Biological Hazards & Animal Health and Welfare (BIOHAW Unit)

Parma, 30 June 2026

Ref. FV/ES/kdb-OC-2026-37040080

Subject: Reply to ESPP on fish sludge

Dear European Sustainable Phosphorus Platform (ESPP),

Thank you for ESPP's interest in EFSA's work on animal by-products (ABP), and more broadly in its risk assessment activities as described in the letter of 18 June 2026. To obtain an EFSA opinion enabling the conversion of fish sludge into fertiliser, the following clarifications are provided following your questions:

1. ***Is it correct that a request for an EFSA Opinion can be submitted by stakeholders (associations or companies, one or more) but that this opinion: must be submitted via a Member State Competent Authority (a State where the process will be applied) and must include required information (142/2011 Annex 7)?***

Generally, EFSA can issue Scientific Opinions at the request of the European Commission, European Parliament, Member States, or on its own initiative or as foreseen in relevant sectoral legislation. Scientific Opinions are prepared and adopted by the Scientific Committee or a Scientific Panel. Opinions find their legal basis in article 29 of Founding Regulation. Please visit the EFSA website for detailed descriptions of EFSA scientific outputs.

Specifically, and with regard to the submission of an ABP application (dossier) to EFSA and in reply to your question below, that seems to concern a different, very specific pathway under EU ABP rules for the so-called alternative methods, as a "sectorial legislation" we referred to above.

2. ***To ensure that any future dossier is prepared in the most appropriate and efficient manner, we would be grateful for your guidance on a number of procedural and regulatory points outlined in the attached letter.***
   Is it possible to submit one dossier for the different processes suggested above (same input material, same and-use) or should it be a number of separate dossiers?

Please note that, applications (for authorisation of alternative processing methods of ABP) should be submitted to the Member State (MS) competent Authority, in accordance with Article 20 of ABP Regulation (EC) No 1069/2009 and Regulation EU 142/2011. Application dossiers are then made available to EFSA by the MS competent Authority. Annex VII of Regulation (EU) No 142/2011 includes provisions on the format, language and content of the application. The MS competent authority evaluates whether the application complies with the standard format for the applications. Then the MS competent authority communicates the application together with a report to EFSA and informs the European Commission. After the submission phase and the completeness check, EFSA performs a risk assessment and publishes an EFSA scientific opinion. Based on this opinion, the European Commission adopts a measure to authorising or rejecting the alternative method.

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If an animal by-product or derived product is included in EU Regulation 1069/201109 with approved processing methods described therein and a new processing (alternative) method was sought, an independent application would need to be submitted to EFSA for each new method to be assessed.

Please visit the EFSA website for details. A visual representation of the procedure and the recording of a webinar are also available for a better understanding.

Please also note that much of the above is also already publicly explained at the Commission ABP websites:

- Either under applying for End Points in ABP Regulations: https://food.ec.europa.eu/food-safety/animal-products/end-points-abp-regulations_en or
- or as related to EFSA Scientific advise: https://food.ec.europa.eu/food-safety/animal-products/scientific-advice_en

About your question:

3. ***Does Norway 'count' as a Member State for this procedure?***

Article 31 of Regulation (EC) No 178/2002 (General Food Law), as incorporated into the EEA Agreement and adapted by Annex I, extends EFSA's role in providing scientific and technical assistance to requests from EEA-relevant bodies, including the EFTA Surveillance Authority.

Although Norway is not formally a Member State, it follows EU legislation on ABP. An ABP application can therefore be submitted to the MS competent authority, which will then forward it to the EU EC, and it will eventually arrive at EFSA.

Concerning the status of "fish sludge" and its impact on the publication of an EFSA Scientific Opinion (Article 29 as explained above):

4. ***Does the status of fish sludge as an ABP or not (or unclear) impact this possibility to request an Opinion?***

As we understand it, while fish sludge is not explicitly referred to in the ABP Regulation (EC) No 1069/2009 (like many other ABP material), it is covered by Article 9(h)[1] of Regulation (EC) No 1069/2009 and by the subsequent ABP rules.

EFSA cannot comment on what is or what is not currently listed as a constituent material component (CMC) in the Fertilisers Regulation (EU) 2019/1009.

In light of the above considerations, it is recommended to seek clarification from the European Commission on this matter.

Please visit the web page with the recent webinar organised by your platform (ESPP) for additional clarifications: https://www.phosphorusplatform.eu/images/scope/ESPP%20SCOPE%20158.pdf

[1] Article 9 - **Category 2 material**. *(h) animal by-products other than Category 1 material or Category 3 material.*

Yours sincerely,

Frank Kamiel D Verdonck

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