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[...] (2022) **XXX** draft

COMMISSION DELEGATED REGULATION (EU) .../...

of XXX

supplementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council as regards the determination of end points in the manufacturing chain of certain organic fertilisers and soil improvers

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Regulation (EC) No 1069/2009 of the European Parliament and of the Council¹ lays down public and animal health rules for animal by-products and derived products to prevent and minimise risks to public and animal health arising from those products, and in particular to protect the safety of the food and feed chain.

Notably, Regulation (EC) No 1069/2009 lays down harmonised rules for the production and placing on the market of organic fertilisers and soil improvers, and the legal basis for the determination of an end point in the manufacturing chain, beyond which organic fertilisers and soil improvers may be placed on the market no longer subject to the requirements of Regulation (EC) No 1069/2009.

This draft Commission Delegated Regulation determines end points for derived products in the manufacturing chain, and in particular for certain organic fertilisers and soil improvers, in order to make them available on the market of EU fertiliser products as referred to in Article 42(5) of Regulation (EU) 2019/1009 of the European Parliament and of the Council².

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

Member States were consulted in the Commission expert group on Animal Health (E00930) in accordance with the Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making³.

Details of those consultations can be found in the minutes of the meetings held on 14 March 2022, 18 May 2022 and 2 June 2022 which are publicly available on the CIRCABC page of that Group⁴.

Interested stakeholders were consulted at the Animal Health Advisory Committee of 7 June 2022 and they provided input on the initiative which was largely supportive for the adoption of this Delegated Regulation.

This draft Delegated Regulation has been published for feedback on the Better Regulation portal during the period from ...to ... [*to be supplemented later on*].

This draft Delegated Regulation has also been notified to the WTO/SPS notification system.

¹ Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

² Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003 (OJ L 170, 25.6.2019, p. 1).

³ OJ L 123, 12.5.2016, p. 1.

⁴ <https://circabc.europa.eu/ui/welcome>

3. LEGAL ELEMENTS OF THE DELEGATED ACT

This Delegated Regulation is to be adopted pursuant to Regulation (EC) No 1069/2009, and in particular Article 5(2), third subparagraph, thereof.

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supplementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council as regards the determination of end points in the manufacturing chain of certain organic fertilisers and soil improvers

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)¹, and in particular Article 5(2), third subparagraph, thereof,

Whereas:

- (1) Regulation (EC) No 1069/2009 lays down public and animal health rules for derived products, in order to prevent and minimise risk to public and animal health arising from those products, and in particular to protect the safety of the food and feed chain. More specifically, it lays down rules as regards the safe treatment, and the processing or transformation of animal by-products into derived products, including rules for the placing on the market and use of organic fertilisers and soil improvers. In addition, Regulation (EC) No 1069/2009, as amended by Regulation (EU) 2019/1009 of the European Parliament and of the Council², provides that the Commission is empowered to adopt delegated acts to determine end points in the manufacturing chain, beyond which certain derived products are no longer subject to the requirements of Regulation (EC) No 1069/2009.
- (2) Regulation (EU) 2019/1009 establishes rules for the marketing of EU fertilising products. That Regulation does not apply to derived products which are subject to the requirements of Regulation (EC) No 1069/2009 when made available on the market. Pursuant to Regulation (EU) 2019/1009, certain derived products may become, or be part of, an EU fertilising product provided that an end point in the manufacturing chain of the derived product is reached, thereby ensuring animal and public health safety. Those derived products, which have reached an end point in the manufacturing chain of certain organic fertilisers and soil improvers, will no longer be subject to the requirements of Regulation (EC) No 1069/2009 and instead come within the scope of Regulation (EU) 2019/1009.

¹ OJ L 300, 14.11.2009, p. 1.

² Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003 (OJ L 170, 25.6.2019, p. 1).

- (3) On 2 December 2021, EFSA published a 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’³. That Scientific Opinion does not provide for a risk assessment of the compost and biogas digestion residues, processed animal protein (PAP) and processed manure because those derived products have been recently assessed by EFSA with a favourable outcome. According to that Scientific Opinion, ash of Category 2 and 3 materials which fulfils the requirements set out in Annex III to Commission Regulation (EU) No 142/2011⁴, glycerine of Category 2 and 3 materials, and other Category 2 materials derived from the production of biodiesel in accordance with alternative methods for the production of biodiesels or renewable fuels set out in Annex IV to that Regulation, represent a low risk for public and animal health due to safe processing. An end point in the manufacturing chain of those derived products can be determined.
- (4) Certain organic fertilisers and soil improvers require risk mitigation measures to reach an end point in the manufacturing chain to ensure compliance with the feed ban laid down in Regulation (EC) No 999/2001 of the European Parliament and the Council⁵. Such organic fertilisers and soil improvers are required to be mixed with a component that excludes the subsequent use of the mixture for feeding purposes. For that reason, it is appropriate to prohibit the use of feed materials listed in the Annex to Commission Regulation (EU) No 68/2013⁶ as mixing components.
- (5) Derived products should be considered as having reached the end point only if they are manufactured in a fertiliser plant in the European Union which is approved in accordance with Article 24(1), point (f), of Regulation (EU) No 1069/2009. An approved fertiliser plant is the last point in the manufacturing chain where derived products are subject to Regulation (EU) No 1069/2009 and the place where they become, after reaching an end point, subject to Regulation (EU) 2019/1009,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation determines end points for derived products in the manufacturing chain for organic fertilisers and soil improvers produced in the Union beyond which they are no longer subject to the requirements of Regulation (EC) No 1069/2009.

Article 2

Definitions

³ EFSA Journal 2021;19(12):6932.

⁴ Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (OJ L 54, 26.2.2011, p. 1).

⁵ Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies(OJ L 147, 31.5.2001, p. 1).

⁶ Commission Regulation (EU) No 68/2013 of 16 January 2013 on the Catalogue of feed materials (OJ L 29, 30.1.2013, p. 1).

For the purposes of this Regulation, the definitions laid down in Annex I to Regulation (EU) No 142/2011 apply.

The following definitions also apply:

- (1) 'EU fertilising product' means a fertilising product as defined in Article 2, point (2), of Regulation (EU) 2019/1009;
- (2) 'end point' means an end point in the manufacturing chain, beyond which a derived product is no longer subject to the requirements of Regulation (EC) No 1069/2009.

Article 3

End point for certain organic fertilisers and soil improvers

The following derived products, other than those imported into the Union, where they are manufactured in a fertiliser plant approved in accordance with Article 24(1), point (f), of Regulation (EC) No 1069/2009, shall be considered as having reached the end point as organic fertilisers and soil improvers:

- (a) ash obtained from Category 2 and 3 materials which fulfils the general and specific requirements set out in Annex III to Regulation (EU) No 142/2011;
- (b) biogas digestion residues which fulfil the requirements set out in Section 1 of Chapter I, Chapter II, and Section 1, point 1, and Section 3 of Chapter III of Annex V to Regulation (EU) No 142/2011;
- (c) compost, which fulfils the requirements, set out in Section 2 of Chapter I, Chapter II, and Section 1(2) and Section 3 of Chapter III of Annex V to Regulation (EU) No 142/2011;
- (d) processed manure and processed frass which fulfil the requirements set out in Section 2, points (a), (b) and (d) of Chapter 1, of Annex XI to Regulation (EU) No 142/2011.

Article 4

End point for certain organic fertilisers and soil improvers conditional upon risk mitigation measures

1. The following derived products, other than those imported into the Union, where they are manufactured in a fertiliser plant approved in accordance with Article 24(1), point (f), of Regulation (EC) No 1069/2009 and they comply with the risk mitigating measures referred to in paragraphs 2 and 3, shall be considered as having reached the end point as organic fertilisers and soil improvers:
 - (a) glycerine of Category 2 and 3 materials, and other Category 2 material resulting from biodiesel process and the production of renewable fuels which fulfil the requirements set out in Section 3, point 2(b), (c) and (f), of Chapter IV of Annex IV to Regulation (EU) No 142/2011;
 - (b) Category 3 materials other than glycerine, which fulfil the requirements set out in Section 3, point 2(b), (c) and (f), of Chapter IV of Annex IV to Regulation (EU) No 142/2011;
 - (c) processed animal protein of Category 3 materials which fulfils the specific requirements for processed animal protein set out in Section 1 of Chapter II of Annex X to Regulation (EU) No 142/2011;

- (d) meat-and-bone meal of Category 2 materials processed with standard processing method 1 set out in Chapter III, point A, of Annex IV and marked with glyceroltriheptanoate (GTH) as set out in Chapter V of Annex VIII to Regulation (EU) No 142/2011;
 - (e) blood products of Category 3 materials which fulfil the specific requirements for blood products set out in Section 2 of Chapter II of Annex X to Regulation (EU) No 142/2011;
 - (f) 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, including hydrolysed protein derived from residues coming from the leather industry;
 - (g) dicalcium phosphate and tricalcium phosphate which fulfil the specific requirements set out in Section 6 or 7 of Chapter II of Annex X to Regulation (EU) No 142/2011, respectively;
 - (h) feathers and down, which fulfil the specific requirements set out in Chapter VII, point C, of Annex XIII to Regulation (EU) No 142/2011;
 - (i) horns, horn products, hooves and hoof products which fulfil the specific requirements set out in Chapter XII of Annex XIII to Regulation (EU) No 142/2011.
2. The derived products referred to in paragraph 1 shall be packaged in ready-to-sell packages of not more than 50 kg in weight for use by the final consumer with a content of derived products of not more than 50 % in volume.
 3. The derived products referred to in paragraph 1 of this Article, may be mixed with the derived products listed in Article 3 of this Regulation, or 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.

Article 5

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in *the Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN