

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

Article 1

Scope

This Directive lays down the general animal health rules governing all stages of the production, processing and distribution within the Community and the introduction from third countries of products of animal origin and products obtained therefrom intended for human consumption.

These rules do not affect the provisions laid down in Directives 89/662/EEC and 97/78/EC and the Directives listed in Annex I.

Article 2

Definitions

For the purposes of this Directive, the definitions in 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⁽¹⁾ and Directive 97/78/EC shall apply as necessary. The following definitions shall also apply:

1. 'all stages of the production, processing and distribution' means any stage from and including the primary production of a food of animal origin, up to and including its storage, transport, sale or supply to the final consumer;
2. 'introduction' means the bringing of goods into one of the territories listed in Annex I to Directive 97/78/EC for the purpose of placing them under the customs procedures referred to in Article 4(16)(a) to (f) of Council Regulation (EC) No 2913/92 of 12 October 1992 establishing the Community Customs Code⁽²⁾;
3. 'official veterinarian' means a veterinarian qualified to act in that capacity appointed by the competent authority;
4. 'products of animal origin' means products obtained from animals and products obtained therefrom, for human consumption, including live animals where they are prepared for such use.

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CHAPTER I

ANIMAL HEALTH REQUIREMENTS APPLICABLE TO ALL STAGES OF THE PRODUCTION, PROCESSING AND DISTRIBUTION OF PRODUCTS OF ANIMAL ORIGIN WITHIN THE COMMUNITY

Article 3

General animal health requirements

- 1 Member States shall take measures to ensure that at all stages of the production, processing and distribution of products of animal origin within the Community, food business operators do not cause the spread of diseases transmissible to animals, in accordance with the following provisions.
- 2 Products of animal origin must be obtained from animals which fulfil the animal health conditions laid down by the relevant Community legislation.
- 3 Products of animal origin shall be obtained from animals:
 - a which do not come from a holding, establishment, territory or part of a territory subject to animal health restrictions applicable to the animals and products concerned, under the rules set out in Annex I;
 - b which, in the case of meat and meat products, were not slaughtered in an establishment in which animals infected or suspected of being infected with one of the diseases covered by the rules referred to in (a), or carcasses or parts thereof of such animals, were present during the slaughtering or production process, unless such suspicion has been ruled out;
 - c which, in the case of aquaculture animals and products, comply with Directive 91/67/EEC⁽⁹⁾.

Article 4

Derogations

- 1 Notwithstanding Article 3 and subject to compliance with the disease control measures referred to in Annex I, Member States may authorise the production, processing and distribution of products of animal origin which come from a territory or part of a territory subject to animal health restrictions but which do not come from a holding which is infected or suspected of being infected, provided that:
 - (i) before being subjected to the treatment referred to below, the products have been obtained, handled, transported and stored separately, or at different times, from products fulfilling all the animal health conditions, and the conditions for transport out of the territory subject to animal health restrictions have been approved by the competent authority;
 - (ii) the products which are to undergo treatment are clearly identified;
 - (iii) the products undergo treatment enabling the animal health problem concerned to be eliminated, and
 - (iv) the treatment is applied at an establishment approved for that purpose by the Member State in which the animal health problem occurred.

The provisions of the first subparagraph shall be applied in accordance with Annexes II and III(1) hereto, or with detailed rules to be adopted in accordance with the procedure referred to in Article 12(2).

2 The production, processing and distribution of aquaculture products not complying with the conditions laid down in Article 3 shall be authorised, subject to the conditions laid down in Directive 91/67/EEC and, where necessary, in accordance with further conditions to be adopted in accordance with the procedure referred to in Article 12(2).

3 Furthermore, where the health situation so permits, derogations from Article 3 may be granted in certain situations, in accordance with the procedure referred to in Article 12(2). In such cases, particular account shall be taken of:

- a the specific characteristics of the disease in the species concerned, and
- b any tests or measures to which the animals must be subjected.

Where such derogations are granted, steps must be taken to ensure that the degree of protection from animal disease will in no way be impaired. Any measures needed to ensure the protection of animal health in the Community shall therefore be adopted in accordance with the same procedure.

Article 5

Veterinary certificates

1 Member States shall ensure that products of animal origin intended for human consumption are subjected to veterinary certification where:

- provisions adopted for animal health reasons under Article 9 of Directive 89/662/EEC require products of animal origin from a Member State to be accompanied by a health certificate, or
- a derogation has been granted under Article 4(3).

2 Under the procedure referred to in Article 12(2), detailed implementing rules, and in particular a model for such certificates, may be drawn up taking into account the general principles set out in Annex IV. Certificates may include details required in accordance with other Community public and animal health legislation.

Article 6

Official veterinary controls

1 Pending adoption of Regulations of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin and rules for controls applicable to foodstuffs and animal feed, Member States shall ensure that official animal health controls are carried out by their competent authorities to ensure compliance with this Directive, its implementing rules and any safeguard measures relating to products of animal origin adopted pursuant to this Directive. As a general rule, inspections must be unannounced and checks carried out in accordance with the provisions of Directive 89/662/EEC.

2 Pending adoption of Regulations of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin and rules for controls applicable to foodstuffs and animal feed, where infringements of animal health rules are identified, Member States shall take the necessary measures to remedy the situation in accordance with the provisions of Directive 89/662/EEC.

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3 Experts from the Commission may carry out on-the-spot checks, including audits, in cooperation with the competent authorities of the Member States, insofar as is necessary for the uniform application of this Directive. The Member States in whose territory checks are made shall provide the experts with all the assistance necessary for carrying out their duties. The Commission shall inform the competent authority of the results of the checks made.

If a serious animal health risk is identified during a Commission audit or inspection, the Member State concerned shall immediately take all measures necessary to safeguard animal health. If such measures are not taken, or if they are considered to be insufficient, the Commission shall, in accordance with the procedure referred to in Article 12(2), take the measures necessary to safeguard animal health and inform the Member States thereof.

4 The rules for the application of this Article, and in particular those governing the procedure for cooperation with the national authorities, shall be adopted in accordance with the procedure referred to in Article 12(2).

CHAPTER II

IMPORTS FROM THIRD COUNTRIES

Article 7

General provisions

Member States shall take measures to ensure that products of animal origin intended for human consumption are introduced from third countries only if they comply with the requirements of Chapter I applicable to all stages of the production, processing and distribution of such products in the Community or if they offer equivalent animal health guarantees.

Article 8

Compliance with Community rules

In order to ensure compliance with the general obligation laid down in Article 7, the following shall be established in accordance with the procedure referred to in Article 12(2):

1. Lists of the third countries or regions of third countries from which imports of specified products of animal origin are permitted. A third country shall appear on such lists only if a Community audit of that country has taken place and demonstrates that the competent veterinary authority provides appropriate guarantees as regards compliance with Community legislation.

When drawing up or updating those lists, particular account shall be taken of:

- (a) the legislation of the third country;
- (b) the organisation of the competent veterinary authority and its inspection services in the third country, the powers of these services, the supervision to which they are subject, and the means at their disposal, including staff capacity, to apply their legislation effectively;

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- (c) the actual animal health requirements applying to the production, manufacture, handling, storage and dispatch of products of animal origin intended for the Community;
 - (d) the assurances which the competent veterinary authority of the third country can give regarding compliance or equivalence with the relevant animal health conditions;
 - (e) any experience of marketing the product from the third country and the results of any import controls carried out;
 - (f) the results of Community inspections and/or audits carried out in the third country, in particular the results of the assessment of the competent authorities or, where the Commission so requests, the report submitted by the competent authorities of the third country on the inspections which they have carried out;
 - (g) the health status of livestock, other domestic animals and wildlife in the third country, with particular regard to exotic animal diseases and any aspects of the general health situation in the country which might pose a risk to public or animal health in the Community;
 - (h) the regularity, speed and accuracy with which the third country supplies information on the existence of infectious or contagious animal diseases in its territory, particularly the notifiable diseases listed by the World Organisation for Animal Health (OIE) or, in the case of diseases of aquaculture animals, the notifiable diseases listed in the Aquatic Animal Health Code of the OIE;
 - (i) the rules on the prevention and control of infectious or contagious animal diseases in force in the third country and their implementation, including rules on imports from other countries.
2. 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. Lists drawn up in accordance with this Article may be combined with other lists drawn up for animal and public health purposes and may also include models of health certificates.
3. Rules of origin for products of animal origin and the animals from which such products are obtained shall be established in accordance with the procedure referred to in Article 12(2).
4. Special import conditions for each third country or group of third countries, having regard to the animal health situation of the third country or countries concerned shall be established in accordance with the procedure referred to in Article 12(2).
5. Where necessary:
 - the detailed rules for the application of this Article,
 - criteria for classifying third countries and regions thereof with regard to animal diseases, and
 - specific rules concerning types of introduction or particular products, such as the introduction of products by travellers or the introduction of commercial samples,may be established in accordance with the procedure referred to in Article 12(2).

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Article 9

Documents

- 1 A veterinary certificate meeting the requirements set out in Annex IV shall be presented with consignments of products of animal origin upon their entry into the Community.
- 2 The veterinary certificate shall certify that the products satisfy:
 - a the requirements laid down for such products under this Directive and under the Community legislation laying down animal health requirements or provisions that are equivalent to those requirements; and
 - b any special import conditions established in accordance with the procedure referred to in Article 12(2).
- 3 Documents may include details required under other provisions of Community public and animal health legislation.
- 4 In accordance with the procedure referred to in Article 12(2):
 - a provision may be made for the use of electronic documents,
 - b model documents may be drawn up,
 - c rules and certification for transit may be established.

Article 10

Community inspections and audits

- 1 Community inspections and/or audits at all stages covered by this Directive may be carried out in third countries by experts from the Commission in order to verify conformity with or equivalence to Community animal health rules. The experts from the Commission may be accompanied by experts from the Member States authorised by the Commission to carry out these inspections and/or audits.
- 2 The inspections and/or audits in third countries referred to in paragraph 1 shall be carried out on behalf of the Community, and the Commission shall meet the costs incurred.
- 3 The procedure for carrying out the inspections and/or audits in third countries referred to in paragraph 1 may be established or modified in accordance with the procedure referred to in Article 12(2).
- 4 If a serious animal health risk is identified during a Community inspection or audit, the Commission shall immediately take the measures necessary to safeguard animal health, in accordance with Article 22 of Directive 97/78/EC, and inform the Member States thereof.

CHAPTER III

FINAL PROVISIONS

Article 11

Update of technical annexes

The annexes hereto may be amended in accordance with the procedure referred to in Article 12(2) in order to take account in particular of:

- (i) scientific opinions and scientific knowledge, particularly concerning new risk assessments;
- (ii) technical developments; and
- (iii) the setting of safety targets for animal health.

Article 12

Committee procedure

1 The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health set up by Article 58 of Regulation (EC) No 178/2002.

2 Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3 The Committee shall adopt its rules of procedure.

Article 13

Transitional provisions

1 As from the date referred to in Article 14(1), the animal health rules laid down by the Directives listed in Annex V shall no longer apply.

2 Implementing rules adopted on the basis of such provisions shall remain in force until they are replaced by rules having the same effect adopted on the basis of this Directive.

3 Transitional measures may be laid down in accordance with the procedure referred to in Article 12(2).

Article 14

1 Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive before 1 January 2005. They shall forthwith inform the Commission thereof.

When Member States adopt these provisions, they shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official

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publication. The procedure for making such reference shall be adopted by the Member States.

2 Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field governed by this Directive.

Article 15

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

Article 16

This Directive is addressed to the Member States.

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- (1) [OJ L 31, 1.2.2002, p. 1.](#)
- (2) [OJ L 302, 19.10.1992, p. 1.](#) Regulation as last amended by Regulation (EC) No 2700/2000 ([OJ L 311, 12.12.2000, p. 17.](#))
- (3) [OJ L 46, 19.2.1991, p. 1.](#)