FOOD, DRUGS AND DISINFECTANTS ACT, No. 13 of 1929
REGULATIONS

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Government Notice No. R. 2130 of29/12/1967
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Government Notice No. R. 3228 of5/9/1969
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Government Notice No. R. 1265 of23/7/1971
Government Notice No. R. 1484 of25/8/1972
Government Notice No. R. 1655 of14/9/1973
Government Notice No. R. 1881 of12/10/1973
Government Notice No. R. 2064 of2/11/1973
Government Notice No. R. 2162 of16/11/1973
Government Notice No. R. 70 of18/1/1974
Government Notice No. R. 230 of18/2/1977
Government Notice No. R. 908 of1977
Government Notice No. R. 956 of1977
Government Notice No. R. 1724 of1977
Government Notice No. R. 756 of20/5/1978
Government Notice No. R. 2307 of30/10/1981
Government Notice No. R. 2254 of14/10/1983
Government Notice No. R. 92 of17/1/1986
Government Notice No. R. 2627 of12/12/1986
Government Notice No. R. 2398 of25/11/1988
Government Notice No. R. 2486 of26/10/1990
Government Notice No. R. 1468 of13/8/1993
Government Notice No. R. 1518 of9/9/1994
Government Notice No. R. 996 of7/7/1995
Government Notice No. R. 1316 of16/8/1996
Government Notice No. R. 692 of16/5/1997

APPLICATION OF CERTAIN PROVISIONS TO SOAP, TOBACCO AND CERTAIN OTHER ARTICLES

The Minister of Public Health, in the exercise of the powers vested in him by section thirty-six of the Food, Drugs and Disinfectants Act, No. 13 of 1929, has been pleased to apply, as from 1st April 1930, to any ointment, cream, powder or similar substance for application to or use for the human skin or hair, soap, tobacco, cigars, cigarettes, snuff, chewing gum and surgical dressings, the provisions contained in the following sections of the said Act, namely: Sections two to seven inclusive; nine to twelve inclusive; twenty

to thirty-five inclusive; and thirty-seven to forty-four inclusive.

REGULATIONS UNDER THE FOOD, DRUGS AND DISINFECTANTS ACT, No. 13 of 1929

The Minister of Public Health, in the exercise of the powers vested in him by sections thirteen, thirty-six and forty-two of the Food, Drugs and Disinfectants Act, No. 13 of 1929, and after due compliance with the procedure mentioned in sections thirty-six and forty-two (see Government Notices Nos. 1223 and 1224 of 5th July 1929, and Nos. 2260 and 2261 of 27th December 1929, and No. 574 of 28th March 1930), has been pleased to make the following regulations to be in force throughout the Union, with effect from 1st April 1930.

REGULATIONS REGARDING FOOD, DRUGS AND DISINFECTANTS

(Framed under sections thirteen, fourteen, nineteen, thirty-three and forty-two of Act No. 13 of 1929).

General

1... . [Reg. 1 repealed by G.N.R. 2398 dd. 25.11.1988.]

Labelling

2... . [Reg. 2 repealed by G.N.R. 908 of 1977, w.e.f. 27.5.1978.]

Prohibition of Unwholesome or Poisonous Substances in Food

3. (1) No package, wrapper, container, or appliance used in connection with food shall be of such composition or nature as to yield, or be liable to yield, to its food contents, or to food with which it comes in contact, any unwholesome, injurious or poisonous substance.

(2) . . . [Subr. (2) amended by G.N.R. 838 dd. 7.6.1957 and G.N.R. 3228 dd. 5.9.1969 and deleted by G.N.R. 1518 dd. 9.9.1994.]

Prohibition of Articles, Devices or Appliances used for Purposes of Adulteration

4... . [Reg. 4 repealed by G.N.R. 2398 dd. 25.11.1988.]

Preservatives in Food

5... . [Reg. 5 repealed by G.N.R. 956 of 1977, w.e.f. 3.12.1977.]

Colouring, Flavouring, Thickening and Artificial Sweetening Substances in Food

6.(1) . . . [Subr. (1) repealed by G.N.R. 2398 dd. 25.11.1988.]

(2) . . . [Subr. (2) substituted by G.N.R. 367 dd. 16.2.1951 and amended by G.N.Rs. 1565 dd. 29.6.1951, 1931 dd. 30.9.1951, 43 dd. 15.1.1960, 525 dd. 5.4.1962, 526 dd. 5.4.1961 and 1296 dd. 17.8.1962 and repealed by G.N.R. 756 dd. 20.5.1978.]

(3). . . [Subr. (3) substituted by G.N.R. 1294 dd. 25.8.1967 and repealed by G.N.R. 908 of 1977, w.e.f. 27.5.1978.]

(4). . . [Subr. (4) repealed by G.N.R. 2398 dd. 25.11.1988.]

(5). . . [Subr. (5) repealed by G.N.R. 908 of 1977, w.e.f. 27.5.1978.]

(6)*(a)* . . . [Subr. (6) *(a)* substituted by G.N.R. 368 dd. 16.2.1951 and repealed by G.N.R. 1881 dd. 12.10.1973.]

(b). . . [Par. *(b)* substituted by G.N.R. 15 dd. 6.1.1956 and repealed by G.N.R. 1881 dd. 12.10.1973.]

Milk and Milk Products

7.. . . [Reg. 7 substituted by G.N.R. 2520 dd. 10.12.1954 and repealed by G.N.R. 1724 of 1977, w.e.f. 2.3.1978.]

Cream

8.. . . [Reg. 8 repealed by G.N.R. 2307 dd. 30.10.1981.]

Butter, Margarine and Ghee

9.. . . [Reg. 9 amended by G.N.R. 1372 dd. 23.8.1940 and repealed by G.N.R. 2307 dd. 30.10.1981.]

Cheese

10.. . . [Reg. 10 substituted by G.N.R. 2399 dd. 26.11.1954 and repealed by G.N.R. 2398 dd. 25.11.1988.]

Ice-Cream and Ice-Cream Products

11. (1) Ice-cream Mix shall be the unfrozen, pasteurized and homogenized product prepared from one or more of the following: Fresh cream, butter, milk, skim-milk, sweetened condensed milk, unsweetened condensed milk, sweetened condensed skim-milk, unsweetened condensed skim-milk, buttermilk powder, milk powder and skim-milk powder. To these may be added glucose, dextrose, sucrose, invert sugar, stabilizer, emulsifier and water.

The finished article shall contain no added preservative, not more than 1 per cent of stabilizer and emulsifier, not less than $33\frac{1}{3}$ per cent by weight of total solids and not less than 10 per cent by weight of milk-fat.

No fat other than milk-fat shall be permitted and the Reichert-Meissl value of the extracted fat shall not be lower than 21.

(2) Ice-cream shall be the frozen or semi-frozen food made from the homogenized mixture prepared from the ingredients mentioned under subsection (1) with the addition of harmless flavouring and permitted colouring matter, with or without the addition of cocoa or chocolate syrup, fruit, nuts or confections and shall contain not less than $33\frac{1}{3}$ per cent by weight of total solids and not less than 10 per cent by weight of milk fat. Every package containing ice cream shall bear a label with the words "ice cream" in type D.

One gallon of ice-cream shall contain not less than 1,7 lb. of total solids, exclusive of any added fruit or nuts, and shall contain no added preservative.

The total number of organisms shall not exceed 50,000 per ml. and E. coli type 1 shall not be present in 0,1 ml. tested at 44°C. The presence of E. coli type 1 shall be confirmed by performing the indole test. No pathogenic organisms shall be present.

No fat other than milk-fat shall be permitted and the Reichert-Meissl value of the extracted fat shall not be lower than 21.

(3) Milk shake shall be prepared with ice-cream and milk or milk powder and harmless flavouring and permitted colouring matter. It may be sweetened with one or more of the following: Glucose, dextrose, sucrose and invert sugar.

(4) Sherbert shall be frozen or semi-frozen food, other than ice-cream, made from a milk product with or without water, wholesome edible fat, sweetening agent, fruit or fruit juice and permitted flavouring and colouring agents. Stabilizers and emulsifiers may be present

in amounts not exceeding 1 per cent by weight of the finished product. Every package containing sherbert shall bear a label with the word "Sherbert" in type D.

The total number of organisms shall not exceed 50,000 per ml. and E. coli type 1 shall not be present in 0,1 ml. tested at 44°C. The presence of E. coli type 1 shall be confirmed by performing the indole test. No pathogenic organisms shall be present.

Cereals

12. . . . [Reg. 12 (1), (2), (3), (4), (7), (8) and (9) deleted by G.N.R. 1655 dd. 14.9.1973 and subregs. (5) and (6) repealed by G.N.R. 2398 dd. 25.11.1988.]

Baking Powder and Other Leavening Substances

13. . . . [Reg. 13 withdrawn by G.N.R. 2486 dd. 26.10.1990 with effect from a date six months from the date of publication thereof.]

Meat and Fish and their Preparations: Edible Fats and Edible Oils

14. (1) *(a)* Meat shall be the clean, sound and wholesome flesh of animals or birds used as food. Meat other than that of bovines, sheep, pigs and goats shall bear a label indicating its nature.

(b) Any preparation or mixture of meat, other than that of bovines, sheep, pigs, goats and poultry shall bear a label stating the kind, composition or origin of the meat and shall correspond to the description or label.

(c) Lean meat shall be meat without any adhering fat.

(2) *(a)* Minced meat shall be the minced skeletal musculature of any animal used for food and shall contain not less than 60 per cent of lean meat with a minimum of 2 per cent of protein nitrogen. It shall not contain any preservative, farinaceous or other foreign substance.

(b) – *(e)* . . . [Pars. *(b)* to *(e)* repealed by G.N.R. 2398 dd. 25.11.1988.]

(3) *(a)* Processed meat, simple or mixed shall be meat which has been subjected to cooking, curing, drying, smoking and any combination of such processes. It may contain common salt, salpetre, sodium or potassium nitrite, sugar, vinegar, spices and/or permitted colouring matter, but no other foreign substances. The minimum total meat content shall be 95 per cent and the amount of nitrite calculated as sodium nitrite, shall not exceed 200 p.p.m. in the finished article. If packed in any container, fat agar-agar and/or gelatin may be used as a packing medium.

(b) . . . [Par. *(b)* added by G.N.R. 1351 dd. 9.8.1968 and repealed by G.N.R. 908 of 1977, w.e.f. 27.5.1978.]

(4) (i) Manufactured meat products shall be meat products which have undergone one or more of the processes enumerated in 14 (3) in addition to mincing and/or grinding, and include polonies, saveloys, meat pastes, brawn, meat loaves or rolls and similar articles containing meat, but exclude food products of the nature of sausage rolls and meat pies.

(ii) Manufactured meat products shall be made from meat as defined in regulation 14 (1) *(a)* with spices and flavouring with or without milk, eggs, agar-agar, gelatin and wholesome farinaceous or other vegetable substances. They may contain added phosphates, not exceeding 0,5 per cent of the final product, added ascorbic

acid, permitted preservatives and colouring matter, salpetre, and potassium or sodium nitrite: provided that the finished article shall not contain more than 200 p.p.m. of nitrite calculated as sodium nitrite. The total meat content shall not be less than 75 per cent. If packed in any container, brine, fat, agar-agar and/or gelatin may be used as a packing medium.

(iii) The standards of composition of canned meat products under this Act shall be the compulsory standard specification for the manufacture, processing or treatment of canned meat products declared by the Minister of Economic Affairs under section fifteen (1) *(a)* and (i) of the Standards Act, No. 24 of 1945. The compulsory standard specifications shall also apply to imported canned meat products.

(iv) Methods of calculation.

In all cases where it is necessary to calculate total meat under regulations 14 (1), (2), (3) and (4), the formula used shall be:—

Percentage Lean Meat = (Percentage Protein Nitrogen × 30).

Percentage Total Meat = (Percentage Lean Meat + Percentage Fat).

(5) *(a)* Meat extract shall be the product obtained by extracting fresh meat with water and concentrating the liquid portion by evaporation after the removal of fat and shall contain not less than 75 per cent of total solids of which not over 27 per cent shall be ash, and not over 12 per cent shall be sodium chloride (calculated from the total chlorine present), not over six-tenths per cent shall be fat and not less than 8 per cent shall be nitrogen.

(b) Meat juice shall be the fluid portion of muscle fibre obtained by pressure or otherwise and may be concentrated by evaporation at a temperature below the coagulation point of the solube proteins. The solids shall contain not more than 15 per cent of ash, not more than 2,5 per cent of sodium chloride (calculated from the total chlorine present), not more than 4 per cent and not less than 2 per cent of phosphoric acid (P^2O^3) and not less than 12 per cent nitrogen.

(c) Peptones shall be products prepared by the digestion of protein material by means of enzymes or otherwise and shall contain not less than 50 per cent of proteoses and peptones.

(6) . . . [Subr. (6) repealed by G.N.R. 2064 dd. 2.11.1973.]

(7) – (11) . . . [Subregs. (7) to 11 deleted by G.N.R. 1316 dd. 16.8.1996.]

(12) . . . [Subr. (12) repealed by G.N.R. 92 dd. 17.1.1986.]

(13) . . . [Subr. (13) repealed by G.N.R. 2254 dd. 14.10.1983.]

[Reg. 14 substituted by G.N.R. 2517 dd. 10.12.1954 and amended by G.N.Rs. 164 dd. 3.2.1956, 1788 dd. 28.9.1956, 1963 dd. 26.10.1956, 85 dd. 17.1.1958, 1795 dd. 11.11.1960, 1009 dd. 5.7.1963, 1191 dd. 13.8.1965 and 159 dd. 4.2.1966.]

14*bis*. . . [Reg. 14*bis* inserted by G.N.R. 952 dd. 2.5.1952 and repealed by G.N.R. 230 dd. 18.2.1977.]

Tea

15. Tea is the leaves and leaf buds of species of *Thea* prepared by fermenting and drying or firing. It shall not contain any exhausted or partly exhausted leaves (that is leaves from which the active constituents have been wholly or partially removed by previous boiling or otherwise) nor any foreign substance.

Coffee, Coffee Mixtures and Preparations of Coffea

16. (1) Coffee is the seed of one or more species of *coffea*.

(2) Ground coffee is coffee roasted and ground or otherwise prepared in a form suitable for making an infusion or decoction. It shall not contain any exhausted or partially exhausted coffee, nor any foreign substance.

(2)*bis*. Decaffeinated coffee shall be coffee from which a large portion of caffeine has been removed. It shall not contain more than 0,1 per cent of caffeine and shall be labelled "decaffeinated coffee" in type G.

(3) Every mixture packed or sold as "Mixed Coffee" or "Coffee Mixture" or under any similar name, no ingredient other than coffee being mentioned in the name of the article, shall consist solely of coffee and chicory, coffee constituting not less than three-quarters of its weight. The name of every such mixture shall be printed on the label in type D.

(4) The label of every mixture containing coffee including "Mixed Coffee" as described in subregulation (3) hereof shall bear a statement in type G, showing the names of the ingredients and the approximate proportion or percentage of each. The names of the ingredients shall be stated in the order of their respective proportions, that present in the largest proportion being stated first. In addition, where the names of the ingredients appear anywhere else on the label or container, they shall be in type of uniform size and prominence and the name of the ingredient which constitutes the highest proportion shall be mentioned first.

(5) Coffee essence or coffee extract shall be prepared only from coffee, with or without sugar (sucrose), or other edible carbohydrates and shall contain not less than 0,5 per cent of caffeine.

(6) Coffee and chicory essence or extract shall be prepared from coffee and chicory with or without sugar or other edible carbohydrates. It shall contain not less than 50 per cent of coffee extract and not less than 0,25 per cent of caffeine, and shall be labelled "Coffee and Chicory Essence" or "Coffee and Chicory Extract" in type D.

(7) Coffee and milk shall be prepared only from milk, sugar and coffee or coffee extract and shall contain not less than 0,12 per cent caffeine.

Chicory

17. Chicory is the dried roasted root of *Cichorium intybus* and shall contain no foreign substance other than a trace of earth or sand unavoidably mixed with it during the process of collection and a trace

of fatty matter used in roasting. It shall yield not more than 7,5 per cent total ash, and the ash remaining undissolved after boiling for five minutes in an aqueous solution of Hydrochloric acid containing 10 per cent of pure HCL, shall not exceed 3 per cent.

Cocoa and Chocolate

18. (1) Cocoa beans are the seeds of *Theobroma cacao*; cocoa nibs or cracked cocoa is the roasted broken cocoa bean freed from its shell or husk, with or without the germ.

(2) Cocoa paste, including cocoa mass, cocoa slab, unsweetened block chocolate, and cocoa liquor, is the solid or semi-solid mass produced by grinding cocoa nibs and containing the whole of the fat naturally present in the nibs. It shall contain in its water and fat-free residue not more than 8 per cent of total ash nor more than 5,5 per cent of ash insoluble in water, nor more than 6½ per cent of crude fibre.

(3) Cocoa or cocoa powder is powdered cocoa paste deprived or not of a portion of its fat. Its water and fat-free residue shall contain nor more than 6½ per cent of crude fibre. Notwithstanding the provisions of subregulation (2) of regulation 3 it shall contain not more than 70 parts per million of copper.

(4) Soluble cocoa, Dutch process cocoa, or cocoa essence, is the product obtained by treating cocoa paste deprived or not of portion of its fat, with alkali or alkaline salts. It shall not contain more than 5 per cent of total water soluble alkali (that is water soluble alkali and alkaline salts naturally present, together with added alkali or alkaline salts) calculated as potassium carbonate. Its water and fat-free and water soluble alkali-free residue shall conform to the standard for cocoa in clause (3) hereof.

(5) Prepared, compounded, homeopathic or sweetened cocoa or soluble cocoa mixed with other wholesome food substances. Every package thereof shall bear a label stating, after the name of the preparation (which shall be in type C) the words "Containing not less than . . . (here insert the number of parts per cent) parts per cent of dry, fat-free cocoa" in type H.

(6) Chocolate paste, confectioner's chocolate, chocolate coatings and chocolate powder are cocoa paste as defined in clause (2) hereof, with or without sugar, eggs, butterfat, spices or harmless flavourings. Every such preparation shall contain not less than 10 per cent of fat-free cocoa, and shall be free from cocoa husks, any weighting substance, paraffin, or foreign fat other than butterfat.

(7) Cocoa and milk, chocolate and milk, or milk chocolate, shall be prepared from milk and cocoa with or without sugar, wholesome food substances and harmless flavouring substances and shall contain not less than 4 per cent of fat-free cocoa.

(8) Chocolate confectionary shall consist solely of wholesome food substances covered or compounded with chocolate paste or milk chocolate as defined in this regulation.

Custard Powder and Pudding Powder

19. . . . [Reg. 19 repealed by G.N.R. 2398 dd. 25.11.1988.]

Curry Powder and Turmeric Compound

20. . . . [Reg. 20 repealed by G.N.R. 1468 dd. 13.8.1993.]

Chilli Powder

20*bis*. . . . [Reg. 20*bis* inserted by G.N.R. 1231 dd. 18.8.1967 and repealed by G.N.R. 1468 dd. 13.8.1993.]

Ginger

21. . . . [Reg. 21 repealed by G.N.R. 1468 dd. 13.8.1993.]

Coconut

21*bis*. . . . [Reg. 21*bis* added by G.N.R. 407 dd. 24.3.1933 and repealed by G.N.R. 692 dd. 16.5.1997.]

Mustard

22. . . . [Reg. 22 repealed by G.N.R. 1468 dd. 13.8.1993.]

Pepper

23. . . . [Reg. 23 repealed by G.N.R. 1468 dd. 13.8.1993.]

Cloves and Other Spices

24. . . . [Reg. 24 repealed by G.N.R. 1468 dd. 13.8.1993.]

Sauces and Chutneys

25. . . . [Reg. 25 repealed by G.N.R. 2398 dd. 25.11.1988.]

Jam, Conserve, Marmalade, Fruit-Jelly, etc.

26. (1) . . . [Subr. (1) withdrawn by G.N.R. 2627 dd. 12.12.1986.]

(2) – (7) . . . [Subregs. (2) to (7) repealed by G.N.R. 2627 dd. 12.12.1986.]

(8) – (11) . . . [Subregs. (8) to (11) renumbered by G.N.R. 16 of 8.1.1971 and repealed by G.N.R. 2398 dd. 25.11.1988.]

Sugar, Confectionary, Dextrose and Icing Sugar

27. (1) Sugar (sucrose) is the product obtained from the juice of the sugar cane and/or the sugar beet.

(a) Refined sugar shall be white, dry, odourless, granulated sucrose, readily soluble in cold water. It shall have no taste other than sweetness. Its sulphated ash content shall not exceed 0,03 per cent and not more than 0,03 per cent of reducing sugars. It shall not contain more than 0,06 per cent of moisture.

(b) Mill-white sugar shall be almost white, dry, odourless, granulated sucrose,

soluble in cold water. Its sweet taste shall be not more than slightly suggestive of that of molasses. Its sulphated ash content shall not exceed 0,01 per cent and not more than 0,03 per cent of reducing sugar shall be present. It shall not contain more than 0,06 per cent of moisture.

(c) Government grade sugar shall be not more than light golden brown in colour, and shall be readily soluble in cold water. The taste shall be sweet and may be suggestive of molasses.

(d) Castor sugar shall be refined sugar of such fineness of grain that not more than 3 per cent will fail to pass through a sieve with 35 meshes to the inch and not more than 5 per cent shall pass through a sieve with 150 meshes to the inch. It may contain tricalcium phosphate in an amount not exceeding 1 per cent or starch in an amount not exceeding 3 per cent.

(e) . . . [Par. *(e)* repealed by G.N. R. 692 dd. 16.5.1997.]

(2) *(a)* Dextrose (anhydrous dextrose) shall be a white crystalline or granular, odourless powder, readily soluble in cold water and with a sweet taste free from foreign flavour. It shall contain not less than 99,9 per cent of anhydrous dextrose and may contain not more than 0,1 per cent of sulphate ash, 0,018 per cent of free acid, calculated as hydrochloric acid, 20 parts per million of copper and 15 parts per million of iron.

(b) Dextrose monohydrate (purified glucose) shall conform to the same specifications laid down for anhydrous dextrose, after correction for its water of crystalization which for the purpose of this regulation is taken as 9,1 per cent.

(c) Liquid glucose is a colourless to light straw coloured, odourless, viscid syrup with a sweet taste free from foreign flavour. It consists of a mixture of dextrose, maltose, dextrin and water. It may contain not more than 0,6 per cent sulphate ash, 0·045 per cent free acid, calculated as hydrochloric acid, 20 parts per million of copper and 20 parts per million of iron.

(d) . . . [Par. *(d)* repealed by G.N.R. 692 dd. 16.5.1997.]

(3) Icing sugar is a powdered sugar prepared from refined sugar. It may contain tricalcium phosphate in an amount not exceeding 1 per cent or starch in an amount not exceeding 3 per cent and permitted colouring matter. The grains shall be of such fineness that not more than 2 per cent shall remain on a sieve with 100 meshes to the inch and not less than 65 per cent shall pass through a sieve with 200 meshes to the inch.

(4) Confectionary is the product made from sugar (sucrose), dextrose and other sweetening substances used for food, with or without permitted colouring matter, harmless flavouring substances, emulsifiers or thickening substances, and with or without other food substances, such as butter, wholesome edible fats, fresh eggs, milk, chocolate, nuts or fruits. It shall not contain any resin or any foreign mineral substances.

Fruit Juices, Diluted Fruit Juices, Sweetened Diluted Fruit Juices, Concentrated Fruit Juices, Fruit Purees and Fruit Nectars

28. . . . [Reg. 28 repealed by G.N.R. 70 dd. 18.1.1974.]

28*bis*. . . . [Reg. 28*bis* repealed by G.N.R. 70 dd. 18.1.1974.]

Perishable Articles

29. . . . [Reg. 29 repealed by G.N.R. 2398 dd. 25.11.1988.]

Preservatives to be used by inspectors

30. . . . [Reg. 30 repealed by G.N.R. 2162 dd. 16.11.1973.]

Drugs

31. . . . [Reg. 31 repealed.]

Dutch Medicines

31*bis*. . . . [Reg. 31*bis* repealed.]

Disinfectants

32. . . . [Reg. 32 repealed by G.N.R. 2398 dd. 25.11.1988.]

Chewing-Gum

33. . . . [Reg. 33 repealed by G.N.R. 2398 dd. 25.11.1988.]

Tobacco, Cigars, Cigarettes and Snuff

34. . . . [Reg. 34 repealed.]

Ointments, Creams and Powders

35. . . . [Reg. 35 repealed by G.N.R. 2398 dd. 25.11.1988.]

Tooth Paste, Tooth Powders and Mouth Washes

35*bis*. *(a)* Tooth powders shall be free from any harmful ingredient and shall not contain any fluoride.

(b) Mouth washes shall be free from any harmful ingredient and shall not contain any added fluoride.

(c) Toothpaste shall be free from any harmful ingredients. It may contain not more than 1 500 parts per million fluoride ion. When fluoridated, toothpaste shall contain not less than 750 parts per million fluoride ion.

(d) . . . [Par. *(d)* repealed by G.N.R. 908 of 1977, w.e.f. 27.5.1978.]

Soap

36. (1) . . . [Subr. (1) repealed by G.N.R. 2398 dd. 25.11.1988.]

(2) . . . [Subr. (2) repealed by G.N. R. 908 of 1977, w.e.f. 27.5.1978.]

(3) – (7) . . . [Subregs. (3) to (7) repealed by G.N.R. 2398 dd. 25.11.1988.]

Duties of Analysts, Pathologists and Inspectors

37. . . . [Reg. 37 repealed by G.N.R. 2162 dd. 16.11.1973.]

Registration of General Warranty

38. (1) Applications for registration of general warranties, and certificates of registration of such warranties, shall be on the form shown in Annexure C.

(2) The fees for registration of general warranties shall be:

	£	s.	d.
(a) For every initial registration, and to cover the period ending 31st March next ensuing.....	5	5	0
(b) For each renewal up to 31st March next ensuing....	1	1	0

Such fees must be paid to the Secretary for Health before the certificate can be issued. Original certificates of registration should accompany all application for renewals.

Vitamins

39. . . . [Reg. 39 substituted by G.N.R. 805 dd. 19.5.1944 and repealed by G.N.R. 2398 dd. 25.11.1988.]

Edible Gelatin

39*bis*.(1) . . . [Subr. (1) repealed by G.N.R. 692 dd. 16.5.1997.]

(2) Edible gelatin shall dissolve completely in hot water to form a colloidal solution which on cooling sets to a jelly, and shall be free from objectionable taste and offensive odour when examined in a 5 per cent aqueous solution at 60°C.

(3) The gelatin shall conform to the following requirements, based on 16 per cent moisture content, except the water content, which is determined on the sample as received—

	Minimum	*Maximum*
Water content.....	-	16 per cent
Ash content.....	-	2.5 per cent
P.H. value.....	4.0	8.4
Sulphur dioxide.....	-	1,000 parts per million
Arsenic (expressed as arsenious oxide).....	-	3.5 parts per million
Lead.....	-	10 parts per million
Copper.....	-	30 parts per million
Zinc.....	-	100 parts per million
Tin.....	-	250 parts per million

(4) . . .

(5) . . .

(6) . . .

[Subregs. (4) - (6) repealed by G.N.R. 692 dd. 16.5.1997.]

(7) The containers shall be clearly labelled "Edible Gelatin".

[Reg. 39*bis* inserted by G.N. R. 941 dd. 8.5.1953 and amended by G.N. R. 837 dd. 7.6.1957.]

Honey

40. . . . [Reg. 40 substituted by G.N.R. 2519 dd. 10.12.1954 and repealed by G.N.R. 2398 dd. 25.11.1988.]

Salt

41. . . . [Reg. 41 repealed by G.N.R. 996 dd. 7.7.1995 w.e.f. 1.12.1995.]

41*bis*. . . . [Reg. 41*bis* inserted by G.N.R. 888 dd. 19.6.1964 and repealed by G.N.R. 439 dd. 19.3.1976.]

Vinegar

41*ter*. . . . [Reg. 41*ter* inserted by G.N.R. 2130 dd. 29.12.1967 and repealed by G.N.R. 2307 dd. 30.10.1981.]

Penalties

42. . . . [Reg. 42 repealed.]

ANNEXURE A

Method of Determining the Carbolic Acid Coefficient of Liquid Germicides

The method of determining the germicidal power of efficacy of liquid germicides for the purposes of the Food, Drugs and Disinfectants Act, No. 13 of 1929, shall be in accordance with the British standard technique for determining the Rideal-Walker coefficient of disinfectants as laid down in pamphlet No. 541, 1934, published by the British Standards Institution, 28 Victoria Street, London, S.W.1, and reprinted hereunder:—

BRITISH STANDARD TECHNIQUE FOR DETERMINING THE RIDEAL-WALKER COEFFICIENT OF DISINFECTANTS

Note:—

(i) In the development of the present technique of the Rideal-Walker test every stage of the procedure has been the subject of the closest analysis, as the result of which inquiry it has become evident that the strictest adherence to every detail is essential if concordance results are to be secured by different workers.

(ii) Cleanliness of working throughout the test is essential to avoid accidental contamination. The test should be conducted in a laboratory free from dust and draughts.

(iii) Organisms that have survived the action of a disinfectant shall in no circumstances be used in the test.

Apparatus

Inoculating Loop

A loop, 4 mm. in internal diameter, is formed at one end of a length of 28 S.W.G. (.0148 in. dia.) wire of platinum, or platinum iridium alloy, which is made 38 mm. long from the loop to the holder, the latter consisting of a thin metal rod or tube.

The loop is bent at such an angle to the length of the wire as will facilitate the removal of the loop vertically from the surface of the liquid while keeping the plane of the loop horizontal.

Incubator

An incubator, set and maintained at a temperature of 37°C. ± 1°C. Care should be taken to ensure that the temperature throughout the incubator is reasonably constant.

Pipettes

Several accurately standardized pipettes, made with a capacity of 5 ml.

Dropping Pipette

A sterile dropping pipette made to deliver 0.2 ml. (in about five drops).

Medication Tubes

Five sterile plugged 5 in. x ¾ in. test tubes. Alternatively, special bottles may be used. Such vessels should be made in fused silica, in two parts, dimensioned as in Fig. 1. The upper part or cover to the bottle should fit loosely as shown.

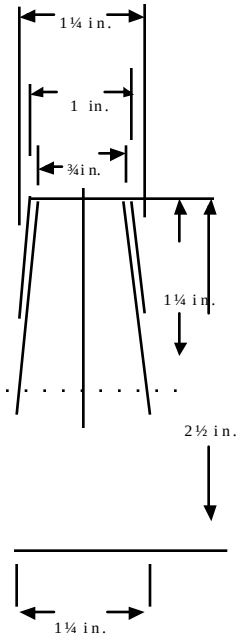

Fig. 1

Slight variations from the dimensions indicated in the figure are permissible so long as the capacity of the bottle (approximately 30 ml.) remains the same and the top fits loosely over it.

Broth Tubes

About two dozen 5 in. x ¾ in. hard glass test tubes.

Measuring Cylinders

One stoppered 1 litre cylinder graduated to 10 ml.

One stoppered 500 ml. cylinder graduated to 10 ml., and having an external diameter of not less than 48 mm. and not greater than 53 mm. and a capacity above the graduated portion of not less than 70 ml. and not greater than 120 ml.

Five stoppered 100 ml. cylinders graduated to 1 ml.

All apparatus must be scrupulously clean and sterile immediately before use.

Reagents

Broth

A standard Rideal-Walker-broth, prepared as follows:—

Twenty grm. of Lab-Lemco, 20 grm. of peptone (Allen and Hanbury's Eupeptone), and 10 grm. of sodium chloride are dissolved in 1,000 ml. of distilled water. The solution is boiled for 30 minutes, cooled, and made up to 1,000 ml. with freshly boiled distilled water. Twenty-five ml. of the broth is then titrated at 37°C with N/10 sodium hydroxide solution, using 0,1 ml. of 0,5 per cent phenolphthalein solution as

indicator.

By calculation from this titration the bulk of the broth is then neutralized at 37°C with normal sodium hydroxide solution. The mixture is brought to the boil or steamed for half-an-hour to bring down phosphates, which are removed by filtration whilst the broth is hot. The broth is then adjusted to a pH value of 7,6 by the addition of normal hydrochloric acid, using a comparator with phenol red. The alkali and the acid should be added slowly and with vigorous shaking.

The broth is then sterilized in bulk, either by autoclaving once for 20 minutes at one atmosphere pressure, or by steaming for 20 minutes on each of three successive days.

It is then filtered through filter paper, and placed in quantities of 5 ml. in the 5 in. x ¾ in. hard glass broth tubes, which have previously been cleaned, plugged and sterilized. The tubes of media are then sterilized either by autoclaving for 10 minutes at one atmosphere pressure, or by steaming for 20 minutes on three successive days. The final reaction of the medium should lie between pH 7,3 and pH 7,5.

When once sterilized, the broth keeps indefinitely in bulk. When in the broth tubes, evaporation is liable to take place through the plugs if the tubes are kept for a long period before use.

Further rsterilization in bulk or in tubes is not permissible.

Organism

The organism used is *Bacillus typhosus*, of which a suitable culture shall be obtained from:—

The Curator,

National Collection of Type Cultures,

Lister Institute,

Chelsea Gardens, London, S.W.1.

The purpose for which the culture is required shall be specified.

The extreme importance of using the standard strain is emphasized.

For the purpose of the test, a little of the growth is placed in a tube of the Rideal-Walker broth and incubated for 24 hours at 37°C. A standard loopful is then transferred to a second tube, which is incubated as before. This is done for at least three successive generations in broth before a test is carried out. Sub-culturing must be limited to fourteen days. It is convenient to start a fresh series from the agar each week.*

It is advisable that a fresh culture be obtained each month and started in this way in broth. If this be impracticable, care must be taken to ensure that the organism satisfies the requirements of the test, as stated below, within the limits of the specified carbolic acid dilutions.

When a test is to be carried out, the plug of the broth culture tube is replaced by the plug of the dropping pipette; the tip of this pipette should be below the surface of the culture, which should be mixed thoroughly and allowed to settle for half-an-hour at 17 – 18°C before use.

Cultures showing signs of clumping must be discarded.

Standard Phenol (Carbolic Acid)

Pure phenol having a crystallizing point of not less than 40,5°C must be used. A 5 per cent stock solution in sterile distilled water (containing 5 grm. of pure phenol in each 100 ml. of solution) is prepared and is used for making the control dilutions, which are to be in the following proportions:—

1 grm. of pure phenol in each 95 ml. of solution made.

1 grm. of pure phenol in each 100 ml. of solution made.

1 grm. of pure phenol in each 105 ml. of solution made.

1 grm. of pure phenol in each 110 ml. of solution made.

1 grm. of pure phenol in each 115 ml. of solution made.

These dilutions shall not be kept for more than a week.

Method

The sample of disinfectant to be tested shall be well mixed immediately before any portion is withdrawn for testing, if necessary transferring it to a dry vessel of sufficient size for the purpose. The test portion shall be withdrawn from the middle of the sample.

* In cases where, on a particular day, sub-culturing would be impossible, a 48-hour culture may be used for subsequent sub-culturing, provided that during the 48-hour period the culture has been kept in the incubator, but in such circumstances a further 24-hour sub-culturing must be carried out before a test is performed.

The test portion of 5 ml. shall be taken as above, by means of a 5 ml. capacity pipette, which is filled to above the mark, wiped clean outside with sterile cotton wool and run down to the mark. The contents shall then be allowed to discharge into the 500 ml. measuring cylinder, previously filled to about the 480 ml. mark with sterile distilled wter at a temperature between 17°C and 18°C, with the nozzle of the pipette below the surface of the water. The pipette shall be rinsed out three times, or more in the case of viscous fluids, by drawing up and returning from the clear portion of the liquid. The whole shall then be made up to 500 ml. with sterile distilled water, the cylinder stoppered, and the contents thoroughly mixed by inverting with a cork-screw motion fifty times.

Suitable test dilutions shall then be immediately prepared from this stock solution, using sterile distilled water (see Appendix A).

In the case of solid substances miscible with water, the stock solution shall be prepared by weight.

Five millilitres of the four dilutions chosen shall be placed in each of four of the plugged sterile 5 in. x ¾ in. medication tubes or bottles, starting with the weakest solution. (When the coefficient is quite unknown, it is necessary to perform one or more ranging tests with broadly separated dilutions). These medication tubes shall then be placed in a rack (provided with a water bath maintained at a constant temperature, which shall lie between 17°C and 18°C.), with the strongest disinfectant on the left. The fifth medication tube, containing 5 ml. of the particular carbolic acid control, shall be placed on the right. A separate pipette must be used for taking the 5 ml. of carbolic acid solution.

Starting at zero time, 0,2 ml. of the cultur shall be added from the special pipette to the left-hand medication tube, which shall then be shaken. Thirty seconds after that addition, the next tube on the right shall be inoculated with 0,2 ml. of culture in a similar manner, and so on with each successive tube, at intervals of 30 seconds, until, finally, the carbolic acid control has been inoculated. Thirty seconds after this last addition (i.e. 2½ minutes from zero), a loopful of the well-shaken contents of the tubes on the extreme left shall be withdrawn and placed in a tube containing 5 ml. of the Rideal-Walker broth, this tube having previously been marked "1". Thirty seconds after this loopful has been withdrawn, a similar operation shall be performed on the second medication tube, the loopful being transferred to a tube of broth marked "2". The procedure shall be repeated at intervals of 30 seconds with each of the five medication tubes, working from left to right, until 4 sets of cultures have been made: i.e. at 2½, 5, 7½ and 10 minutes respectively after exposure. The tubes shall be shaken immediately after medication. In each withdrawal, precautions shall be taken to ensure that the loop is removed vertically from the surface of the liquid with its place horizontal.

The loop shall be sterilized by flaming between each operation, care being taken that the loop is cold before being again used.

These twenty tubes shall then be incubated for not less than 48 hours and not more than 72 hours at 37°C., when the tubes containing *Bacillus typhosus* will be recognized by the opalescence of the broth.

Calculation of Coefficient

The Rideal-Walker coefficient shall be obtained by dividing that dilution of the disinfectant which shows life in 2½ and 5 minutes but no life thereafter, by that dilution of carbolic acid (1:95, 1:100, 1:105, 1:110 of 1:115) which shows life in 2½ and 5 minutes but no life thereafter.

It is convenient to refer to a tube showing life of *Bacillus typhosus* by a + sign and a tube showing no life, or no *Bacillus typhosus* by a – sign.

When no previous tests have been carried out, so that the necessary carbolic acid strength is quite unknown, it is necessary to carry out a separate test with the five carbolic acid dilutions only, in order to obtain the control dilution of carbolic acid which satisfies the above requirements. When a number of tests

have to be carried out at the same time, however, a different carbolic acid dilution may be used for each test, thus avoiding the necessity for a separate carbolic acid test to obtain the control dilution of carbolic acid.

Example

A typical set of results is shown in the following table:—

Sample Disinfectant	Dilution	Time culture was exposed to action of disinfectant in minutes.			
		2½	5	7½	10
A	1:1000	—	—	—	—
A	1:1100	+	—	—	—
A	1:1200	+	+	—	—
A	1:1300	+	+	+	—
Carbolic Acid . . .	1:100	+	+	—	—

Rideal-Walker coefficient = 1200/100 = 12,0.

A table is included in Appendix A showing Rideal-Walker coefficient over the range of dilution of disinfectant from 1:100 to 1:2500.

Note.— The Rideal-Walker test as specified above, is applicable only to water-soluble or water-miscible substances. It may be applied to a water-insoluble or water-immiscible substance, provided that the method of bringing the substance into solution or suspension is specified in detail in the report on the test.

Appendix A

The stock solution of disinfectant contains 5 ml. of disinfectant fluid in 500 ml. of the stock solution.

Five ml. of this stock solution is diluted for the purpose of the test by die addition of water to make a total volume shown in Column 1 of the following table. The proportion of original disinfectant to final dilution is shown in Column 2 of the table.

Column 1	Column 2	Coefficient when growths in disinfectant dilution equal to growths in phenol dilution of one part in—				
		95	100	105	110	115
125	1:2500	26,3	25,0	23,8	22,7	21,7
120	1:2400	25,3	24,0	22,9	21,8	20,9
115	1:2300	24,2	23,0	21,9	20,9	20,0
110	1:2200	23,2	22,0	21,0	20,0	19,1
105	1:2100	22,1	21,0	20,0	19,1	18,3
100	1:2000	21,1	20,0	19,0	18,2	17,4
95	1:1900	20,0	19,0	18,1	17,3	16,5
90	1:1800	18,9	18,0	17,1	16,4	15,7
85	1:1700	17,9	17,0	16,2	15,5	14,8
80	1:1600	16,8	16,0	15,2	14,5	13,9
75	1:1500	15,8	15,0	14,3	13,6	13,0
70	1:1400	14,7	14,0	13,3	12,7	12,2
65	1:1300	13,7	13,0	12,4	11,8	11,3
60	1:1200	12,6	12,0	11,4	10,9	10,4
55	1:1100	11,6	11,0	10,5	10,0	9,6
50	1:1000	10,5	10,0	9,5	9,1	8,7
45	1:900	9,5	9,0	8,6	8,2	7,8
40	1:800	8,4	8,0	7,6	7,3	7,0
35	1:700	7,4	7,0	6,7	6,4	6,1
30	1:600	6,3	6,0	5,7	5,5	5,2
25	1:500	5,3	5,0	4,8	4,5	4,3
20	1:400	4,2	4,0	3,8	3,6	3,5

For weaker germicides 20 ml. of the stock solution is diluted by the addition of water to make a total volume shown in Column 1 of the following table. The proportion of original disinfectant to final dilution is shown in Column 2.

Column 1	Column 2	Coefficient when growths in disinfectant dilution equal to growths in phenol dilution of one part in—				
		95	100	105	110	115
70	1:350	3,7	3,5	3,3	3,2	3,0
60	1:300	32	3,0	2,9	2,7	2,6

Column 1	Column 2	Coefficient when growths in disinfectant dilution equal to growths in phenol dilution of one part in—				
		95	100	105	110	115
50	1:250	2,6	2,5	2,4	2,3	2,2
40	1:200	2,1	2,0	1,9	1,8	1,7
30	1:150	1,6	1,5	1,4	1,4	1,3
20	1:100	1,1	1,0	—	—	—

Note.— These tables are intended to facilitate the calculation of the results and should not be regarded as imposing any limits on the dilutions to be used. They may be extended as desired.

[Annexure A substituted by G.N.R. 739 dd. 29.5.1935.]

ANNEXURE B

[Annexure B amended by G.N.R. 739 dd 29.5.1935 and repealed.]

ANNEXURE C

[Annexure C repealed.]

ANNEXURE D

[Annexure D amended by G.N.R. 1615 dd. 22.11.1933 and repealed.]