

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

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 37 thereof,

Having regard to the proposal from the Commission ⁽¹⁾,

Having regard to the opinion of the European Parliament ⁽²⁾,

Having regard to the opinion of the European Economic and Social Committee ⁽³⁾,

Whereas:

(1) In the context of the single market, specific animal health rules have been laid down to govern intra-Community trade in the production, processing, distribution and introduction from third countries of products of animal origin for human consumption included in Annex I to the Treaty.

(2) Those rules have allowed the removal of obstacles to trade in the products concerned, thereby contributing to the creation of the internal market whilst ensuring a high level of animal health protection.

(3) The aim of those rules is to prevent the introduction or spread of animal diseases resulting from the placing on the market of products of animal origin. They also contain common provisions concerning in particular the restrictions applicable to the placing on the market of products coming from a holding or area infected by epizootic diseases and the obligation to subject products coming from restricted areas to treatment to destroy the disease agent.

(4) Those common provisions should be harmonised in order to remove possible inconsistencies introduced when the specific animal health rules were adopted. Such harmonisation will also ensure uniform implementation of animal health rules throughout the Community and introduce greater transparency in the structure of Community legislation.

(5) Veterinary checks on products of animal origin intended for trade must be carried out in accordance with Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market ⁽⁴⁾. Directive

89/662/EEC contains safeguard measures that may be implemented in the event of a serious hazard to animal health.

(6) Products imported from third countries must not present an animal health hazard for Community livestock.

(7) To that end, procedures should be introduced to prevent the introduction of epizootic diseases. Such procedures include a regular evaluation of the animal health situation in the third countries concerned.

(8) Procedures must also be introduced for establishing general or specific rules or criteria to be applied to imports of products of animal origin.

(9) Provisions concerning the importation of meat of domestic ungulates and meat products prepared from or with such meat are already contained in Council Directive 72/462/EEC of 12 December 1972 on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat from third countries ⁽⁵⁾.

(10) The procedures applicable to the importation of meat and meat products can be used as a model for the importation of other products of animal origin.

(11) Veterinary checks on products of animal origin imported into the Community from third countries must be carried out 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 ⁽⁶⁾; Directive 97/78/EC contains safeguard measures that may be implemented in case of a serious hazard to animal health.

(12) Account must be taken of the guidelines laid down by the World Organisation for Animal Health (OIE) when adopting rules for international trade.

(13) Community audits and inspections must be organised in order to ensure the uniform application of the animal health provisions.

(14) The products covered by this Directive are listed in Annex I to the Treaty.

⁽¹⁾ OJ C 365 E, 19.12.2000.

⁽²⁾ Opinion of the European Parliament delivered on 15 May 2002.

⁽³⁾ Opinion of the Economic and Social Committee delivered on 28 March 2001.

⁽⁴⁾ OJ L 395, 30.12.1989, p. 13. Directive as last amended by Directive 92/118/EEC (OJ L 62, 15.3.1993, p. 49).

⁽⁵⁾ OJ L 302, 31.12.1972, p. 28. Directive as last amended by Regulation (EC) No 1452/2001 (OJ L 198, 21.7.2001, p. 11).

⁽⁶⁾ OJ L 24, 30.1.1998, p. 9.

- (15) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ⁽¹⁾,

CHAPTER I

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

HAS ADOPTED THIS DIRECTIVE:

Article 3

General animal health requirements

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 ⁽²⁾ 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 ⁽³⁾;
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.

⁽¹⁾ OJ L 184, 17.7.1999, p. 23.

⁽²⁾ OJ L 31, 1.2.2002, p. 1.

⁽³⁾ 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).

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 ⁽⁴⁾.

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;

⁽⁴⁾ OJ L 46, 19.2.1991, p. 1.

- (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.

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;
- (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).

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 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.

Done at Brussels, 16 December 2002.

For the Council

The President

M. FISCHER BOEL

ANNEX I

Diseases of relevance to trade in products of animal origin and for which control measures have been introduced under Community legislation

DISEASE	DIRECTIVE
Classical swine fever	Council Directive 2001/89/EC on Community measures for the control of classical swine fever
African swine fever	Council Directive 2002/60/EC laying down specific provisions for the control of African swine fever
Foot-and-mouth disease	Council Directive 85/511/EEC introducing Community measures for the control of foot-and-mouth disease
Avian influenza	Council Directive 92/40/EEC introducing Community measures for the control of avian influenza
Newcastle disease	Council Directive 92/66/EEC introducing Community measures for the control of Newcastle disease
Rinderpest Sheep and goat plague Swine vesicular disease	Council Directive 92/119/EEC introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease
Aquaculture diseases	Council Directive 91/67/EEC concerning the animal health conditions governing the placing on the market of aquaculture animals and products Council Directive 93/53/EEC introducing minimum Community measures for the control of certain fish diseases Council Directive 95/70/EC introducing minimum Community measures for the control of certain diseases affecting bivalve molluscs

ANNEX II

Special identification mark for meat from a territory or a part of a territory

- The health mark for fresh meat must bear a diagonal cross consisting of two straight lines intersecting at the centre of the stamp and enabling the information thereon to remain legible.
- The mark mentioned in paragraph 1 may also be applied using a single oval stamp, 6,5 cm wide by 4,5 cm high; the following information must appear on the mark in perfectly legible characters:
 - on the upper part, the name or ISO code of the Member State in capitals: AT, BE, DE, DK, ES, FI, FR, GR, IE, IT, LU, NL, PT, SE and UK,
 - in the centre, the veterinary approval number of the slaughterhouse,
 - on the lower part, one of the following sets of initials CE, EC, EF, EG, EK or EY,
 - two straight lines crossing at the centre of the stamp in such a way that the information is not obscured.

The letters must be at least 0,8 cm high and the figures at least 1 cm high.

The stamp must also carry information whereby the veterinarian who inspected the meat can be identified.

The mark must be applied under the direct supervision of the official veterinarian controlling the implementation of the animal health requirements.

ANNEX III

1. Treatments to eliminate certain animal health risks linked to meat and milk

MEAT Treatment (*)	Disease							
	Foot-and-mouth disease	Classical swine fever	Swine vesicular disease	African swine fever	Rinderpest	Newcastle disease	Avian influenza	Sheep and goat plague
(a) Heat treatment in a hermetically sealed container with an F_0 value of 3,00 or more (**)	+	+	+	+	+	+	+	+
(b) Heat treatment at a minimum temperature of 70 °C, which must be reached throughout the meat	+	+	+	0	+	+	+	+
(c) Heat treatment at a minimum temperature of 80 °C, which must be reached throughout the meat	+	+	+	+	+	+	+	+
(d) Heat treatment in a hermetically sealed container to at least 60 °C for a minimum of 4 hours, during which time the core temperature must be at least 70 °C for 30 minutes	+	+	+	+	+	-	-	+
(e) Natural fermentation and maturation of not less than nine months for boneless meat, resulting in the following characteristics: Aw value of not more than 0,93 or a pH value of not more than 6,0	+	+	+	+	+	0	0	0
(f) Same treatment as in (e) above although meat may contain bone (*)	+	+	+	0	0	0	0	0
(g) Salami: treatment in accordance with criteria to be defined by the Article 12(2) procedure following an opinion by the relevant Scientific Committee	+	+	+	0	+	0	0	0
(h) Hams and loins: treatment involving natural fermentation and maturation during at least 190 days for hams and 140 days for loins	0	0	0	+	0	0	0	0
(i) Heat treatment ensuring a core temperature of at least 65 °C is reached for the time necessary to achieve a pasteurisation value (pv) equal to or more than 40	+	0	0	0	0	0	0	+

MEAT Treatment (*)	Disease							
	Foot-and-mouth disease	Classical swine fever	Swine vesicular disease	African swine fever	Rinderpest	Newcastle disease	Avian influenza	Sheep and goat plague
MILK and milk products (including cream) for human consumption								
(a) Ultra-high temperature (UHT) (UHT = minimum treatment at 132 °C for at least 1 second)	+	0	0	0	0	0	0	0
(b) If the milk has a pH of less than 7,0, simple high temperature - short-time pasteurisation (HTST)	+	0	0	0	0	0	0	0
(c) If the milk has a pH of 7,0 or more, double HTST	+	0	0	0	0	0	0	0

+: Effectiveness recognised.

0: Effectiveness not recognised.

(*) All the necessary measures must be taken to avoid cross contamination.

(**) F_0 is the calculated killing effect on bacterial spores. An F_0 value of 3,00 means that the coldest point in the product has been heated sufficiently to achieve the same killing effect as 121 °C (250 °F) in three minutes with instantaneous heating and chilling.

ANNEX IV

General principles of certification

1. The representative of the competent authority of dispatch issuing a certificate to accompany a consignment of products of animal origin must sign the certificate and ensure that it bears an official stamp. This requirement applies to each sheet of the certificate if it consists of more than one.
 2. Certificates must be drawn up in the official language or languages of the Member State of destination and those of the Member State in which the border inspection takes place, or be accompanied by a certified translation into that language or those languages. However, a Member State may consent to the use of an official Community language other than its own.
 3. The original version of the certificate must accompany consignments on entry into the Community.
 4. Certificates must consist of:
 - (a) a single sheet of paper; or
 - (b) two or more pages that are part of a single and indivisible sheet of paper; or
 - (c) a sequence of pages numbered so as to indicate that it is a particular page in a finite sequence (for example, 'page 2 of 4 pages').
 5. Certificates must bear a unique identifying number. Where the certificate consists of a sequence of pages, each page must indicate this number.
 6. The certificate must be issued before the consignment to which it relates leaves the control of the competent authority of the country of dispatch.
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ANNEX V

1. Council Directive 72/461/EEC of 12 December 1972 on health problems affecting intra-Community trade in fresh meat ⁽¹⁾, as last amended by the Act of Accession of Austria, Finland and Sweden.
 2. Council Directive 80/215/EEC of 22 January 1980 on animal health problems affecting intra-Community trade in meat products ⁽²⁾, as last amended by the Act of Accession of Austria, Finland and Sweden.
 3. Council Directive 91/494/EEC of 26 June 1991 on animal health conditions governing intra-Community trade in and imports from third countries of fresh poultrymeat ⁽³⁾, as last amended by Directive 93/121/EC.
 4. Council Directive 91/495/EEC of 27 November 1990 concerning public health and animal health problems affecting the production and placing on the market of rabbit meat and farmed game meat ⁽⁴⁾, as last amended by the Act of Accession of Austria, Finland and Sweden.
 5. Council Directive 92/45/EEC of 16 June 1992 on public health and animal health problems relating to the killing of wild game and the placing on the market of wild-game meat ⁽⁵⁾, as last amended by Directive 97/79/EC.
 6. Council Directive 92/46/EEC of 16 June 1992 laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products ⁽⁶⁾.
 7. Council Directive 94/65/EC of 14 December 1994 laying down the requirements for the production and placing on the market of minced meat and meat preparations ⁽⁷⁾.
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⁽¹⁾ OJ L 302, 31.12.1972, p. 24.

⁽²⁾ OJ L 47, 21.2.1980, p. 4.

⁽³⁾ OJ L 268, 24.9.1991, p. 35.

⁽⁴⁾ OJ L 268, 24.9.1991, p. 41.

⁽⁵⁾ OJ L 268, 14.9.1992, p. 35.

⁽⁶⁾ OJ L 268, 14.9.1992, p. 1.

⁽⁷⁾ OJ L 368, 31.12.1994, p. 10.