1995 No. 201

FOOD

MILK AND DAIRIES

Dairy Products (Hygiene) Regulations (Northern Ireland) 1995

Made . . . . . *18th May 1995*

Coming into operation . . *1st July 1995*

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Whereas it appears to the Department of Agriculture and the Department of Health and Social Services that regulation 4 of these Regulations is expedient in the interests of the public health and for the purpose of securing that dairy products comply with food safety requirements;

Now, therefore, those Departments being the Departments concerned(**a**), in exercise of the powers conferred by Articles 15(1) to (3), 16(1) and (2), 17(2), 18, 25, 26(3), 27(2), 30(9), 32(1) and (2), 47(2) and 48(2) of, and paragraphs 4(*b*), 5, 6(1)(*a*) and 7(1) of Schedule 1 to, the Food Safety (Northern Ireland) Order 1991(**b**) and being Departments designated(**c**) for the purposes of section 2(2) of the European Communities Act 1972(**d**) in relation to the common agricultural policy of the European Community, acting jointly, in exercise of the powers conferred on them by the said section 2(2) and of every other power enabling them in that behalf, after consultation in accordance with Article 47(3) of the said Order of 1991 with such organisations as appear to them to be representative of interests likely to be substantially affected by the Regulations, hereby make the following Regulations:

PART I

PRELIMINARY

Citation and commencement

1. These Regulations may be cited as the Dairy Products (Hygiene) Regulations (Northern Ireland) 1995 and shall come into operation on 1st July 1995.

Interpretation

2.—(1) In these Regulations—

"animal" means an animal of the following species: cows, sheep, goats or buffaloes;

(**a**) *See* S.I. 1991/762 (N.I. 7) Article 2(2) for the definitions of "the Department concerned" and "regulations" and with respect to the powers conferred on each Department jointly and severally by virtue of those definitions
(**b**) S.I. 1991/762 (N.I. 7)
(**c**) S.I. 1972/1811
(**d**) 1972 c. 68

"another EEA State" means an EEA State other than the United Kingdom;

"approval" in relation to a dairy establishment means approval by the approving authority in accordance with regulation 6 or 15;

"approving authority" in relation to a dairy establishment means the Department or the district council for the district within which such establishment is situated;

"authorised officer" means a person (whether or not an officer of the Department or a district council) who is authorised in writing by the Department or a district council, either generally or specially, to act in matters arising under these Regulations;

"British Islands" means the United Kingdom, the Channel Islands and the Isle of Man;

"catering establishment" means a restaurant, canteen, club, public house, school, hospital, institution or similar establishment (including a vehicle or a fixed or mobile stall) where, in the course of a business, food is prepared for delivery to the ultimate consumer for immediate consumption without further preparation;

"collection centre" means an establishment where raw milk is collected and where it may be cooled and filtered;

"complete cold mix" in relation to ice-cream means a product which is capable of manufacture into a mixture with the addition of water only, is sent out by the manufacturer in airtight containers, and has been made by evaporating a liquid mixture which has already been submitted to heat-treatment not less effective than that prescribed in paragraph 1 of Part V or paragraph 1 of Part VI of Schedule 6 and to which no substance other than sugar has been added;

"Council Directive 92/46" means Council Directive 92/46/EEC, laying down the health rules for the production and placing on the market of milk and milk-based products(**a**), as amended by Council Directives 92/118/EEC(**b**) and 94/71/EC(**c**), to be read with Council Directive 92/47;

"Council Directive 92/47" means Council Directive 92/47/EEC on the conditions for granting temporary and limited derogations from specific Community health rules on the production and placing on the market of milk and milk-based products(**d**);

"cream" means that part of cows' milk rich in fat which has been separated by skimming or otherwise;

"dairy establishment" means any undertaking handling dairy products and is either—

(*a*) a standardisation centre,

or any one of the following undertakings operating alone or in combination—

(**a**) OJ No. L268, 14.9.92, p. 1
(**b**) OJ No. L62, 15.3.92, p. 49
(**c**) OJ No. L368, 31.12.94, p. 33
(**d**) OJ No. L268, 14.9.92, p. 33

(*b*) a treatment establishment,

(*c*) a processing establishment, or

(*d*) a collection centre;

"dairy product" means milk or any milk-based product;

"distributor" means a person who sells drinking milk which is raw cows' milk, produced on a licensed production holding of which he is not the occupier;

"the Department" means the Department of Agriculture for Northern Ireland;

"drinking milk" means milk intended for delivery as such to the ultimate consumer and in relation to drinking milk which is cows' milk, it has the meaning assigned to it by Article 3(1) of Council Regulation (EEC) No. 1411/71(**a**) laying down additional rules on the common market organisation in milk and milk products for drinking milk, as amended(**b**);

"EEA Agreement" means the Agreement on the European Economic Area signed at Oporto on 2nd May 1992 as adjusted by the Protocol signed at Brussels on 17th March 1993;

"EEA State" means a State which is a Contracting Party to the EEA Agreement but until the EEA Agreement comes into force in relation to Liechtenstein does not include the State of Liechtenstein;

"establishment" in Part II of Schedule 2 means a treatment establishment or a processing establishment;

"farm premises" means a farm occupied by the occupier of a licensed production holding as a single farm and includes the production holding and any processing establishment or other buildings situated on that farm and occupied by the same occupier;

"handling" includes preparing, processing, packaging, treating, wrapping or re-wrapping in the course of a business;

"health mark" means a mark applied in accordance with regulation 11(1) and of a kind and in a manner as set out in Part II of Schedule 10;

"heat-treatment" means any treatment of a dairy product involving heating that causes, immediately after such treatment, a negative reaction to the phosphatase test;

"heat-treated milk" means milk obtained by heat-treatment;

"heat-treated drinking milk" means either drinking milk intended for sale to the ultimate consumer or to institutions, obtained by heat-treatment and presented as pasteurised, UHT or sterilised milk; or milk treated by pasteurisation at the request of an individual consumer, for sale in bulk to that consumer;

(**a**) OJ No. L148, 3.7.71, p. 4 (OJ/SE 1971 vol. II, p. 412)

(**b**) The relevant amending instruments are Council Regulation (EEC) No. 566/76 (OJ No. L67, 15.3.76, p. 23), as read with the corrigendum at OJ No. L107, 24.4.76, p. 22, Commission Regulation (EEC) No. 222/88 (OJ No. L28, 1.2.88, p. 1) and Council Regulation (EEC) No. 2138/92 (OJ No. L214, 30.7.92, p. 6)

"hermetically sealed container" means a container which, when sealed, is impervious and is intended to protect its contents against the entry of micro-organisms during and after heat-treatment;

"ice-cream" means any ice-cream which is a milk-based product;

"licensed" in relation to a production holding means licensed in accordance with regulation 4 or deemed to be licensed in accordance with regulation 14;

"limited production" in relation to the production of heat-treated drinking milk means production by means of a separate circuit within any dairy establishment in which heat-treated drinking milk is manufactured and the annual usage of milk for the production of heat-treated drinking milk by such separate circuit does not exceed 300,000 litres;

"low capacity dairy establishment" means a dairy establishment whose annual usage of milk, or milk-based products converted to the equivalent in liquid milk, for the manufacture of milk-based products does not exceed 300,000 litres;

"marketing authorisation" means a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994(**a**) apply;

"milk" means the milk of cows, ewes, goats or buffaloes intended for human consumption;

"milk-based product" means—

(*a*) a milk product exclusively derived from milk to which other substances necessary for its manufacture may have been added provided that those substances do not replace in part or in whole any milk constituent; and

(*b*) a composite milk product of which no part replaces or is intended to replace any milk constituent and of which milk or a milk product is an essential part either in terms of quantity or for characterisation of the product,

intended for human consumption;

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

"mixture" in Parts V and VI of Schedule 6 means any product which is capable of manufacture into ice-cream by freezing only;

"occupier" means any person carrying on the business of a producer or handler of dairy products or his duly authorised representative;

"the Order" means the Food Safety (Northern Ireland) Order 1991;

(**a**) S.I. 1994/3142

"packaging" in relation to dairy products means the placing of one or more wrapped or unwrapped dairy products in a container, as well as the container itself;

"pasteurisation" means the process of heat-treating milk in accordance with paragraph 2(*a*) of Part III of Schedule 4;

"pasteurised milk" means milk obtained by pasteurisation;

"potable water" means water within the meaning of Council Directive 80/778/EEC(**a**) relating to the quality of water intended for human consumption;

"processing" includes manufacturing as well as operations such as slicing;

"processing establishment" means an establishment where any dairy product is either treated, processed and wrapped or undergoes one or more of those handling activities;

"product licence" means a product licence granted under the Medicines Act 1968(**b**);

"production holding" means premises at which one or more milk-producing cows, ewes, goats or buffaloes are kept;

"raw" in relation to milk means milk produced by the secretion of the mammary glands of one or more cows, ewes, goats or buffaloes, which has not been heated beyond 40°C or undergone any treatment which has an equivalent effect;

"sell" includes offer, expose, advertise or have in possession for sale;

"separate circuit" in relation to production in a dairy establishment means the production of heat-treated drinking milk by means of separate equipment or installations, or in a clearly separated place or at a different time from the production of other dairy products, in that establishment;

"shop premises" means premises (including vehicles) from which any food is sold to the ultimate consumer;

"standardisation centre" means an establishment which is not attached to a collection centre or to a treatment or processing establishment and where raw milk may be skimmed or its natural constituents modified;

"sterilised milk" means milk which has been heat-treated in accordance with paragraph 4 of Part III of Schedule 4;

"sugar" means any soluble carbohydrate sweetening matter and for this purpose "carbohydrate" means a substance containing carbon, hydrogen and oxygen only, in which the hydrogen and the oxygen generally although not always occur in the same proportion as in water;

"thermisation" means the process of treating milk in accordance with the requirements specified in sub-paragraph (*b*) of Part II of Schedule 5;

"thermised milk" means milk which has been subjected to thermisation;

(**a**) OJ No. L229, 30.8.80, p. 11, to which there are amendments not relevant to these Regulations
(**b**) 1968 c. 67

"third country" means a country which is not an EEA State;

"treatment" means heat-treatment or thermisation;

"treatment establishment" means an establishment where milk is heat-treated;

"UHT milk" means milk which has been heat-treated in accordance with paragraph 5(*a*) of Part III of Schedule 4;

"ultimate consumer" means any person who buys otherwise than—

(*a*) for the purpose of re-sale;

(*b*) for the purposes of a catering establishment; or

(*c*) for the purposes of a manufacturing business;

"veterinary surgeon" has the meaning assigned to it by the Medicines (Medicated Animal Feedingstuffs) (No. 2) Regulations 1992(**a**);

"veterinary written direction" has the meaning assigned to it by the Medicines (Medicated Animal Feedingstuffs) (No. 2) Regulations 1992;

"withdrawal period" in paragraph 1(*f*) of Part I of Schedule 3 means the period specified in a current product licence or marketing authorisation relating to a product administered to an animal, or (in the absence of any such specification) specified in a prescription or a veterinary written direction given by a veterinary surgeon in respect of the administration of the product, which is required to elapse from the cessation of the administration of the product to the animal before the taking of its milk for human consumption;

"wrapping" in relation to any dairy product means the protection of that dairy product by the use of an initial wrapping or initial container in direct contact with the product as well as the initial wrapper or initial container itself.

(2) Other expressions used in these Regulations have the same meanings as in Council Directive 92/46.

(3) The Interpretation Act (Northern Ireland) 1954(**b**) shall apply to these Regulations as it applies to a Measure of the Northern Ireland Assembly.

Exemptions

3.—(1) These Regulations shall not apply to—

(*a*) any production holding or dairy establishment producing or handling dairy products exclusively for the consumption of the occupier of that production holding or dairy establishment;

(*b*) any dairy establishment handling dairy products exclusively for the supply by the occupier of that dairy establishment otherwise than on sale;

(*c*) any person engaged in the production or handling of dairy products described in sub-paragraph (*a*) or (*b*).

(**a**) S.I. 1992/1520, to which there are amendments not relevant to these Regulations
(**b**) 1954 c. 33 (N.I.)

(2) Subject to paragraph (3) these Regulations shall not apply to—

(*a*) the handling of any dairy products in any catering establishment or shop premises;

(*b*) the sale of any dairy products from any catering establishment or shop premises; or

(*c*) any person engaged in the selling or handling of dairy products described in sub-paragraph (*a*) or (*b*).

(3) Notwithstanding the exemption in paragraph (2), the requirements of—

(*a*) Parts II to IV of Schedule 6 shall apply in relation to the handling of any heat-treated cream in any catering establishment or shop premises;

(*b*) Parts V and VI of Schedule 6 shall apply in relation to the handling of any ice-cream in any catering establishment or shop premises; and

(*c*) regulation 12 shall apply in relation to any catering establishment or shop premises selling drinking milk which is raw cows' milk.

(4) Subject to paragraph (5)—

(*a*) regulation 6;

(*b*) regulation 9(1)(*a*);

(*c*) regulation 11(1)(*b*) and (*d*); and

(*d*) regulation 13(1)(*b*)(iii), (iv) and (vi), and (*c*) to (*e*),

shall not apply in relation to any processing establishment which comprises part of any farm premises, and from which establishment is carried on the business of selling or handling—

(i) any raw milk wrapped in that establishment; or

(ii) any milk-based product made from raw milk produced on those farm premises,

where such sales are made direct to the ultimate consumer exclusively.

(5) Notwithstanding the exemption in paragraph (4)(*a*), the occupier of a processing establishment which comprises part of any farm premises shall ensure that the requirements of regulation 6(1)(*a*) as read with Part III of Schedule 2 are complied with in that processing establishment.

(6) In paragraph (1)(*a*), "occupier" includes any person forming part of the occupier's household.

PART II

LICENSING AND USE OF PRODUCTION HOLDINGS

Licensing and use of production holdings

4.—(1) A person shall not use any premises as a production holding for the production of raw milk unless those premises—

(*a*) comply with the appropriate requirements of Schedule 1; and

(*b*) are licensed in accordance with the provisions of paragraph (3)(*a*), or are deemed to be licensed in accordance with regulation 14.

(2) A person shall not—

(*a*) despatch for sale from any licensed production holding any raw milk which does not comply with the provisions of these Regulations; or

(*b*) despatch any raw milk to another EEA State, or any part of the British Islands, from a production holding to which this regulation applies but which is not licensed under this regulation or is not deemed to be licensed by regulation 14.

(3) The Department on application made to it under this regulation shall—

(*a*) license the premises to which the application relates as a production holding if it is satisfied that both the premises and the arrangements at those premises for use as a production holding are adequate to comply with the requirements of Schedule 1 and paragraphs 1 and 2 of Schedule 7; or

(*b*) refuse to license the premises as a production holding if it is not so satisfied.

(4) Each application for a licence under this regulation shall be made to the Department by the occupier of, or a person proposing to occupy, the production holding to which the application relates and shall be made in such form and shall contain such particulars as the Department may require.

(5) The Department shall, without unreasonable delay after receipt of the application referred to in paragraph (4), notify the applicant in writing of its decision on that application and of the reasons for any refusal to license such production holding.

(6) Any person who is aggrieved by the imposition by the Department of a licence condition, may appeal against that decision to a court of summary jurisdiction in accordance with the provisions of Article 37(2) of the Order.

(7) Any licence granted in respect of any production holding under this regulation shall be subject to the condition that any alteration to that production holding shall comply with the requirements of Schedule 1 and paragraphs 1 and 2 of Schedule 7, if appropriate.

(8) Without prejudice to Articles 8 to 11 of the Order, where the Department has refused a licence under this regulation, a person who both prior to the coming into operation of these Regulations and immediately before such refusal had been lawfully using any premises for the production of raw milk, may continue to use such premises for that purpose, subject to any reasonable conditions imposed by the Department for the protection of public health, until the time for appeal has expired and, if an appeal is lodged, until the appeal is finally disposed of or abandoned.

(9) The Department shall be entitled to inspect any premises in respect of which an application has been made to the Department to license such premises as a production holding, prior to licensing those premises.

List of production holdings

5.—(1) The Department shall allot a licence number to each licensed production holding including any premises deemed to be licensed in accordance with regulation 14 and keep a list of such production holdings.

(2) Any licensed production holding which ceases to be used as a production holding shall be removed from the list kept by the Department pursuant to paragraph (1).

PART III

APPROVAL AND USE OF DAIRY ESTABLISHMENTS

Approval and use of dairy establishments

6.—(1) A person shall not use any premises as a dairy establishment unless those premises—

(*a*) comply with the appropriate requirements of Schedule 2; and

(*b*) are approved in accordance with the provisions of paragraph (3)(*a*) or (8).

(2) A person shall not—

(*a*) despatch from any approved dairy establishment any dairy products which do not comply with the provisions of these Regulations; or

(*b*) despatch any dairy products to another EEA State or any part of the British Islands, from a dairy establishment to which this regulation applies but which is not approved under this regulation.

(3) Subject to paragraph (8), an approving authority, on application made to it under this regulation, shall—

(*a*) approve the premises to which the application relates as a dairy establishment, if it is satisfied that—

(i) in the case of a collection centre, both the premises and the arrangements at those premises for use as a collection centre are adequate to comply with the requirements of Parts I and III of Schedule 2 and with the appropriate requirements of section B of Part II of that Schedule;

(ii) in the case of a standardisation centre, both the premises and the arrangements at those premises for use as a standardisation centre are adequate to comply with the requirements of Parts I and III of Schedule 2 and with section C of Part II of that Schedule;

(iii) in the case of a processing establishment, both the premises and the arrangements at those premises for use as a processing establishment are adequate to comply with the requirements of Parts I and III of Schedule 2 and with the appropriate requirements of section A of Part II of that Schedule;

(iv) in the case of a treatment establishment, both the premises and the arrangements at those premises for use as a treatment establishment are adequate to comply with the requirements of

Parts I and III of Schedule 2 and with the appropriate requirements of section A of Part II of that Schedule; and

(v) the arrangements at the dairy establishment are adequate to enable the occupier to comply with the requirements of regulation 13(1); or

(*b*) refuse to approve the premises as a dairy establishment if it is not so satisfied.

(4) Each application for an approval under this regulation shall be made to the approving authority by the occupier of, or a person proposing to occupy, the dairy establishment to which the application relates and shall be made in such form and shall contain such particulars as the approving authority may require.

(5) The approving authority shall, without unreasonable delay after receipt of the application referred to in paragraph (4), notify the applicant in writing of its decision on that application and of the reasons for any refusal to approve such dairy establishment.

(6) Any person who is aggrieved by a decision of the approving authority not to grant an approval or by the imposition of any condition specified by the approving authority, may appeal against that decision to a court of summary jurisdiction in accordance with the provisions of Article 37(2) of the Order.

(7) Any approval granted in respect of any dairy establishment under this regulation shall be subject to the condition that any alteration to the establishment shall comply with the requirements of Schedule 2, if appropriate.

(8) The approving authority may approve as a dairy establishment any low capacity dairy establishment which may not comply with any or all of the requirements of Parts I and II of Schedule 2.

(9) Without prejudice to Articles 8 to 11 of the Order, where the approving authority has refused an approval under this regulation, a person who both prior to the coming into operation of these Regulations and immediately before such refusal had been lawfully using any premises for the handling of dairy products, may continue to use such premises for that purpose, subject to any reasonable conditions imposed by the approving authority for the protection of public health, until the time for appeal has expired and, if an appeal is lodged, until the appeal is finally disposed of or abandoned.

(10) The approving authority shall be entitled to inspect any premises in respect of which an application has been made to that authority for approval as a dairy establishment, prior to approving those premises.

List of dairy establishments

7.—(1) The approving authority shall allot an approval number to each dairy establishment which it has approved and shall keep a list of those dairy establishments.

(2) Any approved dairy establishment which ceases to be used as a dairy establishment shall be removed from the list kept by the approving authority pursuant to paragraph (1).

PART IV

REVOCATION OF LICENCES AND APPROVALS

Revocation of licences and approvals

8.—(1) The Department may revoke a licence granted by it under regulation 4, or deemed to be so granted by virtue of regulation 14, in respect of any production holding if, after an inspection of, or an inquiry into, the method of operation of the production holding, it is satisfied that in respect of that production holding—

(*a*) there is an obvious failure to comply with these Regulations;

(*b*) there are obstacles to an adequate inspection of that production holding;

(*c*) the business carried on at the premises in respect of which the licence was granted is no longer being carried on there; or

(*d*) the premises have become exempt under regulation 3.

(2) An approving authority may revoke an approval granted by that authority under regulation 6 or 15 in respect of any dairy establishment if, after an inspection of, or an inquiry into, the method of operation of the dairy establishment, it is satisfied that in respect of that dairy establishment—

(*a*) there is an obvious failure to comply with these Regulations;

(*b*) there are obstacles to an adequate inspection of that dairy establishment;

(*c*) the business carried on at the premises in respect of which the approval was granted is no longer being carried on there; or

(*d*) the premises have become exempt under regulation 3.

(3) In relation to a production holding and to a dairy establishment, the Department shall give the occupier of those premises notice in writing—

(*a*) of any decision by the Department to revoke a licence granted or deemed to be granted in respect of the production holding or of any decision by the Department to revoke the approval of the dairy establishment;

(*b*) of the date on which such revocation is to take effect; and

(*c*) of the reasons for such revocation.

(4) In relation to a dairy establishment, a district council shall give the occupier of those premises notice in writing—

(*a*) of any decision by the district council to revoke the approval of a dairy establishment;

(*b*) of the date on which such revocation is to take effect; and

(*c*) of the reasons for such revocation.

(5) An approval may not be revoked under paragraph (2)(*a*) or (*b*) unless there is in operation in relation to the dairy establishment—

(*a*) a prohibition order under Article 10 of the Order; or

(*b*) an emergency prohibition order under Article 11 of the Order,

and in consequence of compliance with the order dairy products may no longer be handled at those premises.

(6) Any person who is aggrieved by a decision of an approving authority to revoke the approval of a dairy establishment may appeal to a court of summary jurisdiction against that decision in accordance with the provisions of Article 37(2) of the Order.

(7) A revocation shall not take effect until the time for appealing against it has expired and, if an appeal is lodged, until the appeal is finally disposed of or abandoned.

(8) In paragraphs (3) and (4) "occupier", in relation to a proposed revocation by virtue of paragraph (1)(*c*) or (2)(*c*), where the production holding or dairy establishment is vacant, means the last person known to the Department or the district council, as the case may be, to have carried on at the production holding or dairy establishment the business of producing or handling dairy products or his successor in respect of that business.

PART V

CONDITIONS FOR THE HANDLING AND MARKETING OF DAIRY PRODUCTS

General conditions

9.—(1) Subject to paragraphs (10), (11), (12) and (13) and regulation 15, a person shall not sell for human consumption any raw milk, thermised milk, heat-treated drinking milk, heat-treated milk intended for the manufacture of milk-based products or milk-based products unless—

(*a*) it originates from a licensed production holding or an approved dairy establishment which complies with the appropriate requirements set out in Schedules 1 and 2;

(*b*) it complies with the appropriate requirements set out in Schedule 3;

(*c*) the occupier of the dairy establishment has complied with the provisions of regulation 13 in relation to it;

(*d*) it complies with the appropriate conditions specified in paragraph (2), (3), (4), (5) or (6);

(*e*) it complies with paragraphs (7), (8), (9), (10), (11) and (12), if applicable; and

(*f*) it complies with regulation 11.

(2) In the case of raw drinking milk, the appropriate conditions to be complied with are—

(*a*) in the case of raw cows' milk, those specified in Part I of Schedule 4 and regulation 12; and

(*b*) in the case of raw ewes' milk or raw goats' milk, those specified in paragraph 2 of Part I of Schedule 4.

(3) In the case of thermised milk, the appropriate conditions to be complied with are that—

(*a*) it shall be manufactured from raw milk which complies with the requirements of paragraph (1)(*a*), (*b*) and (*c*); and

(*b*) where the thermised milk is intended for the manufacture of milk-based products, it complies with the requirements of Part II of Schedule 5.

(4) In the case of heat-treated drinking milk, the appropriate conditions to be complied with are that—

(*a*) it shall be manufactured from raw milk or thermised milk which complies with paragraph (1)(*a*), (*b*) and (*c*);

(*b*) it shall be manufactured from other heat-treated drinking milk which complies with the appropriate requirements of Part III of Schedule 4; or

(*c*) it shall be manufactured from a mixture of the milk specified in sub-paragraphs (*a*) and (*b*).

(5) In the case of heat-treated milk intended for the manufacture of milk-based products, the appropriate conditions to be complied with are those specified in Parts III and IV of Schedule 5.

(6) In the case of milk-based products, the appropriate conditions to be complied with are those specified in Schedule 6 and that they shall be manufactured from—

(*a*) raw milk or thermised milk which complies with paragraphs (1)(*a*), (*b*) and (*c*) and (3)(*b*), as appropriate;

(*b*) heat-treated drinking milk which complies with paragraph (4)(*b*); or

(*c*) heat-treated milk (not being heat-treated drinking milk) which complies with paragraph (5).

(7) A person shall not sell any cows' milk to any catering establishment without heat-treatment of such milk.

(8) A person shall not sell any thermised cows' milk to the ultimate consumer without heat-treatment of such milk.

(9) A person shall not sell any ice-cream unless it is pasteurised ice-cream which complies with Part V of Schedule 6 or it is sterilised ice-cream which complies with Part VI of that Schedule.

(10) In the case of any milk which does not satisfy the conditions specified in paragraph 2(*a*) and (*c*) of Part I of Schedule 3, it may be sold for human consumption after it has been heat-treated.

(11) In the case of any dairy products which have been handled in an infected area, they may be sold for human consumption if the milk used in the production of such dairy products has been heat-treated.

(12) In the case of cheese with a period of ageing or ripening of at least sixty days and which complies with Part I of Schedule 6, it shall not be necessary for such cheese to—

(*a*) be prepared in a dairy establishment which complies with the requirements of Parts I and II of Schedule 2;

(*b*) be made from raw milk complying with paragraphs 2 and 4 of Part II of Schedule 3; or

(*c*) be wrapped and packaged in accordance with the requirements of Schedule 9.

(13) In the case of milk-based products with traditional characteristics, it shall not be necessary for such products to—

(*a*) be prepared in a dairy establishment which complies with the requirements of Parts I and II of Schedule 2;

(*b*) be made from raw milk which complies with the requirements of Parts II and III of Schedule 3;

(*c*) satisfy the microbiological criteria specified in Part I of Schedule 6; or

(*d*) be wrapped and packaged in accordance with the requirements of Schedule 9.

(14) In this regulation—

(*a*) in paragraph (1)(*c*), "occupier of the dairy establishment" in relation to raw milk purchased by a person for re-sale as described in regulation 13(3), includes the person who purchased that milk for re-sale; and

(*b*) in paragraph (11), "infected area" has the same meaning as in the Foot-and-Mouth Disease Order (Northern Ireland) 1962(**a**).

Methods of analysis

10. For the purposes of these Regulations the methods of analysis and testing of dairy products specified in Schedule 11 shall be used in relation to the requirements referred to in that Schedule.

Storage, transport, wrapping and labelling conditions

11.—(1) Dairy products intended for sale shall—

(*a*) be handled, stored and transported in accordance with Schedules 7 and 8;

(*b*) in the case of any heat-treated drinking milk or milk-based products transported in bulk, be accompanied during transportation by a commercial document as specified in Part III of Schedule 8;

(a) S.R. & O. (N.I.) 1962 No. 209

(*c*) save as specified in regulation 9(12) and (13), be wrapped and packaged in accordance with the requirements of Schedule 9; and

(*d*) subject to paragraph (4) and regulation 15, be marked with a health mark and labelled in accordance with the appropriate requirements of Schedule 10.

(2) Any person who receives a consignment of dairy products together with the commercial document referred to in paragraph (1)(*b*), shall keep that document for a period of at least one year after the date of such receipt, and make it available for inspection at the request of an authorised officer.

(3) A person shall not use on any dairy product which has not been produced in accordance with these Regulations any mark which is not a health mark, but which resembles a health mark in such a way as to be likely to suggest that the product has been produced in accordance with these Regulations.

(4) An occupier may, until 1st January 1996, use on his dairy products any packaging or wrapping which may not comply with the requirements of Part II of Schedule 10.

Restrictions on the sale of raw cows' milk as drinking milk

12.—(1) A person shall not sell drinking milk which is raw cows' milk except in accordance with the following provisions of this regulation.

(2) An occupier of a licensed production holding may sell such milk at or from the farm premises where the animals from which the milk has been obtained are maintained to—

(*a*) the ultimate consumer for consumption other than at those farm premises;

(*b*) a temporary guest or visitor to those farm premises as or as part of a meal or refreshment; or

(*c*) a distributor.

(3) A distributor may sell such milk—

(*a*) in the containers in which he receives the milk with the fastenings of the containers unbroken;

(*b*) from a vehicle which is lawfully used as shop premises; and

(*c*) direct to the ultimate consumer.

PART VI

CONDITIONS RELATING TO ALL DAIRY ESTABLISHMENTS

Duties of occupier or purchaser of raw milk for re-sale

13.—(1) Subject to paragraph (3) the occupier of a dairy establishment shall—

(*a*) take all necessary measures to ensure that, at all stages of handling of dairy products at that dairy establishment, the appropriate requirements of these Regulations are complied with;

(*b*) carry out his own checks to ensure—

(i) that critical points in the dairy establishment relative to the processes used there are identified;

(ii) that methods for monitoring and controlling such critical points are established;

(iii) that appropriate tests are carried out to detect any residues of substances having pharmacological or hormonal action, and of antibiotics, pesticides, detergents and other substances which are harmful to human health or which might alter the organoleptic characteristics of dairy products or make their consumption harmful to human health if those residues exceed permitted tolerance limits;

(iv) that appropriate checks are carried out to detect the presence of any added water in raw milk in accordance with Part III of Schedule 3 and in heat-treated drinking milk in compliance with Part III of Schedule 4;

(v) compliance with the standards for animal health prescribed in Part I of Schedule 3; and

(vi) that samples taken for the purpose of checking the cleaning and disinfection methods, or for the purpose of checking compliance with the standards for dairy products prescribed in Part II of Schedule 3 and Schedules 4, 5 and 6 are analysed and examined as appropriate in a laboratory acceptable to the approving authority which approved the dairy establishment;

(*c*) ensure that as far as is reasonable and practicable a record in permanent form is kept in respect of the matters specified in sub-paragraph (*b*)—

(i) in the case of any dairy product which cannot be stored at ambient temperature, for a period of not less than two months, calculated from the end of the minimum durability indication or "use by" date on the product, and

(ii) in the case of any other dairy product, for a period of not less than two years, calculated from the date to which such record relates;

(*d*) upon demand by an authorised officer produce or cause to be produced any record the occupier is required to keep by sub-paragraph (*c*) for inspection by the authorised officer and allow him to take copies and make extracts from it;

(*e*) ensure that health marking is controlled and carried out properly;

(*f*) ensure that the approving authority which approved the establishment is notified immediately when a laboratory examination of samples or any other information in the occupier's possession or under his control reveals a serious health risk;

(*g*) furnish the approving authority which approved the establishment with such information and assistance as it may reasonably request so as to enable it to take such action as it may consider necessary under these Regulations or the Order; and

(*h*) ensure, in the event of an immediate human health risk, the withdrawal from the market of the quantity of dairy products obtained under technologically similar conditions and likely to present the same risk; and also ensure that any quantity of the dairy product so withdrawn shall be held under the supervision and control of the approving authority which approved the establishment until it is destroyed, or used for purposes other than human consumption, or, with the agreement of that approving authority, reprocessed in a manner appropriate to ensure it is safe for human consumption.

(2) The occupier of any dairy establishment shall ensure that workers at that dairy establishment are given instruction and training with regard to hygiene matters, but the instructions and training given to a worker need only be such as is appropriate to any task undertaken by the worker.

(3) Where raw milk is purchased from a production holding by any person other than the occupier of an approved dairy establishment or a distributor, for re-sale as milk intended for processing, such person shall ensure that the following obligations in relation to that milk are complied with:—

(*a*) the carrying out of appropriate tests to detect any residues of substances as specified in paragraph (1)(*b*)(iii);

(*b*) the carrying out of appropriate checks to detect the presence of added water in accordance with Part III of Schedule 3;

(*c*) the taking of samples for the purpose of checking compliance of the milk with the standards for dairy products prescribed in Part II of Schedule 3;

(*d*) the carrying out of checks to ensure compliance with the standards for animal health prescribed in Part I of Schedule 3;

(*e*) the requirements specified in paragraph 1(*c*) to (*h*), as appropriate; and

(*f*) the requirements specified in Schedules 7 and 8.

PART VII

TRANSITIONAL PROVISIONS RELATING TO PRODUCTION HOLDINGS AND DAIRY ESTABLISHMENTS

Production holdings

14. Subject to regulation 8 any production holding occupied by a person who, in respect of that production holding holds a licence under the Milk Regulations (Northern Ireland) 1987(**a**) immediately before the coming into

(a) S.R. 1987 No. 229 which is revoked by regulation 24 and Schedule 12 of these Regulations

operation of these Regulations and which is in operation as a production holding on the date before the date on which these Regulations come into operation, shall be deemed to be premises licensed under and subject to the provisions of these Regulations as a production holding.

Temporary derogations under Council Directive 92/47

15.—(1) Notwithstanding the requirements of regulation 6(3) and until 31st December 1997 an approving authority shall approve a dairy establishment which does not comply with any or all of the requirements of Schedule 2, and which is listed in the Annex to Commission Decision 94/695/EC(**a**) establishing the list of Community establishments for which temporary and limited derogations are granted from Community health rules on the production and placing on the market of raw milk, heat-treated milk and milk-based products, in accordance with Article 2 of Council Directive 92/47.

(2) Dairy products produced in a dairy establishment approved in accordance with paragraph (1) shall not—

(*a*) bear a health mark; or

(*b*) be exported to another EEA State.

(3) In this regulation, "dairy establishment" includes a part of a dairy establishment, and "dairy products" means dairy products in respect of which a derogation has been granted in accordance with Article 2 of Council Directive 92/47.

PART VIII

ENFORCEMENT, SUPERVISION AND PENALTIES

Enforcement and supervision

16.—(1) Subject to paragraphs (2) to (4) each district council shall enforce and execute these Regulations within its district.

(2) The Department shall enforce and execute these Regulations in relation to—

(*a*) any production holding; and

(*b*) any dairy establishment approved by it in accordance with regulation 6 or 15.

(3) In relation to any production holding the Department shall carry out such supervision of those premises as the Department may consider necessary to ensure that the requirements of these Regulations are complied with.

(4) In relation to any dairy establishment the approving authority which approved that establishment shall carry out such supervision of that establishment as that authority may consider necessary to ensure that the requirements of these Regulations are complied with.

(a) OJ No. L282, 29.10.94, p. 1

Information to be provided by the district councils

17. Each district council shall provide the Department with such information relating to the execution of that district council's duties under these Regulations as the Department may from time to time require for the purpose of its duties under these Regulations or the Order.

Offences and penalties

18. If—

(*a*) a person (other than the Department or a district council) contravenes any provision of these Regulations; or

(*b*) the occupier of any production holding or dairy establishment fails to take all reasonable steps to secure the compliance by any person employed by him or any person admitted to that production holding or dairy establishment with any provision of these Regulations,

he shall be guilty of an offence and shall be liable—

(i) on summary conviction, to a fine not exceeding the statutory maximum; or

(ii) on conviction on indictment, to a fine or imprisonment for a term not exceeding two years or to both.

Authorisations to derogate

19. The approving authority responsible for approving a dairy establishment may authorise derogation from the requirements as to—

(*a*) automatic sealing in the case of limited production specified in paragraph 2 of section A of Part II of Schedule 2 and paragraph 4 of Schedule 9, in accordance with paragraph (*a*) of Chapter V of Annex B and paragraph 3 of Chapter III of Annex C of Council Directive 92/46;

(*b*) equipment specified in paragraph 7(1) of section A of Part II of Schedule 2, in accordance with paragraph (*f*) of Chapter V of Annex B of Council Directive 92/46;

(*c*) times and temperatures specified in paragraph 1 of Part I of Schedule 5, in accordance with paragraph B(1) of Chapter I of Annex C of Council Directive 92/46;

(*d*) temperatures for milk-based products specified in paragraph 2 of Schedule 7 and paragraph 1 of Part I of Schedule 8, in accordance with paragraph A(2) of Chapter III of Annex A of Council Directive 92/46; and

(*e*) use of working areas, instruments and equipment specified in paragraph 4 of section A of Part III of Schedule 2, in accordance with paragraph A(3) of Chapter II of Annex B of Council Directive 92/46.

Application of various Articles of the Order

20.—(1) The following provisions of the Order shall apply for the purposes of these Regulations as they apply for the purposes of Article 7, 13 or 14 of the Order and, unless the context otherwise requires, any reference

in them to the Order shall be construed as a reference to these Regulations—

(*a*) Article 2(4) (extended meaning of "sale" etc.);

(*b*) Article 3 (application to food offered as prizes, etc.);

(*c*) Article 4 (presumptions that food intended for human consumption);

(*d*) Article 19 (offences due to fault of another person);

(*e*) Article 20 (defence of due diligence);

(*f*) Article 30(8) (which relates to documentary evidence); and

(*g*) Article 34 (obstruction, etc., of officers).

(2) Article 7(2) of the Order (which makes presumptions in the case of batches of food) shall apply to food which it is an offence to sell under these Regulations as it applies to food which fails to comply with food safety requirements.

(3) Article 8 of the Order (inspection and seizure of suspected food) shall apply to food which it is an offence to sell under these Regulations as it applies to food which fails to comply with food safety requirements.

PART IX

MISCELLANEOUS AND SUPPLEMENTARY

Dairy products from Great Britain, the Isle of Man and the Channel Islands

21.—(1) The places to which this regulation applies are Great Britain, the Isle of Man and the Channel Islands.

(2) A person—

(*a*) shall not sell for human consumption from an approved dairy establishment any dairy products which have been handled in a place to which this regulation applies which are intended for consignment to another EEA State; or

(*b*) shall not sell for human consumption any dairy products which have been handled in a place to which this regulation applies after the specified date,

unless any handling of those products in that place was in accordance with legislation having effect in that place and corresponding to these Regulations.

(3) Subject to regulation 11(4) and paragraph (4) a person shall not sell for human consumption in Northern Ireland any dairy products which have been handled after the specified date in a place to which this regulation applies unless it carries the relevant EC health mark.

(4) The prohibition in paragraph (3) shall not apply in relation to dairy products produced in a place to which this regulation applies and which do not bear a health mark in accordance with legislation having effect in that place and corresponding to regulation 15 of these Regulations.

(5) In this regulation—

(*a*) the "specified date" means the date on which these Regulations come into operation;

(*b*) the "relevant EC health mark", in relation to any place to which this regulation applies, means a mark applied in accordance with legislation having effect in that place and corresponding to the provisions of Part II of Schedule 10 relating to the health mark.

Imports from third countries and EEA States

22.—(1) A person shall not import into Northern Ireland for sale for human consumption from a third country any cows' milk or cream.

(2) A person shall not import into Northern Ireland for sale for human consumption from a third country any other dairy products except in accordance with paragraphs (3) to (5).

(3) In the case of dairy products produced or manufactured in another EEA State, they shall comply with the legislation having effect in that EEA State which implements Council Directive 92/46.

(4) In the case of dairy products other than cows' milk or cream manufactured in any third country, they shall be accompanied by a health certificate or certificate as specified by Article 23(2)(*b*) or 25(1) of Council Directive 92/46.

(5) In paragraph (3), "the legislation" shall include any administrative provisions enacted in the EEA State referred to in that paragraph to comply with Council Directive 92/46.

Repeals and revocations

23.—(1) The statutory provisions specified in Schedule 12 are hereby repealed or revoked to the extent specified in column 3 of that Schedule.

(2) The Marketing of Milk Products Regulations (Northern Ireland) 1966(**a**), the Marketing of Milk Products (Amendment) Regulations (Northern Ireland) 1980(**b**), the Marketing of Milk Products (Amendment) Regulations (Northern Ireland) 1981(**c**), the Marketing of Milk Products (Amendment) Regulations (Northern Ireland) 1983(**d**), and the Marketing of Milk Products (Amendment) Regulations (Northern Ireland) 1991(**e**), insofar as they are still in operation, are hereby revoked.

Consequential amendments

24.—(1) The Ice-Cream and Other Frozen Confections Regulations (Northern Ireland) 1968(**f**) shall be amended as follows—

(*a*) after regulation 2A there shall be inserted the following regulation—

(**a**) S.R. & O. (N.I.) 1966 No. 204.
(**b**) S.R. 1980 No. 436
(**c**) S.R. 1981 No. 233
(**d**) S.R. 1983 No. 336
(**e**) S.R. 1991 No. 526
(**f**) S.R. & O. (N.I.) 1968 No. 13, the relevant amending Regulations are S.R. 1981 No. 305, S.R. 1991 No. 203, S.R. 1991 No. 344 and S.R. 1992 No. 464

"*Exemptions*

2B.—(1) Part IV (including Schedule 2) shall not apply in relation to any ice-cream which is a milk-based product.

(2) In this regulation "milk-based product" has the same meaning as in the Dairy Products (Hygiene) Regulations (Northern Ireland) 1995."; and

(*b*) the cross-heading to regulation 3 shall be omitted and at the beginning of that regulation there shall be inserted the words "Subject to regulation 2B".

(2) In the Drinking Milk Regulations (Northern Ireland) 1977(**a**), after regulation 5 there shall be inserted the following regulation—

"*Reserved names*

5A. A person shall not use any name specified in Article 3(1) of Council Regulation (EEC) No. 1411/71(**b**), as amended(**c**), except in accordance with paragraph (2) of that Article.".

(3) The Food Labelling Regulations (Northern Ireland) 1984(**d**) shall be amended in accordance with Schedule 13.

(4) The Food Premises (Registration) Regulations (Northern Ireland) 1992(**e**) shall be amended as follows—

(*a*) for sub -paragraph (*a*) of regulation 3(2) there shall be substituted the following sub-paragraph—

"(*a*) as a production holding or as a dairy establishment in each case within the meaning of the Dairy Products (Hygiene) Regulations (Northern Ireland) 1995;"; and

(*b*) sub-paragraph (*b*) of regulation 3(2) shall be deleted.

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland on 18th May 1995.

(L.S.) *P. T. Toal*

Assistant Secretary

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on 18th May 1995.

(L.S.) *D. A. Baker*

Assistant Secretary

(**a**) S.R. 1977 No. 8 to which there are amendments not relevant to these Regulations
(**b**) OJ No. L148, 3.7.71, p. 4 (OJ/SE 1971 vol. II, p. 412)
(**c**) The relevant amending instrument is Council Regulation (EEC) No. 566/76 (OJ No. L67, 15.3.76, p. 23) as read with the corrigendum at OJ No. L107, 24.4.76, p. 22
(**d**) S.R. 1984 No. 407 and the relevant amending Regulations are S.R. 1989 No. 229, S.R. 1990 No. 440, S.R. 1991 Nos. 216 and 344, S.R. 1992 No. 464 and S.R. 1994 No. 214
(**e**) S.R. 1992 No. 167 to which there are amendments not relevant to these Regulations

SCHEDULE 1 Regulations 4(1)(*a*), (3)(*a*) and (7) and 9(1)(*a*)

Conditions for licensing of production holdings

PART I

A. *General conditions of hygiene for production holdings*

1. All animals shall be clean and well-kept. Individual cows in a herd shall be identifiable by an authorised officer.

2. Production holdings shall have the capability to isolate effectively from the rest of the herd any animals infected, or suspected of being infected with tuberculosis, brucellosis or any other disease communicable to humans through consumption of milk.

3. Any creature, including any animal of the species referred to in regulation 2(1) shall be kept away from premises and sites where milk is stored, handled or cooled.

4. Pigs and poultry shall not be housed in premises where animals are housed or milked.

5. Access to premises in which animals are housed or milked or any premises on the production holding in which milk is handled, cooled or stored shall be kept free from accumulations of dung, droppings or other offensive matter. Dung channels and droppings on the production holding shall be cleared regularly as necessary.

6. Adequate measures shall be taken to control insects, rodents and other vermin on the production holding.

7. Store-rooms and cleaning-rooms and the equipment in such rooms shall be kept clean, tidy and in good condition.

8. The holding bay for ewes and goats, where it exists, shall be kept in a clean and tidy condition.

B. *General conditions of hygiene applicable to staff*

1. The highest standards of cleanliness shall be required at all times of staff and persons engaged in milking and handling of raw milk. In particular they shall:

(*a*) wear suitable clean working clothes;

(*b*) wash their hands immediately before commencing milking or handling of raw milk and shall keep them clean, as far as practicable, throughout the milking or handling operation; and

(*c*) keep any wounds to the skin covered with a waterproof dressing.

2. The occupier shall take all requisite measures to prevent persons liable to contaminate raw milk from handling it, unless there is evidence that such persons can do so without risk of contamination.

3. Before the recruitment of any person for milking or handling raw milk, such person shall be required to show that there is no medical impediment to such employment.

PART II

CONDITIONS FOR HOUSING OF ANIMALS

1. The premises housing milking animals shall be designed, sited, constructed, maintained and managed so as to ensure good conditions of housing, hygiene, cleanliness and health of the animals.

2. The stalls or lying areas shall be kept dry, if necessary by the use of bedding which is regularly changed.

3. Washing, cleaning and disinfection of the premises housing milking animals or any outhouses attached to such premises shall be carried out in such a way so as to ensure that it does not have an adverse effect on the milk. Any disinfectants used shall be acceptable to the authorised officer.

4. Where one or more rams or male goats are used for breeding, separate accommodation shall be provided for them so as to avoid contamination with odours.

PART III

CONDITIONS FOR MILKING AND THE HANDLING, COOLING AND STORAGE OF RAW MILK ON THE PRODUCTION HOLDING

A. *Structure of the premises*

1. Premises in which animals are milked or in which raw milk is handled, cooled or stored shall—

(*a*) be designed, sited, constructed, maintained and managed in such a way as to ensure satisfactory hygiene conditions for milking operations and for the handling, cooling and storing of milk and shall provide adequate separation from all sources of contamination, including lavatories and dung heaps;

(*b*) have walls and floorings in areas liable to soiling or infection, and fittings and equipment, which are easy to clean and disinfect;

(*c*) have suitable means of waste disposal, including flooring which allows liquids to drain away;

(*d*) have adequate ventilation and lighting;

(*e*) have a sufficient supply of potable water for use in milking operations, and for the cleaning of equipment and utensils intended to come into contact with milk;

(*f*) have suitable facilities near the place of milking to enable milkers and persons handling milk to wash their hands and arms;

(*g*) in the case of production holdings where milk-producing animals are kept untethered in the open, have a milking parlour, or a milking area for the milking of animals, which is adequately separated from any housing area; and

(*h*) in the case of milk storage premises, have suitable refrigeration equipment, adequately protected against vermin and be adequately separated from any premises where any animals are housed or milked.

2. If a processing or treatment establishment is attached to a production holding for ewes and goats, there shall be no direct communication between premises where the ewes and goats are housed or milked, and the processing or treatment establishment.

B. *Equipment*

1. Equipment and instruments or their surfaces which are intended to come into contact with milk in premises in which animals are milked or in which milk is handled, cooled or stored shall be made of smooth material which is easy to clean and disinfect, which resists corrosion and which will not transfer substances to milk in such quantities as to endanger human health, impair the composition of milk or adversely affect its organoleptic characteristics.

2. Equipment, utensils and all their components used for milking shall be kept clean and maintained in good physical condition at all times.

3. After use, any utensils used for milking, mechanical milking equipment and containers which come into contact with milk shall be cleaned and disinfected and rinsed with potable water.

4. Bulk milk tanks when empty shall be left with an open plug hole or, where appropriate, an open outlet valve.

5. Where milking is done by hand, the pails containing the milk shall be covered and brought as quickly as possible to the milk storage premises.

C. *Open-air milking and moveable milking bails*

1. Where milking is done in the open, the ground where it takes place shall be clean.

2. Where a moveable milking bail is used, it shall—

(*a*) have a sufficient supply of potable water for use in milking operations and for the cleaning of equipment, utensils and all their components intended to come into contact with milk;

(*b*) have fittings and equipment which are easy to wash, clean and disinfect;

(*c*) be sited on ground which is free of any accumulation of excreta or other waste matter;

(*d*) provide adequate protection for the milk during the whole period in which the bail is in use; and

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

D. *Feedingstuffs*

1. Feedingstuffs shall not be stored on a production holding where they can have an adverse effect on milk.

PART IV

CONDITIONS FOR MILKING AND FILTERING OPERATIONS

1. Any work including feeding of animals, that might have an adverse effect on the milk shall not be carried out immediately before or during the milking.

2. Before the milking is started the teats, udder, flank, hindquarters and adjacent parts of the abdomen of the animal shall be clean.

3. At the start of the milking of an individual animal, the milker shall inspect the appearance of the milk. If any physical abnormality in the milk is detected, milk from that animal shall not be allowed to leave the production holding, nor shall it be used for human consumption on that production holding.

4. Animals with clinical udder diseases shall be milked last, or by a separate machine, or handstripped. Milk from such animals shall not be allowed to leave the production holding, nor shall it be used for human consumption on that production holding.

5. Teat dips or sprays for lactating animals other than those to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994(**a**) apply shall only be used immediately after milking, unless otherwise permitted by an authorised officer. The components of the teat dips and sprays used shall be those acceptable to the authorised officer.

6. Where the milk is filtered, the filter used shall, depending on the type, be changed or cleansed before its capacity for absorption is exhausted. In any case, the filter shall be changed or cleansed before each milking. Filtering cloths shall not be used for cows' milk.

(**a**) S.I. 1994/3142

SCHEDULE 2 Regulations 3(5), 6(1)(*a*), (3)(*a*), (7) and (8), 9(1)(*a*) and 19(*a*), (*b*) and (*e*)

Conditions for approval of dairy establishments

PART I

GENERAL CONDITIONS OF HYGIENE FOR DAIRY ESTABLISHMENTS

1. Dairy establishments shall have the following:—

(*a*) facilities for the hygienic handling and protection of raw materials and of non-packaged or non-wrapped dairy products during loading and unloading;

(*b*) appropriate arrangements for protection against pests;

(*c*) instruments and working equipment intended to come into direct contact with raw materials and dairy products which are made of corrosion-resistant material and which are easy to clean and disinfect;

(*d*) special watertight, non-corrodible containers in which to put raw materials or dairy products not intended for human consumption. Where such raw materials or dairy products are removed through conduits, these shall be constructed and installed in such a way so as to avoid any risk of contamination of other raw materials or dairy products;

(*e*) appropriate facilities for the cleaning and disinfecting of equipment and instruments;

(*f*) an adequate waste water disposal system which is hygienic;

(*g*) a supply of potable water only. However a supply of non-potable water is also permitted provided that it is intended only for the cooling of equipment, steam production, fire-fighting and refrigeration equipment, and provided further 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 dairy products.

Non-potable water pipes shall be clearly distinguished from those used for potable water;

(*h*) an appropriate number of changing rooms with smooth, waterproof, washable walls and floors and within the room or in its immediate vicinity, wash basins with non hand-operable taps, hygienic hand-drying facilities and flush lavatories. The lavatories shall not open directly on to the work rooms;

(*i*) a lockable room or a secure place for the storage of detergents, disinfectants and similar substances;

(*j*) a room or cupboard for storing cleaning and maintenance material;

(*k*) adequate facilities for cleaning and disinfecting tanks used for transporting dairy products. However such facilities shall not be compulsory if alternative facilities which are acceptable to the approving authority are available to the dairy establishment for such purpose; and

(*l*) rooms with adequate capacity for storing raw materials and dairy products.

2.—(1) Dairy establishments shall have working areas of sufficient size for work to be carried out under adequate hygienic conditions; their design and layout shall be such as to preclude contamination of the raw materials and the dairy products.

(2) The production of heat-treated milk or the manufacture of milk-based products which might pose a risk of contamination to other dairy products shall be carried out in a clearly separated working area.

(3) In areas where raw materials are handled and dairy products are manufactured, the areas shall have the following:

(*a*) solid, waterproof flooring which is easy to clean and disinfect and which allows water to drain away and equipment to remove water;

(*b*) walls which have smooth surfaces and are easy to clean, are durable and impermeable and which are covered with a light-coloured coating;

(*c*) ceilings or roof linings which are easy to clean in those areas where exposed or non-packaged raw materials or dairy products are handled;

(*d*) doors made of 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; taps in work rooms and lavatories for cleaning and disinfecting hands which shall be non hand-operable; these facilities shall be provided with cleaning and disinfecting materials and a hygienic means of drying hands; and

(*h*) facilities for cleaning tools, equipment and installations.

3.—(1) Subject to sub-paragraphs (2) and (3), the rooms where raw materials and dairy products are stored shall comply with the requirements specified in paragraph 2(3)(*a*) to (*f*).

(2) Raw materials and dairy products may be stored in rooms which do not comply with all or any of the requirements of paragraph 2(3)(*a*) to (*f*) provided that—

(*a*) in the case of chilling and refrigeration rooms they have a floor which is easy to clean and disinfect and which allows water to drain away; or

(*b*) in the case of freezing and deep-freezing rooms they have a floor which is waterproof, rot-proof and easy to clean; and

(*c*) in the cases referred to in heads (*a*) and (*b*), the rooms have a sufficiently powerful refrigeration plant to keep raw materials and dairy products at the temperatures specified by these Regulations.

(3) In the freezing and deep-freezing rooms referred to in sub-paragraph (2)(*b*), the use of wooden walls shall be permitted provided they were built before 1st January 1993.

PART II

SPECIAL CONDITIONS FOR APPROVAL

A. *Special conditions for approval of treatment or processing establishments*

1. In addition to the general requirements laid down in Part I, an establishment shall meet the requirements set out in paragraphs 2 to 10.

2. The establishment shall possess equipment for the mechanical filling and proper automatic sealing of containers (excluding churns, tanks and bulk packaging of more than 4 litres) which are to be used for packaging heat-treated drinking milk and liquid milk-based products, if such operations are carried out at that establishment. However in the case of limited production of liquid milk intended for

drinking, alternative non-automatic filling and sealing methods may be used after authorisation by the approving authority provided that such methods carry equal assurance with regard to hygiene.

3. The establishment shall possess equipment for the cooling and cold storage of heat-treated milk and liquid milk-based products. Where raw milk is stored, purified or standardised at an establishment, that establishment shall also possess equipment for the cooling and cold storage of raw milk. Cold stores shall be equipped with correctly calibrated temperature-measuring apparatus.

4. The establishment shall possess—

(*a*) in the case of dairy products wrapped in disposable containers, an area for the storage of such containers and for storage of the raw materials intended for their manufacture; and

(*b*) in the case of dairy products wrapped in re-useable containers, a special area for their storage and equipment designed to clean and disinfect them mechanically.

5. The establishment shall possess containers for storing raw milk and, if appropriate, standardisation equipment and containers for storing standardised milk.

6. The establishment shall possess centrifuges or any other suitable means for physically purifying milk, if appropriate.

7.—(1) Subject to sub-paragraph (2) a treatment establishment shall possess heat-treatment equipment, approved or authorised by the approving authority for the treatment of dairy products, fitted with:

(*a*) an automatic temperature control;

(*b*) a recording thermometer;

(*c*) an automatic safety device preventing insufficient heating;

(*d*) an adequate safety system preventing the mixture of heat-treated drinking milk with milk which has not been fully heat-treated; and

(*e*) an automatic recording device which records the operation of the safety system referred to in sub-paragraph (1)(*d*) or a procedure for monitoring the system's effectiveness.

(2) A treatment establishment may have equipment different to those specified in sub-paragraph (1) provided that an equivalent performance may be achieved with equal assurances with regard to hygiene and the approving authority has authorised the use of such equipment.

8. A processing establishment shall possess equipment for heating, thermisation or heat-treatment if such operations are carried out in that establishment which meets hygiene requirements.

9. The establishment shall possess equipment for the cooling, wrapping and storage of frozen milk-based products if such operations are carried out at that establishment.

10. The establishment shall possess equipment for drying and wrapping powdered milk products if such operations are carried out at that establishment.

B. *Special conditions for approval of a collection centre*

1. In addition to the general requirements laid down in Part I, a collection centre shall have—

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

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

C. *Special conditions for approval of a standardisation centre*

1. In addition to the general requirements laid down in Part I, a standardisation centre shall have—

(*a*) containers for the cold storage of raw milk;

(*b*) standardisation equipment and containers for the storage of standardised milk; and

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

PART III

GENERAL CONDITIONS OF HYGIENE

A. *General conditions of hygiene applicable to dairy establishments, instruments and equipment*

1. Rodents, insects and any other vermin shall be systematically destroyed in the dairy establishment and any creature, including any animal of the species referred to in regulation 2(1) shall be prevented from entering rooms in which dairy products are manufactured or stored.

2. Instruments and equipment used for working on raw materials and dairy products, floors, ceilings or roof linings, walls and partitions shall be kept in a satisfactory state of cleanliness and repair, so that they do not constitute a source of contamination to raw materials or dairy products.

3. Rodenticides, insecticides, disinfectants and any other potentially toxic substance shall be stored in lockable rooms or a secure place and used in such a way that they do not have an adverse effect on machinery, equipment, instruments, raw materials or dairy products kept in the dairy establishment.

4. Working areas, instruments and working equipment shall be used only for work on dairy products in accordance with these Regulations. However, after authorisation by the approving authority, they may be used at the same time or at other times for work on other foodstuffs fit for human consumption, or other milk-based products fit for human consumption but intended for a use other than human consumption provided that they do not contaminate the dairy products for which approval has been given.

5. Potable water shall be used for all purposes save as permitted by paragraph 1(*g*) of Part I.

6. Equipment, containers and installations which come into contact with dairy products or perishable raw materials used during production shall be cleaned and if necessary disinfected according to a cleaning programme based on risk analysis principles.

7. Other equipment, containers, instruments and installations which come into contact with microbiologically stable dairy products and the rooms in which they are stored shall be cleaned and disinfected according to a cleaning programme based on risk analysis principles drawn up by the occupier of the dairy establishment.

8. As soon as possible after unloading 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, any container or tank used for transporting raw milk shall be cleaned and disinfected before re-use.

9. The treatment establishment shall in principle be cleaned according to a cleaning programme based on risk analysis principles.

10. The occupier of a dairy establishment shall take appropriate measures to avoid cross-contamination of dairy products in accordance with the cleaning programme specified in paragraph 7.

11. Where appropriate, rooms intended for production processes shall be divided into wet and dry areas, each having its own operating conditions.

12. Disinfectants and similar substances used shall be those acceptable to the approving authority and shall be used in such a way that they do not have any adverse effects on the machinery, equipment, raw materials and dairy products kept at the dairy establishment. They shall be in clearly identifiable containers bearing labels with instructions for their use and their use shall be followed by thorough rinsing of such instruments and working equipment with potable water, except in cases where the disinfectant or similar substance is specifically designed not to be rinsed after application.

13. Where a dairy establishment produces foodstuffs containing dairy products, together with other ingredients which have not undergone heat-treatment, or other treatment having an equivalent effect, such dairy products and ingredients shall be stored separately to prevent cross-contamination.

B. *General conditions of hygiene applicable to staff*

1. The occupier of a dairy establishment shall only employ persons in such an establishment to work directly with and handle raw materials or dairy products if those persons have proved to the occupier's satisfaction by means of a medical certificate, on recruitment, that there is no medical impediment to their employment in that capacity. This requirement shall not apply to any persons already working in such a capacity before the date on which these Regulations came into operation.

2. Persons working directly with and handling raw materials or dairy products shall maintain the highest standards of personal cleanliness at all times. In particular they shall:—

(*a*) wear suitable, clean working clothes and headgear which completely encloses their hair;

(*b*) not smoke, spit, eat or drink in rooms where raw materials and dairy products are handled or stored;

(*c*) wash their hands at least each time work is resumed and whenever contamination of their hands has occurred; and

(*d*) cover wounds to the skin with a suitable waterproof dressing.

3. The occupier shall take all necessary measures to prevent persons liable to contaminate raw materials and dairy products from handling them until the occupier has adequate evidence that such persons can do so without risk of contamination.

SCHEDULE 3 Regulations 9(1)(*b*) and (10), 13(1)(*b*)(iv), (v) and (vi) and (3)(*b*), (*c*) and (*d*)

Requirements for raw milk

PART I

ANIMAL HEALTH STANDARDS

1. Raw milk shall come from animals on a licensed production holding and such animals shall undergo regular veterinary inspections to ensure that the requirements of this paragraph are being complied with and shall—

(*a*) not show any symptoms of infectious diseases communicable to human beings through milk;

(*b*) not give the milk any abnormal organoleptic characteristics;

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

(*d*) not show any udder wound likely to affect their milk;

(*e*) not have had substances within the meaning of Council Directive 81/602/EEC(**a**), as amended(**b**), concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action and Council Directive 88/146/EEC(**c**) prohibiting the use in livestock farming of certain substances having a hormonal action, administered illegally; and

(*f*) not have been treated with substances dangerous or likely to be dangerous to human health that are transmissible to milk unless any withdrawal period which may apply to it has been observed.

2. In addition to the requirements specified in paragraph 1:—

(*a*) raw cows' milk and raw buffaloes' milk shall come from animals belonging to a herd which is officially tuberculosis-free and either brucellosis-free or officially brucellosis-free;

(*b*) raw cows' milk shall come from animals yielding at least two litres of milk per day; and

(*c*) raw ewes' milk and raw goats' milk shall come from animals belonging to a production holding which is either brucellosis-free or officially brucellosis-free (*Brucella melitensis*) within the meaning of Article 2(4) and (5) of Council Directive 91/68/EEC(**d**).

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

(**a**) OJ No. L222, 7.8.81, p. 32
(**b**) Council Directive 81/602/EEC was supplemented by Council Directive, 85/358/EEC (OJ No. L191, 23.7.85, p. 46)
(**c**) OJ No. L70, 16.3.88, p. 16
(**d**) OJ No. L46, 19.2.91, p. 19

PART II

RAW MILK STANDARDS

1. Raw milk at the time of its collection from a licensed production holding or at the time of its acceptance at a treatment or processing establishment shall not contain:—

(*a*) any added water;

(*b*) antibiotic residues in excess of the levels authorised in Annexes I and III of Council Regulation (EEC) No. 2377/90 on Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin(**a**), as amended(**b**), nor contain any combination of such substances in excess of a value to be fixed in accordance with that Council Regulation; or

(*c*) residues of substances having a pharmacological or homonal action, or pesticides, detergents or other substances which are harmful or which might alter the organoleptic characteristics of dairy products or make their consumption dangerous or harmful to human health insofar as those residues exceed permitted tolerance limits.

2. In addition to the requirements specified in paragraph 1:—

(*a*) raw cows' milk intended for the production of heat-treated drinking milk, fermented milk, junket, jellied milk, flavoured milk or cream shall meet the following standards:

Plate count at 30°C (per ml.)	≤100,000
Somatic cell count (per ml.)	≤400,000

(*b*) raw cows' milk intended for the manufacture of dairy products other than those referred to in sub-paragraph (*a*) shall meet the following standards:

	From 1.1.94	*From 1.1.98*
Plate count at 30°C (per ml.)	≤400,000	≤100,000
Somatic cell count (per ml.)	≤500,000	≤400,000

(*c*) raw cows' milk intended for the manufacture of any milk-based product (made with raw milk) which has not undergone any heat-treatment during its manufacture shall meet the following standards:

Plate count at 30°C (per ml.)	≤100,000
Somatic cell count (per ml.)	≤400,000
Staphylococcus aureus (per ml.)	n = 5, c = 2, m = 500, M = 2000

(*d*) raw ewes', goats' or buffaloes' milk intended for the production of heat-treated drinking milk or for the manufacture of heat-treated milk-based products shall meet the following standard:

(**a**) OJ No. L224, 18.8.90, p. 1

(**b**) Relevant amending instruments are Commission Regulation (EC) No. 2701/94 (OJ No. L287, 8.11.94, p. 7) which contains consolidated texts of Annexes I, II, III and IV to Council Regulation (EEC) No. 2377/90 and Commission Regulation (EC) No. 2703/94 (OJ No. L287, 8.11.94, p. 19)

	From 1.1.95	*From 1.12.99*
Plate count at 30°C (per ml.)	≤3,000,000	<1,500,000

(*e*) raw ewes', goats' or buffaloes' milk intended for the manufacture of any milk-based product which has not undergone any heat-treatment during its manufacture shall meet the following standards:

	From 1.1.95	*From 1.12.99*
Plate count at 30°C (per ml.)	≤1,000,000	<500,000
Staphylococcus aureus (per ml.)	n = 5, c = 2, m = 500, M = 2000	

3. For the purposes of the tables set out in paragraph 2, the symbols referred to shall have the following meanings:

n = number of sample units comprising the sample;

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

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.

4. The occupier shall ensure that—

(*a*) compliance with the standards for raw cows' milk referred to in paragraph 2(*a*), (*b*) and (*c*) in relation to somatic cell count is checked by random sampling, either—

(i) on a representative sample of the raw milk collected from each production holding, or

(ii) until 1st July 1997, on acceptance of the raw milk at the treatment establishment or processing establishment;

(*b*) compliance with the standards referred to in paragraph 2 in relation to plate count and *Staphylococcus aureus* is checked by random sampling of a representative sample of the raw milk collected from each production holding;

(*c*) the plate count at 30°C is calculated on the basis of a geometric average over a period of two months, with at least two samples a month; and

(*d*) the somatic cell count is calculated on the basis of a geometric average over a period of three months, with at least one sample a month.

PART III

CHECKS FOR ADDED WATER IN RAW MILK

1. Raw milk shall be subjected to regular checks and sampling to ascertain if water is being added to such milk.

2. Such checks shall include regular checks on the freezing point of raw milk supplied by each production holding and shall be carried out in accordance with the following procedure:

(*a*) raw milk supplied by each production holding shall be subjected regularly to random sampling;

(*b*) where the raw milk of a single production holding is delivered directly to a processing establishment or a treatment establishment, the samples for checking shall be taken—

(i) when the raw milk is collected from the production holding for transport to such establishment, provided that adequate precautions are taken to prevent any fraud during such transport of the raw milk; or

(ii) before unloading the raw milk at the processing establishment or treatment establishment, when the delivery there is made by the occupier of the production holding; and

(*c*) where raw milk delivered to a processing establishment or treatment establishment consists of a mixture of raw milk obtained from more than one production holding, the samples for checking shall be taken—

(i) in accordance with sub-paragraph (*b*); or

(ii) when the raw milk enters the dairy establishment, provided that spot checks are also carried out at the production holdings from which the raw milk was obtained; and

(iii) if the results of any of the checks on a sample of such mixture of raw milk lead to a suspicion that water has been added to such milk, samples for checking shall be taken from all the production holdings from which the raw milk was obtained.

SCHEDULE 4 Regulations 9(2) and (4)(*b*) and 13(1)(*b*)(iv) and (vi)

Requirements for drinking milk

PART I

RAW MILK FOR DRINKING

1. Subject to paragraph 2, drinking milk which is raw cows' milk shall meet the following standards after wrapping:—

Plate count at 30°C (per ml.)	≤50,000 calculated on the basis of a geometric average over a period of two months, with at least 2 samples a month.
Staphylococcus aureus (per ml.)	n = 5, c = 2, m = 100, M = 500
Salmonella spp	Absence in 25 ml., n = 5, c = 0

Pathogenic micro-organisms and their toxins shall not be present in quantities such as to affect the health of the ultimate consumer.

2. Drinking milk which is—

(*a*) raw ewes' or goats' milk; or

(*b*) raw cows' milk which is sold directly to the ultimate consumer by a producer of raw milk,

shall meet the following standards:

Plate count at 30°C (per ml.)	≤20,000
Coliforms (per ml.)	<100

3. Where raw milk has not passed through a milk collection centre, it shall be transferred from one tank to another under hygienic conditions.

4. The definition of the symbols specified in paragraph 3 of Part II of Schedule 3 shall apply for the purposes of the table in paragraph 1.

PART II

RAW MILK FOR HEAT-TREATMENT

1.—(1) Raw milk, at the time of its acceptance at a treatment establishment, unless treated within 4 hours of acceptance, shall be cooled to a temperature not exceeding 6°C and maintained at that temperature until heat-treated.

(2) Where raw cows' milk is not treated within 36 hours of acceptance at a treatment establishment, a further test shall be carried out on such 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., then such milk shall not be used for the production of heat-treated drinking milk.

PART III

HEAT-TREATED DRINKING MILK

1. Heat-treated drinking milk shall not contain:—

(*a*) any pharmacologically active substance in a quantity higher than the limits laid down in Annexes I and III of Council Regulation (EEC) No. 2377/90(**a**), as amended(**b**), nor contain any combination of such substances in excess of a value to be fixed in accordance with that Council Regulation; or

(*b*) any added water.

2. In addition to complying with paragraph 1, pasteurised milk shall—

(*a*) have been obtained by means of a heat-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;

(*b*) show a negative reaction to the phosphatase test and a positive reaction to the peroxidase test using the methods of analysis specified in paragraph 2 of Schedule 11 and in the case of high-temperature pasteurised milk, show a negative reaction to both tests and be labelled as "high-temperature pasteurised"; and

(*c*) meet the following microbiological standards in any random sampling checks carried out in the treatment establishment:

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

3. In addition to complying with paragraph 1, sterilised and UHT milk shall, after it has spent fifteen days in a closed container at a temperature of 30°C or where necessary, seven days in a closed container at a temperature of 55°C, meet the following standards—

(*a*) be organoleptically normal;

(*b*) not show any sign of deterioration; and

(*c*) have a plate count at 30°C $\leq$100 per ml..

4. In addition to complying with paragraphs 1 and 3, sterilised milk shall have been heated and sterilised either in a hermetically sealed wrapping or container, the seal of which shall remain intact during such heat-treatment, or by use of the continuous flow process.

5. In addition to complying with paragraphs 1 and 3, UHT milk shall—

(*a*) be obtained by applying heat to a continuous flow of raw milk entailing the application of a high temperature for a short time (not less than 135°C for not less than a second) so that all residual spoilage micro-organisms and their spores are destroyed, but the chemical, physical and organoleptic changes to the milk are minimal;

(*b*) be placed immediately after completion of the heat-treatment process in aseptic opaque containers, or containers made opaque by the packaging; and

(*c*) in cases where it is obtained from a heat-treatment process which employs the direct contact of milk and steam, the steam shall be obtained from potable water. Such steam shall not leave deposits of foreign matter in the milk or

(**a**) OJ No. L224, 18.8.90, p. 1

(**b**) Relevant amending instrument is Commission Regulation (EC) No. 2701/94 (OJ No. L287, 8.11.94, p. 7) which contains consolidated texts of Annexes I, II, III and IV to Council Regulation (EEC) No. 2377/90

affect it adversely. The use of this process shall be so as not to cause any change in the water content of the treated milk.

6. Pasteurised milk which has been subject to high-temperature pasteurisation, UHT milk or sterilised milk may be produced from raw milk which has undergone thermisation or an initial heat-treatment in another processing or treatment establishment provided that—

(*a*) the initial treatment shall have had a time-temperature combination which is lower than or equivalent to the pasteurisation process specified in paragraph 2;

(*b*) milk which has undergone the initial treatment shall have shown a positive reaction to the peroxidase test, using the method of analysis specified in paragraph 2 of Schedule 11, before the second heat-treatment; and

(*c*) such practice is brought to the attention of the approving authority.

7. Pasteurised milk may be produced from raw milk which has undergone only initial thermisation in accordance with the same conditions specified in paragraph 6.

8. The definition of the symbols specified in paragraph 3 of Part II of Schedule 3 shall apply for the purposes of the table in paragraph 2.

SCHEDULE 5

Regulations 9(3)(*b*) and (5), 13(1)(*b*)(vi) and 19(*c*)

Requirements for milk used for the manufacture of milk-based products

PART I

RAW MILK

1. Subject to paragraph 2, the occupier of the processing establishment shall take all necessary steps to ensure that the raw milk is treated or that the production of milk-based products using raw milk shall commence:

(*a*) as soon as possible after acceptance of the raw milk at the processing establishment, if the raw milk has not been refrigerated; or

(*b*) within 36 hours of such acceptance, if the raw milk is kept at a temperature not exceeding 6°C; or

(*c*) within 48 hours of such acceptance, if the raw milk is kept at a temperature of 4°C or lower; and

(*d*) within 72 hours, in the case of ewes', goats' or buffaloes' milk.

2. For technological reasons relating to the manufacture of certain milk-based products the times and temperatures referred to in paragraph 1 may be exceeded with the authorisation of the approving authority.

PART II

THERMISED MILK

Thermised milk shall:

(*a*) be obtained from raw milk and where thermisation of such raw milk has not commenced within 36 hours of its acceptance at the processing establishment, it shall have a plate count at 30°C prior to thermisation which does not exceed 300,000 per ml. in the case of cows' milk;

(*b*) be obtained by the heating of raw milk for at least 15 seconds at a temperature between 57°C and 68°C such that after completion of the heating process the milk shows a positive reaction to the phosphatase test, using the method of analysis specified in paragraph 2 of Schedule 11; and

(*c*) have a plate count at 30°C equal to or less than 100,000 per ml. before heat-treatment if it is used to produce pasteurised, UHT or sterilised milk.

PART III

PASTEURISED MILK

Pasteurised milk shall:

(*a*) be obtained by means of a heat-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; and

(*b*) show a negative reaction to the phosphatase test and a positive reaction to the peroxidase test using the methods of analysis specified in paragraph 2 of Schedule 11 and in the case of high-temperature pasteurised milk, show a negative reaction to both those tests.

PART IV

UHT MILK

UHT milk shall be obtained by applying heat to a continuous flow of milk entailing the application of a high temperature for a short time (not less than 135°C for not less than a second) so that all residual spoilage micro-organisms and their spores are destroyed but the chemical, physical and organoleptic changes to the milk are minimal.

Requirements for milk-based products

PART I

MICROBIOLOGICAL CRITERIA

1. On removal from the processing establishment milk-based products shall not contain pathogenic micro-organisms and toxins from pathogenic micro-organisms in such quantity as to affect the health of the ultimate consumer.

2. Sterilised or ultra heat-treated milk-based products which are in liquid or gel form and are intended for conservation at room temperature shall meet the following standards after incubation at 30°C for 15 days—

(*a*) have a place count at 30°C ≤100 per ml.; and

(*b*) be organoleptically normal.

3. Subject to paragraph 5 milk-based products shall meet the standards referred to in Tables A and B upon removal from the processing establishment—

TABLE A

	Product	*Type of Micro-organism*	*Standard (ml.,g.)*
(i)	Cheese, other than hard cheese	*Listeria monocytogenes*	Absence in 25g. where n = 5, c = 0
(ii)	Milk-based products, other than cheese covered by (i)	*Listeria monocytogenes*	Absence in 1g.
(iii)	Milk powder	*Salmonella* spp	Absence in 25g. where n = 10, c = 0
(iv)	Milk-based products, other than milk powder	*Salmonella* spp	Absence in 25g. where n = 5, c = 0

The sample of 25g. referred to in paragraph (i) of Table A shall consist of 5 specimens of 5g. taken from different parts of the same product.

TABLE B

	Product	*Type of Micro-organism*	*Standard (ml.,g.)*
(i)	Cheese made from raw milk or from thermised milk	*Staphylococcus aureus*	n = 5, c = 2, m = 1000, M = 10,000
		Escherichia coli	n = 5, c = 2, m = 10,000, M = 100,000
(ii)	Soft cheese made from heat-treated milk	*Staphylococcus aureus* / *Escherichia coli*	n = 5, c = 2, m = 100, M = 1,000
(iii)	Fresh cheese	*Staphylococcus aureus*	n = 5, c = 2, m = 10, M = 100
(iv)	Powdered milk		
(v)	Frozen milk-based products including ice-cream		

4. The definition of the symbols specified in paragraph 3 of Part II of Schedule 3 shall apply for the purposes of Tables A and B in paragraph 3.

5. Testing of the milk-based products referred to in Table A of paragraph 3 shall not be compulsory for sterilised milk, preserved milk-based products and milk-based products where the heat-treatment was applied after wrapping or packaging.

6. Sampling programmes shall be drawn up by the occupier of the dairy establishment in light of the nature of the dairy products and the principles of risk analysis.

7. In all cases where the standards in Table A of paragraph 3 are exceeded, the dairy products shall be excluded from human consumption and withdrawn from the market.

8. In all cases where the standards in Table B of paragraph 3 are exceeded, there shall be a review of the implementation of the methods for monitoring and checking critical points applied in the processing establishment. The occupier of the processing establishment shall inform the approving authority of the corrective procedures included in the production monitoring system to prevent any repetition of the occurrence.

9. Wherever the standard M in Table B of paragraph 3 is exceeded in the case of cheese made from raw milk, thermised milk or soft cheese, testing shall be carried out for—

(*a*) the possible presence of strains of enterotoxigenic *Staphylococcus aureus* or *Escherichia coli* that are presumed to be pathogenic; and

(*b*) if necessary the possible presence of staphylococcal toxins in such products,

by a method determined in accordance with Article 31 of Council Directive 92/46, as specified in paragraph 2 of Chapter II of Annex C to that Directive.

10. If the strains referred to in paragraph 9 are identified or staphylococcus enterotoxins are found, then all the batches of the cheese involved shall be withdrawn from the market. In this case the occupier shall inform the approving authority of such findings, of the action taken to withdraw the batches in question and the

corrective procedures introduced into the production monitoring system to prevent any repetition of the occurrence.

PART II

PASTEURISED CREAM

1. Pasteurised cream shall be heated—

(*a*) to a temperature not less than 63°C and retained at that temperature for not less than 30 minutes;

(*b*) to a temperature not less than 72°C and retained at that temperature for not less than 15 seconds; or

(*c*) to such other temperature for such other period of time as has equivalent effect to sub-paragraph (*a*) or (*b*) necessary for the elimination of vegetative pathogenic organisms in the cream.

2. The cream shall—

(*a*) be cooled as soon as practicable after pasteurisation; and

(*b*) show a negative reaction to the phosphatase test, using the method of analysis specified in paragraph 5 of Schedule 11.

PART III

STERILISED CREAM

1. Sterilised cream shall be heated—

(*a*) to a temperature not less than 108°C and retained at that temperature for not less than 45 minutes; or

(*b*) to such other temperature for such other period of time as has equivalent effect to sub-paragraph (*a*) necessary for the elimination of vegetative pathogenic organisms.

2. The cream shall be cooled as soon as practicable after sterilisation.

3. Sterilised cream shall meet the standard referred to in paragraph 2(*a*) of Part I.

PART IV

ULTRA HEAT-TREATED CREAM

1. Ultra heat-treated cream shall be heated—

(*a*) to a temperature not less than 140°C and retained at that temperature for at least 2 seconds; or

(*b*) to such other temperature for such other period of time as has equivalent effect to sub-paragraph (*a*) necessary for the elimination of vegetative pathogenic organisms.

2. The cream shall be cooled as soon as practicable after being ultra heat-treated.

3. Ultra heat-treated cream shall meet the standard referred to in paragraph 2(*a*) of Part I.

PART V

PASTEURISED ICE-CREAM

1. Pasteurised ice-cream shall be obtained by the mixture being heated—

(*a*) to a temperature of not less than 65.6°C and retained at that temperature for not less than 30 minutes;

(*b*) to a temperature of not less than 71.1°C and retained at that temperature for not less than 10 minutes; or

(*c*) to a temperature of not less than 79.4°C and retained at that temperature for not less than 15 seconds,

and then reduced to a temperature of not more than 7.2°C within 1½ hours and kept at such temperature until the freezing process is begun.

2. If the temperature of ice-cream has risen above minus 2.2°C at any time since it was frozen it shall not be sold or offered for sale unless—

(*a*) it has again been subjected to the heat-treatment to which as a mixture it was required to be subjected under paragraph 1; and

(*b*) after having again been frozen, it has been kept at a temperature not exceeding minus 2.2°C.

3. In the case of a complete cold mix which is reconstituted with the addition of water only, it shall not be necessary for it to be subjected to further heat-treatment by pasteurisation as specified in paragraph 1.

4. If a complete cold mix reconstituted with the addition of water only is frozen, it shall comply with paragraph 2.

PART VI

STERILISED ICE-CREAM

1. Sterilised ice-cream shall be obtained by the mixture being heated to a temperature of not less than 148.9°C for at least 2 seconds.

2. After the mixture has been sterilised as specified in paragraph 1, it shall be reduced to a temperature of not more than 7.2°C within 1½ hours and shall be kept at such a temperature until the freezing process is begun.

3. Paragraph 2 shall not apply to a mixture which has been sterilised in accordance with paragraph 1 if immediately after the mixture has been sterilised it is placed in sterile airtight containers under sterile conditions and the containers remain unopened.

4. If the temperature of ice-cream has risen above minus 2.2°C at any time since it was frozen it shall not be sold or offered for sale unless—

(*a*) it has again been subjected to the heat-treatment to which as a mixture it was required to be subjected to under paragraph 1; and

(*b*) after having again been frozen, it has been kept at a temperature not exceeding minus 2.2°C.

5. In the case of a complete cold mix which is reconstituted with the addition of water only, it shall not be necessary for it to be subjected to further heat-treatment by sterilisation as specified in paragraph 1.

6. If a complete cold mix reconstituted with the addition of water only is frozen, it shall comply with paragraph 4.

SCHEDULE 7 Regulations 4(3)(*a*) and (7), 11(1)(*a*), 13(3)(*f*) and 19(*d*)

Storage requirements

1. Immediately after milking, raw milk shall be placed in a clean place which is suitably equipped so as to prevent the raw milk suffering from any adverse effects.

2.—(1) Where raw milk is:

(*a*) collected daily from a production holding it shall, if not collected within two hours of milking, be cooled as soon as practicable after milking to a temperature of 8°C or lower and maintained at that temperature until collected; or

(*b*) not collected daily from a production holding it shall be cooled as soon as practicable after milking to a temperature of 6°C or lower and be maintained at that temperature until collected.

(2) For technological reasons relating to the manufacture of certain milk-based products and provided the end products meet the microbiological criteria specified in Part I of Schedule 6, the temperatures referred to in sub-paragraph (1) may be exceeded with the authorisation of the approving authority.

3. Upon acceptance at a treatment establishment milk shall, unless heat-treated within four hours of acceptance, be cooled to a temperature of 6°C or lower, if not already at such temperature, and maintained at that temperature until heat-treated.

4. When the pasteurisation process is completed, pasteurised milk shall be cooled as soon as practicable to a temperature of 6°C or lower.

5. Subject to paragraph 7 any dairy product not intended to be stored at ambient temperature shall be cooled as quickly as possible to the temperature established by the manufacturer of that product as suitable to ensure its durability and thereafter stored at that temperature.

6. Where dairy products other than raw milk are stored under cooled conditions, their storage temperatures shall be registered and the cooling rate shall be such that the products reach the required temperature as quickly as possible.

7. The maximum temperature at which pasteurised milk may be stored until it leaves the treatment establishment shall be 6°C.

SCHEDULE 8 Regulations 11(1)(*a*) and (*b*), 13(3)(*f*) and 19(*d*)

Transport requirements

PART I

TEMPERATURE

1. The temperature of raw milk during transport to a treatment or processing establishment shall not exceed 10°C, unless the milk has been collected within two hours of milking. However, for technological reasons relating to the manufacture of certain milk-based products and provided that the end products meet the microbiological criteria specified in Part I of Schedule 6, such requirement as to temperature may be exceeded with the authorisation of the approving authority which approved the treatment or processing establishment.

2.—(1) Subject to sub-paragraphs (2) and (3), the temperature of pasteurised milk during transportation in tanks or packed in small containers or in churns shall not exceed 6°C.

(2) Where pasteurised milk is intended for delivery to a retail business, the temperature of such milk during transportation shall not exceed 8°C.

(3) The requirements as to temperature specified in sub-paragraphs (1) and (2) shall not apply to milk intended for doorstep delivery.

3. Any vehicle or container used for transporting raw or pasteurised milk shall be designed and equipped in such a way that the temperatures specified in paragraphs 1 and 2 shall be maintained throughout the period of such transport.

PART II

HYGIENE

1. Any vehicle used for transporting heat-treated drinking milk and milk in small containers or in churns shall be so designed as to give the containers or churns adequate protection against all contamination and atmospheric influences. It shall be maintained in good condition and shall not be used to transport any animals of any species or any other product or object likely to cause the milk to deteriorate. Those parts of the vehicle intended to come into contact with small containers or churns shall be smooth and easy to wash, clean and disinfect.

2. Any tank, churn or other container used for transporting raw milk or pasteurised milk shall be so designed that—

(*a*) any surface which may come into contact with the milk shall be made of a material which is easy to wash, clean and disinfect, resists corrosion, and does not transfer substances to the milk in such quantity as to endanger human health, impair the composition of the milk or adversely affect the organoleptic characteristics of the milk;

(*b*) the milk can drain away completely;

(*c*) if they are fitted with taps, these shall be easy to remove, dismantle, wash, clean and disinfect; and

(*d*) except in the case of a container or tank designed solely for the transport of raw milk, any container or tank in which pasteurised milk is transported shall be hermetically sealed before and during transportation by means of a watertight sealing device.

3. 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, any container or tank used to transport raw milk or pasteurised milk to a dairy establishment shall be washed, cleaned and disinfected after each use and as necessary before further use.

4. Any tank used to transport milk shall bear a clear indication that it may be used only for the transport of foodstuffs.

5. Any tank used to transport dairy products may not be used for the transport of other foodstuffs unless adequate measures are taken to prevent contamination or deterioration of those dairy products.

6. Dairy products shall be despatched in such a way that they are protected during transportation from anything liable to contaminate them or cause them to deteriorate. For this purpose account shall be taken of the duration of the journey, the means of transport employed and the weather conditions.

PART III

COMMERCIAL DOCUMENT

1. Heat-treated drinking milk and milk-based products shall be accompanied during transport by a commercial document bearing the following particulars—

(*a*) the details required on the health mark, specified in paragraphs 4 and 5 of Part II of Schedule 10;

(*b*) an indication of the nature of the heat-treatment used to produce the heat-treated drinking milk or milk-based product;

(*c*) an indication of the initial treatment in the case of heat-treated drinking milk referred to in paragraphs 6 and 7 of Part III of Schedule 4; and

(*d*) an indication enabling the identification of the approving authority responsible for supervising the dairy establishment of origin, if such information is not clear from the approval number.

SCHEDULE 9 Regulations 11(1)(*c*) and 19(*a*)

Wrapping and packaging

The requirements of this Schedule shall apply without prejudice to Council Directive 89/109/EEC on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs(**a**).

1. Wrapping and packaging shall be strong enough to protect the dairy products effectively.

2. The wrapping and packaging of dairy products shall take place under satisfactory hygienic conditions and in rooms provided for that purpose.

3. Notwithstanding paragraph 2, the manufacture of dairy products and packaging operations may take place in the same room if the following conditions are satisfied—

(*a*) the room shall be sufficiently large and equipped to ensure the hygiene of the operations;

(*b*) the wrapping and packaging shall have been brought to the treatment or processing establishment in a protective cover in which they were placed immediately after manufacture and which protects the wrapping or packaging from any damage during transport to the dairy establishment, and they shall have been stored there under hygienic conditions in a room intended for that purpose;

(*c*) the rooms for storing the packaging material shall be free from vermin and from amounts of dust which could constitute an unacceptable risk of contamination of the product and shall be separated from rooms containing substances which might contaminate the products. Packaging shall not be placed directly on the floor;

(*d*) packaging shall be assembled under hygienic conditions before being brought into the room, except in the case of the automatic assembly of packaging, provided that there is no risk of contamination of the products;

(*e*) packaging shall be brought into the room under hygienic conditions and used without delay. It shall not be handled by staff handling unwrapped products, if there is a risk of cross-contamination; and

(*f*) immediately after packaging, the dairy products shall be placed in the rooms provided for storage.

4. Bottling or filling of containers with heat-treated milk or liquid milk-based products shall be carried out mechanically and the sealing of the containers shall be carried out automatically. However, in the case of limited production, non-automatic sealing methods may be used with the authorisation of the approving authority, provided that those methods provide equal assurances with regard to hygiene.

5. Wrapping or packaging may not be re-used for dairy products, except where the containers are of a type which may be re-used after thorough cleaning and disinfecting.

6. Sealing shall be carried out in the dairy establishment in which the last heat-treatment of drinking milk or liquid milk-based products has been carried out, immediately after filling, by means of a sealing device which ensures that the milk is protected from any adverse effects of external origin on its characteristics. The sealing device shall be so designed that once the container has been opened, the evidence of opening remains clear and easy to check.

(**a**) OJ No. L40, 11.2.89, p. 38, to which there are amendments not relevant to these Regulations

SCHEDULE 10 Regulations 11(1)(*d*) and 21(5)(*b*)

Labelling and health marking

PART I

LABELLING

1. In addition to the health mark requirements specified in Part II, the occupier of the dairy establishment shall ensure that the packaging of heat-treated milk and liquid milk-based products shall display visibly and legibly the following particulars for control purposes—

(*a*) the nature of the heat-treatment applied to the milk;

(*b*) an indication, which may be in code, enabling the date of the last heat-treatment referred to in sub-paragraph (*a*) to be established; and

(*c*) in the case of pasteurised milk, the temperature at which the product shall be stored.

2. The particulars specified in paragraph 1 need not appear on reusable glass bottles referred to in regulation 27 of the Food Labelling Regulations (Northern Ireland) 1984(**a**).

3. Without prejudice to the provisions of the Food Labelling Regulations (Northern Ireland) 1984 the labelling must show clearly for inspection purposes the following particulars—

(*a*) the words "raw milk" for raw drinking milk intended for direct human consumption;

(*b*) the words "made with raw milk" for milk-based products manufactured from raw milk whose manufacturing process does not include thermisation or heat-treatment;

(*c*) in the case of milk-based products other than those referred to in sub-paragraph (*b*), the nature of any heat-treatment applied at the end of the manufacturing process; or

(*d*) for milk-based products in which the growth of micro-organisms can occur, the use-by or minimum durability date.

PART II

HEALTH MARK

1. Dairy products shall carry a health mark in an easily visible place. It shall be legible, indelible and its characters easily distinguishable.

2. Marking shall be carried out during or immediately after manufacture in the dairy establishment. The health mark may be applied to the dairy product, or to the wrapping, or to a label affixed to the wrapping. Where small dairy products are individually wrapped and packaged together or where such small individually wrapped portions are supplied to the ultimate consumer, it shall be sufficient for the health mark to be applied to their collective packaging.

(**a**) S.R. 1984 No. 407, the relevant amending statutory rule is S.R. 1990 No. 440

3. Where a dairy product marked in accordance with paragraphs 1 and 2 is subsequently placed in packaging, the health mark shall also be applied to that packaging.

4. Subject to paragraph 5, the health mark shall consist of an oval surround containing in legible form and in printed capital letters the following information—

(*a*) either:

(i) in the upper part, the letters "UK", followed by the approval number of the dairy establishment, and

(ii) in the lower part, the letters "EEC";

(*b*) or:

(i) in the upper part, the words "UNITED KINGDOM",

(ii) in the centre, the approval number of the dairy establishment, and

(iii) in the lower part, the letters "EEC";

(*c*) or:

(i) in the upper part, the letters "UK",

(ii) in the centre, a reference to where the approval number of the establishment is shown, and

(iii) in the lower part, the letters "EEC".

5. In the case of bottles, packaging and containers referred to in regulation 27 of the Food Labelling Regulations (Northern Ireland) 1984, the health mark may indicate only the letters "UK" and the approval number of the establishment.

6. 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.

7. The health mark may also consist of an irremovable plate of resistant material complying with hygiene requirements and bearing the information specified in paragraph 4.

SCHEDULE 11 Regulation 10

Methods of analysis

1. The reference methods for the analysis and testing of dairy products in order to ascertain if they meet the requirements specified in Schedules 3, 4, 5 and 6 shall be those specified in paragraphs 2 to 6.

2. In relation to raw milk and heat-treated milk, the methods shall be those specified in Commission Decision 91/180/EEC(**a**) for the following:—

(*a*) enumeration of micro-organisms — plate count at 30°C;

(*b*) enumeration of somatic cells in cows' milk;

(*c*) determination of phosphatase activity in cows' milk;

(*d*) determination of peroxidase activity in cows' milk;

(*e*) detection of pathogenic micro-organisms;

(*f*) enumeration of coliforms — colony count at 30°C; and

(*g*) enumeration of micro-organisms — plate count at 21°C.

3. In relation to milk-based products, the test for enumeration of micro-organisms — plate count at 30°C shall be the method specified in IDF Standard 100B:1991: Milk and milk products — micro-organisms — colony count at 30°C.

4. In relation to milk-based products, the test for enumeration of coliforms shall be the method specified in ISO 5541 Part 2 1986: Milk and milk products — Part 2; Most probable number technique at 30°C.

5. In relation to the following tests, the methods for the analysis and testing shall be those specified below—

Test	*Method*
(*a*) Enumeration of *Staphylococcus aureus*	Provisional IDF Standard 145:1990. Milk and milk-based products. Enumeration of *Staphylococcus aureus* in products other than dried milk — Colony count technique at 37°C.
(*b*) Enumeration of *Staphylococcus aureus* in powdered milk	Provisional IDF Standard 138:1986. Dried milk. Enumeration of *Staphylococcus aureus.* Colony count technique at 37°C.
(*c*) Detection of *Salmonella* spp	ISO 6579:1993. Microbiology — General guidance on methods for the detection of *Salmonella* and IDF Standard 93A:1985; sample preparation.
(*d*) Detection of *Listeria monocytogenes*	ISO 10560:1993. Milk and milk products — Detection of *Listeria monocytogenes.*
(*e*) Enumeration of *Escherichia coli* in milk-based products	Provisional IDF Standard in milk-based products 170:1994. Milk and milk products — Enumeration of presumptive *Escherichia coli* content by:

(a) OJ No. L93, 13.4.91, p. 1

Test	*Method*
	(i) Most probable number technique.
	(ii) Most probable number technique with use of 4-methylumbelliferyl-β-D-glucuronide (MUG).
	(iii) Colony count technique at 44°C using membranes.
(*f*) Detection of Phosphatase (Residual) in cream	AOAC official method 950.41: Official Methods of Analysis, 16th Edition: 1995.
(*g*) Detection of Phosphatase (Reactivated and Residual) in cream	AOAC official method 965.27: Official Methods of Analysis, 16th Edition: 1995.

6. Any other internationally accepted analysis and test method as referred to in Article 20(1) of Council Directive 92/46 shall be recognised as a reference method.

7. In this Schedule—

"AOAC" means the Association of Official Analytical Chemists;

"IDF Standard" means a standard of the International Dairy Federation; and

"ISO" means a standard of the International Organisation for Standardisation.

Repeals and revocations

Title (Column 1)	*Chapter or Number* (Column 2)	*Extent of repeal or revocation* (Column 3)
Repeals		
Marketing of Milk Products Act (Northern Ireland) 1958.	1958 c. 31 (N.I.).	The whole Act.
Agriculture (Miscellaneous Provisions) Act (Northern Ireland) 1965.	1965 c. 3 (N.I.).	Section 18(1).
Agriculture (Miscellaneous Provisions) Act (Northern Ireland) 1967.	1967 c. 15 (N.I.).	Sections 13 and 14.
The Agriculture (Miscellaneous Provisions) (Northern Ireland) Order 1984.	S.I. 1984/702 (N.I. 2).	Article 23. In the Schedule, the entries relating to the Marketing of Milk Products Act (Northern Ireland) 1958.
The Food Safety (Northern Ireland) Order 1991.	S.I. 1991/762 (N.I. 7).	Paragraphs 2 and 3 of Schedule 2 and in Schedule 4 the entry relating to the Marketing of Milk Products Act (Northern Ireland) 1958.
Revocations		
Local Government (Modifications and Repeals of Agricultural Legislation) Order (Northern Ireland) 1973.	S. R. & O. (N.I.) 1973 No. 343.	In the Schedule the entries relating to the Marketing of Milk Products Act (Northern Ireland) 1958.
Milk Regulations (Northern Ireland) 1987.	S.R. 1987 No. 229.	The whole Regulations.
Importation of Milk Regulations (Northern Ireland) 1988.	S.R. 1988 No. 420.	The whole Regulations.
Milk (Amendment) Regulations (Northern Ireland) 1988.	S.R. 1988 No. 436.	The whole Regulations.
Milk (Amendment) Regulations (Northern Ireland) 1990.	S.R. 1990 No. 13.	The whole Regulations.
Milk (Amendment) Regulations (Northern Ireland) 1991.	S.R. 1991 No. 151.	The whole Regulations.
The Food Safety (Sampling and Qualifications) Regulations (Northern Ireland) 1991.	S.R. 1991 No. 198.	The reference in Schedule 1 to the Milk Regulations (Northern Ireland) 1987.

Title (Column 1)	*Chapter or Number* (Column 2)	*Extent of repeal or revocation* (Column 3)
The Food Safety (Northern Ireland) Order 1991 (Consequential Modifications) Order (Northern Ireland) 1991.	S.R. 1991 No. 203.	Part IV and the entry in Part I of Schedule 1 relating to the Milk Regulations (Northern Ireland) 1987.
The Food Safety (Exports) Regulations (Northern Ireland) 1991.	S.R. 1991 No. 344.	The entry in the Schedule relating to the Milk Regulations (Northern Ireland) 1987.
The Food Safety (Northern Ireland) Order 1991 (Consequential Modifications) Order (Northern Ireland) 1992.	S.R. 1992 No. 302.	The whole Order.
Milk (Standardisation and Importation) Regulations (Northern Ireland) 1992.	S.R. 1992 No. 559.	Regulations 3 and 4.

SCHEDULE 13 Regulation 24(3)

Amendment of Food Labelling Regulations (Northern Ireland) 1984

1. In regulation 2(1)—

(*a*) after the definition of "liqueur wine" there shall be inserted the following definition—

" "milk" means milk intended for sale or sold for human consumption of—

(*a*) one or more cows, and includes raw milk, standardised whole milk, non-standardised whole milk, semi-skimmed milk and skimmed milk; and

(*b*) one or more ewes, goats or buffaloes;";

(*b*) after the definition of "protein" there shall be inserted the following definitions—

" "raw milk", "standardised whole milk", "non-standardised whole milk", "semi-skimmed milk" and "skimmed milk", in relation to cows' milk, have the meanings respectively assigned to them by Council Regulation (EEC) No. 1411/71, as amended;".

2. In regulation 3(1), for the words "they shall not" there shall be substituted the words "Part IV shall not".

3. In regulation 24, in the definition of "prepacked for direct sale" in paragraph (3)—

(*a*) in sub-paragraph (*a*), for the words "and bread" there shall be substituted the words ", bread and milk"; and

(*b*) the full stop at the end of sub-paragraph (*b*) shall be replaced by a semi-colon and after that sub-paragraph there shall be inserted the following sub-paragraph—

"(*c*) in relation to cows' milk, put into containers on the premises where the milk is produced by the person owning or having control of the herd from which the milk is produced for sale by him on those premises or from a vehicle or stall used by him.".

4. After regulation 31A there shall be inserted the following regulation—

"*Health warning on cows' raw milk*

31B.—(1) Subject to paragraph (3) and except in cases to which paragraph (2) applies, the container in which any raw milk is sold shall be marked or labelled with the words "This milk has not been heat-treated and may therefore contain organisms harmful to health".

(2) Subject to paragraph (3) in the case of raw milk which is not pre-packed and is sold at a catering establishment there shall appear—

(*a*) on a label attached to the container in which the milk is sold; or

(*b*) on a ticket or notice that is readily discernible by an intending purchaser at the place where he chooses that milk,

the words "Milk supplied in this establishment has not been heat-treated and may therefore contain organisms harmful to health".

(3) This regulation shall not apply to raw milk from ewes, goats or buffaloes.".

5. In regulation 33, after paragraph (2), there shall be inserted the following paragraph—

"(3) Notwithstanding paragraphs (1) and (2)—

(*a*) in the case of milk that is contained in a bottle, any particulars which are required to be given under these Regulations may be given on the bottle cap; and

(*b*) in the case of raw milk contained in a bottle, the particulars specified in regulation 31B above shall be given elsewhere other than on the bottle cap.".

6. In regulation 35, in paragraphs (1) and (2), after the words "of alcoholic strength by volume" in each paragraph there shall be inserted the words "or, in the case of cows' raw milk, the required cautionary words".

7. For regulation 41 there shall be substituted the following regulation—

"*Enforcement*

41.—(1) Subject to paragraph (2) these Regulations shall be enforced and executed by each district council within its district.

(2) The Department of Agriculture shall enforce and execute these Regulations in relation to milk—

(*a*) in any production holding; and

(*b*) in any dairy establishment approved by it under the Dairy Products (Hygiene) Regulations (Northern Ireland) 1995.

(3) In this regulation "production holding" and "dairy establishment" have the meaning assigned to them by the Dairy Products (Hygiene) Regulations (Northern Ireland) 1995.".

EXPLANATORY NOTE

(This note is not part of the Regulations.)

These Regulations give effect to the provisions of Council Directive 92/46/EEC as defined in regulation 2(1) laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products. They also repeal and revoke the statutory provisions specified in regulation 23 and Schedule 12 and replace them with provisions that are compatible with Council Directive 92/46/EEC.

The Regulations also amend the Drinking Milk Regulations (Northern Ireland) 1977 (S.R. 1977 No. 8) to make it an offence to use a name to describe food in breach of Article 3(2) of Council Regulation (EEC) No. 1411/71 (OJ No. L148, 3.7.71, p. 4) (OJ/SE 1971 vol. II, p. 412), the relevant amendment to which is specified in footnote (*c*) to regulation 24(2).

The principal changes the Regulations make are—

(*a*) the provision of detailed requirements for the approval of dairy establishments;

(*b*) the extension of the health rules applicable for the production of cows' milk, to the milk of sheep, goats and buffaloes;

(*c*) the provision of microbiological standards for the manufacture of dairy products; and

(*d*) subject to specified exemptions, a requirement for the health marking of all dairy products.

The Regulations do not apply to a production holding or dairy establishment where dairy products are produced exclusively for the consumption of the occupier and others in his household, or in the case of a dairy establishment where products are not supplied in the course of a business, neither do they apply to a catering establishment or retail premises selling dairy products, or to persons engaged in the production, handling or sale of such products in a catering establishment or retail premises, (with the exception of specified requirements relating to cream, ice-cream and raw cows' milk). Farm premises where raw dairy products are sold exclusively direct to the ultimate consumer are also exempt from the approval, labelling and other specified requirements (regulation 3).

The Regulations—

(*a*) prohibit the use of any premises as a production holding for the production of raw milk unless they are licensed, and make provision for the licensing of such holdings, on application, by the Department of Agriculture (regulation 4);

(*b*) provide for the allotment of a licence number for each licensed production holding and the keeping of a list of such holdings, by the Department of Agriculture (regulation 5);

(*c*) prohibit the use of any premises as a dairy establishment unless they are approved and make provision for the approval, on application, by the approving authority; they also make special provision for the approval of low capacity dairy establishments which may not comply with all the requirements applicable to other dairy establishments (regulation 6);

(*d*) provide for the allotment of an approval number for each approved dairy establishment and make provision for the keeping of a list of such establishments, by the approving authority (regulation 7);

(*e*) provide for the revocation of licences and approvals (regulation 8);

(*f*) specify the conditions to be complied with in relation to the sale for human consumption of raw milk, thermised milk or heat-treated drinking milk, heat-treated milk intended for the manufacture of milk-based products or milk-based products, and prohibit the sale of any such dairy products unless those conditions are complied with (regulation 9);

(*g*) specify the methods of analysis and testing for dairy products (regulation 10);

(*h*) specify the conditions to be complied with in relation to the handling, storing, transporting, wrapping, packaging, health marking and labelling of dairy products; require the retention and production of specified documents; prohibit the use of a mark resembling a health mark and; specify a temporary exemption (regulation 11);

(*i*) specify restrictions to be complied with in relation to the sale of raw cows' milk as drinking milk (regulation 12);

(*j*) specify the duties of an occupier of a dairy establishment and of any person who buys raw milk for re-sale (regulation 13);

(*k*) provide for a production holding occupied by a person who was licensed under the Milk Regulations (Northern Ireland) 1987 to be deemed to be a licensed production holding under these Regulations (regulation 14);

(*l*) provide for a temporary exemption for specified dairy establishments and provide that dairy products prepared in such establishments shall not bear a health mark (regulation 15);

(*m*) make provision for the enforcement and execution of the Regulations and the supervision of specified premises by the Department of Agriculture and district councils (regulation 16);

(*n*) require district councils to provide specified information to the Department of Agriculture (regulation 17);

(*o*) create offences and prescribe penalties (regulation 18);

(*p*) authorise the approving authority to grant derogations in relation to specified requirements (regulation 19);

(*q*) apply various Articles of the Food Safety (Northern Ireland) Order 1991 for the purposes of the Regulations (regulation 20);

(*r*) make provision for the sale of dairy products from Great Britain, the Isle of Man and the Channel Islands (regulation 21);

(*s*) specify import requirements (regulation 22);

(*t*) provide for repeals and revocations (regulation 23); and

(*u*) amend the Ice-Cream and Other Frozen Confections Regulations (Northern Ireland) 1968 (S.R. & O. (N.I.) 1968 No. 13), the Drinking Milk Regulations (Northern Ireland) 1977 (S.R. 1977 No. 8), the Food Labelling Regulations (Northern Ireland) 1984 (S.R. 1984 No. 407) and the Food Premises (Registration) Regulations (Northern Ireland) 1992 (S.R. 1992 No. 167) (regulation 24).

The Contracting Parties to the EEA Agreement are the fifteen Member States of the European Union, Norway, Iceland and Liechtenstein. (See also the definition of "EEA State" in regulation 2(1)).

The AOAC methods referred to in Schedule 11 are used by the International Dairy Federation and the International Organisation for Standardisation and are published by the Association of Official Analytical Chemists. Copies can be obtained by post from the Assistant Business Manager, Publications, Association of Official Analytical Chemists, 1111 N 19th Street (Suite 210), Arlington, VA22209, USA.

Information as to International Dairy Federation Standards referred to in these Regulations can be obtained by post from the International Dairy Federation, 41 Square Vergote, B-1040 Brussels, Belgium.

Information as to International Organisation for Standardisation Standards referred to in these Regulations can be obtained by post from the International Organisation for Standardisation, 1 Rue de Varembe, Case Postale 56, CH-1211 Geneva 20, Switzerland.