

Faster, safer access to microbial plant biostimulants: a criteria-based simplification of CMC 7

Executive summary

In response to the European Commission's *Reality Check* on the Fertilising Products Regulation (FPR) [Regulation (EU) 2019/1009], the European Biostimulants Industry Council (EBIC) calls for urgent **simplification of Component Material Category 7 (CMC 7)** to enable Single Market access to safe, effective microbial plant biostimulants for EU farmers.

The FPR was designed to harmonise the Single Market and support sustainable innovation. Instead, CMC 7 has become a structural bottleneck. There is no process for manufacturers to request the use of new micro-organisms, and **88% of surveyed EBIC members** report being unable to obtain CE marking for safe, well-characterised microbial plant biostimulants.

The current non-recurring, Commission-led process to update CMC 7, delaying market access in five to seven years, is undermining the EU's **Vision for Agriculture and Food (2025–2029)**, which calls for a competitive, resilient, and sustainable agri-food sector.

EBIC proposes a solution to simplify Single Market access for microbial plant biostimulants under the FPR:

- **Amend Article 42** to ensure continuous market access for microbial plant biostimulants containing micro-organisms meeting defined criteria.
- **Adapt CMC 7** to recognise micro-organisms meeting these criteria.
- **Publish a recognised methodology** for evaluation against defined criteria.
- **Enable accredited third-party evaluation** within the existing regulatory framework.

This would restore Single Market functionality, enable **faster and predictable access through clarity, not by lowering standards**, and ensure the FPR supports, rather than blocks, Europe's transition to climate-resilient, innovation-led agriculture.

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Regulatory background: why the current system is blocking innovation

Under the Fertilising Products Regulation (FPR) [Regulation (EU) 2019/1009], **only four types of micro-organisms are currently permitted for use in microbial plant biostimulants** [PFC 6(A)], as listed under Component Material Category 7 (CMC 7) in Annex II.

During the negotiations leading to the publication of the FPR in 2019, co-legislators considered setting criteria for micro-organisms under CMC 7. However, the final regulation adopted a “positive list”, a static table listing the micro-organisms that are allowed. In the six years since the publication of the FPR, this list has not been updated, excluding many safe, efficient, and well-documented micro-organisms already authorised in EU Member States or under development by companies, with demonstrated potential to improve crop productivity, nutrient availability and use efficiency, soil health, and climate resilience.

Today, there is **no mechanism** in the FPR allowing manufacturers to request the assessment of additional micro-organisms for CMC 7. According to Article 42 in the FPR, only the European Commission (EC) can initiate an update, via a delegated act, and only after having assessed their safety and agronomic efficiency.

Due to resource constraints, the Commission has only launched this process once, in 2022. The timeline and steps involved are shown in **Figure 1**.

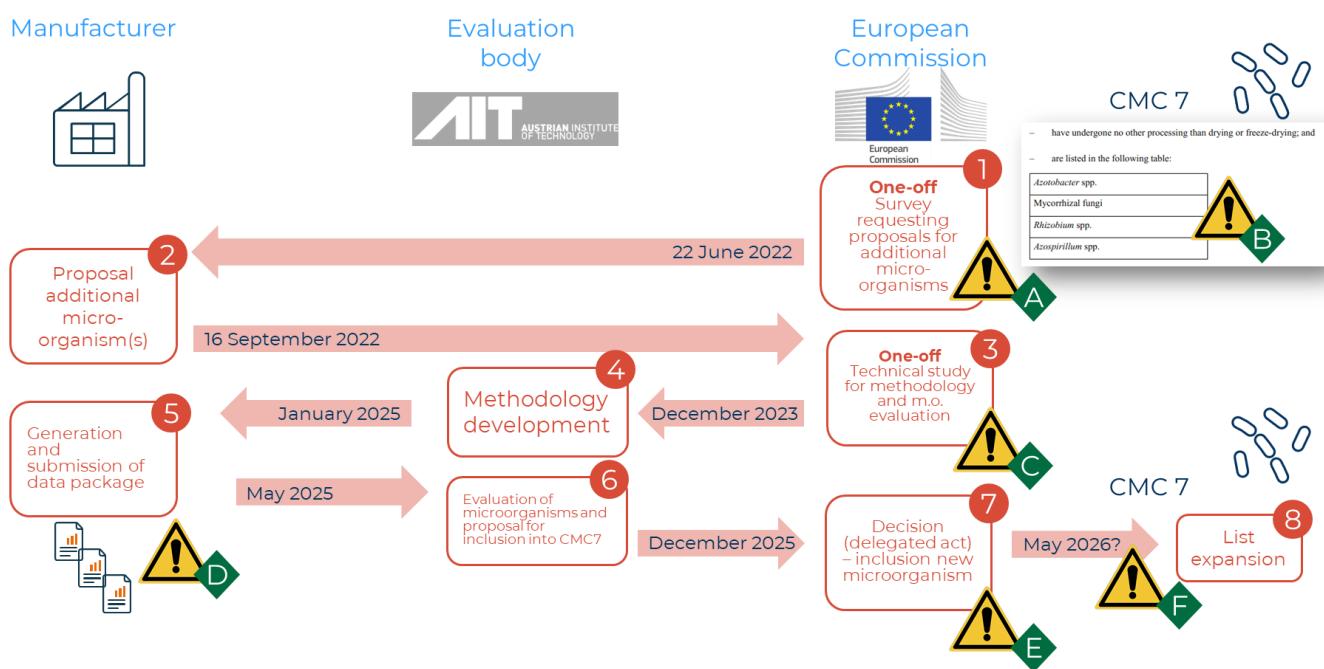


Figure 1: The current update process for CMC7: one-off, complex and slow. Steps in the process are indicated with numbers 1-8. Bottlenecks in the process are indicated with letters A-F.

The current process to update CMC 7 (Figure 1) is started by the EC launching a public EU Survey to collect proposals for new micro-organisms to be included (Step 1), followed by the submission of new proposed micro-organisms (Step 2), launching a call for tenders for a contractor to do a technical study (Step 3), development of an assessment methodology by the contractor (Step 4), data collection from manufacturers (Step 5), micro-organism evaluation according to the methodology (Step 6), recommendation from the contractor to the Commission Expert Group on Fertilising Products for a list

of micro-organisms to be included in CMC 7, and finally adoption by the EC of a Delegated Act (Step 7) to update the list (Step 8).

This process suffers from **several structural limitations or bottlenecks**, represented with exclamation marks in Figure 1:

- A.** The Commission controls the process but lacks the capacity and budget for rolling updates.
- B.** The list under CMC 7 is already outdated upon publication, at genus-, species- or strain-level.
- C.** The technical study cannot easily be repeated; there is no scalable, sustainable mechanism.
- D.** No FPR provisions exist for data protection or confidentiality, deterring submissions.
- E.** Each update requires a Delegated Act, increasing delay and regulatory uncertainty.
- F.** Even if completed on time, the earliest the list might expand is 2026, with CE-marked microbial biostimulants not reaching the market before 2027, a full five years after proposals were submitted.

This slow, one-off process is a major barrier to innovation. It blocks Single Market access for safe and effective microbial tools for farmers, as evidenced by the data provided under point 1, and it undermines the return on public and private R&D investment, diverting innovation toward non-EU markets with more agile regulatory frameworks.

The combination of a static list, the absence of a process for manufacturers to request the addition of new micro-organisms and unpredictable timelines has created a crisis for microbial plant biostimulants that demands urgent structural simplification.

In response to the European Commission's '*Reality check*' on the FPR and its specific questions on CMC 7, EBIC offers the following proposals, grounded in industry data, scientific literature, and regulatory precedents.

1. What are the benefits and risks related to the use of additional micro-organisms in EU fertilising products?

Benefits: proven agronomic and environmental value

The benefits of microbial plant biostimulants are well-established in both peer-reviewed literature and field application. These products improve nutrient availability and use efficiency, enhance crop quality, and increase resilience to abiotic stress.

They directly contribute to the objectives outlined in the European Commission's [Vision for Agriculture and Food \(2025-2029\)](#), including a more competitive, resilient, and sustainable agri-food sector, improved resource efficiency, and future-proofing European agriculture through innovation and smart incentives. By supporting sustainable productivity, soil health, and input efficiency, microbial biostimulants align with the Commission's ambition to make farming more viable for future generations.

Decades of research support the multiple benefits of microbial plant biostimulants, illustrated by the following examples of recent publications.

- **Compan et al. (2025):** reviewed how microbial plant biostimulants can influence and improve crop quality and plant tolerance to abiotic stress.

- **Duri et al. (2025):** found that microbial plant biostimulants combined with compost increased early marketable yield and boosted carotenoid and antioxidant levels in eggplant.
- **Rossini et al. (2025):** reported that a foliar-applied microbial plant biostimulant in durum wheat maintained high yields while reducing nitrogen fertiliser input by 33%.
- **Gazoulis et al. (2024):** demonstrated that inoculation with phosphorus- and potassium-solubilising microbes improved nutrient availability in the soil and significantly increased yields of alfalfa and oilseed rape even under reduced fertilisation regimes.
- **Zia et al. (2021):** proved that several bacterial strains isolated from desertic areas improved wheat growth under drought stress.
- **Todeschini et al. (2018):** showed that arbuscular mycorrhizal fungi and pseudomonads altered volatile profiles and improved the nutritional quality in strawberries.
- **Subramanian et al. (2015):** demonstrated that inoculation with two strains of *Pseudomonas* increased cold tolerance in tomato plants.

In addition to agronomic benefits, microbial plant biostimulants also support long-term soil health by increasing organic carbon content and promoting microbial diversity (Li et al., 2024). For example, when combined with compost or digestate in a fertilising product blend (PFC 7), they can offer synergistic effects, providing sustainable innovative tools to growers and contributing to circular economy ambitions.

Managing Risks: ensuring safety through criteria-based assessment

Any safety concerns around the use of microbial plant biostimulants can be effectively assured through a single, two-tier framework:

- At the **component level (CMC 7)**, risks are addressed by applying clear, science-based criteria to the micro-organism itself, such as the identification and characterisation of the micro-organism through Whole Genome Sequence (WGS) analysis, literature review and testing when necessary. The establishment of clear criteria ensures that only safe, well-characterised strains will be used in EU fertilising products.
- At the **product level**, an additional layer of safety is provided by the conformity assessment process, which evaluates if the product complies with the requirements of the FPR (including several safety requirements) based on technical documentation comprising a description of the intended use of the product, a list of component materials and information about their origin or manufacturing process, a specimen of the product label containing use instructions, test reports, evidence of plant biostimulant function, etc.

Together, these two levels provide a robust and proportionate system. EBIC advocates for assessments to be based on defined criteria and thresholds, allowing for consistent, transparent decisions by accredited evaluators. This would remove ambiguity, reduce the need for subjective risk assessments, and enable a streamlined conformity assessment process in line with the [New Legislative Framework](#).

EBIC members are committed to placing only safe microbial plant biostimulants on the EU Single Market. This paper sets out how a manufacturer-led, criteria-based, evaluator-dependent approach can achieve that while removing the structural barriers that are currently preventing microbial plant biostimulants to reach EU farmers.

Blocked market access: Innovation lost due to CMC 7

The current regulatory system is failing to deliver market access. A growing number of beneficial and safe microbial plant biostimulants are being blocked by an outdated list under CMC 7 and a dysfunctional process to update it.

To illustrate the magnitude of the problem, EBIC distributed an anonymous online survey among 65 member companies in April of 2025. It was answered by 32 companies across all size categories, **53% of which were SMEs**.

Among the respondents, **88% reported being unable to place microbial plant biostimulants on the EU Single Market** under the FPR because their **microorganism(s) of interest is/are not on the CMC 7 list** (Figure 2). This barrier is particularly restrictive for SMEs, which often lack the resources to pursue fragmented national authorisations or navigate multi-year EU-level processes.

Has your company obtained the CE mark under the FPR for any microbial plant biostimulants?

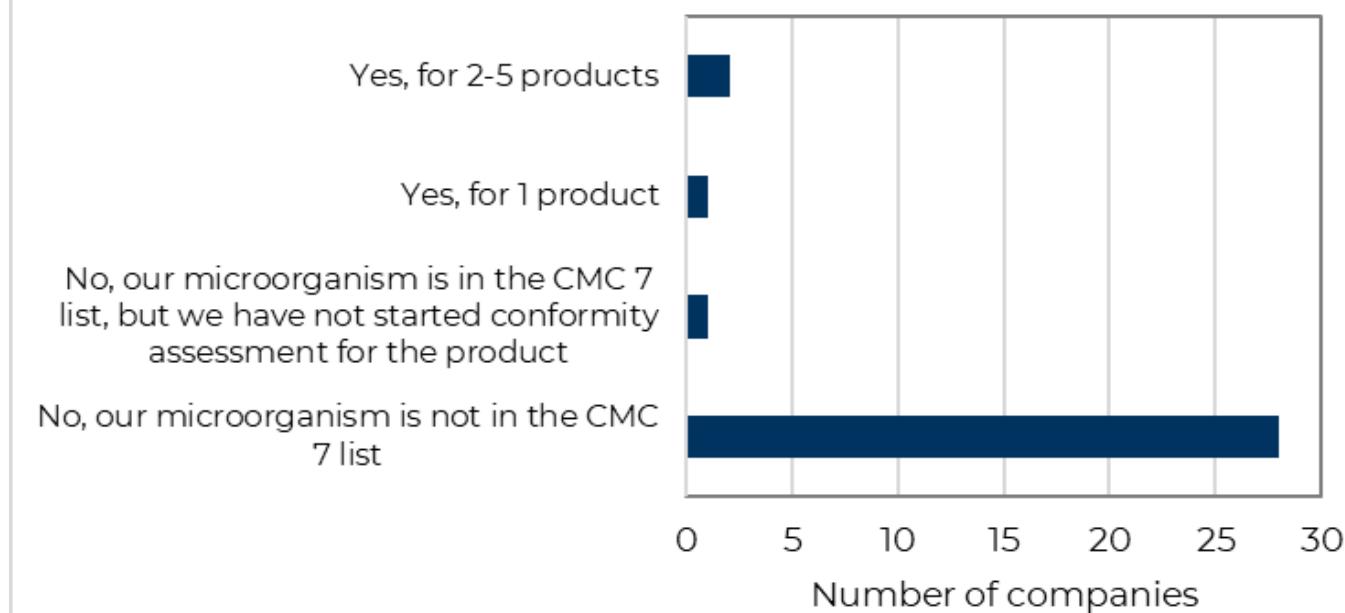


Figure 2: Most companies surveyed are excluded from the FPR

Among the companies that could not obtain the CE mark for their microbial plant biostimulants, most of them (72%) said that they would have been able to place at least one or more products on the market under the FPR if an agile process to update CMC 7 had been in place. (Figure 3).

For how many microbial plant biostimulants (for which the microorganism is not in the CMC 7 list) would your company have tried to obtain the CE mark if it had been possible under the FPR?

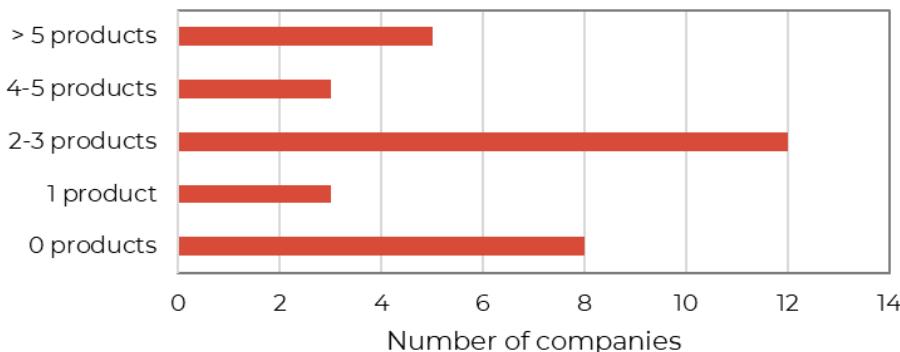


Figure 3: Microbial plant biostimulants that could have accessed the Single Market under the FPR.

In the absence of a workable EU pathway, companies turned to national authorisations (Figure 4). Since 2022, when the FPR started to apply:

- Most respondents placed 1 to 5 products on the market via national rules
- Approval times ranged from 6 months to 3 years
- Costs varied from under €5,000 to over €30,000

While national rules allow farmers to access some of these tools, they are burdensome, especially for SMEs who don't usually have the resources to become familiar with the particularities of each member state, they prevent harmonisation and they undermine the EU's ambitions for competitiveness.

Since July 2022, has your company obtained authorisation for microbial plant biostimulants in one or more EU countries under national rules?

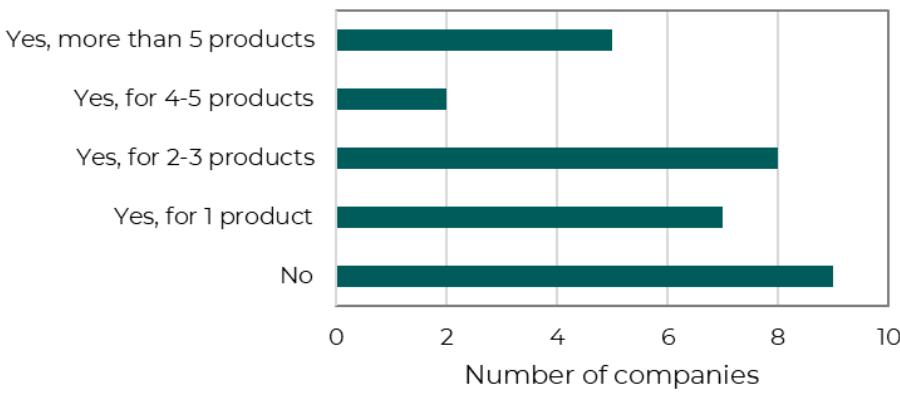


Figure 4: National routes used out of necessity, not preference.

Since the FPR started to apply, many companies have continued to commercialise their microbial plant biostimulants in countries outside the EU, including Argentina, Australia, Brazil, Canada, India, Mexico, South Africa, the United States of America, and many countries in Central America, Africa or Asia.

Despite the EU blockage, research on microbial plant biostimulants has continued. In fact, 72% of respondents (23 out of 32 EBIC members) said that they would have multiple products ready for conformity assessment within 2 years, if the CMC 7 issue was unblocked (Figure 5).

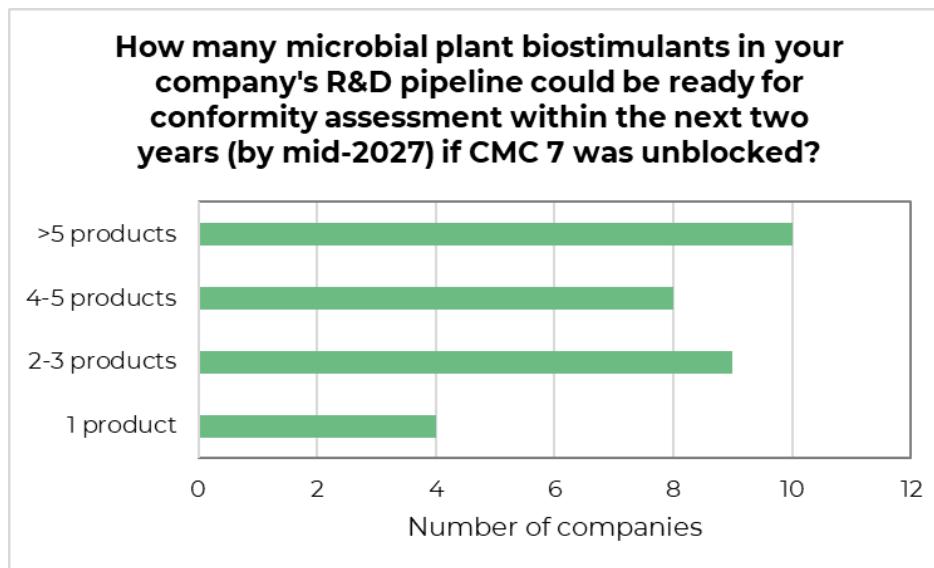


Figure 5: Strong R&D pipeline awaiting regulatory access to EU Single Market

When asked to indicate two key impacts of the CMC 7 blockage, many companies highlighted a shift on investments to markets outside the EU, reduced investment in EU microbial R&D, delays in EU market innovation entry, and a negative impact on competitiveness.

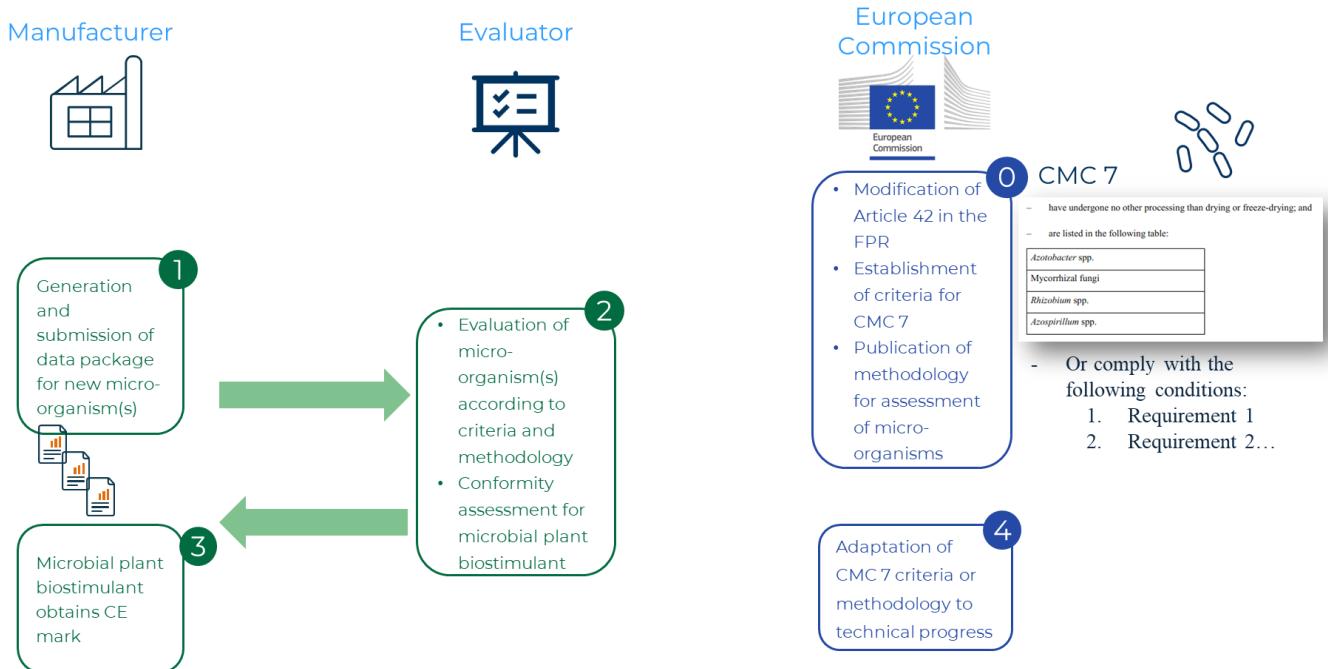
More information collected through this survey is available on EBIC's Briefing note "[Urgent action required: obstacles to microbial plant biostimulants under CMC 7 of the Fertilising Products Regulation \(FPR\) are eroding competitiveness](#)"

2. How could the assessment procedure be simplified without compromising safety?

A new pathway for microbial plant biostimulant access to the Single Market under the FPR must be grounded in scientific rigour, full transparency, predictable timelines, and enforceable criteria. EBIC does not support regulatory shortcuts or exemptions. Instead, we propose a procedure that maintains the current level of **proven agronomic efficiency while ensuring safety** through **clear criteria applied consistently across all manufacturers**.

Empowering manufacturers to start the process to assess new micro-organisms

EBIC members are convinced that the assessment procedure for micro-organisms to be used in microbial plant biostimulants could be simplified by introducing a **manufacturer-led, criteria-based process with independent evaluation by accredited third-party evaluators** (Figure 6).



Through the process proposed by EBIC (Figure 6), manufacturers interested in placing a new microbial plant biostimulant on the EU Single Market would check the criteria established under CMC 7 and generate the data to demonstrate that their micro-organism fulfils the criteria (step 1). They would choose an accredited-third party evaluator and sign an agreement addressing data protection and confidentiality. The evaluator would assess the micro-organism on the basis of the established criteria following a published methodology, and if the micro-organism complies, the evaluator would proceed with the assessment of the microbial plant biostimulant product according to the requirements in the FPR (step 2). As a result, the manufacturer would obtain the CE mark for their product (step 3), and would gain access to the EU Single Market, subject to market surveillance by the relevant authorities. Importantly, the manufacturer could initiate a new process for a new product whenever desired.

To enable this process, EBIC members believe that Article 42 of the FPR, and particularly 42(4), should be changed from the European Commission (EC) having the power to add new micro-organisms, to the EC having the power to add criteria for micro-organisms in CMC 7 (step 0) and also having the power to adapt the criteria to technical progress (step 4). The process would also require the establishment of the criteria under CMC 7, and the publication of a methodology for the assessment of micro-organisms according to the criteria (step 0).

Therefore, establishing the process represented in Figure 6 will likely require a **change in Article 42 of the FPR**, which will have to go **through the ordinary legislative procedure**. This modification could be done as part of the European Commission's efforts to reduce unnecessary administrative burdens, particularly around agriculture. Once Article 42 and any other relevant parts of the FPR are modified, the Commission could immediately adopt a delegated act to establish and operationalise the CMC 7 criteria. To avoid unnecessary delays, EBIC encourages the Commission to begin **informal consultations on this delegated act as soon as possible**.

Adding criteria for new micro-organisms under CMC 7

EBIC fully supports the EU's commitment to the highest standards of safety for human health, the environment, EU farmers and consumers. The proposed criteria-based system does not lower safety standards. Instead, it enables clearer, more consistent, and enforceable safety assessments, based on defined thresholds and scientific evidence.

The existing positive list under CMC 7 (*Azotobacter* spp., *Azospirillum* spp., *Rhizobium* spp., mycorrhizal fungi), and its imminent enlargement as a result of the technical study contracted to AIT, could remain in place to avoid re-assessing well-accepted micro-organisms.

EBIC further proposes to **amend CMC 7 to include an additional clause such as:**

“...or comply with the following conditions: [criteria list].”

This clause would **unlock a pathway for additional micro-organisms that meet such criteria**, overcoming bottlenecks B, C, E and F in the current process, as represented in Figure 1.

The Commission Expert Group on Fertilising Products could define a list of criteria for new micro-organisms under CMC 7 based on data currently requested under Article 42(4) in the FPR or data reviewed as part of the technical study contracted to the Austrian Institute of Technology (AIT), aligned with the requirements of PFC 6(A).

A provision should also be introduced in the FPR to **allow updates to the criteria over time**, reflecting scientific progress.

EBIC members have started identifying possible criteria, but feel it is premature to suggest a list of criteria before the technical study contracted to AIT is finalised. As soon as discussions on criteria for CMC 7 are started, EBIC would like to participate in those discussions and share the proposal from manufacturers.

Managing risks through rigorous, science-based assessment

The criteria would be applied at the component level (CMC 7) to determine the intrinsic eligibility of the micro-organism. At the product level, the conformity assessment procedure under the FPR would ensure that safety is addressed in relation to intended use, including dosage, crop stage, mode of application, and other relevant use conditions. This two-tiered model is already embedded in the FPR and provides a robust framework for assessing safety at both the component and product levels.

Assessments would be conducted by accredited third-party evaluators, potentially including Notified Bodies, using a harmonised methodology aligned with the standards expected of EU agencies. This would ensure that risk assessments remain science-based, reproducible, and legally robust, while enabling innovation to proceed within a transparent and trusted framework. This would overcome bottlenecks A and C in Figure 1.

EBIC stands ready to work with the Commission and Member States to implement a system that gives assurance to all parties involved.

Consolidating assessments while ensuring data protection and confidentiality

EBIC supports a **one-step assessment model**, in which both the micro-organism (CMC 7 eligibility) and the final product (PFC 6(A) conformity) are evaluated together, although flexibility should be provided

such that assessment of the micro-organism and the product could occur independently when desired by manufacturers.

Importantly, this one-step model does not reduce safety oversight. It maintains the two-level safety logic embedded in the FPR, with micro-organism eligibility based on intrinsic characteristics, and product-level safety based on intended use, with product use conditions (including dosage, application method, and timing) appropriately considered within a unified conformity assessment procedure. This integrated model reduces administrative burden and reflects the conformity logic already used across other EU fertilising products. Several parts of the FPR would likely have to be modified to allow this change, including Article 42 and Annex II (CMC 7 criteria list).

To address concerns around **data protection and confidentiality** (overcoming bottleneck D), contractual agreements between manufacturers and evaluators could:

- Prohibit the use of submitted data for the benefit of other applicants (data protection);
- Prevent the disclosure of commercially sensitive information (confidentiality).

Once a micro-organism is assessed favourably under this system, it could be included in a microbial plant biostimulant, and the product could complete the conformity assessment procedure. Upon certification, the product may be placed on the EU market and made available to farmers, with full traceability and documentation available to market surveillance authorities.

This approach offers a credible, science-based pathway to simplify access while upholding the EU's strong safety and regulatory integrity standards.

3. Could the AIT methodology for assessing safety be used by industry and notified bodies?

EBIC welcomes the technical study undertaken by the Austrian Institute of Technology (AIT) and considers it a useful step towards establishing a practical and harmonised methodology for the assessment of micro-organisms under CMC 7. It will not be possible to determine the usability of the AIT draft methodology until it is finalised, and the technical study is completed. However, based on the latest draft presented by AIT, EBIC members acknowledge that, once finalised and properly reviewed, the methodology under development could provide the basis for accredited evaluators to carry out science-based assessments using the defined criteria within the FPR's conformity assessment process.

EBIC members believe that any methodology should at least meet the following conditions:

- To be usable, the methodology must be **structured around the criteria** defined under CMC 7, steering evaluators towards the data points to check, and preventing subjective or open-ended risk assessments.
- To ensure clarity and consistency, the methodology must establish **clear thresholds or points of sufficiency** for each criterion. These will allow assessors to make consistent and replicable decisions, reducing ambiguity and ensuring legal robustness.
- While the methodology should be based on clear thresholds, EBIC recognises that some aspects of safety assessment may require expert judgment. To guarantee that the system remains transparent while allowing flexibility, the proposed methodology must require **clearly**

documented decision pathways. The use of accredited evaluators should not reduce rigour but rather enable implementation in line with existing FPR structures.

- To ensure legal clarity and operational use, the methodology should be **publicly available** and **periodically reviewed** to adapt it to scientific progress
- Micro-organisms that are not favourably assessed should not be permanently excluded. Applicants should retain the right to **update and resubmit dossiers**.
- While the methodology must distinguish between micro-organism suitability and product-level safety, EBIC emphasises that both assessments can be conducted **within a single procedure** under the existing FPR framework, as described in our response to Question 2.

4. Any other remarks or suggestions?

Ensure continuity for AIT-assessed strains

As the Commission moves forward with structural reforms to CMC 7, it is essential that the micro-organisms currently undergoing evaluation in the technical study contracted to AIT are not left behind. These strains were submitted via the EU Survey in 2022 according to the current assessment process. Once this process is completed, strains that meet the safety and agronomic efficiency requirements should be granted access under the existing legal framework. EBIC proposes to retain these microorganisms in the CMC 7 'positive list'.

Introducing a new criteria-based pathway should not nullify progress already made. The system must finalise and honour the current process for submitted strains, and implement a forward-looking model for all future inclusions. This approach ensures continuity, fairness, and trust, and avoids unnecessary duplication or regulatory delay.

Replace *Rhizobium* spp. with *rhizobia* in CMC 7

If the CMC 7 table is maintained under the conditions suggested in this paper, EBIC recommends replacing *Rhizobium* spp. with "rhizobia", a scientifically accurate and inclusive term covering *Rhizobium*, *Mesorhizobium*, *Bradyrhizobium*, *Ensifer* and other related nitrogen-fixing bacterial genera. These genera share nitrogen-fixing functionalities and safety profiles, but recent taxonomical classification based on genome sequencing mean they are no longer technically captured under *Rhizobium* spp., and are thus excluded from CMC 7.

This mismatch creates a growing regulatory inconsistency. While [EN 17718:2024](#) does include these genera, the Commission is reportedly planning to cite the standard in the OJEU with a restriction (excluding genera not listed in the FPR) to maintain internal consistency. Updating CMC 7 terminology would prevent this divergence between the regulation and the standard.

This adjustment is:

- **Feasible under the Commission's current empowerment in the FPR;**
- **Scientifically justified** based on taxonomy and functionality;
- **Consistent with decades of agronomic use and safety data;**

EBIC has developed a detailed [position paper](#) on this issue, most recently discussed during the meeting of the Commission Expert Group on Fertilising Products in November of 2024.

This small but important update would ensure regulatory coherence, avoid unnecessary bottlenecks, and support continued innovation in microbial biostimulants. As an umbrella term, “rhizobia” reflects functional equivalence across nitrogen-fixing genera and would future-proof both the FPR and its supporting standard (EN 17718:2024) as microbial taxonomy continues to evolve.

Conclusion

Delays in time-to-market are the most serious risk to innovation, and directly undermine the EU’s [Vision for Agriculture and Food \(2025\)](#), which calls for a competitive, resilient, and sustainable agri-food sector that values innovation, empowers farmers, and supports climate goals.

Without meaningful simplification, the current pathway for innovative microbial plant biostimulants to access the EU Single Market under the FPR is bound to repeating the same regulatory deadlock experienced under other EU frameworks, where safe biological innovations face delays of five to seven years, or never reach the market at all.

According to the current legislative text in the FPR, the only route to expand CMC 7 is through a one-off, Commission-initiated technical study. There is no mechanism for manufacturers to propose new micro-organisms, no recurring process, and no certainty about future updates due to resource constraints. This model is slow, centralised, and incompatible with the needs of a dynamic, innovation-driven sector.

EBIC proposes a pragmatic and proportionate solution:

- **Amend Article 42** through the Commission's simplification initiatives to allow criteria-based assessment of micro-organisms in the FPR;
- **Adopt a delegated act** to define those criteria under CMC 7 and publish a harmonised assessment methodology;
- **Enable accredited third-party evaluation** within the existing regulatory framework;
- **Implement a two-tier safety model**, where micro-organism eligibility is determined at the CMC level, and intended use is assessed at the product level via existing CE-marking procedures.

This approach is fully aligned with the Commission’s objectives to simplify legislation, reduce administrative burden, and promote sustainable innovation. It offers a credible path to unlock microbial potential while maintaining a high level of safety and regulatory integrity.

EBIC stands ready to work with the Commission and Member States to deliver this reform, ensuring that the FPR supports, rather than stifles, the future of microbial plant biostimulants in Europe.

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