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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.

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(Continued on inside back cover)

DECISION No 1/2004 OF THE COMMUNITY/SWITZERLAND AIR TRANSPORT COMMITTEE

of 6 April 2004

amending the Annex to the Agreement between the European Community and the Swiss Confederation on Air Transport

(2004/404/EC)

THE COMMUNITY/SWITZERLAND AIR TRANSPORT COMMITTEE,

Having regard to the Agreement between the European Community and the Swiss Confederation on Air Transport, hereinafter referred to as 'the Agreement', and in particular Article 23(4) thereof,

HAS DECIDED AS FOLLOWS:

Article 1

1. In point 1 (Third aviation package of liberalisation and other civil aviation rules) of the Annex to the Agreement the following shall be moved and added to the reference to Council Regulation (EEC) No 2299/89 on a code of conduct for computerised reservation systems:

', and by Council Regulation no 323/1999 of 8 February 1999.'

2. In point 1 (Third aviation package of liberalisation and other civil aviation rules) of the Annex to the Agreement the following shall be deleted:

'No 3089/93

Council Regulation of 29 October 1993 amending Regulation (EEC) No 2299/89 on a code of conduct for computerised reservation systems.

(Article 1)'

Article 2

1. In point 2 (Competition rules) of the Annex to the Agreement the following shall be added to the reference to Council Regulation (EEC) No 17/62:

', and by Council Regulation (EC) No 1216/1999 of 10 June 1999.'

2. In point 2 (Competition rules) of the Annex to the Agreement the term '(see below)' shall be deleted from the reference to Council Regulation No 3975/87.

3. In point 2 (Competition rules) of the Annex to the Agreement the following shall be moved and added to the reference to Council Regulation No 3975/87:

', as amended by Council Regulation No 1284/91 of 14 May 1991 (Article 1) and by Council Regulation No 2410/92 of 23 July 1992 (Article 1).'

4. In point 2 (Competition rules) of the Annex to the Agreement the term '(see below)' shall be deleted from the reference to Council Regulation No 3976/87.

5. In point 2 (Competition rules) of the Annex to the Agreement the following shall be moved and added to the reference to Council Regulation No 3976/87:

', as amended by Council Regulation No 2344/90 of 24 July 1990 (Article 1), and by Council Regulation No 2411/92 of 23 July 1992 (Article 1).'

6. In point 2 (Competition rules) of the Annex to the Agreement the following shall be moved and added to the reference to Commission Regulation (EEC) No 1617/93:

'as amended by Commission Regulation (EC) No 1523/96 of 24 July 1996 (Articles 1,2), by Commission Regulation (EC) No 1083/99 of 26 May 1999, by Commission Regulation (EC) No 1324/2001 of 29 June 2001.'

7. In point 2 (Competition rules) of the Annex to the Agreement the following shall be moved and added to the reference to Commission Directive (EEC) No 80/723:

', as amended by Commission Directive No 85/413 of 24 July 1985 (Articles 1-3)'

Article 3

The following shall be added to point 2 (Competition rules) of the Annex to the Agreement, after the reference to Commission Directive (EEC) No 80/723 as amended by article 2.7 of the present Decision:

'No 447/98

Commission Regulation of 1 March 1998 on the notifications, time limits and hearings provided for in Council Regulation (EEC) No 4064/89 on the control of concentrations between undertakings.

No 2842/98

Commission Regulation of 22 December 1998 on the hearing of parties in certain proceedings under Articles 85 and 86 of the EC Treaty.

No 2843/98

Commission Regulation of 22 December 1998 on the form, content and other details of applications and notifications provided for in Council Regulations (EEC) No 1017/68, (EEC) No 4056/86 and (EEC) No 3975/87 applying the rules on competition to the transport sector.'

Article 4

This Decision shall be published in the *Official Journal of the European Union,* and the *Official Compendium of Swiss Federal Law*. It will enter into force on the first day of the second month following its adoption.

Done at Brussels, 6 April 2004.

For the Joint Committee
The Head of the Community Delegation

Michel AYRAL

The Head of the Swiss Delegation

Max FRIEDL

DECISION No 2/2004

OF THE COMMUNITY/SWITZERLAND AIR TRANSPORT COMMITTEE

of 22 April 2004

adopting its rules of procedure

(2004/405/EC)

THE COMMUNITY/SWITZERLAND AIR TRANSPORT COMMITTEE,

Having regard to the Agreement between the European Community and the Swiss Confederation on Air Transport, hereinafter referred to as 'the Agreement', and in particular Article 21(3) thereof,

HAS DECIDED AS FOLLOWS:

Sole Article

The rules of procedure of the Joint Committee annexed to this decision are hereby adopted.

Done at Brussels, 22April 2004.

For the Joint Committee
The Head of the Community Delegation
Enrico Grillo PASQUARELLI

The Head of the Swiss Delegation
Dante MARTINELLI

ANNEX

Rules of procedure of the Community/Switzerland Air Transport Committee

Article 1
Chair

1. The Chair of the Committee shall be held in turn for a period of one calendar year by a representative of the Commission of the European Communities, on behalf of the European Community, hereinafter referred to as "the Community", and by a representative of the Swiss Confederation. It shall be held by Switzerland during the year of entry into force of the Agreement.

2. The head of delegation of the party which holds the Chair or, where appropriate, his or her alternate, shall be Chair of the Committee.

Article 2
Delegations

1. Before each meeting, the heads of delegation shall inform the Chair of the intended composition of their delegation.

2. The Parties shall appoint the heads of delegation who, outside the meetings, are to be the contact persons for all matters relating to the Agreement.

3. The Chair, in agreement with the other head of delegation, may invite persons who are not members of the delegations to take part in a meeting of the Committee in order to provide information on specific subjects.

4. The parties shall inform each other, at least one week before the meeting, of the composition of their delegation.

Article 3
Secretariat

1. A representative of the Commission and a representative of the Swiss Confederation shall jointly provide the Secretariat for the Committee. The Secretaries shall be designated by their respective head of delegation and shall continue to perform their duties until a new Secretary is appointed. Each party shall send the name and address of its Secretary to the other party.

2. The Secretaries shall be responsible for communication between the delegations, including the transmission of documents, and shall supervise the duties performed by the Secretariat.

3. The Secretariat to the Committee shall be under the direction of the party which holds the Chair.

Article 4
Meetings of the Committee

1. The Committee shall meet at least once a year. It shall be convened by the Chair. The Chair may also convene the Committee at the request of the head of the other delegation.

2. The Chair shall draw up the draft agenda and fix the date and place of the meeting in agreement with the head of the other delegation.

3. The Chair shall send the notice of meeting, together with the draft agenda and the documents for the meeting, to the head of the other delegation no later than 15 working days before the meeting.

4. One of the two heads of delegation may ask the Chair to shorten the period indicated in paragraph 3 in order to take account of the urgency of a particular matter.

5. Meetings of the Committee shall not be public, unless decided otherwise by the Chair, with the agreement of the other head of delegation.

6. Depending on who holds the Chair, the Committee shall meet in Brussels or Berne, unless the parties agree on another meeting place.

7. By joint agreement between the Chair and the other head of delegation, the meeting may also be held by telephone or video conference. In this case, the instruments of the Committee shall be adopted by written procedure, in accordance with Article 7(5), *mutatis mutandis*.

Article 5
Agenda

1. The Chair shall draw up the provisional agenda for each meeting.

2. The heads of delegation may propose one or more additional items to be included in the agenda at the latest 24 hours before the meeting is due to begin. Any request for additional items to be included in the agenda must be duly substantiated and sent in writing to the Chair or to the head of the other delegation.

3. At the beginning of the meeting, the Chair and the other head of delegation shall approve the agenda.

Article 6
Working parties

1. The composition and functioning of the working parties or groups of experts set up in accordance with Article 21(5) of the Agreement shall be agreed, *mutatis mutandis*, in accordance with the rules applicable to the Committee.

2. The working parties or groups of experts shall work under the authority of the Committee, to which they shall report after each of their meetings. They are not authorised to take decisions but may make recommendations for the Committee's attention.

3. The Committee may decide to terminate or to amend the mandate of the working parties or groups of experts.

Article 7
Adoption of instruments

1. The recommendations and decisions of the Committee within the meaning of Article 21(1) of the Agreement shall be adopted by consensus between the two delegations. They shall be entitled "recommendation" or "decision", followed by a sequential number, the date of adoption and an indication as to the subject.

2. The decisions and recommendations of the Committee shall be covered by the signature of the Chair and the head of delegation of the party which does not hold the Chair. An original copy shall be kept by each of the parties.

3. Each party may decide to publish any instrument adopted by the Committee.

4. The instruments of the Committee may be adopted by written procedure if the two heads of delegation so agree.

5. The party which proposes use of the written procedure shall submit the draft instrument to the other party. The other party shall reply indicating whether or not it accepts the draft, whether it proposes any changes to the draft, and whether it requests additional time to consider it. If the draft is adopted, the Chair shall finalise the decision or the recommendation in accordance with paragraphs 1 and 2 above.

Article 8
Minutes

1. The Secretariat shall draw up draft minutes of each meeting. The draft shall indicate the decisions taken, the recommendations made and the conclusions adopted. The minutes shall be signed by the Chair and by the head of the other delegation. An original copy shall be held by each party.

2. The draft minutes shall be drawn up within ten working days of the end of the meeting and shall be submitted for the approval of the Chair and the head of the other delegation by written procedure. If this procedure is not completed, the minutes shall be adopted by the Committee at its next meeting.

Article 9
Confidentiality

The Committee's deliberations shall be confidential.

Article 10
Expenses

1. Each party shall bear any expenses it incurs relating to its participation in the meetings of the Committee and of the working parties or groups of experts.

2. The Committee shall agree on the breakdown of expenses relating to any missions assigned to experts.

Article 11
Correspondence

All correspondence to or from the Chair of the Committee shall be sent to the Secretariat of the Committee. The Secretariat shall send a copy of all correspondence concerning the Agreement to the heads of delegation and to the Swiss Mission to the European Communities.

DECISION No 3/2004

OF THE COMMUNITY/SWITZERLAND AIR TRANSPORT COMMITTEE No 3/2004

of 22 April 2004

amending the Annex to the Agreement between the European Community and the Swiss Confederation on Air Transport

(2004/406/EC)

THE COMMUNITY/SWITZERLAND AIR TRANSPORT COMMITTEE,

Having regard to the Agreement between the European Community and the Swiss Confederation on Air Transport, hereinafter referred to as 'the Agreement', and in particular Article 23(4) thereof,

HAS DECIDED AS FOLLOWS:

Article 1

1. The following shall be added to point 1 (Third aviation package of liberalisation and other civil aviation rules) of the Annex to the Agreement, after the reference to Council Regulation (EEC) No 2299/89:

'2002/30

Directive of the European Parliament and of the Council of 26 March 2002 on the establishment of rules and procedures with regard to the introduction of noise-related operating restrictions at Community airports.
(Articles 1-12, 14-18)

The provisions of the Directive shall, for the purposes of the Agreement, be read with the following adaptation:

Switzerland shall apply the Directive after a transitional period of the same length as the implementation period laid down in the Directive for the Member States of the Community.'

2. The following shall be added to point 1 (Third aviation package of liberalisation and other civil aviation rules) of the Annex to the Agreement, after the inclusion referred to in article 1.1 of the present Decision:

'2000/79

Council Directive of 27 November 2000 concerning the European Agreement on the Organisation of Working Time of Mobile Workers in Civil Aviation concluded by the Association of European Airlines

(AEA), the European Transport Workers' Federation (ETF), the European Cockpit Association (ECA), the European Regions Airline Association (ERA) and the International Air Carrier Association (IACA).

The provisions of the Directive shall, for the purposes of the Agreement, be read with the following adaptation:

Switzerland shall apply the Directive after a transitional period of the same length as the implementation period laid down in the Directive for the Member States of the Community.'

3. The following shall be added to point 1 (Third aviation package of liberalisation and other civil aviation rules) of the Annex to the Agreement, after the inclusion referred to in article 1.2 of the present Decision:
'93/104

Council Directive of 23 November 1993 concerning certain aspects of the organization of working time as amended by Directive 2000/34/EC of 22 June 2000.

The provisions of the Directive shall, for the purposes of the Agreement, be read with the following adaptation:

Switzerland shall apply the Directive after a transitional period of the same length as the implementation period laid down in the Directive for the Member States of the Community.'

Article 2

The following shall be added to the reference to Commission Regulation 1617/93 in point 2 (Competition rules) of the Annex to the Agreement:

', and by Commission Regulation (EC) No 1105/2002 of 25 June 2002.

The provisions of the Regulation shall, for the purposes of the Agreement, be read with the following adaptation:

Switzerland shall apply the Regulation after a transitional period of the same length as the implementation period laid down in the Regulation for the Member States of the Community.'

Article 3

This Decision shall be published in the *Official Journal of the European Union,* and the *Official Compendium of Swiss Federal Law*. It will enter into force on the first day of the second month following its adoption.

Done at Brussels, 22 April 2004.

For the Joint Committee
The Head of the Community Delegation
Enrico Grillo PASQUARELLI

The Head of the Swiss Delegation
Dante MARTINELLI

COMMISSION DECISION

of 26 April 2004

on transitional sanitary and certification rules under Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards import from certain third countries of photographic gelatine

(notified under document number C(2004) 1516)

(Only the English, French and Dutch texts are authentic)

(Text with EEA relevance)

(2004/407/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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

Whereas:

(1) According to the Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies[2], specified risk material may not be imported into the Community,

(2) According to the Regulation (EC) No 1774/2002, Category 1 materials, which may contain specified risk material, may be imported into the Community in accordance with rules laid down in that Regulation or to be established by Comitology procedure.

(3) Commission Regulation (EC) No 812/2003 of 12 May 2003 on transitional measures under Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards the importation and transit of certain products from third countries[3] provides that the Commission is to propose detailed transitional rules for products for which adequate justification has been provided.

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1 OJ L 273, 10.10.2002, p. 1. as last amended by Regulation (EC) No 808/2003 (OJ L 117, 13.5.2003, p. 1).

2 OJ L 147, 31.5.2001, p. 1. as last amended by Regulation (EC) No. 2245/2003 (OJ L 333 , 20.12.2003, p. 28).

3 OJ L 117, 13.5.2003, p. 19.

(4) residual risk of bovine spongiform encephalopathy (BSE) in a number of bovine-derived products such as gelatine, collagen and tallow and derived products, which is expected in the near future.

(5) Pending such advice, it is therefore appropriate to provide transitional measures allowing the continued import from Japan and the United States of America of gelatine produced from materials containing bovine vertebral column classified as Category 1 material under Regulation (EC) No 1774/2002, intended for the photographic industry ("photographic gelatine").

(6) The specific technical properties of photographic gelatine require the implementation of strict channelling and enforcement measures, further reducing the risk of diversion into the food and feed chains and other unintended technical purposes.

(7) The French, Dutch and United The Commission has requested scientific advice on a quantitative assessment of the Kingdom competent authorities have confirmed the need to maintain the existing trade in such gelatine with USA and Japan. Accordingly France, the Netherlands and the United Kingdom should continue to authorise the import of photographic gelatine subject to compliance with the conditions set out in this Decision.

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

HAS ADOPTED THIS DECISION:

Article 1
Derogation regarding the import of photographic gelatine

By way of derogation from Article 29(1) of Regulation (EC) No 1774/2002, France, the Netherlands and the United Kingdom shall authorise the import of gelatine produced from materials containing bovine vertebral column classified as Category 1 material under that Regulation, exclusively intended for the photographic industry ("photographic gelatine"), in compliance with this Decision.

Article 2
Conditions for import of photographic gelatine

1. Import of photographic gelatine shall be allowed only from the third countries of origin and plants of origin, through the border inspection posts of first entry, and to the photographic factories of destination approved by the competent authorities of the Member States of destination ("approved photographic factories"), listed in Annex I.

2. Once the photographic gelatine has entered the Member State of destination, it shall not be traded between Member States but shall only be used in the approved photographic factory in the same Member State of destination and solely for photographic production purposes.

3. A health certificate corresponding to the model laid down in Annex III, certifying that the photographic gelatine meets the conditions set out in Annex II and comes from the plants of origin listed in Annex I, shall accompany all consignments of photographic gelatine.

Article 3
Obligations of the operator of the approved photographic factory

1. The operator of the approved photographic factory shall ensure that any surpluses or residues of and other waste derived from the photographic gelatine are –

   (a) transported in sealed leak-proof containers labelled "for disposal only" in vehicles under satisfactory hygiene conditions;

   (b) disposed of as waste by incineration in accordance with Directive 2000/76/EC of the European Parliament and of the Council[4] or in a landfill site in accordance with Council Directive 1999/31/EC[5]; or.

   (c) exported to the country of origin in accordance with Regulation (EC) No 259/93 on the supervision and control of shipments of waste within, into and out of the European Community.

2. The operator of the approved photographic factory shall keep records for at least two years detailing the purchases and uses of photographic gelatine, as well as the disposal of residues and surplus material.

   The records shall be made available to the competent authority for the purpose of checking compliance with this Decision.

Article 4
Obligations of the competent authority

1. The competent authority shall control compliance by operators of premises and facilities with the conditions set out in Articles 2 and 3.

2. In accordance with the provisions for the monitoring of channelled consignments laid down in Article 8(4) of Council Directive 97/78/EC[6], the competent authority shall ensure that the consignments are sent directly from the border inspection post of first entry to an approved photographic factory listed in Annex I, by means of vehicles that at the same time do not transport any products intended for food or feed, including gelatine intended for other purposes than use in the photographic industry.

3. The competent authority shall ensure that the approved photographic factories on their territory use the consigned photographic gelatin exclusively for the authorised purpose.

4. The competent authority shall carry out documentary checks at regular intervals, at least twice a year on the channelling chain from the border inspection posts of first entry to the approved photographic factory for the purpose of reconciliation of the quantities of products imported, used and disposed of, ensuring compliance with the provisions of this Decision.

   The competent authority shall take appropriate measures immediately in the case of any non-compliance with this Decision.

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4 OJ L 332, 28.12.2000, p. 91.
5 OJ L 182, 16.7.1999, p. 1.
6 OJ L 24, 30.1.1998, p. 9.

5. Notwithstanding the provisions of Article 2(1) above, the competent authority of the Member State of destination may by way of exception designate a different or additional border inspection post of first entry in the same Member Sates provided the conditions of this Decision are met.

Article 5
Withdrawal of approvals and disposal of material not complying with this Decision

1. Individual approvals by the competent authority for the use of photographic gelatine in the approved photographic factories listed in Annex I shall be immediately and permanently withdrawn in respect to any operator, premises or facilities if the conditions set out in this Decision are no longer fulfilled. The competent authority shall inform the Commission immediately in writing of such withdrawal.

2. Any material that does not comply with the requirements of this Decision shall be disposed of in accordance with the instructions of the competent authority.

Article 6
Review

The Commission shall review the operation of this Decision as appropriate in the light of new scientific advice.

Article 7
Compliance with this Decision by the concerned Member States

France, the Netherlands and the United Kingdom shall immediately take the necessary measures to comply with this Decision and shall publish those measures. They shall immediately inform the Commission thereof.

Article 8
Applicability

This Decision shall apply from 1 May 2004.

Article 9
Addressees

This Decision is addressed to the French Republic, the Kingdom of the Netherlands and the United Kingdom of Great Britain and Northern Ireland.

Done at Brussels, 26 April 2004.

For the Commission
David BYRNE
Member of the Commission

ANNEX I

THIRD COUNTRIES AND PLANTS OF ORIGIN, MEMBER STATES OF DESTINATION, BORDER INSPECTION POSTS OF FIRST ENTRY AND APPROVED PHOTOGRAPHIC FACTORIES

Third Country of origin	*Plants of origin*	*Member State of destination*	*Border Inspection Post of first entry*	*Approved Photographic Factories*
Japan	Nitta Gelatin Inc. 2-22 Futamata Yao-City, Osaka 581 – 0024 Japan Jellie Co. ltd. 7-1, Wakabayashi 2-Chome, Wakabayashi-ku, Sendai-city, Miyagi, 982 Japan NIPPI Inc. Gelatin Division 1 Yumizawa-Cho, Fujinomiya City Shizuoka 418 – 0073 Japan	The Netherlands	Rotterdam	Fuji Photo Film BV, Tilburg
Japan	Nitta Gelatin Inc 2-22 Futamata Yao-City Osaka 581 – 0024, Japan	France	Le Havre	Kodak Zone Industrielle Nord, 71100 Châlon sur Saône
		United Kingdom	Liverpool Felixstowe	Kodak Ltd Headstone Drive, Harrow, MIDDX HA4 4TY
USA	Eastman Gelatine Corporation, 227 Washington Street, Peabody, MA, 01960 USA Gelita North America, 2445 Port Neal Industrial Road Sergeant Bluff, Iowa, 51054 USA	France	Le Havre	Kodak Zone Industrielle Nord, 71100 Châlon sur Saône
		United Kingdom	Liverpool Felixstowe	Kodak Ltd Headstone Drive, Harrow, MIDDX HA4 4TY

ANNEX II

PRODUCTION OF PHOTOGRAPHIC GELATINE, WRAPPING AND PACKAGING

1. Photographic gelatine shall be produced only in plants, which do not produce gelatine for food, feed or other technical uses intended for dispatch to the European Community, and which are approved for this purpose by the competent authority of the third country concerned.

2. (a) Photographic gelatine shall be produced by a process that ensures that the raw material is treated by processing Method 1 set out in Chapter III of Annex V to Regulation (EC) No 1774/2002 or subjected to a treatment with acid or alkali for at least two days, washing with water and –

   (i) following an acid treatment, treating with an alkaline solution for at least 20 days; or

   (ii) following an acid treatment, treating with an acid solution for 10-12 hours.

   The pH must then be adjusted and the material purified by means of filtration and sterilisation at 138-140 °C for 4 seconds.

   (b) After having been subjected to the process referred to in sub-paragraph (a), the photographic gelatine may undergo a drying process and, where appropriate a process of pulverisation or lamination.

   (c) The photographic gelatine must be wrapped, packaged in new packages, stored and transported in sealed leak-proof, labelled containers in a vehicle under satisfactory hygiene conditions. If leakage is observed, the vehicle and containers shall be thoroughly cleaned and inspected before re-use.

   (d) Wrapping and packages containing the photographic gelatine must carry the words “photographic gelatine for the photographic industry only”.

ANNEX III

MODEL HEALTH CERTIFICATES FOR THE IMPORTATION FROM THIRD COUNTRIES OF TECHNICAL GELATINE TO BE USED BY THE PHOTOGRAPHIC INDUSTRY

Notes

(a)	Veterinary certificates for the importation of technical gelatine to be used by the photographic industry shall be produced by the exporting country, based on the model appearing in this Annex III. They shall contain the attestations that are required for any third country and, as the case may be, those supplementary guarantees that are required for the exporting third country or part thereof.	(e)	When the certificate, including additional schedules referred to in d), comprises more than one page, each page shall be numbered -*(page number)* of *(total number of pages)*– on its bottom and shall bear the code number of the certificate that has been designated by the competent authority on its top.
(b)	The original of each certificate shall consist of a single page, both sides, or, where more text is required, it shall be in such a form that all pages needed are part of an integrated whole and indivisible.	(f)	The original of the certificate must be completed and signed by an official veterinarian. In doing so, the competent authorities of the exporting country shall ensure that the principles of certification equivalent to those laid down in Council Directive 96/93/EC are followed.
(c)	It shall be drawn up in at least one of the official languages of the EU Member State in which the inspection at the border post shall be carried out and of the EU Member State of destination. However, these Member States may allow other languages, if necessary, accompanied by an official translation.	(g)	The colour of the signature shall be different to that of the printing. The same rule applies to stamps other than those embossed or watermark.
(d)	If for reasons of identification of the items of the consignment, additional pages are attached to the certificate, these pages shall also be considered as forming part of the original of the certificate by the application of the signature and stamp of the certifying official veterinarian, in each of the pages.	(h)	The original of the certificate must accompany the consignment at the EU border inspection post until it reaches the photographic factory of destination.

Health certificate

For technical gelatine not intended for human consumption to be used by the photographic industry, intended for dispatch to the European Community

Note for the importer: This certificate is only for veterinary purposes and has to accompany the consignment until it reaches the photographic factory of destination from the border inspection post.

1. **Consignor** (name and address in full)	**VETERINARY CERTIFICATE** **For technical gelatine not intended for human consumption to be used by the photographic industry, intended for dispatch to the European Community** Reference number(1) ORIGINAL
2. **Consignee** (name and address in full)	**3.** **Origin of the photographic gelatine** 3.1. Country : Japan or USA (2) 3.2. Code of territory : .....
	4. **Competent Authority** 4.1. Responsible Ministry : ..... 4.2. Certifying department : ....
5. **Intended destination of the photographic gelatine** 5.1. EU Member State : France or the Netherlands or the United Kingdom(2) 5.2. Name and address of the photographic factory of destination :	**6.** **Place of loading for exportation** ....
7. **Means of transport and consignment identification** 7.1. (Lorry, Rail-wagon, Ship, or Aircraft)(2) 7.2. Number of seal (if applicable) : ..... 7.3. Registration number(s), ship name or flight number:	7.4. Nature of packaging : .... 7.5. Number of packages : ..... 7.6. Net weight : ..... 7.7. Lot/batch production reference number : ....
8. **Identification of the photographic gelatine** 8.1. Nature of the photographic gelatine: ..... 8.2. Photographic gelatine of: ..... *(animal species)* 8.3. Address and approval number of the approved establishment of origin:	

9.	**Health attestation**
	I, the undersigned official, declare hat I have read and understood Regulation (EC) No 1774/2002 [3] and certify that the photographic gelatine described above:
9.1.	consists exclusively of photographic gelatine for photographic uses and is not intended for any other purpose;
9.2.	has been prepared and stored in a plant approved, validated and supervised by the competent authority in accordance with Article 18 of Regulation (EC) No 1774/2002, which do not produce gelatine for food, feed or other technical uses intended for dispatch to the European Community;
9.3.	has been prepared with Category 3 animal by-products and/or bovine vertebral column classified as Category 1 material;
9.4.	(a) has been wrapped, packaged, stored and transported under satisfactory hygiene conditions.
	(b) has been produced by a process ensuring that the raw material is treated by Method 1[4] of Annex V of Regulation (EC) No 1774/2002 or subjected to a treatment with acid or alkali for at least two days, washing with water and –
	(i) following an acid treatment, treating with an alkaline solution for at least 20 days; or
	(ii) following an acid treatment, treating with an acid solution for 10-12 hours.
	The pH was adjusted and the material purified by means of filtration and sterilised at 138-140 °C for 4 seconds.
9.5.	has been wrapped and packaged in wrappings and packages carrying the words "PHOTGRAPHIC GELATINE FOR THE PHOTOGRAPHIC INDUSTRY ONLY"
	Official stamp and signature
	Done at ..... on ..... (place) (date)
	(stamp) [5] ..... (Signature of the official veterinarian/official of the competent authority) [5]
	..... (name, qualifications and title, in capital letters)

Notes

(1) Issued by the competent authority.

(2) Delete as appropriate.

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

(4) Method 1 is as follows -

"Reduction

1. If the particle size of the animal by-products to be processed is more than 50 millimetres, the animal by-products must be reduced in size using appropriate equipment, set so that the particle size after reduction is no greater than 50 millimetres. The effectiveness of the equipment must be checked daily and its condition recorded. If checks disclose the existence of particles larger than 50 millimetres, the process must be stopped and repairs made before the process is resumed.

Time, temperature and pressure

2. After reduction the animal by-products must be heated to a core temperature of more than 133°C for at least 20 minutes without interruption at a pressure (absolute) of at least 3 bars produced by saturated steam; the heat treatment may be applied as the sole process or as a pre- or post-process sterilisation phase.

3. The processing may be carried out in batch or continuous systems."

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

COMMISSION DECISION

Of 26 April 2004

amending Decisions 2001/881/EC and 2002/459/EC as regards changes and further additions to the list of border inspection posts

(notified under document number C(2004) 1518)

(Text with EEA relevance)

(2004/408/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries[1], and in particular Article 6(2) thereof,

Having regard to Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organisation of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC[2], and in particular Article 6(4) thereof,

(1) The list of border inspection posts for veterinary checks on live animals and animal products from third countries, approved by Commission Decision 2001/881/EC[3], which includes the ANIMO unit number for every border inspection post, should be updated to take account in particular of developments in certain Member States and of inspections carried out by the Food and Veterinary Office.

(2) Following confirmation of completion of facilities in Liège, Belgium and at Århus, Denmark, additional categories should be added to the entries for these border inspection posts.

(3) Following a satisfactory Community inspection an additional border inspection post at Norrkoping, Sweden should be added to the list.

(4) Following requests from certain Member States certain other inspection centres or border inspection posts should be deleted from the list.

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1 OJ L 24, 30.1.1998, p. 9.

2 OJ L 268, 24.9.1991, p. 56. Directive as last amended by Directive 96/43/EC (OJ L 162, 1.7.1996, p. 1.).

3 OJ L 326, 11.12.2001, p. 44. Decision as last amended by Decision 2003/831/EC (OJ L 313, 28.11.2003, p. 61.).

(5) In addition, a number of amendments have been requested by Member States and should be introduced to the listing details as regards categories and inspection centres for several other border inspection posts that have already been approved.

(6) The list of ANIMO units in Commission Decision 2002/459/EC[4], which includes the ANIMO unit number for each border inspection post in the Community, should accordingly be updated to take account of any relevant changes and to maintain an identical list to that in Decision 2001/881/EC.

(7) The amendments concerning Piraeus, Greece and Karlskrona, Karlshamn and Ystad in Sweden are a result of the enlargement process and those amendments should therefore take effect only from the date of Accession.

(8) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health.

HAS ADOPTED THIS DECISION:

Article 1

In the Annex to Decision 2001/881/EC, the entries for the following Member States, Belgium, Denmark, Greece, Spain, France, Portugal, Sweden and the United Kingdom, are replaced by the corresponding entries in Annex I to this Decision.

Article 2

The Annex to Decision 2002/459/EC is amended in accordance with Annex II to this Decision.

Article 3

The amendments as regards the listing for Piraeus (Greece), and delisting for Karlskrona, Karlshamn and Ystad (Sweden) shall apply from 1 May 2004.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 26 April 2004.

For the Commission
David BYRNE
Member of the Commission

[4] OJ L 159, 17.6.2002, p. 27. Decision as last amended by Decision 2003/831/EC.

ANNEX I

”ANNEX

……”

ANNEX II

The Annex to Decision 2002/459/EC is amended as follows:

(1) In the section for border inspection posts in DENMARK, the following entry is deleted:

"0931699 P Køge "

and the following entry is added

"0951699 P Ålborg 2"

(2) In the section for border inspection posts in SWEDEN, the following entries are deleted:

"1610299 P Karlshamn

1610199 P Karlskrona

1612199 P Ystad"

and the following entry is added:

"1605299 P Norrköping"

(3) In the section for border inspection posts in THE UNITED KINGDOM, the following entry is deleted:

"0713399 P Newhaven"

COMMISSION DECISION

of 26 April 2004

recognising in principle the completeness of the dossiers submitted for detailed examination in view of the possible inclusion of ethaboxam in Annex I to Council directive 91/414/EEC

(notified under document number C(2004) 1526)

(Text with EEA relevance)

(2004/409/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant-protection on the market[1], and in particular Article 6(3) thereof,

Whereas:

(1) Directive 91/414/EEC provides for the development of a Community list of active substances authorised for incorporation in plant protection products.

(2) A dossier for the active substance ethaboxam was submitted by LG Life Sciences Ltd. to the authorities of the United Kingdom on 30 September 2003 with an application to obtain its inclusion in Annex I to Directive 91/414/EEC.

(3) The authorities of the United Kingdom have indicated to the Commission that, on preliminary examination, the dossier for the active substance concerned appears to satisfy the data and information requirements set out in Annex II to Directive 91/414/EC. The

[1] OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2004/20/EC (OJ L 70, 9.3.2004, p. 32.

dossier submitted appears also to satisfy the data and information requirements set out in Annex III to Directive 91/414/EEC in respect of one plant protection product containing the active substance concerned. In accordance with Article 6(2) of Directive 91/414/EC, the dossier was subsequently forwarded by the applicant to the Commission and other Member States, and was referred to the Standing Committee on the Food Chain and Animal Health.

(4) By this Decision it should be formally confirmed at Community level that the dossier is considered as satisfying in principle the data and information requirements provided for in Annex II and, for at least one plant protection product containing the active substance concerned, the requirements set out in Annex III to Directive 91/414/EEC.

(5) This Decision should not prejudice the right of the Commission to request the applicant to submit further data or information to the Member State designated as Rapporteur in respect of a given substance in order to clarify certain points in the dossier.

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

HAS ADOPTED THIS DECISION:

Article 1

The dossier concerning the active substance identified in the Annex to this Decision, which was submitted to the Commission and the Member States with a view to obtaining the inclusion of that substance in Annex I to Directive 91/414/EEC, satisfies in principle the data and information requirements set out in Annex II to Directive 91/414/EEC.

The dossier also satisfies the data and information requirements set out in Annex III to Directive 91/414/EEC in respect of one plant protection product containing the active substance, taking into account the uses proposed.

Article 2

The rapporteur Member State shall pursue the detailed examination for the dossier concerned and shall report the conclusion of this examination accompanied by any recommendations on the inclusion or non-inclusion of the active substance concerned in

Annex I of Directive 91/414/EEC and any conditions related thereto to the Commission as soon as possible. and by 30 April 2005 at the latest.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 26 April 2004.

For the Commission
David BYRNE
Member of the Commission

ANNEX

ACTIVE SUBSTANCE CONCERNED BY THIS DECISION

No	Common Name, CIPAC Identification Number	Applicant	Date of application	Rapporteur Member State
1	Ethaboxam CIPAC-No. not yet available	LG Life Sciences Ltd.	30.09.2003	UK

COMMISSION DECISION

of 28 April 2004

concerning specific animal health conditions for importation of certain animals from Saint Pierre and Miquelon and amending Council Decision 79/542/EEC

(notified under document number C(2004) 1548)

(Text with EEA relevance)

(2004/410/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 72/462/EEC of 12 December 1972 on health and veterinary inspection problems upon importation of bovine, ovine and caprine animals and swine, fresh meat or meat products from third countries[1], and in particular, Article 6(3) thereof,

Having regard to Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A(I) to Directive 90/425/EEC[2], and in particular Article 17 paragraph (3), 18(1) and 19 thereof,

Whereas:

(1) Council Directive 92/65/EEC establishes that the import of ungulate animals of species other than those referred to in Directives 64/432/EEC, 90/426/EEC and 91/68/EEC shall be allowed only from those third countries included in a list drawn up in accordance with its Article 17.

(2) Council Decision 79/542/EEC[3], draws up a list of third countries from which the Member States authorise imports of certain live animals, lays down the specific animal and public health and veterinary certification conditions for the import of these animals, and provides for a residency period in the exporting country of more than six months.

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1 OJ L 302, 31.12.1972 p. 28., as last amended by Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36.).

2 OJ L 268, 14.9.1992, p. 52., last amended by Commission Decision 2001/298/EC of 30 March 2001 (OJ L 102, 12.4.2001, p. 63.).

3 OJ L 146, 14.6.1979, p. 15., last amended by Commission Decision 2004/…./EC [C(2003)5248]

(3) Following a Commission veterinary inspection in Saint Pierre and Miquelon, the animal health situation appears to be under the satisfactory control of the official veterinary services and, in particular, the availability of a quarantine station allows the safe import into Saint Pierre and Miquelon of certain animals.

(4) The facilities of the quarantine station in Saint Pierre and Miquelon allow for the residence of certain kind of ungulate animals of species other than those referred to in Directives 64/432/EEC, 90/426/EEC and 91/68/EEC.

(5) Therefore it is appropriate to lay down the list of animal species and the specific animal health and certification conditions for imports of live animals in accordance with the animal health situation of Saint Pierre and Miquelon.

(6) Council Decision 79/542/EEC should therefore be amended to allow imports of animals of species referred to in Directives 72/462/EEC and 92/65/EEC and in particular camelidae from Saint Pierre and Miquelon, and to lay down the necessary conditions.

(7) On 1 May 2004 the 10 Acceding States are due to become full members of the European Community and Community rules will be applicable to them. Following their accession, these countries will than become part of the internal market and they should then be deleted from the list of third countries laid down in Commission Decision 79/542/EEC.

(8) The restrictions for Bulgaria concerning the import into the Community of live bovine ovine and caprine animals in relation to bluetongue have been lifted by Commission Decision 2003/845/EC[4].

(9) The list of third countries and regions laid down in Commission Decision 79/542/EEC should be amended accordingly.

(10) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health.

HAS ADOPTED THIS DECISION:

Article 1

Annex I to Decision 79/542/EEC is amended as follows:

1. The list of third countries in Part 1 is replaced by the list in Annex I to this Decision.

2. Part 2 is amended as follow:

   a) in the list of "Models", the following entry is added at the end:

      "CAM : Model of specific attestation for animals imported from St Pierre et Miquelon under the conditions provided for in Part 4 of Annex I."

[4] OJ L 321, 6.12.2003, p. 61.

b) The "Model RUM" is replaced by the model in Annex II to this Decision.

c) The model of specific attestation in Annex III to this Decision is added after the model "SUI".

3. The text in Annex IV to this Decision is inserted as Part 4.

Article 2

This Decision shall apply from 1 May 2004.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 28 April 2004.

For the Commission
David BYRNE
Member of the Commission

ANNEX I

"ANNEX I

LIVE ANIMALS

Part 1

List of third countries or parts thereof(*)

Country	***Code of Territory***	***Description of territory***	***Veterinary certificate***		***Specific conditions***
			Model(s)	*SG*	
1	*2*	*3*	*4*	*5*	*6*
BG- Bulgaria	*BG-0*	*Whole country*	-		***VI***
	BG-1	*The provinces of Varna, Dobrich, Silistra, Choumen, Targovitchte, Razgrad, Rousse, V.Tarnovo, Gabrovo, Pleven, Lovetch, Plovdic, Smolian, Pasardjik, Sofia distric, Sofia city, Pernik, Kustendil, Blagoevgrad, Sliven, Starazagora, Vratza, Montana and Vidin*	*BOV-X, BOV-Y, RUM, OVI-X, OVI-Y*	**A**	
CA - Canada	*CA-0*	*Whole country*	*POR-X*		***IVb*** ***IX***
	CA-1	*Whole country except the Okanagan Valley region of British Columbia described as follows:* • *From a point on the Canada/United States border 120°15' longitude, 49° latitude* • *Northerly to a point 119°35' longitude, 50°30' latitude* • *North-easterly to a point 119° longitude, 50°45' latitude* *Southerly to a point on the Canada/United States border 118°15' longitude, 49° latitude*	*BOV-X, OVI-X, OVI-Y*	**A**	
CH - Switzerland	*CH-0*	*Whole country*	*BOV-X, BOV-Y OVI-X, OVI-Y RUM*		
			POR-X, POR-Y SUI	***B***	
CL - Chile	*CL-0*	*Whole country*	*OVI-X, RUM*		
			POR-X, SUI	***B***	
CY – Cyprus(**)	*CY-*	*Whole country*	*POR-X, POR-Y*	***B***	
CZ - Czech Republic(**)	*CZ-0*	*Whole country*	*BOV-X, BOV-Y,RUM, OVI-X, OVI-Y POR-X, POR-Y*		***IVa*** ***V***
EE - Estonia(**)	*EE-0*	*Whole country*	*BOV-X, BOV-Y, RUM, OVI-Y*		
GL - Greenland	*GL-0*	*Whole country*	*OVI-X, RUM*		***V***
HR - Croatia	*HR-0*	*Whole country*	*BOV-X, BOV-Y, RUM, OVI-X, OVI-Y*		
HU - Hungary(**)	*HU-0*	*Whole country*	*BOV-X, BOV-Y, RUM, OVI-X, OVI-Y*		***V***
			POR-X, POR-Y	***B***	
IS - Iceland	*IS-0*	*Whole country*	*BOV-X, BOV-Y RUM, OVI-X, OVI-Y*		***I***
			POR-X, POR-Y	***B***	
LT - Lithuania(**)	*LT-0*	*Whole country*	*BOV-X, BOV-Y OVI-Y, RUM*		
LV - Latvia(**)	*LV-0*	*Whole country*	*BOV-X, BOV-Y OVI-Y, RUM*		

MT - Malta(**)	*MT-0*	*Whole country*	*RUM, OVI-X, OVI-Y*		
NZ - New Zealand	*NZ-0*	*Whole country*	*BOV-X, BOV-Y,*		***I***
PL - Poland(**)	*PL-0*	*Whole country*	*BOV-X, BOV-Y, RUM, OVI-X, OVI-Y*		
PM - St Pierre Miquelon	*PM-0*	*Whole country*	*BOV-X, BOV-Y, RUM, OVI-X, OVI-Y CAM*		
RO - Romania	*RO-0*	*Whole country*	*BOV-X, BOV-Y, RUM, OVI-X, OVI-Y*		***V***
SI – Slovenia(**)	*SI-0*	*Whole country*	*BOV-X, BOV-Y, RUM, OVI-Y*		
SK – Slovakia(**)	*SK-0*	*Whole country*	*BOV-X, BOV-Y, RUM, OVI-X, OVI-Y*		***V***

"

(*) Without prejudice to specific certification requirements provided for by any relevant Community agreement with third countries.

(**) Only applicable until this Acceding State becomes a Member State of the Community'

Specific Conditions (see footnotes in each certificate):

"I" : *territory where the presence of BSE in native cattle has been assessed as highly unlikely, for the purpose of exporting to the European Community animals certified according to the models of certificate BOV-X and BOV-Y.*

"II" : *territory recognised as having an official tuberculosis-free status for the purposes of exports to the European Community of animals certified according to the model of certificate BOV-X*

"III" : *territory recognised as having an official brucellosis-free status for the purposes of exports to the European Community of animals certified according to the model of certificate BOV-X.*

"IVa": *territory recognised as having an official enzootic-bovine-leukosis (EBL) free status for the purposes of exports to the European Community of animals certified according to the model of certificate BOV –X.*

"IVb": *territory with approved holdings recognised as having an official enzootic-bovine-leukosis (EBL) free status for the purposes of exports to the European Community of animals certified according to the model of certificate BOV –X.*

"V": *territory recognised as having an official brucellosis-free status for the purposes of exports to the European Community of animals certified according to the model of certificate OVI-X.*

"VI": *Geographical constraints:*

"VII": *territory recognised as having an official tuberculosis-free status for the purposes of exports to the European Community of animals certified according to the model of certificate RUM.*

"VIII": *territory recognised as having an official brucellosis-free status for the purposes of exports to the European Community of animals certified according to the model of certificate RUM.*

"IX": *territory recognised as having an official Aujeszky's disease -free status for the purposes of exports to the European Community of animals certified according to the model of certificate POR-X.*

Annex II

"Model RUM

VETERINARY CERTIFICATE
for non domestic animals[1] other than Suidae, consigned to the European Community

No[2] ORIGINAL

1. Consignor (name and address in full)
……………………………………………………………
……………………………………………………………
……………………………………………………………
……………………………………………………………

2. Consignee (name and address in full)
……………………………………………………………
……………………………………………………………
……………………………………………………………
……………………………………………………………

3. Origin of the animals[3]
3.1 Country :…………………………………………………
3.2 Code of territory : ………………………………………

4. Competent Authority
4.1 Ministry:…………………………………………………
4.2 Service:…………………………………………………
……………………………………………………………
4.3 Local/Regional level:…………………………………
……………………………………………………………
……………………………………………………………

5. Intended destination of the animals
5.1 EU Member State:………………………………………
5.2 Name, address and registration number of the holding :
……………………………………………………………
……………………………………………………………
……………………………………………………………
……………………………………………………………

6. Establishment where animals are loaded for exportation
(name and address of the holding)
……………………………………………………………
……………………………………………………………
……………………………………………………………
……………………………………………………………
……………………………………………………………
……………………………………………………………
……………………………………………………………
……………………………………………………………
……………………………………………………………
……………………………………………………………

7. Means of transport and consignment identification[4]
7.1 (Lorry, Rail-wagon, Ship, or Aircraft)[5]
7.2 Registration number(s), ship name or flight number :
……………………………………………………………
……………………………………………………………
7.3 Consignment identification details[6]:
……………………………………………………………
……………………………………………………………
……………………………………………………………
……………………………………………………………

8. Identification of the animals and tests
8.1 Animal species : …….*(one single animal species)*……..…………………………………………………………………...
8.2 Individual identification of the animals included in this consignment [7]

Official identification numbers[7]	Age and Sex[8]	Tests[5][9]:

8.3 Total number of animals (in figures and letters):……………………………………………………………………………..

9.	**Public Health attestation**
	I, the undersigned official veterinarian, hereby certify, that the animals described in this certificate :
9.1	come from a holding which has been free from any official prohibition on health grounds, for the last 42 days in the case of brucellosis and tuberculosis, for the last 30 days in the case of anthrax, for the last six months in the case of rabies, and, have not been in contact with animals from holdings which did not satisfy these conditions;
9.2	have not received :
	- any stilbene or thyrostatic substances,
	- oestrogenic, androgenic, gestagenic or β- agonist substances for purposes other than therapeutic or zootechnic treatment (as defined in Council Directive 96/22/EC).
10.	**Animal Health attestation**
	I, the undersigned official veterinarian, hereby certify, that the animals described above meet the following requirements:
10.1	they come from the territory with code :…… [3] which, at the date of issuing this certificate :
	a) has been free for 24 months from foot-and-mouth disease, for 12 months from rinderpest, bluetongue, Rift valley fever, contagious bovine pleuropneumonia, lumpy skin disease, peste des petits ruminants, sheep pox and goat pox, contagious caprine pleuropneumonia and epizootic haemorrhagic disease and for 6 months from vesicular stomatitis, and
	b) where during the last 12 months, no vaccination against these diseases has been carried out and imports of cloven-hoofed animals vaccinated against these diseases are not permitted;
10.2	they have remained
either	in the territory described under point 10.1 since birth, or for at least the last six months before dispatch to the European Community and without contact with cloven-hoofed animals imported into this territory less than six months ago;
or	*in the country of dispatch for at least 60 days since entry, if they are animals of the relevant species listed in Annex IV, Part 4 to Decision 79/542/EEC and they were imported directly under the conditions specified for each species in Annex IV, Part 4 to Decision 79/542/EEC from a third country during a period of less than six months prior to embarkation to the European Community and in any case they have been separated from other animals not of the same health status after being released in the exporting country and before exportation to the EU*[10]
10.3	they have remained since birth or at least 40 days before dispatch in the holding/*establishment*[5] described under point 6:
	a) in and around which in an area of radius of 150 km, there has been no case/outbreak of bluetongue and epizootic haemorrhagic disease during the previous 100 days, and
	b) in and around which in an area of 20 km radius, there has been no case/outbreak of the other diseases mentioned under point 10.1 during the previous 40 days;
10.4	they are not animals to be killed under a national programme for the eradication of diseases, nor have they been vaccinated against any of the diseases mentioned under point 10.1 , and they:
[5][11] *either*	[come from a herd which is recognised as officially tuberculosis free, and]
[5][12] *or*	[have been subjected to an intradermal tuberculin test within the past 30 days with negative results, and]
	they have not been vaccinated against brucellosis and they:
[5][11] *either*	[come from a herd which is recognised as officially brucellosis free;]
[5][12] *or*	[have been subjected to a serum agglutination test which showed a brucella count of less than 30 IU of agglutination per ml, within the past 30 days;]
[5] *or*	[are castrated males of any age;]

10.5 according to my knowledge and to the written declaration made by the owner, the animals:

a) do not come from holdings/*establishments*[5], and have not been in contact with animals of a holding, in which the following diseases have been clinically detected :

i) contagious agalactia of sheep or goats (Mycoplasma agalactiae, Mycoplasma capricolum, Mycoplasma mycoides var. mycoides 'large colony'), within the last six months,

ii) paratuberculosis and caseous lymphadenitis, within the last 12 months,

iii) pulmonary adenomatosis, within the last three years, and

iv) Maedi/Visna or caprine viral arthritis/encephalitis,

[5] *either* [within the last three years,]

[5] *or* [within the last 12 months, and all the infected animals were slaughtered and the remaining animals subsequently reacted negatively to two tests carried out at least six months apart,]

b) are included in an official system for notification of these diseases, and

c) have been free from clinical or other evidence of tuberculosis and brucellosis during the three years prior to export;

10.6 they are dispatched from the holding described under point 6 directly to the European Community and, until dispatched to the European Community:

a) they did not come in contact with other cloven-hoofed animals not complying with at least the same health requirements as described in this certificate, and

b) they were not at any place where, or around which within a 20 kms radius, during the previous 30 days there has been a case/outbreak of any of the diseases mentioned under point 10.1;

10.7 any transport vehicles or containers in which they were loaded were cleaned and disinfected before loading with an officially authorised disinfectant;

10.8 they were examined by an official veterinarian within 24 hours of loading and showed no clinical sign of disease;

10.9 they have been loaded for dispatch to the European Community the …….. [13] in the means of transport described under point 7 above that were cleaned and disinfected before loading with an officially authorised disinfectant and so constructed that faeces, urine, litter or fodder could not flow or fall out of the vehicle or container during transportation.

11. Animal transport attestation

I, the undersigned official veterinarian, hereby certify, that the animals described above have been treated before and at the time of loading in accordance with the relevant provisions of Council Directive 91/628/EEC, in particular as regards watering and feeding, and they are fit for the intended transport.

[5] [14] [**12. Specific requirements**

12.1 According to official information, no clinical or pathological evidence of infectious bovine rhinotracheitis (IBR) has been recorded in the holding/establishment[5] *of origin referred to in point 6, for the last 12 months;*

12.2 the animals referred to in point 8:

a) have been isolated in accommodation approved by the competent authority for the last 30 days immediately prior to dispatch for export, and

b) have been subjected to a serological test for IBR on sera taken at least 21 days after entry into isolation, with negative results, and all animals in isolation have also given negative results to this test, and

c) have not been vaccinated against IBR.;

[5][*12.3 …….(further requirements and/or tests)…….*

…… ……..]]

Official stamp and signature

Done at …….. on .....

(signature of official veterinarian)

(stamp)

(name in capital letters, qualifications and title)

Notes

(1) Live animals of the taxa Proboscidea and Artiodactyla (excluding Suidae, Bos taurus, Bison bison, Bubalus bubalis, Ovis aries and Capra hircus).

After importation the animals must be conveyed without delay to the holding of destination where they shall remain for a minimum period of 30 days before further movement outside the holding, except in the case of a dispatch to a slaughterhouse.

(2) Issued by the competent authority.

(3) Country and code of territory as appearing in Part 1 of Annex I to Council Decision 79/542/EEC (as last amended).

(4) The registration number(s) of rail-wagon or lorry and the name of the ship should be given as appropriate. If known, the flight number of the aircraft.

In case of transport in containers or boxes, the total number, their registration and seal numbers, if present, should be indicated under point 7.3.

(5) Keep as appropriate.

(6) Complete if appropriate.

(7) The animals must bear:

a) an individual number which permits tracing of the holding of origin. Specify the identification system (i.e. tag, tattoos, brand, chip, transponder) and the anatomic place used in the animal,

b) an ear tag that includes the ISO code of the exporting country.

(8) Age (months). Sex (M = male, F = female, C = castrated).

(9) Tests that may have been carried out in the animal during 30 days prior to dispatch for exportation. Use, as appropriate, the codes as appearing in Part 3.C of this Annex I identifying the diseases, that have been tested in accordance with the protocols of this Part 3.C or using tests for diseases requested by the Member State of destination.

(10) In this case the health certificate has to be accompanied by the official document on quarantine and test conditions in Annex I, Part 1 to Decision 79/542/EEC (model "CAM").

(11) Officially tuberculosis/brucellosis free regions or herds recognised as equivalent to the requirements laid down in Annex A to Council Directive 64/432/EEC and which appear in column 6 of Part 1 of Annex I to Council Decision 79/542/EEC (as last amended), with the entry " VII ", as regards tuberculosis, " V**III** ", as regards brucellosis.

(12) Tests carried out in accordance with the protocols that, for the disease concerned, are described in Part 3.C of this Annex I. However for the tuberculin test a result of an increase in skin fold thickness of 2mm or more, or clinical signs of such as oedema, exudation, necrosis, pain and/or inflammation shall be deemed to be positive.

(13) Date of loading. Imports of these animals shall not be allowed when the animals were loaded either prior to the date of authorisation for exportation to the European Community of the territory mentioned under (3), or during a period where restrictive measures have been adopted by the European Community against imports of these animals from this territory.

(14) When required by the EU Member State of destination.

Annex III

"

Specific animal health attestation for animals quarantined in St. Pierre and Miquelon prior to export to the European Community

CAM

1. Quarantine conditions attestation

I, the undersigned official veterinarian, hereby certify, that the animals(1) described in the animal health certificate(2) number…….. released on……. have been resident from …… (date of entry(3)) in the quarantine station of St.Pierre and Miquelon under the conditions provided for in Annex IV Part 4 to Decision 79/542/EEC for a period of :…… days before being released for exportation to the EU and during this period they have been subject to the following tests(4), carried out in an approved laboratory within the European Community, with a negative result(5):

1.2. BRUCELLOSIS:

a) B.abortus: SAT and RBT within two days after arrival and after at least 42 days

b) B.ovis: CFT within two days after arrival and after at least 42 days

c) B.melitensis: SAT and RBT within two days after arrival and after at least 42 days

1.3. BLUETONGUE and EPIZOOTIC HAEMORRHAGIC DISEASE

either

two tests using Bluetongue competitive Elisa test within two days after arrival and after at least 21 days(6)

or

they have been quarantined for more than 100 days and during this period the quarantine station remained free of Blue Tongue vectors (Culicoides), and no evidence of clinical disease has been detected(6).

1.4 .TUBERCULOSIS

two intradermal tuberculin test according to annex B of Directive 64/432/EC using bovine and avian tuberculin performed within two days after arrival and after at least 42 days from the first test

1.5. FMD: ELISA test for the detection of antibodies and a virus neutralizaton test within two days after arrival and after at least 42 days

1.6. RINDERPEST: competitive ELISA test within two days after arrival and after at least 42 days

1.7. VESCICULAR STOMATITIS: ELISA or virus- neutralisation test within two days after arrival and after at least 42 days

1.8. RIFT VALLEY FEVER: an ELISA test or a virus neutralisation test within two days after arrival and after at least 42 days

1.9. LUMPY SKIN DISEASE: ELISA or virus neutralization test within two days after arrival and after at least 42 days

1.10. CRIMEAN CONGO HAEMORRAGIC FEVER: ELISA or VN test within two days after arrival and after at least 42 days

1.11. SURRA: blood microscopy within two days after arrival and after at least 42 days

1.12. MALIGNANT CATARRHAL FEVER: IMMUNOFLUORESCENCE test within two days after arrival and after at least 42 days

2. Supplementary guarantees

2.1 BOVINE LEUKOSIS: AGID test or ELISA within two days after arrival and after at least 42 days (When required by the EU Member State of destination) (6)

3. TREATMENTS

They have been subjected to:

3.1 an internal and external antiparasitic treatment during the quarantine period

3.2 either

- a treatment with streptomycin 25mg/kg(6)

- or an antibiotic treatment effective against Leptospira spp (specify ……..……mg/kg……..)(6)

3.3 a vaccination against rabies (if requested) on …… (dd/mm/aa) using vaccine ……(type, producer and lot) test result……(6)

Official stamp and signature

Done at on

(signature of official veterinarian)

(stamp)

(name in capital letters, qualifications and title)

Notes for guidance:

(1) Live animals of the family *Camelidae*.

(2) Animal health certificate for non domestic animals other than Suidae, consigned to the European Community (model "RUM") as laid down in Annex I part 2 to Council Decision 79/542/EEC.

(3) Date in which the last animal in a group entered the quarantine facility.

(4) Tests performed in accordance with the methods described in point 1.1 of Chapter 2, part 4 of Annex I to Council Decision 79/542/EEC.

(5) Results of the tests performed must be attached in original to this health attestation.

(6) Delete as appropriate.

NB Sampling and testing procedures must be grouped as much as possible while respecting the minimum time intervals to avoid excessive handling and manipulation of the animals.

"

Annex IV

"Part 4

Animal species

Taxon		
ORDER	***FAMILY***	***GENUS AND SPECIES***
Artiodactila	Camelidae	Camelus ssp., Lama ssp., Vicugna ssp.

Animal health conditions

Import and quarantine conditions for animals imported into St. Pierre and Miquelon within a period of less than six months prior to export to the European Community

Chapter 1

Residence and quarantine

1. Animals imported into St. Pierre and Miquelon must reside in an authorised quarantine station for a minimum period of 60 days preceding export to the European Community. This period may be increased due to testing requirements for individual species. In addition the animals must comply with the following requirements:

   (a) Separate consignments may enter the quarantine station. However, upon entry in the quarantine station all animals of the same species should be considered as a single group, and referred to as such. The quarantine period would commence for the whole group at the point that the last animal entered the facility.

   (b) Within the quarantine station each specific group of animals must be maintained in isolation, with no direct or indirect contact with any other animals, including those from other consignments that may be present. Each consignment must be kept in the approved quarantine station and protected from vector insects.

   (c) If, during the period of quarantine, the isolation of a group of animals is not maintained and contact is made with other animals, the quarantine is considered null and void, and the group must begin a new period of quarantine of the same time period as initially prescribed on entry into the quarantine station.

   (d) animals to be exported to the European Community which pass through the quarantine station must be loaded and dispatched directly to the European Community:

(i) without coming into contact with animals other than animals which fulfil the health conditions established for the importation of the relevant category of animal into the European Community;

(ii) segregated into consignments so that no consignment can came in contact with animals not eligible for importation into the European Community;

(iii) in transport vehicles or containers which have first been cleansed and disinfected with a disinfectant officially authorized in St. Pierre and Miquelon as effective in the control of the diseases mentioned in Chapter II below and which are so constructed that faeces, urine, litter or fodder cannot flow or fall out of the vehicle during transportation.

2. The quarantine premises must at least meet the minimum standards laid down in Annex B to Directive 91/496/EEC, and the following conditions:

(a) they shall be supervised by an official veterinarian.

(b) they shall be situated at the centre of an area 20 km in diameter in which, according to official findings, for at least 30 days prior to their use as quarantine station there has been no case of foot-and-mouth disease.

(c) they shall, before being used as quarantine station, be cleansed and disinfected with a disinfectant officially authorized in St Pierre et Miquelon as effective in the control of the diseases mentioned in Chapter II.

(d) they shall operate, taking into account their animal capacity:

(i) a facility dedicated exclusively for this purpose, including adequate housing to a suitable standard for the animals;

(ii) appropriate facilities, that

- are easy to completely clean and disinfect,
- include facilities for safe loading and unloading,
- are able to fulfil all watering and feeding requirements for the animals,
- allow any necessary veterinary treatment to be easily administered;

(iii) appropriate facilities for inspection and isolation;

(iv) appropriate equipment for cleaning and disinfecting rooms and transport vehicles;

(v) an appropriate storage area for fodder, litter and manure;

(vi) an appropriate system for collecting waste water;

(vii) an office for the official veterinarian.

(e) when operating, they shall have sufficient veterinarians to carry out all duties,

(f) they shall only admit animals that are individually identified so as to guarantee traceability. To this end, when animals are admitted the owner or person in charge of the quarantine station shall ensure the animals are properly identified and accompanied by health documents or certificates for the species and categories involved. Moreover, this person shall record on a register or a data base, and retain for at least 3 years, the name of the owner, the origin, date of entry and exit, number and identification of the animals and their destination,

(g) the competent authority shall determine the procedure for official supervision of the quarantine station and shall ensure that such supervision is carried out; this supervision shall include regular inspections in order to ascertain that the requirements for approval continue to be fulfilled. In case of failure and suspension, the approval may only be restored when the competent authority is satisfied that the quarantine premises are in full compliance with all the provisions mentioned above.

Chapter 2

Animal health tests

1. GENERAL REQUIREMENTS

The animals must be subjected to the following tests carried out on samples of blood taken, if not specified otherwise, not earlier than 21 days after the commencing of the isolation period. The laboratory tests must be carried out in an approved laboratory in the European Community and all laboratory test and their results, vaccinations and treatments must be enclosed with the health certificate. In order to keep animal interventions to a minimum, sampling, tests and any vaccinations must be grouped as far as is possible whilst respecting the minimum time intervals required by the testing protocols.

2. SPECIFIC REQUIREMENTS

2.1 CAMELIDS

2.1.1 Tuberculosis

a) **Test to be used**: comparative intradermal reaction test using Bovine PPD and Avian PPD conforming to the standards for the manufacture of bovine and avian tuberculins as described in Annex B of Council Directive 64/432/EEC. The test has to be executed in the area behind the shoulder (axillary region) following the technique described in Annex B of Council Directive 64/432/EEC.

b) **Timing**: the animals have to be tested within two days from their arrival in the quarantine station and after 42 days from the first test.

c) **Interpretation of tests:**

the reaction has to be considered:

– negative if the increased skin thickness is less than 2 mm.

– positive if the increased skin thickness is more than 4 mm.

– inconclusive if the increased skin thickness to the bovine PPD is between 2mm and 4 mm, or more than 4 mm but less then the reaction to the avian PPD.

d) **Options for action following testing:**

If an animal presents a positive result to the intradermal-reaction to the bovine PPD, this animal shall be excluded from the group and the other animals have to be re-tested starting at least 42 days after the first positive test was administered: this has to be considered as the first test described in b).

If more than one animal of the group presents a positive result, the whole group shall to be rejected for exportation to the EC.

If one or more animals of the same group present an inconclusive reaction, the whole group will be re-tested after 42 days considering it as the first test described in b).

2.1.2 Brucellosis.

a) **Test to be used:**

- B. Abortus: SAT and RBT as described respectively in point (2.6) and (2.5) in Annex C to Directive 64/432/EEC. In case of positive result, a Complement fixation test has to be performed for confirmation.

- B. Melitensis: SAT and RBT as described respectively in point (2.6) and (2.5) in Annex C to Directive 64/432/EEC. In case of positive result, a Complement fixation test following the method described in Annex C to Directive 91/68/EC has to be performed for confirmation.

- B. Ovis: Complement fixation test as described in Annex D to Directive 91/68/EC

b) **Timing:** the animals have to be tested within two days from their arrival in the quarantine station and after 42 days from the first test.

c) **Interpretation of tests:**

A positive reaction to the tests will be as defined in Annex C to Directive 64/432/EEC.

d) **Options for action following testing:**

Animals tested positive to one of the tests shall be excluded from the group and the other animals have to be re-tested starting at least 42 days after the first positive test was performed: this has to be considered as the first test described in b).

Only the animals that tested negative to two consecutive tests performed as described in b) shall be allowed for exportation to the EC.

2.1.3 Bluetongue and Epizootic haemorrhagic disease (EHD).

a) **Test to be** used: AGID test as described in Part 3 (C) of Annex I to Council Decision 79/542/EEC.

In case of positive reaction the animals have to be tested with Competitive ELISA test as described in Part 3 (C) of Annex I to Council Decision 79/542/EEC to discriminate between the two diseases.

b) **Timing**:

The animals have to be tested with negative result to two tests: the first within two days from their arrival in the quarantine station and the second after at least 21 days from the first test.

c) **Options for action following testing:**

i) Bluetongue

If one or more animals tested positive to the ELISA as described in Part 3 (C) of Annex I to Council Decision 79/542/EEC, the positive animal/animals shall be excluded from the group, and the whole remaining group will be quarantined for 100 days starting from the date in which the samples for the positive test were collected. The group can only be considered free of disease if regular checks by official veterinarians through the duration of the quarantine period fail to reveal clinical symptoms of disease, and the quarantine station remains free of Blue Tongue vectors (*Culicoides)*.

If a further animal presents clinical symptoms of disease during the quarantine period as described above, the whole group shall be rejected for exportation to the EC.

ii) Epizootic haemorrhagic disease (EHD).

If one or more animals tested positive reveals presence of antibodies to the EHD virus during confirmatory ELISA testing, the animal(s) shall be considered positive and shall be excluded from the group, and the whole group must be subject to repeat testing beginning at least 21 days after the initial positive diagnosis and again at least 21 days subsequently, both with negative results. If any additional animals are tested positive during repeat testing, the whole group shall be rejected for exportation to the EC.

2.1.4 Foot and Mouth Disease (FMD)

a) **Test to be used**: Diagnostic tests (probang and serology) using ELISA and NV techniques under the protocols described in Part 3 (C) of Annex I to Council Decision 79/542/EEC.

b) **Timing**: the animals have to be tested with negative results to two tests: the first within two days from their arrival in the quarantine station and the second after at least 42 days from the first test.

c) **Options for action following testing:** If any animal tests positive for FMD virus, then all animals present in the quarantine station are not considered eligible for entry into the EC.

Note: Any detection of antibodies to structural or not structural proteins of FMD virus will be considered as a result of previous infection of FMD irrespective of the vaccination status.

2.1.5 Rinderpest

a) **Test to be used**: The competitive ELISA test as described in the OIE manual is the prescribed test for international trade and is test of choice. Serum neutralisation test, or other recognised tests in accordance with the protocols described in relevant sections of the OIE manual can also be used.

b) **Timing**: the animals have to be tested twice: the first within two days from their arrival in the quarantine station and the second after at least 42 days from the first test.

c) **Options for action following testing:** If any animal tests positive for Rinderpest virus, then all animals present in the quarantine station are not considered eligible for entry into the EC.

2.1.6 Vesicular Stomatitis

a) **Test to be used**: ELISA, virus neutralisation test, or other recognised test in accordance with the protocols described in relevant sections of the OIE manual.

b) **Timing**: the animals have to be tested twice: the first within two days from their arrival in the quarantine station and the second after at least 42 days from the first test.

c) **Options for action following testing:** If any animal tests positive for Vesicular Stomatitis virus, then all animals present in the quarantine station are not considered eligible for entry into the EC.

2.1.7 Rift Valley Fever

a) **Test to be used**: ELISA, virus neutralisation test, or other recognised test in accordance with the protocols described in relevant sections of the OIE manual.

b) **Timing**: the animals have to be tested twice: the first within two days from their arrival in the quarantine station and the second after at least 42 days from the first test.

c) **Options for action following testing:** If any animal displays evidence of exposure to Rift Valley Fever agent, then all animals present in the quarantine station are not considered eligible for entry into the EC.

2.1.8 Lumpy Skin Disease

a) **Test to be used**: Serology using ELISA, virus neutralisation test, or other recognised test in accordance with the protocols described in relevant sections of the OIE manual.

b) **Timing**: the animals have to be tested twice: the first within two days from their arrival in the quarantine station and the second after at least 42 days from the first test.

c) **Options for action following testing:** If any animal displays evidence of exposure to Lumpy Skin Disease, the whole group shall be rejected for exportation to the EC.

2.1.9 Crimean Congo Haemorrhagic fever

a) **Test to be used**: ELISA, virus neutralisation test, Immunofluorescence test or other recognised test.

b) **Timing**: the animals have to be tested twice: the first within two days from their arrival in the quarantine station and the second after at least 42 days from the first test.

c) **Options for action following testing:** If any animal displays evidence of exposure to Crimean Congo Haemorrhagic fever agent, then that animal shall be excluded from the group.

2.1.10 Surra (Trypanosoma evansi)

a) **Test to be used**: The parasitic agent can be identified in concentrated blood samples in accordance with the protocols described in relevant sections of the OIE manual.

b) **Timing**: the animals have to be tested twice: the first within two days from their arrival in the quarantine station and the second after at least 42 days from the first test.

c) **Options for action following testing:** If *T. evansi* is detected in any animal, then that animal shall be excluded from the group. The remaining group should then undergo internal and external antiparasitic treatment using suitable agents that are effective against *T. evansi*.

2.1.11 Malignant Catarrhal Fever

a) **Test to be used**: Detection of viral DNA is the preferred method, based on identification by immunofluorescence or immunocytochemistry using the protocols described in relevant sections of the OIE manual.

b) **Timing**: the animals have to be tested twice: the first within two days from their arrival in the quarantine station and the second after at least 42 days from the first test.

c) **Options for action following testing:** If any animal displays evidence of exposure to MCF, then the whole group shall be rejected for exportation to the EC.

2.1.12 Rabies

Vaccination: Rabies vaccination may be carried out in certain cases and the animal should be blood sampled and a serum neutralisation test for antibodies carried out.

2.1.13 Bovine Leucosis. (only in the case the animals are destined to a free region)

a) **Test to be used**: AGID or blocking ELISA, in accordance with the protocols described in the OIE manual.

b) **Timing**: the animals have to be tested twice: the first within two days from their arrival in the quarantine station and the second after at least 42 days from the first test.

c) **Options for action following testing**: animals tested positive to the test shall be excluded from the group and the other animals have to be re-tested starting at least 21 days after the first positive test was performed: this has to be considered as the first test described in b).

Only the animals that tested negative to two consecutive tests performed as described in b) shall be allowed for exportation to the EC.

COMMISSION DECISION

of 28 April 2004

on the adequate protection of personal data in the Isle of Man

(notified under document number C(2004) 1556)

(Text with EEA relevance)

(2004/411/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

having regard to the Treaty establishing the European Community,

having regard to Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data[1], and in particular Article 25(6) thereof,

After consulting the Working Party on the Protection of Individuals with regard to the processing of Personal Data[2],

whereas:

(1) Pursuant to Directive 95/46/EC Member States are required to provide that the transfer of personal data to a third country may take place only if the third country in question ensures an adequate level of protection and if the Member States' laws implementing other provisions of the Directive are complied with prior to the transfer.

(2) The Commission may find that a third country ensures an adequate level of protection. In that case, personal data may be transferred from the Member States without additional guarantees being necessary.

(3) Pursuant to Directive 95/46/EC the level of data protection should be assessed in the light of all the circumstances surrounding a data transfer operation or a set of data transfer operations, and giving particular consideration to a number of elements relevant for the transfer and listed in Article 25(2) thereof.

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[1] OJ L 281, 23.11.1995, p. 31

[2] Opinion 6/2003 on the level of protection of personal data in the Isle of Man, adopted by the Working Party on 21 November 2003, available at http://europa.eu.int/comm/internal_market/privacy/workingroup/wp2003/wpdocs03_en.htm

(4) Given the different approaches to data protection in third countries, the adequacy assessment should be carried out, and any decision based on Article 25(6) of Directive 95/46/EC should be made and enforced in a way that does not arbitrarily or unjustifiably discriminate against or between third countries where like conditions prevail, nor constitute a disguised barrier to trade, regard being had to the Community's present international commitments.

(5) The Isle of Man is one of the dependencies of the British Crown (being neither part of the United Kingdom nor a colony) that enjoys full independence, except for international relations and defense which are the responsibility of the United Kingdom Government. The Isle of Man should therefore be considered as a third country within the meaning of the Directive.

(6) At the island's request, with effect from May 1993, the United Kingdom's ratification of the Council of Europe Convention on the Protection of Individuals with regard to Automatic Processing of Personal Data (Convention No 108) was extended to the Isle of Man.

(7) As regards the Isle of Man, the legal standards on the protection of personal data based on the standards set out in Directive 95/46/EC have been provided for in the Data Protection Act 2002 ("the Act"), which entered into force on 1 April 2003. This Act repeals and replaces the Data Protection Act 1986 ("the 1986 Act").

(8) Other laws which impact or are likely to impact upon data protection include the Human Rights Act 2001, which was passed by Parliament on 16th January 2001 and is not yet fully in force and the Access to Health Records and Reports Act 1993.

(9) The legal standards applicable in the Isle of Man cover all the basic principles necessary for an adequate level of protection for natural persons. The application of these standards is guaranteed by judicial remedy and by independent supervision carried out by the authorities, such as the Data Protection Commissioner invested with powers of investigation and intervention.

(10) The Isle of Man should therefore be regarded as providing an adequate level of protection for personal data as referred to in Directive 95/46/EC.

(11) In the interest of transparency and in order to safeguard the ability of the competent authorities in the Member States to ensure the protection of individuals as regards the processing of their personal data, it is necessary to specify the exceptional circumstances in which the suspension of specific data flows may be justified, notwithstanding the finding of adequate protection.

(12) The measures provided for in this Decision are in accordance with the opinion of the Committee established under Article 31(1) of Directive 95/46/EC,

HAS ADOPTED THIS DECISION:

Article 1

For the purposes of Article 25(2) of Directive 95/46/EC, the Isle of Man is considered as providing an adequate level of protection for personal data transferred from the Community.

Article 2

This Decision concerns the adequacy of protection provided in the Isle of Man with a view to meeting the requirements of Article 25(1) of Directive 95/46/EC and does not affect other conditions or restrictions implementing other provisions of that Directive that pertain to the processing of personal data within the Member States.

Article 3

1. Without prejudice to their powers to take action to ensure compliance with national provisions adopted pursuant to provisions other than Article 25 of Directive 95/46/EC, the competent authorities in Member States may exercise their existing powers to suspend data flows to a recipient in the Isle of Man in order to protect individuals with regard to the processing of their personal data in the following cases:

   (a) where a competent Isle of Man authority has determined that the recipient is in breach of the applicable standards of protection; or

   (b) where there is a substantial likelihood that the standards of protection are being infringed, there are reasonable grounds for believing that the competent Isle of Man authority is not taking or will not take adequate and timely steps to settle the case at issue, the continuing transfer would create an imminent risk of grave harm to data subjects and the competent authorities in the Member State have made reasonable efforts in the circumstances to provide the party responsible for processing established in the Isle of Man with notice and an opportunity to respond.

2. The suspension shall cease as soon as the standards of protection are assured and the competent authority of the Member States concerned is notified thereof.

Article 4

1. Member States shall inform the Commission without delay when measures are adopted on the basis of Article 3.

2. The Member States and the Commission shall inform each other of cases where the action of bodies responsible for ensuring compliance with the standards of protection in the Isle of Man fails to secure such compliance.

3. If the information collected under Article 3 and under paragraphs 1 and 2 of this Article provides evidence that any body responsible for ensuring compliance with the standards of protection in the Isle of Man is not effectively fulfilling its role, the Commission shall inform the competent Isle of Man authority and, if necessary, present draft measures in accordance with the procedure referred to in Article 31(2) of Directive 95/46/EC with a view to repealing or suspending this Decision or limiting its scope.

Article 5

The Commission shall monitor the functioning of this Decision and report any pertinent findings to the Committee established under Article 31 of Directive 95/46/EC, including any evidence that could affect the finding in Article 1 of this Decision that protection in the Isle of Man is adequate within the meaning of Article 25 of Directive 95/46/EC and any evidence that this Decision is being implemented in a discriminatory way.

Article 6

Member States shall take all the measures necessary to comply with the Decision within four months of the date of its notification.

Article 7

This Decision is addressed to the Member States.

Done at Brussels, 28 April 2004.

For the Commission

Frederik BOLKESTEIN

Member of the Commission

COMMISSION DECISION

of 28 April 2004

authorising Austria to make use of the system established by Title I of Regulation (EC) No 1760/2000 to replace surveys of bovine livestock

(notified under document number C(2004) 1557)

(Only the German text is authentic)

(Text with EEA relevance)

(2004/412/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 93/24/EEC of 1 June 1993 on the statistical surveys to be carried out on bovine animal production,[1] and in particular Article 1(2) and (3) thereof,

Whereas:

(1) Title I of Regulation (EC) No 1760/2000 of the European Parliament and of the Council [2] establishes a system for the identification and registration of bovine animals.

(2) Commission Decision 1999/571/EC recognises the fully operational character of the Austrian database for bovine animals [3].

(3) Pursuant to Directive 93/24/EEC the Member States may, at their request, be authorised to use administrative statistical sources instead of surveys of bovine animals on condition that they satisfy the obligations arising out of that Directive.

(4) In support of its request of 12 June 2003, Austria has submitted technical documentation as to the structure and the updating of the database referred to in Title I of Regulation (EC) No 1760/2000 and the methods of calculating the statistical data.

(5) Austria has previously been authorised, by Commission Decision 2000/554/EC[4], to make use of the register of bovine animals to partially replace surveys of bovine livestock; however, that authorisation expired on 31 December 2003.

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[1] OJ L 149, 21.6.1993, p. 5; Directive as last amended by Regulation (EC) N° 1882/2003 of the European Parliament and the Council (OJ L 284, 31.10.2003, p. 1).

[2] OJ L 204, 11.8.2000, p. 1.

[3] OJ L 217, 17.8.1999, p. 62

(6) Following examination of the request based on the technical documentation provided by the Austrian authorities, the request should be met.

(7) This Decision is in accordance with the opinion of the Standing Committee on Agricultural Statistics set up by Council Decision 72/279/EEC [5],

HAS ADOPTED THIS DECISION:

Article 1

Austria is authorised to replace the surveys of bovine animals provided for by Council Directive 93/24/EEC by using the system for the identification and registration of bovine animals as referred to in Title I of Regulation (EC) No 1760/2000 to obtain all the statistical data required to comply with the obligations arising out of that Directive.

Article 2

If the system referred to in Article 1 ceases to be operational or if its content no longer makes it possible to obtain reliable statistical information regarding all or certain categories of bovine animals, Austria shall return to a statistical survey system for the purpose of estimating the cattle population or the relevant categories.

Article 3

This Decision is addressed to the Republic of Austria.

Done at Brussels, 28 April 2004.

For the Commission
Pedro SOLBES MIRA
Member of the Commission

[4] OJ L 235, 19.9.2000, p. 23.
[5] OJ L 179, 7.8.1972, p. 1

COMMISSION DECISION

of 28 April 2004

amending Commission Decision 2000/585/EC as regards the animal health conditions and veterinary certification for rabbit meat and certain wild and farmed game meat transiting or being temporarily stored in the Community

(notified under docyment number C(2004) 1560)

(Text with EEA relevance)

(2004/413/EC)

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], in particular Article 8 (5), third indent, and Article 9 (2) (b) and (4) (c),

Whereas:

(1) Council Directive 91/494/EEC of 26 June 1991 lays down animal health conditions governing intra-Community trade in and imports from third countries of fresh poultry meat[2].

(2) Council Directive 92/45/EEC of 16 June 1992 lays down provisions on public health and animal health problems relating to the killing of wild game and the placing on the market of wild game meat[3].

(3) Council Directive 92/118/EEC of 17 December 1992 lays down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A, Chapter I, to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC[4].

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1 OJ L 18, 23.1.2002, p. 11.

2 OJ L 268, 24.9.1991, p. 35. Directive as last amended by Directive 1999/89/EC (OJ L 300, 23.11.1999, p. 17.).

3 OJ L 268, 14.9.92, p. 35. Directive as last amended by Council Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1.).

4 OJ L 62, 15.3.1993. p. 49. Directive as last amended by Commission Decision 2003/721/EC (OJ L 260, 11.10.2003, p. 21.).

(4) Commission Decision 2000/585/EC lays down a list of third countries from which Member States authorise imports of rabbit meat and certain wild and farmed game meat, and provides for the animal and public health and the veterinary certification conditions for such imports[5].

(5) Council Directive 97/78/EC lays down the principles governing the organisation of veterinary checks on products entering the Community from third countries[6] and certain provisions for transit are already provided for in Article 11 such as the use of ANIMO messages and of the common veterinary entry document.

(6) However, it is necessary in order to safeguard the disease situation in the Community to further ensure that consignments of game meat transiting through the Community, comply with the animal health import conditions applicable for authorised countries in regard to the relevant species concerned.

(7) Council Decision 79/542/EEC drawing up a list of third countries or parts of third countries, and laying down animal and public health, and veterinary certification conditions for the importation into the Community of certain live animals and their fresh meat[7], has recently been amended to include general transit conditions and a derogation for transit between Russia with a reference to the specific border inspection posts designated for this latter purpose.

(8) In the light of experience, it appears that the presentation to the border inspection post, pursuant to Article 7 of Directive 97/78/EC, of the original veterinary documents established in the exporting third country to fulfil the regulatory requirement of the third country of destination, is not sufficient to ensure that the animal health conditions required for the safe introduction into the territory of the Community of the products concerned are effectively satisfied; it is therefore appropriate to establish a specific model of animal health certificate to be used in transit situations for the products concerned.

(9) It is further appropriate to clarify the implementation of the condition laid down in Article 11 of Directive 97/78/EC, that transit is only allowed from third countries whose products are not prohibited for introduction in the territory of the Community, by making reference to the list of third countries annexed to Decision 2000/585/EC.

(10) However specific conditions for transits via the Community of consignments to and from Russia should be foreseen due to the geographical situation of Kaliningrad and taking into account climatic problems impeding the use of some ports at certain times of the year.

(11) Commission Decision 2001/881/EC draws up a list of border inspection posts agreed for veterinary checks on animals and animal products from third countries[8] and it is

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5 OJ L 251, 6.10.2000, p. 1. Decision as last amended by Commission Decision 2004/212/EC (OJ L 73, 11.3.2004, p. 11.).

6 OJ L 24, 30.1.1998, p. 9. Directive as last amended by the Act concerning the conditions of Accession (OJ L 236, 23.9.2003, p. 381.).

7 OJ L 146, 14.6.1979, p. 15. Decision as last amended by Commission Decision 2004/212/EC (OJ L 73, 11.3.2004, p. 11.).

8 OJ L 326, 11.12.2001, p. 44. Decision as last amended by Commission Decision 2003/831/EC (OJ L 313, 28.11.2003, p. 61.).

appropriate to specify the border inspection posts designated for the control of such transits taking into account this Decision.

(12) The animal health certificate Model E in Annex III to the English version of Decision 2000/585 contains a redactional error as regards identification of meat. This error should be corrected for reason of clarity.

(13) Commission Decision 2000/585/EC should be amended accordingly.

(14) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health.

HAS ADOPTED THIS DECISION:

Article1

Commission Decision 2000/585/EC is amended as follows:

1. The following Article 2a is inserted:

"Article 2a

Member States shall ensure that consignments of rabbit and game meat for human consumption introduced into the territory of the Community and which are destined for a third country either by transit immediately or after storage in accordance with Articles 12 (4) or 13 of Directive 97/78/EC, and not intended for importation into the EC shall comply with the following requirements:

(a) they shall come from the territory of a third country or a part thereof listed in Annex I to this Decision for the import of fresh meat of that species.

(b) they shall meet the specific animal health guarantees and conditions for the species concerned set out in Annex II and in the corresponding model animal health certificate drawn up under Annex III.

(c) they shall be accompanied by an animal health certificate established in accordance with the model K laid down in Annex III, signed by an official veterinarian of the competent veterinary services of the third country concerned.

(d) they are certified as acceptable for transit or storage (as appropriate) on the Common Veterinary Entry Document by the Official Veterinarian of the Border Inspection Post of introduction."

2. The following Article 2b is inserted:

"Article 2b

1. By way of derogation from Article 2a Member States shall authorise the transit by road or by rail through the Community, between designated Community border inspection posts listed in Annex to Decision 2001/881/EC, of consignments coming from and destined to Russia directly or via another third country provided that the following conditions are met:

   (a) the consignment shall be sealed with a serially numbered seal at the border inspection post of entry to the EC by the veterinary services of the competent authority;

   (b) the documents accompanying the consignment and referred to in Article 7 of Directive 97/78/EC shall be stamped "ONLY FOR TRANSIT TO RUSSIA VIA THE EC" on each page by the official veterinarian of the competent authority responsible for the BIP;

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

   (d) the consignment is certified as acceptable for transit on the Common Veterinary Entry Document by the Official Veterinarian of the Border Inspection Post of introduction.

2. unloading or storage, as defined in Article12 (4) or Article 13 of Directive 97/78/EC, on EC territory of such consignments shall not be allowed.

3. regular audits shall be made by the competent authority to ensure that the number of consignments and the quantities of products leaving the EC territory matches the number and quantities entering."

3. The Annexes are amended in accordance with the Annex to this Decision.

Article 2

This Decision shall apply from 1 May 2004.

Article 1 point 1 and the Annex shall only apply from 1 January 2005.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 28 April 2004.

For the Commission
David BYRNE
Member of the Commission

ANNEX

Annex III to Decision 2000/585/EC is amended as follow:

1. in Model E, section **I.**, the word "zebra" is deleted.

2. in Model E, section **IV**, point (4), the word "zebra" is replaced by "land mammals".

3. the following model K is added:

"MODEL K

ANIMAL HEALTH CERTIFICATE
(Transit and/or storage)

Model TRANSIT/STORAGE

1. Consignor (name and address in full) …… …… …… ……	**VETERINARY CERTIFICATE** **for fresh rabbit meat and certain wild and farmed game meat [1], for [transit] / [storage][2] [7] in the European Community** No[3] ORIGINAL
2. Consignee (name and address in full) …… …… …… ……	**3. Origin of the meat** [4] 3.1 ISO code and name of Country: …… 3.2 Code of territory : ……
	4. Competent Authority 4.1 Ministry:…… 4.2 Service:…….. …… 4.3 Local/Regional level:…… …… ……
5. Intended [transit] / [storage][2] [7] destination of the meat 5.1 Storage in EU Member State:…… Name and address of the establishment[5] [10] :…… …… 5.2 Transit final third country destination[10]: …… Exit Community BIP name and address[10]: ……	**6. Place of loading for exportation** …… ……
7. Means of transport and consignment identification[6] 7.1 [Lorry] / [Rail-wagon] / [Ship] / [Aircraft][7] 7.2 Registration number(s), ship name or flight number :….. …… ……	7.3 Consignment identification details[8]: …… …… …… ……

8. Identification of the meat

8.1 Meat from: ……..…….. *(animal species).*

8.2 Temperature conditions of the meat included in this consignment : [chilled]/[frozen][7]

8.3 Individual identification of the meat included in this consignment :

Nature of cuts[8]	Number of the establishment(s) Slaughterhouse	Cutting/Manufacturing	Cold store	Number of packages/pieces	Net weight(kg) .
					.
					.
					.
					.
					.
					.
					.
					.
					.
					.
			Total		.

9. Animal Health attestation

I, the undersigned official veterinarian, hereby certify, that the meat described above :

9.1 comes from a country as laid down in Annex II or region authorized for imports into the EC as laid down in Annex I to Commission Decision 2000/585/EC at the time of slaughter and

9.2 complies with the relevant animal health conditions as laid down in the animal health attestation in the model certificate [C]/[D]/[E]/[H]/[I] [7] in Annex III to Commission Decision 2000/585/EC and

9.3 is derived from animals which were slaughtered and processed on or between ……. [9].

Official stamp and signature

Done at …….. on .....

(signature of official veterinarian) [11]

(stamp) [11]

(name in capital letters, qualifications and title)

Notes

(1) meat of wild game birds that do not contain offal, except in the case of unplucked and uneviscerated game birds; meat of farmed game birds, meat of wild leporidae, defined as 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 accordance with Article 12 (4) or Article 13 of Council Directive 97/78/EC.

(3) Issued by the competent authority.

(4) Country as laid down in Annex II and description of territory as appearing in Annex I to Commission Decision 2000/585/EC (as last amended).

(5) Address (and approval number if known) of the warehouse in a free zone, free warehouse, customs warehouse or ship chandler shall be included.

(6) The registration number(s) of rail-wagon or lorry and the name of the ship should be given as appropriate. If known, the flight number of the aircraft.

In case of transport in containers or boxes, the total number, their registration and seal numbers, if present, should be indicated under point 7.3.

(7) Keep as appropriate.

(8) Complete if appropriate.

(9) Date or dates of slaughter. Imports of this meat shall not be allowed when obtained from animals slaughtered either prior to the date of authorisation for exportation to the European Community of the territory mentioned under (4), or during a period where restrictive measures have been adopted by the European Community against imports of this meat from this territory.

(10) Complete as appropriate.

(11) The colour of the signature shall be different to that of the printing. The same rule applies to stamps other than those embossed or watermark.

“

COMMISSION DECISION

of 28 April 2004

amending Commission Decision 2003/779/EC as regards the animal health conditions and veterinary certification for animal casings transiting or being temporarily stored in the Community

(notified under document number C(2004) 1561)

(Text with EEA relevance)

(2004/414/EC)

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], in particular Article 8(5), third indent, and Article 9(2)(b) and (4)(c),

Whereas:

(1) Council Directive 92/118/EEC lays down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A(1) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC [2].

(2) Commission Decision 2003/779/EC lays down animal health conditions and veterinary certificates for the importation of animal casings from third countries [3].

(3) Council Directive 97/78/EC lays down the principles governing the organisation of veterinary checks on products entering the Community from third countries [4] and certain provisions for transit are already provided for in Article 11 such as the use of ANIMO messages and of the common veterinary entry document.

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1 OJ L 18, 23.1.2002, p. 11.

2 OJ L 62, 15.3.1993, p. 49. Directive as last amended by Decision 2003/721/EC (OJ L 260, 11.10.2003, p. 21).

3 OJ L 285, 1.11.2003, p. 38.

4 OJ L 24, 30.1.1998, p. 9. Directive as last amended by the Act concerning the conditions of Accession (OJ L 236, 23.9.2003, p. 381).

(4) However, it is necessary in order to safeguard the disease situation in the Community to further ensure that consignments of animal casing transiting through the Community, comply with the animal health import conditions applicable for authorised countries.

(5) Council Decision 79/542/EEC drawing up a list of third countries or parts of third countries, and laying down animal and public health, and veterinary certification conditions for the importation into the Community of certain live animals and their fresh meat [5], has recently been amended to include transit conditions and a derogation for transit between Russia with a reference to the specific border inspection posts designated for this latter purpose.

(6) In the light of experience, it appears that the presentation to the border inspection post, pursuant to Article 7 of Directive 97/78/EC, of the original veterinary documents established in the exporting third country to fulfil the regulatory requirement of the third country of destination, is not sufficient to ensure that the animal health conditions required for the safe introduction into the territory of the Community of the products concerned are effectively satisfied; it is therefore appropriate to establish a specific model of animal health certificate to be used in transit situations for the products concerned.

(7) However specific conditions for transits via the Community of consignments to and from Russia should be foreseen due to the geographical situation of Kaliningrad and taking into account climatic problems impeding the use of some ports at certain times of the year.

(8) Commission Decision 2001/881/EC draws up a list of border inspection posts agreed for veterinary checks on animals and animal products from third countries [6] and it is appropriate to specify the border inspection posts designated for the control of such transits taking into account this Decision.

(9) It is opportune to amend the animal health certificate for the import of animal casings to reflect the format laid down for other certificates.

(10) Commission Decision 2003/779/EC should be amended accordingly.

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

HAS ADOPTED THIS DECISION:

Article 1

Commission Decision 2003/779/EC is amended as follows:

1. Article 1 is replaced with the following:

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[5] OJ L 146, 14.6.1979, p. 15. Decision as last amended by Commission Decision 2004/212/EC (OJ L 73. 11.3.2004, p. 11).

[6] OJ L 326, 11.12.2001, p. 44. Decision as last amended by Commission Decision 2003/831/EC (OJ L 313, 28.11.2003, p. 61.).

'*Article 1*

Member States shall authorise the importation of animal casings from any third country accompanied by a health certificate as laid down in Annex I A, which shall consist of one sheet and shall be completed in at least one official language of the Member State carrying out the import control.'

2. The following Article 1a is inserted:

'*Article 1a*

Member States shall ensure that consignments of animal casing for human consumption introduced into the territory of the Community and which are destined for a third country either by transit immediately or after storage in accordance with Articles 12 (4) or 13 of Directive 97/78/EC, and not intended for importation into the EC shall comply with the following requirements:

(a) they shall meet the specific animal health conditions set out in the model animal health certificate drawn up under Annex I A;

(b) they shall be accompanied by an animal health certificate established in accordance with the model laid down in Annex I B, signed by an official veterinarian of the competent veterinary services of the third country concerned;

(c) they are certified as acceptable for transit or storage (as appropriate) on the Common Veterinary Entry Document by the Official Veterinarian of the Border Inspection Post of introduction.'

3. The following Article 1b is inserted:

'*Article 1b*

1. By way of derogation from Article 1a, Member States shall authorise the transit by road or by rail through the Community, between designated Community border inspection posts listed in Annex to Decision 2001/881/EC, of consignments coming from and destined to Russia directly or via another third country provided that the following conditions are met:

   (a) the consignment shall be sealed with a serially numbered seal at the border inspection post of entry to the EC by the veterinary services of the competent authority;

   (b) the documents accompanying the consignment and referred to in Article 7 of Directive 97/78/EC shall be stamped "ONLY FOR TRANSIT TO RUSSIA VIA THE EC" on each page by the official veterinarian of the competent authority responsible for the BIP;

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

(d) the consignment is certified as acceptable for transit on the Common Veterinary Entry Document by the Official Veterinarian of the Border Inspection Post of introduction.

2. unloading or storage, as defined in Article 12 (4) or Article 13 of Directive 97/78/EC, on EC territory of such consignments shall not be allowed.

3. regular audits shall be made by the competent authority to ensure that the number of consignments and the quantities of products leaving the EC territory matches the number and quantities entering.'

4. Annex I is replaced by the Annex to this Decision.

Article 2

The previous animal health certificate drawn up under Commission Decision 2003/779/EC for the importation of animal casings may be used until 6 months after the date laid down in paragraph 1 of Article 3 at the latest.

Article 3

1. This Decision shall apply from 1 May 2004.

2. Article 1 point 2 and the Annex I B shall only apply from 1 January 2005.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 28 April 2004.

For the Commission
David BYRNE
Member of the Commission

ANNEX

'ANNEX IA

ANIMAL HEALTH CERTIFICATE

(for animal casings intended for dispatch to the European Community)

Model CAS

1. Consignor (name and address in full) …… …… …… ……	**ANIMAL HEALTH CERTIFICATE** **for animal casing for importation into the European Community** No (1) ORIGINAL
2. Consignee (name and address in full) …… …… …… ……	**3. Origin of the animal casing** 3.1 ISO code and name of Country:…… 3.2 Territory (4):…….
5. Intended destination of casings 5.1 EU Member State:…… Name, number and address of the establishment (5) …… ……	**4. Competent Authority** 4.1 Ministry:…… 4.2 Service:…… …… 4.3 Local/Regional level:…… …… …… **6. Place of loading for exportation** …… ……
7. Means of transport and consignment identification (2) 7.1 [Lorry]/[Rail-wagon]/[Ship]/[Aircraft] (3) 7.2 Registration number(s), ship name or flight number :….. …… ……	7.3 Consignment identification details (5): …… …… …… ……

8. Identification of the animal casing

8.1 Casings from: ……*(animal species).*

8.2 Identification of the casings included in this consignment :

Description (5)	Treatment (7)	Address and approval number of the establishment(s)	Number of packages/pieces	Net weight(kg) .
				.
				.
				.
				.
				.
				.
				.
				.
				.
				.
		Total		.

9. Animal Health attestation

I, the undersigned official veterinarian, hereby certify, that the animal casings described above

(a) come from plants approved by the competent authority;

(b) have been cleaned, scraped and:

either

[salted with NaCl for 30 days] (3)

or

[bleached] (3)

or

[dried after scraping] (3)

(c) have undergone all precautions to avoid recontamination after treatment.

Official stamp and signature

Done at …….. on .....

(signature of official veterinarian) (6)

(stamp) (6)

(name in capital letters, qualifications and title)

Notes

(1) Issued by the competent authority.

(2) The registration number(s) of rail-wagon or lorry and the name of the ship should be given as appropriate. If known, the flight number of the aircraft.

In case of transport in containers or boxes, the total number, their registration and seal numbers, if present, should be indicated under point 7.3.

(3) Keep as appropriate.

(4) Complete if appropriate.

(5) Complete as appropriate.

(6) The colour of the signature shall be different to that of the printing. The same rule applies to stamps other than those embossed or watermark.

(7) Treatment that has been applied from the options listed in the Animal Health attestation in Section 9b.

ANNEX IB

(for animal casings in transit and/or storage)

Model TRANSIT/STORAGE

1. Consignor (name and address in full) …… …… …… ……	**VETERINARY CERTIFICATE** **for animal casing for [transit] [storage] (1) (6) in the European Community** No (2) ORIGINAL
2. Consignee (name and address in full) …… …… …… ……	**3. Origin of the animal casing** 3.1 ISO code and name of Country:…… 3.2 Territory (7): ……
5. Intended [transit]/[storage] (6) destination of casings 5.1 Storage in: EU Member State:…… Name and address of the establishment (3) (4) …… …… 5.2 Final third country destination (9) after [transit]/[storage] (6): …… Exit Community BIP name and address (4): ……	**4. Competent Authority** 4.1 Ministry:…… 4.2 Service:…… …… 4.3 Local/Regional level:…… …… …… **6. Place of loading for exportation** …… ……
7. Means of transport and consignment identification (5) 7.1 [Lorry]/[Rail-wagon]/[Ship]/[Aircraft](6) 7.2 Registration number(s), ship name or flight number :….. …… ……	7.3 Consignment identification details (7): …… …… …… ……

8. Identification of the animal casing

8.1 Casings from: ……..…….. *(animal species).*

8.2 Identification of the casings included in this consignment:

Description (4)	Treatment (9)	Address of the establishment(s)	Number of packages/pieces	Net weight(kg) .
				.
				.
				.
				.
				.
				.
				.
				.
				.
				.
		Total		.

9. Animal Health attestation

I, the undersigned official veterinarian, hereby certify, that the animal casings described above complies with the animal health conditions laid down in the Animal Health attestation in section 9 of the model certificate in Annex IA to 2003/779/EC

Official stamp and signature

Done at …….. on .....

(signature of official veterinarian) [8]

(stamp) [8]

(name in capital letters, qualifications and title)

Notes

(1) In accordance with Article 12 (4) or Article 13 of Council Directive 97/78/EC.

(2) Issued by the competent authority.

(3) Address (and approval number if known) of the warehouse in a free zone, free warehouse, customs warehouse or ship chandler shall be included

(4) Complete as appropriate

(5) The registration number(s) of rail-wagon or lorry and the name of the ship should be given as appropriate. If known, the flight number of the aircraft.

In case of transport in containers or boxes, the total number, their registration and seal numbers, if present, should be indicated under point 7.3.

(6) Keep as appropriate.

(7) Complete if appropriate.

(8) The colour of the signature shall be different to that of the printing. The same rule applies to stamps other than those embossed or watermark.

(9) Treatment that has been applied from the options listed in section 9 (b) of the model health certificate laid down in Annex IA of Commission Decision 2003/779/EC. This states that casings should be cleaned and scraped, and either salted with NaCl for 30 days, or bleached, or dried after scraping.'

COMMISSION DECISION

of 29 April 2004

amending Commission Decision 2000/609/EC as regards the animal health conditions and veterinary certification for farmed ratite meat transiting or being temporarily stored in the Community

(notified under document number C(2004) 1580)

(Text with EEA relevance)

(2004/415/EC)

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], in particular Article 8 (5), third indent, and Article 9 (2) (b) and (4) (c),

Whereas:

(1) Council Directive 92/118/EEC lays down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (1) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC[2].

(2) Council Directive 91/494/EEC lays down animal health conditions governing intra-Community trade in and imports from third countries of fresh poultry meat[3].

(3) Commission Decision 2000/609/EC lays down animal health conditions and veterinary certificates for the importation of farmed ratite meat from third countries[4].

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1 OJ L 18, 23.1.2002, p. 11.

2 OJ L 62, 15.3.1993, p. 49. Directive as last amended by Decision 2003/721/EC (OJ L 260, 11.10.2003, p. 21.).

3 OJ L 268, 24.9.1991, p. 35. Directive as last amended by Directive 1999/89/EC (OJ L 300, 23.11.1999, p. 17.).

4 OJ L 258, 12.10.2000, p. 9. Decision as last amended by Commission Decision 2004/118/EC (OJ L 36, 7.2.2004, p. 34.).

(4) Council Directive 97/78/EC lays down the principles governing the organisation of veterinary checks on products entering the Community from third countries[5] and certain provisions for transit are already provided for in Article 11 such as the use of ANIMO messages and of the common veterinary entry document.

(5) However, it is necessary in order to safeguard the disease situation in the Community to further ensure that consignments of ratite meat transiting through the Community, comply with the animal health import conditions applicable for authorised countries in regard to the relevant species concerned.

(6) Council Decision 79/542/EEC drawing up a list of third countries or parts of third countries, and laying down animal and public health, and veterinary certification conditions for the importation into the Community of certain live animals and their fresh meat[6], has recently been amended to include transit conditions and a derogation for transit between Russia with a reference to the specific border inspection posts designated for this latter purpose.

(7) In the light of experience, it appears that the presentation to the border inspection post, pursuant to Article 7 of Directive 97/78/EC, of the original veterinary documents established in the exporting third country to fulfil the regulatory requirement of the third country of destination, is not sufficient to ensure that the animal health conditions required for the safe introduction into the territory of the Community of the products concerned are effectively satisfied; it is therefore appropriate to establish a specific model of animal health certificate to be used in transit situations for the products concerned.

(8) It is further appropriate to clarify the implementation of the condition laid down in Article 11 of Directive 97/78/EC, that transit is only allowed from third countries whose products are not prohibited for introduction in the territory of the Community, by making reference to the list of third countries annexed to Decision 2000/609/EC.

(9) However specific conditions for transits via the Community of consignments to and from Russia should be foreseen due to the geographical situation of Kaliningrad and taking into account climatic problems impeding the use of some ports at certain times of the year.

(10) Commission Decision 2001/881/EC draws up a list of border inspection posts agreed for veterinary checks on animals and animal products from third countries[7] and it is appropriate to specify the border inspection posts designated for the control of such transits taking into account this Decision.

(11) Commission Decision 2000/609/EC should be amended accordingly.

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5 OJ L 24, 30.1.1998, p. 9. Directive as last amended by the Act concerning the conditions of Accession (OJ L 236, 23.9.2003, p. 381.).

6 OJ L 146, 14.6.1979, p. 15. Decision as last amended by Commission Decision 2004/212/EC (OJ L 73, 11.3.2004, p. 11.).

7 OJ L 326, 11.12.2001, p. 44. Decision as last amended by Commission Decision 2003/831/EC (OJ L 313, 28.11.2003, p. 61.).

(12) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health.

HAS ADOPTED THIS DECISION:

Article 1

Commission Decision 2000/609/EC is amended as follows:

1. The following Article 1a is inserted:

"Article 1a

Member States shall ensure that consignments of farmed ratite meat for human consumption introduced into the territory of the Community and which are destined for a third country either by transit immediately or after storage in accordance with Articles 12 (4) or 13 of Directive 97/78/EC, and not intended for importation into the EC shall comply with the following requirements:

(a) they shall come from the territory of a third country or a part thereof listed in Annex I to this Decision for the import of fresh meat of that species.

(b) they shall meet the specific animal health conditions for the species concerned set out in the animal health attestation part in the model certificate, part 2 model A or B of health attestation drawn up under Annex II.

(c) they shall be accompanied by an animal health certificate established in accordance with the model laid down in Annex III, signed by an official veterinarian of the competent veterinary services of the third country concerned.

(d) they are certified as acceptable for transit or storage (as appropriate) on the Common Veterinary Entry Document by the Official Veterinarian of the Border Inspection Post of introduction."

2. The following Article 1b is inserted:

"Article 1b

1. By way of derogation from Article 1a, Member States shall authorise the transit by road or by rail through the Community, between designated Community border inspection posts listed in Annex to Decision 2001/881/EC, of consignments coming from and destined to Russia directly or via another third country provided that the following conditions are met:

(a) the consignment shall be sealed with a serially numbered seal at the border inspection post of entry to the EC by the veterinary services of the competent authority;

(b) the documents accompanying the consignment and referred to in Article 7 of Directive 97/78/EC shall be stamped "ONLY FOR TRANSIT TO RUSSIA VIA THE EC" on each page by the official veterinarian of the competent authority responsible for the BIP;

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

(d) the consignment is certified as acceptable for transit on the Common Veterinary Entry Document by the Official Veterinarian of the Border Inspection Post of introduction.

2. unloading or storage, as defined in Article12 (4) or Article 13 of Directive 97/78/EC, on EC territory of such consignments shall not be allowed.

3. regular audits shall be made by the competent authority to ensure that the number of consignments and the quantities of products leaving the EC territory matches the number and quantities entering."

3. A new Annex III is added in accordance with the Annex to this Decision.

Article 2

This Decision shall apply from 1 May 2004.

Article 1 point 1 and the Annex shall only apply from 1 January 2005.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 29 April 2004.

For the Commission
David BYRNE
Member of the Commission

ANNEX

"ANNEX III

(Transit and/or storage)

Model TRANSIT/STORAGE

1. Consignor (name and address in full) …… …… …… ……	**VETERINARY CERTIFICATE** **for fresh ratite meat(1), for [transit][storage](2) (7) in the European Community** No(3) ORIGINAL
2. Consignee (name and address in full) …… …… …… ……	**3. Origin of the meat** (4) 3.1 ISO code and name of Country:…… 3.2 Territory(10): ……
5. Intended [transit]/[storage](7) destination of the meat 5.1 Storage in EU Member State:…… Name and address of the establishment(5) (10) :…… …… 5.2 Final third country destination after [transit]/[storage] (10): …… Exit Community BIP name and address(10): ……	**4. Competent Authority** 4.1 Ministry:…… 4.2 Service:…….. …… 4.3 Local/Regional level:…… …… …… **6. Place of loading for exportation** …… ……
7. Means of transport and consignment identification(6) 7.1 [Lorry]/[Rail-wagon]/[Ship]/[Aircraft](7) 7.2 Registration number(s), ship name or flight number :….. …… ……	7.3 Consignment identification details(8): …… …… …… ……

8. Identification of the meat

8.1 Meat from: ……..……..……. *(animal species).*

8.2 Individual identification of the meat included in this consignment :

Nature of cuts(8)	Number of the establishment(s) Slaughterhouse	Cutting/Manufacturing	Cold store	Number of packages/pieces	Net weight(kg) .
					.
					.
					.
					.
					.
					.
					.
					.
					.
					.
			Total		.

9. Animal Health attestation

I, the undersigned official veterinarian, hereby certify, that the fresh ratite meat described above :

9.1 comes from a country or region authorized for imports into the EC as laid down in Annex I to 2000/609/EC at the time of slaughter and

9.2 complies with the relevant animal health conditions as laid down in the animal health attestation in the model certificate part [A] [7] or [B] [7] in Annex II part 2 to 2000/609/EC and

9.3 is derived from animals which were slaughtered and processed on or between ……. [9].

Official stamp and signature

Done at …….. on .....

(signature of official veterinarian) [11]

(stamp) [11]

(name in capital letters, qualifications and title)

Notes

(1) Meat means any parts of ratites which are fit for human consumption and which have not undergone any treatment other than cold treatment to ensure its preservation: vacuum-wrapped meat or meat wrapped in a controlled atmosphere must also be accompanied by a certificate according to this model.

(2) In accordance with Article 12 (4) or Article 13 of Council Directive 97/78/EC.

(3) Issued by the competent authority.

(4) Country and description of territory as appearing the Annex I to Commission Decision 2000/609/EC (as last amended).

(5) Address (and approval number if known) of the warehouse in a free zone, free warehouse, customs warehouse or ship chandler shall be included.

(6) The registration number(s) of rail-wagon or lorry and the name of the ship should be given as appropriate. If known, the flight number of the aircraft.

In case of transport in containers or boxes, the total number, their registration and seal numbers, if present, should be indicated under point 7.3.

(7) Keep as appropriate.

(8) Complete if appropriate.

(9) Date or dates of slaughter. Imports of this meat shall not be allowed when obtained from ratites slaughtered either prior to the date of authorisation for exportation to the European Community of the territory mentioned under (4), or during a period where restrictive measures have been adopted by the European Community against imports of this meat from this territory.

(10) Complete as appropriate.

(11) The colour of the signature shall be different to that of the printing. The same rule applies to stamps other than those embossed or watermark.

“

COMMISSION DECISION

of 29 April 2004

on temporary emergency measures in respect of certain citrus fruits originating in Argentina or Brazil

(notified under document number C(2004) 1584)

(2004/416/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community [1], and in particular Article 16(3) thereof,

Whereas:

(1) Spain informed the other Member States and the Commission that in plant health checks carried out in 2003, numerous infestations of citrus fruits originating in Argentina or Brazil with harmful organisms have been found, and in particular with *Guignardia citricarpa* Kiely (all strains pathogenic to *Citrus*), and *Xanthomonas campestris* (all strains pathogenic to *Citrus*). Moreover, infestations of citrus fruits originating in Brazil with *Guignardia citricarpa* Kiely (all strains pathogenic to *Citrus*), were also reported in 2003 by the Netherlands and the United Kingdom.

(2) Spain took official emergency measures prohibiting the import of citrus fruits originating in Argentina or Brazil into its territory as of 12 November 2003.

(3) Directive 2000/29/EC requires that, in order to protect the Community from the introduction of the harmful organisms concerned, citrus fruits originating in third countries are to comply with certain technical requirements, in particular those laid down in points 16.2 and 16.4 of Section I of Part A of Annex IV to that Directive. The information received from Spain, the Netherlands and the United Kingdom shows that those requirements have not been complied with as regards citrus fruits imported from Argentina and Brazil.

(4) Therefore temporary emergency measures should be taken which apply to imports of citrus fruits, originating in Argentina or Brazil, into the Community.

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1 OJ L 169, 10.7.2000, p. 1. Directive as last amended by Commission Directive 2004/31/EC (OJ L 85, 23.3.2004, p. 18).

(5) If it becomes apparent that those emergency measures are not sufficient to prevent the entry of the harmful organisms concerned, or have not been complied with, more stringent or alternative measures should be envisaged.

(6) The effect of the emergency measures should be assessed continually until 30 November 2004, in particular on the basis of information to be provided by Member States. Possible subsequent measures should be considered in the light of the results of that assessment.

(7) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plant Health,

HAS ADOPTED THIS DECISION:

Article 1

By way of derogation from points 16.2 and 16.4 of Section I of Part A of Annex IV to Directive 2000/29/EC, from 1 May 2004 fruits of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf., and their hybrids (hereinafter referred to as citrus fruits), originating in Argentina or Brazil may only be introduced into the territory of the Community if they comply with the requirements laid down in the Annex to this Decision.

Article 2

Without prejudice to the provisions of Commission Directive 94/3/EC [2], each Member State importing citrus fruits originating in Argentina or Brazil shall provide the Commission and the other Member States, by 31 December 2004 at the latest, with a detailed technical report on the results of plant health checks carried out on those fruits in accordance with Article 13(1) of Directive 2000/29/EC between 1 May and 30 November 2004.

Article 3

Between 1 May and 30 November 2004, the Commission shall continually follow the development of the situation. If it becomes apparent that those emergency measures are not sufficient to prevent the entry of *Guignardia citricarpa* Kiely (all strains pathogenic to *Citrus*) or *Xanthomonas campestris* (all strains pathogenic to *Citrus*), or have not been complied with, the Commission shall take more stringent or alternative measures, under the procedure laid down in Article 16(3) of Directive 2000/29/EC.

Article 4

Spain shall adjust by 30 April 2004 at the latest the measures which it has adopted with a view to protect itself against the introduction and the spread of *Guignardia citricarpa* Kiely (all strains pathogenic to *Citrus*) and *Xanthomonas campestris* (all strains pathogenic to

2 OJ L 32, 5.2.1994, p. 37 and corrigendum (OJ L 59, 3.3.1995, p. 30).

Citrus) in such a manner that the measures comply with Articles 1 and 2, and shall forthwith inform the Commission of the adjusted measures.

Article 5

This Decision shall be reviewed by 31 January 2005 at the latest.

Article 6

This Decision is addressed to the Member States.

Done at Brussels, 29 April 2004.

For the Commission
David BYRNE
Member of the Commission

ANNEX

Without prejudice to the provisions applicable to the fruits in points 16.1, 16.3 and 16.5 of Section I of Part A of Annex IV to Directive 2000/29/EC, the following requirements shall apply:

1. Citrus fruits originating in Argentina or Brazil shall be accompanied by a certificate referred to in paragraph 1 of Article 13 of Directive 2000/29/EC, officially stating that:

   (a) the fruits originate in an area recognised as being free from *Xanthomonas campestris* (all strains pathogenic to *Citrus*), in accordance with the procedure referred to in Article 18(2) of Directive 2000/29/EC, and mentioned on the certificate;

   or

   (b) – in accordance with an official control and examination regime, no symptoms of *Xanthomonas campestris* (all strains pathogenic to *Citrus*) have been observed in the place of production since the beginning of the last cycle of vegetation,

   and

   – in accordance with an official control and examination regime, including an appropriate testing regime, the fruits harvested in the place of production are free from *Xanthomonas campestris* (all strains pathogenic to Citrus),

   and

   – the fruits have been subjected to treatment such as sodium orthophenylphenate and mentioned on the certificate ,

   and

   – the place of production, the packing facilities, exporters and any other operator involved in the handling of the fruits are officially registered for this purpose.

2. Citrus fruits, other than *Citrus aurantium* L., originating in Argentina or Brazil shall be accompanied by a certificate referred to in paragraph 1 of Article 13 of Directive 2000/29/EC, officially stating that:

   (a) the fruits originate in an area recognised as being free from *Guignardia citricarpa* Kiely (all strains pathogenic to *Citrus*), in accordance with the procedure referred to in Article 18(2) of Directive 2000/29/EC, and mentioned on the certificate;

or

(b) – no symptoms of *Guignardia citricarpa* Kiely (all strains pathogenic to *Citrus*), have been observed in the place of production since the beginning of the last cycle of vegetation, and none of the fruits harvested in the place of production has shown, in appropriate official examination, symptoms of this organism,

and

– the place of production, the packing facilities, exporters and any other operator involved in the handling of the fruits are officially registered for this purpose.

3. Fruits covered by this Decision may only enter the Community if their movement, from their place of production to the point of export to the Community, is accompanied by documents issued under the authority of and supervised by the National Plant Protection Organisation of Argentina or Brazil respectively, as part of a documentary system on which information is made available to the Commission.

COMMISSION DECISION

of 29 April 2004

concerning the financial contribution by the Community towards the OIE Conference on rabies in Europe and Central Asia in 2004

(notified under document number C(2004) 1619)

(2004/417/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field[1], and in particular Article 20 thereof,

Whereas:

(1) Under Decision 90/424/EEC the Community is to undertake or assist the Member States in undertaking the technical and scientific measures necessary for the development of Community veterinary legislation and for the development of veterinary education or training.

(2) The Office International des Epizooties (OIE) with the two European OIE reference laboratories FCRV-Wusterhausen and AFSSA-Nancy have taken the initiative of organising a large scale Conference on rabies in Europe and Central Asia. This Conference is to focus on new scientific developments in the field of rabies diagnostic, epidemiology and vaccine and practical aspects of the control of the disease.

(3) The Community has for almost ten years made financial contributions towards programmes for the eradication of rabies in infected Member States under Decision 90/424/EEC. As a result of that measure the disease has been almost eradicated throughout the territory of the Community. Nevertheless programmes are still maintained in regions bordering certain Acceding States and third countries.

(4) It was decided in 2003 to co-finance, within the PHARE programme, rabies control programmes in Estonia, Hungary, Latvia, Lithuania, Poland and Slovenia. Those campaigns are to start in 2004 and will continue until 2006.

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[1] OJ L 224, 18.8.1990, p. 19. Decision as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

(5) Programmes for the eradication of rabies in the Czech Republic and in Slovakia for the year 2004 have been approved and granted financial contributions from the Community under Commission Decision 2003/849/EC[2].

(6) Any action which could facilitate policy decisions in favour of a promotion of rabies control in countries in Eastern Europe and Central Asia should be encouraged.

(7) A Conference on rabies control which could result in improvements in the strategies in force and in better information for competent authorities in Eastern Europe and Central Asia should make a useful contribution and the Community should consequently support the organisation of that conference.

(8) The publication and dissemination by the Community of technical and scientific materials related to the OIE conference on rabies in Europe and Central Asia in December 2004 will contribute to the further development of Community veterinary legislation and veterinary education or training.

(9) The financial resources necessary for the Community contribution to the OIE Conference on rabies in December 2004 should therefore be engaged.

(10) This financial contribution from the Community should be granted subject to the conference actually being carried out as planned.

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

HAS DECIDED AS FOLLOWS:

Sole Article

The action to publish and disseminate the technical and scientific materials related to the OIE conference on rabies in Europe and Central Asia in December 2004, to be financed from budget line 17.04.02 of the budget of the European Union for 2004 to a maximum amount of EUR 50 000 is hereby approved.

Done at Brussels, 29 April 2004

For the Commission
David BYRNE
Member of the Commission

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[2] OJ L 322, 9.12.2003, 16.

COMMISSION DECISION

of 29 April 2004

laying down guidelines for the management of the Community Rapid Information System (RAPEX) and for notifications presented in accordance with Article 11 of Directive 2001/95/EC

(notified under document number C(2004) 1676)

(Text with EEA relevance)

(2004/418/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety ([1]), and in particular the third subparagraph of paragraph 1 of Article 11 thereof,

After consulting the Committee set up by Article 15 of Directive 2001/95/EC,

Whereas:

(1) Directive 2001/95/EC establishes a Community Rapid Information System (RAPEX) for the rapid exchange of information between the Member States and the Commission on measures and actions relating to products posing a serious risk to the health and safety of consumers.

(2) The RAPEX helps to prevent the supply to consumers of products which pose a serious risk to their health and safety, facilitates the monitoring of the effectiveness and consistency of market surveillance and enforcement activities in the Member States, and provides a basis for identifying needs for action at Community level.

(3) The notification procedure under Article 11 of Directive 2001/95/EC provides for an exchange of information between the Member States and the Commission on measures and actions relating to dangerous products which do not present a serious risk to the health and safety of consumers.

[1] OJ L 11, 15.1.2002, p. 4.

(4) The effective operation of the notification procedures under Directive 2001/95/EC by the Commission and the competent authorities of the Member States requires consistent implementation of the relevant provisions of that Directive, in particular of the concept of serious risk and of risks the effects of which do not, or cannot, go beyond the territory of one Member State but which can be of interest for all Member States.

(5) In order to facilitate the operation of RAPEX and of the Article 11 notification procedure, the guidelines should include a standard notification form and criteria for the classification of notifications according to the degree of urgency. The guidelines should also define the operating arrangements including deadlines for the various steps of the notification procedures.

(6) The guidelines should be addressed to the national authorities designated as contact points in the RAPEX and in charge of the notification procedure under Article 11 of Directive 2001/95/EC. The Commission should use the guidelines as the reference document for managing RAPEX and the Article 11 notification procedure,

HAS ADOPTED THIS DECISION:

Article 1

The Commission hereby adopts guidelines to supplement Directive 2001/95/EC for the management of the Community Rapid Information System (RAPEX) and for notifications presented in accordance with Article 11 of that Directive.

The guidelines are set out in the Annex to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 29 April 2004.

For the Commission
David BYRNE
Member of the Commission

ANNEX

GUIDELINES

for the management of the Community Rapid Information System (RAPEX) and for notifications presented in accordance with Article 11 of Directive 2001/95/EC

TABLE OF CONTENTS

1. INTRODUCTION

1.1 Background and Objectives of the guidelines

Directive 2001/95/CE[1] on general product safety (GPSD) establishes a Community Rapid Information System (RAPEX) for the rapid exchange of information between the Member States and the Commission on measures and actions in relation to consumer products posing a serious risk for the health and safety of consumers in so far as there are no specific provisions in Community law with the same objective.

Furthermore, the notification procedure in Article 11 of the GPSD is intended for exchange of information between the Member States and the Commission on measures and actions in relation to consumer products that do not present a serious risk to the health and safety of consumers.

These procedures are part of the provisions of the GPSD aimed at ensuring an effective and consistent enforcement of the applicable safety requirements.

The objectives of the RAPEX system are:

a) to provide a rapid exchange of information between Member States and the Commission about measures and actions taken in relation to consumer products because of a serious risk to the health and safety of consumers;

b) to inform Member States and the Commission about the existence of a serious risk even before measures are adopted or actions taken;

c) to obtain and circulate to all Member States information on the follow-up given to the information exchanged by the Member States receiving it;

with the aim of:

a) preventing the supply to consumers of products which pose a serious risk to their health and safety, and where necessary withdrawing them from the market or recalling them from consumers;

b) facilitating the monitoring of the effectiveness and consistency of market surveillance and enforcement activities in the Member States;

c) identifying the need and providing a basis for action at Community level, where necessary;

d) contributing to the consistent enforcement of Community product safety requirements and to the proper functioning of the internal market.

The notification mechanism of Article 11 of the GPSD also facilitates prevention of the supply to consumers of dangerous products (not presenting a serious risk) and monitoring of market surveillance activities in the Member States.

[1] OJ L 11, 15.1.2002, p. 4.

The GPSD provides for the "establishment of non-binding guidelines aimed at indicating simple and clear criteria and practical rules, which may change in order to be completed, improved or adapted in the light of the experience and new developments, to facilitate the effective operation of RAPEX by the Commission and the competent authorities of the Member States[2]", in other words these guidelines are intended to facilitate the effective and consistent application of the provisions of the GPSD related to notification procedures.

The objectives of these guidelines are:

a) to clarify the scope of RAPEX from the operational point of view, by

- setting a conceptual framework for the provisions of the Directive related to products posing serious risks and in particular criteria for applying the concept of "serious risk";
- giving guidance on the types of measures, action and situations that need to be notified;
- providing guidance on how to notify the Commission of measures taken by producers or distributors on a voluntary basis, in agreement with the authorities or when required by these authorities;
- providing criteria for identifying "local events" (cases where the effects of the risk in question do not, or cannot, go beyond the territory of one Member State) that could be of interest for all Member States, in which case they would have to be notified;
- setting criteria for notifying information on dangerous products to the Commission before a Member State decides to adopt measures or take actions;
- identifying the products covered by a specific equivalent exchange of information systems, therefore excluded from the scope of RAPEX;
- classifying and indexing notifications according to the degree of urgency.

b) to define the contents of the notifications, in particular the information and data required, and the forms to be used for the RAPEX system;

c) to define the follow-up action to be taken by the Member States receiving a notification and the information to be provided on such follow-up;

d) to describe the treatment of the notifications and of the follow-up information by the Commission;

e) to set the deadlines for the various steps of the RAPEX processes;

f) to define and document the practical arrangements at Commission and Member States level for the operation of RAPEX and all the relevant technical details.

These guidelines provide also guidance on the notification procedure of Article 11 of the GPSD by clarifying the scope of the procedure, detailing the contents of notifications and establishing arrangements for treatment and transmission of notifications.

[2] In the context of this document the term "Member States" means all States which belong to the European Union and also those States which are parties to the EEA Agreement.

1.2 Status and further developments of the guidelines

Status:

These are operational guidelines. These guidelines are adopted by the Commission, after consultation of the Member States within the GPSD Committee acting in accordance with the advisory procedure.

They therefore represent the reference document for the application of the provisions of the GPSD concerning RAPEX as well as for notifications presented according to Article 11 of the GPSD.

Further developments:

These guidelines will need to be adapted in the light of experience and of new developments. The Commission will update or amend them as necessary in consultation with the Committee referred to in Article 15 GPSD.

1.3 To whom are the guidelines addressed

These guidelines are addressed to the Member States' national authorities designated to participate in the RAPEX network as contact points and in charge of the notification procedure under Article 11 of the Directive. The Commission will use these guidelines as the reference document for managing RAPEX and the notification procedure under Article 11 of the Directive.

2. GENERAL SCOPE OF RAPEX

2.1 Definition of the products covered by the GPSD and criteria for applying this definition for the aims of RAPEX

The provisions of the GPSD, and in particular the RAPEX procedure, apply to consumer products that pose a serious risk to consumers in so far as there are no specific provisions in Community law with the same objective. Examples of products covered by RAPEX are toys, domestic electrical appliances, lighters, childcare articles, cars and tyres, etc.

The products covered by the GPSD are defined in its Article 2(a):

"product" shall mean any product – including in the context of providing a service – which is intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them, and is supplied or made available, whether for consideration or not, in the course of a commercial activity, and whether new, used or reconditioned."

The following elements are particularly relevant:

- products must be intended for and supplied or made available to consumers; or

- likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for consumers. Products "migrating" from professional use to the consumer market should also be covered. In other words, products that had been originally developed for professional use and allowed on the market as intended for professionals, which have subsequently also been marketed to consumers;

- products provided in the context of a service: the GPSD also covers products supplied or made available to consumers in the course of a service provided to them. Consumer products are often made available in connection with certain services (for example renting of machines). The equipment used by the service provider to supply a service is beyond the scope of the GPSD, in particular, equipment on which consumers ride or travel operated by a service provider.

2.2 Products excluded from RAPEX because covered by specific and equivalent requirements for the rapid exchange of information

The following products are excluded from RAPEX because they are covered by equivalent notification mechanisms established by Community legislation:

- pharmaceuticals covered by Directives 75/319/EEC[3] and 81/851/EEC[4];

- active implantable medical devices covered by Directive 90/385/EEC[5], medical devices covered by Directive 93/42/EEC[6], and in vitro diagnostic medical devices covered by Directive 98/79/EC[7];

- food and feed covered by Regulation (EC) No 178/2002[8].

Further information on the relationship between the different notification procedures established by Community law can be found in chapter 9.1 and in the separate "Guidance Document on the Relationship between the GPSD and Certain Sector Directives[9]".

2.3 Measures, decisions and actions to be notified under RAPEX

An indicative list of the different types of measures and actions of the competent authorities of the Member States that should be notified under RAPEX, can be found in Article 8 GPSD. These measures and actions are aimed at:

- imposing conditions prior to the marketing of a product;

- requiring that a product be marked with warnings concerning any risks;

- alerting consumers about a risk related to a product;

- banning temporarily or definitively the supply, the offer to supply or the display of a product;

- organising the withdrawal or the recall of a product;

- ordering producers and distributors to withdraw a product, recall it from consumers, and destroy it.

Other measures and actions that authorities can adopt or take and should notify are:

[3] OJ L 147, 9.6.1975, p. 13. Directive as last amended by Directive 2000/38/EC (OJ L 139, 10.6.2000, p. 28).
[4] OJ L 317, 6.11.1981, p. 1. Directive as last amended by Directive 2000/37/EC (OJ L 139, 10.6.2000, p. 25).
[5] OJ L 189, 20.7.1990, p.17
[6] OJ L 169, 12.7.1993, p.1
[7] OJ L 331, 7.12.1998, p.1
[8] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 031, 01/02/2002 p. 1.
[9] http://europa.eu.int/comm/consumers/cons_safe/prod_safe/gpsd/revisedGPSD_en.htm

- agreements with producers and distributors to take actions necessary to avoid the risks posed by products;

- agreements with producers and distributors to organise jointly the withdrawal, the recall of products from consumers and their destruction or any other relevant action;

- agreements with producers and distributors to coordinate the recall of a product from consumers and its destruction.

Member States should notify all such measures even if an appeal against them is likely or they are under appeal at national level or subject to publication requirements. Member States should indicate in the notification whether the measure is of a definitive nature (because it has not been contested by the manufacturer or importer, or because it has been finally confirmed) or if it is still likely to be, or is currently, under appeal. In any case, any subsequent change in the status of the measure should be communicated to the Commission.

Under Article 5 producers and distributors are obliged to inform the national authorities of voluntary actions or measures taken to prevent risk to the consumer. The authorities must notify these voluntary measures to the Commission when the product poses a serious risk (see chapter 4.3).

2.4 Other information on serious risks that may be exchanged under RAPEX

Member States may inform the Commission of:

- any information regarding the existence of a serious risk at the stage before deciding to adopt measures or to take action (Article 12.1, third subparagraph). In such cases RAPEX contact points should also inform the Commission about the final decision;

- measures on a specific production batch which has been withdrawn from the market by a Member State due a serious risk and when all items in this batch have been withdrawn from the market by the Member State;

- customs authority decisions to block or to reject products at the EU borders if the consumer product blocked or rejected presents a serious risk. Contact points should circulate this information to their customs authorities (see details in chapter 8.3).

The Commission may receive information relating to products that present a serious risk to the health of the consumer from Third Countries or through equivalent information systems established by other organisations including non-EU countries. The Commission will evaluate the information and may transmit it to the Member States.

These types of additional information on serious risks that may be exchanged under RAPEX do not require a formal reaction from the rest of Member States and the use of a standard form is not required.

2.5 Criteria for notifying measures related to risks not going beyond the territory of a Member State

Measures and actions related to risks where the effects do not or cannot go beyond the territory of a Member State are excluded from the scope of RAPEX.

However, in certain cases such measures and actions are likely to interest the enforcement authorities of the other Member States. In order to assess whether a measure dealing with a risk of

local effect involves information on product safety likely to be of interest for the other Member States, the authority should take into account for example whether the measure is taken in response to a new type of risk which has not yet been reported in other notifications, or whether it is related to a new risk arising from a combination of products or whether it is a new type or category of product that is dangerous.

Measures related to second-hand products sold by private individuals and custom-made products that present a serious risk are excluded from the scope of RAPEX if the Member State which took the measure can conclude from the existing information that the product could not be found in another Member State.

Taking into account the free circulation of products at European level, the openness of the European economy and the fact that consumers buy products not only in their home market but also during holidays abroad or by Internet, contact points are encouraged to report actions taken when there is uncertainty whether the risk could be relevant or of interest for another Member States.

3. CRITERIA FOR IDENTIFYING SERIOUS RISKS

3.1 Definition of serious risk in the GPSD and objectives of the guidance on serious risks

Serious risk is defined in Article 2(d) of the GPSD as follows: "serious risk shall mean any serious risk, including those the effects of which are not immediate, requiring rapid intervention by the public authorities".

This definition of serious risk is characterised by two key elements. First, it includes all types of serious risk to consumers created by a product (immediate threats as well as possible long-term risks); second, the risks considered are those requiring a rapid intervention.

The following subchapters give general guidance to assist the authorities in assessing the level of seriousness of the risk and deciding whether a rapid intervention is necessary. The objective is to help the authorities in identifying the cases to which the concept of serious risk under the GPSD applies. The guidelines in this chapter are not exhaustive and do not try take account of all possible factors. The national authorities should judge each individual case on its merits taking into account the criteria set out in these guidelines as well as their own experience and practice, other relevant considerations and appropriate methods.

3.2 Criteria on the level of gravity of risks

A consumer product may present one or more intrinsic hazard. The hazard may be of various types (chemical, mechanical, electrical, heat, radiation etc.). The hazard represents the intrinsic potential of the product to damage the health and safety of users under certain conditions.

The severity of each type of hazard may be given a rating, based on qualitative and sometimes quantitative criteria related to the type of damage that they are liable to produce.

It may happen that not all individual products present the hazard in question, but only some of the items placed on the market. The hazard may in particular be related to a defect that appears only in some of the products of a certain type (brand, model…) placed on the market. In such cases the probability of the defect/hazard being present in the product should be considered.

The potential of a hazard to materialise as an actual negative effect on the health/safety will depend on the degree to which the consumer is exposed to it when using the product as intended

or as could reasonably be expected during its lifetime. In addition the exposure to certain hazards may in some cases involve more than one person at a time. Finally when determining the level of the risk presented by a product by combining the severity of the hazard with the exposure, consideration should be given also to the ability of the exposed consumer to prevent or react to the hazardous situation. This will depend on the evidence of the hazard, the warnings given and the vulnerability of the consumer who may be exposed.

Taking into account the above considerations, the following conceptual approach may assist enforcement officers to decide whether a specific hazardous situation caused by a consumer product constitutes a serious risk under the GPSD.

The officer should:

- As a first step, use Table A to determine the gravity of the outcome of a hazard, depending on both its severity and probability to materialise under the conditions of use considered, and of the possible health/safety effect related to the intrinsic hazardous characteristics of the product;

- As a second step, use Table B to further assess the gravity of the outcome depending on the type of consumer and, for normal adults, whether the product has adequate warnings and guards and whether the hazard is sufficiently obvious to make it possible to grade the risk level qualitatively.

Table B indicates the gravity of the outcome from Table A for which a serious risk situation exists and for which rapid action is to be adopted by the enforcement authorities.

Table A: Risk Estimation: severity and probability of health/safety damage

In Table A the two main factors affecting the risk estimation, namely the severity and the probability of health/safety damage, are combined. The following definitions of severity and probability have been drawn up to assist the selection of appropriate values.

Severity

The assessment of severity is based on consideration of the potential health/safety consequences of the hazards presented by the product considered. A grading should be established specifically for each type of hazard[10].

[10] As an example, for certain mechanical risks the following definitions of the severity classifications may be proposed, with their typical injuries:

Slight	Serious	Very Serious
<2% incapacity usually reversible and not requiring hospital treatment.	2 – 15% incapacity usually irreversible requiring hospital treatment	>15% incapacity usually irreversible
Minor cuts	Serious cuts	Serious injury to internal organs
Minor fractures	Loss of finger or toe	Loss of limbs
	Damage to sight	Loss of sight
	Damage to hearing	Loss of hearing

The assessment of severity should also take into account the number of people who could be affected by a dangerous product. This means that the risk from a product which could pose a risk to more than one person at a time (e.g. fire or gas poisoning from a gas appliance) should be classified as more severe than a hazard which can only affect one person.

The initial risk estimation should refer to the risk to any person exposed to the product and should not be influenced by the size of the population at risk. However, it may be legitimate for the authorities to take account of the total number of people exposed to a product in deciding on the action to be taken.

For many hazards it is possible to envisage unlikely circumstances which could lead to very serious effects, e.g. tripping over cable, falling and banging head leading to death, although a less serious outcome is more likely. The assessment of the severity of the hazard should be based on reasonable evidence that the effects selected for characterizing the hazard could occur during foreseeable use. This could be worst case experience involving similar products.

Overall Probability

This refers to the probability of negative health/safety effects to a person exposed to the hazard. It does not take into account the total number of people at risk. Where the guide refers to the probability of a product being defective, this should not be applied if it is possible to identify each one of the defective samples. In this situation, the users of the defective products are exposed to the full risk and the users of the other products to no risk.

The overall probability is the combination of all the contributing probabilities such as:

- the probability of the product being or becoming defective (if all products carry the defect then this probability would be 100%)

- the probability of the negative effect materialising for a normal user who has an exposure corresponding to the intended or reasonably expected use of the defective product.

These two probabilities are combined in the following table to give an overall probability which is entered into table A.

Overall Probability of Health/Safety Damage		Probability of hazardous product		
		1%	10%	100% (All)
Probability of health/safety damage from regular exposure to hazardous product	Hazard is always present and health/safety damage is likely to occur in foreseeable use	Medium	High	Very High
	Hazard may occur under one improbable or two possible conditions	Low	Medium	High
	Hazard only occurs if several improbable conditions are met	Very Low	Low	Medium

Combining the severity and overall probability in Table A gives an estimation of the gravity of the risk. The accuracy of this assessment will depend upon the quality of the information available to the enforcement officer. However, this assessment needs to be modified to take account of the society's perception of the acceptability of the risk. Society accepts much higher risks in some circumstances such as motoring, than in others, such as children's toys. Table B is used to input this factor.

Table B Grading of Risk: type of person, knowledge of the risk and precautions

Society accepts higher risks in some circumstances than in others. It is considered that the main factors affecting the level of risk that is considered to be serious are the vulnerability of the type of person affected and for normal adults, the knowledge of the risk and the possibility of taking precautions against it.

Vulnerable people

The type of person using a product should be taken into account. If the product is likely to be used by vulnerable people, the level of risk which is serious should be set at a lower level. Two categories of vulnerable people are proposed below, with examples:

Very vulnerable	Vulnerable
Blind	Partially sighted
Severely disabled	Partially disabled
Very old	Elderly
Very young (< 3yrs)	Young (3 – 11yrs)

Normal adults

The adjustment of the seriousness of risk for normal adults should only apply if the hazard is obvious and necessary for the function of the product. For normal adults the level of risk which is serious should be dependent on whether the hazard is obvious and whether the manufacturer has taken adequate care to make the product safe and to provide safeguards and warnings, especially if the hazard is not obvious. For example, if a product has adequate warnings and safeguards and the hazard is obvious, a high gravity of outcome may not be serious in terms of grading the risk (Table B), although some action may be needed to improve the safety of the product. Conversely, if the product does not have adequate safeguards and warnings, and the hazard is not obvious, a moderate gravity of outcome is serious in terms of grading the risk (Table B).

Risk Assessment of consumer products for the GPSD

This procedure is proposed to assist enforcement officers when deciding whether a specific hazardous situation caused by a consumer product is intolerable and constitutes a serious risk under the General Product Safety Directive.

Table A - Risk Estimation

Probability of Health/Safety Damage	Severity of Health/Safety Damage: Slight	Serious	Very Serious	Overall Gravity of Outcome
		Very High	High	Very High
Very High		High	Medium	High
High		Medium	Low	Moderate
Medium		Low	Very Low	Low
Low		Very Low		Very low

Table B – Grading of Risk

Vulnerable people		Normal adults				
Very vulnerable	Vulnerable	No	Yes	No	Yes	Adequate warnings and safeguards?
		No	No	Yes	Yes	obvious hazard?
SERIOUS RISK - RAPID ACTION REQUIRED						
Moderate risk - Some action required						
		Low risk - Action unlikely				

Table A is used to determine the gravity of the outcome of a hazard, depending on the severity and probability of the possible health/safety damage (see tables in notes)

Table B is used to determine the rating of the gravity of risk depending on the type of user and, for normal adults, whether the product has adequate warnings and safeguards and whether the hazard is sufficiently obvious, and to decide whether a serious risk situation exists and rapid action is required

Example (indicated by the arrows above)

A chain saw user has suffered a badly cut hand and it is found that the chain saw has an inadequately designed guard which allowed the user's hand to slip forward and touch the chain. The enforcement officer makes the following risk assessment.

Table A - The assessment of probability is **High** because the hazard is present on all products and may occur under certain conditions. The assessment of severity is **Serious** so the overall gravity rating is **High.**

Table B – The chain saw is for use by normal adults, has an obvious hazard but inadequate guards, so the risk rating would be **Moderate**.

The **High** gravity is therefore intolerable so a **serious risk** situation exists and rapid action is required.

4. CONTENTS OF RAPEX NOTIFICATIONS

4.1 Information to be entered on the notification form

Information should be as complete as possible: contact points should fill in all the fields in the notification form (Annex I of the Guidelines). If information is not available, this should be indicated and explained. A timetable for providing the missing information should be transmitted.

Responsibility for the information provided lies with the notifying Member State (GPSD Annex II.10).

In order to be useful to the authorities of the other Member States in their market surveillance activities, the notification must include all the data needed to identify the dangerous product, trace its origin, identify the marketing and distribution channels, determine the related risks, etc.

Confidentiality could be requested if disclosure of the information would undermine the protection of court proceedings, monitoring and investigation activities or professional secrecy, unless there were an overriding public interest in disclosure of the information to protect the health and safety of consumers.

The notifying Member State could also require confidentiality for annexes to the notification, such as legal proceedings, that do not contain information relevant for consumer protection and need to be protected.

According to the GPSD, the public must have access to information relating to the safety properties of products, the nature of the risk, product identification and the measure taken.

Contact points should pay special attention to checking that the following items of essential information appear in the notification:

- a detailed description of the product (including if possible the customs code of the product) together with a photograph in order to facilitate its identification by enforcement authorities. The identification and description of the product should be accurate in order to avoid any confusion with similar products in the same category that are safe;

- the risk assessment including, in particular, results of tests carried out by the authority;

- the scope and the nature of the measure taken in order to avoid the risk, its duration and the follow-up. The notifying Member State should inform the Commission of any amendment to the measure taken and of the final decision taken on the product in question. The Member State should indicate in the notification whether the measure has a definitive character (i.e. it has not been contested by the manufacturer or importer, or has been confirmed by an instance that does not admit appeal) or could be, or is currently, subject to appeal. In any case, any change in the status of the measure should be communicated to the Commission;

- the information needed to identify the product's distribution channels and its origin, in particular its producer, importer or exporter, as well as other information related to its traceability.

In the case of products imported from Third Countries, and in order to facilitate investigation by the authorities of the Third Country of origin of the product, the following documents and information should also be communicated (if available): copies of Sales Contract, Letter of Credit, date and port of export and batch number of the products.

4.2 Information to provide in relation to measures concerning use of chemicals

When the measure notified pursuant to Article 11 or Article 12 seeks to limit the marketing or use of a chemical substance or preparation, the Member States must provide as soon as possible either a summary or the references of the relevant data relating to the substance or preparation considered and to known and available substitutes, where such information is available.

They will also communicate the anticipated effects of the measure on consumer health and safety together with the assessment of the risk carried out in accordance with the general principles for the risk evaluation of chemical substances as referred to in Article 10(4) of Regulation (EEC) No 793/93[11] in the case of an existing substance or in Article 3(2) of Directive 67/548/EEC[12] in the case of a new substance.

4.3 Notification of the voluntary measures taken by producers and distributors

Article 5(3) of the GPSD obliges producers and distributors to inform the national authorities of any voluntary action or measure taken to prevent risk to the consumer.

Article 12(1) fourth subparagraph requires Member States to notify the Commission of the voluntary measures taken by producers and distributors in the case of a serious risk.

When the authorities receive information from producers and distributors concerning a risk and the voluntary actions taken to avoid it, they should examine this information in order to assess whether a notification to the Commission is justified due to the involvement of a serious risk, taking into account the criteria outlined in chapter 3.

Such notification at Community level is required in the case of a serious risk the effects of which can go beyond the territory of a Member State (taking into account the criteria for notifying local events: see chapter 2.5).

The information transmitted to the Commission should include details of the voluntary action taken by the producers or distributors. All relevant information on the risk should also be notified. In particular:

- information to identify and trace the product or batch of products;

[11] OJ L 84, 5.4.1993, p. 1.
[12] OJ 196, 16.8.1967, p. 1/67. Directive as last amended by Commission Directive 2000/33/EC (OJ L 136, 8.6.2000, p. 90).

- description of the risk;
- identification of the producers and distributors participating in the application of the measure;
- description of the action taken by producers and distributors to avoid risks to consumers (scope, countries covered, monitoring);
- final destination of the dangerous product (destruction, recondition);
- follow-up actions that national authorities would take in order to monitor the effectiveness of the voluntary measures taken by producers and distributors;
- actions provided for in other Member States by the producers or distributors.

5. DEADLINES FOR SUBMISSION AND CIRCULATION OF RAPEX NOTIFICATIONS

5.1 Deadlines for submitting notifications to the Commission by the Member States

National contact points are required to notify the Commission as soon as possible and at the latest 10 days[13] after the competent authorities have taken the decision or have decided to adopt measures[14] relating to products presenting a serious risk.

Measures or action taken in agreement between authorities and producers and/or distributors should be notified to the Commission as soon as possible and at the latest 10 days after the agreement has been concluded.

Contact points are required to transmit information to the Commission on voluntary measures taken by producers and distributors which have been notified to the authorities by reason of a serious risk and which go beyond the territory of a Member State. This should be done as soon as possible and at the latest 10 days after the producer and/or distributor have informed the national authority.

In the case of notifications requiring emergency action from Member States (as defined in Chapter 7.1), the notifying national contact point is required to inform the Commission as soon as possible and at the latest three days after the measure has been adopted. This type of notification should always be preceded by a phone call to the Commission RAPEX mobile phone number (in particular during week-ends and holiday periods).

Information on serious risks to be exchanged under RAPEX as described in point 2.4 is to be transmitted to the Commission as soon as possible and at the latest 10 days after the contact point was informed.

[13] All deadlines mentioned in the text are expressed in calendar days.

[14] The measures, decisions and actions to be notified under RAPEX are described in point 2.3 of these guidelines.

National contact points are required to notify the Commission as soon as possible and at the latest 15 days after the competent authorities have taken the decision or have decided to adopt measures restricting the marketing or use of products by reason of a risk that is not serious.

These deadlines apply to the exchange of information between national contact points and the Commission. They do not take into account national deadlines applicable internally in the Member States (for instance between local and central authorities). Appropriate arrangements should be put in place at national level in order to ensure rapid transmission of the information between the different national authorities in charge of product safety.

These deadlines apply irrespective of any appeal procedure entered into by the producer or distributor or official publication requirements.

5.2 Commission deadlines for the transmission of notifications to all the Member States

The Commission will transmit the notification to the contact points only if the notifying Member State has provided the essential information described in chapter 4.1. Any follow-up by other Member States would not be feasible if such essential information were missing.

The Commission will treat the information received in accordance with the following degrees of urgency:

- Notifications requiring emergency action from Member States will be treated as priority by the Commission and transmitted to Member States as soon as possible and at the latest three days after reception;

- Alert notifications (Article 12 of the GPSD) will be transmitted to Member States within five days of reception. This category includes measures or action taken by authorities, agreements for action between authorities and producers and distributors, and voluntary measures taken by producers and distributors relating to products that present a serious risk;

- Other information on serious risks to be exchanged under RAPEX will be transmitted within five days of reception;

- Notifications presented in accordance with Article 11 of the GPSD will be sent by the Commission within 15 days of reception. These notifications relate to measures taken by the authorities which restrict the placing on the market or require the withdrawal or recall of products that do not create a serious risk.

5.3 Deadlines for updating the information provided by the Member States

Member States are required to notify the Commission of any modification or lifting of measures or actions at the latest five days after the competent authorities have taken the decision to modify or lift the measure.

Member States may provide information to the Commission at the stage preceding the decision on the measures to be taken, as provided for in GPSD Article 12(1) third subparagraph. The Member State will confirm or modify this information within 45 days of the first communication (GPSD Annex II.4).

6. FOLLOW-UP TO THE RAPEX NOTIFICATIONS

6.1 Action by the Member States to follow up the notifications

Upon receipt of a notification Member States are required to examine all the information supplied in order to:

- find out whether the product has been marketed in their territory;
- enquire in order to collect any relevant information;
- perform any additional assessment of the risk (if needed);
- evaluate whether national measures should be adopted in the light of their own circumstances.

6.2 Contents of the reaction to be communicated to the Commission

Only notifications requiring emergency action from Member States and Alert notifications (Article 12) require a reaction from the Member States informing the Commission of their follow-up activities and conclusions. On the other hand, notifications presented according Article 11 and as "Other information on serious risks that may be exchanged under RAPEX" do not require Member States to inform the Commission of the follow-up given to the information received.

After receiving a notification requiring emergency action from Member States or an Alert notification (Article 12) all Member States are required to inform the Commission, using the Reaction form in Annex II, of the conclusions of their market surveillance activities and in particular:

- whether or not the product has been found;
- any differing assessment of the risk notified;
- the measures taken or decided on and the reasons justifying a different measure;
- the special circumstances justifying lack of action or follow-up.

If the product is manufactured in the EU and the notifying Member State is not the country of origin of the product, the authorities of the Member State where the product is manufactured should inform the Commission about:

- any contacts with the manufacturer;
- the measures adopted to ensure that the manufacturer solves the problem at source, where appropriate;

- the distributors or retailers of the product in other Member States.

If the product is not manufactured in the EU and the notifying Member State is not the country where the product was first marketed in the EU, the authorities of this country should inform the Commission about:

- any contacts with the manufacturer's representative or with the importer of the product;

- the measures adopted by the manufacturer's representative or by the importer to ensure that the problem is solved at source;

- the distributors or clients of the product in other Member States.

6.3 Circulation by the Commission to the Member States of the reactions received

The Commission will circulate as a priority case-by-case reactions:

- to notifications requiring emergency follow-up from Member States;

- containing a different assessment of the risk;

- containing a different measure to deal with the risk.

The Commission will circulate in the form of weekly reports reactions received after the deadlines and reactions informing it:

- that the product has been found and similar actions taken;

- of a lack of action or of follow-up by Member States;

- that the product has not been found on the national market.

6.4 Deadlines for submitting reactions to the Commission by the Member States

Adequate follow-up by the Commission will not be possible if Member States do not fulfil their obligation to react to the notifications received.

Member States are required to react:

- as soon as possible and in any case not later than 20 days if the reaction relates to a notification requiring emergency action from Member States;

- as soon as possible and in any case not later than 45 days in the case of alert notifications on measures taken by authorities, actions agreed between authorities and producers and distributors, or voluntary actions notified at Community level concerning products presenting a serious risk.

If the product is manufactured in the EU and the notifying Member State is not the country of origin of the product, the authorities of the Member State where the product is manufactured should react to the notification within 15 days, providing information about the contacts with the manufacturer and the measures adopted to

ensure that the manufacturer will solve the problem at source. The same deadline is applicable to the Member State where the manufacturer's representative or the importer of the product is established in cases where the product is not manufactured in the EU and the notifying Member State is not the country where the product was first marketed in the EU.

A reminder will be sent to the Member States that have not reacted to the notifications after 45 days from the date when the notification was sent. The GPSD Committee will also be informed about any missing reactions.

The Commission will circulate the reactions as follows:

- as soon as possible and in any case not later than three days if the reaction relates to a notification requiring emergency follow-up from Member States;

- as soon as possible and in any case not later than five days for other reactions to notifications on national measures, agreements between authorities and producers, or voluntary actions.

7. EXAMINATION BY THE COMMISSION OF NOTIFICATIONS

7.1 Examination of the completeness and correctness of the notifications

The Commission contact point checks all information received through the system before further transmission. The examination of the notifications by the Commission does not imply any assumption of responsibility for the information transmitted which remains with the notifying Member State.

Specific internal arrangements have been put in place in order to circulate information to the Commission services concerned.

The examination includes the following steps to check and complete the information, if necessary:

Completeness check:

If the information is incomplete, additional details are requested from the contact point of origin.

If the product is manufactured in the EU and the notifying Member State is not the country of origin of the product and has not obtained the essential information for the notification, the Commission will contact the authorities of the Member State where the product is manufactured in order to complete the information on the distribution channels and destinations of the product. The authorities of the Member State of origin will be requested to obtain this information by contacting the producer or distributors.

If the product is not manufactured in the EU and the notifying Member State is not the country where the product was first marketed in the EU and has not obtained the essential information of the notification, the Commission will contact the authorities

of the Member State where the product was first marketed in order to obtain information on the possible distribution of the product to other Member States.

To check the notifications received, the Commission will:

- verify in general whether the information received is in conformity with EU legislation and with the provisions applicable to the functioning of RAPEX as defined in these guidelines;

- contact the notifying country, if necessary, in order to obtain extra information.

Classification:

Notifications will be classified according to the degree of urgency (GPSD Annex II. 11) in:

a) Notifications requiring emergency action from Member States (serious risk, foreseeable need for measures to be agreed at Community level and/or likely political visibility of the issue and/or mass-media coverage);

b) Alert notifications (Article 12 of the GPSD): measures or actions taken on products presenting a serious risk;

c) Notifications under Article 11 of the GPSD: measures or actions taken by the competent authorities on products not posing a serious risk;

d) For Information Only: information on serious risks to be exchanged under RAPEX as described in chapter 2.4.

Consultations:

When the product notified falls under the scope of specific sector legislation, the Commission contact point will ask for expert advice from other Commission services, if necessary. The Commission may, whenever it considers it to be necessary, carry out an investigation on its own initiative or ask for scientific advice.

Database research:

The Member States and the Commission should avoid any unnecessary duplication of notifications by checking previous notifications in the available database used by national authorities or by the Commission.

7.2 Examination in relation to the scope of RAPEX

The Commission will check whether the product notified is a consumer product falling under the scope of the GPSD as far as RAPEX provisions are concerned and whether it is covered by equivalent alert system.

The Commission will also verify that the notification complies with the GPSD and with the provisions applicable to the functioning of RAPEX.

The Commission will not make a risk assessment of the product. Therefore, Member States should include in all notifications a complete summary of their risk evaluation and the results of any tests or analyses carried out to assess the level of risk.

In the first instance, the Commission will base its conclusions on the classification of the notification on the information provided by the notifying Member State.

After examination the Commission will forward the notification to the other Member States or ask for clarification or additional information from the notifying Member State.

7.3 Examination of the follow-up reactions

On the basis of the examination of the information obtained from the notifications and reactions, the Commission will decide on the appropriate action, such as to:

- convene the GPSD Committee to discuss the information received and the results obtained and to evaluate the measures taken or to adopt;

- request an independent risk assessment;

- institute an investigation in cooperation with Member States;

- consult a Commission Scientific Committee;

- mandate the standardisation bodies to draft new standards or amend existing ones if clear and consistent safety specifications are not available for a category of products;

- inform Third countries;

- prepare proposals for new or modified legislation;

- launch the procedure for a Commission Decision based on Article 13 of the GPSD in urgent cases.

15 days after the date on which the reaction period has expired (45 days after the notification was sent), the Commission will send the national contact points a report with:

- the final conclusion on the notification taking into account the information received as reactions from Member States. If no further follow-up is required the file will be closed. If new developments concerning the notification occur later, the Commission will reopen the file;

- the follow-up actions to be taken by the Member States if any reactions are still outstanding or if there are different national approaches.

The GPSD Committee will be periodically informed of all the notifications received and of the follow-up.

8. NETWORK FOR THE EXCHANGES UNDER RAPEX

8.1 Setting up of two-way internal networks by the Member States to collect and to distribute the relevant information

Member States should ensure that there are systems at national level so that their national, regional or local authorities are aware of their responsibilities and of the action they should take to inform other services if a problem comes to light in their area.

Member States should establish a two-level internal structure consisting of:

- a single contact point with the Commission. This contact point will send the Commission and receive from the Commission all information exchanged through RAPEX; and

- a national network involving all the authorities responsible for product safety. These authorities send to and receive from the contact point the notifications and reactions. The composition of the network should be communicated to the Commission.

8.2 Designation of the authorities in charge of notifying the Commission and to whom the Commission communicates notifications

The main tasks of the national contact points are:

a) before sending a notification to the Commission

   - to verify the information received from the national, regional or local authorities in order to decide whether use of the RAPEX system is required (based on the Directive, the guidelines and previous experience);

   - to check if the product has already been notified or information related to it exchanged in order to avoid any unnecessary duplication;

   - to check that the notification form and the information are complete;

   - to classify the information into one of the predefined categories of notifications.

b) after receiving information from the Commission

   - to transmit the information to the national, regional or local authorities responsible for product safety at the various different levels;

   - to ensure follow-up of the information;

   - to inform the Commission of their conclusions.

National contact points should also:

- help explain the obligations and requirements created by Community and national legislation for producers and distributors concerning the notification of dangerous products;

- assist in the creation of a network culture among the different national authorities at the various different levels;

- assist these authorities in the use of RAPEX;

- ensure that the internal procedures for information exchange work properly.

8.3 Setting up of cooperation arrangements between the competent authorities, in particular with customs.

Customs officials' decisions to block or to reject products at the EU borders for safety reasons are also of interest to market surveillance authorities and the Commission. The legal basis for such decisions is Council Regulation (EEC) No 339/93 of 8 February 1993[15] on checks for conformity with the rules on product safety in the case of products imported from Third countries and Commission Decision 93/583/EEC of 28 July 1993[16] drawing up a priority and non-exhaustive list of products as provided for in Article 8 of Regulation 339/93/EEC.

Contact points should inform the Commission about these decisions. This information is only pertinent if the consumer product blocked or rejected presents a serious risk. The Commission will transmit the information to the contact points and they should circulate this information to customs officials in their country in order to prevent the entry of these products within the European market.

The reasons for prohibiting entry into the EU should be mentioned in the documents accompanying the dangerous products.

Contact points should also inform their customs authorities of the measures and actions taken by market surveillance authorities relating to imported products presenting a serious risk in order to avoid further imports of the same product into the EU market.

8.4 Means of communication, practical and technical arrangements applicable

Languages:

The contact points in the Member States may issue the notification in their national language and/or in English. The notifications will be translated into English, French, German, Italian and Spanish by the Commission.

Transmission via Internet

The RAPEX system uses an Internet-based software application as a communication tool between the contact points linked to a database containing all the information

[15] OJ L 040, 17/02/1993 p. 1
[16] OJ L 279, 12/11/1993 p. 0039

from the notifications and reactions. This system, which is accessible via https://reis.cec.eu.int/reis, includes all the forms and a User's Guide.

If there are technical problems with this site, contact points may send notifications and reactions by e-mail (mail box: Sanco-Reis@cec.eu.int) or by fax if (and only if) e-mail transmission is not possible (+32.2.296.43.23).

Out-of-hours service and permanent staffing during periods of closure:

As emergencies may arise out of working hours, Member States should ensure that their national, regional or local authorities can be contacted in urgent cases such as for notifications requiring emergency action by Member States.

Changes at national contact point level are to be communicated immediately to the Commission, which will forward them to the other Member States.

The Commission will ensure the proper functioning of the RAPEX system during weekends, periods of closure and holidays.

Weekends:

The contact points can reach the officials in charge of RAPEX operations by telephone (mobile phone) in case of an emergency. This will allow rapid organisation of an early warning.

Longer periods of closure:

It should be noted that the Commission contact point ensures holiday coverage by using a mobile phone and a laptop computer that can be linked into the system via the Internet. In emergencies, before sending the notification to the Commission, national contact points should contact the Commission official in charge of the permanent staffing, using a mobile phone number which will be communicated to contact points before the holiday period starts.

Contact points are also requested to provide similar coverage during weekends, short periods of closure and holiday periods. A list of emergency phone numbers, e-mails and faxes for the RAPEX contact points is established by the Commission to ensure that RAPEX members can be reached without delay. Any subsequent change should be communicated to the Commission.

9. COORDINATION BETWEEN RAPEX AND OTHER NOTIFICATION MECHANISMS

9.1 Cases in which a measure notified under RAPEX must also be notified under another mechanism

Whenever a measure with binding legal effects relates to consumer products covered by specific community legislation such as toys, electrical appliances, etc., it should also be considered under the sector specific notification mechanism applicable (safeguard

clause). The RAPEX system and the sector specific safeguard clauses involve separate legal obligations to notify because they serve different purposes.

For further information on the relationship between the notification procedures and their purposes, please see the separate "*Guidance Document on the Relationship between the GPSD and Certain Sector Directives*[17]".

9.2 Arrangements for simplifying the submission of notifications due under different mechanisms

When products are covered by other Community legislation with a notification procedure for national measures (safeguard clause), the Commission will, through its internal procedures, ensure that a single notification from national authorities fulfils the different obligations to inform the Commission under Community legislation.

A common notification form covering both the safeguard clause of Directive 88/378/EEC on Safety of Toys[18] and RAPEX is given in Annex III.

10.NOTIFICATIONS UNDER ARTICLE 11 OF THE GPSD

10.1 Scope of these notifications

The procedure in Article 11 of the GPSD covers the exchange of information between the Member States and the Commission for consumer products (as described in chapter 2.1) that do not present a serious risk to the health and safety of consumers (taking into account the criteria on serious risk outlined in chapter 3).

Measures that Member States adopt, such as those described in chapter 2.3, which restrict the placing on the market of products that do not pose a serious risk, have to be notified to the Commission specifying the reasons for adopting them.

The notifying Member State should inform the Commission of any amendment to the measure taken and of the final decision taken on the product in question.

If the Member State considers that the effects of the risk do not, or cannot, go beyond its territory, it should notify the measures concerned insofar as they involve information likely to be of interest to other Member States as defined in chapter 2.5.

10.2 Contents of the notifications

The notifying Member State has to include in the Notification Form (Annex I):

- a detailed description and photograph of the product in order to facilitate its identification by the enforcement authorities;

- the results of the risk assessment carried out by the authority that justify the measure adopted;

[17] http://europa.eu.int/comm/consumers/cons_safe/prod_safe/gpsd/revisedGPSD_en.htm
[18] OJ L 187, 16/07/1988 p. 1

- the scope, nature, duration and follow-up of the measure taken in order to avoid the risk;

- information enabling the product's distribution channels and origin to be identified, and other information relating to its traceability.

If all the information is not available, this should be indicated and justified together with a timetable for providing the missing information.

10.3 Processing and deadlines for circulation of Article 11 notifications

National contact points are required to notify the Commission of the measures and actions taken as soon as possible and in any case not later than 15 days after the competent authorities have taken the decision restricting the marketing or use of products by reason of a risk.

This deadline is irrespective of any appeal procedure entered into by the producer or distributor and of official publication requirements.

The Commission will assess, on the basis of the information contained in the notification, whether it complies with Community law and with the guidelines. If necessary it will contact the notifying country to obtain additional information.

The Commission will circulate the notification to the other Member States within 15 days of its reception unless it concludes that the measure does not comply with the requirements. In this case the Commission will inform the Member State which initiated the action, explaining the reasons for its conclusion.

The Member State which initiated the action may resubmit the notification taking into account the comments from the Commission.

Under this procedure the other Member States receiving a new Article 11 notification are not required to inform the Commission about the follow-up given to the notification.

10.4 Practical arrangements for the transmission of Article 11 notifications

Contact points and the Commission will use the Internet site https://reis.cec.eu.int/reis for the transmission of Article 11 notifications. The standard form for Article 11 notifications and the User's Guide for the Internet application are available on this site.

If there are technical problems with this site, contact points may send notifications by e-mail (mail box: Sanco-Reis@cec.eu.int) or by fax if (and only if) e-mail transmission is not possible (+32.2.296.43.23).

(Annex I)

NOTIFICATION FORM

☐ **in application of Article 11 of Directive 2001/95/EC**

☐ **in application of Article 12 of Directive 2001/95/EC**

☐ **requiring emergency action from Member States**

GENERAL INFORMATION

01. Notifying country and contact person:

02. Date of notification:

PRODUCT

03. Category of products and Customs code:

04. Product name, brand, price and country of origin:

05. Type/Number of model/Bar Code/Batch code:

06. Description/photograph (format .jpg) of the product and its packaging:

07. Standards or regulations applicable:

08. Proof of conformity:

PRODUCER

09. Name, address and contact information for the manufacturer or its representative:

10. Name, address and contact information of the exporter/importer:

DISTRIBUTOR and RETAILER

11. Name, address and contact information for the distributors or their representatives:

12. Supplier (shop, supermarket, by mail, Internet) and countries of destination:

DANGER

13. Type of risk :

14. Summary of the results of tests/analyses and conclusions:

15. Description of accidents which have occurred:

MEASURES ADOPTED

16. Voluntary measures (scope, nature and duration):

17. Compulsory measures (scope, nature and duration):

OTHER INFORMATION

18. Additional information:

(Annex II)

REACTION TO NOTIFICATION in application of Article 12 of Directive 2001/95/EC

01. **Reacting country and contact person:**

02. **Date of reaction:**

03. **Notification number, notifying country and product name**:

04. **Product found:** yes/no

05. **Assessment of the risk:**

06. **Voluntary measures** (scope, nature, duration and justification):

07. **Compulsory measures** (scope, nature, duration and justification):

08. **Duration:**

09. **Other information:**

(Annex III)

NOTIFICATION FORM FOR TOYS

Please tick the appropriate box below:

[ ] Notification under Article 7 of Directive 88/378/EEC of 3 May 1988 on Safety of Toys – Safeguard clause	Use ***Parts 1*** and ***2*** of the form To be sent via the Permanent Representation to the EU to the Secretary General of the Commission with electronic copy to Entr-Textile-Leather-Toys@cec.eu.int
[ ] Notification under Article 12 of Directive 2001/95/EC on General Product Safety and under Article 7 of Directive 88/378/EEC on Safety of Toys	Use ***Parts 1*** and ***2*** of the form To be sent via https://reis.cec.eu.int/reis and to ENTR-Textile-Leather-Toys@cec.eu.int As the notification is a safeguard clause it must also be sent via the Permanent Representation to the Secretary-General of the Commission.

PART 1

SAFEGUARD CLAUSE UNDER ARTICLE 7 OF DIRECTIVE 88/378/EEC ON TOY SAFETY

Please tick the appropriate box below, and state the reasons for:

	Non-compliance is a result of:	Reasons
	[ ] Failure to meet the essential requirements referred to in Article 3, if the toy does not meet the standards (Article 7(1)(a))	
	[ ] Incorrect application of the standards (Article 7(1)(b))	
	[ ] Shortcomings in the standards (Article 7(1)(c))	
ADDITIONAL INFORMATION ANNEXED		
	Copy of the test reports, certificates, examinations, etc.	
	Copy of the national measure	

PART 2

☐ in application of Article 12 of Directive 2001/95/EC

☐ requiring emergency action from Member States

GENERAL INFORMATION

01. Notifying country and contact person:

02. Date of notification:

PRODUCT

03. Category of products and Customs code:

04. Product name, brand, price and country of origin:

05. Type/Number of model/Bar Code/Batch code:

06. Description/photograph (format .jpg) of the product and its packaging:

07. Standards or regulations applicable:

08. Proof of conformity:

PRODUCER

09. Name, address and contact information for the manufacturer or its representative:

10. Name, address and contact information of the exporter/importer:

DISTRIBUTOR and RETAILER

11. Name, address and contact information for the distributors or their representatives:

12. Supplier (shop, supermarket, by mail, Internet) and countries of destination:

DANGER

13. Type of risk:

14. Summary of the results of tests/analyses and conclusions:

15. Description of accidents which have occurred:

MEASURES ADOPTED

16. Compulsory measures (scope, nature and duration):

OTHER INFORMATION

17. Additional information:

(Annex IV)

DEADLINES for NATIONAL CONTACT POINTS

ACTION	DEADLINE (see chapter 5)
Send notifications relating to emergency situations to the Commission	ASAP or maximum three days
Notify the Commission of decisions and actions taken: - by the authorities in cases of serious risk; - as agreed between authorities and producers and distributors.	ASAP or maximum 10 days
Notify the Commission of voluntary measures by producers and distributors	ASAP or maximum 10 days
Send the Commission information on serious risks liable to be exchanged under RAPEX	ASAP or maximum 10 days
Inform the Commission of decisions and actions taken by the authorities in case of products not presenting a serious risk	ASAP or maximum 15 days
Confirm or modify information already provided before the decision on the measure was taken	ASAP or maximum 45 days
Update the Commission on any modification or lifting of the notified measure or action	ASAP or maximum five days
React to a notification requiring emergency action from Member States	ASAP or maximum 20 days
React to a notification of decisions and actions taken by the authorities, of measures and actions agreed between authorities and producers and distributors, of voluntary measures by producers and distributors	ASAP or maximum 45 days
React to notifications related to products manufactured or first marketed in its territory	ASAP or maximum 15 days

(Annex V)

DEADLINES for the COMMISSION CONTACT POINT

ACTION	**DEADLINE** (from reception of the information by the Commission)
Send notifications relating to emergency situations to national contact points	ASAP or maximum three days
Notify national contact points of decisions and actions taken by the authorities, of measures and actions agreed between authorities and producers and distributors, of voluntary measures by producers and distributors	ASAP or maximum five days
Send information on serious risks liable to be exchanged under RAPEX to the national contact points	ASAP or maximum five days
Send the national contact points notifications presented under Article 11 of the GPSD	ASAP or maximum 15 days
Send reactions to notifications requiring emergency follow-up by the national contact points	ASAP or maximum three days
Send reactions to notifications of decisions and actions taken by the authorities, of measures and actions agreed between authorities and producers and distributors, of voluntary measures by producers and distributors	ASAP or maximum five days
Send a reminder to national contact points that have not reacted to a notification	45 days after the original notification was sent

DECISION No 3/2004
OF THE JOINT COMMITTEE
of 29 April 2004
on the amendments to the Appendices to Annex 9 to the Agreement between the European Community and the Swiss Confederation on trade in agricultural products

(2004/419/EC)

THE JOINT COMMITTEE ON AGRICULTURE,

Having regard to the Agreement between the European Community and the Swiss Confederation on trade in agricultural products, and in particular Article 11 thereof,

Whereas:

(1) This Agreement entered into force on 1 June 2002.

(2) The purpose of Annex 9 is to foster trade in organically produced agricultural products and foodstuffs from the Community and Switzerland.

(3) Under Article 8(2) of Annex 9, the Working Party is to review the Parties' internal laws and regulations and put forward proposals to the Joint Committee on Agriculture with a view to adapting and updating the relevant Appendices.

(4) Appendix 1 to Annex 9 concerns the laws and regulations applicable to the marketing of agricultural products and foodstuffs organically produced in the Community and in Switzerland,

HAS ADOPTED THIS DECISION:

Article 1

Appendix 1 is hereby replaced by the text attached to this Decision.

Article 2

This Decision shall enter into force on 1 July 2004.

Done at Brussels, 29 April 2004.

For the Joint Committee on Agriculture

The Chairman and Head of the Community Delegation

Aldo LONGO

The head of the Swiss delegation

Christian HÄBERLI

The Committee secretary

Hans-Christian BEAUMOND

APPENDIX 1 TO ANNEX 9

List of acts referred to in Article 3 relating to organically produced agricultural products and foodstuffs

Regulations applicable in the Community

– Council Regulation (EEC) No 2092/91 of 24 June 1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs (OJ L 198, 22.7.1991, p. 1), as last amended by Commission Regulation (EC) No 599/2003 of 1 April 2003 (OJ L 85, 2.4.2003, p.15)

– Commission Regulation (EEC) No 94/92 of 14 January 1992 laying down detailed rules for implementing the arrangements for imports from third countries provided for in Regulation (EEC) No 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs (OJ L 11, 17.1.1992, p. 14), as last amended by Commission Regulation (EC) No 545/2003 of 27 March 2003 (OJ L 81, 28.3.2003, p.10)

– Commission Regulation (EEC) No 207/93 of 29 January 1993 defining the content of Annex VI to Regulation (EEC) No 2092/91 of 24 June 1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs and laying down detailed rules for implementing the provisions of Article 5(4) thereof (OJ L 25, 2.2.1993, p. 5), as last amended by Commission Regulation (EC) No 2020/2000 of 25 September 2000 (OJ L 241, 26.9.2000, p. 39)

– Commission Regulation (EC) No 1788/2001 of 7 September 2001 laying down detailed rules for implementing the provisions concerning the certificate of inspection for imports from third countries under Article 11 of Council Regulation (EEC) No 2092/91 of 24 June 1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs (OJ L 243, 13.9.2001, p. 3), as last amended by Regulation (EC) No 1918/2002 of 25 October 2002 (OJ L 289, 26.10.2002, p. 15)

– Commission Regulation (EC) No 223/2003 of 5 February 2003 on labelling requirements related to the organic production method for feedingstuffs, compound feedingstuffs and feed materials and amending Council Regulation (EEC) No 2092/91 (OJ L 31, 6.2.2003, p. 3))

Regulations applicable in Switzerland

– Ordinance of 22 September 1997 on organic farming and the labelling of organically produced products and foodstuffs (Ordinance on organic farming), as last amended on 26 November 2003 (RO 2003 5347)

– Ordinance of the Département Fédéral de l'Economie of 22 September 1997 on organic farming, as last amended on 26 November 2003 (RO 2003 5357).

Exclusion from the equivalence arrangements

– Swiss products based on ingredients produced under the arrangements for conversion to organic farming.

– Swiss goat products, where the animals are covered by the derogation provided for in Article 39d of Ordinance 910.18 on organic farming and the labelling of organically produced products and foodstuffs.

APPENDIX 2 TO ANNEX 9

Implementing rules

The labelling rules of the importing Party shall apply to labelling related to the organic production method for feedingstuffs.