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## **Position: End points for animal by-products used in EU Fertilising Products should recognise the history of safe use of many common materials**

### **EXECUTIVE SUMMARY**

Regulation (EU) 2019/1009 on Fertilising Products (FPR) foresees a Component Material Category (CMC) for Animal By-Products, and Article 46 of the same regulation specifies the minimum list of materials to be reviewed. Article 42(1) of the FPR outlines the criteria that should guide the Commission in this (and other) tasks: potential for significant intra-EU trade, absence of risk to human, animal or plant health, to safety or to the environment and "agronomic efficiency. This paper provides input on these points from the European Biostimulants Industry Council (EBIC) and the European Consortium of the Organic-Based Fertilizer Industry (ECOFI), two of the sectors directly concerned; many plant biostimulants and organic -based fertilizers and soil improvers contain materials derived from animal by-products.

Given the significant obstacles that currently face fertilising products containing animal by-products and their derivatives, we expect the establishment of end points allowing for free circulation within the EU Single Market to significantly increase the flows of such products in future, assuming that an adequate list of end points is defined.

- Our paper argues that there is a long history of safe use for many of these materials that demonstrates that risks can be and have been successfully managed. On that basis and previous EFSA risk assessments, we argue for many end points.

We also advocate for much more precise terminology to be used to distinguish between raw materials that don't yet have end-point status and those that have undergone processing that allows an end point to be met. The process for establishing the animal by-product end points for the Fertilising Products Regulation and its current status leave us with a number of questions:

1. Why are some end points defined in Regulation (EU) 142/2011 being revisited? Doesn't this go against the very concept of an end point?
2. Will the other end points already defined in Regulation (EU) 142/2011 apply to the Fertilising Products Regulation? If not, on what basis will they be excluded?
3. Do the comments of the BIOHAZ Panel chair in October 2020 that the EFSA mandate only covers hydrolysed proteins from ruminants mean that hydrolysed proteins from other animal sources are considered to have an end point?
4. What assessment is being done for the materials that are listed in Article 46 of the Fertilising Products Regulation but are not covered by the Terms of Reference given to EFSA?
5. In September and October, the BIOHAZ Panel discussed the scope of the risk assessment, the hazard identification, the definition of risk, data needs and data sources, uncertainty assessment and protocol development as well as clarification from the EC on the scope of the risk assessment and the literature review on the identification of biological hazards in the nine groups of materials. On this basis, the Commission mandate to EFSA appears to have been tweaked or clarified. Is it possible for stakeholders to receive information on the revised/clarified mandate? At this time, the only information has been shared on the original mandate issued before these discussions.
6. Why aren't meat-and-bone meal included in the mandate to EFSA (with the exception of ashes)? Is this because EFSA's 2005 "Quantitative risk assessment of the animal BSE risk posed by meat and bone meal with respect to the residual BSE risk" is considered sufficient to define an end point?

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### **The legal basis for the evaluation of the end points for animal by-products that can be used in EU Fertilising Products**

Regulation (EU) 2019/1009 on Fertilising Products (FPR) foresees a Component Material Category (CMC) for Animal By-Products, but until this date, the CMC remains unpopulated. Article 46 of the FPR inserts the following paragraph into the Animal By-Products Regulation (EC) 1069/2009:

**"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.**

This assessment shall cover at least the following products: meat meal, bone meal, meat-and-bone meal, hydrolysed proteins of Category 3 materials, processed manure, compost, biogas digestion residues, feather meal, glycerine and other products of Category 2 or 3 materials derived from the production of biodiesel and renewable fuels, as well as petfood, feed and dog chews that have been refused for commercial reasons or technical failures, and derived products from blood of animals, hides and skins, hoofs and horns, guano of bats and birds, wool and hair, feather and downs, and pig bristles. Where the assessment concludes that those derived products no longer pose any significant risk to public or animal health, the Commission shall determine 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."

In line with Article 46 of the FPR, April 2020, CE requested EFSA to issue a scientific opinion in the context of this assessment (SANTE/G2/MK/ise(2020) 8792057)<sup>ii</sup> with the following terms:

“This assessment shall cover at least the following products

- meat meal, bone meal, meat-and-bone meal, hydrolysed proteins of Category 3 materials,
- processed manure, compost, biogas digestion residues, feather meal, glycerine and other products of Category 2 or 3 materials derived from the production of biodiesel and renewable fuels,
- petfood, feed and dog chews that have been refused for commercial reasons or technical failures,
- derived products from blood of animals, hides and skins, hoofs and horns, guano of bats and birds, wool and hair, feather and downs, and pig bristles.

Terms of Reference [of the mandate given to EFSA by DG SANTE]:

In the light of the above, and in accordance with Article 29 of Regulation (EC) No 178/2002/20, the Commission requests EFSA to provide a scientific opinion concerning the capacity of certain specific processing or transformation methods used in the production of organic fertilisers and soil improvers (OF/SI) in view of determining the endpoints in the manufacturing chain of CE-marked EU fertilising products.

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 processed in accordance with Regulation (EU) No 1069/2009 and Regulation (EU) No 142/2011: (1) biogas digestion residues and compost; (2) ash derived from incineration, co-incineration and combustion; (3) glycerine and other products of materials derived from the production of biodiesel and renewable fuels; (4) pet food; (5) feed and dog chews, (6) hides and skins, (7) wool and hair, (8) feather and downs, (9) and pig bristles.”

These materials are widely used in organic fertilisers, organo-mineral fertilisers, organic soil improvers, and plant biostimulants.

**Comparison of the ABPs listed in Article 46 of the FPR, the “request” section (p.5) of the mandate from DG SANTE to EFSA and the “Terms of Reference” (p.7) section of the mandate from DG SANTE to EFSA**

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|---|--|
| <p><b>ABPs listed in Article 46 of the FPR and mentioned on page 3 of the DG SANTE mandate under the header, “This assessment shall cover at least the following products:”</b></p> | <p><b>On page 7 of the mandate, the Commission outlines the Terms of References of its request to EFSA to provide a scientific opinion 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 processed in accordance with Regulation (EU) No 1069/2009 and Regulation (EU) No 142/2011:</b></p> |
| <p>meat meal, bone meal, meat-and-bone meal,</p>  | <p>[These materials are not specifically mentioned in the Terms of Reference but considering the discussion of incineration on page 3 of the mandate, where meat-and-bone meal are included, we can deduce that some of these materials are included under point 2 of the list of materials to be evaluated in the Terms of Reference.]</p>  |
| <p>hydrolysed proteins<sup>iii</sup> of Category 3 materials,</p>   | <p>Not included in the Terms of Reference</p>  |
| <p>processed manure</p>   | <p>Not included in the Terms of Reference</p>  |
| <p>compost<br/>biogas digestion residues</p>  | <p>biogas digestion residues and compost;<br/>[The different word order in the ToR imply that only composts of biogas digestion residues are covered.]</p>   |
| <p>feather meal, feather and downs</p>  | <p>feather and downs<br/><br/>[According to Article 3, point (f) of Commission Regulation (EU) No 142/2011, feathers and down have reached an end point for further commercialisation when they have been factory-washed and treated with hot steam at 100 °C for at least 30 minutes]</p>   |

|  |   |
|--|---|
| glycerine and other products of Category 2 or 3 materials derived from the production of biodiesel and renewable fuels | Not included in the Terms of Reference  |
| petfood, feed and dog chews that have been refused for commercial reasons or technical failures                        | pet food; feed and dog chews  |
| derived products from blood of animals   | Not included in the Terms of Reference  |
| hides and skins  | hides and skins<br><br>[Hides and skins of ungulates are granted end-point status as foreseen in Annex XIII, Chapter V, point C with reference to Article 3, point (d) of Regulation (EU) No 142/2011]  |
| hoofs and horns  | Not included in the Terms of Reference  |
| guano of bats and birds  | Not included in the Terms of Reference<br><br>According to Article 22, point 2 of Regulation (EC) 142/2011, seabird guano requires no processing to be use in fertilising products  |
| wool and hair  | wool and hair<br><br>[Article 3 point (e) of Regulation (EU) No 142/2011 and Chapter VII of Annex XIII of the same regulation specify an end point for factory-washed wool and hair, and wool and hair which has been treated by another method which ensures that no unacceptable risks remain.] |
| pig bristles   | pig bristles  |
|  | ash derived from incineration, co-incineration and combustion; <sup>iv</sup>  |

The mandate from DG SANTE to EFSA was discussed by the EFSA Scientific Committee on Biological Hazards (BIOHAZ Panel) on 8 September 2020 and again during its 141<sup>st</sup> Plenary on 21-22 October, which was an open session with observers. During the open session, the BIOHAZ Panel chair replied that while hydrolysed proteins appear in the list proposed by

Regulation (EC) 1009/2019 for assessment to be done by July 2022, they are not part of the list of materials included in the Commission mandate to EFSA. He elaborated that the remit of the BIOHAZ Panel only deals with ABP within Regulation 2009/1069 and Regulation (EU) 142/2011 only provides provisions for ruminant hydrolysed proteins because of the potential risk of TSE.

**In light of the above, EBIC and ECOFI have the following questions about the assessment of animal by-products mandated by Article 46 of the FPR:**

1. Why are some end points defined in Regulation (EU) 142/2011 being revisited? Doesn't this go against the very concept of an end point?
2. Will the other end points already defined in Regulation (EU) 142/2011 apply to the Fertilising Products Regulation? If not, on what basis will they be excluded?
3. Do the comments of the BIOHAZ Panel chair in October 2020 mean that hydrolysed proteins from animal sources other than ruminants are considered to have an end point?
4. What assessment is being done for the materials that are listed in Article 46 of the Fertilising Products Regulation but are not covered by the Terms of Reference given to EFSA?
5. Given the fact that that the September meeting of the BIOHAZ Panel discussed the scope of the risk assessment, the hazard identification, the definition of risk, data needs and data sources, uncertainty assessment and protocol development as well as clarification from the EC on the scope of the risk assessment and the literature review on the identification of biological hazards in the nine groups of materials, is it possible for stakeholder to receive an update on what the detailed mandate to EFSA is today?
6. Why aren't meat-and-bone meal included in the mandate to EFSA (with the exception of ashes)? Is this because EFSA's 2005 "Quantitative risk assessment of the animal BSE risk posed by meat and bone meal with respect to the residual BSE risk" is considered sufficient to define an end point?

## **Industry evaluation of animal by-product materials to be considered for end-point status when used in an EU Fertilising Product**

Our industries have reviewed existing methods for processing the materials mentioned above and provide below our argumentation of which animal by-product materials we believe can be used safely in EU Fertilising Products and thus be relieved of further obligations imposed by the Animal By-Products Regulation (ABPR). Our evaluation takes into account Article 42(1) of the Fertilising Products Regulation, which outlines the **criteria that should guide the Commission when amending annexes II, III, and IV of the FPR: potential for significant intra-EU trade, absence of risk to human, animal or plant health, to safety or to the environment and "agronomic efficiency."** According to these criteria, identifying materials derived from animal by-products for use in EU fertilising products should be a straightforward task: there is a long history of such products being used safely and providing farmers with high-quality, carbon-rich fertilisers. It is therefore important that evaluations for end-point status do not only consider the existence of risks but also look at how effectively such risks have been managed in practice.

Since these would be end points, it goes without saying that any materials derived from end point materials would also benefit from end-point status as long as they were not combined with "raw" animal by-products that could introduce a new risk of contamination.

### **Our evaluation takes into account the following contextual factors:**

- The Animal By-Products Regulation does not use different terminology for raw materials and materials that have undergone sanitizing treatments, etc. We feel that this is a source of confusion regarding discussion around animal by-products, particularly when defining end points that effectively transform them from by-products into secondary raw materials (i.e. derivatives instead of "raw" by-products). Such derivatives may, depending on the case, be considered end-user products and in other cases are simply component materials combined with others in such a fertilising product. We therefore suggest different terminology for materials before and after they have undergone treatment processes.
- The potential for greater intra-EU trade of EU Fertilising Products containing animal by-products is large. To date, intra-EU trade has been restricted by rules on cross-border movements of animal by-products, the ineffectiveness of mutual recognition to catalyse such trade, and the resulting difficulties for a truly European industry to emerge (as most companies have remained contained within national markets).
- Fertilising products placed on the market are subject to **requirements relating to contaminants such as heavy metals and pathogens under Regulation (EU) 2019/1009**. These controls **ensure an additional level of protection beyond those imposed by the transformation processes outlined below**. Furthermore, the control of pathogens at the product level for conformity assessment protect against concerns of recontamination between the time the ABPR end point is reached and when the EU Fertilising Product is placed on the market. Therefore, **a full assessment of the appropriateness of end points for animal by-products materials used in EU**

**fertilising products is incomplete if it does not also consider the safety requirements for Product Function Categories in Regulation (EU) 2019/1009.**

- Before reaching an end point, raw materials would be subject to all the conditions foreseen in the Animal By-Products Regulation (EC) 1069/2009, including the requirement for the processing to occur in sanitation plants authorized pursuant to Article 24 of Regulation (EC) 1069/2009.
- Recital 22 of the introduction to Regulation (EC) 1069/2009, points out that the determination of an “end point” in the manufacturing chain is possible for all products “which no longer have direct relevance for the safety of feed chain”. The recital continues “For certain products regulated under other Community legislation, such an end point should be determined at the stage of manufacturing,” which is precisely the point of determining end points for using materials derived from animal by-products in EU Fertilising Products to be placed on the market under Regulation (EU) 2019/1009. This means that safety concerns should be the sole reason for refusing to grant end-point status, not simple fraud that does not pose safety risks.
- The **conformity assessment process** foreseen by the FPR in Annex IV, Part I, Paragraph 3.1 “Module B [EU-TYPE EXAMINATION] followed by Module C [INTERNAL PRODUCTION CONTROL] may be used for an EU fertilising product composed solely of one or more of the following component materials...derived products within the meaning of Regulation (EC) No 1069/2009 as specified in CMC 10 in Part II of Annex II.” In this case, the **technical dossier submitted will describe the production process in detail, making it clear how any end points are reached** (assuming the manufacture conducts its own transformations) and how re-contamination is prevented. We note that Module D1 [QUALITY ASSURANCE OF THE PRODUCTION PROCESS] may be substituted for Modules B + C at the manufacturer’s discretion. In this case, the manufacturing site is subject to periodic controls by certifying agents.
- Finally, although EU Fertilising Products circulate freely, traceability will still be maintained as products will bear batch numbers.

**General comments**

- Discussions around the definition of end points for animal by-products should not lose sight of the great benefits to society of upcycling and revalorising these materials. If they are not given new functions, the alternative is disposal, which is an inefficient use of resources and an economic drain. Disposal is also not without its own risks. We therefore advocate for the approval of animal by-products to be transformed into secondary raw materials in any case where it can be done safely. Thanks to careful selection of raw materials, reliable operations, and controls by veterinarians and accredited laboratories, our industries have demonstrated that animal by-products can be safely upcycled into safe and effective fertilising products. 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. With regard to BSE, EFSA has confirmed that Category 2 & 3 materials do not pose a BSE risk<sup>vi</sup> and should be treated similarly to one another with regard to this particular concern. EFSA has also issued numerous opinions over the years that the approved ABP transformation methods effectively control the risk of transmitting BSE<sup>vii</sup>.

- The use of fertilising products containing animal by-products needs to address concerns about cross-contamination (i.e. of Category 2 & 3 materials by Category 1 materials), fraud, and contamination of grazing animals but distinctions should be made between management practices for transport, handling, and use and end points which should only consider safety and the potential for significant intra-EU trade. **Cross-contamination** is best addressed by requirements for certification of facilities that treat and transport animal by-products. Furthermore, the likelihood of packaged fertilising products being cross-contaminated is extremely low, so it is useful to distinguish between products that are transported in bulk and those that are packaged. **Contamination of grazing animals** can be addressed through additives to prevent erroneous feeding (e.g. colorants), additives to render the products inappetising (a challenge to find a universally effective additive) and most importantly – through good on-farm management practices, such as avoiding the application of fertilising products containing materials derived from animal by-products to pastures. **Fraudulent use of fertilizer-grade materials in the feed chain** is best controlled through the use of marker substances (such as GHT) and controls in the feed chain, not through end points, which should focus on the absence of risk to human, animal or plant health, to safety or to the environment and “agronomic efficiency” as specified in Article 42 of Regulation (EU) 1009/2019.
- When defining the endpoints for use of materials derived from animal by-products in EU Fertilising Products, it should be made explicit that the endpoints are valid for use in all appropriate EU Fertilising Products (e.g. organo-mineral fertilisers, growing media, plant biostimulants, and blends) and not just for organic fertilisers and soil improvers. The language used in the ABPR itself today is misleading, which some companies have exploited to create unfair competition by claiming that their organo-mineral fertilizers (OMFs) are not subject to the ABPR regulation because it does not mention organo-mineral fertilizers when the organic fraction of those products should have met the requirements of the ABPR before being incorporated into OMFs. (A similar clarification is needed regarding the nationally authorised products, although this paper focuses on EU Fertilising Products<sup>viii</sup>). Throughout this document, we will use the term “fertilising products” unless we are specifically referring to existing text in the Animal By-Products Regulation.
- According to Regulation (EU) 2019/1009, Annex III, paragraph 4, EU Fertilising Products are subject to the following labelling requirement: “Where the EU fertilising product contains derived products within the meaning of Regulation (EC) No 1069/2009 other than manure, the following instruction shall be provided on the label: ‘Farmed animals shall not be fed, either directly or by grazing, with herbage from land to which the product has been applied unless the cutting or grazing takes

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place after the expiry of a waiting period of at least 21 days.” The labelling requirement provides an additional layer of protection at the management level.

Our analysis below considers materials in the following groups:

- Existing end points defined under Regulation (EC) No 1069/2009 (Section I);
- Authorised uses defined under Regulation (EC) No 1069/2009 (Section II);
- Other materials to consider for end points (Section III).

## **Section I. Existing end points defined under Regulation (EC) No 1069/2009**

Article 5, paragraph 2 of Regulation (EC) No 1069/2009 (ABPR) states: "For derived products referred to in Articles 32, 35 and 36 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..."

That article now empowers the Commission to adopt delegated acts in accordance with Article 51a supplementing this Regulation [1069/2009] by determining an end point in the manufacturing chain, beyond which derived products referred to in this paragraph are no longer subject to the requirements of this Regulation. However, there are already several such end points, which are listed in Articles 3 and 22 of Commission Regulation (EU) No 142/2011 as detailed in the table below. Since these end points are defined "without restriction" in the ABPR, there should be no scientifically justified safety concerns about applying with regard to EU Fertilising Products.

| Raw materials                       | Transformation process and legal basis   | Component materials in FPR<br>(Examples of PFCs where they might be used, but which should not be used to define the end points.) <sup>ix</sup>          | Potential risks and risk management  |
|-------------------------------------|--|--|--|
| <b>Hides and skins of ungulates</b> | As foreseen in Annex XIII, Chapter V, point C with reference to Article 3, point (d) of Regulation (EU) No 142/2011  | <ul style="list-style-type: none"> <li>• <b>Tanned hides and skins</b> (PFCs 1A, 1B and 3A)</li> <li>• <b>'wet blue'</b> (PFCs 1A, 1B and 3A)</li> </ul> | The tanning process is considered to eliminate risks related to prion contamination. There would therefore seem to be no reason why they could not be safely incorporated into EU Fertilising Products circulating freely on the Single Market.  |
| <b>Hides and skins of ungulates</b> | <p>Article 3, point (d) of Regulation (EU) No 142/2011 specifies an end point for hides and skins of ungulates treated according to the provisions outlined in Annex XIII, Chapter V, point C:</p> <p><b>AND provided that the raw material is accompanied by a commercial document in accordance with the model set out under point 6 of Chapter III of Annex VIII of Regulation (EC) 1069/2006</b> when sourced for use in the EU Fertilising Product.</p> | <ul style="list-style-type: none"> <li>• <b>'pickled pelts'</b> (PFCs 1A, 1B and 3A)</li> <li>• <b>limed hides</b> (PFCs 1A, 1B and 3A)</li> </ul>       | The safety requirements for EU Fertilising Products provide an additional level of control on contaminants and other safety risks related to the use of these materials in EU Fertilising Products.  |
| <b>Hides and skins of ungulates</b> | Provided that they comply with the requirements of Regulation (EC) No 853/2004 for raw materials for gelatine or collagen intended for use in food (End point already defined under Annex XIII Chapter V point C of the Regulation (EU) 142/2011, these hides and skins are end point and may be placed on the market without restrictions.)   | <ul style="list-style-type: none"> <li>• <b>Food-grade hides and skins of ungulates</b> (PFCs 1A, 1B and 3A)</li> </ul>                                  | Collagen and gelatine derived from animal bones, hides, skins and tendons (and sinews, for gelatine) are listed in Commission Regulation (EU) 68/2013 as materials permitted in animal feed, so there should be no concerns for the same materials to be used in EU Fertilising Products given the safety requirements and conformity assessment |

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|                          |   |   | process foreseen by Regulation (EU) 2019/1009.   |
| <b>Wool and hair</b>     | Article 3, point (e) of Regulation (EU) No 142/2011 and Chapter VII of Annex XIII of the same regulation specify an end point for factory-washed wool and hair, and wool and hair which has been treated by another method which ensures that no unacceptable risks remain. | <ul style="list-style-type: none"> <li>• <b>Factory-washed wool and hair</b> (PFCs 1A, 1B and 3A)</li> <li>• <b>Processed wool and hair</b> (PFCs 1A, 1B and 3A)</li> </ul> | The pathogen limits on EU Fertilising Products would protect against the possibility of recontamination of the materials between the time they are rejected for pets and applied in fertilising materials. |
| <b>Feathers and down</b> | According to Article 3, point (f) of Commission Regulation (EU) No 142/2011, feathers and down have reached an end point for further commercialisation when they have been factory-washed and treated with hot steam at 100 °C for at least 30 minutes                      | <ul style="list-style-type: none"> <li>• <b>Sanitized feathers and down</b> (PFCs 1A, 1B, 3A, and 6A)</li> </ul>  | <p>Feathers, down and feather meal do not pose prion issues.</p> <p>The limits on EU Fertilising Products would protect against pathogens.</p>   |
| <b>Fur</b>               | According to Article 3, point (g) of Regulation (EU) No 142/2011, furs which have been dried at an ambient temperature of 18 °C for two days at a humidity of 55 % may be placed on the market without restrictions   | <ul style="list-style-type: none"> <li>• <b>Dried fur</b> (PFCs 1A, 1B and 3A)</li> </ul>   | The limits on EU Fertilising Products would protect against pathogens.   |

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| <p><b>Guano from wild sea birds</b>, collected in the Union or imported from third countries</p>   | <p>According to Article 22, point 2 of Regulation (EC) 142/2011, seabird guano requires no processing to be use in fertilising products</p>  | <p><b>Collected seabird guano</b><br/>(PFCs 1A, 1B and 3A)</p> | <p>Wild sea bird guano is not subject to any animal health conditions.</p>                   |
| <p>Growing <b>media</b>, other than that imported &amp; derived products of Category 3 material, Category 2 material other than processed manure</p> | <p>The final product may not contain more than</p> <ul style="list-style-type: none"> <li>(i) 5 % in volume of derived products of Category 3 material or of Category 2 material other than processed manure;</li> <li>(ii) 50 % in volume of processed manure.</li> </ul> | <p><b>Ready-to-sell growing media</b></p>                      | <p>This end point is already defined in Regulation (EC) 142/2011 Article 22, para. 2(b).</p> |

## **Section II. Authorised uses defined under Regulation (EC) No 1069/2009**

Article 32 of Regulation (EC) No 1069/2009 (ABPR) states that *"organic fertilisers and soil improvers may be placed on the market and used provided:*

- (a) they are derived from Category 2 or Category 3 material;*
- (b) they have been produced in accordance with the conditions for pressure sterilisation or with other conditions to prevent risks arising to public and animal health, in accordance with the requirements laid down pursuant to Article 15 and any measures which have been laid down in accordance with paragraph 3 of this Article;*
- (c) they come from approved or registered establishments or plants, as applicable; and*
- (d) in the case of meat-and-bone meal derived from Category 2 material and processed animal proteins intended to be used as or in organic fertilisers and soil improvers, they have been mixed with a component to exclude the subsequent use of the mixture for feeding purposes and marked when required by measures adopted under paragraph 3. [Except for materials whose use for feeding purposes is excluded due to their composition or packaging.]*

*In addition, digestion residues from transformation into biogas or compost may be placed on the market and used as organic fertilisers or soil improvers."*

The regulation then specifies that the implementing measures related to use of animal by-products in organic fertilisers and soil improvers may cover topics such as:

- "(a) public and animal health conditions for the production and use of organic fertilisers and soil improvers;*
- (b) components or substances for the marking of organic fertilisers or soil improvers;*
- (c) components to be mixed with organic fertilisers or soil improvers;*
- (d) supplementary conditions, such as the methods to be used for marking and the minimum proportions to be observed when preparing the mixture, in order to exclude the use of such fertilisers or soil improvers for feeding purposes; and*
- (e) cases where the composition or packaging allows the materials to be exempted from the mixing requirement."*

Based on their long history of safe use in fertilising products, we recommend that the following authorised uses (in the table below) be elevated to end-point status when these materials are used in fertilising products.

| Raw materials  | Transformation process and legal basis   | Component materials in FPR   | Potential risks and risk management  |
|--|--|--|--|
| <b>Ungulate manure, poultry litter, lagomorph droppings, bat guano and insect frass</b>                                    | Transformation processes specified in points (a), (b), (d) and (e) of Section 2 of Annex XI to Regulation (EU) No 142/2011   | <b>Processed manures</b> (PFCs 1A, 1B and 3A)  | The heat processing specified in Regulation (EU) No 142/2011 ensures a satisfactory level of pathogen control, consistent with the pathogen limits specified in other relevant CMCs.   |
| <b>Category 2 and 3 materials (including former foodstuffs) other than meat and bone meal and processed animal protein</b> | Point 1 of Section 1 and point 1 of Section 2 of Chapter III of Annex V to Regulation (EU) No 142/2011<br><br>Point 2 of Section 1 and point 1 of Section 2 of Chapter III of Annex V to Regulation (EU) No 142/2011 | <b>Compost</b> (PFCs 1A, 1B and 3A)<br><br><b>Biogas digestion residues</b> (PFCs 1A, 1B and 3A) | The requirements for processing composts and digestion residues under Regulation (EU) No 142/2011 are stricter than the conditions under CMCs 3 and 5 of the FPR since the ABPR process is intended to ensure hygienisation whereas the CMC 3 and 5 processes are intended to improve the agronomic benefits of the materials.   |
| <b>Feathers and down</b>   | Methods 1-5 <sup>x</sup> set out in Chapter III of Annex IV to Regulation (EU) No 142/2011   | <b>Sanitised feather meal</b> (PFCs 1A, 1B and 3A)   | Feathers, down and feather meal do not pose prion issues. Heat treatment kills pathogens, which are further controlled at the product level by the FPR.<br><br>Feather meal is listed in Commission Regulation (EU) 68/2013 as a material permitted in animal feed, so there should be no concerns for the same materials to be used in EU Fertilising Products given the safety requirements and conformity assessment process foreseen by Regulation (EU) 2019/1009. |

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| <p><b>Hoofs and horns</b></p> | <p>In accordance with Chapter XII of Annex XIII to Regulation (EU) No 142/2011, hoofs and horns must be removed without opening the cranium from animals declared fit for human consumption. Heated for at least 60 min. at core temp. of at least 80C.</p>  | <p><b>Sanitised hoofs and horns</b> (PFCs 1A, 1B and 3A)</p> | <p>As long as the cranium is not opened when horns are removed, these materials pose no risk for the transmission of prions.</p> <p>Heat treatment eliminates potential pathogens and the potential for recontamination is controlled by the PFC-level limits on pathogens.</p>   |
| <p><b>Pig bristles</b></p>    | <p>Pig bristles which have (a) undergone factory washing; (b) been obtained from tanning; or (c) been treated processed by processing methods 1-5<sup>xi</sup> referred to in Chapter III of Annex IV to Regulation (EU) No 142/2011 or processing referred to in point D of Section 5 of Annex X to Regulation (EU) No 142/2011.</p>  | <p><b>Sanitised pig bristles</b> (PFCs 1A, 1B and 3A)</p>    | <p>Pig bristles pose no risk for the transmission of prions.</p> <p>Heat treatment eliminates potential pathogens and the potential for recontamination is controlled by the PFC-level limits on pathogens.</p>   |
| <p><b>Meat meal</b></p>       | <p>Reg (EU) 142/2011 Annex XI, Chapter II, Section 1, Points 2-4 outline the following requirements for the production of organic-based fertilisers and soil improvers which consist of or which have been produced from meat-and-bone meal derived from Category 2 material or from processed animal protein:</p> <ul style="list-style-type: none"> <li>• applying processing method 1 (pressure sterilisation), when Category 2 material is used as starting material;</li> <li>• by applying any of the processing methods 1 to 6<sup>xii</sup>, as set out in Chapter III of Annex IV, when Category 3 material is used as starting material which is not used for the production of processed animal protein.</li> </ul> <p>In addition, the processed meat meal must fulfil one of the following two conditions to reach an end point for use in an EU Fertilising Product:</p> | <p><b>Processed meat meal (MM)</b> (PFCs 1A, 1B and 3A)</p>  | <p>EFSA has evaluated that MM, BM and MBM can be used safely on numerous occasions.<sup>xiii</sup> Other scientific opinions that support the safety of the application to land of organic fertilisers and soil improvers derived from these materials include:</p> <ul style="list-style-type: none"> <li>• The 1998 opinion of the Scientific Steering Committee on the safety of organic fertilisers derived from mammalian animals;</li> <li>• The 2001 opinion of the Scientific Committee on Toxicity, Ecotoxicity and the Environment on the evaluation of sludge treatments for pathogen reduction;</li> <li>• The 2001 opinion 2001 of the Scientific Steering Committee on the safety of</li> </ul> |

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|  | <ol style="list-style-type: none"> <li>1. The processed meat meal should be used in a PFC 1B EU Organo-Mineral Fertiliser since the mineral fraction of an OMF is considered sufficient to prevent ingestion by animals.</li> <li>2. The processed meat meal should contain sufficient glyceroltriheptanoate (GTH) per kg fat to prevent fraudulent mixing with feed, as the marker will be visible even after dilution. GTH may not always prevent accidental ingestion, but it does make it possible to distinguish fraudulent use by its visible presence.</li> </ol> |  | <p>organic fertilisers derived from ruminant materials;</p> <ul style="list-style-type: none"> <li>• The 2004 opinion of the Scientific Panel on Biological Hazards of the European Food Standards Authority (EFSA) on the safety vis-à-vis biological risk including TSEs of the application on pastureland of organic fertilisers and soil improvers.</li> </ul> <p>The remaining concerns seem to relate to the inappropriate reintroduction of these materials into the feed chain. The combination of unappetizing additives and marker substances to prevent fraudulent reselling into the feed chain should mitigate this risk, as demonstrated by the safe history of use of organic-based fertilisers and soil improvers containing these component materials. However, we would like to stress that fraudulent uses of any material in the feed chain should be managed in the feed chain and not displaced onto products that are placed on the market with the function of a fertilising product.</p> <p>The exact level of GTH required should be fixed in consultation with decision-makers responsible for setting rules for organic production so that these EU Fertilising Products remain eligible for use in organic farming. Bone and meat meals are important sources of nitrogen in organic farming.</p> |
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| <p><b>Bone meal</b></p>          | <p>Reg (EU) 142/2011 Annex XI, Chapter II, Section 1, Points 2-4 outline the following requirements for the production of organic-based fertilisers and soil improvers which consist of or which have been produced from meat-and-bone meal derived from Category 2 material or from processed animal protein:</p> <ul style="list-style-type: none"> <li>• applying processing method 1 (pressure sterilisation), when Category 2 material is used as starting material;</li> <li>• by applying any of the processing methods 1 to 6<sup>xiv</sup>, as set out in Chapter III of Annex IV, when Category 3 material is used as starting material which is not used for the production of processed animal protein.</li> </ul> <p>In addition, the processed bone meal must fulfil one of the following two conditions to reach an end point for use in an EU Fertilising Product:</p> <ol style="list-style-type: none"> <li>1. The processed bone meal should be used in a PFC 1B EU Organo-Mineral Fertiliser since the mineral fraction of an OMF is considered sufficient to prevent ingestion by animals.</li> <li>2. The processed bone meal should contain sufficient glyceroltriheptanoate (GTH) per kg fat to prevent fraudulent mixing with feed, as the marker will be visible even after dilution. GTH may not always prevent accidental ingestion, but it does make it possible to distinguish fraudulent use by its visible presence.</li> </ol> | <p><b>Processed and marked bone meal (BM)</b> (PFCs 1A, 1B and 3A)</p>           |  |
| <p><b>Meat-and-bone meal</b></p> | <p>Reg (EU) 142/2011 Annex XI, Chapter II, Section 1, Points 2-4 outline the following requirements for the production of organic-based fertilisers and soil improvers which consist of or which have been produced from meat-and-bone meal</p>   | <p><b>Processed and marked meat-and-bone meal (MBM)</b> (PFCs 1A, 1B and 3A)</p> |  |

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|   | <p>derived from Category 2 material or from processed animal protein:</p> <ul style="list-style-type: none"> <li>• applying processing method 1 (pressure sterilisation), when Category 2 material is used as starting material;</li> <li>• by applying any of the processing methods 1 to 6, as set out in Chapter III of Annex IV, when Category 3 material is used as starting material which is not used for the production of processed animal protein.</li> </ul> <p>In addition, the processed meat-and-bone meal must fulfil one of the following two conditions to reach an end point for use in an EU Fertilising Product:</p> <ol style="list-style-type: none"> <li>1. The processed meat-and-bone meal should be used in a PFC 1B EU Organo-Mineral Fertiliser since the mineral fraction of an OMF is considered sufficient to prevent ingestion by animals.</li> <li>2. The processed meat-and-bone meal should contain sufficient glyceroltriheptanoate (GTH) per kg fat to prevent fraudulent mixing with feed, as the marker will be visible even after dilution. GTH may not always prevent accidental ingestion, but it does make it possible to distinguish fraudulent use by its visible presence.</li> </ol> |  |  |
| <p><b>Category 3 products</b> (including blood meal and fishmeal)</p> | <p>Regulation (EU) 142/2011 Annex XI, Chapter II, Section 1, Points 2-4 outline the requirements for the production of organic-based fertilisers and soil improvers which consist of or which have been produced from processed animal protein, including:</p> <p>(a) ....</p>  | <p><b>Processed animal proteins</b> (PFCs 1A, 1B and 3A)</p> | <p>Blood meal, fish meal, fishbone meal, and processed animal proteins are listed in Commission Regulation (EU) 68/2013 as materials permitted in animal feed, and there is no reason to consider that its used in EU Fertilising Products should be more problematic, given the safety requirements and</p> |

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|                                    | <p>(b) using processed animal protein which has been produced from Category 3 material in accordance with Section 1 of Chapter II of Annex X, or materials which have been subject to another treatment, where such materials may be used for organic fertilisers and soil improvers in accordance with this Regulation...</p> <p>In addition, the processed animal protein must fulfil one of the following two conditions to reach an end point for use in an EU Fertilising Product:</p> <ol style="list-style-type: none"> <li>1. The processed animal protein should be used in a PFC 1B EU Organo-Mineral Fertiliser since the mineral fraction of an OMF is considered sufficient to prevent ingestion by animals.</li> <li>2. The processed animal protein should contain sufficient glyceroltriheptanoate (GTH) per kg fat to prevent fraudulent mixing with feed, as the marker will be visible even after dilution. GTH may not always prevent accidental ingestion, but it does make it possible to distinguish fraudulent use by its visible presence.</li> </ol> |  | <p>conformity assessment process foreseen by Regulation (EU) 2019/1009.</p> |
| <p><b>Category 3 materials</b></p> | <p>Annex XI, Chapter II section 1, 1 c) of Regulation (EU) 142/2011 specifies that animal proteins (other than PAPs) can be incorporated into organic fertilisers and soil improvers after application of any of the processing methods 1 to 6<sup>xv</sup> described in Chapter III of Annex IV when Category 3 material is used as starting material and is not used for the production of processed animal protein.</p>   | <p><b>Animal proteins (other than PAP) derived from Category 3 material</b> (PFCs 1A, 1B and 3A)</p> |   |

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| <p><b>Fish material</b> (from aquatic animals) that are classified as Category 2 materials referred to in Article 9(f)(i) and (iii) of Regulation (EC) No 1069/2009 or Category 3 materials.</p> | <p>Annex IV, Chapter IV, section 2, Paragraph K, Point 2 of Regulation (EU) 142/2011 describes the acceptable conditions for the ensilage of fish material</p> <p>2.1. The materials to be treated shall be collected at aquaculture farms and food processing establishments on a daily basis and without undue delays, ground or chopped, and thereafter subjected to ensiling at a pH of 4 or below, with formic acid or other organic acid authorised in accordance with the feed legislation. The resulting fish silage must be a suspension of parts of aquatic animals liquefied by the action of endogenous enzymes in the presence of the added acid. The proteins of aquatic animals must be reduced into smaller soluble units, by the enzymes and the acid, in order to prevent microbial spoilage. The ensiled material is transported to the processing plant.</p> <p>2.2. At the processing plant the ensiled material of aquatic animals must be piped into closed storage tanks. The incubation time must be at least 24 hours at a pH of 4 or below before heat treatment can be conducted. Before the heat treatment the ensilage of aquatic animals must have a pH of 4 or below and have a particle size of less than 10 mm following a filtration or maceration at the plant. During processing it must be subjected to preheating to a temperature above 85 °C, followed by incubation in an insulated container to obtain 85 °C throughout the fish material for 25 minutes. The process must take place in a closed production line with tanks and pipelines.</p> <p>Annex IV, Chapter IV, section 3, Paragraph 2(e) then goes on to specify that the final product derived from ensiling</p> | <p><b>Ensiled fish material</b><br/>(PFCs 1A, 1B and 3A)</p> | <p>In the case of Category 2 fish materials, the processing requirements ensure that pathogens are destroyed and marking prevents the sanitised materials from being reintroduced into the feed chain.</p> <p>In the case of Category 3 fish materials, other processing methods ensure that pathogens are destroyed.</p> <p>This requirement is stricter than the conditions for the use of fish meal in organic farming, as Commission Regulation (EC) 889/2008 does not refer to the treatment methods required in Commission Regulation (EU) No 142/2011 implementing Regulation (EC) 1069/2009.</p> |
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|  | <p>Category 2 fish material <b>may be used</b> (among other possible uses) <b>for the manufacturing of organic fertilisers or soil improvers</b> to be placed on the market in accordance with Article 32 <b>following processing by pressure sterilisation</b>, when applicable, <b>and permanent marking of the resulting material “without further processing”</b>.<br/>           Category 3 ensiled fish materials may be treated with alternate processes besides pressure sterilisation as specified in Article 14 of Regulation (EC) No 1069/2009.</p> |  |  |
| <p><b>Glycerine and other products of Category 2 and 3 materials derived from certain biodiesel and renewable fuels production</b></p> | <p>According to 142/2011, Annex IV, Chapter IV, Section 3, certain by-products from biodiesel production may be used as fertilisers or soil improvers provided that they meet the following requirements:</p> <p>Point 2(b)(i): “...in the case of potassium sulphate, used for the production of derived products for application to land”.</p>   | <ul style="list-style-type: none"> <li>• <b>Potassium sulphate</b> (PFCs 1A and 1B)</li> </ul> |  |
| <p><b>Glycerine and other products of Category 2 and 3 materials derived from certain biodiesel and renewable fuels production</b></p> | <p>According to 142/2011, Annex IV, Chapter IV, Section 3, certain by-products from biodiesel production may be used as fertilisers or soil improvers provided that they meet the following requirements:</p> <p>Point 2(c)(ii) in the case of used clay from bleaching and sludge from the pre-treatment process referred to in point J(2)(a) of Section 2:</p> <p>— composted or used for the manufacture of derived products referred to in Article 36(a)(i) of Regulation (EC) No 1069/2009;</p>   | <ul style="list-style-type: none"> <li>• <b>Used clay</b> (PFC 3A)</li> </ul>                  |  |
| <p><b>Glycerine and other products of Category</b></p>   | <p>According to 142/2011, Annex IV, Chapter IV, Section 3, certain by-products from biodiesel production may be used as</p>  |  |  |

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| <p><b>2 and 3 materials derived from certain biodiesel and renewable fuels production</b></p>  | <p>fertilisers or soil improvers provided that they meet the following requirements:</p> <p>Point 2(d) the lime-treated mixture of pig and poultry manure may be applied to land as processed manure;</p>   | <ul style="list-style-type: none"> <li>• <b>Lime-treated manures</b> (PFCs 1A and 1B)</li> </ul>      |  |
| <p><b>Glycerine and other products of Category 2 and 3 materials derived from certain biodiesel and renewable fuels production</b></p> | <p>According to 142/2011, Annex IV, Chapter IV, Section 3, certain by-products from biodiesel production may be used as fertilisers or soil improvers provided that they meet the following requirements:</p> <p>Point 2 (e) The final product derived from the ensilaging of fish material may:</p> <p>(i) for Category 2 materials, be used for purposes referred to in Article 13(a) to (d) and (g) to (i) of Regulation (EC) No 1069/2009 without further processing or as feed for animals referred to in Article 18 or Article 36(a)(ii) of that Regulation; or</p> <p>(ii) for Category 3 materials, be used for purposes referred to in Article 14 of Regulation (EC) No 1069/2009;</p> | <ul style="list-style-type: none"> <li>• <b>Ensiled fish material</b> (PFCs 1A, 1B and 3A)</li> </ul> |  |

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| <p><b>A material having already reached an end point defined in Regulation (EC) No 1069/2009 (ABPR)</b></p> | <ul style="list-style-type: none"> <li>- Thermal hydrolysis</li> <li>- Chemical hydrolysis (acid or alkaline)</li> <li>- Enzymatic hydrolysis</li> <li>- A combination of two or more of these hydrolysis</li> </ul> | <p><b>Hydrolysed proteins</b> (PFCs 1A, 1B, 3A, 6A and 6B)</p> | <p>If a raw material has already reached an end point, then it stands to reason that hydrolysis will only maintain or improve the safety of the material relative to end point status.</p> <p>Proteins are hydrolysed to break the peptide bonds in amino acid chains to generate smaller peptide fragments or even free amino acids. This process reduces the molecular weight of the original protein. Hydrolysed proteins can be distinguished from processed animal proteins through laboratory analysis.</p> |
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| <p><b>Category 3 Materials from non-ruminants</b></p> | <p>According to Commission Regulation (EU) No 68/2013 of 16 January 2013 on the Catalogue of feed materials, Hydrolysed proteins are obtained by heat and/or pressure, chemical, microbiological or enzymatic hydrolysis of animal protein.</p> <p>If hydrolysed proteins from non-ruminants can be accepted directly as feed materials without further conditions, there is no reason why they would not be appropriate to apply to crops that might be later fed to animals. Therefore, an end point could be defined for the use of hydrolysed proteins from non-ruminants in EU Fertilising Products.<sup>xvi</sup></p> | <p><b>Hydrolysed proteins</b> (PFCs 1A, 1B, 3A, 6A and 6B )</p> | <p>With regard to feed, the Commission has in the past accepted alternative processing methods for non-ruminant hydrolysed proteins of Category 3 Material, provided that they meet the criteria in point 14 of Annex I to Reg (EU) 142/2011. It is therefore consistent to apply the same logic to the hydrolysis of proteins for use in fertilising products.</p> <p>Recital 6 of Commission Regulation (EC) No 1292/2005 notes that in its opinions of 17 September 1999 on intra-species recycling and 27 and 28 November 2000 on the scientific basis for banning animal protein from feed for all farmed animals, the Scientific Steering Committee (SSC) stated that there is no evidence of the natural occurrence of TSE in non-ruminant farmed animals producing food, such as pigs and poultry. Furthermore, given that controls on the ban on animal proteins are based on the detection of bones and muscles fibres in feedingstuffs, blood products and hydrolysed proteins derived from non-ruminants should not jeopardise controls on the presence of potentially TSE infected proteins. Therefore, the restrictions on feeding to farmed animals of blood products and hydrolysed derived from non-ruminants should be relaxed.</p> |
| <p><b>Category 3 Materials from ruminants</b></p>     | <p>Regulation (EU) 142/2011</p>   | <p><b>Hydrolysed proteins</b> (PFCs 1A, 1B, 6A and 6B)</p>      | <p>The inclusion of alkaline hydrolysis in Regulation (EU) 142/2011 was based on the</p>  |

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|  | <ul style="list-style-type: none"> <li>• Annex IV, Chapter IV, Section 1 Paragraph 1, Point A (Alkaline hydrolysis process)</li> <li>• Annex IV, Chapter IV, Section 2 Point B (High pressure high temperature hydrolysis process)</li> <li>• Annex X, Chapter II, Section 5, Point D.</li> </ul> <p>To reach the end point to be used in the Fertilising Products Regulation, the hydrolysed proteins must have a molecular weight of less than 50,000 Daltons when derived from ruminants.</p> |  | <p>April 2003 Opinion of the Scientific Steering Committee (SSC) that alkaline hydrolysis is a safe method for disposing of ABPs from Categories 1, 2, and 3. Proteins are hydrolysed to break the peptide bonds in amino acid chains to generate smaller peptide fragments. This process reduces the molecular weight of the original protein. Hydrolysed proteins can be distinguished from processed animal proteins (PAPs) through laboratory analysis.</p> <p>In contrast to PAPs, hydrolysed proteins with molecular weight of less than 50,000 Daltons are completely soluble, which is a precondition for the “agronomic efficiency” of these materials in fertilising products.</p> <p>For hydrolysed proteins derived from Category 3 Materials [as defined in Article 10 of Regulation (EC) 1069/2009] used as organic fertilizers and soil amendments, Regulation (EU) 142/2011 specifies no upper limit to the molecular weight of hydrolysed proteins that may be used in fertilising products.</p> <p>2) In Regulation (EC) 1292/2005 amending Annex IV to Regulation (EC) 999/2001 establishing provisions for the prevention, control and eradication of certain transmissible spongiform encephalopathies, it is indicated that hydrolysed proteins from non-ruminant parts and from ruminant hides and skins may be used for animal feed.</p> |
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### Section III. Other materials to consider for end points

In the interest of promoting the circular economy, we suggest also considering the following materials for end point status.

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| <p><b>Hides and skins of animals besides ungulates</b></p> | <p>Processing should also be according to the provisions outlined in Annex XIII, Chapter V, point C:</p> <p>Provided that they comply with the requirements of Regulation (EC) No 853/2004 for raw materials for gelatine or collagen intended for use in food:</p> <p>AND provided that they are accompanied by a commercial document in accordance with the model set out under point 6 of Chapter III of Annex VIII of Regulation (EC) 1069/2006 When sourced for use in the EU Fertilising Product.</p> | <ul style="list-style-type: none"> <li>• <b>Tanned hides and skins</b> (PFCs 1A, 1B and 3A)</li> </ul> | <p>It is a small market but now, some skins of fishes are tanned.</p> |
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### ABOUT US



The European Biostimulant 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 Biostimulant Industry.



The European Consortium of the Organic-Based Fertilizer Industry (ECOFI) is the representative voice of European producers of organic fertilizers, organo-mineral fertilizers and organic soil improvers.

## **END NOTES**

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<sup>i</sup> EFSA Journal (2005) 257, 1-30

<sup>ii</sup> The mandate was accepted in June 2020 and assigned the reference number "EFSA-Q- 2020-00401".

<sup>iii</sup> According to Regulation (EC) 142/2011, Annex 1, the definition of 'hydrolysed proteins' is "polypeptides, peptides and amino acids, and mixtures thereof, obtained by the hydrolysis of animal by-products."

<sup>iv</sup> The proposed CMC 13 on Thermal Oxidation materials explicitly excludes ABPs as the input material.

<sup>v</sup> EFSA Journal (2005) 257, 1-30

<sup>vi</sup> Opinion of the Scientific Panel on Biological Hazards of the European Food Safety Authority on the safety vis-à-vis biological risk including TSEs of the application on pastureland of organic fertilisers and soil improvers; The EFSA Journal (2004) 40, 1-10).

<sup>vii</sup> Overview of the BSE risk assessments of the European Commission's Scientific Steering Committee (SSC) and its TSE/BSE ad hoc Group (P. Vossen, J. Kreysa and M. Goll), 5 June 2003

- Opinion on open burning of potentially tse-infected animal materials adopted by the scientific steering committee at its meeting of 16-17 January 2003

- Opinion on the use of small incinerators for BSE risk reduction scientific steering committee meeting of 16-17 January 2003

- Scientific opinion - The safety of meat and bone meal from mammalian animals, naturally or experimentally susceptible to transmissible spongiform encephalopathies. adopted by the scientific steering committee at its meeting of 26-27 March 1998 following a public consultation on the preliminary opinion adopted on 19-20 February 1998

- The safe handling, transport and temporary storage of meat-and-bone meal which may be contaminated with a BSE agent or other pathogens - adopted by the Scientific Steering Committee at its meeting of 26-27 October 2000

- EFSA Journal (2005) 257, 1-30.

- EFSA Journal 2011;9(1):1947.

- EFSA Journal 2017;15(7):4885.

- EFSA Journal 2018; 16(7):5314

<sup>viii</sup> For this reason, it would be useful for the European Commission to publish guidance that specifies that if an organic material deriving from an animal by-product (ABP) is used as a component to produce any type of fertilising products, whether under national rules or the Fertilising Products Regulation, it must previously comply with the ABPR requirements.

<sup>ix</sup> The scope of EBIC and ECOFI cover PFCS 1A, 1B, 3A and 6 (A and B). Some of these materials may be used in other PFCs that are not covered here, such as growing media.

<sup>x</sup> We do not include Method 7 because it requires national approval and is therefore not appropriate for a European-level end point for administrative reasons.

<sup>xi</sup> We do not include Method 7 because it requires national approval and is therefore not appropriate for a European-level end point for administrative reasons.

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<sup>xii</sup> We do not include Method 7 because it requires national approval and is therefore not appropriate for a European-level end point for administrative reasons.

<sup>xiii</sup> EFSA Journal 2018; 16(7):5314; EFSA Journal 2017;15(7):4885; EFSA Journal 2011;9(1):1947; EFSA Journal (2005) 257, 1-30; Scientific Panel on Biological Hazards of the European Food Safety Authority. EFSA Journal (2004) 40, 1-10. Safety vis-à-vis biological risk including TSEs of the application on pastureland of organic fertilisers and soil improvers; P. Vossen, J. Kreysa and M. Goll (2003) Overview of the BSE risk assessments of the European Commission's Scientific Steering Committee (SSC) and its TSE/BSE ad hoc Group: [https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com\\_ssc\\_out364\\_en.pdf](https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_ssc_out364_en.pdf); European Commission Scientific Steering Committee (2003) Opinion on Open Burning of Potentially TSE-Infected Animal Materials: [https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com\\_ssc\\_out310\\_en.pdf](https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_ssc_out310_en.pdf); European Commission Scientific Steering Committee (2003) Opinion on the Use of Small Incinerators for BSE Risk Reduction: [https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com\\_ssc\\_out311\\_en.pdf](https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_ssc_out311_en.pdf); European Commission Scientific Steering Committee (2000) Opinion on the Safe Handling, Transport and Temporary Storage of Meat-and-Bone Meal which May Be Contaminated with a BSE Agent or Other Pathogens: [https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com\\_ssc\\_out145\\_en.pdf](https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_ssc_out145_en.pdf); European Commission Scientific Steering Committee (1998) Opinion on the Safety of Meat and Bone Meal from Mammalian Animals, Naturally or Experimentally Susceptible to Transmissible Spongiform Encephalopathies: [https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com\\_ssc\\_out10\\_en.pdf](https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_ssc_out10_en.pdf).

<sup>xiv</sup> We do not include Method 7 because it requires national approval and is therefore not appropriate for a European-level end point for administrative reasons.

<sup>xv</sup> We do not include Method 7 because it requires national approval and is therefore not appropriate for a European-level end point for administrative reasons.

<sup>xvi</sup> We have not proposed a threshold molecular weight in Daltons because there is no basis for applying stricter requirements to this group of hydrolysed proteins than to those from ruminant materials nor to those applied to non-ruminant hydrolysed proteins in feed.