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From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	30 May 2023
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

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Subject:	COMMISSION DELEGATED REGULATION (EU) .../... of 30.5.2023 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

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Delegations will find attached document C(2023) 3366 final.

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Encl.: C(2023) 3366 final



EUROPEAN  
COMMISSION

Brussels, 30.5.2023  
C(2023) 3366 final

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

**of 30.5.2023**

**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)

## **EXPLANATORY MEMORANDUM**

### **1. CONTEXT OF THE DELEGATED ACT**

Regulation (EC) No 1069/2009 of the European Parliament and of the Council<sup>1</sup> 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 that Regulation .

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 as EU fertilising products, as referred to in Article 42(5) of Regulation (EU) 2019/1009 of the European Parliament and of the Council<sup>2</sup>.

### **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-Making<sup>3</sup>.

Details of those consultations can be found in the minutes of the meetings held on 14 March 2022, 18 May 2022, 2 June 2022, 7 September 2022 and 19 January 2023 which are publicly available on the page of that Group<sup>4</sup>.

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 26 September 2022 to 24 October 2022. Following the feedback from fertilisers industry, the Commission revised the draft Delegated Regulation.

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

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<sup>1</sup> 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).

<sup>2</sup> 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).

<sup>3</sup> OJ L 123, 12.5.2016, p. 1.

<sup>4</sup> [https://food.ec.europa.eu/animals/animal-health/expert-group-animal-health\\_en#meetings-2022](https://food.ec.europa.eu/animals/animal-health/expert-group-animal-health_en#meetings-2022)

### **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.

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

of 30.5.2023

## 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)<sup>1</sup>, 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 risks 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 Council<sup>2</sup>, 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 making available on the market 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 will fall only within the scope of Regulation (EU) 2019/1009.

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<sup>1</sup> OJ L 300, 14.11.2009, p. 1.

<sup>2</sup> 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, the European Food Safety Authority (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’<sup>3</sup> (EFSA Scientific Opinion of 2 December 2021). 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 142/2011<sup>4</sup>, 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. Those derived products should reach the end point if they are used as component material in accordance with Regulation (EU) No 2019/1009.
- (4) Certain derived products are not included in the EFSA Scientific Opinion of 2 December 2021 since they have been recently assessed by other EFSA Scientific Opinions. Compost and biogas digestion residues subject to the standard transformation parameters were assessed in 2015 as safe in the EFSA Scientific Opinion of 13 November 2015 ‘Risk to public and/or animal health of the treatment of dead-in-shell chicks (Category 2 material) to be used as raw material for the production of biogas or compost with Category 3 approved method’<sup>5</sup>. A EFSA Scientific Opinion on the revision of the quantitative risk assessment (QRA) of the BSE risk posed by processed animal proteins (PAP)<sup>6</sup> was adopted on 17 July 2018 for the purpose of the partial revision of the feed ban laid down in Regulation (EC) No 999/2001 of the European Parliament and of the Council<sup>7</sup>. Processed manure was assessed by the EFSA Scientific Opinion of 27 April 2021 ‘Ability of different matrices to transmit African swine fever virus’<sup>8</sup> which includes an assessment of the animal health safety of the heat treatment for processed manure.
- (5) 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. Under Regulation (EU) No 142/2011, some of those organic fertilisers and soil improvers are required to be mixed with a component that excludes the subsequent use of the mixture for feeding purposes to prevent the introduction of certain transmissible spongiform encephalopathies through fertilisers into the feed chain for farmed animals. It is appropriate to introduce a combination of the existing risk mitigation measures laid down in Regulation (EU) No 142/2011, based on the packaging, labelling and composition.

<sup>3</sup> EFSA Journal 2021;19(12):6932.

<sup>4</sup> 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).

<sup>5</sup> EFSA Journal 2015;13(11):4306.

<sup>6</sup> <https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2018.5314> (EFSA Journal 2018;16(7):5314).

<sup>7</sup> 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).

<sup>8</sup> EFSA Journal 2021;19(4): 6558.

- (6) Derived products should be considered as having reached the end point only if they are manufactured in a fertiliser plant in the 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 the requirements laid down in Regulation (EU) No 1069/2009 and the place where they become, after reaching an end point, only subject to those laid down in Regulation (EU) 2019/1009,

HAS ADOPTED THIS REGULATION:

*Article 1*  
*Subject matter*

This Regulation determines end points in the manufacturing chain for organic fertilisers and soil improvers manufactured in the Union beyond which they are no longer subject to the requirements laid down in Regulation (EC) No 1069/2009, provided that they are used as component materials in EU fertilising products in accordance with Regulation (EU) 2019/1009.

*Article 2*  
*Definitions*

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) residues resulting from the transformation of animal by-products in a biogas plant which fulfil the requirements set out in the following provisions of Annex V to Regulation (EU) No 142/2011:
  - (i) Chapter I, Section 1, point 1, point 2(a), (b), (c) and (e), and points 3 and 4;
  - (ii) Chapter II;
  - (iii) Chapter III, Section 1, point 1, first and last paragraphs, and Section 3, point 1;
- (c) compost, which fulfils the requirements, set out the following provisions of Annex V to Regulation (EU) No 142/2011:
  - (i) Chapter I, Section 2, points 1, 3 and 4;

- (ii) Chapter II;
- (iii) Chapter III, Section 1, point 2, and Section 3, point 1;
- (d) processed manure and processed frass which fulfil the requirements set out in Chapter I, Section 2, points (a), (b), (d) and (e), 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 shall be considered as having reached the end point as organic fertilisers and soil improvers if they are used in the EU fertilising product in not more than 5% by volume:
  - (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 Chapter IV, Section 3, point 2(b), (c) and (f), of Annex IV to Regulation (EU) No 142/2011;
  - (b) Category 3 materials other than glycerine, which fulfil the requirements set out in Chapter IV, Section 3, point 2(b), (c) and (f), 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 Chapter II, Section 1, point A, point B(1) and (2), point B(3)(a) and point C, of Annex X to Regulation (EU) No 142/2011;
  - (d) meat-and-bone meal of Category 2 materials processed with the 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 Chapter II, Section 2, of Annex X to Regulation (EU) No 142/2011;
  - (f) hydrolysed protein, including hydrolysed protein derived from residues coming from the leather or textile industry, which fulfils the specific requirements for hydrolysed protein set out in Chapter II, Section 5, point D, of Annex X to Regulation (EU) No 142/2011;
  - (g) dicalcium phosphate and tricalcium phosphate which fulfil the specific requirements set out in Chapter II, Section 6 or 7, of Annex X to Regulation (EU) No 142/2011, respectively;
  - (h) 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 of this Article which are present in the EU fertilising product in more than 5% by volume shall be considered as having reached the end point as organic fertilisers and soil improvers if they are packed in



ready-to-sell packages for use by the end-user, labelled in accordance with labelling requirements for the EU fertilising products containing derived products laid down in Part I of Annex III to Regulation (EU) No 2019/1009 and comply with the conditions laid down either in the following point (a) or in point (b):

- (a) the packages weigh no more than 50 kg; or
- (b) the packages weigh no more than 1 000 kg of which at least 10 % in volume is one of the following:
  - (i) lime;
  - (ii) mineral fertilisers or
  - (iii) derived products referred to in Article 3.

*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, 30.5.2023

*For the Commission*  
*The President*  
*Ursula VON DER LEYEN*