Commission Regulation (EC) No 523/2008 of 11 June 2008 amending Annexes VIII, X and XI to Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards the import of blood products for the manufacture of technical products (Text with EEA relevance)

COMMISSION REGULATION (EC) No 523/2008

of 11 June 2008

amending Annexes VIII, X and XI to Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards the import of blood products for the manufacture of technical products

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption[(1)], and in particular Article 4(4), the second paragraph of Article 28, the first subparagraph of Article 29(3) and Article 32(1),

Whereas:

(1) Regulation (EC) No 1774/2002 lays down animal and public health requirements for the import into and transit through the Community of blood products intended for technical purposes, including model import health certificates and list of countries authorised for imports.

(2) Regulation (EC) No 1774/2002 provides that animal by-products which have been derived from animals treated with certain substances prohibited under Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stock farming of certain substances having a hormonal or thyrostatic action and of ß-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC[(2)] may only be imported into the Community in accordance with Regulation (EC) No 1774/2002 or with specific rules to be laid down.

(3) The possibility to import such blood products is vital for the biotechnology industry for the manufacture of various technical products used mainly by the pharmaceutical and research community. As those products are not intended either for human or animal consumption and during their processing and technical use they pose no risk to animal and human health by reason of being derived from animals treated with certain substances prohibited under Directive 96/22/EC, it is appropriate to allow the imports into the Community of such blood products.

(4) Regulation (EC) No 1774/2002 provides that the blood products used for the manufacture of technical products must be specifically treated or the country or region

of origin of the products must be free from certain diseases without vaccination. However, several countries or certain regions are eligible to deliver fresh meat of ruminants to the Community by reason of being free from foot-and-mouth disease with vaccination, provided that the risk against possible virus circulation is mitigated. Similarly, it is appropriate to allow imports of untreated blood products of ruminants from such countries or regions, provided that those products are channelled to their place of destination under secure conditions for further processing.

(5) Regulation (EC) No 1774/2002 also provides, in case of blood products of ruminant origin that the region of origin must be eligible for the import of live animals of the same species into the Community. According to international standards, blood products are less likely to transmit diseases of concern than live animals. It is therefore appropriate to delete this condition from the relevant requirements.

(6) Part VI(A) of Annex XI to Regulation (EC) No 1774/2002 sets out lists of third countries from which Member States may authorise imports of blood products intended for technical purposes. Those lists are currently limited to countries from which the import of all categories of fresh meat of the respective species for human consumption is authorised.

(7) Since the applicable requirements allow for the treatment of the blood products, those lists should be extended also to countries which are not authorised to export fresh meat of the respective species into the Community but are able to comply with the treatment requirements. However, for the sake of clarity, separate health certificates should be laid down for treated and untreated blood products.

(8) It is appropriate to update the requirements related to the import of blood products from poultry and other avian species by referring to the international standards laid down in the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE).

(9) Annexes VIII, X and XI to Regulation (EC) No 1774/2002 should therefore be amended accordingly.

(10) A transitional period should be provided for after the date of entry into force of this Regulation, in order to provide the necessary time for the stakeholders to comply with the new rules and to allow for the continued importation into the Community of the blood products as currently covered by Regulation (EC) No 1774/2002.

(11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes VIII, X and XI to Regulation (EC) No 1774/2002 are amended in accordance with the Annex to this Regulation.

Article 2

Consignments of blood products accompanied by health certificates completed and signed in accordance with the provisions of Regulation (EC) No 1774/2002 applicable

before the date of entry into force of this Regulation shall be accepted for import into the Community until 12 December 2008 at the latest.

Such consignments shall also be accepted until 12 February 2009 at the latest if the accompanying health certificates were completed and signed by 12 December 2008 at the latest.

Article 3

This Regulation shall enter into force and apply on the third 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, 11 June 2008.

For the Commission

Androulla VASSILIOU

Member of the Commission

ANNEX

The Annexes to Regulation (EC) No 1774/2002 are amended as follows:

(1) In Annex VIII, Chapter IV is replaced by the following:

CHAPTER IV

Requirements for blood and blood products, excluding from equidae, for the manufacture of technical products

A. Importation

1. Imports of blood are subject to the requirements laid down in Chapter XI.

2. Member States must authorise imports of blood products for the manufacture of technical products, including material originating from animals to which substances prohibited pursuant to Directive 96/22/EC have been administered, if they:

(a) come from third countries that appear on the list in Part VI (A) of Annex XI as applicable;

(b) come from a technical plant meeting the specific conditions laid down in this Regulation or from the establishment of collection;

(c) are accompanied by a health certificate that conforms to the model set out in Chapter 4(C) or Chapter 4(D) of Annex X as appropriate.

3. The blood from which blood products for the manufacture of technical products are produced must have been collected:

(a) in slaughterhouses approved in accordance with Community legislation;

(b) in slaughterhouses approved and supervised by the competent authority of the third country; or

(c) from live animals in facilities approved and supervised by the competent authority of the third country.

4. In the case of blood products for the manufacture of technical products which have been derived from animals belonging to the *taxa Artiodactyla, Perissodactyla* and *Proboscidea*, including their crossbreeds, they must comply with the conditions of either points (a) or (b):

(a) the products have undergone one of the following treatments guaranteeing the absence of pathogens of the diseases referred to in point (b):

(i) heat treatment at a temperature of 65 °C for at least three hours, followed by an effectiveness check,

(ii) irradiation at 25 kGy by gamma rays, followed by an effectiveness check,

(iii) heat treatment of at least 80 °C throughout their substance, followed by an effectiveness check,

(iv) in the case of animals other than *Suidae* and *Tayassuidae* only: change in pH to pH 5 for two hours, followed by an effectiveness check;

(b) in case of blood products not treated in accordance with point (a) the products originate from a country or region:

(i) where no case of rinderpest, *peste des petits* ruminants and Rift Valley fever has been recorded for 12 months and in which vaccination has not been carried out against those diseases for at least 12 months,

(ii) where no case of foot-and-mouth disease has been recorded for 12 months and in which vaccination has not been carried out against this disease for at least 12 months, or

where no case of foot-and-mouth disease has been recorded for 12 months and in which vaccination programmes against foot-and-mouth disease are being officially carried out and controlled in domestic ruminant animals for at least 12 months; in this case, following the border check provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, the products must be transported directly to the technical plant of destination and all precautions, including safe disposal of waste, unused or surplus material, must be taken to avoid risks of spreading diseases to animals or humans.

In addition to points (i) and (ii), in the case of animals other than *Suidae* and *Tayassuidae*, one of the following conditions must be complied with:

— in the country or region of origin no case of vesicular stomatitis and bluetongue (including the presence of seropositive animals) has been recorded for 12 months and vaccination has not been carried out against those diseases for at least 12 months in the susceptible species,

— following the border check provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, the products must be transported directly to the technical plant of destination and all precautions, including safe disposal of waste, unused or surplus material, must be taken to avoid risks of spreading diseases to animals or humans.

In addition to points (i) and (ii), in the case of *Suidae* and *Tayassuidae*, in the country or region of origin no case of swine vesicular disease, classical swine fever and African swine fever has been recorded for at least 12 months, vaccination has not been carried out against those diseases for at least 12 months and one of the following conditions are complied with:

— in the country or region of origin no case of vesicular stomatitis (including the presence of seropositive animals) has been recorded for 12 months and vaccination has not been carried out against this disease for at least 12 months in the susceptible species,

— following the border check provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, the products must be transported directly to the technical

plant of destination and all precautions, including safe disposal of waste, unused or surplus material, must be taken to avoid risks of spreading diseases to animals or humans.

5. In the case of blood products for the manufacture of technical products which have been derived from poultry and other avian species, they must comply with the conditions of either points (a) or (b):

(a) the products have undergone one of the following treatments guaranteeing the absence of pathogens of the diseases referred to in point (b):

(i) heat treatment at a temperature of 65 °C for at least three hours, followed by an effectiveness check,

(ii) irradiation at 25 kGy by gamma rays, followed by an effectiveness check,

(iii) heat treatment of at least 70 °C throughout their substance, followed by an effectiveness check;

(b) in case of blood products not treated in accordance with point (a) the products originate from a country or region:

(i) which has been free from Newcastle disease and highly pathogenic avian influenza as defined in the Terrestrial Animal Health Code of the OIE,

(ii) which during the last 12 months has not carried out vaccination against avian influenza,

(iii) where the poultry or other avian species from which the products derive have not been vaccinated against Newcastle disease with vaccines prepared from a Newcastle disease master strain showing a higher pathogenicity than lentogenic virus strains.

(2) Annex X is amended as follows:

(a) Chapter 4(C) is replaced by the following:

CHAPTER
4(C)

COUNTRY

Untreated blood prod
for technical products

Part II: Certification

II. Health information		II.a. Certificate reference number	II.b.
II.	Health attestation I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC)		
II.1.	the blood products described above consist of blood products that satisfy the health requirements		
II.2.	they consist exclusively of blood products not intended for human or animal consumption;		
II.3.	they have been prepared and stored in a plant approved, validated and supervised by the competer with Article 18 or in the establishment of collection and where appropriate Article 11 of Regulatio exclusively with the following animal by-products:		
(2) *either*	[— blood of slaughtered animals, which is fit for human consumption in accordance with Commu intended for human consumption for commercial reasons;]		
(2) *and/or*	[— blood of slaughtered animals, which is rejected as unfit for human consumption but is not diseases communicable to humans or animals, derived from carcasses that are fit for human co with Community legislation;]		
(2) *and/or*	[— blood obtained from animals other than ruminants that are slaughtered in a slaughterhouse, afte inspection, and were fit, as a result of such inspection, for slaughter for human consump Community legislation;]		
(2) *and/or*	[— blood and blood products originating from live animals that did not show clinical signs of ar through these products to humans or animals;]		
II.4.	the blood from which such products are manufactured has been collected:		
(2) *either*	[in slaughterhouses approved in accordance with Community legislation,]		
(2) *or*	[in slaughterhouses approved and supervised by the competent authority of the third country,]		
(2) *or*	[from live animals in facilities approved and supervised by the competent authority of the third cou		
(2) II.5.	in the case of blood products derived from animals belonging to the *taxa Artiodactyla, Perissoc* including their crossbreds, the products come:		
II.5.1.	from a country where no case of rinderpest, *peste des petits* ruminants and Rift Valley fever has bee and in which vaccination has not been carried out against those diseases for at least 12 months,		
(2) [II.5.2. *either*	[from the territory of a country or region with code … (3) where no case of foot-and-mouth disease months and in which vaccination has not been carried out against this disease for at least 12 mor		
(2) [II.5.2. *or*	[from the territory of a country or region with code … (3) where no case of foot-and-mouth disease months and in which vaccination programmes against foot-and-mouth disease are being officially ca domestic ruminant animals for at least 12 months (4)]]		
(2) II.5.3.	In addition, in case of animals other than *Suidae* and *Tayassuidae*:		
(2) *either*	[in the country or region of origin no case of vesicular stomatitis and bluetongue (2) (including the animals) has been recorded for 12 months and in which vaccination has not been carried out aga least 12 months,]		
(2) *or*	[in the country or region of origin vesicular stomatitis and bluetongue (2) seropositive animals are		
(2) [II.5.4.	In addition, in case of *Suidae* and *Tayassuidae*:		
II.5.4.1.	[in the country or region of origin no case of swine vesicular disease, classical swine fever and Afri recorded for at least 12 months and vaccination has not been carried out against those diseases for susceptible species,]]		
(2) [II.5.4.2. *either*	[in the country or region of origin no case of vesicular stomatitis (including the presence of seropo recorded for 12 months and in which vaccination has not been carried out against this disease		

COUNTRY

Untreated blood prod
for technical products

II. Health information	II.a. Certificate reference number	II.b.

(2) [II.5.4.2. *or* [in the country or region of origin vesicular stomatitis seropositive animals are present (4),]]

(2) [II.6. in the case of blood products derived from poultry or other avian species the animals and the products c
country or region with code ... (5)]

which has been free from Newcastle disease and highly pathogenic avian influenza as defined in the
Code of the OIE,

which for at least 12 months has not carried out vaccination against avian influenza,

where the animals from which the products derive have not been vaccinated against Newcastle diseas
from a Newcastle disease master strain showing a higher pathogenicity than lentogenic virus strains.

II.7. the products were:

(2) *either* [packed in new or sterilised bags or bottles,]

(2) *or* [transported in bulk in containers or other means of transport that were thoroughly cleaned and disin
approved by the competent authority before use,]

the outer packaging or containers bear labels indicating "NOT FOR HUMAN OR ANIMAL CONSUMPT

II.8. the products were stored in enclosed storage;

II.9. the products have undergone all precautions to avoid contamination with pathogenic agents during tra

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in the European Community: this box is to be filled in only if
commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The prod
stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (s
provided in case of unloading and reloading.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

Part II:

(1) OJ L 273, 10.10.2002, p. 1.

(2) Delete as appropriate.

(3) Code of the territory as it appears in Part 1 of Annex II to Decision 79/542/EEC.

(4) In this case following the border check provided for in Directive 97/78/EC, and in accordance with the conditions laid d
Directive, the products must be transported directly to the technical plant of destination.

(5) Code of the territory as it appears in Part 1 of Annex II to Decision 2006/696/EC.

— The signature and the stamp must be in a different colour to that of the printing.

— Note for the person responsible for the consignment in the European Community: this certificate is only for veterin
accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:'

(b) The following Chapter 4(D) is added:

CHAPTER
4(D)

COUNTRY

Treated blood pro
for technical produ

Part II: Certification

II. Health information

II.a. Certificate reference number | II.b.

II.	**Health attestation**
	I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) particular Article 4(1)(c), Article 6 and Chapter IV of Annex VIII thereof and certify that:
II.1.	the blood products described above consist of blood products that satisfy the requirements below;
II.2.	they consist exclusively of blood products not intended for human or animal consumption;
II.3.	they have been prepared and stored in a plant approved, validated and supervised by the competer with Article 18 or in the establishment of collection and where appropriate Article 11 of Regulatio exclusively with the following animal by-products:
(2) *either*	[— blood of slaughtered animals, which is fit for human consumption in accordance with Commu intended for human consumption for commercial reasons;]
(2) *and/or*	[— blood of slaughtered animals, which is rejected as unfit for human consumption but is not diseases communicable to humans or animals, derived from carcasses that are fit for human co with Community legislation;]
(2) *and/or*	[— blood obtained from animals other than ruminants that are slaughtered in a slaughterhouse, afte inspection, and were fit, as a result of such inspection, for slaughter for human consump Community legislation;]
(2) *and/or*	[— blood and blood products originating from live animals that did not show clinical signs of an through these products to humans or animals.]
II.4.	the blood from which such products are manufactured has been collected:
(2) *either*	[in slaughterhouses approved in accordance with Community legislation,]
(2) *or*	[in slaughterhouses approved and supervised by the competent authority of the third country,]
(2) *or*	[from live animals in facilities approved and supervised by the competent authority of the third cou
(2) II.5.	In case of blood products derived from *taxa Artiodactyla, Perissodactyla* and *Proboscidea* including than *Suidae* and *Tayassuidae,* the products have undergone one of the following treatments, gua pathogens of foot-and-mouth disease, vesicular stomatitis, rinderpest, *peste des petits* ruminants, P tongue:
(2) *either*	[heat treatment at a temperature of 65 °C for at least three hours, followed by an effectiveness ch
(2) *or*	[irradiation at 25 kGy by gamma rays, followed by an effectiveness check,]
(2) *or*	[change in pH to pH 5 for two hours, followed by an effectiveness check,]
(2) *or*	[heat treatment of at least 80 °C throughout their substance, followed by an effectiveness check]
(2) II.6.	In the case of blood products derived from *Suidae, Tayassuidae,* poultry and other avian spe undergone one of the following treatments guaranteeing the absence of pathogens of the follo mouth disease, vesicular stomatitis, swine vesicular disease, classical swine fever, African swine and highly pathogenic avian influenza as appropriate to the species;
(2) *either*	[heat treatment at a temperature of 65 °C for at least three hours, followed by an effectiveness ch
(2) *or*	[irradiation at 25 kGy by gamma rays, followed by an effectiveness check,]
(2) *or*	[heat treatment of at least 80 °C for *Suidae/Tayassuidae* (2) and at least 70 °C for poultry an throughout their substance, followed by an effectiveness check]
(2) [II.7.	In the case of blood products derived from species other than listed under II.5 or II.6 the product following treatment (please specify): …]
II.8.	The products were:
(2) *either*	[packed in new or sterilised bags or bottles,]
(2) *or*	[transported in bulk in containers or other means of transport that were thoroughly cleaned and disi approved by the competent authority before use,]
	the outer packaging or containers bear labels indicating "NOT FOR HUMAN OR ANIMAL CONSU

COUNTRY

Untreated blood prod
for technical products

II. Health information	II.a. Certificate reference number	II.b.

II.9. the products were stored in enclosed storage;

II.10. the products have undergone all precautions to avoid contamination with pathogenic agents after treat

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in the European Community: this box is to be filled in only if commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The prod stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (s provided in case of unloading and reloading.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

Part II:

(1) OJ L 273, 10.10.2002, p. 1.

(2) Delete as appropriate.

— The signature and the stamp must be in a different colour to that of the printing.

— Note for the person responsible for the consignment in the European Community: this certificate is only for veterin accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:'

(3) In Annex XI, Part VI (A) is replaced by the following:

A. Blood products:

1. Untreated blood products of ungulates:

Third countries or parts of third countries listed in Part 1 of Annex II to Decision 79/542/EEC from which imports of fresh meat of any domestic ungulate species is authorised and only for the period indicated in columns 7 and 8 of that Part,

Japan.

2. Untreated blood products of poultry and other avian species:

Third countries or parts of third countries listed in Part 1 of Annex II to Decision 2006/696/EC,

Japan.

3. Untreated blood products of other animals:

Third countries listed either in Part 1 of Annex II to Decision 79/542/EEC, in Part 1 of Annex II to Commission Decision 2006/696/EC or in Annex I to Commission Decision 2000/585/EC,

Japan.

4. Treated blood products of any species:

Third countries listed in Part 1 to Annex II of Decision 79/542/EEC, in Part 1 of Annex II to Decision 2006/696/EC or in Annex I to Decision 2000/585/EC,

Japan.

(**1**) OJ L 273, 10.10.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 437/2008 (OJ L 132, 22.5.2008, p. 7).

(**2**) OJ L 125, 23.5.1996, p. 3. Directive as amended by Directive 2003/74/EC of the European Parliament and of the Council (OJ L 262, 14.10.2003, p. 17).

Changes to legislation:
Commission Regulation (EC) No 523/2008 is up to date with all changes known to be in force on or before 21 December 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

– Regulation implicit repeal by EUR 2009/1069 Regulation