
STATUTORY INSTRUMENTS

1995 No. 1086

The Dairy Products (Hygiene) Regulations 1995

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⁽¹⁾, as amended

(1) OJ No. L268, 14.9.92, p.1.

by Council Directives [92/118/EEC\(2\)](#) and [94/71/EC\(3\)](#), 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(4);

“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\(5\)](#) laying down additional rules on the common market organisation in milk and milk products for drinking milk, as amended(6);

“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

(2) OJ No. L62, 15.3.92, p.49.

(3) OJ No. L368, 31.12.94, p.33.

(4) OJ No. L268, 14.9.92, p.33.

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

(6) 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).

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(7) 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;

“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\(8\)](#) relating to the quality of water intended for human consumption;

(7) S.I.1994/3142

(8) OJ No. L229, 30.8.80, p.11, to which there are amendments not relevant to these Regulations.

- “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⁽⁹⁾;
- “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—
- (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 Feeding Stuff) (No. 2) Regulations 1992⁽¹⁰⁾;

⁽⁹⁾ 1968 c. 67.

⁽¹⁰⁾ S.I. 1992/1520, to which there are amendments not relevant to these Regulations.

“veterinary written direction” has the meaning assigned to it by the Medicines (Medicated Animal Feeding Stuff) (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) any 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 subparagraph (a) or (b) above;

(2) Subject to paragraph (3) below 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 subparagraph (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—

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- (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.