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**L.N. 119 of 2004**

# VETERINARY SERVICES ACT, 2001
# (ACT XXIII OF 2001)

## Health Problems Affecting the Production and Marketing of Meat Products and Certain other Products of Animal Origin Regulations, 2004

IN exercise of the powers conferred by article 10(1) and (2) of the Veterinary Services Act, 2001, the Minister for Rural Affairs and the Environment has made the following regulations:-

### Title, scope and application

**1.** (1) The title of these regulations is the Health Problems Affecting the Production and Marketing of Meat Products and Certain other Products of Animal Origin Regulations, 2004.

(2) The scope of these regulations is the implementation of European Union Council Directive 77/99/EEC on health problems affecting the production and marketing of meat products and certain other products of animal origin.

(3) These regulations lays down health rules for the production and placing on the market of meat products and other products of animal origin intended, after treatment, for human consumption or for the preparation of other foodstuffs.

(4) These regulations shall not apply to the preparation and storage, in retail shops or in premises adjacent to sales points, of meat products and other products of animal origin intended for human consumption, where the preparation and storage are performed solely for the purpose of supplying the consumer directly.

### Definitions

**2.** For the purposes of these regulations the following definitions shall apply -

(a) "meat products" means products prepared from or with meat which has undergone treatment such that the cut surface shows that the product no longer has the characteristics of fresh meat. However, the following shall not be regarded as meat products:

(i) meat which has undergone only cold treatment; such meat shall remain subject to the rules in the Directives referred to in (d) ;

(ii) products subject to European Union Council Directive 94/65/EEC;

(b) "other products of animal origin" means -

(i) meat extracts;

(ii) "rendered animal fat" means fat derived from rendering meat, including bones, and intended for human consumption;

(iii) "greaves" means the protein containing residue of rendering, after partial separation of fat and water;

(iv) meat powder, powdered rind, salted or dried blood, salted or dried blood plasma;

(v) stomachs, bladders and intestines, cleaned, salted or dried, and, or heated;

(c) prepared meat meals; wrapped meat products corresponding to culinary preparations, cooked or precooked and preserved by cold;

(d) "meat" means meat as defined in -

- article 2 (a) of European Union Council Directive 64/433/EEC,

- article 2 of European Union Council Directive 71/118/EEC,

- article 2 of European Union Council Directive 72/461/EEC,

- article 2 of European Union Council Directive 72/462/EEC,

- article 2 of European Union Council Directive 94/65/EEC,

- article 2 (1) and (2) of European Union Council Directive 91/495/EEC;

- article 2 (1) (d) of European Union Council Directive 92/45/EEC and meeting the requirements of regulations 3 and 5;

(e) "raw material" means any animal product used as an ingredient to obtain products referred to in (a) and (b) or used in the preparation of prepared meals;

(f) "treatment" means chemical or physical process such as heating, smoking, salting, marinating, curing or drying, intended to lengthen the preservation of meat or animal products whether or not associated with other foodstuffs, or a combination of these various processes;

(g) "heating" means use of dry or damp heat;

(h) "salting" means use of salt;

(i) "curing" means distribution of salts throughout the product;

(j) "maturing" means treatment of salted raw meat, applied under climatic conditions which, in the course of a slow and gradual reduction of humidity, are capable of generating natural fermentation or enzymatic processes, involving changes over a period of time which give the product typical organoleptic characteristics and ensure its preservation and wholesomeness at normal ambient temperature;

(k) "drying" means natural or artificial reduction of the water content;

(l) "batch" means a quantity of a meat product which is covered by the same accompanying commercial document or health certificate;

(m) "wrapping" means the protection of the products referred to in regulation 1 (3) by the use of an initial wrapping or initial container in direct contact with the product concerned as well as the initial wrapper or initial container itself;

(n) "packaging" means the placing of one or more wrapped or unwrapped products as referred to in regulation 1 (3) in a container, as well as the container itself;

(o) "hermetically sealed container" means container intended to protect the contents against the entry of micro-organisms during and after heat treatment and which is impermeable to air;

(p) "establishment" means any undertaking manufacturing the products referred to in (a), (b) and (c) ;

(q) "re-wrapping centre" means a workshop or depot where batches intended for placing on the market are reassembled and, or re-wrapped;

(r) "trading partner" in the meaning of article 2 of the Veterinary Services Act shall mean –

(i) Member States of the European Community;

(ii) Third countries to the European Community.

(s) "placing on the market" means the stocking or the display with a view to sale, offering for sale, sale, delivery or any other manner of disposal in the territory of Malta and in the European Community; with the exception of retail sale;

(t) "competent authority" means the central authority of a Member State competent to carry out veterinary checks or any authority to which it has delegated that competence. The "competent authority" to Malta is the Veterinary Services.

**General rules for meat products which may be placed on the market**

**3.** Without prejudice to the conditions laid down in regulation 4 only meat products which abide with the following may be placed on the market in the territory of Malta -

(1) have been prepared and stored in an establishment approved and supervised -

(a) in accordance with regulation 8, and meeting the requirements of these regulations, in particular those of Schedule A and Chapters I and II of Schedule B,

or

(b) in accordance with regulation 9, in the case of establishments which do not have an industrial structure or production capacity;

(2) (i) Have been prepared from fresh meat as defined in regulation 2 (d), on the understanding that meat imported from a third country must meet the requirements laid down under Chapter III of Council Directive 71/118/EEC and have been inspected in accordance with European Union Council Directive 97/78/EC;

(ii) meat imported in accordance with article 15 of European Union Council Directive 71/118/EEC and the second paragraph of article 17 of European Union Council Directive 91/495/EEC may not be used unless -

- products obtained from this meat fulfil the requirements set out in these regulations;

- these products do not bear the health marking laid down in Chapter VI of Annex B, the placing on the market of these products remains subject to the national provisions of the Member State of destination.

Meat declared unfit for consumption in compliance with the requirements of articles 5 and 6 of European Union Council Directive 64/433/EEC the third subparagraph of article 5 (1), and Chapter IX of Annex I to European Union Council Directive 71/118/EEC, and in general any meat declared unfit for human consumption under Maltese rules and the following items may not be used in the preparation of meat products -

(a) genital organs of female or male animals, except testicles;

(b) urinary organs, except the kidneys and the bladder;

(c) the cartilage of the larynx, the trachea and the extra-lobular bronchi;

(d) eyes and eyelids;

(e) the external, auditory duct;

(f) corneous tissues;

(g) in poultry, the head, except the comb and the ears, the wattles and caruncles the oesophagus, the crop, the intestines and the genital organs. Items may be added to or removed from this list in accordance with the procedure laid down under article 10 of the Veterinary Services Act.

(3) Have been prepared in accordance with the requirements of Chapter III of Schedule B and, in the case of pasteurised or sterilised products in hermetically sealed containers or of prepared meals, comply with the requirements of Schedule B, Chapter VIII, or Chapter IX respectively;

(4) Have undergone the establishment's own checks provided for in regulation 7 and are supervised by the Veterinary Services in accordance with Chapter IV of Schedule B;

(5) If necessary, also meet the requirements laid down in regulation 7 (2);

(6) Where wrapping, packaging or labelling take place, have been wrapped, packaged or labelled in accordance with Chapter V of Schedule B on the spot or in wrapping centres specially approved by the Veterinary Services for that purpose. However, the provisions of these regulations concerning the sales description of meat products shall apply without prejudice of other rules concerning products of designated origin or to typical products;

(7) Without prejudice to the marking requirements of European Union Council Directive 80/215/EEC, have been marked, on the responsibility of the operator or manager of the establishment, with -

(a) a national health mark, where the raw material used is marketed with that mark,

(b) a mark to be determined in accordance with article 10 of the Veterinary Services Act be marketed locally where the meat used must, under European Community rules, be marketed locally,

(c) in other cases, a health mark in accordance with Chapter VI of Schedule B.

The mark must be printed on the label or affixed to the product or the wrapping, on the understanding that the printing or reprinting of labels or marks must be authorised by the Veterinary Services;

(8) Have been handled, stored and transported in accordance with Chapter VII of Schedule B and, if they are stored in a cold-storage plant separate from the establishment, this plant must have been approved and inspected in accordance with article 10 of European Union Council Directive 64/433/EEC;

(9) Are accompanied during transportation by -

(i) an accompanying commercial document which must -

- in addition to the particulars provided for in Schedule B, Chapter VI, point 4, bear a code number by which the Veterinary Services responsible for supervising the establishment of origin can be identified and be kept by the consignee for at least one year so that it can be produced at the request of the Veterinary Services,

(ii) a health certificate in accordance with Schedule D, in the case of products referred to in regulation 1 obtained from meat from a slaughterhouse situated in a region or area subject to a restriction on animal health grounds, or from meat referred to in article 6 of European Union Council Directive 64/433/EEC, or from products to be sent to a Member State, after transit through a third country in a sealed means of transport.

This obligation shall not apply to meat products in hermetically sealed containers and having undergone one of the treatments referred to in Schedule B, Chapter VIII, point B, first indent, if the health mark is indelibly marked on the container.

Detailed rules for applying (ii) and in particular those concerning the allocation of code numbers and the compilation of one or more lists identifying the competent authorities, shall be adopted in accordance with the procedure laid down in article 10 of the Veterinary Services Act.

(10) Pending possible European Community rules, meat products may not have been subjected to ionising radiation. This provision shall not affect national rules applicable to ionisation for medical purposes.

**Further general requirements**

**4.** In addition to the general requirements laid down in regulation 3 -

(1) meat products must -

(a) have been prepared by heating, curing, marinating or drying, which processes may be combined with smoking or maturing, possibly under specific microclimatic conditions, and have been associated, in particular, with certain curing agents in compliance with Maltese specific rules on additives. The meat products may also be associated with other foodstuffs and condiments;

(b) have, if appropriate, been obtained from a meat product or from a meat preparation;

(2) The meat products referred to in the first and second indents of regulation 3 (7) cannot be sent to the territory of a Member State and their national or local marketing is strictly supervised.

**Hygiene rules for prepared meals**

**5.** Where they are manufactured in an establishment defined in regulation 2 (p), prepared meals shall comply with the hygiene rules laid down in Schedule A, Chapter II, and such meals also shall meet the specific requirements set out in Schedule B, Chapter IX, and shall be supervised in accordance with regulation 7.

**Other products of animal origin which can be placed on the market**

**6.** (1) Are only placed on the market other products of animal origin which -

(a) have been obtained in establishments which meet the requirements of regulation 7, have been authorised and registered in accordance with regulation 11, meet the standards of Schedule A and are inspected in accordance with regulation 8,

(b) are manufactured in accordance with the specific conditions laid down in Schedule C,

(c) are inspected as provided for in Chapter IV of Schedule B,

(d) are accompanied, as provided for in regulation 3 (9), by a commercial document specifying the origin of the products.

(2) Under the procedure laid down in article 10 of the Veterinary Services Act, additional conditions may be set for the other products of animal origin so as to ensure the protection of public health.

**Measures to be taken by the operator of manager of the establishment or re-wrapping centre**

**7.** (1) The operator or manager of the establishment or the re-wrapping centre shall takes all necessary measures to ensure that, at all stages of production or re-wrapping, the specifications of these regulations are complied with. To that end, the said persons must constantly carry out their own checks based on the following principles -

(a) identification of critical points in their establishment on the basis of the processes used,

(b) establishment and implementation of methods for monitoring and checking such critical points,

(c) taking samples for analysis in a laboratory approved by the Veterinary Services for the purpose of checking cleaning and disinfection methods and for the purpose of checking compliance with the standards established by these regulations,

(d) keeping a written or registered record of the information required in accordance with the preceding indents with a view to submitting it to the Veterinary Services.

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 the products referred to in (b) for which this period may be reduced to six months after the minimum conservation date of the product,

(e) guarantees as regards the administration of the health marking, particularly the labels bearing the health mark,

(f) when the laboratory examination or any other information at their disposal reveals that there is a serious health risk, inform the Veterinary Services thereof,

(g) in the event of an immediate human health risk, withdraw 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 Veterinary Services until it is destroyed, used for purposes other than human consumption or, after authorisation by the Veterinary Services, reprocessed in an appropriate manner to ensure its safety,

(h) the requirements of the first and second indents must have been drawn up in conjunction with the Veterinary Services, which must regularly monitor compliance therewith.

(2) For inspection purposes, the operator or manager of the establishment or the re-wrapping centre must ensure that the packaging of meat products which cannot be stored at ambient temperatures bears a clear and legible indication of the temperature at which the products must be transported and stored, as well as the minimum durability date or, in the case of microbiologically perishable products, the use by date.

(3) 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 has adequate qualifications attested by diplomas. This training programme may be of a specific type for the establishments referred to in regulation 9. The Veterinary Services must be involved in the planning and implementation of the programme.

**List of approved establishments**

**8.** (1) Veterinary Services shall draw up a list of approved establishments, other than those referred to in regulation 11, each establishment having an approval number. This list shall be sent to the Member States and to the European Commission. A single approval number may be given to -

(a) an establishment or re-wrapping centre processing or re-wrapping products obtained from or with raw materials covered by several of the Directives referred to in regulation 2 (d) ;

(b) an establishment located on the same site as an establishment approved in accordance with one of the Directives referred to in regulation 2 (d).

The Veterinary Services 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, 91/493/EEC or 91/495/EEC, the premises, equipment and installations for staff and all premises where there is no risk of contamination of raw materials or unwrapped products may be common to both establishments.
Where the Veterinary Services 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 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 Veterinary Services, the latter shall withdraw approval.

The Veterinary Services in question shall in particular be obliged to comply with the conclusions of any check carried out in accordance with regulation 12. The Member States and the European Commission shall be informed by the Veterinary Services of the suspension or withdrawal of approval.

(2) Inspection and supervision of establishments shall be carried out by the Veterinary Services.

The establishment shall remain under the permanent supervision of the Veterinary Services on the understanding that the need for permanent or periodic presence of the Veterinary Services 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 fifth and last indents of the second subparagraph of regulation 7 (1).

The Veterinary Services must at all times have free access to all parts of establishments in order to ensure that these regulations are being complied with and, where there is doubt as to the origin of meat, to accounting documents which enable the slaughterhouse or holding of origin of the raw material to be traced.

The Veterinary Services must regularly analyse the results of the checks provided for in regulation 7 (1). 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 may be established under the procedure laid down in article 10 of the Veterinary Services Act and the relevant European Community rules.

The results of these analyses shall be written up in a report, the conclusions or recommendations of which shall be notified to the operator or manager of the establishment, who shall rectify the shortcomings noted with a view to improving hygiene.

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

(4) Other arrangements for implementing this regulation may be adopted in accordance with European Community rules and the procedure laid down in article 10 of the Veterinary Services Act.

**Derogation for establishments manufacturing meat products without an industrial structure**

**9.** (1) Malta Veterinary Services may, for the purpose of their approval, grant establishments manufacturing meat products without an industrial structure or production capacity derogations from the requirements of Chapter I of Schedule B and from those of Schedule A, Chapter I, point 2 (g) (as regards taps) and point 11 (to substitute lockers for changing rooms). Moreover, derogations may be granted from point 3 of Schedule A, Chapter I, as regards rooms where the raw materials and finished products are stored. However, in this case, the establishment must have at least -

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

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

(2) Veterinary Services may extend the derogation provided for in sub-regulation (1) to the establishments referred to in article 4, section A, point (a)(I), and sections C, D and E of Council Directive 64/433/EEC, on the understanding that the processing of products in those establishments must meet the other requirements of these regulations.

(3) The provisions of Schedule B, Chapter VII shall not apply to storage operations in the establishments referred to in sub-regulation (1), nor to the transporting of products other than those referred to in regulation 7 (2).

**Minimum production limit for each establishment**

**10.** (1) For the purpose of granting the derogation referred to in regulation 9 (1) and (2), Veterinary Services shall fix a maximum production limit for each establishment.

When fixing that limit, they shall take particular account of the following parameters: the establishment's structure and layout, the flow of the products, and the storage capacity for raw materials and end products.

(2) The granting of the derogation referred to in sub-regulation (1) is subject to observance by each establishment of the production limit laid down in pursuance of sub-regulation (1).

(3) In no case shall the production limit laid down in sub-regulation (1) exceed a quantity of 7,5 tonnes of finished product per week, or one tonne per week in the case of *foie gras* production.

**Derogation from regulation 8**

**11.** (1). By way of derogation from regulation 8, and where the products concerned are not produced in an establishment approved in accordance with regulation 8, Veterinary Services shall authorise and register all establishments producing other products of animal origin defined in regulation 2 (b) and give each of them a specific official number for inspection purposes and in order to be able to trace the establishment of origin of the products concerned.

However, where production takes place in premises adjacent to an approved slaughterhouse, this approval shall, provided the requirements of these regulations are complied with, be extended to cover the premises in question.

(2) The inspection and monitoring of establishments shall be carried out by the Veterinary Services, which shall at all times have free access to all parts of the establishments, in order to ensure compliance with the requirements of these regulations.

(3) If such inspections reveal that the requirements of these regulations are not being met, the Veterinary Services shall take appropriate action, up to and including the measures provided for in regulation 8 (1), third and fourth subparagraphs.

(4) The analyses and tests must be carried out in accordance with proven and scientifically recognised methods, in particular those laid down in European Community provisions or international standards.

**On-site checks**

**12.** (1) Experts from the European Commission may in co-operation with the Veterinary Services, make onsite checks. Where a check is being carried out, Veterinary Services shall give all the necessary assistance to the experts in carrying out their duties.

In particular access on the same basis as officials of the competent authority shall be given to all concerned persons, information and documentation as well as access to places, establishments, installations and means of transport in order for the checks to be carried out.

**Derogation from regulation 3**

**13.** (1) By way of derogation from the conditions stipulated in regulation 3, it may be decided, in accordance with the procedure laid down in article 10 of the Veterinary Services Act, that some provisions of these regulations shall not apply to meat products which contain other foodstuffs and only a small percentage of meat, meat product or meat preparation. These derogations shall relate only to -

(a) the conditions for approval of establishments as laid down in Schedule A, Chapter I and in Schedule B, Chapter I;

(b) the inspection requirements described in Schedule B, Chapter IV;

(c) the marking requirements laid down in Schedule B, Chapter VI. When considering whether to grant derogations such as those provided for under this regulation, both the nature and the composition of the product shall be taken into account. Notwithstanding the provisions of this regulation, only wholesome products prepared from fresh meat, meat products or products covered by European Union Council Directive 94/65/EC are placed on the market in the territory of Malta.

(2) Until such time as a decision is taken in accordance with sub-regulation (1), European Union Council Directive 83/201/EEC shall continue to apply.

**Rules on veterinary checks in trade**

**14.** The provisions of article 15 of the Veterinary Services Act concerning veterinary checks in trade with Member States, 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 are to be applied.

**Wholesale market**

**15.** (1) For the purposes of these regulations "wholesale market"' means - a market comprising a number of separate establishments which may share common facilities, including common areas in which meat products are produced, stored, displayed and put on the market. A wholesale market may be attached to other approved establishments.

(2) An establishment situated in a wholesale market cannot be placed on the list of approved establishments provided for in regulation 8 (1) of these regulations unless it complies with the conditions of sub-regulation (4).

(3) (a) The establishments or combinations of establishments operating in a wholesale market can receive a veterinary approval number.

(b) The veterinary approval number mentioned in paragraph (a) can be temporarily suspended or withdrawn by the Veterinary Services if an establishment or combination of establishments no longer fulfils the conditions set out in these regulations. This suspension

or withdrawal does not necessarily affect the approval of other establishments of the wholesale market.

(4) (a) Establishments must meet the conditions for the approval of establishments laid down in Chapter 1 of Schedule A to these regulations. However the areas, equipment and facilities referred to at points 1, 3, 4 and 8 to 15 of that Chapter may be used jointly.

To the room referred to in point 12 of Chapter I for the veterinary service, extra rooms may be added if necessary; the room or rooms, may be situated in another part of the wholesale market.

(b) Depending on the product and the working activities the establishments must fulfil the relevant provisions laid down in Chapter I of Schedule B.

(c) "Storage" -

Meat products have to be stored and transported under the conditions laid down in Chapter VII of Schedule B.

If necessary cold rooms for inspecting the goods or cool boxes for displaying the goods shall be provided.

(d) The hygiene conditions laid down in Chapter II of Schedule A and Chapters II, III, IV, V of Schedule B to these regulations must be respected.

All practicable measures must be taken to ensure that persons who have access to the areas in which meat is handled or displayed comply with the requirements as to hygiene in Chapter II of Schedule A and of Schedule B to these regulations.

(e) Supervisory measures are observed as provided for in regulation 8 (2), (3) of these regulations and Chapters IV and VI of Schedule B thereto.

When establishments combine, the operators or owners of the establishments, or their representatives, shall be jointly liable for meeting the conditions for approval and fulfilling the hygiene requirements. For this purpose they shall name a person to be responsible for the regular supervision of general hygiene with regard to production conditions in the combined establishments in accordance with regulation 7 (1) of these regulations.

The name of this person shall be given to the Veterinary Services.
Such an agreement with the combined establishments shall be an essential part of the approval.

(f) The requirements of regulation 3 (i)(9) (b) of these regulations must be respected.

**Conditions for re-wrapping centres which reassemble products**

**16.** (1) (a) Re-wrapping centres which only reassemble products without removing the wrapping must fulfil the relevant conditions set out in Schedule B, Chapter VII, point 1 to these regulations.

(b) Re-wrapping centres carrying out unwrapping and re-wrapping operations, must fulfil the relevant conditions set out in Schedule A, Chapters I and II to these regulations and the pertinent conditions set out in Schedule B, Chapter I, points 1 (a), (b), (d), (e) and (f) and 2 (a), (c), (i) and (j).

(2) (a) Products from the re-wrapping centres referred to in (1) (a) must keep the health mark of the production establishment of origin.

Products from the re-wrapping centres referred to in (1) (b) must carry a health mark in accordance with the provisions set out in Schedule B, Chapter VI to these regulations. The health mark shall be issued to the re-wrapping centres by the Veterinary Services.

Where products from different sources are reassembled, the health mark of the re-wrapping centre must be applied to the last packaging made in the re-wrapping centres.

(b) Re-wrapping centres must set up a special registration system so as to enable the Veterinary Services to trace a re-wrapped product back to the establishment of origin.

**Requirements that may apply to certain products**

**17.** At the request, the Veterinary Services of Malta or on their initiative may decide the relevant requirements in these regulations which would apply to any product with authorisation to be placed on the market in the territory of Malta but whose composition or presentation might give rise to differing interpretation. They may decide also on the methods for checking that the containers referred to in Chapter VIII, point 1 (f), of Schedule B are correctly sealed,

Microbiological standards including sampling plans and methods of analysis for the products referred to in regulation 7 (2) may be decided according to European Community rules and to the procedure laid down in article 10 of the Veterinary Services Act.

**Further checks by Veterinary Services**

**18.** (1) Without prejudice to the specific provisions of these regulations, the Veterinary Services 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 the appropriate administrative or penal measures shall be taken to penalise any infringement of these regulations, in particular where it is found that the certificates or documents drawn up do not correspond to the actual state

of the products referred to in regulation 1, that the marks on the products concerned do not comply with the rules, that the products have not undergone the checks provided for in these regulations or that they were not used for the purpose originally intended.

## SCHEDULE A

## GENERAL CONDITIONS

### CHAPTER I
### General conditions for approval of establishments

Establishments shall afford at least the following facilities -

1. working areas of sufficient size for work to be carried out under adequate hygienic conditions. Their design and layout shall be such as to preclude contamination of the raw materials and the products referred to in these regulations;

2. in areas where the raw materials are handled, prepared and processed and the products referred to in these regulations manufactured -

(a) solid, waterproof flooring which is easy to clean and disinfect and laid in such a way as to facilitate the drainage of the water or provided with equipment to remove water;

(b) walls which have smooth surfaces and are easy to clean, durable and impermeable, covered with a light-coloured, washable coating up to a height of at least two metres, or at least storage height in refrigeration and storage rooms;

(c) ceilings or roof linings which are easy to clean;

(d) doors in non-corrodible materials which are easy to clean;

(e) adequate ventilation and, where necessary, good steam and water-vapour extraction facilities to eliminate as far as possible condensation on surfaces such as walls and ceilings or roof linings;

(f) adequate natural or artificial lighting;

(g) an adequate number of facilities with hot and cold running water, or water premixed to a suitable temperature, for cleaning and disinfecting hands. In work rooms and lavatories, taps must not be hand-operable. These facilities must be provided with cleaning and disinfecting products and hygienic means of drying hands;

(h) facilities for cleaning tools, equipment and utensils;

3. in rooms where the raw materials and the products covered by these regulations are stored, the same conditions as those in point 2 apply, except in -

- chilling and refrigeration rooms, where a floor which is easy to clean and disinfect, laid in such a way as to facilitate the draining of water is sufficient,

- freezing and deep-freezing rooms, where waterproof and rot-proof flooring which is easy to clean is sufficient, in that case, a sufficiently powerful refrigeration plant to keep the raw materials and products at the temperatures prescribed in these regulations must be available. The use of wooden walls in the rooms referred to in the second indent does not constitute grounds for withdrawing approval provided they were built before 1 January 1983. The capacity of the store rooms must be adequate to store the raw materials used and the products referred to in these regulations;

4. facilities for hygienic handling and protection of raw materials and non-packaged or wrapped finished products during loading and unloading;

5. appropriate arrangements for protection against pests such as insects, rodents, birds, etc.;

6. instruments and working equipment such as cutting tables, containers, conveyor belts, saws and knives, intended to come into direct contact with raw materials and products made of corrosion-resistant material and easy to clean and disinfect;

7. special watertight, non-corrodible containers, with lids and fasteners to prevent unauthorised persons from removing things from them, in which to put raw materials or products not intended for human consumption, or a lockable room for such purposes if the quantities are large enough to necessitate this or if they are not removed or destroyed at the end of each stage of work. Where such raw materials or products are removed through conduits, these must be so constructed and installed as to avoid any risk of contamination of the other raw materials or products;

8. appropriate facilities for the cleaning and disinfecting of equipment and utensils. For disinfecting equipment and utensils, water of a temperature of not less than 82°C or other disinfection methods approved by the Veterinary Services, must be used;

9. a waste water disposal system which meets hygiene requirements;

10. a supply of potable water only, within the meaning of Malta rules on the quality of water intended for human consumption. However, the use of non potable water is authorised in exceptional cases for steam production, fire fighting and refrigeration equipment, provided that the pipes installed for this purpose preclude the use of this water for other purposes and present no direct or indirect risk of contamination of the product. Non-potable water pipes must be clearly distinguished from those used for potable water;

11. an appropriate number of changing rooms with smooth, waterproof washable walls and floors, wash basins and flush lavatories. The latter must not open directly on to the work rooms. Wash basins must be equipped for hand washing and have hygienic means of drying hands; washbasin taps must not be hand operable;

12. if the volume of products treated requires regular or permanent presence, an adequately equipped lockable room for the exclusive use of the inspection service. Where the Veterinary Services is not required to be present at all times, a lockable device of sufficient capacity for storage of equipment and materials is sufficient

13. a room or a secure place for the storage of detergents, disinfectants and similar substances;

14. a room or cupboard for storing cleaning and maintenance material;

15. adequate facilities for cleaning and disinfecting means of transport; unless with the agreement the Veterinary Services, facilities not situated in the establishment may be used;

16. where the treatment applied requires the absence of water for manufacture of the products, certain requirements of this Chapter, in particular those laid down in points 2 (a) and (g), may be adjusted. Should recourse be had to such a derogation, cleaning and disinfecting processes which do not make use of water may, with the authorisation of the Veterinary Services, be applied in the parts of the establishment concerned.

## CHAPTER II
## General conditions of hygiene

A. General conditions of hygiene applicable to premises, equipment and tools

1. Equipment and instruments used for working on raw materials and products, floors, walls and partitions, ceilings or roof linings, must be kept in a satisfactory state of cleanliness and repair, so that they do not constitute a source of contamination for raw materials or products. Cleaning and disinfecting must be performed with a frequency and by means of processes, which are in line with the principles set out in regulation 7 of these regulations.

2. No animals may enter the establishments. Rodents, insects and any other vermin must be systematically exterminated in the premises or on the equipment; rodenticides, insecticides, disinfectants and any other potentially toxic substances must be stored in premises or cupboards, which can be locked; their use must not present any risk of contamination of the products.

3. Working areas, instruments and working equipment must be used only for work on products for which approval has been granted. However, following authorisation by the Veterinary Services, they may be used at the same time or other times for work on other foodstuffs fit for human consumption. This restriction does not apply to transport equipment used in premises where no work is done on raw materials or products covered by these regulations.

4. Potable water, within the meaning of Maltese rules on supplying of potable water, must be used for all purposes. However, by way of exception, non-potable water may be used for steam production, fire fighting and the cooling of equipment, provided that the pipes installed for the purpose preclude the use of such water for other purposes and present no risk of contamination of the raw materials and products.

5. Detergents, disinfectants and similar substances must be used in accordance with the manufacturer's instructions in such a way that they do not have adverse effects on the machinery, equipment, raw materials and products. Their use must be followed by thorough rinsing of such instruments and working equipment with potable water except where the directions for use of such substances render such rinsing unnecessary. Products for maintenance and cleaning must be kept in the room provided for in Chapter I (14) of this Schedule.

6. The spreading of sawdust or any other similar substance on the floor of the workrooms and storage rooms for the raw materials and products referred to in these regulations is prohibited.

B. General conditions of hygiene applicable to staff

1. Absolute cleanliness is required of staff. Specifically -

(a) staff must wear suitable clean working clothes and headgear which completely encloses the hair. This applies particularly to persons handling exposed, non-packaged raw materials and products;

(b) staff assigned to the handling and preparation of raw materials and products must be required to wash their hands at least each time work is resumed and, or where contamination has occurred; wounds to the hands must be covered by a waterproof dressing;

(c) smoking, spitting, eating and drinking in rooms where raw materials and products are worked on or stored is prohibited.

2. The employer shall take all the requisite measures to prevent persons liable to contaminate raw materials and products from handling them, until there is evidence that such persons can do so without risk. When recruited, any person working on and handling raw materials and products shall be required to prove, by a medical certificate, that there is no impediment to such employment. The medical supervision of such a person shall be governed by the Maltese legislation in force or in the case of third countries by specific guarantees to be fixed under the procedure laid down in European Community rules.

## SCHEDULE B

## SPECIAL CONDITIONS FOR MEAT PRODUCTS

### CHAPTER I
### Special conditions for approval of establishments preparing meat products

1. In addition to the general requirements laid down in Schedule A, Chapter I, establishments manufacturing, handling and wrapping meat products shall have at least -

(a) suitable rooms large enough for the separate storage -

(i) of raw materials, under refrigeration;

and

(ii) of meat products at ambient temperature or, where appropriate, depending on the nature of the products, under refrigeration; on the understanding that non-packaged raw materials, meat products and other products of animal origin must be stored separately from packaged raw materials and products;

(b) one or more appropriate rooms large enough for the manufacture and wrapping of meat products. Provided these operations constitute a single production cycle complying with the requirements of these regulations and guaranteeing the safety of the raw materials and finished products, and provided the design and dimensions of the manufacturing room allow, they may be carried out in the same room;

(c) a room or a secure place for the storage of certain ingredients such as food additives;

(d) a room for packaging, unless the conditions laid down for packaging in Chapter V, point 3 are fulfilled, and for dispatch;

(e) a room for the storage of wrapping and packaging materials;

(f) a room for cleaning equipment and instruments, such as hooks and containers.

2. Depending on the type of product involved, the establishment must have -

(a) a room or of there is no danger of contamination an area where packaging is removed;

(b) a room or if there is no danger of contamination an area for thawing raw materials;

(c) a cutting room;

(d) a room or equipment for drying or maturing;

(e) a room or equipment for smoking;

(f) a room for desalting, soaking and any other treatment, particularly of natural guts, where these raw materials have not undergone such operations in the establishment of origin;

(g) a room for the prior cleaning of the raw materials needed to prepare meat products;

(h) a room for salting, if necessary with air-conditioning facilities to maintain the temperature provided for in Chapter II (4) ;

(i) a room for the prior cleaning, if necessary, of meat products to be sliced or cut and wrapped;

(j) a room, if necessary with air-conditioning facilities, for slicing or cutting and packaging of meat products intended for sale in pre-packed form;

(k) the specific rooms provided for in Schedule C, where the products referred to therein are manufactured in the establishments referred to in this Chapter;

(l) where the conditions laid down in 1 (b) are met, it may be decided following agreement by the Veterinary Services, that some of these operations may be carried out in the same room. Where the conditions laid down in 1 (b) are not met, operations which might constitute a health risk in the case of certain products manufactured simultaneously and operations associated with excessive heat production must be carried out in a separate room.

## CHAPTER II
## Special conditions of hygiene for establishments preparing meat products

1. Rooms used for storing or working on foodstuffs other than meat or meat products, liable to form part of the composition of meat products, must be subject to the general rules on hygiene laid down in these regulations.

2. Raw materials and the ingredients forming part of the composition of meat products as well as the products themselves and products of animal origin and their containers shall not come into direct contact with the ground and shall be handled under conditions which preclude any risk of contamination. Care must be taken to ensure that there is no contact between raw materials and finished products.

3. The use of wood is permitted in rooms in which meat products are smoked, cured, matured, pickled, stored or dispatched, when essential for technological reasons, provided there is no risk of the products being contaminated. Wooden pallets may be brought into the said rooms solely for transporting packaged meat or meat products and for no other purposes. In addition, the use of galvanised metals may be authorised for the drying of hams and sausages, provided that they are not corroded and do not come into contact with the meat products.

4. The temperature in rooms or parts of rooms where work on meat, minced meat used as a raw material, meat products and meat preparations is carried out must ensure hygienic production; if necessary, such rooms or parts of rooms must be provided with air-conditioning facilities. During cutting, slicing and curing operations rooms for cutting and curing must be kept at a temperature not exceeding 12° C, except in the case of the establishments referred to in regulation 9. However, in the case of other establishments the Veterinary Services may derogate from this requirement where it considers such a derogation justified in the light of the technology used in preparing the meat product.

## CHAPTER III
## Requirements for raw materials to be used for the manufacture of meat products

1. Meat which is to be used for the manufacture of meat products must -

- come from an establishment approved in accordance with the Directives referred to in regulation 2 (d) and have been transported under satisfactory hygiene conditions in accordance with the said Directives,

- from the time of its arrival in the processing establishment until the time of its use, be kept in accordance with the requirements of the Directives referred to in regulation 2 (d).

2. Minced meat and meat preparations, unless produced in the manufacturing room referred to in Chapter I (1) (b), must -

- come from an establishment approved and have been transported under satisfactory health conditions,

- from the time of their arrival in the processing establishment until the time of their use, be kept in accordance with the requirements of European Union Council Directive 94/65/EEC.

3. The presence of products of animal origin, other than meat as defined in regulation 2 (d) contained in meat products, is authorised only if these products comply with the requirements laid down in the relevant Maltese legislation.

## CHAPTER IV
## Supervision of production

1. Establishments shall be subject to supervision by the Veterinary Services, which must ensure that the requirements of these regulations are met and in particular -

(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 regulation 7, notably by examining the results and taking samples;

(iii) the microbiological and hygienic condition of the products of animal origin;

(iv) the efficacy of the treatment of the meat products;

(v) the hermetically sealed containers by means of random sampling;

(vi) the appropriate health marking of the meat products and identification of products declared unfit for human consumption and what is done with the latter;

(vii) the storage and transport conditions;

(b) take any samples required for laboratory tests;

(c) make any other checks it considers necessary to ensure compliance with these regulations;

(d) establish whether a meat product has been made from meat in which other foodstuffs, additives or condiments have been incorporated, by submitting it to an appropriate inspection and establishing whether it complies with the production criteria laid down by the producer and especially whether the composition of the product truly corresponds to the information on the label, in particular where the sales description referred to in Chapter V (4) is used.

2. The Veterinary Services 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 V
## Wrapping, packaging and labelling

1. Wrapping, packaging and labelling must take place under satisfactory hygiene conditions in rooms provided for that purpose. Without prejudice to the Maltese legislation relating to materials and articles intended to come into contact with foodstuffs, wrapping and packaging must comply with all the rules of hygiene, and be strong enough to protect the meat products effectively.

2. Wrapping or packaging may not be reused for meat products, with the exception of certain special types of containers such as earthenware, glass or plastic containers which may be re-used after thorough cleaning and disinfecting.

3. Manufacture of meat products and packaging operations may take place in the same room if the packaging is as described in 2 or subject to the following conditions -

(a) the room must be sufficiently large and so equipped that the hygiene of the operations is assured;

(b) the packaging and wrapping must be enclosed in a sealed protective cover immediately after manufacture; this cover must be protected from damage during transport to the establishment and stored under hygienic conditions in a room intended for that purpose;

(c) the rooms for storing the packaging material must be free from dust and vermin and have no atmospheric connection with rooms containing substances which might contaminate meat, minced meat, meat preparations or meat products. Packaging must not be placed directly on the floor;

(d) packaging must be assembled under hygienic conditions before being brought into the room. A derogation from this requirement may be granted in the case of the automatic assembly of packaging, provided there is no risk of contamination of the meat products;

(e) packaging must be brought to the room under hygienic conditions and used without delay. It may not be handled by staff handling unwrapped meat, minced meat, meat preparations or meat products;

(f) immediately after packaging, the meat products must be placed in the storage rooms provided for the purpose.

4. In addition to the Maltese requirements relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer, the following information ([1]) must be visible and legibly displayed on the wrapping or on the label of meat products -

- where it is not clear from the sales description of the product or from the list of ingredients, the species from which the meat was obtained,

- a reference permitting identification of a quantity of products obtained in technologically similar conditions and likely to present the same risk,

- for packaging not intended for the final consumer, the date of preparation or a code which can be interpreted by the recipient and by the Veterinary Services allowing the identification of that date

- the sales description followed by a reference to the national standard or legislation ([2]) authorising it,

- where is authorised the use of proteins or starch, a reference to such use in connection with the sales description other than that which is authorised in relation with a technological viewpoint.

([1]) This information must accompany the meat products up to the final consumer stage, except in the case referred to in the third indent.

([2]) The words "national standard or legislation" cover -

(a) the conditions of production or preparation authorised under national law;

(b) the particular rules of national law imposing specific constraints on conditions of production or preparation for certain products;

(c) all sales descriptions which, in the absence of national standards limiting them, are permitted by the law of a Malta or where that description has been confirmed by usage.

## CHAPTER VI
## Health mark

1. Meat products must carry a health mark. Marking must be carried out during or immediately after manufacture in the establishment or wrapping centre, in an easily visible place in legible and indelible characters which are easy to distinguish. The health mark may be applied directly to the product or to its wrapping, if the meat product is individually wrapped, or to a label affixed to the wrapping in accordance with point 4 (b). However, where a meat product is wrapped and packaged individually, a health mark applied to the packaging is sufficient.

2. Where meat products carrying a health mark in accordance with point 1 are then packaged, the health mark must also be applied to the packaging.

3. By way of derogation from points 1 and 2, the health marking of meat products is not necessary -

(a) where the health mark, in compliance with point 4, is applied to the external surface of each sales unit containing them;

(b) where, for meat products in consignments intended for further processing or wrapping in an approved establishment -

- the said consignments bear the health mark of the approved establishment consigning them in a visible place on the external surface, together with a clear indication of the intended destination,

- the recipient establishment maintains a record of the quantities, type and origin of meat products received in accordance with this point, and stores that record for the period laid down in the fourth indent of the second subparagraph of regulation 7 (1) of these regulations.
However, meat products in large packaging which are intended for immediate sale without further processing or wrapping must bear a health mark in compliance with point 1, 2 or 3 (a) (c) where, for meat products which are not wrapped or packaged but sold in bulk by the manufacturer directly to a retailer:

- the health mark, in compliance with point 1, is applied to the container carrying them,. the manufacturer maintains a record of the quantities and type of the meat products consigned in accordance with this point, and of the name of the recipient and stores that record for the period laid down in the fourth indent of the second subparagraph of regulation 7 (1) of these regulations.

4 (a) The health mark must give the following particulars within an oval surround -

(i) either -

- above: Iso code for Malta in printed capitals, followed by the approval number of the establishment or, the re-wrapping centre in accordance with regulatiuon 16, if necessary accompanied by a code number stating the type of product for which the establishment is approved,

- below. the following sets of initials. KE

(ii) or -

- above, MALTA in capitals,

- in the centre, the approval number of the establishment or, the re-wrapping centre in accordance with regulation 16. if necessary accompanied by a code number stating the type of product for which the establishment is approved,

- below, the following sets of initials: KE;

(b) the health mark may be applied directly to the product by authorised means, or be pre-printed on its wrapping or packaging, or to a label affixed to the product, its wrapping or packaging. Where it is applied to the wrapping, the stamp must be destroyed when the wrapping is opened. Failure to destroy the stamp can be tolerated only where the wrapping is destroyed opening it. In the case of products in hermetically sealed containers, the mark must be applied indelibly either to the lid or the can;

(c) the health mark may also consist of an irremovable plate of resistant material complying with all the hygiene requirements and bearing the information specified in (a).

5. Where a meat product contains other foodstuffs of animal origin such as fishery products, dairy products or egg products, only one health mark must be applied

## CHAPTER VII
## Storage and transport

1 Meat products must be stored in the rooms provided for in Schedule B, Chapter I, point 1 (a). However, meat products may also be stored outside the rooms provided for in that point on the following conditions -

a) meat products which cannot be kept at ambient temperatures may be stored in cold storage plant as provided under European Community rules or in cold storage plants approved in accordance with the other Community rules;

b) meat products which can be kept at ambient temperatures may be stored in stores, of solid construction, easy to clean and disinfect, and approved by the Veterinary Services.

2. Meat products for which certain storage temperatures are indicated in accordance with regulation 7 (2) must be maintained at those temperatures.

3. Meat products must be dispatched in such a way that they are protected during transportation from anything, which might contaminate or adversely affect them. For this purpose account shall be taken of the length of the journey, the means of transport employed and the weather conditions.

4. Meat products must, if the product so requires, be transported in vehicles equipped to ensure that they can be transported at the required temperatures and in particular that the temperatures indicated in accordance with regulation 7 (2) are not exceeded.

5. The commercial document referred to in regulation 3 (9) (b) (i) of these regulations must accompany meat products during the first stage of marketing. For transport and marketing at subsequent stages, the products must be accompanied by a commercial document bearing the approval number of the consigning establishment identifying the Veterinary Services responsible for control.

## CHAPTER VIII
## Special conditions for pasteurised or sterilised products in hermetically sealed containers

A. In addition to the conditions laid down in Schedule A, establishments manufacturing pasteurised or sterilised products in hermetically sealed containers -

1. must have -

(a) a device for conveying empty cans hygienically to the work room;

(b) equipment enabling cans to be thoroughly cleaned immediately before filling;

(c) equipment for washing containers in potable water hot enough to remove grease after they have been hermetically sealed and before retorting;

(d) a suitable room, area or installation for cooling and drying containers after heat treatment;

(e) facilities for the incubation of samples taken from meat products packed in hermetically sealed containers;

(f) adequate facilities for checking whether containers are hermetically sealed and undamaged;

2. must ensure that -

(a) hermetically sealed containers are removed from the heating equipment at a sufficiently high temperature to ensure rapid evaporation of humidity and are not touched by hand until completely dry;

(b) containers in which gas appears to be present undergo a further examination;

(c) the thermometers of heating equipment are checked against calibrated thermometers;

(d) containers are -

- rejected if damaged or badly made,

- rejected or cleaned if they are dirty and, in the case of cans, thoroughly cleaned immediately before filling, by means of the cleaning equipment referred to in 1 (b) ; the use of stagnant water is not authorised,

- if necessary, drained for a sufficiently long time after cleaning and before filling,

- if necessary, washed in potable water, sufficiently hot to remove grease if appropriate, after they have been hermetically sealed and before retorting, by means of the equipment referred to in 1 (c),

- cooled, after heating, in water meeting the requirements in the fifth indent of B,

- handled, before and after heat treatment, in such a way that any damage or contamination is avoided.

B. The operator or manager of an establishment manufacturing meat products in hermetically sealed containers must also check by sampling that -

1) a heat treatment is applied to meat products intended for storing at ambient temperature which is capable of destroying or inactivating pathogenic germs and the spores of pathogenic micro-organisms. A register of manufacturing parameters such as duration of heating, temperature, filling, size of containers, etc must be kept. The heat treatment apparatus must be fitted with control devices making it possible to check that containers have undergone effective heat treatment,

2) the material used for the containers meets European Community requirements relating to materials intended to come into contact with foodstuffs;

3) checks on the daily output are carried out at intervals determined in advance, to ensure the efficacy of the sealing. To this end, suitable equipment must be available for examining perpendicular sections and the seams of the sealed containers.

4) additional checks by sampling are carried out be the manufacturer to ensure that -

a) sterilised products have undergone effective treatment, by means of -

- incubation tests. Incubation must be performed at least 37°C for seven days or at least 35°C for 10 days, or any other time-temperature combination recognised as equivalent by the Veterinary Services.

- microbiological examination of the contents and the containers in the establishment's laboratory or in another approved laboratory;

b) pasteurised products in hermetically sealed containers satisfy criteria recognised by the Veterinary Services;

5) the necessary checks are carried out to ensure that the cooling water contains a residual level of chlorine after use. Veterinary Services may, however, grant derogation from this requirement if the water fulfils the requirements of Maltese rules on potable water.

C. The Veterinary Services may authorise the addition of certain substances to the water used in retorts in order to prevent corrosion of cans and to soften and disinfect the water. A list of these substances will be drawn up by the Veterinary Services.

The Veterinary Services may allow the use of re-circulated water for cooling heat-processed containers. Such water must be purified and have either been treated with chlorine or undergone some other treatment approved by the Veterinary Services. The purpose of such treatment is to make the re-circulated water comply with the standards laid down in Malta rules on supplying of potable water so that it cannot contaminate the products and does not constitute a hazard to human health. The re-circulated water shall circulate in closed circuit so that it cannot be used for other purposes.

Where there is no risk of contamination, the water used for cooling containers and water from retorts may be used at the end of a working period for cleaning floors.

## CHAPTER IX
## Special conditions for meat-based prepared meals

In addition to the general conditions in Schedule A and in Chapters I, II and III of this Schedule -

1. establishments manufacturing prepared meals must have a separate room for the preparation and wrapping of prepared meals; a separate room is not required where meat products and meat are handled at separate times, provided the rooms used for these operations are cleaned and disinfected between use for each type of product;

2. (a) the meat product contained in the prepared meal must, as soon as it has been cooked -

(i) either be mixed with the other ingredients as soon as practically possible; in that event the time during which the temperature of the meat product is between 10 and 60°C must be kept to a maximum of 2 hours;

(ii) or be refrigerated to 10°C or less before being mixed with the other ingredients;

Where other preparation methods are applied, these must be approved by the Veterinary Services, which shall inform the European Commission accordingly

(b) the meat product and the prepared meal must be refrigerated to an internal temperature of + 10°C or less within a period of not more than two hours after the end of cooking and to the storage temperature as soon as possible. However, the Veterinary Services may authorise the establishment to derogate from the two-hour period where a longer period is justified for reasons connected with the production technology employed, provided that the safety of the end product is guaranteed;

(c) the prepared meal must, where appropriate, be frozen or quick-frozen immediately after cooling.

3. labelling of prepared meals must comply with Maltese requirements relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer. The list of ingredients shall, for the purpose of these regulations, include an indication of the animal species. Prepared meals shall bear the date of manufacture very clearly on one of the outer surfaces of the wrapping in addition to the information already specified;

4. the results of the various checks to be carried out by the operator or manager must be kept, so that they can be shown on receipt of any request from the Veterinary Services, for a minimum period to be specified by the Veterinary Services according to the durability of the product concerned.

## SCHEDULE C

## SPECIFIC HYGIENE STANDARDS FOR THE MANUFACTURE OF OTHER PRODUCTS OF ANIMAL ORIGIN

### CHAPTER I
### General conditions

The premises may be used for the production of products not intended for human consumption only under the following conditions -

(a) raw materials unfit for human consumption must be stored in a completely separate room or separate reception area;

(b) they must be processed in separate rooms using separate installations and equipment, except where the processing takes place in completely enclosed installation or equipment used exclusively for this purpose;

(c) the final products from these raw materials must be stored in a different room or separate tanks which are labelled appropriately and must not go for human consumption.

### CHAPTER II
### Special conditions for rendered animal fats, greaves and by-products

In addition to the conditions in Schedule A, the following conditions apply -

A. Standards applicable to establishments collecting or processing raw materials

1. Centres for the collection of raw materials and further transport to processing establishments must be equipped with a cold store to store raw materials at a temperature of 7° C or less, unless the raw materials are collected and rendered within the time limits laid down in B (3) (b) and (c).

2. The processing establishment must have at least –

(a) a cold store, unless the raw materials are collected and rendered within the time limits laid down in B (3) (b) and B (3) (c) ;.

(b) a room or place to receive raw materials;

(c) an installation to facilitate the visual inspection of raw materials;

(d) if appropriate, an installation to crush raw materials;

(e) equipment for the rendering of raw materials by heat or pressure or other appropriate method;

(f) containers or tanks in which the fat can be kept in liquid state;

(g) apparatus for plastification or crystallisation of the fat to facilitate market preparation and packaging, unless the establishment dispatches liquid rendered animal fat only;

(h) a dispatch room, unless the establishment dispatches melted animal fat only by means of tankers;

(i) watertight containers for the disposal of raw materials unfit for human consumption;

(j) if appropriate, suitable equipment for the preparation of products consisting of rendered animal fat mixed with other foodstuffs and, or seasonings;

(k) if greaves are intended for human consumption, suitable facilities ensuring hygienic collection, wrapping and packaging and storage under the conditions laid down in B (9).

B. Additional hygiene requirements relating to the preparation of rendered animal fat, greaves and by-products

1. Raw materials shall originate from animals which, after ante and post mortem inspection, have been found fit for human consumption.

2. The raw materials shall consist of adipose tissues or bones found fit for human consumption and which are reasonably free from blood and impurities. They must not show signs of deterioration and must be obtained under hygienic conditions.

3 (a) For the preparation of rendered animal fat, only adipose tissues or bones, collected at slaughterhouses, cutting plants or meat processing establishments shall be used. Raw materials shall be transported and stored until rendering in hygienic conditions and at an internal temperature of 7°C or less;

(b) by way of derogation from (a), raw materials may be stored and transported un-refrigerated provided that they are rendered within twelve hours after the day on which they were obtained;

(c) by way of derogation from (a), raw materials collected at retail shops or in premises adjacent to sales points, where the cutting and the storage of meat or poultry-meat is performed for the sole purpose of supplying the final consumer directly, may be used for the preparation of rendered animal fat, provided they are in satisfactory hygienic condition and properly packed. When the raw materials are collected daily the temperature requirements laid down in (a) and (b) must be complied with. If the raw materials are not collected daily, they must be refrigerated immediately after they have been obtained.

4. Vehicles and containers for the collection and transport of raw materials must have smooth internal surfaces, easy to wash, clean and disinfect and vehicles must be adequately covered. Vehicles for refrigerated transport must have been designed in such a way that the temperature required can be maintained throughout the period of transport.

5. Before rendering, raw materials shall be inspected for the presence of raw materials unfit for human consumption, or extraneous matter. When present these must be removed.

6. Raw materials shall be rendered by heat, pressure or other appropriate method, followed by separation of the fat by decantation, centrifugation, filtration or other appropriate method. The use of dissolvent is prohibited.

7. Rendered animal fat which is prepared in accordance with points 1, 2, 3, 5 and 6 may be refined in the same or another establishment to improve its physicochemical quality when the fat for refining satisfies the standards laid down in point 8.

8. Rendered animal fat, depending on type, must meet the following standards –

| | **Bovines** | | | **Pigs** | | | **Other animal fat** | |
|---|---|---|---|---|---|---|---|---|
| | Edible tallow | | Tallow for refining | Edible pig fat | | Lard and other pork fat for Refining | Edible | For refining |
| | Premier jus ([1]) | Other | | Lard ([2]) | Other fat | | | |
| FFA (m/m oleic acid) maximum | 0, 75 | 1.25 | 3, 0 | 0, 75 | 1, 25 | 2, 0 | 1, 25 | 3, 0 |
| Maximum peroxide | 4 meq/kg | 4 meq/kg | 6 meq/kg | 4meq/kg | 6 meq/kg | 6 meq/kg | 4 meq/kg | 10 meq/ kg |
| Moisture and impurities | max 0.5% | | | | | | | |

| | |
|---|---|
| Odour, taste, colour | Normal |

(1) Rendered animal fat obtained by the low-temperature rendering of fresh fat from the heart, caul, kidneys and mesentery of bovine animals, and fat from cutting rooms.
(2) Fresh fat obtained from rendering the adipose tissues of swine.

9. Greaves intended for human consumption shall be stored -

(i) when rendered at a temperature of 70°C or less: at a temperature of less than 7°C for a period not exceeding 24 hours or at 18°C or lower;

(ii) when rendered at a temperature of more than 70°C and having a moisture content of 10 % (m/m) or more -

- at a temperature of less than 7°C for a period not exceeding 48 hours or at a time, temperature ratio offering an equivalent guarantee,

- at 18°C or lower;

(iii) when rendered at a temperature of more than 70°C and having a moisture content of less than 10 % (m/m) : no specific requirement.

## CHAPTER III
## Special conditions for stomachs, bladders and intestines

In addition to the conditions in Schedule A, and Chapters I, II and III of Schedule B, establishments treating stomachs, bladders and intestines must comply with the following conditions -

1. premises, instruments and tools must be used only for work on the products concerned; there must be a clear division between clean and unclean sections;

2. the use of wood is forbidden; however the use of wooden pallets is authorised for the transport of the containers of the products concerned;

3. premises must be provided for storing wrapping and packaging materials;

4. wrapping and packaging must take place under hygienic conditions in a room or in a place intended for that purpose;

5. products which cannot be kept at ambient temperature must be stored until their dispatch in premises intended for that purpose. In particular, products which are not salted or dried must be kept at a temperature not exceeding 3°C;

6. Raw materials must be transported from the slaughterhouse of origin to the establishment under satisfactory hygiene conditions and, where appropriate in the light of the period between slaughter and the collection of the raw materials, refrigerated. Vehicles and containers for transporting such materials must have smooth internal surfaces, which are easy to wash, clean and disinfect. Vehicles for refrigerated transport must have been designed in such a way that the temperature required can be maintained throughout the period of transport.

## ANNEX D

## HEALTH CERTIFICATE FOR MEAT PRODUCTS ([1])

No ([2]): .....
Exporting country:.....
Ministry:.....
Department concerned: .....
Reference ([2]): .....

I. Identification of meat products
Products manufactured with meat from:.....
(Animal species)

Nature of products ([3]): .....
Nature of packaging:.....
Number of individual items or of packages:.....
Storage and transport temperature ([3]): .....
Storage life ([4]): .....
Net weight:.....

II. Origin of meat products
Address (es) and approval number (s) of approved processing establishment (s)
:.....
If necessary:
Address (es) and approval number (s) of approved cold store (s)
:.....

III. Destination of meat products
The meat products are to be sent from:.....
(Place of dispatch)

to:.....
(Country of destination).

by the following means of transport ([5]) :.....
Name and address of consignor:.....
.....
Name and address of consignee:.....
.....

IV. Health attestation
I, the undersigned, certify that the meat products described above -
(a) were manufactured from fresh meat or meat products under the specific conditions laid down in European Union Council Directive 77/99/EEC ([6]) ;
(b) were prepared with meat from animal species other than those referred to in article 2(d) of European Union Council Directive 77/99/EEC ([6]);
(c) are intended for the Hellenic Republic ([6]).

V. If necessary: In the event of unloading and reloading in an approved establishment or approved cold store, indicate:
(a) the place of unloading and reloading (address and approval number) -
(b) the means of transport ([5])

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

.....

Stamp

(Signature of competent authority).

.....
(Name in capital letters)

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([1]) Within the meaning of article 2 of European Union Council Directive 77/99/EEC.
([2]) Optional.
([3]) Mention any ionising radiation for medical reasons.
([4]) To be completed where an indication is given in accordance with article 7 of the European Union Council Directive 77/99/EEC.
([5]) Indicate the number or registration number (railway wagons and lorries), the flight number (aircraft) or the name (ship).
([6]) Delete as appropriate.

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