MEMORANDUM

TO	Syngenta Crop Protection AG		
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Re : 20240000825- Syngenta – Biocontrol Products

EXECUTIVE SUMMARY

I. Introduction

There is a growing shift towards biological alternatives to chemical plant protection products (PPPs), broadly known as 'biocontrol products'. Many observers have highlighted the difficulties that these products face in gaining market access within the current regulatory framework, set by Regulation 1107/2009. There appears to be a broad consensus that legislative action is needed to elevate their uptake in the EU. The topic's significance has been underscored once more at the onset of the new legislative term, after the EU elections in June 2024.

One of the legal questions that presents itself is how to approach such legislative intervention: amend Regulation 1107/2009 to include specific provisions on biocontrol products or adopt a legal act that distinctly regulates them, separate from Regulation 1107/2009? This memorandum outlines the legal advantages of the second option, regulating biocontrol products in a distinct act.

II. The rigidity of Regulation 1107/2009

Underlying Regulation 1107/2009 are concerns about risks and hazards. The Regulation addresses these concerns through a prior approval and authorisation process for PPPs and their active substances. The framework is underpinned by the precautionary principle and aims to ensure a high level of protection of human and animal health and the environment.

The Regulation primarily targets chemical PPPs, namely those containing active *substances*, meaning chemical elements and their compounds. While micro-organisms are nominally included in the scope, their minimal mention suggests that they hardly played a role, if any, in shaping the Regulation. Articles

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4 and 29 form the core by setting approval criteria for active substances and PPPs respectively, upon which the rest of the regulation—including data requirements—is grafted.

Assessing biocontrol products under the chemically oriented, rigid framework of Regulation 1107/2009 reportedly creates problems: data requirements are extensive and inappropriate, resulting in slow, expensive authorisation procedures and limiting the potential for innovation.

Regulation 1107/2009 has been the subject of various CJEU cases. A central theme is the Court's consistent emphasis on the precautionary principle and the Regulation's purpose to ensure a high level of protection of health and the environment. This case law raises concerns as to whether the Regulation can effectively serve as a framework for biocontrol products. It urges competent authorities to err on the side of caution and hold any doubts against the applicants. An attempt to streamline the assessment for biocontrol products under Regulation 1107/2009 may furthermore be defeated by the Court's findings in the Dutch Reference Cases (308/22 & 309/22-310/22).

III. The constraints of dealing with biocontrol products within the confines of Regulation 1107/2009

Given the rigidity of Regulation 1107/2009 it is no surprise that there would be serious drawbacks to dealing with biocontrol products within the Regulation.

The challenge starts with the Regulation's scope, which is tied to the definitions of "plant protection products" and "active substance". It remains ambiguous whether the framework in fact covers all biocontrol products. The scope of Regulation would have to be clarified and expanded to properly address (all) biocontrol products. Such an amendment requires an act on par with the Regulation, meaning one adopted through the ordinary legislative procedure. A definitional amendment thus seems required under either approach, i.e. to properly *include* or *exclude* biocontrol products from the Regulation. The recent carve-out of biostimulants from Regulation 1107/2009 in any case implies that scope *reduction* – should biocontrol products be regulated distinctly - does not pose any problems. Scope expansion is arguably more demanding.

The key point of the constraints is this: the hierarchy of norms and the CJEU's emphasis on the Regulation's overarching principles severely limit the Commission's flexibility to offer a solution for biocontrol products within the four corners of Regulation 1107/2009.

- Guidance documents (adopted pursuant to Article 77) offer flexibility but lack authority. They cannot change the legal reality that national competent authorities will still be bound to assess applications against the provisions of Regulation 1107/2009, and in particular the benchmarks set by Articles 4 and 29.
- A Commission regulation (adopted pursuant to Article 78(1)) will have to be limited to "non-essential" elements. Any changes that would touch upon matters such as the scope of the Regulation, its core definitions, or the approval criteria/authorisation requirements, would most likely qualify as "essential" which cannot be delegated. In this sense an amendment to the data requirements aimed at facilitating biocontrol products, for example, would probably not have a profound impact in legal terms. It would leave the Regulation's core principles and key provisions unchanged, allowing them to continue asserting precedence.

- Addressing biocontrol products at the level of the approach taken by the risk assessor, such as the 'need-to-know approach', would suffer the same fate as guidance documents. In practice, due to the rigidity of the Regulation, authorities may strongly prefer to err on the side of caution, resisting flexibility and requesting data rather on a 'like to know' basis.

IV. The legal benefits of a distinct act for biocontrol products

A distinct legal act on biocontrol products is arguably more conducive to legal certainty. The intermingling of provisions for different categories of products within a single regulatory framework risks diluting the specific standards for biocontrol products. In contrast, a separate act can formulate its own purpose and delineate clear, precise rules, tailored to biocontrol products, thereby enhancing clarity and precision. Furthermore, with a separate act, the EU legislator would grant legislative legitimacy to the tailored approach.

Clear language in a separate act could address the ambiguity surrounding the scope of the term 'biocontrol' and mitigate the risk of internal market fragmentation caused by unilateral attempts of Member States, such as France, to define biocontrol. The novel framework could furthermore revitalize EU harmonization via a centralized authorization procedure, thereby avoiding the struggles of 'mutual recognition' that burden Regulation 1107/2009. Also, biocontrol products will likely continue to evolve. A tailored legal act would future-proof the regulatory framework, enabling it to adapt more swiftly and effectively to new scientific developments. This aligns with the EU's obligation under Article 114(3) TFEU.

Directive 2009/128/EC on sustainable use makes apparent that the EU legislator has deliberately chosen to promote biocontrol products over chemical pesticides. But this is not thoroughly reflected in Regulation 1107/2009, resulting in a mismatch. A dedicated legal framework can bring about an uptake in the availability of biocontrol products, promoting consistency with the broader framework on pesticides.

In similar contexts, a separate legal act has also been the preferred choice:

- The proposal for a Regulation on New Genomic Techniques (NGT) implicitly carves out certain NGTs from the GMO Directive. The Commission has highlighted that the risk assessment requirements and authorisation procedure of the current GMO legislation are disproportionate and not conducive to the development of innovative products.
- In 2018, the legislator updated the regulatory framework for veterinary medicines, emphasizing that the framework should be adapted to scientific progress, the current market conditions and economic reality. The legislator furthermore wanted to reduce the administrative burden and increase the availability of these products. Consequently, veterinary medicines were carved out of Regulation 726/2004.
- Also Advanced Therapy Medicinal Products are dealt with in a separate act. The legislator deemed that they require a specific approach and that because of their novelty, complexity and technical specificity, specially tailored and harmonised rules were needed to ensure their free movement.

It should be highlighted that the proposal to regulate biocontrol products in a distinct act, was also put forward by the European Parliament Rapporteur at the inception of Regulation 1107/2009. The

justification given was that the Regulation was designed for synthetic PPPs, and that a separate regulation should be foreseen to take account of the specific properties of biological control products.

As to the possibility to organize a centralised authorisation procedure, this has also been installed in similar context, such as for feed additives, novel food and certain medicinal products. Moreover, for biocontrol products in particular, this seems to already have been part of official discussions at EU institutional level for some time.

Finally, a dedicated biocontrol products act seems more in line with the principle of proportionality. Firstly, to reduce the regulatory burden and, secondly, to promote alternatives to synthetic PPPs and encapsulate a more long-term vision.

Conclusion

An approach to addressing biocontrol products within the confines of Regulation 1107/2009 must adhere to its rigid core principles and key provisions. Given the EU hierarchy of norms, any Commission action remains necessarily subordinate to the Regulation. Moreover, the CJEU's consistent emphasis on the precautionary principle and the Regulation's primary objective of ensuring high standards of health and environmental protection suggests that the framework of Regulation 1107/2009 may be inherently unsuited to enabling an alternative approach for biocontrol products.

The principle legal benefit of a distinct act is that it would not be hampered by such constraints. A separate legal act can formulate its own purpose and delineate clear, precise rules, tailored to biocontrol products.

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I. Introduction: the (future) regulation of biocontrol products in the EU

1. One of the most important ways of protecting plants against harmful organisms and of improving agricultural production, is with the use of plant protection products ('**PPP**').

2. Conventionally, PPPs used in agriculture have been developed on the basis of (synthetic) chemical substances. But we understand that there is a growing shift towards biological alternatives.[1] These alternatives - sometimes called biopesticides, biological control or biocontrol - are yet to be neatly defined but they typically encompass four categories: plant extracts/botanicals, semiochemicals, microbials, and macrobials/invertebrates.[2] In this memorandum we will refer to them as '**biocontrol products**'.

3. **Regulation 1107/2009**[3] lays down rules for the authorisation of PPPs and for the approval of the active substances that they contain. Although not all biocontrol products may fall under its scope[4], many observers have pointed out the challenges for biocontrol products in gaining market access under the current regulatory framework.[5]

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[1] See LIÉGEOIS E. (EU Commission – DG SANTE E.4), 'Achieving more sustainable food systems by fostering registration of biopesticides in EU', presentation at the FAO webinar 'Registration of Biopesticides', 13 December 2021.

[2] These categories were suggested for example by the European Commission, in a non-exhaustive way, in the definition for 'biological control' in Article 3(23) of its proposal for a Regulation on the sustainable use of plant protection products, COM/2022/305 final.

[3] 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.

[4] For macrobials/invertebrates, the EU consensus seems to be that they fall outside the scope of Regulation 1107/2009, European Commission, 'Study on the Union's situation and options regarding invertebrate biological control agents for the use in plant health and plant protection', 2022, p. 4: "*IBCAs* [invertebrate biocontrol agents] *are not covered by the current European regulation for the placing into the market of PPPs*"; See also the answer given by Ms Kyriakides on behalf of the European Commission to parliamentary question E-004380/19: "*Macro-organisms are not within the scope of Regulation (EC) No 1107/2009* (…) *and it is up to Member States to decide whether and how to regulate them.*"; See most recently Commission Implementing Regulation (EU) 2024/2746 laying down rules for the application of Council Regulation (EC) No 1217/2009 setting up the Farm Sustainability Data Network: "*Biological control means the control of organisms harmful to plants or plant products using natural means of biological origin or substances identical to them, such as micro-organisms, semiochemicals, extracts from plant products as defined in Article 3(6) of Regulation (EC) No 1107/2009, or invertebrate macro-organisms.*"

[5] See para 4 below.

4. There now appears to be a **consensus** among EU institutions[6], advisory bodies[7] and industry[8] that **legislative action is needed** to elevate the uptake of biocontrol products in the EU. A clear recommendation to that end has been encapsuled in the final report on the Strategic Dialogue on the Future of EU Agriculture (p. 62): "*As conventional products keep disappearing from the market, and in response to the growing significance of biological control tools in agriculture and environmental management, it is recommended that the development, entry into market and application of biocontrol will be accelerated*".

The topic was most recently discussed in the context of the proposal for a Regulation on the sustainable use of pesticides (**SUR**).[9] While the proposal as such was ultimately withdrawn,[10] several cross-party amendments had been put forward that sought to further harmonize and prioritise biocontrol within the general PPP framework.[11] These amendments concerned e.g. the following topics:

- A definition of 'biological control';
- The establishment of 'green priority lanes' for biocontrol;
- No more periodic re-registration for biocontrol;
- The re-activation of provisional authorisations;
- A facilitated label expansion of already authorised products to all proposed uses; and
- The need for a new biological control-specific legislation in the long term.

5. The **significance of biocontrol products** has been underscored once more at the onset of the new legislative term, after the EU elections in June 2024: indirectly in Commission President von der Leyen's political guidelines for the next European Commission (where reference is made to the "biotech

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[6] See e.g. European Parliament resolution of 15 February 2017 on low-risk pesticides of biological origin, P8_TA(2017)0042; Strategic Dialogue on the Future of EU Agriculture, p. 62: "(…) *the European Commission should, by 2025, enable a robust legislative framework for biocontrol products and approaches*"; Communication from the Commission to the European Parliament, the Council, the European Economic And Social Committee and the Committee of the Regions - Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU, 20 March 2024, COM(2024) 137 final, p. 17; European Parliamentary Research Service, 'Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market – European Implementation Assessment', April 2018, p. 136.

[7] See e.g. Opinion of the European Economic and Social Committee on the 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, OJ C 100, 16.3.2023, p. 137–144, point 1.11; European Commission, Regulation of Biological Control Agents (REBECA), 'Final Activity Report'.

[8] See e.g. International Biocontrol Manufacturers Association, 'IBMA White Paper – New EU Regulatory Framework for Bioprotection Agents', September 2018.

[9] 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.

[10] Withdrawal of Commission proposals, OJ C, C/2024/3117, 6.5.2024.

[11] Report on the 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, 2022/0196(COD), A9-0339/2023; see their brief discussion in International Biocontrol Manufacturers Association, 'Making the fast-track of biocontrol products a priority for the next European Commission', 2 July 2024.

revolution")[12] and more directly in the respective mission letters to the Commissioners-designate for Health and Animal Welfare[13] and Agriculture and Food[14]. This also seems to transpire in the written answers given by these Commissioners-designate to the European Parliament ahead of their confirmation hearings.[15]

6. One of the legal questions that subsequently presents itself is how to approach legislative intervention for biocontrol products. Broadly speaking, there seem to be two options: amending Regulation 1107/2009 to include specific provisions on biocontrol products or adopting a legal act that distinctly regulates biocontrol products, separate from Regulation 1107/2009.

As requested, **this memorandum outlines the legal advantages of regulating biocontrol products in a distinct act**. We will do so in two steps.

In step 1, we look at Regulation 1107/2009, its underpinnings and how this has reportedly held back biocontrol products (Title II.A). We also turn to the case law of the EU Court of Justice, which has solidified the rigidity of the legal framework (Title II.B). Secondly and against this background, we describe the constraints of possible legislative intervention for biocontrol products within the confines of Regulation 1107/2009 (Title III).

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[12] VON DER LEYEN U., 'Europe's Choice – Political Guidelines for the next European Commission 2024-2029', 18 July 2024, p. 11.

[13] VON DER LEYEN U., 'Mission letter to Olivér Várhelyi – Commissioner-designate for Health and Animal Welfare', 17 September 2024, p. 6: "*You will work to improve the sustainability, safety and affordability of food production and consumption across the food chain, including through organic production and the accelerated use of bio-controls*".

[14] VON DER LEYEN U., 'Mission letter to Christophe Hansen – Commissioner-designate for Agriculture and Food', 17 September 2024, p. 5: "*Building on the recommendations of the Strategic Dialogue and in consultation with the future European Board for Agriculture and Food, you will prepare in the first 100 days a Vision for Agriculture and Food* (…). *It should also look at food waste and promotion of cutting-edge science, innovative technologies and emerging products in the agri-food sector*".

[15] European Parliament, 'Questionnaire to the Commissioner-designate Olivér Várhelyi', 22 October 2024, p. 10: "*If confirmed, I will look at ways to further improve the implementation of the* [Sustainable Use of Pesticides] *Directive or assess new legislative initiatives, in dialogue with the Member States and other stakeholders, and based on the recommendation of the Strategic Dialogue that the European Commission would enable a robust legislative framework for biocontrol products and approaches*. (…) *I am committed to increasing the availability of alternatives to chemical pesticides, such as biopesticides, by fostering their access to the market. During the last mandate, the Commission simplified data requirements and assessment methods for pesticides based on micro-organisms and developed specific guidance for other biopesticides such as plant extracts and pheromones. If confirmed, I intend to take additional steps so that applications for biopesticide authorisation are evaluated with high priority and that these pesticides can have faster access to the market to expand the toolbox of farmers protecting their crops. This would support innovation, cater for the evolving needs of plant protection and address emerging phytosanitary problems*" (emphasis added); European Parliament, 'Questionnaire to the Commissioner-designate Christophe Hansen', 22 October 2024, p. 8: "*Soil health, adaptation to climate change, pollination, nutrient balance, decarbonisation and sustainable use of pesticides and fertilisers, as well as their alternatives, to name some key examples, are essential for long term viability*" (emphasis added).

In step 2, we juxtapose these constraints with the legal advantages that a distinct act would benefit from (Title IV).

II. The rigidity of Regulation 1107/2009

A. At its core, Regulation 1107/2009 addresses risks associated with *chemical* PPPs

7. Underlying Regulation 1107/2009 are concerns about the risks and hazards of PPPs. The Regulation addresses these concerns through a prior-approval process for PPPs and their active substances. The framework is underpinned by the precautionary principle and aims to ensure a high level of protection of human and animal health and the environment.[16]

This follows from the recitals ((6)-(10) and (24)) and is made express in Article 1 of Regulation 1107/2009, which defines the subject matter and purpose of the Regulation.

8. Article 2 - on the scope - furthermore, makes it clear from the onset that the Regulation focuses on chemical products. Indeed, the Regulation deals with PPPs containing active *substances*, i.e. chemical elements and their compounds (as defined in Article 3.2). The notion 'active substance' is foundational to the Regulation.

It is true that 'micro-organisms' are also in the scope, namely through an (oddly formulated) extension in the definition of 'active substance' in Article 2.2 of Regulation 1107/2009: "*This Regulation shall apply to substances, including micro-organisms*". But the absence of any reference to micro-organisms in the recitals or in any of the enacting terms (other than Article 77 on guidance documents) of the Regulation as adopted in 2009, demonstrates that they hardly played a role, if any, in shaping the Regulation.[17]

9. In addition to the purpose and scope of the Regulation (Articles 1-2), also the enacting terms appear geared towards chemicals.[18] The provisions consider chemical hazard classifications (including references to CLP Regulation 1272/2008), physico-chemical properties, toxicological assessments, residues, purity

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[16] The 'improvement of agricultural production' is also mentioned in Article 1.3 as a purpose of the Regulation. But it does not appear to hold the same legal force - see footnote 25 below.

[17] See also ALABOUVETTE C. and CORDIER C., 'Risks of Microbial Biocontrol agents and regulation: are they in Balance?', in EHLERS R-U., *Regulation of Biological Control Agents*, 2011, p. 158-159, noting that Directive 91/414 was established with chemicals in mind and describing problems when applying it to microbials, as well as EHLERS R-U., 'Regulation of Biological Control Agents and the EU Policy Support Action REBECA', in EHLERS R-U., *Regulation of Biological Control Agents*, 2011, p. 10-13 on the history of EU biocontrol registration.

[18] See also STEENBERG A. (Dutch Board for the Authorisation of Plant Protection Products and Biocides - Ctgb), 'Registration of biopesticides: Experience of the regulator of the Netherlands', December 2021, slide 11: "*EU framework for pesticides was developed for synthetic, conventional PPP; Hazards are based on actual, observed hazards for these compounds (e.g., persistence, toxicity); Not developed for naturally occurring substances/microorganisms*".

standards, and impurity controls.[19] They seem to address the inherent risks associated with chemical PPPs, ensuring that they are rigorously evaluated.

10. Articles 4 and 29 form the core of these enacting terms, as they set the approval criteria/requirements for active substances and PPP respectively. A PPP *cannot* be marketed unless it has been authorized in accordance with Regulation 1107/2009. And a PPP may *only* be authorized where it complies with the requirements set out in Article 29, which includes the approval of the active substance pursuant Article 4. Articles 4 and 29 thus set the basic requirements that all products must meet and on which the remainder of the Regulation, including the data requirements, is grafted.

11. **Biocontrol products are, by definition, different from synthetic PPPs. Assessing them under the chemically-oriented, rigid framework of Regulation 1107/2009 creates problems** as has been widely reported: data requirements are extensive and inappropriate[20], resulting in slow, expensive authorisation procedures[21] and limiting the potential for innovation.[22]

B. EU Court of Justice: the precautionary principle underpins all assessments under the Regulation – data gaps

12. Regulation 1107/2009 has been the subject of various cases before the Court of Justice of the EU. We will discuss three lines of cases below. The central theme is the Court's **consistent emphasis on the precautionary principle and on the Regulation's purpose to ensure a high level of protection of health and the environment**. Thus, the Court has solidified the interpretation that all matters related to Regulation 1107/2009 must be viewed *in light of these overarching principles*[23], also downplaying the principle of legal

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[19] See also European Parliamentary Research Service, 'Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market – European Implementation Assessment', April 2018, II-29, remarking that the consideration of efficacy in targeting pests - one of the evaluation criteria for the approval of active substances - rewards synthetic chemicals.

[20] European Commission: Directorate-General for Health and Food Safety, 'Study supporting the REFIT Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005) – Executive summary', 2018, , vi; VEKEMANS M-C and MARCHAND P.A., 'The fate of biocontrol agents under the European phytopharmaceutical regulation: how this regulation hinders the approval of botanicals as new active substances', *Environmental Science and Pollution Research* 2020, 39879–39887;

[21] European Commission, Fit For Future Opinion on Biosolutions, 13 December 2022, p. 4, 5, 8, 10-12; European Commission, 'Single Market Enforcement Taskforce – Project : Improving the authorisation process for biosolutions'.

[22] European Parliamentary Research Service, 'Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market – European Implementation Assessment', April 2018, II-92.

[23] That the precautionary principle underpins Regulation 1107/2009, according to the General Court, means that also "*any act adopted on the basis of [the Regulation] is ipso jure founded on the precautionary principle*", Judgment of the General Court of 17 May 2018, Case T-584/13, *BASF Agro,* para. 153.

certainty[24] as well as the relevance of another stated purpose of the Regulation, namely the 'improvement of agricultural production'.[25]

13. In the 2017 *Blaise* case,[26] a French court questioned whether Regulation 1107/2009 sufficiently protects human health in accordance with the precautionary principle. The Court (ruling in Grand Chamber formation) upheld the validity of Regulation 1107/2009, and in doing so highlighted the strict standards set by the Regulation.

The Court noted that, in accordance with Articles 4 and Article 29, a PPP can be authorized only if it is established that it has no immediate or delayed harmful effect on human health (para. 114). Furthermore, the burden of adducing that proof lies with the applicant, there being no presumption of harmlessness (paras. 78-80 and para. 114).

The Court also stressed the responsibility of the Member States (and EFSA) to undertake an independent, objective and transparent assessment in the light of current scientific and technical knowledge (§§ 88-97). According to the Court, the approach taken by the authorities must not be passive: if they find the applicant's evidence insufficient, they are **obligated to request additional information**. Furthermore, the authorities must consider all relevant evidence beyond the applicant's submissions. With that in mind, it is the duty of the competent authorities, in particular, to **take account of the most reliable scientific data available and the most recent results of international research**. If, after evaluating all the information available, the applicant fails to meet the required standard, the authorities must reject the application.

14. The observations in *Blaise* were made even more concrete in recent cases C-308/22[27] as well as C-309/22 and C-310/22[28] (the "Dutch Reference Cases"), stemming from challenges to PPP authorizations in the Netherlands. In both cases, the NGO 'Pesticide Action Network Europe' (PAN Europe) alleged that the assessment of the Dutch authority, which eventually lead to the authorisation of the PPPs in question, was incomplete.

In Case C-308/22, the Court noted that there is essentially **no limit on the information that may be raised to challenge a PPP authorization**, "*irrespective of the source of that information or the time when it became available*" (paras 91-92).

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[24] Judgment of the Court of 25 April 2024, Case C-308/22 ("*Closer*"), para. 107.

[25] With reference to recital (24), the Court of Justice has held that, in the context of the authorisation for placing PPPs on the market, it deems the objective of protecting health and the environment to take priority over the improvement of agricultural production, Judgment of the Court of 19 January 2023, *Pesticide Action Network Europe and Others*, Case C-162/21, para. 48. It is perhaps no surprise then, that the general sentiment appears to be that Regulation 1107/2009 has *not* succeeded in meeting its objective of improving agricultural production, see European Parliamentary Research Service, 'Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market – European Implementation Assessment', April 2018, I-15 and I-110.

[26] Judgment of the Court of 1 October 2019, Case C-616/17, *Blaise and Others*.

[27] Judgment of the Court of 25 April 2024, Case C-308/22 ("*Closer*").

[28] Judgment of the Court of 25 April 2024, Joined Cases C-309/22 and C-310/22 ("*Pitcher*").

In joint Cases C-309/22 & C-310/22, the Court arguably went one step further, holding that competent **national authorities** are required, when assessing a PPP, to **take into account the adverse effects that the** (endocrine disrupting or 'ED') **properties of an active substance** contained in this PPP may cause. The Court dismissed that this distorts the distinction between the assessment, at EU level, of the properties of active substances and the examination of the PPP, at Member State level (para. 75).

15. The high standards (in term of criteria and data requirements) of Regulation 1107/2009 have led the authorities to readily identify so-called '**data gaps**', referring to the absence or insufficiency of information that is deemed necessary to perform a comprehensive risk assessment. And because the burden is on the applicant (see *Blaise*), data gaps may be seen as a legitimate basis to reject or revoke regulatory approval under Regulation 1107/2009. This approach has repeatedly been endorsed by the EU courts.[29]

16. The above is without prejudice to the fact that the **current framework urges competent authorities to err on the side of caution** and hold any doubts against the applicants. Cautious authorities may find 'data gaps' in biocontrol dossiers, as the European Parliament also pointed out,[30] which may be sufficient grounds to reject or contest approvals or authorizations. And an attempt to streamline the assessment for biocontrol products may be defeated by the Court's findings in the Dutch Reference Cases, which point to the necessity of a broad assessment in every case. NGOs may always choose to bring additional cases to seek confirmation that biocontrol products – despite any Guidance documents or aspirational wording to the contrary – remain subject to the full complement of data requirements and procedures set out for all "active ingredients".

III. The constraints of dealing with biocontrol products within the confines of Regulation 1107/2009

17. In Title II, we observed how (A) the rigid, chemically-oriented nature of Regulation 1107/2009 has reportedly hindered biocontrol products, and (B) the CJEU has solidified the interpretation that all matters related to Regulation 1107/2009 must be viewed in light of the precautionary principle and the Regulation's purpose to ensure a high level of protection of health and the environment.

With this background in mind, we will discuss in this Title III the legal constraints of the first option for legislation intervention, i.e. to address biocontrol products *within* the confines of Regulation 1107/2009.

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[29] For example: Order of the General Court of 21 January 2019, Case T-574/18, *Agrochem-Maks* (appeal rejected in Case C-374/20 P), and Judgment of the General Court of 9 February 2022, Case T-740/18, *Taminco* (appeal rejected in Case C-259/22 P).

[30] European Parliament resolution of 16 January 2019 on the Union's authorisation procedure for pesticides (2018/2153(INI)), BR.

A. Definitions and scope

18. As already said, Regulation 1107/2009 has a set scope that is linked to the definitions of "plant protection products" and "active substance". Micro-organisms are explicitly brought within the scope, but for other types of biocontrol products it remains ambiguous whether the framework in fact covers them. This ambiguity arises because **non-micro-organism-based biocontrol products may not fit the definition of "substances"**, defined in Article 3(2) of Regulation 1107/2009 as "*chemical elements and their compounds, as they occur naturally or by manufacture* (…)." Additionally, the definition of "non-chemical methods" in Article 3(8) supports this uncertainty by stating that there are non-chemical biocontrol options, which include "*alternative methods to chemical pesticides for plant protection and pest management* (…) *based on biological pest control methods*".

19. **If biocontrol products were to be dealt with in Regulation 1107/2009, its scope would thus have to be clarified and expanded** to properly address (all) biocontrol products.[31] Although legally possible, such an amendment would almost certainly transcend a "non-essential element" in the sense of Article 78 (see below, Title B.2.). In other words, it would require an act on par with the Regulation, meaning one adopted through the ordinary legislative procedure. Therefore, whether to remove "biocontrol products" to separately regulate them, or to retain within 1107/2009, a definitional amendment is required in either case.

B. Hierarchy of norms and groundwork laid by Regulation 1107/2009

20. An important point to be made when considering whether or not to carve out biocontrol products into a new separate legal framework is that any approach to address biocontrol products within the four corners of Regulation 1107/2009 would have to adhere to the Regulation's core principles and key provisions. Indeed, **any form of legal action taken by the Commission alone or other non-legislative acts such as guidelines are necessarily subordinate to Regulation 1107/2009 as a consequence of the EU hierarchy of norms**.[32] Furthermore, the CJEU's case law, which emphasizes the Regulation's overarching principles, suggests that even an amendment to the Regulation via a legislative act, may fall short of enabling an alternative approach for biocontrol products. The flexibility offered by the solution to address biocontrol products within the four corners of Regulation 1107/2009 is therefore severely limited.

21. Allowing competent national authorities the option to use alternative data requirements supposedly tailored to biocontrol products, while still operating within Regulation 1107/2009, may indeed not be effective, as these authorities still risk preferring to err on the side of caution and adhere to the more stringent data requirements intended for chemical pesticides. This **overly cautious approach is less likely if data requirements for biocontrol products are established in a legal act distinct from Regulation 1107/2009**.

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[31] Legislative practice prescribes that the scope must be respected throughout the act; rights and obligations must not go beyond what is stated to be covered by the act or extend to other fields, Joint Practical Guide of the European Parliament, the Council and the Commission for persons involved in the drafting of European Union legislation ('**Joint Practical Guide**'), § 4.2.1.

[32] EUR-lex Glossary on the EU hierarchy of norms.

In other words, when given the choice between two sets of data requirements and in the absence of a separate act, there is a significant risk that regulatory authorities would choose the stricter set, even if it is less suitable for the product being assessed.

B.1. Guidance documents may lack the authority and effectiveness of legislation

22. Article 77 Regulation 1107/2009 expressly foresees in a legal basis empowering the Commission to adopt (or amend) guidance documents on the content of the application concerning "micro-organisms, pheromones and biological products".

23. Although **guidance documents** offer flexibility, they **are not meant as a substitute for legislation**. Indeed, guidance documents lack direct force of law.[33]

24. Concretely, guidance documents on the topic cannot change the legal reality that **national competent authorities will still be bound to assess applications against the provisions of Regulation 1107/2009, and in particular the benchmarks set by Articles 4 and 29, as interpreted by the CJEU**. These benchmarks, approved by the EU legislator and forming one of the pillars of the Regulation, cannot be lowered by a non-legislative act (such as a guidance document). Moreover, and as seen in the Dutch Reference Cases, Member States are obliged to consider relevant information (even where Guidance documents have previously suggested that this is not required). As an example, the Commission argued in the Dutch Reference cases, among other things, that EFSA guidance on the identification of endocrine disrupting substances was only applicable to the assessment of active substances as it concerns the application of the criteria of Regulation 2018/605. This was ineffective and the Court found that Member States are indeed not bound by such Guidance – raising the possibility that even if Member States were to adhere uniformly to any consensus approach and new Guidance, authorisations may be challenged by third parties on this basis to the extent that they deviate from the more general requirements of Regulation 1107/2009.

B.2. The tools embedded in Regulation 1107/2009 to amend and further implement also come with important limitations – Article 78

25. The EU legislator incorporated a certain amount of adaptability into Regulation 1107/2009 by means of Article 78.

On the one hand, Article 78(1) lists the measures designed to amend **non-essential** elements of the Regulation, which must be adopted in accordance with the regulatory procedure with scrutiny (RPS). While

[33] Guidance documents do not figure among the acts to which the Treaties have accorded the status of (secondary) EU law - see Article 288 TFEU: "*To exercise the Union's competences, the institutions shall adopt regulations, directives, decisions, recommendations and opinions*".

RPS has evolved into the system of Delegated Acts (with their legal basis in Article 290 TFEU) at the occasion of the entry into force of the Lisbon Treaty, it still applies for the purposes of Regulation 1107/2009.[34]

Essential elements are outside the RPS's purview. This is because, according to settled case law of the EU Court of Justice, the adoption of rules essential to the subject-matter envisaged is reserved to the EU legislature and thus the essential rules governing the matter in question must be laid down in the basic legislation.[35] Provisions which, in order to be adopted, require political choices falling within the responsibilities of the EU legislature cannot be delegated.[36]

Any changes that would touch upon matters such as the scope of Regulation 1107/2009, including its core definitions, or the approval criteria/authorisation requirements that it lays down, would most likely qualify as "essential element" which cannot be delegated to the Commission. In this sense, an amendment to the data requirements in accordance with Article 78.1(b) with a view to facilitating biocontrol products, would not have a profound impact in legal terms. It would leave the Regulation's core principles and key provisions unchanged, allowing them to continue asserting precedence.

26. The Commission has made use of Article 78(1) when it adopted a package of four Commission Regulations in 2022 to facilitate the approval of micro-organisms for use as active substances and the authorisation of PPPs containing them.[37] Together, these regulations were meant to base the regulatory requirements for micro-organisms more on their particular characteristics.

27. In practice, **the aforementioned Commission Regulations do not seem to have made much of a tangible difference** in accelerating regulatory pathways for micro-organism-based PPPs. E.g. we understand that the most recent micro-organism approved in the EU dates from 2019.[38] Already at the time of adoption of these regulations, the Netherlands voiced criticism within the SCOPAFF, by way of a protocol declaration, vis-à-vis the proposals and stated that it did "(…) *not expect them to significantly accelerate the approval process for micro-organisms because the regulatory procedure remains unchanged and a significant amount of data is still requested*".[39] This is probably unsurprising, as amendments via Article 78(1) are intended to permit further granularity to be inserted under the existing overarching requirements – not to dispense with or alter them.

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[34] See Article 12 of Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers: "*The effects of Article 5a of Decision 1999/468/EC shall be maintained for the purposes of existing basic acts making reference thereto*"; See also CHAMON M., 'Dealing with a Zombie in EU Law. The Regulatory Comitology Procedure with Scrutiny', *Maastricht Journal of European and Comparative Law* 2016, 23(4), 714-724.

[35] Judgment of the Court of 5 September 2012, Case C-355/10, *Parliament v Council*, para. 64.

[36] *Ibid*., para. 65.

[37] Commission Regulations (EU) 2022/1438, (EU) 2022/1439, (EU) 2022/1440 and (EU) 2022/1441.

[38] When executing a search (on 31 October 2024) on the EU Pesticides database concerning the amount of micro-organisms approved as an active substance since the applicability of the new data requirements, no results are found.

[39] European Commission Standing Committee on Plants, Animals, Food and Feed (SCOPAFF) Section Phytopharmaceuticals-Legislation, 'Summary report 27-28 January 2022', p. 22.

28. The procedure foreseen in Article 78(1) of Regulation 1107/2009, would therefore seem ill-equipped as a basis to thoroughly regulate biocontrol products within said Regulation.

29. For the sake of completeness, Article 78(2) also provides that any further measures necessary for the implementation of Regulation 1107/2009 may be adopted under comitology. **In contrast to Delegated Acts, Implementing Acts do not alter or supplement the basic act but provide further detail in relation to the content of the legislative act.**[40] Therefore, other implementing measures cannot effectively regulate biocontrol products either, as they are limited to expanding on provisions already outlined in the basic act and are not meant to supplement the basic act with new provisions. This is equally true if implementing measures do not specify particular alternate approaches (that unambiguously and consciously deviate from the 'default' approach) but rather indicate to national regulators that they may 'exempt' a requirement (i.e. not apply the requirement) if deemed 'justified' (without the act necessarily specifying when that threshold is supposed to be attained). Attempting to implement such exemptions would likely be ineffective, as they cannot override the general requirements of the Regulation. Member State regulators do not have the discretion to waive key elements of Regulation 1107/2009 even if a non-legislative act would seemingly provide a legal basis to do so.

B.3. Need-to-know approach

30. Another form of flexibility that could be leveraged within the framework of Regulation 1107/2009 is at the level of the approach taken by the risk assessor.

31. The need-to-know approach in the authorisation procedure for PPPs is designed to streamline the regulatory process by focusing on essential information rather than on extraneous data. This method prioritizes the submission and evaluation of only the necessary data required for making informed decisions about the safety, efficacy, and environmental impact of pesticides.[41] This also ties to the tiered-based approach which sets, on the one hand, mandatory (i.e. baseline) requirements and, on the other hand, conditional requirements. Both the need-to-know approach and the tiered-based approach have been highlighted by the Commission.[42]

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[40] Judgment of the Court of 18 March 2014, Case C-427/12, *Commission v Parliament and Council*, para. 39.

[41] BUSSCHERS B., 'Data decision tree for identifying potential risks for natural substances when used in plant protection', *Biocontrol Science and Technology* 2023, Vol. 33, No. 7, (597) 619.

[42] See European Commission Standing Committee on Plants, Animals, Food and Feed - Section Phytopharmaceuticals-Legislation, 'Summary Report, 10 and 11 July 2024', 7: "*The need-to-know approach was recalled once again as an important principle for their assessment in line with the guidance document on secondary metabolites*"; See also European Commission Advisory Group on the Food Chain and Animal and Plant Health, 'Plant Protection Products Regulation 1107/2009 - an update', November 2019, slide 5; European Commission Advisory Group on the Food Chain and Animal and Plant Health, 'Plant protection products – update and ongoing developments', 7 May 2021, slide 13; European Commission Advisory Group on the Food Chain and Animal and Plant Health, 'Plant protection products – update and ongoing developments', 17 November 2023, slide 6.

32. As discussed in Title II, **the rigidity of Regulation 1107/2009 questions whether these approaches are suitable to produce any reliable effects in terms of facilitating biocontrol products. In practice, authorities may strongly prefer to err on the side of caution[43] requesting data rather on a 'like to know' basis**[44]. And indeed, as exemplified by the Dutch Reference Cases, the Court requires a potentially broad approach in every case.

C. No guarantee that national competent authorities will be able to handle separate authorisation lanes for biocontrol products in Regulation 1107/2009

33. Should Regulation 1107/2009 introduce separate authorisation lanes for biocontrol products, as previously suggested in the European Parliament's SUR report[45], there is no guarantee that – on the ground – this will lead to accelerated timelines. It is known that the timelines, already today, are much longer in practice than what is prescribed by the regulatory framework.[46]

D. Risk of discriminatory provisional authorisations

34. It has been suggested to re-instate the option of the provisional authorization under Article 30 of Regulation 1107/2009, which expired in June of 2016, to facilitate the marketing of biocontrol products that have been evaluated and assessed by the Rapporteur Member State and concluded that the substance can be approved.[47] This re-instatement was also pursued by one of the amendments to the SUR proposal.[48] That it was proposed in the context of the SUR proposal also suggests that the re-instatement of Article 30 likely transcends the "non-essential" qualifier of Article 78.1.

35. Reinstating this option could, however, create a risk of differential treatment of applicants over time. Originally, **the derogation allowing provisional authorisations under Article 30 of the Regulation was meant to be a temporary measure, unless extended through the regulatory procedure with scrutiny. Since this extension was not adopted, reintroducing it now could create inconsistencies** compared to the original

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[43] HUBER L. and LORENZ C.S., 'Registration or the Sword of Damocles over the Development of Biopesticides' in PUOPOLO G. (ed.), *Microbial Biocontrol Agents: Developing Effective Biopesticides*, CAB International 2023: "*Nevertheless, as agricultural practice shows, the regulatory approach of box-ticking regulatory requirements is often placed above scientific argumentation.*"

[44] Term coined in BUSSCHERS B., 'Data decision tree for identifying potential risks for natural substances when used in plant protection', *Biocontrol Science and Technology* 2023, Vol. 33, No. 7, (597) 619.

[45] European Parliament, 'Report on the 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', 2022/0196(COD), A9-0339/2023, ', amendment 396.

[46] European Commission, 'Fit For Future Platform Opinion on Biosolutions', 13 December 2022, p. 8.

[47] *Ibid*., p. 10.

[48] See amendment 396, Report on the 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, 2022/0196(COD), A9-0339/2023.

legislative framework, leading to potential inequalities in how applicants are treated based on when they submitted their applications.

Furthermore, should provisional authorisations become a common practice, there might be less incentive for national competent authorities to adhere strictly to the evaluation timelines. This could potentially lead to a culture of dependency on provisional authorisations, thereby delaying the final approval process and creating uncertainty for applicants about the long-term status of their biocontrol products.

Finally, it is uncertain whether provisional authorisations for biocontrol products would actually speed up their time to market, even on a provisional basis. As foreseen in Article 30(1)(c) of Regulation 1107/2009, one of the prerequisites for the issuance of a provision authorisation is that "*the Member State concludes that the active substance can satisfy the requirements of Article 4(2) and (3) and that the plant protection product may be expected to satisfy the requirements of Article 29(1)(b) to (h)*." Thus, even though the intended authorisation is only provisional, Member States must still conduct an assessment to ensure that the thresholds are met ("can satisfy" and "expected to satisfy").

IV. The legal benefits of a distinct act for biocontrol products

36. We have discussed in Title III the constraints of addressing biocontrol products within the confines of Regulation 1107/2009. The principle legal benefit of a distinct act, as discussed in this Title IV, is that it would not be hampered by such constraints. A separate legal act can formulate its own purpose and delineate clear, precise rules, tailored to biocontrol products.

A. Increasing legal certainty

37. The principle of legal certainty is a general principle of EU law.[49] According to the Court's case law, it requires "*that rules of law be clear, precise and predictable as regards their effects*".[50] Furthermore, the application of legal rules must "*be foreseeable by those subject to them*".[51] This has been incorporated in the EU's legislative practice.[52]

38. It is submitted that a separate legal act on biocontrol products is more conducive to legal certainty than legislative intervention that stays within the boundaries of Regulation 1107/2009.

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[49] VAN MEERBEECK J., 'The Principle of Legal Certainty in the Case Law of the European Court of Justice: From Certainty to Trust', *European Law Review* 2016, Vol. 41, (275) 280.

[50] Judgment of the Court of 16 February 2012, Case C-72/10, *Criminal proceedings against Costa*, para. 74.

[51] Judgment of the Court of 10 September 2009, Case C-201/08, *Plantanol GmbH & Co KG v Hauptzollamt Darmstadt*, para. 46.

[52] Joint Practical Guide, §§ 1.1-1.2.

Firstly, a distinct legal act specifically tailored to biocontrol products **ensures clarity**. Regulation 1107/2009, seems primarily designed for chemical pesticides. Amending the Regulation to address biocontrol products can lead to ambiguity and confusion. The intermingling of provisions for different categories of products within a single regulatory framework risks diluting the specific requirements and standards applicable to biocontrol products. In contrast, a separate legal act can formulate its own purpose and delineate clear, precise rules, tailored to biocontrol products, thereby enhancing clarity and specificity. Furthermore, with a separate act, the EU legislator would grant legislative legitimacy to the tailored approach.

Secondly, a standalone legal act arguably **promotes precision** in legal rights and obligations. Amending an existing act like Regulation 1107/2009 to fit biocontrol products might result in convoluted provisions that are neither precise nor coherent. This might increase uncertainty for economic operators who need to navigate the act to fully comprehend their obligations. A dedicated legal act, however, can more precisely outline the regulatory framework applicable to biocontrol products.

The precision of a legal act also relates to its scope. For example, under Regulation 1107/2009, macro-organisms are excluded from its material scope.[53] But also 'semiochemicals' and 'plant extracts' do not fit well within the current definitions of Regulation 1107/2009 (see above). Finally, the current extension to micro-organisms is imprecise as it subjected to the notion of "substance".

Thirdly and finally, **predictability could arguably be better safeguarded** with a separate legal act. Targeted amendments to Regulation 1107/2009 could lead to subsequent and piecemeal legislative changes, which can undermine the predictability of the legal framework. On the other hand, a distinct legal act increases the likelihood of a stable and foreseeable legal environment for biocontrol products.

B. Tailoring the precautionary principle

39. The case law of the EU Court of Justice, as discussed in Title II.B, raises concerns about whether Regulation 1107/2009 can effectively serve as a framework for biocontrol products. The EU Courts' expansive application of the precautionary principle may hinder initiatives aimed at facilitating the approval of biocontrol products under that regulation. According to the General Food Law,[54] the precautionary principle, as defined in Article 7, involves identifying potential harm, recognizing scientific uncertainty, and implementing risk management measures that are proportionate to the identified risks. However, under Regulation 1107/2009 in particular, these measures may lack proportionality when a low-risk product is concerned. This is further complicated by the provisions in Regulation 283/2013, which state that the information required must be sufficient to evaluate foreseeable risks.[55] As can be deduced from the

[53] LIÉGEOIS E. (EU Commission – DG SANTE E.4), 'Achieving more sustainable food systems by fostering registration of biopesticides in EU', presentation at the FAO webinar 'Registration of Biopesticides', 13 December 2021.
[54] Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p. 1–24.
[55] See e.g. point 1.1. of the Annex to Commission Regulation (EU) No 283/2013 setting out the data requirements for active substances in accordance with Regulation (EC) No 1107/2009, OJ L 93, 3.4.2013, p. 1–84.

emphasis put by the Commission on the foreseeable risk principle in its new guidance documents for micro-organisms, scientific uncertainty regarding naturally occurring substances is typically lower due to existing knowledge and safe exposure levels for humans and the environment.[56]

40. **Establishing a separate framework for biocontrol products could help clarify the boundaries of the precautionary principle and the foreseeable risk principle, allowing for a more balanced approach that does not compromise safety standards**. In other words, this separate framework could allow for a more adaptable (i.e. more proportionate to the identified risks) application of the precautionary principle. The degree to which the precautionary principle is applied should indeed depend on the characteristics of the product in question and the risks these entail. This approach could serve as a guiding principle in the new legal framework for biocontrol products. As mentioned earlier (see footnote 25), the Court of Justice of the EU has grounded this hierarchical relationship between the different objectives pursued by Regulation 1107/2009 in its recital (24).

C. Promoting the internal market and future-proofing the regulatory framework

41. The establishment and functioning of an internal market – an area **without internal frontiers and with free movement of goods -** is a **fundamental constitutional objective** of the EU.[57] To further this objective, the EU is competent, by virtue of Article 114 TFEU, to harmonize Member States' laws. In fact, one of the legal bases of Regulation 1107/2009 is the predecessor of the aforementioned provision, namely Article 95 of the Treaty establishing the European Community (TEC).

42. **Free movement is not guaranteed for all biocontrol products**. A natural corollary of the EU internal market is the judge-made principle of mutual recognition that finds its origin in the *Cassis de Dijon* case.[58] In essence, the principle of mutual recognition proclaims that a product should be able to move freely between the Member States on the basis of complying with a one national regulatory framework (most of the time, that of the Member State of exportation), even in the absence of EU harmonisation.[59]

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[56] See e.g. European Commission, 'Explanatory notes for the implementation of the data requirements on micro-organisms and plant protection products containing them in the framework of Reg. (EC) No 1107/2009', 12 October 2023, p. 14: "*In effect, this means that all the information needed to conclude that the use of a PPP is sufficiently effective and does not have harmful effects on human and animal health and has no unacceptable effects on the environment must be submitted. It also means that information should not be required if – due to the properties of the substance or its use – the information is not necessary to evaluate foreseeable risks*".

[57] See Article 26(1) TFEU; The importance of advancing the internal market has recently been emphasised by the Letta and Draghi reports, see LETTA E., 'Much more than a market – Speed, Security, Solidarity, Empowering the Single Market to deliver a sustainable future and prosperity for all EU Citizens', April 2024; DRAGHI M., 'The future of European competitiveness - Part A | A competitiveness strategy for Europe', September 2024.

[58] Judgment of the Court of 20 February 1979, Case C-120/78, *Rewe v Bundesmonopolverwaltung für Branntwein*.

[59] GOVAERE I, ''Ceci n'est pas .. Cassis de Dijon': Some Reflections on its Triple Regulatory Impact', *College of Europe Research Papers in Law*, 3/2020, p. 4.

For PPPs, however, Regulation 1107/2009 has positively harmonised common marketing standards. The EU legislator, with the aim of *inter alia* assuring a more harmonised availability of PPPs, expressly included the principle of mutual recognition in Regulation 1107/2009. It requires that authorisations for PPPs granted by one Member State should, as a principle, be accepted by other Member States where agricultural, plant health and environmental conditions are comparable.[60] In other words, **the mutual recognition procedure assumes that the assessment conducted by one Member State should not be repeated by other Member States** (thereby limiting the administrative burden) when recognizing an authorisation, except in clearly defined national-specific circumstances.

While mutual recognition is the default approach under Regulation 1107/2009, its practical implementation has reportedly not been plain sailing as national authorities still insist on enforcing their specific national authorisation requirements.[61] National authorities will most likely find support for this approach in at least one of the Dutch Reference Cases (i.e. Case C-308/22, which, admittedly, concerned a zonal authorisation procedure, not a mutual recognition procedure, but the same logic applies) where the EU Court of Justice seemed to downplay an earlier assessment of the rapporteur Member State. In its interpretation of Regulation 1107/2009, the Court, in para. 68 of the judgment, refers to recital 24 and its earlier case law to justify that the objective of protecting human and animal health and the environment should take priority over the objective of improving plant production. While this may be in line with the Regulation's rationale, it is striking that the Court either does not mention, or only mentions in passing (see para. 69 of the judgment), the principles of harmonisation and mutual recognition. **Allowing Member States more wiggle room to issue deviating decisions for the same product under a harmonised framework such as Regulation 1107/2009 sits uneasily with the principle of mutual trust as a fundamental principle of the EU legal order** and the Court's established case law that that principle requires Member States to assume that all other Member States adhere to EU law and respect EU fundamental rights.[62]

If all Member States within the same zone are to carry out their own scientific evaluation independent of the conclusions from other Member States - regardless of whether this happens within the framework of the mutual recognition procedure or the zonal evaluation procedure - it may raise questions as to what extent the improvement of the freedom of movement of plant protection products, which is nevertheless still one of the main objectives pursued by Regulation 1107/2009, has actually been achieved.

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[60] See recital 29 and Articles 40-42 of Regulation 1107/2009.

[61] European Commission, 'Study supporting the REFIT Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005)', 10 October 2018, p. 51: "*The mutual recognition process is not sufficiently harmonised to allow for an effective implementation, even between MSs belonging to the same zone, although efforts have been made especially in the Northern zone. Specific national requirements and the quality of the dossier are often factors that undermine the objective of the mutual recognition process to streamline and facilitate the placing on the market of products already authorised in the other MSs. The legal deadlines are consequently not sufficiently respected.*"

[62] Opinion 2/13 of the Court, para. 191: "(…) *it should be noted that the principle of mutual trust between the Member States is of fundamental importance in EU law, given that it allows an area without internal borders to be created and maintained. That principle requires, particularly with regard to the area of freedom, security and justice, each of those States, save in exceptional circumstances, to consider all the other Member States to be complying with EU law and particularly with the fundamental rights recognised by EU law* (…)."

43. The internal market is a shared competence[63] meaning that Member States have competence to the extent that the EU has not exercised its competence.[64] A strict interpretation of said division of competences would imply that Member States, in the absence of an EU-wide definition of biocontrol (products), are supposedly free to lay down their own definitions. This is what happened, for example, in France. Article L. 253-6 of the French Rural and Maritime Fisheries Code defines 'biocontrol' as "(…) *agents and products using natural mechanisms as part of integrated pest management. They include in particular : 1° Macro-organisms; 2° Plant protection products comprising micro-organisms, chemical mediators such as pheromones and kairomones and natural substances of plant, animal or mineral origin*".[65]

The current ambiguity as to the scope of the term 'biocontrol' and the one-sided attempts of Member States to define it, may negatively impact the internal market by creating **fragmentation**[66], increasing compliance costs, and establishing trade barriers. An EU intervention to define and regulate biocontrol products separately could thus strengthen the internal market.[67]

44. Furthermore, in approximating the laws of the Member States to further the internal market by means of proposals that concern health, safety, environmental protection and consumer protection, the Commission is, in accordance with Article 114(3) TFEU, obliged to particularly **take into account "*any new development based on scientific facts*"**.

Biocontrol products will likely continue to evolve. A separate legal act tailored specifically to biocontrol products would allow future-proofing the regulatory framework: adapting more swiftly and appropriately to new scientific findings. This aligns with the EU's obligation under Article 114(3) TFEU.

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[63] See Art. 4(2)(a) TFEU.

[64] See Art. 2(2) TFEU.

[65] See the official publication of the French Code rural et de la pêche maritime.

[66] In Commission Staff Working Document SWD(2022) 446 final, p. 6, the European Commission admitted that the different national laws identified in the study differed in terms of scope, risk assessment, authorisation processes and monitoring.

[67] Judgment of the Court of 12 December 2006, Case C-380/03, *Germany v Parliament and Council*, para. 41: "(…) *when there are obstacles to trade, or it is likely that such obstacles will emerge in the future, because the Member States have taken, or are about to take, divergent measures with respect to a product or a class of products, which bring about different levels of protection and thereby prevent the product or products concerned from moving freely within the Community, Article 95 EC authorises the Community legislature to intervene by adopting appropriate measures, in compliance with Article 95(3) EC and with the legal principles mentioned in the EC Treaty or identified in the case-law, in particular the principle of proportionality* (…)".

D. Consistency with the broader EU legal framework: bridge the gap between Regulation 1107/2009 and Directive 2009/128

45. Directive 2009/128/EC (**SUD**) aims to achieve sustainable pesticide use in the EU by reducing the risks and impacts of pesticides on human health and the environment, and by promoting Integrated Pest Management (IPM).

The SUD's puts a particular **emphasis on promoting non-chemical alternatives**[68] to pesticides:

- Member States are obliged, by virtue of Article 14(1) SUD, to take all necessary measures to promote low pesticide-input pest management, giving wherever possible priority to non-chemical methods.

- Under Article 14(4) SUD, Member States must describe in their National Action Plans how they ensure that the general principles of IPM as set out in Annex III are implemented by all professional users. Point 4 of Annex III expressly states that "[s]*ustainable biological, physical and other non-chemical methods must be preferred to chemical methods if they provide satisfactory pest control*".

46. Based on the above, it is apparent that the EU legislator has deliberately chosen to promote biocontrol products over chemical pesticides whenever possible. But this is not thoroughly reflected in Regulation 1107/2009. There thus seems to be a mismatch between the SUD's goal of promoting non-chemical alternatives to pesticides, on the one hand, and the difficulty to authorise biocontrol products under Regulation 1107/2009, on the other.

A dedicated legal framework for biocontrol products can arguably bring about an uptake in the availability of such products on the European market, promoting consistency within the broader framework on pesticides.

E. A separate legal act (and a centralised authorisation procedure) has been the preferred choice in similar regulatory contexts

47. In the past, the Commission has used its prerogative as the main instigator of new EU legislation to propose a **separate legal act in areas where EU legislation was already in place**. A separate legal act was chosen in those instances because it concerned a new technology or product category with unique characteristics that were best addressed within a distinct legal framework. In various cases, this entailed a **separate EU centralised authorisation procedure**.

- *New Genomic Techniques*

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[68] The SUD uses the term 'non-chemical methods' to define "*alternative methods to chemical pesticides for plant protection and pest management, based on agronomic techniques such as those referred to in point 1 of Annex III, or physical, mechanical or biological pest control methods*" (Article 3(8)).

A recent example whereby the Commission opted for a distinct legal act, is the proposal for a Regulation on New Genomic Techniques (NGTs).[69] The Commission iterated that NGTs (i.e. targeted mutagenesis and cisgenesis (including intragenesis)) are different from established genomic techniques because they have novel features, such as higher precision and speed in introducing the desired genetic modifications and the insertion of genetic material only from a crossable five species.[70] The envisioned regulation would bring about a(n) (implicit) 'carve-out' of certain NGT plants (obtained by certain techniques of mutagenesis) from the GMO Directive[71]. Additionally, the decision to propose a separate Regulation was influenced by several factors[72], resembling the present regulatory context for biocontrol products in various ways:

- "*The risk assessment requirements and authorisation procedure of the current GMO legislation are not adapted to the variety of potential plant products that can be obtained by targeted mutagenesis and cisgenesis and, as a result, are disproportionate or inadequate in certain cases*";[73]

- "*The application of the current GMO legislation to NGTs is not conducive to the development of innovative products that are potentially beneficial for breeders, farmers, food business operators, consumers and the environment*".

- *Veterinary medicines*

Regulation 726/2004 originally dealt with the authorisation and supervision of medicinal products for human and veterinary use. In 2018, the legislator updated the regulatory framework for veterinary medicines. The recitals of the new Regulation 2019/06 on veterinary medicines shed light on the rationale for this update (recitals (2), (4) and (5), emphasis added):

- "(…) *the regulatory framework for veterinary medicinal products should be adapted to scientific progress, the current market conditions and economic reality, while continuing to ensure a high level of protection of animal health, animal welfare and environment and safeguarding public health";*

- "*Experience has shown that the needs of the veterinary sector differ substantially from those of the human sector in relation to medicinal products. (…)*";

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[69] Proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625, COM(2023) 411 final.

[70] See the explanatory memorandum under 'Reasons for and objectives of the proposal'.

[71] Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, as interpreted by Judgment of the Court of 25 July 2018, Case C-528/16, *Confédération paysanne and Others*.

[72] *Ibid*., nr. 76.

[73] In a similar vein, see the proposal's explanatory memorandum under the section 'Ex-post evaluations/fitness checks of existing legislation': "*Two external studies on the Union GMO legislation were carried out on behalf of the Commission in 2010 (on GM food and feed) and 2011 (GMO cultivation and placing of GMOs on the market). They noted concerns that the legislative framework was only focused on risks and not suited for the Union to take advantage of new developments in biotechnology*".

- "*This Regulation aims to reduce the administrative burden, enhance the internal market and increase the availability of veterinary medicinal products, while guaranteeing the highest level of public and animal health and environmental protection*".

The new Regulation 2019/06 on veterinary medicines now also deals with the procedure for marketing authorisations. Consequently, veterinary medicines were carved out of Regulation 726/2004.[74]

- *Advanced Therapy Medicinal Products*

This is not just a recent phenomenon. Regulation 1394/2007 on Advanced Therapy Medicinal Products[75] (ATMPs) is an example from 2007. ATMPs are medicinal products for human use that are based on genes, tissues or cells. As inferred from the Regulation's recitals, similar to NGTs, their distinctiveness compared to 'classic' medicinal products was likely a reason why a separate legal act was considered more suitable (recitals (3) – (6), emphasis added):

- "*For reasons of clarity, complex therapeutic products require precise legal definitions. Gene therapy medicinal products and somatic cell therapy medicinal products have been defined in Annex I to Directive 2001/83/EC, but a legal definition of tissue engineered products remains to be laid down*";

- "*According to Directive 2001/83/EC and the Medical Device Directives the basis for deciding which regulatory regime is applicable to combinations of medicinal products and medical devices is the principal mode of action of the combination product. However, the complexity of combined advanced therapy medicinal products containing viable cells or tissues requires a specific approach*";

- "*Because of the novelty, complexity and technical specificity of advanced therapy medicinal products, specially tailored and harmonised rules are needed to ensure the free movement of those products within the Community, and the effective operation of the internal market in the biotechnology sector*";

- "*This Regulation is a lex specialis, which introduces additional provisions to those laid down in Directive 2001/83/EC*".

48. The fact that a distinct act would be appropriate for biocontrol products was already put forward at the inception of Regulation 1107/2009. The European Parliament Rapporteur proposed an amendment to the scope of the Regulation, stipulating that it would cease to apply to biological control products once a specific regulation was adopted:

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[74] Regulation (EU) 2019/05 of the European Parliament and of the Council of 11 December 2018 amending Regulation (EC) No 726/2004, recital (2)

[75] Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004.

Amendment 35 Article 2, paragraph 2	
2. This Regulation shall apply to substances, including micro-organisms and viruses, having general or specific action against harmful organisms or on plants, parts of plants or plant products, hereinafter 'active substances'.	2. This Regulation shall apply to substances, including micro-organisms and viruses, having general or specific action against harmful organisms or on plants, parts of plants or plant products, hereinafter 'active substances'. ***It shall, however, cease to apply to micro-organisms, viruses, pheromones and biological products once a specific regulation on biological control products has been adopted.***

The justification given was that Regulation 1107/2009 was designed for synthetic PPPs, and that a separate regulation should be foreseen to take account of the specific properties of biological control products.[76] Ultimately, the Commission rejected this amendment,[77] but the question is whether the rationale for rejecting the solution in 2008 remains valid today.

Meanwhile the European Parliament, the Council and other EU institutional actors have reiterated the specificity of biocontrol products on several occasions:

- "*Whereas data gaps in the case of low-risk biological pesticides primarily occur because the data requirements are designed for chemical plant protection products, and are thus unsuitable for low-risk biological ones*";[78]

- "[W]*hereas the present regulatory framework for plant protection products does not legally differentiate between biological and synthetic chemical plant protection products*";[79]

- "*There is a wide diversity between Member States in their approaches and the types of regulations that they apply to the release, evaluation and movement of BCAs. However, BCAs* [biocontrol agents] *know no borders and can spread beyond the territories where they have been deliberately*

[76] European Parliament, 'Report on the proposal for a regulation of the European Parliament and of the Council concerning the placing of plant protection products on the market', A6-0359/2007, justification accompanying amendment 35: "*It should be emphasized that the provisions foreseen in* [Regulation 1107/2009] *are designed to reduce harmful effects of synthetic plant protection products and are not in all cased suited for assessing risks and the potential impact of biological control substances. In order to take account of the specific properties of such products, a regulation on biological products should be foreseen*."

[77] European Commission, 'Amended Proposal for a Regulation of the European Parliament and of the Council concerning the placing of plant protection products on the market', COM(2008) 93 final, p. 5: "*The Commission retains that there is no need for a specific regulation as specific data requirements and criteria for authorisation are already in place and for some of these substances the provisions concerning low risk substances could potentially apply. Therefore, the amendment has not been endorsed by the Commission*".

[78] European Parliament resolution of 16 January 2019 on the Union's authorisation procedure for pesticides, 2018/2153(INI).

[79] European Parliament resolution of 15 February 2017 on low-risk pesticides of biological origin, 2016/2903(RSP).

released in order to control plant pests, weeds and invasive alien plants. Often used in greenhouse production, BCAs have a growing importance in sustainable agriculture and forestry, namely in the implementation of integrated pest management (IPM) and organic farming. Sustainable farming systems provide a vital contribution to the Union's transition to sustainable food systems, as set out in the Commission's Communication 'A Farm to Fork strategy for a fair, healthy and environmentally-friendly food system' and the Commission's Communication on a 'European Green Deal', and supported by the future Common Agricultural Policy. The use of BCAs in this context helps to reduce dependence on chemical plant protection products";[80]

- "*Some substances that may be low-risk, such as micro-organisms, botanicals and semiochemicals (e.g. pheromones), also proved to have different characteristics than conventional chemical active substances used for plant protection*".[81]

49. Under the hypothesis that a separate 'biocontrol products act' were to be proposed, the Commission has broadly two choices for the authorisation process. It can model it on the decentralized approach for PPPs under Regulation 1107/2009 where each Member State issues a separate marketing authorisation, albeit with a system of mutual recognition in place. Alternatively, the Commission can opt for a centralized authorisation process where one authorisation is valid across the entire EU (which is generally considered to be faster). In the past, the EU legislator has opted for a centralised authorisation procedure in *inter alia* the following areas:

- Articles 7-9 of the Feed Additives Regulation[82] establishes a common procedure for authorising feed additives that leads to authorisations, issued in the form an Implementing Regulation, valid for 10 years throughout the EU and the European Economic Area (EEA);

- In accordance with Articles 10-12 of the Novel Food Regulation[83], food business operators can place a novel food on the EU market only after the Commission has processed an application for the authorisation of a novel food, and has adopted an implementing act authorising the placing on the market of a novel food and updating the Union list;

- As mentioned in the above-discussed Regulation on advanced therapy medicinal products, "*all other modern biotechnology medicinal products currently regulated at EU level are subject to a centralised authorisation procedure*".[84]

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[80] 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.

[81] Expert Group on Sustainable Plant Protection, 'Implementation Plan on increasing low-risk plant protection product availability and accelerating integrated pest management implementation in Member States', 10 June 2016, p. 7.

[82] Regulation (EC) No 1831/2003 on additives for use in animal nutrition.

[83] Regulation (EU) 2015/2283 on novel foods.

[84] See recital (9).

For biocontrol products in particular, **the possibility of establishing a centralised authorisation procedure, to promote them in the EU, has already been part of official discussions at EU institutional level for some time**:

- In 2016, under the impulse of the then Dutch Council Presidency, the Expert Group on Sustainable Plant Protection presented an 'Implementation Plan on increasing low-risk plant protection product availability and accelerating integrated pest management implementation in Member States' with the recommendation vis-à-vis the Commission to "[e]*xplore advantages and disadvantages of a renewed zonal or Union authorisation procedure for low-risk products, which provides simultaneous single application for the same zone (directly applicable with no mutual recognition needed) or even for all EU countries in the same time (similar to the EU authorisation procedure for biocides)*".[85] The Dutch Presidency supported this Implementation Plan and encouraged other Member States and the Commission to do the same.[86]

- In 2007, a Commission-funded project (REBECA) acknowledged that the number of biocontrol products on the European market was low in spite of considerable research and worldwide uptake in integrated crop protection programmes, which aimed to accelerate the introduction of biocontrol solutions.[87]

- More recently, in 2022, the Final Opinion on Biosolutions of the Commission's Fit for Future Platform noted that while recent modifications can serve as a short- to mid-term fix, these are "*insufficiently conducive to achievement of the Farm to Fork targets* (…)".[88] Among the 10 suggestions presented, the report's suggestion 5 advocates to "*further develop the regulatory framework for biological control products*".

F. Principle of proportionality

50. The principle of proportionality, enshrined in Article 5(4) TEU and Protocol (No 2) on the Application of the Principles of Subsidiarity and Proportionality, obliges the EU authorities to strike a balance **between the means used and the intended aim** in the exercise of their powers.[89] Legislative intervention must be both **appropriate** to attain its objectives and **indispensable** in the sense that it cannot go beyond what is necessary to achieve said objectives.[90]

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[85] Expert Group on Sustainable Plant Protection, 'Implementation Plan on increasing low-risk plant protection product availability and accelerating integrated pest management implementation in Member States', 10 June 2016, p. 26.

[86] See Council of the EU, 'AGRIFISH Council meeting on 27 and 28 June 2016: Acceleration of Sustainable Plant Protection', which mentions as subject "*Endorsement of the implementation plan (including the recommendations)*".

[87] REBECA (Registration of Biological Control Agents), 'Final Activity Report'.

[88] European Commission, 'Fit for Future Platform Opinion on Biosolutions', 13 December 2022, p. 14.

[89] LENAERTS K. and VAN NUFFEL K., *European Union Law*, Sweet & Maxwell, 2011, p. 141.

[90] *Ibid.*, 143.

Legislative action is deemed indispensable when **no alternative legislative measure can achieve the same effectiveness for the intended aim while being less harmful to other aims or interests** protected by EU law. This means that, while a legislative measure may be appropriate, it should not entail needless adverse effects.[91]

51. A dedicated biocontrol products act seems more in line with the principle of proportionality, from two perspectives. Firstly, the regulatory burden of Regulation 1107/2009,which reportedly does not align well with the biological nature of biocontrol products, may harm the economic interests of operators.[92] These interests are moreover protected by primary EU law, notably Article 16 of the EU Charter of Fundamental Rights, which safeguards the freedom to conduct a business. Secondly, the above-discussed tailored approach aligns with the broader policy pursued by the EU to promote alternatives to synthetic PPPs (discussed in para. 4) and encapsulates a more long-term vision.

G. Facilitation under EU institutional law

52. Although going beyond the purpose of the present memorandum, in our view, amending Regulation 1107/2009 to carve out biocontrol products does not inherently carry the risk of 'opening' a discussion on the Regulation at large.

53. Firstly, it seems possible to introduce targeted amendments to Regulation 1107/2009 via the separate biocontrol products act, provided it is a principal legislative act, adopted through the ordinary legislative procedure. Where an act with autonomous provisions alters the legal context of a given field to such an extent that other acts governing other areas within the same field need to be amended, it is acceptable to also set out amending provisions in the same act.[93] This is acceptable on the condition that the amendment is secondary to the main scope of the act.[94]

54. This very approach was used for biostimulants. Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 introduced a new framework for fertilizers. It also contained provisions on biostimulants. Article 47 of Regulation 2019/1009 amended Article 2.1(b) to remove biostimulants from the scope of Regulation 1107/2009. **This could serve as an example for biocontrol products. Indeed, creating a separate biocontrol products act would arguably require minimal changes to**

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[91] See for example judgment of the Court of 6 December 2005, Joined cases C-453/03, C-11/04, C-12/04 and C-194/04, *ABNA and Others*.

[92] This is also reflected in Article 5, last sentence of Protocol (No 2) on the Application of the Principles of Subsidiarity and Proportionality: "*Draft legislative acts shall take account of the need for any burden, whether financial or administrative, falling upon the Union, national governments, regional or local authorities, economic operators and citizens, to be minimized and commensurate with the objective to be achieved*" (emphasis added).

[93] § 19.1 European Union, Joint Practical Guide of the European Parliament, the Council and the Commission for persons involved in the drafting of European Union legislation ('**Joint Practical Drafting Guide**').

[94] If this is not the case (i.e. if the act effectively becomes primarily intended to be an amending act, for example because there are too many amending provisions), the act should be split into two separate acts, § 19.4 Joint Practical Drafting Guide.

the substantive provisions of Regulation 1107/2009. Essentially, only micro-organisms would be removed from the Regulation's scope, with specific provisions for biocontrol products being consolidated into a separate act. This approach is likely less burdensome and complex than a comprehensive overhaul of Regulation 1107/2009 to better accommodate biocontrol products.

55. Secondly, Regulation 1107/2009 could be amended via 'recasting'. **Recasting** involves adopting a new legal act that combines the amendments and unchanged provisions of an earlier act into a single text, replacing and repealing the original act.[95] As a legislative technique, it enables a focused approach on the proposed amendments.[96]

56. Lastly, although not officially recognised by the Treaties, the European Commission has the right to withdraw a legislative proposal under certain conditions. This right is a *de facto* corollary to the Commission's right of legislative initiative. As has been recognised by the EU Court of Justice, **if the Parliament and Council introduce an amendment to a legislative proposal that alters it so significantly that it effectively undermines its purpose, the Commission has the right to withdraw** the proposal but must do so with respect for the principle of sincere cooperation enshrined in Art. 13(2) TEU.[97] Arguably and insofar as necessary, the right of withdrawal (as opposed to the right to propose legislation) may act as a political 'deterrent' for the co-legislators to attempt starting a broader discussion on the potential amendments to Regulation 1107/2009. The limits to the amending power of the co-legislators were recently confirmed in Case C-24/20.[98] In that case, the European Commission challenged the Council's decision to modify its proposal regarding the EU's accession to the Geneva Act of the Lisbon Agreement on Appellations of Origin and Geographical Indications. The Commission asserted that the Council's amendment infringed on its right of initiative by allowing Member States to also accede. The Court ruled in the Commission's favour, stating that the Council had distorted the proposal's subject matter and objectives, violating the principles of conferral and institutional balance.

H. Alignment with international policy

57. As plant pests and diseases do not know national borders, biocontrol is also treated as an **international issue**. International organizations, such as the Organisation for Economic Co-operation and

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[95] Interinstitutional Agreement of 28 November 2001 on a more structured use of the recasting technique for legal acts, OJ C 77, 28.3.2002, p. 1–3.

[96] See Rules of Procedure of the European Parliament - 9th parliamentary term, July 2019, OJ L 302, 22.11.2019, p. 1–128, Rule 110.3: "(…) *In such a case, over and above the conditions laid down in Rules 180 and 181, amendments shall be admissible within the committee responsible for the subject-matter only if they concern those parts of the proposal which contain changes. However, amendments to parts of the proposal which remain unchanged may, by way of exception and on a case-by-case basis, be accepted by the Chair of the committee responsible for the subject matter if he or she considers that this is necessary for pressing reasons relating to the internal logic of the text or because the amendments are inextricably linked to other admissible amendments. Such reasons must be stated in a written justification to the amendments.*"

[97] Judgment of the Court of 14 April 2015, Case C-409/13, *Council v. Commission*, para. 83.

[98] Judgment of the Court of 22 November 2022, Case C-24/20, *Commission v Council*.

Development (**OECD**) and the Food and Agriculture Organization of the United Nations (**FAO**), have frequently addressed biocontrol as a distinct issue.

When discussed in these international fora, a recurring theme is the **unique nature of biocontrol products** compared to chemical alternatives, which should accordingly be **reflected in the applicable regulatory and legal framework**. See e.g.:

- "*In most countries, microbials, botanicals and semiochemicals are evaluated and registered following the same system as for conventional chemical pesticides. However, this approach can pose an unnecessarily high and inappropriate regulatory burden. This is because many, if not most, of the data requirements and evaluation criteria are not relevant to biological pest control agents (e.g. the data requirements for chemical identity are not relevant for a microorganism but appropriate studies on taxonomy are critical). Further, the level of risk resulting from the use of biological pest control agents is often lower than for conventional chemical pesticides, so higher tier testing is usually unnecessary.* (…) *Therefore, registration authorities may wish to consider including specific provisions for biological pest control agents in existing legislation regulating chemical pesticides, or developing separate and specific legislation or regulation for biological pest control agents. Harmonization of the different approaches is important for streamlining and facilitating the research, development, commercialization and use of biopesticides for plant protection and public health. Using similar data requirements and evaluations should make it easier for applicants to submit applications to different countries and for regulatory agencies to benefit from each other's reviews*".[99] (emphasis added)

- "*Biological pesticides act differently from chemical pesticides, so different data are required for their registration*".[100] (emphasis added)

There has been an international push for countries to assess biocontrol products differently from chemical pesticides. **This push emphasizes that not all data requirements for synthetic pesticides are relevant or useful for biocontrol products**, which generally pose a lower level of risk. International organizations have even advised regulating biocontrol products in standalone legislation. Therefore, a separate EU biocontrol products act would align with these international discussions and recommendations.

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[99] Food and Agriculture Organization of the United Nations and World Health Organization, '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 uses', 7 December 2017, p. 1.

[100] Organisation for Economic Co-operation and Development, 'Data Requirements and Approaches to Biological Pesticide Registration', 11 February 2022.