

European Communities
(Hygienic Production and Placing on the Market of Raw Milk,
Heat-Treated Milk and Milk-Based Products) Regulations, 1996.

REGULATIONS
1996

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S.I. No. 9 of 1996.

REGULATIONS,

1996.

I, IVAN YATES, Minister for Agriculture, Food and Forestry, in exercise of the powers conferred on me by section 3 of the European Communities Act, 1972 (No. 27 of 1972), and for the purposes of giving effect to Council Directive No. 92/46/EEC of 16 June 1992 as amended by Council Directive No. 94/71/EEC of 31 December 1994, Council Directive No. 92/47/EEC of 16 June 1992 and Commission Directive No. 89/362/EEC of 26 May 1989, hereby make the following Regulations:

- 1 O.J. No. L 268 of 14 September, 1992, P.1
- 2 O.J. No. L 368 of 31 December, 1994, P.33
- 3 O.J. No. L 268 of 14 September, 1992, P.33
- 4 O.J. No. L 156 of 8 June, 1989, P.30
- 1 O.J. No. L 268 of 14 September, 1992, P.1
- 2 O.J. No. L 368 of 31 December, 1994, P.33
- 3 O.J. No. L 268 of 14 September, 1992, P.33
- 4 O.J. No. L 156 of 8 June, 1989, P.30

REG 1

Citation.

1. These Regulations may be cited as the European Communities (Hygienic Production and Placing on the Market of Raw Milk, Heat-Treated Milk and Milk-Based Products) Regulations, 1996.

REG 2

Operative Date.

2. These Regulations shall come into operation on the 15th day of January, 1996.

REG 3

3 Definitions.

3. (1) In these Regulations—

"Annex A", "Annex B" and "Annex C" mean, respectively, Annex A, Annex B and Annex C set out in the Schedule to these Regulations;

"approval number" means the reference number referred to in Regulation 14 (1) (a) or 16 (2), as appropriate;

"approved collection centre" means a centre registered in the Register of Approved Milk Collection Centres maintained by the Minister under Regulation 15;

"approved processing establishment" means an establishment registered in the Register of Approved Milk Processing Establishments maintained by the Minister under Regulation 12;

"approved processing establishment with limited production capacity" means an establishment registered in the Register of Approved Limited Capacity Milk Processing Establishments maintained by the Minister under Regulation 12;

"approved standardisation centre" means a centre registered in the Register of Approved Milk Standardisation Centres maintained by the Minister under Regulation 15;

"approved treatment establishment" means an establishment registered in the Register of Approved Milk Treatment Establishments maintained by the Minister under Regulation 12;

"authorised officer" means a person authorised in writing by the Minister under Regulation 4 to exercise for the purposes of these Regulations and the Directives some or all of the functions conferred on an authorised officer by these Regulations in so far as those functions comprise the designated functions of the particular authorised officer;

"the Directives" means Council Directive No. 92/46/EEC of 16 June 1992 as amended by Council Directive 94/71/EEC of 31 December 1994, Council Directive No. 92/47/EEC of 16 June 1992 and Commission Directive No. 89/362/EEC of 26 May 1989;

"the Principal Directive" means Council Directive No. 92/46/EEC of 16 June 1992;

"functions" includes powers and duties;

"health mark" means the mark referred to and meeting the conditions specified in paragraph A of Chapter IV A of Annex C, to the Principal Directive;

"inspections" includes, where the context admits, examinations, tests, checks and analyses, and cognate words shall be construed accordingly;

"Member State" means a Member State of the European Community;

"the Minister" means the Minister for Agriculture, Food and Forestry;

"official veterinarian" means a person who is a veterinary surgeon and who is authorised by the Minister to exercise the powers of an official veterinarian for the purposes of Regulations 9 and 10;

"temporarily authorised milk treatment establishment", and "temporarily authorised milk processing establishment" mean respectively, an establishment referred to in Regulation 23 or 26, as the case may be;

"veterinary surgeon" means a person who is registered in the register established under the Veterinary Surgeons Act, 1931;

"production holding" means a production unit operated by a single producer and/or producers acting together at which one or more milk-producing cows, ewes, goats or buffaloes are kept;

"registered holding" means a production holding which is registered in the Register of Milk Production Holdings maintained under Regulation 6;

(2) In these Regulations a reference to any enactment is, save where the context otherwise requires, a reference to that enactment as amended by any other enactment.

(3) In these Regulations—

(a) a reference to a Regulation is to a Regulation of these Regulations, unless it is indicated that reference to some other enactment is intended, and

(b) a reference to a paragraph, subparagraph or clause is to the paragraph, subparagraph or clause of the regulation in which the reference occurs, unless it is indicated that reference to some other regulation or provision is intended.

(4) A word or expression that is used in these Regulations and is also used in the Directives has, unless the contrary intention appears, the same meaning in these Regulations that it has in the Directives.

REG 4

Authorised Officers.

4. (1) There shall be appointed in writing such and so many officers as the Minister thinks fit to be authorised officers for the purposes of some or all of the provisions of these Regulations.

(2) A warrant of appointment as an authorised officer stating the designated functions of such authorised officer for the purposes of these Regulations and the Directives shall be issued to every person appointed under this Regulation and when exercising any function conferred on the person as an authorised officer, the authorised officer shall, if requested by a person affected, produce the warrant to that person or, where appropriate, an identity document issued pursuant to section 17 of the Animal Remedies Act, 1993 (No. 23 of 1993), which relates to this Regulation.

(3) The Minister may at any time terminate an appointment as an authorised officer.

REG 5

Powers of Authorised Officers.

5. (1) An authorised officer may, for the purposes of these Regulations and the Directives—

(a) at any time enter—

(i) all parts of any milk production holding, processing establishment, treatment establishment, limited capacity milk processing establishment, collection centre or standardisation centre,

(ii) all parts of any other premises or other land which are material to the operation of the holding or establishment or centre or where it is proposed to establish such a holding, establishment or centre,

(iii) any other place in respect of which the officer reasonably suspects that—

(I) milk for human consumption or for use in milk-based products for human consumption is being produced, or

(II) milk, heat-treated milk, or any milk-based product is being heat-treated, processed, packaged, standardised, collected or stored, and there carry out or have carried out such inspection of the premises, equipment, processing systems, production, hygienic practices and records as the officer reasonably considers to be necessary or expedient and to inspect any substance found therein or thereat which the officer reasonably believes to be milk or a milk-based product or any substance used in or in connection with the processing of milk, milk-based products or any other product covered by these Regulations and the Directives and, where appropriate, require it to be kept for such period. and at such place as the officer may specify,

(b) require any person in or on such premises or other land or at such other place (as appropriate) to give, or arrange to be given, to the officer such information and to produce to the officer such documents or other records, including computerised records within the possession, power or procurement of that person relating to the origin of raw milk, heat-treated milk or milk-based products for the purposes of checking compliance with the Directives and to enable the holding or establishment of origin of the raw material to be traced,

(c) have access to, inspect and take in the original form or as a copy thereof, as appropriate, any such documents or other records including computerised records as aforesaid, and

(d) take, without payment, such samples of any substance which the officer reasonably believes to be raw milk, heat-treated milk or a milk-based product or any substance used in or in connection with the processing of milk, milk-based products or any other product covered by the Directives found in or on the premises or other land or at the place and carry out or have carried out on the sample such inspections according with any relevant provisions of the Directive, as the officer considers necessary or expedient.

(2) In this Regulation "place" includes any vehicle, goods container, wagon, vessel or aircraft situated at the place.

(3) The provisions of Regulation 40 shall apply in the event of

the authorised officer being obstructed in the carrying out of the powers conferred on an authorised officer by this Regulation.

REG 6

Register of Holdings.

6. (1) Persons who acquire milk for the preparation of heat-treated drinking milk or for processing into milk-based products shall maintain a register of the holdings on which such milk is produced. This register shall contain the following information:

- (a) the address of the holding on which the milk is produced;
- (b) the name of the owner or person in charge of the holding;
- (c) a unique number to identify the holding for the purpose of these Regulations;
- (d) the number assigned by the Minister to the herd from which the milk was produced;
- (e) such other relevant information as the Minister may from time to time require to be kept.

(2) Save with the written permission of the Minister, the register shall be maintained at the establishment at which the records relating to the test results of the milk carried out for compliance with the standards prescribed in Regulation 20 are kept. The Minister may, in response to a request in writing, give written permission for the maintenance of the register at any other location, subject to any conditions the Minister may attach.

(3) The register shall, at all reasonable times, be made available for inspection by any authorised officer or any European Commission appointee referred to in Regulation 33.

(4) No holding shall be registered nor, once registered, shall it be removed from the register, save with the approval of the Minister.

(5) The register of persons who use milk produced on their own holdings for the production of milk based products or to supply raw milk for direct human consumption shall be maintained by the Minister. Such persons shall apply in writing to the Minister for the registration of their holdings in the register and shall supply such information as the Minister may require. The Minister shall deal with such applications in accordance with the provisions of Regulation 7.

REG 7

Registration of Holdings.

7. (1) (a) A production holding shall be inspected by an authorised officer before it is registered in order to determine whether or not it meets the requirements set out in Chapter II of Annex A, the general code of hygiene laid down in the Annex to Commission Directive No. 89/362/EEC of 26 May 1989, and the standards laid down in Chapter III of the said Annex A.

(b) Production holdings already producing milk on or before the date these Regulations come into force shall be deemed to be registered.

(2) Where as a result of an inspection of a production holding by an authorised officer under these Regulations, the Minister is satisfied that the requirements, code of hygiene and standards referred to in paragraph (1) (a) are being met by the holding, the Minister shall register the holding.

REG 8

Inspection of Holdings.

8. (1) (a) Every registered holding shall be subject to regular inspection by an authorised officer, to determine whether or not the requirements and code of hygiene referred to in paragraph (1) of Regulation 7 are being met.

(b) Where, as a result of an inspection of a production holding, the Minister is not satisfied that the requirements and code referred to in paragraph (1) of Regulation 7 are being met, the Minister shall serve on the proprietor or person in charge of the holding a written notice in accordance with paragraph (2) of the shortcomings found and, except in circumstances to which paragraph (4) applies allow the proprietor or person in charge the period of time specified in the notice in which to rectify the shortcomings.

(2) Except in circumstances to which paragraph (4) apply, the Minister shall neither withhold consent to the registration of a production holding under this Regulation nor have the registration of any registered holding revoked without first—

(a) serving, or causing to be served, a notice in writing on the proprietor or person in charge of the holding concerned of the Minister's intention to withhold consent to or to have revoked the registration, as the case may be,

(b) specifying, or causing to be specified, in the notice referred to in subparagraph (a) the Minister's reasons for the intention to withhold consent or to have the registration revoked, as the case may be, by reference to the shortcomings on the holding for the purposes of the Directives and these Regulations, and

(c) affording, or causing to be afforded to, the proprietor or

person in charge of the holding concerned an opportunity of making representations in writing or having representations made in writing on behalf of the proprietor or person in charge, to the Minister, within a period specified in the notice referred to in subparagraph (a) (being a period of not less than 7 days from the date of receipt of that notice by that proprietor or person in charge), in relation to the proposed withholding of consent or revocation of registration.

(3) If upon the expiration of the period specified in the notice to which paragraph (1) (b) relates in respect of a production holding, or at any time thereafter, or, if deemed necessary by the Minister, as a result of a further inspection of the holding by an authorised officer, the Minister is satisfied that the holding does not meet the requirements and code referred to in paragraph (1) of Regulation 7, the Minister shall refuse to consent to the registration of the holding or shall have revoked the registration, as the case may be, and that holding shall not be registered unless and until a further application for registration is lodged and the Minister is satisfied that the holding meets the requirements and code referred to in paragraph (1) of Regulation 7.

(4) Notwithstanding paragraphs (1) to (3) of this Regulation, where, as a result of an inspection carried out by an authorised officer, the Minister is satisfied that the milk being produced on the registered holding poses a serious and immediate or potential danger to public health, the Minister shall revoke the registration of the holding forthwith,

REG 9

Animal Health Checks.

9. (1) Every proprietor or person in charge of a registered milk production holding shall have the milking animals on the holding inspected and certified, at such intervals as the Minister shall specify, by a veterinary surgeon. The certification in question shall be drawn up by the Minister and shall deal with some or all of those aspects of Chapter 1 of Annex A.

(2) (a) Where, as a result of an inspection carried out under paragraph (1), the veterinary surgeon concerned is satisfied that the animal health requirements referred to in that paragraph are being met, the veterinary surgeon shall furnish a signed certificate [in duplicate] to that effect, to the proprietor or person in charge of the holding concerned.

(b) The proprietor or person in charge of a holding to whom a certificate has been furnished under subparagraph (a) shall—

(i) retain, for inspection by an authorised officer, one copy of each such certificate so furnished until the results of a subsequent inspection are available;

(ii) send one copy to the establishment or centre which purchases or takes delivery of the milk, as appropriate.

(c) Persons who prepare raw milk for direct human consumption or milk-based products from raw milk or heat-treated drinking milk or milk-based products from some or all of the milk produced on their own holdings shall send the certificate referred to in subparagraph (a) to the Minister.

(3) Where as a result of an inspection carried out under paragraph (1), the veterinary surgeon concerned is not satisfied that the animal health requirements referred to in that paragraph are being met, the veterinary surgeon shall notify in writing the proprietor or person in charge of the holding concerned that milk from that holding must not be used in or supplied for the preparation of heat-treated drinking milk or milk-based products for human consumption and shall notify, in writing, the Minister of the position. The notification shall be sent to such office of the Department as the Minister may from time to time direct.

(4) Inspections carried out in accordance with this Regulation and the Directives may take place on the occasion of veterinary checks carried out pursuant to other Community or National provisions.

(5) The Minister shall exercise a supervisory function in relation to the regime outlined in this Regulation for the purposes of determining whether or not the provisions of this Regulation are being complied with.

REG 10

Official Veterinarians.

10. (1) The Minister shall, for the purpose of exercising supervisory functions in respect of subparagraph (5) of Regulation 9 appoint in writing one or more registered veterinary surgeons as the Minister designates to be official veterinarians for this purpose.

(2) A warrant of appointment as an official veterinarian shall be issued to every person appointed under this Regulation and when exercising any function conferred on the person as an official veterinarian, the official veterinarian shall, if requested by a person affected, produce the warrant to that person or, where appropriate, an identity document issued pursuant to section 17 of the Animal Remedies Act, 1993, which relates to this Regulation.

(3) An official veterinarian may at any time inspect milking animals on a milk production holding for the purpose of determining whether or not the provisions of Regulation 9 are being complied with.

REG 11

Revocation of Registration of Holdings.

11. Where the Minister is satisfied following any inspection under Regulation 9 or 10, or other inspections which the Minister may deem necessary that the animal health requirements of Chapter 1 of Annex A are not being complied with on a registered holding, the

Minister shall prohibit the sale for human consumption of milk produced on that holding.

REG 12

Register of Treatment and Processing Establishments.

12. (1) The Minister shall establish and maintain or cause to be established and maintained

(a) a register of all approved milk treatment establishments within the State, to be known as the Register of Approved Milk Treatment Establishments,

(b) a register of all approved milk processing establishments within the State, to be known as the Register of Approved Milk Processing Establishments, and

(c) a register of all approved milk processing establishments with limited production capacity within the State as defined in Regulation 30 to be known as the Register of Approved Limited Capacity Milk Processing Establishments

which are approved by the Minister for the purposes of these Regulations and the Directives.

(2) The Register of Approved Milk Treatment Establishments and the Register of Approved Milk Processing Establishments and the Register of Approved Limited Capacity Milk Processing Establishments shall each contain, as appropriate, the following information:

(a) the name and address of each approved establishment;

(b) the name of the proprietor or person in charge of each such establishment, as appropriate, together with the trading name or names of each such establishment;

(c) the date of registration of each establishment;

(d) a registration number for each such establishment, as appropriate which number shall also be the approval number for the establishment concerned;

(e) such other information as the Minister may require to be contained in each such register.

(3) Any application for registration under this Regulation shall be made to the Minister.

(4) Each register established under this Regulation may be maintained in a non-legible form that is machine readable.

REG 13

Approval of Treatment and Processing Establishments.

13. (1) The Minister shall, before approving any milk treatment establishment or milk processing establishment or limited capacity milk processing establishment for registration under Regulation 12, require that it be inspected by an authorised officer for the purpose of determining whether or not—

(a) subject to Regulation 30, the establishment concerned complies

with—

(i) the general conditions for approval set out in Chapter I of Annex B,

(ii) the special requirements for approval set out in Chapter V of Annex B,

(iii) the general conditions of hygiene set out in Chapter II of Annex B,

and

(b) it is operated in accordance with the principles set out in Regulation 31 and the hygiene requirements set out in Chapter VI of Annex B.

(2) The Minister shall specify the product or products to which the approval relates.

(3) Where, as a result of an inspection of a milk treatment establishment or a milk processing establishment or a limited capacity milk processing establishment by an authorised officer under these Regulations, the Minister is satisfied that the conditions, requirements and principles referred to in paragraph (1) are not being met by the establishment concerned, the Minister shall refuse to approve the establishment.

(4) (a) Every approved establishment shall be subject to inspection by an authorised officer for the purpose of determining whether or not the conditions, requirements, and principles referred to in paragraph (1) are being met.

(b) Where as a result of an inspection of an approved establishment, the Minister is not satisfied that the conditions, requirements and principles referred to in paragraph (1) are being met, the Minister, without prejudice to paragraph (8)—

(i) shall serve on the proprietor or person in charge of the establishment a written notice of the shortcomings found and, except in circumstances to which paragraph (8) applies, allow that proprietor or person in charge the period of time specified in the notice in which to rectify the shortcomings;

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

(iii) if the measures provided for in clause (ii) prove insufficient, may temporarily suspend approval, if appropriate, for the type of production in question;

(5) If the proprietor or person in charge of the establishment concerned does not make good the shortcomings noted within the period fixed by the Minister, the Minister shall revoke the approval of that establishment.

(6) Except in circumstances to which paragraph (8) applies, the Minister shall neither refuse an application for the approval of an establishment under Regulation 12 nor revoke nor suspend the approval of any establishment without first—

(a) serving, or causing to be served, a notice in writing on the proprietor or person in charge of the establishment concerned of the Minister's intention to refuse or suspend or revoke the

approval, as the case may be,

(b) specifying, or causing to be specified, in the notice referred to in subparagraph (a) the Minister's reasons for the intended refusal or suspension or revocation as the case may be, by reference to the shortcomings of the establishment for the purposes of the Directives and these Regulations, and

(c) affording, or causing to be afforded to, the proprietor or person in charge of the establishment concerned an opportunity of making representations in writing or having representations made in writing on behalf of that proprietor or person in charge to the Minister, within a period specified in the notice referred to in subparagraph (a) (being a period of not less than 14 days from the date of receipt of that notice by that proprietor or person in charge), in relation to the proposed refusal, suspension or revocation.

(7) If upon the expiration of the period specified in the notice to which paragraph (6) relates in respect of an establishment, or any time thereafter, or, if deemed necessary by the Minister, as a result of a further inspection of the establishment by an authorised officer, the Minister is satisfied that the establishment does not meet the conditions, requirements and principles referred to in paragraph (1) the Minister shall refuse to approve the establishment or suspend or revoke approval, as the case may be, and that establishment shall not be approved unless and until the Minister receives a further application for approval and is satisfied that the establishment meets the requirements referred to in paragraph (1).

(8) Where the Minister considers it necessary for the protection of public health the Minister may withdraw approval with immediate effect and take whatever action may be deemed necessary to prevent further use of the milk for the manufacture of heat-treated milk or milk-based products destined for human consumption.

REG 14

Health Mark/Approval Number.

14. (1) (a) The Minister shall assign to each approved treatment establishment and approved processing establishment and approved limited capacity milk processing establishment an individual reference number which, for the purposes of these Regulations, shall also be known as and is referred to as its approval number.

(b) The approval number assigned under subparagraph (a) shall be incorporated into the health mark to be used by the establishment concerned in labelling its production as provided for by the provisions set out in Chapter IV, point A of Annex C.

(2) Where the Minister has temporarily suspended approval or has revoked the approval of a treatment establishment or a processing establishment or limited capacity milk processing establishment or has revoked approval for the production of any particular product or

products at such an establishment, all seals, unused labels, unused wrapping material, cartons or the like, bearing the health mark of the establishment on all such items relating to the establishment or to the product or products in respect of which approval has been temporarily suspended or has been revoked, as the case may be, shall, as the Minister may decide—

(a) be deposited in a secure, locked store at the establishment or elsewhere under the sole control of an authorised officer, or

(b) be handed over by the proprietor or person in charge of the establishment to an authorised officer for safe keeping or for destruction as the Minister may see fit.

REG 15

Register of Centres.

15. (1) The Minister shall establish and maintain or cause to be established and maintained—

(a) a register of all approved milk collection centres within the State, to be known as the Register of Approved Milk Collection Centres, and

(b) a register of all approved milk standardisation centres within the State, to be known as the Register of Approved Milk Standardisation Centres,

which are approved by the Minister for the purposes of these Regulations and the Directives.

(2) The Register of Approved Milk Collection Centres, and the Register of Approved Milk Standardisation Centres shall each contain the following information:

(a) the address of each approved milk collection centre or approved milk standardisation centre, as appropriate;

(b) the name of the proprietor or person in charge, of each such centre, as appropriate, together with the trading name or names of each such centre;

(c) the date of registration for each such approved centre;

(d) a registration number for each such approved centre, which number shall also be the approval number for the centre concerned;

(e) such other information as the Minister may require to be contained in each such register.

(3) Any application for registration under this Regulation shall be made to the Minister.

(4) Each register established under this Regulation may be maintained in a non--legible form that is machine readable.

REG 16

Approval of Centres.

16. (1) The Minister shall, before approving any milk collection centre or milk standardisation centre for registration under Regulation 15, require that it be inspected by an authorised officer for the purpose of determining whether or not the centre concerned complies with—

(i) the general conditions for approval set out in Chapter I of Annex B, and

(ii) in the case of a milk collection centre, the special requirements set out in Chapter III of Annex B, or

(iii) in the case of a milk standardisation centre, the special requirements set out in Chapter IV of Annex B.

(2) The Minister shall assign to each approved collection centre and approved standardisation centre an individual reference number which, for the purposes of these Regulations, shall also be known as and is referred to as its approval number.

(3) Where, as a result of an inspection of a milk collection centre or milk standardisation centre the Minister is satisfied that the conditions and appropriate requirements referred to in paragraph (1) are not being met by the centre concerned, the Minister shall refuse to approve the centre.

(4) (a) Every approved collection centre and every approved standardisation centre shall be subject to inspection by an authorised officer for the purpose of determining whether or not the conditions and appropriate requirements referred to in paragraph (1) are being met.

(b) Where, as a result of an inspection of a milk collection centre or milk standardisation centre, the Minister is not satisfied that the conditions and appropriate requirements are being met, the Minister, without prejudice to paragraph (8)—

(i) shall serve on the proprietor or person in charge of the centre a written notice of the shortcomings found and, except in circumstances to which paragraph (8) applies, allow that proprietor or person in charge the period of time specified in the notice in which to rectify the shortcomings;

(ii) may act in respect of the use of equipment or premises or any part of premises and take any requisite measures which may go as far as requiring the limitation or temporary suspension of operation;

(iii) if the measures provided for in clause (ii) prove insufficient the Minister may temporarily suspend approval, if appropriate, for the type of operation in question.

(5) If the proprietor or person in charge of the centre concerned does not make good the shortcomings noted within the period fixed by the Minister, the Minister shall revoke the approval of that centre.

(6) Except in circumstances to which paragraph (8) applies, the Minister shall neither refuse an application for the approval of a

centre under Regulation 15 nor revoke nor suspend the approval of any centre without first—

(a) serving, or causing to be served, a notice in writing on the proprietor or person in charge of the centre concerned of the Minister's intention to refuse or suspend or revoke the approval, as the case may be,

(b) specifying, or causing to be specified, in the notice referred to in subparagraph (a) the Minister's reasons for the intended refusal or suspension or revocation as the case may be, by reference to the shortcomings of the centre for the purposes of the Directives and these Regulations, and

(c) affording, or causing to be afforded to, the proprietor or person in charge of the centre concerned an opportunity of making representations in writing or having representations made in writing on behalf of that proprietor or person in charge to the Minister, within a period specified in the notice referred to in subparagraph (a) (being a period of not less than 14 days from the date of receipt of the notice by that proprietor or person in charge), in relation to the proposed refusal or suspension or revocation.

(7) If upon the expiration of the period specified in the notice to which paragraph (6) relates in respect of a centre or any time thereafter, or, if deemed necessary by the Minister, as a result of a further inspection of the centre by an authorised officer, the Minister is satisfied that the centre does not meet the conditions and appropriate requirements referred to in paragraph (1) the Minister shall refuse to approve the centre or suspend or revoke approval, as the case may be, and that centre shall not be approved unless and until the Minister receives a further application for approval and is satisfied that the centre meets the conditions and appropriate requirements referred to in paragraph (1).

(8) Where the Minister considers it necessary for the protection of public health the Minister may withdraw approval granted under this Regulation with immediate effect.

REG 17

Approval of Laboratories.

17. Laboratories may be approved by the Minister for the purposes of carrying out tests required under these Regulations.

REG 18

Records to be kept.

18. The proprietor or person in charge of any approved treatment establishment, approved processing establishment, approved limited capacity milk processing establishment, approved collection centre or approved standardisation centre, shall keep such records in respect of milk purchases and deliveries as the Minister may deem necessary

to ensure that the provisions of these Regulations and the Directives are being complied with in relation to—

- (a) the holding on which the milk originated,
- (b) the quality and, as appropriate, composition of raw milk,
- (c) the production, handling, transport, processing and placing on the market of raw and heat-treated milk or milk-based products,
- (d) the animal health certification referred to in Regulation 9.

REG 19

Raw Milk for Human Consumption.

19. (1) Raw milk shall not be placed on the market in that state for human consumption unless it meets the following requirements:

- (a) it has been obtained from animals belonging to a herd which satisfies the requirements specified in Chapter I of Annex A;
- (b) in the case of raw cow's milk it meets the standard laid down for somatic cell count at Chapter IV, paragraph 1, point A of Annex A and the criteria laid down at Chapter II, paragraph 1, point B of Annex C;
- (c) it meets the provisions of subparagraphs (a) and (c) of Regulation 20 (1);
- (d) the words "raw milk" shall be clearly displayed on the container or packaging in which the milk is sold as provided for at Chapter IV, paragraph 1, point B of Annex C.

(2) Raw milk shall not be placed on the market unless the vendor has obtained the written consent of the Minister for its sale. This consent shall be subject to such conditions as the Minister, in consultation with the Minister for Health, may consider necessary.

(3) Paragraph 1 (b), (c) & (d) of this Regulation shall not apply to raw milk sold directly on the holding to a consumer by its producer. However, the Minister may draw up detailed rules and conditions governing the production of such milk.

REG 20

20 Standards for Raw Milk for use in Heat-Treated Milk or Milk-Based Products.

20. (1) Save as provided for by Regulations 23, 26 and 27, raw milk shall not be used for the manufacture of milk-based products or heat-treated milk for human consumption unless—

- (a) it is produced on a registered holding;
- (b) save as provided for by paragraph (2), it is obtained from animals which meet the requirements laid down in Chapter I of Annex A;
- (c) it is produced, transported and stored on a registered holding in accordance with the hygiene requirements set out in Chapter III of Annex A;
- (d) save as provided for by Regulation 21, it meets the

standards set out—

- (i) at Chapter IV, paragraph 1, point A of Annex A in the case of cow's milk used for heat-treated drinking milk, or
- (ii) at paragraph 2, point A of the said Chapter IV in the case of cow's milk used for the manufacture of milk-based products, and
- (iii) the relevant provisions of the said Chapter IV in all other cases;

(e) the requirements relating to antibiotic residues, as set out at Chapter III, paragraph 3, point D of Annex A, are met.

(2) Milk from healthy animals belonging to herds that do not meet the requirements set out at Chapter I, subparagraphs (a) (i) or (b)

(i) of paragraph 1 of Annex A shall not be used in the manufacture of heat-treated milk or for the manufacture of milk-based products unless—

(a) it is first subjected to heat-treatment by the processor under the supervision of or on behalf of the Minister, and

(b) in all other respects it satisfies the requirements of this Regulation:

Provided that, in the case of goat's milk or sheep's milk intended for export to another Member State such heat-treatment shall be carried out at the place of milking.

REG 21

Use of Milk which does not meet the requirements of Chapter IV of Annex A.

21. Milk which meets the requirements set out in Regulation 20 other than paragraph (1) (d) thereof shall not be used for the production of heat-treated milk or for the manufacture of milk-based products except in accordance with the provisions of Regulation 24 or 27, as the case requires.

REG 22

Standards for Heat-Treated Drinking Milk.

22. (1) Heat-treated drinking milk shall not be placed on the market for human consumption unless:

(a) it has been heat-treated at a treatment establishment registered under Regulation 12 except where Regulation 23 applies;

(b) it has been obtained from raw milk which meets the requirements of Regulation 20 except where Regulation 24 applies;

(c) it has been obtained from raw milk, purified or filtered, if appropriate, by equipment referred to in Chapter V, paragraph (e) of Annex B;

(d) in the case of cow's milk, it complies with the definition of "drinking milk" provided for in the second, third or fourth indents of paragraph 1 (b) of Article 3 of Council Regulation No. 1411/71/EEC of 29 June 1971(1) and the provisions of paragraph 3 of

Article 6 of that Regulation;

(1) O.J. Sp. Edn. 1971 (II), p. 412.

(e) if appropriate, it has passed through an approved milk collection centre and if appropriate, has been transferred from one tank to another under proper hygiene and distribution conditions;

(f) if appropriate, it has passed through an approved milk standardisation centre;

(g) if appropriate, milk intended for the production of sterilised milk and UHT milk may have undergone an initial heat-treatment in an approved heat-treatment establishment;

(h) it has been obtained from raw milk which complies with the requirements set out in Chapter I, point A of Annex C;

(i) it has been produced under a production regime which satisfies the requirements set out in Regulation 31, and the provisions relating to health checks and supervision of production set out in Chapter VI of Annex C;

(j) it meets the microbiological criteria applicable to heat-treated milk set out in Chapter II, point B of Annex C;

(k) it is

(i) marked and labelled in accordance with the conditions set out in Chapter IV of Annex C, and

(ii) wrapped and packaged in accordance with the provisions of Chapter III of Annex C, at an approved treatment establishment where the milk has been subjected to final treatment;

(l) it has, after treatment, been transported and stored in accordance with the requirements of Chapter V of Annex C;

(m) it is accompanied during transport, except transport for direct delivery to the final consumer, by a commercial document containing sufficient information for—

(i) the nature of the heat treatment to which it was subjected to be established, and

(ii) the name of the national controlling authority responsible for supervising the establishment of origin to be identified; and

(n) in the case of cow's milk, it is free of added water and has a weight of not less than 1028 grammes per litre, as determined in whole milk at 20°C or the equivalent as determined in totally fat-free milk at 20°C and contains a minimum of 28 grammes of protein per litre, obtained by multiplying the percentage of total nitrogen content of the milk by 6.38, and a fat free dry matter content of not less than 8.5%.

(2) Every document to which paragraph (1) (m) relates shall be retained by the consignee for at least one year and shall be made available to an authorised officer for inspection, if requested.

REG 23

Production of Heat-Treated Milk from Treatment Establishments that do not comply with all the requirements of Chapters I & V of Annex B.

23. (1) Until the 31st day of December, 1997, the Minister may authorise the production of heat-treated drinking milk at a milk treatment establishment not registered under Regulation 12 by virtue of it not meeting some of the requirements of Chapters I and V of Annex B (in these Regulations referred to as a "temporarily authorised milk treatment establishment") and such milk may be sold for human consumption or for use in the manufacture of any milk-based product for human consumption where—

(a) the proprietor or person in charge of the temporarily authorised milk treatment establishment obtains the written authorisation of the Minister to undertake the production of heat-treated milk at that establishment;

(b) it satisfies the requirements of subparagraphs (b) to (j) and (l) to (n) of paragraph (1) of Regulation 22;

(c) it is wrapped or packaged in accordance with the provisions of Chapter III of Annex C and the wrapping or packaging does not show any mark appearing or purporting to be a health mark as provided for in Chapter IV, point A of Annex C.

(2) (a) An application for authorisation under paragraph (1) shall be accompanied by a work plan and programme indicating the period within which it is intended that the milk treatment establishment will be brought up to the standard required for registration in the Register of Approved Milk Treatment Establishments.

(b) An authorisation under paragraph (1) as a temporarily authorised milk treatment establishment shall be subject to such conditions as the Minister thinks fit to impose, either at the date of authorisation or subsequently.

(3) Heat-treated drinking milk produced on or after the coming into force of these Regulations at a temporarily authorised milk treatment establishment or any food product in the manufacture of which such milk is used shall not be exported from the State to any other Member State.

(4) (a) Temporarily authorised milk treatment establishments shall be subject to regular inspection by an authorised officer to ensure that the provisions of paragraphs (1) to (3) are being met.

(b) Where as a result of an inspection by an authorised officer under subparagraph (a), the Minister is not satisfied that the provisions of paragraphs (1) to (3) are being met the Minister may:

(i) act in respect of the use of equipment, premises or part of a premises and take any requisite measures which may go as far as requiring the limitation or temporary suspension of production;

(ii) if the measures provided for by clause (i) prove insufficient, the Minister may temporarily suspend the authorisation of the establishment under this Regulation, if appropriate, for the type of production in question;

(iii) if the establishment is not brought up to the standards required by paragraphs (1) to (3) within the period fixed by the Minister, the Minister shall withdraw authorisation.

(5) Where the Minister considers it necessary for the protection of

public health, the Minister shall withdraw authorisation and suspend production with immediate effect.

(6) The Minister may require the proprietor or person in charge of any temporarily authorised milk treatment establishment to keep records in respect of milk purchases and usage as the Minister may deem necessary to ensure that the requirements of these Regulations are being met.

REG 24

Production of Heat-Treated Milk from Milk which does not comply with all the requirements of Chapter IV of Annex A.

24. (1) Heat-treated drinking milk produced until 31st day of December, 1997, at an approved milk treatment establishment or at a temporarily authorised milk treatment establishment may be sold and may be supplied for human consumption or for use in the manufacture of any milk-based product for human consumption where—

(a) the proprietor or person in charge of the establishment at which it is produced—

(i) has obtained the written authorisation of the Minister to undertake the production of heat-treated milk in accordance with this Regulation, and

(ii) observes all of the conditions subject to which the authorisation concerned was granted.

(b) it is made from milk which satisfies the provisions of Regulation 21,

(c) it satisfies the provisions of subparagraphs (c) to (j) and (l) to (n) of paragraph (1) of Regulation 22,

(d) it is wrapped or packaged in accordance with the provisions of Chapter III of Annex C and the wrapping or packaging does not show any mark appearing or purporting to be a health mark as provided for in Chapter IV, point A of Annex C.

(2) Heat-treated drinking milk which is produced in accordance with this Regulation on or after the coming into force of these Regulations and which is permitted to be supplied for human consumption or used in the manufacture of any foodstuff for human consumption shall not be exported from the State to any other Member State.

REG 25

Standards for Milk-Based Products.

25. (1) Save as is provided for by Regulations 26 to 30, milk-based products shall not be placed on the market for human consumption unless—

(a) they have been manufactured in a processing establishment registered under Regulation 12;

(b) they have been obtained from—

- (i) raw milk which meets the requirements of Regulation 20 and Chapter I, point B of Annex C and if appropriate, has passed through an approved milk collection centre or an approved milk standardisation centre; or
 - (ii) milk intended for the manufacture of milk-based products obtained from raw milk which meets the requirements of clause (i) and comes from an approved treatment establishment and has been stored and transported in accordance with the requirements of Chapter V of Annex C; or
 - (iii) other milk-based products which meet the requirements of this Regulation;
 - (c) they have undergone heat-treatment during the manufacturing process or are made from products that have undergone heat-treatment or involve hygiene specifications that are sufficient to meet the prescribed hygiene criteria for all finished products;
 - (d) they have been produced under a production regime which satisfies the requirements set out in Regulation 31, and the provisions relating to health checks and supervision of production set out in Chapter VI of Annex C;
 - (e) save as provided for in Regulations 26 and 27, they are wrapped and packaged in accordance with the provisions of—
 - (i) Chapter III of Annex C, and
 - (ii) if they are in liquid form and intended for sale to the final consumer, point 3 of the said Chapter III;
 - (f) they meet the microbiological criteria for milk-based products laid down in Chapter II of Annex C;
 - (g) they have been stored and transported in accordance with Chapter V of Annex C;
 - (h) they contain only substances other than milk that are fit for human consumption;
 - (i) they have not been subjected to ionizing radiation;
 - (j) they have been accompanied during transport, other than transport for direct delivery to the final consumer, by a commercial document containing sufficient information for the nature of the heat treatment to which they were subjected to be established;
 - (k) they are marked and labelled in accordance with Chapter IV of Annex C at the registered processing plant where their manufacture was completed.
- (2) The commercial document referred to in paragraph (1) (j) shall indicate the name of the national controlling authority and be retained by the consignee for one year and be made available to an authorised officer if required for inspection.

REG 26

Production of Milk-Based Products from Processing Establishments that do not comply with all the requirements of Chapters I & V of Annex B.

26. (1) Until the 31st day of December, 1997, the Minister may

authorise the production of milk-based products at a milk processing establishment not registered under Regulation 12 by virtue of not meeting some of the requirements of Chapters I and V of Annex B (in this Regulation referred to as a "temporarily authorised milk processing establishment") and such products may be sold for human consumption or for use in the manufacture of any other milk-based product for human consumption where—

(a) the proprietor or person in charge of the temporarily authorised milk processing establishment obtains the written authorisation of the Minister to undertake the production of milk-based products at that establishment;

(b) they satisfy the requirements of subparagraphs (b) to (d) and (f) to (j) of paragraph (1) of Regulation 25;

(c) they are wrapped or packaged in accordance with the provisions of Chapter III of Annex C and the wrapping or packaging does not show any mark appearing or purporting to be a health mark as provided for in Chapter IV, point A of Annex C; without prejudice to Council Directive No. 79/112/EEC of 18 December 1978(1) and Regulations made thereunder, the provisions of Chapter IV, point B of Annex C shall apply.

(1) O.J. No. L33 of 8 February, 1979, P.1.

(2) (a) An application for authorisation under paragraph (1) shall be accompanied by a work plan and programme indicating the period within which it is intended that the milk processing establishment will be brought up to the standard required for registration in the Register of Approved Milk Processing Establishments.

(b) An authorisation under paragraph (1) as a temporarily authorised milk processing establishment shall be subject to such conditions as the Minister thinks fit to impose, either at the date of authorisation or subsequently.

(3) Milk-based products produced at a temporarily authorised establishment shall not be exported from the State to any other Member State.

(4) (a) Temporarily authorised milk processing establishments shall be subject to regular inspection by an authorised officer to ensure that the provisions of paragraphs (1) to (3) are being met.

(b) Where as a result of an inspection by an authorised officer under subparagraph (a), the Minister is not satisfied that the provisions of paragraphs (1) to (3) are being met the Minister may:

(i) act in respect of the use of equipment, premises or part of a premises and take any requisite measures which may go as far as requiring the limitation or temporary suspension of production;

(ii) if the measures provided for by clause (i) prove insufficient, the Minister may temporarily suspend the authorisation under this Regulation, if appropriate, for the type of production in question;

(iii) if the proprietor or person in charge of the establishment does not bring the establishment to the standards required by paragraphs (1) to (3) within the period fixed by the Minister, the Minister shall withdraw authorisation.

(5) Where the Minister considers it necessary for the protection of public health, the Minister shall withdraw approval and suspend production with immediate effect.

(6) The Minister may require the proprietor or person in charge of any temporarily authorised milk processing establishment to keep such records in respect of milk purchases and usage as the Minister may deem necessary to ensure that the requirements of these Regulations are being met.

REG 27

Production of Milk-Based Products from Milk which does not comply with all the requirements of Chapter IV of Annex A.

27. (1) Milk-based products produced until 31st day of December 1997 in accordance with this Regulation may be sold or supplied for human consumption or for use in the manufacture of any foodstuff for human consumption where—

(a) the proprietor or person in charge of the establishment at which they are produced—

(i) has obtained the written authorisation of the Minister to undertake the manufacture of dairy products in accordance with this Regulation, and

(ii) observes all of the conditions subject to which the authorisation concerned was granted.

(b) they are manufactured in an approved milk processing establishment or in an approved limited capacity milk processing establishment, or in a temporarily authorised milk processing establishment;

(c) (i) they are made from milk which satisfies the requirements of Regulation 21; or

(ii) they satisfy the provisions of subparagraphs (b) to (d) and (f) to (j) of paragraph (1) of Regulation 25;

(d) they meet the requirements of Chapter I, point B of Annex C;

(e) they are wrapped and packaged in accordance with the provisions of Chapter III of Annex C and the wrapping or packaging does not show any mark purporting or appearing to be a health mark as provided for in Chapter IV, point A of Annex C; without prejudice to Council Directive No. 79/112/EEC of 18 December 1978 and Regulations made thereunder, the provisions of Chapter IV of Annex C shall apply.

(2) Milk-based products which are produced in accordance with the provisions of this Regulation and which are permitted to be supplied for human consumption shall not be exported from the State to any other Member State.

REG 28

60 Day Cheese.

28. In the case of the manufacture of cheese with a period of ageing or ripening of at least 60 days the Minister may, on foot of a written application and subject to such terms and conditions as the Minister thinks fit, grant exemptions as follows:

(a) from the requirements of Annex A Chapter IV in respect of the characteristics of the raw milk.

(b) where the finished product has the characteristics provided for in Chapter II, point A of Annex C—

(i) from the obligations that the establishment meets the conditions set out in Chapters I and II of Annex B, the requirements set out in Chapters V and VI of Annex B and the requirements set out in Regulation 31; and

(ii) from the obligation that they be wrapped and packaged in accordance with the provisions of Chapter III of Annex C;

(c) from the condition governing labelling in Chapter IV, paragraph 2, point B of Annex C.

REG 29

Traditional Products.

29. (1) In the case of the manufacture of milk-based products with traditional characteristics the Minister may grant exemptions from the requirement that—

(a) the milk meets the requirements set out at subparagraphs (a) and (c) of paragraph (1) of Regulation 20;

(b) the milk meets the standards set out at—

(i) Chapter IV, paragraphs 2 and 3, point A of Annex A, in the case of cow's milk;

(ii) Chapter IV, point B of Annex A, in the case of buffalo milk, and

(iii) Chapter IV, point C of Annex A, in the case of milk of goat's and sheep milk;

provided the manufacturer of the product has obtained the written permission of the Minister for the use of such milk and abides by any and all the terms and conditions which may be attached to such permission;

(2) and provided that subject to the permission referred to at paragraph (1), the products manufactured therefrom meet all relevant microbiological criteria set out at Chapter II, point A of Annex C;

(3) and provided that subject to the permission referred to at paragraph (1), the products are wrapped, packaged, marked and labelled in accordance with the provisions of Chapters III and IV of Annex C.

(4) For the purposes of the exemption referred to in Paragraph (1), milk-based products with traditional characteristics shall be those products which are;

(a) recognised historically, or

(b) manufactured in accordance with technical standards or

manufacturing methods codified and registered in the State, or
(c) recognised or protected as such under national or community
law.

REG 30

Approval of Limited Production Establishments.

30. (1) The Minister may, subject to such terms and conditions as the Minister may deem appropriate, and provided that they do not affect the hygienic conditions of production, authorise the registration under Regulation 12 of milk processing establishments which;

(a) do not meet the conditions and requirements relating to structural standards set out, respectively, in Chapters I and V of Annex B and the requirements in relation to staff training set out in Regulation 31 (7) where—

(i) the processing capacity of the establishment does not exceed 500,000 litres of milk per year;

(ii) the premises and equipment are of a suitable hygienic standard and meet the conditions set out at Chapter II of Annex B;

(iii) the products produced at such premises meet the microbiological criteria set out at Chapter II, point A of Annex C; or

(b) do not meet the conditions and requirements relating to structural standards set out, respectively, in Chapters I and V of Annex B where—

(i) the processing capacity of the establishment does not exceed 2,000,000 litres of milk per year;

(ii) the premises and equipment are of a suitable hygienic standard and meet the conditions set out at Chapter II of Annex B;

(iii) the products produced at such premises meet the microbiological criteria set out at Chapter II, point A of Annex C.

The establishments referred to at subparagraphs 1 (a) and (b) shall be registered in accordance with Regulation 12 as Approved Limited Capacity Milk Processing Establishments.

(2) The provisions of paragraphs (3) to (8) of Regulation 13 and Regulation 14 shall apply to establishments falling within the scope of this Regulation.

REG 31

Critical Point Analysis.

31. (1) For the purpose of ensuring that, at all stages of production, the relevant specifications of the Directives and the provisions of these Regulations are complied with, it shall be the responsibility of the proprietor or the person in charge of every milk treatment establishment and milk processing establishment and limited capacity milk processing establishment registered under Regulation 12 and of every temporarily authorised establishment, as

provided for in Regulations 23 and 26:

(a) to conduct or cause to be conducted adequate checks and tests to ensure—

(i) the identification of critical points in the establishment concerned on the basis of the processes used and the monitoring and checking of such critical points by appropriate methods in order to guard against the contamination of the product in the course of production; the nature of the checks and methods referred to shall be to the satisfaction of the Minister.

(ii) the taking of samples for analysis in a laboratory approved by the Minister for the purpose of checking cleaning and disinfection methods and for the purpose of checking compliance with the standards established by these Regulations, and that person shall ensure that sufficient information has been supplied to the Minister or an authorised officer in respect of those checks and tests to enable the Minister to regularly monitor compliance with this subparagraph;

(b) to keep records of the results and other information on the checks and tests undertaken for the purpose of compliance with subparagraph (a) and to make those results and other information available to authorised officers for inspection or, where directed by the Minister or an authorised officer, to submit them to the Minister or an authorised officer;

(c) when any laboratory examination or other information at the disposal of the proprietor or person in charge reveals that there is a serious health risk, to submit such information forthwith to the Minister;

(d) in the event of an immediate human health risk, to withdraw forthwith from the market the quantity of products obtained in technologically similar conditions and likely to present the same risk, and the products so withdrawn shall be held under the supervision and control of the Minister until they are destroyed, used for purposes other than human consumption, or where authorised by the Minister, reprocessed in an appropriate manner to ensure their safety.

(2) (a) Without prejudice to the generality of paragraph (1)

(a), the proprietor or person in charge of a milk treatment establishment or milk processing establishment or a limited capacity milk processing establishment or a temporarily authorised establishment shall ensure that in carrying out the checks and tests under paragraph (1) (a), checks and 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, to the extent that those residues exceed the permitted tolerance limits, are harmful or might alter the organoleptic characteristics of milk or milk-based products or make their consumption dangerous or harmful to human health;

(b) the proprietor or person in charge of a milk treatment establishment or milk processing establishment or a limited capacity milk processing establishment or a temporarily authorised establishment

shall ensure that where milk or milk-based products examined show traces of residues which exceed the permitted tolerances they shall be excluded from human consumption.

(3) The results and information to which paragraph (1) (b) relates shall be maintained for a period of at least two years, except in the case of milk-based products which cannot be stored at ambient temperature, for which the period shall be reduced to two months after the use-by or minimum durability date.

(4) Subject to compliance with the other relevant provisions of these Regulations an approved milk treatment establishment or an approved milk processing establishment or an approved limited capacity milk processing establishment shall not be operated unless a written undertaking has been given to the Minister by the proprietor or person in charge of the establishment that there will be compliance with the provisions of these Regulations, and with any conditions laid down by the Minister, regarding the use of the health mark.

(5) Without prejudice to any other provisions of these Regulations, where the Minister has reason to believe that these Regulations are not being complied with, the Minister may carry out or cause to be carried out such investigations, checks and tests as are considered appropriate and if necessary take or cause to be taken such measures as are seen to be fit, which may include the suspension of approval of the milk treatment establishment or milk processing establishment or limited capacity milk processing establishment concerned.

(6) Disinfectants and similar substances to be used in milk treatment establishments or milk processing establishments or limited capacity milk processing establishments or temporarily authorised establishments shall—

(a) be approved by or on behalf of the Minister and used in such a way that they do not have adverse effects on the equipment, raw materials and products to which these Regulations relate, and
(b) be in containers which are clearly identifiable and which bear labels with instructions for their use,
and, after being used, be followed by thorough rinsing with potable water.

(7) The proprietor or person in charge of the approved milk treatment establishment or approved milk processing establishment shall—

(i) provide or cause to be provided one or more than one staff training programme to assist staff in complying with conditions of hygienic production unless, in the opinion of the Minister, any member of the staff of a milk treatment establishment or milk processing establishment should not be required to undergo a staff training programme because such member has adequate qualifications attested by diplomas or other accreditation;

(ii) inform the Minister of the planning and implementation of each such staff training programme or, in the case of each programme already in existence, of their progress.

REG 32

Hygiene in Transporting and Storing Milk.

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

(2) Every tank (other than fixed or immovable tanks forming part of the installation concerned) used for milk shall bear a clear indication that it may be used only for the transport of foodstuffs.

(3) Where an approved processing establishment, an approved treatment establishment, an approved limited capacity milk processing establishment or an establishment to which Regulation 23 or 26 relates 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 shall be stored separately to prevent cross-contamination and be treated or processed in premises suitable for the purpose.

(4) The measures at paragraph (1) and the storage arrangements at paragraph (3) shall be brought to the notice of and shall require prior approval by an authorised officer.

REG 33

Commission Inspectors.

33. An expert duly appointed by the European Commission for the purposes of Article 17 of the Principal Directive shall be entitled to make on-site checks on registered holdings, approved collection centres, approved processing establishments, approved processing establishments with limited production capacity, approved standardisation centres or approved treatment establishments in so far as this is necessary to ensure the uniform application of the Directives.

REG 34

Non-Milk Constituents.

34. The manufacture of products in which some milk constituents are replaced by ingredients other than milk-based products shall be subject to the hygiene provisions of the Directives and these Regulations.

REG 35

Powers of the Minister.

35. (1) Without prejudice to any specific provision of these Regulations, where it is suspected that the provisions of these Regulations are not being complied with or there is doubt as to whether the milk or milk-based products to which any of those provisions relate are fit for human consumption, the Minister may check or test or cause to have checked or tested the milk or milk-based product and if necessary may—

(a) detain and, subject to Regulation 36, have destroyed, reprocessed or denatured, such product as the Minister considers appropriate, in order to prevent its transport, storage, sale or consumption, and

(b) prohibit the continued treatment or production of milk or milk-based products at the place concerned.

(2) The Minister may, where it is suspected that the provisions of these Regulations have not been complied with, or that the products in question are unfit for human consumption, carry out or cause to be carried out, an examination of the milk or milk-based products in accordance with the provisions of Council Directive No. 89/662/EEC of 11 December 1989(1) and if considered necessary take whatever steps the Minister deems appropriate to prevent the transport, sale or consumption of milk or milk-based products.

(1) O.J. No. L 395 of 30 December 1989, P.13.

REG 36

Additional Controls.

36. (1) Where in respect of any milk or milk-based product it is suspected that the provisions of these Regulations are not being complied with or there is doubt as to whether it is fit for human consumption, an authorised officer may—

(a) detain it, and

(b) by a notice in writing served on the proprietor or person in charge of any holding or centre or establishment concerned require anything specified in the notice to be done in relation to the milk or milk-based product at the expense of that proprietor or person in charge, including, where considered appropriate, its destruction, reprocessing or denaturing and where the notice under this paragraph requires and specifies something to be done in relation to such milk or milk-based product, then the authorised officer shall retain control over it until the requirements of the notice have been duly complied with.

(2) Pending compliance with the requirements of a notice served under this Regulation, a person shall not sell, move, dispose or otherwise interfere or deal with the milk or milk-based product concerned without the consent of the authorised officer by whom the notice was served or of any other authorised officer directed by

the Minister for the purpose of this Regulation.

(3) The proprietor or person in charge of the holding or centre or establishment to which a notice served under this Regulation relates shall comply with the requirements of the notice—

(a) in so far as the notice may relate to the sale or consumption of the milk or milk-based product concerned, on receipt of the notice where the authorised officer is of the opinion, and so states in the notice, that there is a doubt about its fitness for human consumption,

(b) where subparagraph (a) does not apply and no appeal is taken against the notice, on the expiration of the period during which such appeal could have been taken,

(c) where subparagraph (a) or (b) does not apply and an appeal is taken under paragraph (4) and the notice is confirmed on appeal or the appeal is withdrawn, on the next day following the day on which the notice is so confirmed or the appeal is withdrawn.

An authorised officer may, at any time, revoke a notice served under this Regulation.

REG 37

Appeals Procedure.

37. (1) The proprietor or person in charge of the holding or centre or establishment concerned who is aggrieved by an exercise of power by the Minister under Regulation 35 or a notice under Regulation 36 herein may, not later than the expiration of the period of 14 days beginning on the date of the notice, appeal to a Judge of the District Court against the notice and in determining the appeal the Judge may—

(a) if satisfied that in the circumstances of the case it is reasonable so to do, confirm the notice with or without modification, or

(b) cancel the notice.

(2) (a) Notice of an appeal made pursuant to this paragraph shall be served on the Minister or on the authorised officer concerned at least 14 days prior to the hearing of the application;

(b) the Minister and the authorised officer concerned shall be entitled to be heard and to adduce evidence at the hearing of the appeal brought under this paragraph.

(3) (a) An appeal under this paragraph by the proprietor or person in charge of the holding or centre or establishment concerned shall be brought before and heard and determined by a Judge of the District Court for the time being assigned to the district where that holding or centre or establishment, or any part thereof, to which the notice served under this Regulation relates, is situated;

(b) the Judge determining the appeal under this paragraph may make such order as to the payment of costs in respect of the appeal as that Judge considers appropriate.

(4) Nothing in this Regulation shall be construed as restricting the

exercise of functions by the Minister under Regulations 7, 8, 13 or 16.

REG 38

Imports from Other Member States and Third Countries.

38. A person shall not import into the State any raw milk, heat-treated milk or milk-based products—

(a) from any other Member State unless they are produced, processed, packaged, marked and labelled in accordance with the provisions of the Principal Directive;

(b) from any other state unless—

(i) where the case requires, that other state or the part of that other state from where the milk or milk-based products originated and from which they are being exported and the establishments and centres (being of a standard required by Regulations 13 and 16) at which they were produced stand approved by the European Commission in accordance with the procedure in Article 31 of the Principal Directive for the purpose of exporting milk or milk-based products to the Member States,

(ii) all such milk and milk-based products are accompanied by either—

(I) an official health certificate duly issued by the Competent Authority of the exporting state at the time of export from that state and which has been drawn up in accordance with the procedure laid down in Article 31 of the Principal Directive and which certifies that the milk and milk-based products being imported meet the requirements of the Principal Directive and of clause (i) of subparagraph (b) of this Regulation and that they have satisfied the checks required by the European Communities (Importation of Animal and Animal Products from Third Countries) Regulations, 1994 (S.I. No. 255 of 1994), or

(II) where there is no such certificate provided for in respect of that state, an official health certificate duly issued by the Competent Authority of that state which certifies that the raw milk, heat-treated milk or milk-based products, as appropriate, were produced under conditions no less stringent than those prescribed in the Principal Directive and that those products themselves meet the standard prescribed by these Regulations and by the Principal Directive and Council Directive No. 89/362/EEC of 26 May 1989.

REG 39

Offences.

39. (1) Any person who contravenes a provision of Regulations 6, 18, 19, 20, 21, 22, 25, 38 and 40 shall be guilty of an offence.

(2) Any person who fraudulently tampers with or otherwise interferes, whether by act of commission or omission, with any raw milk,

heat-treated milk or milk-based products so as to procure that any sample taken under these Regulations does not correctly represent such milk or milk-based products or who tampers or interferes with any sample taken under these Regulations shall be guilty of an offence.

(3) (a) Any person who fraudulently applies a health mark or any mark or stamp appearing or purporting to be a health mark to any milk or milk-based products or the wrapping, labelling or packaging of any milk or milk-based products shall be guilty of an offence.

(b) without prejudice to subparagraph (a), any operator or person in charge of a milk treatment establishment, milk processing establishment, or limited capacity milk processing establishment, who applies or causes to be applied a health mark to any milk or milk-based products which are produced otherwise than in accordance with conditions, requirements and principles necessary to qualify for the right to bear the health mark under these Regulations shall be guilty of an offence.

(4) Where an offence under these Regulations has been committed by a body corporate and is proved to have been so committed with the consent or connivance of, or to be attributable to any neglect on the part of a person being a director, manager, secretary or other officer of the body corporate or a person who was purporting to act in any such capacity, that person, as well as the body corporate, shall be guilty of an offence and shall be liable to be proceeded against in respect of the first-mentioned offence.

REG 40

Obstruction of Authorised Officers.

40. A person who obstructs or impedes an authorised officer in the exercise of a power or, without reasonable excuse, does not comply with a requirement under these Regulations or who, in purported compliance with such a requirement, gives information to an authorised officer that the said person knows to be false or misleading in a material respect shall be guilty of an offence.

REG 41

Penalties.

41. A person guilty of an offence under these Regulations shall, on summary conviction, be liable to a fine not exceeding £1,500 or to imprisonment for a term not exceeding 12 months or to both such fine and such imprisonment.

REG 42

Proceedings.

42. Notwithstanding section 10 (4), of the Petty Sessions (Ireland) Act, 1851, proceedings for an offence under these Regulations may be instituted at any time within twenty-four months after the date of the offence.

REG 43

43 Prosecutions.

43. An offence under these Regulations may be prosecuted by the Minister.

REG 44

Fees.

44. (1) There may be charged such fees in respect of inspections carried out by authorised officers under Regulation 7, 8, 9, 13 or 16 or in respect of services performed by the Minister or an officer of the Minister in connection with matters to which these Regulations relate, as the Minister, with the consent of the Minister for Finance, may determine.

(2) Any fees charged for inspections or other services provided under these Regulations shall be in addition to, and not in substitution for, fees charged under section 3 of the Milk (Miscellaneous Provisions) Act 1979 (No. 24 of 1979).

(3) The Public Offices Fees Act, 1879, shall not apply to these Regulations.

REG 45

Revocation of S.I. 124 of 1990.

45. (1) The European Communities (Standards for Heat Treated Milk in Intra-Community Trade) Regulations, 1990 (S.I. No. 124 of 1990), are hereby revoked.

(2) These Regulations shall apply in lieu of the provisions of the Dairy Produce Acts 1924 to 1984, the Creamery Acts, 1928 to 1934 and the Milk and Dairies Acts, 1935 to 1956 in relation to the hygienic production and placing on the market of raw milk, heat-treated milk and milk-based products.

SCHEDULE

Annex to the Regulations

ANNEX 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 Directive 64/432/EEC(1), is;

(1) O.J. No. 121 of 29 July 1964, P.1977.

— 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 recognizable 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 Community provisions or, if absent, in national provisions;

(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 Directive 91/68/EEC(1), except where the milk is intended for the manufacture of cheese with a maturation period of at least two months;

(1) O.J. No. L46 of 19 February 1991, P.19.

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

(c) Milk and milk-based products must not come from a surveillance zone established under Directive 85/511/EEC(2), unless the milk has undergone, under the supervision of the Minister, initial pasteurization (71.7°C for 15 seconds) followed by:

(2) O.J. No L 315 of 26 November 1985, p. 11.

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

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

(c) a second treatment whereby pH is reduced and kept for at

least one hour at less than 6.

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 the procedure laid down in Article 31 of the Principal Directive.

4. Raw milk must be excluded from treatments, processing, sale and consumption if it:

(a) is obtained from animals to which substances within the meaning of Directives 81/602/EEC(1) and 88/146/EEC(2) have been administered illegally;

(1) O.J. No L 222 of 7 August 1981, p.32.

(2) O.J. No L 70 of 16 March 1988, p.16.

(b) contains residues of substances within the meaning of Article 15 of the Principal Directive and Regulations 31(2) and 31(6) herein which exceed the permitted level.

CHAPTER II

Hygiene of the holding

1. The raw milk must come from holdings which are registered and checked in accordance with Article 13 (1) of the Principal Directive and Regulations 8 and 9 herein. 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 Annexes D and E to Directive 80/778/EEC(1), for use in milking and in cleaning the equipment and instruments referred to in Chapter III B of this Annex;

(1) O.J. No L 229 of 30 August 1980, p.11.

(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 by Directive 89/362/EEC.

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 Minister may authorise derogations from the temperatures laid down in the first subparagraph provided the end product meets the standards set out in Chapter II of Annex 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 reuse.

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 Member State concerned or in the case of third countries by specific guarantees to be fixed under the procedure laid down in Article 31 of the Principal Directive.

D. Production hygiene

1. A monitoring system shall be established under the supervision of the Minister 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 Minister to suspect that water is being added, the Minister 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 Minister 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 Minister when the maximum standards fixed for the plate count and somatic cell count have been reached. The Minister 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 one of the substances referred to in Annexes I and III to Regulation (EEC) No 2377/90(1), exceeds the levels authorised therein; the combined total of residues of antibiotic substances may not exceed a value to be fixed in accordance with the procedure laid down in Article 31 of the Principal Directive.

(1)OJ No L 224, 18 of August 1990, p.1.

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 cow's milk

Without prejudice to the limits laid down in Annexes I and III to Regulation (EEC) No 2377/90:

1. Raw cow's 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, the Minister may apply a different method of

calculating results during the low lactation period.

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

from 1.1.1994 from 1.1.1998 Plate count 30°C (per ml) £ 400,000 (a) £

100,000 (a) Somatic cell count (per ml) £ 500,000 (b) £ 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, the Minister may apply a different method of calculating results during the low lactation period.

3. Raw cow's milk intended for direct human consumption and raw cow's 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(1):

Staphylococcus aureus (per ml):

$n = 5$

$m = 500$

$M = 2,000$

$c = 2$

B. Raw buffalo milk

Without prejudice to compliance with the limits laid down in Annexes I and III to Regulation (EEC) No 2377/90:

(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.

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

from 1.1.1994 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.

The standards for plate count at 30°C and somatic cell count to apply as from 1 January 1998 will be set in accordance with Article 21 of the Principal Directive.

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 goat's, sheep's and buffalo's milk must meet the following standards:

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

From 1.1.1995	From 1.2.1999	Plate count at 30°C (per ml)	£ 3,000,000	£ 1,500,000(a)
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(a) without prejudice to the result of the re-examination to be carried out in accordance with Article 21 of the Principal Directive.

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

From 1.1.1995	From 1.1.1999	Plate count at 30°C (per ml)	£ 1,000,000	£ 500,000
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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 Minister 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.

ANNEX 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 the Principal Directive and 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 the Principal Directive and 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 the Principal Directive and these Regulations manufactured;

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

products 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 pre-mixed 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 the Principal Directive and 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 rotproof 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 the Principal Directive and 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 the Principal Directive and 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 Directive 80/778/EEC. 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 Minister;
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 Minister.

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 Minister, 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 Directive 80/778/EEC, 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

the Principal Directive and these Regulations.

5. Disinfectants and similar substances must be approved by the Minister and used in such a way that they do not have adverse effects on the machinery, equipment, raw materials and products covered by the Principal Directive and 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 the Principal Directive and 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 the Principal Directive and 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 the Principal Directive and 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 the Principal Directive and 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 the Principal Directive and these Regulations shall be required to prove, by a medical certificate, that there is no medical impediments to such employment.

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 Minister 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 re-usable 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 Minister, 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 system's effectiveness.

However, when approving establishments, the Minister 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, thermization 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

in so far 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 Article 14 of the Principal Directive and Regulation 31 herein, 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 reuse.
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 Article 14 (1) of the Principal Directive and Regulation 31 herein.
4. The treatment premises must be cleaned according to a frequency and procedures consistent with the principles referred to in Article 14 (1) of the Principal Directive and Regulation 31 herein.
5. For the cleaning of other equipment, containers and installations which come into contact with microbiologically 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 Article 14 of the Principal Directive and Regulation 31 herein. 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 the Principal Directive and these Regulations as a result of inadequate cleaning methods.

ANNEX 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 Annex 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 cow's 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 cow's 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 Minister. When extraneous water is detected the Minister shall take appropriate measures.

In establishing a control system the Minister shall take account of;

—the results of the checks on raw milk referred to in Annex 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 microbiological 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 in accordance with the procedure laid down in Article 31 of the Principal Directive.

4. (a) Pasteurized 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";

(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) Sterilized milk must:

— have been heated and sterilized 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) Pasteurized milk which has been subjected to high-temperature pasteurization, UHT milk and sterilized milk may be produced from raw milk which has undergone thermization or an initial heat treatment in another establishment. In this case the time-temperature set must be lower than or equivalent to pasteurization 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 Minister. Mention of the first treatment must be made on the document provided for in Regulation 22 (1) (m) and 22 (2) herein. Pasteurized milk may be produced in the same conditions from raw milk which has undergone only initial thermization.

(e) Heating processes, the temperatures and duration of heating in respect of pasteurised, UHT and sterilized 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 Minister in accordance with Community or 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 an authorised officer to inspect the establishment, save in the case of microbiologically 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 microbiological standards laid down in Chapter II;

(b) not contain pharmacologically active substances in quantities higher than the limits laid down in Annexes I and III to Regulation (EEC) No 2377/90; the combined total of residues of all

antibiotic residues may not exceed a value to be fixed in accordance with the procedure laid down in 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's, sheep's and goat's milk.

However, for technological reasons concerning the manufacture of certain milk-based products, the Minister 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 Annex A, Chapter IV.

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

(a) thermized 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 thermization which does not exceed 300,000 per ml in the case of cow's milk;

(ii) have been obtained by treatment as defined in Article 2 (6) of the Principal Directive;

(iii) if it is used for the production of pasteurised, UHT or sterilized milk, meet the following standards before treatment: plate count at 30°C equal to or less than 100,000 per ml;

(b) pasteurized 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 pasteurization 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: Pathogenic micro-organisms

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

(a) 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) Testing not compulsory for sterilized milk and milk-based products where the heat treatment was applied after wrapping or packaging.

(c) The 25g sample to consist of 5 specimens of 5g taken from different parts of the same product.

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 Article 14 (1) of the Principal Directive.

Sampling programmes 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 from thermized milk	m = 1,000 M = 10,000 n=5
	Soft cheese (made from heat-treated milk)	m=100 M = 1,000 n=5
	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

thermized milk m = 10,000

M = 100,000

n=5

c=2Soft cheese (made
from heat-treated milk) m=100

M = 1,000

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 Article 14 of the Principal Directive and Regulation 31 herein. The Minister 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 thermized 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 possible presence of staphylococcal toxins in such products by means of methods to be determined in accordance with the procedure laid down in Article 31 of the Principal Directive. 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 Minister shall be informed of the findings, pursuant to the fifth indent of the second subparagraph of Article 14 (1) of the Principal Directive and Regulation 31 (1) (c) herein, and of the action taken to withdraw the suspect batches and the corrective procedures introduced into the production monitoring system.

3. Indicator organisms: guidelines

Type of micro-organism Product Standard (ml, g)—Coliforms 30°C Liquid
milk-based

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 = 10,000

M = 100,000

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 = 50,000

M = 100,000

n = 5

c = 2 Frozen milk-based products (including ice-cream)(b) m = 100,000

M = 500,000

n = 5

c = 2

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

(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 sterilization 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 cow's milk for drinking in that state must meet the following standards after wrapping:

Plate count at 30°C (per ml): £ 50,000(a)>

— Staphylococcus aureus (per ml)

m = 100, M = 500, n = 5, c = 2

— Salmonella: absent in 25g

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 microbiological standards(1):

Pathogenic micro-organisms:absent in 25gn = 5, c = 0, m = 0, M =

0Coliforms (per ml):n = 5, c = 1, m = 0, M = 5After incubation

at 6°C for five daysPlate count at 21°C (per ml):n = 5, c = 1,

m = 5 x 10 4M = 5 x 10 5.

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

(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 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.

3. In the random sampling checks carried out in the treatment establishment, sterilized 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 Regulation (EEC) No 2377/90.

The combined total of residues of all substances may not exceed a value to be fixed in accordance with the procedure laid down in Regulation (EEC) No 2377/90.

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

C. Where necessary detailed rules may be established by the Minister 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,

— microbiological 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 Directive 89/109/EEC(1), wrapping and packaging must comply with all the rules of hygiene, and be strong enough to protect effectively the products covered by the Principal Directive and these Regulations.

(1) O.J. No. L 40, 11 of February 1989, p. 38.

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 Minister 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 the Principal Directive and 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 in Article 11 (6) of Directive 79/112/EEC.

6. Product manufacture and packaging operations may take place in the same room, notwithstanding point 1, if the packaging is as described in 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 labelling

A. Conditions governing health marking

1. The products covered by the Principal Directive and 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: in capitals, IRL, followed by the approval number of the establishment,

— below: in capitals, EEC;

(ii) or:

— above: in capitals, IRELAND,

— in the centre, the approval number of the establishment,

— below: in capitals, EEC;

(iii) or:

— above: in capitals, IRL,

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

— below: in capitals, EEC;

In the case of the bottles, packaging and containers referred to in Article 11 (4) and (6) of Directive 79/112/EEC, the health mark may indicate only the initials IRL 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).

B. Conditions governing labelling

Without prejudice to the provisions of Directive 79/112/EEC, 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 thermization;

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 use-by or minimum durability date.

CHAPTER V

Storage and transport requirements

1. Products covered by the Principal Directive and 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 Annex 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 Minister must regularly check that the means of transport and loading conditions meet the hygiene requirements of this Chapter.

6. The products covered by the Principal Directive and 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 Minister may grant a derogation from this requirement for doorstep deliveries and authorise a tolerance of +2°C during deliveries to retail establishments.

CHAPTER VI

Health checks and supervision of production

1. Establishments shall be subject to supervision by the Minister to ensure that the requirements of the Principal Directive and 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 Article 14 of the Principal Directive and Regulation 31 herein, notably by examining the results and taking samples;

(iii) the microbiological 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 the Principal Directive.

2. The Minister 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.

GIVEN under my Official Seal, this 15th day of January, 1996.

IVAN YATES,

Minister for Agriculture, Food and

Forestry.