19. Do you have access to sufficient information regarding the existing frameworks and do you know who should be contacted to have further information or obtain information on the market?

20. Do you consider that the users of IBCAs are sufficiently informed and trained? How could it be further improved?

21. What are the main difficulties you identify regarding the implementation of the regulation for the introduction, production and release of IBCAs in the Member State?

22. What is the average time needed for the assessment and approval of products in the different Member States?

23. Which costs are associated to these procedures for businesses (compliance costs, notification costs, record keeping costs)?

24. What are the main difficulties encountered by producers for the production of data required during approval processes in the different Member States?

25. What are the main difficulties encountered by producers or retailers regarding the monitoring of storage and use of IBCAs?

26. What do you think of the mitigation measures developed by the Member States to limit the risk of cross border spread? Do you consider that these measures are realistic, affordable and sufficient?

27. How is quality control and effectiveness of the IBCAs used ensured?

Section 3 - Other instruments and perspectives

Other instruments

28. What is the current use of EPPO guidelines in the Member States?

29. Are the Member States using other guidance documents to regulate or assess risks of IBCAs?

30. What is the current support for research and development at European and national levels?

31. Could you provide examples of success stories of the contribution of research and development to the availability and usability of IBCAs? What are the main success factors?

32. Do you have examples of failures in research and development of IBCAs? What were the main reasons?

33. What do you think about the current knowledge transfer organisation regarding IBCAs? Do you think it is effective to ensure knowledge transfer?

34. What are the current incentives (economic and financial) for the development and use of IBCAs? Do you have examples of best practices in the European Member States?

35. What do you think about the current training activities implemented at Member States level? Do you think that support of training is sufficient to ensure that the main stakeholders have sufficient knowledge on this subject?

36. What is your perception of the extension and advisory services provided to the users? Do you identify best practices in some Member States?

Perspectives

37. In your opinion, how could the existing regulatory instruments in the Member States be better implemented?

38. Do you expect more engagement by EFSA on the issues related to IBCAs?

39. In your opinion, in which ways could a more harmonised decision-making system be achieved?

40. Which positive effects would you expect from an EU centralised assessment of IBCAs before import, commercialisation and use? Which negative effects would you expect from an EU centralised assessment of IBCAs before import, commercialisation and use?

41. Which positive impacts would you expect from an EU-centralised decision-making? Which negative impacts would you expect from a centralised decision-making?

42. Do you consider that a voluntary scheme would be relevant? What benefits would you expect from voluntary schemes? What limits would you expect from voluntary schemes?

43. In your opinion, which regulatory instruments may foster innovation on IBCAs?

5.5 Annex 5 - Overview of the data collected and available in the Member States

Member States	Sales (in volume or value)	Permits holders / Producers	Number of IBCAs uses / products	Number / List of species authorised	Sources
Austria	Authorisation holders have to report annually the sold amount of each PPP to the competent authority, including IBCAs. This info is not consolidated	Available	107 products authorised	List of authorised species available: 37	https://psmregister.baes.gv.at/psmregister/faces/main#
Belgium	-	-	-	For Flanders: 43	
Bulgaria	-	Available at central administration level	-	NA	
Croatia	250 000 € for the use of 1 SIT	-	-	2 species authorised	
Czech Republic	Data from users and data on sales are collected however not aggregated	Yes: Act No 326/2004 on phytosanitary care (§. 46a and 46b)	256 uses authorized based on the local authorisation and unknown number of uses based on the	30 and unknown number under mutual recognition	https://eagri.cz/public/app/eagriapp/POR/Vyhledavani.aspx?type=0&vyhledat=A&stamp=1664193703569

Member States	Sales (in volume or value)	Permits holders / Producers	Number of IBCAs uses / products	Number / List of species authorised	Sources
	specifically for IBCAs		automatic mutual recognition		
Denmark	-	No	-	7	https://www.retsinformation.dk/eli/lta/2021/1986#id46e86d4a-732a-4276-81ef-ffebf76f2c31
Estonia	-	-			
Finland	4,5 million €	No	190 uses	55	https://www.ruokavirasto.fi/en/farmers/plant-production/torjuntaeliot-ja-polyttajat/accepted-species/biological-control-agents/
France	The national IBMA branch forwards the consolidated data of their members to the State 23,6 million €	Non-native IBCA producers and introducers have to register, but not retailers	-	144 species, 440 strains (included 369 non-indigenous organism)	Legal documents
Germany	-	In development	-	Around 80 species	Julius-Kühn Institut
Greece	-	Registration (no list was shared)	-	53	http://www.minagric.gr/images/stories/docs/agrotis/Georgika_Farmaka/Makroorganismoi/Ethnikos_Katalogos_MakroOrganismwn_tr_161019.pdf

Member States	Sales (in volume or value)	Permits holders / Producers	Number of IBCAs uses / products	Number / List of species authorised	Sources
Hungary	-	-	-	46	Presentation made by the NCA for EPPO
Ireland	-	No	-	15 species used (no authorisation system)	List of used IBCAs provided by the NCA
Italy	-	Registration (no list was shared)	-	-	
Latvia	-	Registration (no list was shared)	67 products	34 species	https://www.vaad.gov.lv/lv/media/3398/download
Lithuania	-	-	-	-	
Luxembourg	-	-	-	-	
The Netherlands	-	Registration (no list was shared)	-	160 species	https://wetten.overheid.nl/BWBR0038668/2019-10-04/#Bijlage8 https://opendata.cbs.nl/statline/#/CBS/nl/dataset/84008NED/table?ts=1656676963062
Poland	-	-	About 65, insome cases we mean a crop (like apple tree, strawberry), sometimes a	24 (estimation)	

Member States	Sales (in volume or value)	Permits holders / Producers	Number of IBCAs uses / products	Number / List of species authorised	Sources
			group of crops (like berry bushes, ornamental plants).		
Portugal	-	No	-	-	
Romania	-	-	Approximately 45	Approximately 25	
Slovakia	-	-			https://www.uksup.sk/orp-datasety
Slovenia	Estimated amount: 300 000€	Registration (Rules on biological plant protection, Article 10) but no list	91	35	Biotično varstvo rastlin | GOV.SI
Spain	-	Registration (Art 5 RD 951/2014), no list	1116 "IBCA products"	107 species	https://www.mapa.gob.es/app/omdfocb/ResBusCon.aspx?id=es
Sweden	Estimated amount: under 2,6 million €	No	-	33 in total 29 IBCAs are authorized by SEPA	https://www.naturvardsverket.se/amnesomraden/miljofororeningar/biologiska-bekampningsmedel/

Member States	Sales (in volume or value)	Permits holders / Producers	Number of IBCAs uses / products	Number / List of species authorised	Sources
				4 IBCAs are still authorized through the Swedish Chemical Agency´s product authorizations but will be evaluated by SEPA before the approvals end (May 2023)	

5.6 Annex 6 - Overview of the content of risk assessment at national level

		Austria	France	Hungary	Slovakia	Spain	Sweden
Part 1. Application information							
(A) Information on the applicant			X	X	X	X	X
(B) Purpose of the application and use	*Purpose of use*		X			X	
	Import / Research / (Mass) rearing / Release Trials / Commercial		X	X (function)			
	Type of biocontrol programme		X				
	Type of area where BCA will be released						
	Facilities and procedures		*Rearing methods, historicity*		*Rearing localisations*		
	Describe how the risks, in particular probability of escape and possible extent into the wild for import / rearing of non-indigenous organisms will be managed.						
	Contingency plan		X				
	Standard Operating Procedures		X				
	Quality control management		X				
	Accreditation						
	Information about the target organism(s)				*X*		X
	Give a description of the biology and ecology of the target pest(s), including weeds.						

	Target host taxon						
	Names of target pests				X		
	Original area of distribution of the pests						
	Biology of pests						
	Target crops hosting the pest				X	X	X
Part 2. Information on indigenous and non-indigenous BCAs							
(A) Taxonomy and origin	*Identity*		X		X	X	X
	For what species / organism is the application made? Indicate which species is involved (a single species per application) and full scientific name and taxonomy						X
	Class		X		X		X
	Order		X		X		X
	Family		X		X		X
	Genus		X		X		X
	Species		X		X		X
	Sub-species		X				X
	Common names		X	X	X		X
	Alternative names		X				
	Associated organisms		X				X
	Indicate means, methods of ID confirmation and reference (voucher) specimen (Authority / Methodology / Reference (voucher) specimen deposits)		X			X	X
	Characterization of BCA						
	Specify life-stages, strains or taxonomic constraints.		X				

	Diagnostic descriptions		X				
	Specific characteristics		X				
	Taxonomic characteristics		X				
	Origin and distribution of BCA						
	Origin (Indigenous / Non-indigenous)		X				
	Field collected		X				
	Laboratory culture		X				
	Producer ⁄ supplier		X (localisation)				
	Original area and distribution		X		X		
	Areas where introduced before		X (data required)				
(B) Product information	*Product information*		description of storage and rearing structures	packaging: filling weight and volume, sizes, materials used for packaging, mode of sealing, test results certifying reliability of packaging	X	X	
	Product ⁄ trade name		X	X	X		
	Producer ⁄ supplier		X	X	X	X	

	Method of supply						
	Life stages			X			
	Label information		X		X	X	
	Storage		X	X	X	X	
	Method of use		classical /augmentative/ autocidal releasing areas number of organisms per release and number of yearly releases	Mode of mass reproduction of the macro-organism Recommendation for use (mode of use, field of use, crop, target pest, dose, number of release, date of treatment,, etc)	X (number of organisms per unit treated, number and timing of applications, instructions for use)	X (doses, time of the application, etc.)	
	2.5 Product composition		X	concentration of the macro-organisms, moisture	X	X	
	Co-formulants		X	X	X		
	Contaminants		X	Role in spreading other pests			

	2.6 Particular situations						
Part 3. Information requirements for intentional release of a non-indigenous BCA with reference to:							
(A) Biology and ecology	*Information regarding biology and ecology*		X	X			
	Give a description of the biology and ecology of the BCA		X	X			
	Life cycle – generations / year		X	X	X		
	Developmental biology		X	X	X		
	Mechanisms of survival		X				
	Mechanisms of dispersal		X	X	X		
	Climatic conditions		X	X	X		
	Habitat range		X	X			
	Host range		X	X	X		
	Natural enemies		X		X		
(B) Assessment of risks and benefits	*Safety and health effects*		X	X, Fire safety, quality contrtol	X	X	
	Potential hazards of BCA, product or any co-formulants, and measures taken to limit operator exposure, with emphasis on Human health Animal health Measures of prevention			Fire safety, quality control, effects on human and animal health, risks jof affectin g gene diversity	Waste disposal and deconta minatio n of packagi ng material s		
	Information about environmental risk assessment	X	X	X			
	Potential for establishment	X	X	X			

	Physical constraints		X				
	Resource constraints						
	Survival data and methods used						
	Evidence of establishment		X				
	Host range assessment	X	X	X			
	Known hosts		X				
	Organisms tested						
	Procedures used for host range testing						
	Effects on plants used by target and non-target hosts		X				
	Dispersal	X	X	X	X		
	Ability to disperse		X (+ dispersal speed)	X	X (+ mobility)		
	Direct and/or indirect non-target effects	X	X	X	X		
	Summary of available information and conclusions on risks		Plant health		Plant health		
	Efficacy and benefits of the BCA		X	X			
	Assessment of efficacy, economic and environmental benefits		X	X			
	Method(s) to determine efficacy		X		X		
	Results of efficacy trials		X				
	Economic benefits		X				
	Environmental benefits		X				

5.7 Annex 7 - Synopsis report on the stakeholder consultation

5.7.1 Introduction

This synopsis report presents the results of the consultation activities conducted to prepare the study on the Union's situation and options regarding invertebrate biological control agents for the use in plant health and plant protection. It contains a summary of the consultation activities, reflecting the diversity of the stakeholders' positions, and an analysis of the quality of the information collected – both qualitative and quantitative.

5.7.2 Presentation of the consultation strategy

The consultation method defined in the terms of reference for this study was a targeted consultation: stakeholders were pre-selected and only the explicitly invited stakeholder groups and individuals could participate in the consultation activity and provide insight into the challenges and possible scope of action of the European Union.

The objective of the consultation strategy was twofold: firstly, to obtain information on the Union's situation on IBCAs for the use in plant health and plant protection (market, uses, regulatory situation across Member states, main challenges), and secondly to consult stakeholders and Member States on their views on the potential for evolution of this sector in the European Union, and the opportunity and shape of a possible European intervention. It targeted mainly European stakeholders and national competent authorities in 27 Member States.

Stakeholders were consulted through **three consultation tools**. Each tool aimed to collect evidence that complement desk research by providing additional qualitative and quantitative inputs which are not available in official documentation:

- **Surveys**, by the mean of two structured questionnaires sent respectively to National Competent Authorities (NCAs) and other stakeholders. Questionnaires were developed to collect as much information as possible to answer questions of the Study and feed into the problem definition and the identification of possible options for an EU initiative.
- **Targeted interviews** that aimed to confirm the problem definition and collect additional views and data to measure the impact of the different options and identify main pros and cons of policy options. For 7 Member States with a specific focus (Austria, France, Hungary, the Netherlands, Portugal, Spain, and Sweden), interviews also allowed the collection of data regarding questions specific to these Member States.
- **A validation workshop**, that was organised to on August 30th and 31st to present the results of the study, validate the main findings, and discuss over some more challenging topics identified such as the main

drivers and opportunities for the IBCA market, and a potential EU-approach to harmonisation. The validation workshop was opened for participation to representatives of key stakeholders concerned by IBCAs at European level, e.g., the national competent authorities of each Member State, representatives of business operators (producers and users), representatives of NGOs, as well as recognised experts in IBCAs. Overall, participation was high, with 60 people (including the EC and the study team) present on the 30th and 56 people on the 31st

As a summary, these three tools aimed to consult the following stakeholders' groups (planed consultation strategy):

Type of stakeholders	Surveys	Interviews	Validation workshop
Member State "national competent authorities", e.g. contact points identified within each national authority in charge of IBCA in their respective country.	√ (27 MS)	√ (7 MS) Interviews with national competent authorities in Austria, France, Hungary, the Netherlands, Portugal, Spain, and Sweden	√
Intergovernmental organisations: - IPPC / EPPO, - IAEA-FAO - CABI	√	√	√
Industry associations representing the interests of manufacturers and retailers of IBCAs: - IBMA			
Farmers', forestry and home gardener's associations: - COPA COGECA, - IFOAM, - EUSTAFOR			
Environmental NGOs:			

Type of stakeholders	Surveys	Interviews	Validation workshop
- PAN			
Scientific organisations: - EFSA, - IOBC-WPRS			
National competent authority from third countries: - New Zealand - the USA	√	√	

This consultation plan has been established in accordance with the Terms of Reference of the Study with a view to considering the interests of all relevant stakeholders' group, e.g. national authorities, industry, farmers, civil society, intergovernmental organisations, and scientific organisations.

5.7.3 Description of consultation activities

For each stakeholders' groups (NCA on the one hand and other groups on the other hand), consultation tools were implemented in a sequential manner: surveys were implemented between May and June 2022, whilst interviews were performed in July and August 2022. Starting with written and tailored questionnaires (adjusted to the type of stakeholder, their scope and the relevance of the consultation topic) (before interviews) aimed to leave sufficient time to targeted stakeholders to collect relevant documentation and consult with other authorities, where needed, to provide useful and as exhaustive as possible answers prior to being interviewed. Subsequent interviews allowed to go more in-depth and complement collected data with additional information and insights.

5.7.3.1 Consultation at MS level (survey and interviews with NCAs)

Consultation at national level targeted NCAs only. NCAs were consulted through both a survey (for 27 MS) and interviews (for 7 MS, as well as some NCAs that required follow-up interviews).

- **The survey** process (written questionnaire) aimed to collect information and views on the situation of IBCAs in each MS, e.g. on the market of IBCAs in each country (used, production, market value, existing research and development programmes, etc.) and on the national regulatory frameworks in relation with IBCAs, as well as views

on the future development of IBCAs. The questionnaires covered three main topics: (1) the regulatory framework, (2) the market and uses, and (3) the perspectives on possible future harmonisation options.

- Several follow up tasks were undertaken to support NCAs and ensure a high response rate to the questionnaire and ensure better quality of the responses: phone calls, follow-up interviews, flexibility on the mode of response, but also reviews of documentation (either available online or transmitted by the Member States) and of scientific evidence to refine the elements transmitted by the Member States.
- In total **26 questionnaires** were received (including 3 questionnaires covering the federal and regional levels in Belgium), corresponding to 24 different Member States. 2 additional questionnaires could be completed by the study team based on interviews. As a result, the survey covers all Member States, except Malta and the region of Wallonia in Belgium, leading to a response rate of 28 responses out of the 30 solicited.

- **13 interviews** were organised with following Member States' NCAs: Belgium, Czech Republic, Cyprus, France, Germany, Greece, Luxembourg, the Netherlands, Portugal, Spain, Finland, Denmark and Sweden. In addition to these interviews, Austria and Hungary decided to replace interviews with written contributions.

Table 15 - Member State involvement in consultation activities

Member State	Questionnaire	Interview	Workshop
Austria*	✓	Replaced with written Q&A at the request of the NCA	
Belgium (Federal)	✓		
Belgium (Brussels)	✓	✓	
Belgium (Flanders)	✓		✓
Belgium (Wallonia)	No		
Bulgaria	✓		

Member State	Questionnaire	Interview	Workshop
Croatia	✓		
Cyprus	✓	✓	
Czech Republic	✓	✓	✓
Denmark	✓	✓	✓
Estonia	✓		✓
Finland	✓	✓	✓
France*	✓	✓	✓
Germany	✓	✓	✓
Greece	✓	✓	
Hungary*	✓	Replaced with written Q&A at the request of the NCA	
Ireland	✓		✓
Italy	✓		✓
Latvia	✓		✓
Lithuania	✓		✓
Luxembourg	(questionnaire completed with the interview)	✓	✓
Malta	NO (documentary review)		
Netherlands*	✓		✓
Poland	✓		
Portugal*	(questionnaire completed with the interview)	✓	✓
Romania	✓		
Slovakia	✓		✓
Slovenia	✓		✓
Spain*	✓	✓	
Sweden*	✓	✓	✓

Note: an asterisk indicates the 7 case study Member States

Overall, the participation from the NCAs was good, with some differences linked to the specific situation in each MS:

- Most Member States with extensive experience in regulating IBCAs showed a high interest and provided detailed contributions;
- Several Member States with no IBCA-specific regulation showed a high interest and participated actively to the consultation activities with a learning objective and to feed into national reflexions on regulating IBCAs;
- Several Member States, mainly those with less important agricultural, showed less interest in the process.

5.7.3.2 Consultation at EU and international level (survey and interviews with other stakeholders' groups)

Other stakeholders' groups were also consulted to collect available data, and qualitative information on the IBCA market, the uses, and the challenges encountered.

- Participation to the questionnaires was rather low, with **3 questionnaires** being received out of the 13 targeted stakeholders.
- Most stakeholders opted for interviews, either to complement the questionnaires or to replace them. As such, **8 interviews** were led with the different stakeholders, out of the 13 targeted.

Additionally, the third countries selected for case studies participated through a questionnaire (New Zealand), written comments (the USA) and an interview (both third countries).

Participation across the different stakeholder groups differed according to their relative interest and knowledge of the subject:

- **Intergovernmental and scientific organisations** were most involved and provided factual inputs and views on the relevance and feasibility of potential options for an EU initiative;
- The main **industry organisation representing the interests of manufacturers and retailers of IBCAs** was highly active and interested in the subject. It provided key inputs on the market of IBCAs as well as feedbacks that have been considered during the process (main drivers and obstacles for IBCA producers and views on a future initiative).
- **Farmers' associations** had little knowledge on invertebrate biological control specifically, but contributed to reflexions on IPM. As such, some of them were responsive but did not participate in all steps of the consultation. While it was decided, in accordance with the terms of

reference specified, to focus consultation on representative organisations at European level only, this may have led to limited inputs from actual/ potential users, as they are not being consulted specifically on the subject of IBCAs.

- Finally, it was more challenging to get input from **environmental NGOs**: they rarely had a specific position on IBCAs, which they tend to view in the context of IPM strategies and advocating for a system change around agricultural practices.

Table 16 – Stakeholder involvement in consultation activities

Type of stakeholders	Surveys	Interviews	Workshop
Intergovernmental organisations: IPPC / EPPO, IAEA-FAO CABI	√ EPPO	√ EPPO, IAEA-FAO CABI Europe	√ EPPO, IAEA-FAO
Industry associations representing the interests of manufacturers and retailers of IBCAs: IBMA, Crop Life Europe	√ received (IBMA)	√ IBMA,	√ IBMA
Farmers', forestry and home gardener's associations: COPA COGECA, IFOAM, and EUSTAFOR	All stakeholders opted for interviews	√ COPA-COGECA, EUSTAFOR	√ COPA-COGECA
Environmental NGOs: EEB, IUCN and PAN		√ PAN Europe	
Scientific organisations: EFSA, IOBC-WPRS	√ IOBC-WPRS	√ EFSA	√ EFSA, IOBC-WPRS

Type of stakeholders	Surveys	Interviews	Workshop
National competent authorities from New Zealand and the USA	√ New Zealand, the USA (written comments)	√ New Zealand	

5.7.3.3 Validation workshop

The validation workshop was organized on August 30th and 31st 2022.

This workshop aimed to present the results of the study, confirm the accuracy of the main findings, and discuss over some more challenging topics identified. It was opened for participation to representatives of key stakeholders concerned by IBCAs at European level, e.g., the national competent authorities of each Member State, representatives of business operators (producers and users), representatives of NGOs, as well as recognised experts in IBCAs. Overall, participation was high, with 60 people (including the EC and the study team) present on the 30th and 56 people on the 31st. As all Member States and stakeholders were invited to send multiple participants, 27 participants represented 18 different Member States and 15 participants represented 7 stakeholders.

During the workshop, Member States expressed their opinions less vocally than within the surveys regarding the options, but some views and inputs could be collected in roundtables and with the help of an online survey tool (Mentimeter). Some Member States also chose to contribute more through the chat (Sweden, Finland, Portugal…). Finally, some Member States participated rather vocally: the Netherlands, France, Ireland. On the stakeholder side, the most invested stakeholders were present and engaged in the conversations

Alongside the data collection, the workshop's outputs were included in the report.

5.7.4 Results of the consultation

The results from the consultation activities were used as the base for the Study. Contributions from the Member States were at the core of all questions, and especially the regulatory framework. Contributions from the industry and from the users' associations alimented Question 1 on the market and uses of IBCAs, and Question 2 and 3 on the perceived fitness of the different regulatory frameworks. The scientific organisations, as well as the intergovernmental organisations, gave hindsight into the uses of IBCAs and their challenges, but also on their own role to play in a future European framework.

Consultation activities allowed to collect complementary inputs that were all used for the Study, both data/ information and views that were fully considered in the report.

5.7.4.1 Information on the situation of IBCAs in the territory of the Union

The surveys and interviews allowed to gather input unequally according to the different study areas:

- The **regulatory framework** regarding IBCAs was an area that gathered the most input from the Member States which have a regulation. Member States currently developing one also provided details. The consulted industry association also provided information on the different regulatory frameworks, and their appreciation of their respective fitness. This allowed to have a rather complete and comprehensive view on the current situation of IBCA regulations in the different Member States as well as on their strengths and weaknesses.
- Sections on the **use of IBCAs** were more unequally completed. Very few Member States were able to provide data regarding the current uses of IBCAs on their territory. Generally, the number of uses (as in one solution for one crop) is seldom if ever collected in the Member States (Austria and the Netherlands have databases on the uses for authorised organisms). There are no monitoring strategies in place in the Member States, leading to very few knowledge on the current situation within NCAs. When available, NCAs communicated the number of authorized IBCAs (for 15 Member States). Crop type data related to IBCA use was available only in a few cases (through previously mentioned uses databases). Chemical pesticide use and distribution among crops was also rarely provided. Users' associations and scientific organisations were able to provide additional information on the general context and conditions of IBCA uses.

  Similarly, data on the **IBCA market** was difficult to obtain. No NCAs collected the information, although a few Member States have indicative information on the market from national IBMA branches. Some interviews allowed for more qualitative but less precise descriptions of the market and uses. At European level, stakeholders from the industry do not collect country specific information for the IBCA market. As such, the consulted industry association provided market trends for IBCAs.
- **Perspectives** were generally expressed in a very concise way by the Member States in the questionnaires. A few Member States left the section empty. A hypothesis for this response behaviour is that some respondents might think they were not at the right decision or political level to reply. Other Member States provided very detailed and exhaustive answers and were also visible during the workshop.

A detailed appreciation of the contents of the survey to NCAs is available in annex 5.5.5.

5.7.4.2 Views on the future of IBCAs and the impact of potential initiatives at EU level

Despite partial diverging interests, the different stakeholder groups (especially industry on the one side and NCAs on the other) showed a shared assessment on the current problems and mostly converging views on the need for the EU to act to foster the safe development of IBCAs in the European Union.

All stakeholders agree that the development and use of IBCAs has to accelerate on the territory of the Union and that some actions could be taken at an EU level to foster that development. They also all agree that some harmonisation is needed in that respect. The level and shape of this harmonisation has however let to some debated, as reflected below.

Perspectives for development

All stakeholders and Member States consulted foresaw potential for development in the IBCA market and uses. The consultation and validation workshop highlighted several drivers that all participants agreed upon:

- Most Member States cited the **types of agricultural systems** (including the presence of greenhouses), the **public policies in place** (about pesticides, MRLs, etc.), the **expertise/knowledge of farmers and advisors**, to be the most important drivers. This analysis was also shared by the other stakeholders consulted.
- Other important drivers considered by participants included: **research and new technologies** for storage, transport, and field delivery, **public opinion** and **social demand**, as well as the availability and easiness of access of IBCAs to farmers, beyond the mere authorisation of the organisms.
- Less cited drivers included **specific regulatory incentives** (e.g., asking for a justification of the use of chemical pesticides when sustainable alternatives exist), **partnerships on R&D and knowledge transfers**, **communication on benefits of IBCAs** (awareness-raising on returns on investment and impact on sustainability), and **collective organisations and sharing** (through associations and cooperatives). Lack of effectiveness of some products, the time needed to develop a new product and the emergence of new pests which can disrupt current IPM strategies were cited as blocking factors.

These perspectives were especially integrated in the analysis of Question 1 (market and uses, and potential for development) and Question 4 (regulatory instruments). Furthermore, these insights allowed to refine the problem definition.

Instruments to foster innovation and adoption by users

For all participants to the consultation, the European Union has a role to play in fostering the IBCA sector (R&D, tools, knowledge sharing, returns on experience…). Inputs and discussions during interviews and the workshop mainly relied on how the Commission could act and the tools which could be used. Users associations underlined that direct financing is a very potent tool when it comes to adoption of new agricultural methods. Most Member States also reported that IBCAs are rarely explicitly included in their national CAP plan.

These elements were also included in the report in sections on the potential for development, and on regulatory instruments.

Opportunity for harmonisation

This section was the most debated. Most Member States and stakeholders agree that the current situation requires some harmonisation at European

level, either to cover cross-border possible issues, to provide a framework for smaller Member States, or to make the market more homogeneous and develop the use. Points of view differ on the form this harmonisation could take (centralisation of a risk-assessment, centralisation of the authorisation process, balance between European and national regulations), and on the risks and benefits each option would entail. Finally, most stakeholders agreed that the harmonisation and common guidelines could rely on the existing guidance (e.g. from EPPO) and should strive towards no duplication of work between the regional and European scales.

Member States have rising interest in this matter. In total, 19 Member States provided an analysis on the hypothesis of centralisation of the assessment of IBCAs in the questionnaire. Views on the degree of harmonisation tend to diverge: 6 expressed a clearly positive opinion towards centralised harmonisation, 5 expressed a clearly negative opinion, and 9 had an intermediate position. Similar points of view were expressed in the interviews and in the workshop.

- Member States without a regulation were most favourable to a common European framework and open to discussions on the centralisation of the risk-assessment and the authorisation process. (Ireland, Belgium, Portugal, Luxembourg). As a Member States who already have a regulation, Slovenia and Finland also expressed interest in a centralised risk-assessment system.
- Most Member States who expressed views on harmonisation and centralisation are favourable to some harmonisation. On the opportunity to centralise the risk-assessment, they however expressed concerns on the impacts on the market, on national biodiversity, and the administrative load, while also recognising that it can lead to positive effects. Often, these stakeholders are Member States who have already developed a regulation and who are favourable to some harmonisation to the extent where they would retain national authority on the subject.
- Finally, a few Member States expressed opposition to a centralised risk-assessment (Greece, the Netherlands, Poland, Romania, and one Member State without a regulation, Croatia).

Overall, interrogated NCAs positively saw a role of EFSA. There was relative consensus on the interest of having EFSA involved in the production of guidance documents and organisation of expert panels and opinions (out of the 15 Member States that expressed an opinion on the involvement of EFSA, 13 were positive and 2 negative). The perspective of making EFSA in charge of risk assessment was more debated (10 positive, 5 negative). This was viewed relevant at two conditions:

- impact assessments do not interfere with existing national procedures and rather facilitate the work performed at national level thanks to preliminary advice at the level of species, creation of negative and positive lists that Member States can rely on in their own analysis and decision, and if EFSA can compile data to define if the species are already resident or not in each of the Member States.
- if the involvement of EFSA does not add a significant administrative burden and unnecessary delays in the processes already in place.

Industry associations have clear opinions on the topic of harmonising and regulating IBCAs, as it is their field of expertise. They are favourable to some harmonisation at European level, which could alleviate the authorisation and marketing processes (by reducing the proliferation of national regulations imposing different criteria) and help the economic viability of the IBCA industry. they are also cautious of the time and constraints that could arise from a European-wide process. Thus, they argue for a simple process at the EU-level, corresponding to the strict application of the EPPO guidance documents and lists (while seeing an interest in improving these documents and lists), as a way of reaching harmonisation. A possible involvement of EFSA is seen as a risk (administrative load and risk to have a process too similar to chemical pesticides, which is not considered to be fit-for-purpose).

Scientific associations have differing views according to the nature of their activities. EPPO is in favour of a harmonized system with clear guidelines, that could rely on their historical guideline-setting work.

- Among the stakeholders, EFSA provided factual elements (processes, human resources, etc.), allowing to further consider harmonisation scenarios within the Union. One intergovernmental organisation also pointed that many countries feel they do not have resources to risk-assess (both on the benefits and on the environmental risk), and that having an overarching convention across Europe for risk assessment would be beneficial

Users' associations (farmers, forestry) do not have clear positions on this specific subject, given its technicality and the lack of inside dedicated expertise

5.7.5 Annex: Quality and completeness of the surveys to Member States

Member State	Answers to questionnaire received?	Part 1: Regulatory framework		Part 2: Market, uses and potential for development		Part 3: Perspectives	
		Completion rate	Quality and reliability of the data	Completion rate	Quality and reliability of the data	Completion rate	Quality and reliability of the data
Austria	YES	Complete	Detailed information with additional documents	Partial	Data provided on authorized uses No data provided on the market (although authorisation holders have to report annually the sold amount of each plant protection product to the competent authority (AGES, BAES), including IBCAs. Partial data on R&D	Partial	Views are expressed on the harmonization but not on other instruments.
Belgium (Federal)	YES	NA	There is no regulation at federal level	Not completed	Only the number of authorized pesticide uses was estimated	Partial	Views are expressed (except for other regulatory instruments)

Member State	Answers to questionnaire received?	Part 1: Regulatory framework		Part 2: Market, uses and potential for development		Part 3: Perspectives	
		Completion rate	Quality and reliability of the data	Completion rate	Quality and reliability of the data	Completion rate	Quality and reliability of the data
Belgium (Brussels)	YES (complemented with an interview)	Complete	There is no regulatory framework yet, but a legislation is being developed and some elements of the future legislation were included	Not completed	No data was provided as it does not exist at regional level	Partial	Views are expressed (except for other regulatory instruments)
Belgium (Flanders)	YES	Partial	Reliability is to be confirmed as there seems to be an informal procedure regarding non-native species	Not completed	Information on use was not available but no other entity was suggested to fill the gap	Partial	Only some questions are answered
Belgium (Wallonia)	No						
Bulgaria	YES	Complete	Detailed information with additional legal documents	Not completed		Not completed	

Member State	Answers to questionnaire received?	Part 1: Regulatory framework		Part 2: Market, uses and potential for development		Part 3: Perspectives	
		Completion rate	Quality and reliability of the data	Completion rate	Quality and reliability of the data	Completion rate	Quality and reliability of the data
Croatia	YES	Complete	No regulation of IBCAs at national level, one specific exception exist for SIT control of Ceratitis capitata	Complete	Few uses of IBCAs: SIT on orchards and one use on forestry	Complete	Views are expressed and most questions answered
Cyprus	YES (complemented with an interview)	NA	No regulatory framework	Not completed	Only the number of authorized pesticide uses was provided	Partial	Only some questions are answered
Czech Republic	YES (complemented with an interview)	Complete	Detailed answers	Partial	There is some data on the authorized uses but the market data is not specific to IBCA	Complete	Views are expressed and most questions answered
Denmark	YES (complemented with an interview)	Complete	Detailed answers	Not completed		Not completed	
Estonia	YES	NA	No regulatory framework	Not completed		Complete	Views are expressed and most questions answered

Member State	Answers to questionnaire received?	Part 1: Regulatory framework		Part 2: Market, uses and potential for development		Part 3: Perspectives	
		Completion rate	Quality and reliability of the data	Completion rate	Quality and reliability of the data	Completion rate	Quality and reliability of the data
Finland	YES (complemented with an interview)	Complete	Detailed information with additional documents	Complete	There is some data on the uses, estimated market value	Complete	Views are expressed and most questions answered
France	YES (complemented with an interview)	Complete	Detailed information with additional documents	Complete	A large quantity of data was provided on the uses, market value, production costs	Complete	Views are expressed and most questions answered
Germany	YES (complemented with an interview)	Partial	There is no regulatory framework specific to IBCAs yet, but some elements of the future legislation were included	Partial	There is some data on the authorized uses and actual uses on the crops No data on the market Large information on R&D	Complete	Views are expressed and most questions answered
Greece	YES (complemented with an interview)	Complete	Detailed information with additional documents	Partial	There is some data on the authorized uses and actual uses on the crops No data on the market	Partial	Only some questions are answered

Member State	Answers to questionnaire received?	Part 1: Regulatory framework		Part 2: Market, uses and potential for development		Part 3: Perspectives	
		Completion rate	Quality and reliability of the data	Completion rate	Quality and reliability of the data	Completion rate	Quality and reliability of the data
					Large information on R&D		
Hungary	YES (follow-up questions via email)	Complete	Detailed information with additional documents	Partial	There is some data on the authorized uses No data on the market	Not completed	Only one question was covered
Ireland	YES	NA	No regulatory framework	Not completed	The number of authorized pesticide uses and pesticide market was estimated. A list of BCAs was communicated	Complete	Views are expressed and most questions answered
Italy	YES	Complete	Detailed information with additional documents	Partial	No data on the market Some information on R&D	Partial	Only some questions are answered
Latvia	YES	Complete	Detailed information with additional documents	Partial	There is some data on the authorized uses	Not completed	Only yes/no questions were covered

Member State	Answers to questionnaire received?	Part 1: Regulatory framework		Part 2: Market, uses and potential for development		Part 3: Perspectives	
		Completion rate	Quality and reliability of the data	Completion rate	Quality and reliability of the data	Completion rate	Quality and reliability of the data
					No data on the market available to NCA Large information on R&D		
Lithuania	YES	Partial	No regulatory framework specific to IBCA but reference to the general framework was provided. There seems to be a risk assessment				
Luxembourg	YES (interview only)	NA	No regulation. Interview showed that the Nature protection law regulates the introduction of non-indigenous species for agricultural production.	Not completed	There is no data available on market and uses. Limited use and market (interview)	Partial	A few elements were covered in the interview

Member State	Answers to questionnaire received?	Part 1: Regulatory framework		Part 2: Market, uses and potential for development		Part 3: Perspectives	
		Completion rate	Quality and reliability of the data	Completion rate	Quality and reliability of the data	Completion rate	Quality and reliability of the data
Malta	No	NA	Desk research showed the absence of a regulatory framework		Desk research suggests that there are few uses in Malta		
Netherlands	YES (complemented with an interview)	Complete	Detailed information with additional documents	Partial	Estimation of surface covered by IBCA in greenhouses. Number and detail of authorized pesticide uses	Complete	Views are expressed and most questions answered
Poland	YES	Complete	No regulatory framework	Partial	Some information regarding the current uses of IBCAs	Complete	Views are expressed and most questions answered
Portugal	YES (interview only)	NA	There is no regulatory framework specific to IBCAs yet, but some elements of the future legislation could be collected	Not completed	No data is available Qualitative information on the market (growing market)	Partial	Views on EU options were expressed by email

Member State	Answers to questionnaire received?	Part 1: Regulatory framework		Part 2: Market, uses and potential for development		Part 3: Perspectives	
		Completion rate	Quality and reliability of the data	Completion rate	Quality and reliability of the data	Completion rate	Quality and reliability of the data
Romania	YES	NA	There is no regulatory framework	Partial	Estimated data on uses, data on pesticides Qualitative information on the market (small market relying on imported IBCA)	Complete	Views are expressed and most questions answered
Slovakia	YES	Complete	Detailed answers	Partial	There is some data on the authorized uses No data on the market	Not completed	
Slovenia	YES	Complete	Detailed information with additional documents	Complete	A large quantity of data was provided on the uses including crop distribution, market value, production costs	Complete	Views are expressed and most questions answered
Spain	YES (complemented	Complete	Detailed information with	Not completed	No data was communicated but might exist	Not completed	

Member State	Answers to questionnaire received?	Part 1: Regulatory framework		Part 2: Market, uses and potential for development		Part 3: Perspectives	
		Completion rate	Quality and reliability of the data	Completion rate	Quality and reliability of the data	Completion rate	Quality and reliability of the data
	with an interview)		additional documents				
Sweden	YES (complemented with an interview)	Complete	Detailed information with additional documents	Complete	A large quantity of data was provided on the uses including crop distribution, market value, production costs	Complete	Views are expressed and most questions answered thoroughly

Directorate General For Health and Food Safety

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