

**L.N. 145 of 2005**

**VETERINARY SERVICES ACT  
(CAP. 437)**

**Animal Health (Production, Processing, Distribution and  
Introduction of Products for Human Consumption), Rules, 2005**

IN exercise of the powers conferred by articles 11 and 12 of the Veterinary Services Act, the Minister for Rural Affairs and the Environment, in agreement with the Minister of Health, the Elderly and Community Care, has made the following rules:-

**1.** (1) The title of these rules is the Animal Health (Production, Processing, Distribution and Introduction of Products for Human Consumption), Rules, 2005. Title, scope and applicability.

(2) The scope of these rules is to implement the provisions found under European Union Council Rule 2002/99/EC governing the production, processing, distribution and introduction of products of animal origin for human consumption.

(3) These rules shall apply without prejudice to Community or national provisions on the production, processing, distribution and introduction of products of animal origin for human consumption.

**2.** (1) For the purposes of these rules, the definitions in Rule (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 and Directive 97/78/EC shall apply as necessary. Definitions.

(2) The following definitions shall also apply:

“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;

“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 Rule (EC) No 2913/92 of 12 October 1992 establishing the Community Customs Code;

“official veterinarian” means a veterinarian qualified to act in that capacity appointed by the competent authority;

“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.

General animal  
health requirements.

**3.** (1) Malta 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 schedule I to these rules;

(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 paragraph (a) hereof, 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.

Derogations.

**4.** (1) Notwithstanding rule 3 hereof and subject to compliance with the disease control measures referred to in Schedule I, Malta 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:

(a) 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;

(b) the products which are to undergo treatment are clearly identified;

(c) the products undergo treatment enabling the animal health problem concerned to be eliminated, and

(d) the treatment is applied at an establishment approved for that purpose by the Member State in which the animal health problem occurred.

(2) The provisions of the sub-rule shall be applied in accordance with Schedules II and III(1) hereto, or with detailed rules to be adopted in accordance with the procedure referred to in Article 12(2) of Directive 2002/99/EC.

(3) The production, processing and distribution of aquaculture products not complying with the conditions laid down in rule 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) of Directive 2002/99/EC.

(4) Furthermore, where the health situation so permits, derogations from rule 3 may be granted in certain situations, in accordance with the procedure referred to in Article 12(2) of Directive 2002/99/EC. 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.

(5) 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.

**5.** (1) Malta shall ensure that products of animal origin intended for human consumption are subjected to veterinary certification where: Veterinary certificates.

(a) 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

(b) a derogation has been granted under rule 4(4).

(2) Under the procedure referred to in Article 12(2) of Directive 2002/99/EC, detailed implementing rules, and in particular a model for such certificates, may be drawn up taking into account the general principles set out in Schedule IV. Certificates may include details

required in accordance with other Community public and animal health legislation.

Official veterinary controls.

**6.** (1) Pending adoption of Rules 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, Malta shall ensure that official animal health controls are carried out by their competent authorities to ensure compliance with this rule, its implementing rules and any safeguard measures relating to products of animal origin adopted pursuant to this rule. 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 Rules 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, Malta 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 Malta, insofar as is necessary for the uniform application of this rule. Malta shall provide the experts if checks are being carried out in its territory, 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, Malta 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) of Directive 2002/99/EC, take the measures necessary to safeguard animal health and inform the Member States thereof.

General provisions applicable to imports from third countries.

**7.** (1) Malta 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 this rule applicable to all stages of the production, processing and distribution of such products in the Community or if they offer equivalent animal health guarantees.

(2) The rules for the application of this rule, 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) of Directive 2002/99/EC.

Compliance with Community rules.

**8.** (1) In order to ensure compliance with the general obligation laid down in rule 7, the following shall be established in accordance with the procedure referred to in Article 12(2) of Directive 2002/99/EC.

(2) In 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.

(3) 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.

(4) The Commission shall arrange for up-to-date versions of all lists drawn up or updated in accordance with this rule to be available to the public. Lists drawn up in accordance with this rule may be combined with other lists drawn up for animal and public health purposes and may also include models of health certificates.

(5) 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 rule 12 (2).

(6) 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) of Directive 2002/99/EC.

(7) Where necessary:

(a) the detailed rules for the application of this rule,

(b) criteria for classifying third countries and regions thereof with regard to animal diseases, and

(c) 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) of Directive 2002/99/EC.

Documents.

**9.** (1) A veterinary certificate meeting the requirements set out in Schedule 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 rule 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) of Directive 2002/99/EC.

(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) of Directive 2002/99/EC:

- (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.

**10.** (1) Community inspections and, or audits at all stages covered by this rule 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 Malta authorised by the Commission to carry out such inspections and/or audits. Community inspections.

(2) The inspections and/or audits in third countries referred to in sub-rule (1) hereof 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 sub-rule (1) may be established or modified in accordance with the procedure referred to in Article 12(2) of Directive 2002/99/EC.

(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.

**11.** (1) The Schedules hereto may be amended in accordance with the procedure referred to in Article 12(2) of Directive 2002/99/EC in order to take account in particular of: Update of technical schedules.

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

## SCHEDULE I

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



## SCHEDULE II

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

- (1) 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.
- (2) The mark mentioned in sub-rule 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:
  - (a) on the upper part, the name or ISO code of Malta in capitals:
  - (b) in the centre, the veterinary approval number of the slaughterhouse,
  - (c) on the lower part, one of the following sets of initials **KEE**,
  - (d) two straight lines crossing at the centre of the stamp in such a way that the information is not obscured.
- (3) The letters must be at least 0,8 cm high and the figures at least 1 cm high.
- (4) The stamp must also carry information whereby the veterinarian who inspected the meat can be identified.
- (5) The mark must be applied under the direct supervision of the official veterinarian controlling the implementation of the animal health requirements.

## SCHEDULE III

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

MEAT Treatment (*)	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 F0 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	+	+	+	0	+	0	0	0

defined by the Article 12(2) procedure following an opinion by the relevant Scientific Committee								
(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	+
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
<p>+: Effectiveness recognised.</p> <p>0: Effectiveness not recognised.</p> <p>(*) All the necessary measures must be taken to avoid cross contamination.</p> <p>(**) F0 is the calculated killing effect on bacterial spores. An F0 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.</p>								

## SCHEDULE 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, Malta may consent to the use of an official European Community language other than its own.
- (3) The original version of the certificate must accompany consignments on entry into the European 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.

**SCHEDULE 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).

