Proposal for a Council Regulation laying down the animal-health rules governing the production, placing on the market and importation of products of animal origin intended for human consumption  

(2000) C 365 E/05

(Text with EEA relevance)


(Submitted by the Commission on 14 July 2000)

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,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas:

(1) In the context of the common agricultural policy, specific animal health rules have been laid down to govern intra-Community trade in and imports from third countries of products of animal origin included in Annex I to the Treaty.

(2) These rules have ensured 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) These specific rules are contained in the following Directives:


— 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 (7), as last amended by the Act of Accession of Austria, Finland and Sweden,


(4) The aim of these Directives is to prevent the spread of animal diseases resulting from the placing on the market of products of animal origin.

(5) These Directives contain common provisions such as those restricting the placing on the market of products coming from a holding or area infected by epizootic diseases and those requiring products from restricted areas to undergo treatment to destroy the disease agent.

These common provisions can be harmonised, thereby removing possible inconsistencies introduced when the specific animal health rules were adopted. Such harmonisation will also ensure uniform implementation of the animal health rules throughout the Community and greater transparency in the structure of Community legislation.


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

To that end, procedures must be introduced to prevent the introduction of epizootic diseases. Such procedures include an evaluation of the animal health situation in the third countries concerned.

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

Rules 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, ovine and caprine animals and swine, fresh meat or meat products from third countries (2), as last amended by Directive 97/79/EC.

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.

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 (3); Directive 97/78/EEC contains safeguard measures that may be implemented in case of a serious hazard to animal health.

Account must be taken of the rules laid down by the ‘Office International des Epizooties’ (OIE) when adopting rules for international trade.

Provision must be made for the organisation of Community audits and inspections in order to ensure the uniform application of the animal health provisions.

The products covered by this Regulation are listed in Annex I of the Treaty.

Since the measures necessary for the implementation of this Regulation are measures of general scope within the meaning of Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (4), they should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision.

HAS ADOPTED THIS REGULATION:

Article 1

This Regulation lays down the animal-health rules governing the placing on the market of and imports from third countries of products of animal origin.

Article 2

For the purposes of this Regulation, the definitions laid down in the Directives referred to in Annex I and, where applicable, in Council Regulation . . ./. . . on the hygiene of foodstuffs, shall apply.

CHAPTER I

ANIMAL HEALTH REQUIREMENTS FOR THE PRODUCTION AND MARKETING OF COMMUNITY PRODUCTS

Article 3

The marketing of products of animal origin must not result in the spreading of diseases transferable to animals. To that effect, the following rules shall be complied with:

1. Products of animal origin shall be obtained from animals which fulfil the animal health conditions laid down by the relevant Community legislation.

2. Products of animal origin shall be obtained from animals:

(a) which come from a holding, territory or part of a territory or, in the case of aquaculture products, from a farm, zone or part of a zone, not subject to animal health restrictions applicable to the animals and products concerned, and in particular restrictions under the rules referred to in Annex I or other disease-control measures imposed by Community legislation,

(b) which 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 at (a) above, or carcases of such animals, were present at the time of slaughter.

3. Notwithstanding part 2 and subject to compliance with the disease-control measures referred to in Annex I:

(a) the marketing of products of animal origin coming from a territory or part of a territory subject to animal health restrictions but which are not coming from a holding which is infected or suspected of being infected shall be permitted provided, as the case may be, that:

— the products, before being submitted to the treatment referred to hereunder, are obtained, handled, transported and stored separately from or at different times than products fulfilling all the animal-health conditions,

— the products have undergone a treatment sufficient to eliminate the animal-health problem concerned,

— the treatment is applied at an establishment approved for that purpose by the Member State where the animal-health problem occurred,

— the products which must be submitted to a treatment are properly identified.

This paragraph shall be applied in accordance with Annexes II and III(1) and (2) hereto, or with detailed rules to be adopted in accordance with the procedure referred to in Article 11;

(b) the marketing of aquaculture products not complying with the conditions laid down in paragraph 2 shall be permitted subject to the conditions laid down in Annex III(3) hereto and where necessary in accordance with further conditions to be laid down in accordance with the procedure referred to in Article 11.

4. Derogations from paragraph 2 may be granted in specific situations, in accordance with the procedure referred to in Article 11. In such cases, particular account shall be taken of:

(a) any measure or test to be carried out on the animals;

(b) the specific characteristics of the disease in the species concerned.

Where such derogations are granted, any measures needed to ensure the protection of animal health in the Community shall be adopted in accordance with the same procedure.

5. 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

— products must be accompanied by a certificate on account of the animal health situation in a Member State or part of a Member State,

the specimen for such certificates must conform to the model established in accordance with the procedure referred to in Article 11. Certificates must be drawn up at least in the language of the certifying official and the language of the place of destination. The products must be accompanied by the original certificate, which must consist of a single sheet of paper and be made out for a single consignee.

Article 4

Official controls

Official controls shall be carried out by the competent authorities of the Member States to ensure compliance with this Regulation, its implementing rules and any safeguard measures applied to products of animal origin, pursuant hereto.

Detailed rules on these controls, their results and the decisions to be taken on the basis of those results shall be adopted in accordance with the procedure referred to in Article 11.

Article 5

Follow-up of official controls and right of appeal

Where infringements of the animal-health rules are found, action shall be taken to remedy the situation.

Where the legal or natural person or persons involved in the infraction fail to remedy the situation within the time fixed by the competent authority, or if a serious animal-health risk is found, restrictions shall be placed on the production and marketing of the products concerned. Such restrictions may entail a ban on the production and marketing of products of animal origin and the withdrawal and, if necessary, destruction of products already placed on the market.

Infringements of this Regulation, its implementing rules or any safeguard health measures applied to products of animal origin, as well as any failure to cooperate with the competent authority shall result in the imposition of the appropriate criminal and/or administrative penalties by the competent national authorities.

In taking corrective action or imposing criminal and/or administrative penalties, Member States shall take account of the findings of Community checks.
Rights of appeal against decisions taken by the competent authorities as provided for by the national legislation in force in the Member States shall not be affected by this Regulation.

Article 6
Community audits and inspections

1. Experts from the Commission may, in cooperation with the competent authorities of the Member States, make audits and/or inspections at all stages in the production and marketing of products of animal origin as well as on the organisation and functioning of the competent authorities in the Member States, in order to ensure the uniform application of this Regulation, its implementing rules and any safeguard measures pursuant hereto. Commission experts may be accompanied by the competent authority of the Member State and any expert appointed by the Commission for the purpose of an audit and/or inspection.

2. The Commission shall communicate its general programme of audits and/or inspections to the Member States on a regular basis and shall inform them of the results.

3. The procedure for inspections and/or audits referred to in paragraph 1 may be determined or amended in accordance with the procedure referred to in Article 11.

4. To enable audits and/or inspections to be carried out efficiently, the Member State in whose territory an audit and/or inspection is undertaken shall give all necessary assistance and provide all documentation requested by the Commission experts for the purpose of the audit.

5. The Commission shall ensure that the experts referred to in paragraph 1 received adequate training in food hygiene and safety, auditing techniques and where relevant to their duties the principles of the hazard analysis and critical control points system, in order for them to undertake their duties competently.

6. Member States shall ensure that the experts referred to in paragraph 1 have access to all premises or parts of premises and information relevant to the execution of their duties under this Regulation.

If during a Commission audit or inspection a serious risk to animal health is identified, 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 take the measures necessary to safeguard animal health and inform the Member States thereof.

CHAPTER II
IMPORTS FROM THIRD COUNTRIES

Article 7
General provisions

The provisions applicable to the importation of products of animal origin from third countries shall comply with or be equivalent to those applicable to the production and marketing of Community products.

Article 8
Compliance with Community rules

In order to ensure the respect of the general obligation laid down in Article 7, the following shall be established in accordance with the procedure referred to in Article 11:

1. Lists of the third countries or parts of third countries from which imports of specified products of animal origin are permitted.

When establishing these lists, particular account shall be taken of:

— the legislation of the third country,
— the organisation of the competent authority and its inspection services in the third country, the powers of these services, the supervision to which they are subject, and their authority to monitor effectively the application of their legislation,
— the actual animal health conditions applied to the production, manufacture, handling, storage and dispatch of products of animal origin intended for the Community,
— the assurances the third country can give regarding compliance with the relevant animal health conditions,
— experience of marketing the product from the third country and the results of import checks carried out,
— the results of Community inspections in the third country,
— the health status of the livestock, other domestic animals and wildlife in the third country, having 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,
— the regularity and speed with which the third country supplies information about the existence of infectious or contagious animal diseases in its territory, in particular the diseases mentioned in Lists A and B of the International Office of Epizootic Diseases (OIE) or, in the case of diseases of aquaculture animals, the notifiable diseases as listed in the Aquatic Animal Health Code of the OIE,
— 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.

The list drawn up under this paragraph may be combined with other lists drawn up for public health purposes.

2. Special import conditions for each third country or group of third countries, having regard to the health situation of the third country or countries concerned. Such conditions shall include details of the health certificate to accompany consignments bound for the Community. Such certificates must:

— be drawn up in the language or languages of the Member State of destination and those of the Member State in which the border inspection takes place; the Member State of inspection or destination may consent to the use of a Community language other than its own,

— accompany the products in the original,

— consist of a single sheet of paper,

— be made out for a single consignee.

The certificate must be issued on the day the products are loaded for dispatch to the country of destination and be signed by a representative of the competent authority. It may be combined with the certificate to be provided for under the public health rules.

3. Where necessary,

— the detailed rules for the application of this Article, and

— criteria for classifying third countries and parts thereof with regard to animal diseases.

Article 9

Community inspections and audits

1. Audits and/or inspections at all stages covered by this Regulation may be carried out by experts from the Commission in third countries in order to verify compliance or equivalence with Community animal health rules. Commission experts may be accompanied by any other expert appointed by the Commission for the purposes of the audit and/or inspection.

2. The audits and/or inspections in third countries referred to in paragraph 1 shall be carried out on behalf of the Commission and the latter shall meet the costs incurred.

3. The procedure for the audits and/or inspections in third countries referred to in paragraph 1 may be determined or amended in accordance with the procedure referred to in Article 11.

4. If during a Community audit and/or inspection a serious risk to animal health is identified, the Commission shall immediately take the measures necessary to safeguard animal health and shall immediately inform the Member States thereof.

5. The Commission shall ensure that its experts and other experts referred to in paragraph 1 have received adequate training in animal health and auditing techniques in order for them to undertake their duties competently.

CHAPTER III

FINAL PROVISIONS

Article 10

The Annexes hereto may be amended or supplemented in accordance with the procedure referred to in Article 11. This procedure shall in particular be followed to lay down the criteria for classifying third countries and parts thereof with regard to particular diseases.

Article 11

Standing Veterinary Committee procedure

1. The Commission shall be assisted by the Standing Veterinary Committee, instituted by Council Decision 68/361/EEC (1).

2. Where reference is made to this paragraph, the Regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7(3) and Article 8 thereof.

3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be 3 months.

Article 12

Member States shall notify the Commission of any provisions they adopt specifically to implement this Regulation and all the legal instruments used and measures taken for its implementation and enforcement.

Article 13

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Communities.

It shall apply from 1 January 2004.

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

**ANNEX I**

**DISEASES OF CONCERN IN TRADE WITH PRODUCTS OF ANIMAL ORIGIN**

**I. Diseases for which control measures have been introduced under Community legislation**

<table>
<thead>
<tr>
<th>Disease</th>
<th>Directive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molluscs diseases</td>
<td>Council Directive 95/70/EC introducing minimum Community measures for the control of certain diseases affecting bivalve molluscs</td>
</tr>
</tbody>
</table>

**II. Measures relating to African swine fever**

Pending the adoption of specific control measures for African swine fever, Directive 80/217/EEC shall apply, *mutatis mutandis*, in the event of outbreaks of African swine fever. Notwithstanding that Directive, decisions to lift the restrictions applied under this point shall be taken in accordance with the procedure referred to in Article 11.

1. Meat

A Member State in whose territory African swine fever has been recorded shall impose an immediate ban on movements of fresh pigmeat from the part of its territory in which the outbreak occurred to the rest of the Community.

For the purpose of defining parts of the territory as referred to above, particular account shall be taken of:

- the methods used to combat the disease, in particular the elimination of pigs from holdings which are infected, contaminated or suspected of infection or contamination,
- the surface area of the parts of the territory concerned and their administrative and geographical boundaries,
- the incidence of the disease and its tendency to spread,
- the measures taken to prevent the disease from spreading,
- the measures taken to restrict and control the movement of pigs both inside and outside the part of the territory concerned.

2. Meat products

A Member State in whose territory African swine fever has been recorded shall impose an immediate ban on movements of meat products from the part of its territory in which the outbreak occurred to the rest of the Community. However, the derogation provided for in Article 3(3) shall apply to meat products that have undergone one of the treatments referred to in Annex III points 1(a) and (c).
ANNEX II

Special identification mark for fresh meat coming from a territory or a part of a territory not fulfilling all relevant animal health requirements

Fresh meat obtained from animals coming from a holding situated in an area under animal health restrictions for one of the diseases referred to in Annex I and to be submitted to a treatment to eliminate the animal health problem concerned must be identified as follows:

1. The health mark for fresh meat must be covered by a cross consisting of two straight lines crossing at right angles with the point of intersection in the centre of the stamp and the information thereon remaining legible.

2. The mark may also be made with a single stamp; the following information must appear on the mark in perfectly legible characters:

   — on the upper part, the name of the exporting country in capitals,
   — in the centre, the veterinary approval number of the slaughterhouse,
   — on the lower part, one of the following abbreviations: CE — EF — EK — EC — EY — EG,
   — two straight lines crossing the stamp, intersecting at right angles at the centre of the stamp in such a way that the information is not obscured,
   — information whereby the veterinarian who inspected the meat may be identified.

The mark must be applied by or under the responsibility of the official veterinarian responsible for controlling the implementation of the animal health requirements.
1. Treatments in order to eliminate animal health risks from meat

<table>
<thead>
<tr>
<th>Treatment (*)</th>
<th>Foot-and-mouth disease</th>
<th>Classical swine fever</th>
<th>Swine vesicular disease</th>
<th>African swine fever</th>
<th>Rinderpest</th>
<th>Newcastle disease</th>
<th>Avian influenza</th>
<th>Peste des petits ruminants</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) Heat treatment in a hermetically sealed container with a F₀ value of 3,00 or more</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>(b) Heat treatment at a minimum temperature of 70 °C, which must be reached throughout the meat</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>—</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>(c) Heat treatment at a minimum temperature of 80 °C which must be reached throughout the meat</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>(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</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>(e) Natural fermentation and maturation of not less than 9 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</td>
<td>+</td>
<td>+</td>
<td>—</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>(f) As (e) above but meat may contain bone. All the necessary measures must be taken to avoid cross contamination</td>
<td>+</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>(g) Salami processing in accordance with criteria to be laid down in accordance with the Standing Veterinary Committee procedure, following opinion of the relevant Scientific Committee</td>
<td>+</td>
<td>+</td>
<td>—</td>
<td>+</td>
<td>+</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>(h) Ham and loins which have undergone natural fermentation and maturation, of at least 190 days for hams and 140 days for loins</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>+</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>(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</td>
<td>+</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>+</td>
</tr>
</tbody>
</table>

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

2. Treatment to eliminate animal health risks from milk

Milk of species susceptible to foot-and-mouth disease and milk products manufactured entirely or partly with such milk, may not come from a surveillance area as provided for by Directive 85/811/EEC unless the milk or milk product has undergone one of the following treatments, under the supervision of the competent authority:

(a) sterlisation to an F₀ value of 3 or above; or
(b) a single UHT treatment at 130 °C for 2-3 sec.;
(c) an initial heat treatment having a heating effect at least equivalent to that obtained by pasteurisation at a temperature of at least 72 °C for at least 15 seconds and sufficient to result in a negative reaction to the phosphatase test, followed by:
(i) a second heat treatment, resulting in a negative reaction to the peroxidase test, or
(ii) in the case of milk powder or a product containing milk powder, a second heat treatment having an effect at least equivalent to that obtained by the first heat treatment and sufficient to result in a negative reaction to the phosphatase test, followed by a drying procedure, or

(iii) an acidification procedure whereby the pH is reduced to below 6 and maintained at that level for at least one hour,

(iv) a second heat treatment having an effect at least equivalent to that obtained by the first heat treatment; both heat treatments shall be applied to milk with a pH above 7.0 (this treatment is not allowed for milk from a protection and surveillance zone);

(d) the initial heat treatment referred to under (c), applied to milk with a pH of less than 7.0 (this treatment is not allowed for milk from a protection and surveillance zone).

3. Treatment to reduce animal health risks in aquaculture products

(a) Aquaculture fish susceptible to infectious haematopoietic necrosis and viral haemorrhagic septicaemia originating in a zone not approved for those diseases may be introduced into an approved zone only if such fish are killed, headed and eviscerated prior to dispatch. This requirement shall be waived for fish from an approved farm in a non-approved zone.

(b) Live molluscs susceptible to bonamiosis and marteciliosis originating in a zone not approved for those diseases may be introduced into an approved zone only where they are either intended for direct human consumption or delivered to the canning industry. They shall not be relayed unless:

— they originate in an approved farm in a non-approved zone, or

— they are temporarily immersed in storage ponds or purification centres specially equipped and approved for that purpose by the competent authority, and having, in particular, a system for the treatment and disinfection of waste water.

Any detailed rules needed for the implementation of these requirements shall be adopted in accordance with the procedure referred to in Article 11.