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.