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Author:	K. Sukalac
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## POSITION PAPER

# Comments on the EFSA Opinion “Inactivation of indicator microorganisms and biological hazards by standard and/or alternative processing methods in Category 2 and 3 animal by-products and derived products to be used as organic fertilisers and/or soil improvers”

EBIC and ECOFI have concerns that the scoping provided to EFSA in the revised mandate to produce its opinion “Inactivation of indicator microorganisms and biological hazards by standard and/or alternative processing methods in Category 2 and 3 animal by-products and derived products to be used as organic fertilisers and/or soil improvers,” could lead to inappropriate conclusions when the European Commission proposes end points for animal by-products subsequently used in EU Fertilising Products.

- Inappropriate biological indicators were used for some materials;
- EFSA itself noted significant data gaps, in some cases stemming from the disconnect between the biological indicator and the animal by-product;
- Existing end points for some animal by-products were not taken into account;
- The full processing used to make the final fertilising product was not taken into account, so the assessments do not reflect real-life cases;
- EFSA itself noted that it did not conduct a full risk assessment.

### Introduction

On 2 December 2021, EFSA published the Scientific Opinion “Inactivation of indicator microorganisms and biological hazards by standard and/or alternative processing methods in Category 2 and 3 animal by-products and derived products to be used as organic fertilisers and/or soil improvers” in response to a mandate from the European Commission. This opinion is meant to inform the Commission’s proposal to SCoPAFF concerning end points for animal by-products under Regulation (EC) 1069/2009 to be cited in CMC 10 of Regulation (EU) 2019/1009 on Fertilising Products. In these comments, EBIC and ECOFI would like to highlight several essential points that should be taken into consideration in this deliberation.

[EFSA presented its opinion to the Animal Health and Welfare section of the SCOPAFF Committee on 10 February 2022.](#)

### Specific comments

- The title of the EFSA Opinion states that it concerns materials to be “used as organic fertilisers and/or soil improvers.” However, this is inexact. On page 9, EFSA notes that the Commission explicitly told EFSA to disregard any “further transformation processes the fertiliser industry might apply to produce the final OF/SI.” Therefore, the EFSA opinion only considers input materials, not necessarily the component materials found in the final fertilising product. Furthermore, the Commission asked EFSA to make the assessment “without considering the use or applications of the final OF/SI product” (page 9, next line). This means that, even if the EFSA had made an assessment of component materials, it would have been difficult to set an end point for the specific use as fertiliser, which was the stated objective of the original mandate by the Commission (“[...]In particular, the scientific opinion should comprise an assessment of the biological risks to animal and public health deriving from the use as OF/SI of the following Category 2 and 3 materials and derived products [...]”)
- These discrepancies matter because Annex II of Regulation 2019/1009 differentiates between “component materials, and the input materials used to produce them.” If the end points determined for fertilising products under Regulation (EC) 1069/2009 are for **input materials**, there is a fundamental mismatch with CMC 10 of Regulation (EU) 2019/1009, which is supposed to list **permitted component materials**.

In addition, as the European Commission proposes end points, it is important to specify that component materials derived from specified end-point materials may also be used in EU Fertilising Products to address this gap.

- As stated in the conclusions (p. 80), EFSA did not conduct a full risk assessment and the absence of real-world factors, such as the application of additional processing methods and their impact is problematic. For example, in 2018 (the latest official data available), 62,468 controls were conducted in Italy, with only nine cases requiring further investigation for possible contamination by pathogens, and all nine cases were finally determined to be negative for contamination. **EBIC and ECOFI therefore second the recommendation from EFSA that a full risk assessment be conducted that includes additional processing and real-world data on the occurrence of incidents.**
- EBIC and ECOFI would like the Commission to **explain the rationale for asking EFSA to apply the conditions for biogas digestion residues and composts to other ABP materials**. This means that some indicators (such as *Ascaris* spp.) were applied to materials where they would not normally be found, such as skins and hides. This is particularly puzzling since the ABPs under assessment already have an end point defined under Regulation (EU) No 142/2011 that guarantees the safety of these materials, so that they can be placed on the market without restrictions. Instead of using these well-established end points and treatment methods, the EFSA study uses safety parameters that are ill-adapted to these materials, so it is not surprising that EFSA found minimal reduction of biological indicators in a context within which it admits that there is ample uncertainty and lack of data. We are therefore concerned to understand how DG Sante will use this data.
- **EFSA’s reasoning concerning the generalised use of *Ascaris* spp. as an indicator for all parasites seems inconsistent.** In the summary (p. 3), EFSA states that “Hazards intrinsically present in the matrix were considered, while hazards deriving from external sources or cross-contamination were excluded from hazard

identification.” However, as stated on p. 37 “*Ascaris* spp. are parasites “which can colonise the intestinal tract of animal and humans.” It is therefore unsurprising that the “[i]nactivation of *Ascaris* spp. and *Ascaris* eggs has mainly been studied in sewage sludge, manure and similar materials,” (p. 53) as this is where an intestinal parasite is expected to be found. Therefore, although the hardiness of *Ascaris* spp. may appear to make it a useful indicator for parasites in theory (p. 37), its natural absence from other matrices makes it a poor indicator in those matrices, questioning the usefulness of the evaluation of estimated reduction factors for *Ascaris* spp. in Table 13 (p. 76) in hides and skins or wool and hair.

- Regarding the second point in Table 12 (p.71), we are unsure if this is a question of uncertainty. **If the preparatory treatments truly affect hygienisation, then the point raised seems more like a lack of essential information than an uncertainty.** However, the treatments listed are intended more to prepare the hides and skins for handling rather than for hygienisation and, in any case, precede hygienisation, so any effect they have is unlikely to be in addition to the intentional, subsequent hygienisation.
- As stated in the 5th point on page 72, most of the studies quoted in the opinion were conducted on very different matrices (such as melted chocolate) than the materials to which their results have been extrapolated. **We therefore support EFSA’s recommendation (p. 80) to study the survival of biological hazards in ABP matrices.** We refer to the Italian data cited above as an example of how well standard operating procedures appear to control these risks under real-world conditions.
- Finally, we note that not all accepted processes were considered since EFSA did not look at Method 7 processes authorised by national authorities. The stated reason for EFSA not considering these methods is that they are not accepted by all Member States. However, under CMC 11 on by-products, it is sufficient for a component material to be considered a by-product in the country where it is incorporated into an EU fertilising product; the subsequent product can then circulate freely in the EU. EBIC and ECOFI argue that the same logic could be applied to ABP processing since the Regulation (EU) 2019/1009 differentiates between component materials and final products, unlike Regulation (EC) 1069/2009: **an animal by-product authorised in the country of manufacture could be a component material of a fertilising product that can subsequently circulate on the Single Market if it meets the requirements for conformity assessment.**

## Conclusion

EBIC and ECOFI urge the European Commission to take the limits of the EFSA Opinion into account when drafting end points for animal by-products used in EU Fertilising Products. End points should result from risk assessments that take into account real-world conditions and the positive track record of industrial processes to control relevant biological indicators for various animal by-products. Existing end points should be preserved. Finally, we ask the Commission to also consider the capacity of nationally approved treatment processes to deliver Fertilising Products that meet the safety standards of Regulation (EU) 2019/1009, which echo those in Regulation (EC) 1069/2009 with regard to biological hazards.

## References

- **Joint EBIC-ECOFI position paper** (public): “[End points for animal by-products used in EU Fertilising Products should recognise the history of safe use of many common materials](#)”
- **EBIC position paper** (public): “[Hydrolysed proteins, chitin, and hygienised insect frass should be granted end point status for use in EU Fertilising Products under Regulation \(EU\) 2019/1009](#)”
- **EBIC public webpage** “[In a loss for the Circular Economy, Fertilising Products containing animal by-products are frustrated from entering the Single Market under the Fertilising Products Regulation \(FPR\)](#)”
- **EFSA opinion** “[Inactivation of indicator microorganisms and biological hazards by standard and/or alternative processing methods in Category 2 and 3 animal by-products and derived products to be used as organic fertilisers and/or soil improvers](#)” in either Word or PDF formats

For more information about this topic, please contact Kristen Sukalac (kristen@prospero.ag).

## ABOUT EBIC & ECOFI



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.



The European Consortium of the Organic-Based Fertiliser Industry (ECOFI) represents European producers of organic fertilisers, organo-mineral fertilisers, and organic soil improvers. ECOFI membership is open to European producers in the sector whose production fully ensures the upstream traceability and the origin of raw material components.