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VETERINARY SERVICES ACT, 2001
(ACT XXIII OF 2001)

Health Rules for the Production and Placing on the market of Raw Milk, Heat-Treated Milk and Milk-Based Products Regulations, 2004

IN exercise of the powers conferred by articles 10, 11, 12 of the Veterinary Services Act, 2001, the Minister for Rural Affairs and the Environment has made the following regulations -

CHAPTER I

General Rules

Title, scope and application

1. (1) The title to these regulations is Health Rules for the Production and Placing on the market of Raw Milk, Heat-Treated Milk and Milk-Based Products Regulations, 2004.

(2) The scope of these regulations is the implementation of European Union Council Directive 92/46/EEC laying down health rules for the production and placing on the market of raw milk, heat-treated drinking milk, milk for the manufacture of milk-based products and milk-based products intended for human consumption.

(3) These regulations shall not affect national rules applicable to the direct sale to the consumer by a producer of raw milk obtained from a herd officially free of tuberculosis and officially free or free of brucellosis, or of milk-based products made on his holding with such raw milk, provided that the hygiene conditions of the holding comply with the minimum health rules laid down in accordance with the procedure laid down in article 10 of the Veterinary Services Act.

(4) These regulations shall apply, as regards the health rules, without prejudice to European Community rules concerning-

(a) the common organisation of the market in milk and milk products;

(b) certain partly or wholly dehydrated preserved milk for human consumption;

(c) certain lactoproteins (caseins and caseinates) intended for human consumption;

(d) the protection of designations used in marketing of milk and milk products and listed in Schedule E of these regulations.

Definitions

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

(1) "raw milk" shall mean milk produced by secretion of the mammary glands of one or more cows, ewes, goats or buffaloes, which has not been heated beyond 40°C or undergone any treatment that has an equivalent effect;

(2) "milk for the manufacture of milk-based products" shall mean either raw milk for processing or liquid or frozen milk obtained from raw milk, whether or not it has undergone an authorised physical treatment, such as heat treatment or thermisation, or is modified in its composition, provided that these modifications are restricted to the addition and, or removal of natural milk constituents;

(3) "heat-treated drinking milk" shall mean either drinking milk intended for sale to the final consumer and to institutions, obtained by heat treatment and presented in the forms defined in Schedule C, Chapter I.A. 4 (a), (b), (c) and (d) or milk treated by pasteurisation for sale in bulk at the request of the individual consumer;

(4) "milk-based products" shall mean milk products, namely products exclusively derived from milk, it being accepted that substances necessary for their manufacture may be added, provided that these substances are not used to replace in part or in whole any milk constituent, and composite milk products, namely products of which no part replaces or is intended to replace any milk constituent and of which milk or a milk product is an essential part either in terms of quantity or for characterisation of the product;

(5) "heat treatment" shall mean any treatment involving heating that causes, immediately after it has been applied, a negative reaction to the phosphatase test;

(6) "thermisation" shall mean the heating of raw milk for at least 15 seconds at a temperature between 57°C and 68°C such that after treatment the milk shows a positive reaction to the phosphatase test;

(7) "production holding" shall mean an establishment at which one or more milk-producing cows, ewes, goats or buffaloes are kept;

(8) "collection centre" shall mean an establishment where raw milk may be collected and possibly cooled and filtered;

(9) "standardisation centre" shall mean an establishment, which is not attached to a collection centre or a treatment or processing establishment, in which raw milk may be skimmed or the natural constituents modified;

(10) "treatment establishment" shall mean an establishment where milk is heat treated;

(11) "processing establishment" shall mean an establishment or production holding where milk and, or milk-based products are treated, processed and wrapped;

(12) "competent authority" shall mean the central authority of a Member State or a third country responsible for carrying out health or public health checks or any authority to which it has delegated that responsibility; in Malta the competent authority is the Veterinary Services;

(13) "wrapping" shall mean the protection of the products referred to in regulation 1 (2) by the use of an initial wrapping or initial container in direct contact with the products concerned as well as the initial wrapper or initial container itself;

(14) "packaging" shall mean the placing of one or more wrapped or unwrapped products as referred to in regulation 1 (2) in a container, as well as the container itself;

(15) "hermetically sealed container" shall mean container which, when sealed, is intended to protect the contents against the entry of micro-organisms during and after heat treatment and which is impervious;

(16) "placing on the market" shall mean the stocking or display with a view to sale, offering for sale, sale, delivery or any other manner of disposal in the territory of Malta with the exception of retail sale, which must be subject to the checks to be laid down according to the European Union Council Directive 93/43/EEC;

(17) "trade" shall mean trade with Member States in goods.

In addition, the definitions in the provisions listed below shall apply as necessary -

Article 2 of European Union Council Directive 64/432/EEC on animal health problems affecting trade with Member States in bovine animals and swine, article 2 of European Union Council Directive 91/68/EEC on animal health conditions governing trade with Member States in ovine and caprine animals. If necessary the definitions enclosed in Maltese rules on organisation of the market in milk and milk products, and on the protection of designations used in marketing of milk and milk products, are also relevant.

(18) "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.

CHAPTER II

Rules governing production in the territory of the Territory of Malta

Requirements for the use of raw milk

3. (1) In the territory of Malta, raw milk is not used for the manufacture of milk-based products or heat-treated drinking milk unless it meets the following requirements -

(a) it comes from animals and holdings which are checked at regular intervals by the Veterinary Services, pursuant to regulation 11 (1);

(b) it is checked in accordance with regulation 9 (2) and regulation 12 and 13 and meets the standards laid down in Schedule A, Chapter IV;

(c) it meets the conditions laid down in Schedule A, Chapter I;

(d) it comes from holdings which meet the conditions laid down in Schedule A, Chapter II;

(e) it meets the hygiene requirements defined in Schedule A, Chapter III.

(2) In the territory of Malta, milk from healthy animals belonging to herds that do not meet the requirements of Schedule A, Chapter I (1) (a) (i) and (b) (i) can be used only for the manufacture of heat-treated milk or for the manufacture of milk-based products after heat treatment under the supervision of the Veterinary Services. In the case of goats milk and sheep milk intended for trade, this heat treatment must take place on the spot.

Requirements for the placing on the market of raw milk for human consumption

4. In the territory of Malta, the placing on the market of raw milk for human consumption in that state is authorised only if such milk meets the following requirements -

(1) it complies with the provisions of regulation 3, Schedule A, Chapter IV.A.3 and Schedule C, Chapter II.B.1;

(2) where it is not sold to the consumer within two hours after the end of milking, it is cooled in accordance with Schedule A, Chapter III;

(3) it satisfies the requirements of Schedule C, Chapter IV;

(4) it satisfies any additional requirements which may be set in accordance with European Community requirements.

Conditions for the placing on the market of heat-treated drinking milk

5. In the territory of Malta heat-treated drinking milk is not placed on the market unless it meets the following conditions -

(1) it must have been obtained from raw milk, purified or filtered by the equipment provided for in Schedule B, Chapter V (e), which must -

(i) comply with regulation 3;

(ii) in the case of cows milk, comply with the provisions of European Community rules on the organisation of the market in milk and milk products for drinking milk;

(iii) if appropriate, have passed through a milk-collection centre fulfilling the conditions laid down in Schedule B, Chapters I, II, III and VI or have been transferred from one tank to another in good hygiene and distribution conditions;

(iv) if appropriate, have passed through a milk-standardisation centre fulfilling the conditions laid down in Schedule B, Chapters I, II, IV and VI. If appropriate, milk intended for the production of sterilised milk and UHT milk may have undergone an initial heat treatment in an establishment fulfilling the conditions laid down in point 2;

(2) it must come from a treatment establishment which meets the conditions laid down in Schedule B, Chapters I, II, V and VI and has been checked in accordance with regulation 9 (2) and regulation 12;

(3) it must have been treated in accordance with Schedule C, Chapter I.A;

(4) it must meet the standards laid down in Schedule C, Chapter II.B;

(5) it must be labelled in accordance with Schedule C, Chapter IV, and be wrapped in accordance with Schedule C, Chapter III, at a treatment establishment where the milk has been subjected to final treatment;

(6) it must have been stored in accordance with Schedule C, Chapter V;

(7) it must be transported under satisfactory conditions of hygiene in accordance with Schedule C, Chapter V;

(8) it must be accompanied during transport by an accompanying commercial document which must -

(a) in addition to the particulars provided for in Schedule C, Chapter IV, bear some indication by which the nature of the heat treatment and the Veterinary Services responsible for supervising the establishment of origin can be identified, if this is not clear from the approval number,

(b) be kept by the consignee for at least one year so that it can be produced at the request of the Veterinary Services.

However, an accompanying document shall not be required in the case of milk transported by the producer for direct delivery to the final consumer;

(9) in the case of cows milk, it must have a freezing point not higher than 0, 520°C and a weight of not less than 1 028 grams per litre, as determined in whole milk at 20°C, or the equivalent as determined in totally fat-free milk at 20°C, and contain a minimum of 28 grams of protein per litre, obtained by multiplying the percentage total nitrogen content of the milk by 6, 38, and a fat-free dry matter content of not less than 8, 50 %.

However, a freezing point higher than 0.52°C shall be acceptable subject to the checks provided for in Schedule C, Chapter I, A.3 (b) showing that there is no extraneous water present.

In the light of seasonal considerations, on the understanding that the relationship between the above parameters must be maintained, these requirements may be amended in accordance with the requirements of the European Community.

Manufacture of milk-based products

6. In the territory of Malta, milk-based products are manufactured only from -

(1) raw milk that either complies with the requirements set out in regulation 3 and the standards and specifications laid down in Schedule C, Chapter I, and if appropriate has passed through a milk-collection or a milk-standardisation centre fulfilling the conditions laid down in Schedule B, Chapters I, II, III, IV and VI; or

(2) milk intended for the manufacture of milk-based products obtained from raw milk which meets the requirements of sub-regulation (1) and -

(a) comes from a treatment establishment which meets the requirements of Schedule B, Chapters I, II, V and VI;

(b) has been stored and transported in accordance with the requirements of Schedule C, Chapter V.

Requisites for milk-based products

7. Milk-based products must -

(1) have been obtained from milk that meets the requirements of regulation 6 or from milk-based products that satisfy the requirements of this regulation;

(2) be prepared in a processing establishment that meets the standards and specifications of Schedule B, Chapters I, II, V and VI and has been checked in accordance with regulation 9 (2) and regulation 12;

(3) meet the standards laid down in Schedule C, Chapter II;

(4) be wrapped and packaged in accordance with Schedule C, Chapter III, and, if they are in liquid form and intended for sale to the final consumer, with point 3 of that Chapter;

(5) be labelled in accordance with Schedule C, Chapter IV;

(6) be stored and transported in accordance with Schedule C, Chapter V;

(7) be checked in accordance with regulation 12 and with Schedule C, Chapter VI;

(8) where appropriate, contain only substances, other than milk, that are fit for human consumption;

(9) have undergone heat treatment during the manufacturing process or be made from products that have undergone heat treatment or involve hygiene specifications that are sufficient to meet the guaranteed hygiene criteria for all finished products. In addition, milk-based products must meet the requirement in regulation 5 (8) regarding the accompanying commercial document.

(10) Milk and milk-based products intended for trade must not have been subjected to ionising radiation.

Manufacture of cheese

8. (1) For the manufacture of cheese with a period of ageing or ripening of at least sixty days the Veterinary Services may grant individual or general derogation as follows -

(a) as regards the characteristics of raw milk, from the requirements of Schedule A, Chapter IV;

(b) provided that the finished product has the characteristics provided for in Schedule C, Chapter II.A, from regulation 7 sub-regulations (2) and (4);

(c) from Schedule C, Chapter IV.B.2. general and particular requirements applicable to the manufacture of individual products and standards specific to this type of product shall be adopted, as necessary in accordance European Community requirements and the procedure laid down in article 10 of the Veterinary Services Act.

(2) In accordance European Community rules and with the procedure laid down in article 10 of the Veterinary Services Act, Veterinary Services may, in so far as certain requirements of these regulations are likely to affect the manufacture of milk-based products with traditional characteristics, be authorised to grant individual or general derogation from regulation 7 (1) to (4), provided that the milk used in the manufacture of such products meets the requirements of Schedule A, Chapter I.

When the decision provided for herein is taken, the general and particular conditions applicable to the manufacture of each specific product shall, if necessary, be determined.

(3) A list of products made with raw milk may be drawn up in accordance with European Community rules and the procedure laid down in article 10 (1) of the Veterinary Services Act.

List of processing and treatment establishments

9. (1) Veterinary Services shall draw up a list of processing establishments and treatment establishments approved by it other than those referred to in regulation 10 and a list of approved collection centres and standardisation centres. Each such establishment or centre shall have an approval number. The Veterinary Services shall not approve the establishments or centres in question unless it is satisfied that they comply with the requirements of these regulations. Where the Veterinary Services finds an obvious failure to comply with the hygiene rules laid down by these regulations or obstacles to an adequate inspection, it shall be empowered -

(i) to act in respect of the use of equipment or premises and to take any requisite measures which may go as far as limiting or temporarily suspending production;

(ii) if the measures provided for in (i) or the measures provided for in the last indent of the second subparagraph of regulation 12 (1) have proved insufficient, to temporarily suspend approval, if appropriate, for the type of production in question. If the operator or manager of the establishment or the centre does not make good the shortcoming noted within the period fixed by the Veterinary Services, the latter shall withdraw approval.

The Veterinary Services 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 of the suspension or withdrawal of approval.

(2) Inspection and supervision of establishments or centres shall be carried out by the Veterinary Services in accordance with Schedule C, Chapter VI.

The establishment or centre 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 or centre will depend on the size of the establishment or centre, the type of product manufactured, risk assessment and the guarantees offered in accordance with the fifth and sixth indents of the second subparagraph of regulation 12 (1).

The Veterinary Services must at all times have free access to all parts of establishments or centres in order to ensure that these regulations is being complied with and, where there is doubt as to the origin of milk or milk-based products, to accounting documents which enable the holding or establishment of origin of the raw material to be traced. Access on the same basis as officials of the competent authority shall be given to the veterinary inspectors of the European Commission, to all concerned persons, by means of information and documentation as well as access to places, establishments, installations and means of transport in order for the checks to be carried out. The Veterinary Services must regularly analyse the results of the checks provided for the regulation 12(1).

It may, on the basis of these analyses, conduct further examinations at all stages of production or on the products. The nature of the checks, their frequency and the methods of sampling and of carrying out micro-biological examinations shall be established in accordance with requirements of European Community and with the procedure laid down in article 10 of the Veterinary Services Act.

The results of the 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 or centre, 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) The detailed rules for the application of this regulation shall be adopted in accordance with European Community requirements and the procedure laid down in article 10 of the Veterinary Services Act.

Granting of approval and derogation

10. (1) Veterinary Services may, when granting approval, grant derogation from the provisions of regulation 7 (2), regulation 12 (2) and Schedule B, Chapters I and V, to establishments manufacturing milk-based products whose production is limited. The Veterinary Services shall assess whether an establishment or a category of establishments

may benefit from derogation as referred to in the first subparagraph according to some criteria.

(2) Uniform criteria for the application of this regulation shall be established in accordance with European Community requirements and with the procedure laid down in article 10 of the Veterinary Services Act.

Veterinary inspections and checks

11. (1) In the territory of Malta -

(a) animals on production holdings undergo regular veterinary inspections to ensure that the requirements of Schedule A, Chapter I, are being complied with.

These inspections may take place on the occasion of veterinary checks carried out pursuant to other animal health or welfare provisions.

If there are grounds for suspecting that the animal health requirements laid down in Schedule A are not being complied with, the Veterinary Services shall check the general state of health of the dairy animals and, should it prove necessary, shall have an additional examination of those animals carried out,

(b) production holdings shall undergo regular checks to ensure that hygiene requirements are being complied with.

If the inspection or inspections referred to in the first subparagraph show that hygiene is inadequate, the Veterinary Services shall take appropriate steps.

(2) The frequency of these checks must take account of the assessment of risk on the production holding concerned. These measures may be amended or supplemented in accordance with European Community requirements and the procedure laid down in articles 10 and 11 of the Veterinary Services Act.

(3) The general hygiene conditions to be complied with by production holdings, in particular the conditions for the upkeep of premises and those relating to milking, shall be adopted in accordance with European Community requirements and the procedure laid down in article 10 of the Veterinary Services Act.

Measures to be taken by the operator or manager of the treatment or processing establishment

12. (1) In territory of Malta the operator or manager of the treatment and, or processing establishment takes all necessary measures to ensure that, at all stages of production, the relevant specifications of these regulations are complied with. To that end, the operator or manager of the establishment must constantly carry out his own checks based on the following principles –

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

(b) monitoring and checking of such critical points by appropriate methods,

(c) taking samples for analysis in a laboratory recognised 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 milk-based products which cannot be stored at ambient temperature, for which this period shall be reduced to two months after the useby or minimum durability date,

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

(f) 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.

In addition, the operator or manager of the establishment must guarantee the correct administration of the health marking.

The requirements of the second subparagraph, first and second indents, and of the third subparagraph must have been communicated to the Veterinary Services, which must regularly monitor compliance therewith.

(2) The operator or manager of the establishment must apply or organise 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 Veterinary Services responsible for the establishment must be involved in the planning and implementation of the programme or, in the case of a programme already in existence on the date of notification of these regulations, in the monitoring of the programme.

(3) Where there are reasonable grounds for suspecting that the requirements of these regulations are not being complied with, the Veterinary Services shall carry out the

necessary checks and, if that suspicion is confirmed, take appropriate measures, up to and including the suspension of approval

(4) The detailed rules for the application of this regulation shall, if necessary, be determined in accordance with European Community requirements and the procedure laid down in article 10 of the Veterinary Services Act.

National measures for the extension of raw milk, heat-treated milk and milk based products examination

13. (1) Veterinary Services shall establish in accordance with the principles and rules of European Union Council Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products, the national measures to be implemented to extend to raw milk, heat-treated milk and milk-based products examination for residues of substances as set up in Annex II of that European Union Directive.

(2) In the territory of Malta, in the context of the checks provided for in regulation 12 tests are carried out to detect any residues of substances having a pharmacological or hormonal action, and of antibiotics, pesticides, detergents and other substances which are harmful or which might alter the organoleptic characteristics of milk or milk-based products or make their consumption dangerous or harmful to human health, insofar as those residues exceed the permitted tolerance limits. If the milk or milk-based products examined show traces of residues which exceed the permitted tolerances, they must be excluded from human consumption. Examinations for residues must be carried out in accordance with proven methods which are scientifically recognised, and in particular those laid down at European Community and International level.

(3) The Veterinary Services shall make spot checks on compliance with the requirements of sub-regulation (2).

(4) A residue control plan shall be established by the veterinary services in accordance with the requirements of European Union Council Directive 96/23/EC taking account of European Community legislation laying down a community procedure for the establishment of maximum residue limits of veterinary medicine products in foodstuffs of animal origin. The veterinary services will submit this residue control plan to the European Commission. The examination of substances may be extended to other than those referred to in sub-regulation (1) according to European Community requirements.

Measures for the usage for other foodstuffs of milk tanks, premises installations and working equipment

14. (1) Milk tanks, premises, installations and working equipment may be used for other foodstuffs provided that all appropriate measures are taken to prevent contamination or deterioration of drinking milk or milk-based products.

(2) Tanks used for milk must bear a clear indication that they may be used only for the transport of foodstuffs.

(3) Where establishments produce foodstuffs containing milk or milk-based products together with other ingredients which have not undergone heat treatment or another treatment having an equivalent effect, such milk, milk-based products and ingredients must be stored separately to prevent cross-contamination, and treated or processed in premises suitable for the purpose.

(4) The detailed rules for the application of this regulation, and in particular the conditions relating to washing, cleaning and disinfecting before reuse, and the conditions of transport, shall be adopted in accordance with European Community rules and with the procedure laid down under article 10 of the Veterinary Services Act.

Onsite checks by experts from the European Commission

15. Experts from the European Commission may, in co-operation with the Veterinary Services, make onsite checks. In particular, they may verify by checking a representative percentage of establishments whether the Veterinary Services are ensuring that approved establishments are complying with these regulations.

Veterinary Services shall give all the necessary assistance to the experts in carrying out their duties.

Access on the same basis as given to officials of the competent authority shall be given to the veterinary inspectors of the European Commission, 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.

Hygiene rules to be ensure by the territory of Malta

16. The territory of Malta shall ensure that the manufacture of products covered by these regulations in which some milk constituents are replaced by products other than milk-based products is subject to the hygiene rules laid down in these regulations.

Organisation, checks and safeguard measures

17. (1) The provisions of European Union Council Directive 89/662/EEC 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 taken.

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

(3) In accordance with the rules laid down under the Veterinary Services Act, the Director for Veterinary Services shall cause a notice in writing where he has reasonable cause to believe that the appropriate administrative or penal measures to penalise any infringement of these regulations would be appropriate to impose, in particular where it is found that the certificates or documents drawn up do not correspond to the actual state of the products referred 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.

Rules which may be established under European Community requirements and article 10 of the Veterinary Services Act

18. (1) In accordance with European Community requirements and the procedure laid down in article 10 of the Veterinary Services Act the following may be established –

(a) the requirements applicable to any product with authorisation to be placed on the market in the territory of Malta or in a Member State but whose composition or presentation might give rise to differing interpretation in Member States,

(b) the methods for checking that the hermetically sealed containers are impervious,

(c) the reference methods and, where necessary, the criteria governing routine methods of analysis and testing to be used to monitor compliance with the requirements of these regulations, and the methods of sampling,

(d) limits and methods to enable a distinction to be made between different types of heat-treated milk as defined in Schedule C, Chapter I,

(e) the methods of analysis for the standards referred to in Schedule A, Chapter IV, and in Schedule C, Chapter I and II.

(2) By way of derogation from regulations 3 and 6, it may be decided, in accordance with European Community requirements and with the procedure laid down in article 10 of the Veterinary Services Act that some provisions of these regulations shall not apply to milk-based products containing other foodstuffs, where percentage of milk or milk-based product is not essential within the meaning of regulation 2 (4). The derogation referred to in the first subparagraph may not relate to -

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

(b) the marking requirements laid down in Schedule C, Chapter IV;

(c) the inspection requirements laid down in Schedule C, Chapter VI. In granting derogation both the nature and the composition of the product shall be taken into account.

(3) Notwithstanding sub-regulation (2), Veterinary Services shall ensure that all milk-based products placed on the market are wholesome products prepared from milk or from milk-based products meeting the requirements of these regulations.

Amendments to the Schedules of these regulations

19. The Schedules to these regulations shall be amended as necessary, in accordance with European Community requirements.

CHAPTER III

Imports from third countries

Conditions applicable to the imports from third countries

20. The conditions applicable to imports from third countries of raw milk, heat-treated milk and milk-based products covered by these regulations must be at least equivalent to those laid down in Chapter II of European Union Council Directive 92/46/EEC for European Community production.

Provisions applicable to regulation 20

21. (1) For the purposes of application of regulation 20, the provisions of the following sub-regulations shall apply.

(2) In order to be imported into the European Community via a border inspection post of the territory of Malta, milk or milk-based products must -

(a) come from a third country on the list to be drawn up in accordance with sub-regulation (3) (a);

(b) be accompanied by a health certificate corresponding to a specimen to be drawn up in accordance with European Community requirements and with the procedure laid down in articles 10 and 12 of the Veterinary Services Act, signed by the competent authority of the exporting country and certifying that the milk or milk-based products meet the requirements of Chapter II of European Union Council Directive 92/46/EEC or any additional conditions or offer the equivalent guarantees referred to in sub-regulation (3) and come from establishments offering the guarantees provided for in Schedule B.

(3) The following shall be established in accordance with European Community requirements and with the procedure laid down in article 12 of the Veterinary Services Act.

(a) a list of third countries or parts of third countries able to provide the territory of Malta, Member States and the European Commission with guarantees equivalent to those provided for in Chapter II and a list of the establishments for which they are able to give these guarantees. This provisional list shall be compiled from the lists of establishments approved and inspected by the competent authorities;

(b) updates of that list in the light of the checks provided for in sub-regulation (4);

(c) the specific requirements and equivalent guarantees established for third countries, which may not be more favourable than those provided for in Chapter II;

(d) the types of heat treatment to be prescribed for certain third countries presenting an animal health risk.

(4) Experts from the European Commission and the Member States shall carry out on-the-spot inspections to verify whether the guarantees given by the third country regarding the conditions of production and placing on the market can be considered equivalent to those applied in the European Community.

(5) Pending the organisation of the inspections referred to in sub-regulation (4), national rules applicable to inspection in third countries shall continue to apply, subject to notification by the Veterinary Services to all the Member States in the relevant Committee, of any failure to comply with hygiene rules found under those inspections.

(6) Individual recognition of treatment or processing establishments shall be replaced by official recognition when these have been established by the European Community.

Organisation and follow up of inspections

22. The principles and general rules laid down in European Union Council Directive 97/78/EC shall apply, with particular reference to the organisation of and follow up to the inspections to be carried out by the Veterinary Services and the safeguard measures to be implemented.

Requirements for the importation into the European Community via border inspection posts

23. The products covered by these regulations are imported into the European Community via a border inspection post of the territory of Malta only if -

(a) they are accompanied by a certificate to be issued by the competent authority of the third country at the time of loading. The certificate must conform to the specimen drawn up in accordance with the procedure of the European Community;

(b) they have satisfied the checks required by European Union Council Directive 97/78/EC and 91/496/EEC.

(2) Pending the establishment of detailed rules for the application of this regulation, the national rules applicable to imports from third countries for which such requirements have not been adopted at European Community level shall continue to apply, provided they are not more favourable than those laid down in Chapter II of European Union Council Directive 92/46/EEC.

Provisions applicable to the lists provided in regulation 21

24. The lists provided for in regulation 21 may include only third countries or parts of third countries -

(a) from which imports are not prohibited as a result of the existence of diseases as referred to in Schedule A or of any other disease exotic to the European Community or pursuant to articles 6, 7 and 14 of European Union Council Directive 72/462/EEC;

(b) which, in view of their legislation and the organisation of their competent authority 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, as capable of guaranteeing the implementation of their legislation in force;

(c) the veterinary services of which are able to guarantee that health requirements at least equivalent to those laid down in Chapter II are being complied with.

CHAPTER IV

Final provisions

National reference laboratories

25. (1) The territory of Malta shall designate one or more national reference laboratories for the analysis and testing of milk and milk based products in Malta. These laboratories shall be responsible for -

(a) co-ordinating the activities of the laboratories whose task it is to conduct analyses to check the chemical or bacteriological standards and to conduct the tests provided for in these regulations,

(b) assisting the Veterinary Services in organising the system of checking milk and milk-based products,

(c) periodically organising comparative tests,

(d) disseminating the information supplied by the European Community reference laboratory to the Veterinary Services and the laboratories carrying out analyses and tests on milk and milk-based products.

European Community reference laboratory for analysis and testing of milk and milk-products

26. The European Community reference laboratory for the analysis and testing of milk and milk products is indicated in Schedule D, Chapter I. The duties and tasks of that laboratory are set out in Chapter II of that Schedule and include the co-ordination of the activities of the national reference laboratories referred to in regulation 25.

Transitional Period

27. The provisions of European Union Council Directive 92/46/EEC Annex A, Chapters I, II and IV will come into force on the 31st December 2009.

SCHEDULE A

REQUIREMENTS RELATING TO THE ACCEPTANCE OF RAW MILK AT TREATMENT AND, OR PROCESSING ESTABLISHMENTS

CHAPTER I

Animal health requirements for raw milk

1. Raw milk must originate as follows -

(a) from cows or buffaloes -

(i) belonging to a herd which, pursuant to paragraph 1 of Annex A to European Union Council Directive 64/432/EEC, is; officially tuberculosis-free, brucellosis-free or officially brucellosis-free;

(ii) which do not show any symptoms of infectious diseases communicable to human beings through milk;

(iii) incapable of giving the milk abnormal organoleptic characteristics;

(iv) whose general state of health is not impaired by any visible disorder and which are not suffering from any infection of the genital tract with discharge, enteritis with diarrhoea and fever, or a recognisable inflammation of the udder;

(v) which do not show any udder wound likely to affect the milk;

(vi) which, in the case of cows, yield at least two litres of milk per day;

(vii) which have not been treated with substances dangerous or likely to be dangerous to human health that are transmissible to milk, unless the milk has complied with an official waiting period laid down in European Community provisions on a European Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin;

(b) from sheep and goats -

(i) belonging to a sheep and goat holding officially free or free of brucellosis (Brucella melitensis) within the meaning of article 2 (4) and (5) of European Union Council Directive 91/68/EEC; except where the milk is intended for the manufacture of cheese with a maturation period of at least two months;

(ii) which satisfy the requirements laid down in (a), with the exception of those in points (i) and (vi).

2. When different animal species are kept together on the holding, each species must satisfy the health conditions which would be required if it were alone.

3. If goats are kept together with cows they must undergo a tuberculosis check in accordance with arrangements to be determined in accordance with European Community requirements and the procedure laid down in article 11 of the Veterinary Services Act .

4. Raw milk must be excluded from treatment, processing, sale and consumption if it -

(a) is obtained from animals to which substances within the meaning of European Union Council Directive 96/22/EEC have been administered illegally;

(b) contains residues of substances within the meaning of regulation 13 of these regulations which exceed the permitted level. Milk and milk-based products must not come from a surveillance zone established under European Union Council Directive 85/511/EEC relating to veterinary control in case of occurrence of foot and mouth disease, unless the milk has undergone, under the supervision of the Veterinary Services, initial pasteurisation (71, 7°C for 15 seconds) followed by -

(i) a second heat treatment resulting in a negative reaction to the peroxidase test;

or,

(ii) a drying procedure including heating having an effect equivalent to the heat treatment provided for in (i) ;

or

(iii) a second treatment whereby pH is reduced and kept for at least one hour at less than 6.

CHAPTER II

Hygiene of the holding

1. The raw milk must come from holdings, which are registered and checked in accordance with regulation 11 (1). Where buffaloes, sheep and goats are not kept in the open, the premises used must be designed, constructed, maintained and managed in such a way as to ensure -

(a) good conditions of housing, hygiene, cleanliness and health of the animals;

and

(b) satisfactory hygiene conditions for milking, handling, cooling and storing milk.

2. Premises where milking is performed or milk is stored, handled or cooled must be so sited and constructed as to avoid all risk of contamination of the milk. They must be easy to clean and disinfect and have at least –

(a) walls and flooring which are easy to clean in those areas liable to soiling or infection;

(b) flooring laid in such a way as to facilitate the draining of liquids and satisfactory means of disposing of waste;

(c) adequate ventilation and lighting;

(d) an appropriate and sufficient supply of potable water, complying with the parameters laid down in European Community rules relating to potability of water, for use in milking and in cleaning the equipment and instruments referred to in Chapter III B of this Schedule;

(e) adequate separation from all sources of contamination such as lavatories and dung heaps;

(f) fittings and equipment which are easy to wash, clean and disinfect. In addition, premises for the storage of milk must have suitable milk refrigeration equipment, must be protected against vermin and must have adequate separation from any premises where animals are housed.

3. If a movable milking bail is used, the requirements in point 2 (d) and (f) must be satisfied and in addition the bail must -

(a) be sited on fresh ground which is free from any accumulation of excreta or other waste matter;

(b) provide protection for the milk during the whole period in which it is in use;

(c) be so constructed and finished as to permit the interior surfaces to be kept clean.

4. Where milk-producing animals are kept untethered in the open, the holding must also have a milking parlour or milking area adequately separated from the housing area.

5. The isolation of animals which are infected, or suspected of being infected, with any of the diseases referred to in Chapter I.1 or the separation of the animals referred to in Chapter I.3 from the rest of the herd must be possible and effective.

6. Animals of all species must be kept away from premises and sites where milk is stored, handled or cooled.

CHAPTER III

Hygiene in milking, the collection of raw milk and its transport from the production holding to the collection or standardisation centre or to the treatment establishment or processing establishment - Hygiene of staff

A. Hygiene in milking

1. Milking must be carried out hygienically and under the conditions established in accordance with European Community rules and according to the procedure laid down in article 10 of the Veterinary Services Act.

2. Immediately after milking, the milk must be placed in a clean place, which is so equipped as to avoid adverse effects on the quality of the milk. If the milk is not collected within two hours of milking, it must be cooled to a temperature of 8°C or lower in the case of daily collection or 6°C if collection is not daily.

While the milk is being transported to the treatment and, or processing establishment, the temperature of the cooled milk must not exceed 10°C unless the milk has been collected within two hours of milking. For technological reasons concerning the manufacture of certain milk-based products, the competent authorities may authorise derogation from the temperatures laid down in the first subparagraph provided the end product meets the standards set out in Chapter II of Schedule C.;

B. Hygiene of premises, equipment and tools

1. Equipment and instruments or their surfaces which are intended to come into contact with milk (utensils, containers, tanks, etc., intended for milking, collection or transport) must be made of smooth material which is easy to clean and disinfect, resists corrosion and does not transfer substances to the milk in such quantities as to endanger human health, impair the composition of the milk or adversely affect its organoleptic characteristics.

2. After use, the utensils used for milking, the mechanical milking equipment and the containers which come into contact with the milk must be cleaned and disinfected. After each journey, or after each series of journeys where there is only a very short space of time between unloading and the following loading, but in any event at least once a day, containers and tanks used for transporting raw milk to the milk collection or standardisation centre or to the milk treatment or processing establishment must be cleaned and disinfected before re-use.

C. Staff hygiene

1. Absolute cleanliness shall be required of staff. Specifically -

(a) persons performing milking and handling raw milk must wear suitable clean milking clothes;

(b) milkers must wash their hands immediately before the milking commences and keep them clean as far as practicable throughout the milking. For this purpose, near the place of milking, suitable facilities are required to enable persons performing milking or handling raw milk to wash their hands and arms.

2. The employer shall take all the requisite measures to prevent persons liable to contaminate raw milk from handling it, until there is evidence that such persons can do so without risk of contamination. Any person performing milking or handling raw milk shall be required to show that there is no medical impediment to such employment. The medical supervision of such a person shall be governed by the national legislation in force in the territory of Malta or in the case of third countries by specific guarantees fixed by European Community legislation

D. Production hygiene

1. A monitoring system shall be established under the supervision of the Veterinary Services to prevent water being added to raw milk. This system shall in particular include regular checks on the freezing point of milk from each production facility, in accordance with the following procedure -

(a) the raw milk of each holding must be checked regularly by random sampling. Where the milk of a single holding is delivered directly to a treatment or processing establishment, these samples are to be taken either when the milk is collected from the holding, provided that precautions are taken to prevent any fraud during transport, or before unloading at the treatment or processing establishment when the milk is delivered there directly by the farmer.

If the results of a check lead the Veterinary Services to suspect that water is being added, it shall take an authentic sample on the holding. An authentic sample is a sample representing the milk of one completely supervised morning or evening milking beginning not less than eleven hours or more than thirteen hours after the previous milking. Where milk is delivered from several holdings, samples may only be taken when the raw milk enters the treatment or processing establishment or collection or standardisation centre, provided that spot checks are, however, carried out on the holdings. If the results of a check lead to suspicion that water has been added, samples shall be taken at all holdings which took part in the collection of the raw milk at issue. If necessary, the Veterinary Services shall take authentic samples within the meaning of the second subparagraph above;

(b) if the results of the check show that water has not been added, the raw milk may be used for producing raw drinking milk, heat-treated milk or milk for the manufacture of milk-based products for human consumption.

2. The treatment and, or processing establishment shall inform the Veterinary Services when the maximum standards fixed for the plate count and somatic cell count have been reached. The Veterinary Services shall take the appropriate measures.

3. If, within three months of notification of the results of the checks referred to in point 1 (a) and of the investigation provided for in Chapter IV.D, and after the standards of Chapter IV have been exceeded, milk from the holding in question does not meet those standards, that holding shall no longer be authorised to supply raw milk until such milk again meets the said standards.

Milk must not be used for human consumption if it contains antibiotic residues in a quantity which in respect of any of the substances referred to in Annexes I and II to European Union Council Regulation

(EEC) No. 2377/90 exceeds the levels authorised therein; the combined total of residues of antibiotic substances may not exceed the value fixed in accordance with European Community legislation.

CHAPTER IV

Standards to be met at the time of collection from the production holding for acceptance of raw milk at treatment or processing establishments

For compliance with these standards, a separate test shall be carried out on a representative sample of the raw milk collected from each production holding.

A. Raw cows milk

Without prejudice to the limits laid down in Annexes I and II to European Union Council Regulation (EEC) No. 2377/90 –

1. Raw cows milk intended for the production of heat-treated drinking milk, fermented milk, junket, jellied or flavoured milk and cream must meet the following standards -

Plate count 30°C (per ml)	100 000 (a)
Somatic cell count (per ml)	400 000 (b)

(a) Geometric average over a period of two months, with at least two samples a month.

(b) Geometric average over a period of three months, with at least one sample a month. Where production levels vary considerably according to season, Veterinary Services may in conformity with the approval of the European Community apply a different method of calculating results during the low lactation period;

2. Raw cows milk for the manufacture of milk-based products other than those referred to in point 1 must meet the following standards -

Plate count 30°C (per ml)	≤100 000 (a)
Somatic cell count (per ml)	≤400 000 (b)

(a) Geometric average over a period of two months, with at least two samples a month.

(b) Geometric average over a period of three months, with at least one sample a month. Where production levels vary considerably according to season, Veterinary Services may in conformity with the approval of the European Community apply a different method of calculating results during the low lactation period;

3. Raw cows milk intended for direct human consumption and raw cows milk for the manufacture of products made with raw milk whose manufacturing process does not involve any heat treatment must -

(a) meet the standards of point 1;

(b) in addition meet the following standard -

Staphylococcus aureus (per ml): n = 5
m = 500
M = 2 000
c = 2.

Where -
n = number of sample units comprising the sample;
m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all sample units does not exceed m;

M = maximum value for the number of bacteria; the result is considered unsatisfactory if the number of bacteria in one or more sample units is M or more;
c = number of sample units where the bacteria count may be between m and M the sample being considered acceptable if the bacteria count of the other sample units is m or less.

B. Raw buffalo milk

Without prejudice to compliance with the limits laid down in Annexes I and II to European Union Regulation (EEC) No. 2377/90 -

1. Raw buffalo milk for the manufacture of milk-based products must meet the following standards -

Plate count 30°C (per ml)	≤1 000 000 (a)
Somatic cell count (per ml)	≤500 000 (b)

(a) Geometric average over a period of two months, with at least two samples a month.

(b) Geometric average over a period of three months, with at least one sample a month.

2. Raw buffalo milk intended for the manufacture of products made with raw milk whose manufacturing process does not involve any heat treatment must meet the following requirements -

Plate count 30 C (per ml)	≤500 000
Somatic cell count (per ml)	≤400 000
Staphylococcus aureus - as for cow's milk	

C. Raw goats, sheep and buffalo milk

Must meet the following standards -

Without prejudice to compliance with the limits laid down in Annexes I and II to European Union Regulation (EEC) No. 2377/90 -

1. if it is intended for the manufacture of heat-treated drinking milk or heat-treated milk-based products -

Plate count at 30°C (per ml)	≤1 500 000 (a)

2. if it is intended for the manufacture of products made with raw milk by a process which does not involve any heat treatment -

Plate count at 30°C (per ml)	≤500 000 (a)

D. When the maximum standards laid down in A, B and C are exceeded and when subsequent investigation indicates a potential danger to health, the Veterinary Services shall take appropriate measures.

E. Compliance with the standards of A, B and C must be checked by random sampling, either on collection at the production holding or on acceptance of the raw milk at the treatment or processing establishment.

SCHEDULE B

CHAPTER I

General conditions for approval of treatment establishments and processing establishments

Treatment establishments and processing establishments shall have at least –

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 products covered by these regulations. Production of heat-treated milk or manufacture of milk-based products which might pose a risk of contamination to other products covered by these regulations must be carried out in a clearly separated working area;

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

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

(c) in premises where exposed, non-packaged raw materials are handled, prepared or processed, 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;

(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 installations;

3. in rooms where the raw materials and the products covered by these regulations are stored, the same conditions as those at 2 (a) to (f), except -

chilling and refrigeration rooms, where a floor which is easy to clean and disinfect and 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 such cases, 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 of the first subparagraph does not constitute grounds for withdrawing approval provided they were built before 1 January 1993. The capacity of the storerooms must be adequate to store the raw materials used and the products covered by 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;

6. instruments and working equipment 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 in which to put raw materials or products not intended for human consumption. 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;

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

10. a supply of potable water only, within the meaning of Maltese rules relating to the potability of water. However, the supply 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 Veterinary Services;

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 tanks used for transporting milk and liquid or powdered milk-based products. However, such facilities are not compulsory if there is a requirement for the means of transport to be cleaned and disinfected in installations officially approved by the Veterinary Services.

CHAPTER II

General conditions of hygiene in treatment establishments and processing establishments

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

1. Equipment and instruments used for working on raw materials and products, floors, ceilings or roof linings, walls and partitions, 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.

2. No animals may enter rooms in which milk and milk-based products are manufactured and stored. 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 rooms 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 or other products based on milk for human consumption but intended for use other than human consumption, provided they do not create contamination of the products for which approval has been given.

4. Potable water, within the meaning of Malta rules relating to the potability of water, must be used for all purposes. However, by way of exception, non-potable water may be used for the cooling of equipment, steam production and fire-fighting, 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 covered by these regulations.

5. Disinfectants and similar substances must be approved by the Veterinary Services and used in such a way that they do not have adverse effects on the machinery, equipment, raw materials and products covered by these regulations. Their containers must be clearly identifiable and must bear labels with instructions for their use. Their use must be followed by thorough rinsing of such instruments and working equipment with potable water.

B. General conditions of hygiene applicable to staff

1. Absolute cleanliness is required of staff. This applies particularly to persons handling exposed, non-packaged raw materials and products covered by these regulations. Specifically -

(a) staff must wear suitable clean working clothes and clean headgear which completely encloses the hair;

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

(c) smoking, spitting, eating and drinking in rooms where raw materials and products covered by these regulations are worked on or stored shall be prohibited.

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

CHAPTER III

Special requirements for approval of collection centres

In addition to the general requirements laid down in Chapter I, collection centres must have at least –

(a) cooling equipment or appropriate means for cooling milk and, if milk is stored at the collection centre, a cold-storage installation;

(b) if milk is purified at the collection centre, centrifuges or any other apparatus suitable for the physical purification of milk.

CHAPTER IV

Special requirements for approval of standardisation centres

In addition to the general requirements laid down in Chapter I, standardisation centres must have at least -

(a) containers for the cold storage of raw milk, standardisation equipment and containers for the storage of standardised milk;

(b) centrifuges or any other apparatus suitable for the physical purification of milk.

CHAPTER V

Special requirements for the approval of treatment establishments and processing establishments

In addition to the general requirements laid down in Chapter I, treatment establishments and processing establishments must have at least –

(a) equipment for the mechanical filling and proper automatic sealing of containers which are to be used for packaging heat-treated drinking milk and milk-based products in liquid form, after filling, in so far as such operations are carried out there. This requirement does not apply to churns, tanks and bulk packaging of more than 4 litres. However, in the case of limited production of liquid milk intended for drinking, the competent authorities may authorise alternative methods using means of filling and sealing which are not automatic, provided that such methods carry equal assurances with regard to hygiene;

(b) equipment for the cooling and cold storage of heat-treated milk, liquid milk-based products and, in the cases provided for in Chapters II and IV, raw milk, in so far as such operations are carried out there. Cold stores must be equipped with correctly calibrated temperature-measuring apparatus;

(c) in the case of wrapping in disposable containers, an area for the storage of such containers and for storage of the raw materials intended for their manufacture, in the case of wrapping in reusable containers, a special area for their storage and equipment designed to clean and disinfect them mechanically;

(d) containers for storing raw milk, standardisation equipment and containers for storing standardised milk;

(e) if appropriate, centrifuges or any other suitable means for physically purifying milk;

(f)

1. in the case of treatment establishments, heat-treatment equipment approved or authorised by the Veterinary Services, fitted with -

an automatic temperature control, a recording thermometer, an automatic safety device preventing insufficient heating, an adequate safety system preventing the mixture of heat-treated milk with incompletely heated milk, an automatic recording device for the safety system referred to in the preceding indent or a procedure for monitoring the systems effectiveness.

However, when approving establishments, the Veterinary Services may authorise different equipment with equivalent performance guarantees and equal assurances with regard to hygiene.

2. in the case of processing establishments, in so far as such operations are carried out there, equipment and methods for heating, thermisation or heat treatment, meeting the hygiene requirements;

(g) equipment for the cooling, wrapping and storage of frozen milk-based products in so far as such operations are carried out there;

(h) equipment for drying and wrapping powdered milk-based products insofar as such operations are carried out there.

CHAPTER VI

Hygiene requirements relating to the premises equipment and staff of treatment establishments and processing establishments

In addition to the general requirements laid down in Chapter II, establishments must comply with the following conditions -

1. Cross-contamination between operations by equipment, ventilation or staff must be avoided. If appropriate, and in the light of the risk analysis referred to in regulation 12 of these regulations, rooms intended for production processes shall be divided into wet and dry areas, each having its own operating conditions.

2. As soon as possible after each journey, or after each series of journeys where there is only a very short space of time between unloading and the following loading, but in any event at least once each working day, containers and tanks used for transporting raw milk to the milk collection or standardisation centre or to the milk treatment or processing establishment must be cleaned and disinfected before re-use.

3. Equipment, containers and installations which come into contact with milk or milk-based products or other perishable raw materials during production must be cleaned and if necessary disinfected according to a frequency and procedures consistent with the principles referred to in regulation 12 (1).

4. The treatment premises must be cleaned according to a frequency and procedures consistent with the principles referred to in regulation 12 (1)

5. For the cleaning of other equipment, containers and installations which come into contact with micro-biologically stable milk-based products and with rooms in which such substances are placed, the operator or manager of the establishment shall draw up a cleaning programme based on the risk analysis referred to in regulation 12 of these regulations. This programme must meet the requirement referred to in point 1 of this Chapter and must also ensure that there is no health risk to products covered by these regulations as a result of inadequate cleaning methods.

SCHEDULE C

CHAPTER I

Requirements for the manufacture of heat-treated milk and milk-based products

A. Requirements for the production of heat-treated drinking milk

1. Heat-treated drinking milk must be obtained from raw milk which complies with the standards laid down in Schedule A, Chapter IV.

2. Upon acceptance at a treatment establishment milk must, unless treated within four hours of acceptance, be cooled to a temperature not exceeding +6°C and maintained at that temperature until heat-treated. If raw cows milk is not treated within 36 hours of acceptance, a further test must be carried out on that milk before it is heat-treated. If it is found by means of a direct or indirect method that the plate count of that milk at 30°C exceeds 300 000 per ml the milk in question must not be used for the production of heat-treated drinking milk.

3. The manufacture of heat-treated drinking milk shall include all necessary measures, in particular random sampling checks, relating to -

(a) the plate count, to ensure that -

raw milk, if it is not treated within 36 hours of acceptance, does not exceed immediately before heat treatment a plate count at 30°C of 300 000 per ml in the case of cows milk; milk which has been subjected to a previous pasteurisation has, immediately before the second heat treatment, a plate count at 30°C not exceeding 100 000 per ml;

(b) the presence of extraneous water in the milk

Heat-treated drinking milk shall be subjected to regular checks for the presence of extraneous water, in particular by verification of the freezing point. For this purpose a control system shall be established under the supervision of the Veterinary Services.

When extraneous water is detected the Veterinary Services shall take appropriate measures. In establishing a control system the Veterinary Services shall take account of;

- the results of the checks on raw milk referred to in Schedule A, Chapter III D.1, and in particular their variation and average,

- the effect of storage and processing of milk under Good Manufacturing Practices (GMP) on the freezing point.

Heat-treated drinking milk may be subjected to any test which gives an indication of the micro-biological condition of the milk before heat treatment. The rules for the application of such tests and the criteria to be met in this regard shall be established by the European Community.

4. (a) Pasteurised milk must –

(i) have been obtained by means of a treatment involving a high temperature for a short time (at least 71, 7°C for 15 seconds or any equivalent combination) or a pasteurisation process using different time and temperature combinations to obtain an equivalent effect;

(ii) show a negative reaction to the phosphatase test and a positive reaction to the peroxidase test. However, the production of pasteurised milk which shows a negative reaction to the perioxidase test is authorised, provided that the milk is labelled as high-temperature pasteurised;

(iii) immediately after pasteurisation, have been cooled to a temperature not exceeding 6°C as soon as possible.

(b) UHT milk must -

have been obtained by applying to the raw milk a continuous flow of heat entailing the application of a high temperature for a short time (not less than +135°C for not less than a second) the aim being to destroy all residual spoilage micro-organisms and their spores using aseptic opaque containers, or containers made opaque by the packaging, but so that the chemical, physical and organoleptic changes are minimal, be of preservability such that no deterioration can be observed by means of random sampling checks after it has spent 15 days in a closed container at a temperature of +30°C;

where necessary, provision can also be made for a period of seven days in a closed container at a temperature of +55°C. Where the ultra high temperature milk treatment process is employed by direct contact of milk and steam, the steam must be obtained from potable water and must not leave deposits of foreign matter in the milk or affect it adversely. Moreover, the use of this process must not cause any change in the water content of the treated milk.

(c) Sterilised milk must -

have been heated and sterilised in hermetically sealed wrappings or containers, the seal of which must remain intact, in the event of random sampling, be of preservability such that no deterioration can be

observed after it has spent 15 days in a closed container at a temperature of +30°C; where necessary, provision can also be made for a period of seven days in a closed container at a temperature of +55°C.

(d) Pasteurised milk which has been subjected to high-temperature pasteurisation, UHT milk and sterilised milk may be produced from raw milk which has undergone thermisation or an initial heat treatment in another establishment.

In this case the time-temperature set must be lower than or equivalent to pasteurisation and the milk must show a positive reaction to the peroxidase test before the second treatment. Recourse to this practice must be brought to the attention of the Veterinary Services.

Mention of the first treatment must be made on the document provided for in regulation 5 (8) of these regulations.

Pasteurised milk may be produced in the same conditions from raw milk which has undergone only initial thermisation;

(e) Heating processes -

the temperatures and duration of heating in respect of pasteurised, UHT and sterilised milk, the types of heating equipment, the flow-diversion valve and the types of temperature controlling and recording devices shall be approved or authorised by the Veterinary Services in accordance with international standards.

(f) The data produced by recording thermometers must be dated and kept for two years so that they can be shown upon request to the officials appointed by the Veterinary Services to inspect the establishment, save in the case of micro-biologically perishable products, for which this period may be reduced to two months after the use by or minimum durability date.

5. Heat-treated drinking milk must -

(a) meet the micro-biological standards laid down in Chapter II;

(b) not contain pharmacologically active substances in quantities higher than the limits laid down in Annexes I and II to European Union Regulation (EEC) No. 2377/90; the combined total of residues of all antibiotic residues may not exceed the value fixed in accordance with the procedure laid down under European Union Regulation (EEC) No. 2377/90.

B. Requirements for milk for the manufacture of milk-based products

1. The operator or manager of the processing establishment must take all necessary steps to ensure that the raw milk is heat treated or used, in the case of products made with raw milk -

as soon as possible after acceptance if the milk has not been refrigerated, within 36 hours of acceptance if the milk is kept at a temperature not exceeding 6°C, within 48 hours of acceptance if the milk is kept at a temperature not exceeding 4°C, within 72 hours for buffalo, sheep and goats milk.

However, for technological reasons concerning the manufacture of certain milk-based products, the Veterinary Services may authorise the times and temperatures referred to in the above indents to be exceeded.

2. Heat-treated milk intended for the manufacture of milk-based products must be obtained from raw milk which complies with the standards laid down in Schedule A, Chapter IV.

3. Heat-treated milk must meet the following requirements -

(a) thermised milk must -

(i) have been obtained from raw milk which, if it is not treated within 36 hours of acceptance by the establishment, has a plate count at 30°C prior to thermisation which does not exceed 300 000 per ml in the case of cows milk;

(ii) have been obtained by treatment as defined in regulation 2 (6) of these regulations;

(iii) if it is used for the production of pasteurised, UHT or sterilised milk, meet the following standards before treatment -

plate count at 30° C equal to or less than 100 000 per ml;

(b) pasteurised milk must -

(i) have been obtained by means of a treatment involving a high temperature for a short time (at least 71, 7°C for 15 seconds or any equivalent combination) or a pasteurisation process using different time and temperature combinations to obtain an equivalent effect;

(ii) show a negative reaction to the phosphatase test and a positive reaction to the peroxidase test. However, the production of pasteurised milk which shows a negative reaction to the peroxidase test is authorised, provided that the milk is labelled as high-temperature pasteurised;

(c) UHT milk must have been obtained by applying to the raw milk a continuous flow of heat entailing the application of a high temperature for a short time (not less than +135°C for not less than a second) the aim being to destroy all residual spoilage micro-organisms and their spores so that the chemical, physical and organoleptic changes are minimal.

CHAPTER II

Microbiological criteria for milk-based products and drinking milk

A. Microbiological criteria for certain milk-based products on removal from the processing establishment

1. Compulsory criteria:

Type of micro-organism	Product	Standard (ml, g)[1]
- Listeria monocytogenes	Cheese, other than hard cheese	Absent in 25^3 g n = 5, c = 0
	- Other products[2]	Absent in 1 g
- Salmonella spp	- All except milk powder	Absent in 1 g n = 5.

[1] Where -

n = number of sample units comprising the sample;
m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all sample units does not exceed m;
M = maximum value for the number of bacteria; the result is considered unsatisfactory if the number of bacteria in one or more sample units is M or more;
c = number of sample units where the bacteria count may be between m and M the sample being considered acceptable if the bacteria count of the other sample units is m or less.

	- Milk powder	c = 0 Absent in 1 g n = 10, c = 0

In addition, pathogenic micro-organisms and their toxins must not be present in quantities such as to affect the health of consumers.

If these standards are exceeded, the foodstuffs must be excluded from human consumption and withdrawn from the market in accordance with the fifth and sixth indents of regulation 12 (1) of these regulations. Sampling programs will be drawn up in the light of the nature of the products and the risk analysis.

2. Analytical criteria –

organisms indicating poor hygiene

Type of micro-organism	Product	Standard (ml, g)
- Staphylococcus aureus	Cheese, made from raw milk and thermised milk	m=1000 M=10000 n=5 c=2
	Soft cheese made from heat treated milk	m=100 M=1000 n=5 c=2
	Fresh cheese Powdered milk Frozen milk-based products (including ice-cream)	m=10 M=100 n=5 c=2
- Escherichia coli	Cheese made from raw milk and from thermised	m=10000 M=100000 n=5 c=2
	Soft cheese (made from heat-treated milk)	m=100 M=100 n=5 c=2

In all cases where these standards are exceeded there must be a review of the implementation of the methods for monitoring and checking critical points applied in the processing establishment pursuant to regulation 12 of these regulations. The Veterinary Services shall be informed of the corrective procedures included in the production monitoring system to prevent any repetition of the occurrence.

In addition, whenever the standard M is exceeded in the case of cheese made from raw milk and from thermised milk and soft cheese, testing must be carried out for the possible presence of strains of enterotoxinogenic S. aureus or E. coli that are presumed to be pathogenic and also, if necessary, the

[2] Testing not compulsory for sterilised milk and milk-based products where the heat treatment was applied after wrapping or packaging.

[3] The 25 g sample to consist of 5 specimens of 5 g taken from different parts of the same product.

possible presence of staphylococcal toxins in such products by means of methods to be determined in accordance with European Community legislation. If the above-mentioned strains are identified and, or staphylococcal enterotoxins are found, all the batches involved shall be withdrawn from the market. In this case, the Veterinary Services shall be informed of the findings, pursuant to the fifth indent of the second subparagraph of regulation 12 (1) of these regulations, and of the action taken to withdraw the suspect batches and the corrective procedures introduced into the production monitoring system;

3. Indicator organisms: guidelines

1.

Type of micro-organism	Product	Standard (ml, g)
- Coliforms 30 C	Liquid based milk products.	m=0 M=5 n=5 c=2
	Butter made from pasteurised milk or cream	m=0 M=10 n=5 c=2
	Soft cheese made from heat-treated milk.	m=10000 M=100000 n=5 c=2
	Powdered milk based Products	m=0 M=10 n=5 c=2
	Frozen milk-based products Including ice-cream .	m=10 M=100 n=5 c=2
- Plate count	Liquid heat-treated unfermented milk-based products (a)	m=50000 M=100000 n=5 c=2
	Frozen milk-based products Including ice-cream .	m=50000 M=100000 n=5 c=2

a) After incubation at 6°C for five days (plate count at 21°C).

b) (b) Plate count at 30°C.

These guidelines should help producers in ensuring proper operation of their establishments and in implementing the system and the procedure for carrying out their own checks on their production.

4. In addition, milk-based products in liquid or gel form which have undergone UHT treatment or sterilisation which are intended for conservation at room temperature must meet the following standards after incubation for 15 days at 30°C -

(a) plate count at 30°C (per 0,1 ml): 10
(b) organoleptic test: normal.

B. Microbiological criteria for drinking milk

1. Raw cows milk for drinking in that state must meet the following standards after wrapping:

Plate count at 30°C (per ml)	≤50 000[4]
Staphylococcus aureus (per ml)	m = 100, M = 500, n = 5, c = 2
Salmonella	absent in 25 g n = 5, c = 0

In addition, pathogenic micro-organisms and their toxins must not be present in quantities such as to affect the health of consumers.

2. In the random sampling checks carried out in the treatment establishment pasteurised milk must meet the following micro-biological standards -

Pathogenic micro-organisms –

Pathogenic micro-organisms:	absent in 25 g n = 5, c = 0, m = 0, M = 0
Coliforms (per ml)	n = 5, c = 1, m = 0, M = 5
After incubation at 6°C for five days	
Plate count at 21°C (per ml)	n = 5, c = 1, m = 5×10^4 M = 5×10^5

3. In the random sampling checks carried out in the treatment establishment, sterilised milk and UHT milk must meet the following standards after incubation at 30°C for 15 days -

plate count (30°C):	≤10 (per 0,1 ml)
organoleptic	check: normal
pharmacologically active substances	

Not exceeding the limits set in Annexes I and III to European Union Regulation (EEC) No. 2377/9. The combined total of residues of all substances may not exceed a value to be fixed in accordance with these rules.

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[4] Geometric average over a period of two months, with at least two samples a month. n = number of sample units comprising the sample;

m = threshold value for the number of bacteria;
the result is considered satisfactory if the number of bacteria in all sample units does not exceed m;

M = maximum value for the number of bacteria;
the result is considered unsatisfactory if the number of bacteria in one or more sample units is M or more;

c = number of sample units where the bacterial count may be between m and M, the sample still being considered acceptable if the bacterial count of the other sample units is bacteria m or less.

4. When the maximum standards and compulsory criteria are exceeded and when subsequent investigation indicates a potential danger to health, the Veterinary Services shall take appropriate measures.

C. Detailed rules

Where necessary, detailed rules may be established in accordance with European Community requirements and the procedure laid down in article 10 of the Veterinary Services Act for the application of this Chapter and in particular -

- criteria other than those set out in paragraphs A and B in respect of drinking milk and milk-based products,

- micro-biological criteria applicable, under conditions managed and controlled by the operator or manager of the establishment, to the use-by date.

CHAPTER III

Wrapping and packaging

1. Wrapping and packaging must take place under satisfactory hygiene conditions in rooms provided for that purpose.

2. Without prejudice to European Community rules 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 effectively the products covered by these regulations.

3. Bottling, filling of containers with heat-treated milk and liquid milk-based products and sealing of containers and of packaging must be carried out automatically. However, in the case of limited production, the competent authorities may authorise non automatic sealing methods provided that these provide equal assurances with regard to hygiene.

4. Wrapping or packaging may not be reused for the products covered by these regulations, with the exception of certain types of containers which may be reused after thorough cleaning and disinfecting. Sealing must be carried out in the establishment in which the last heat treatment of drinking milk and, or milk-based products in liquid form has been carried out, immediately after filling, by means of sealing devices which ensure that the milk is protected from any adverse effects of external origin on its characteristics. The sealing system must be so designed that once the container has been opened, the evidence that it has been opened remains clear and easy to check.

5. The operator or manager of the establishment must ensure for control purposes that, in addition to the information required by Chapter IV, the following information is visibly and legibly displayed on the packaging of the heat-treated milk and milk-based products in liquid form –

the nature of the heat treatment which the milk has undergone, an indication, in code or not, whereby the date of the last heat treatment may be established, in the case of pasteurised milk, the temperature at which the product must be stored. However, these details need not appear on the reusable glass bottles referred to European Community legislation.

6. Product manufacture and packaging operations may take place in the same room, notwithstanding point 1, if the packaging is as described in point 2 and 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 wrapping and packaging must have been brought to the treatment or processing establishment in a protective cover in which they were placed immediately after manufacture and

which protects them from any damage during transport to the establishment and must have been stored there under hygiene conditions in a room intended for that purpose;

(c) the rooms for storing the packaging material must be free from dust and vermin and separated from rooms containing substances which might contaminate the 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 products;

(e) packaging must be brought into the room under hygienic conditions and used without delay. It may not be handled by staff handling unwrapped products;

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

CHAPTER IV

Conditions governing health marking and labeling

A. Conditions governing health marking

1. The products covered by these regulations must carry a health mark. Marking must be carried out during or immediately after manufacture in the establishment, in an easily visible place. The mark shall be legible, indelible and its characters easily distinguishable. The health mark may be applied to the product or to the wrapping, if the product is individually wrapped, or to a label affixed to this wrapping. However, where small products are individually wrapped and then packaged together or where such small individually wrapped portions are supplied to the final consumer, it will suffice for the health mark to be applied to their collective packaging.

2. Where products marked in accordance with point 1 are subsequently placed in a packaging, the health mark must also be applied to the packaging.

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

(i) either -

above -

the initial letter or letters of the consigning country in capitals, i.e. the letters, **MT** followed by the approval number of the establishment,

below -

one of the following sets of initials -

KEE;

(ii) or -

above, the name of the consigning country in capitals, in the centre, the approval number of the establishment, below, the following of initials –

KEE;

(iii) or above - the name or initial letter or letters of the consigning country in capitals, i.e. for the territory of Malta, the letters, **MT**,

in the centre - a reference to where the approval number of the establishment is shown,

below - one of the following sets of initials - **KEE**;

In the case of the bottles, packaging and containers referred to in article 11(4) and (6) of European Union Council Directive 79/112/EEC, the health mark may indicate only the initials of the consigning country and the approval number of the establishment;

(b) the health mark may be applied to the product, wrapping or packaging by an ink stamp or by branding, or it may be printed on or applied to a label.

(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).

4. To take account of the disposal of existing packaging, application of the health mark on packaging shall be compulsory only from 1 January 1996. However, the information to be given on the health mark must be shown on the accompanying commercial document provided for in regulation 5 (8) and the last subparagraph of regulation 7 (9) of these regulations;

B. Conditions governing labelling

Without prejudice to the provisions of European Community rules relating to the labelling, presentation and advertising of foodstuffs the labelling must clearly show for inspection purposes -

1. the words "raw milk" for raw milk intended for direct human consumption;

2. the words "made with raw milk" for milk-based products manufactured from raw milk whose manufacturing process does not include any heat treatment, including thermisation;

3. for other milk-based products the nature of any heat treatment applied at the end of the manufacturing process;

4. for milk-based products in which growth of micro-organisms can occur, the useby or minimum durability date.

CHAPTER V

Storage and transport requirements

1. Products covered by these regulations which cannot be stored at ambient temperature must be stored at the temperatures established by the manufacturer to ensure their durability. In particular, the maximum temperature at which pasteurised milk may be kept until it leaves the establishment and during transport must be 6°C. When stored under cooled conditions the storage temperatures must be registered and the cooling rate must be such that the product reaches the required temperature as quickly as possible.

2. Tanks, churns and other containers which are used for the transport of pasteurised milk must comply with all the rules of hygiene and in particular the following -

their inside surfaces and any other part which may come into contact with the milk must be made of smooth material which is easy to wash, clean and disinfect, resists corrosion and does not transfer substances to the milk in such quantities as to endanger human health, impair the composition of the milk or adversely affect its organoleptic characteristics, they must be designed so that the milk can drain away completely; if they are fitted with taps, these must be easy to remove, dismantle, wash, clean and disinfect, they must be

washed, cleaned and disinfected immediately after each use and as necessary before further use; cleaning and disinfection must be carried out in accordance with Schedule B, Chapter VI, 2 and 3, they must be hermetically sealed before and during transport by means of a watertight sealing device.

3. Vehicles and containers used for transporting pasteurised milk must be designed and equipped in such a way that the required temperatures can be maintained throughout the period of transport.

4. Vehicles used for transporting heat-treated drinking milk and milk in small containers or in churns must be in good condition. They may not be used to transport any other product or object likely to cause the milk to deteriorate. Their internal surfaces must be smooth and easy to wash, clean and disinfect. The interiors of vehicles intended for transporting milk must comply with all the rules of hygiene. Vehicles intended for the transport of heat-treated milk in small containers or churns must be so designed as to give the containers or churns adequate protection against all contamination and atmospheric influences and may not be used to transport animals.

5. To that end, the Veterinary Services must regularly check that the means of transport and loading conditions meet the hygiene requirements of this Chapter.

6. The products covered by these regulations must be dispatched in such a way that they are protected from anything liable to contaminate them or to cause them to deteriorate, having regard to the duration and conditions of transport and the means of transport employed.

7. During transport, the temperature of pasteurised milk transported in tanks or packed in small containers and in churns must not exceed 6°C. However, the competent authorities may grant a derogation from this requirement for doorstep deliveries and authorise a tolerance of +2°C during deliveries to retail establishments.

8. In accordance with the procedure laid down in article 10 of the Veterinary Services Act there may be established additional conditions for the storage and transport of specific milk-based products.

CHAPTER VI
Health checks and 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 12 of these regulations, notably by examining the results and taking samples;

(iii) the micro-biological and hygienic condition of the milk-based products;

(iv) the efficacy of the treatment of the milk-based products and heat-treated drinking milk;

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

(vi) the appropriate health marking of the milk-based products;

(vii) 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.

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

SCHEDULE D

CHAPTER I
European Community reference laboratory

Laboratoire Central d'Hygiene Alimentaire
43, Rue de Dantzig 75015
PARIS

CHAPTER II
Duties and tasks of European Community reference laboratory

1. The European Community reference laboratory for the analysis and testing of milk and milk products shall be responsible for –

Providing national reference laboratories with details of analytical methods and comparative testing, co-ordinating the application, by national reference laboratories, of the methods referred to in the first indent, in particular by organising comparative testing, co-ordinating research into new analytical methods and informing national reference laboratories of advances in this field, conducting initial and further training courses for the benefit of staff from national reference laboratories, providing scientific and technical assistance to the European Commission, including the European Community Bureau of References, especially in cases where the results of analyses are contested between Member States.

2. The European Community reference laboratory shall ensure that the following operating conditions are maintained.

It must –

Have suitably qualified staff with adequate training in the techniques applied to the analysis and testing of milk and milk products, possess the equipment and substances needed to carry out the tasks provided for in paragraph 1, have an appropriate administrative infrastructure, ensure that its staff respect the confidential nature of certain subjects, results or communications, have sufficient knowledge of international standards and practices, have available, if appropriate, an updated list of reference substances held by the European Community Bureau of References and an updated list of the manufacturers and suppliers of such substances

SCHEDULE E

European Community rules referred to in regulation 1 (4)

- The common organisation of the market in milk and milk products

European Union Council Regulation (EEC) No 804/68 of 28 June 1968 on the common organisation of the market in milk and milk products (OJ L 196 08.08.68 p. 4), repealed and replaced by European Union Council Regulation (EEC) No 1255/1999 of 17 May 1999 (OJ L 160 26.06.99 p. 48). Last amended by European Union Council Regulation (EEC) No 1670/2000 (OJ L 193 29.07.2000 p. 10).

- Certain partly or wholly dehydrated preserved milk for human consumption

European Union Council Directive 76/118/EEC of 18 December 1975 on the approximation of the laws of the Member States relating to certain partly or wholly dehydrated preserved milk for human consumption

(OJ L 24 30.01.76 p. 30), repealed and replaced by European Union Council Directive 2001/114/EC (OJ L 15 17.01.02 p.19).

- Certain lactoproteins (caseins and caseinates) intended for human consumption,

European Union Council Directive 83/417/EEC of 25 July 1983 on the approximation of the laws of the Member States relating to certain lactoproteins (caseins and caseinates) intended for human consumption, (OJ L 237 26.08.83 p. 25).

- the protection of designations used in marketing of milk and milk products

European Union Council Regulation (EEC) No 1898/87 of 2 July 1987 on the protection of designations used in marketing of milk and milk products (OJ L 182 03.07.87 p. 36) last amended by European Commission Regulation (EEC) No 222/88 of 22 December 1987 (OJ L 28 01.02.88 p. 1).

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