

# Simplifying EU Rules to Support Innovation in Plant Biostimulants

# EBIC position for the agricultural simplification package

Plant biostimulants are essential tools for a more sustainable, competitive, and resilient EU agriculture. They optimise input use, improve soil health, enhance water resilience, and support the bioeconomy.

However, the complexity and rigidity of the Fertilising Products Regulation (FPR) 1009/2019 currently blocks innovation, delays market entry, and imposes unnecessary burdens on businesses and farmers, as well as restricting their access to innovation and increased productivity.

Simplifying these rules is critical not only to improve regulatory efficiency, but also to:

- Improve return on investment for EU farmers and accelerate access to effective, sustainable solutions
- Create clear pathways for innovative products that currently have none
- Strengthen the competitiveness and strategic autonomy of the agri-food sector
- Ensure a functioning and resilient EU single market

This paper will also highlight where certain simplifications – particularly in relation to REACH – could be achieved through secondary legislation, offering the Commission a path to near-term impact on simplification.

As it stands, any innovation that is not already listed in a CMC has no pathway to reach the EU market under the FPR. There is no general mechanism to evaluate or approve new types of materials – effectively closing the door to novel solutions. National authorisations are not a viable alternative, as they fragment the market and undermine harmonisation.

A shift to clear, science-based, criteria-driven systems – rather than rigid positive lists and disproportionate data requirements – will unlock Europe's potential for improved productivity, resilience, and green innovation.

It will also ensure that European farmers can access cost-effective, high-performing solutions without delays – reinforcing food security, competitiveness, and strategic autonomy.

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# 1. Micro-organisms in CMC 7

**Problem:** The current list under CMC 7 in the FPR allows only four types of micro-organisms to be used in microbial plant biostimulants. This excludes numerous other safe, efficient, and well-documented micro-organisms already registered in EU Member States or being developed by companies, many of which have strong potential to improve crop productivity, nutrient use efficiency, soil health, and climate resilience.

**Key issue:** There is currently no mechanism under the FPR to assess additional micro-organisms beyond the current list. This blocks Single Market access for essential tools for farmers, and discourages investment in sustainable agricultural inputs.

The absence of such a process risks pushing innovation and investment to other global regions with more agile regulatory systems. National authorisations are not a viable solution, as they fragment the market and undermine harmonisation.

#### **Proposal:**

- Introduce a criteria-based process to assess new micro-organisms for CMC 7.
- The process should be transparent, efficient, and predictable, as well as aligned with EU goals for innovation, safety, and the bioeconomy.

**Impact:** Unlock access to the Single Market for a broader range of effective, sustainable microbial plant biostimulants, helping EU farmers adopt better solutions and reinforcing Europe's leadership in agricultural innovation.

# 2. Animal By-Products in CMC 10

**Problem:** Circularity is a key priority for the EU – but the current rules for fertilising products prevent many safe materials from being reused in agriculture despite clear agronomic benefits. This includes most animal by-products (ABPs), which are widely used in national markets but blocked at EU level due to outdated, feed-based requirements and regulatory misalignment.

**Key issue:** Regulation (EC) 1069/2009 requires specific raw material–process combinations to be individually evaluated by EFSA and inscribed in an implementing act. There is no mechanism to authorise ABPs for fertilising products based on general scientific criteria.

As a result, circular materials like hydrolysed proteins – which have a long history of safe use, are essential to many biostimulant formulations, and have been evaluated by EFSA as of low concern for application to crops – are subject to disproportionate mitigation measures without appropriate impact assessment.

#### **Proposal:**

- Introduce a science-based, criteria-driven mechanism to authorise appropriately treated ABPs for use in fertilising products including hydrolysed proteins used in biostimulants.
- Improve coherence between the FPR and ABPR by:
  - o Defining clear, fertiliser-specific endpoints based on risk and function
  - o Clarifying distinctions between transformation and sanitisation processes
  - o Ensuring coherent treatment of ABPs across different use cases (e.g. food, feed, fertiliser)
- Remove mitigation measures that are not justified by a risk assessment related to the use as a fertilising product



**Impact:** Enables biostimulants to contribute meaningfully to the EU's circular economy by revalorising safe, animal-derived materials. Supports innovation, improves product availability, and helps farmers access more sustainable biostimulant solutions.

# 3. REACH+ Requirements under the FPR

**Problem:** The Fertilising Products Regulation imposes stricter-than-REACH requirements on ingredients used in EU fertilising products – even for low-risk, low-volume substances and susbstances already approved for use in food and feed. These "REACH+" obligations go beyond what REACH itself requires, creating unnecessary regulatory burdens.

**Key issue:** These additional requirements were introduced without a proper impact assessment and do not enhance safety, but they greatly increase the administrative burden on companies.

Manufacturers often lack the leverage or resources to convince upstream suppliers to update their REACH dossiers for fertilising product use – meaning that even safe, widely used substances may be legally blocked. This challenge is particularly acute for small manufacturers. This has led to shortages of key components, delays in product development, manufacturers opting for national paths to market, and reformulation of products to use older, less effective technical additives.

#### Proposal:

- Reinstate normal REACH rules for ingredients in EU fertilising products including exemptions for non-hazardous substances and low-volume use.
- Clarify that impurities and unintended, non-isolated substances are not subject to REACH+ obligations.
- Introduce tiered, risk-based requirements, exempting ingredients under 0.1% w/w where appropriate.

These changes could all be made via secondary legislation – allowing the Commission to quickly and smoothly deliver meaningful simplification where it is most urgently needed.

**Impact:** Eliminates unnecessary testing and compliance costs, particularly for SMEs. Restores access to safe, essential biostimulant components, accelerates innovation, and ensures that EU farmers benefit from a broader range of sustainable, high-performing solutions.

You can find more information about EBIC's position on REACH+ in our joint position paper.

#### Conclusion

To drive sustainability, innovation, and competitiveness in the EU agri-food sector, the Fertilising Products Regulation and related frameworks must become more agile, science-based, and growth-friendly.

That means moving away from rigid, slow-to-update systems toward clear, predictable mechanisms that support the green transition, EU competitiveness, and the economic resilience of farmers.

Without these changes, safe and effective biostimulant products will continue to be blocked - not because of safety concerns, but due to outdated structures and unnecessary regulatory hurdles.



Addressing these bottlenecks will accelerate access to better tools for farmers, stimulate investment, and strengthen the competitiveness of the European biostimulants sector.

In parallel, clearer implementation of the FPR is needed to avoid diverging interpretations at national level. Greater consistency is essential to ensure legal certainty, maintain a functioning Single Market, and support innovation across Member States.

EBIC stands ready to work with the European Commission and Member States to deliver practical, high-impact simplification — and is happy to provide more detailed proposals or engage in further exchanges to support this process.

For more information on this topic, please contact <u>Jessica@prospero.ag</u> or visit our website <u>www.biostimulants.eu</u>

