



EXTERNAL CONTRIBUTION | 20 October (v3) | Public circulation

Biostimulant industry comments on proposed end points in the manufacturing chain for certain organic fertilisers and soil improvers (Ares(2022)6618010)

On 26 September 2022, the European Commission published [for public consultation](#) a draft delegated act supplementing Reg (EC) 1069/2009 regarding the determination of end points in the manufacturing chain of certain organic fertilisers and soil improvers (Ares(2022)6618010).

While the plant biostimulants industry is pleased to finally have a public draft available for discussion, we regret that more consultation did not happen. In their current form, the proposed measures would be unworkable because they are divorced from operational realities and therefore would make little or no contribution to the European Union's ambitions for the Circular Economy under the European Green Deal. The Farm to Fork Strategy notes the need to speed up adoption of circular, bio-based tools in food production, and the current draft delegated act unfortunately falls short of this ambition by failing to acknowledge the positive risk assessments of key materials like hydrolysed proteins. We hope that the current consultation will make it possible to correct these shortcomings while maintaining the high levels of health and safety that are the objective of safety-based end points.

While we **welcome the inclusion of insect frass in Article 3** of the draft delegated act, we note the **following shortcomings**, which are explained in more detail in this document:

- The statement in Article 4(3) of the draft delegated regulation that the **derived products in Article 4 may be mixed with “any material of non-animal origin which is not listed in the catalogue of feed materials set out in the Annex to Regulation (EU) No 68/2013” should be deleted**. This is simply unworkable as every single plant micronutrient (Fertilising Products Regulation CMC 1 materials) is listed in the catalogue of feed materials as are many of the plant materials explicitly included in the Fertilising Products Regulation under Component Material Categories 2 and 6. Indeed, the mineral fraction of fertilising products is generally considered to make them less appetizing to animals.
- The draft delegated act **does not provide legal clarity** on whether the proposed end points could be used in all appropriate Product Function Categories of EU Fertilising Products. This could be easily corrected by adding the following sentence to Article 2(1) of the draft: “For the purposes of this regulation, certain organic fertilisers and soil improvers should be understood to include all relevant Product Function Categories of Reg (EU) 2019/1009.”
- **Hydrolysed proteins (Article 4(1)(f)), including the treatment processes in Annex XI of Reg. (EU) 142/2011, should be moved into Article 3**, justified by EFSA risk assessments “[Scientific Opinion on the revision of the quantitative risk assessment \(QRA\) of the BSE risk posed by processed animal proteins \(PAPs\)](#)” (2011) and “[Updated quantitative risk assessment \(QRA\) of the BSE risk posed by processed animal protein \(PAP\)](#)” (2018). Furthermore, **non-proteinaceous hydrolysates should be explicitly mentioned** in the new point in Art. 3.

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- **Articles 3 and 4 should refer to plants authorised under Article 24(1) of Regulation (EU) No 1069/2009** without a reference to subpoint (f) as many producers of hydrolysed proteins also sell their products into other value chains and do not actually sell anything packaged as fertilising products per se.
- The proposed **risk mitigation measures should be deleted as incompatible with the definition of an end point and the status of these materials as components**, not final products, under Regulation (EU) 2019/1009.
- The explanatory memorandum glosses over negative feedback provided to date by stakeholders and competent authorities on fertilising products.

FOR DETAILED EXPLANATIONS OF OUR COMMENTS

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Introduction

While the plant biostimulants industry is pleased to finally have a public draft delegated act determining end points for certain organic fertilisers and soil improvers (Ares(2022)6618010) available for discussion, we regret that a lack of upstream consultation means that the measures proposed are divorced from standard operating procedures applied today. We hope that the current consultation will make it possible to correct these problems while maintaining the high levels of health and safety that are the objective of safety-based end points, and we offer the suggestions below to improve the proposal. Our comments focus on insect frass and hydrolysed proteins as these are the derived products that are most relevant for plant biostimulants.

Aspects of the draft that we support

We welcome the inclusion of insect frass in Article 3 of the draft delegated act.

Aspects of the draft that should be modified

1. The end points should focus on essential characteristics of products, particularly safety when used as intended

The draft delegated act is out of scope of the mandate given in Article 5 of Regulation 1069/2009 (as amended by Article 46 of the Fertilising Products Regulation (EU) 2019/1009 (FPR)). The revised Article 5 states that:

“For derived products referred to in Articles 32 [organic fertilisers and soil improvers], 35 [pet food] and 36 [other derived products] which **no longer pose any significant risk to public or animal health**, an end point in the manufacturing chain may be determined, beyond which they are no longer subject to the requirements of this Regulation.

Those derived products may subsequently be **placed on the market without restrictions** under this Regulation and shall no longer be subject to official controls in accordance with this Regulation.”

Rather than focusing on determining manufacturing end points for safe fertilising products for their intended use, the draft delegated regulation focuses instead on preventing fraud in a completely different value chain, which is outside the scope of the mandate given in Article 5(2) of the ABPR. Furthermore, since Article 5 states that derived products having reached an end point under the ABPR “may subsequently be placed on the market without restrictions under this regulation,” the imposition of the proposed mitigation measures appears contradictory, since both the packaging and dilution requirements would be “restrictions under this regulation.”

The Fertilising Products Regulation imposes labelling measures on certain types of EU Fertilising Products to avoid their being accidentally ingested by animals. Therefore **Article 4(2) and Article 4(3) of the draft delegated act should be deleted as they do not change the risk profile of the derived products themselves; they have no effect on safety. As**



demonstrated below with data on how the market in hydrolysed proteins functions today, the proposed risk mitigation measures are unworkable for at least half of such hydrolysates currently sold (and probably more when we consider the knock-on effect of intermediates). Furthermore, these risk mitigation measures are unnecessary for EU Fertilising Products, which are already subject measures to prevent animals from ingesting fertilising products, including conformity assessment and labelling requirements. The provisions of Regulation (EU) 2019/1009 also provide for traceability.

2. The reference to the catalogue of feed materials needs to be deleted because most fertilising products containing materials derived from ABPs also contain a common component

Article 4(3) of the draft delegated regulation states that the derived products in Article 4 may be mixed with “any material of non-animal origin which is not listed in the catalogue of feed materials set out in the Annex to Regulation (EU) No 68/2013.” This is simply unworkable as every single plant micronutrient (Fertilising Products Regulation CMC 1 materials) is listed in the catalogue of feed materials as are many of the plant materials explicitly included in the Fertilising Products Regulation under Component Material Categories 2 and 6. Examples include sunflower seed expeller, grape pulp, olive pulp, cocoa husks, and vinasse. Many organic-based fertilisers are complex mixtures of animal by-products, plant materials and -- in the case of organo-mineral fertilisers -- minerals. The mixtures allow manufacturers to achieve reliable formulations that provide the desired agronomic performance. Furthermore, the mineral fraction of fertilising products is generally considered to make them less appetizing to animals.

Forbidding any product containing any materials in the catalogue of feed materials would render the definition of end points pointless since virtually no product containing these derived materials could meet this requirement. A rapid survey of the fertilising products industry conducted in early October 2022¹ **half of respondents noted that more than 75% of their products contain at least one component that is listed in the catalogue of feed materials. Only two companies stated that none of their products contain materials in common with the list of feed materials.**

Furthermore, this language would cause problems for the functioning of the Fertilising Products Regulation. A concrete example will help illustrate the point: If we assume that a PFC 1A organic fertiliser or a PFC 6 plant biostimulant contained an animal by-product meeting this requirement, subsequently incorporating either of them into a PFC 7 blend with

¹ 45 companies responded. They are members of AEFA (Spanish national association), Afaïa (France), Artemis (Netherlands), Assofertilizzanti (Italy), Belfertil (Belgium), EBIC, ECOFI (European Consortium of Organic-Based Fertilizer Industry), IVA (Germany), SPEL (Greece), and UNIFA (France). Companies were asked to include any sales that would fall under the Product Function Categories of Regulation (EU) 2019/1009 and to exclude any production that is destined for feed, cosmetics, or other non-fertilising product uses.

a micronutrient would undo the end point in two ways: 1) It would require unpacking the derived end point material from the small packs that are currently specified in the draft delegated regulation and 2) it would entail mixing the end point material with micronutrients, which are listed in the catalogue of feed materials.

3. It is not clear whether the draft delegated act would create a legal basis for use of these materials in all appropriate Product Function Categories

The draft delegated act does not provide legal clarity on whether the proposed end points could be used in all appropriate Product Function Categories of EU Fertilising Products. This could be easily corrected by **adding the following sentence to Article 2(1) of the draft: “For the purposes of this regulation, the term “certain organic fertilisers and soil improvers” should be understood to include all relevant Product Function Categories of Reg (EU) 2019/1009.”**

4. Hydrolysed proteins, including the treatment processes in Annex XI of Reg. (EU) 142/2011, should be moved into Article 3, and non-proteinaceous hydrolysates should be specifically mentioned

Hydrolysed proteins (Article 4(1)(f) of the draft) should be moved into Article 3 and the processes according to Annex XI of Reg. (EU) 142/2011 should be included. These changes are justified by EFSA risk assessments “Scientific Opinion on the revision of the quantitative risk assessment (QRA) of the BSE risk posed by processed animal proteins (PAPs)” (2011) and “Updated quantitative risk assessment (QRA) of the BSE risk posed by processed animal protein (PAP)” (2018). Their model specifically considered the use of Cat. 3 materials in fertilising products. Following these and other risk assessments conducted by EFSA, the feed ban laid down by regulation 999/2001 has been lightened and most of the restriction have subsequently been removed. Specifically, Chapter II of Annex IV of Regulation 999/2001 was amended subsequent to these risk assessments to explicitly exclude “hydrolysed proteins derived from parts of non-ruminants or from ruminant hides and skins” from the feed ban. If these materials are deemed safe for feed uses, there is no scientific basis for considering them unsafe for fertilising products. Indeed, in Italy and some other Member States, hydrolysed proteins are specifically exempted from requirements to mix derived products with repulsive additives to discourage accidental animal feeding. The draft delegated regulation ignores 20 years of scientific evaluation and empirical evidence of the safe production and use of hydrolysed proteins in fertilising products.

The new point in **Article 3 should explicitly include “non-proteinaceous hydrolysates such as amino acids and peptides”** since they cannot under any circumstances be considered a risk factor for transmissible spongiform encephalopathies (TSEs). Although the source materials contained proteins, hydrolysed amino acids and peptides are purified to ensure that they no longer contain any residual proteins and therefore no prions. The term “hydrolysed proteins” implies that the hydrolysates still contain proteins.



Considering that the aim of the draft delegated act is to determine end points in the manufacturing chain of certain organic fertilisers and soil improvers, which are currently produced (and widely used safely) according to the conditions set out in Annex XI to Reg. (EU) 142/2011, **the new point on the hydrolysed proteins in article 3 of the delegated act should be modified as follows:**

hydrolysed protein which fulfils the specific requirements for hydrolysed protein set out in Section 5, point D, of Chapter II of Annex X to Regulation (EU) No 142/2011 2011 or obtained through transformation process from 1 to 6 (Annex IV Chapter III Reg. 142/2011) starting from category 3 materials, as per Annex XI Chapter II Section 1, point 1 (C). Non-proteinaceous hydrolysates of these same materials are also considered to have reached an end point.

The abovementioned rapid survey of the fertilising products industry conducted in early October 2022 indicates that **27% of respondents currently deliver 75% of more of the hydrolysed proteins they sell in either tanker trucks** (usually for uses as intermediates by other producers) **or other bulk forms** like big bags and container tanks. This represents about 23,000 tonnes delivered by tanker truck and 115,000 tonnes delivered in other forms of bulk (container tanks, big bags, etc.) Respondents reported delivering about 150,000 tonnes in small packs, making it roughly half of reported sales; however, it should be noted that many of the small pack sales are dependent on bulk deliveries upstream. Only 40% of producers of hydrolysed proteins reported that they have no sales as intermediates; in contrast, 18% of respondents indicated that more than 75% of their sales of hydrolysed proteins are as intermediates. Two-thirds of respondents indicated that more than 75% of their sales of hydrolysed proteins are used in agricultural field applications and not in horticulture or amateur uses. **Ninety percent of the companies who reported sales via tanker truck specify that more than half of these sales entail products at a concentration of more than 75% hydrolysed proteins. (100% concentration was not offered as a possible answer.)** For other bulk forms, 59% of producers of hydrolysed proteins reported that more than half of these sales cross the 50% concentration threshold.

Where hydrolysed proteins are sold in small packages, ten out of seventeen respondents said that more than half of these products are sold in concentrations of 50% or greater, with more than a third of the products being above 75% concentration (100% concentration was not an option).

5. Component Material Category 10 of the Fertilising Products Regulation is for component materials, not final products

Article 5 of Regulation 1069/2009 (as amended by Article 46 of the Fertilising Products Regulation (EU) 2019/1009 (FPR)) gives a mandate to define end points in order to allow derived materials from animal by-products to be included as component materials in EU Fertilising Products. Since these component materials may well be combined with other component materials, the **end points cannot be dependent on end-user packaging as that is logically incoherent with the concept of a component material.** As described above, it



would be impossible to respect the requirements on end-user packaging with the possibility of creating PFC 7 blends under the Fertilising Products Regulation.

It is also difficult to see how such measures could be implemented with regard to conformity assessment. In order to achieve conformity assessment, the FPR requires companies to demonstrate to a Notified Body that their product meets all the requirements for an EU Fertilising Product. If the EU Fertilising Product contains a component material under CMC 10, the company must demonstrate that the CMC 10 material has already reached the end point: but that is impossible since the product cannot be packaged for end users until after receiving conformity assessment.

However, the conformity assessment process offers an opportunity to control that end-point materials are being incorporated into *bona fide* fertilising products and not being misdirected to other value chains.

6. The reference to Article 24(1), point (f), of Regulation (EU) No 1069/2009 is overly restrictive

Articles 3 and 4 should refer to plants authorised under Article 24(1) of Regulation (EU) No 1069/2009 without a reference to point (f). A rapid survey of the fertilising products industry conducted in early October 2022 indicates that 25% of the respondents are authorised to process animal by-products under a different sub-paragraph other than point f. Their activities are authorised under Article 24(1) of Regulation (EU) No 1069/2009 more generally. This is because it is economically more interesting for an operator to have a “higher level” authorisation that allows them to sell their products into more than one value chain. For example, while it is forbidden for a fertilising product grade hydrolysate to be sold into the feed chain, there is no safety reason for preventing a feed-quality hydrolysate from being incorporated into a fertilising product since no contamination could result from this operation. This is especially relevant for hydrolysed proteins, where many companies that carry out hydrolysis under the conditions in the Animal By-Product Regulation do not sell fertilising products for end use: they sell intermediates that are packaged as fertilising products by a different company. Therefore, the fertiliser plant is downstream from where the hydrolysis is conducted. The end point should be dependent on the technical process applied, since that is what determines if the material can be safely used in fertilising products.

To ensure optimal resource use, the general hierarchy of food-chain recycling is:

- products should be re-used as food if possible (according to safety and quality parameters);
- if not, incorporated into feed if possible;
- if not, incorporated into fertilising products if possible;
- if not, incinerated (and then possibly incorporated into fertilising products, depending on the technical quality of the material).



7. We dispute the description of stakeholder views given in the section 'Consultations prior to adoption' in the Explanatory Memorandum

Under point 2. 'Consultations prior to the adoption of the act', the Explanatory Memorandum of the draft delegated regulation describes the feedback from stakeholders at the 7 June 2022 meeting of the Animal Health Advisory Group as being "largely supportive" of this delegated regulation. EBIC was a participant in this meeting and contests this description. Stakeholders did express support in general for defining end points so that materials derived from animal by-products can be incorporated into EU Fertilising Products under Regulation (EU) 2019/1009. However, we were given few details and were not shown the draft delegated regulation, so it would have been impossible to express support for the draft as we had no details of what it would contain. Second, a number of our questions went unanswered, and several stakeholders voiced frustrations with the process during this meeting. Therefore, it seems disingenuous to claim stakeholder support for this draft Delegated Regulation.

Furthermore, when the end points and risk mitigation measures were described to stakeholders and competent authorities at the 14-15 July meeting of the Commission Expert Group on Fertilising Products, both stakeholders and Member States were vocal that the proposals were not aligned with the functioning of the market or fertilising products.

Conclusion

In conclusion, in order to get the balance right between ensuring health and safety in ways that will not disrupt the operation of existing markets and will allow the Fertilising Products Regulation to fulfill its Circular Economy ambitions, the following changes are needed to the draft delegated act defining fertilising product end points for derived products from animal by-products:

- ✓ The reference to the catalogue of feed materials needs to be deleted.
- ✓ The legal basis for incorporating materials that meet these end points into EU Fertilising Products should be clarified.
- ✓ Hydrolysed proteins (Article 4(1)(f)), including the production conditions described in Reg. (EU) 142/2011, Annex XI, Chapter II, section 1, should be moved into Article 3, and non-proteinaceous hydrolysates (e.g. purified amino acids and peptides) should be explicitly included.
- ✓ Articles 3 and 4 should refer to plants authorised under Article 24(1) of Regulation (EU) No 1069/2009 without a reference to point (f).
- ✓ The proposed risk mitigation measures should be deleted as incompatible with the definition of an end point and the status of these materials as components, not final products, under Regulation (EU) 2019/1009.
- ✓ The explanatory memorandum should be more honest about stakeholder feedback.

About the associations co-signing this position



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 Biostimulants 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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Costituita nel 1985, Assofertilizzanti - Associazione nazionale produttori di fertilizzanti - è una delle 17 Associazioni di Federchimica - Federazione Nazionale dell'Industria Chimica - che tutela e rappresenta tutte le realtà produttive del settore dei fertilizzanti. Per perseguire questo scopo raggruppa i principali operatori del settore dei fertilizzanti, con un fatturato complessivo di circa un miliardo di euro, pari a oltre il 90% dell'intero mercato nazionale.

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Der Industrieverband Agrar e. V. (IVA) mit Sitz in Frankfurt am Main vertritt die Interessen der agrochemischen Industrie in Deutschland. Der Verband informiert die Öffentlichkeit über die Themen der Branche, insbesondere zur Bedeutung von Forschung und Innovation für eine moderne und nachhaltige Landwirtschaft. Der IVA ist Initiator und Schaltstelle für die Formulierung gemeinsamer Positionen und für die Durchführung von Projekten und Aktionen insbesondere in den Bereichen Zulassung, Wirtschaft und Recht, Biodiversität, Gewässerschutz, Lebensmittelsicherheit, Anwenderschutz sowie der Kommunikation.

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About the associations co-signing this position



Artemis is de belangenvereniging van producenten en distributeurs van biologische bestrijders en bestuivers, gewasbeschermingsmiddelen van natuurlijke oorsprong en biostimulanten.

Voor meer informatie over dit onderwerp kunt u contact opnemen met Helma Verberkt (Helma.Verberkt@artemisnatuurlijk.nl | +31 6 20 39 1477).



Organisation professionnelle, l'UNIFA a pour mission l'expression collective des besoins et positions de ses membres. Elle produit également les statistiques officielles de livraisons d'engrais pour le compte de l'Etat.

Si vous avez encore des questions sur le contenu de la position, merci de contacter Florence Catrycke (fcatrycke@unifa.fr | +336 26 03 49 01).



Le représentant pour la France des entreprises fournissant les matières fertilisantes et intrants innovants des cultures végétales durables. Syndicat professionnel des acteurs de la filière des supports de culture, paillages, amendements organiques, engrais organiques et organo-minéraux et biostimulants.

Si vous avez encore des questions sur le contenu de la position, merci de contacter Stéphanie Tiprez (stephanie.tiprez@afaia.fr | +33 6 49 34 46 73).