

COMMISSION REGULATION (EC) No 2007/2006**of 22 December 2006****implementing Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards the importation and transit of certain intermediate products derived from Category 3 material intended for technical uses in medical devices, in vitro diagnostics and laboratory reagents and amending that Regulation****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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

Whereas:

- (1) Regulation (EC) No 1774/2002 provides that certain animal by-products may be imported into the Community for the production of technical products provided that they comply with that Regulation.
- (2) Annex VIII to Regulation (EC) No 1774/2002 sets out the requirements for the placing on the market of certain technical products including starting materials to be used for or in the production of technical products which may include medical devices, in vitro diagnostics and laboratory reagents.
- (3) However, certain Member States, trading partners and operators have expressed concerns over the importation of certain products sourced from Category 3 material intended for the production of medical devices, in vitro diagnostics and laboratory reagents ('the intermediate products'). It is therefore necessary to clarify the importation requirements and to lay down specific conditions for those intermediate products.
- (4) Although the intermediate products concerned may have been subjected to preliminary processing, the way in which they are transported to the Community does not make it possible to differentiate them from other types of animal by-products intended for other technical uses, except by taking into account their intended destination and uses. The monitoring of their intended destination

and uses under other Community legislation should be sufficient to ensure that they are not diverted into the food and feed chains at a later stage, provided that risk-appropriate channelling, recording and control measures are put in place.

- (5) The placing on the market of the intermediate products concerned should therefore be channelled in accordance with 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 ⁽²⁾, and subjected to specific identification and control measures, in order to reduce the risk of diversion into the food and feed chains and other unintended uses.
- (6) Annex VIII to Regulation (EC) No 1774/2002 sets out the requirements for the placing on the market of technical products. A comprehensive review and clarification of that Annex is to be undertaken once the transitional regime provided for in that Regulation has expired. It is therefore, appropriate to lay down in the meantime the rules required for the importation of intermediate products intended for technical uses in medical devices, in vitro diagnostics and laboratory reagents in a specific regulation complementing the rules already laid down in that Annex.
- (7) Until a full review and clarification has been undertaken, it is necessary to clarify the scope of Chapters IV and XI of Annex VIII to Regulation (EC) No 1774/2002 to take into account this specific Regulation being laid down. The rules set out in Chapter IV should concern blood used for all technical purposes and blood products other than the serum of equidae used for technical purposes other than medical devices, in vitro diagnostics or laboratory reagents. The rules set out in Chapter V should continue to concern the serum of equidae intended for any technical purposes, including medical devices, in vitro diagnostics or laboratory reagents, and thus such rules do not need to be amended. The rules set out in Chapter XI should concern the importation of other non-processed animal by-products, which are not covered by this Regulation, imported for any purposes, including medical devices, in vitro diagnostics or laboratory reagents.

⁽¹⁾ OJ L 273, 10.10.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 208/2006 (OJ L 36, 8.2.2006, p. 25-31).

⁽²⁾ OJ L 24, 30.1.1998, p. 9. Directive as last amended by Regulation (EC) No 882/2004 of the European Parliament and of the Council (OJ L 165, 30.4.2004, p. 1).

- (8) As a consequence of such clarification, some amendments need to be made to certain model health certificates laid down in Annex X to Regulation (EC) No 1774/2002.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Scope

This Regulation shall apply to the importation and transit through the Community of an 'intermediate product', as defined in Article 2 of this Regulation.

Article 2

Definition

An 'intermediate product' means a product derived from Category 3 material intended for the manufacture of medical devices, in vitro diagnostics or laboratory reagents, and whose design, transformation and manufacturing stages have been sufficiently completed in order to be regarded as processed products and to qualify the material for that purpose, except for the fact that it requires some further handling or transformation such as mixing, coating, assembling, packaging or labelling to make it suitable for placing on the market or putting into service in accordance with the Community legislation applicable to the final products concerned.

Article 3

Importation

Member States shall authorise imports of the intermediate products that comply with the following conditions:

- (a) they come from a third country listed as member of the World Organisation for Animal Health (OIE) in the OIE Bulletin;
- (b) they come from a plant registered or approved by the competent authority of a third country referred to in point (a) of this Article in accordance with the conditions set out in Annex I to this Regulation;
- (c) they are derived exclusively from Category 3 material;
- (d) each consignment must be accompanied by a commercial document indicating:
- (i) the country of origin,

(ii) the name of the establishment of production; and

(iii) that the outer packaging of intermediate products is labelled 'FOR MEDICAL DEVICES/IN VITRO DIAGNOSTICS/LABORATORY REAGENTS ONLY'.

The commercial document must be in at least one of the official languages of the EU Member State in which the inspection at the border inspection post shall be carried out and of the EU Member State of destination. These Member States may allow other languages, if necessary, accompanied by an official translation.

(e) they are accompanied by a declaration of the importer in accordance with the model declaration set out in Annex II to this Regulation. The declaration must be in at least one of the official languages of the EU Member State in which the inspection at the border inspection post shall be carried out and of the EU Member State of destination. These Member States may allow other languages, if necessary, accompanied by an official translation.

Article 4

Checks, transport and labelling

1. The intermediate products imported into the Community shall be checked at the border inspection post of first entry in accordance with Article 4 of Directive 97/78/EC and transported directly from the border inspection post of entry into the Community either:

- (a) to a technical plant approved in accordance with Article 18 of Regulation (EC) No 1774/2002, where the intermediate products shall be further mixed, used for coating, assembled, packaged or labelled before they are placed on the market or put into services in accordance with the Community legislation applicable to the final product; or
- (b) to a Category 3 intermediate plant or storage plant approved in accordance with Article 10(3) or with Article 11 of Regulation (EC) No 1774/2002.

2. Intermediate products in transit through the Community shall be transported in accordance with Article 11 of Directive 97/78/EC.

3. The official veterinarian at the border inspection post concerned shall inform the authority in charge of the plant at the place of destination of the consignment via the TRACES system.

4. The outer packaging of intermediate products shall be labelled: 'FOR MEDICAL DEVICES/IN VITRO DIAGNOSTICS/LABORATORY REAGENTS ONLY'.

*Article 5***Use and dispatch**

The operator or owner of the plant of destination or his representative shall use and/or dispatch the intermediate products exclusively for the technical purposes specified in the approval of the plant, as referred to in point (a) of Article 4(1).

*Article 6***Records on use and dispatch**

The operator or owner of the plant of destination or his representative shall keep records in accordance with Article 9(1) of Regulation (EC) No 1774/2002 and shall provide the competent authority on request with the necessary details of purchases, sales, uses, stocks and disposals of surplus of the intermediate products for the purposes of checking compliance with this Regulation.

*Article 7***Control**

1. The competent authority shall ensure, in accordance with Directive 97/78/EC, that the consignments of intermediate products are sent from the EU Member State in which the inspection at the border inspection post shall be carried out to the plant of destination, as referred to in Article 4(1) of this Regulation, or in the case of transit, to the post of exit.

2. The competent authority shall carry out documentary checks at regular intervals for the purpose of reconciliation of the quantities of intermediate products imported on the one hand, and stocked, used, dispatched or disposed of on the other, in order to check compliance with this Regulation.

3. For consignments of intermediate products in transit, the competent authorities responsible for the border inspection posts of entry and of exit respectively shall cooperate as necessary to ensure that effective checks are carried out and to ensure the traceability of such consignments.

*Article 8***Amendment to Annexes VIII and X of Regulation (EC) No 1774/2002**

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

*Article 9***Entry into force**

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

It shall apply from 1 January 2007.

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

Done at Brussels, 22 December 2006.

For the Commission

Markos KYPRIANOU

Member of the Commission

ANNEX I

Conditions for the registration or approval of the plant of origin in accordance with point (b) of Article 3

1. The operator or owner of the plant or his representative shall:
 - (a) ensure that the plant has adequate facilities for the transformation of Category 3 material, to ensure the completion of the design, transformation and manufacturing stages referred to in Article 2;
 - (b) establish and implement methods of monitoring and checking the critical control points on the basis of the process used;
 - (c) keep a record of the information obtained pursuant to (b) for a period of at least two years for submission to the competent authority;
 - (d) inform the competent authority if any available information reveals the existence of a serious animal health or public health hazard.
 2. The competent authority of the third country shall at regular intervals carry out inspections of and supervise the plants registered or approved in accordance with this Regulation.
 - (a) The frequency of inspections and supervision shall depend on the size of the plant, the type of products manufactured, risk assessment and guarantees offered, based on the principles of the system of HACCP.
 - (b) If the inspection carried out by the competent authority reveals that the provisions of this Regulation are not being complied with, the competent authority shall take appropriate action.
 - (c) The competent authority shall draw up a list of plants approved in accordance with this Regulation within its territory. It shall assign an official number to each plant, which identifies the plant with respect to the nature of its activities. The list and subsequent amendments shall be submitted to the EU Member State in which the inspection at the border inspection post shall be carried out and to the Member State of destination.
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ANNEX II

Model declaration for the importation from third countries and for the transit through the European Community of intermediate products to be used for medical devices, in vitro diagnostics and laboratory reagents

COUNTRY				Model declaration				
Part I: Details of dispatched consignment	I.1. Consignor <input type="checkbox"/> Name Address Tel. No				I.2. Document reference number		I.2.a	
					I.3. Central Competent Authority			
					I.4. Local Competent Authority			
	I.5. Consignee Name Address Postal code Tel. No				I.6. Person responsible for the consignment in EU Name Address Postal code Tel. No			
	I.7. Country of origin		ISO code	I.8. Region of origin		Code	I.9. Country of destination	
							I.10. Region of destination	
	I.11. Place of origin Name Address				I.12. Place of destination Custom warehouse <input type="checkbox"/> Name Address Postal code			
	I.13. Place of loading				I.14. Date of departure			
	I.15. Means of transport Aeroplane <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/> Road vehicle <input type="checkbox"/> Other <input type="checkbox"/> Identification: Documentary references:				I.16. Entry BIP in EU			
				I.17.				
I.18. Description of commodity				I.19. Commodity code (HS code)				
				I.20. Quantity				
I.21. Temperature of product Ambient <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/>				I.22. Number of packages				
I.23. Identification of container/Seal number				I.24. Type of packaging				
I.25. Commodities certified for: Technical use <input type="checkbox"/> Other <input type="checkbox"/>								
I.26. For transit to 3rd Country vis-à-vis EU <input type="checkbox"/> 3rd country ISO code				I.27. For import or admission into EU <input type="checkbox"/>				
I.28. Identification of the commodities Species Approval number of Net weight Batch number (Scientific name) establishments Manufacturing plant								

MODEL DECLARATION FOR INTERMEDIATE PRODUCTS TO BE USED FOR MEDICAL DEVICES, IN VITRO DIAGNOSTICS AND LABORATORY REAGENTS, FOR DISPATCH TO OR FOR TRANSIT THROUGH THE EUROPEAN COMMUNITY

I, the undersigned, declare that the intermediate products referred to above are intended to be imported by me into the Community and that:

1. they are derived from Category 3 material referred to in Article 6 of Regulation (EC) No 1774/2002 ⁽¹⁾ and are intended for the manufacture of medical devices, in vitro diagnostics or laboratory reagents;
2. their design, transformation and manufacturing stages have been sufficiently completed in order to be regarded as processed products and to qualify them for that purpose, except for the fact that they require some further handling or transformation such as mixing, coating, assembling, packaging or labelling to make them suitable for placing on the market or putting into service in accordance with the Community legislation applicable to the final products concerned;
3. their outer packaging is labelled 'FOR MEDICAL DEVICES/IN VITRO DIAGNOSTICS/LABORATORY REAGENTS ONLY'; and
4. they will not be diverted at any stage within the Community for any use in food, feed material, organic fertilisers or soil improvers and will be conveyed directly to the following establishment:

Name: Address:

The importer

Name: Address:

Done at:
(place) (date)

Signature:

⁽¹⁾ List of Category 3 materials (referred to in Regulation (EC) No 1774/2002 (OJ L 273, 10.10.2002, p. 1):

- (a) parts of slaughtered animals, which are fit for human consumption in accordance with Community legislation, but are not intended for human consumption for commercial reasons,
- (b) parts of slaughtered animals, which are rejected as unfit for human consumption but are not affected by any signs of diseases communicable to humans or animals and derive from carcasses that are fit for human consumption in accordance with Community legislation,
- (c) hides and skins, hooves and horns, pig bristles and feathers originating from animals that were slaughtered in a slaughterhouse, after undergoing ante-mortem inspection, and were fit, as a result of such inspection, for slaughter for human consumption in accordance with Community legislation,
- (d) blood obtained from animals other than ruminants that are slaughtered in a slaughterhouse, after undergoing ante-mortem inspection, and were fit, as a result of such inspection, for slaughter for human consumption in accordance with Community legislation,
- (e) animal by-products derived from the production of products intended for human consumption, including degreased bones and greaves,
- (f) former foodstuffs of animal origin, or former foodstuffs containing products of animal origin, other than catering waste, which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects which do not present any risk to humans or animals,
- (g) milk originating from animals which do not show any clinical signs of any disease communicable through that product to humans or animals,
- (h) fish or other sea animals, except sea mammals, caught in the open sea for the purposes of fishmeal production,
- (i) by-products from fish from plants manufacturing fish products for human consumption,
- (j) shells, hatchery by-products and cracked egg by-products originating from animals which did not show clinical signs of any disease communicable through that product to humans or animals.

ANNEX III

Annexes VIII and X to Regulation (EC) No 1774/2002 are amended as follows:

1. Annex VIII is amended as follows:

(a) the heading of Chapter IV is replaced by the following:

'Requirements for blood and blood products used for technical purposes, excluding the serum of equidae and excluding intermediate products as referred to in Article 1 of Commission Regulation (EC) No 2007/2006'

(b) the heading of Chapter XI is replaced by the following:

'Requirements for animal by-products for the manufacture of feed including petfood, and of technical products, excluding intermediate products as referred to in Article 1 of Commission Regulation (EC) No 2007/2006'

2. Annex X is amended as follows:

(a) In Chapter 4(C), the heading of the Health certificate: 'For blood products to be used for technical purposes, including pharmaceuticals, in vitro diagnostics and laboratory reagents, but excluding serum of equidae, intended for dispatch to the European Community', is replaced by the following heading:

'For blood products, excluding serum of equidae and intermediate products as referred to in Article 1 of Commission Regulation (EC) No 2007/2006, to be used for technical purposes, intended for dispatch to the European Community.'

(b) In Chapter 8, the heading of the Health certificates: 'For animal by-products for the manufacture of technical products (including pharmaceutical products) ⁽¹⁾, intended for dispatch to the European Community', is replaced by the following heading:

'For animal by-products ⁽¹⁾ to be used for technical purposes, intended for dispatch to the European Community'

⁽¹⁾ Excluding raw blood, raw milk, hides and skins of ungulates and pig bristles (see relevant specific certificates for the import of these products) as well as wool, hair, feathers or parts of feathers. This certificate is not to be used for intermediate products as defined by Regulation (EC) No 2007/2006 (see relevant conditions and model declaration for import of these products).