EBIC rejects the new version of the answer to FAQ 1.3

This paper outlines EBIC's position on the European Commission's FAQ 1.3 (December 4 2024), which is supposed to provide guidance on the question of whether the FPR covers fertilising products containing substances or microorganisms which have a pesticide effect.

While EBIC recognises DG GROW's efforts to provide clarity on this question, our members are concerned that the text that was recently inserted in the answer to this FAQ contradicts established regulatory principles, goes beyond the FPR requirements, triggers uncertainty around access to the EU Single Market and cannot be implemented in practice.

Therefore, EBIC would like to urge DG GROW to **remove the new text from the published answer to FAQ 1.3, effectively going back to the version from 29 March 2024**, which captured the compromise reached by the Commission Expert Group on Fertilising Products (CEG-FP) after several consultations.

EBIC's position is in line with Fertilizers Europe's position on this topic. Our members remain open to transparent discussions on FAQ 1.3.

Background

The FAQ 1.3 was intended to provide clarity on a historical issue: how to classify products containing substances or microorganisms with multiple potential effects that can be included in different products that fulfil different functions. For example, components such as copper or iron sulphate are used in products intended to be used as fertilising products or as plant protection products (PPPs).

The classification of fertilising products versus PPPs has been the subject of extensive stakeholder consultations and legislative developments. Over time, a clear regulatory consensus has emerged, codified in key instruments, including the Fertilising Products Regulation (FPR) [Regulation (EU) 2019/1009] and the Plant Protection Product Regulation (PPPR) [Regulation (EC) 1107/2009], as well as national rules.

These regulatory instruments reflect a **consensus built over years of consultations** involving the European Commission, European Parliament, European Council, national authorities, industry and many other stakeholders, which has provided clarity and predictability for manufacturers, fostering investment in innovative agricultural inputs.

While the principle that **intended use defines classification** is clear and was maintained in the first part of the answer to 1.3, the recent addition of text suggesting the need for evidence of **crop or dosage differences** or **absence of pesticide function**[1] deviates from established regulatory practice. This

[1] The text changed from:

additional text pretends to shift the burden of proof onto manufacturers to demonstrate absence of certain effects for uses that are not intended, which, in essence:

- Contradicts the established principle of classification by intended use.
- Implies pre-market obligations that go beyond the scope of the FPR.
- Creates non-proportional requirements for manufacturers to demonstrate what their product is not.
- Creates practical and operational challenges, given the undefined scope of such evidence.
- Casts doubts on the robustness of EU legislation.

EBIC's concerns about the new answer to FAQ 1.3

A more detailed explanation of EBIC's concerns can be found in the Annex. In a nutshell, EBIC believes that the current answer to FAQ 1.3:

- **Contradicts Established Classification Principles**: Product classification under FPR and PPPR is based on intended use. Requiring manufacturers to prove the absence of unintended functions contradicts this principle and diverges from how products are classified across many sectors in the EU.
- **Undermines Regulatory Stability**: The established framework for classifying fertilising products and PPPs has been built through extensive stakeholder consultation. Revisiting these principles in a non-legally-binding document without broad support creates uncertainty, undermines trust and discourages further investment.
- **Threatens Market Harmonisation**: The new requirements may push manufacturers toward national rules instead of the harmonised EU pathway envisaged under Article 115 TFEU and the FPR, thereby increasing barriers to trade.
- **Creates Practical Implementation Challenges**: The additional evidence required by the new text is vaguely defined, not mandated by the FPR and it sits outside the conformity assessment procedure.
- **Raises Questions About the FAQ's Validity:** The FAQ document is intended to facilitate the implementation of the FPR and provide clear guidance. It should not introduce new requirements unsupported by legal text. Furthermore, the answers should reflect transparent discussions within the Commission Expert Group on Fertilising Products and the agreement of the majority.
- **Suggests a Need for revisiting the question:** FAQ 1.3 was originally raised years ago when the FPR was newly published. While the answer has been revised multiple times to clarify certain

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"In such case, the product/formulation containing this substance or microorganism can fall under the scope of the FPR if the manufacturer can explain and account for through documentary evidence, why at the proposed use instructions, the product complies to the conditions of the FPR and does not have a pesticide function" (version of 29 March 2024) to
"In such case the product/formulation containing this substance or microorganism can fall under the scope of the FPR if the manufacturer can explain and account for through documentary evidence, why at the proposed use instructions, the product complies to the conditions of the FPR and does not have a pesticide function either 1) justify based on a comparison of the crop and dosage specified in the pesticide approval and the user instruction specified on the label intended for the FPR that e.g. dosage as a EU-fertilising product is significantly lower than the efficient pesticide dose rate or 2) provide documentary evidence, in the form of experiments performed with the specific plants and organisms included in the pesticide approval, demonstrating that the EU-fertilising product does not have a pesticide function when used according to the user instructions specified on the FPR label" (version of 4 December 2024).

aspects, the core concept remained stable. However, the new text introduces a completely different approach, jeopardising the understanding of key terms such as “function” and “effect”. This suggests that the question and the answer could benefit from rephrasing to avoid further confusion and provide clearer guidance.

Conclusion

EBIC acknowledges DG GROW’s commitment to providing regulatory clarity for the classification of fertilising products under the FPR. Our members have consistently supported the core principle in FAQ 1.3 that product classification is based on intended use.

However, the new text introduced in FAQ 1.3, specifically the suggestion for comparative justification or experimental evidence, represents a significant departure from this well-established regulatory consensus. This shift undermines regulatory stability, creates uncertainty around market access and threatens harmonisation efforts by placing disproportional burdens on manufacturers.

Given the purpose of the FAQ document, the vagueness of the new text, and the experience gained since the application of the FPR, EBIC strongly recommends **reverting to the previous version of FAQ 1.3 from 29 March 2024**, which had broad support within the CEG-FP. Our members support Fertilizers Europe's similar position on this topic.

EBIC remains committed to working collaboratively with DG GROW and the CEG-FP to consolidate a regulatory framework for fertilising products that safeguards public interests while encouraging innovation and sustainable growth. We believe a balanced approach that upholds the principle of classification by intended use, that enhances post-market surveillance, and reinforces established regulatory consensus can address concerns without imposing unnecessary burdens.

If further clarification is required, EBIC is open to engaging in transparent discussions to refine both the question and answer of FAQ 1.3 to ensure they provide clear and effective guidance.

References

1. **FPR 2019/1009** – Regulation of the European Parliament and of the Council laying down rules on the making available on the market of EU fertilising products.
   Link to full text
2. **PPPR 1107/2009** – Regulation concerning the placing of plant protection products on the market.
   Link to full text
3. **REGULATION (EU) 2021/1768** – Amending Annexes I, II, III, and IV to FPR 2019/1009 concerning labelling and permitted compositions of EU fertilising products.
   Link to full text
4. **The European Commission’s Blue Guide on the implementation of EU product rules** – Guidance document outlining key principles of product classification, conformity assessment, and enforcement.
   Link to Blue Guide
5. **EBIC’s Submission to FAQ 1.3 – September 2024** – EBIC’s detailed comments on the earlier draft of FAQ 1.3, highlighting concerns about proportionality, regulatory clarity, and market access.
   Link to full text

Annex – EBIC's concerns in more detail

Contradicting the foundations of product classification

The new text in the answer to FAQ 1.3 undermines the core principle of classification by intended use, which underpins both the FPR and PPPR. Products are classified based on their **declared function**, verified through conformity assessments by Notified Bodies when applicable (e.g., PFC 6).

Requiring manufacturers to disprove potential effects beyond intended use shifts the regulatory focus to incidental effects, creating a double standard. While PPPs are not required to prove the absence of fertilising effects, the new text in FAQ 1.3 suggests that fertilising products would need to disprove pesticidal effects. However, a plant biostimulant designed to enhance nutrient efficiency should not need to disprove incidental plant protection effects, as this contradicts conformity assessment principles.

This approach also jeopardises the ability to use beneficial components across different product categories, which is essential for fostering innovation in sustainable agriculture. Components such as copper, iron sulphate, or yeast (*Saccharomyces cerevisiae*) are used in the formulations of many different products intended for varied functions.

Such an imbalance imposes unnecessary burdens on manufacturers, stifles innovation, and undermines the flexibility required to develop versatile, sustainable agricultural inputs.

Undermining regulatory stability

The classification of fertilising products and plant protection products has already been extensively debated, resulting in a clear, well-established regulatory framework. Revisiting this classification in a non-legally-binding FAQ without broad support risks destabilising the regulatory foundation for placing critical agricultural inputs on the market, eroding trust, and discouraging further investment.

Manufacturers of fertilising products have made significant investments to comply with the requirements of the FPR and gain access to the EU single market. Introducing new requirements without legal clarity or broad consensus creates uncertainty around these investments, hinders market access and hampers innovation.

The FPR establishes "rules on the making available on the market of EU fertilising products", classifying them by function rather than regulating their use. Shifting focus to unintended effects through an FAQ adds unwarranted complexity, misaligns with the FPR's purpose, and jeopardises its role in fostering regulatory certainty and harmonisation.

Threatening harmonisation

A key objective of the FPR under **Article 114 of the Treaty on the Functioning of the European Union (TFEU)**, is to harmonise the EU single market for fertilising products. The proposed requirements risk fragmenting the market by:

- **Encouraging national routes**: Companies may opt for national rules that do not require comparative justification or experimental evidence of absence of function, leading to inconsistencies in market access across member states.
- **Increasing Trade Barriers:** Increased regulatory complexity and costs discourage cross-border trade, undermining the harmonisation achieved by the FPR.

Disproportional Implementation Challenges

The additional evidence suggested in the new text is impractical and vague. Key concerns include:

- **Legal Misalignment:** The new requirements fall outside the legal scope of the FPR and the established conformity assessment procedure. This makes them impossible for Notified Bodies to verify, and difficult for market surveillance authorities to enforce.
- **Vague Definitions and Scope:** The new text is vaguely defined and open to a wide range of interpretations. Among other issues, it confuses concepts such as “function” or “effect”, creating uncertainty about compliance. Why would a manufacturer need to test a function that is not part of the intended use of a product? Wouldn’t that be an effect?
- **Ambiguity Around “Pesticide Approval”:** It is unclear whether the term “pesticide approval” refers to active substances registered at EU level or plant protection products authorised at member state level, leading to uncertainty around the scope of the evidence needed. Additionally, there is no explanation of why a particular “pesticide approval” would be comparable to a certain fertilising product.
- **Undefined Testing Parameters**: The text fixates on dosages or rates as the main differentiation factor, and fails to specify how many crops, application methods, pests, or environmental conditions should be tested, making compliance burdensome and unpredictable.

These ambiguities impose significant uncertainty on manufacturers regarding the evidence needed for regulatory compliance. This is especially problematic given that these requirements go beyond the FPR’s legal framework, creating unnecessary complexity and costs that undermine the goals of harmonisation and innovation.

Challenging the validity of the FPR FAQ document

The primary role of FAQs is to facilitate the implementation of the FPR by providing clear and practical guidance. The first part of the answer to FAQ 1.3 correctly reinforces the legal principle that products are classified based on their declared function. However, the new suggestions for comparative justification or absence-of-function evidence go beyond clarification. Rather than shedding light on existing rules, these additions create uncertainty by demanding extensive evidence beyond what is necessary to ensure compliance.

The proposed amendment to FAQ 1.3 is based on a comment from a single member state. During the November 2024 meeting, several Member States questioned the necessity and feasibility of the proposed changes, highlighting the lack of consensus.

Including such a controversial amendment in a published FAQ document undermines the principles of transparency and collaboration that are critical to regulatory guidance. It also risks setting a dangerous precedent where FAQs become a vehicle for introducing de facto regulatory changes without proper consultation or legal backing.

If FAQs are to remain a trusted tool for stakeholders, their content must reflect legal frameworks and the consensus of the regulatory community. Without this, the FAQ could lose its credibility as a reliable source of guidance for implementing the FPR.

Suggesting that a revision of the entire question might be needed

FAQ 1.3 was initially raised many years ago to clarify the boundary between the FPR and the PPPR, at a point in time when the FPR had just been published and the PPPR had subsequently been amended to exclude plant biostimulants from the definition of PPPs.

Since then, the answer to FAQ 1.3 has been revised multiple times within the CEG-FP. For years, the core concept of the answer has remained stable while the CEG-FP tried to clarify some aspects of it. EBIC was pleased to participate in those discussions and bring the point of view of the industry, which was always acknowledged.

However, the new answer to FAQ 1.3 completely changes the approach and threatens the understanding of key terms such as “function” (i.e., purpose or task of a specific product type or category established by a legal framework based on its intended use or claims made for the product) or “effect” (i.e., the change that the product brings about in the plant or the soil/rhizosphere compared to a control).

EBIC recommends reverting to the previous version of FAQ 1.3, as also recommended by Fertilizers Europe. If needed, EBIC would be willing to participate in a transparent revision of the question and answer to ensure they meet their intended purpose.

For more information on this topic, please contact sara.gfiguera@prospero.ag