

COMMISSION REGULATION (EU) 2019/1091**of 26 June 2019****amending Annex IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the requirements for export of products containing processed animal protein derived from ruminants and non-ruminants****(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 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 ⁽¹⁾, and in particular the first paragraph of Article 23 and Article 23a (m) thereof,

Whereas:

- (1) Regulation (EC) No 999/2001 lays down rules for the prevention, control and eradication of transmissible spongiform encephalopathies ("TSEs") in animals. It applies to the production and placing on the market of live animals and products of animal origin and in certain specific cases to exports thereof.
- (2) The ban on exports to third countries of processed animal protein derived from ruminants and of products containing such processed animal protein, thus including organic fertilisers and soil improvers, was initially introduced by Commission Regulation (EC) No 1234/2003 ⁽²⁾ to prevent the transmission of bovine spongiform encephalopathies (BSE) to third countries through potentially contaminated processed animal protein and to prevent the risk of it re-entering the Union.
- (3) The European Food Safety Authority (EFSA) updated the quantitative risk assessment of the BSE risk posed by processed animal proteins in June 2018 ⁽³⁾. EFSA concluded that total BSE infectivity posed by processed animal protein was in 2018 four times lower than that estimated in 2011.
- (4) Following the opinion delivered by EFSA related to processed animal protein, it is appropriate to include organic fertilisers or soil improvers containing processed animal proteins derived from ruminants in the derogation laid down in point 2 of Section E of Chapter V of Annex IV to Regulation (EC) No 999/2001, should they not contain Category 1 material and products derived therefrom or Category 2 material and products derived therefrom other than processed manure.
- (5) Point 2 of Section E of Chapter V of Annex IV to Regulation (EC) No 999/2001 which prohibits the export of products containing processed animal protein derived from ruminants should therefore be amended accordingly.
- (6) Point 3 of Section E of Chapter V of Annex IV to Regulation (EC) No 999/2001 lays down the conditions applicable to exports of processed animal proteins derived only from non-ruminants or compound feed containing such protein. However, the conditions to export organic fertilisers or soil improvers containing processed animal proteins derived from non-ruminants have not been established. A new point 5 should therefore be added to Section E of Chapter V of Annex IV to Regulation (EC) No 999/2001 laying down such conditions.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 147, 31.5.2001, p. 1.

⁽²⁾ Commission Regulation (EC) No 1234/2003 amending Annexes I, IV and XI to Regulation (EC) No 999/2001 of the European Parliament and of the Council and Regulation (EC) No 1326/2001 as regards transmissible spongiform encephalopathies and animal feeding (OJ L 173, 11.7.2003, p. 6).

⁽³⁾ EFSA Journal 2018;16(7):5314.

HAS ADOPTED THIS REGULATION:

Article 1

Annex IV to Regulation (EC) No 999/2001 is amended in accordance with the Annex to this Regulation.

Article 2

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, 26 June 2019.

For the Commission
The President
Jean-Claude JUNKER

ANNEX

Annex IV to Regulation (EC) No 999/2001 is amended as follows:

(1) in Section E of Chapter V, point 2 is replaced by the following:

‘2. Without prejudice to point 1, the export of products containing processed animal protein derived from ruminants shall be prohibited.

By way of derogation, that prohibition shall not apply to:

(a) processed petfood containing processed animal protein derived from ruminants which:

(i) has been processed in establishments or plants approved in accordance with Article 24(1)(e) of Regulation (EC) No 1069/2009; and

(ii) is packaged and labelled in accordance with Union legislation.

(b) organic fertilisers or soil improvers, as defined in point 22 of Article 3 of Regulation (EC) No 1069/2009, that contain in their composition processed animal proteins derived from ruminants or a mixture of processed animal proteins from ruminants and non-ruminants provided that:

(i) they do not contain Category 1 material and products derived therefrom or Category 2 material and products derived therefrom, other than manure, as defined in point 20 of Article 3 of Regulation (EC) No 1069/2009, processed in accordance with the rules for placing on the market of processed manure, laid down in Section 2(a), (b), (d) and (e) of Chapter I of Annex XI to Commission Regulation (EU) No 142/2011;

(ii) the processed animal proteins contained in the organic fertilisers or soil improvers are in compliance with the specific requirements described in Section 1 of Chapter II of Annex X to Regulation (EU) No 142/2011;

(iii) the organic fertilisers or soil improvers may contain other category 3 materials, that have been processed in accordance to:

— any of the processing methods 1 to 7 set out in Chapter III of Annex IV to Regulation (EU) No 142/2011, or

— the requirements laid down in Section 1 Chapter III of Annex V to Regulation (EU) No 142/2011 in the case of compost or digestion residues from the transformation of animal by-products into biogas, or;

— the specific requirements set out in Annex XIII to Regulation (EU) No 142/2011, where such materials may be used for organic fertilisers and soil improvers in accordance to that Regulation.

(iv) they have been produced in establishments or plants approved in accordance with Article 24(1)(f) of Regulation (EC) No 1069/2009;

(v) are mixed with a sufficient proportion of a component, authorised by the competent authority of the Member State where the organic fertilisers or soil improvers are produced, which renders the product unpalatable to animals or is otherwise effective to prevent misuse of the mixture for feeding purposes. This component is to be mixed with the organic fertilizers or soil improvers in the plant manufacturing them or in a plant registered for this purpose in accordance with point 2 of Section 1 of Chapter II of Annex XI to Regulation (EU) No 142/2011.

If required by the competent authority of the third country of destination, the competent authority of the Member State where the organic fertilisers or soil improvers are produced may accept the use of other components or other methods to prevent the use of the organic fertilisers or soil improvers as feed, different than those authorised in this Member State, provided that these are not in contradiction with the rules laid down in point 3 of Article 22 and point 3 of Section 1 of Chapter II of Annex XI to Regulation (EU) No 142/2011;

(vi) they have been processed to ensure decontamination of pathogens in accordance with point 5 of Section 1 of Chapter II of Annex XI to Regulation (EU) No 142/2011;

- (vii) they have a label attached to the packaging or container bearing the words “organic fertilisers or soil improvers/no grazing of farmed animals or use of crops as herbage during at least 21 days following application”;
- (viii) they are exported in compliance with the following conditions:
 - they shall be transported in sealed containers, directly from the plant manufacturing the organic fertilisers or soil improvers or the registered plant where the component which renders the product unpalatable to animals is added, to the point of exit from the Union territory, which shall be a border control post listed in Annex I to Commission Decision 2009/821/EC. Before leaving the Union territory, the operator responsible for arranging the transport of the organic fertilisers or soil improvers shall inform the competent authority at that border control post of the arrival of the consignment at the point of exit;
 - the consignment shall be accompanied by a duly completed commercial document produced according to the model set out in point 6 of Chapter III of Annex VIII to Regulation (EU) No 142/2011 and issued from the integrated computerised veterinary system (TRACES) introduced by Commission Decision 2004/292/EC. On that commercial document, the border control post of exit must be indicated in Box I.28;
 - when the consignment arrives at the point of exit, the competent authority at the border control post shall, on a risk basis, verify the seal of the containers presented at the border control post. If the seal is verified and the verification is not satisfactory, the consignment must either be destroyed or must be re-dispatched to the establishment of origin, indicated in box I.12 of the commercial document;
 - the competent authority at the border control post shall inform, via TRACES, the competent authority indicated in box I.4 of the commercial document of the arrival of the consignment at the point of exit and, where applicable, of the outcome of the verification of the seal and of any corrective action taken;
 - The competent authority responsible for the manufacturing plant of origin or the registered plant where the component which renders the product unpalatable to animals is added shall carry out risk based official controls to verify compliance with the first and second indents and to verify that, for each consignment of organic fertilisers and soil improvers that contain in their composition processed animal proteins derived from ruminants or a mixture of processed animal proteins from ruminants and non-ruminants exported, the confirmation of the control carried out at the exit point was received from the competent authority of the border control post, through TRACES.

The conditions set out in points (v), (vii) and (viii) of point 2(b) shall not apply to organic fertilisers or soil improvers which are in ready-to-sell packages of not more than 50 kg in weight for use by the final consumer.’

(2) in Section E of Chapter V, the following point 5 is added:

- ‘5. The export of organic fertilisers or soil improvers that contain in their composition processed animal proteins derived only from non-ruminants and do not contain any materials of ruminant origin, shall be subject to compliance with the following conditions:
 - (a) the requirements set out in points 2(b)(i), (ii), (iii), (iv), (v), (vi) and (vii) of this section shall apply. The conditions set out in points 2(b)(v) and (vii) shall not apply to organic fertilisers or soil improvers which are in ready-to-sell packages of not more than 50 kg in weight for use by the final consumer.
 - (b) the processed animal protein derived from non-ruminants contained in them shall be produced in processing plants which fulfil the requirements point (c) of Section D of Chapter IV, and are listed in accordance with point 1(d) of Section A of Chapter V.
 - (c) they have been produced in establishments or plants that are dedicated exclusively to processing non-ruminant organic fertilisers or soil improvers.

By way of derogation from this specific condition, the competent authority may authorise the export of organic fertilisers or soil improvers referred to in this point produced in establishments or plants processing organic fertilisers or soil improvers containing ruminant material, if effective measures to prevent cross contamination between organic fertilisers or soil improvers containing only non-ruminant material and organic fertilisers or soil improvers containing ruminant material are implemented;

- (d) they are transported to the point of exit from the Union territory in new packaging material, or in bulk containers which are not used for the transport of materials of ruminant origin or that have been cleaned beforehand in order to avoid cross-contamination in accordance with a documented procedure which has been given prior authorisation by the competent authority.

The conditions set out in points (c) and (d) of point 5 shall not apply to organic fertilisers or soil improvers which are in ready-to-sell packages of not more than 50 kg in weight for use by the final consumer.'
