

Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (repealed)

### [<sup>X1</sup>CHAPTER III

#### PROCEDURES CONCERNING IMPORTS

##### [<sup>F1</sup>Article 10

To ensure the uniform application of the principles and conditions laid down in Article 11 of Regulation (EC) No 178/2002 and Title VI, Chapter II, of Regulation (EC) No 882/2004 the procedures laid down in this Chapter shall apply.]

#### Textual Amendments

- F1** Substituted by [Regulation \(EC\) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.](#)

##### Article 11

#### **Lists of third countries and parts of third countries from which imports of specified products of animal origin are permitted**

1 Products of animal origin shall be imported only from a third country or a part of third country that appears on a list drawn up and updated in accordance with the procedure referred to in Article 19(2).

[<sup>F12</sup> A third country shall appear on such lists only if a Community control in that country has taken place and demonstrates that the competent authority provides appropriate guarantees as specified in Article 48(3) of Regulation (EC) No 882/2004. However, a third country may appear on such lists without a Community control having taken place if:

- a the risk determined in accordance with Article 46(3)(a) of Regulation (EC) No 882/2004 does not warrant it;
- and
- b it is determined, when deciding to add a particular third country to a list in accordance with paragraph 1, that other information indicates that the competent authority provides the necessary guarantees.]

3 Lists drawn up in accordance with this Article may be combined with other lists drawn up for public and animal health purposes.

[<sup>F14</sup> When drawing up or updating lists, particular account shall be taken of the criteria listed in Articles 46 and 48(3) of Regulation (EC) No 882/2004. Regard shall also be had to:]

- a the legislation of the third country on:
  - (i) products of animal origin,

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*Changes to legislation: There are outstanding changes not yet made to Regulation (EC) No 854/2004 of the European Parliament and of the Council (repealed). Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)*

- (ii) the use of veterinary medicinal products, including rules on their prohibition or authorisation, their distribution, their placing on the market and the rules covering administration and inspection;
  - and
  - (iii) the preparation and use of feedingstuffs, including the procedures for using additives and the preparation and use of medicated feedingstuffs, as well as the hygiene quality of the raw materials used for preparing feedingstuffs and of the final product;
- [<sup>F2</sup>b the organisation of the third countries' competent authorities, their powers and independence, the supervision to which they are subject and the authority that they have effectively to enforce the applicable legislation;
- c the training of staff in the performance of official controls;
  - d the resources, including diagnostic facilities available to competent authorities;
  - e the existence and operation of documented control procedures and control systems based on priorities;
  - f where applicable, the situation regarding animal health and procedures for notifying the Commission and relevant international bodies of outbreaks of animal diseases;
  - g the extent and operation of official controls on imports of animals and products of animal origin;
  - h the assurances which the third country can give regarding compliance with, or equivalence to, Community requirements;]
  - i the hygiene conditions of production, manufacture, handling, storage and dispatch actually applied to products of animal origin destined for the Community;
  - j any experience of marketing of the product from the third country and the results of any import controls carried out;
  - k the results of Community controls carried out in the third country, in particular the results of the assessment of the competent authorities, and the action that competent authorities have taken in the light of any recommendations addressed to them following a Community control;
  - l the existence, implementation and communication of an approved zoonoses control programme;
- and
- m the existence, implementation and communication of an approved residue control programme.
- 5 The Commission shall arrange for up-to-date versions of all lists drawn up or updated in accordance with this Article to be available to the public.

#### Textual Amendments

- F1** Substituted by Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.
- F2** Deleted by Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

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## Article 12

### **List of establishments from which imports of specified products of animal origin are permitted**

1 Products of animal origin may be imported into the Community only if they have been dispatched from, and obtained or prepared in, establishments that appear on lists drawn up and updated in accordance with this Article, except:

a when, on a case-by-case basis, it is decided, in accordance with the procedure referred to in Article 19(2), that the guarantees that a specified third country provides in respect of imports of specified products of animal origin are such that the procedure provided for in this Article is unnecessary to ensure compliance with the requirements of paragraph 2;

and

b in the cases specified in Annex V.

In addition, fresh meat, minced meat, meat preparations, meat products and mechanically separated meat (MSM) may be imported into the Community only if they have been manufactured from meat obtained in slaughterhouses and cutting plants appearing on lists drawn up and updated in accordance with this Article or in approved Community establishments.

2 An establishment may be placed on such a list only if the competent authority of the third country of origin guarantees that:

a that establishment, together with any establishments handling raw material of animal origin used in the manufacture of the products of animal origin concerned, complies with relevant Community requirements, in particular those of Regulation (EC) No 853/2004, or with requirements that were determined to be equivalent to such requirements when deciding to add that third country to the relevant list in accordance with Article 11;

b an official inspection service in that third country supervises the establishments and makes available to the Commission, where necessary, all relevant information on establishments furnishing raw materials;

and

c it has real powers to stop the establishments from exporting to the Community in the event that the establishments fail to meet the requirements referred to under (a).

3 The competent authorities of third countries appearing on lists drawn up and updated in accordance with Article 11 shall guarantee that lists of the establishments referred to in paragraph 1 are drawn up, kept up-to-date and communicated to the Commission.

4

a The Commission shall provide the contact points that Member States have designated for this purpose with regular notifications concerning new or updated lists that it has received from the competent authorities of third countries concerned in accordance with paragraph 3.

b If no Member State objects to the new or updated list within 20 working days of the Commission's notification, imports shall be authorised from establishments appearing on the list 10 working days after the day on which the Commission makes it available to the public.

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- c The Commission shall, whenever at least one Member State makes written comments, or whenever it considers that the modification of a list is necessary in the light of relevant information such as Community inspection reports or a notification under the rapid alert system, inform all Member States and include the point on agenda of the next meeting of the relevant section of the Standing Committee on the Food Chain and Animal Health for decision, where appropriate, in accordance with the procedure referred to in Article 19(2).
- 5 The Commission shall arrange for up-to-date versions of all lists to be available to the public.

### *Article 13*

#### **Live bivalve molluscs, echinoderms, tunicates and marine gastropods**

- 1 Notwithstanding Article 12(1)(b), live bivalve molluscs, echinoderms, tunicates and marine gastropods shall come from production areas in third countries that appear on lists drawn up and updated in accordance with Article 12.
- 2 The requirement of paragraph 1 shall not apply to pectinidae harvested outside classified production areas. However, official controls with respect to pectinidae shall take place in accordance with Annex II, Chapter III.
- 3
- a Before the lists referred to in paragraph 1 are drawn up, particular account shall be taken of the guarantees that the competent authority of the third country can give concerning compliance with the requirements of this Regulation on the classification and control of production zones.
- b An on-the-spot Community inspection visit shall take place before such lists are drawn up unless:
- (i) the risk determined in accordance with Article 18(18) does not warrant it;  
and
- (ii) it is determined, when deciding to add a particular production area to a list in accordance with paragraph 1, that other information indicates that the competent authority provides the necessary guarantees.
- 4 The Commission shall arrange for up-to-date versions of all lists drawn up or updated in accordance with this Article to be available to the public.

### *Article 14*

#### **Documents**

- 1 A document meeting the requirements set out in Annex VI shall accompany consignments of products of animal origin when they are imported into the Community.
- 2 The document shall certify that the products satisfy:
- a the requirements laid down for such products according to Regulation (EC) No 852/2004 and Regulation (EC) No 853/2004 or provisions that are equivalent to those requirements;

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and

[<sup>F1</sup>b any specific import conditions established in accordance with Article 48 of Regulation (EC) No 882/2004.]

3 Documents may include details required in accordance with other Community legislation on public and animal health matters.

4 Exemptions from paragraph 1 may be granted in accordance with the procedure referred to in Article 19(2) when it is possible to obtain the guarantees referred to in paragraph 2 of this Article in another manner.

#### Textual Amendments

- F1** Substituted by [Regulation \(EC\) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.](#)

### Article 15

#### Special provisions for fishery products

1 The procedures laid down in this Chapter do not apply to fresh fishery products landed in the Community directly from a fishing vessel flying the flag of a third country.

Official controls with respect to such fishery products shall take place in accordance with Annex III.

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- a Fishery products imported from a factory or freezer vessel flying the flag of a third country shall come from vessels that appear on a list drawn up and updated in accordance with the procedure set out in Article 12(4).
- b However, by way of exemption from Article 12(2)(b), a vessel may also be included on such lists:
- (i) on the basis of a joint communication from the competent authority of the third country the flag of which the vessel is flying and from the competent authority of another third country to which the former competent authority has delegated responsibility for the inspection of the vessel concerned, on condition that:
- that third country appears on the list of third countries, drawn up in accordance with Article 11, from which imports of fisheries products are permitted,
  - all fishery products from the vessel concerned that are destined for placing on the market in the Community are landed directly in that third country,
  - the competent authority of that third country has inspected the vessel and has declared that it complies with Community requirements,
- and
- the competent authority of that third country has declared that it will regularly inspect the vessel to ensure that it continues to comply with Community requirements;

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or

- (ii) on the basis of a joint communication from the competent authority of the third country the flag of which the vessel is flying and from the competent authority of a Member State, to which the former competent authority has delegated responsibility for the inspection of the vessel concerned, on condition that:
- all fishery products from the vessel concerned that are destined for placing on the market in the Community are landed directly in that Member State,
  - the competent authority of that Member State has inspected the vessel and has declared that it complies with Community requirements,
- and
- the competent authority of that Member State has declared that it will regularly inspect the vessel to ensure that it continues to comply with Community requirements.
- c The Commission shall arrange for up-to-date versions of all lists drawn up or updated in accordance with this Article to be available to the public.

3 When fishery products are imported directly from a fishing or freezer vessel, a document signed by the captain may replace the document required under Article 14.

4 Detailed rules for the implementation of this Article may be laid down in accordance with the procedure referred to in Article 19(2).]

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**Editorial Information**

- X1** Substituted by [Corrigendum to Regulation \(EC\) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption \(Official Journal of the European Union L 139 of 30 April 2004\)](#).

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