

**Mandate** Question Output Pesticides Dossier Help

Mandate Number

Reception Date

Mandate Type

Requestor

Acceptance By EFSA ( )

Acceptance  Non Acceptance

Date:

Back

## Questions

Question Number	Subject	Unit	Status	Last Updated
<a href="#">EFSA-Q-2020-00401</a>	Request for a scientific opinion on the capacity of certain specific processing and transformation methods in the manufacturing chain of organic fertilisers and soil improvers	Biological hazards and contaminants	In progress	19/06/2020 09:23

<< < 1 > >>

## Documents

File Name	Public Title	Type	Upload Date
<a href="#">Ares(2020)2316808 Mandate for scientific and technical assistance on endpoints for certain fertilisers.pdf</a>	<input type="text" value="mandate"/>	<input type="text" value="Mandate"/>	27/05/2020
<a href="#">2020_06_09_Acceptance Organic fertilisers_223302241.pdf</a>	<input type="text" value="acceptane"/>	<input type="text" value="EFSA Request"/>	09/06/2020



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EXECUTIVE DIRECTOR

Ref. BU/JK/ELC/AOP/cv (2020) – out 23302241

Ms. Anne Bucher  
Director General  
Directorate General for  
Health and Food Safety  
European Commission  
200, rue de la Loi  
B-1049 Brussels  
Belgium

**Re: Request for a scientific opinion on the capacity of certain specific processing and transformation methods of animal by-products used in the production of organic fertilisers and soil improvers in view of determining the endpoints in the manufacturing chain of certain derived products**

*Ref. Ares(2020) 2316808 – 30/04/2020*

Dear Ms Bucher,

I acknowledge receipt of your letter Ref. Ares(2020) 2316808 – 30/04/2020 which requests EFSA to prepare a scientific opinion on the capacity of certain specific processing and transformation methods of animal by-products used in the production of organic fertilisers and soil improvers in view of determining the endpoints in the manufacturing chain of certain derived products.

I am pleased to inform you that the mandate has been accepted by EFSA and has been assigned the question number EFSA-Q- 2020-00401.

The mandate has been allocated to the Scientific Panel on Biological Hazards (BIOHAZ Panel) and was presented to this Panel during their 138<sup>th</sup> plenary meeting on 3 June 2020.

EFSA aims to deliver the scientific opinion by the proposed deadline of 31 October 2021.

Yours sincerely,

Bernhard Url

Cc: J. Kleiner, E. Liebana (EFSA)  
B. Van Goethem (DG SANTE)



**EUROPEAN COMMISSION**  
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Crisis management in food, animals and plants  
**Director**

Brussels,  
SANTE/G2/MK/ise(2020) 8792057

Dear Dr Url,

**Subject: Request for a scientific opinion on the capacity of certain specific processing or transformation methods of animal by-products used in the production of organic fertilisers and soil improvers in view of determining the endpoints in the manufacturing chain of certain derived products**

I would like to submit a formal request to EFSA for a scientific opinion on the capacity of certain specific processing or transformation methods of animal by-products used in the production of organic fertilisers and soil improvers, which would allow to determine the end points in the manufacturing chain of certain derived products.

Therefore, in the context of Article 29 of Regulation (EC) No 178/2002, I would like to ask EFSA to provide a scientific opinion to the Commission as detailed in the background and the terms of reference annexed to this letter. Our services would appreciate it, if the results of your assessment could be made available by 31 October 2021.

Should you need further information, please contact Mr Matjaz Klemencic, responsible for this dossier or the coordinating desk officer within SANTE, Ms Marina Marini.

Yours sincerely,

Bernard Van Goethem

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R. Reig Rodrigo, L. Carrouee, D. Von Buxhoeveden, E. Thevenard,  
E. Zamora, M. Marini, A.-E. Füssel, (SANTE)

Dr Bernhard Url  
Executive Director  
European Food Safety Authority  
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# **Request for a scientific opinion on the capacity of certain specific processing or transformation methods of animal by-products used in the production of organic fertilisers and soil improvers in view of determining the endpoints in the manufacturing chain of certain derived products**

## **Background**

Derived products referred to in Article 3(2) of Regulation (EC) No 1069/2009<sup>1</sup> that reached the end point in the manufacturing chain of animal by-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 Regulation (EC) No 1069/2009 and Regulation (EU) 2017/625<sup>2</sup>.

Article 32 of Regulation (EC) No 1069/2009 provides for rules for placing on the market and use of organic fertilisers and soil improvers (OF/SI) of Category 2 and 3 materials. By the exclusion of Category 1 material from the production of OF/SI certain risks to animal and public health and to the environment are already addressed. However, for the use of those animal by products, which are classified as Category 2 material referred to in Article 9(c), a specific risk assessment is necessary to ensure that the use of such animal by product as organic fertilizer does not entail a risk to animal and public health and to the environment.

Regulation (EU) 2019/1009<sup>3</sup> establishing rules for the placing on the market of EU fertilising products, introduced in Article 5(2) of Regulation (EC) No 1069/2009 a reference to Article 32 of that Regulation, and thus the possibility to determine the end point in the manufacturing chain of OF/SI<sup>4</sup>.

Derived products of Category 2 and Category 3 materials<sup>5</sup>, referred to respectively in Articles 9 and 10 of Regulation (EU) No 1069/2009, may be placed on the market and used as OF/SI. Those materials present comparable TSE/BSE risks since none of them includes specific risk materials as defined in Article 3(1)(g) of Regulation (EC) No 999/2001<sup>6</sup>.

The European Parliament and the Council asked the Commission to initiate an assessment of derived products referred to in Article 32 that are already widely used in the Union as OF/SI.

This assessment shall cover at least the following products:

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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) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, (OJ L 95, 7.4.2017, p. 1).

<sup>3</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>4</sup> In the original text of Article 5(2) of Regulation (EU) No 1069/2009, the end point in the manufacturing chain of OF/SI was not included in order to prevent the transmission of transmissible spongiform encephalopathies (TSE/BSE)

<sup>5</sup> As defined in Article 32(1)(a) of Regulation (EU) No 1069/2009.

<sup>6</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).

- 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.

The following derived products are widely placed on the market for use as OF/SI:

1. Biogas digestion residues and compost referred to in the second subparagraph of Article 32(1) of Regulation (EU) No 1069/2009.

Standard transformation parameters for compost and biogas transformation residues are laid down in Section 1 of Chapter III of Annex V to Regulation (EU) No 142/2011<sup>7</sup>. With reference to point 2(a) of Section 1 and point 2(b) of Section 2 of Chapter II of the aforementioned Annex V, Category 2 materials intended for compost or biogas transformation should be processed in accordance with processing method 1.

Biogas and compost transformation has been subject to several EFSA assessments in 2005<sup>8</sup>; 2009<sup>9</sup> and 2015<sup>10</sup>:

2. Ash derived from incineration, co-incineration and combustion, carried out in accordance with methods laid down in Annex III to Regulation (EU) No 142/2011, of Category 2 and 3 materials and derived products may be used as fertilising products.

The disposal of animal by-products, including meat-and-bone meal, by incineration, co-incineration and combustion has been subject to EFSA assessment on several occasions.

The following scientific opinions led to the conclusion that direct incineration of carcasses and incineration or burning under appropriate controlled condition of rendered material are economically feasible technologies for safe disposal of TSE risk material:

- Overview of the BSE risk assessments of the European Commission’s Scientific Steering Committee (SSC) and its TSE/BSE ad hoc Group<sup>11</sup>;
- Opinion on open burning of potentially TSE-infected animal materials adopted by the Scientific Steering Committee at its meeting of 16-17 January 2003<sup>12</sup>;
- Opinion on the use of small incinerators for BSE risk reduction by the Scientific Steering Committee meeting of 16-17 January 2003<sup>13</sup>; and

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<sup>7</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 054 26.2.2011, p. 1).

<sup>8</sup> EFSA Journal (2005) 264, 1-21.

<sup>9</sup> EFSA Journal 2009; 7(11):1370.

<sup>10</sup> EFSA Journal 2015; 13(11):4306.

<sup>11</sup> [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)

<sup>12</sup> [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)

<sup>13</sup> [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)

- Opinion of the Scientific Panel on Biological Hazards of the European Food Safety Authority on the “Quantitative risk assessment of the animal BSE risk posed by meat and bone meal with respect to the residual BSE risk”<sup>14</sup>.

Based on those scientific opinions, standards for the disposal of animal by-products as waste by incineration, the disposal or recovery by co-incineration and the use as a fuel for combustion have been laid down in Regulation (EU) No 142/2011<sup>15</sup>.

3. Article 3 of Regulation (EU) No 142/2011 sets out end points for certain Category 2 and 3 materials which may be used in the manufacturing of OF/SI, such as derived products referred to in points (b) to (h) or side product of biofuel and oleochemical production referred to in points (a), (i), (j) and (k) of that Article.

Certain end points have been determined based on EFSA assessments of 2004<sup>16</sup>, 2010<sup>17</sup>, 2011<sup>18</sup> and 2015<sup>19</sup>.

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<sup>14</sup> EFSA Journal (2005) 257, 1-30.

<sup>15</sup> Article 6 of and Annex III to Regulation (EU) No 142/2011.

<sup>16</sup> EFSA Journal (2004), 23, 1-3.

<sup>17</sup> EFSA Journal 2010; 8(12):1934.

<sup>18</sup> EFSA Journal 2011; 9(2):1976.

<sup>19</sup> EFSA Journal 2015; 13(11):4307.

## Terms of Reference

In the light of the above, and in accordance with Article 29 of Regulation (EC) No 178/2002<sup>20</sup>, 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.

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<sup>20</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).