STATUTORY INSTRUMENTS

1983 No. 1508

FOOD

The Milk-based Drinks (Hygiene and Heat Treatment) Regulations 1983

Made - - - -	18*th October* 1983
Laid before Parliament	26*th October* 1983
Coming into Operation	16*th November* 1983

The Minister of Agriculture, Fisheries and Food, the Secretary of State for Social Services and the Secretary of State for Wales, acting jointly, in exercise of the powers conferred by sections 4, 7, 13, 87(3) and 123 of the Food and Drugs Act 1955(**a**), and now vested in them(**b**), and of all other powers enabling them in that behalf, hereby make the following regulations, after consultation in accordance with section 123(6) of that Act with such organisations as appear to them to be representative of interests substantially affected by the regulations:—

Title, commencement and extent

1.—(1) These regulations may be cited as the Milk-based Drinks (Hygiene and Heat Treatment) Regulations 1983 and shall come into operation on 16th November 1983.

(2) These regulations extend to England and Wales.

Interpretation

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

"the Act" means the Food and Drugs Act 1955;
"catering establishment" means a restaurant, canteen, club, public house, school, hospital or other 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;
"container" includes a bottle;
"milk-based drink" has the meaning assigned to it by regulation 3;
"milk-based drink processor" means a person who subjects milk-based drinks to heat treatment and "the processing of milk-based drinks" shall be construed accordingly;
"sale" includes possession for sale, offer for sale and exposure for sale and "sell" shall be construed accordingly.

(**a**) 1955 c.16 (4&5 Eliz.2); section 4 was amended by the European Communities Act 1972 (c.68), Schedule 4, paragraph 3(1), section 7 was amended by the Weights and Measures Act 1963 (c.31), Schedule 9, Part II, section 13 was amended by the Slaughterhouses Act 1974 (c.3), Schedule 4, paragraph 1, section 87(3) was amended by the Weights and Measures Act 1963, Schedule 9, Part II, and section 123 was amended by the Weights and Measures Act 1963, Schedule 9, Part I, the Slaughterhouses Act 1974, Schedule 4, paragraph 4, and the Food and Drugs (Amendment) Act 1982 (c.26), section 4.

(**b**) In the case of the Secretary of State for Social Services, by virtue of S.I. 1968/1699; in the case of the Secretary of State for Wales, by virtue of S.I. 1978/272.

(2) Any reference in these regulations to a numbered regulation or schedule shall, unless the reference is to a regulation of, or schedule to, specified regulations, be construed as a reference to the regulation or schedule so numbered in these regulations.

(3) Any reference in a regulation of or a schedule or a part of a schedule to these regulations to a numbered paragraph shall be construed as a reference to the paragraph so numbered in that regulation, schedule or part of a schedule (unless the reference specifies a different regulation, schedule or part of a schedule).

Meaning of 'milk-based drink'

3.—(1)*(a)* In these regulations 'milk-based drink' means a liquid drink (other than a fermented drink) being a mixture comprising by weight at least 85% milk as specified in paragraph (1)(b) and comprising as to the remainder any of, or any mixture of, the ingredients listed in paragraph (2).

(b) The milk specified for the purposes of this paragraph is cows' milk (whether or not separated) but not cream separated from the milk, dried milk, condensed milk, evaporated milk or butter milk.

(2) The ingredients listed in this paragraph are—

(a) any substance, suitable for use as food and commonly used as food, which is wholly a natural product, whether or not that substance has been subjected to any process or treatment;

(b) flavouring;

(c) any permitted solvent as defined in the Solvents in Food Regulations 1967 (**a**);

(d) any permitted colouring matter as defined in the Colouring Matter in Food Regulations 1973 (**b**);

(e) any permitted emulsifier as defined in the Emulsifiers and Stabilisers in Food Regulations 1980 (**c**);

(f) any permitted stabiliser as defined in the Emulsifiers and Stabilisers in Food Regulations 1980;

(g) any permitted miscellaneous additive as defined in the Miscellaneous Additives in Food Regulations 1980 (**d**);

(h) any permitted sweetener as defined in the Sweeteners in Food Regulations 1983 (**e**);

(i) starch (whether modified or not);

(j) salt;

(k) any vitamin preparation;

(l) any mineral preparation;

(m) water fit for human consumption and used in combination with any of the other ingredients listed in this paragraph.

Exemption

4. These regulations shall not apply to any food which is intended to be exported to any place outside the United Kingdom.

(**a**) S.I. 1967/1582, amended by S.I. 1967/1939, 1980/1832, 1982/1727, 1983/1211.
(**b**) S.I. 1973/1340, amended by S.I. 1974/1119, 1975/1488, 1976/2086, 1978/1787, 1979/1254, 1982/1727.
(**c**) S.I. 1980/1833, amended by S.I. 1982/16, 1727, 1983/1211.
(**d**) S.I. 1980/1834, amended by S.I. 1980/1849, 1982/14, 1727, 1983/1211.
(**e**) S.I. 1983/1211.

Restriction on use of certain words in labelling

5. No person shall sell or advertise any food (other than a milk-based drink) in the labelling of which the words 'milk-based drink' or 'milk drink' are used.

Application of Schedule 1

6. Schedule 1 shall apply (without prejudice to the application of the Food Hygiene (General) Regulations 1970 (**a**)) in respect of the preparation, transport, storage, packaging, wrapping, exposure for sale, service and delivery of milk-based drinks intended for sale or sold for human consumption.

Heat treatment of milk-based drinks

7.—(1) Subject to regulation 8, no person shall sell any milk-based drink intended for human consumption unless the general requirements of Schedule 2 in connection with heat treatment of that milk-based drink and the special requirements of—

(a) Schedule 3, Part I, in connection with such heat treatment by pasteurisation, or

(b) Schedule 3, Part II, in connection with such heat treatment by sterilisation, or

(c) Schedule 3, Part III, in connection with such heat treatment by the ultra high temperature method—

are satisfied.

(2) The provisions as to sampling set out in Schedule 4, Part I, shall apply for the purposes of Schedule 3, the tests set out in Schedule 4, Parts II and III, shall apply for the purposes of Schedule 3, Part I, and the test set out in Schedule 4, Part IV, shall apply for the purposes of Schedule 3, Parts II and III.

Milk-based drink from Scotland and Northern Ireland

8.—(1) Where milk-based drink is brought into England and Wales from Scotland, the requirements of Schedule 2, paragraphs 2, 3 and 4, and of any Part of Schedule 3 shall, so far as they would relate to anything to be done before that milk-based drink enters England and Wales, be deemed to be satisfied if the corresponding requirements of any legislation having effect for the time being in Scotland in relation to the heat treatment of that milk-based drink are satisfied.

(2) Where milk-based drink is brought into England and Wales from Northern Ireland—

(a) the requirements of Schedule 2, paragraphs 2, 3 and 4, and of Schedule 3, Part II or III, shall, so far as they would relate to anything to be done before that milk-based drink enters England and Wales, be deemed to be satisfied if the corresponding requirements of any legislation having effect for the time being in Northern Ireland in relation to the heat treatment of that milk-based drink are satisfied, and

(b) in cases of such deemed satisfaction of those requirements of these regulations, Schedule 2, paragraph 1, shall be deemed to be satisfied if the milk used to make that milk-based drink has been produced in Northern Ireland.

(**a**) S.I. 1970/1172.

Records

9. Every milk-based drink processor shall keep accurate records of—

(a) the quantities of milk purchased or produced by him for milk-based drink production and of milk-based drinks sold and delivered by him, and

(b) the names and addresses of the persons—

(i) from whom milk was purchased by him for milk-based drink production, and

(ii) to whom milk-based drinks were sold and delivered by him otherwise than by retail—

and retain each such record for a period of 12 months from the date of the transaction to which it relates.

Penalties and enforcement

10.—(1) If any person contravenes or fails to comply with any provision of these regulations, he shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding £1,000.

(2) Each local authority shall—

(a) enforce and execute these regulations in their area, and

(b) give such assistance and information to any other local authority as that other local authority may reasonably require for the purpose of carrying out their duties under these regulations.

(3) For the purpose of these regulations subsection (7) of section 91 of the Act (which relates to powers of sampling) shall be modified to read as if the powers referred to in that subsection were exercisable throughout the area of any local authority by an authorised officer of that local authority.

Applications of various provisions of the Act

11.—(1) Subject to paragraph (2), the following provisions of the Act shall apply for the purposes of these regulations as if references therein to proceedings, or a prosecution, under or taken or brought under the Act included proceedings, or a prosecution, as the case may be, taken or brought for an offence under these regulations:—

(a) section 108(3) and (4) (which relates to prosecutions);

(b) section 110(1), (2) and (3) (which relates to evidence of analysis);

(c) section 112 (which relates to the power of a court to require analysis by the Government Chemist);

(d) section 113 (which relates to a contravention due to some person other than the person charged);

(e) section 115 (2) (which relates to the conditions under which a warranty may be pleaded as a defence);

(f) section 116 (which relates to offences in relation to warranties and certificates of analysis).

(2) Section 112 of the Act shall apply for the purposes of these regulations as if the reference therein to section 108(4) of the Act included a reference to that subsection as applied by paragraph (1).

In Witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 11th October 1983.

L.S.

Michael Jopling,
Minister of Agriculture, Fisheries and Food.

Norman Fowler,
Secretary of State for Social Services.

18th October 1983.

John Stradling Thomas,
Minister of State for Wales.

11th October 1983.

Regulation 6

SCHEDULE 1

1. No milk-based drink processor shall carry out processing of milk-based drinks on premises which are not provided with a supply of water suitable and sufficient for the requirements of these regulations.

2. Each milk-based drink processor shall ensure that every receptacle used on his premises for the storage and conveyance of water shall be emptied and cleaned as often as may be necessary to prevent the pollution of the water and to maintain it in a suitable condition for the purpose for which it is required.

3. Each milk-based drink processor shall cause the interior of his premises and any furniture and fittings therein to be cleaned as often as may be necessary to maintain them at all times in a state of thorough cleanliness and shall (except in the case of any part of his premises in which milk-based drinks are solely or mainly dealt with by way of retail sale)—

(a) cause all floors on his premises to be constructed of such material and in such a manner as to render the surfaces impervious so that it is practicable to remove any liquid matter which may fall thereon, and cause such floors to be sloped as to convey such liquid matter to a suitably and properly trapped drain,

(b) cause the surface of any wall or part of a wall on his premises which is liable to splashing to be smooth and impervious, and

(c) cause all such floors and any such wall or part of a wall to be cleansed with water at least once in every day.

4.—(1) Subject to subparagraph (2) of this paragraph, no milk-based drink processor shall carry out the processing of, handle or store milk-based drinks in any room on his premises—

(a) which is used as a kitchen or scullery, or

(b) which communicates directly by door, window or otherwise with any cesspool, receptacle for ashes or other refuse, boiler house, fuel store, or room in which an internal combustion engine (other than an engine the exhaust of which is discharged into the external air) is operated.

(2) Subparagraph (1) of this paragraph shall not prohibit the use of an electric or gas boiler in a room communicating directly with a room used for the processing, handling or storage of milk-based drinks.

5.—(1) Each milk-based drink processor shall ensure that vessels on his premises containing milk-based drinks are properly covered or that milk-based drinks on his premises are otherwise effectively protected from dust, dirt, flies and other sources of contamination.

(2) No milk-based drink processor shall store, or carry out the processing of, milk-based drinks (or keep any appliances connected with such processing) in any room in which any cows are milked or in which any animal or poultry is kept.

6. Each milk-based drink processor shall ensure that no foul or noxious matter or soiled bed or body clothing shall be conveyed through any part of his premises used for the keeping or storage of milk-based drinks.

7.—(1) Each milk-based drink processor shall ensure that any room used on his premises for the processing of milk-based drinks shall not be used for any purposes other than such processing, with the exception of the following:—

(a) the cooling, processing, handling and storage of any drink of a kind commonly sold by dairymen;

(b) the manufacturing of milk into, and the storage of, milk products;

(c) the storage of ice cream;

(d) the storage of any ingredient listed in regulation 3(2);

(e) the cleansing of bottles which before cleansing have contained any drink of a kind commonly sold by dairymen;

(f) the cleansing and storage of utensils used in connection with milk products and drinks of a kind commonly sold by dairymen;

(g) the storage of clean bottles and non-returnable packaging materials to be used in connection with any drink of a kind commonly sold by dairymen.

(2) In this paragraph "dairyman" and "milk product" have the meanings which they have respectively in the Milk and Dairies (General) Regulations 1959(**a**) .

8.—(1) Every person having access to milk-based drinks (or to utensils used for milk-based drinks) shall keep his outer clothing and person clean at all times during such access.

(2) Every person having access to milk-based drinks in open containers shall wear a clean and washable or disposable overall and a clean and washable or disposable head covering.

9.—(1) Each milk-based drink processor shall ensure that—

(a) every appliance used on his premises in connection with milk-based drinks shall, immediately before contact with milk-based drinks, be cleansed to a state of thorough cleanliness in accordance with subparagraph (2) of this paragraph, and

(**a**) S.I. 1959/277, amended by S.I. 1960/1777, 1962/1288, 1973/1064, 1977/171, 1979/1567, 1982/1703.

(b) every vessel (including the lid) used by him for containing milk-based drinks shall—

(i) if used previously for any purpose whatsoever, be cleansed to a state of thorough cleanliness in accordance with subparagraph (2) of this paragraph, and

(ii) in any event be in a state of thorough cleanliness.

(2) For the purpose of cleansing any vessel or appliance as indicated in subparagraph (1) of this paragraph—

(a) such vessel (other than a glass bottle effectively cleansed in a bottle-washing machine) or appliance shall be thoroughly rinsed and washed with or without detergents and scalded with boiling water or otherwise thoroughly cleansed with steam or an appropriate and effective chemical agent;

(b) where any chemical agent or detergent has been used for cleansing any vessel or appliance, all traces of that chemical agent or detergent shall be removed from that vessel or appliance.

(3) Where any appliance or vessel, previously used in connection with milk-based drinks, is used for another purpose, the requirements of subparagraphs (1) and (2) of this paragraph shall apply in relation to that other purpose as they apply to the processing of milk-based drinks.

10.—(1) Subject to subparagraph (2) of this paragraph, no person shall open any container containing a milk-based drink, or tamper with any device used for closing any such container, before delivery of that container to the consumer.

(2) Subparagraph (1) of this paragraph shall not apply to anything done—

(a) in pursuance of statutory authority,

(b) for the purpose of sampling, or

(c) in respect of the sale of a milk-based drink—

(i) as part of a meal, or

(ii) as a refreshment,

in circumstances where all practicable precautions are taken to prevent contamination of that milk-based drink.

11. Every person who sells, conveys or distributes milk-based drinks shall—

(a) take all practical precautions to prevent them from being unnecessarily exposed to heat and from contamination,

(b) refrain from leaving them on a public highway (except on a final delivery on retail sale),

(c) protect them so far as practicable (in any place where he habitually leaves them to await collection or further conveyance) from direct rays of the sun, and

(d) keep any vehicle used for conveying them clean and free from offensive matter.

Regulations 7(1) and 8

SCHEDULE 2

General requirements in connection with the heat treatment of milk-based drinks

1. Only milk which has been produced in Great Britain shall be used in connection with the heat treatment of milk-based drinks.

2. The milk and other ingredients referred to in regulation 3 shall, if mixed to make a milk-based drink before commencement of the heat treatment of that milk-based drink, be so mixed not more than four hours before such treatment or pre-heating in accordance with paragraph 3(2).

3.—(1) Subject to paragraph (2) of this paragraph, no milk-based drink shall, before the commencement of heat treatment in accordance with Schedule 3, be kept for more than one hour at any temperature which exceeds 10°C.

(2) Subparagraph (1) of this paragraph shall not prohibit the keeping of a milk-based drink for more than one hour at a temperature which exceeds 10°C in circumstances where the milk-based drink has been pre-heated (that is to say subjected to any heat treatment prior to sterilisation in accordance with Schedule 3, Part II).

4. Each milk-based drink processor shall take such measures as are adequate to ensure that any milk-based drink heat treated in accordance with these regulations shall, until such milk-based drink has been put into the containers in which it is to be supplied to consumers or to a catering establishment (and those containers have been closed so as to prevent contamination), be kept apart at all times from other milk-based drinks, milk or food containing milk.

SCHEDULE 3 Regulations 7(1) and 8

Special requirements in connection with the heat treatment of milk-based drinks

PART I—PASTEURISATION

1.—(1) The milk-based drink shall be pasteurised, that is to say it shall be heated—

(a) to a temperature of not less than 63°C and retained at that temperature for not less than thirty minutes,

(b) to a temperature of 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 as has equivalent effect to paragraph (a) or (b) of this subparagraph in relation to the elimination of vegetative pathogenic organisms in the milk-based drink.

(2) The milk-based drink shall as soon as practicable after pasteurisation be cooled to a temperature of not more than 10°C.

2. Where milk-based drink is heated by a continuous-flow method, the apparatus in which the milk-based drink is to be heated shall be provided with a device which shall automatically divert the flow or prevent the onward flow of any of the milk-based drink which is not raised to the appropriate temperature required by paragraph 1.

3.—(1) Indicating and recording thermometers shall be installed in suitable places in the pasteurising apparatus in order to indicate and record the temperature at which the milk-based drink has been retained and to which it is cooled.

(2) The records of those recording thermometers shall give clear readings of the minimum temperatures achieved and they shall be dated and preserved for a period of not less than 3 months.

4.—(1)*(a)* Milk-based drink which is pasteurised in bottles shall be supplied to the consumer or to a catering establishment in those bottles.

(b) Those bottles shall be securely closed before or during pasteurisation.

(2) Where milk-based drink is pasteurised otherwise than in bottles, the following processes shall be carried out, at the premises where pasteurisation has taken place, as soon as practicable after pasteurisation has taken place:—

(a) the milk-based drink shall be put into containers in which it is to be supplied to the consumer or to a catering establishment; and

(b) those containers shall be securely closed.

5. Following pasteurisation and cooling as specified in paragraph 1, the temperature of milk-based drink remaining on the premises where pasteurisation has taken place shall not rise above 10°C.

6. The whole of any apparatus in which milk-based drink is pasteurised, cooled, mixed or packaged shall be so constructed as to give adequate protection from the risk of atmospheric contamination by dust or otherwise.

7.—(1) Where milk-based drink is made by mixing the milk from which it is made with its other ingredients after pasteurisation of that milk—

(a) paragraphs 1 to 6 (other than paragraph 4(1)) shall apply as if references in those paragraphs to milk-based drink included references to that milk and as if the mixing of that milk with those other ingredients were a process to be carried out under paragraph 4(2) immediately before the processes described in paragraph 4(2)(a) and (b), and

(b) prior to being mixed with that milk, those other ingredients shall be subjected to such treatment (if any) as may be necessary to ensure that the effect achieved, in relation to the elimination of vegetative pathogenic organisms in the milk-based drink, is equivalent to the effect which would have been achieved had the milk-based drink been mixed prior to pasteurisation and then pasteurised.

(2) Where milk-based drink is made by mixing partly prepared drink (that is to say the milk and part of the remaining ingredients from which the milk-based drink is made) with its other ingredients after pasteurisation of that partly prepared drink, subparagraph (1) of this paragraph shall apply as if references in that subparagraph to milk were references to partly prepared drink.

8. Any sample of the milk-based drink procured (after heat treatment with a view to pasteurisation) in accordance with Schedule 4, Part I, as indicated in a subparagraph of column (1) of this paragraph shall satisfy the test or tests set out in the corresponding subparagraph of column (2) of this paragraph:—

(1)	(2)
(a) Non-phosphatase sample (that is to say a sample the colour of which is such as to interfere with the phosphatase test prescribed in Schedule 4, Part III) taken not later than the day following heat treatment and before departure from premises where heat treatment took place.	*(a)* The coliform test prescribed in Schedule 4, Part II.
(b) Sample (other than non-phosphatase sample) taken not later than the day following heat treatment and before departure from premises where heat treatment took place.	*(b)* Whichever of— (i) the coliform test prescribed in Schedule 4, Part II, and (ii) the phosphatase test prescribed in Schedule 4, Part III— is applied and, if both tests are applied, both of them.
(c) Sample (other than non-phosphatase sample) taken before delivery to the consumer or to a catering establishment, in circumstances where subparagraph (b) of this column does not apply.	*(c)* The phosphatase test prescribed in Schedule 4, Part III.

PART II—STERILISATION

1. The milk-based drink shall be sterilised, that is to say it shall be heated in a hermetically sealed container in which it is to be supplied to the consumer or to a catering establishment—

(a) to a temperature of 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 as has equivalent effect to subparagraph (a) of this paragraph in relation to the rendering of the milk-based drink free from viable micro-organisms and their spores—

and cooled as soon as practicable thereafter.

2. There shall be installed in suitable places in the apparatus used for sterilisation such thermometers or temperature calibrated pressure gauges as are necessary to ascertain that sterilisation has been correctly carried out.

3. Any sample of the milk-based drink procured in accordance with Schedule 4, Part I, after heat treatment with a view to sterilisation and before delivery to the consumer or to a catering establishment shall satisfy the colony count test prescribed in Schedule 4, Part IV.

PART III—ULTRA HIGH TEMPERATURE METHOD

1. The milk-based drink shall be heat treated by the ultra high temperature method, that is to say it shall be heated—

(a) to a temperature of 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 as has equivalent effect to subparagraph (a) of this paragraph in relation to the rendering of the milk-based drink free from viable micro-organisms and their spores.

2. The apparatus in which the milk-based drink is heat treated shall be provided with a device which shall automatically divert the flow or prevent the onward flow of any of the milk-based drink which has not been heated to a temperature sufficient for the purposes of paragraph 1.

3.—(1) Indicating and recording thermometers shall be installed in suitable places in the apparatus in which the milk-based drink is heat treated in order to record the temperature to which the milk-based drink is heated.

(2) The records of the recording thermometers shall give clear readings and they shall be dated and preserved for a period of not less than 12 months.

4. The following processes shall be carried out, at the premises where milk-based drink has been heat treated by the ultra high temperature method, after such treatment and with such aseptic precautions as are necessary to ensure the protection of the milk-based drink from risk of contamination:—

(a) the milk-based drink shall be put into sterile containers in which it is to be supplied to the consumer or to a catering establishment; and

(b) those containers shall be securely sealed.

5. The following requirements shall apply (in addition to those of paragraphs 1 to 4) when milk-based drink is heat treated by direct application of steam:—

(a) the apparatus used for treatment of milk-based drink by direct steam injection shall be so constructed as to ensure that water is separated from the steam and does not enter the milk-based drink heating equipment, and so that only pure steam and the internal surfaces of the equipment come in contact with the milk-based drink;

(b) the steam shall be dry and saturated and produced in such manner as shall ensure that it is wholesome and free from all impurities and there shall be automatic and continuous control to ensure that any entrained water droplets carried over from the boiler shall be separated from the steam before it enters the milk-based drink heating equipment;

(c) the treatment shall be carried out in such a way as to ensure that no external matter other than steam enters the milk-based drink and that there is no adulteration of the milk-based drink at any time before, during or after the heat treatment process;

(d) the steam shall be produced from water which is wholesome, free from pollution and contain no additives other than the following permitted boiler feed water treatment compounds:—

Potassium Alginate
Sodium Alginate
Potassium Carbonate
Sodium Carbonate
Sodium Hydroxide
Monosodium Dihydrogen Orthophosphate
Disodium Monohydrogen Orthophosphate
Trisodium Orthophosphate
Sodium Tripolyphosphate
Sodium Hexametaphosphate
Tetrasodium Pyrophosphate
Sodium Silicate
Sodium Metasilicate
Sodium Sulphate
Magnesium Sulphate
Neutral or Alkaline Sodium Sulphite
Unmodified Starch
Sodium Aluminate
Polyoxyethylene Glycol (Minimum Molecular Weight 1,000);

(e) the equipment shall be constructed so as to enable samples of the steam to be taken immediately before it is applied to the milk-based drink.

6.—(1) Where milk-based drink is made by mixing the milk from which it is made with its other ingredients after heat treatment of that milk by the ultra high temperature method—

(a) paragraphs 1 to 5 shall apply as if references in those paragraphs to milk-based drink included references to that milk and as if the mixing of that milk with those other ingredients were a process to be carried out under paragraph 4 immediately before the processes described in paragraph 4(a) and (b), and

(b) those other ingredients shall, at the time of being mixed with that milk, be sterile.

(2) Where milk-based drink is made by mixing partly prepared drink (that is to say the milk and part of the remaining ingredients from which the milk-based drink is made) with its other ingredients after heat treatment of that partly prepared drink by the ultra high temperature method, subparagraph (1) of this paragraph shall apply as if references in that subparagraph to milk were references to partly prepared drink.

7. Any sample of the milk-based drink procured in accordance with Schedule 4, Part I, after heat treatment with a view to use of the ultra high temperature method and before delivery to the consumer or to a catering establishment shall satisfy the colony count test prescribed in Schedule 4, Part IV.

SCHEDULE 4 Regulation 7(2) and Schedule 3

PART I—PROVISIONS AS TO SAMPLING

Taking of sample

1. A sample (or a reasonable number of samples) of milk-based drink may be taken at any time before the milk-based drink is delivered to the consumer or to a catering establishment, except that any sample to which it is proposed to apply the coliform test prescribed in Part II of this Schedule may only be taken from premises where heat treatment of the milk-based drink has taken place and not later than the day following that heat treatment.

2.—(1) Where the milk-based drink has been heat treated with a view to sterilisation or use of the ultra high temperature method, a sample shall consist of one sealed container of the milk-based drink.

(2) Where the milk-based drink has been heat treated with a view to pasteurisation, then—

(a) if the milk-based drink is in containers not exceeding one litre capacity, a sample shall consist of one such closed container;

(b) if the milk-based drink is in containers exceeding one litre capacity—

(i) prior to the taking of the sample the milk-based drink shall be thoroughly mixed,

(ii) a sample (consisting of no less than 250 ml) shall be taken from well below the surface of the milk-based drink,

(iii) the instruments used for mixing and sampling shall be sterile,

(iv) the sample shall be transferred as soon as possible after it is taken into a sterile bottle which shall be immediately closed,

(v) the part of the stopper of the sterile bottle which comes into contact with the milk-based drink shall be sterile, and

(vi) where a seal on the container from which the sample has been taken is broken, the person who takes the sample shall reseal the container immediately after the sample is taken and attach to it a label certifying that it has been opened and resealed by him.

Identification of sample

3. For the purpose of identification in the testing laboratory the person taking a sample shall mark the container of the sample with a number or other suitable identification mark at the time of sampling and shall enter in a book or on a paper, which shall accompany the sample, the following particulars:—

(a) the number or identification mark;

(b) the name and address of the milk-based drink processor, or the person on whose premises the sample was taken; and

(c) the date and time of sampling.

Transport and holding of sample

4. In the case of milk-based drink heat treated with a view to pasteurisation:—

(a) unless the sample is to be delivered to the testing laboratory within two hours of sampling, the bottle or container containing any sample of milk-based drink shall be placed in an insulated container containing an adequate quantity of suitable refrigerant for transport to the testing laboratory;

(b) the sample shall be transported in its intact closed bottle or other container to the testing laboratory with the least possible delay and any sample which does not reach the testing laboratory on the day on which it is taken shall be discarded;

(c) on arrival at the laboratory the sample shall be removed from the carrying container and if the tests are not then immediately begun, the sample shall be maintained at a temperature of not more than 5°C (without freezing) pending testing;

(d) testing shall commence not later than the morning after the day of arrival of the sample at the testing laboratory.

5. In the case of milk-based drink heat treated with a view to sterilisation or use of the ultra high temperature method, the sample shall be delivered intact to the testing laboratory.

PART II—THE COLIFORM TEST FOR PASTEURISED MILK-BASED DRINK

Apparatus and sterility requirement

1.—(1) The apparatus shall consist of:—

(a) culture medium tubes complying with British Standard 3218:1982 or 625:1959, nominal size 150/16, and closed with closely-fitting metal caps (each culture medium tube containing an inverted Durham tube conforming to British Standard 3218:1982 or 625:1959, 35/8);

(b) dilution tubes which shall be stoppered by means of rubber stoppers to fit or tight fitting covers; and

(c) pipettes which shall be 1.0 ml straight-sided blow-out delivery pipettes.

(2) The medium, diluent and all glass-ware, stoppers, covers and caps shall be sterile.

Diluent

2. The diluent shall be one-quarter strength Ringers solution made according to the following formula:—

Sodium chloride	9.0g
Potassium chloride	0.42g
Calcium chloride	0.24g
Sodium bicarbonate	0.2g
Distilled or de-ionised water	4,000 ml.

Culture Medium

3.—(1)*(a)* The culture medium shall be Single Strength Brilliant Green Lactose Bile broth (BGLBB) prepared according to the following formula:—

Peptone	10g
Lactose	10g
Bile Salts	20g
Brilliant Green	0.0133g
Distilled or de-ionised water	1,000 ml.

(b) (i) Because of difficulties in standardising the bile salts and brilliant green a complete dehydrated medium should be purchased.

(ii) The solid components should be added to 1 litre of distilled or de-ionised water in accordance with the manufacturer's instructions.

(iii) The pH should be adjusted if necessary so that after sterilisation it is approximately 7.4.

(iv) The broth should be mixed well, distributed in 5 ml amounts into the culture tubes fitted with Durham tubes and sterilised at 121°C for 15 minutes.

(2) The medium shall have a final pH of 7.4 approximately.

(3) Other media may be used provided that they give similar results.

Method

4. Each dilution tube or flask shall contain sterile diluent of a volume not less than 8.9 ml and not more than 9.1 ml.

5.—(1) A 1-in-10 dilution of the milk-based drink sample shall be prepared by thoroughly mixing the milk-based drink sample, then introducing a 1 ml pipette and withdrawing 1 ml of the milk-based drink which shall be transferred into the dilution tube.

(2) After addition of the milk-based drink the contents of the dilution tube shall be thoroughly mixed.

6.—(1) After mixing a fresh pipette shall be introduced into the 1-in-10 dilution and a 1 ml portion transferred to each of 3 culture tubes containing 5 ml of the culture medium.

(2) The culture tubes shall be incubated at 30°C ± 1°C for 48 ± 2 hours and examined for gas production.

(3) Since the presence of sugars may affect the result of the test, tubes showing gas production shall be sub-cultured into fresh tubes of BGLBB, re-incubated and examined again for gas production.

Interpretation

7. The sample shall be regarded as satisfactory if (after sub-culture and re-incubation if required) 2 out of 3 tubes are found to be free from gas.

PART III—THE PHOSPHATASE TEST FOR PASTEURISED MILK-BASED DRINK

Precautions

1. The following precautions shall be taken:—

(a) a sample which shows evidence of taint or souring shall not be tested;

(b) all glassware shall be clean immediately before use;

(c) a fresh pipette shall be used for each sample of milk-based drink;

(d) pipettes shall not be contaminated with saliva;

(e) the test shall not be carried out in direct sunlight; and

(f) distilled or de-ionised water shall be used throughout.

Apparatus

2. The apparatus to be used shall be:—

(a) a Lovibond "all purposes" comparator complete with stand for work in reflected light;

(b) a Lovibond comparator disc A.P.T.W. or A.P.T.W.7;

(c) two fused glass cells, 25mm depth;

(d) a water bath or incubator maintained at 37°C ± 0.5°C;

(e) a pipette suitable to deliver 5.0 ml;

(f) a supply of 1.0 ml straight-sided pipettes of an accuracy equal to that of N.P.L. grade B;

(g) a 1,000 ml graduated flask;

(h) a 100 ml measuring cylinder; and

(i) a supply of test tubes conforming to British Standard 3218:1982 or 625:1959, nominal size 150/16, with rubber stoppers to fit.

Reagents

3. Whenever possible, reagents of analytical quality shall be used.

4. The buffer-substrate solution shall be prepared as follows:—

(a) buffer solution: 3.5g of anhydrous sodium carbonate and 1.5g of sodium bicarbonate shall be dissolved in distilled or de-ionised water, and made up to one litre;

(b) substrate: disodium p-nitrophenyl phosphate (the solid substrate being kept in a refrigerator);

(c) buffer-substrate solution:—

(i) 0.15g of the substrate shall be placed in a 100 ml measuring cylinder, and made up to 100 ml with the buffer solution and mixed;

(ii) the buffer-substrate solution shall be stored in a refrigerator and protected from light;

(iii) the buffer-substrate solution shall give a reading of less than the standard marked 10 on the comparator disc A.P.T.W. or A.P.T.W.7 when viewed in transmitted light through a 25mm cell in the "all purposes" comparator, distilled or de-ionised water being used for comparison;

(iv) the buffer-substrate solution shall not be used for more than one week.

Care of apparatus

5.—(1) New glassware shall be cleaned and free from contamination from substances which may interfere with the test.

(2) After use, each test tube shall be emptied, rinsed in water, well washed in hot water containing soda, rinsed in warm water, rinsed in distilled or de-ionised water and finally air dried.

(3) If after treatment in accordance with subparagraph (2) of this paragraph a test tube does not appear to be clean, the treatment shall be repeated with the addition that after being rinsed in warm water it shall be soaked in 50 per cent commercial hydrochloric acid and then rinsed again in warm water before being rinsed in distilled or de-ionised water and finally dried.

(4) Glassware used for the test shall not be used for any other purpose and shall be kept apart from all other apparatus in the laboratory.

Method

6.—(1) 5 ml of the buffer-substrate solution shall be transferred to a test tube using a pipette and the test tube shall be stoppered and brought to a temperature of 37°C ± 0.5°C.

(2) 1 ml of the milk-based drink to be tested shall be added, the test tube stopper replaced and the contents well mixed by shaking.

(3) The test tube shall then be incubated for 120 minutes at 37°C ± 0.5°C.

(4) One blank prepared from boiled milk-based drink of the same type as the sample or series of samples undergoing the test shall be incubated with each sample or series of samples.

(5) After incubation the test tube shall be removed from the water bath and its contents shall be well mixed.

(6) The blank shall be placed on the left hand ramp of the stand and the test sample on the right.

(7) Readings shall be taken in reflected light by looking down onto the two apertures with the comparator facing a good source of daylight (preferably north light).

(8) If artificial light is needed for matching, a "daylight" type of illumination must be used.

(9) The disc shall be revolved until the test sample is matched.

(10) Readings falling between two standards shall be recorded by affixing a plus or minus sign to the figure for the nearest standard.

Interpretation

7. The test shall be deemed to be satisfied by milk-based drink which gives a reading of 10μg or less of p-nitrophenol/ml of milk-based drink.

PART IV—THE COLONY COUNT TEST FOR STERILISED MILK-BASED DRINK AND MILK-BASED DRINK HEAT TREATED BY THE ULTRA HIGH TEMPERATURE METHOD

Apparatus and sterility requirement

1.—(1) The following apparatus shall be used:—

(a) McCartney bottles of 28 ml capacity;

(b) test tubes plugged with cotton wool or covered with closely fitting aluminium caps or stored in such a way as to prevent contamination;

(c) a standardised loop to transfer about 0.01 ml of milk-based drink to the molten medium in a tube or a McCartney bottle;

(d) an incubator operating at 37°C and maintained within ± 1°C;

(e) a water bath capable of maintaining the water at a temperature of not less than 45°C and not more than 50°C; and

(f) a refrigerator fitted with a reliable automatic thermo-regulator capable of maintaining a temperature of between 3°C and 5°C.

(2) The medium and all glass-ware, stoppers, covers and caps shall be sterile.

Culture medium

2. The culture medium to be used shall be prepared as follows:—

(a) yeastrel milk agar shall be made from the constituents listed below:—

Yeastrel	3g
Peptone	5g
Agar	15g

(If New Zealand agar is used 12g is normally sufficient)

Skimmed milk powder (antibiotic free)	1g
Distilled or de-ionised water	1,000 ml;

(b) (i) the yeastrel and peptone shall be dissolved in the distilled or de-ionised water in a steamer and the reaction at room temperature adjusted to pH 7.4 using phenol red as an indicator or using a pH meter;

(ii) when phenol red is used a brightness screen must be employed with Lovibond phenol red disc 2/IJ;

(iii) the agar and the milk shall then be added to the broth and autoclaved at 121°C for 25 minutes;

(iv) if shredded agar is used, it shall be wrapped in muslin and washed in running water for 15 minutes, the excess water being squeezed out before the agar is added to the broth;

(v) to ensure thorough mixing and that heat treatment of the bulk at this stage is equivalent to the final sterilisation of the tubed medium, quantities of not more than 2 litres shall be autoclaved in 3-litre conical flasks;

(vi) the hot medium shall then be filtered through paper pulp in a Buchner funnel;

(c) (i) the pulp shall be prepared by mashing up small pieces of filter paper in water and boiling;

(ii) the funnel shall be inserted into an Erlenmeyer flask fitted with a side piece and a single layer of filter paper laid on the top of the Buchner funnel to prevent the pulp being sucked through;

(iii) the hot pulp shall be poured on to the filter paper and a filter pump applied to suck through the excess water, which shall then be poured away;

(iv) the pulp should be firmly packed down just before the last of the water is sucked through, at which stage a layer of filter paper shall be laid on the filter bed, so that the hot medium can subsequently be poured on to it without disturbing the pulp;

(v) the filter when ready for use should have a total depth of about 1.5mm;

(vi) it should be assumed that a pulp layer of suitable and approximately the same depth for any size of funnel is obtained by pulping an area of filter paper equal to four times the square of the diameter of the funnel, and that with ordinary grade filter paper 1g of the dry paper will be required for every 20 sq cm of filtering area;

(d) (i) the flask and funnel shall be thoroughly hot before filtering commences and these and the medium shall be kept hot during filtering;

(ii) the medium shall be taken direct from the autoclave, poured on to the pulp where the filter paper is laid and the vacuum pump connected;

(e) (i) the reaction of the filtrate shall be tested at 50°C and adjusted if necessary to pH 7.0;

(ii) adjustment at this stage should not normally be necessary and, if it is needed at all frequently, the method of preparation should be checked;

(f) the medium shall be distributed in 5 ml quantities in test tubes conforming to British Standard 3218:1982 or 625:1959, nominal size 150/16, or in 28 ml McCartney bottles and autoclaved at 121°C for 15 minutes;

(g) the final reaction of the medium at room temperature shall be pH 7.2.

Other media available

3.—(1) A prepared or dehydrated medium may be used in place of the medium described in paragraph 2 provided that it has been shown to give similar results to the medium described in paragraph 2.

(2) The medium described below may be used in place of the medium described in paragraph 2:—

(a) the medium should be constituted as follows:—

Yeast extract	2.5g
Tryptone	5.0g
Glucose	1.0g
Skimmed milk powder (antibiotic free)	1.0g
Agar	10–15g (depending upon gel strength)
Distilled or de-ionised water	1,000 ml;

(b) the pH after sterilisation should be 6.9 ± 0.1 at 30°C;

(c) in all cases it is necessary to add skimmed milk powder even if the supplier considers such an addition unnecessary;

(d) the solid components should be added to 1 litre of distilled or de-ionised water in accordance with the manufacturers' instructions;

(e) the pH should be adjusted if necessary so that after sterilisation it is 6.9 ± 0.1;

(f) the medium should be mixed well and distributed in 5 ml amounts in the tubes or McCartney bottles and sterilised at 121°C for 15 minutes.

Incubation of sample

4. On arrival at the laboratory the sample shall be placed unopened in the incubator at a temperature of 37°C ± 1°C and retained at that temperature for 24 hours.

Mixing of sample prior to examination

5. At the end of the 24-hour incubation period, the sample shall be removed from the incubator and shall be mixed thoroughly by inverting the container and shaking it.

Method of carrying out the test

6.—(1) After the sample has been thoroughly mixed as described above, it shall be opened with aseptic precautions.

(2) *(a)* Immediately after opening the sample container, the cap from a sterile McCartney bottle shall be removed and approximately 10 ml of the sample transferred by means of a sterile pipette to the bottle, the cap replaced and the McCartney bottle put in the refrigerator.

(b) A further 10 ml (approximately) of the sample shall be transferred to a sterile test tube after removing the plug.

(c) The plug shall then be replaced.

(3) *(a)* With as little delay as practicable a loopful of milk-based drink from the test tube sample shall be transferred to a sterile test tube or 28 ml McCartney bottle containing about 5 ml of melted medium at 45°C to 50°C.

(b) The loop, after being flame sterilised and cooled, shall be lowered into the milk-based drink about 25 mm from the surface and a loopful of milk-based drink withdrawn and transferred to the molten medium in the tube or McCartney bottle.

(c) The contents of the tube or bottle shall then be carefully mixed, the tube or bottle placed in a sloping position (the medium being at least 12 mm from the closure) and the medium allowed to set.

(d) The tube or bottle shall then be incubated in a sloping position at a temperature of 37°C ± 1°C for 48 hours and at the end of that time it shall be examined for the presence of colonies.

Counting of colonies

7. Colonies shall be counted within 4 hours of the expiry of the incubation period.

Interpretation

8.—(1) The test shall be deemed to be satisfied by a sample if the number of colonies is found to be less than 10.

(2) If there is any doubt about the result, the test should be repeated using the sample in the McCartney bottle placed in the refrigerator.

EXPLANATORY NOTE

(*This Note is not part of the Regulations.*)

These regulations prescribe standards of hygiene for production and handling of milk-based drinks (regulation 6 and Schedule 1). They also require that milk-based drinks sold for human consumption shall have been heat treated by pasteurisation, sterilisation or the ultra high temperature method in accordance with prescribed requirements (regulation 7(1) and Schedules 2 and 3), and specify sampling provisions and tests which such drinks must satisfy (regulation 7(2) and Schedule 4) and the records required to be kept (regulation 9). The regulations extend to England and Wales, (regulation 1(2)) and do not apply to products intended for export (regulation 4); allowance is made for the entry into England and Wales of milk-based drink heat treated in Scotland or heat treated (by sterilisation or the ultra high temperature method) in Northern Ireland (regulation 8).

Milk-based drinks are defined by reference to ingredients (regulation 3) and the words 'milk drink' and 'milk-based drink' are prohibited in the labelling of foods outside the definition (regulation 5).

Offences against these regulations are punishable on summary conviction by a fine not exceeding £1,000 (regulation 10(1)).

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