European Biostimulants Industry Council

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EXTERNAL CONTRIBUTION

EBIC comments to item 3.3 FAQs-1.3_DK remarks_2.docx

Title: FAQ on the Fertilising Products Regulation (FPR) – Question 1.3: "Does the FPR cover fertilising products containing substances or microorganisms which have a pesticide effect, such as copper compounds or calcium cyanamide?"

Link: CIRCABC Link to the FAQ document

BIC's Contribution to the Discussion on Multiple Use and Regulatory Clarity:

The European Biostimulants Industry Council (EBIC) has the following comments in response to the Danish authorities' remarks on Question 1.3 of the European Commission's FAQ on the Fertilising Products Regulation (FPR). EBIC's contribution is aimed at ensuring that the regulatory framework remains clear, consistent, and supportive of innovation within the biostimulant sector, particularly concerning the principles of multiple use and product classification based on intended function.

Introduction

Clarifying Product Function and Regulatory Scope

It is essential to clearly distinguish between the 'function' of a product and the 'effects' of substances that may be contained therein. As articulated in COMMISSION DELEGATED REGULATION (EU) 2021/1768 of 23 June 2021, which amends Regulation (EU) 2019/1009, an EU fertilising product containing an active substance is not classified as a plant protection product (PPP) unless it is intended to have a plant protection function. Specifically, Article 5a inserted into Annex I, Part II of Regulation (EU) 2019/1009 states:

- "An EU fertilising product may contain an active substance within the meaning of Article 2(2) of Regulation (EC) No 1107/2009 only if that EU fertilising product does not have a plant protection function within the meaning of Article 2(1) of that Regulation."

The intended uses, as defined in the Plant Protection Products Regulation (Regulation (EC) No 1107/2009), include:

- Protecting plants or plant products against harmful organisms
- Influencing the life processes of plants other than as a nutrient or a biostimulant
- Preserving plant products, provided the substance is not classified as a preservative under special Community provisions

- Destroying or preventing the growth of undesired plants, except in certain exempt cases

An intended use as a plant biostimulant is explicitly excluded from the scope of the plant protection regulation. Therefore, the intention is an integral part of the function.

This nuanced distinction is crucial for defining a product's function, emphasising that a product qualifies as a PPP if it is intended for such uses; that means that incidental effects that are not part of the intended use, do not affect that product's function. Furthermore, article 2 of the PPP regulation specifies that, "This Regulation shall apply to **products, in the form in which they are supplied to the user**… and **intended for one of the following uses**…"; this clarifies that it function is applied at the level of the product, and not one of its component parts. The clarification helps ensure that products are marketed and used in compliance with their defined functions, avoiding misclassification and promoting regulatory transparency.

Specific comments

Regulatory Oversight and Conformity Assessment

- **Conformity Assessment:** The Fertilising Products Regulation (FPR) operates on the principle of conformity assessment to essential quality and safety requirements. As outlined in the European Commission's Blue Guide on the implementation of EU product rules, this approach ensures that products are considered compliant if they meet the relevant essential requirements, without requiring formal approval processes. Presumption of conformity is granted to report data that is produced using a "harmonised European standard" that has been explicitly linked to the FPR. This approach is crucial for ensuring efficiency and proportionality in the conformity assessment process.
- **Role of Notified Bodies:** We recognise and advocate for the utilisation of Notified Bodies in performing conformity assessments. These bodies play a critical role in ensuring that the methodology developed is practical, sustainable, and streamlines the process for faster times to market, while still ensuring compliance with EU standards.
- **Market Dynamics:** It is crucial that regulatory definitions are aligned with how products are sold, as only market behaviours can be effectively monitored. This alignment ensures that products are used as intended and prevents off-label use, thereby maintaining regulatory integrity.

Other observations / suggestions

Evaluating Function Beyond Dosage Considerations

We emphasise that the function of a product should be primarily determined by its intended use rather than the dosage (or any other single characteristic) alone. Focusing solely on dosage can lead to misconceptions and potentially restrict the innovative use of substances in lower dosages or different formulations for biostimulant purposes. Regulatory guidance should also consider other parameters like application rate, timing, method of application, formulation,

and the specific conditions under which the product is used, all of which can influence the function. These factors are crucial in determining the function of a product as either a PPP or a biostimulant, ensuring that the same component can contribute safely and effectively to plant biostimulation in one context while serving a protective role in another since each product provides a different function.

Maintaining Regulatory Integrity

- **Addressing Off-Label Use:** Off-label use is inappropriate and should be managed by market surveillance. EBIC deplores off-label uses for plant protection of any product that is not authorised for plant protection. Our Code of Conduct forbids such unethical practices. However, the way to avoid such misuse is by ensuring that product claims are clear and supported by robust data, thus preventing misuse while fostering trust in the regulatory system. The data supporting plant biostimulant claims are reviewed by Notified Bodies during the conformity assessment process.
- **Ensuring Compliance through Conformity Assessments:** Conformity assessments are intended to ensure that products are compliant with their intended uses as stated on the label. Manufacturers should provide empirical documentary evidence, such as historical data, comparative studies, or documented use cases, to support their claims. However, it is crucial that this does not evolve into a requirement for specific testing aimed at proving the absence of a PPP effect for components of the product; the function is determined as stated above by the intended use, supported by the product characterisation and data to justify claims. This approach not only supports regulatory simplification but also ensures that the FPR remains practical, effective, and proportionate to the risks and benefits involved.
- **Enforcement and Coordination:** Effective policing and enforcement of off-label uses require is primarily the responsibility of market surveillance officers but benefits from cooperation between national authorities, Notified Bodies, manufacturers, and those working under other regulatory frameworks like the PPPR. This coordination is essential for maintaining the integrity of the regulatory environment and ensuring that products remain within their intended use.

Simplification of Regulatory Language

We support the need to maintain clear and non-restrictive regulatory interpretations. The term "account for" is imprecise and could lead to overly burdensome requirements that would necessitate proving the absence of a pesticide effect through extensive trials, regardless of the manufacturers intentions; it is therefore counter to one of the fundamental principles of product function: that intended use is the primary determinant. Instead, we advocate for regulatory language that focuses on behaviours that can be easily monitored, such as clear labelling and marketing based on intended use, thereby simplifying compliance and reducing the risk of misinterpretation. This approach ensures that the regulation supports innovation while maintaining necessary safeguards.

Regulatory consensus should not be re-opened *ad infinitum*

While we welcome clarifications that enhance understanding and compliance, we also recognise the importance of building upon the established regulatory consensus. The

discussions surrounding the function of biostimulants versus effect of their active substances have been comprehensive, involving extensive stakeholder consultations. This established consensus has effectively supported the development of clear regulatory pathways and fostered innovation within the industry. Moving forward, it is beneficial to continue these discussions constructively, enhancing our collective understanding and application of the regulations without revisiting previously resolved debates unnecessarily. The text cited above from REGULATION (EU) 2021/1768 of 23 June 2021 was introduced specifically to address this issue concerning the classification of products by function, including intended use.

Moreover, under the EBIC Code of Conduct, our members are committed to marketing their products transparently and in strict adherence to regulatory classifications, ensuring that any claims of plant protection benefits are appropriately authorised to maintain product integrity and compliance. EBIC and its members play a leadership role in encouraging all companies in the industry to adhere to the same standards of ethical business practices.

Proposed Approach and Ensuring Compliance and Innovation

EBIC therefore advocates for a regulatory focus on the intended function of biostimulants, as explicitly stated on product labels and in marketing materials, and substantiated by the data provided during the conformity assessment to support claims justification. Conformity assessments should ensure that products meet safety and efficacy standards for their claimed functions without imposing the burden of disproving unclaimed effects. By maintaining these distinctions and ensuring that product claims do not include PPP functions unless appropriately authorised, regulators can ensure compliance with EU regulations while fostering innovation within the biostimulant sector.

Thank you for considering our comprehensive perspective. We look forward to continuing this important conversation and finding a path forward that supports safe, innovative, and sustainable agricultural practices.

Supporting documents

CIRCABC Link to the FAQ document

European Commission's Blue Guide on the implementation of EU product rules

References

COMMISSION DELEGATED REGULATION (EU) 2021/1768 of 23 June 2021 amending Annexes I, II, III, and IV to Regulation (EU) 2019/1009 of the European Parliament and of the Council laying down rules on the making available on the market of EU fertilising products. Official Journal of the European Union, L 356/1, 8 October 2021. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021R1768&qid=1633946581524

ABOUT EBIC

The European Biostimulants Industry Council (EBIC) promotes the contribution of plant biostimulants to make agriculture more sustainable and resilient and in doing so promotes the growth and development of the European Biostimulants Industry. Our mission is to ensure biostimulant technologies are valued as integral to sustainable agriculture, while securing an enabling regulatory framework for all of them. For more information about this topic, please contact **David Barton** (david@prospero.ag).