Official Journal
of the European Union

EN
L series

2024/887

25.3.2024

COMMISSION REGULATION (EU) 2024/887

of 22 March 2024

amending Annexes IV, VIII and IX to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards animal feeding, placing on the market and importation into the Union

(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 Article 23a, the introductory phrase and point (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) Article 7 of Regulation (EC) No 999/2001 lays down prohibitions concerning animal feeding, for which specific rules are set out in Annex IV to that Regulation. Commission Regulation (EU) 2021/1372 ([2]) amended Annex IV to Regulation (EC) No 999/2001 in order to authorise the use of processed animal protein derived from insects, poultry and porcine animals, and compound feed containing such processed animal protein for feeding porcine animals and poultry. However, it appears that (d), (e) and (f) were added by mistake in Annex IV, Chapter III, Section B, point 1, to Regulation (EC) No 999/2001. Point 1 should have remained dedicated to the conditions for the production of compound feed which contain feed materials that are allowed for the feeding of any non-ruminant farmed animal, considering that the specific conditions in the case of use of other feed materials are set out in the appropriate Sections of Chapter IV of that Annex. It also unintentionally resulted in the duplication of some listing obligations by the Member States set out in Chapter V. Various appropriate corrections of Annex IV to Regulation (EC) No 999/2001 should therefore be made in Section B of Chapter III, Section H of Chapter IV, and Section A of Chapter V of that Annex. Annex IV to Regulation (EC) No 999/2001 should therefore be corrected accordingly.

(3) In addition, Regulation (EC) No 1069/2009 of the European Parliament and of the Council ([3]), as amended by Commission Delegated Regulation (EU) 2023/1605 ([4]), introduced specific requirements for official controls in fertiliser processing plants for the purpose of the determination of the end points for certain fertilisers and soil improvers, after which these products can be put on the market without further animal health controls. This should be reflected in the conditions relating to the export of organic fertilisers and soil improvers containing ruminant processed animal protein, set out in Annex IV to Regulation (EC) No 999/2001. Chapter V, Section E, of that Annex should therefore be amended accordingly.

([1]) OJ L 147, 31.5.2001, p. 1.

([2]) Commission Regulation (EU) 2021/1372 of 17 August 2021amending Annex IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the prohibition to feed non-ruminant farmed animals, other than fur animals, with protein derived from animals (OJ L 295, 18.8.2021, p. 1.).

([3]) 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 (OJ L 300, 14.11.2009, p. 1).

([4]) Commission Delegated Regulation (EU) 2023/1605 of 22 May 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 (OJ L 198, 8.8.2023, p. 1).

(4) Furthermore, Annexes VIII and IX to Regulation (EC) No 999/2001 set out detailed requirements relating to the placing on the market and importation into the Union of, inter alia, ovine and caprine animals and products derived from these species.

(5) Regulation (EC) No 999/2001, as amended by Commission Regulation (EU) No 630/2013 ([5]), lays down transitional conditions in Annex VIII, Chapter A, Section A, points 1.2 and 1.3, to Regulation (EC) No 999/2001, that were designed to ensure a smooth transition for a period of seven years, from 1 January 2014 until 1 January 2021. It is now appropriate to delete those transitional conditions.

(6) In addition, Annex VIII to Regulation (EC) No 999/2001 refers to Council Directive 92/65/EEC ([6]) in Chapter A, Section A, points 1.2, 1.3 and 4.1., of that Regulation. As Directive 92/65/EEC has now been repealed by Regulation (EU) 2016/429 of the European Parliament and of the Council ([7]), as of 21 April 2021, those references should be updated.

(7) Annexes I, VII and VIII to Regulation (EC) No 999/2001 were amended by Commission Regulation (EU) 2020/772 ([8]) to take account of the recommendations of the Scientific Opinion of the European Food Safety Authority (EFSA) of 5 July 2017 on Genetic resistance to transmissible spongiform encephalopathies (TSE) in goats ([9]), in order to recognise that goats can also be genetically resistant to classical scrapie strains known to occur naturally in the Union's goat population, when they have the K222, D146 or S146 alleles. However, the amendments made to Regulation (EC) No 999/2001 by Regulation (EU) 2020/772 did not fully align the conditions applicable to genetically resistant goats with the ones applicable to genetically resistant sheep, particularly as regards the provisions for a holding to be recognised as having a negligible risk or a controlled risk of classical scrapie and the requirements for intra-Union trade of caprine semen and embryos set out in Annex VIII to Regulation (EC) No 999/2001, and the requirements for importation into the Union of milk and milk products of caprine animals, caprine animals intended for breeding, as well as of caprine semen and embryos set out in Annex IX to that Regulation. It appears appropriate to finalise this alignment to promote the best possible use of genetically resistant animals and their germinal products to control classical scrapie.

(8) Annexes IV, VIII and IX to Regulation (EC) No 999/2001 should therefore be amended and corrected accordingly.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EC) No 999/2001

Annexes IV, VIII and IX to Regulation (EC) No 999/2001 are amended in accordance with Part A of the Annex to this Regulation.

([5]) Commission Regulation (EU) No 630/2013 of 28 June 2013 amending the Annexes to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 179, 29.6.2013, p. 60).

([6]) Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC (OJ L 268, 14.9.1992, p. 54).

([7]) Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (OJ L 84, 31.3.2016, p. 1).

([8]) Commission Regulation (EU) 2020/772 of 11 June 2020 amending Annexes I, VII and VIII to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards eradication measures for transmissible spongiform encephalopathies in goats and endangered breeds (OJ L 184, 12.6.2020, p. 43).

([9]) *EFSA Journal* 2017;15(8):4962.

Article 2

Corrections to Regulation (EC) No 999/2001

Annex IV to Regulation (EC) No 999/2001 is corrected in accordance with Part B of the Annex to this Regulation.

Article 3

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, 22 March 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

PART A

AMENDMENTS TO REGULATION (EC) NO 999/2001

Annexes IV, VIII and IX to Regulation (EC) No 999/2001 are amended as follows:

(1) in Annex IV, in Chapter V, Section E is amended as follows:

(a) in point 2(b), the introductory phrase is replaced by the following:

'(b) organic fertilisers or soil improvers, as defined in Article 3, point 22, 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 either they have reached the end point as defined in Article 4, point 1(c) or in Article 4, point 2, of Commission Delegated Regulation (EU) 2023/1605 (*), or:

_____

(*) Commission Delegated Regulation (EU) 2023/1605 of 22 May 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 (OJ L 198, 8.8.2023, p. 1).';

(b) in point 5, the following paragraph is added:

'The organic fertilisers or soil improvers that have reached the end point as defined in Article 4, point 1(c) or in Article 4, point 2, of Delegated Regulation (EU) 2023/1605 shall be exempted from the conditions set out in the first paragraph of this point.';

(2) in Annex VIII, in Chapter A, Section A is amended as follows:

(a) points 1.2 and 1.3 are replaced by the following:

'1.2. A holding of ovine animals having the TSE-resistance level I status, as laid down in Annex VII, Chapter C, Part 4, point 1(a), and where no case of classical scrapie has been confirmed for a period of at least the preceding seven years, may be recognised as having a negligible risk of classical scrapie.

A holding of ovine animals, caprine animals, or ovine and caprine animals may also be recognised as having a negligible risk of classical scrapie provided that it has complied with the following conditions for a period of at least the preceding seven years:

(a) ovine and caprine animals are permanently identified and records are maintained, to enable them to be traced back to their holding of birth;

(b) records of movements of ovine and caprine animals in and out of the holding are maintained;

(c) only the following ovine and caprine animals are introduced into the holding:

(i) ovine and caprine animals from holdings with a negligible risk of classical scrapie;

(ii) ovine and caprine animals from holdings which have met the conditions set out in points (a) to (i) for a minimum period of the preceding seven years or for at least the same period of time as the period of time during which the holding, where they are to be introduced, has met the conditions set out in those points;

(iii) ovine animals of the ARR/ARR prion protein genotype and caprine animals carrying at least one of the K222, D146 or S146 alleles;

(iv) ovine or caprine animals that comply with the conditions set out in point (i) or (ii) except during the period when they were kept at a semen collection centre, provided that the semen collection centre complies with the following conditions:

— the semen collection centre is approved in accordance with Part II, Chapter 1, of Commission Delegated Regulation (EU) 2020/686 (*),

— for a period of the preceding seven years, only those ovine or caprine animals from holdings which have fulfilled during that period the conditions set out in points (a), (b) and (e), and which were subject to regular checks by an official veterinarian or a veterinarian authorised by the competent authority, were introduced into the semen collection centre,

— no case of classical scrapie has been confirmed at the semen collection centre for a period of the preceding seven years,

— biosecurity measures are in place at the semen collection centre to ensure that ovine and caprine animals kept at that centre and coming from holdings with a negligible or a controlled risk status for classical scrapie have no direct or indirect contact with ovine and caprine animals coming from holdings of a lower classical scrapie status;

(d) the holding is subject to regular checks to verify compliance with the conditions set out in points (a) to (i) by an official veterinarian or a veterinarian authorised for that purpose by the competent authority, to be conducted at least on an annual basis;

(e) no case of classical scrapie has been confirmed;

(f) all ovine and caprine animals over 18 months of age that have died or have been killed for reasons other than slaughter for human consumption are tested in a laboratory for classical scrapie in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, point 3.2.

By way of derogation from that specific condition, Member States may decide that all ovine and caprine animals over 18 months of age with no commercial value, culled at the end of their productive life instead of being slaughtered for human consumption, are inspected by an official veterinarian, and all those exhibiting wasting signs or neurological signs are tested in a laboratory for classical scrapie in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, point 3.2;

(g) only the following ova and embryos of animals of the ovine and caprine species are introduced into the holding:

(i) ova and embryos from donor animals which have been kept since birth in a Member State with a negligible risk of classical scrapie, or in a holding with a negligible or a controlled risk of classical scrapie, or which comply with the following requirements:

— they are permanently identified to enable them to be traced back to their holding of birth,

— they have been kept since birth in holdings in which no case of classical scrapie has been confirmed during their residency,

— they showed no clinical sign of classical scrapie at the time of collection of the ova or embryos;

(ii) ova and embryos of animals of the ovine species carrying at least one ARR allele and of animals of the caprine species carrying at least one of the K222, D146 or S146 alleles;

(h) only the following semen of animals of the ovine and caprine species are introduced into the holding:

(i) semen from donor animals which have been kept since birth in a Member State with a negligible risk of classical scrapie, or in a holding with a negligible risk or a controlled risk of classical scrapie, or which comply with the following requirements:

— they are permanently identified to enable them to be traced back to their holding of birth,

— they showed no clinical sign of classical scrapie at the time of semen collection;

(ii) semen from rams of the ARR/ARR prion protein genotype and from bucks carrying at least one of the K222, D146 or S146 alleles;

(i) ovine and caprine animals on the holding have no direct or indirect contact, including shared grazing, with ovine and caprine animals from holdings of a lower classical scrapie status.

1.3. A holding of ovine animals, caprine animals or ovine and caprine animals may be recognised as having a controlled risk of classical scrapie provided that it has complied with the following conditions for a period of at least the preceding three years:

(a) ovine and caprine animals are permanently identified and records are maintained, to enable them to be traced back to their holding of birth;

(b) records of movements of ovine and caprine animals in and out of the holding are maintained;

(c) only the following ovine and caprine animals are introduced into the holding:

(i) ovine and caprine animals from holdings with a negligible or a controlled risk of classical scrapie;

(ii) ovine and caprine animals from holdings which have met the conditions set out in points (a) to (i) for a minimum period of the preceding three years or for at least the same period of time as the period of time during which the holding, where they are to be introduced, has met the conditions set out in those points;

(iii) ovine animals of the ARR/ARR prion protein genotype and caprine animals carrying at least one of the K222, D146 or S146 alleles;

(iv) ovine or caprine animals that comply with the conditions set out in point (i) or (ii) except during the period when they were kept at a semen collection centre, provided that the semen collection centre complies with the following conditions:

— the semen collection centre is approved in accordance with Part II, Chapter 1, of Delegated Regulation (EU) 2020/686,

— for a period of the preceding three years, only those ovine or caprine animals from holdings which have fulfilled during that period the conditions set out in points (a), (b) and (e), and which were subject to regular checks by an official veterinarian or a veterinarian authorised by the competent authority, were introduced into the semen collection centre,

— no case of classical scrapie has been confirmed at the semen collection centre during the period of the preceding three years,

— biosecurity measures are in place at the semen collection centre to ensure that ovine and caprine animals kept at that centre and coming from holdings with a negligible or a controlled risk status for classical scrapie have no direct or indirect contact with ovine and caprine animals coming from holdings of a lower classical scrapie status;

(d) the holding is subject to regular checks to verify compliance with the conditions set out in points (a) to (i) by an official veterinarian or a veterinarian authorised for that purpose by the competent authority, to be conducted at least on an annual basis;

(e) no case of classical scrapie has been confirmed;

(f) all ovine and caprine animals over 18 months of age that have died or have been killed for reasons other than slaughter for human consumption are tested in a laboratory for classical scrapie in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, point 3.2.

By way of derogation from that specific condition, Member States may decide that all the ovine and caprine animals over 18 months of age with no commercial value culled at the end of their productive life instead of being slaughtered for human consumption, are inspected by an official veterinarian, and all those exhibiting wasting signs or neurological signs are tested in a laboratory for classical scrapie in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, point 3.2;

(g) only the following ova and embryos of animals of the ovine and caprine species are introduced into the holding:

(i) ova and embryos from donor animals which have been kept since birth in a Member State with a negligible risk of classical scrapie, or in a holding with a negligible or a controlled risk of classical scrapie, or which comply with the following requirements:

— they are permanently identified to enable them to be traced back to their holding of birth,

— they have been kept since birth in holdings in which no case of classical scrapie has been confirmed during their residency,

— they showed no clinical sign of classical scrapie at the time of collection of the ova or embryos,

(ii) ova and embryos of animals of the ovine species carrying at least one ARR allele and of animals of the caprine species carrying at least one of the K222, D146 or S146 alleles;

(h) only the following semen of animals of the ovine and caprine species are introduced into the holding:

(i) semen from donor animals which have been kept since birth in a Member State with a negligible risk of classical scrapie, or in a holding with a negligible risk or with a controlled risk of classical scrapie, or which comply with the following requirements:

— they are permanently identified to enable them to be traced back to their holding of birth,

— they showed no clinical sign of classical scrapie at the time of semen collection;

(ii) semen from rams of the ARR/ARR prion protein genotype and from bucks carrying at least one of the K222, D146 or S146 alleles;

(i) ovine and caprine animals of the holding have no direct or indirect contact, including shared grazing, with ovine and caprine animals from holdings of a lower classical scrapie status.

_____

(*) Commission Delegated Regulation (EU) 2020/686 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the approval of germinal product establishments and the traceability and animal health requirements for movements within the Union of germinal products of certain kept terrestrial animals (OJ L 174 3.6.2020, p. 1).';

(b) in point 4.1, (c) is replaced by the following:

'(c) By way of derogation from points (a) and (b), the requirements set out in those points shall not apply to ovine and caprine animals which are kept in and moved exclusively between confined establishments as defined in Article 4, point (48), of Regulation (EU) 2016/429 (*).

_____

(*) Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health (Animal Health Law) (OJ L 84 31.3.2016, p. 1).';

(c) in point 4.2, (d) and (e) are replaced by the following:

'(d) in the case of semen of animals of the ovine species, be collected from male animals of the ARR/ARR prion protein genotype and in the case of semen of animals of the caprine species, be collected from male animals carrying at least one of the K222, D146 or S146 alleles; or

(e) in the case of embryos of animals of the ovine species, be carrying at least one ARR allele, in the case of embryos of animals of the caprine species, be carrying at least one of the K222, D146 or S146 alleles.';

(3) Annex IX is amended as follows:

(a) in Chapter D, in Section B, in point 3, (c) is replaced by the following:

'(c) the milk and milk products of ovine or caprine animals originate from holdings where no case of classical scrapie has been diagnosed during a period of at least the preceding seven years or, following the confirmation of a case of classical scrapie:

(i) all ovine and caprine animals on the holding have been killed and destroyed or slaughtered, except for breeding rams of the ARR/ARR genotype, breeding ewes carrying at least one ARR allele and no VRQ allele, other ovine animals carrying at least one ARR allele and caprine animals carrying at least one of the K222, D146 or S146 alleles;

or

(ii) all animals in which classical scrapie was confirmed have been killed and destroyed, and the holding has been subjected for a period of at least two years since the date of confirmation of the last classical scrapie case to intensified TSE monitoring, including testing with negative results for the presence of TSE in accordance with the laboratory methods set out in Annex X, Chapter C, point 3.2, of all of the following animals which are over the age of 18 months, except ovine animals of the ARR/ARR genotype and caprine animals carrying at least one of the K222, D146 or S146 alleles:

— animals which have been slaughtered for human consumption; and

— animals which have died or been killed on the holding but which were not killed in the framework of a disease eradication campaign.';

(b) Chapter E is amended as follows:

(i) in point (5), (b) is replaced by the following:

'(b) they are ovine animals of the ARR/ARR prion protein genotype or caprine animals carrying at least one of the K222, D146 or S146 alleles, and they come from a holding or holdings where no official movement restriction has been imposed due to BSE or classical scrapie during the last 2 years; or';

(ii) in point (6), (b) is replaced by the following:

'(b) they are ovine animals of the ARR/ARR prion protein genotype or caprine animals carrying at least one of the K222, D146 or S146 alleles, and they come from a holding where no official movement restriction has been imposed due to BSE or classical scrapie during the last two years.';

(c) in Chapter H, in point (2), (a) and (b) are replaced by the following:

'(a) in the case of semen of animals of the ovine species, the semen has been collected from male animals of the ARR/ARR prion protein genotype and in the case of semen of animals of the caprine species, the semen has been collected from male animals carrying at least one of the K222, D146 or S146 alleles; or

(b) in the case of embryos of animals of the ovine species, the embryos carry at least one ARR allele and in the case of embryos of animals of the caprine species, the embryos carry at least one of the K222, D146 or S146 alleles.'.

PART B

CORRECTIONS TO REGULATION (EC) NO 999/2001

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

(1) in Chapter III, Section B is amended as follows:

(a) in point 1, (d), (e) and (f) are deleted;

(b) in point 3, (b) is replaced by the following:

'(b) they must keep only non-ruminant animals;';

(2) in Chapter IV, in Section H, the last indent of point (d) is replaced by the following:

'— regular sampling and analysis of the compound feed destined for farmed animals other than porcine animals, aquaculture and fur animals in order to verify the absence of unauthorised constituents of animal origin using the methods of analysis for the determination of constituents of animal origin for the control of feed set out in Annex VI to Regulation (EC) No 152/2009; the frequency of such sampling and analysis shall be determined on the basis of a risk assessment carried out by the operator as part of its procedures based on the HACCP principles; the results must be kept available to the competent authority for a period of at least five years;';

(3) in Chapter V, in Section A, in point 1, (i) is replaced by the following:

'(i) authorised compound feed establishments producing, in accordance with Chapter III, Section B, compound feed containing fishmeal, dicalcium and tricalcium phosphate of animal origin and blood products derived from non-ruminants;'.