Brussels, 2 April 2024

Ms Sandra GALLINA
Director General
Directorate-General for Health and Food Safety (SANTE)
European Commission
1049 Brussels

CC: **Ms Claire Bury**, Deputy Director General for Food Sustainability Responsible for Directorates E, F and G
Ms Roser DOMENECH AMADO, Director SANTE.A
Mr Bernard VAN GOETHEM, Director SANTE.G

RE: **The EU needs an approach to materials from animal origin in the food chain that is fit for the Circular Economy**

Dear Ms Gallina,

The undersigned organisations are writing to express our concerns at the gap between the ambitions for the Circular Economy and for Critical Raw Materials under the European Green Deal and the regulation and evaluation of the revalorisation in agriculture and the food and feed chain of materials originating from animals. We emphasise our complete commitment to ensuring that all routes for valorisation in agriculture and the food and feed chain of materials from animal origin are fully safe and are perceived as such by consumers and stakeholders. However, the current, fragmented regulatory framework requires far more resources than could be the case from bodies such as the European Food Safety Authority (EFSA) and places an unnecessary administrative burden on businesses, contrary to the spirit of the Commission's own Better Regulation framework. There is no gain for public health, animal safety, or environmental protection from these arrangements compared to alternatives, and they are in contradiction with objectives to increase circularity, whether for environmental reasons or to serve open strategic autonomy.

Nor is the current system fit for the purpose of the new 'One Health' approach as substances that are used in multiple value chains are not treated in a coherent and resource-efficient manner.

Unclear terminology is another problem of the current legislation around the revalorisation of materials derived from animal origin. For example, the blanket term "hydrolysed proteins" under in Regulation (EC) 1069/2009 is misleading since some hydrolysates such as amino acids and peptides no longer contain any proteins. In many cases, the regulation uses the same terminology to refer to materials before and after treatment. Even the term "animal by-product" is confusing because it is used differently in general discourse than it is by EU policymakers, where is only applies to animal materials under Regulation (EC) 1069/2009.

The **undersigned organisations call on the Commission to include a work item in its 2024-2029 work program to undertake a comprehensive review of the European Union's approach to the regulation of materials from animal origin** so that a better system can be designed to promote innovation in the revalorisation of materials of animal origin in line with the Circular Economy objectives while ensuring high levels of protection of people, animals, and the environment, and consumer confidence in this safety.

In the annex to this letter, we offer examples of inefficiencies and incoherencies, regulatory obstacles, or recycling routes currently facing a lack of regulatory status that have been submitted by some of the signatories to illustrate our concerns.

Our organisations would be happy to engage in a dialogue with all interested parties to explore how the Union's One Health objectives are compatible with approaches that would also better promote the revalorisation of materials derived from animals within a bio-based, Circular Economy.

Sincerely,

Arne Pingel, President
European Biostimulants Industry Council (EBIC)

Lucile Sever, Policy Officer for Circular Economy
European Biogas Association

Dr Stefanie Siebert, Executive Director
European Compost Network (ECN)

Chiara Manoli, President
European Consortium of the Organic-Based Fertilizer Industry (ECOFI))

Dirk Dobbelaere, Secretary General
European Fat Processors and Renderers Association (EFPRA)

Leon Fock, Chairman
Eurofema

Arnaud Bouxin, Director for Feed Safety and Regulatory Affairs
European Feed Manufacturers' Federation (FEFAC)

Robert Van Spingelen, President
European Sustainable Phosphorus Platform

Cecilia Luetgebrune, Secretary General
Growing Media Europe

Stéphanie Tiprez, Director
Afaïa

Camino García Martínez de Morentin, Director General
Asociación Española de Fabricantes de Agronutrientes (AEFA)

Dr Theresa Krato, Head of Plant Nutrition and Biostimulants
Industrieverband Agrar e.V. (IVA)

Dr Fotini Giannakopoulou, General Manager
Hellenic Fertilizers' Association (SPEL)

Delphine Guey, President
L'union des industries de la fertilization (UNIFA)

Nicolas Marquet, General Manager
Union des Entreprises pour la Protection des Jardins et des Espaces Publics (UPJ)

Bill Wirtz, Senior Policy Analyst
Consumer Choice Center

Annex: Case studies illustrating how the EU regulatory framework for the re-use of materials from animal origin is no longer fit-for purpose

Examples of incoherencies and inefficiencies

- The current approach **does not distinguish between animal materials that are simply sanitised and those that are fundamentally transformed** during processing.
- **Submitted by EBIC** – **As highly refined products, food grade amino acids** must meet the requirements of Regulations (EC) 853/2004 (specifying the acceptable raw materials and the ability of the producer to ensure an absence of any animal or public health risk), (EC) 1333/2008 (defining amino acids), EC) 1334/2008 (listing amino acids as a flavouring substance), and (EC) 852/2004 on food hygiene. The business operator must be registered according to the provisions of (EC) 854/2004, which entails a visit from competent authorities. Periodic inspections complement the implementation of best practices and HACCP principles. Only raw materials that are from sources fit for human consumption may be used. However, if a producer wants to place **the same amino acid on the market for animal feed, a nationally authorised fertilising product, and/or an EU Fertilising Product,** the producer must register as an authorised entity according to Regulation (EC) 1069/2009[1]. Depending on the intended use, the substance – or more accurately the combination of raw materials and treatment process – must be considered by national authorities, EFSA, and DG SANTE, but the procedure is different for each use,[2] and there is no way for a substance to undergo a single evaluation that would consider all possible uses at the same time.

  While each of these evaluation processes makes sense on its own, when applied to the same substance for multiple uses, it becomes obvious that there are considerable inefficiencies, both in the use of public authorities' time and expertise and in the administrative burden for companies that must complete 3-4 different dossiers.

  A centralised evaluation process that allowed companies to submit a substance for evaluation under all the uses for which the company would create considerable savings in public resources and time. This would be coherent with the Commission's principle of 'one substance, one assessment'.

- **Submitted by EBA and ECN –** The Commission Delegated Regulation (EU) 2023/1605 supplementing Regulation (EC) No 1069/2009 finally provided an end point in the manufacturing chain for composting and anaerobic digestion residues, allowing for compost and digestate-derived from animal by-products to be used as a component material of EU Fertilising Products. Nevertheless, only the standard transformation parameters (70 °C for at least 1 hour with a maximum particle size of 12 mm) have been allowed for composts and digestate from animal by-products in the delegated regulation resulting in a major barrier for the commercialisation of this type of digestate under the Fertilising Products Regulation [Reg. (EU) 2019/1009]. Other composts and digestates obtained by alternative transformation parameters authorised by competent authorities and incorporated into nationally authorised fertilising products must be accepted by other Member States under Mutual Recognition but are not currently eligible for inclusion in EU Fertilising Products.

[1] Some Member States will not allow a single facility to register under both regulations, even when all the substances produced are identical, derived from the same raw materials, fit for human consumption, and meet all the corresponding the requirements.
[2] We are happy to provide details upon request.

Examples of complete transformations that are not fully acknowledged by the current system

Where materials of animal origin are transformed significantly by treatment processes, better outcomes would be achieved by an evaluation of the final substances rather than the evaluation of individual treatment processes (which may ignore other treatments the same substance undergoes during manufacturing). Such a criteria-based approach could ensure high-levels of animal, human, and environmental protection while fostering innovation in treatment processes.

- **Submitted by EBIC and ECOFI** – As noted above, Hydrolysed proteins, peptides, and amino acids, are completely transformed from the animal materials that serve as raw materials for the hydrolysis processes. Furthermore, the characteristics of the final substance are not taken into account, even when additional downstream processing has further improved the safety profile of the substance.
- **Submitted by ESPP** – Inorganic phosphates may be recovered from sewage sludge incineration ash or ashes of other animal by-products such as manures or meat-and-bone meal. Incineration eliminates risks of pathogen contamination and process phosphates that could be used in animal feed as a substitute for ingredients derived from mined phosphate rock.
- **Submitted by ESPP** – Similarly, inorganic phosphates recovered from incineration ash of Category 1 ABPs could safely be used as fertilisers, thus revalorisaing materials that were previously excluded from the Circular Economy; however, the mandate to EFSA for the official evaluation of these materials has been pending for more than two years, illustrating that the current system is not responsive to innovation.

Examples of innovative materials where the regulatory pathway is currently unclear

- **Submitted by ESPP** – The interface between animal by-products and other sectors sometimes makes the regulatory pathway for innovations unclear. This is the case for potential feed uses of algae or aquatic plants grown using municipal wastewater as a substrate, or of materials extracted from such algae or aquatic as well as fertilisers containing algae or aquatic plants grown using manures as a substrate their extracts.
- **Submitted by ESPP** –Concepts such as “end point” or “a processed form” are complicated when considering the increasingly complex transformations within the Circular Economy. For example, if you synthesise a bio-plastic from CO_2 captured from the incineration of manure, is the bio-plastic considered to be an animal by-product in a processed form? Or is it now outside the scope of the animal by-products regulation?