The Dairy Products (Hygiene) Regulations 1995 -

The Minister of Agriculture, Fisheries and Food, the Secretary of State for Health and the Secretary of State for Wales, acting jointly, in relation to England and Wales, in exercise of the powers conferred on them by sections 6(4), 16(1) and (3), 17(1) and (2), 19, 26 and 48(1) of, and paragraphs 5, 6(1)(a) and 7(1) of Schedule 1 to, the Food Safety Act 1990[1] and of all other powers enabling them in that behalf after consultation in accordance with section 48(4) of the said Act 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

Title and commencement
1. —(1) These Regulations may be cited as the Dairy Products (Hygiene) Regulations 1995 and shall come into force on 9th May 1995.

(2) These Regulations shall apply to England and Wales.

Interpretation
2. —(1) In these Regulations, unless the context otherwise requires—

"the Act"means the Food Safety Act 1990; "animal"means an animal of the following species: cows, sheep, goats or buffaloes; "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 and "approved"shall be construed accordingly; "approving authority"means the food authority for the area within which a dairy establishment is situated; "authorised officer"means an authorised officer of the Minister or of an approving authority, as the case may be; "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[2], as amended by Council Directives 92/118/EEC[3] and 94/71/EC[4], 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[5] ; "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:—

(b) 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 cow's milk, produced on a registered production holding of which he is not the occupier; "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[6] laying down additional rules on the common market organisation in milk and milk products for drinking milk, as amended[7] ; "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 registered production holding as a single farm and includes the production holding and any processing establishment or other building or buildings situated on that farm and occupied by the same occupier; "handling"includes preparing, processing, packaging, treating, wrapping or rewrapping 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 and "heat-treated"shall be construed accordingly; "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; "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; "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[8] apply; "milk"means the milk of cows, ewes, goats or buffaloes intended for human consumption; "milk-based product"means—

() 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; "Minister"means—

(a) in relation to England, the Minister of Agriculture, Fisheries and Food, and
(b) in relation to Wales, the Secretary of State; "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; "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[9] 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[10] ; "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; "registration"in relation to a production holding means registration in accordance with regulation 4 or 14 and "registered"shall be construed accordingly; "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 paragraph 1(b) of Part II of Schedule 5; "thermised milk"means milk which has been subjected to thermisation; "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—

() 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 Feeding Stuffs)

(No. 2) Regulations 1992[11] ; "veterinary written direction"has the meaning assigned to it by the Medicines (Medicated Animal Feeding Stuffs) (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, in so far as the context admits, the same meaning as in Council Directive 92/46.

(3) Except in so far as the context otherwise requires, any reference in these Regulations to a numbered regulation or Schedule shall be construed as a reference to the regulation or Schedule bearing that number in these Regulations.

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) ny dairy establishment handling dairy products exclusively for the supply by the occupier of that dairy establishment otherwise than on sale; or

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

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

(a) he 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) above.

(3) Notwithstanding the exemption in paragraph (2) above, 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) below—

(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) above, 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) above, "occupier"includes any person forming part of the occupier's household.

PART II
REGISTRATION AND USE OF PRODUCTION HOLDINGS

Registration

4. —(1) No person shall 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 registered in accordance with the provision of paragraph (3)(a) below, or are deemed to be registered in accordance with regulation 14.

(2) No person shall—

(a) despatch for sale from any registered 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 registered under this regulation or is deemed to be registered by regulation 14.

(3) The Minister on application made to the Minister under this regulation shall—

(a) register the premises to which the application relates as a production holding if the Minister 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 register the premises as a production holding if the Minister is not so satisfied.

(4) Each application for registration under this regulation shall be made in writing to the Minister by the occupier of, or a person proposing to occupy, the production holding to which the application relates.

(5) The Minister shall, without unreasonable delay after receipt of the application referred to in paragraph (4) above, notify the applicant in writing of the Minister's decision on that application and of the reasons of any refusal to register such production holding.

(6) Any person who is aggrieved by the decision of the Minister not to grant a registration or by the imposition of any condition specified by the Minister, may appeal against that decision to a magistrates' court.

(7) Sections 37(3) to (6) of the Act shall have effect in relation to an appeal under this regulation as they have effect in relation to an appeal under that section but with the omission—

(a) of the references to appeals for which provision is made by regulations under section 37(2); and

(b) of subsection 5(b) and the word "or"immediately preceding it.

(8) Any registration 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.

(9) Without prejudice to sections 9 to 12 of the Act, where the Minister has refused a registration under this regulation, a person who both prior to the coming into force 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 Minister 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 Minister shall be entitled to inspect any premises in respect of which an application had been made to the Minister to register such premises as a production holding, prior to registering those premises.

List of production holdings

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

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

Approvals

6. —(1) No person shall 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 (9) below.

(2) No person shall—

(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 anther 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 (9) below, an approving authority on application made to that authority under this regulation shall—

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

(i) in the case of a collection centre, both the premises and the arrangements at those premises for use 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 the approving authority is not so satisfied.

(4) Each application for an approval under this regulation shall be made in writing to the approving authority by the occupier of, or a person proposing to occupy, the dairy establishment to which the application relates.

(5) The approving authority shall, without unreasonable delay after receipt of the application referred to in paragraph (4) above, 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 magistrates' court.

(7) Sections 37(3) to (6) of the Act shall have effect in relation to an appeal under this regulation as they have effect in relation to an appeal under than section but with the omission—

(a) of the references to appeals for which provision is made by regulations under section 37(2); and

(b) of subsection 5(b) and the word "or"immediately preceding it.

(8) 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.

(9) 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.

(10) Without prejudice to sections 9 to 12 of the Act, where the approving authority has refused an approval under this regulation, a person who both prior to the coming into force 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.

(11) 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 that authority 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) above.

PART IV
CANCELLATION OF REGISTRATIONS AND RECOVATION OF APPROVALS

Cancellation revocation and appeal

8. —(1) The Minister may cancel a registration granted by the Minister under regulation 4 or deemed to be 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, the Minister is satisfied that in respect of that production holding—

(a) here 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 registration 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 the Minister and in relation to a dairy establishment the approving authority shall give the occupier of those premises notice in writing—

(a) of the decision by the Minister or the approving authority, as the case may be, to cancel the registration of the production holding or to revoke the approval of the dairy establishment;

(b) of the date on which the cancellation or revocation is to take effect; and

(c) of the reasons for cancellation or revocation.

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

(a) a prohibition order under section 11 of the Act; or

(b) an emergency prohibition order under section 12, and in consequence of compliance with the order dairy products may no longer be handled at those premises.

(5) Any person who is aggrieved by the cancellation of a registration, or the revocation of an approval may appeal to a magistrates' court.

(6) Sections 37(3) to (6) of the Act shall have effect in relation to an appeal under this regulation as they have effect in relation to an appeal under that section but with the omission—

(a) of the references to appeals for which provision is made by regulations under section 37(2); and

(b) of subsection 5(b) and the word "or"immediately preceding it.

(7) A cancellation or 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 paragraph (3) above "occupier", in relation to a proposed cancellation or revocation by virtue of paragraph (1)(c) or (2)(c) above, where the production holding or dairy establishment is vacant, means the last person known to the Minister or the approving authority, 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) below and regulation 15, no person shall 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 registered 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) t complies with the appropriate conditions specified in paragraph (2), (3), (4), (5) or (6) below;
(e) it complies with paragraphs (7), (8), (9), (10), (11) and (12) below, 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 that—

(a) in the case of raw cows' milk, those specified in Part I of Schedule 4 and regulation 12; and
(b) in the case if raw eyes' milk of 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) above; 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) above; or
(b) it shall be manufactured from other heat-treated 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) above.

(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 it shall be manufactured from—

(a) raw milk or thermised milk which complies with paragraphs (1)(a), (b) and (c) and (3)(b) above, as appropriate;
(b) heat-treated drinking milk which complies with paragraph (4)(b) above; or
(c) heat-treated milk (not being heat-treated drinking milk) which complies with paragraph (5) above.

(7) No person shall sell any cows' milk to any catering establishment without heat-treatment of such milk.

(8) No person shall sell any thermised cows' milk to the ultimate consumer without heat-treatment of such milk.

(9) No person shall sell any ice-cream unless it is pasteurised ice-cream which complies with Part V of Schedule 6 or it is sterilised ice-cream with 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 1983[12] . 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 such transportation by a commercial document as specified in Part III of Schedule 8;

(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) below 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) above, 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) No person shall 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) No person shall sell drinking milk which is raw cows' milk, except in accordance with the following provisions of this regulation.

(2) An occupier of a registered 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 purchasers of raw milk for re-sale

13. —(1) Subject to paragraph (3) below, 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;

(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) above—

(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) above 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 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 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 Act; 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 until it is destroyed, or used for purposes other than human consumption, or, with the agreement of the 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 as specified in paragraph (1)(b)(iii) above;

(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) above, as appropriate; and

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

PART VII
TRANSITIONAL PROVISIONS RELATING TO DAIRY FARMS AND DAIRY ESTABLISHMENTS

Dairy Farms

14. Any production holding which is both registered as a dairy farm before the coming into force of these Regulations, pursuant to the Milk and Dairies (General) Regulations 1959[13], and is in operation as such on the date before the date on which these Regulations come into force, shall be deemed to be premises registered under and subject to the provisions of these Regulations as a production holding.

Temporary derogations under 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 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[14], in accordance with Article 2 of Council Directive 92/47.

(2) Dairy products produced in a dairy establishment approved in accordance with paragraph (1) above 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"mean 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 paragraph (2) below, each approving authority shall enforce and execute these Regulations within its area.

(2) The Minister shall enforce and execute these Regulations in relation to any registered production holding and, in relation to the sale of any raw cows' milk which is drinking milk, any farm premises

or any processing establishment which comprises part of any farm premises.

(3) In relation to any registered production holding, farm premises or processing establishment referred to in paragraph (2) above, the Minister shall carry out such inspection and supervision of those premises and any sampling, analysis and examination of any raw cows' milk which is drinking milk as the Minister may consider necessary to ensure that the requirements of these Regulations are complied with.

(4) In relation to any approved dairy establishment within its area, each approving authority shall carry out such inspection and supervision of that establishment and any sampling, analysis and examination of any dairy products as that authority may consider necessary to ensure that the requirements of these Regulations are complied with.

Information to be provided by approving authorities

17. Every approving authority shall provide the Minister with such information relating to the execution of its duties under these Regulations as the Minister may from time to time require.

Offences and penalties

18. —(1) If—

(a) a person (other than an approving authority or the Minister) 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 Regulation, 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.

(2) No prosecution for such an offence shall commence after the expiry of—

(a) three years from the commission of the offence; or

(b) one year from its discovery by the prosecutor; whichever is the earlier.

Authorisations to derogate

19. The approving authority 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) imes and temperatures specified in paragraph 1 of Part 1 of Schedule 5, in accordance with paragraph B(1) of Chapter I of Annex C of Council Directive 92/46;

(d) temperature 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;

(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 sections of the Act

20. —(1) The following provisions of the Act shall apply for the purposes of these Regulations as they apply for the purposes of section 8, 14 or 15 of the Act and, unless the context otherwise requires, any reference in them to the Act shall be construed as a reference to these Regulations—

(a) section 2 (extended meaning of "sale"etc.);

(b) section 3 (presumption that food is intended for human consumption);
(c) section 20 (offences due to fault of another person);
(d) section 21 (defence of due diligence);
(e) section 30(8) (which relates to documentary evidence);
(f) section 33 (obstruction etc. of officers);
(g) section 36 (offences by bodies corporate); and
(h) section 44 (protection of officers acting in good faith).

(2) Section 5(6) (appointment of a person who is not an officer) of the Act shall apply in relation to an appointment by a food authority for the purposes of these Regulations as it applies in relation to matters arising under the Act.

(3) Section 8(3) (which makes presumptions in the case of batches of food) of the Act 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.

(4) Section 9 (inspection and seizure of suspected food) of the Act shall apply to food which it is a 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 Scotland, Northern Ireland, the Isle of Man and the Channel Islands
21. —(1) The places to which this regulation applies are Scotland, Northern Ireland, the Isle of Man and the Channel Islands.

(2) No person—
(a) shall 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 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) below, no person shall sell for human consumption in England and Wales 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) above 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 force;
(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 relation to the health mark.

Imports from third countries and EEA States
22. —(1) No person shall import into England and Wales for sale for human consumption from a third country any cows' milk or cream.

(2) No person shall import into England and Wales for sale for human consumption from a third country any other dairy products except in accordance with the following paragraphs of this regulation.

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

Revocations

23. The Regulations specified in Schedule 12 to these Regulations are revoked to the extent specified in Column 3 of that Schedule from the date these Regulations come into force.

Consequential amendments

24. —(1) In the Ice Cream (Heat Treatment etc) Regulations 1959[15], after regulation 2A there shall be inserted the following regulation—

> **"Exemption**
> **2B.** —(1) These Regulations 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 1995."

(2) In the Drinking Milk Regulations 1976[16], after regulation 5 there shall be inserted the following regulation—

> **"Reserved names**
> **5A.** No person shall use any name specified in Article 3(1) of Council Regulation (EEC) No. 1411/71[17], as amended[18], except in accordance with paragraph (2) of that Article."

(3) The Good Labelling Regulations 1984[19] shall be amended in accordance with Schedule 13.

(4) The Food Premises (Registration) Regulations 1991[20] 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, in relation to England and Wales, of the Dairy Products (Hygiene) Regulations 1995;" ; and

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

Angela Browing

Parliamentary Secretary,
Ministry of Agriculture, Fisheries and Food

14th April 1995

Signed by authority of the Secretary of State for Health

Cumberlege

Parliamentary Under Secretary of State,
Department of Health

11th April 1995
Signed by authority of the Secretary of State for Wales

Gwilym Jones

Parliamentary Under Secretary of State,
Welsh Office

6th April 1996

Notes:

[1] 1990 c. 16; "the Ministers"is defined in section 4(1) of the Act; section 6(4)(a) was amended by the Deregulation and Contracting Out Act 1994 (c. 40), section 31 and Schedule 9, paragraph 6. back
[2] OJ No. L268, 14.9.92, p.1. back
[3] OJ No. L62, 15.3.92, p.49. back
[4] OJ No. L368, 31.12.94, p.33. back
[5] OJ No. L268, 14.9.92, p.33. back
[6] OJ No. L148, 3.7.71, p.4 (OJ/SE 1971 vol. II, p.412). back
[7] 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). back
[8] S.I. 1994/3142 back
[9] OJ No. l229, 30.8.80, p.11, to which there are amendments not relevant to these Regulations. back
[10] 1968 c. 67. back
[11] S.I. 1992/1520, to which there are amendments not relevant to these Regulations. back
[12] S.I. 1983/1950, to which there is an amendment not relevant to these Regulations. back
[13] S.I. 1959/277, the relevant provisions of which are revoked by regulation 24 and Schedule 12 of these Regulations. back
[14] S.I. 1994/3142. back
[15] OJ No. L 282, 29.10.94, p.1. back
[16] 1968 c. 67. back
[17] S.I. 1959/734 to which there are amendments not relevant to these Regulations. back
[18] S.I. 1976/1883, to which there are amendments not relevant to these Regulations. back
[19] OJ No. L148, 3.7.71, p.4 (OJ/SE 1971 vol. II, p.412). back
[20] 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. back