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COMMISSION STAFF WORKING DOCUMENT

Study on the Union's situation and options regarding the introduction, production, evaluation, marketing and use of invertebrate biocontrol agents within the territory of the Union

Contents

List of abbreviations

APHIS – Animal and Plant Health Inspection Service of the United States of America

BTSF – Better Training for Safer Food

CAP – Common Agricultural Policy

EFSA – European Food Safety Authority

EPPO - European Plant Protection Organization

FAO – Food and Agriculture Organization of the United Nations

IBCA – Invertebrate Biological Control Agent

IOBC-WPRS – International Organisation for Biological and Integrated Control – West Palaearctic Regional Section

IPM – Integrated Pest Management

IPPC – International Plant Protection Convention

NCA – National Competent Authority in charge of IBCAs in a Member State

OECD – Organisation for Economic Co-operation and Development

R&D – Research and development

SIT – Sterile Insect Technique

SME – Small- and medium-sized enterprises

Executive summary

On 22 June 2021 the Council, based on Article 241 of the Treaty on the Functioning of the European Union, requested the Commission to submit by 31 December 2022 a study on the Union's situation and options regarding the introduction, production, evaluation, marketing and use of invertebrate biocontrol agents (IBCAs) within the territory of the Union and a proposal, if appropriate in view of the outcome of the study[1].

The use of IBCAs has the potential to contribute to the objectives of the EU's Green Deal[2] and in particular to the Farm to Fork Strategy[3] that aims at paving the way towards a new system of food production and consumption by reducing the use of chemical inputs (including plant protection products).

The assessment or mitigation of possible risks from the use of IBCAs is not subject to EU legislation. The objective of this study is to provide a systematic overview of the approaches which are in place in the different Member States and to identify areas of improvement. Particular emphasis is put on the possibilities for harmonisation of regulatory procedures in the EU, to facilitate the deployment of, and market access to IBCAs, to support investment and innovation in and to contribute to a safe us of IBCAs.

For the purpose of this study, 'Invertebrate Biological Control Agents' (IBCAs) are defined as invertebrate animals (such as insects, mites and nematodes) which can be used to control plant pests and diseases, or the vectors of such pests and diseases, and unwanted plants. They include indigenous or non-indigenous[4] living invertebrate animals which are released in high quantities either directly into the environment or are released under protected conditions and may escape from there where insufficient preventive measures are taken. IBCAs are alternatives to chemical pesticides and have a growing importance in sustainable agriculture and forestry, namely in the implementation of Integrated Pest Management (IPM) and organic farming. This study was supported by the work of an external contractor[5] that was conducted between February and October 2022.

[1] 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.

[2] European Commission, Communication to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions - The European Green Deal, Brussels, 11.12.2019, COM(2019) 640 final, https://ec.europa.eu/info/sites/info/files/european-green-deal-communication_en.pdf

[3] 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

[4] The terms 'indigenous' and 'non-indigenous' are used throughout this report to describe whether or not an organism naturally occurs in a specific area.

[5] The work of the contractor will be referred to as "contractor's report".

The current EU-market of IBCAs is characterised by its small size but strong growth: IBCAs represent a market volume of around 30% of the European biocontrol market (between 300 and 350 m€) which has doubled in the period between 2016 and 2020. This study confirms that there is an ongoing interest in investing in the development and placing on the market of IBCAs in the EU.
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. At present, most IBCAs in use act against animals (such as insects, mites or snails), some are antagonists to plants and few show the potential to control fungi.
The majority of IBCA producers are SMEs and only a few large companies exist in the EU. Several Member States have few or no implanted producers.

Uses of IBCAs primarily depend on the type of biological control applied. The EU market focuses on augmentative biological control (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 rests upon one-off introducing a natural enemy not yet present in the field and establishing a permanent population and is therefore a very cost effective form of biocontrol. Introduction programs rely mainly on national initiatives, coordinated and led by research. Classical biological control introductions used to be frequent during the last century: So far, there is a history of about 130 successful introductions of classical biocontrol IBCAs in the territory of the EU. However, recent restrictive developments in policy and regulation in some Member States with regard to the environment have created negative impacts for the release of IBCAs and the further development of classical biocontrol: The number of new introductions remarkably dropped in the last years, and since 2010, there were not more than 12 introductions reported by Member States as executed or planned.

The current market share and its development do not adequately reflect the importance and possible contribution of IBCAs to meeting the future needs of plant protection following the significant reduction of availability of chemical pesticides necessary to achieve the sustainability goals of the Green Deal and the Farm to Fork Strategy. Several drivers have been identified behind that problem:

- The type of agricultural production prevailing in a given Member State: Member States with sophisticated horticulture and substantial areas of protected cropping feature a much larger number of uses.
- The general policy approach of a Member State: Member States that support the implementation of Integrated Pest Management (IPM) through policy initiatives, dedicated R&D and industry engagements have a much better chance to increase

familiarity with and broader adoption of IBCA use.

- The agricultural approach of growers: IBCA use is frequent among growers focusing on the reduction of chemical pesticides, like organic growers, growers of high value crops following specific IPM schemas or where bumblebees are released for pollination services.
- The efficacy of IBCA, especially in outdoor crops: Adoption by farmers, especially in outdoor use, may be hampered by the lower immediate efficacy of IBCAs that is often delayed in comparison with chemical pesticides. Substituting one pesticide by IBCAs in systems developed for chemical pesticide use, may lead to biocontrol failures and a sense among growers that biocontrol is not effective or efficient. The use of IBCAs often requires integration into a broader pest management concept and impacts may be observed only after a while. Profound system changes in cropping approaches have a higher chance to be more efficient in speeding up the development of biocontrol. In particular, guidance to farmers is important.
- The costs of the IBCA solutions: The technicity of IBCA development, transport, storage and application in the field is complex, which can lead to costs that are higher than for a chemical pesticide.
- The demand on the final consumers' side: Concerns regarding the environment, biodiversity and the use of chemical pesticides 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.

Projections taking into account the market evolution so far and future developments under EU policy indicate, that IBCAs may have the potential to reduce the use of chemical pesticide of 1 to 2% by 2030 (representing then around 3-4% of the EU market for plant protection). In the long run, IBCAs are expected to have a potential for substituting up to 10.5% of the use of chemical pesticides[6].

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

[6] This figure is based on a theoretical scenario where all chemical pesticides are replaced by alternatives. IBCAs may potentially substitute up to half of the insecticides currently used (7.5% of the current pesticide market) and a limited number of herbicides and fungicides (counting for 2% and 1% of the current market, respectively). This would sum up to 10.5%.

Fourteen 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 differ in terms of:

- Scope: Some Member States treat release and introduction differently, and may regulate one and not the other. Transport is regulated in only one, production in five Member States.
- Risk assessment: Among the Member States who carry out a formal risk-assessment, the requirements also vary according to the status of the species: native, 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. Some Member States include an analysis of benefits: they cover mostly plant protection/phytosanitary effects, benefits to local biodiversity, and environmental benefits. Obtaining the right data is however a recurrent challenge for Member States, and dossier preparation risks to be cumbersome. However, most applications finally pass the assessment and are approved by the authorities.
- Authorisation processes: They can take different shapes, and can cover a specific IBCA (species, strain, source), a specific product (containing one or more specific IBCA organisms), and specific uses (research, commercial, indoors, outdoors).
- Monitoring: nine Member States register IBCA producers and retailers, one Member State only registers producers. Provisions on quality control and active post-release monitoring are nearly absent from the legislation. Member States rather request the submission of alerts where unexpected effects of IBCAs are identified.

Five Member States have environmental legislation which prohibits the introduction of all non-native species (nevertheless, in some of these Member States a derogation may be granted).
Seven Member States have neither national (or regional) environmental legislation restricting the introduction of native or non-native species nor specific legislation on IBCAs.

The availability of new, innovative IBCA solutions depends heavily on research and development to generate effective concepts and ensure that they do not pose a risk to the environment. Inversely, even if some IBCA research programmes have shown results and interest from farmers, there could be a lack of interest on the side of producers 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 occasional professional users may be considerably less knowledgeable. Also on the side of regulators, not all Member States dispose of the same level of expertise. However, as the use of IBCAs is technically demanding, the availability of biocontrol expertise is crucial for all parties involved.

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 remains very modest, even in the most active Member States. Member States have the possibility to financially support the use of IBCA by farmers with the Common Agricultural Policy (CAP). The new national CAP Strategic Plans starting in 2023 may, if the Member States decides so, include policy interventions, such as eco-schemes or rural development schemes financing such practices, including under the use of biological control, integrated pest management or organic farming. In this respect IBCA is explicitly mentioned in at least two national CAP Strategic Plans.

The framework of two third countries, New Zealand and the USA, has been analysed as well. In New Zealand, the framework regulates the introduction, release, commercialisation, quality control and transport of all new organisms that were not present in New Zealand before a certain date. Few incentives are given to develop the use of IBCAs, which are principally classical biological control uses. Procedural costs are much higher than in Europe (25000 dollars), but most dossiers are approved thanks to an open informal feedback channel between the authority and the petitioners. In the USA, the federal regulatory framework covers the importation, transit through the USA and a list of indigenous or established species that can be moved interstate without a permit. Any introduction, interstate movement or release of an organism which is non-indigenous to a certain state is prohibited there; exemptions may be granted by the federal authorities for specific use situations and areas (including the entire territory of the US), based on a risk assessment carried out by the North American Plant Protection Organisation. Such permit is free of charge. IBCAs are the subject of federal funding of research: the “Biocontrol Target Pest Canvassing and Evaluation” is a process conducted every five years. It relies on a broad input and its goal is to identify important exotic insects and weeds that can be considered as possible targets for a cooperative biological control programme.

Key instruments already exist in a few Member States or at the level of international organisations: Member States authorities and international organisations 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 procedures to assess potential costs and benefits of the use of a specific IBCA.

As a synthesis of the information collected, 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 (classical or augmentative biocontrol and Sterile Insect Technique). In addition, the risk assessment should also put in balance the societal and environmental 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 for the applicants. It is the case 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 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. Innovation pull seems to offer promising opportunities.

In line with the request from the Council, several areas for improvement of the current situation have been identified, putting an emphasis on the market situation and availability as well as on the safety aspects. The analysis took due account of interconnections with other policy areas, notably the stimulation of research and development as well as training and other forms of knowledge transfer between the different groups of actors.

Insufficient quantitative data are, however, available to allow a proper analysis of possible impacts of the stakeholders' suggestions and of the possible added value of EU intervention compared to action that could be taken at Member State level. The study is inconclusive, and the Commission is not in a position at this stage to formulate any appropriate proposal.

1. Background

On 22 June 2021, the Council, based on Article 241 of the Treaty on the Functioning of the European Union, requested the Commission to submit by 31 December 2022 a study on the Union's situation and options regarding the introduction, production, evaluation, marketing and use of invertebrate biocontrol agents (IBCAs) within the territory of the Union and a proposal, if appropriate in view of the outcome of the study[7]. Beside the collection of information on the status quo, the study is supposed to explore the possibilities of harmonisation of procedures in the EU, so as to facilitate the promotion of the deployment of, and market access to IBCAs, to support investment and innovation in and to contribute to a safe us of IBCAs. This study (the 'IBCA study') responds to that request. It is supported by the work of an external contractor (which will be referred to as 'the contractor's report' in this document) that was conducted between February and October 2022.

The contractor collected information, among others, via structured questionnaires and interviews, from the national competent authorities of all Member States, key stakeholders on European level (Biocontrol industry, growers and foresters, NGOs, scientific organisations and academia and international organisations) and the national competent authorities of two third countries (New Zealand and United States of America). More comprehensive information was collected from a group of seven Member States (Austria, France, Hungary, the Netherlands, Portugal, Spain, Sweden), considered to represent the composition of the EU in terms of geographical situation, climate and size. Targeted interviews were carried out as well with at least one representative of the different stakeholder groups (industry, users, NGOs, etc.) and the authorities of the U.S. and New Zealand.

IBCAs are invertebrate animals (such as insects, mites and nematodes) which can be used to control pests and diseases or vectors of such pests and diseases, and unwanted organisms. They include indigenous as well as non-indigenous[8] living invertebrate animals which are released in high quantities either directly into the environment or are released under protected conditions and may escape from there where insufficient preventive measures are taken. Their interaction with the natural fauna and flora may lead to unwanted consequences, like mass propagation of the IBCA or changes in population density of other species.

IBCAs are applied in different ways and three main approaches for their application can be distinguished: augmentative biocontrol[9], Sterile Insect Technique (SIT)[10] and classical

[7] 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%3A32021D1102&qid=1665559130607

[8] The terms 'indigenous' and 'non-indigenous' are used throughout this report to describe whether or not an organism naturally occurs in a specific area. Different terminology may be found in the underlying literature describing this concept, like 'native/non-native' or 'endemic/exotic'.

[9] "Augmentation involves efforts to increase populations or beneficial effects of natural enemies (parasitoids, predators, pathogens, entomopathogenic nematodes) of pest insects, mites and weeds. Various techniques can be employed in augmentation, but augmentation typically involves releases of natural enemies or environmental manipulation to enhance effectiveness of naturally occurring natural enemies. Environmental manipulation may involve providing alternative hosts or prey, food or nesting sites or modifying cropping

biocontrol[11] and they differ in many aspects, e.g. target pests, objective of application, application techniques and risks. This study will differentiate between them, where necessary. The scope of this study is limited to IBCAs which are released for the control of plant pests, weeds and invasive alien plants, as requested by the Council.

IBCAs can be used as alternatives to chemical plant protection products and have a growing importance in sustainable agriculture and forestry, namely in the implementation of Integrated Pest Management and organic farming. IBCAs are expected to have an overall favourable risk profile in comparison to chemical pesticides: based on current knowledge, IBCAs show no particular risk to humans, do not leave residues in food, do not produce toxins or other harmful metabolites and are not considered to form a risk to groundwater[12]. Unlike for chemical pesticides, pests hardly develop resistance against IBCAs. IBCAs may unlock pest control options for situations where there is no adequate treatment available. Classical biocontrol helps to reduce the plant protection costs for growers, as no further release of the IBCA is necessary, once a population is successfully established. Augmentative control is often used in protected crops (e.g. greenhouses), under conditions preventing or seriously impeding their spread beyond the location where the organisms have been released. If intentionally (e.g. in classical biocontrol) or unintentionally released into the environment, undesired effects on the ecosystems and biodiversity may occur through their interaction with non-target species. Furthermore, IBCAs may serve as carriers for agents which are noxious to non-target plants or animals, e.g. plant pests, hyperparasites/-parasitoids or pathogens. The risk assessment therefore focuses on environmental effects.

14 Member States have (and another 3 Member States intend to) put national requirements in place on the introduction, production, marketing, placing on the market and/or use of IBCAs. Usually, potential risks from the release of IBCAs are assessed and safe conditions of use are defined.

Internationally agreed guidance is available through standards provided on global level by the International Plant Protection Convention (IPPC) of the Food and Agriculture Organization of

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practices to favor natural enemies." Cited from: Hoy, M.A. (2008). Augmentative Biological Control. In: Capinera, J.L. (eds) Encyclopedia of Entomology. Springer, Dordrecht. https://doi.org/10.1007/978-1-4020-6359-6_10394.

[10] "The sterile insect technique (SIT) is a form of birth control imposed on a population of an insect pest to reduce its numbers. Thus far, this has involved rearing large numbers of the target insect pest species, exposing them to gamma rays to induce sexual sterility and releasing them into the target population of the pest on an ecosystem-wide or area-wide basis." Cited from: Klassen, W. (2008). Sterile Insect Technique. In: Capinera, J.L. (eds) Encyclopedia of Entomology. Springer, Dordrecht. https://doi.org/10.1007/978-1-4020-6359-6_4389.

[11] Classical Biological Control "[…] involves importing and establishing natural enemies in order to assist in the long-term control of newly introduced, foreign pests. Classical biological control involves a series of steps and usually takes a number of years." Cited from: Hoy, M.A. (2008). Classical Biological Control. In: Capinera, J.L. (eds) Encyclopedia of Entomology. Springer, Dordrecht. https://doi.org/10.1007/978-1-4020-6359-6_698.

[12] They are not identified as a risk under the current legislative framework of the EU for the protection of groundwater https://ec.europa.eu/environment/water/water-framework/groundwater/framework.htm,

the United Nations (FAO) and for the European countries and the littoral countries of the Mediterranean by the European Plant Protection Organization (EPPO).

Council Decision 2021/1102 considered the diversity of national regulations in the EU as a potential drawback against the full exploitation of the market potential of IBCAs in the EU as well as a potential risk vis-à-vis an unintended and uncontrolled spread of IBCAs beyond the national borders.

The objective of this study is to provide a systematic overview of the approaches which are in place in the different Member States and to identify areas of improvement, with a particular emphasis on the possibilities for harmonisation.

2. Legal and political context

The introduction, production, evaluation, marketing or use of IBCAs are not subject to specific legal provisions at EU level. They may, however, be partly covered by existing provisions from other regulatory areas:

Regulation (EC) 1107/2009[13] on the placing of plant protection products on the market ('the Pesticides Regulation') provides for a harmonised framework for the authorisation of plant protection products and for their use, control and placing on the market in the EU. It in particular aims to ensure that there are no harmful effects on human or animal health and no unacceptable effects on the environment from the use of such products, if used in accordance with the conditions set out in their authorisation. To this end, a comprehensive, scientific assessment of the potential risks of their active substances is carried out on EU-level followed by an assessment of specific plant protection products on Member State level. Synthetic chemicals, microorganisms, viruses, semiochemicals[14] and plant extracts are all included in the scope of that Regulation. IBCAs are not regulated as plant protection products under EU legislation. In some Member States[15], however, the national legislation concerning IBCAs shows similarities with the Pesticides Regulation.

Regulation (EU) 2016/2031[16] on protective measures against pests of plants ('the Plant Health Regulation') establishes rules to determine the phytosanitary risk by any species, strain or

[13] Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24. 11. 2009, p. 1. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32009R1107&qid=1665567126096

[14] Semiochemicals: chemical substances or mixtures released by one organism and affecting the behaviour of other individuals.

[15] E.g. by treating IBCAs as 'products', like in France, Austria, Finland, Greece and Latvia. The former legislation in Sweden (revised in 2016) and the planned legislation in the Belgian region Brussels treat IBCAs as if they were a subgroup of pesticides.

[16] 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, 76/647/EEC, 93/85/EEC, 98/57/EC, 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%3A32016R2031&qid=1665567200879

biotype of pathogenic agents, animals or parasitic plants injurious to plants or plant products and to reduce those risks to an acceptable level. It furthermore lays down criteria to establish, following a scientific assessment, whether an organism should be classified as a quarantine pest or as a non-quarantine pest requiring further regulation. These pests are added to a positive list and Member States are obliged to survey their presence and to take measures with a view of their eradication or, if eradication is no longer possible, their containment.

IBCAs can be used for the control of plant pests and may help to achieve the objective of the Plant Health Regulation. Although IBCAs are used with the intention to protect plants, they may exceptionally form a risk to plants, if non-indigenous IBCAs would establish in the EU territory and change their feeding behaviour towards naturally occurring plants.

Regulation (EU) 1143/2014[17] on invasive alien species sets out rules to prevent, minimise and mitigate the adverse impact of biodiversity of the introduction and spread, both intentional and unintentional, of invasive alien species. It provides for a scientific assessment of the invasive potential of living organisms which are alien to the EU territory. Invasive alien species are added to a positive list, and Member States are obliged to survey their presence and to take measures with a view of their eradication or management. Non-indigenous IBCAs may be considered under the Regulation on invasive alien species, but only with a view to their potential for negatively impacting biodiversity in the EU.

IBCAs have a considerable legacy of utilisation and biological control has been applied in agriculture and forestry long before synthetic plant protection products were available. The introduction of a growing number of highly efficient and cost-effective chemical plant protection products in EU agriculture of the 20th century went along with a steep overall decline of the importance of biocontrol agents for professional operators in agriculture and forestry. Biocontrol agents kept their importance in the different forms of 'ecological' or 'organic' agriculture, which were developed following the fundamental research of A. and G. Howard as well as R. Steiner in the 1920s and brought to full maturity in the second half of the 20th century. Being merely a niche market in economic terms, biocontrol still participated in the intensification and diversification of cropping systems in modern agriculture (e.g. protected cropping systems) as organic farming systems progressively expanded their market share.

More recently, reducing the carbon and biodiversity footprint of EU agriculture was put at the heart of food policy in the EU and worldwide. Sustainable conventional agriculture systems attracted political attention as a second pillar of a future-proof food system, beside the continued development of organic farming. The reduction of the dependence on chemical plant protection products is recognised as one of the key factors towards sustainable agriculture. It is also a direct consequence of a growing demand on the side of consumers. In 2020, the Commission has adopted the Farm to Fork Strategy[18], a comprehensive 10-year

[17] 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%3A32014R1143&qid=1665567678706

[18] 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

plan, standing in line with the Sustainable Development Goals (SDGs). It is the flagship initiative of the European Green Deal[19] in the area of agriculture and food production and aims at increasing resilience and sustainability of European food systems. In line with the objectives of the Biodiversity Strategy[20], it provides clear goals for the extension of organic production as well as the reduction of overall use and risk of chemical pesticides[21] and foresees a revision of Directive 2009/128/EC[22] on sustainable use of pesticides by 2022[23].

Thus, this policy framework establishes a favourable context and clear support of the Commission for the development of the utilisation of the IBCAs as an alternative to or in combined use with chemical pesticides.

The increased efforts to provide sustainable instruments together with the need to replace chemical plant protection products which may no longer be available in future, is expected to lead to an increased demand for safer, environmentally friendly, and innovative alternatives. In the future, phytosanitary instruments may evolve towards systems approaches where several instruments are combined, instead of depending from one single product. This may increase the role of IBCAs for the protection of plants in the EU, regardless of the actual production system.

The expansion of IBCA use must, however, not lead to a reduction of the high safety standards for human or animal health and the environment enshrined in EU legislation. Member States' activities in the field are not harmonised on EU level. There are, however, internationally agreed guidance and standards in place that can be used by the Member States when taking decisions on IBCAs:

- At international level, a guideline on 'export, shipment, import and release of biological control agents and other beneficial organisms' (ISPM 3[24]) provides for a basic phytosanitary

[19] European Commission, Communication to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions - The European Green Deal, Brussels, 11.12.2019, COM(2019) 640 final, https://ec.europa.eu/info/sites/info/files/european-green-deal-communication_en.pdf

[20] European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: EU Biodiversity Strategy for 2030 Bringing nature back into our lives. COM/2020/380 final. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0380&from=EN

[21] A 50% reduction of use and risk of chemical pestcides and a 50% reduction of use of more hazardous pesticdes by 2030 is foreseen. Accompanying measures, like enhancing the provisions on integrated pest management, are set out as well.

[22] Directive 2009/128/EC of the European Parliament and of the Council establishing a framework for Community action to achieve the sustainable use of pesticides. OJ L 309, 24.11.2009, p. 71–86. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32009L0128&qid=1664871994632

[23] 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 (COM/2022/305 final). https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=COM:2022:305:FIN

[24] 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. http://www.fao.org/3/j5365e/j5365e.pdf

framework. The scope of that guideline is broader than IBCAs and includes, amongst others, microorganisms and beneficial organisms (e.g. pollinators).
It encourages the contracting parties to carry out risk analyses prior import and release, to assure compliance with existing phytosanitary import requirements, to provide and assess adequate documentation relevant to export, shipment, import or release, assure a proper placing on the market and use and to carry out appropriate monitoring.

- At regional level[25], the standard series on 'Safe use of biological control' (PM 6)[26] provides for more instruments, notably guidance on the introduction and release of exotic IBCAs (including a decision-support scheme), and a positive list of IBCAs with a history of safe use within the EPPO region. Moreover, a Panel on biological control agents has been established[27], operating along the lines set out by the IPPC, strongly focusing on invertebrate animals, because it was recognised by the countries represented in these organisations that they are not governed by unified regulatory regimes.

As members of FAO and EPPO, EU Member States participated in the development of these standards and adhere to them. Different countries may interpret and implement the same standard in different ways. In Decision 2021/1102, the Council calls for a more consistent approach amongst Member States and reinforced cooperation with the relevant international organisations.

3. Description of the status quo

One of the main objectives of the IBCA report is to describe the status quo in the EU. The contractor's study revealed, that only limited information on the market and use of IBCAs in the EU is available.

3.1. Market situation[28]

The International Biomanufacturer's Association (IBMA)[29] carries out an annual market survey amongst its members, providing aggregated data. The EU-market of IBCAs is

[25] EPPO is the regional organisation under IPPC relevant to the EU (all EU Member States are member countries of EPPO).

[26] https://www.eppo.int/RESOURCES/eppo_standards/pm6_biocontrol

[27] Joint EPPO and IOBC-WPRS (International Organisation for Biological and Integrated Control – West Palaearctic Regional Section) panel on Biological Control Agents, https://www.eppo.int/ABOUT_EPPO/panel_composition/pm_biocontrol

[28] No products of classical biological control are currently available on the EU market and commercial perspectives are low because there is no business model available which may be replicated from one year to another: classical biocontrol aims at establishing an IBCA population; once that population is established, no further release is necessary. Therefore, this subchapter exclusively relates to augmentative control.

[29] Following the current member's directory https://ibma-global.org/ibma-members-directory, IBMA has 236 member companies, including companies from European non-EU countries. Its representative status for the EU biocontrol industry is assumed to be high, but it cannot be quantified in this study.

characterised by strong growth but still small size at the same time. The whole European biocontrol market in 2020 accounted for around 1 bn€ (around 30% of the global biocontrol market)[30]. IBCAs represent around 30% of the European biocontrol market (between 300 to 350 m€). IBCAs market share is still modest in comparison with chemical pesticides, representing 3% of the current crop protection market[31]. The market share of IBCAs however doubled between 2016 and 2020 (from 89 to 180 m€, a growth of 103%), while the pesticide sales decreased from 370 000 tonnes in 2016 to 333 418 tonnes in 2019 (-10% in terms of weight))[32]. The growth in other segments of the biocontrol market was even faster in the period represented[33].

It may be expected that IBCAs have the potential to contribute to a reduction of the use of chemical pesticides of 10.5% in the long run. Depending upon several factors, a potential for substituting by 2030 around 1 to 2% of the amount of chemical pesticides may be expected.[34].

Market data on IBCAs were available from four Member States (France, Finland, Sweden and Slovenia). In the other Member States requiring producers to communicate data about their national sales, National Competent Authorities (NCAs) were not able to provide adjusted data exclusive for IBCAs. No quantifiable information about the market share of imported[35] IBCAs in Member States was available.

Despite this lack of quantitative data, most Member States were able to provide qualitative descriptions of the main uses in their territory and some examples of best practice.

The IBCA industry is dominated by small and medium-sized enterprises: In 2019, SMEs made up 61% of biocontrol (all categories included) sales value, and 87% of biocontrol products sales. Large producers of IBCAs, having several production sites, are located in The Netherlands, France and Spain. Germany has a relatively high numbers of producers

[30] Source: IBMA annual survey, as referred to in the contractor's report. The most recent report (year 2022) was only partly available to the contractor at the time of drafting the report.

[31] In France, IBCAs accounted for 1.2% of the crop protection market in 2020. Similar ratios may be expected for the other Member States with an extensive horticultural sector and production under protected conditions. In Member States where mostly arable crops are grown, the share is expected to be lower. Also, the number of authorised IBCA species somewhat correlated with the importance of the horticultural sector.

[32] 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

[33] Growth 2016 – 2020: Microorganisms: +228% (approximately 25% of the market in 2020), natural substances: +182% (approximately 36% of the market in 2020), semiochemicals: +110% (approximately 10% of the market in 2020). Total growth of all four segments: +188%

[34] This figure is based on a theoretical scenario where all chemical pesticides are replaced by alternatives. IBCAs may potentially substitute up to half of the insecticides currently used (7.5% of the current pesticide market) and a limited number of herbicides and fungicides (counting for 2% and 1% of the current market, respectively). This would sum up to 10.5%. More details are given in the contractor's report, pages 82 and 98.

[35] Neither for IBCAs introduced from another Member State not for IBCAs introduced from a third country.

(seven), but all of them are SMEs. At the same time, these four countries show a high proportion of producers of high-value crops (often in glasshouses or in plastic tunnels), making them the 4 largest producers of agricultural crops in terms of value. Local IBCA producers have been identified in 10 other Member States, which implies that 13 Member States are expected to have no or only very limited production capacity for IBCAs (e.g. by industry which is not represented by an association on EU level).

On growers' side, the actual market size depends on the agricultural approach of growers in a certain sector. Biocontrol is common practice amongst organic growers, as they do only have access to a limited choice of chemical pesticides. Consequently, organic growers do not only have a particular interest in their availability, but they also may play an important role in the extension of existing applications (to control new pests or for use in new crops) and in the development of new ones.
The majority of IBCA users does, however, not adhere to a scheme of organic agriculture. They typically grow high-value crops under an IPM schema, using IBCAs in combination with other phytosanitary tools, including the use of pesticides. Typically (but not exclusively) these crops are cultivated under protected conditions (glasshouses, plastic tunnels). Growers who do not adhere to a low input or organic scheme and who do not mainly grow high-value crops typically apply IBCAs case-by-case, but might also switch to using pesticides when that seems to be more appropriate.
In general, a growing demand for more alternative options in pest control can be seen amongst all growers, irrespective of the farming system they apply.

In summary, the market for IBCAs tends to be larger in Member States with a significant production in the sectors horticulture and specialty crops as well as in protected crops, whereas it is smaller in Member States where arable crops prevail.

3.2. Use situation

Similar to the situation for the market share, there is limited data available on IBCA use in the different Member States. Only a few of them (France, Slovenia and Sweden) were able to provide precise data on the actual use of IBCAs in their territory and their repartition per crop.

Classical biological control in the EU relies on public research and development, as industry serving this market did not invent a suitable business model so far. Release is not in the hands of private users, but is subject to release programmes under the surveillance or control of national competent authorities. From a user's point of view, apart from the economic aspects (no need to purchase and release the IBCA), this may also increase the confidence in the excellence of the assessment and the management of possible risks, as the whole process is in the hands of public bodies.

Classical biocontrol may be associated with an increased potential risk for unacceptable environmental effects, as the goal is to establish a population of an organism (the IBCA) which is non-indigenous to the area of release, but which has the ecological potential to survive and reproduce there. Therefore, particular emphasis should be put on a thorough

assessment of the possible risk to the environment from the release of an IBCA. Such assessment should include the dispersal power of the organism, e.g. the risk of spread into and establishment in areas other than the area of release.

Historically, the intentional introduction of exotic species (e.g. the introduction of European farm animals or pets to different parts of the world in the 17th and 18th century) has led to severe disruption of ecosystems in the past all over the world. It is, however, important to note that none of these severe cases was related to the voluntary release of IBCAs for the purpose of pest control[36]. Considering the whole legacy of IBCA releases, measurable effects on the populations of non-target species have only been observed in a limited number of cases[37].
Despite of the potential risk, the practical experience with classical biocontrol is very positive: Around 650 IBCAs have been introduced into EU Member States in the past. Amongst these, around 200 introductions lead to a successful establishment of the taxon in the area of introduction and ca. 130 were efficacious, i.e. they significantly affected the population of the targeted pest.

Around 50% of the introductions were made in Italy, France, Spain or Greece. Although most of the cases target agricultural pests, a number of successful introductions concern forestry[38]. Against an international trend, where IBCAs are also used to control exotic weeds, there is only one example documented for the EU where an IBCA is used to control an exotic weed species. 42 species are listed in the positive list published by EPPO[39] as successfully established in the EPPO region[40]. The number of new introductions remarkably dropped in the near past, and since 2010, there were only 12 introductions reported by Member States as executed or planned. This may be associated with a changing legal environment, putting more emphasis on potential environmental risks.

Augmentative control follows a different approach. Establishing a population in the area of release is not a goal and a recurrent release of the IBCA in question is required, if the phytosanitary effect is supposed to remain. This creates a business model to producing

[36] The example of *Harmonia axyrides*, a ladybeetle which has been introduced into Europe found its way into the public awareness. A thorough study of the pertinent scientific literature, as provided in the contractor's report, shows, that there were some negative consequences on biodiversity following the spread of *H. axyrides*, but this did not lead to the local extinction of indigenous species.

[37] Van Lenteren et al, 2006 (as cited in the contractor's report) reviewed over 5000 introductions of 2000 exotic IBCAs into 196 countries or islands over the past 120 years and conclude that only 1% appears to have caused population-level effects in non-target species and another 3-5% gave reason to some smaller effects. No population-level effects have been observed in augmentative biocontrol.

[38] According to the contractor's report, which refers to the release of *Rhizophagus grandis* in France and the UK (pre-Brexit) and *Torymus sinensis* in Italy, France, Croatia, Hungary and Slovenia.

[39] Annex 2 to EPPO standard PM 6/3(5) Biological control agents safely used in the EPPO region – 2022 version https://www.eppo.int/media/uploaded_images/RESOURCES/eppo_standards/pm6/pm6-3(5)-2022-en.pdf

[40] According to the information provided in the standard, establishment in the territory of the EU is confirmed for 32 species and unsure for the remaining 10 species because of a lack of data.

them and placing them on the market that can be used by companies. Retailers and end-users (public or private) are the potential customers. 112 species are considered either indigenous or established or in use since more than 5 years in (parts of) the EPPO area and no unacceptable adverse effects have been observed (species listed in Annex I to PM 6/3(5)).

Augmentative control is most common in protected crops, under conditions preventing or excluding the spread of the IBCA outside the area of release. This drastically reduces the possible risk from their use. Typically, they are applied to control pests like thrips, whiteflies, spider mites or aphids - pests of high importance in protected crops, and which are often difficult to control with the chemical pesticides currently available in the EU. Other uses include the release of nematodes to control insects (e.g. species of the genera *Heterorhabditis* and *Steinernema*), slugs (*Phasmarhabditis hermaphrodita*) or nematodes (e.g. species of the genera *Labronema* and *Mononchus*). Mostly being used in protected conditions, only a few products have reached large market value and a use of a substantial proportion of crop surfaces. There is one example of a significant use of IBCAs in arable crops in the EU: the utilisation of micro-wasps of the genus *Trichogramma* against the European corn borer in maize in some Member States (and particularly in France, where 25% of the infested area is treated with the wasp). Besides that, there is a large number of IBCA products available on the EU market for different crops and pests, but only with a low uptake.

The following obstacles have been identified by growers and industry as hampering a broader adoption of the utilisation of IBCAs in the EU:

- Lack of knowledge about IBCAs;
- High costs for growers where the use of IBCAs is not subsidised[41];
- Low efficacy comparing to chemical pesticides, especially in outdoor crops, and if used outside an integrated approach;
- IBCAs restrict grower's choice of agricultural practices, (e.g. where a zero-tolerance to specific pests is mandatory, like in seed potato production);
- Regulatory barriers, in terms of administrative burden to industry, time consuming regulatory procedures or lack of authorisation for existing solutions.

Sterile Insect Technique (SIT) may be seen as a special case: being an augmentative technique on one hand, SIT-solutions cannot be counted as simple commercial products and their use relies on business models mixing service and products.

[41] The number of specimen of IBCAs necessary for efficient pest control under open-field conditions does not increase linear, but logistically with the size of the field. This leads to disproportionate increase of costs for the product and its application.

In SIT, no pest organisms are killed and the technique does not aim at immediately reducing a pest population, but at preventing or reducing their reproduction rate within a number of years. The potential direct risk to biodiversity therefore is considered to be low. IBCAs produced for SIT are not applied by a grower to control a pest in a field, but they are applied in the framework of an extinction or suppression strategy within a larger area. Their efficient use requires a coordinated application within large areas and beyond specific field borders. Their production and use is technically demanding and costly. As SIT includes the deliberate release of a pest (though sterilised) into the environment, it may interfere with legislation for the protection of the environment or agricultural production in some Member States[42].

Use of SIT has been identified in four Member States (Croatia, France, The Netherlands, Spain) and against a limited number of pests (e.g. the fruit fly *Ceratitis capitata* or the onion fly *Delia antiqua*). Consequently, there is only a limited number of existing applications of SIT in the EU, although the technique offers some intrinsic advantages, like very high target specificity, very low risk to additional effects on biodiversity and possibility for eradication of the target[43].

3.3. (Regulatory) systems in place in Member States[44]

IBCAs are not subject to specific provisions in EU legislation.
Specific provisions concerning IBCAs exist in national legislation in about half of the Member States[45], and the majority of them was adopted in 2010 or later. Amongst the Member States which do not have specific legislation, the unauthorised introduction of non-native species is prohibited under environmental legislation in six Member States and the Belgian regions Brussels and Flanders. An overview of regulatory frameworks can be found in Annex I, a typology of the different regulatory frameworks can be found in Annex II.

3.3.1. Characterisation of the regulatory approaches in EU Member States

Legislative frameworks in place differ considerably. However, they are characterised by a set of elements with a limited number of variations:

[42] Source: contractor's report.

[43] For ecological reasons, it is very unlikely to eradicate a pest by the sole use of predators or parasitoids, i.e. IBCAs, in the open field where sufficient shelters are available. SIT is based on a different effect, namely the outcompeting of fertile by a very high number of sterile animals.

[44] In Belgium, IBCAs are regulated on the level of the three regions Flanders, Wallonia and Brussels and differences exist between these three. These differences are considered in this report and the underlying contractor's report, but they are not explicitly detailed in the following, as they are not relevant within the scope of the exercise.

[45] 14 Member States have established provisions specifically regulating the introduction, production and/or release of IBCAs in their national territory, three Member States currently prepare such provisions, 10 Member States do not have legal provisions.

- **Taxonomic level**: Authorisation may be granted on the taxonomic level of a species or on a taxonomic level below the species (subspecies, strain, ecotype).

- **Content of authorisation**: In a number of Member States, the authorisation of an IBCA has similarities to the authorisation of a pesticide: a specific IBCA is authorised for the use in defined crops against defined pests. In others, only the name of the IBCA (species or lower taxon) is authorised. Additional elements (origin, applicant, ecological potency) may be part of the authorisation in single Member States.

- Alien vs. native[46]: The majority of Member States discriminates between indigenous and non-indigenous species, in three Member States, specific provisions exclusively cover non-indigenous IBCAs.

- **Environmental vs. pesticide legislation**: In some Member States, IBCA-specific rules are embedded into environmental legislation, in others into pesticide legislation[47]. This has consequences for the structure and the content of the procedure, the taxonomic level of the authorisation, but also for the identity of the national competent authorities in charge of IBCAs.

- **Product chain**: There are differences amongst Member States in which steps of the product chain are regulated. Whereas the introduction of an IBCA is regulated in the majority of Member States, production, placing on the market or release are not consistently part of the regulatory system. The place of production (within or outside EU) is only considered in exceptional cases.

- **SIT** is explicitly mentioned in the legislation of only four Member States. Only one Member State explicitly discriminates between **augmentative** and **classical biocontrol**, although the risk assessment schemes of several Member States include invasiveness and the majority of Member States discriminates between indigenous and non-indigenous IBCAs (see above). One other Member State discriminates between **professional** and **amateur** applications.

- Fees[48]: Three Member States (Finland, Belgium, France) do not raise fees for the assessment and/or registration of IBCAs. The scale of fees known from Member States is modest in comparison to e.g. New Zealand, with four of five Member States raising fees between ca. 750€ and 1000€ (outliers are Latvia with 248€ and Austria with 2300€).

[46] For the purpose of this report, 'indigenous' refers to species which occur naturally in a specific area, 'non-indigenous' refers to species that do not naturally occur there. Amongst the Member States that discriminate between these two groups, there is no common understanding about the underlying concept, e.g. how long a species must be present in an area in order to be considered as 'indigenous'.

[47] Notwithstanding that, all Member States with a regulatory framework have legislative provisions for IBCAs which are distinct from that for pesticides.

[48] Figures on fees as reported in the contractor's report, following data provided by industry.

3.3.2. Risk and benefit assessments

Almost all Member States that regulate IBCAs also carry out risk assessments. Non-indigenous species are prohibited by default in some Member States and two Member States allow the release of all IBCAs that are authorised in another Member State. The scope of application (whether and how indigenous organisms are included) and its content vary considerably across the EU. Common elements are the risk of unintended spread, the risk to non-target organisms as well as the risk to biodiversity. Two Member States look into the risk from diseases that may be introduced through the IBCA as a contamination. See also Annexes I and II for a detailed overview.

Risk assessments carried out by Member States mainly rely on data and information provided by applicants, on published scientific data and on existing risk assessments available from other sources. Such information must be comprehensive, relevant and scientifically valid. The contractor's report, which analysed in more detail the data requested by 7 Member States[49], showed, that a large part of the information requested is similar, but that the format of the application may differ. In two Member States, the requested data is aligned with EPPO standard PM6/2(3)[50]. Country-specific requirements exist in all Member States, but only count for a smaller part of the application.

According to the experience gained so far, there is an overall low risk to biodiversity from IBCAs: some undesirable impacts have been reported from five Member States so far (in the most cases in relation to *Harmonia axyrides*, a ladybeetle that is non-indigenous for the EU), but they did not lead to serious consequences for the local ecosystems.

Seven Member States also carry out an assessment of benefits beyond plant protection/phytosanitary effects, e.g. benefits to local biodiversity, environmental benefits and, in one Member State, economic and social benefits, including the reduction of insecticide use (more information is provided in Annex I).

Nearly all Member States which regulate IBCAs provide some level of administrative support to applicants. Typical elements of such support are publicly available guidance documents and the opportunity for pre-submission advice by the competent authorities on content and format.

Applications are only rejected in rare cases[51]. More commonly, Member States approve the use in combination with risk mitigation measures, e.g. restriction to be used under specific conditions or with specific equipment.

[49] Austria, France, Hungary, The Netherlands, Portugal, Spain and Sweden.

[50] https://onlinelibrary.wiley.com/doi/epdf/10.1111/epp.12153

[51] With the exemption of Spain, where between 2012 and 2021 ca. 25% of the applications were rejected.

3.3.3. Other requirements

In nine Member States, producers and retailers of IBCAs must be registered. Only in very few Member States (France, Greece, The Netherlands) quality control is a part of the regulatory process, and even in these countries, there are no strong provisions.

A post-release monitoring framework is established in Denmark, France Italy and Slovenia. As a stand-alone measure or in combination with the monitoring framework, also Austria, Greece, The Netherlands and Spain require users to report effects of the IBCA[52] use to the authorities.

Several Member States oblige the users of IBCAs to record the IBCAs they purchase and/or store and/or use (similar to a common requirement for the use of pesticides).

In 13 Member States and one Belgian region, IBCAs are considered as 'non-chemical alternatives' when a comparative assessment according to Article 50 of the Regulation on plant protection products[53].

Due to the overall low risk from their use, there are no requirements for IBCA users to undergo a training or certification of their knowledge and amateur users have unrestricted access to all IBCAs in all Member States that regulate the IBCA use.

3.3.4. The role of international guidance documents

In developing their regulatory frameworks, most of the Member States made use of the EPPO standards PM6/1/(1), 6/2(3) and 6/4(1)[54], either by using them as a basis for developing provisions or by explicit references[55]. This concerns procedural aspects as well as data requirements or the scheme used in decision-making.
Other guidance documents mentioned by Member States as being (implicitly) used in their national regulatory systems are guidance documents adopted by OECD, EFSA or IOBC.

A prominent role takes the positive list of commercially or officially used and of successfully established IBCAs within the EPPO region, which is provided in Appendices 1 and 2 of EPPO PM6/3(5). Although it is rarely used as an exclusive

[52] Such effects may include impacts on biodiversity, the longevity of the IBCA in the environment or interactions with natural populations of non-target organisms.

[53] That article provides, that Member States, when receiving an application for authorisation of a pesticide containing an active substance from a specific group, the 'candidates for substitution', first have to carry out an assessment whether safer pesticides or non-chemical alternatives exist. The term 'non-chemical alternatives' is not defined in that Regulation and therefore Member States may apply a margin of discretion.

[54] As referred to under https://www.eppo.int/RESOURCES/eppo_standards/pm6_biocontrol

[55] Some Member States use EPPO as the sole regulatory framework for decision making.

basis for decision-making, it plays an important role for that process in all Member States that regulate IBCAs[56].

3.4. Shortcomings and challenges

Four Member States (Spain, Sweden, Latvia and The Netherlands) reported to be rather satisfied with the functioning of the regulatory framework and were not aware of fundamental problems. Nevertheless, these Member States, together with others, still identified areas for improvement during the research done by the contractor.

One of the main challenges identified by Member States is obtaining the right data regarding the risks and, if relevant under the national regulation, benefits from the utilisation of an IBCA. In many other regulatory systems in the EU (e.g. pesticides, GMOs), it is the task of applicants to make sure that sufficient and relevant information is submitted in a data dossier together with an application to allow a proper assessment. Compiling such dossier and assessing them may be time- and resource-consuming, depending on the characteristics of the organism and the amount of publicly available scientific data.
It is difficult to exactly predict on the basis of standardised laboratory and semi-field test protocols, how a species will behave after release into a specific ecosystem, as not all relevant factors might be known and not all topics might already be addressed by existing research. This creates an additional challenge for dossier submitters and risk assessors and may lead to very conservative regulatory decisions.
Regulators have to assure the comprehensiveness of the assessment while keeping in mind the cost incurred for the national administration and for the applicant, as otherwise the authorisation of use for new IBCAs may be jeopardised.

Similar challenges exist around the necessity to carry out post-release monitoring: depending on the characterisation of risk from releasing an IBCA (which is different e.g. amongst predatory and herbivore IBCAs), different monitoring strategies may become necessary, some having higher costs than others. For pragmatic reasons, most Member States strongly rely on reporting of unexpected effects instead of systematic, active monitoring.

Other problems or challenges regarding the implementation of national regulatory frameworks mentioned by individual Member States are:

- Lengthy and complicated administrative processes;

- High registration costs, disadvantaging SMEs;

- Applications that do not fulfil the needs of the regulators;

[56] Germany and the Belgian region Brussels, where this standard has currently no legal role yet, indicated that this is foreseen to be changed in a future revision of the legislation. Portugal indicated that the standard will become part of a legislative project on IBCAs which is under development.

- Absence of an appropriate definition of indigenous species and lack of environmental aspects in the assessment;
- Absence of specific training;
- Lack of an efficient and effective monitoring system;
- Difficulty to produce new data following the identification of data gaps;
- Absence of provisions on SIT from the legislation.

From industry's point of view, a lack of experience on the side of the regulators may lead to disproportionate data requirements and overly conservative decision-making. As a result, the regulatory process may become lengthy and its outcome may become less predictable, as regulators may identify a high number of data to be generated after the initial dossier has been submitted. This does not only increase the overall cost to bring a certain IBCA to the market, but it will also prolong the time to market, deferring the point when profit may be realised.

Another challenge identified by industry is the diversity of the current regulatory system in the EU. Decisions are taken per Member State, which leads to a multiplication of costs to be spent on the several regulatory processes, when applications for the same IBCA are made in several countries. In addition to purely procedural issues of multiplication of regulatory fees, different data sets are required in different Member States when the assessments are not aligned or harmonised.

The possibility to claim intellectual property rights may form an important factor in some businesses. For IBCA industry it is, however, only of minor concern: although IBCAs-species or -strains themselves cannot be patented, particular conditions of their production process or the application system in which they are used can benefit from patent protection. Industry representatives reported an increase in applications relating to protection of intellectual property rights.

3.5. Complementary instruments

3.5.1. The contribution of research projects and funding on product development and availability

Advancing the use of IBCAs requires continued research and development. Research and development for classical biological control and development of SIT are mainly supported by public authorities due to high development costs and offers limited commercial perspectives.

At EU level, there is a steady increase of funding for projects associated with biocontrol (including biocontrol options other than IBCAs) and 44 projects have been funded under the Horizon 2020 programme. They mainly concerned the mobility of researchers and their training and exchange of knowledge, support 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.

At national level, the organisation of research and development is strongly related to the potential for commercial development of IBCAs. Consequently, most initiatives are linked to augmentative biocontrol and involve partial contributions regarding research and development through private-public partnerships. IBCA producers, through their marketing and post-marketing activities tend to be in closer contact to growers. They create feedback loops allowing to better understand the actual and emerging needs and to invest in the development of needs-based solutions for emerging and recurring pests. In parallel, local grower's associations, research and academic institutions survey pest incidents and prioritize R&D needs. Much of the latter is done in collaboration with private IBCA producer with a view to possible commercialization at a later stage.

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 MS organisations. However, most investments are of small size (when compared to that on pesticides or other biocontrol categories).

The size of the investments as well as of the R&D public or private community is relatively small and their members are 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).

3.5.2. Knowledge transfer and training

In contrast to the training requirements for the purchase and application of pesticides, no training or certificate are required for the unlimited purchase and use of IBCAs in EU Member States. But a distinct level of knowledge is necessary for the successful application of IBCAs and for reproducible results. Unlike pesticides, where knowledge is most important in relation to safety issues, IBCA users must be knowledgeable about the biology of the IBCA and the controlled pest. The situation becomes even more complex, where IBCAs are part of a systems approach, where several phytosanitary tools are combined.

Across the EU, authorities mainly provide general information that, even where publicly available, primarily targets professional users. Professional users also benefit from more detailed advice provided by industry. According to the provisions of the Directive on sustainable use of pesticides, all professional users of pesticides[57] must demonstrate sufficient knowledge about pesticides and their use. Such training

[57] Products containing e.g. microorganisms or plant extracts and used in pest control count as pesticide as well. Therefore, the vast majority of professional organic growers are included here as well.

includes also general content concerning IPM and biological pest control. Authorities and industry agree that professional users are generally well informed about the principles and strategies for using IBCAs but that this training is not sufficient to instruct growers which IBCA may be used in a concrete situation. The amount and quality of information available on which IBCAs are available and how they may be used successfully depends upon the size of the market in the respective sector: it is high in sectors where the market for IBCAs is already well developed, e.g. for crops grown under protection. It is rather low in sectors with a low market penetration of IBCAs, like arable crops. Across all sectors, information deficits are more likely to occur where phytosanitary problems are in the state of emergence, i.e. where chemical pesticides are readily available or where new pests occur.

In particular industry raised concerns about the availability of biocontrol experts having expertise in both, IBCA and pest biology as well as crop production, and who therefore are competent to judge the practicability of measures and their conciliation with grower's needs.

Good practices have been identified which could improve the knowledge transfer from academic research to grower's practice. These include the installation of demonstration farms, regular meetings amongst researchers, industry, advisers and growers, maintaining central (national) internet portals that would bundle information in the form of a one-stop-shop and a net of regional competence clusters facilitating the information flow top-down and bottom-up.

3.5.3. Strategic approaches in individual Member States

Several Member States (including France, Austria, The Netherlands, Germany or Spain) have developed strategic plans to support the development and use of IBCAs or, more generally, of biocontrol or low input farming. Such plans typically include elements, like: improvements of the national regulatory process, fostering research for alternative crop protection solutions, creation of specific labels for biocontrol products, promotion campaigns vis-à-vis prospective users or financial support.

Financial support may take different forms: Raising higher taxes on chemical pesticides than on biocontrol products, financial aids to growers for using IBCAs, programmes financing public-private developments, tax credits for research and development of biocontrol products.

Member States have the possibility to financially support the use of IBCA by farmers with the Common Agricultural Policy (CAP). The new national CAP Strategic Plans starting in 2023 may, if the Member States decides so, include policy interventions, such as eco-schemes or rural development schemes financing such practices, including under the use of biological control, integrated pest management or organic farming. In

this respect IBCA is explicitly mentioned in at least two national CAP Plans (Germany and France)[58].

3.6. Examples from third countries

The study carried out by the contractor included an analysis of the systems in two countries, with a view to identify best practices and possibly solutions, which have not been mentioned by Member States or EU stakeholders:

New Zealand is a country, which is characterised by its isolated location as a group of islands and unique indigenous fauna and flora, creating a particularly vulnerable baseline. The importance of the primary sector is high, chemical pesticides are used intensively and there are no financial incentives given to using IBCAs[59]. IBCAs are less used in agriculture, but more to control weeds or harmful insects outside agricultural areas.

There is a long record of regulating the introduction of non-indigenous organisms. The regulatory process for IBCAs is described in a legal act which regulates 'hazardous substances' and 'new organisms'[60] and which dates from 1996. 39 biocontrol agents (IBCAs and others) have been approved since the act entered into force in 1998.
The regulatory system of New Zealand is characterised by a binding deadline for decision-making: once an application has formally been submitted, the risk assessment must be completed within 100 days. The assessment takes the form of a probabilistic analysis of risks and benefits for the environment, plant health, human health, society, the market economy and international obligations. It includes a public consultation and the different steps follow short and legally binding deadlines. The assessment is issued in the form of a recommendation and will be transformed in a legal decision by risk managers.

A pre-submission period for applications is foreseen, where applicants are allowed to submit draft applications that will be reviewed and commented by the national authority free of charge, leading to extensive discussions between applicant and assessor in many cases. Any fee is only due after an application has formally be submitted[61].

In the **United States of America**, the regulatory system has to take into account the share of competencies between the federal and the states' level. Any introduction, interstate movement or release of an organism which is non-indigenous to that state is prohibited; exemptions may be granted by the Animal and Plant Health Inspection Service of the United States of America (APHIS) for specific use situations and areas (including the

[58] Source: contractor's report.

[59] Source: contractor's report.

[60] The definition 'new organisms' includes any species of animal, plant, bacterium, virus and genetically modified organisms; biological control agents are listed as a subgroup. Source: contractor's report.

[61] A fee of 25000 $ is raised for the application; this is relatively high in comparison the fees in EU-Member States (see also chapter 3.3.1)

entire territory of the US), based on a risk assessment carried out by NAPPO (North American Plant Protection Organisation, the EPPO-equivalent for the North American region)[62]. APHIS established and maintains a list of organisms present in the territory of the US that are considered to be established throughout their complete geographical or ecological range in the continental US and are determined not to present any additional plant pest risk. These organisms are exempted from any further authorisation.

APHIS funds and coordinates a significant programme for development of biological control activities. The 'Biocontrol Target Pest Canvassing and Evaluation' is an exercise which is executed every five years and which solicits input from agencies, universities, weed management districts and the plant health directors of the states in order to identify non-indigenous insects and weeds that may be considered as targets for cooperative biological control programmes.

4. Problem definition

Following the consultation of Member States and key stakeholders, two core problems have been identified:

- The use of IBCAs is growing slowly considering their potential contribution to achieving the sustainability goals of the Green Deal as well as the Farm to Fork Strategy by providing viable alternatives to chemical pesticides.

On the basis of a preliminary assessment[63], the IBCA may be expected to continue to develop during the next 5 to 10 years. IBCAs are expected to have a potential to replace around 10% of the current chemical pesticides use in the EU in the long range. It can be estimated that the IBCAs will represent around 3-4% of the EU crop protection market by 2030, thus contributing to a reduction of the use of chemical pesticides by 1 to 2% (this value largely depends on the amount and efficiency of measures being put in place until then to increase the market penetration of augmentative biocontrol and SIT).

- The level of protection of the environment is not harmonised in the EU, but IBCAs are capable to spread beyond the national borders.

The introduction of a non-indigenous species with a view establishing a population (i.e. classical biocontrol) bears a higher potential risk to biodiversity than augmentative applications. IBCAs with a high potential to spread may also pose a risk to other Member States.

Three main groups of drivers may be distinguished: market drivers, factors linked to regulatory systems, societal needs. An overview about the core problems, drivers behind and the main consequences can be found in the problem tree in Annex IV.

[62] Further details may be found in the contractor's report.

[63] source: contractor's report, p. 77 and 93. The figures given are based on expert judgement and are therefore more of illustrative character.

4.1. Market drivers

For the time being, the use of IBCAs may not be sufficiently interesting for some growers from an economic point of view: according to the growers' organisations consulted for the consultant's report, growers feel that IBCAs do not offer sufficient benefits in relation to the cost linked to their use[64]. The use of IBCAs requires an advanced level of knowledge about the biological and ecological background of pest control and even well-trained growers may be unaware of the full potential offered by IBCA use[65]. It is possible to substitute a more harmful chemical pesticide by a less harmful chemical or a biological pesticide, but the substitution of chemical pesticides by IBCAs in most cases requires a completely new, integrated, pest control strategy. Strengthening the implementation of IPM practices, as foreseen in the proposal for a revision of the Directive on sustainable use of pesticides, may have positive impacts on the demand for IBCAs as well.

The development and commercialisation of new IBCAs is not always sufficiently interesting for producers. For augmentative biocontrol, costs and time for development and possibly product authorisation may require substantial investments in comparison to the expected profits and applicants for authorisation may easily be confronted with unforeseen delays in the procedure because of gaps in their data dossiers identified only after dossier submission in Member States that do not offer systematically pre-submission advice[66]. SMEs, which represent the majority of IBCA producers, may lack financial reserves to cope with them.

IBCAs fall under the Nagoya Protocol[67] on access and benefit-sharing of genetic resources. The obligation to share in the countries of origin to benefits from the use of IBCAs might negatively impact the development of new IBCAs which are not native to the countries where they are applied. The International Organisation for Biological and Integrated Control (IOBC) developed a best practice to ensure a fair share of benefits[68].

[64] According to information provided in the consultant's report, the pure application costs for IBCAs may be up to 2-3 times higher than for chemical pesticides. This neither factors in the cost for the product (which are expected to be higher for IBCAs) nor societal or environmental costs (which are expected to be lower for IBCAs).

[65] This is well illustrated by anecdotic information provided by a representative of industry during the validation workshop on the outcome of the contractor's consultation. He informed that even growers using IBCAs in one of their cultures (e.g. greenhouses) are not aware about IBCA applications in other cultures (e.g. arable crops) cultivated at their farm.

[66] Despite of the generally low level of concern from the use of IBCAs, the potential long term effects in rare cases and a low level of harmonisation in the assessment bears a certain risk of additional data requests and delays in the assessment process.

[67] https://www.cbd.int/abs

[68] 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.

Over the years, **innovation push**[69] activities had only modest influence on the evolution of IBCA innovation and market. After a peak around the end of the last and beginning of the current millenium, there is a steady, but slow growth across all sectors, driven by punctual rapid and strong growth in special sectors following specific incidents[70]. Classical push activities, like direct or indirect funding of innovation activities carried out around the same time, apparently had only little influence on the innovation development and support activities to private R&D have been recurrently underused in the past.

Generally speaking, public funding of R&D, which is proportional to the investment from the private sector is expected to show only moderate effects because of the small market size for augmentative biocontrol and the absence of a market for classical biocontrol and SIT. This effect is largely independent from the proportion of the funding (whether 1:1 or otherwise).

Seemingly, innovative processes were rather triggered by specific events that acted as systemic game changers and resulted in **innovation pull** instead[71]. Replacing one chemical pesticide by one IBCAs will not lead to comparable results in most of the cases. The successful application of IBCAs regularly requires a systemic strategy, i.e. a profound switch towards an integrated approach. Such strategy has to be (partly or entirely) crop-specific. Recent research underlines the importance of the interplay between innovation of IBCAs and the evolution of the agricultural and agrifood value chains and markets[72].

Two significant knowledge gaps were identified:

- The available knowledge about the actual market and use of IBCAs in the EU is rather restricted. Insufficient information about the actual market makes it difficult for industry to identify market opportunities and to develop a good investment and market strategy.

- Albeit there is no record of non-acceptable impacts of the use of IBCAs in the EU so far, conjectures about potential long-term effects may remain, mainly because there is hardly any data to prove the contrary. This may lead to refusal of authorisation in regulatory system where risk management follows very conservative criteria, thus increasing for applicants the uncertainty in relation to the return of investments.
As a consequence, further investments into the extended exploration of existing solutions

[69] No quantitative or scientifically sound impact study could be identified by the contractor in reporting about innovation push and innovation pull. Also, only very little input could be collected during the field research. Hence, the contractor provided an analysis, which is based on qualitative evaluations, discussions, expert judgement and scientific publications providing data and innovation trends.

[70] Examples cited in the contractor's report are the crisis in greenhouse vegetables after some pesticide residue scandals in the early years 2000 or the prohibition of use of chemical pesticide in public areas and private gardens in France.

[71] This hypothesis is underpinned by the observation that innovation pull for biological control methods, which have been used already long before the breakthrough of agrochemicals since the beginning of the 20th century, was locked since then.

[72] Source : contractor's report.

as well as into new, innovative IBCA products may be discouraged and suitable products may not be available or accessible to the extent possible.

4.2. Diversity of regulatory systems and systemic shortcomings

The national provisions on assessment, introduction, production, placing on the market and release of IBCAs vary considerably: whilst some Member States apply rather strict provisions, other Member States do not possess any regulation (see Annexes I and II for more detailed information). Requirements and procedures differing between Member States increase the administrative and financial burden on applicants when they try to introduce an application for the same IBCA in different Member States.
As a consequence, competitive and market issues may arise, resulting in a lack of availability or accessibility of products in the EU or in certain Member States only.

Based on the contractor's report, it seems that there is space for homogenisation of procedures at EU level, provided that Member States are left a sufficient level of freedom at the national or regional level. The contractor's report notes a higher openness towards stricter alignment and harmonisation amongst Member States that do currently not have legislation in place.

A large majority of Member States clearly supports an increased level of harmonisation in the risk assessment, whereas industry fears that increased harmonisation in the risk assessment might lead to increased administrative and financial burden on their side, thus negatively impacting the economic circumstances.

Some Member States note a lack of resources of authorities to carry out risk assessments or a lack of underlying scientific data in the dossiers to carry out a comprehensive scientific risk assessment and a systematic post-release monitoring is lacking across the EU. Together with existing differences in the scope of the regulatory procedure, potential risks to biodiversity may be undetected during the regulatory process or in the post-release phase.

From an industry point of view, the regulatory process plays a crucial role for the development of new products and for finding new markets for existing products. Much more important than the mere application and registration cost, which may differ considerably amongst Member States, is the market access expenditure, i.e. the cost for industry to bring a product on the market. This cost, incurred at a critical point in time, largely depends on the duration of the authorisation process, which varies between 2 weeks and 24 months amongst different Member States.
A clear regulatory framework, precise requirements and a good communication with applicants should help to reduce the length of the regulatory process, and therewith the time to market. Furthermore, it should also help industry to submit better produce dossiers focusing on the information necessary for decision-making, therewith curtailing the dossier cost. It should also increase predictability and help industry to better plan their innovation investments. Keeping in mind the overall structure of IBCA industry (mostly

represented by SMEs), targeted measures might be necessary to make sure that SMEs are not affected by the complexity or the degree of harmonisation of the framework.

4.3. Societal needs

The limited development of the current IBCA market is becoming a growing issue with regard to the potential of IBCAs to contribute to replacing chemical pesticides. 'Little or no use of pesticides' is for many citizens a key characteristic when it comes to define terms like 'sustainable food' or 'healthy diet'[73].

This is underpinned by initiatives like the European Citizens Initiative "Save Bees and Farmers"[74], calling on the Commission to reduce the use of synthetic pesticides in EU agriculture by 80% until 2030 and to completely phase it out by 2035, that was supported by more than 1 million citizens and by studies referring to very negative effects on health and biodiversity from the use of chemical pesticides[75].

Growing concern amongst citizens about the integrity of biodiversity in the EU may result in a more negative view of a number of citizens on IBCAs; population shifts following the establishment of an IBCA in a new environment which are easy to detect, but impartially has no a severe impact on biodiversity (as it happened during the spread of *Harmonia axyrides* in parts of the EU), may negatively influence the public perception of the safety of IBCA use and have some political and societal repercussions. A continued and transparent communication strategy may help to mitigate this.

The participation of NGOs in the study was nevertheless low, given the potential role of IBCAs in the reduction of chemical pesticides. This might reflect the challenge to define an agreed position on NGOs side, but in any event prevents a deeper analysis of aspects specific to societal drivers related to the current situation of IBCAs in the framework of this study.

5. Possible areas for improvement

In line with the Council Decision requesting a study on IBCAs, the purpose of this study was to describe the current situation and to identify possibilities to improve it. A particular emphasis should be put on the opportunities for harmonisation. A comprehensive list of potential options, as identified by Member States and stakeholders during the consultation ,

[73] Source: https://europa.eu/eurobarometer/surveys/detail/2241

[74] https://www.savebeesandfarmers.eu/eng

[75] Source : contractor's report, p. 76.

together with a preliminary analysis of pros and cons as well as their feasibility, was provided by the contractor[76].

5.1. Regulatory approach

The high diversity of regulatory approaches was identified a priori by the Council as a particular issue in connection to the current situation of IBCAs. Reducing this diversity may address several drivers behind the problems identified and therewith improve the current situation. The diversity could be reduced by harmonising elements of the process (i.e. including EU action), or by more and stricter alignments amongst Member States (based on mutual consent, not EU action). It is not possible to decide in the framework of this study, whether harmonisation or alignment would be the more favourable option, as the risks and benefits of harmonisation vs. alignment for specific options have not been specifically compared in the contractor's report which is the basis for this study.

Major elements for further alignment/harmonisation and expected consequences are:

- The establishment of a common (positive) list of approved IBCAs and/or a (negative) list of forbidden IBCAs would decrease the current separation of the markets in the different Member States. It would reduce the cost to market for industry and get down the prices of products, making the use of IBCAs economically more profitable for growers. Publicly funded pest control programmes (vital for classical biocontrol and SIT) would similarly profit from lower costs for development and implementation. A higher return to existing products would encourage industry to invest in new, innovative IBCA solutions, thus increasing the availability of IBCAs for users. Furthermore, it would increase the visibility of IBCAs to growers. It would enable Member States that did not have sufficient resources to sufficiently support IBCAs in the past to profit from synergistic effects. Based on the current experience with a positive list for classical IBCAs, a positive list for augmentative IBCAs and a common negative list for IBCAs compiled by EPPO which are not legally binding, it may be assumed that only a legally binding list will show noticeable positive effects.

- The alignment of the assessment is expected to further increase the opening of the market with all positive effects on the problem drivers that were described above. It may increase the predictability of the outcome of the process for industry. Such alignment could include a common definition of key terms (e.g.: IBCA, non-indigenous species), common guidance on procedures, scope and content of the assessment, a common list of risk mitigation measures. Not all potential options would influence the problem drivers in the same direction, making it necessary to carry out a detailed analysis of expected costs and benefits. As a last consequence, the introduction of a centralised risk assessment, as it used in a number of regulatory areas (e.g. pesticides, GMOs, food additives) may be considered. The more the assessment is harmonised, the more the administrative burden on industry and authorities is expected to raise; a more detailed analysis of the expected

[76] see chapter 4.3 of the contractor's report.

costs and benefits would require an exact description of the desired degree of harmonisation (i.e. which elements of the process will be harmonised, which elements will be not). A higher degree of harmonisation is expected to show additional benefits on the scientific excellence, transparency and equality of the regulatory process.

- In addition to the use of common list for IBCAs or of a harmonisation of the assessment, the decision-making on and authorisation of IBCAs may be harmonised or completely centralised. A harmonisation or centralisation of the authorisation is expected to further increase the transparency and equality of the administrative process and would result in a more common market for IBCAs in the EU. It may further be expected, that it would increase the complexity of the process. From within the group of Member States diverging expectations concerning the potential impacts of such a system have been raised, e.g. smaller Member States without a regulatory system see more advantages in a harmonised authorisation process than larger Member States with an existing regulatory system. It may be expected that a similar situation exists for industry: companies operating on a multinational level may profit more from a harmonised market than small, local producers.

- Timing was identified as another important factor in the regulatory process. A best practice example has been identified for New Zealand, where the assessment process is strictly structured and complex, but at the same time, its duration is relatively short[77] and limited by law to 100 days. During the pre-submission phase, applicants have the opportunity to complete their application, thus minimising the risk of non-approval because of an incomplete dossier. The assessment is not restricted to possible risks, but is based on a cost-benefit analysis.

As the different approaches to use IBCAs (classical use, augmentative use, SIT) are associated with different levels of risk, it may be expected that an optimal cost-benefit ratio would probably be achieved at different levels of alignment/homogenisation for the three different approaches, respectively.

5.2. Market data and evolution

Data regarding the production and use of IBCAs in the Member States would inform the understanding of the actual market structure, its evolution over time and future opportunities. This would help industry to sharpen market strategies and to plan innovation. It would allow Member States to verify the achievements under their action plans regarding the roll-out of sustainable food systems (with regard to the aspect of IBCAs) and to demonstrate the progress in reducing chemical pesticides (and achieving other sustainability goals) to citizens. Similar to private research and development, publicly funded programmes (in the field of classical biocontrol and SIT) would also

[77] Based on information from industry as referred in the contractor's report, the regulatory process in EU Member States (assessment plus approval) varies between 3 and 24 months and takes in most cases between 6 to 9 months

profit from more market intelligence resulting in more efficient use of the available resources.

The systematic exchange of information between Member States concerning applications and assessments may increase equality and predictability of the process and may lead to quicker decision-making. It may complement measures on aligning the risk assessment and increase the benefits.

Post-release monitoring would increase the understanding about the presence or absence of possible long-term effects, with a potential to increase confidence in IBCAs on the side of industry (foster innovation), regulators (improve the risk assessment), growers and citizens (political feedback and encouragement to increase the use).

Classical biocontrol may offer a potential for further market development. All projects in the EU are financed by the public sector. However, experiences in two third countries[78] show that classical biocontrol may have a remarkable success to often outstanding cost-benefit ratios also if it is subject to a cooperation between public and private actors (food business operators, food chain value actors, civil society), if there is sufficient coordination and a constant reach-out to the public. The exploration of possible business models and innovative structures should be fostered by public efforts, thus allowing private sector classical biocontrol opportunities to emerge.

5.3. Fostering research and development

Several financial schemes exist in the EU and in Member States in order to support stakeholders and public-private partnerships that may create an innovation push for IBCAs, e.g. Horizon programme, CAP (through EARDF), ERDF. The European Investment Partnership for Agricultural Productivity and Sustainability (EIP AGRI)[79] brings together innovation actors (farmers, advisers, researchers, businesses, NGOs and others) in agriculture and forestry, at EU level. Such programs may alleviate costs on the side of industry, research institutes and growers and foster the development of new innovative products and the use of products available on the market.

Specific programs focused on generating data and references about the biology of IBCAs, their impacts (environmental, economic, social), could be beneficial to the assessment process and remove constraints to development and use. Horizon Europe calls may be used in different ways: they may specifically target this objective of producing data on biocontrol sustainability (including that of IBCAs) within the next years. They could as well time target the scaling up of research projects for getting them on the market.

[78] Examples from Australia and New Zealand, source: Page et al. 2006 and Hardwick et al 2016, as cited in the contractor's report.

[79] https://ec.europa.eu/eip/agriculture/en/node

Getting a product on the market is inextricably linked to the research into new, innovative products. Financial instruments aiming at star-up and microenterprises (like the EIC Accelerator[80]) or investment programmes (like InvestEU[81]) help developers of innovative products to make bridge the gap between research and the market.

Financial incentives to growers for the use of IBCAs could support the demand of IBCAs making investments into the IBCA market more attractive. Such system is currently in place in France as part of the CAP National Strategic Plan.

A more strategic approach in the planning of common biocontrol programmes may help to make them more demand-oriented. A best practice has been identified in the U.S. and their strategic approach towards identifying objectives and targets for cooperative biological control programmes under the auspice of public bodies, the "Biological Target Pest Canvassing and Evaluation".

5.4. Knowledge transfer

Several drivers of the current problems are linked to knowledge, and more precisely, a lack of knowledge and an absence of knowledge transfer. There is the clear expectation that an increase of knowledge may contribute to improving the current situation under several aspects.

On the side of regulators, an increase of knowledge may improve the capacity to cope with the assessment and the decision-making, resulting in a more efficient process. The same benefits are expected from an increase of knowledge about the procedural aspects of the authorisation process on the side of industry.

A considerable level of knowledge about the biological and ecological context is required from all users of IBCAs, whether they professional growers or amateur users, to assure the successful application of IBCAs. Therefore, a strict correlation exists in general between the level of knowledge and the intensity of IBCA uses. The existing knowledge flow mainly goes from industry to growers; this transfer may be facilitated by advisors, who may be dependent from a company.

Citizens in the EU are concerned about potential risks to human health and to the environment (nature protection, biodiversity). Strengthening the level of information on citizen's side about IBCAs may help to create a realistic risk perception and an impartial (positive) position of citizens towards the use of IBCAs.

Specific platforms (on Member State and/or EU level) may facilitate the information flow and information exchange between all stakeholder groups at the same time. Additional guidance and tools, success stories as well as feedback from one stakeholder group to

[80] https://eic.ec.europa.eu/eic-funding-opportunities/eic-accelerator_en

[81] https://investeu.europa.eu/index_en

another (to overcome the current one-way approach, e.g. systematic feedback on emerging needs from growers to industry or information about upcoming developments from research to IBCA users) may create market opportunities for IBCA, increase the efficiency of the regulatory processes and help citizens and politics to achieve the sustainability goals of the European Green deal and to sharpen the policy discussion about future actions.

Specific training measures for growers[82], industry and regulators respectively addressing the particular needs of each of these groups would aim at similar effects, creating a further boost towards achieving their objectives.

6. Conclusions

As requested by the Council, the Commission has carried out a study on the EU's situation and options regarding invertebrate control agents for the use in plant health and plant protection.

Based on the input from Member States and stakeholders as well as on desk and literature research by the contractor, this study provides a comprehensive overview about the IBCA market in the EU and the regulatory approaches taken by the 27 Member States. It identifies shortcomings resulting from the current situation and possible ways forward.

Core problems, drivers and consequences have been described and possible areas for improvement have been identified.

There are, however, insufficient quantitative data on the potential market and use of IBCAs in the Member States available to allow a proper analysis of possible impacts of the stakeholders' suggestions and of the possible added value of EU intervention compared to action that could be taken at Member State level. In these respects, a better understanding of the situation is needed. The study is inconclusive, and the Commission is not in a position at this stage to formulate any appropriate proposal.

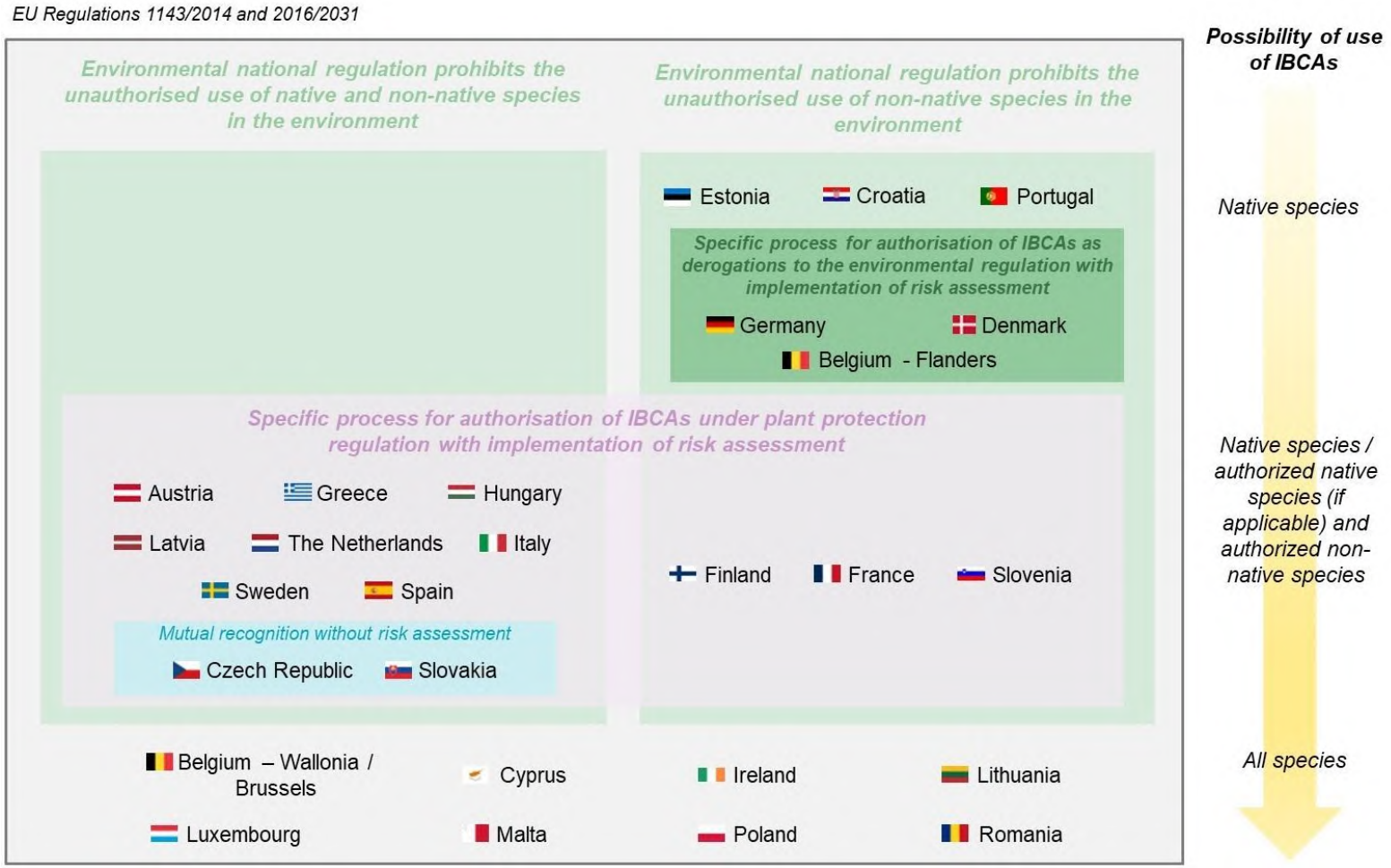
[82] Training measures are foreseen under the existing Directive on sustainable use of pesticides and reinforced by the Commission proposal concerning a Regulation on sustainable use of pesticides, where they are placed under the umbrella of IPM. Specific training regarding IBCAs (or, as a minimum on biological control) may be expected to have a much stronger effect.

7. Annex I - Regulatory systems in Member States

Member States	Specific Regulatory framework for IBCAs: ➢ in place ➢ in development ➢ absent	Risk assessment: Native organism	Risk assessment: Non-native organism	IBCA of the EPPO list	IBCA authorised in another Member State	Benefit assessment	Coverage: ➢ introduction ➢ production ➢ placing on the market ➢ release
Austria	In place	Risk assessment (no environmental risk assessment required)	Risk assessment	If crop/IBCA combination listed in EPPO PM 6/3, no efficacy assessment required	Risk assessment		introduction
Belgium	Wallonia, Brussels: absent		Flanders: Can provide derogations for IBCAs				introduction
Bulgaria							introduction
Croatia	absent		Not allowed derogations for IBCAs				introduction
Cyprus	absent						introduction
Czech Republic	In place	mutual recognition without risk assessment	Risk assessment	Risk assessment	IBCA regulation doesn't cover species imported and authorised in other European countries		introduction
Denmark	In place	Use without authorisation	Can provide derogations for IBCAs	Risk assessment		Local biodiversity	Introduction production
Estonia	absent		Not allowed derogations for IBCAs				introduction
Finland	In place	Notification	Risk assessment	Automatic approval	Risk assessment		introduction
France	In place	Use without authorisation	Risk assessment	Risk assessment		Local biodiversity, environment	Introduction commercialisation/release
Germany	In development		Can provide derogations for IBCAs				introduction
Greece	In place	Risk assessment restricted to efficacy,	Risk assessment (detailed)	Risk assessment	Risk assessment	Environment	Introduction production

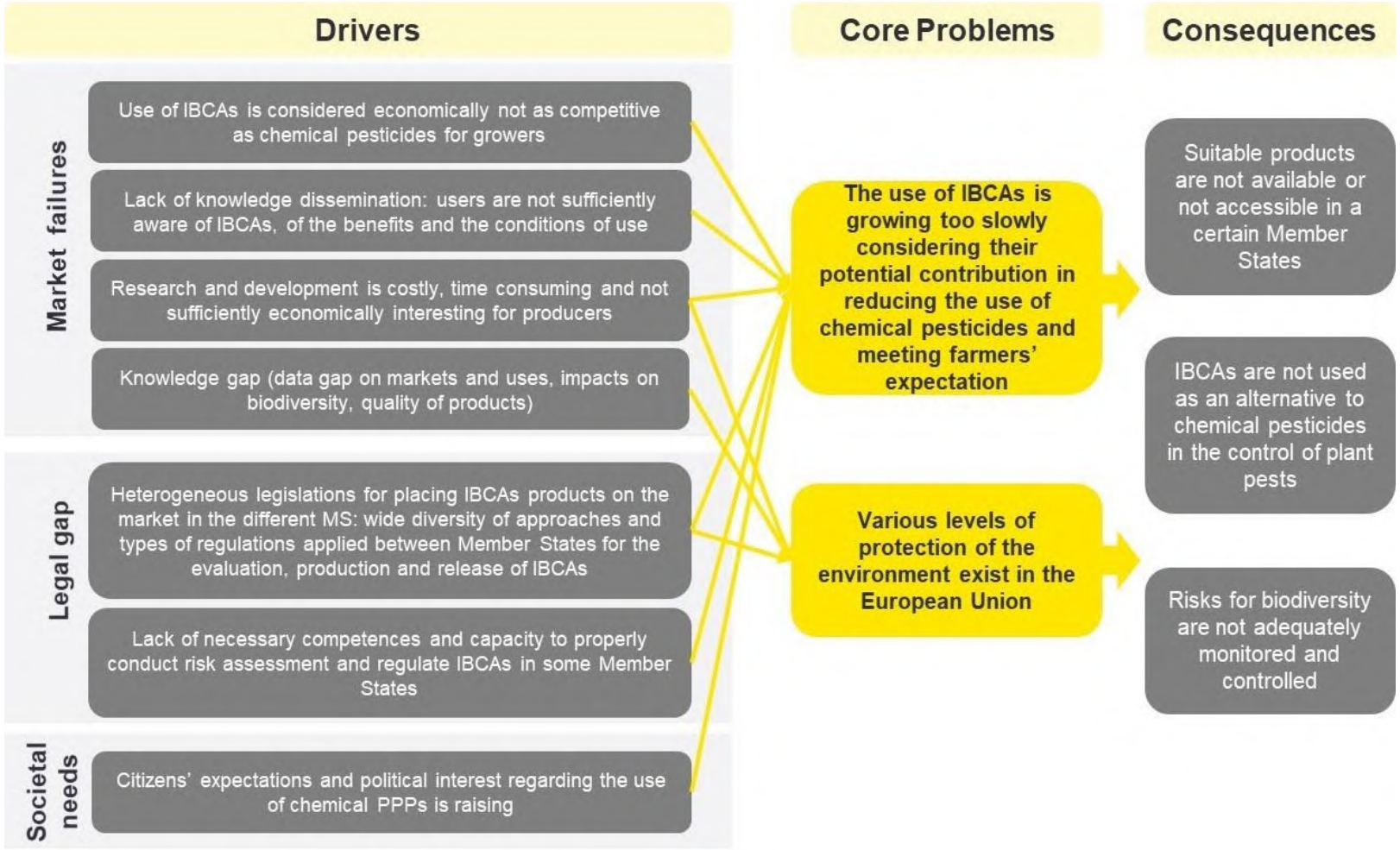
		environment and health					
Hungary	In place						release/commercialisation
Ireland	absent	Risk assessment	Risk assessment				introduction
Italy	In place	Risk assessment	Risk assessment	Risk assessment	Risk assessment	Environment, economy, social, reduction goals pesticide	Introduction production and release transport
Latvia	In place	Risk assessment	Risk assessment (detailed)	Risk assessment	Risk assessment	Local biodiversity	release/commercialisation
Lithuania	absent						introduction
Luxembourg	absent						introduction
Malta	absent						introduction
The Netherlands	In place	Risk assessment		Automatic approval	Risk assessment	Environment	Introduction production
Poland	absent						introduction
Portugal	In development		Not allowed derogations for IBCAs				introduction
Romania	absent						introduction
Slovakia	In place	mutual recognition without risk assessment	Risk assessment	Risk assessment	IBCA regulation doesn't cover species imported and authorised in other European countries		release/commercialisation
Slovenia	In place	Use without authorisation	Risk assessment	Risk assessment	Risk assessment	Local biodiversity, environment	Introduction production
Spain	In place	Risk assessment	Risk assessment	Risk assessment	Risk assessment		introduction
Sweden	In place	Risk assessment		Risk assessment financed by the State	Risk assessment		introduction

8. Annex II - Typology of the different regulatory settings for IBCAs in Member States[83]



[83] source: contractor's report, page 46

9. Annex III - Problem tree[84]



[84] see page 79 of the contractor's report