

L.N. 118 of 2004

**VETERINARY SERVICES ACT, 2001
(ACT NO. XXIII OF 2001)**

Requirements for the Production and Placing on the Market of Minced Meat and Meat Preparations Regulations, 2004

IN exercise of the powers conferred by articles 10 and 12 of the Veterinary Services Act, 2001, the Minister for Rural Affairs and the Environment has made the following regulations:-

Part I

Title, scope and applicability

1. (1) The title to these regulations is the Requirements for the Production and Placing on the Market of Minced Meat and Meat Preparations Regulations, 2004.

(2) The scope of these regulations is the implementation of European Union Council Directive 94/65/EC laying down the requirements for the production and placing on the market of minced meat and meat preparations.

(3) These regulations lay down rules for the production, placing on the market in the territory of Malta and importing of meat preparations and minced meat.

(4) These regulations shall not apply to meat preparations and minced meat which are produced in retail shops or in premises adjacent to sales points, with a view to sale there directly to the final consumer, such operations remaining subject to the health checks required by national rules governing supervision of the retail trade.

(5) These regulations shall not apply to mechanically recovered meat for industrial use which undergoes heat treatment in establishments approved in accordance with European Union Council Directive 77/99/EEC.

(6) The rules applicable to the production and placing on the market of minced meat intended for use as raw material for the manufacture of sausage meat intended for the subsequent production of a meat-based product shall be unaffected by these regulations.

Definitions

2. For the purposes of these regulations -

(1) The definitions contained in article 2 of European Union Council Directives 64/433/EEC, 71/118/EEC and 72/462/eec shall apply as necessary.

(2) The following definitions shall apply -

(a) “competent authority” means the central authority of a Member State or third country competent to carry out veterinary checks or any authority to which it has delegated that power. The Veterinary Services are the competent authority for Malta.

(b) “meat preparations” means meat within the meaning of article 2 of European Union Council Directives 64/433/EEC, 71/118/EEC and 92/45/EEC), and meat satisfying the requirements of articles 3, 6 and 8 of European Union Council Directive 91/495/EEC which has had foodstuffs, seasonings or additives added to it or which has undergone a treatment insufficient to modify the internal cellular structure of the meat and thus to cause the characteristics of the fresh meat to disappear;

(c) “minced meat” means meat which has been minced into fragments or passed through a spiral-screw mincer;

(d) “production plant” means any plant in which minced meat or meat preparations are produced -

- which is located in a cutting plant and satisfies the requirements of Chapter I of Schedule I to these regulations;

- which in the case of the production of meat preparations, is located in an establishment fulfilling the requirements of Chapter III of Schedule I to these regulations;

- which, if it is not located on the premises of, or in an Annex to, an establishment approved under European Union Council Directives 64/433/EEC, 71/118/EEC or 77/99/EEC, fulfils the requirements of point 2 of Chapter I or point 2 of Chapter III of Schedule I to these regulations;

(e) “seasonings” means salt intended for human consumption, mustard, spices and aromatic spice extracts, aromatic herbs and aromatic extracts thereof;

(f) “trade” means exchange with Member States;

(g) “trading partner” as in the meaning of article 2 of the Veterinary Services Act shall apply to –

- Member States of the European Union;
- Third Countries to the European Union.

Part II
Placing on the market of minced meat

Minced meat which can be traded

3. (1) Only fresh meat obtained from bovine animals, pigs, sheep or goats and presented in the form of minced meat, which meets the following requirements is traded, and -

(a) it must have been prepared from striated muscle except heart muscle which meets the requirements of -

(i) article 3 of European Union Council Directive 64/433/EEC;

or, for import minced meat -

(ii) European Union Council Directive 72/462/EEC;

and has been inspected in accordance with European Union Council Directive 90/675/EEC. In the case of fresh pig-meat, it must furthermore have been examined for trichinae in accordance with article 2 of European Union Council Directive 77/96/EEC or have undergone cold treatment as referred to in Annex IV to that Directive;

(b) it must have been prepared, in accordance with the requirements of Chapter II of Schedule I in a plant which -

(i) meets the requirements of points 1, 2 and 3 of Chapter I of Schedule I, and,

(ii) has been approved and is included on the list(s) drawn up in accordance with regulation 8 (1) ;

(c) it must have been inspected in accordance with Chapter V of Schedule I and with regulation 8;

(d) it must be marked and labelled in accordance with Chapter VI of Schedule I;

(e) it must have been wrapped, packaged and stored in accordance with the respective provisions of Chapters VII and VIII of Schedule I;

(f) it must be transported in accordance with Chapter IX of Schedule I;

(g) it must, during transport, be accompanied by -

(i) an accompanying commercial document which must -

- be drawn up by the dispatching establishment;

- bear the veterinary approval number of the approved production plant and in the case of frozen minced meat, the month and year of freezing in clear;

- for minced meat intended for Finland and Sweden, bear one of the indications provided for in the third indent of Part IV of the specimen health certificate for fresh meat referred to in article 3 (A) (1) (f) (iii) of European Union Council Directive 64/433/EEC, be kept by the consignee so that it can be produced at the request of the competent authority. Computer data must be printed out at the request of the aforesaid authority. However, at the request of the competent authority in the Member State of destination, a health certification must be provided when meat is intended for export to a third country after mincing. The cost of such certification shall be borne by the operators;

- (ii) a health certificate in accordance with Schedule III, in the case of minced meat from a production plant situated in a restricted region or area of the territory of Malta, or minced meat to be sent to a Member State, after transit through a third country in a sealed lorry.

(2) Minced meat must meet the following requirements in addition to those listed in sub-regulation (1) -

(a) the fresh meat from which it is obtained must -

- (i) where it has been frozen or deep-frozen, be obtained from fresh boned meat which has been stored for no longer than 18 months for beef and veal, 12 months for sheep-meat and six months for pig-meat, after freezing or deep-freezing, in a cold store approved in accordance with article 10 of European Union Council Directive 64/433/EEC. However, the competent authority may authorise the boning of pig-meat and sheep-meat on the spot immediately before mincing where this operation is carried out in satisfactory conditions of hygiene and quality;

- (ii) where it has been chilled, be used -

- within no more than six days after slaughter of the animals, or

- within no more than 15 days after slaughter of the animals in the case of boned, vacuum-packed beef and veal;

(b) the minced meat must have undergone cold treatment within a period of not more than one hour after portioning and wrapping, except where processes requiring the lowering of the internal temperature of the meat during production are used;

(c) the minced meat must be packaged and presented in one of the following forms -

- (i) chilled and in this case obtained from meat as described in (a);

(ii) and cooled to an internal temperature below + 2 °C in the shortest time possible. However, the addition of a limited quantity of frozen meat satisfying the conditions laid down in (a)(i) shall be authorised to accelerate the refrigeration process provided that this addition is mentioned on the label. In such cases, the period referred to above must not exceed one hour;

(iii) deep-frozen, and in this case obtained from meat as described in (a) and cooled to an internal temperature below 18°C as quickly as possible, in accordance with Maltese rules relating to quick-frozen foodstuffs for human consumption;

(d) the minced meat must not have been subjected to ionising radiation or ultraviolet treatment;

(e) the designations in Section 1 of Schedule II, possibly combined with the name of the species of animal from which the meat was obtained, may be used on packages only if the requirements set out in Section 1 of Schedule II are met for those designations.

(3) Minced meat to which not more than 1 % salt has been added shall be subject to the requirements of sub-regulation (1) and (2).

Authorisation for the production and placing on the market of minced meat

4. (1) In order to take account of particular habits of consumption and while ensuring that the health requirements of these regulations are observed, the Veterinary Services may authorise the production and placing on the market of minced meat to be sold in the territory of Malta only obtained:

a) from meat referred to in regulation 2 (2) (b);

b) from production plants which are approved or registered and have the premises referred to in Schedule I,

c) by derogation from -

i) point 4 of Chapter VI of Schedule I;

ii) regulation 3(1) (f) and (g) and regulation 3(2), except for the first, second and third indents of Schedule II, point 1.

(2) Minced meat obtained in accordance with this regulation must not bear the health mark provided for in Chapter VI of Schedule I.

(3) To make use of the provisions of sub-regulation (1) the Veterinary Services shall take into account the nature of the derogation granted in the Member States.

Part III
Placing on the market of meat preparations

Meat preparations which may be traded

5. (1) Meat preparations within the meaning of regulation 2 (2) (b) may be traded only if -

(a) they have been prepared from fresh meat, other than meat from solipeds, which -

(i) complies with article 3 of the Directives referred to in article 2 (2) (b);

(ii) in the case of imported meat, complies with European Union Council Directive 72/462/EEC or Chapter III of European Union Council Directives 71/118/EEC and 92/45/EEC and the requirements laid down in articles 3, 6 and 8 of European Union Council Directive 91/495/EEC, or Chapter 11 of Annex I to European Union Council Directive 92/118/EEC and be inspected in accordance with article 16 of the Veterinary Services Act. In the case of fresh meat from pigs, it must have been examined for trichinae in accordance with article 2 of European Union Council Directives 77/96/EEC or have undergone cold treatment in accordance with Annex IV to that Directive;

(b) they have been prepared in one of the establishments referred to in regulation 2 (2) (d) which -

(i) meets the requirements of Chapter III of Schedule I;

and

(ii) has been approved and is included on any list drawn up in accordance with regulation 8 (1).

(c) they have been obtained from meat which, if it has been deep-frozen, must be used within a maximum period after slaughter of 18 months for beef and veal, 12 months for sheep-meat and goat-meat, poultry-meat, rabbit meat and farmed game meat and six months for meat from other species:

Provided that, the competent authority may authorise boning of pig-meat and sheep-meat on the spot immediately before preparation, provided this operation is carried out in satisfactory conditions of hygiene and quality.

(d) they have been packaged and where they are to be placed on the market -

(i) chilled, they must be cooled as quickly as possible to an internal temperature below + 2°C for meat preparations obtained from minced meat, + 7°C for preparations obtained from fresh meat, + 4°C for preparations of poultry meat and + 3°C for preparations containing offal;

(ii) deep-frozen, they must be cooled to an internal temperature below 18° C as quickly as possible, in accordance with Malta rules relating to quick-frozen foodstuffs for human consumption.

(2) Meat preparations must fulfil the following requirements in addition to those laid down in sub-regulation (1) -

(a) they must have been prepared in accordance with Chapter IV of Schedule I;

(b) they must have been inspected in accordance with regulation 8 and Chapter V of Schedule I;

(c) they must be marked and labelled in accordance with Chapter VI of Schedule I;

(d) they must be wrapped and packaged in accordance with the requirements of Chapter VII of Schedule I and stored in accordance with Chapter VIII of Schedule I;

(e) they must be transported in accordance with Chapter IX of Schedule I;

(f) they must during transport be accompanied by a health certificate in accordance with Schedule V, which must be kept by the consignee for a period of not less than one year for presentation on request to the competent authority.

(3) With the exception of fresh sausages and sausage meat, meat preparations obtained from minced meat of slaughter animals may be traded only if they fulfil the requirements of regulation 3.

(4) Meat preparations must not have been subjected to ionising radiation. This provision shall not affect rules applicable to ionisation for medical purposes.

(5) The Veterinary Services may, for the purpose of their approval, grant manufacturing plants manufacturing meat preparations without an industrial structure or production capacity derogations from the requirements of Chapter I of Schedule I to these regulations and from those of Chapter I of Annex B to European Union Council Directive 77/99/EEC and of Chapter I (2) (a) (as regards taps) and point 11 (as regards lockers) of Annex I to European Union Council Directive 64/433/EEC. Moreover, derogations may be granted from point 7 of Chapter I of Annex B to European Union Council Directive 77/99/EEC as regards rooms where raw materials and finished products are stored. However, in this case, the establishment must have at least -

(i) a room or secure place for the storage of raw materials, if such storage takes place;

(ii) a refrigerated room or secure place for the storage of finished products, if such storage takes place.

Authorisation for the production and placing on the market of meat preparations

6. (1) In order to take account of particular habits of consumption and while ensuring that the health requirements of these regulations are observed, the Veterinary Services may authorise the production and placing on the market of meat preparations to be sold in the territory of Malta only obtained -

- (a) from meat referred to in regulation 2 (2) (b);
- (b) from production plants which are approved or registered and have the premises referred to in Chapter III of Schedule I;
- (c) by derogation from points (b) and (d) of Chapter IV of Schedule I -
 - regulation 5 (1) (c) and (d),
 - point 4 of Chapter VI of Schedule I,
 - regulation 5 (2) (e) and (f) and regulation 5 (3).

(2) Meat preparations obtained in accordance with sub-regulation (1) must not bear the health mark provided for in Chapter VI of Schedule I.

(3) To make use of the provisions of sub-regulation (1) the Veterinary Services should take into account the nature of the derogation granted in the Member States.

**Part IV
Common provisions**

Measures to ensure the application of these regulations

7. (1) The competent authority shall ensure that the operator or manager of the production plant takes all necessary measures to ensure that, at all stages of production, the provisions of these regulations are complied with. To that end, the said persons must apply HACCP principles and the competent authority, if it considers it appropriate, may recommend food business operators European Standards of the EN 29000 series in order to implement the general rules of hygiene and the guides to good hygiene practice. In addition, the operator or manager of the production plant must constantly carry out their own checks in compliance with the following principles -

- checking raw materials entering the establishment to ensure compliance with the criteria in Schedules II and IV in respect of the final product,
- checking cleaning and disinfection methods,
- taking samples for analysis in a laboratory recognised by the competent authority,

- keeping written or recorded track of the information required in accordance with the preceding indent with a view to submitting it to the competent authority. The results of the different checks and tests shall in particular be kept for a period of at least two years, save in the case of chilled products for which this period may be reduced to six months after the use-by date of the product,
- providing guarantees for the competent authority as regards the administration of the health marking, particularly the labels bearing the health mark,
- when the laboratory examination or any other information at their disposal reveals that there is a health risk, informing the competent authority
- in the event of an immediate human health risk, withdrawing from the market the quantity of products obtained in technologically similar conditions and likely to present the same risk. This withdrawn quantity must stay under the supervision and control of the competent authority until it is destroyed, used for purposes other than human consumption or, after authorisation by the competent authority, reprocessed in an appropriate manner to ensure its safety.

(2) For inspection purposes, the operator or manager of the establishment must ensure that the packaging of the products bears a clear and legible indication of the temperature at which the products must be transported and stored, as well as the use by date for deep-frozen products or the minimum conservation date for chilled products. The operator or manager of the establishment must arrange or establish a staff training programme enabling workers to comply with conditions of hygienic production adapted to the production structure, unless such staff already have adequate qualifications attested by diplomas. The competent authority responsible for the establishment must be involved in the planning and implementation of the programme.

(3) Microbiological tests must be carried out on minced meat as referred to in regulation 3 and minced-meat preparations as referred to in regulation 5 on a daily basis and at least weekly on other minced meat and meat preparations. These tests must be carried out either in the production plant, if it is recognised by the competent authority, or in an approved laboratory.

The sample taken for analysis must comprise five units and be representative of daily production. Samples of meat preparations must be taken from deep in the muscle after the skin has been cauterised. The microbiological checks must be carried out in accordance with proven methods, which are scientifically recognised, in particular those laid down in European Community legislation or other international standards.

The results of the microbiological checks must be assessed using the criteria for interpretation laid down in Schedule II in the case of minced meat and meat preparations obtained from minced meat of slaughter animals, except for fresh sausages and sausage meat, in accordance with the criteria in Schedule IV in the case of other meat preparations. In the event of disputes arising in trade, the Veterinary Services shall recognise the EN methods as reference methods.

(4) The requirements as regards self-monitoring must have been drawn up in conjunction with the competent authority, which must regularly monitor compliance therewith.

(5) The arrangements for implementing this regulation, in particular in cases where sub-regulation (1) applies, shall be detailed in accordance with the procedure laid down in article 10 of the Veterinary Services Act.

List of establishments which produce minced meat or meat preparations

8. (1) The competent authority shall draw up a list of establishments producing minced meat or meat preparations, making a distinction between those approved under regulations 3 and 5 and those registered under regulations 4 and 6. It shall send a list of the production plants approved under regulations 3 and 5 to the Member States and to the European Commission.

It shall assign to each production plant the approval number of the establishment approved in accordance with European Union Council Directives 64/433/EEC, 71/118/EEC, 77/99/EEC, 91/495/EEC or 92/45/EEC with an indication that it has been approved for the production of minced meat or meat preparations, and to each independent production unit an individual approval number. A single approval number may be given to -

(i) an establishment making preparations obtained from or with raw materials covered by more than one of the Directives referred to in the following subparagraph;

(ii) an establishment located on the same site as an establishment approved in accordance with article 2 of one of the above Directives. Production plants thus approved shall be entered either for the production of minced meat or for that of meat preparations in a separate column in the list of establishments referred to in article 10 of European Union Council Directive 64/433/EEC, article 6 of European Union Council Directive 71/118/EEC, article 8 of European Union Council Directive 77/99/EEC or that referred to in article 7 of European Union Council Directive 92/45/EEC and, in the case of an independent production unit, on a separate list drawn up according to the same criteria.

The competent authority shall not approve an establishment unless it is satisfied that it complies with these regulations with respect to the nature of its activities. However, if an establishment seeking approval pursuant to these regulations forms an integral part of an establishment approved under European Union Council Directives 64/433/EEC, 71/118/EEC, 79/99/EEC or 92/45/EEC, the premises, equipment and installations for staff and, generally, all premises where there is no risk of contamination of raw materials or unwrapped products may be common to both establishments.

(2) Production plants must remain under the control of the competent authority, which shall inspect and monitor them with the following frequency -

- for production plants attached to cutting plants: same frequency as for the said cutting plants,

- for approved production plants producing the products referred to in regulation 3, at least once a day during the production of minced meat,
- for other production plants: the need for permanent or periodic presence of the competent authority in a given establishment will depend on the size of the establishment, the type of product manufactured, risk assessment and the guarantees offered in accordance with the second subparagraph of regulation 7.

The competent authority must at all times have free access to all parts of establishments in order to ensure that these regulations is being complied with and, where there is doubt as to the origin of meat, to accounting documents which enable the slaughterhouse or establishment of origin of the raw material to be traced and, as regards compliance with the criteria laid down in Schedules II and IV, to the results of the self-monitoring provided for in regulation 7, including the result of checks on raw materials. In the case of computer data, they must be printed out at the request of the competent authority.

The competent authority must regularly analyse the results of the checks provided for in regulation 7. It may, on the basis of these analyses, conduct further examinations at all stages of production or on the products. The nature of these checks, their frequency and the methods of sampling and of carrying out microbiological examinations shall be established under the procedure laid down in article 10 of the Veterinary Services Act.

The results of these analyses shall be set out in a report, the conclusions or recommendations of which shall be notified to the operator or manager of the establishment, who shall be obliged to rectify the shortcomings noted with a view to improving hygiene. The competent authority may, when carrying out the said checks, be helped by assistants who hold the professional qualifications specified in Annex III to European Union Council Directive 64/433/EEC or in Annex III to European Union Council Directive 71/118/EEC.

(3) Where the competent authority finds, in the course of checks carried out in accordance with Chapter V of Schedule I, that there is repeated non-compliance during self-monitoring with the criteria laid down in Schedules II and IV, it shall intensify the measures for monitoring the production of the establishment in question, and may seize the labels and other items bearing the health mark referred to in Chapter VI of Schedule I.

If, after the expiry of 15 days, the output from production plants still fails to meet the above standards, the competent authority shall take all appropriate measures to make good the shortcomings noted and shall if necessary require products from the establishment in question to undergo heat treatment. If these measures are not adequate, the establishment's approval shall be suspended.

(4) Where the competent authority finds an obvious failure to comply with the hygiene rules laid down by these regulations or obstacles to an adequate health inspection -

(i) it shall be empowered to act in respect of the use of equipment or premises and to take any requisite measures which may go as far as reducing the rate of production or temporarily suspending the production process;

(ii) where these measures or the measures provided for in the final indent of regulation 7 (1) have proved insufficient to remedy the situation, it shall temporarily suspend approval, if appropriate, for the type of production in question. If the operator or manager of the establishment does not make good the shortcomings noted within the period fixed by the competent authority, the latter shall withdraw approval. The competent authority in question shall in particular be obliged to comply with the conclusions of any check carried out in accordance with regulation 9. The Member States and the European Commission shall be informed of the suspension or withdrawal of approval.

(5) In the event of repeated shortcomings, checks shall be increased and, where appropriate, labels, seals or other items bearing the health mark shall be removed.

(6) The arrangements for implementing this regulation, in particular details of help by assistants, shall be adopted in accordance with the procedure laid down in article 10 of the Veterinary Services Act.

Onsite checks by experts

9. Experts from the European Commission may in co-operation with the competent authorities, make onsite checks.

The competent authority and all the administrative bodies or persons involved in these checks shall give all the necessary assistance to the experts in carrying out their duties.

Veterinary checks in trade with Member States

10. The provisions of article 15 of the Veterinary Services Act concerning veterinary checks in trade with Member States shall apply, in particular with respect to the organisation of and the action to be taken on the checks carried out at destination and the safeguard measures to be applied.

Additives

11. Any addition of additives to the minced meat or meat preparations covered by these regulations shall take place in compliance with Maltese rules relating to colours for use in foodstuffs.

Checks made by the competent authority if these regulations are not followed

12. (1) Without prejudice to the specific provisions of these regulations, the competent authority shall, where it is suspected that the provisions of these regulations have not been complied with or there is doubt as to whether the products referred to in regulation 1 are fit for consumption, carry out any checks it deems appropriate.

(2) According to the Part IX of the Veterinary Services Act it shall be determined the penalties to be applied in the event of infringement of the provisions of these regulations.

Part V

Provisions applicable to imports from third countries of meat preparations and minced meat into the territory of Malta

Importation of minced meat

13. (1) Imports into the territory of Malta of minced meat satisfying the requirements of regulation 3 which has been deep-frozen at the production plant of origin and meat preparations satisfying the requirements of regulation 5, which have been deep-frozen at the production plant of origin are not authorised unless they meet the requirements of this Part.

(a) The guarantees provided by the production plant of origin and confirmed by the competent authority of the third country regarding compliance with the requirements laid down for the placing on the market of products originating from Malta or from Member States obtained in accordance with regulations 3 and 5 must be approved in accordance with the procedure laid down in article 12 of the Veterinary Services Act.

(b) For the purposes of application of sub-paragraph (a), the provisions of the following paragraphs shall apply -

(i) In order to be imported into the territory of Malta, deep-frozen minced meat as referred to in regulation 3 and deep-frozen meat preparations as referred to in regulation 5 must -

- come from third countries or parts of third countries from which imports are not prohibited on animal health grounds in accordance with European Union Council Directive 91/494/EEC, 92/118/EEC, 72/462/EEC and 92/45/EEC;

- come from a third country on the lists drawn up in accordance with the European Directives governing health and animal health aspects to be complied with for imports of meat used in meat preparations and offering the guarantees provided for in these regulations;

- be accompanied by the animal and public health certificate which is to be drawn up in accordance with the procedure laid down in article 12 (2) (c) of the Veterinary Services Act supplemented by a declaration signed by the official veterinarian to the effect that this minced meat and these meat preparations fulfil respectively the requirements laid down in regulations 3 and 5, come from establishments offering the guarantees provided for in Schedule I, and have been deep-frozen at the production plant of origin.

(ii) The following shall be established in accordance with the procedure laid down in articles 12 (1) and (2) (b) of the Veterinary Services Act -

- a list of establishments which satisfy the requirements in the second indent to this sub-paragraph;

- the specific conditions relating to the requirements of these regulations, other than those enabling meat to be excluded from human consumption, in accordance with European Union Council Directives 64/433/EEC and 71/118/EEC. Such conditions and guarantees may not be less stringent than those laid down in regulations 3 and 5.

(iii) Experts from the competent authority shall, in co-operation with the competent authorities of the Member States, carry out on-the-spot inspections to check -

- the guarantees given by the third country regarding the conditions of production and placing on the market;

- whether the conditions of sub-paragraphs (i) and (ii) are fulfilled.

(2) Under the procedure laid down in article 12 of the Veterinary Services Act, other provisions to this regulation may be introduced.

Lists

14. The lists provided for in regulation 13(1)(b)(ii) may include only third countries or parts of third countries -

(a) from which imports are not prohibited pursuant to articles 9 to 12 of European Union Council Directive 91/494/EEC and articles 14, 17 and 20 of European Union Council Directive 72/462/EEC

(b) which, in view of their legislation and the organisation of their veterinary services and of their inspection services, the powers of such services and the supervision to which they are subject, have been recognised, in accordance with article 3 (2) of European Union Council Directive 72/462/EEC of article 9 (2) of European Union Council Directive 91/494/EEC, as capable of guaranteeing and supervising the implementation of their legislation in force, or the veterinary services of which are able to guarantee that health requirements at least equivalent to those laid down in regulations 3 and 5 are being complied with.

Deep frozen minced meat and meat preparations

15. Deep-frozen minced meat as referred to in regulation 3 and deep-frozen meat preparations as referred to in regulation 5 are imported into the territory of the territory of Malta only if they -

- are accompanied by the certificate provided for in regulation 13 (1) (b) (i)

- have satisfied the checks required by article 16 of the Veterinary Services Act .

Organisation and follow-up of inspections

16. The principles and rules laid down in article 16 of the Veterinary Services Act shall apply, with particular reference to the organisation of and follow-up to the inspections to be carried out by the Maltese Veterinary Services and the safeguard measures to be implemented.

SCHEDULE I

CHAPTER I

Special conditions for the approval of establishments producing minced meat

1. Production plants within the meaning of regulation 2 (2) (d). Over and above compliance with the conditions laid down in Annex I, Chapters I and III, to European Union Council Directive 64/433/EEC production plants must have at least:

(a) a room for mincing and wrapping separate from the cutting room and equipped with a recording thermometer or recording tele-thermometer. However, the competent authority may authorise the mincing of meat in the cutting room provided that the mincing is carried out in specific area that is clearly separate;

(b) a room for packaging, unless the conditions laid down in point 63 of Chapter XII of Annex I to European Union Council Directive 64/433/EEC are fulfilled;

(c) a room or cabinets for storing salt;

(d) refrigeration equipment enabling the temperatures laid down in these regulations to be adhered to.

2. Over and above the general conditions laid down in Chapter I of Annex A to European Union Council Directive 77/99/EEC, independent production units must have at least -

(a) rooms in accordance with point 1 of Chapter I of Annex B to European Union Council Directive 77/99/EEC;

and

(b) rooms as described in point 1.a of this chapter.

3. The rules laid down in Chapter V of Annex I to European Union Council Directive 64/433/EEC shall apply as regards the hygiene of the staff, premises and equipment in the establishments. Staff engaged in the manual preparation of minced meat must in addition wear masks covering the mouth and nose. The competent authority may also oblige staff to wear smooth, moisture-proof gloves, either for once-only use or capable of being cleaned and disinfected.

CHAPTER II

Conditions for the production of minced meat

1. Meat must be examined before mincing or cutting up, in accordance with regulation 7. All soiled and suspect parts shall be removed and condemned before the meat is minced.

2. Minced meat may not be obtained from scrap cuttings, scrap trimmings or from mechanically recovered meat. In particular, it may not be prepared from the meat referred to in article 5 of European Union Council Directive 64/433/EEC or from meat from the following parts of bovine animals, pigs, sheep or goats: muscles from the head, with the exception of the masseters, and the non-muscular part of the linea alba, the carpus and tarsus region and bone scrapings.

The muscles of the diaphragm after removal of serosa and of the masseters may be used only after an investigation for cysticercosis has been carried out. The fresh meat must not contain any bone fragments. Where the operations carried out from the time when the meat enters the room referred to in Chapter I to the time when the finished product undergoes the chilling or deepfreezing process are performed within a maximum period of one hour, the internal temperature of the meat must be no higher than +7 °C and the temperature of the production premises must be no higher than +12 °C. The competent authority may authorise a longer time limit in individual cases where the addition of salt justifies this on technical grounds, provided that health rules are not affected by that derogation.

Where the duration of these operations is over one hour or over the period authorised by the competent authority in accordance with the preceding subparagraph, the fresh meat may not be used until the internal temperature of the meat has been reduced to a maximum of -4°C .

3. Minced meat may be deep-frozen only once.

4. Immediately after production the minced meat must be hygienically wrapped and, after packaging, be cooled to and stored at the temperatures laid down in regulation 3 (2) (c).

CHAPTER III

Special conditions for the approval of establishments producing meat preparations

1. Production plants within the meaning of regulation 2 (2) (d) must have premises which at least meet the requirements of -

(a) Chapters I and III of Annex I to European Union Council Directive 64/433/EEC;

or

(b) Chapters I and III of Annex I to European Union Council Directive 71/118/EEC;

or

(c) Chapters I and IV, point 1, of Annex I to European Union Council Directive 92/45/EEC;

as well as having -

- a room separate from the cutting room for the production of meat preparations, the addition of other foodstuffs and wrapping, equipped with a recording thermometer or recording tele-thermometer. However, the competent authority may authorise the production of meat preparations in the cutting room provided that the production is carried out on a specific area that is clearly separate. The addition of seasonings to whole poultry carcasses may be authorised in a specific room that is clearly separate from the slaughter premises,

- a room for packaging, unless the conditions laid down in point 63 of Chapter XII of Annex I to European Union Council Directive 64/433/EEC or point 74 of Chapter XIV of Annex I to European Union Council Directive 71/118/EEC or point 5 of Chapter VIII of Annex I to European Union Council Directive 92/45/EEC are fulfilled,

- a room for storing seasonings and other cleaned foodstuffs ready for use,

- refrigerated rooms for the storage of -

- fresh meat as referred to in regulation 5 (1) (a),

- meat preparations,

- refrigeration equipment enabling the temperatures laid down in these regulations to be adhered to.

2. Independent production units must meet the requirements of Chapter I of Annex A and Chapter I of Annex B to European Union Council Directive 77/99/EEC.

3. The rules laid down in Chapter V of Annex I to European Union Council Directives 64/433/EEC or 71/118/EEC or those of Chapter II of European Union Council Directive 92/45/EEC shall apply by analogy as regards the hygiene of the staff, premises and equipment in the establishments. Staff engaged in the manual production of meat preparations must also wear masks covering their noses and mouths. The competent authority may also require such staff to wear smooth, moisture-proof gloves, either or once-only use or capable of being cleaned and disinfected.

CHAPTER IV
Special requirements for the production of meat preparations

Over and above compliance with the general requirements of Chapter III, and depending on the type of production concerned –

- (a) the production of meat preparations must take place under conditions of temperature control;
- (b) meat preparations must be wrapped in dispatch units in such a way as to obviate any risk of contamination;
- (c) meat preparations may be deep-frozen only once and may be traded only within a period not exceeding 18 months;
- (d) meat preparations must, immediately after the production process, be wrapped in accordance with Chapter VII and, after packaging, be cooled to the relevant temperature laid down in regulation 5 (1) (d).

CHAPTER V
Inspection

1. Production plants which produce minced meat and meat preparations shall be subject to monitoring by the competent authority, which must ensure that the requirements of these regulations are met and in particular must –

- (a) check -
 - (i) the cleanliness of the premises and equipment and staff hygiene;
 - (ii) the efficacy of the checks carried out by the establishment, in accordance with these regulations, in particular by examining the results and taking samples;
 - (iii) the microbiological and hygienic condition of the minced meat and the meat preparations;
 - (iv) the appropriate health marking of the minced meat and the meat preparations;
 - (v) storage and transport conditions;
- (b) within the framework of the official checks, take any samples required for laboratory tests to confirm the results of the self-monitoring;
- (c) make any other checks it considers necessary to ensure compliance with these regulations, it being understood that the results of the microbiological tests must be evaluated by the competent authority on the basis of the criteria laid down in Schedule II for minced meat and in Schedule IV for meat preparations.

2. The competent authority must have free access at all times to the cold stores and all working premises to check that these provisions are being strictly complied with.

CHAPTER VI
Marking and labelling

- 1. Minced meat and meat preparations must be marked on the wrapping or packaging with a health mark.
- 2. Only minced meat obtained in accordance with regulation 3 and meat preparations obtained in accordance with Article 5 and produced in a production plant approved in accordance with regulation 8, may be given the territory of Malta health mark. That health mark must correspond -
 - (a) to point 50 of Chapter XI of Annex I to European Union Council Directive 64/433/EEC and the same corresponding rules laid down under Maltese regulations for minced meat;

(b) for meat preparations -

(i) of fresh meat of slaughter animals or farmed game meat, to point 50 of Chapter XI of Annex I to European Union Council Directive 64/433/EEC and the same corresponding rules found under Maltese regulations;

(ii) of poultry-meat or small feathered or furred farmed game, to point 66 of Chapter XII of Annex I to European Union Council Directive 71/118/EEC and the same corresponding rules found under Maltese regulations;

(iii) of killed game, to point 2 of Chapter VII of Annex I to European Union Council Directive 92/45/EEC and the corresponding rules found under Maltese regulations.

3. Where minced meat or meat preparations are produced in an independent production unit, the health mark must include the approval number assigned by the competent authority pursuant to regulation 8 (1).

4. Without prejudice to Maltese rules relating to the labelling, presentation and advertising of foodstuffs, in the case of meat preparations the following information must be visibly and legibly displayed for inspection purposes on the packaging, where it is not clear from the sales description or from the list of ingredients in accordance with Maltese rules relating to the labelling, presentation and advertising of foodstuffs -

- the species from which the meat was obtained and, in the case of a mixture, the percentage of each species and, for packaging not intended for the final consumer, the date of preparation. In the case of minced meat and meat preparations made from minced meat except for fresh sausages and sausage meat bearing the health mark provided for in this chapter, the labelling must also display the following words -

- “percentage of fat under”,

- “Collagen: meat protein ratio under”.

CHAPTER VII Wrapping and packaging

1. Packaging (for example packing cases, paperboard boxes) must fulfil all rules of hygiene, and in particular -

- must not alter the organoleptic characteristics of the minced meat or meat preparations,

- must not be capable of transmitting to the minced meat or meat preparations substances harmful to human health,

- must be strong enough to ensure effective protection of the minced meat or meat preparations during transport and handling.

2. Packaging must not be reused for minced meat or meat preparations unless it is made of corrosion-resistant materials which are easy to clean and has been previously cleaned and disinfected.

3. Wrapped minced meat or meat preparations must be packaged.

4. However, when wrapping fulfils all the protective conditions of packaging it need not be transparent and colourless and placing in a second container is not necessary provided that the other conditions of point 1 above are fulfilled.

CHAPTER VIII Storage

1. Minced meat and meat preparations must be chilled immediately after wrapping and, or packaging. Minced meat must be stored at the temperatures indicated in regulation 3 (2) (c) and meat preparations at the temperatures indicated in regulation 5 (1) (d).

2. Minced meat and meat preparations may be deep-frozen only in rooms of the production establishment or independent production unit or in approved cold stores.

3. In cold stores, minced meat and meat preparations may be stored together with other foodstuffs only if it is ensured by means of packaging that the minced meat or meat preparations cannot be affected unfavourably.

CHAPTER IX

Transport

1. Minced meat and meat preparations must be dispatched in such a way that during transport they are protected from anything liable to contaminate them or to affect them unfavourably, having regard to the duration and conditions of transport and to the means of transport employed. In particular, vehicles used to transport minced meat and meat preparations must be equipped in such a way as to ensure that the temperatures laid down in these regulations are not exceeded during transport and they must be equipped with a recording thermometer to record that the latter requirement is fulfilled.

2. The Competent authority may, by way of derogation from paragraph 1, authorise the transport of meat preparations originating in the establishments referred to in regulation 5 (5) at temperatures higher than those laid down in these regulations from a production plant or independent production unit to nearby retail premises or local communities, provided that such transportation takes not more than one hour.

3. In the case of transit through a third country and where the production plant is situated in an area subject to restrictions for animal health reasons, the means of transport must remain sealed.

SCHEDULE II
Composition criteria and microbiological criteria

I. Composition criteria checked on the basis of a daily average

	Fat content	Collagen meat protein ratio
- lean minced meat <7 % <12	= or <7 %	= or <12
- minced pure beef <20 % <15	= or <20 %	= or <15
- minced meat containing pig-meat <30 % <18	= or <30 %	= or <18
- minced meat of other species <25 % <15	= or <25 %	= or <15

II. Microbiological criteria

Production plants and independent production units must ensure that, during the checks provided for in regulation 7 (3) and in accordance with the methods of interpretation set out below, minced meat complies with the following –

	M (a)	m (b)
Aerobic mesophile bacteria n (c) = 5; c (d) = 2	5×10^6 /g	5×10^3 /g
Escherichia coli n = 5; c = 2	5×10^2 /g	50/g
Salmonella n = 5; c = 0	absence in 10 g	
Staphylococcus aureus n = 5; c = 2	5×10^3 /g	10^2 /g

(a) M = acceptability threshold, above which results are no longer considered satisfactory where M equals 10 m where the count is made in a solid medium and M equals 30 m where the count is made in a liquid medium.

(b) m = threshold below which all results are considered satisfactory.

(c) n = number of units making up the sample.

(d) c = number of units in the sample giving values between n and M.

The results of the microbiological analyses must be interpreted according to -

A. Three categories of contamination for aerobic mesophile bacteria, Escherichia coli and Staphylococcus aureus, viz. -

- up to and including the criterion m, between the criterion m and the threshold M,

- above the threshold M.

1. The quality of the consignment shall be considered -

(a) satisfactory, where all the values observed are equal to or less than 3 m where a solid medium has been used or 10 m where a liquid medium has been used;

(b) acceptable, where all the values observed are between -

(i) 3 m and 10 m (= M) in a solid medium;

(ii) 10 m and 30 m (= M) in a liquid medium;

and where c/n is equal to or less than 2/5 where n = 5 and c = 2 or any other figures of equivalent or greater reliability to be recognised by the Council, acting in accordance with European Community rules.

2. The quality of the consignment shall be considered unsatisfactory -

- in all cases where values in excess of M are observed,

- when c/n is $> 2/5$. However, where this latter threshold has been exceeded for aerobic micro-organisms at + 30 °C while all the other criteria have been fulfilled, this exceeding of the threshold must be the subject of a further interpretation, in particular in the case of raw products. In any event, the product must be considered toxic or tainted when contamination reaches the microbic limit value S, which for general purposes is set at 10^3 m. In the case of *Staphylococcus aureus*, the value of S must never be allowed to exceed 5×10^4 .

Tolerances related to analytical techniques shall not apply to the values M and S.

B. Two categories for salmonella, with no category tolerance permitted -

- "Absence in" - the result is considered satisfactory;

- "Presence in" - the result is considered unsatisfactory.

SCHEDULE III

HEALTH CERTIFICATE FOR MINCED MEAT ⁽¹⁾ NO.

Exporting country:
Ministry:
Department concerned:
Reference ⁽²⁾

I. Identification of minced meat

Products prepared with meat from:
(Animal species)

Nature of products ⁽³⁾ :
Nature of packaging:
Number of individual items or packages:
Storage and transport temperature:
Storage life:
Net weight:

II. Origin of minced meat

Address (es) and approval number (s) of approved manufacturing establishment (s)
:
If necessary: Address (es) and approval number (s) of approved cold store (s) :
.....

III. Destination of minced meat

The minced meat is to be sent from:
(Place of dispatch)
to:
(Country of destination)
by the following means of transport ⁽⁴⁾:
Name and address of consignor:
Name and address of consignee:

IV. Health attestation

I, the undersigned, certify that the minced meat described above:
(a) was manufactured from fresh meat under the specific conditions laid down in European Union Council Directive 94/65/EC;
(b) is intended for the Hellenic Republic ⁽⁵⁾.

Done at on
(place) (date)

.....
(Stamp signature of the official veterinarian)

.....
(Name in capital letters)

⁽¹⁾ Within the meaning of article 2 of European Union Council Directive 94/65/EC.
⁽²⁾ Optional.
⁽³⁾ To be completed with the words provided for in article 3 (2) (e) of European Union Council Directive 94/65/EC.

⁽⁴⁾ Indicate the number or registration number (railway wagons and lorries), the flight number (aircraft) or the name (ship). This information must be updated in the event of transshipment.

⁽⁵⁾ If appropriate

SCHEDULE IV

MICROBIOLOGICAL CRITERIA

Production plants and independent production units must ensure that, during the checks provided for in regulation 7 (3) and in accordance with the methods of interpretation specified in Annex II, meat preparations comply with the following criteria –

Meat preparations	M ⁽¹⁾	m ⁽²⁾
Escherichia coli n=5 c=2	5 x 10 ³ /g	5 x 10 ² /g
Staphylococci aureus n=5 c=1	5 x 10 ³ /g	5 x 10 ² /g
Salmonella n=5 c=0	absence. in 1 g	

⁽¹⁾ M = acceptability threshold, above which results are no longer considered satisfactory where M equals 10 m where the count is made in a solid medium and M equals 30 m where the count is made in a liquid medium.

⁽²⁾ m = threshold below which all results are considered satisfactory.

SCHEDULE V

HEALTH CERTIFICATE FOR MEAT PREPARATIONS (1) NO.

Exporting country:
Ministry:
Department concerned:
Reference (2)

I. Identification of minced meat

Products prepared with meat from:.....
(Animal species)

Nature of products (3) :.....
Nature of packaging:.....
Number of individual items or packages:.....
Storage and transport temperature:.....
Storage life:
Net weight:

II. Origin of meat preparations

Address (es) and approval number (s) of approved production plants(s)
:.....

If necessary:

Address (es) and approval number (s) of approved cold store (s) :
.....

III. Destination of meat preparations

from:
(Place of dispatch)

to:
(Country of destination)

by the following means of transport(4):

Name and address of consignor:.....
.....

Name and address of consignee:.....
.....

IV. Health attestation

IV. Health attestation

I, the undersigned, certify at the meat preparations described above

a) were manufactured from fresh meat under the specific conditions laid down in European Union Council Directive 94/65/EC;

b) are intended for the Hellenic Republic

Done at....., on.....
(place) (date)

.....
(Stamp signature of the official veterinarian)

.....
(Name in capital letters)

(1) Within the meaning of article 2 of European Union Council Directive 94/65/EC.

(2) Optional.

(3) Mention any ionising radiation for medical reasons.

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(4) Indicate the number or registration number (railway wagons and lorries), the flight number (aircraft) or the name (ship). This information must be updated in the event of transshipment.

(5) If appropriate.