EBIC Position

EBIC's comments on the COM concept note on the "Reality check of the FPR" regarding Animal By-Products

As part of its broader effort to reduce administrative burdens and enhance competitiveness, the European Commission is carrying out a "Reality Check of the Fertilising Products Regulation" (FPR). This initiative aims to identify opportunities for simplification without compromising safety, and stakeholders are invited to provide practical input to support this objective.

In this paper, we argue that chitosan derived from shells from shellfish with the soft tissue and flesh removed, which are outside the scope of the Animal By-Products Regulation according to point f of Article 2 of Reg (EC) 1069/2009 can be safely used in EU Fertilising Products.

Chitosan is a naturally derived polymer, commonly sourced from crustacean shells such as shrimp and crabs through the partial deacetylation of chitin using concentrated alkali. Because the deacetylation process transforms it into a chemical, the substance is no longer recognisable as animal-derived. Chitosan can therefore be classified under CMC 1 of the FPR as a REACH-compliant, chemically defined, naturally occurring polymer, with safety being assured by REACH requirements.

According to the 2024 EU Fish Market report[1], EU citizens consume a total of 890 tonnes in Live Weight Equivalent (LWE) of crustaceans, with a corresponding mass of shells. There are therefore both environmental and economic imperatives to scale up the valorisation of those shells into other products, including fertilising products such as plant biostimulants rather than disposing of them.

From a policy coherency perspective, fostering the valorisation of those shells into fertilising products supports:

- Circular Economy objectives;
- Organic agriculture objectives (as the resulting plant biostimulants may be appropriate for organic agriculture);
- Bioeconomy objectives.

Since the **Commission is empowered to modify the provisions of Annex II of the FPR through delegated regulations**, the above-mentioned modifications would not require the Ordinary Legislative Procedure (OLP).

Since they are not science-based and are incoherent with regulatory simplification, we also call on the Commission to remove the mitigation measures applied to hydrolysed proteins in Commission Delegated Regulation 2023/1605. Again, the Commission has the power to update its own Delegated Regulation through another delegated act without going through OLP.

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Introduction

As part of its broader effort to reduce administrative burdens and enhance competitiveness, the European Commission is carrying out a "Reality Check" of the Fertilising Products Regulation (FPR). This initiative aims to identify opportunities for simplification without compromising safety, and stakeholders are invited to provide practical input to support this objective.

One area under review covers animal by-products (ABPs). Some ABPs are out of scope from the Animal By-Products Regulation (ABPR) according to Article 2 of Regulation (EC) 1069/2009 itself, yet cannot be used in EU Fertilising Products. In this context, the European Commission has sought input on:

- ABPs outside the scope of the ABPR that would make safe and efficient component materials for EU fertilising products;
- Economic impacts of their not being able to be incorporated into EU Fertilising Products;
- Appropriate assessment methods for their safe use in fertilisers.

EBIC's contribution addressing ABP-related issues under the FPR[1] is detailed below.

Q1 - Are there any animal by-products that are currently outside the scope of the Animal By-Products Regulation that you would consider a safe and efficient component material for EU fertilising products (e.g. guano)?

A relevant material that is safe and suitable for use in EU fertilising products (or as a precursors to component materials) and is out of scope of the Animal By-Products Regulation (ABPR) according to Article 2 of Reg (EC) 1069/2009 is shells from shellfish with the soft tissue and flesh removed (point f of Article 2).

This material is low-risk and, when properly processed, poses negligible threats to human, animal, or environmental health.

It is important to recall that materials such as shellfish shells were explicitly put outside the scope of the ABPR because either the nature of the materials themselves and/or the conditions of use meant that they were not of concern with regard to the issues that the ABPR was designed to address, namely pathogen and prion contamination.

First, all shellfish are invertebrates, which immediately eliminates concerns about prions.

In the case of soft shellfish, the shells can either be cleaned and dried and used directly as a fertiliser or transformed into chitosan through deacetylation. The latter case is the most relevant for plant biostimulants.

Chitosan is a naturally derived polymer, commonly sourced from crustacean shells such as shrimp and crabs through the partial deacetylation of chitin using concentrated alkali. It can be characterised as a chemical substance under REACH, structurally defined by three parameters: degree of polymerisation

[1] In addition to previous work carried out on the topic, EBIC surveyed the members of its Project Team on animal by-products to gather responses to the specific questions provided by the Commission in its concept note on the "Reality Check of the Fertilising Products Regulation".

(DP), fraction (or degree) of acetylation (FA/DA), and pattern of acetylation (PA). These molecular features are measurable and directly influence chitosan's functional properties. Due to its structural similarity to polysaccharides, chitosan is sometimes informally viewed as a "sugar-type" substance.

Q2 - If yes, what is the economic impact of not being allowed to use these products in EU fertilising products (e.g. from not using these animal by-products, from using other, more expensive, materials)?

The economic argument for allowing shellfish under the Fertilising Products Regulation cannot be separated from the environmental argument. According to the 2024 EU Fish Market report[2], EU citizens consume a total of 890 tonnes in Live Weight Equivalent (LWE) of crustaceans, with a corresponding mass of shells. There are therefore both environmental and economic imperatives to scale up the valorisation of those shells into other products, including fertilising products such as plant biostimulants rather than disposing of them.

From a policy coherency perspective, fostering the valorisation of those shells into fertilising products supports:

- Circular Economy objectives;
- Organic agriculture objectives (as the resulting plant biostimulants may be appropriate for organic agriculture);
- Bioeconomy objectives.

Q3 - What would be, in your view, the best way of assessment of those animal by-products to ensure their safe use as component materials for EU fertilising products?

Because the deacetylation process transforms it into a chemical, the substance is no longer recognisable as animal-derived. Chitosan can therefore be classified under CMC 1 of the FPR as a REACH-compliant, chemically defined, naturally occurring polymer, with safety being assured by REACH requirements.

Q4 - Other remarks or suggestions

Mitigation measures applied to hydrolysed proteins in Commission Delegated Regulation 2023/1605 are not science-based and are incoherent with regulatory simplification

The mitigation measures applied to hydrolysed proteins in Commission Delegated Regulation 2023/1605 such as small packaging requirements **should be removed in the interest of regulatory coherence and simplification. These measures impose a disproportionate burden because they are incoherent with EFSA evaluations of hydrolysed proteins applied to certain crops**.[3] In its evaluation, EFSA reaches the following conclusions:

1. **Low toxicological concern:** EFSA considers HPs to be of low concern due to their natural occurrence and biodegradability. No toxicological reference values were deemed necessary.

[2] https://op.europa.eu/en/publication-detail/-/publication/22f27511-b382-11ef-acb1-01aa75ed71a1
[3] https://www.efsa.europa.eu/en/efsajournal/pub/2545

2. **Consumer safety:** A consumer risk assessment was not required because residues from HPs are indistinguishable from naturally occurring proteins and peptides, even when contact with edible parts of the crop was not excluded.
3. **Environmental safety:** EFSA identified low risk for birds, mammals, and aquatic organisms, with very low environmental persistence and no bioaccumulation potential. Even where data gaps existed (e.g., non-target arthropods and bees), a low risk was concluded using a weight-of-evidence approach.
4. **No mitigation measures proposed:** EFSA did not propose any risk mitigation measures for the representative uses evaluated.
5. **No critical areas of concern identified.**

Therefore, there does not appear to be any scientific justification for the mitigation measures imposed on hydrolysed proteins using in EU Fertilising Products under Commission Delegated Regulation 2023/1605. Their removal would streamline compliance while maintaining safety, aligning with the goals of the FPR Reality Check.

Furthermore, we would like to point out a procedural irregularity that we believe led to this EFSA expertise being overlooked. Article 46 of the Regulation (EU) 2019/1009 modified Regulation (EC) 1069/2009 to include language that "Within six months after 15 July 2019, the Commission shall initiate a first assessment of derived products referred to in Article 32 that are already widely used in the Union as organic fertilisers and soil improvers…[with a view to determining] an end point in the manufacturing chain pursuant to paragraph 2 of this Article without undue delay and in any case no later than six months after the assessment is finalised. Hydrolysed proteins were explicitly mentioned in that list, but they were not included in the resulting mandate to EFSA that informed the drafting of Commission Delegated Regulation 2023/1605. We believe that – had EFSA been properly consulted – it would have concluded that there was no need for mitigation measures when hydrolysed proteins are used in fertilising products, in line with its "Conclusion on the peer review of the pesticide risk assessment of the active substance hydrolysed proteins."

EBIC strongly supports shifting to a criteria-based approach for assessing whether ABPs should be allowed in EU fertilising products

EBIC strongly supports shifting to a criteria-based approach for assessing whether ABPs should be allowed in EU fertilising products. A criteria-based model would provide more predictable and transparent pathways for innovation and market access. More than 25 years after the BSE crisis, it is time to take a step back, examine what has been learned collectively, consider data evaluating real-world practices, and to design a new framework for animal by-products that is compatible with the Circular Economy, based on the scientific knowledge accumulated over the past quarter century, and innovation friendly. The current approach is ad hoc, subjective, and often requires companies to accept that the intellectual property of their process engineering will be published in the EFSA Journal.

Such criteria might include:

- Whether the substance resulting from any given processing method satisfies thresholds for the presence or absence of pathogens or contaminants
- End-use and exposure risk

In the case of end points determined for materials used in EU Fertilising Products, consideration needs to take into account the risk mitigation measures imposed by the Fertilising Products Regulation itself, including contaminant and pathogen limits already defined for various Product Function Categories.

There is also an urgent to incorporate intelligent read-across or to have one evaluation for core criteria. For example, it is not logical that food-grade amino acids have to start at square one when being evaluated for use in food or fertilising products. Furthermore, even the operational authorisations of treatments plants should be able to consider that a manufacturer of a food-grade substance derived from animals can be safely authorised to produce the same substance for non-food uses.

About EBIC

EBIC is the European Biostimulants Industry Council, the trade association for plant biostimulants in Europe. Founded in 2011, our vision is sustainable agriculture supported by the global adoption of plant biostimulants. We are dedicated to fostering the growth, development and fair regulation of our industry. We promote plant biostimulants as essential to advanced food systems, providing education, advocacy, and support to members, policymakers, and farmers. www.biostimulants.eu

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