REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2017/731

of 25 April 2017

amending model veterinary certificates BOV-X, BOV-Y, BOV and OVI set out in Annexes I and II to Regulation (EU) No 206/2010, the model certificates GEL, COL, RCG and TCG set out in Annex II to Implementing Regulation (EU) 2016/759 and the model certificate for composite products set out in Annex I to Regulation (EU) No 28/2012 in relation to the rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption ([1]), and in particular Article 9(2)(b) and 9(4)(b) thereof,

Having regard to Council Directive 2004/68/EC of 26 April 2004 laying down animal health rules for the importation into and transit through the Community of certain live ungulate animals, amending Directives 90/426/EEC and 92/65/EEC and repealing Directive 72/462/EEC ([2]), and in particular Article 13(1)(e) thereof,

Having regard to Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption ([3]), and in particular the second paragraph of Article 16 thereof,

Whereas:

(1) Commission Regulation (EU) No 206/2010 ([4]) lays down, inter alia, the veterinary certification requirements for the introduction into the Union of certain consignments of live animals including domestic bovine animals and consignments of fresh meat intended for human consumption, including fresh meat of domestic bovine, ovine and caprine animals.

(2) Part 2 of Annex I to Regulation (EU) No 206/2010 sets out a model of veterinary certificate for domestic bovine animals (including *Bubalus* and *Bison* species and their cross-breeds) intended for breeding and/or production after importation (BOV-X) and a model of veterinary certificate for domestic bovine animals (including *Bubalus* and *Bison* species and their cross-breeds) intended for immediate slaughter after importation (BOV-Y). Part 2 of Annex II to that Regulation sets out a model of veterinary certificate for fresh meat, including minced meat, of domestic bovine animals (including *Bubalus* and *Bison* species and their cross-breeds) (BOV) and a model of veterinary certificate for fresh meat, including minced meat, of domestic ovine animals (*Ovis aries*) and domestic caprine animals (*Capra hircus*) (OVI). Those models of veterinary certificates include guarantees for bovine spongiform encephalopathy (BSE).

(3) Commission Implementing Regulation (EU) 2016/759 ([5]) lays down, inter alia, the veterinary certification requirements for the introduction into the Union of certain products of animal origin intended for human consumption.

([1]) OJ L 18, 23.1.2003, p. 11.
([2]) OJ L 139, 30.4.2004, p. 320.
([3]) OJ L 139, 30.4.2004, p. 206.
([4]) Commission Regulation (EU) No 206/2010 of 12 March 2010 laying down lists of third countries, territories or parts thereof authorised for the introduction into the European Union of certain animals and fresh meat and the veterinary certification requirements (OJ L 73, 20.3.2010, p. 1).
([5]) Commission Implementing Regulation (EU) 2016/759 of 28 April 2016 drawing up lists of third countries, parts of third countries and territories from which Member States are to authorise the introduction into the Union of certain products of animal origin intended for human consumption, laying down certificate requirements, amending Regulation (EC) No 2074/2005 and repealing Decision 2003/812/EC (OJ L 126, 14.5.2016, p. 13).

(4) Annex II to Implementing Regulation (EU) 2016/759 sets out a model certificate for imports of gelatine intended for human consumption (GEL) in Part III thereof, a model certificate for imports of collagen intended for human consumption (COL) in Part IV thereof, a model for imports of the raw materials for the production of gelatine and collagen intended for human consumption (RCG) in Part V thereof, and a model certificate for imports of the treated raw materials for the production of gelatine and collagen intended for human consumption (TCG) in Part VI. Those models of veterinary certificates include guarantees for BSE for products of bovine, ovine and caprine origin.

(5) Commission Regulation (EU) No 28/2012 ([1]) lays down, inter alia, the health certification requirements for imports into or transit through the Union of consignments of certain composite products intended for human consumption.

(6) Annex I to Regulation (EU) No 28/2012 sets out the model of health certificate for imports into the European Union of composite products intended for human consumption. That model of health certificate includes guarantees for BSE for products of bovine, ovine and caprine origin.

(7) Regulation (EC) No 999/2001 of the European Parliament and of the Council ([2]) lays down rules for the prevention, control and eradication of transmissible spongiform encephalopathies (TSEs) in bovine, ovine and caprine animals. Chapter B of Annex IX to Regulation (EC) No 999/2001 lays down the conditions for import into the Union of bovine animals as regards BSE and Chapter C of that Annex lays down the conditions for import into the Union of products of animal origin for human consumption from bovine, ovine and caprine animals as regards BSE.

(8) Regulation (EC) No 999/2001 was amended by Commission Regulation (EU) 2016/1396 ([3]). Those amendments provide, inter alia, for clarification of the rules laid down in Chapter B and Chapter C of Annex IX to Regulation (EC) No 999/2001. They also provide for the amendment of the requirement to indicate a blue stripe on the label of the carcasses or wholesale cuts of the carcasses of bovine animals when removal of the vertebral column is not required as set out in Chapter C of Annex IX to that Regulation. This amendment requires that a red stripe should be indicated instead on the label when such removal is required for products of bovine animal origin imported into the Union.

(9) In particular Regulation (EC) No 999/2001, as amended by Regulation (EU) 2016/1396, permits the imports of products of animal origin for human consumption of bovine, ovine and caprine animal origin from third countries with a negligible BSE risk as laid down in Section B of Chapter C of Annex IX, also where those products are derived from raw material coming from countries with a controlled or an undetermined BSE risk, provided that specified risk material has been removed from such raw material.

(10) The model veterinary certificates BOV-X and BOV-Y set out in Part 2 of Annex I and BOV and OVI set out in Part 2 of Annex II to Regulation (EU) No 206/2010, the model veterinary certificates GEL, COL, RCG and TCG set out in Annex II to Implementing Regulation (EU) 2016/759 and the model health certificate for import into the Union of composite products set out in Annex I to Regulation (EU) No 28/2012 should therefore be amended in order to reflect the requirements relating to imports of bovine animals and of fresh meat of bovine, ovine and caprine animals and of products of animal origin for human consumption of bovine, ovine and caprine animal origin, laid down in Regulation (EC) No 999/2001, as amended by Regulation (EU) 2016/1396.

(11) Regulation (EU) No 206/2010, Implementing Regulation (EU) 2016/759 and Regulation (EU) No 28/2012 should therefore be amended accordingly.

(12) Regulation (EU) 2016/1396 provides that the amendments that it made to Annex IX to Regulation (EC) No 999/2001 are to apply from 1 July 2017.

([1]) Commission Regulation (EU) No 28/2012 of 11 January 2012 laying down requirements for the certification for imports into and transit through the Union of certain composite products and amending Decision 2007/275/EC and Regulation (EC) No 1162/2009 (OJ L 12, 14.1.2012, p. 1).

([2]) 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).

([3]) Commission Regulation (EU) 2016/1396 of 18 August 2016 amending certain 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 225, 19.8.2016, p. 76).

(13) In order to avoid any disruption of imports into the Union of consignments of live bovine, ovine and caprine animals, of fresh meat of domestic bovine, ovine and caprine animals, of gelatine, collagen, raw materials for production of gelatine and collagen and treated raw materials for the production of gelatine and collagen intended for human consumption and of certain composite products intended for human consumption, the use of certificates issued in accordance with Regulation (EU) No 206/2010, Implementing Regulation (EU) 2016/759 and Regulation (EU) No 28/2012 as applicable prior to the amendments being introduced by this Regulation should continue to be authorised during a transitional period subject to certain conditions.

(14) 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

Annexes I and II to Regulation (EU) No 206/2010 are amended in accordance with Annex I to this Regulation.

Article 2

Annex II to Implementing Regulation (EU) 2016/759 is amended in accordance with Annex II to this Regulation.

Article 3

Annex I to Regulation (EU) No 28/2012 is amended in accordance with Annex III to this Regulation.

Article 4

1. For a transitional period until 31 December 2017, consignments of live bovine, ovine and caprine animals, accompanied by a model certificate issued in accordance with the model set out in Part 2 of Annex I to Regulation (EU) No 206/2010 and consignments of fresh meat of domestic bovine, ovine and caprine animals, accompanied by a model certificate issued in accordance with the model set out in Part 2 of Annex II to Regulation (EU) No 206/2010, as applicable before the amendments made by this Regulation, shall continue to be authorised for importation into the Union provided that the certificate was issued no later than 30 November 2017.

2. For a transitional period until 31 December 2017, consignments of gelatine intended for human consumption, collagen intended for human consumption, raw materials for production of gelatine and collagen intended for human consumption and treated raw materials for the production of gelatine and collagen intended for human consumption, accompanied by a model certificate issued in accordance with the model set out respectively in Parts III, IV, V and VI of Annex II to Implementing Regulation (EU) 2016/759, as applicable before the amendments made by this Regulation, shall continue to be authorised for importation into the Union provided that the certificate was issued no later than 30 November 2017.

3. For a transitional period until 31 December 2017, consignments of certain composite products intended for human consumption, accompanied by a model certificate issued in accordance with the model set out in Annex I to Regulation (EU) No 28/2012, as applicable before the amendments made by this Regulation, shall continue to be authorised for importation into the Union provided that the certificate was issued no later than 30 November 2017.

Article 5

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

It shall apply from 1 July 2017.

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

Done at Brussels, 25 April 2017.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

Annexes I and II to Regulation (EU) No 206/2010 are amended as follows:

(1) In Annex I, Part 2 is amended as follows:

(a) The model veterinary certificate BOV-X is amended as follows:

(i) In Part II.1, Public Health Attestation, point II.1.3 is replaced by the following:

'II.1.3. with regard to bovine spongiform encephalopathy (BSE):

(a) the animals are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin, and they have not been exposed to the following animals:

(i) any BSE cases;

(ii) bovine animals which, during their first year of life, were reared with the BSE cases during their first year of life, and which investigation has shown consumed the same potentially contaminated feed during that period; or

(iii) if the results of the investigation referred to in indent (ii) are inconclusive, bovine animals born in the same herd as, and within 12 months of the birth of, the BSE cases;

([1]) ([2]) *either* [(b) if there have been BSE indigenous cases in the country concerned, the animals were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants, as defined in the Terrestrial Animal Health Code of the World Organisation for Animal Health, was effectively enforced or after the date of birth of the last BSE indigenous case if born after the date of the feed ban.]

([1]) ([3]) *or* [(b) the animals were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants as defined in the Terrestrial Animal Health Code of the World Organisation for Animal Health, was effectively enforced or after the date of birth of the last BSE indigenous case if born after the date of the feed ban.]

([1]) ([4]) *or* [(b) the animals were born at least two years after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants, as defined in the Terrestrial Animal Health Code of the World Organisation for Animal Health, was effectively enforced or after the date of birth of the last BSE indigenous case if born after the date of the feed ban.]'

(ii) In Part II of the Notes, the footnotes (2), (3) and (4) are replaced by the following:

'([2]) Only if the animals were born and continuously reared in a country or region or countries or regions classified in accordance with Decision 2007/453/EC as countries or regions posing a negligible BSE risk.

([3]) Only if the country or region of origin is classified in accordance with Decision 2007/453/EC as a country or region posing a controlled BSE risk.

([4]) Only if the country or region of origin has been classified in accordance with Decision 2007/453/EC as a country or region posing an undetermined BSE risk.'

(b) The model veterinary certificate BOV-Y is amended as follows:

(i) In Part II.1, Public Health Attestation, point II.1.3 is replaced by the following:

'II.1.3. with regard to bovine spongiform encephalopathy (BSE):

(a) the animals are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin, and have not been exposed to the following animals:

(i) any BSE cases;

(ii) bovine animals which, during their first year of life, were reared with the BSE cases during their first year of life, and which investigation has shown consumed the same potentially contaminated feed during that period; or

(iii) if the results of the investigation referred to in indent (ii) are inconclusive, bovine animals born in the same herd as, and within 12 months of the birth of, the BSE cases;

([1]) ([2]) *either* [(b) if there have been BSE indigenous cases in the country concerned, the animals were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants, as defined in the Terrestrial Animal Health Code of the World Organisation for Animal Health, was effectively enforced or after the date of birth of the last BSE indigenous case if born after the date of the feed ban.]

([1]) ([3]) *or* [(b) the animals were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants as defined in the Terrestrial Animal Health Code of the World Organisation for Animal Health, was effectively enforced or after the date of birth of the last BSE indigenous case if born after the date of the feed ban.]

([1]) ([4]) *or* [(b) the animals were born at least two years after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants, as defined in the Terrestrial Animal Health Code of the World Organisation for Animal Health, was effectively enforced or after the date of birth of the last BSE indigenous case if born after the date of the feed ban.]'

(ii) In Part II of the Notes, footnotes (2), (3) and (4) are replaced by the following:

'([2]) Only if the animals were born and continuously reared in a country or region or countries or regions classified in accordance with Decision 2007/453/EC as countries or regions posing a negligible BSE risk.

([3]) Only if the country or region of origin is classified in accordance with Decision 2007/453/EC as a country or region posing a controlled BSE risk.

([4]) Only if the country or region of origin has been classified in accordance with Decision 2007/453/EC as a country or region posing an undetermined BSE risk.'

(2) Annex II, Part 2 is amended as follows:

(a) The model veterinary certificate BOV is amended as follows:

(i) In Part II.1, Public Health Attestation, point II.1.9 is replaced by the following:

'([1]) *either* [II.1.9. with regard to bovine spongiform encephalopathy (BSE):

(a) the country or region of dispatch is classified in accordance with Decision 2007/453/EC as a country or region posing a negligible BSE risk;

([1]) *either* [(b) the animals, from which the meat or minced meat was derived:

(i) were born, continuously reared and slaughtered in a country or region classified in accordance with Decision 2007/453/EC as a country or region posing a negligible BSE risk;

(ii) were slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity;]

([1]) *or* [(b) the animals, from which the meat or minced meat was derived, were not slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity;]

([1]) *either* [(c) the meat or minced meat does not contain and is not derived from specified risk material as defined in point 1 of Annex V to Regulation (EC) No 999/2001 (*);]

(1) *or* [(c) (i) the meat or minced meat is derived from animals which originate from a country or region classified in accordance with Decision 2007/453/EC as a country or region posing a controlled or an undetermined BSE risk;

(ii) the carcasses, half carcasses or half carcasses cut into no more than three wholesale cuts, and quarters contain no specified risk material other than the vertebral column, including dorsal root ganglia;

(iii) the carcasses or wholesale cuts of carcasses of animals aged over 30 months and containing vertebral column are identified by a clearly visible red stripe on the label referred to in Article 13 or 15 of Regulation (EC) No 1760/2000 (3);]

(1) *either* [(d) the meat or minced meat is derived from mechanically separated meat, obtained from bones of bovine animals which were born, continuously reared and slaughtered in a country or region classified in accordance with Decision 2007/453/EC as a country or region posing a negligible BSE risk and in which there have been no BSE indigenous cases;]

(1) *or* [(d) the meat or minced meat is not derived from mechanically separated meat, obtained from bones of bovine animals;]

(1) [(e) (i) the animals, from which the meat or minced meat is derived, originate from a country or region classified in accordance with Decision 2007/453/EC as a country or region posing an undetermined BSE risk;

(ii) the animals, from which the meat or minced meat is derived, have not been fed with meat-and-bone meal or greaves, as defined in the Terrestrial Animal Health Code of the World Organisation for Animal Health;

(iii) the meat or minced meat was produced and handled in a manner which ensures that it did not contain and was not contaminated with nervous and lymphatic tissues exposed during the deboning process.]]

(1) *or* [II.1.9. with regard to bovine spongiform encephalopathy (BSE):

(a) the country or region of dispatch is classified in accordance with Decision 2007/453/EC as a country or region posing a controlled BSE risk;

(b) the animals from which the bovine meat or minced meat is derived were not been killed after stunning by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injected into the cranial cavity;

(1) *either* [(c) the meat or minced meat does not contain and is not derived from specified risk material as defined in point 1 of Annex V to Regulation (EC) No 999/2001, or mechanically separated meat obtained from bones of bovine animals.]

(1) *or* [(c) the carcasses, half carcasses or half carcasses cut into no more than three wholesale cuts, and quarters contain no specified risk material other than the vertebral column, including dorsal root ganglia. The carcasses or wholesale cuts of carcasses of animals aged over 30 months and containing vertebral column are identified by a clearly visible red stripe on the label referred to in Article 13 or 15 of Regulation (EC) No 1760/2000 (3).]]

(1) *or* [II.1.9. with regard to bovine spongiform encephalopathy (BSE):

(a) the country or region of dispatch has not been classified in accordance with Decision 2007/453/EC or is classified as a country or region with an undetermined BSE risk;

(b) the animals from which the meat or minced meat is derived were not fed meat-and-bone meal or greaves derived from ruminants, as defined in the Terrestrial Animal Health Code of the World Organisation for Animal Health;

(c) the animals from which the meat or minced meat is derived were not killed, after stunning, by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injected into the cranial cavity;

([1]) *either* [(d) the meat or minced meat does not contain and is not derived from:

(i) specified risk material as defined in point 1 of Annex V to Regulation (EC) No 999/2001;

(ii) nervous and lymphatic tissues exposed during the deboning process;

(iii) mechanically separated meat obtained from bones of bovine animals.]

([1]) *or* [(d) the carcasses, half carcasses or half carcasses cut into no more than three wholesale cuts, and quarters contain no specified risk material other than the vertebral column, including dorsal root ganglia. The carcasses or wholesale cuts of carcasses of animals aged over 30 months and containing vertebral column are identified by a clearly visible red stripe on the label referred to in Article 13 or 15 of Regulation (EC) No 1760/2000 ([3]).]]'

(ii) In Part II of the Notes, footnote (3) is replaced by the following:

'([3]) The number of bovine carcasses or wholesale cuts of carcasses, from which removal of the vertebral column is required shall be added to the Common Veterinary Entry Document (CVED) referred to in Article 2(1) of Regulation (EC) No 136/2004.'

(iii) In Part II of the Notes, the following footnote (*) is added:

'(*) The removal of specified risk material is not required if the meat or minced meat derives from animals born, continuously reared and slaughtered in a third country or region of a third country classified in accordance with Decision 2007/453/EC as posing a negligible BSE risk.'

(b) The model veterinary certificate OVI is amended as follows:

(i) In Part II.1, Public Health Attestation, point II.1.9 is replaced by the following:

'([1]) *either* [II.1.9. with regard to bovine spongiform encephalopathy (BSE):

(a) the country or region of dispatch is classified in accordance with Decision 2007/453/EC as a country or region posing a negligible BSE risk;

([1]) *either* [(b) the animals, from which the meat or minced meat is derived, were not slaughtered after stunning, by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity;]

([1]) *or* [(b) the animals, from which the meat or minced meat is derived:

(i) were born, continuously reared and slaughtered in a country or region classified in accordance with Decision 2007/453/EC as a country or region posing a negligible BSE risk;

(ii) were slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity;]

(c) the meat or minced meat does not contain and is not derived from specified risk material as defined in point 1 of Annex V to Regulation (EC) No 999/2001 (*);

([1]) *either* [(d) the meat or minced meat is not derived from mechanically separated meat, obtained from bones of ovine or caprine animals;]

([1]) *or* [(d) the meat or minced meat is derived from mechanically separated meat obtained from bones of ovine or caprine animals which were born, continuously reared and slaughtered in a country or region classified in accordance with Decision 2007/453/EC as a country or region posing a negligible BSE risk and in which there have been no BSE indigenous cases;]

([1]) [(e) (i) the animals, from which the meat or minced meat is derived, originate from a country or region classified in accordance with Decision 2007/453/EC as a country or region posing an undetermined BSE risk;

(ii) the animals, from which the meat or minced meat is derived, have not been fed with meat-and-bone meal or greaves, as defined in the Terrestrial Animal Health Code of the World Organisation for Animal Health;

(iii) the meat or minced meat was produced and handled in a manner which ensures that it did not contain and was not contaminated with nervous and lymphatic tissues exposed during the deboning process.]]

([1]) *or* [II.1.9. with regard to bovine spongiform encephalopathy (BSE):

(a) the country or region is classified in accordance with Decision 2007/453/EC as a country or region posing a controlled BSE risk;

(b) the animals from which the meat or minced meat is derived were not killed after stunning by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injected into the cranial cavity;

(c) the meat or minced meat does not contain and is not derived from specified risk material as defined in point 1 of Annex V to Regulation (EC) No 999/2001, or mechanically separated meat obtained from bones of ovine or caprine animals.]

([1]) *or* [II.1.9. with regard to bovine spongiform encephalopathy (BSE):

(a) the country or region has not been classified in accordance with Decision 2007/453/EC or is classified as a country or region with an undetermined BSE risk;

(b) the animals from which the meat or minced meat is derived were not fed meat-and-bone meal or greaves derived from ruminants, as defined in the Terrestrial Animal Health Code of the World Organisation for Animal Health;

(c) the animals from which the meat or minced meat is derived were not killed after stunning by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injected into the cranial cavity;

(d) the meat or minced meat does not contain and is not derived from:

(i) specified risk material as defined in point 1 of Annex V to Regulation (EC) No 999/2001;

(ii) nervous and lymphatic tissues exposed during the deboning process;

(iii) mechanically separated meat obtained from bones of ovine or caprine animals.]'

(ii) In Part II of the Notes, the following footnote (*) is added:

'(*) The removal of specified risk material is not required if the meat or minced meat derives from animals born, continuously reared and slaughtered in a third country or region of a third country classified in accordance with Decision 2007/453/EC as posing a negligible BSE risk.'

ANNEX II

Annex II to Implementing Regulation (EU) 2016/759 is amended as follows:

(1) In Part III, the model certificate for imports of gelatine intended for human consumption, Model GEL, is amended as follows:

(a) Part II.1, Public Health Attestation, is replaced by the following:

'I, the undersigned, declare that I am aware of the relevant provisions of 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), Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1) and Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55) and certify that the gelatine described above was produced in accordance with those requirements, in particular that:

— it comes from (an) establishment(s) implementing a programme based on the Hazard analysis and critical control points (HACCP) principles in accordance with Article 5 of Regulation (EC) No 852/2004,

— it has been produced from raw materials that met the requirements of Chapters I and II of Section XIV of Annex III to Regulation (EC) No 853/2004,

— it has been manufactured in compliance with the conditions set out in Chapter III of Section XIV of Annex III to Regulation (EC) No 853/2004,

— it satisfies the criteria of Chapter IV of Section XIV of Annex III to Regulation (EC) No 853/2004 and of Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1);

and, if of bovine, ovine and caprine animal origin,

it has been derived from animals which have passed *ante mortem* and *post mortem* inspections,

([1]) and, except for gelatine derived from hides and skins,

([1]) *either* — [it comes from a country or a region classified in accordance with Commission Decision 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk (OJ L 172, 30.6.2007, p. 84) as a country or region posing a negligible BSE risk,

— the gelatine does not contain and is not derived from specified risk material as defined in point 1 of Annex V 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 (OJ L 147, 31.5.2001, p. 1) ([2]),

— the gelatine does not contain and is not derived from mechanically separated meat obtained from bones of bovine, ovine or caprine animals, except for gelatine derived from animals that were born, continuously reared and slaughtered in a country or region classified in accordance with Decision 2007/453/EC as a country or region posing a negligible BSE risk in which there have been no BSE indigenous cases,

— the animals, from which the gelatine is derived were not slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, except if the animals were born, continuously reared and slaughtered in a country or region classified in accordance with Decision 2007/453/EC as a country or region posing a negligible BSE risk,

— (1) [the animals, from which the gelatine is derived, originate from a country or region classified in accordance with Decision 2007/453/EC as a country or region posing an undetermined BSE risk, and the animals were not fed with meat-and-bone meal or greaves, as defined in the Terrestrial Animal Health Code of the World Organisation for Animal Health],

— (1) [the animals, from which the gelatine is derived, originate from a country or region classified in accordance with Decision 2007/453/EC as a country or region posing an undetermined BSE risk, and the gelatine was produced and handled in a manner which ensures that it did not contain and were not contaminated with nervous and lymphatic tissues exposed during the deboning process.]]

or — [it comes from a country or a region classified in accordance with Decision 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk (OJ L 172, 30.6.2007, p. 84) as a country or region posing a controlled BSE risk,

— the animals, from which the gelatine is derived, were not killed after stunning by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injected into the cranial cavity,

— the gelatine does not contain and is not derived from specified risk material as defined in point 1 of Annex V to Regulation (EC) No 999/2001, or mechanically separated meat obtained from bones of bovine, ovine or caprine animals.]

or — [it comes from a country or a region classified in accordance with Decision 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk (OJ L 172, 30.6.2007, p. 84) as a country or region posing a negligible BSE risk,

— the gelatine is derived both from animals born, continuously reared and slaughtered in a country or region with negligible BSE risk in accordance with Decision 2007/453/EC, and from animals born in a country or region classified in accordance with Decision 2007/453/EC as a country or region posing a controlled BSE risk, and which were not killed after stunning by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injected into the cranial cavity,

— the gelatine does not contain and is not derived from specified risk material as defined in point 1 of Annex V to Regulation (EC) No 999/2001, or mechanically separated meat obtained from bones of bovine, ovine or caprine animals.]

or — [it comes from a country or a region classified in accordance with Decision 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk (OJ L 172, 30.6.2007, p. 84) as a country or region with an undetermined BSE risk,

— the animals, from which the gelatine is derived, were not fed meat-and-bone meal or greaves derived from ruminants, as defined in the Terrestrial Animal health Code of the World Organisation for Animal Health,

— the animals, from which the gelatine is derived, were not killed after stunning by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injected into the cranial cavity,

— the gelatine is not derived from:

(i) specified risk material as defined in point 1 of Annex V to Regulation (EC) No 999/2001;

(ii) nervous and lymphatic tissues exposed during the deboning process;

(iii) mechanically separated meat obtained from bones of bovine, ovine or caprine animals.]'

(b) In Part II of the Notes, the following footnote (2) is added:

'(2) The removal of specified risk material is not required if the gelatine derives from animals born, continuously reared and slaughtered in a third country or region of a third country classified in accordance with Decision 2007/453/EC as posing a negligible BSE risk.'

(2) In Part IV, the model certificate for imports of collagen for human consumption, Model COL, is amended as follows:

(a) Part II.1, Public Health Attestation, is replaced by the following:

'I, the undersigned, declare that I am aware of the relevant provisions of 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), Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1) and Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55) and certify that the collagen described above was produced in accordance with those requirements, in particular that:

— it comes from (an) establishment(s) implementing a programme based on the Hazard analysis and critical control points (HACCP) principles in accordance with Article 5 of Regulation (EC) No 852/2004,

— it has been produced from raw materials that met the requirements of Chapters I and II of Section XV of Annex III to Regulation (EC) No 853/2004,

— it has been manufactured in compliance with the conditions set out in Chapter III of Section XV of Annex III to Regulation (EC) No 853/2004,

— it satisfies the criteria of Chapter IV of Section XV of Annex III to Regulation (EC) No 853/2004 and of Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1);

([1]) and, if of bovine, ovine and caprine animal origin,

it has been derived from animals which have passed *ante mortem* and *post mortem* inspections,

([1]) and, except for collagen derived from hides and skins,

([1]) *either* — [it comes from a country or a region classified in accordance with Commission Decision 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk (OJ L 172, 30.6.2007, p. 84) as a country or region posing a negligible BSE risk,

— the collagen does not contain and is not derived from specified risk material as defined in point 1 of Annex V 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 (OJ L 147, 31.5.2001, p. 1) ([2]),

— the collagen does not contain and is not derived from mechanically separated meat obtained from bones of bovine, ovine or caprine animals, except for collagen derived from animals that were born, continuously reared and slaughtered in a country or region classified in accordance with Decision 2007/453/EC as a country or region posing a negligible BSE risk in which there have been no BSE indigenous cases,

— the animals from which the collagen was derived have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, except if the animals were born, continuously reared and slaughtered in a country or region classified in accordance with Decision 2007/453/EC as a country or region posing a negligible BSE risk,

— (1) [the animals, from which the collagen is derived, originate from a country or region classified in accordance with Decision 2007/453/EC as a country or region posing an undetermined BSE risk, and the animals were not fed with meat-and-bone meal or greaves, as defined in the OIE Terrestrial Animal Health Code],

— (1) [the animals, from which the collagen is derived, originate from a country or region classified in accordance with Decision 2007/453/EC as a country or region posing an undetermined BSE risk, and the collagen was produced and handled in a manner which ensures that it did not contain and were not contaminated with nervous and lymphatic tissues exposed during the deboning process.]]

(1) *or* — [it comes from a country or a region classified in accordance with Decision 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk (OJ L 172, 30.6.2007, p. 84) as a country or region posing a controlled BSE risk,

— the animals, from which the collagen is derived, were not killed, after stunning, by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injected into the cranial cavity,

— the collagen does not contain and is not derived from specified risk material as defined in point 1 of Annex V to Regulation (EC) No 999/2001, or mechanically separated meat obtained from bones of bovine, ovine or caprine animals.]

(1) *or* — [it comes from a country or a region classified in accordance with Decision 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk (OJ L 172, 30.6.2007, p. 84) as a country or region with an undetermined BSE risk,

— the animals, from which the collagen is derived, were not fed meat-and-bone meal or greaves derived from ruminants, as defined in the Terrestrial Animal health Code of the World Organisation for Animal Health,

— the animals, from which the collagen is derived, were not killed after stunning by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injected into the cranial cavity,

— the collagen is not derived from:

(i) specified risk material as defined in point 1 of Annex V to Regulation (EC) No 999/2001,

(ii) nervous and lymphatic tissues exposed during the deboning process,

(iii) mechanically separated meat obtained from bones of bovine, ovine or caprine animals.]'

(b) In Part II of the Notes, the following footnote (2) is added:

'(2) The removal of specified risk material is not required if the collagen derives from animals born, continuously reared and slaughtered in a third country or region of a third country classified in accordance with Decision 2007/453/EC as posing a negligible BSE risk.'

(3) In Part V, the model certificate for imports of raw material for the production of gelatine/collagen intended for human consumption, Model RCG, is amended as follows:

(a) Part II.1, Public Health Attestation, is replaced by the following:

'I, the undersigned, declare that I am aware of the relevant provisions of 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), Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1), Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene

rules for food of animal origin (OJ L 139, 30.4.2004, p. 55) and Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (OJ L 139, 30.4.2004, p. 206) and certify that the raw materials described above comply with those requirements, in particular that:

— (1) [bones, hides and skins of domestic and farmed ruminant animals, pigs and poultry and tendons and sinews described above are derived from animals which were slaughtered in a slaughterhouse and the carcasses of which were found fit for human consumption following *ante* and *post mortem* inspection,]

and/or

— (1) [wild game hides, skins and bones described above are derived from killed animals whose carcasses have been found fit for human consumption following *post mortem* inspection,]

and/or

— (1) [fish skins and bones described above are derived from plants manufacturing fishery products for human consumption authorised for export,]

(1) and, if of bovine, ovine and caprine animal origin,

— they have been derived from animals which passed *ante mortem* and *post mortem* inspections,

(1) and, except for hides and skins of ruminants,

(1) *either* — [they come from a country or a region classified in accordance with Decision 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk (OJ L 172, 30.6.2007, p. 84) as a country or region posing a negligible BSE risk,

— they do not contain and are not derived from specified risk material as defined in point 1 of Annex V 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 (OJ L 147, 31.5.2001, p. 1) (6),

— they do not contain and are not derived from mechanically separated meat obtained from bones of bovine, ovine or caprine animals, except for raw materials derived from animals that were born, continuously reared and slaughtered in a country or region classified in accordance with Decision 2007/453/EC as a country or region posing a negligible BSE risk in which there have been no BSE indigenous cases,

— the animals, from which the raw materials are derived, were not slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, except if the animals were born, continuously reared and slaughtered in a country or region classified in accordance with Decision 2007/453/EC as a country or region posing a negligible BSE risk,

— (1) [the animals, from which the raw materials are derived, originate from a country or region classified in accordance with Decision 2007/453/EC as a country or region posing an undetermined BSE risk, and the animals were not fed with meat-and-bone meal or greaves, as defined in the Terrestrial Animal Health Code of the World Organisation for Animal Health],

— (1) [the animals, from which the raw materials are derived, originate from a country or region classified in accordance with Decision 2007/453/EC as a country or region posing an undetermined BSE risk, and the raw materials were produced and handled in a manner which ensures that they did not contain and were not contaminated with nervous and lymphatic tissues exposed during the deboning process.]]

([1]) *or* — [they come from a country or a region classified in accordance with Decision 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk (OJ L 172, 30.6.2007, p. 84) as a country or region posing a controlled BSE risk,

— the animals, from which the raw materials of bovine, ovine and caprine animal origin intended for export are derived, were not killed, after stunning, by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injected into the cranial cavity,

— the raw materials of bovine, ovine and caprine animal origin do not contain and are not derived from specified risk material as defined in point 1 of Annex V to Regulation (EC) No 999/2001, or mechanically separated meat obtained from bones of bovine, ovine or caprine animals;]

([1]) *or* — [they come from a country or a region classified in accordance with Decision 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk (OJ L 172, 30.6.2007, p. 84) as a country or region with an undetermined BSE risk,

— the animals, from which the raw materials are derived, were not fed meat-and-bone meal or greaves derived from ruminants, as defined in the Terrestrial Animal Health Code of the World Organisation for Animal Health,

— the animals from which the raw materials of bovine, ovine and caprine animal origin are derived, were not killed, after stunning, by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injected into the cranial cavity,

— the raw materials are not derived from:

(i) specified risk material as defined in point 1 of Annex V to Regulation (EC) No 999/2001;

(ii) nervous and lymphatic tissues exposed during the de-boning process;

(iii) mechanically separated meat obtained from bones of bovine, ovine or caprine animals.]'

(b) In Part II of the Notes, the following footnote (6) is added:

'([6]) The removal of specified risk material is not required if the raw materials derive from animals born, continuously reared and slaughtered in a third country or region of a third country classified in accordance with Decision 2007/453/EC as posing a negligible BSE risk.'

(4) In Part VI, the model certificate for imports of treated raw material for the production of gelatine/collagen intended for human consumption, Model TCG, is amended as follows:

(a) Part II.1, Public Health Attestation, is replaced by the following:

'I, the undersigned, certify that the treated raw materials described above comply with the following requirements:

— they have been derived from establishments under the control of and listed by the competent authority,

and

— ([1]) [bones, hides and skins of domestic and farmed ruminant animals, pigs and poultry described above are derived from animals which were slaughtered in a slaughterhouse and the carcasses of which were found fit for human consumption following *ante* and *post mortem* inspection,]

([1]) and/or

— [wild game hides, skins and bones described above are derived from killed animals whose carcasses were found fit for human consumption following *post mortem* inspection,]

([1]) and/or

— [fish skins and bones described above are derived from plants manufacturing fishery products for human consumption authorised for export,]

and

([1]) *either* — [they are dried bones of species from bovine, ovine, caprine, porcine and equine animals, including farmed and wild animals, poultry including ratites and feathered game for the production of collagen or gelatine, they derived from healthy animals slaughtered in a slaughterhouse, and they have been treated as follows:

([1]) *either* — [crushed to pieces of approximately 15 mm and degreased with hot water at a temperature of minimum 70 °C for at least 30 minutes, minimum 80 °C for at least 15 minutes, or minimum 90 °C for at least 10 minutes, and then separated and subsequently washed and dried for at least 20 minutes in a stream of hot air with an initial temperature of minimum 350 °C, or for 15 minutes in a stream of hot air with an initial temperature of more than 700 °C.]

([1]) *or* [sun-dried for a minimum of 42 days at an average temperature of at least 20 °C.]

([1]) *or* [acid treatment such that the pH is maintained at less than 6 to the core for at least one hour before drying.]]

([1]) *or* [they are hides and skins of farmed ruminant animals, pig skins, poultry skins or wild game hides and skins, they derived from healthy animals and they:

([1]) *either* — [have undergone an alkali treatment which ensures a pH > 12 to the core followed by salting for at least 7 days]

([1]) *or* [were dried for at least 42 days at a temperature of at least 20 °C.]

([1]) *or* [have undergone an acid treatment that provides at least a pH of less than 5 to the core for a minimum of 1 hour.]

([1]) *or* [have undergone an alkali treatment which ensures a pH > 12 to the core for at least 8 hours.]]

([1]) *or* [they are bones, hides or skins of farmed ruminant animals, pig skins, poultry skins, fish skins and wild game hides and skins from third countries, parts of third countries and territories referred to in Part IV of Annex I to Commission Implementing Regulation (EU) 2016/759 of 28 April 2016 drawing up lists of third countries, parts of third countries and territories from which Member States are to authorise the introduction into the Union of certain products of animal origin intended for human consumption, laying down certificate requirements, amending Regulation (EC) No 2074/2005 and repealing Decision 2003/812/EC (OJ L 126, 14.5.2016, p. 13) that have undergone any other treatment than those listed above, and that come from establishments registered or approved in accordance with to Regulation (EC) No 852/2004 or in accordance with Regulation (EC) No 853/2004

([1]) and, if of bovine, ovine and caprine animal origin,

— they are derived from animals which passed *ante mortem* and *post mortem* inspections,

([1]) and, except for hides and skins of ruminants,

([1]) *either* — [they come from a country or a region classified in accordance with Decision 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk (OJ L 172, 30.6.2007, p. 84) as a country or region posing a negligible BSE risk,

— they do not contain and are not derived from specified risk material as defined in point 1 of Annex V 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 (OJ L 147, 31.5.2001, p. 1) ([4]),

— they do not contain and are not derived from mechanically separated meat obtained from bones of bovine, ovine or caprine animals, except for treated raw materials derived from animals that were born, continuously reared and slaughtered in a country or region classified in accordance with Decision 2007/453/EC as a country or region posing a negligible BSE risk in which there have been no BSE indigenous cases,

— the animals, from which the treated raw materials are derived, were not slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, except if the animals were born, continuously reared and slaughtered in a country or region classified in accordance with Decision 2007/453/EC as a country or region posing a negligible BSE risk,

— [1] [the animals, from which the treated raw materials are derived, originate from a country or region classified in accordance with Decision 2007/453/EC as a country or region posing an undetermined BSE risk, and the animals have not been fed with meat-and-bone meal or greaves, as defined in the Terrestrial Animal Health Code of the World Organisation for Animal Health],

— [1] [the animals, from which the treated raw materials are derived, originate from a country or region classified in accordance with Decision 2007/453/EC as a country or region posing an undetermined BSE risk, the products were produced and handled in a manner which ensures that they did not contain and were not contaminated with nervous and lymphatic tissues exposed during the deboning process.]]

[1] *or* — [they come from a country or a region classified in accordance with Decision 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk (OJ L 172, 30.6.2007, p. 84) as a country or region posing a controlled BSE risk,

— the animals, from which the treated raw materials of bovine, ovine and caprine animal origin destined for export are derived, were not killed, after stunning, by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injected into the cranial cavity,

— the treated raw materials of bovine, ovine and caprine animal origin do not contain and are not derived from specified risk material as defined in point 1 of Annex V to Regulation (EC) No 999/2001, or mechanically separated meat obtained from bones of bovine, ovine or caprine animals;]

[1] *or* — [they come from a country or a region classified in accordance with Decision 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk (OJ L 172, 30.6.2007, p. 84) as a country or region with an undetermined BSE risk,

— the animals from which the treated raw materials were derived have not been fed meat-and-bone meal or greaves derived from ruminants, as defined in the Terrestrial Animal Health Code of the World Organisation for Animal Health,

— the animals, from which the treated raw materials of bovine, ovine and caprine animal origin are derived, were not killed after stunning by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injected into the cranial cavity,

— the treated raw materials are not derived from:

(i) specified risk material as defined in point 1 of Annex V of Regulation (EC) No 999/2001;

(ii) nervous and lymphatic tissues exposed during the de-boning process;

(iii) mechanically separated meat obtained from bones of bovine, ovine or caprine animals.]]'

(b) In Part II of the Notes, the following footnote (4) is added:

'(4) The removal of specified risk material is not required if the treated raw materials derive from animals born, continuously reared and slaughtered in a third country or region of a third country classified in accordance with Decision 2007/453/EC as posing a negligible BSE risk.'

ANNEX III

In Annex I to Regulation (EU) No 28/2012, the model health certificate for import into the European Union of composite products intended for human consumption is amended as follows:

(1) In Point II.2.A of Part II, Health Information, point (E) is replaced by the following:

'(E) If containing material from bovine, ovine or caprine animals, the fresh meat and/or intestines used in the preparation of the meat products and/or treated intestines shall be subject to the following conditions depending on the BSE risk category of the country of origin:

([1]) [(E.1) for imports from a country or a region classified in accordance with Decision 2007/453/EC as a country or region posing a negligible BSE risk:

1. the animals, from which the products of bovine, ovine and caprine animal origin are derived, have passed *ante mortem* and *post mortem* inspection;

2. the products of bovine, ovine and caprine animal origin do not contain and are not derived from specified risk material as defined in point 1 of Annex V to Regulation (EC) No 999/2001 of the European Parliament and of the Council ([11]);

3. the products of bovine, ovine and caprine animal origin do not contain and are not derived from mechanically separated meat obtained from the bones of bovine, ovine or caprine animals, except for products of bovine, ovine and caprine animal origin derived from animals that were born, continuously reared and slaughtered in a country or region classified in accordance with Decision 2007/453/EC as a country or region posing a negligible BSE risk in which there have been no BSE indigenous cases;

4. the animals, from which the products of bovine, ovine and caprine animal origin are derived, were not slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, except if the animals were born, continuously reared and slaughtered in a country or region classified in accordance with Decision 2007/453/EC as a country or region posing a negligible BSE risk;

5. if the animals, from which the products of bovine, ovine and caprine animal origin are derived, originate from a country or region classified in accordance with Decision 2007/453/EC as posing an undetermined BSE risk, those animals were not fed with meat-and-bone meal or greaves, as defined in the Terrestrial Animal Health Code of the World Organisation for Animal Health, and the products were produced and handled in a manner which ensures that it did not contain and was not contaminated with nervous and lymphatic tissues exposed during the deboning process.]

([1]) *or* [(E2) for imports from a country or a region classified in accordance with Decision 2007/453/EC as a country or region posing a controlled BSE risk;

1. the animals, from which the products of bovine, ovine and caprine animal origin are derived, have passed *ante mortem* and *post mortem* inspection and were not killed after stunning by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injected into the cranial cavity;

2. the products of bovine, ovine and caprine animal origin do not contain and are not derived from specified risk material as defined in point 1 of Annex V to Regulation (EC) No 999/2001, or mechanically separated meat obtained from the bones of bovine, ovine or caprine animals.

([1]) ([4]) 3. In the case of intestines originally sourced from a country or a region with a negligible BSE risk, imports of treated intestines have been subject to the following conditions:

(a) the country or region was classified in accordance with Decision 2007/453/EC as a country or region posing a controlled BSE risk;

(b) the animals, from which the products of bovine, ovine and caprine animal origin are derived, were born, continuously reared and slaughtered in the country or region with a negligible BSE risk and have passed *ante mortem* and *post mortem* inspections;

([1]) (c) if the intestines are sourced from a country or region where there have been BSE indigenous cases:

(i) the animals were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants was enforced; or

(ii) the products of bovine, ovine and caprine animal origin do not contain and are not derived from specified risk material as defined in point 1 of Annex V to Regulation (EC) No 999/2001.]

([1]) *or* [(E.3) for imports from a country or a region classified in accordance with Decision 2007/453/EC as a country or region with an undetermined BSE risk:

1. the animals, from which the products of bovine, ovine and caprine animal origin are derived, were not fed meat-and-bone meal or greaves derived from ruminants, as defined in the Terrestrial Animal health Code of the World Organisation for Animal Health, and have passed *ante mortem* and *post mortem* inspections;

2. the animals, from which the products of bovine, ovine and caprine animal origin are derived, were not killed, after stunning, by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injected into the cranial cavity;

3. the products of bovine, ovine and caprine animal origin are not derived from:

(a) specified risk material as defined in point 1 of Annex V to Regulation (EC) No 999/2001;

(b) nervous and lymphatic tissues exposed during the deboning process;

(c) mechanically separated meat obtained from bones of bovine, ovine or caprine animals.

([1]) ([4]) 4. In the case of intestines originally sourced from a country or a region with a negligible BSE risk, imports of treated intestines have been subject to the following conditions:

(a) the country or region was classified in accordance with Decision 2007/453/EC as a country or region posing a undetermined BSE risk;

(b) the animals, from which the products of bovine, ovine and caprine animal origin are derived, were born, continuously reared and slaughtered in the country or region with a negligible BSE risk and have passed *ante mortem* and *post mortem* inspections;

([1]) (c) if the intestines are sourced from a country or region where there have been BSE indigenous cases:

(i) the animals were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants was enforced; or

(ii) the products of bovine, ovine and caprine animal origin do not contain and are not derived from specified risk material as defined in point 1 of Annex V to Regulation (EC) No 999/2001.]'

(2) In Part II of the Notes, the following footnote (11) is added:

'(11) The removal of specified risk material is not required if the products of bovine, ovine and caprine animal origin derive from animals born, continuously reared and slaughtered in a third country or region of a third country classified in accordance with Decision 2007/453/EC as posing a negligible BSE risk.'