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Biocontrol Agents: Risks and Opportunities from Farm to Fork

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Abstract

One of the less popular and less investigated topics of law is the use of biocontrol agents (BCAs). Despite the general growing attention to the use of BCAs in primary production, a comprehensive regulatory framework is still lacking. When shifting to possible uses of BCAs in the following phases of the food chain, legislation is even more incomplete (and inadequate) despite the challenging opportunities they offer both for pest control and for pathogen control. The paper will provide an overview of the uses of BCAs taking into consideration all the food chain stages, the relevant partial EU regulatory scheme and its critical issues.

Keywords: biodiversity; biological control agents; pesticides

1. Introduction

The need for greener agriculture, able to ensure resource conservation against soil degradation and protect biodiversity has been felt since the last century, as shown by the pioneers of organic agriculture, who promoted the “biological completeness” of farming.¹ In recent times, however, such a need has become more pressing as well as more structured, due to a number of interrelated factors which have emerged, starting with climate change. As stated also by the Heads of State and Government taking part in the recent COP 28, with the “Declaration on sustainable agriculture, resilient food systems, and climate action,”² agriculture should be integrated along with food systems into climate actions. This should help in the achievement of several environmental and socio-economic objectives, including the containment and reduction of harmful effects “associated with agriculture and food systems by conserving, protecting and restoring land and natural ecosystems, enhancing soil health, and biodiversity, and shifting from higher greenhouse gas-emitting practices to more sustainable production and consumption approaches.” Despite being fundamental for life, since it represents the first source of food, agriculture is also considered one of the main drivers of negative impacts on the environment, due to several factors. First, its high use of resources. According to the 2023 FAO-OECD Report “Environmental Sustainability in Agriculture,” while agriculture has the potential to offer ecosystem advantages, it also has the capacity to significantly affect the utilisation of natural resources. It is considered responsible for 72% of all freshwater withdrawals around the world and is a potential contributor to water stress, as well as a major contributor to soil degradation. According to

¹ Lord Northbourne, *Look to the land* (Sophia Perennis, second revised special edition 2003), p 58, first published by J.M. Dent & Sons 1940.

² <https://www.cop28.com/en/food-and-agriculture> [last accessed on December 18, 2023].

the FAO and ITPS 2015 report “Status of the World’s Soil Resources (SWSR),” a significant proportion of the Earth’s soil resources are classified as fair, poor, or very poor in quality.³ At the time of the mentioned report, approximately one-third (33%) of the land was significantly degraded as a result of soil erosion, salinisation, compaction, acidification and chemical contamination.⁴ Conventional farming is considered one of the main drivers of biodiversity loss: the increasing conversion of land for agricultural uses and the farming practices oriented toward intensification result in a diminishing of habitat quality and quantity.⁵ Freshwater wildlife is also affected, due to water diversion and consumption and to the chemical pollution derived both from fertilisers and pesticides.⁶ Also the most recent strategies of the European Union as well as the targets of the Common Agricultural Policy (CAP) recognise the need for more sustainable farming. Several studies and techniques in different fields (nature-based solutions, breeding techniques, vertical farming, zootechnics, biological and technological advancements, digital applications, organisational improvements and product developments) are currently being developed and implemented to contribute to the aim of rethinking agriculture and food production systems.⁷ When implementing innovative solutions, however, the regulatory framework, which has usually been designed some years before and in a different technology and development context, might require an adaptation or might need to be built from the foundations. This is even more urgent when the method or technique starts acquiring relevance on the market and when some risks could be associated with its implementation. This is the case of biological control which is, in simple words, the use of organisms (invertebrates, such as insects, mites, or nematodes) or micro-organisms (viruses, fungi, bacteria, protozoa) that act as natural antagonists of pests and microbiological contaminants, thus possibly replacing the use of pesticides and disinfection chemical substances.

As reported by the Commission in its impact assessment report accompanying the document Proposal for a Regulation of the European Parliament and of the Council on the sustainable use of plant protection products,⁸ the biocontrol agent market is experiencing significant growth. According to the data⁹ reported in the mentioned document, from 2016 to 2019, the European Union (EU) witnessed a significant growth in the market for macroorganisms, with a 70% increase. Similarly, the market for microbials experienced a substantial surge of 228%. Additionally, the market for other substances used in biological control saw a remarkable growth ranging from 300% to 400%.¹⁰

If, on the one hand, according to the Commission Staff Working Document, biological control is an effective alternative to chemical pesticide,¹¹ on the other hand, the regulatory

³ Report of the FAO and ITPS, “Status of the World’s Soil Resources (SWSR) - Main Report” (Rome, Food and Agriculture Organization of the United Nations and Intergovernmental Technical Panel on Soils 2015), p XIX.

⁴ *Ibid.*

⁵ TG Benton et al, *Food system impacts on biodiversity loss. Three levers for food system transformation in support of nature* (London, Chatham House 2021) p 8.

⁶ *Ibid.*

⁷ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *The Future of Food and Farming*, COM/2017/0713 final, para. 3.1.

⁸ Commission Staff Working Document Impact Assessment Report, Accompanying the document 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, SWD/2022/170 final, para. 1.2.

⁹ Data shown in the Impact Assessment Document originate from the DunhamTrimmer Global Biocontrol Market Report, which is cited without reference to the year of publication, but which should have been reasonably issued in 2020 or 2021.

¹⁰ *Ibid.*

¹¹ A single article, cited in the Commission Staff Working Document (footnote XXXIV of the document), forms the basis of this statement. However, the article is referenced without a full citation and the provided link is no

framework is still quite fragmented and incomplete. Such fragmentation also depends on the fact that the word “biocontrol” encompasses several techniques or methods connected with different fields, from invasive alien species to chemicals and biocides. Biocontrol in the strict sense includes, as a matter of fact, the use of living organisms, which might be microorganisms, such as viruses or bacteria, or macroorganisms, such as invertebrates, nematodes, or mites, to contain or eradicate other organisms of which they are competitors or antagonists. Literature refers then to extended biocontrol, meaning the control or eradication of pests by means of natural methods in general.¹² this could include, besides the use of microorganisms and macroorganisms, as indicated above, the use of semiochemicals, which are chemical substances (pheromones and allelochemicals) normally released by organisms, such as plants and animals, and which “elicit a physiological or behavioural response in individuals of the same or another species.”¹³ Extended biocontrol also includes the use of plant-based substances (botanicals) as insecticides, fungicides, nematocides, herbicides, etc. (an example are pyrethrines).¹⁴ Some Authors include in extended biocontrol the use of plants or seeds which have been made resistant to pests.¹⁵

Considering therefore the wide nature of biocontrol agents, while focusing mainly on EU policy and provisions, the aim of the paper is to understand the regulatory gaps and risks related to the total or partial replacement of chemical pesticides with biocontrol methods, identifying areas for future lawmaking.

II. A definition ... or two

One of the fundamental parts of the regulatory framework of a subject, for any legal scholar, are definitions. Defining the boundaries for the application of law is essential as it determines what is included and excluded within the scope of an act. The starting point of this dissertation will therefore be the delimitation of the juridical meaning of “biological control” and “biological control agents.” While the Food and Agriculture Organization has defined biological control as a “Pest control strategy making use of living natural enemies, antagonists or competitors and other self-replicating biotic entities,”¹⁶ in the EU legislative framework, several acts lay down descriptions rather than definitions, which are applicable only in the context of the same acts. According to Recital no. 1 of Council Decision (EU) 2021/1102:¹⁷ “Biological control agents are natural enemies, antagonists or

longer functional at the time of writing this paper. The document does not take into consideration studies that show how biocontrol cannot just be the replacement of chemical pesticide, since the transition would require a systematic rethinking of farming systems. Just to give an example, M Valantin-Morison et al, “Integrating Biocontrol into Cropping System Design”, in X Fauvergue et al (eds), *Extended biocontrol* (Dordrecht, Springer 2022) p ix.

¹² C Lannou, “Introduction” in X Fauvergue et al (eds), *Extended biocontrol* (Dordrecht, Springer 2022) p ix.

¹³ R Rico-Martínez et al, “Fate and adverse effects of pesticides in the environment” in P Singh et al (eds), *Pesticides in the Natural Environment. Sources, Health Risks, and Remediation* (Amsterdam, Elsevier 2022).

¹⁴ M Siegwart, V Lavoie, “Botanical Pesticides as Biocontrol Products” in X Fauvergue et al (eds), *Extended biocontrol* (Dordrecht, Springer 2022) pp 149–54.

¹⁵ J Buitink et al, “New Technologies for the Deployment of Extended Biocontrol” in X Fauvergue et al. (eds), *Extended biocontrol* (Dordrecht, Springer 2022) pp 245 et sqq.

¹⁶ FAO, *Code of conduct for the import and release of exotic biological control agents* (Rome, FAO 1996). The same definition is now included also in the *International Code of Conduct on Pesticide Management Guidelines for the registration of microbial, botanical and semiochemical pest control agents for plant protection and public health use* (FAO, Rome 2017) p vii.

¹⁷ Council Decision (EU) 2021/1102 of 28 June 2021 requesting the Commission to submit a study on the Union’s situation and options regarding the introduction, 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, pp 81–83, ELI: <http://data.europa.eu/eli/dec/2021/1102/oj>

competitors, or other organisms which are used to control, either directly or indirectly, plant pests, including quarantine pests, by controlling their vectors, weeds and invasive alien plants.” The Decision, however, specifies that, just for its purpose, “only invertebrate Biological Control Agents such as insects, including male sterile insects, mite and nematode species (BCAs) are covered.” This means that other forms of biocontrol, including microorganisms, pheromones, plant-based substances are not covered by the definition.

The Commission Staff Working Document Impact Assessment, accompanying the document Proposal for a Regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union, while reporting the activities of the biocontrol industry, identifies as their object “techniques for crop-protection that uses “biocontrol agents”,” meaning “select predatory or parasitic living organisms to control pests.”¹⁸ Such predatory or parasitic living organisms are therefore called “biocontrol agents.”

A close study of all the documents and acts in the European Union did not reveal any interesting results. This is because there is not a single definition of biocontrol that applies to all the different methods. To confirm this lack, we could also remind the Commission Staff Working Document Impact Assessment Report accompanying the document 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, which reports that during the meeting a representative of the bioprotection and biocontrol industry asked for a definition of biocontrol to be included in the future directive on sustainable use of pesticides.¹⁹

Staying on the subject of definitions, a question might arise when referring to biocontrol as an alternative to chemical pesticides: are the tools of biological control covered by the definition of pesticides? The answer to the question is not an end in itself. If the definition includes biocontrol and biocontrol agents, the relevant provisions on pesticides will apply; if not, some regulatory gaps might be perceived.

According to Directive 2009/128/EC,²⁰ pesticide means: “a plant protection product as defined in Regulation (EC) No. 1107/2009”²¹ or “a biocidal product as defined in Directive 98/8/EC.”²²

Let's focus on the first part of the definition. According to Regulation (EC) No. 1107/2009, plant protection products (PPP) consist of or contain active substances, safeners or synergists. Active substances are “substances, including micro-organisms having general or specific action against harmful organisms or on plants, parts of plants or plant products”; safeners are “substances or preparations which are added to a plant protection

¹⁸ Commission Staff Working Document Impact Assessment, Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union, SWD/2012/0292 final, p 14.

¹⁹ Commission Staff Working Document Impact Assessment Report, Accompanying the document 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.

²⁰ Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides, OJ L 309, 24.11.2009, pp 71-86. For further notes on the Directive, please refer to E Bozzini, *La regolazione europea sui pesticidi. Ricerca, pratiche agricole, consumi alimentari* (Roma, Carocci 2021), p. 44.

²¹ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, OJ L 309, 24.11.2009, pp 1-50.

²² Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market, OJ L 123, 24.4.1998, pp 1-63. The Directive was repealed by Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, OJ L 167, 27.6.2012, pp 1-123.

product to eliminate or reduce phytotoxic effects of the plant protection product on certain plants” while synergists are substances or preparations which can enhance the activities of active substances in plant protection products.

All the three categories have in common the word “substances” which means, according to Article 2 no. 2 of the Regulation (EC) No. 1107/2009 “chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process.”

This first part of the definition of “pesticide” does not cover all biocontrol methods. Macroorganisms are definitely considered outside the semantic domain we are considering. Substances are not living organisms, but chemical elements and compounds. The only exception is constituted by microorganisms, meant as “any microbiological entity, including lower fungi and viruses, cellular or non-cellular, capable of replication or of transferring genetic material”: they are included in the definition of pesticides by an express reference.

The second part of the definition includes biocidal products which are defined by Article 3, para. 1, a) of Regulation (EU) no. 528/2012 as “any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action” and as “any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.” Once again, the definition grounds in the word “substance” which is outlined, in Regulation (EU) No. 528/2012, with a reference to Regulation (EC) No. 1907/2006²³ (REACH). According to Article 3, no. 1 of the latter, a substance is a “chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.”

As a result, only biocontrol by means of microorganism and extended biological control are covered by the definition of pesticide and the relevant provisions of Regulation (EC) No. 1107/2009 and Directive 2009/128/EC. Macroorganisms (invertebrates, mites, nematodes) used as biocontrol agents will not therefore be considered “pesticides”.

III. Applicability of biological control from farm to fork

Despite the best-known application of biological control is primary production, where it has been used for decades as one of the components of integrated pest management, this method could be implemented along the whole food chain for cleanliness and sanitation (by means of biocides or microorganisms) or to eradicate pests in warehouses (by means of invertebrates).²⁴ One of the uses that research has investigated is the possibility of removing contamination caused by *Listeria monocytogenes*, which frequently takes place

²³ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ L 396, 30.12.2006, pp 1–849.

²⁴ V Paganizza, “Biocidi, batteriofagi ed enzimi: i soliti ignoti” in S Carmignani, N Lucifero (eds), *Le regole del mercato agroalimentare tra sicurezza e concorrenza. Diritti nazionali, regole europee e convenzioni internazionali su*

throughout the manufacturing process.²⁵ Some biocides that are composed of essential oils have the potential to destroy biofilms that are created by bacteria²⁶ and might therefore be applied to food manufacturing. Some of these essential oils are compounds that are frequently utilised as flavourings in the European Union as well. In this regard, it is interesting to note that, despite the fact that Regulation (EU) No 528/2012 does not cover flavourings because they are governed by Regulation (EC) No 1334/2008, it still becomes applicable where the biocidal product regulated by the flavouring provisions is used for purposes that are not specified in those acts (Article 2, paragraph 2). Therefore, where an essential oil is utilised for a biocidal purpose, it will be subject to Regulation (EC) No 528/2012 even if it is also listed in the food flavouring regulation.

Biological control in the food sector can also entail the exploitation of microorganisms like bacteria and viruses (phages), which could be “added in sufficient quantities to overwhelm all target organisms by primary infection, or by lysis from without”²⁷ (passive treatment) or which could be added to cause “secondary infections due to replication and transmission from neighbouring organisms”²⁸ (active treatment).

Up till now, the European Union has not regulated biological control in the food chain with a dedicated act since biological control by means of biocides or microorganisms can be covered by the systems of authorisation that are currently in use. The enactment of biological control by means of macroorganisms, such as insects, nematodes or mites in the food sector is instead still controversial. On the one hand, there is no provision which expressly prohibits the application of the method, which could turn out to be of utmost interest since it can replace the use of chemical pesticides in food production plants; on the other hand, however, the presence of insects or other animals in a food manufacturing plant or warehouse could barely comply with the principles of food hygiene, to the extent that they cannot be controlled with the risk of contamination by foreign bodies. If the food business operator, however, in the HACCP, includes the possible issues deriving from the presence of auxiliary macroorganisms in the hazard analysis and identifies the possible “critical control points,” it will then be able to assess the acceptability limits, enact adequate control measures, adopt corrective actions and monitoring tools.

IV. Biological control in the EU policies

In the last few years, in line with the European Green Deal, the Biodiversity Strategy, and the Farm to Fork Strategy, the European Union has started to take stock of the situation of the use of invertebrate biocontrol agents (IBCA), at least for plant protection.²⁹ EU Institutions recognised that Member States were demonstrating significant heterogeneity in their methodologies and the regulatory frameworks they employed for the release,

agricoltura, alimentazione, ambiente. Atti del Convegno di Firenze del 21 e 22 novembre 2019 in onore della Prof.ssa Eva Rook Basile (Napoli, Editoriale Scientifica 2020) pp 1101–122.

²⁵ A Roede et al, “Biocide-tolerant *Listeria monocytogenes* isolates from German food production plants do not show crossresistance to clinically relevant antibiotics” (2019) 85(20) *Applied and Environmental Microbiology*.

²⁶ NG Chorianopoulos et al, “Disinfectant test against monoculture and mixed-culture biofilms composed of technological, spoilage and pathogenic bacteria: bactericidal effect of essential oil and hydrosol of *Satureja thymbra* and comparison with standard acid–base sanitizers” (2008) 104(6) *Journal of Applied Microbiology* 1586–596.

²⁷ EFSA, “Scientific Opinion of the Panel on Biological Hazards on a request from European Commission on the use and mode of action of bacteriophages in food production” (2009) 1076 *EFSA Journal* para. 3.2.

²⁸ *Ibid.*

²⁹ In organic farming, biocontrol has always been considered one of the tools for integrated pest management. The European Parliament resolution of 3 May 2022 on an EU action plan for organic agriculture (2021/2239(INI)) OJ C 465, 6.12.2022, p. 22–32, has emphasised the need to invest in research and innovation also in biocontrol solutions (point 61).

monitoring and movement of biological control agents.³⁰ Thus, Council Decision (EU) 2021/1102 requested the Commission to submit a study on the Union's situation and options regarding the introduction, production, evaluation, marketing and use of invertebrate biocontrol agents (IBCA) and to put forward a proposal, if deemed appropriate, based on the results of the investigation (Article 2 of the Decision). The Council's call was grounded in the consideration that enhancing consistency among Member States could promote the advancement and availability of secure BCA, hence facilitating market access (recital no. 10 of the Council Decision). At the end of 2022, the European Commission answered the Council's request with a study in the form of a Commission Staff Working Document,³¹ accompanied by the report of an external contractor.³² The study analysed the EU market for IBAs and focused on the uses of invertebrates as biocontrol agents and the reasons for different approaches: the results showed an extremely fragmented regulatory framework within the EU Member States. One of the most significant elements of the study (despite the fact that the report dedicates just a few lines to the topic) is related to the lack of knowledge and expertise on biological control, on the farmers' and advisers' side.³³ The lack, in some States, of specific provisions regulating the purchase, use and monitoring of living organisms for biocontrol, along with operators' nescience, could result in a risk for the environment in cases of misuse of biocontrol agents.

Based on the outcomes of the study, the EU Commission decided not to put forward any proposals because of the impossibility of properly analysing "the possible added value of EU intervention compared to action that could be taken at Member State level," due to "insufficient quantitative data on the potential market and use of IBAs in the Member States."

While for what concerns invertebrates used as biocontrol agents, some work still needs to be done, for biocontrol based on microorganisms for plant protection, the Commission adopted, in 2022, four regulations to simplify the authorisation process, namely Commission Regulations (EU) 2022/1438,³⁴ 2022/1439,³⁵ 2022/1440,³⁶ 2022/1441.³⁷

At this point, after having mentioned some recent acts that seem to support the transition towards alternatives to chemical pest control, one should expect to perceive an active commitment by the EU Institutions on the theme. Even if such expectations will remain partially unfulfilled following the recent rejection by the Parliament of the Commission's proposal for a sustainable use of pesticides, on the 22 November 2023, there

³⁰ See Recital no. 3 of Council Decision (EU) 2021/1102.

³¹ 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, 20 December 2022, SWD(2022) 446 final.

³² European Commission, Directorate General for Health and Food Safety, C Castella et al., *Study on the Union's situation and options regarding invertebrate biological control agents for the use in Plant Health and Plant Protection* (Luxembourg, Publications Office of the European Union 2022).

³³ *Ibid.*, p 41.

³⁴ Commission Regulation (EU) 2022/1438 of 31 August 2022 amending Annex II to Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards specific criteria for the approval of active substances that are micro-organisms, OJ L 227, 1.9.2022, pp 2–7.

³⁵ Commission Regulation (EU) 2022/1439 of 31 August 2022 amending Regulation (EU) No 283/2013 as regards the information to be submitted for active substances and the specific data requirements for micro-organisms, OJ L 227, 1.9.2022, pp 8–37.

³⁶ Commission Regulation (EU) 2022/1440 of 31 August 2022 amending Regulation (EU) No 284/2013 as regards the information to be submitted for plant protection products and the specific data requirements for plant protection products containing micro-organisms, OJ L 227, 1.9.2022, pp 38–69.

³⁷ Commission Regulation (EU) 2022/1441 of 31 August 2022 amending Regulation (EU) No 546/2011 as regards specific uniform principles for evaluation and authorisation of plant protection products containing micro-organisms, OJ L 227, 1.9.2022, pp 70–116.

are still some acts that anticipate possible future actions of the EU in the area of biocontrol, which however sketch a regulatory framework which will still remain fragmented. Just to make a few examples, among the alternatives that the Communication from the Commission “Ensuring resilient and sustainable use of EU’s natural resources”³⁸ has presented to the Parliament and the Council the possibility to speed up the procedures on biocontrol active substances is put forward.³⁹ The Commission suggests shorter timelines for Member States to deliver draft assessment reports for new biocontrol active substances and the possibility for Member States to issue provisional authorisations for biocontrol products. In addition, the Institution proposes that approvals for biocontrol active substances should be granted for an unlimited period of time at the EU level.

In the “Commission Staff Working Document Impact Assessment Report on Soil Monitoring Law,”⁴⁰ biocontrol is simply listed within “integrated pest management” to reduce contamination, meant as an “aspect of soil degradation,” while the Commission Staff Working Document Impact Assessment Report SWD/2021/609 final⁴¹ mentions biocontrol among the “options, based on a smart use of natural ecological processes and improved technologies, reducing the use of synthetic pesticides and fertilisers and promoting integrated pest management,” that “contribute to improving the quality, diversity and resilience of ecosystems, all of which have substantial benefits for biodiversity.”

Biocontrol agents are also considered by the EU Institutions when dealing with pollinators, such as in the European Parliament resolution of 2019⁴² where the Commission and Member States are invited to encourage the maintenance of hedgerows, buffer strips and perennial flowering areas, to promote biodiversity, thus protecting, among others, pollinators and biocontrol agents. Also the Commission Staff Working Document SWD/2018/302 final on the EU Pollinator Initiatives⁴³ recognises that some hoverfly species are both pollinators and biocontrol agents.

V. Authorities

One of the consequences of the fragmentation of EU provisions on biocontrol – fragmentation that is destined to persist if we consider that the acts and documents mentioned in the previous section do not design a consistent horizontal framework for biocontrol – is the fact that also technical and scientific competences are shared among

³⁸ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *Ensuring resilient and sustainable use of EU’s natural resources*, COM/2023/410 final.

³⁹ The document partially approves the European Parliament’s indications of the European Parliament resolution of 3 May 2022 on an EU action plan for organic agriculture, point 65, which had called on the Commission, “to define biocontrol products and to increase the availability of biocontrol solutions and natural substances, which have scope for much wider use, by improving and speeding up the evaluation and authorisation process.”

⁴⁰ Commission Staff Working Document Impact Assessment Report *Accompanying the proposal for a Directive of the European Parliament and of the Council on Soil Monitoring and Resilience (Soil Monitoring Law)* SWD/2023/417 final.

⁴¹ Commission Staff Working Document Impact Assessment Report *Accompanying the document Proposal for a Regulation of the European Parliament and the Council amending Regulations (EU) 2018/841 as regards the scope, simplifying the compliance rules, setting out the targets of the Member States for 2030 and committing to the collective achievement of climate neutrality by 2035 in the land use, forestry and agriculture sector, and (EU) 2018/1999 as regards improvement in monitoring, reporting, tracking of progress and review* SWD/2021/609 final.

⁴² European Parliament resolution of 18 December 2019 on the EU Pollinators Initiative (2019/2803(RSP)), OJ C 255, 29.6.2021, pp 29–36.

⁴³ Commission Staff Working Document *Accompanying the document Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, EU Pollinators Initiative*, SWD/2018/302 final.

different authorities. The European Food Safety Authority,⁴⁴ for instance, is the scientific authority competent for risk assessment on plant protection products, the category of pesticides that contains or consists of active substances, safeners or synergists.⁴⁵ The European Chemical Agency (ECHA) is the competent authority to issue an opinion on the active substance when biological control is related to the use of biocides, after the risk assessment of the national authority. The biocide authorisation could instead be performed either at a national level or an EU level, depending on the operators' choice. Lacking harmonised legislation for invertebrates used as biological control agents, instead, the competence is entirely reserved to Member States, as anticipated in section no. II.

The complexity of the topic goes even further, covering the assessment of single substances, for several different uses. To simplify procedures and assessment, the European Commission, in its Chemical Strategy for Sustainability, adopted the One Substance, One Assessment (1S1A) approach.⁴⁶ Following this premise, in the Staff Working Document accompanying the proposal for legislative acts on the re-attribution of scientific and technical tasks among agencies, the EU Commission widened the 1S1A (which was first intended for chemicals) to "microbials, natural substances and semiochemicals used as biocontrol." It proposed to establish a group of microbial experts from Member States, EFSA, ECHA and other institutions to evaluate and assess the microbial active substances, thus ensuring consistent and science-based procedures. The Commission's proposal moves from the fact that biocontrol agents, such as micro-organisms, could be used for a specific purpose, like crop protection, but they can also be used for further aims (for instance, fertilisers or biostimulants). This would entail two different procedures (which could also lead to divergent results), a set of data to be provided and different legislation.⁴⁷

VI. Invasive alien species and biocontrol

One of the most delicate aspects of biocontrol is the prevention and management of invasive alien species. Alien species are "any live specimen of a species, subspecies or lower taxon of animals, plants, fungi or micro-organisms introduced outside its natural range; it includes any part, gametes, seeds, eggs or propagules of such species, as well as

⁴⁴ On the role of the European Food Safety Authority in the field of pesticides, please refer to L Pastorino, E Tomasella, "il ruolo dell'EFSA per la riduzione della presenza di residui fitosanitari negli alimenti" (2022) XVI(4) Riv. dir. alim. 104–119.

⁴⁵ It is noteworthy that the demand for openness in EU processes originated from a lack of trust on the EFSA assessment on a plant protection product, the "glyphosate." R Fusco, "Autorizzazione dei pesticidi e principio di precauzione: il caso del glifosato" (2016) X(4) Riv. dir. alim. 45–58. D Bevilacqua, "La regolazione dei prodotti fitosanitari e il precautionary test" (2020) XXVI(1) Giorn. dir. amm. 69–76, case note on Judgment of the Court (Grand Chamber) of 1 October 2019, Criminal proceedings against Mathieu Blaise and Others., Case C-616/17, Court reports – general, ECLI identifier: ECLI:EU:C:2019:800. On the same judgment, please refer also to A Donati, "The Glyphosate Saga, a Further but Not a Final Step: The CJEU Confirms the Validity of the Regulation on Plant Protection Products in Light of the Precautionary Principle" (2020) XI(1) EJRR 148–54 and S Paulini, "Fact or fiction? : Case C-616/17 and the compatibility of the EU authorisation procedure for pesticides with the precautionary principle" (2020) XI(3), EJRR 481–97.

⁴⁶ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *Chemicals Strategy for Sustainability Towards a Toxic-Free Environment*, COM/2020/667 final, para. 2.3.1.

⁴⁷ Commission Staff Working Document Accompanying the documents Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals and Proposal for a Directive of the European Parliament and the Council amending Directive 2011/65/EU of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency, SWD/2023/850 final.

any hybrids, varieties or breeds that might survive and subsequently reproduce.” Such species are considered “invasive” when their introduction or spread has been discovered to pose a threat or have a negative influence on biodiversity and the associated ecosystem services. Invasive alien species which are able to survive and adapt to the climate and environmental conditions of the EU Countries often succeed in spreading due to the lack of natural antagonists that are usually present in the ecosystems where these alien species originate from and which are, in turn, alien species. According to Regulation (EU) no 1143/2014,⁴⁸ invasive alien species cannot be brought into the territory of the Union; kept; bred; transported to, from or within the Union, except for the transportation of species to facilities in the context of eradication; placed on the market; used or exchanged; permitted to reproduce, grown or cultivated; or released into the environment. The mentioned Regulation authorises however Member States to establish a permit system to allow research or ex-situ conservation of invasive alien species of Union concern, setting some general requirements to ensure that such species, once in the EU territory, are managed in a safe way by experts, to avoid intentional or unintentional spread. Member States are also authorised to maintain stricter provisions to prevent the introduction, establishment and spread of invasive alien species (Article 23).

Releasing in the environment a natural allochthonous species for biological control is therefore not permitted unless the launch is decided by the competent authority as a means for the eradication of the invasive alien species and after careful consideration of all possible risks.⁴⁹

VII. Standards and international provisions

It is evident that where the regulatory framework for biological control is not entirely harmonised under EU law, standards, international and national provisions, when existing, might become applicable. The most significant standards in this area have been adopted by the European and Mediterranean Plant Protection Organization (EPPO), whose panel deals with the safety aspects of the introduction and use of biocontrol agents. The current EPPO standards applicable to biological control are the following: PM 6/1 First import of exotic biological control agents for research under contained conditions; PM 6/2 Import and release of non-indigenous biological control agents; PM 6/3 Biological control agents safely used in the EPPO region; PM 6/4 Decision-support scheme for import and release of biological control agents of plant pests.⁵⁰

Also the International Plant Protection Convention issued, in 1995, and revised, in 2021, the International Standard for Phytosanitary Measures 3, “Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms.”

Despite the undeniable value of these documents, recognised also in Council Decision 2021/1102 (recital no. 8) and which should be considered as a set of minimum requirements in a sector where consistent provisions are still lacking, standards and guidelines are characterised by a voluntary acceptance, unless they are incorporated into

⁴⁸ Regulation (EU) No 1143/2014 of the European Parliament and of the Council of 22 October 2014 on the prevention and management of the introduction and spread of invasive alien species, OJ L 317, 4.11.2014, pp 35–55.

⁴⁹ An example can be the Italian attempts to contain and eradicate the marmorated stink bug (*Halyomorpha halys*), by means of its allochthonous natural antagonist *Trissolcus japonicus*. The authorisation, to Regions, to use this biocontrol agent was released by the Ministry for the Environment (Decree 20 July 2020), after the submission of a two-year study on risks, carried out by the Research Council on Agriculture and of a monitoring plan and in compliance with the conditions set by the decision of the Council of the National System for Environmental Protection. The first program on biological control of *Halyomorpha halys* run in the years 2020–2022.

⁵⁰ EPPO standards can be retrieved on the Organisation’s website https://www.eppo.int/RESOURCES/eppo_standards/pm6_biocontrol.

national or regional provisions. Where they are not generally accepted, they might thus contribute to further fragmentation of the applicable regulatory framework.

VIII. Concluding remarks

Despite the growing attention that the market is paying to biological control, the European Union is still lacking a harmonised regulatory framework. As we mentioned in Section I, the methods of biological control are different. Designing a single coordinated regulatory structure becomes difficult due to the types of control agents that can be used, even when considering only the biocontrol *stricto sensu*.

In this sense, attempts by EU Institutions have nevertheless been made: when asking the Commission to submit a study on the use and criticalities of biological control agents, starting from the assumption that EU Member States had different national approaches, the Council Decision 2021/1102 was aiming at identifying possible paths for the harmonisation of criteria, procedures and decision-making. To speed up market access and to make biocontrol agents more available, the Council act emphasised the need for cooperation with international organisations; while also recognising the necessity of further research and knowledge dissemination programs, and supporting investment, innovation and the safe use of BCAs in plant pest control, “as a first step towards a harmonised definition of a broader concept of biocontrol.”

Even though the Council Decision focuses only on invertebrates used as biocontrol agents, the future direction, which clearly goes towards EU harmonisation, seems to be already set, even if some criticalities still remain.

The first and most relevant relates to the lack of expertise and knowledge by operators, which might result in the misuse of biocontrol agents and consequent negative impact on ecosystems. We mentioned in Section II that some biocontrol agents can be covered by the pesticide regulatory framework while macroorganisms are outside the scope of the relevant provisions. The distinction has a direct consequence when talking about training. For biological control agents that fall under the pesticide regulation, the appropriate training of professional users, distributors and advisors requested by Article 5 of the Directive 2009/128/EC should apply: provided that Member States have correctly implemented it, knowledge should be acquired, even if the effectiveness of such training might be debatable. Professional (and non-professional) users of biological control agents that are not covered by the pesticide regulatory framework, instead, will not be subject to such preparation. The reduction of risks and impacts of farming on human health and the environment requires therefore supplementary provisions that could extend the knowledge of biocontrol methods and their implementation.

As underlined also by Council Decision 2021/1102, harmonisation of provisions asks for further research and innovation which should be taken into account also by EU Institutions in the exercise of both policy and legislative functions. When drafting the present paper and checking the sources reported in official documents to ground statements that could also have remarkable weight, such as the Commission’s declaration according to which biological control is an effective alternative to chemical pesticide,⁵¹ it was interesting to note that some of these assertions were based on single studies, focused on peculiar situations that were not necessarily scalable up to general truths or on statistics of private companies with specific interests in the sector they were describing. When coming to data on the risks of both pesticides and alternative methods, more substantiated sources should be referred to, above all in official acts from the EU Institutions.

⁵¹ *Supra*, n 12.

One last thought. Most of the academics and professionals in the agrifood sector have been waiting, in the last few months, for the publication of the proposal on the sustainable food system, which should have organised in a systemic way the principles, objectives, requirements and responsibilities of the different components of the food sector. That would have represented the chance to also anticipate a systematisation of the area of biocontrol, given to the importance that the method could assume in the transition towards a greener Europe.

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