# STATUTORY INSTRUMENTS

# 1983 No. 1514 (S. 138)

# **FOOD**

# The Milk-based Drinks (Scotland) Regulations 1983

Made - - - - 17th October 1983

Laid before Parliament 26th October 1983

Coming into Operation 16th November 1983

In exercise of the powers conferred on me by sections 4, 7, 13, 26(3) and 56 of the Food and Drugs (Scotland) Act 1956(a), and of all other powers enabling me in that behalf, after consultation in accordance with section 56(6) of that Act with such organisations as appear to me to be representative of interests substantially affected by the regulations, I hereby make the following regulations:—

#### Citation and commencement

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

- 2.—(1) In these regulations, unless the context otherwise requires—
  - "the Act" means the Food and Drugs (Scotland) Act 1956;
  - "the 1914 Act" means the Milk and Dairies (Scotland) Act 1914(b);
  - "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;
  - "local authority" means a district or islands council;
  - "milk" means cows' milk (whether or not separated) but does not include cream, dried milk, condensed milk, evaporated milk or butter milk;
  - "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;

<sup>(</sup>a) 1956 c. 30; section 4 was amended by the European Communities Act 1972 (c. 68), Schedule 4, paragraph 3(1), section 26(3) was amended by the Local Government (Scotland) Act 1973 (c. 65), Schedule 27, Part II, paragraph 123(a) and the Local Government and Planning (Scotland) Act 1982 (c. 43), Schedule 4, Part I, and section 56 was amended by the Weights and Measures Act 1963 (c. 31), Schedule 9, Part II, the European Communities Act 1972, Schedule 4, paragraph 3(2), and the Criminal Justice Act 1982 (c. 48), Schedule 15, paragraph 8.

(b) 1914 c. 46.

- "sell" includes offer or exposure for sale and have in possession for sale, and "sale" and "sold" shall be construed accordingly;
- "ultimate consumer" means any person who buys otherwise than—
  - (a) for the purposes of re-sale;
  - (b) for the purposes of a catering establishment; or
  - (c) for the purposes of a manufacturing business.
- (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.

# Meaning of 'milk-based drink'

- 3. 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 and comprising as to the remainder any of, or any mixture of, the following ingredients:—
  - (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 (Scotland) Regulations 1968(a);
  - (d) any permitted colouring matter as defined in the Colouring Matter in Food (Scotland) Regulations 1973(b);
  - (e) any permitted emulsifier as defined in the Emulsifiers and Stabilisers in Food (Scotland) Regulations 1980(c);
  - (f) any permitted stabiliser as defined in the Emulsifiers and Stabilisers in Food Regulations 1980(**d**);
  - (g) any permitted miscellaneous additive as defined in the Miscellaneous Additives in Food (Scotland) Regulations 1980(e);
  - (h) any permitted sweetener as defined in the Sweeteners in Food (Scotland) Regulations 1983(f);
  - (i) starch (whether modified or not);
  - (j) salt;
  - (k) any vitamin preparation;
  - (1) any mineral preparation;
  - (m) water fit for human consumption and used in combination with any of the other ingredients listed in this regulation.

<sup>(</sup>a) S.I. 1968/263, amended by S.I. 1980/1887, 1983/270.

**<sup>(</sup>b)** S.I. 1973/1310, amended by S.I. 1974/1340, 1975/1595, 1976/2232, 1979/107, 1983/270.

<sup>(</sup>c) S.I. 1980/1888, amended by S.I. 1982/514, 1983/270.

<sup>(</sup>d) S.I. 1980/1833, amended by S.I. 1982/16, 1727, 1983/1211.

<sup>(</sup>e) S.I. 1980/1889, amended by S.I. 1981/137, 1982/515, 1983/270.

<sup>(</sup>f) S.I. 1983/1497.

# Exemption

- 4. These regulations shall not apply to any food which is—
  - (a) not intended for human consumption;
  - (b) intended for export to any place outwith the United Kingdom.

# 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 I

6. Without prejudice to the application of the Food Hygiene (Scotland) Regulations 1959(a), Schedule I shall apply in respect of the preparation, transport, storage, packaging, wrapping, 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 regulations 4 and 8, no person shall sell any milk-based drink in Scotland 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 heat treatment by pasteurisation, or
  - (b) Schedule 3, Part II, in connection with heat treatment by sterilisation, or
  - (c) Schedule 3, Part III, in connection with heat treatment by the ultra high temperature (UHT) 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 tests set out in Schedule 4, Part IV shall apply for the purposes of Schedule 3, Parts II and III.

# Milk-based drink from England, Wales and Northern Ireland

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

- (2) Where milk-based drink is brought into Scotland from Northern Ireland-
  - (a) the requirements of Schedule 2 (except paragraph 1) 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 Scotland, 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 that milk-based drink has been produced in Northern Ireland from milk produced in Northern Ireland.

#### 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—
  - (a) on summary conviction to—
  - a fine not exceeding £1000 or to imprisonment for a term not exceeding six months, or both; or
  - (b) on conviction on indictment to—
  - a fine or to imprisonment for a term not exceeding one year, or both.
  - (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.

Application of various sections of the Act

- 11.—(1) Sections 41(2) and (5) (proceedings), 42(1), (2) and (3) (evidence of certificates of analysis), 44 (power of a court to require analysis by the Government Chemist), 46(2) (conditions under which a warranty may be pleaded as a defence) and 47 (offences in relation to warranties and certificates of analysis) of the Act(a) shall apply for the purposes of these regulations as if references therein to proceedings, or a prosecution, under or taken under the Act included references to proceedings, or a prosecution as the case may be, taken for an offence against these regulations and in addition as if—
  - (a) in the case of section 44(1) of the Act, the reference therein to section 41(5) of the Act included a reference to said section 41(5) as applied by these regulations; and
  - (b) in the case of section 47(1) and (2) of the Act, the references therein to an offence against the Act included references to an offence against these regulations.
- (2) Section 41(4) of the Act shall apply for the purposes of these regulations as if the reference therein to section 47 of the Act included a reference to said section 47 as applied by these regulations.

New St. Andrew's House, Edinburgh. 17th October 1983. George Younger,
One of Her Majesty's Principal
Secretaries of State.

# SCHEDULE 1

Regulation 6

- 1.—(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, and
  - (b) every vessel (including the lid) used by him for containing milk-based drinks shall be cleansed to a state of thorough cleanliness.
- (2) For the purpose of cleansing any vessel or appliance as indicated in sub-paragraph (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 water at not less than 82°C or otherwise effectively cleansed with steam or a chemical agent approved by the Secretary of State;
  - (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.
- 2.—(1) Subject to sub-paragraph (2) of this paragraph, no person shall open any container containing a milk-based drink, or tamper with or break the seal of any such container, before delivery of that container to the ultimate consumer or catering establishment, as appropriate.

- (2) Sub-paragraph (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.

3. Every person who sells, conveys or distributes milk-based drinks shall, at all times before delivery to the ultimate consumer, take all practicable measures to protect milk-based drinks from exposure to heat or sunlight and from contamination by dirt, dust, rain or otherwise, and in particular retail containers of milk-based drinks shall not be left, except on delivery to the ultimate consumer, anywhere other than on premises registered under section 7 of the 1914 Act(a).

Regulation 8(1)

#### SCHEDULE 2

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

- 1. Only milk which has been produced in Great Britain and which has not been previously subjected to a process of heat treatment or treated in any other manner likely to affect its nature and qualities shall be used in connection with the heat treatment of milk-based drinks.
- 2. Heat treatment shall be carried out only at premises registered under section 7 of the 1914 Act.
- 3. The milk and any of the ingredients referred to in regulation 3 shall be mixed to make a milk-based drink before, but not more than four hours before, commencement of the heat treatment of that milk-based drink.
- 4. Before the commencement of heat treatment no milk-based drink shall be kept for more than one hour at any temperature which exceeds 7°C; and for this purpose 'heat treatment' includes any preliminary heating of the milk-based drink necessary for any of the heat treatment processes specified in Schedule 3.
- 5. Each milk-based drink processor shall take such measures as are adequate to ensure that until any milk-based drink is put into the containers in which it is to be supplied to the ultimate consumer or to a catering establishment, it shall 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 drink

#### PART I

#### **PASTEURISATION**

- 1.—(1) 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 30 minutes; or
  - (b) to a temperature of not less than 72°C and retained at that temperature for not less than 15 seconds.
- (2) Milk-based drink shall be cooled as soon as practicable after pasteurisation to a temperature of not more than 7°C and shall be maintained at or below that temperature until put into containers in which it is to be supplied to the ultimate consumer or to a catering establishment.
- 2. The whole of any apparatus in which milk-based drink is pasteurised, cooled or packaged shall be so constructed as to protect the milk-based drink from risk of contamination by dust or otherwise.
- 3. Apparatus in which milk-based drink is pasteurised in accordance with paragraph 1(1)(b) above shall be provided with a device which shall automatically prevent the onward flow of any milk-based drink which has not been heated to the temperature and retained for the period required by paragraph 1(1) above.
- 4.—(1) Indicating and recording thermometers shall be installed in suitable places in the pasteurising apparatus in order to indicate and record the temperature to which the milk-based drink has been treated and retained and to which it has been cooled.
- (2) The records of recording thermometers shall give clear readings and shall be dated and preserved for a period of not less than 3 months.
- 5. The following measures shall be taken as soon as practicable after pasteurisation at the premises where pasteurisation has taken place:—
  - (a) the milk-based drink shall be put into containers in which it is to be supplied to the ultimate consumer or to a catering establishment; and
  - (b) those containers shall be securely closed.
- 6. Any sample of milk-based drink taken in accordance with Schedule 4, Part I, shall on being tested in accordance with the provisions of Schedule 4, Parts II and III—
  - (a) on submission to a phosphatase test give a reading not exceeding  $10\,\mu g$  of p-nitrophenol/ml of milk-based drink, and
  - (b) be found to contain no coliform bacteria in one hundredth of a millilitre:

Provided that where the colour of the sample is such as to interfere with the phosphatase test prescribed in Schedule 4, Part III, the coliform test prescribed in Schedule 4, Part II shall apply.

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#### PART II

# **STERILISATION**

- 1. Milk-based drink shall be heated in a hermetically sealed container in which it is to be supplied to the ultimate 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 period as has equivalent effect to subparagraph (a) above 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.—(1) There shall be installed in suitable places in the apparatus thermometers or temperature calibrated pressure gauges to ascertain that the process has been correctly carried out.
- (2) The records of recording thermometers shall give clear readings and shall be dated and preserved for a period of not less than 12 months.
- 3. Any sample of sterilised milk-based drink taken in accordance with Schedule 4, Part I, shall on being tested in accordance with the provisions of Schedule 4, Part IV, be found to contain not more than 1,000 bacteria per millilitre.

#### PART III

# ULTRA HIGH TEMPERATURE METHOD

- A. Requirements applicable in all cases
- 1. 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 not less than 2 seconds, or
  - (b) to such other temperature for such period as has equivalent effect to sub-paragraph (a) above in relation to the rendering of the milk-based drink free from viable micro-organisms and their spores.
- 2. Apparatus in which milk-based drink is heated by the ultra high temperature method shall be provided with a device which shall automatically prevent the onward flow of any milk-based drink which has not been heated to the temperature and retained for the appropriate time required by paragraph 1 above.
- 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 indicate and record the temperature to which the milk-based drink has been heated and retained.
- (2) The records of the recording thermometers shall give clear readings and shall be dated and preserved for a period of not less than 12 months.
- 4.—(1) Milk-based drink which is treated by the ultra high temperature method shall, as soon as practicable after such treatment, be put into sterile containers in which it is to be supplied to the ultimate consumer or to a catering establishment.

- (2) Such containers shall be filled and securely sealed at the premises at which the heat treatment is carried out, and in respect of that filling and sealing such aseptic precautions as are necessary to ensure the protection of the milk-based drink from risk of contamination shall be taken.
- 5. Any sample of milk-based drink heat treated by the ultra high temperature method taken in accordance with Schedule 4, Part I, shall on being tested in accordance with the provisions of Schedule 4, Part IV, be found to contain not more than 1,000 bacteria per millilitre.
- B. Additional requirements applicable when the heat treatment of the milk-based drink is by direct application of steam
- 1. Apparatus in which milk-based drink is heated 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.
- 2. 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.
- 3.—(1) The treatment shall be carried out in such a way as to ensure that no foreign 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.
- (2) The steam shall be produced from water which is wholesome, free from pollution and contains no additives other than the permitted boiler feed water treatment compounds specified in Schedule 5.
- (3) 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.

SCHEDULE 4 Regulation 7(2) and Schedule 3

# PART I

# PROVISIONS AS TO SAMPLING

Taking of sample

- 1. Milk-based drink may be sampled at any time after heat treatment and before the milk-based drink is delivered to the ultimate consumer.
- 2.—(1) Where the milk-based drink is in containers not exceeding 1 litre capacity, sampling shall be carried out by taking one unopened container of the milk-based drink.
- (2) Where the milk-based drink is in containers exceeding 1 litre capacity, sampling shall be carried out as follows:—
  - (a) prior to the taking of the sample the milk-based drink shall be thoroughly mixed;
  - (b) a sample (consisting of no less than 250 ml) shall be taken from well below the surface of the milk-based drink;
  - (c) instruments used for mixing and sampling shall be sterile;

- (d) the sample shall be transferred as soon as possible after it is taken into a sterile bottle which shall be immediately closed;
- (e) the part of the stopper of the sterile bottle which comes into contact with the milk-based drink shall be sterile; and
- (f) 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:

Provided that where milk-based drink is sampled in accordance with this sub-paragraph from each container of a consignment, the volume of the sample taken from each such container shall be proportionate to the volume of milk-based drink in that container and the samples so taken shall then be mixed so as to constitute a sample of the consignment.

# 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 sampled in accordance with paragraph 2(1) above, the sample shall be delivered intact to the testing laboratory.
  - 5. In the case of milk-based drink sampled in accordance with paragraph 2(2) above—
- (a) The bottle or container of the sample of milk-based drink shall be placed in an insulated container and shall be transported therein to the testing laboratory with the least possible delay:

Provided that where there is delay in despatch to the laboratory such additional measures as are practicable shall be taken to prevent the temperature of the sample from rising,

- (b) 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, and
- (c) testing shall commence not later than the morning after the day of arrival of the sample at the testing laboratory.

# PART II

# THE COLIFORM TEST FOR PASTEURISED MILK-BASED DRINK

# Treatment of sample before testing

1. All samples of milk-based drink shall be examined as soon as possible after arrival at the testing laboratory. If a sample is not examined immediately on arrival at the testing laboratory, it shall be kept at a temperature not higher than 5°C until examined, provided that no sample shall be so kept for a period exceeding 24 hours.

# **Apparatus**

- 2. The apparatus shall consist of-
  - (a) culture medium tubes which comply with B.S. 3218:1982 or B.S. 625:1959, 150/16 (each culture medium tube containing an inverted Durham tube conforming to B.S. 3218:1982 or 625:1959, 35/8);
  - (b) dilution tubes or flasks 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.

# Culture medium

3. The medium to be used shall be bile salt lactose broth, either compounded in the laboratory or prepared in accordance with the manufacturer's directions from a granular desiccated medium and shall have the following composition:—

| Peptone                   | 20.0 grams |
|---------------------------|------------|
| Bile salts                | 5.0 grams  |
| Sodium chloride (A.R.)    | 5.0 grams  |
| Lactose (A.R.)            | 10.0 grams |
| Distilled water           | to 1 litre |
| Brom-cresol purple (1.6%) | 2.5 ml     |

The medium shall be tubed in 5 ml quantities in  $150 \times 16$  mm tubes provided with a rimless Durham tube ( $50 \times 6.5$  mm) and sterilised either by autoclaving at  $121^{\circ}$ C for 15 minutes or in a steamer for 30 minutes on three successive days.

The final reaction of the medium at room temperature shall be pH 7.2.

#### Dilutions

4. Quarter-strength Ringer's solution shall be used. The composition of full-strength Ringer's solution shall be—

| Sodium chloride            | 9.00 grams |
|----------------------------|------------|
| Potassium chloride         | 0.42 grams |
| Anhydrous calcium chloride | 0.24 grams |
| Sodium bicarbonate         | 0.20 grams |
| Distilled water            | 1,000 ml   |

Add 1 part of the above solution to 3 parts of distilled water. Fill into test tubes or bottles and sterilise by autoclaving at 121°C for 15 minutes. The quantity to be filled into the container before sterilisation must be predetermined to allow for evaporation losses during sterilisation.

Alternatively, sterile tubes and bottles may be filled aseptically with measured quantities of sterile quarter-strength Ringer's solution.

# Temperature and time of incubation of the cultures

5. The coliform cultures shall be incubated at  $30^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$  for 72 hours.

# Technique of tests

6. In testing milk-based drink 1 ml of 1 in 100 dilution shall be used. For each sample being tested three tubes shall be prepared.

# Examination of cultures

7. The culture tubes shall be examined for the production of acid and gas after the required period of incubation. Those tubes showing acid with gas production in the Durham tube shall be considered to be positive.

# Interpretation of the coliform test

8. If acid and gas production are absent from two of the three tubes the portion of the sample which has been tested shall be presumed to contain no coliform bacteria.

# General precautions

- 9.—(1) The sterility of the media and apparatus shall be tested by carrying out a blank test using sterile water in place of milk-based drink when each batch of sample is examined.
  - (2) Before the dilutions are prepared, the milk-based drink shall be thoroughly mixed.
  - (3) Each dilution shall be thoroughly mixed without vigorous shaking.
- (4) In the preparation of the dilutions a separate sterile pipette shall be used for each dilution and for transferring the dilution to the bile salt broth.
- (5) Not more than 15 minutes shall elapse between the dilution of the milk-based drink and its admixture with the bile salt broth.
- (6) The temperature of the incubator shall be frequently checked by means of a thermometer conforming to the British Standards Institution's specification and adjusted if necessary.
- (7) Bile salt broth tubes showing any air in the Durham tube shall not be used to carry out the test.
- (8) Distilled water: water prepared with a glass still or water of equal quality shall be used.

#### PART II

# Provisions as to the Testing of Samples of Pasteurised Milk-based Drink by Means of the Phosphatase Test

# Treatment of sample before testing

1. The sample of milk-based drink shall be examined as soon as possible after arrival at the testing laboratory. If it is not examined immediately on arrival at the testing laboratory, it shall be kept at a temperature not higher than 5°C until examined. The sample shall be raised to room temperature immediately before being tested.

# 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, 25 mm depth;
  - (d) a water bath or incubator maintained at  $37^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$ ;
  - (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 B.S. 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: 3.5 g of anhydrous sodium carbonate and 1.5 g of sodium bicarbonate shall be dissolved in distilled 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) 0.15 g 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-substance 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 25 mm cell in the "all purposes" comparator, distilled 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 water and finally air dried.
- (3) If after treatment in accordance with sub-paragraph (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 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  $37^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$ .
- (2) I 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  $37^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$ .
- (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.

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- (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 10 µg or less of p-nitrophenol/ml of milk-based drink.

# General precautions

- 8.—(1) A sample which shows evidence of taint or souring shall not be tested.
- (2) The test shall not be carried out in direct sunlight.
- (3) All glassware shall be clean immediately before use.
- (4) A fresh pipette shall be used for each sample.
- (5) Distilled water: water prepared with a glass still or water of equal quality shall be used.

#### PART IV

# THE COLONY COUNT TEST FOR STERILISED MILK-BASED DRINK AND MILK-BASED DRINK TREATED BY THE ULTRA HIGH TEMPERATURE METHOD

# Treatment of sample before testing

1. On arrival at the laboratory the sample shall be placed unopened in an incubator at a temperature of  $30^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$  and be retained at that temperature for 24 hours.

# Culture medium

2. The medium to be used shall be yeastrel milk agar either compounded in the laboratory or prepared in accordance with the manufacturer's directions from a granular desiccated medium and shall have the following composition:—

| Yeastrel  | 3.0 grams  |
|---|------------|
| Peptone   | 5.0 grams  |
| Agar  | 15.0 grams |
| Milk (fresh or spray dried, skim or whole milk) | 10·0 ml    |
| Distilled water                                 | to 1 litre |

Where the medium is compounded in the laboratory it shall be filtered through a pulp-paper filter.

The medium shall be sterilised either by autoclaving at  $121^{\circ}$ C for 20 minutes or in a steamer for 30 minutes on three successive days. The final reaction of the medium at room temperature shall be pH 7·2.

#### Dilutions

3. Quarter-strength Ringer's solution shall be used. The composition of full-strength Ringer's solution shall be—

Sodium chloride 9.00 grams
Potassium chloride 0.42 grams
Anhydrous calcium chloride 0.24 grams
Sodium bicarbonate 0.20 grams
Distilled water 1.000 ml

Add 1 part of the above solution to 3 parts of distilled water. Fill into test tubes or bottles and sterilise by autoclaving at 121°C for 15 minutes. The quantity to be filled into the container before sterilisation must be predetermined to allow for evaporation losses during sterilisation.

Alternatively, sterile tubes and bottles may be filled aseptically with measured quantities of sterile quarter-strength Ringer's solution.

#### Technique of tests.

- 4.—(1) At the end of the 24 hours' incubation period the sample shall be removed from the incubator, mixed thoroughly and the container opened with aseptic precautions. Immediately after opening the sample container approximately 10 ml of the sample shall be transferred by means of a sterile pipette into a sterile McCartney bottle or other suitable container which shall then be closed and placed in a refrigerator capable of maintaining a temperature between 3°C and 5°C.
- (2) From the remainder of the sample 1 ml of 1 in 10 dilution shall be plated. For each sample being tested not less than two plates shall be prepared.
  - (3) The Petri plate cultures prepared shall be incubated at  $30^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$  for 48 hours.

# Examination of cultures

5. All colonies (including "pin-point" colonies) on each plate shall be counted and the arithmetic mean count obtained. To facilitate counting it is desirable to use a counting chamber, a suitable lens and a tally counter. The result of the count shall be recorded as the number of bacteria per millilitre. If there is any doubt about the result, the test should be repeated using the sample in the McCartney bottle placed in the refrigerator.

# Interpretation

6. The test shall be deemed to be satisfied by milk-based drink if it is found to contain not more than 1,000 bacteria per millilitre.

# General precautions

- 7.—(1) The sterility of the media and apparatus shall be tested by carrying out a blank test using sterile water in place of milk-based drink when each batch of samples is examined.
  - (2) Before the dilutions are prepared, the milk-based drink shall be thoroughly mixed.
  - (3) Each dilution shall be thoroughly mixed without vigorous shaking.
- (4) In the preparation of the dilutions a separate sterile pipette shall be used for each dilution and for transferring the dilution to the Petri plate.
  - (5) The pipettes shall be straight-sided.
- (6) Not more than 15 minutes shall elapse between the dilution of the milk-based drink and its admixture with the agar medium.
  - (7) The melted agar shall be cooled to 45°C before it is poured into the Petri plates.

- (8) If Petri plates are stacked in the incubator, so far as possible no stack shall consist of more than six Petri plates.
- (9) The temperature of the incubator shall be frequently checked by means of a thermometer conforming to the British Standards Institution's specification and adjusted if necessary.
- (10) Distilled water: water prepared with a glass still or water of equal quality shall be used.

# SCHEDULE 5

# 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

# **EXPLANATORY NOTE**

Polyoxyethylene glycol (minimum molecular weight 1,000).

(This Note is not part of the Regulations.)

These regulations prescribe certain standards of hygiene for production and handling of milk-based drinks in Scotland (regulation 6 and Schedule 1) not already covered by the Milk and Dairies (Scotland) Act 1914. 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 milk-based drinks must satisfy (regulation 7(2) and Schedule 4) and the records required to be kept (regulation 9).

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).

SI 1983/1514 ISBN 0-11-037514-9

