European Biostimulants Industry Council

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POSITION PAPER

The Fertilising Products Regulation should allow microbial plant biostimulants to access the EU market in a way that fosters innovation

The European Biostimulants Industry Council (EBIC) welcomes the European Commission's intention to collect data on candidate materials and microorganisms for future developments of Annex II in the Fertilising Products Regulation (FPR) [Regulation (EU) 2019/1009], as stated on the agenda of the next meeting of the Commission Expert Group on Fertilising Products (CEG-FP) scheduled for April 4-5, 2022.

Since the FPR was published in 2019, EBIC has expressed concern about the **limited scope of the positive list under Component Material Category (CMC) 7** in Annex II in the FPR, which only allows four genera of microorganisms to be used as components of microbial plant biostimulants.

There are **many other microorganisms** that are **currently being used as components of microbial plant biostimulants,** or are **in the research and development phase**. In fact, the Commission already submitted a consultation to the Member States and stakeholders in 2021 to gather information about these microorganisms. Now, the Commission seems to be taking a step back proposing to launch a new EUSurvey about microbial plant biostimulants that will supposedly lead to a study to be started in 2023, which will last 2 or 3 years. **EBIC members are extremely concerned about the proposed timelines**, which would block access to the EU market and delay the establishment of harmonised rules for microbial plant biostimulants for several years, allowing the divergent national rules to dictate investments in innovation under uncertain circumstances for too many years while these solutions are desperately needed by EU growers.

Therefore, EBIC would like to propose **two parallel but ultimately convergent pathways** for the development of CMC 7 that would match the ambitions of the Commission and the CEG-FP, while allowing the industry to continue investing in microbial plant biostimulants. EBIC's proposal would be to **allow access to the positive list under CMC 7 to those microorganisms that have already proven their trade potential, safety and agronomic efficiency** as components of microbial plant biostimulant under national rules, **while the full study of new microorganisms and materials is ongoing.** EBIC is willing to collaborate with the Commission and the CEG-FP to enable the inclusion of these microorganisms in the FPR within a reasonable time frame that allows for investments in innovation, while the industry gathers the necessary data for the full assessment of any new microorganisms to be definitively included in the FPR.

Background information

The FPR established a specific Product Function Category (PFC) for microbial plant biostimulants [PFC 6(A)], which have to fulfil at least one of the plant biostimulant functions

defined for PFC 6, and "shall consist of a microorganism or consortium of microorganisms referred to in Component Material Category (CMC) 7" in the FPR. The approach taken in the FPR was to establish a positive list of microorganisms under CMC 7, in which only four genera of microorganisms were included in 2019: *Azotobacter* spp., mycorrhizal fungi, *Rhizobium* spp. and *Azospirillum* spp, with the provision to have undergone no other process than drying or freeze-drying.

This positive list opened the door for microbial plant biostimulants containing these four microorganisms to obtain CE marking, but it left many of the microorganisms that are commonly used outside the scope of the FPR. Even though microbial plant biostimulants with other microorganisms should still be allowed to be placed on the market under national rules when the FPR starts to apply in July 2022, these rules significantly differ among Member States, creating uncertainty among companies when it comes to investing in innovation.

When asked about the possibility to include new microorganisms under CMC 7, the Commission directed stakeholders to Article 42 in the FPR. This article allows the adoption of delegated acts that amend some of the Annexes in the FPR to adapt them to technical progress and facilitate internal market access and free movement for EU fertilising products, if they (a) have the potential to be the subject of significant trade on the internal market; and (b) there is scientific evidence that they: (i) do not present a risk to human, animal or plant health, to safety or to the environment, and (ii) ensure agronomic efficiency.

Based on this, EBIC members have been working over the past years to ensure that there is a possibility for more microorganisms to be added as components of plant biostimulants in a way that can foster innovation and diversify the offer of efficient products on the market.

In June of 2021, the Commission launched a consultation to Member States to assess the requirements to place microbial plant biostimulants on the market under national rules. Based on that consultation, the Commission shared a note with the CEG-FP proposing options for the development of CMC 7, and they launched a survey asking about preferences to move forward with the development of CMC 7.

EBIC sent a position paper to the members of the CEG-FP before their meeting in November of 2021 to express EBIC's preference to have the assessment of entries into CMC 7 done by a sub-group of the CEG-FP [option b], and the rationale behind that preference. As was indicated in the note from the Commission to the CEG-FP, a sub-group of the expert group would be permanent, it would meet regularly, and once a guidance document for the assessment of CMC 7 proposals are created, the subgroup could "work on various proposals the moment they receive them". On the other hand, if the assessment were done by an external contractor such as the Joint Research Centre (JRC) [option a], the note indicated that "the process would be slow (2 years for launching the study and having the final report is a minimum period to consider) and would not be a regular exercise. It would imply launching a study every 3-4 years". EBIC already indicated in the position paper submitted in November that those timelines were unfeasible for the industry, and particularly unjustified in the case of microbial plant biostimulants that were already lawfully placed on the market in several EU member states.

After the CEG-FP meeting, the Commission asked stakeholders to "share any information on the micro-organisms candidates for inclusion in CMC 7, taking into account only micro-organisms which have the potential to be subject to significant trade on the internal market". In response to this last request, EBIC submitted a document to the Commission in December of 2021 with an extensive list of microorganisms that are being used or had the potential to be

used in microbial plant biostimulants (*see Annex*). No feedback was received from the Commission after submitting that document.

The unfeasibility of the current proposal from the Commission for the development of CMC 7

In February of 2022, the Commission told EBIC that CEG-FP members had indicated that they preferred the assessment of microorganisms to be included into CMC 7 to be done by the JRC or an external contractor [option a], despite EBIC's argumentation in favour of option b. The Commission indicated the intention to launch an EUSurvey requesting interested parties to submit information on new materials and microorganisms, including requests for technical information needed on market data analysis, safety and efficiency. The Commission also indicated that this collection of data would then be the starting point for a new study that would start running in 2023 and would last for 2 to 3 years.

These timelines are absolutely unfeasible for the microbial plant biostimulants industry. A potential timeline of 3-4 years just to develop the guidance that would allow more microorganisms to be added to CMC 7 plus the time it would take for those microorganisms to be assessed, to be included in the positive list under CMC 7 through the publication of a technical amendment to the FPR, and to go through the conformity assessment procedure at the product level would lead to **a total of 6 years (at minimum) for those products to reach the Single market from now**. This time horizon would block any investments in the development of microbial plant biostimulants, especially considering that the circumstances under which EU agriculture operates and the priorities of the EU institutions and the Member States could significantly change in the meantime, and it would practically imply a failure of the FPR in harmonising the requirements for plant biostimulants for many years after its publication in 2019.

Therefore, EBIC members would like to discuss an alternative option with the Commission and the CEG-FP that would at least allow access to the EU market to those microorganisms that have already proven their trade potential, safety and agronomic efficiency, while the full assessment of new microorganisms and materials is ongoing.

EBIC's proposal to unblock innovation in microbial plant biostimulants

EBIC would like to propose two parallel but ultimately convergent pathways for the development of CMC 7 that would match the ambitions of the Commission and the Member States while allowing the industry to continue investing in microbial plant biostimulants.

In December of 2021, EBIC submitted a list of microorganisms to the Commission that included more than 10 genera and 45 species that could be used as components of plant biostimulants:

i. Some of those microorganisms are components of microbial plant biostimulants already placed on the market in some EU Member States according to national rules or mutual recognition;

ii. Others were microorganisms in products sold in third countries, which could be introduced to the EU market; or

iii. Others were microorganisms that were being assessed for their plant biostimulant effects.

That list would be the starting point of the parallel but convergent approach outlined below.

The Commission already launched a consultation to the Member States about national rules for microbial plant biostimulants, which indicated that there are at least 10 Member States that require prior authorization for these products, including Austria, Belgium, the Czech Republic, Spain, Finland, Hungary, Latvia, Lithuania, Portugal and Slovakia. Although France was not included in the table shared by the Commission, it also requires an authorization for microbial plant biostimulants.

In any case, there are many microbial plant biostimulants from the list that EBIC submitted that have been on the market in these Member States for several years and have therefore proven their agronomic efficacy, safety and market potential, matching the requirements of Article 42 to justify a technical amendment to the FPR to modify the list under CMC 7. **EBIC would like to propose the inclusion of these microorganisms directly in the positive list under CMC 7 without having to undergo the entire assessment by an external contractor that would take 3-4 years**.

In fact, EBIC members are currently putting together an updated version of the list of microorganisms that was submitted in December to indicate which microorganisms are part of microbial plant biostimulants that have proven their market potential, safety and agronomic efficacy, so that it can be evaluated by the CEG-FP and proposed for inclusion into CMC 7 through a technical amendment to the FPR. Some examples would be strains of the species *Bacillus subtilis, Bacillus licheniformis, Bacillus amyloliquefaciens, Nitrosomonas europaea, Nitrobacter winogradskyi, Rhodopseudomonas palustris* or *Trichoderma atroviride*, which are part of microbial plant biostimulants lawfully placed on the market in most of the EU member states since at least 2011.

In parallel, EBIC members would also participate in the EUSurvey to indicate which microorganisms and materials they would like to include in the FPR, submitting any required data under the appropriate confidentiality terms. EBIC would then collaborate with the Commission, the Member States and the external contractor while the study takes place over the following years to provide any additional information that may be required, and EBIC members would continue characterizing new microorganisms for their potential inclusion in plant biostimulants.

After the completion of the study and the definition of the requirements for the inclusion of additional microorganisms into CMC 7, EBIC members would go back to the microorganisms that were temporarily included into CMC 7, and they would prepare the potential additional documentation to prove that these microorganisms (as well as new microorganisms that might have been characterized in the meantime) comply with the requirements.

Conclusion

Innovation in the microbial plant biostimulants sector is key to improve crop tolerance to abiotic stress, increase the quality of EU crops and improve the availability and efficiency of plant nutrients. A wide range of microorganisms has already proven to have plant biostimulant effects and therefore could contribute to the EU Green Deal targets, and could also help ensure EU food security under the current challenging circumstances.

A timeframe of at least 6 years for most microbial plant biostimulants to reach the EU market, on top of the time that has already been spent in FPR negotiations, would block any significant investments in this sector, with the negative consequences to be felt by the entire EU

agricultural sector. The possibility to continue selling microbial plant biostimulants under national rules would not be enough to justify investments in innovation, as member states differ in their approach to assess microbial plant biostimulants, mutual recognition is almost impossible, and national rules are constantly evolving.

That is why EBIC is willing to collaborate with the Commission and the CEG-FP to define a mechanism that would at least allow access to the list under CMC 7 to those microorganisms that have already proven their trade potential, agronomic efficacy and safety in certain member states, which would nevertheless have to go through the conformity assessment procedure at the product level. This would allow the industry to continue investing in this sector and characterising new microorganisms while the requirements are being defined.

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 Biostimulant 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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Annex

On December 7th, EBIC submitted a document to the European Commission, which was updated on December 14th, outlining the genera and species of microorganisms that EBIC members identified as relevant for plant biostimulants, which are specified in **Table 1** [also attached as the spreadsheet 20211207-EBIC-AgendaItem4.7-CMC7-Proposals-Spreadsheet-v2.xlsx, which was submitted to the Commission]. The format of Table 1 should not be assumed to mean that EBIC supports the inclusion of these microorganisms in CMC 7 at the genus or species level. For more information about EBIC's position on the assessment of microorganisms for CMC 7, please see "EBIC proposal on procedural options for future developments of CMC 7 (microorganisms)", uploaded to CIRCABC before the CEG-FP meeting.

Table 1: EBIC microorganisms candidates for inclusion in CMC 7

Genus or species	Reasons for inclusion into CMC 7 in the FPR
Acidithiobacillus sp.	Plant growth-promoting bacteria in the Proteobacteria phylum
Acinetobacter calcoaceticus	Soil bacterium involved in the processes of solubilization of mineral elements. Play a role in different biogeochemical cycles

Arthrobacter sp.	Gram-positive bacteria with plant growth-promoting properties
Azospirillum brasilense	Micro-organisms already approved nationally in some EU countries as seed inoculants
Azotoformans sp.	Nitrogen-fixing bacteria, some species approved under PPP regulation in EU; Some species approved as MFSC in France
Bacillus amyloliquefaciens	Proven to be of significant trade in the internal market. Safety assessment carried out under CEPA, 1999 (Canada) indicates no environmental, human or animal risks in the quantities or under the conditions that may constitute a danger. Signicant trade in organic agriculture as it is organic certified by IOA (Ireland) and FiBL (Germany). Extensive literature on its PGPR properties. Soil enhancer, provides phosphorus solubilisation and release of ammonia from organic compounds. One strain approved in EU regulation for feed 2017/173, 1292/2008, 336/2011
Bacillus atrophaeus	Approved for use in fertilising products by the Spanish fertilisers regulation (Real Decreto 506/2013)
Bacillus licheniformis	Proven to be of significant trade in the internal market. Safety assessment carried out under CEPA, 1999 (Canada) indicates no environmental, human or animal risks in the quantities or under the conditions that may constitute a danger. Signicant trade in organic agriculture as it is organic certified by IOA (Ireland) and FiBL (Germany). Extensive literature on its PGPR properties. Soil enhancer, provides phosphorus solubilisation and plant growth hormones and precursors. One strain approved by EU regulation for feed 2017/447
Bacillus majavensis	Micro-organisms already approved nationally in some EU countries as biostimulants
Bacillus megaterium	Species of Bacillus endemic to the rhizospheric soil, showing significant PGPR activities and no known toxicity.They have shown a good capability to solubilies Phosphate from soil in vitro and in vivo trials, there is a lot of

	information in patents and publication that describe and support the biostimulant/biofertilizer capacity
Bacillus methylotrophicus	Species of Bacillus endemic to the rhizospheric soil, showing significant PGPR activities and no known toxicity.
Bacillus mucilaginosus	Species of Bacillus endemic to the rhizospheric soil, showing significant PGPR activities and no known toxicity. Approved in France for use in a fertilising product and in other EU countries as component for plant biostimulants
Bacillus ochrobacterium	Micro-organisms already approved nationally in some EU countries as biostimulants
Bacillus paralicheniformis	Approved for use in many EU countries (see Table in second tab). One EBIC member indicated an expectation of 19 Kl commercialised in 2022. The longer term projections could be up to 130 Kl+ (2030).
Bacillus pumilus	Species of Bacillus endemic to the rhizospheric soil, showing significant PGPR activities and no known toxicity.
Bacillus safensis	Approved for use in fertilising products by the Spanish fertilisers regulation (Real Decreto 506/2013)
Bacillus siamensis	Micro-organisms already approved nationally in some EU countries as biostimulants
Bacillus subtilis	Proven to be of significant trade in the internal market. Safety assessment carried out under CEPA, 1999 (Canada) indicates no environmental, human or animal risks in the quantities or under the conditions that may constitute a danger. Signicant trade in organic agriculture as it is organic certified by IOA (Ireland) and FiBL (Germany). Extensive literature on its PGPR properties. Soil enhancer, provides phosphorus solubilisation and release of ammonia from organic compounds.
Bacillus velezensis/ amyloliquefaciens	A new group of Bacillus amyloliquefaciens, velezensis and others that are very close genetically and endemic to the soil (mainly the rhizosphere), often showing PGPR activities, with

	little or no antimicrobial activity and no known toxicity.
Bradyrhizobium arachis	Micro-organisms already approved nationally in some EU countries as seed inoculants
Bradyrhizobium elkanii	Micro-organisms already approved internationally as seed inoculants
Bradyrhizobium japonicum	Micro-organisms already approved nationally in some EU countries as seed inoculants
Bradyrhizobium lupinus	Micro-organisms already approved nationally in some EU countries as seed inoculants
Bradyrhizobium sp.	Nitrogen-fixing bacteria covered by Italian regulation and allowed in some other EU countries
Burkholderia sp.	It is one of the most important bacterial groups and the most represented in the soils of the five continents and in the rhizosphere. Many functions are performed by Burkholderia in soils. On the other hand, it is important to control the toxicity before putting it on the market.
Clostridium pasteurianum	Many bacteria can fix nitrogen even under aerobic conditions. Anaerobic bacteria of the genus Clostridium spp. are widespread and of great importance. They develop in almost all soils and are functional anaerobes . Clostridium pasteurianum (previously known as Clostridium pastorianum) was discovered in 1890 by the Russian microbiologist Sergei Winogradsky. It was the first free living (non-symbiotic) micro-organism discovered that could fix free nitrogen from the air .
Delftia acidovorans	A species endemic to the rhizospheric soil, showing significant PGPR activities and no known toxicity. Published data demonstrate this organism enhances plant growth by iron acquisition.
Enterobacter ludwigii	Endemic and representative bacteria of the soil. It is very common in the rhizosphere and is often selected by plants. A lot of bibliography is available about its PGPR activities and benefits for plants

Herbaspirillum frisingense	This Bacteria can fix nitrogen in the soil (non-symbiotic or endophytic). It is widespread in soils. It is often selected in the rhizosphere of herbaceous plants. It can be assimilated to the behavior and prevalence in soils to the Azotobacter genus
Herbaspirillum huttiense	This Bacteria can fix nitrogen in the soil (non-symbiotic or endophytic). It is widespread in soils. It is often selected in the rhizosphere of herbaceous plants. It can be assimilated to the behavior and prevalence in soils to the Azotobacter genus
Lactobacillus plantarum	Micro-organisms already approved nationally in some EU countries as biostimulants
Lysinibacillus xylanilyticus	Micro-organisms already approved nationally in some EU countries as biostimulants
Mesorhizobium ciceri	Micro-organisms already approved nationally in some EU countries as seed inoculants
Nitrobacter winogradskyi	Proven to be of significant trade in the internal market. Safety assessment carried out under CEPA, 1999 (Canada) indicates no environmental, human or animal risks in the quantities or under the conditions that may constitute a danger. Signicant trade in organic agriculture as it is organic certified by IOA (Ireland) and FiBL (Germany). Assists with plant growth promotion and P solubilisation.
Nitrosomonas europaea	Proven to be of significant trade in the internal market. Safety assessment carried out under CEPA, 1999 (Canada) indicates no environmental, human or animal risks in the quantities or under the conditions that may constitute a danger. Signicant trade in organic agriculture as it is organic certified by IOA (Ireland) and FiBL (Germany). Assists with plant growth promotion and P solubilisation.
Novosphingobium sp.	A genus of plant-beneficial Gram-negative bacteria commonly found in soils and ground waters. Very often encountered in different rhizospheres, it contains some nitrogen-fixing species and species capable of degrading aromatic compounds.

Ochrobactrum pseudogrignonense	Endophytic bacterium expressing PGPR activities in the same way as Azospirillum
Paenibacillus sp.	Endemic genus of the soil grouping PGPR species
Pantoea sp.	
Penicillium bilaiae	Plant growth-promoting fungi with a good capability to solubilize Phosphate from soil in vitro and in vivo trials, there is a lot of information in patents and publication that describe and support the biostimulant/biofertilizer capacity
Penicillium smithii	They have shown a good capability to solubilize Phosphate from soil in vitro and in vivo trials, there is a lot of information in patents and publication that describe and support the biostimulant/biofertilizer capacity
Pseudomonas azotoformans	Gram-negative bacterium with plant growth-promoting properties
Pseudomonas brassicacearum	Gram-negative bacterium with plant growth-promoting properties
Pseudomonas fluorescens	The plant growth-promoting properties of the Pseudomonas fluorescens-putida group were described many years ago (Kloepper et al., 1980). Specific strains have recently been used as seed inoculants on crop plants to promote growth and increase yields
Pseudomonas fulva	regulation unknown
Pseudomonas koreensis	Gram-negative bacterium with plant growth-promoting properties
Pseudomonas putida	The plant growth-promoting properties of the Pseudomonas fluorescens-putida group were described many years ago (Kloepper et al., 1980). Specific strains have recently been used as seed inoculants on crop plants to promote growth and increase yields
Pseudomonas sp.	Important genus in size and function. Some species / strains are used in Biocontrol (putida, fluorescens, ...), others are pathogenic or phytopathogenic (aeruginosa, fluorescens, ...) and finally some are 100% PGPR (azotoformans, koreensis, some fluorescens, ...). Some strains express functions in biocontrol as well as biostimulation / promotion of growth.

Rhizobium leguminosarum	Nitrogen-fixing bacterium already approved nationally in some EU countries as seed inoculants
Rhodopseudomonas palustris	Proven to be of significant trade in the internal market. Safety assessment carried out under CEPA, 1999 (Canada) indicates no environmental, human or animal risks in the quantities or under the conditions that may constitute a danger. Signicant trade in organic agriculture as it is organic certified by IOA (Ireland) and FiBL (Germany). Nitrogen fixation, enhances photosysthesis.
Sinorhizobium meliloti	Gram-negative nitrogen-fixing bacterium already approved for use in seed inoculants in some EU countries
Stenotrophomonas rhizophila	Species frequently found in the rhizosphere and having significant PGPR activities. Does not show any known biocontrol activities and has a level 1 health status
Streptomyces sp.	Endemic and representative genus of Gram-positive bacteria commonly found in soils. They contribute to the humification of soil organic matter and improve soil structure, providing a positive impact on soil life in general and also showing plant growth-promoting effects
Stretomyces beta-vulgaris	Micro-organisms already approved nationally in some EU countries as biostimulants
Talaromyces adpressus	Fungal species that have shown a good capability to solubilize Phosphate from soil in vitro and in vivo trials, there is a lot of information in patents and publication that describe and support the biostimulant/biofertilizer capacity
Trichoderma (afro)harzianum	Fungus that has several modes of action, both as plant growth stimulator and as elicitor/biocontrol organism
Trichoderma asperellum	Fungal species endemic to the rhizospheric soil, showing significant PGPR activities and no known toxicity.
Trichoderma saturnisporum	Trichoderma species are covered by the Italian regulation for fertilising products and allowed in some other EU countries. There is scientific

	information that supports the use of species in this genus as components of plant biostimulants