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EXTERNAL CONTRIBUTION

EBIC comments to “Draft EU survey on possible future development of the FPR”

The European Biostimulants Industry Council (EBIC) welcomes the European Commission’s initiative to launch a survey to propose new materials and microorganisms for inclusion into the Fertilising Products Regulation [Regulation (EU) 2019/1009], as expressed in the “Draft EU survey on possible future development of the FPR”, to which EBIC would like to make the comments developed in this document.

In summary, EBIC would like to highlight the need to grant confidentiality for some of the business-critical information that is being required under this survey, and to point out that the timelines that the Commission is currently proposing will place a significant burden on innovation, particularly for microbial plant biostimulants and other materials that EBIC had already proposed for inclusion in the FPR in past calls, notably the ones that were separately launched in November of 2021.

Europe is increasingly suffering the consequences of climate change and is facing an unprecedented fertiliser supply crisis. EU farmers need access to a wider range of fertilising products now, not in five years. For this reason, key components of plant biostimulants, which improve tolerance to abiotic stress, increase nutrient availability and nutrient use efficiency, should be expedited for inclusion in the FPR, especially where products incorporating these components are already sold in several Member States that have evaluated them as safe and effective.

Introduction

The meeting of the Commission Expert Group on Fertilising Products (CEG-FP) that took place on April 4th and 5th included one point on the agenda that concerned a potential technical amendment to the FPR to allow the inclusion of new materials and microorganisms in Annex II of the FPR. Under this agenda point (4.1), the Commission (DG GROW) presented the draft of a survey to collect data for future developments of the FPR¹, which was shared with CEG-FP members and observers through CIRCABC on March 30th.

During the CEG-FP meeting, DG GROW indicated that the timeline associated with the survey would be to collect comments to the draft survey until April 30th, to launch the survey in mid-May, to leave it indefinitely open, but closing the first round of proposals by September, and

¹ “Draft EU survey on possible future development of the FPR”, available on CIRCABC: <https://circabc.europa.eu/ui/group/36ec94c7-575b-44dc-a6e9-4ace02907f2f/library/8345aa04-88fd-469f-9501-aff563a467ad/details>

then to mandate a study by an external contractor to assess if there was sufficient evidence of trade potential, agronomic efficiency and safety from those materials to justify an amendment to Annex II in the FPR.

Although it was not specifically mentioned during the CEG-FP meeting, DG GROW had previously indicated in a note from November 2021² that the study would be launched in 2023 and would take 2-3 years to be completed. Moreover, the note from November 2021 indicated that the study would not be a regular exercise and would only be launched every 3-4 years.

EBIC would like to highlight the importance of having an agile procedure for new materials to be included in the FPR to allow for innovation in the fertilising products sector. The current timeline, which implies the launching of the study in 2023, 2-3 years to complete it, then the proposal for an amendment to be approved at the CEG-FP, and then the legal procedure to publish it, will imply a minimum 5-year delay from now for these new materials to reach the EU market, and a longer delay for any materials that are submitted after September.

This delay in accessing the EU market is particularly worrying for companies investing in microbial plant biostimulants, as EBIC pointed out in a position paper that was submitted for upload to CIRCABC ahead of the CEG-FP meeting³. To mitigate this delay, the position paper contained a proposal to:

- expedite the inclusion into CMC 7 of those microorganisms that are part of microbial plant biostimulants already lawfully placed on the market in the EU members states under national rules, which have proven their trade potential, safety and agronomic efficiency [see *non-exhaustive Table 1 in Annex*];
- while the EU survey and the study for new materials and microorganisms are ongoing.

The goal behind this proposal is to allow access to the EU market to some microbial plant biostimulants that comply with the requirements of Article 42, while companies are putting together and submitting the data required under the EU survey, and these data is being evaluated through the study by an external contractor.

In addition, EBIC made a proposal for the inclusion in the FPR of other new materials in response to the call that was launched after the CEG-FP meeting in November of 2021, under agenda point 6. Some of the materials proposed were: materials that had been left out of CMC 11 (vinasses from feed production, oilcakes treated with solvents, filter cakes, residues from seaweed extraction, residues from alkaline extraction from leonardite), hydrolysed proteins, hydro-alcoholic plant extracts, substances approved as food and feed additives, or blue-green algae. EBIC received no feedback on that proposal. Our understanding is that these materials could now be considered under this EU survey, but EBIC regrets the missed opportunity and the lack of communication regarding that consultation.

² See point 2.a in the “Note to the Commission expert group on Fertilising Products on procedural options for future developments of CMC 7, micro-organisms”, available on CIRCABC: <https://circabc.europa.eu/ui/group/36ec94c7-575b-44dc-a6e9-4ace02907f2f/library/0f26593e-a828-4fb1-9d8b-49c3ad89d43f/details>

³ EBIC position paper: “The Fertilising Products Regulation should allow microbial plant biostimulants to access the EU market in a way that fosters innovation”, available on CIRCABC at: <https://circabc.europa.eu/ui/group/36ec94c7-575b-44dc-a6e9-4ace02907f2f/library/68038b50-eb29-4f94-af0e-5ae2524aefe0/details>

Hoping that DG GROW and CEG-FP members will take into consideration EBIC's position paper on microbial plant biostimulants, as well as previous proposals for new materials, EBIC would like to make the following general and specific comments regarding the "Draft EU survey on possible future development of the FPR".

General comments

In general, EBIC members are confused about the scope of the study that will be launched based on the EU survey. If the aim of the EU survey and the subsequent study is to both develop the criteria for future developments of the FPR and to evaluate submissions to this survey (e.g., to include a microorganism in the CMC 7 positive list), this should be clearly indicated, and DG GROW should clarify what will happen with the data that is submitted in response to the majority of the survey questions.

In fact, EBIC members are very concerned about submitting data through the EU survey given the current lack of confidentiality provisions. This point was already raised during the CEG-FP meeting on April 4th-5th, and DG GROW indicated that they were exploring the capacities of the EU survey platform to allow confidential data submission. DG GROW also indicated that they would share the Commission's criteria to determine what would be considered "business-critical information" in case a request for information was received to justify a particular decision. EBIC members would absolutely need this information before submitting any data through the EU survey.

If no protection or safeguard is provided, companies would have little incentive to provide data, as it could later be used by competitors "for free". Thus, there should be a provision to ensure some form of protection of data (e.g., compensation), with a distinction between (a) data that is business-critical and (b) data that is proprietary, which could be accessible based on reasoned demand, but would not be allowed to be used for commercial purposes. For example, information such as production methods should be considered business-critical and not be made publicly available.

EBIC members would also like to inquire about the format of data submissions: will the survey supply an empty text box; will it give the option for an attachment to be uploaded? These details should be shared as soon as possible so that respondents can prepare their data submissions.

Finally, EBIC would like to request clarification about the sentence in page 2 of the draft, which states that "the study, which GROW/F2 is considering launching, will cover a selection of the proposals submitted via the EU survey in the period mid-May-1 September 2022". With regard to that sentence, EBIC would like to know which criteria will be followed to make any potential selection of proposals, and to point out that gathering data during the summer period will be very challenging for companies. Therefore, EBIC would like to suggest an extension of the deadline to submit proposals for the study at least until September 30th, 2022.

Specific comments

Specific comments to Section C:

- Question 4: Information provided here should have some form of protection in case it includes non-public information (e.g. specific assessments / screenings).
- Question 5: Information provided here needs to be considered as business-critical and not be made (publicly) available.

- Question 6: Information provided here needs to be considered as business-critical and not be made (publicly) available.
- Question 7: The agronomic efficiency of plant biostimulants will be assessed at the product level through the conformity assessment procedure. What type of evidence is supposed to be submitted here?
- Question 8: EBIC would like to point out that microorganisms are not generally tested for their plant biostimulant effects (as isolated components) in field trials. Trials for this purpose are usually conducted in the laboratory or under controlled conditions (greenhouses, growth chambers, etc.). What is usually tested in the field is a formulated product applied to a particular crop with certain use instructions, but microbial plant biostimulant products will be tested through the conformity assessment procedure, so what type of “technical information from field trials’ results” is expected to be submitted in response to this question? Moreover, what would be considered sufficient information to answer this question? In case no formulated product is available yet, what type of data would be expected? Also, if a formulated product is available, is the expectation to supply the same data as for conformity assessment?
- Question 9: The FPR already requires these analyses at the product level. Will manufacturers also have to run those analyses on the new components that they are proposing? Are they supposed to follow the same methods?
- Question 10: Information provided here should have some form of protection in case it includes non-public information. The volume of scientific literature available will greatly depend on the specific microorganism, and even on the particular strain within a microorganism species.
- Question 11: Information provided here should have some form of protection in case it includes non-public information. In fact, some of the data that is required under this question will have to be generated through specific studies concerning a particular microbial strain, which does not seem to be aligned with the current structure of the positive list under CMC 7. In addition, further clarification would be needed in terms of the scope of information required. Although EBIC members understand the rationale behind most of these data requirements, they would need further input from authorities for the interpretation and implementation of existing guidance documents, or the development of new guidance documents, to reply to this question. Apart from that, EBIC members would like to point out that asking for “residue levels of residual intermediates” is unheard of for plant biostimulants, and it would require both significant guidance from authorities and significant investment from companies to conduct the relevant studies, while the scientific evidence to support this requirement from a risk-management perspective is very weak. Overall, EBIC members would need much more guidance and confidentiality assurance from DG GROW and the CEG-FP to reply to this question.
- Question 12: EBIC would like to propose that any materials that have a positive reply to the two questions under 12 should be expedited for inclusion into the FPR without having to wait until the 2–3-year study by an external contractor is completed.

Specific comments to Section D:

- Question 1: Materials are marketed as part of products, so this question should be rephrased to something like “Is the material/micro-organism part of a product already marketed in more than one MS?”

- Question 2: Information provided here needs to be considered as business-critical and not be made (publicly) available.
- Question 3: Information provided here should have some form of protection in case it includes non-public information.

Specific comments to Section F: What is expected here, a drafting of the specific amendment that is being proposed in line with the legal text in the FPR?

Specific comments to Section G: Will all the supporting documents be required at the end of the survey, or through the different questions? Also, many of these supporting documents will contain business-critical information and should not be made (publicly) available.

Specific comments to Section H: EBIC would like to propose the addition of another option: (c) except my personal data and data marked as CONFIDENTIAL BUSINESS INFORMATION or BUSINESS-CRITICAL INFORMATION.

Other observations

Allowing new materials and microorganisms to be used as components of plant biostimulants for placement on the EU market under the FPR is crucial for innovation, and for helping EU agriculture face the current challenging circumstances.

Because plant biostimulants contribute to climate-smart agriculture and nutrient use efficiency, they can be important tools to help alleviate the impacts of the Ukraine crisis on the food chain and avert a secondary food crisis. Furthermore, they simultaneously contribute to the objectives in the European Green Deal and Farm to Fork Strategy. Peer-reviewed literature and manufacturer trials indicate that plant biostimulants can increase nutrient use efficiency by 5-10% or more under real-world conditions, while Europe is predicted to face a shortfall of 9% or more in its supply of nitrogen fertilisers this year⁴. Some microbial plant biostimulants that improve nitrogen availability or use efficiency could be particularly relevant to mitigate the impact of this shortfall, and there are many more than can solubilize phosphorus, improve tolerance to abiotic stress, improve quality traits, etc.

While EBIC understands that microorganisms which have not yet proven their trade potential, safety and agronomic efficiency are expected to submit the data required under the EU survey to go through the study for inclusion into CMC 7, EBIC would like to reiterate the proposal that was made in the position paper: to expedite the inclusion under CMC 7 of those microorganisms that have already proven their trade potential, safety and agronomic efficiency, so that they can help mitigate the effect of the current crisis on EU agriculture and allow for return on investment in the microbial plant biostimulants sector, while the EU survey and the study are ongoing.

⁴ EBIC position paper: "Plant biostimulants can alleviate a secondary food security crisis triggered by the conflict in Ukraine", available on CIRCABC at: <https://circabc.europa.eu/ui/group/36ec94c7-575b-44dc-a6e9-4ace02907f2f/library/b2bd24b1-8752-438e-8b16-868d40435d2b/details>

Supporting documents

1. EBIC position paper: [“The Fertilising Products Regulation should allow microbial plant biostimulants to access the EU market in a way that fosters innovation”](#).
2. EBIC position paper: [“Plant biostimulants can help prevent the Ukraine crisis from creating a secondary food security crisis”](#)

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.

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