ISSN 1725-2555

Official Journal of the European Union

L 39

English edition

Legislation

Volume 52

10 February 2009

Contents

[1] Text with EEA relevance

(Continued overleaf)

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

Note to the reader (see page 3 of the cover)

EN

(1) Text with EEA relevance

I

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is obligatory)

REGULATIONS

COUNCIL REGULATION (EC) No 116/2009

of 18 December 2008

on the export of cultural goods

(Codified version)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 133 thereof,

Having regard to the proposal from the Commission,

Whereas:

(1) Council Regulation (EEC) No 3911/92 of 9 December 1992 on the export of cultural goods [1] has been substantially amended several times [2]. In the interests of clarity and rationality the said Regulation should be codified.

(2) In order to maintain the internal market, rules on trade with third countries are needed for the protection of cultural goods.

(3) It seems necessary to take measures in particular to ensure that exports of cultural goods are subject to uniform controls at the Community's external borders.

(4) Such a system should require the presentation of a licence issued by the competent Member State prior to the export of cultural goods covered by this Regulation. This necessitates a clear definition of the scope of such measures and the procedures for their implementation. The implementation of the system should be as simple and efficient as possible.

(5) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [3].

(6) In view of the considerable experience of the Member States' authorities in the application of Council Regulation (EC) No 515/97 of 13 March 1997 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of the law on customs and agricultural matters [4], the said Regulation should be applied to this matter.

(7) Annex I to this Regulation is aimed at making clear the categories of cultural goods which should be given particular protection in trade with third countries, but is not intended to prejudice the definition, by Member States, of national treasures within the meaning of Article 30 of the Treaty,

HAS ADOPTED THIS REGULATION:

Article 1

Definition

Without prejudice to Member States' powers under Article 30 of the Treaty, the term 'cultural goods' shall refer, for the purposes of this Regulation, to the items listed in Annex I.

Article 2

Export licence

1. The export of cultural goods outside the customs territory of the Community shall be subject to the presentation of an export licence.

[1] OJ L 395, 31.12.1992, p. 1.
[2] See Annex II.
[3] OJ L 184, 17.7.1999, p. 23.
[4] OJ L 82, 22.3.1997, p. 1.

2. The export licence shall be issued at the request of the person concerned:

(a) by a competent authority of the Member State in whose territory the cultural object in question was lawfully and definitively located on 1 January 1993;

(b) or, thereafter, by a competent authority of the Member State in whose territory it is located following either lawful and definitive dispatch from another Member State, or importation from a third country, or re-importation from a third country after lawful dispatch from a Member State to that country.

However, without prejudice to paragraph 4, the Member State which is competent in accordance with points (a) or (b) of the first subparagraph is authorised not to require export licences for the cultural goods specified in the first and second indents of category A.1 of Annex I where they are of limited archaeological or scientific interest, and provided that they are not the direct product of excavations, finds or archaeological sites within a Member State, and that their presence on the market is lawful.

The export licence may be refused, for the purposes of this Regulation, where the cultural goods in question are covered by legislation protecting national treasures of artistic, historical or archaeological value in the Member State concerned.

Where necessary, the authority referred to in point (b) of the first subparagraph shall enter into contact with the competent authorities of the Member State from which the cultural object in question came, and in particular the competent authorities within the meaning of Council Directive 93/7/EEC of 15 March 1993 on the return of cultural objects unlawfully removed from the territory of a Member State [1].

3. The export licence shall be valid throughout the Community.

4. Without prejudice to the provisions of paragraphs 1, 2 and 3, direct export from the customs territory of the Community of national treasures having artistic, historic or archaeological value which are not cultural goods within the meaning of this Regulation is subject to the national law of the Member State of export.

Article 3

Competent authorities

1. Member States shall furnish the Commission with a list of the authorities empowered to issue export licences for cultural goods.

2. The Commission shall publish a list of the authorities and any amendment to that list in the 'C' series of the *Official Journal of the European Union*.

Article 4

Presentation of licence

The export licence shall be presented, in support of the export declaration, when the customs export formalities are carried out, at the customs office which is competent to accept that declaration.

Article 5

Limitation of competent customs offices

1. Member States may restrict the number of customs offices empowered to handle formalities for the export of cultural goods.

2. Member States availing themselves of the option afforded by paragraph 1 shall inform the Commission of the customs offices duly empowered.

The Commission shall publish this information in the 'C' series of the *Official Journal of the European Union*.

Article 6

Administrative cooperation

For the purposes of implementing this Regulation, the provisions of Regulation (EC) No 515/97, and in particular the provisions on the confidentiality of information, shall apply *mutatis mutandis*.

In addition to the cooperation provided for under the first paragraph, Member States shall take all necessary steps to establish, in the context of their mutual relations, cooperation between the customs authorities and the competent authorities referred to in Article 4 of Directive 93/7/EEC.

Article 7

Implementing measures

The measures necessary for the implementation of this Regulation, in particular those concerning the form to be used (for example, the model and technical properties) shall be adopted in accordance with the procedure referred to in Article 8(2).

Article 8

Committee

1. The Commission shall be assisted by a committee.

2. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply.

[1] OJ L 74, 27.3.1993, p. 74.

Article 9

Penalties

The Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive.

Article 10

Reporting

1. Each Member State shall inform the Commission of the measures taken pursuant to this Regulation.

The Commission shall pass on this information to the other Member States.

2. Every three years the Commission shall present a report to the European Parliament, the Council and the European Economic and Social Committee on the implementation of this Regulation.

The Council, acting on a proposal from the Commission, shall examine every three years and, where appropriate, update the amounts indicated in Annex I, on the basis of economic and monetary indicators in the Community.

Article 11

Repeal

Regulation (EEC) No 3911/92, as amended by the Regulations listed in Annex II, is repealed.

References to the repealed Regulation shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex III.

Article 12

Entry into force

This Regulation shall enter into force on the 20th day following 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, 18 December 2008.

For the Council
The President
M. BARNIER

ANNEX I

Categories of cultural objects covered by Article 1

A. 1.	Archaeological objects more than 100 years old which are the products of:	
	— excavations and finds on land or under water	9705 00 00
	— archaeological sites	9706 00 00
	— archaeological collections	
2.	Elements forming an integral part of artistic, historical or religious monuments which have been dismembered, of an age exceeding 100 years	9705 00 00 9706 00 00
3.	Pictures and paintings, other than those included in categories 4 or 5, executed entirely by hand in any medium and on any material [1]	9701
4.	Watercolours, gouaches and pastels executed entirely by hand on any material [1]	9701
5.	Mosaics in any material executed entirely by hand, other than those falling in categories 1 or 2, and drawings in any medium executed entirely by hand on any material [1]	6914 9701
6.	Original engravings, prints, serigraphs and lithographs with their respective plates and original posters [1]	Chapter 49 9702 00 00 8442 50 99
7.	Original sculptures or statuary and copies produced by the same process as the original [1], other than those in category 1	9703 00 00
8.	Photographs, films and negatives thereof [1]	3704 3705 3706 4911 91 80
9.	Incunabula and manuscripts, including maps and musical scores, singly or in collections [1]	9702 00 00 9706 00 00 4901 10 00 4901 99 00 4904 00 00 4905 91 00 4905 99 00 4906 00 00
10.	Books more than 100 years old, singly or in collections	9705 00 00 9706 00 00
11.	Printed maps more than 200 years old	9706 00 00
12.	Archives, and any elements thereof, of any kind or any medium which are more than 50 years old	3704 3705 3706 4901 4906 9705 00 00 9706 00 00
13. (a)	Collections [2] and specimens from zoological, botanical, mineralogical or anatomical collections;	9705 00 00
(b)	Collections [2] of historical, palaeontological, ethnographic or numismatic interest	9705 00 00

[1] Which are more than 50 years old and do not belong to their originators.

[2] As defined by the Court of Justice in its judgment in Case 252/84, as follows: 'Collectors' pieces within the meaning of heading No 97.05 of the Common Customs Tariff are articles which possess the requisite characteristics for inclusion in a collection, that is to say, articles which are relatively rare, are not normally used for their original purpose, are the subject of special transactions outside the normal trade in similar utility articles and are of high value'.

14. Means of transport more than 75 years old	9705 00 00 Chapters 86-89
15. Any other antique items not included in categories A.1 to A.14	
(a) between 50 and 100 years old	
toys, games	Chapter 95
glassware	7013
articles of goldsmiths' or silversmiths' wares	7114
furniture	Chapter 94
optical, photographic or cinematographic apparatus	Chapter 90
musical instruments	Chapter 92
clocks and watches and parts thereof	Chapter 91
articles of wood	Chapter 44
pottery	Chapter 69
tapestries	5805 00 00
carpets	Chapter 57
wallpaper	4814
arms	Chapter 93
(b) more than 100 years old	9706 00 00

The cultural objects in categories A.1 to A.15 are covered by this Regulation only if their value corresponds to, or exceeds, the financial thresholds under B.

B. Financial thresholds applicable to certain categories under A (in euro)

Value:

Whatever the value

— 1 (Archaeological objects)

— 2 (Dismembered monuments)

— 9 (Incunabula and manuscripts)

— 12 (Archives)

15 000

— 5 (Mosaics and drawings)

— 6 (Engravings)

— 8 (Photographs)

— 11 (Printed maps)

30 000

— 4 (Watercolours, gouaches and pastels)

50 000

— 7 (Statuary)

— 10 (Books)

— 13 (Collections)

— 14 (Means of transport)

— 15 (Any other object)

150 000

— 3 (Pictures)

The assessment of whether or not the conditions relating to financial value are fulfilled must be made when an application for an export licence is submitted. The financial value is that of the cultural object in the Member State referred to in Article 2(2).

For the Member States which do not have the euro as their currency, the values expressed in euro in Annex I shall be converted and expressed in national currencies at the rate of exchange on 31 December 2001 published in the *Official Journal of the European Communities*. This countervalue in national currencies shall be reviewed every two years with effect from 31 December 2001. Calculation of this countervalue shall be based on the average daily value of those currencies, expressed in euro, during the 24 months ending on the last day of August preceding the revision which takes effect on 31 December. This method of calculation shall be reviewed, on a proposal from the Commission, by the Advisory Committee on Cultural Goods, in principle two years after the first application. For each revision, the values expressed in euro and their countervalues in national currency shall be published periodically in the *Official Journal of the European Union* in the first days of the month of November preceding the date on which the revision takes effect.

ANNEX II

Repealed Regulation with its successive amendments

Council Regulation (EEC) No 3911/92 (OJ L 395, 31.12.1992, p. 1)	
Council Regulation (EC) No 2469/96 (OJ L 335, 24.12.1996, p. 9)	
Council Regulation (EC) No 974/2001 (OJ L 137, 19.5.2001, p. 10)	
Council Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1)	Annex I, point 2 only

---

ANNEX III

CORRELATION TABLE

Regulation (EEC) No 3911/92	This Regulation
Article 1	Article 1
Article 2(1)	Article 2(1)
Article 2(2), first subparagraph, introductory wording	Article 2(2), first subparagraph, introductory wording
Article 2(2), first subparagraph, first indent	Article 2(2), first subparagraph, point (a)
Article 2(2), first subparagraph, second indent	Article 2(2), first subparagraph, point (b)
Article 2(2), second subparagraph	Article 2(2), second subparagraph
Article 2(2), third subparagraph	Article 2(2), third subparagraph
Article 2(2), fourth subparagraph	Article 2(2), fourth subparagraph
Article 2(3)	Article 2(3)
Article 2(4)	Article 2(4)
Articles 3 to 9	Articles 3 to 9
Article 10, first paragraph	Article 10(1), first subparagraph
Article 10, second paragraph	Article 10(1), second subparagraph
Article 10, third paragraph	Article 10(2), first subparagraph
Article 10, fourth paragraph	—
Article 10, fifth paragraph	Article 10(2), second subparagraph
—	Article 11
Article 11	Article 12
Annex, points A.1, A.2 and A.3	Annex I, points A.1, A.2 and A.3
Annex, point A.3A	Annex I, point A.4
Annex, point A.4	Annex I, point A.5
Annex, point A.5	Annex I, point A.6
Annex, point A.6	Annex I, point A.7
Annex, point A.7	Annex I, point A.8
Annex, point A.8	Annex I, point A.9
Annex, point A.9	Annex I, point A.10
Annex, point A.10	Annex I, point A.11
Annex, point A.11	Annex I, point A.12
Annex, point A.12	Annex I, point A.13
Annex, point A.13	Annex I, point A.14
Annex, point A.14	Annex I, point A.15
Annex, point B	Annex I, point B
—	Annex II
—	Annex III

COMMISSION REGULATION (EC) No 117/2009

of 9 February 2009

establishing the standard import values for determining the entry price of certain fruit and vegetables

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) [1],

Having regard to Commission Regulation (EC) No 1580/2007 of 21 December 2007 laying down implementing rules for Council Regulations (EC) No 2200/96, (EC) No 2201/96 and (EC) No 1182/2007 in the fruit and vegetable sector [2], and in particular Article 138(1) thereof,

Whereas:

Regulation (EC) No 1580/2007 lays down, pursuant to the outcome of the Uruguay Round multilateral trade negotiations, the criteria whereby the Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex XV, Part A thereto,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 138 of Regulation (EC) No 1580/2007 are fixed in the Annex hereto.

Article 2

This Regulation shall enter into force on 10 February 2009.

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

Done at Brussels, 9 February 2009.

For the Commission
Jean-Luc DEMARTY
Director-General for Agriculture and Rural Development

---

[1] OJ L 299, 16.11.2007, p. 1.
[2] OJ L 350, 31.12.2007, p. 1.

ANNEX

Standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)

CN code	Third country code (1)	Standard import value
0702 00 00	IL	111,0
	JO	68,6
	MA	45,0
	TN	134,4
	TR	89,8
	ZZ	89,8
0707 00 05	JO	155,5
	MA	134,2
	TR	151,1
	ZZ	146,9
0709 90 70	MA	116,3
	TR	117,2
	ZZ	116,8
0709 90 80	EG	126,4
	ZZ	126,4
0805 10 20	EG	47,5
	IL	54,0
	MA	59,3
	TN	40,6
	TR	65,8
	ZA	44,9
	ZZ	52,0
0805 20 10	IL	152,1
	MA	100,5
	TR	52,0
	ZZ	101,5
0805 20 30, 0805 20 50, 0805 20 70, 0805 20 90	CN	72,2
	IL	87,2
	JM	101,6
	MA	158,6
	PK	40,0
	TR	62,7
	ZZ	87,1
0805 50 10	EG	64,1
	MA	67,1
	TR	53,5
	ZZ	61,6
0808 10 80	AR	91,9
	CA	90,4
	CL	67,8
	CN	82,1
	MK	32,6
	US	114,6
	ZZ	79,9
0808 20 50	AR	107,7
	CL	73,7
	CN	58,5
	US	108,5
	ZA	104,3
	ZZ	90,5

(1) Nomenclature of countries laid down by Commission Regulation (EC) No 1833/2006 (OJ L 354, 14.12.2006, p. 19). Code 'ZZ' stands for 'of other origin'.

COMMISSION REGULATION (EC) No 118/2009

of 9 February 2009

amending the representative prices and additional import duties for certain products in the sugar sector fixed by Regulation (EC) No 945/2008 for the 2008/2009 marketing year

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (single CMO Regulation) [1],

Having regard to Commission Regulation (EC) No 951/2006 of 30 June 2006 laying down detailed rules for the implementation of Council Regulation (EC) No 318/2006 as regards trade with third countries in the sugar sector [2], and in particular Article 36(2), second subparagraph, second sentence thereof,

Whereas:

(1) The representative prices and additional duties applicable to imports of white sugar, raw sugar and certain syrups for the 2008/2009 marketing year are fixed by Commission Regulation (EC) No 945/2008 [3]. These prices and duties have been last amended by Commission Regulation (EC) No 100/2009 [4].

(2) The data currently available to the Commission indicate that those amounts should be amended in accordance with the rules and procedures laid down in Regulation (EC) No 951/2006,

HAS ADOPTED THIS REGULATION:

Article 1

The representative prices and additional duties applicable to imports of the products referred to in Article 36 of Regulation (EC) No 951/2006, as fixed by Regulation (EC) No 945/2008 for the 2008/2009, marketing year, are hereby amended as set out in the Annex hereto.

Article 2

This Regulation shall enter into force on 10 February 2009.

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

Done at Brussels, 9 February 2009.

For the Commission

Jean-Luc DEMARTY

Director-General for Agriculture and Rural Development

---

[1] OJ L 299, 16.11.2007, p. 1.
[2] OJ L 178, 1.7.2006, p. 24.
[3] OJ L 258, 26.9.2008, p. 56.
[4] OJ L 34, 4.2.2009, p. 3.

ANNEX

Amended representative prices and additional import duties applicable to white sugar, raw sugar and products covered by CN code 1702 90 95 from 10 February 2009

(EUR)

CN code	Representative price per 100 kg net of the product concerned	Additional duty per 100 kg net of the product concerned
1701 11 10 (1)	25,95	3,50
1701 11 90 (1)	25,95	8,56
1701 12 10 (1)	25,95	3,37
1701 12 90 (1)	25,95	8,13
1701 91 00 (2)	29,84	10,31
1701 99 10 (2)	29,84	5,79
1701 99 90 (2)	29,84	5,79
1702 90 95 (3)	0,30	0,35

(1) For the standard quality defined in point III of Annex IV to Regulation (EC) No 1234/2007.
(2) For the standard quality defined in point II of Annex IV to Regulation (EC) No 1234/2007.
(3) Per 1 % sucrose content.

COMMISSION REGULATION (EC) No 119/2009

of 9 February 2009

laying down a list of third countries or parts thereof, for imports into, or transit through, the Community of meat of wild leporidae, of certain wild land mammals and of farmed rabbits and the veterinary certification requirements

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 the first subparagraph of point 1 of Article 8, Article 9(2)(b) and Article 9(4)(b) and (c) thereof,

Having regard to Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs [2], and in particular Article 12 thereof,

Having regard to 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 [3], and in particular Article 9 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 [4], and in particular Articles 11(1) and 14(4) thereof,

Having regard to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules [5], and in particular Article 48(1) thereof,

Whereas:

(1) Commission Decision 2000/585/EC [6] draws up a list of third countries from which Member States are to authorise imports of rabbit meat and certain wild and farmed game meat, and lays down the animal and public health and the veterinary certification conditions for such imports.

(2) In the interests of consistency of Community legislation, Community rules for imports of meat of wild leporidae, of certain wild land mammals and of farmed rabbits should take into account the public health requirements laid down in Regulations (EC) No 852/2004, (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004.

(3) The measures provided for in this Regulation shall be without prejudice to legislation implementing Council Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein [7].

(4) With a view to harmonising Community conditions for imports into the Community of the commodities concerned, as well as making them more transparent and simplifying the legislative procedure for amending such conditions, those conditions should be set out in the appropriate model veterinary certificates set out in this Regulation.

(5) The veterinary certificates for imports into and transit, including storage during transit, through the Community of meat of wild leporidae, of certain wild land mammals and of farmed rabbits should comply with the appropriate standard models set out in Annex I to Commission Decision 2007/240/EC of 16 April 2007 laying down new veterinary certificates for importing live animals, semen, embryos, ova and products of animal origin into the Community pursuant to Decisions 79/542/EEC, 92/260/EEC, 93/195/EEC, 93/196/EEC, 93/197/EEC, 95/328/EC, 96/333/EC, 96/539/EC, 96/540/EC, 2000/572/EC, 2000/585/EC, 2000/666/EC, 2002/613/EC, 2003/56/EC, 2003/779/EC, 2003/804/EC, 2003/858/EC, 2003/863/EC, 2003/881/EC, 2004/407/EC, 2004/438/EC, 2004/595/EC, 2004/639/EC and 2006/168/EC [8].

---

[1] OJ L 18, 23.1.2003, p. 11.
[2] OJ L 139, 30.4.2004, p. 1, corrected by OJ L 226, 25.6.2004, p. 3.
[3] OJ L 139, 30.4.2004, p. 55, as corrected by OJ L 226, 25.6.2004, p. 22.
[4] OJ L 139, 30.4.2004, p. 206, as corrected by OJ L 226, 25.6.2004, p. 83.
[5] OJ L 165, 30.4.2004, p. 1, as corrected by OJ L 191, 28.5.2004, p. 1.
[6] OJ L 251, 6.10.2000, p. 1.
[7] OJ L 61, 3.3.1997, p. 1.
[8] OJ L 104, 21.4.2007, p. 37.

(6) The model veterinary certificates, set out in this Regulation, for imports into and transit, including storage during transit, through the Community of meat of wild leporidae, of certain wild land mammals and of farmed rabbits should also be compatible with the Traces system, as provided for in Commission Decision 2004/292/EC of 30 March 2004 on the introduction of the Traces system ([1]).

(7) The list of third countries or parts thereof, listed in Annex II to Council Decision 79/542/EEC ([2]) should be used for imports into, or transit through, the Community of meat of wild leporidae and of farmed rabbits. The list of countries should be laid down for imports into or transit through, the Community of meat of wild land mammals other than ungulates and leporidae.

(8) Specific conditions for transit via the Community of consignments to and from Russia should be provided for, owing to the geographical situation of Kaliningrad which only concerns Latvia, Lithuania and Poland.

(9) To avoid any disruption of trade, the use of the veterinary certificates issued in accordance with Decision 2000/585/EC should be authorised during a transitional period.

(10) In the interests of clarity of Community legislation, Commission Decision 2000/585/EC should be repealed and replaced by this Regulation.

(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

Subject matter and scope

1. This Regulation lays down:

(a) a list of third countries or parts thereof from which the following commodities may be imported into, or transit through the Community:

(i) meat of wild leporidae not containing offal, except for unskinned and uneviscerated wild leporidae;

(ii) meat of wild land mammals other than ungulates and leporidae, not containing offal;

(iii) meat of farmed rabbits;

(b) the veterinary certification requirements for the commodities listed in points (i), (ii) and (iii) (the commodities).

2. Without prejudice to the restriction provided for in Article 5(2), for the purposes of this Regulation, transit covers storage during transit (including putting into storage, as referred to in Article 12(4) and Article 13 of Council Directive 97/78/EC ([3])).

3. This Regulation shall apply without prejudice to:

(i) specific certification requirements provided for in Community agreements with third countries;

(ii) the relevant rules on certification contained within legislation implementing Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade therein.

Article 2

Definition

For the purposes of this Regulation, 'wild leporidae' means wild rabbits and hares.

Article 3

Lists of third countries or parts thereof from which commodities may be imported into, or transit through, the Community

The commodities shall only be imported into, or transit through, the Community from a third country or parts thereof listed or referred to in Part 1 of Annex I.

Article 4

Veterinary certification

1. Commodities imported into the Community shall be accompanied by a veterinary certificate drawn up in accordance with the model certificate set out in Annex II, for the commodity concerned, completed in accordance with the notes set out in Part 4 of Annex I.

([1]) OJ L 94, 31.3.2004, p. 63.
([2]) OJ L 146, 14.6.1979, p. 15.
([3]) OJ L 24, 30.1.1998, p. 9.

2. Commodities in transit through the Community shall be accompanied by a certificate drawn up in accordance with the model certificate set out in Annex III.

3. Compliance with the additional guarantees, as required for a certain Member State or part thereof in columns 4, 6 and 8 of the Table in Part 1 of Annex I and as described in Part 3 of Annex I, shall be certified by completing the appropriate section in the veterinary certificate for the commodity concerned.

4. Electronic certification and other agreed systems harmonised at Community level may be used.

Article 5

Derogation for transit through Latvia, Lithuania and Poland

1. By way of derogation from Article 4(2), transit by road or by rail shall be authorised between the border inspection posts in Latvia, Lithuania and Poland listed in the Annex to Commission Decision 2001/881/EC [1], of consignments of commodities coming from and bound for Russia, directly or via another third country, where the following conditions are met:

(a) the consignment is sealed with a serially numbered seal by the official veterinarian at the border inspection post of entry;

(b) the documents accompanying the consignment, as provided for in Article 7 of Directive 97/78/EC, are stamped with the words 'Only for transit to Russia via the EC' on each page by the official veterinarian at the border inspection post of entry;

(c) the procedural requirements provided for in Article 11 of Directive 97/78/EC are complied with;

(d) the consignment is certified as acceptable for transit on the common veterinary entry document issued by the official veterinarian at the border inspection post of entry.

2. The consignments, as referred to in paragraph 1, may not be unloaded or put into storage, as referred to in Article 12(4) or in Article 13 of Directive 97/78/EC, within the Community.

3. Regular audits shall be conducted by the competent authority to ensure that the number of consignments, as referred to in paragraph 1, and the corresponding quantities of products leaving the Community correspond with the number and quantities entering the Community.

Article 6

Repeal

Decision 2000/585/EC is repealed.

References to the repealed Decision shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex IV.

Article 7

Transitional provisions

Commodities in respect of which the relevant veterinary certificates have been issued in accordance with Decision 2000/585/EC may be imported into or transit through the Community until 30 June 2009.

Article 8

Entry into force and applicability

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from 1 June 2009.

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

Done at Brussels, 9 February 2009.

For the Commission
Androulla VASSILIOU
Member of the Commission

[1] OJ L 326, 11.12.2001, p. 44.

ANNEX I

MEAT OF WILD LEPORIDAE, OF CERTAIN WILD LAND MAMMALS AND OF FARMED RABBITS

PART 1

List of third countries and parts thereof and additional guarantees

Country	Code of territory	Leporidae				Wild land mammals other than ungulates and leporidae	
		Wild		Farmed rabbits			
		MC	AG	MC	AG	MC	AG
1	2	3	4	5	6	7	8
Australia	AU	WL		RM		WM	
Canada	CA	WL		RM		WM	
Greenland	GL	WL		RM		WM	
New Zealand	NZ	WL		RM		WM	
Russia	RU	WL		RM		WM	
Any other third country or part thereof listed in columns 1 and 3 of the table in Part 1 of Annex II to Decision 79/542/EEC		WL		RM			

MC: Model veterinary certificate.
AG: Additional guarantees.

PART 2

Model veterinary certificates

Model(s):

'WL': Model veterinary certificate for meat of wild leporidae (rabbits and hares)

'WM': Model veterinary certificate for meat of wild land mammals other than ungulates and leporidae

'RM': Model veterinary certificate for meat of farmed rabbits

PART 3

Additional guarantees

PART 4

Notes for veterinary certification

(a) Veterinary certificates based on the models in Part 2 of this Annex and following the layout of the model that corresponds to the commodity concerned shall be issued by the exporting third country or part thereof. They shall contain, in the order appearing in the model, the attestations that are required for any third country and, where applicable, those additional health requirements required for the exporting third country or part thereof.

Where additional guarantees are required by the Member State of destination for the commodity concerned, these shall also be entered on the original of the veterinary certificate.

(b) A separate, single certificate must be presented for each consignment of the commodity concerned, exported to the same destination from a territory appearing in column 2 of the table in Part 1 of this Annex and transported in the same railway wagon, lorry, aircraft or ship.

(c) The original of certificates shall consist of a single page printed on both sides or, where more text is required, such that all the pages form a whole and cannot be separated.

(d) The certificate shall be drawn up in at least one official language of the Member State where the border inspection takes place and in one official language of the Member State of destination. However, those Member States may allow another Community language instead of their own, accompanied, if necessary, by an official translation.

(e) Where additional pages are attached to the certificate for the purposes of identifying the items making up the consignment, such additional pages shall also be considered to form part of the original of the certificate, provided the signature and stamp of the certifying official veterinarian appear on each page.

(f) Where the certificate, including any additional pages as provided for in (e), comprises more than one page, each page shall be numbered '–x (*page number*) of y (*total number of pages*)–' on the bottom and shall bear the code number of the certificate allocated by the competent authority on the top.

(g) The original of the certificate must be completed and signed by an official veterinarian not more than 24 hours prior to loading of the consignment for imports into the Community, unless otherwise stated in the Community legislation. To that end, the competent authority of the exporting third country shall ensure that principles of certification equivalent to those laid down in Council Directive 96/93/EC [1] are followed.

The colour of the signature shall be different from that of the printing. The same rule shall apply to stamps other than embossed stamps.

(h) The original of the certificate must accompany the consignment as far as the border inspection post of entry into the European Community.

[1] OJ L 13, 16.1.1997, p. 28.

ANNEX II

MODEL VETERINARY CERTIFICATES FOR THE IMPORT OF MEAT OF WILD LEPORIDAE, CERTAIN WILD LAND MAMMALS AND FARMED RABBITS INTO THE EUROPEAN COMMUNITY

Model veterinary certificate for the import of meat of wild leporidae (rabbits and hares) (1) (WL)

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor Name Address Tel. No		I.2. Certificate reference No	I.2.a.
		I.3. Central Competent Authority	
		I.4. Local Competent Authority	
I.5. Consignee Name Address Postal code Tel. No		I.6.	
I.7. Country of origin ISO code	I.8. Region of origin Code	I.9. Country of destination ISO code	I.10. Region of destination Code
I.11. Place of origin Name Approval number Address		I.12. Place of destination	
I.13. Place of loading		I.14. Date of departure	
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification: Documentary references:		I.16. Entry BIP in EU	
		I.17. No(s) of CITES	
I.18. Description of commodity		I.19. Commodity code (HS code) **02.08.10**	
			I.20. Quantity
I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐			I.22. Number of packages
I.23. Identification of container/Seal No			I.24. Type of packaging
I.25. Commodities certified for: Human consumption ☐			
I.26.		I.27. For import or admission into EU ☐	

I.28. Identification of the commodities

Species (Scientific name)	Nature of commodity	Approval No of establishments Abattoir	Number of packages	Net weight

COUNTRY **WL (meat of wild leporidae (rabbits and hares))**

Part II: Certification

II.	HEALTH INFORMATION	II.a. Certificate reference No	II.b.

II.1. **Public health attestation**

I, the undersigned, official veterinarian, declare that I am aware of the relevant provisions of Regulations (EC) No 178/2002, (EC) No 852/2004, (EC) No 853/2004 and (EC) No 854/2004 and hereby certify that the meat of wild leopridae (rabbits and hares) ([1]) described in this certificate has been obtained in accordance with those requirements and, in particular that:

(a) it comes from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004;

(b) it has been obtained in compliance with Section IV of Annex III to Regulation (EC) No 853/2004;

(c) it has been found fit for human consumption following post-mortem inspections carried out in accordance with Section I, Chapter II and Section IV, Chapter VIII of Annex I to Regulation (EC) No 854/2004;

(d) it has been marked with an identification mark in accordance with Section I of Annex II to Regulation (EC) No 853/2004;

([2]) either [(e) in the case of meat of skinned and eviscerated wild leporidae, the meat was obtained and inspected in accordance with Regulations (EC) Nos 853/2004 and 854/2004;]

([2]) or [(e) in the case of unskinned and uneviscerated wild leporidae:

— the meat was chilled to + 4 °C or below for a maximum of 15 days prior to the intended time of import but has not been frozen or deep-frozen;

— an official veterinary health inspection has been carried out on a representative sample of the carcases and the meat was obtained and inspected in accordance with Regulations (EC) Nos 853/2004 and 854/2004;

— the meat has been identified by affixing an official mark of origin, the details of which are recorded in the box 1.28;]

(f) the guarantees covering live animals and products thereof provided by the residue plans submitted in accordance with Directive 96/23/EC, and in particular Article 29 thereof, are fulfilled;

(g) it has been stored and transported in accordance with the relevant requirements of Section IV of Annex III to Regulation (EC) No 853/2004.

II.2. **Animal health attestation**

I, the undersigned official veterinarian, hereby certify that the meat of wild leopridae (rabbits and hares) ([1]) described in this certificate:

II.2.1 (a) was obtained from wild leporidae which were killed in the territory described in Annex I to Regulation (EC) No 119/2009 with the code ..... ([3]) and in a hunting area where during the last 40 days no animal health restrictions for viral haemorrhagic disease, tularaemia and myxomatosis have been applied;

(b) was obtained from leporidae which, after killing, were transported within 12 hours to a collection centre and/or an approved game handling establishment for chilling;

II.2.2 comes from

([4]) either [a collection centre;]

([4]) or [an approved game handling establishment;]

([4]) or [a collection centre and an approved game handling establishment;]

which at the time of dressing, was (were) not subject to animal health restrictions for diseases listed by the World Organisation for Animal Health (OIE) to which the animals are susceptible;

II.2.3 has during all stages of its production, been handled, stored and transported in accordance with the animal health requirements of Directive 2002/99/EC and strictly separated from meat:

— not conforming to the requirements laid down in Directive 2002/99/EC,

— not conforming to the requirements laid down in Regulation (EC) No 119/2009;

II.2.4 was obtained from wild leporidae which were killed on or between .....;

COUNTRY **WL (meat of wild leporidae (rabbits and hares))**

II. HEALTH INFORMATION	II.a. Certificate reference No	II.b.

III. ADDITIONAL GUARANTEES

([2]) [I, the undersigned, official veterinarian, certify that:

.....

(Additional guarantees when required in part 3 of Annex I and as described in Part 3 of Annex I to Regulation (EC) No 119/2009)].

Notes

Part I

— Box reference I.7: name of the country of origin which must be the same as the country of export.

— Box reference I.8: provide the code for the territory of origin, if necessary, as it appears in column 2 of Part 1 of Annex I to Regulation (EC) No 119/2009.

— Box reference I.11: Name, address and approval number of establishment of dispatch.

— Box reference I.12: where the meat has to undergo a post-mortem inspection after skinning, the name and address of the game handling establishment of destination in the Member State must be inserted.

— Box reference I.15: Indicate the registration number(s) of railway wagons and lorries, the names of ships and, if known, the flight numbers of aircraft. In the case of transport in containers, the total number of these and their registration and where there is a serial number of the seal it has to be indicated in box I.23.

— Box reference I.28: (Nature of commodity): select one of the following: 'skinned and eviscerated leporidae', 'cuts', 'unskinned and uneviscerated leporidae'.

(Abattoir): includes game handling establishments.

Part II

([1]) Meat of wild leporidae (rabbits and hares) excluding offal except for unskinned and uneviscerated leporidae.

([2]) Keep if appropriate.

([3]) Code of the territory as it appears in column 2 of Part 1 of Annex I to Regulation (EC) No 119/2009.

([4]) Keep as appropriate.

— The signature and the seal must be in a different colour from that of the printing.

— Note for the importer: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection point.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

Model Veterinary certificate for the import of meat (1) of wild land mammals other than ungulates and leporidae (WM)

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor Name Address Tel. No			I.2. Certificate reference No	I.2.a.	
			I.3. Central Competent Authority		
			I.4. Local Competent Authority		
I.5. Consignee Name Address Postal code Tel. No			I.6.		
I.7. Country of origin	ISO code	I.8. Region of origin Code	I.9. Country of destination	ISO code	I.10. Region of destination Code
I.11. Place of origin Name Approval number Address			I.12. Place of destination		
I.13. Place of loading			I.14. Date of departure		
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification: Documentary references:			I.16. Entry BIP in EU I.17. No(s) of CITES		
I.18. Description of commodity			I.19. Commodity code (HS code) **02.08.90**		
			I.20. Quantity		
I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐			I.22. Number of packages		
I.23. Identification of container/Seal No			I.24. Type of packaging		
I.25. Commodities certified for: Human consumption ☐					
I.26.			I.27. For import or admission into EU ☐		

I.28. Identification of the commodities

Species (Scientific name)	Nature of commodity	Approval No of establishments Abattoir	Number of packages	Net weight

COUNTRY **WM (meat of wild land mammals other than ungulates and *leporidae*)**

Part II: Certification

II. HEALTH INFORMATION	II.a. Certificate reference No	II.b.

II.1. **Public health attestation**

I, the undersigned, official veterinarian, declare that I am aware of the relevant provisions of Regulations (EC) No 178/2002, (EC) No 852/2004, (EC) No 853/2004 and (EC) No 854/2004 and hereby certify that the meat of wild land mammals other than ungulates and leporidae [1] described in this certificate has been obtained in accordance with those requirements and, in particular that:

(a) it comes from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004;

(b) it has been obtained in compliance with Section IV of Annex III to Regulation (EC) No 853/2004;

([2]) [(c) it fulfils the requirements of Commission Regulation (EC) No 2075/2005 laying down specific rules on official controls for Trichinella in meat, and in particular has been subjected to an examination by a digestion method with negative results];

(d) it has been found fit for human consumption following post-mortem inspections carried out in accordance with Section IV, Chapters VIII and IX of Annex I to Regulation (EC) No 854/2004;

(e) the carcass or parts of the carcass of large wild mammals have been marked with a health mark in accordance with Section I, Chapter III of Annex I to Regulation (EC) No 854/2004;

([4]) either [(f) the carcass or parts of the carcass of small wild mammals have been marked with an identification mark in accordance with Section I, of Annex II to Regulation (EC) No 853/2004;]

([4]) or [(f) the packages of the meat of small or large wild mammals has been marked with an identification mark in accordance with Section I, of Annex II to Regulation (EC) No 853/2004;]

(g) the guarantees covering live animals and products thereof provided by the residue plans submitted in accordance with Directive 96/23/EC, and in particular Article 29 thereof, are fulfilled;

(h) it has been stored and transported in accordance with the relevant requirements of Section IV of Annex III to Regulation (EC) No 853/2004;

II.2. **Animal health attestation**

I, the undersigned official veterinarian, hereby certify that the meat of wild land mammals other than ungulates and leporidae [1] described in this certificate:

II.2.1 (a) was obtained from wild land mammals other than ungulates and leporidae which were killed in the territory described in Annex I to Regulation (EC) No 119/2009 with the code ..... ([3]) and in a hunting area where during the last 30 days no animal health restrictions because of outbreaks of disease to which these animals are susceptible have been applied;

(b) was obtained from wild land mammals other than ungulates and leporidae which, after killing, were transported within 12 hours to a collection centre and/or an approved game handling establishment for chilling;

II.2.2 comes from

([4]) either [a collection centre;]

([4]) or [an approved game handling establishment;]

([4]) or [a collection centre and an approved game handling establishment;]

which at the time of dressing, was (were) not subject to animal health restrictions for diseases listed by the World Organisation for Animal Health (OIE) to which the animals are susceptible;

II.2.3 has during all stages of its production, been handled, stored and transported in accordance with the animal health requirements of Directive 2002/99/EC and strictly separated from meat:

— not conforming to the requirements laid down in Directive 2002/99/EC,

— not conforming to the requirements laid down in Regulation (EC) No 119/2009;

II.2.4 was obtained from wild land mammals other than ungulates and leporidae which were killed on or between ..... ;

COUNTRY **WM (meat of wild land mammals other than ungulates and *leporidae*)**

II.	HEALTH INFORMATION	II.a. Certificate reference No	II.b.

III. ADDITIONAL GUARANTEES

([5]) [I, the undersigned, official veterinarian, certify that:

.....

(Additional guarantees when required in part 3 of Annex I and as described in Part 3 of Annex I to Regulation (EC) No 119/2009)].

Notes

Part I

— Box reference I.7: name of the country of origin which must be the same as the country of export.

— Box reference I.8: provide the code for the territory of origin, if necessary, as it appears in column 2 of Part 1 of Annex I to Regulation (EC) No 119/2009.

— Box reference I.11: Name, address and approval number of establishment of dispatch.

— Box reference I.15: Indicate the registration number(s) of railway wagons and lorries, the names of ships and, if known, the flight numbers of aircraft. In the case of transport in containers, the total number of these and their registration and where there is a serial number of the seal it has to be indicated in box I.23.

— Box reference I.28: (Abattoir) includes game handling establishments.

Part II

([1]) Excluding offal.

([2]) Only for species susceptible for trichinellosis.

([3]) Code of the territory as it appears in column 2 of Part 1 of Annex I to Regulation (EC) No 119/2009.

([4]) Keep as appropriate.

([5]) Keep if appropriate.

— The signature and the seal must be in a different colour from that of the printing.

— Note for the importer: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection point.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

Model Veterinary certificate for the import of meat of farmed rabbits (1) (RM)

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor Name Address Tel. No			I.2. Certificate reference No	I.2.a.
			I.3. Central Competent Authority	
			I.4. Local Competent Authority	
I.5. Consignee Name Address Postal code Tel. No			I.6.	
I.7. Country of origin ISO code	I.8. Region of origin Code		I.9. Country of destination ISO code	I.10. Region of destination Code
I.11. Place of origin Name Approval number Address			I.12. Place of destination	
I.13. Place of loading			I.14. Date of departure	
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification: Documentary references:			I.16. Entry BIP in EU	
			I.17. No(s) of CITES	
I.18. Description of commodity			I.19. Commodity code (HS code) **02.08.10**	
				I.20. Quantity
I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐				I.22. Number of packages
I.23. Identification of container/Seal No				I.24. Type of packaging
I.25. Commodities certified for: Human consumption ☐				
I.26.			I.27. For import or admission into EU ☐	

I.28. Identification of the commodities

Species (Scientific name)	Nature of commodity	Approval No of establishments: Abattoir	Manufacturing plant	Cold store	Number of packages	Net weight

COUNTRY **RM (meat of farmed rabbits)**

Part II: Certification

II. HEALTH INFORMATION	II.a. Certificate reference No	II.b.

II.1. **Public health attestation**

I, the undersigned, official veterinarian, declare that I am aware of the relevant provisions of Regulations (EC) No 178/2002, (EC) No 852/2004, (EC) No 853/2004 and (EC) No 854/2004 and hereby certify that the meat of farmed rabbits ([1]) described in this certificate has been obtained in accordance with those requirements and, in particular that:

(a) it comes from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004;

(b) it has been obtained in compliance with Section II of Annex III to Regulation (EC) No 853/2004;

(c) it has been found fit for human consumption following ante-mortem and post-mortem inspections carried out in accordance with Section I, Chapter II and section IV, Chapters VI and IX of Annex I to Regulation (EC) No 854/2004;

(d) it has been marked with an identification mark in accordance with Section I of Annex II to Regulation (EC) No 853/2004;

(e) the guarantees covering live animals and products thereof provided by the residue plans submitted in accordance with Directive 96/23/EC, and in particular Article 29 thereof, are fulfilled;

(f) it has been stored and transported in accordance with the relevant requirements of Section II of Annex III to Regulation (EC) No 853/2004;

II.2. **Animal health attestation**

I, the undersigned official veterinarian, hereby certify that the meat of farmed rabbits ([1]) described in this certificate:

II.2.1 has been obtained from farmed rabbits slaughtered in the territory described in Annex I to Regulation (EC) No 119/2009 with the code ..... ([2]) where they have been kept for at least six weeks before slaughter or since birth in the case of animals less than six weeks old;

II.2.2 has been obtained from rabbits which:

(a) come from farms or areas where no animal health restrictions have been in force for at least the previous 40 days in response to outbreaks of viral haemorrhagic disease, tularaemia or myxomatosis;

(b) have not been slaughtered under any animal-health scheme for the control or eradication of rabbit diseases;

(c) during transport to the slaughterhouse, did not come into contact with rabbits infected with viral haemorrhagic disease, tularaemia or myxomatosis;

(d) have not been in contact at any time during slaughter, cutting, storage or transport with rabbits or meat of lower health status;

II.2.3 comes from

([3]) either [an approved slaughterhouse;]

([3]) or [an approved game handling establishment;]

([4]) II.2.4 was obtained from farmed rabbits which were slaughtered on or between ..... ;

III. IDENTIFICATION

Batches of rabbits were so identified that their holdings of origin could be traced.

IV. ADDITIONAL GUARANTEES

([5]) [I, the undersigned, official veterinarian, certify that:

.....

(Additional guarantees when required in part 3 of Annex I and as described in Part 3 of Annex I to Regulation (EC) No 119/2009)].

V. ANIMAL WELFARE ATTESTATION

I, the undersigned official veterinarian, hereby certify that I have read and understood Directive 93/119/EC and that the meat described in this certificate comes from farmed rabbits that have been treated in accordance with the relevant provisions of Directive 93/119/EC in the slaughterhouse before and at the time of slaughter or killing.

COUNTRY **RM (meat of farmed rabbits)**

II. HEALTH INFORMATION	II.a. Certificate reference No	II.b.

Notes

Part I

— Box reference I.7: name of the country of origin which must be the same as the country of export.

— Box reference I.8: provide the code for the territory of origin, if necessary, as it appears in column 2 of Part 1 of Annex I to Regulation (EC) No 119/2009.

— Box reference I.11: Name, address and approval number of establishment of dispatch.

— Box reference I.15: Indicate the registration number(s) of railway wagons and lorries, the names of ships and, if known, the flight numbers of aircraft. In the case of transport in containers, the total number of these and their registration and where there is a serial number of the seal it has to be indicated in box I.23.

Part II

([1]) Meat of farmed rabbits means all parts of domestic rabbits which are fit for human consumption.

([2]) Code of the territory as it appears in column 2 of Part 1 of Annex I to Regulation (EC) No 119/2009.

([3]) Keep as appropriate.

([4]) Indicate the date or dates of slaughter.

([5]) Keep if appropriate.

— The signature and the seal must be in a different colour from that of the printing.

— Note for the importer: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection point.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

ANNEX III

(as referred to in Article 4(2))

Model veterinary certificate for the transit/storage of meat of wild leporidae, farmed rabbits and wild land mammals other than ungulates

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor Name Address Tel. No		I.2. Certificate reference No	I.2.a.
		I.3. Central Competent Authority	
		I.4. Local Competent Authority	
I.5. Consignee Name Address Postal code Tel. No		I.6. Person responsible for the load in EU Name Address Postal code Tel. No	
I.7. Country of origin ISO code	I.8. Region of origin Code	I.9. Country of destination ISO code	I.10. Region of destination Code
I.11. Place of origin Name Approval number Address		I.12. Place of destination Customs warehouse ☐ Ship supplier ☐ Name Approval number Address Postal code	
I.13. Place of loading		I.14. Date of departure	
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification: Documentary references:		I.16. Entry BIP in EU I.17. No(s) of CITES	
I.18. Description of commodity		I.19. Commodity code (HS code)	I.20. Quantity
I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐			I.22. Number of packages
I.23. Identification of container/Seal No			I.24. Type of packaging
I.25. Commodities certified for: Human consumption ☐ Animal feedingstuff ☐ Further process ☐ Technical use ☐ Other ☐			
I.26. For transit through EU to third Country ☐ Third country ISO code		I.27.	

I.28. Identification of the commodities

Species (Scientific name)	Nature of commodity	Approval No of establishments: Abattoir	Manufacturing plant	Cold store	Number of packages	Net weight

COUNTRY

Transit/storage of meat of wild leporidae, farmed rabbits and wild land mammals other than ungulates

Part II: Certification

II. HEALTH INFORMATION	II.a. Certificate reference No	II.b.

II.1. **Health attestation**

I, the undersigned official veterinarian, hereby certify that meat of wild leporidae, farmed rabbits and wild land mammals ([1]) described in this certificate:

II.1.1. comes from a third country, or part thereof appearing in Part 1 of Annex I to Regulation (EC) No 119/2009;

([2]) II.1.2. complies with the relevant animal health conditions laid down in the animal health attestation in the model certificates in Annex II to Regulation (EC) No 119/2009.

Notes

Part I

— Box reference I.8: provide the code for the territory of origin, if necessary, as defined under code of column 2 of Part 1 of Annex I to Regulation (EC) No 119/2009.

— Box reference I.11: Name, address and approval number of the establishment of dispatch. Name of the country of origin which must be the same as the country of export.

— Box reference I.15: Indicate the registration number(s) of railway wagons and lorries, the names of ships and, if known, the flight numbers of aircraft. In the case of transport in containers, the total number of these and their registration and where there is a serial number of the seal it has to be indicated in box I.23.

— Box reference I.19: use the appropriate Harmonised System (HS) code of the World Customs Organisation: 02.08.10 or 02.08.90.

— Box reference I.28: (Nature of commodity): select one of the following: 'skinned and eviscerated leporidae', 'cuts', 'unskinned and uneviscerated leporidae'.

(Abattoir): includes game handling establishments.

Part II

([1]) Meat of wild leporidae (rabbits and hares) that do not contain offal, except in the case of unskinned and uneviscerated leporidae, meat of farmed rabbits, meat of wild land mammals, other than ungulates and leporidae, that do not contain offal.

([2]) In the case of meat of wild leporidae (WL) or meat of farmed rabbits (RM) or meat of wild land mammals (WM).

— The signature and the seal must be in a different colour from that of the printing.

— Note for the importer: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection point.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

ANNEX IV

(as referred to in Article 6)

Correlation Table

Decision 2000/585/EC	This Regulation
Article 2	Article 1
—	Article 2
Article 2a (a)	Article 3
Article 2a (b, c and d)	Article 4
Article 2b	Article 5
Article 4(1)	Article 6
Article 4(2)	Article 7
Article 3	Article 8

COMMISSION REGULATION (EC) No 120/2009

of 9 February 2009

amending Council Regulation (EEC) No 574/72 laying down the procedure for implementing Regulation (EEC) No 1408/71 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 574/72 of 21 March 1972 laying down the procedure for implementing Regulation (EEC) No 1408/71 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community [1], and in particular Article 122 thereof,

Whereas:

(1) Some Member States or their competent authorities have requested amendments to the Annexes to Regulation (EEC) No 574/72.

(2) The proposed amendments derive from decisions taken by the Member States concerned or their competent authorities designating the authorities which are responsible for ensuring that social security legislation is implemented in accordance with Community law.

(3) The bilateral arrangements for the implementation of the provisions of Regulation (EEC) No 574/72 are listed in Annex 5 to that Regulation.

(4) The unanimous opinion of the Administrative Commission on Social Security for Migrant Workers has been obtained,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes 2 to 5 to Regulation (EEC) No 574/72 are amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the 20th day following 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, 9 February 2009.

For the Commission
Vladimír ŠPIDLA
Member of the Commission

[1] OJ L 74, 27.3.1972, p. 1.

ANNEX

Annexes 2 to 5 to Regulation (EEC) No 574/72 are amended as follows:

1. Annex 2 is amended as follows:

(a) In section 'R. NETHERLANDS', point 5 is replaced by the following:

'5. Family benefits:

The General Child Benefit Act (Algemene Kinderbijslagwet) and the Regulations governing contributions towards the upkeep of physically disabled children living at home 2000 (Regeling tegemoetkoming onderhoudskosten thuiswonende gehandicapte kinderen 2000, TOG):

(a) where the person entitled to benefits resides in the Netherlands:

— the local office of the Social Insurance Institution (Districtskantoor van de Sociale Verzekeringsbank) in whose district he resides;

(b) where the person entitled to benefits resides outside the Netherlands, but his employer resides or is established in the Netherlands:

— the local office of the Social Insurance Institution (Districtskantoor van de Sociale Verzekeringsbank) in whose district the employer resides or is established;

(c) other cases:

— the Social Insurance Bank (Sociale Verzekeringsbank), Postbus 1100, 1180 BH Amstelveen.

The Childcare Act (Wet Kinderopvang) and the Child-related Budget Act (Wet op het kindgebonden budget):

— the Tax Office/Benefits Service (Belastingdienst/Toeslagen), Utrecht.';

(b) in section 'T. POLAND', point 5 is replaced by the following:

'5. Unemployment:

(a) benefits in kind:

Narodowy Fundusz Zdrowia, Warszawa (National Health Fund, Warsaw),

(b) cash benefits:

wojewódzkie urzędy pracy (voivodeship Latour offices) with territorial jurisdiction over the place of residence or stay.';

2. Annex 3 is amended as follows:

(a) In section 'R. NETHERLANDS', point 5 is replaced by the following:

'5. Family benefits:

The General Child Benefit Act (Algemene Kinderbijslagwet) and the Regulations governing contributions towards the upkeep of physically disabled children living at home 2000 (Regeling tegemoetkoming onderhoudskosten thuiswonende gehandicapte kinderen 2000, TOG):

— the local office of the Social Insurance Institution (Districtskantoor van de Sociale Verzekeringsbank) in whose district the family member resides;

The Childcare Act (Wet Kinderopvang) and the Child-related Budget Act (Wet op het kindgebonden budget):

— the Tax Office/Benefits Service (Belastingdienst/Toeslagen), Utrecht.';

(b) section 'T. POLAND' is amended as follows:

(i) point 2(g) is replaced by the following:

'(g) for persons who have completed exclusively foreign periods of insurance:

1. Zakład Ubezpieczeń Społecznych (Social Insurance Institution - ZUS) - Branch Office in Łódź - for persons who have completed foreign periods of insurance, including periods completed lately in Spain, Portugal, Italy, Greece, Cyprus or Malta;

2. Zakład Ubezpieczeń Społecznych (Social Insurance Institution - ZUS) - Branch Office in Nowy Sącz - for persons who have completed foreign periods of insurance, including periods completed lately in Austria, the Czech Republic, Hungary, Slovakia, Slovenia or Switzerland;

3. Zakład Ubezpieczeń Społecznych (Social Insurance Institution - ZUS) - Branch Office in Opole - for persons who have completed foreign periods of insurance, including periods completed lately in Germany;

4. Zakład Ubezpieczeń Społecznych (Social Insurance Institution - ZUS) - Branch Office in Szczecin - for persons who have completed foreign periods of insurance, including periods completed lately in Denmark, Finland, Sweden, Lithuania, Latvia or Estonia;

5. Zakład Ubezpieczeń Społecznych (Social Insurance Institution - ZUS) - I Oddział w Warszawie — Centralne Biuro Obsługi Umów Międzynarodowych (I Branch In Warsaw - Central Bureau for International Agreements) - for persons who have completed foreign periods of insurance, including periods completed lately in Belgium, France, the Netherlands, Luxembourg, Ireland or the United Kingdom.';

(ii) point 3(b)(ii) is replaced by the following:

'(ii) disability or death of main wage earner:

— for persons who have been recently employed or self-employed (excluding self-employed farmers):

units of Social Insurance Institution (Zakład Ubezpieczeń Społecznych) listed in point 2(a),

— for persons who have been recently self-employed farmers:

units of Agricultural Social Insurance Fund (Kasa Rolniczego Ubezpieczenia Społecznego) listed in point 2(b),

— for professional soldiers and officers listed in point 2 sub-point (c), in the case of Polish periods of service, if the last period has been the period of military service or service in one of the formations mentioned in point 2 sub-point (c), and foreign periods of insurance:

Wojskowe Biuro Emerytalne w Warszawie (Military Pension Office in Warsaw), if it is the competent institution mentioned in Annex 2(3)(b)(ii) third indent,

— for Prison Guard officers, in the case of Polish periods of service, if the last period has been the period of mentioned service and foreign periods of insurance:

Biuro Emerytalne Służby Więziennej w Warszawie (Pension Office of Prison Service in Warsaw), if it is the competent institution mentioned in Annex 2(3)(b)(ii) fifth indent,

— for judges and prosecutors:

specialised entities of the Ministry of Justice,

— for persons who have completed exclusively foreign periods of insurance:

units of the Social Insurance Institution (Zakład Ubezpieczeń Społecznych) listed in point 2(g).';

3. Annex 4 is amended as follows:

(a) in section 'G. GREECE', a new point 5 is added as follows:

'5. For farmers:

Agricultural Insurance Organisation (OGA), Athens (Οργανισμός Γεωργικών Ασφαλίσεων, Αθήνα).';

(b) in section 'R. NETHERLANDS', a new point 3 is added as follows:

'3. Collection of national insurance and employee insurance contributions:

Tax Office/Benefits Service/FIOD-ECD International, Amsterdam (De Belastingdienst/FIOD-ECD International, Amsterdam).';

4. Annex 5 is amended as follows:

(a) Section '283. LUXEMBOURG – FINLAND' is replaced by the following:

'283. LUXEMBOURG – FINLAND

No Convention'

(b) Section '323. AUSTRIA – UNITED KINGDOM' is replaced by the following:

'(a) Article 18(1) and (2) of the Arrangement of 10 November 1980 for the implementation of the Convention on social security of 22 July 1980 as amended by Supplementary Arrangements No 1 of 26 March 1986 and No 2 of 4 June 1993 with regard to persons who cannot claim treatment under Chapter 1 of Title III of the Regulation.

(b) …

(c) Agreement of 30 November 1994 concerning the reimbursement of expenditure for social security benefits.'

COMMISSION REGULATION (EC) No 121/2009

of 9 February 2009

fixing the additional amount to be paid in Bulgaria for peaches for processing under the 2007/08 marketing year in accordance with Regulation (EC) No 679/2007

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to the Treaty of Accession of Bulgaria and Romania,

Having regard to the Act of Accession of Bulgaria and Romania,

Having regard to Commission Regulation (EC) No 679/2007 of 18 June 2007 fixing the aid for peaches for processing for the 2007/2008 marketing year [1], and in particular Article 2(1) thereof,

Whereas:

(1) In accordance with Article 39(2) of Commission Regulation (EC) No 1535/2003 of 29 August 2003 laying down detailed rules for applying Council Regulation (EC) No 2201/96 as regards the aid scheme for products processed from fruit and vegetables [2], Bulgaria has notified the Commission that processing aid was granted in respect of 119,46 tonnes of peaches under this arrangement for the 2007/2008 marketing year. The processing threshold given for that Member State in Annex III to Council Regulation (EC) No 2201/96 [3] was not therefore exceeded. An additional amount of EUR 11,92 per tonne must therefore be paid in respect of the quantities concerned.

(2) For the 2007/2008 marketing year, producers in Romania submitted no applications for aid for peaches for processing. No additional amount should therefore be paid in that Member State for that marketing year,

HAS ADOPTED THIS REGULATION:

Article 1

An additional amount of EUR 11,92 per tonne of peaches for processing, as referred to in Article 2(1) of Regulation (EC) No 679/2007, shall be paid in Bulgaria after the 2007/2008 marketing year.

Article 2

This Regulation shall enter into force on the third day following 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, 9 February 2009.

For the Commission
Mariann FISCHER BOEL
Member of the Commission

[1] OJ L 157, 19.6.2007, p. 12.
[2] OJ L 218, 30.8.2003, p. 14.
[3] OJ L 297, 21.11.1996, p. 29.

II

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is not obligatory)

DECISIONS

COMMISSION

COMMISSION DECISION

of 3 February 2009

amending Decision 2002/364/EC on common technical specifications for *in vitro*-diagnostic medical devices

(notified under document number C(2009) 565)

(Text with EEA relevance)

(2009/108/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro*-diagnostic medical devices [1], and in particular the second subparagraph of Article 5(3) thereof,

Whereas:

(1) The common technical specifications for *in vitro*-diagnostic medical devices are laid down in Commission Decision 2002/364/EC [2].

(2) In the interest of public health and in order to reflect technical progress including the evolution in the performance and analytical sensitivity of devices, it is appropriate to revise the common technical specifications laid down in Decision 2002/364/EC.

(3) The definition of rapid test should be refined in order for it to be more precise. For the sake of clarity further definitions should be included.

(4) To bring the common technical specifications in line with current scientific and technical practices it is necessary to update a number of scientific and technical references.

(5) The requirements for HIV screening assays should be clarified. In order to ensure that the performance criteria appropriate to today's technology is reflected in the common technical specifications it is necessary to add requirements for HIV antibody/antigen combined tests and further specification of the sample requirements for certain assays.

(6) The Annex to Decision 2002/364/EC should therefore be amended accordingly and, for the purpose of clarity, be replaced.

(7) Manufacturers whose devices are already on the market should be given a transition period in order to adapt to the new common technical specifications. On the other hand, in the interest of public health, manufacturers who so wish should be able to apply the new common technical specifications before the expiry of the transition period.

(8) The measures provided for in this Decision are in accordance with the opinion of the committee set up by Article 6(2) of Council Directive 90/385/EEC [3],

[1] OJ L 331, 7.12.1998, p. 1.
[2] OJ L 131, 16.5.2002, p. 17.
[3] OJ L 189, 20.7.1990, p. 17.

HAS ADOPTED THIS DECISION:

Article 1

The Annex to Decision 2002/364/EC is replaced by the text in the Annex to this Decision.

Article 2

This Decision shall apply from 1 December 2010 for those devices first placed on the market prior to 1 December 2009.

It shall apply from 1 December 2009 for all other devices.

However, Member States shall allow manufacturers to apply the requirements set out in the Annex before the dates set out in the first and second paragraph.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 3 February 2009.

For the Commission
Günter VERHEUGEN
Vice-President

ANNEX

'ANNEX

COMMON TECHNICAL SPECIFICATIONS (CTS) FOR *IN VITRO*-DIAGNOSTIC MEDICAL DEVICES

1. SCOPE

The common technical specifications set out in this Annex shall apply for the purposes of Annex II List A to Directive 98/79/EC.

2. DEFINITIONS AND TERMS

(Diagnostic) sensitivity

The probability that the device gives a positive result in the presence of the target marker.

True positive

A specimen known to be positive for the target marker and correctly classified by the device.

False negative

A specimen known to be positive for the target marker and misclassified by the device.

(Diagnostic) specificity

The probability that the device gives a negative result in the absence of the target marker.

False positive

A specimen known to be negative for the target marker and misclassified by the device.

True negative

A specimen known to be negative for the target marker and correctly classified by the device.

Analytical sensitivity

Analytical sensitivity may be expressed as the limit of detection, i.e. the smallest amount of the target marker that can be precisely detected.

Analytical specificity

Analytical specificity means the ability of the method to determine solely the target marker.

Nucleic acid amplification techniques (NAT)

The term "NAT" is used for tests for the detection and/or quantification of nucleic acids by either amplification of a target sequence, by amplification of a signal or by hybridisation.

Rapid test

"Rapid test" means qualitative or semi-quantitative *in vitro*-diagnostic medical devices, used singly or in a small series, which involve non-automated procedures and have been designed to give a fast result.

Robustness

The robustness of an analytical procedure means the capacity of an analytical procedure to remain unaffected by small but deliberate variations in method parameters and provides an indication of its reliability during normal usage.

Whole system failure rate

The whole system failure rate means the frequency of failures when the entire process is performed as prescribed by the manufacturer.

Confirmation assay

Confirmation assay means an assay used for the confirmation of a reactive result from a screening assay.

Virus typing assay

Virus typing assay means an assay used for typing with already known positive samples, not used for primary diagnosis of infection or for screening.

Seroconversion HIV samples

Seroconversion HIV samples mean:

— p24 antigen and/or HIV RNA positive, and

— recognised by all of the antibody screening tests, and

— positive or indeterminate confirmatory assays,

Early seroconversion HIV samples

Early seroconversion HIV samples mean:

— p24 antigen and/or HIV RNA positive, and

— not recognised by all of the antibody screening tests, and

— indeterminate or negative confirmatory assays.

3. COMMON TECHNICAL SPECIFICATIONS (CTS) FOR PRODUCTS REFERRED TO IN ANNEX II, LIST A OF DIRECTIVE 98/79/EC

3.1. **CTS for performance evaluation of reagents and reagent products for the detection, confirmation and quantification in human specimens of markers of HIV infection (HIV 1 and 2), HTLV I and II, and hepatitis B, C, D**

General Principles

3.1.1. Devices which detect virus infections placed on the market for use as either screening or diagnostic tests, shall meet the requirements for sensitivity and specificity set out in Table 1. See also principle 3.1.11 for screening assays.

3.1.2. Devices intended by the manufacturer for testing body fluids other than serum or plasma, e.g. urine, saliva, etc. shall meet the same CTS requirements for sensitivity and specificity as serum or plasma tests. The performance evaluation shall test samples from the same individuals in both the tests to be approved and in a respective serum or plasma assay.

3.1.3. Devices intended by the manufacturer for self-test, i.e. home use shall meet the same CTS requirements for sensitivity and specificity as respective devices for professional use. Relevant parts of the performance evaluation shall be carried out (or repeated) by appropriate lay users to validate the operation of the device and the instructions for use.

3.1.4. All performance evaluations shall be carried out in direct comparison with an established state-of-the-art device. The device used for comparison shall be one bearing CE marking, if on the market at the time of the performance evaluation.

3.1.5. If discrepant test results are identified as part of an evaluation, these results shall be resolved as far as possible, for example:

— by evaluation of the discrepant sample in further test systems,

— by use of an alternative method or marker,

— by a review of the clinical status and diagnosis of the patient, and

— by the testing of follow-up-samples.

3.1.6. Performance evaluations shall be performed on a population equivalent to the European population.

3.1.7. Positive specimens used in the performance evaluation shall be selected to reflect different stages of the respective disease(s), different antibody patterns, different genotypes, different subtypes, mutants, etc.

3.1.8. Sensitivity with true positives and seroconversion samples shall be evaluated as follows:

3.1.8.1. Diagnostic test sensitivity during seroconversion has to represent the state of the art. Whether further testing of the same or additional seroconversion panels is conducted by the notified body or by the manufacturer the results shall confirm the initial performance evaluation data (see Table 1). Seroconversion panels should start with a negative bleed(s) and should have narrow bleeding intervals.

3.1.8.2. For blood screening devices (with the exception of HBsAg and anti-HBc tests), all true positive samples shall be identified as positive by the device to be CE marked (Table 1). For HBsAg and anti-HBc tests the new device shall have an overall performance at least equivalent to that of the established device (see 3.1.4).

3.1.8.3. Regarding HIV tests:

— all seroconversion HIV samples shall be identified as positive, and

— at least 40 early seroconversion HIV samples shall be tested. Results should conform to the state of the art.

3.1.9. Performance evaluation of screening assays shall include 25 positive (if available in the case of rare infections) "same day" fresh serum and/or plasma samples (≤ 1 day after sampling).

3.1.10. Negative specimens used in a performance evaluation shall be defined so as to reflect the target population for which the test is intended, for example blood donors, hospitalised patients, pregnant women, etc.

3.1.11. For performance evaluations for screening assays (Table 1) blood donor populations shall be investigated from at least two blood donation centres and consist of consecutive blood donations, which have not been selected to exclude first-time donors.

3.1.12. Devices shall have a specificity of at least 99,5 % on blood donations, unless otherwise indicated in the accompanying tables. Specificity shall be calculated using the frequency of repeatedly reactive (i.e. false positive) results in blood donors negative for the target marker.

3.1.13. Devices shall be evaluated to establish the effect of potential interfering substances, as part of the performance evaluation. The potential interfering substances to be evaluated will depend to some extent on the composition of the reagent and configuration of the assay. Potential interfering substances shall be identified as part of the risk analysis required by the essential requirements for each new device but may include, for example:

— specimens representing "related" infections,

— specimens from multipara, i.e. women who have had more than one pregnancy, or rheumatoid factor positive patients,

— for recombinant antigens, human antibodies to components of the expression system, for example anti-E. coli, or anti-yeast,

3.1.14. For devices intended by the manufacturer to be used with serum and plasma the performance evaluation must demonstrate serum to plasma equivalency. This shall be demonstrated for at least 50 donations (25 positive and 25 negative).

3.1.15. For devices intended for use with plasma the performance evaluation shall verify the performance of the device using all anticoagulants which the manufacturer indicates for use with the device. This shall be demonstrated for at least 50 donations (25 positive and 25 negative).

3.1.16. As part of the required risk analysis the whole system failure rate leading to false-negative results shall be determined in repeat assays on low-positive specimens.

3.1.17. If a new *in vitro*-diagnostic medical device belonging to Annex II List A is not specifically covered by the common technical specification, the common technical specification for a related device should be taken into account. Related devices may be identified on different grounds, e.g. by the same or similar intended use or by similar risks.

3.2. **Additional Requirements for HIV antibody/antigen combined tests**

3.2.1. HIV antibody/antigen combined tests intended for anti-HIV and p24 antigen detection which include claims for single p24 antigen detection shall follow Table 1 and Table 5, including criteria for analytical sensitivity for p24 antigen.

3.2.2. HIV antibody/antigen combined tests intended for anti-HIV and p24 detection which do not include claims for single p24 detection shall follow Table 1 and Table 5, excluding criteria for analytical sensitivity for p24.

3.3. **Additional Requirements for Nucleic Acid Amplification Techniques (NAT)**

The performance evaluation criteria for NAT assays can be found in Table 2.

3.3.1. For target sequence amplification assays, a functionality control for each test sample (internal control) shall reflect the state of the art. This control shall as far as possible be used throughout the whole process, i.e. extraction, amplification/hybridisation, detection.

3.3.2. The analytical sensitivity or detection limit for NAT assays shall be expressed by the 95 % positive cut-off value. This is the analyte concentration where 95 % of test runs give positive results following serial dilutions of an international reference material for example a WHO standard or calibrated reference material.

3.3.3. Genotype detection shall be demonstrated by appropriate primer or probe design validation and shall also be validated by testing characterised genotyped samples.

3.3.4. Results of quantitative NAT assays shall be traceable to international standards or calibrated reference materials, if available, and be expressed in international units utilised in the specific field of application.

3.3.5. NAT assays may be used to detect virus in antibody negative samples, i.e. pre-seroconversion samples. Viruses within immune-complexes may behave differently in comparison to free viruses, for example during a centrifugation step. It is therefore important that during robustness studies, antibody-negative (pre-seroconversion) samples are included.

3.3.6. For investigation of potential carry-over, at least five runs with alternating high-positive and negative specimens shall be performed during robustness studies. The high positive samples shall comprise of samples with naturally occurring high virus titres.

3.3.7. The whole system failure rate leading to false-negative results shall be determined by testing low-positive specimens. Low positive specimens shall contain a virus concentration equivalent to three times the 95 % positive cut-off virus concentration.

3.4. **CTS for the manufacturer's release testing of reagents and reagent products for the detection, confirmation and quantification in human specimens of markers of HIV infection (HIV 1 and 2), HTLV I and II, and hepatitis B, C, D (Immunological assays only)**

3.4.1. The manufacturers release testing criteria shall ensure that every batch consistently identifies the relevant antigens, epitopes, and antibodies.

3.4.2. The manufacturer's batch release testing for screening assays shall include at least 100 specimens negative for the relevant analyte.

3.5. **CTS for performance evaluation of reagents and reagent products for determining the following blood group antigens: ABO blood group system ABO1 (A), ABO2 (B), ABO3 (A,B); Rh blood group system RH1 (D), RH2 (C), RH3 (E), RH4 (c), RH5 (e); Kell blood group system KEL1 (K)**

Criteria for performance evaluation of reagents and reagent products for determining the blood groups antigens: ABO blood group system ABO1 (A), ABO2 (B), ABO3 (A,B); Rh blood group system RH1 (D), RH2 (C), RH3 (E), RH4 (c), RH5 (e); Kell blood group system KEL1 (K) can be found in Table 9.

3.5.1. All performance evaluations shall be carried out in direct comparison with an established state-of-the-art device. The device used for comparison shall be one bearing CE marking, if on the market at the time of the performance evaluation.

3.5.2. If discrepant test results are identified as part of an evaluation, these results shall be resolved as far as possible, for example:

— by evaluation of the discrepant sample in further test systems,

— by use of an alternative method,

3.5.3. Performance evaluations shall be performed on a population equivalent to the European population.

3.5.4. Positive specimens used in the performance evaluation shall be selected to reflect variant and weak antigen expression.

3.5.5. Devices shall be evaluated to establish the effect of potential interfering substances, as part of the performance evaluation. The potential interfering substances to be evaluated will depend to some extent on the composition of the reagent and configuration of the assay. Potential interfering substances shall be identified as part of the risk analysis required by the essential requirements for each new device.

3.5.6. For devices intended for use with plasma the performance evaluation shall verify the performance of the device using all anticoagulants which the manufacturer indicates for use with the device. This shall be demonstrated for at least 50 donations.

3.6. **CTS for the manufacturers release testing of reagents and reagent products for determining the blood group antigens: ABO blood group system ABO1 (A), ABO2 (B), ABO3 (A,B); Rh blood group system RH1 (D), RH2 (C), RH3 (E), RH4 (c), RH5 (e); Kell blood group system KEL1 (K)**

3.6.1. The manufacturer's release testing criteria shall ensure that every batch consistently identifies the relevant antigens, epitopes, and antibodies.

3.6.2. Requirements for manufacturers batch release testing are outlined in Table 10.

Table 1

"Screening" assays: anti-HIV 1 and 2, anti-HTLV I and II, anti-HCV, HBsAg, anti-HBc

		Anti-HIV-1/2	Anti-HTLV-I/II	Anti-HCV	HBsAg	Anti-HBc
Diagnostic sensitivity	Positive specimens	400 HIV-1 100 HIV-2 including 40 non-B-subtypes, all available HIV/1 subtypes should be represented by at least 3 samples per subtype	300 HTLV-I 100 HTLV-II	400 (positive samples) Including samples from different stages of infection and reflecting different antibody patterns. Genotype 1-4: > 20 samples per genotype (including non-a sub-types of genotype 4); 5: > 5 samples; 6: if available	400 Including subtype-consideration	400 Including evaluation of other HBV-markers
	Seroconversion panels	20 panels 10 further panels (at Notified Body or manufacturer)	To be defined when available	20 panels 10 further panels (at Notified Body or manufacturer)	20 panels 10 further panels (at Notified Body or manufacturer)	To be defined when available
Analytical sensitivity	Standards				0,130 IU/ml (Second International Standard for HBsAg, subtype adw2, genotype A, NIBSC code: 00/588)	
Specificity	Unselected donors (including first-time donors)	5 000	5 000	5 000	5 000	5 000
	Hospitalised patients	200	200	200	200	200
	Potentially cross-reacting blood-specimens (RF+, related viruses, pregnant women, etc.)	100	100	100	100	100

Table 2

NAT assays for HIV1, HCV, HBV, HTLV I/II (qualitative and quantitative; not molecular typing)

HIV1			HCV		HBV		HTLV I/II		Acceptance criteria
NAT	qualitative	quantitative	qualitative	quantitative As for HIV quantitative	qualitative	quantitative As for HIV quantitative	qualitative	quantitative As for HIV quantitative	
Sensitivity Detection limit Detection of analytical sensitivity (IU/ml; defined on WHO standards or calibrated reference materials)	According to EP validation guideline ([1]): several dilution series into borderline concentration; statistical analysis (e.g. Probit analysis) on the basis of at least 24 replicates; calculation of 95 % cut-off value	Detection limit: as for qualitative tests; Quantification limit: dilutions (half-log10 or less) of calibrated reference preparations, definition of lower, upper quantification limit, precision, accuracy, "linear" measuring range, "dynamic range". Reproducibility at different concentration levels to be shown	According to EP validation guideline ([1]): several dilution series into borderline concentration; statistical analysis (e.g. Probit analysis) on the basis of at least 24 replicates; calculation of 95 % cut-off value		According to EP validation guideline ([1]): several dilution series into borderline concentration; statistical analysis (e.g. Probit analysis) on the basis of at least 24 replicates; calculation of 95 % cut-off value		According to EP validation guideline ([1]): several dilution series into borderline concentration; statistical analysis (e.g. Probit analysis) on the basis of at least 24 replicates; calculation of 95 % cut-off value		
Genotype/subtype detection/ quantification efficiency	At least 10 samples per subtype (as far as available)	Dilution series of all relevant genotypes/ subtypes, preferably of reference materials, as far as available	At least 10 samples per genotype (as far as available)		As far as calibrated genotype reference materials are available		As far as calibrated genotype reference materials are available		

HIV1			HCV		HBV		HTLV I/II		Acceptance criteria
NAT	qualitative	quantitative	qualitative	quantitative As for HIV quantitative	qualitative	quantitative As for HIV quantitative	qualitative	quantitative As for HIV quantitative	
	Cell culture supernatants (could substitute for rare HIV-1 subtypes) According to EP validation guideline [1] as far as calibrated subtype reference materials are available; *in vitro* transcripts could be an option	Transcripts or plasmids quantified by appropriate methods may be used.	According to EP validation guideline [1] as far as calibrated subtype reference materials are available; *in vitro* transcripts could be an option		According to EP validation guideline [1] as far as calibrated subtype reference materials are available; *in vitro* transcripts could be an option		According to EP validation guideline [1] as far as calibrated subtype reference materials are available; *in vitro* transcripts could be an option		
Diagnostic specificity negative samples	500 blood donors	100 blood donors	500 blood donors		500 blood donors		500 individual blood donations		
Potential cross-reactive markers	By suitable assay design evidence (e.g. sequence comparison) and/or testing of at least 10 human retrovirus (e.g. HTLV)-positive samples	As for qualitative tests	By assays design and/or testing of at least 10 human flavivirus (e.g. HGV, YFV) positive samples		By assays design and/or testing of at least 10 other DNA-virus positive samples		By assay design and/or testing of at least 10 human retrovirus (e.g. HIV-) positive samples		
Robustness		As for qualitative tests							

HIV1			HCV		HBV		HTLV I/II		Acceptance criteria
NAT	qualitative	quantitative	qualitative	quantitative As for HIV quantitative	qualitative	quantitative As for HIV quantitative	qualitative	quantitative As for HIV quantitative	
Cross-contamination	At least 5 runs using alternating high positive (known to occur naturally) and negative samples		At least 5 runs using alternating high positive (known to occur naturally) and negative samples		At least 5 runs using alternating high positive (known to occur naturally) and negative samples		At least 5 runs using alternating high positive (known to occur naturally) and negative samples		
Inhibition	Internal control preferably to go through the whole NAT procedure		Internal control preferably to go through the whole NAT procedure		Internal control preferably to go through the whole NAT procedure		Internal control preferably to go through the whole NAT procedure		
Whole system failure rate leading to false-neg results	At least 100 samples virus-spiked with 3 x the 95 % pos cut-off concentration		At least 100 samples virus-spiked with 3 x the 95 % pos cut-off concentration		At least 100 samples virus-spiked with 3 x the 95 % pos cut-off concentration		At least 100 samples virus-spiked with 3 x the 95 % pos cut-off concentration		99/100 assays positive

([1]) European Pharmacopoeia guideline.

Notes: Acceptance criteria for "whole system failure rate leading to false-neg results" is 99/100 assays positive.

For quantitative NATs a study shall be performed on at least 100 positive specimens reflecting the routine conditions of users (e.g. no pre-selection of specimens). Comparative results with another NAT test system shall be generated in parallel.

For qualitative NATs a study on diagnostic sensitivity shall be performed using at least 10 seroconversion panels. Comparative results with another NAT test system shall be generated in parallel.

Table 3

Rapid tests: anti-HIV 1 and 2, anti-HCV, HBsAg, anti-HBc, anti-HTLV I and II

		Anti-HIV 1/2	Anti-HCV	HBsAg	Anti-HBc	anti-HTLV I/II	Acceptance criteria
Diagnostic sensitivity	Positive specimens	Same criteria as for screening assays	Same criteria as for screening assays	Same criteria as for screening assays	Same criteria as for screening assays	Same criteria as for screening assays	Same criteria as for screening assays
	Seroconversion panels	Same criteria as for screening assays	Same criteria as for screening assays	Same criteria as for screening assays	Same criteria as for screening assays	Same criteria as for screening assays	Same criteria as for screening assays
Diagnostic specificity	Negative specimens	1 000 blood donations 200 clinical specimens 200 samples from pregnant women 100 potentially interfering samples	1 000 blood donations 200 clinical specimens 200 samples from pregnant women 100 potentially interfering samples	1 000 blood donations 200 clinical specimens 200 samples from pregnant women 100 potentially interfering samples	1 000 blood donations 200 clinical specimens 100 potentially interfering samples	1 000 blood donations 200 clinical specimens 200 samples from pregnant women 100 potentially interfering samples	≥ 99 % (anti-HBc: ≥ 96 %)

Table 4

Confirmatory/supplementary assays for anti-HIV 1 and 2, anti-HTLV I and II, anti-HCV, HBsAg

		Anti-HIV Confirmatory Assay	Anti-HTLV Confirmatory Assay	HCV Supplementary Assay	HBsAg Confirmatory Assay	Acceptance criteria
Diagnostic sensitivity	Positive specimens	200 HIV-1 and 100 HIV-2 Including samples from different stages of infection and reflecting different antibody patterns	200 HTLV-I and 100 HTLV-II	300 HCV (positive samples) Including samples from different stages of infection and reflecting different antibody patterns. Genotypes 1 – 4: > 20 samples (including non-a sub-types of genotype 4); 5: > 5 samples; 6: if available	300 HBsAg Including samples from different stages of infection 20 "high pos" samples (> 26 IU/ml); 20 samples in the cut-off range	Correct identification as positive (or indeterminate), not negative
	Seroconversion panels	15 seroconversion panels/ low titre panels		15 seroconversion panels/ low titre panels	15 seroconversion panels/ low titre panels	
Analytical sensitivity	Standards				Second International Standard for HBsAg, subtype adw2, genotype A, NIBSC code: 00/588	
Diagnostic specificity	Negative specimens	200 blood donations 200 clinical samples including pregnant women 50 potentially interfering samples, including samples with indeterminate results in other confirmatory assays	200 blood donation 200 clinical samples including pregnant women 50 potentially interfering samples including samples with indeterminate results in other confirmatory assays	200 blood donations 200 clinical samples including pregnant women 50 potentially interfering samples including samples with indeterminate results in other supplementary assays	10 false positives as available from the performance evaluation of the screening assay. (1) 50 potentially interfering samples	No false-positive results/ (1) no neutralisation

(1) Acceptance criteria no neutralisation for HBsAg confirmatory assay.

Table 5

HIV 1 Antigen

		HIV-1 Antigen Assay	Acceptance criteria
Diagnostic sensitivity	Positive specimens	50 HIV-1 Ag-positive 50 cell culture supernatants including different HIV-1 subtypes and HIV-2	Correct identification (after neutralisation)
	Seroconversion panels	20 seroconversion panels/low titre panels	
Analytical sensitivity	Standards	HIV-1 p24 Antigen, 1st International Reference Reagent, NIBSC code: 90/636	≤ 2 IU/ml
Diagnostic specificity		200 blood donations 200 clinical samples 50 potentially interfering samples	≥ 99,5 % after neutralisation

Table 6

Serotyping and Genotyping Assay: HCV

		HCV Serotyping and Genotyping Assay	Acceptance criteria
Diagnostic sensitivity	Positive specimens	200 (positive samples) Including samples from different stages of infection and reflecting different antibody patterns. Genotypes 1 – 4: ≥ 20 samples (including non-a sub-types of genotype 4); 5: ≥ 5 samples; 6: if available	≥ 95 % agreement between serotyping and genotyping ≥ 95 % agreement between genotyping and sequencing
Diagnostic specificity	Negative specimens	100	

Table 7

HBV Markers: anti-HBs, anti-HBc IgM, anti-HBe, HBeAg

		Anti-HBs	Anti-HBc IgM	Anti-HBe	HBeAg	Acceptance criteria
Diagnostic sensitivity	Positive specimens	100 vaccinees 100 naturally infected persons	200 Including samples from different stages of infection (acute/chronic, etc.) The acceptance criteria should only be applied on samples from acute infection stage.	200 Including samples from different stages of infection (acute/chronic, etc.)	200 Including samples from different stages of infection (acute/chronic, etc.)	≥ 98 %
	Seroconversion panels	10 follow-ups or anti-HBs seroconversions	When available			
Analytical sensitivity	Standards	WHO 1st International Reference Preparation 1977; NIBSC, United Kingdom			HBe – Referenzantigen 82; PEI Germany	Anti-HBs: < 10 mIU/ml
Diagnostic specificity	Negative specimens	500 Including clinical samples 50 potentially interfering samples	200 blood donations 200 clinical samples 50 potentially interfering samples	200 blood donation 200 clinical samples 50 potentially interfering samples	200 blood donations 200 clinical samples 50 potentially interfering samples	≥ 98 %

Table 8

HDV markers: anti-HDV, anti-HDV IgM, Delta Antigen

		Anti-HDV	Anti-HDV IgM	Delta Antigen	Acceptance criteria
Diagnostic sensitivity	Positive specimens	100 Specifying HBV-markers	50 Specifying HBV-markers	10 Specifying HBV-markers	≥ 98 %
Diagnostic specificity	Negative specimens	200 Including clinical samples 50 potentially interfering samples	200 Including clinical samples 50 potentially interfering samples	200 Including clinical samples 50 potentially interfering samples	≥ 98 %

Table 9

Blood group antigens in the ABO, Rh and Kell blood group systems

	1	2	3
Specificity	Number of tests per recommended method	Total number of samples to be tested for a launch product	Total number of samples to be tested for a new formulation, or use of well-characterised reagents
Anti-ABO1 (anti-A), anti-ABO2 (anti-B), anti-ABO3 (anti-A,B)	500	3 000	1 000
Anti-RH1 (anti-D)	500	3 000	1 000
Anti-RH2 (anti-C), anti-RH4 (anti-c), anti-RH3 (anti-E)	100	1 000	200
Anti-RH5 (anti-e)	100	500	200
Anti-KEL1 (anti-K)	100	500	200

Acceptance criteria:

All of the above reagents shall show comparable test results with established reagents with acceptable performance with regard to claimed reactivity of the device. For established reagents, where the application or use has been changed or extended, further testing should be carried out in accordance with the requirements outlined in column 1 (above).

Performance evaluation of anti-D-reagents shall include tests against a range of weak RH1 (D) and partial RH1 (D) samples, depending on the intended use of the product.

Qualifications:

Clinical samples: 10 % of the test population
Neonatal specimens: > 2 % of the test population
ABO samples: > 40 % A, B positives
"weak D": > 2 % of RH1 (D) positives

Table 10

Batch release criteria for reagents and reagent products to determine blood group antigens in the ABO, Rh and Kell blood group systems

Specificity Testing Requirements on each reagent

1. **Test reagents**

Blood Group Reagents	Minimum number of control cells to be tested							
	Positive reactions					Negative reactions		
	A1	A2B	Ax			B	0	
Anti-ABO1 (anti-A)	2	2	2 (*)			2	2	
	B	A1B				A1	0	
Anti-ABO2 (anti-B)	2	2				2	2	
	A1	A2	Ax	B		0		
Anti-ABO3 (anti-A,B)	2	2	2	2		4		
	R1r	R2r	WeakD			r'r	r"r	rr
Anti-RH1 (anti-D)	2	2	2 (*)			1	1	1
	R1R2	R1r	r'r			R2R2	r"r	rr
Anti-RH2 (anti-C)	2	1	1			1	1	1
	R1R2	R1r	r'r			R1R1		
Anti-RH4 (anti-c)	1	2	1			3		
	R1R2	R2r	r"r			R1R1	r'r	rr
Anti-RH 3 (anti-E)	2	1	1			1	1	1
	R1R2	R2r	r"r			R2R2		
Anti-RH5 (anti-e)	2	1	1			3		
	Kk					kk		
Anti-KEL1 (anti-K)	4					3		

(*) Only by recommended techniques where reactivity against these antigens is claimed.

Note: Polyclonal reagents must be tested against a wider panel of cells to confirm specificity and exclude presence of unwanted contaminating antibodies.

Acceptance Criteria:

Each batch of reagent must exhibit unequivocal positive or negative results by all recommended techniques in accordance with the results obtained from the performance evaluation data.

2. **Control Materials (red Cells)**

The phenotype of red cells used in the control of blood typing reagents listed above should be confirmed using established device.'

NOTE TO THE READER

The institutions have decided no longer to quote in their texts the last amendment to cited acts.

Unless otherwise indicated, references to acts in the texts published here are to the version of those acts currently in force.