Briefing note

Urgent action required: obstacles to microbial plant biostimulants under CMC 7 of the Fertilising Products Regulation (FPR) are eroding competitiveness

Summary

Recent survey data from over 50% of EBIC membership exposes systemic failures in the EU regulatory pathway for microbial plant biostimulants under the Fertilising Products Regulation (FPR).

The FPR was intended to harmonise market access. Instead, for microbial plant biostimulants, it is blocking innovation, investment, and competitiveness, while creating regulatory uncertainty that pushes innovation and investment outside the EU.

Our survey revealed that:

- Most microbial biostimulants developed in Europe are not able to reach the Single Market. Some are being placed on the market through national pathways, an option that is disproportionately out-of-reach for SMEs with limited resources. National authorisations are not the first choice for most of the respondents, but they are the only option to commercialise products in Europe.
- Critical EU innovations benefitting nutrient availability or use efficiency, climate resilience and crop quality are currently stuck or exported abroad.
- EU farmers are losing competitiveness as innovative, safe, and effective microbial products (including those developed in the EU) are being sold abroad and not in the EU.

In short, the obstacles created by the FPR's approach to microbial plant biostimulants are already negatively reshaping Europe's innovation ecosystem, undermining strategic autonomy, and diverting investment and talent away from the EU.

Methodology

The sample reflects a balanced cross-section of the plant biostimulants industry: 53% of respondents are SMEs and 47% are large or very large companies. This reinforces the credibility of the findings and highlights that the current regulatory system is failing both major market leaders and the smaller, innovation-driven companies critical to the EU's objectives for competitiveness, resilience, and strategic autonomy.

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Data analysis

The table below describes the key findings from the survey.

Metric	Count	Comment
Total respondents	32 companies	Balanced across company sizes
Companies with microbial biostimulants, but microorganisms not listed in CMC 7	28 companies (88%)	Products exist, but are denied access to conformity assessment
Companies that obtained CE mark for microbial plant biostimulant(s) under FPR	3 companies (9%)	Few have successfully navigated the system
Companies that would have obtained CE mark for microbial plant biostimulant if possible	20 companies (63%)	Significant unrealised innovation potential (microorganisms not listed under CMC 7)
Companies with new national authorisations since FPR started to apply	18 companies (56%)	Not all FPR-intending companies used national authorisation.
Companies exporting products to non-EU markets	19 companies (59%)	Innovation redirected; faster access in non-EU markets
Companies ready to register (>2 products) if CMC 7 unblocked within the next 2 years	17 companies (53%)	Pipeline of blocked innovation trapped
Companies participating in EU R&D programmes since 2020	6 companies (19%)	Strategic mismatch: EU R&D funded but blocked from Single EU Market

The following sections illustrate the real-world consequences already resulting from the current regulatory failure of CMC 7 in the FPR.

Structural failures are blocking innovation and exporting EU value: evidence from industry

The CMC 7 positive list is the structural source of exclusion

Only 9% of companies have obtained CE marks for microbial plant biostimulants. A further 63% said they would have registered under the FPR if it had been possible, but were blocked because their microorganism is not listed under CMC 7. These companies had clear intent to use the EU system but were structurally excluded before the process could begin.

The CMC 7 list is fixed; there is currently no process or mechanism to evaluate new microorganisms, and no certainty if or when another technical study will be initiated to expand the list. As a result, companies are effectively locked out of the EU market, regardless of the agronomic efficiency or safety of their microorganisms.

National authorisations are not a satisfactory or scalable solution

National authorisation is not a viable alternative to the FPR. 56% of companies used national routes, but this was out of necessity – not by choice. Among them, 75% stated they would have used the FPR if a

functioning pathway had been available. This shows that reliance on national authorisations is a symptom of EU-level failure, not evidence of a workable alternative to market.

While only 18 of 32 companies responded to a question on national authorisation costs, the responses offer valuable insights. Over a quarter of respondents (28%) reported regulatory costs between €10,001 and €30,000 per product. While the majority of responses fell below €10,000, these costs can still represent a significant burden, particularly when multiplied across multiple Member States due to the lack of a harmonised EU pathway. The high non-response rate may also imply that many companies have not pursued national routes at all, reinforcing the point that these pathways are not accessible or viable for all operators.

SMEs are disproportionately burdened by the lack of access to the Single Market

Both SMEs (44%) and large companies (44%) suffer from their microorganisms not being listed on CMC 7, but the burden of the CMC 7 blockage is more onerous for SMEs. National authorisations create higher relative costs, greater administrative complexity, and reduced scalability for smaller companies, directly undermining the EU's commitments to support SME-driven innovation.

The return on R&D investment in microbial biostimulants is blocked

EU-funded R&D is being blocked from reaching farmers. 19% of companies reported having participated in projects with EU funding since 2020, but the closed list under CMC 7 and the lack of a process to update it means that the technologies developed are locked out of the Single Market and the EU fails to capture the benefits of its own investment.

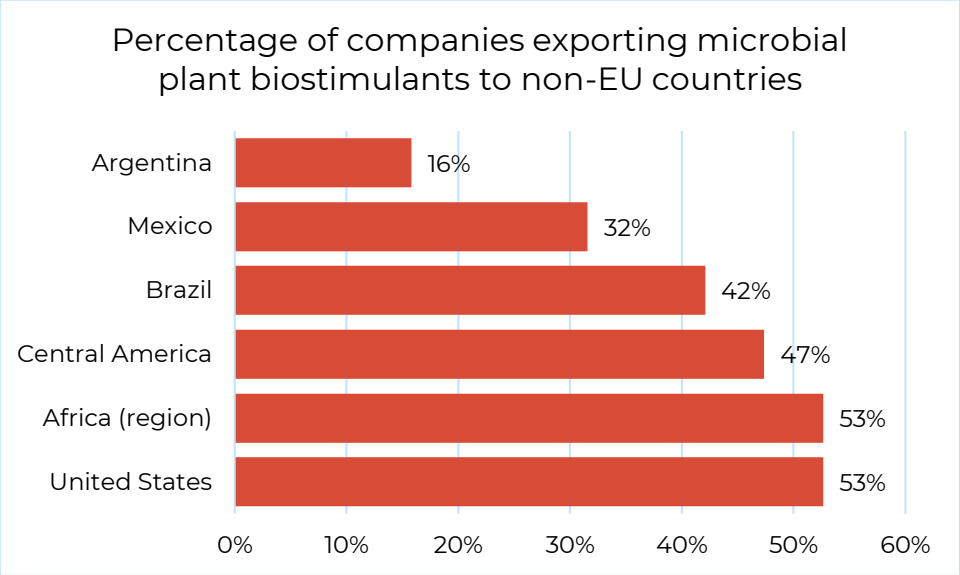
These structural failures are not isolated technical issues. They are already negatively reshaping Europe's innovation ecosystem, undermining strategic autonomy, and diverting investment and talent away from the EU.

EU innovation is being sold elsewhere, eroding the competitiveness of EU farmers

59% of companies have reported placing microbial biostimulant innovations fit for the EU market in non-EU markets. As shown below, the most frequently cited destinations were the United States (53%), Africa (53%), Central America (47%), and Brazil (42%).
This reflects a growing disparity in market access: farmers outside the EU are benefiting from technologies that remain unavailable to EU farmers due to the lack of an agile process to include additional microorganisms in CMC 7.

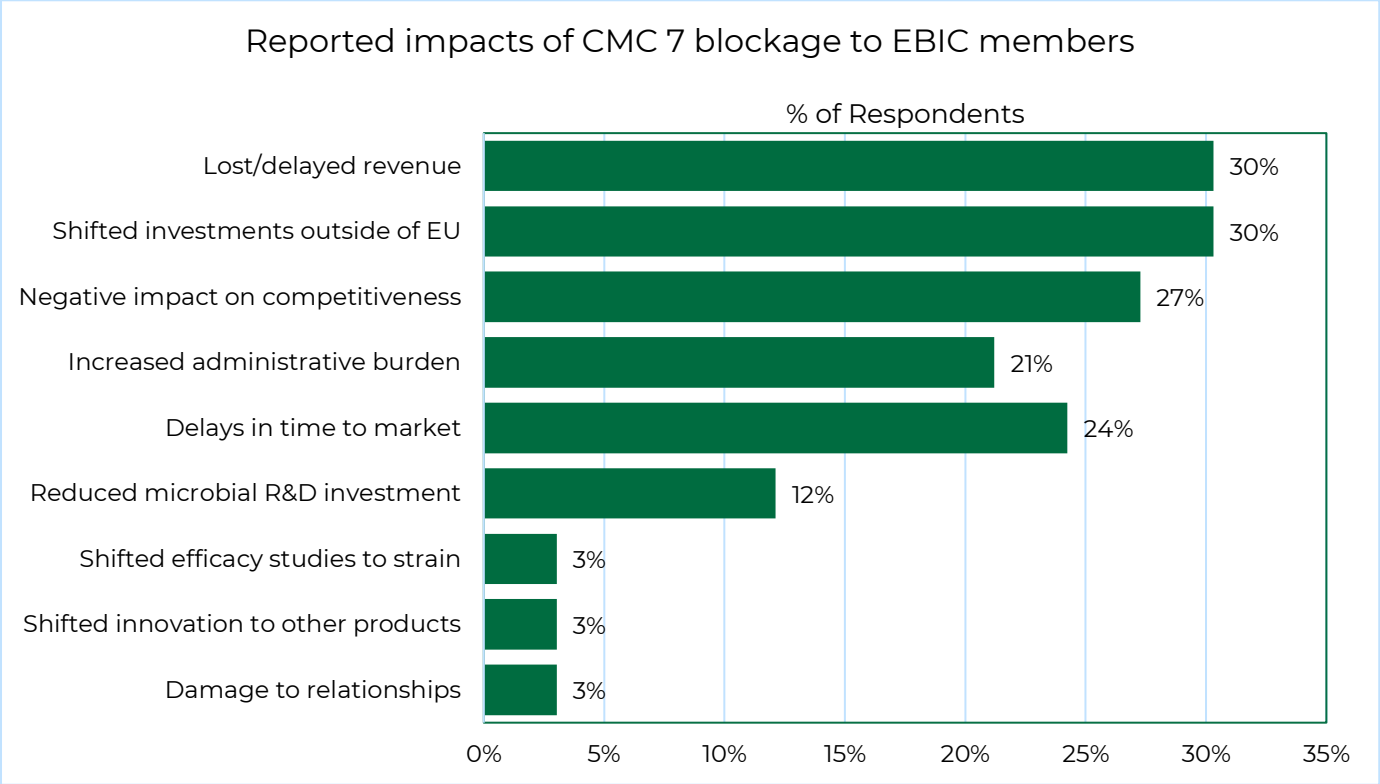
Real-world consequences of CMC 7 blockage: Evidence from industry

EU market loss



These results show that the United States and Brazil are now key country recipients of microbial innovation fit for the EU market - a direct consequence of the CMC 7 blockage.

Impact on the industry



These findings make clear that the consequences of regulatory inaction are not hypothetical or long-term: they are already undermining innovation, investment, and Europe's competitiveness today. Correcting the CMC 7 barrier is essential to safeguarding the resilience of Europe's agri-food system.

The negative consequences of blocked microbial innovation hurt the competitiveness of EU farmers and the biostimulants industry

The following analysis outlines the broader strategic consequences if the CMC 7 blockage is not urgently addressed.

European market-ready microbial biostimulants are stuck in a regulatory dead-end

Companies have sustainable microbial innovations ready for market but blocked from conformity assessment because of structural flaws in CMC 7.

The Single Market is not functioning for microbial biostimulants

63% of companies would have registered under the FPR if a pathway had existed. 75% of companies who used national routes would have preferred harmonised EU access.

A critical mass of innovation is out of reach for EU farmers, but not their competitors

47% of viable innovators had two or more microbial products ready, representing potential major advances in nutrient availability or use efficiency, climate resilience or crop quality - now stuck or being exported abroad. These tools could help farmers produce food despite volatility, reduce emissions related to crop production, increase yields and mitigate food chain risks.

The data reflect a gap between the EU's stated commitment to sustainable agriculture and its ability to deliver the tools needed by farmers

Innovation and investment are increasingly redirected to markets with more agile regulatory systems, notably the United States, Brazil, and Central America.

The FPR, without urgent correction of CMC 7, is not merely ineffective, it is actively pushing microbial innovation and market leadership out of Europe.

Conclusion

The European Commission must urgently correct the CMC 7 blockage. The FPR requires a functional process for microbial plant biostimulants to reach the EU market in order to bolster farmer competitiveness and EU strategic autonomy. Relying on the current FPR structure and fragmented national authorisations is not sufficient for scaling up competitive and sustainable agriculture.

EBIC is preparing a proposal for addressing the issues with CMC 7 in the FPR. We look forward to working with the European Commission and the Commission Expert Group on Fertilising Products on an urgent solution for microbial plant biostimulants in the EU.