## SUBSIDIARY LEGISLATION

# FOOD AND DRUGS REGULATIONS

ARRANGEMENT OF REGULATIONS

**REGULATION**



*L.R.O. 1/2009*

**REGULATION**



**PART III—DRUGS**

**GENERAL**

ARRANGEMENT OF REGULATIONS—*Continued*

**REGULATION**

130/1964. [94/1969 53/1972 52/1974 105/1974 9/1985].

# *FOOD AND DRUGS REGULATIONS

*made under section 25*

## PART I

Citation.

**1.** These Regulations may be cited as the Food and Drugs Regulations.

Requirements prescribed by Regulation.

**2.** These Regulations, where applicable, prescribe the standards of composition, strength, potency, purity, quality, or other property of the article of food, drug, cosmetic, or device, to which they refer.

## INTERPRETATION

Interpretation. [94/1969].

**3.** In these Regulations—

"acceptable method" means a method of analysis or examination indicated by the Minister as acceptable for use in the administration of the Act;

"cubic centimetre" and its abbreviation "cc" shall be deemed to be interchangeable with the term "millilitre" and its abbreviation "ml" ;

"Director" means the Chief Chemist and Director of Food and Drugs;

"inner label" means the label on or affixed to an immediate container of a food, drug, cosmetic, or device;

"lot number" or "batch number" means any combination of letters or figures, or both, by which any food or drug can be traced in manufacture and identified in distribution;

"official method" means the method of analysis or examination designated by the Minister by Notification for use in the administration of the Act;

"outer label" means the label on or affixed to the outside of a package of a food, drug, cosmetic, or device.

Request to Director. [94/1969].

**4.** The Director shall, upon request—

*(a)* furnish copies of official methods; and

*(b)* indicate that a method submitted to him for his ruling is acceptable or otherwise.

*These Regulations have been further amended by LNs 111/1986; 49/1987; 37/1991; 72/1996; 192/1999; 199/1999; 118/2003.

## INSPECTORS

Functions, duties, responsibilities of Inspectors.

**5.** (1) Inspectors shall perform the functions and duties, and carry out the responsibilities, prescribed by the Act, these Regulations and the Minister.

(2) The authority of an inspector extends to and includes the whole of Trinidad and Tobago.

Certificate of appointment. Form A. Third Schedule.

**6.** A certificate that a person has been appointed as an inspector shall be in the form set out as Form A in the Third Schedule and shall be signed by the Minister and the person appointed.

Taking of photographs.

**7.** (1) An inspector may take photographs of premises and articles as may be relevant to the administration of the Act or these Regulations, in so far as they apply to unsanitary conditions.

(2) For the purposes of subregulation (1), the expression "articles" includes—

*(a)* food, drugs, cosmetics, and devices, and anything used for the manufacture, preparation, preservation, packaging or storing of such articles; and

*(b)* any labelling or advertising material.

## IMPORTATIONS

Taking samples and detention pending further examination.

**8.** (1) An inspector may examine, take samples of, and detain pending further examination, any food, drug, cosmetic, or device, imported into Trinidad and Tobago but not delivered out of the charge of Customs.

(2) Where a sample of a food, drug, cosmetic, or device is taken, the inspector shall, as soon as may be practicable thereafter, submit the sample to an analyst for examination or analysis.

Violation of Act or Regulations and re-labelling or re-conditioning of food, drug, cosmetic or device.

**9.** (1) Subject to subregulation (2), where, as a result of an examination or analysis of a sample of a food, drug, cosmetic, or device, an analyst reports that the food, drug, cosmetic, or device would, if sold in Trinidad and Tobago, constitute a violation of the Act or of these Regulations, the food, drug, cosmetic, or device shall not be admitted into Trinidad and Tobago for use as a food,

drug, cosmetic, or device, as the case may be, and the inspector shall send a report of the analysis or examination to the Comptroller of Customs and a copy to the importer.

(2) Where a food, drug, cosmetic, or device, sought to be admitted into Trinidad and Tobago would, if sold in Trinidad and Tobago, constitute a violation of the Act or of these Regulations, the food, drug, cosmetic, or device may be admitted into Trinidad and Tobago for the purpose of re-labelling or re-conditioning under the supervision of an inspector in compliance with such written conditions as may be specified in the report of an analyst, and where the re-labelling or re-conditioning is not satisfactorily carried out within three months after the report is made, or such lesser period as may be specified in the report, the food, drug, cosmetic, or device shall be exported, and, if not exported within a further period of three months, are forfeited to the State and may be disposed of as the Minister may direct; but the Minister may extend the time for complying with conditions or for exporting the said goods.

Issue of certificate.

**10.** A certificate required under section 32(2) of the Act shall be a certificate in the English Language issued by the official body or Government Department having authority to issue the certificate in the country in which the article of food, drug, cosmetic, or device was manufactured or produced; and where no official body or Government Department has authority to issue such a certificate, the certificate may be issued by any person acceptable to the Minister.

## SAMPLING

Taking a sample, notification of intention and division of sample.

**11.** When taking a sample pursuant to section 21 of the Act, an inspector shall, after procuring a suitable quantity of the article in question and paying for the same the usual price therefor, notify the owner thereof or the person from whom the sample was obtained of his intention to submit a sample thereof to an analyst for analysis or examination, and

*(a)* if the owner or the person from whom the sample

was obtained, demands it, but not otherwise, then and there divide the quantity into three parts, and shall—

(i) cause each of the three parts to be marked and sealed in such manner as the nature of such sample will permit;

(ii) deliver one of the parts to the owner or person from whom the sample was obtained, or leave the same upon the premises wherein the sample was obtained; and

(iii) retain one of the parts for future comparison or verification, and shall submit the third part to the analyst for analysis or examination;

*(b)* if no demand is made for the division of the sample into three parts, the inspector shall—

(i) divide the same into two parts;

(ii) cause each of those parts to be marked and sealed in such manner as the nature of the sample will permit; and

(iii) retain one of the parts for future comparison or verification, and submit the other to the analyst for analysis or examination.

Division an interference and objection to procedure by owner or person.

**12.** (1) Notwithstanding regulation 11, where in the opinion of the inspector division of the procured quantity of a sample would interfere with analysis or examination, the inspector may, subject to subregulation (2), seal and submit the entire sample for analysis or examination.

(2) Where the owner or person from whom the sample was obtained objects to the procedure provided for in subregulation (1) at the time the sample was obtained, and supplies at his own expense a sufficient quantity of the article, the inspector shall follow the procedure described in regulation 11.

## CERTIFICATE OF ANALYSIS

Certificate of Analysis. Form B. Third Schedule. [94/1969].

**13.** A certificate of an analyst stating that he has analysed or examined an article or a sample submitted to him by an inspector shall be in the form set out as Form B in the Third Schedule, with such variations as circumstances may require.

**PART II**

Definition of terms in Part II. [94/1969 52/1974 118/2003].

**14.** In this Part—

"alcoholic beverage" means a liquid food containing sufficient ethyl alcohol to make it liable to Excise duty and includes—

*(a)* a spirit, liqueur, wine, cider, perry, champagne or spirit compound used as a food; and

*(b)* a brewery product containing sufficient ethyl alcohol to make it liable to Excise duty,

but does not include a flavouring preparation or liquid food in which ethyl alcohol is used as a preservative;

"alcoholic content by volume" means the volume of ethyl alcohol in a food, expressed as a percentage of the total volume of the food;

"baked confectionery" means any solid or semi-solid food ready for human consumption without any further preparation except heating, and which is principally composed of ground cereal (not including a filling) whether or not flavoured, coated or containing sweetening agents, chocolate or cocoa and includes cakes, pastries, sponges and meringues but does not include bread, biscuits, rusks or any product containing meat, fish, fruit or fruit pulp as a filling;

"batch number" or "lot number" means any letters or figures or a combination of both used for marking, identifying or tracing a batch or lot of pre-packaged food when manufactured, distributed or sold, and includes a date mark;

"biscuits" includes crisp bread, wafers, rusks, oatcakes and biscuits which have been coated, filled or flavoured with chocolate or cocoa;

"brewery product" means a beverage which is derived from a cereal and includes a beverage which is manufactured, distributed or sold under any of the following common names:

*(a)* ale;

*(b)* beer;

*(c)* lager or lager beer;

*(d)* malta;

*(e)* malt liquor;

*(f)* porter;

*(g)* shandy; or

*(h)* stout;

"bulk container" means a container in which more than one duly labelled package of a food and its contents are placed for purposes of wholesale, but in which the packages and their contents are not intended to be retained for retail sale;

"chocolate confectionery" means any solid or semi-solid food principally composed of chocolate or cocoa with or without the addition of fruits or nuts, and includes food made by covering, coating or embodying sugar confectionery in chocolate but does not include biscuits which have been cooked, filled or flavoured with chocolate or chocolate ice cream, or baked confectionery flavoured with chocolate;

"common name" means the name printed in bold type in these Regulations or—

*(a)* where the name is not so printed, the name by which the food is generally known and which is sufficient in each particular case to indicate to the purchaser the true nature of the food; or

*(b)* where the name of the food consists of the common names of two or more of its principal ingredients, the common names of these ingredients arranged in descending order of proportion by weight;

"component" means any substance which forms part of an ingredient;

"confectionery" includes baked confectionery, chocolate confectionery and sugar confectionery;

"date mark" means any declaration by letters or figures, whether declared expressly or in code, of any date indicative of the age of a food;

"expiry date" means any date after which the manufacturer or packager of a food does not guarantee the quality or any other property of the food;

"flavouring preparation" includes any food for which a standard is prescribed or which is defined in Division 5 of the First Schedule; First Schedule.

"food additive" means any substance the use of which would result or is likely to result in the substance or any of its by-products becoming a part of or affecting the characteristics of a food and includes a preservative and a food colour, but does not include—

*(a)* a nutritive material used, recognised or commonly sold as an article of food;

*(b)* vitamins, mineral nutrients or amino-acids;

*(c)* spices, seasonings, essential oils, oleoresins or extractives from plants;

*(d)* veterinary drugs that may be used on animals that may subsequently be consumed as food or be used to produce food;

*(e)* pesticides or their by-products;

*(f)* materials used for packing or any substance from such materials that may have entered food packed therein;

"food colour" means those colours permitted for use in or upon food by Division 2 of the First Schedule; First Schedule.

"ingredient" means any substance including a food additive used in the preparation of a food and which is present in the final product;

"instant" means in relation to a food so described, that the food has been processed to such a degree that it may be converted into a state similar to that in which it is usually consumed, merely by the addition of one or more substances with which it may be easily and readily mixed;

"main panel" means that part of a label normally intended to be presented to the consumer or intended to be most conspicuous to the consumer at the time when the food to which the label relates is offered or exposed for sale;

"package" means anything in which a food is wholly or partly contained, placed, packed or enclosed for sale;

"prepackaged" means packaged or made up in advance in a package for retail sale;

"preservative" means a substance classified as such in Division 7 of the First Schedule; First Schedule.

"proof spirit" means proof spirit as defined in the Customs Act or the Excise (General Provisions) Act; Ch. 78:01. Ch. 78:50.

"registration number" means any letters or figures or a combination of letters and figures assigned to a food factory in accordance with the provisions of these Regulations so as to identify its products;

"storage instructions" means information on the manner in which a pre-packaged food should be handled and stored so that its quality, safety or properties may be retained until the expiry date, or in the event that there is no such date such information that is necessary to ensure the retention of the quality, safety or properties of the food;

"sugar confectionery" means any solid or semi-solid food, ready for human consumption, which is composed principally of sugar with or without the addition of edible oil or fats, milk products, gelatine, edible gums, nuts, fruits, natural or synthetic flavours, food additives, food colours or preserved fruit and includes sugar-cake, sweetened liquorice and chewing gum, but does not include chocolate confectionery, sugared baked marzipan, meringues or sweetened flavoured powders which may be used in the preparation of soft drinks;

"sweetening agent" means a sugar, molasses, honey or any other carbohydrate which may be used as a sweetener;

"vending machine" means a machine one of the purposes of which is to dispense or supply a food automatically when money or money's worth is inserted into it whether or not any further operation is required prior to its dispensing or supplying the food.

**15.** Any person who sells a food that is not labelled in accordance with the provisions of this Part is guilty of an offence. Offence to sell unlabelled food. [52/1974].

**16.** (1) Except as otherwise provided by this Part the label of a package of food shall carry— Labelling of package. [94/1969 52/1974 9/1985 118/2003].

*(a)* on the main panel of the label—

(i) the brand or trade name of the food;

(ii) the common name of the food; and

(iii) a correct declaration of the net contents of the package in terms of weight, volume or number in accordance with the usual practice in describing the food;

*(b)* on any panel except the bottom of the package—

(i) in the case of a food which consists of more than one ingredient, a complete list of ingredients in descending order of proportion by weight or a complete list of ingredients in which the proportion or quantity of each ingredient is stated in terms of percentage;

(ii) the name and address of the manufacturer or the person preparing the food and its country of preparation or origin as required by subregulations (8) and (9);

(iii) a declaration by name of any added Class II, Class III or Class IV preservative;

(iv) a declaration of any added food colour;

(v) a declaration of any added flavouring preparation;

(vi) the expiry date or other date mark;

(vii) storage instructions, where applicable;

(viii) preparation instructions, where applicable;

(ix) instructions for safe handling, where applicable; and

(x) any other statement which may be required to be declared or made by these Regulations; and

*(c)* on any panel, including the panel at the bottom of the package—

(i) the batch or lot number; and

(ii) any registration number which may be required by these Regulations.

(2) The declaration of net contents specified in subregulation (1)*(a)*(iii) shall be made in terms of metric

(Systeme Internationale) units or imperial (Avoirdupois) units, or any accepted abbreviations thereof until such terms are varied with respect to any class of food by notice made by the Minister and published in the *Gazette;* the notice shall state specifically the date on or after which the variation becomes effective.

(3) Where a food is packed in a liquid medium which is usually not consumed with the food, a declaration of the drained weight of the food shall be made.

(4) The list of ingredients required by subregulation (1)*(b)*(i) shall include the components of any ingredient which is not exempted by these Regulations from being labelled with a list of its ingredients.

(5) In the case of a dehydrated food the ingredients shall be listed in descending proportion by weight in the food when it is reconstituted and the list shall begin with a statement such as "ingredients when reconstituted".

(6) Except when it is present as a usual component of an ingredient (such as gravy, broth, brine, milk or syrup), or when it is used in usual manufacturing processes, added water shall be declared as an ingredient.

(7) A distinct and specific name shall be used in the list of ingredients for each ingredient (other than a food additive sold as such) except that the class titles may be used—

*(a)* in the case of ingredients falling into the following classes:

animal fats (except pork and beef fats and tallow);

animal oils (except pork and beef oils and tallow)

animal shortening (except pork and beef shortening);

herbs;

marine oils (that is to say oils from marine animals);

spices;

starches (except modified starches);

vegetable fats;
vegetable oils;
vegetable shortening;

*(b)* for food additives falling into the following classes:

acidifiers;
anticaking agents (or free-flowing agents);
antifoaming agents;
antioxidants (or Class IV preservatives);
bleaching agents;
carbohydrate binder;
cereal binder;
food colours;
emulsifiers;
emulsifying salts;
enzymes;
firming agents;
maturing agents;
modified starches;
natural or synthetic flavours;
neutralisers;
preservatives (except Class II preservatives);
stabilisers;
thickening agents;
vegetable or edible gums.

(8) Where the food is prepared by a person in Trinidad and Tobago who is not the manufacturer within the meaning of section 2 of the Act, the name and postal address in Trinidad and Tobago of the person by whom the food was prepared shall be legibly stated next to the name and address of the manufacturer.

(9) Where the food is prepared in a country other than the country of the manufacturer a declaration of the country of preparation or origin shall be made on the label.

(10) The declarations specified in subregulation (1) and in regulation 16A shall be made in English but where a label is applied to a food in a country the official language of which is not English, the declarations shall appear in English on any panel except the bottom of the package.

Labelling of breastfeeding substitutes. [9/1985].

**16A.** (1) Every manufacturer or distributor of a breast-milk substitute shall display on the outer label of the container—

*(a)* a statement headed "Important Notice" proclaiming the superiority of breastfeeding over other methods of infant feeding and advising that such substitute should be used only on proper medical advice having been obtained as to the need for, and the proper methods of its use;

*(b)* directions for use and a warning of the consequences of failure to follow those directions.

(2) The manufacturer or distributor of a breast-milk substitute shall not display on the container or label—

*(a)* any statement, picture or other visual impression of a person that would tend to encourage the use of that substitute in preference to breast-milk;

*(b)* the words "humanised" or "maternalised" or any such words that may tend to extol the virtues of that substitute.

(3) The manufacturer or distributor of every food product which is not a breast-milk substitute but which is capable of being modified to become one, shall include on the label a warning that the product is not to be used as the sole source of nourishment for babies.

(4) The manufacturer or distributor of condensed milk shall not include on the label, instructions for its modification as a baby food.

(5) In addition to the provisions of this regulation the provisions of regulation 16 also apply to manufacturers or distributors of breast-milk substitutes.

Labelling of beverages containing alcohol. [118/2003].

**16B.** (1) This regulation applies to the labelling of a beverage containing alcohol in addition to regulation 16.

(2) The common name of an alcoholic beverage associated with a particular country or locality shall not be applied to an alcoholic beverage produced in any country unless the name is generally recognised as being associated with the distinctive type of alcoholic beverage.

(3) The common name of an alcoholic beverage associated with a particular type of alcoholic beverage produced in a particular country or locality and protected by the law of the country, may only be applied to an alcoholic beverage produced in another country where the common name is preceded by a name or adjective in identical lettering, indicating the true country or locality of origin.

(4) Subject to subregulations (5) and (6), the common name "wine" shall be applied to an undistilled fermented alcoholic beverage prepared from fresh or preserved grapes.

(5) The common name "(naming the fruit, flower, leaf, grain or other botanical substance) wine" shall be applied to an undistilled fermented alcoholic beverage prepared wholly or principally from a fruit, flower, leaf, grain or other botanical substance, other than fresh or preserved grapes.

(6) The common name "non-alcoholic wine" may be applied to a beverage prepared principally from a fruit, which although not an alcoholic beverage, resembles it but shall not be applied to a beverage which contains more than 0.5 per cent alcoholic content by volume.

(7) The label on the package of a beverage containing more than 1.0 per cent alcoholic content by volume, shall state on its main panel, its alcoholic strength in terms of any of the following:

*(a)* alcoholic content by volume;
*(b)* degrees Gay-Lussac (°G.L.);
*(c)* degrees proof spirit or per cent proof spirit;
*(d)* degrees or per cent U.S. proof; or
*(e)* any other term authorised by the Minister.

(8) The common names "brandy", "rum", "gin" or "vodka" shall not be applied to an alcoholic beverage, the alcoholic strength of which is below seventy-five degrees proof spirit, except in the case of fruit brandy and brandy that has been matured in a cask.

(9) The common names referred to in subregulations (2) and (3) may be in a language other than English, but shall be printed in the English alphabet, with accent marks where appropriate.

Labelling of brewery products. [118/2003].

**16C.** (1) This regulation applies to the labelling of a brewery product in addition to regulation 16 and where there is a conflict between this regulation and regulation 16, this regulation prevails.

(2) The label on the package of a brewery product for retail sale shall state, on any panel except the panel at the bottom of the package—

*(a)* the name and address of the manufacturer;

*(b)* the name and address of the person preparing the brewery product, where different from the name and address of the manufacturer;

*(c)* the country of origin;

*(d)* the name and address of the importer or the distributor, if any;

*(e)* its alcoholic strength in terms of alcoholic content by volume; and

*(f)* a declaration of the net contents.

(3) Notwithstanding regulation 18(1)*(d)*, the label on a package of shandy for retail sale shall state, in addition to the information set out in subregulation (2)

*(a)* the vegetable flavour, juice or extract used in the shandy, if any; and

*(b)* a list of ingredients in descending order of proportion by weight.

(4) Notwithstanding regulation 18(1)*(d)*, the label on a package of malta for retail sale shall state, in addition to the information set out in subregulation (2)—

*(a)* the word "non-alcoholic"; and

*(b)* a list of ingredients which may include the word "wort".

(5) The label on the package of a brewery product for retail sale may state the following information:

*(a)* nutritional information, in terms of the Recommended Daily Allowances for vitamins and minerals set by the Caribbean Food and Nutrition Institute or by authorities in the United States of America;

*(b)* a warning as to the effects of alcohol on health or safety;

*(c)* whether the package may be returned to the dealer or manufacturer, in which case, the word "returnable" may be used, or disposed of otherwise;

*(d)* whether a refund or payment is made for an empty package which is returned; or

*(e)* where the package is made of plastic or metal, whether the package may be recycled.

(6) The label on a bulk package of a brewery product shall state—

*(a)* the common name;

*(b)* the brand or trade name;

*(c)* the name and address of the manufacturer;

*(d)* the name and address of the person preparing the brewery product, where different from the name and address of the manufacturer;

*(e)* the average net contents as determined by an acceptable method;

*(f)* where the brewery product is imported or exported, the name of the country of origin;

*(g)* the name and address of the importer or the distributor, if any; and

*(h)* the expiry date or other date mark.

(7) In this regulation "bulk package" includes a package in which one or more duly labelled packages of a brewery product and its contents intended for retail sale are placed for the purpose

of wholesale and a barrel, cask or pressurized container in which a brewery product is placed for sale from draught.

Declaration of net contents not required on certain labels. [52/1974].

**17.** Notwithstanding the provisions of regulation 16(1)*(a)*(iii), a declaration of net contents in terms of weight, volume or number is not required on the label of—

*(a)* any package of food, the weight of which including the package is less than two ounces (56 grams) or the volume of net contents is less than two fluid ounces (56 millilitres);

*(b)* milk, sterilised milk, flavoured sterilised milk, skim milk or U.H.T. milk sold in glass, plastic or laminated plastic containers the capacity of which is ten fluid ounces (half pint), twenty fluid ounces (one pint), one quart or half gallon;

*(c)* eggs, fresh fruit or fresh vegetables packaged in transparent, colourless and flexible materials where the fruit or vegetable is customarily sold by number, or if sold by weight by multiples of one pound or of half a kilogram provided that a true statement of the number or the weight per package is prominently displayed adjacent to the place, shelf or bin where the packages are displayed;

*(d)* eggs packed in cartons which may be easily opened so that their contents may be checked.

List of ingredients not required on certain labels. [52/1974].

**18.** (1) Notwithstanding the provisions of regulation 16(1)*(b)*(i), a list of ingredients is not required on the labels of—

*(a)* preparations of synthetic food colours for household use containing less than fifteen per cent of pure dye and sold in containers of two fluid ounces ( 56 millilitres) or less;

*(b)* dairy products, except ice cream, dairy ice cream, milk ices and water ices;

*(c)* flavouring preparations;

*(d)* carbonated beverages, soft drinks and flavouring syrups;

*(e)* bread, cakes and plain biscuits;

*(f)* sugar confectionery and baked confectionery;

*(g)* blood pudding;

*(h)* gelatin desserts;

*(i)* alcoholic beverages;

*(j)* packages less than fifty millimetres in size and with a capacity of less than two ounces (56 grams) or two fluid ounces (56 millilitres);

*(k)* foods for which a compositional standard is provided in these Regulations, unless the standard requires a list of ingredients to be declared;

*(l)* Angostura aromatic bitters.

(2) The provisions of subregulation (1) do not apply to any food exempted from the provisions of regulation 16(1)*(b)*(i) if that food is labelled with any statement of an ingredient other than its brand, trade or common name, or any other statement required by the Regulations.

(3) Notwithstanding the provisions of regulation 16(1)*(b)*(iv), no declaration is required to indicate the presence of added food colour in the following:

*(a)* bakery products, except brown bread;

*(b)* butter, margarine, shortening;

*(c)* cheese or processed cheese;

*(d)* sugar confectionery or baked confectionery;

*(e)* gelatin desserts;

*(f)* ice cream, water ices or milk ices;

*(g)* icing sugar;

*(h)* liqueurs, alcoholic cordials or Angostura aromatic bitters;

*(i)* sherbets;

*(j)* carbonated beverages.

(4) Notwithstanding the provisions of regulation 16(1)*(b)*(iv), no declaration is required to indicate the presence of caramel as a food colour in the following:

*(a)* non-excisable fermented beverages;

*(b)* sauces;
*(c)* spirits (except gin);
*(d)* vinegar;
*(e)* wine;
*(f)* dilute acetic (food grade).

Declaration not required. [52/1974].

**19.** (1) Notwithstanding the provisions of regulation 16(1)*(b)*(v), no declaration is required—

*(a)* to indicate the presence of sulphur dioxide, sulphurous acid or its salts, in or upon—
(i) glucose or glucose syrup;
(ii) molasses, fancy molasses, table molasses or refined molasses;
(iii) white sugar, granulated sugar, yellow crystal sugar or washed grey sugar;
(iv) confectionery;
(v) malt liquors;
(vi) wines;
(vii) syrups;

*(b)* to indicate the presence of Class III preservatives in—
(i) bread;
(ii) bakery products;
(iii) wines;
(iv) cheese, processed cheese or processed cheese products.

(2) Class I preservatives shall be declared by name as if they were ingredients of a food.

Declaration not required to indicate presence of flavouring. [52/1974].

**20.** Notwithstanding the provisions of regulation 16(1)*(b)*(iv), no declaration is required to indicate the presence of added artificial or imitation flavouring preparation in or upon—

*(a)* bakery products;
*(b)* confectionery;
*(c)* ice cream or water ices;
*(d)* sherbets;

*(e)* soft drinks, including flavouring syrups unless they are labelled as "fruit drink" or "juice" ;

*(f)* carbonated beverages;

*(g)* flavoured sterilised milk, flavoured skim milk, flavoured malted milk, or flavoured malted milk products;

*(h)* sugar confectionery.

Dried or dehydrated products. [52/1974 37/1991 118/2003].

**21.** (1) Where a food is commonly sold both in its normal state and as a dried or dehydrated product, the latter shall be labelled with the words "dried", "dehydrated" or "desiccated" as part of its common name.

(2) Subregulation (1) does not apply to a food prepared by drying or dehydration if—

*(a)* the Regulations prescribe a standard for the food so prepared;

*(b)* a common name is customarily and exclusively applied to such food; or

*(c)* the word "instant" is used with the name of the food so prepared.

(3) Where a food is prepared by adding water to concentrated or dehydrated ingredients the word "reconstituted" shall appear clearly on the label in close proximity to the common name if—

*(a)* the food resembles another food commonly sold under a common name or for which a standard is prescribed by Regulations; and

*(b)* the food is packaged and sold as a reconstituted food and its composition is similar to that of the other food.

(4) Where a food is sold pre-packaged by retail as a mixture of ingredients, dry or otherwise, and is intended to be made into other food for human consumption by the addition of any food or substance other than water—

*(a)* the name of the substance required to be added shall appear on the label preceded by such words as "Add" "Needs", or "Mixed With"; and

*(b)* the words required by paragraph *(a)* shall appear in close proximity to the common name of the mixture of the ingredients sold.

(5) A food which contains saccharin, or cyclohexylsulphamic acid (cyclamate) or the salts of either of them shall state clearly on the label the name of the artificial sweetener it contains, and a statement that it is a non-nutritive sweetener.

(6) Every person is guilty of an offence who—

*(a)* makes on a label or in any advertisement of a food a reference, direct or otherwise to the Act, the Regulations made thereunder, the Ministry of Health or the Food and Drugs Division, unless the reference is a specific requirement of the Act or the Regulations made thereunder;

*(b)* uses on a label or in any advertisement of a food a name or designation given to any standard, grade or definition prescribed for a food by any law in force in Trinidad and Tobago, unless the food conforms to the prescribed standard, grade or definition;

*(c)* uses on a label or in any advertisement of a food any words, mark, device or design generally recognised as certifying or implying conformity with a specification, standard or grade, unless the food conforms with the specification, standard or grade certified or implied by the words, mark, device or design.

(6A) Subregulation (6)*(a)* does not apply to a label on meat or poultry products intended for export to the effect that the product has been inspected and passed for wholesomeness by an inspector appointed under the Act.

(7) Where a food or any of its ingredients is derived from an animal, the common name of the animal or of its meat shall be used in any declaration required by these Regulations.

(8) ***(Revoked by LN 118/2003).***

**22.** (1) No person shall sell food in or from a vending machine unless there is on the machine, in a position clearly visible to the

Food from vending machine. [52/1974].

purchaser, a label bearing all information regarding the food as prescribed by these Regulations, and in particular the trade name or common name of the food and the quantity thereof to be sold.

(2) Where a food that has been pre-packaged is sold in or from a vending machine each package shall be labelled as prescribed by these Regulations.

(3) For the purposes of regulation 16, the outer surface of any crown cork or closure on a glass bottle used for packaging carbonated beverages or liquid dairy products may be accepted as a main panel for a period not exceeding ten years after the coming into operation of the Food and Drugs (Amendment) Regulations 1974 (that is, 28th February 1974).

(4) Any new glass bottles used for packaging carbonated beverages or liquid dairy products shall, on the expiration of one year from the coming into operation of the Food and Drugs (Amendment) Regulations 1974 (that is, 28th February 1974), bear clearly and legibly as a label fixed on the body of the bottle, the name and address of the manufacturer and a statement of net contents as prescribed by regulation 16.

(5) Glass bottles, used for packaging international brands of carbonated beverages, which may be imported by way of a chandler's trade with ships, aircraft or hovercraft or any other means of international transport may be used for packaging such brands in Trinidad and Tobago if the Director is satisfied that the brands are international brands.

(6) A manufacturer of carbonated beverages who has changed his address may continue to use his former address on old glass bottles if the Director is informed of the new address.

Non-application of regulation 16. [52/1974 118/2003].

**23.** (1) Regulation 16 does not apply to a food which is—

*(a)* sold unpackaged, or in an open or uncovered package;

*(b)* weighed or measured in or counted into the package in the presence of the purchaser, or weighed, measured or counted in the presence of the purchaser before being packaged;

(c) pre-packaged from bulk at the place where the food is sold by retail provided that there is placed on every shelf, bin or any other place where the food is displayed in a position clearly visible to an intending purchaser a legible statement in English giving correct details of—

(i) the common name or trade name of the food;

(ii) the net contents of the package;

(iii) the price of the unit quantity of the food as it is customarily measured; and

(iv) the price of the package;

(d) a pastelle sold only in the vegetable wrapping in which it was cooked provided that the name and address of the manufacturer are clearly shown on the shelf, bin or any other place where it is displayed for sale if retailed by a person other than the manufacturer.

(2) Notwithstanding regulation 16, the label on a bulk container of a food or food additive shall state—

(a) the common name;

(b) the name and address of the manufacturer, packager, importer or wholesaler;

(c) the country of origin;

(d) the net contents; and

(e) the expiry date or other date mark,

and may state the batch or lot number, registration number and storage instructions.

(3) Notwithstanding regulation 16(1), a package containing a food additive or a mixture of food additives (other than a preparation of synthetic food colours for household use) and no other food ingredient may carry a batch number, date mark or expiry date and shall be labelled with—

(a) the common or chemical name of the food additive and the specification to which it conforms;

(b) the brand or trade name of the food additive;

(c) the net contents of the package;

*(d)* the name and address of the manufacturer or packager of the food additive;

*(e)* any direction in English that the Director may consider necessary to ensure its safe use in accordance with the Act, Regulations made thereunder or with food manufacturing practice, or to prevent injury to the consumer or to persons who may use the food additive in the preparation of a food;

*(f)* the name, percentage by weight and the specification of each food additive present, where there is a mixture of food additives.

Standard for a food.

**24.** Where a standard for a food is provided in this Part, only those ingredients named in the standard shall be used in the food.

Name of designation given to standard, grade or definition. [94/1969].

**25.** Where by any law in force in Trinidad and Tobago a standard, grade or definition is prescribed for a food and the standard, grade or definition is given a name or designation by the law, no person shall use that name or designation on a label or in any advertisement of a food unless the food conforms to the standard, grade or definition prescribed.

Adulteration of food. [53/1972 192/1999].

**26.** For the purposes of the Act and these Regulations, a food is adulterated if any of the following substances or classes of substances is present therein or has been added thereto:

*(a)* mineral oil or paraffin wax, or any preparation thereof;

*(b)* coumarin or an extract of tonka beans, the seed of *Dipteryx odorata Willd.* or *Dipteryx oppositifolia Willd.*;

*(c)* synthetic sweetener(s) other than those approved by the Minister;

*(d)* iso-propyl alcohol;

*(e)* synthetic food colours in a proportion greater than 0.03 per cent of the food when prepared for consumption as directed, or as it is usually consumed (except in food colour preparations as defined in Division 2 of the First Schedule).

First Schedule.

Non-adulteration.

**27.** Notwithstanding regulation 26—

*(a)* a food is not adulterated by reason only that it contains mineral oil not exceeding 0.3 per cent if good manufacturing practice required its use; and

*(b)* chewing gum is not adulterated by reason only that it contains a paraffin wax base.

Contents of package.

**28.** (1) Where the contents of a package of food are expressed in terms of weight, measure, or number, no variations below the quantity declared on the label are permitted except, subject to subregulation (2)—

*(a)* variations due exclusively to differences in the capacity of containers resulting solely from unavoidable difficulties in manufacturing; and

*(b)* variations in weight, measure, or number that unavoidably result from the ordinary and customary exposure of the package to evaporation, or to the absorption of water, under normal atmospheric conditions.

(2) Where the contents of a package of food are expressed in terms of minimum weight, measure, or number, the contents of the package shall not be less than the minimum expressed.

Display of information on label.

**29.** (1) All information required by this Part to be carried on a label shall be—

*(a)* clearly and prominently displayed thereon; and

*(b)* readily discernible to the purchaser or consumer under the customary conditions of purchase and use.

(2) For the purpose of regulation 16(1)*(a)*, a common name consisting of more than one word shall be deemed to be clearly and prominently displayed on the main panel of the label if each word (other than article, conjunction, or preposition) is in identical type and identically displayed.

(3) On any label of or in any advertisement of an artificial, imitation, substitute, or synthetic food, the word "artificial",

"imitation", "substitute", "synthetic", or other appropriate word shall be stated in full, and shall—

*(a)* be an integral part of the name of the food; and

*(b)* be an identical type and be identically displayed with the name.

(4) Where inner and outer labels are employed on a package of food, all label declarations required by this Part shall appear on both the inner and outer labels.

First Schedule.

**30.** The provisions of the First Schedule shall be read as one with this Part.

Offence.

**31.** A person who contravenes a provision of this Part is liable on summary conviction to a penalty of three hundred dollars or to imprisonment for three months.

## PART III—DRUGS

### GENERAL

Definition of terms in Part III. [94/1969 52/1974].

**32.** In this Part—

"antibiotic" means any of the substances, whether made by the action of micro-organisms or synthetically, specified in the Schedule to the Antibiotics Act, and includes all compounds of, and all medicinal preparations containing any of, such substances;

Ch. 30:02.

"bulk package" means—

*(a)* a package in which one or more duly labelled packages of a drug and its contents intended for retail are placed for the purpose of wholesale;

*(b)* a package containing a drug intended to be sold by wholesale; or

*(c)* a package containing a drug supplied by a wholesaler to a pharmacist or dispensary and intended to be re-packaged by the retailer in smaller quantities for dispensing or retail, but does not include packing cases used in import or export for the protection of drugs;

"common name" means, with reference to a drug, the name in English by which the drug is commonly known, or the

name by which the drug is commonly known in Trinidad and Tobago;

"controlled drug" means any of the drugs classified as such in Division 2 of the Second Schedule, and includes a preparation; Second Schedule.

"dentist" means a person qualified by law to practise dentistry in Trinidad and Tobago;

"expiration date" means the date after which a drug is not recommended by the manufacturer for use;

"hospital" means any public hospital or licensed private hospital;

"internal use" means ingestion by mouth or application for systemic effect to any part of the body in which the drug comes into contact with mucous membrane;

"narcotic drug" means any of the substances specified in the Schedule to the Narcotics Control Ordinance; *27 of 1961.

"official drug" means any drug for which a standard is provided—

*(a)* in this Part; or

*(b)* in any of the publications mentioned in the Second Schedule to the Act; Second Schedule.

"parenteral use" means administration of a drug by means of a hypodermic syringe, needle, or other instrument, through or into the skin or mucous membrane; and "parenteral" shall be construed accordingly;

"Patent or Proprietary Medicine" means any drug which—

*(a)* is intended for internal or external use by man, and the name, composition, or definition of which is not to be found in any of the publications mentioned in the Second Schedule to the Act, or in any formulary, pharmacopoeia, or publication issued by any official body approved by the Minister; and Second Schedule.

*(b)* is sold and labelled with a trade name or registered trade mark indicating that the drug is manufactured by a particular person or company; and includes any drug approved as a Patent or Proprietary Medicine by the Pharmacy Board of Trinidad and Tobago;

*Act No. 27 of 1961 was repealed by Act No. 38 of 1991.

"per cent" means per cent by weight unless otherwise stated;

"pharmacist" means a person who is registered as a member of the Pharmacy Board of Trinidad and Tobago;

"pharmacy" means an establishment where drugs or devices are dispensed or prepared or sold by retail;

"physician" means a person who is registered as a member of the Medical Board of Trinidad and Tobago;

Third Schedule. Ch. 29:52.

"poisonous drug" means a drug mentioned in the Third Schedule to the Pharmacy Board Act;

"practitioner" means a dentist, physician, or veterinary surgeon;

"preparation" means a drug that contains in a recognised therapeutic form, a controlled drug and one or more drugs other than controlled drugs;

"prescription" means a direction given in writing, and dated and signed, by a practitioner, that a stated amount of a drug or mixture of drugs be dispensed for the person named therein;

"proper name" means with reference to a drug—

*(a)* the name in English that is assigned to the drug by this Part;

*(b)* the name in English of the drug printed in bold type in this Part, and, where the drug is dispensed in a form other than described in this Part, the name of the dispensing form;

*(c)* the name published by—

(i) the British Pharmacopoeia Commission of the General Medical Council of the United Kingdom as the approved name; or

(ii) the Adopted Name Council of the United States Pharmacopoeial Convention as the adopted name of the drug; or

*(d)* in the case of a drug not included in paragraph *(a)*, *(b)* or *(c)*, the name in English assigned to the drug in any of the publications mentioned in the Second Schedule to the Act; or

Second Schedule.

*(e)* international non-proprietary names proposed by the World Health Organisation;

"Third Schedule drug" means any drug mentioned in the Third Schedule to the Act; Third Schedule.

"veterinary drug" means a drug sold for veterinary use, and includes a drug supplied on a prescription given by a veterinary surgeon;

"veterinary surgeon" means a person who is registered under the Veterinary Surgeons (Registration) Act. Ch. 67:04.

**33.** No person shall sell a drug that is not labelled as required by this Part. Labelling of drug.

**34.** Except as provided in this Part, the label of a drug shall carry— Contents of label. [94/1969 52/1974].

*(a)* on the main panel of both the inner and the outer labels—

(i) the proper name and the standard under which the drug was manufactured which, if the standard is contained in any publication mentioned in the Second Schedule to the Act, shall be stated in full or by the abbreviation therein provided; or Second Schedule.

(ii) if there is no proper name, the common name;

*(b)* on both the inner and outer labels—

(i) the name of the manufacturer or distributor of the drug;

(ii) the address of the manufacturer or distributor, except that where the immediate container contains five millilitres or less, this statement need not be made on the inner label;

(iii) where a drug is intended for internal or parenteral use, the lot number or batch number, the number being preceded by the words "Lot number", or "Lot", "Batch Number" or "Batch", or by an abbreviation of the words "lot" or "batch", except on labels of Patent or Proprietary Medicines;

(iv) adequate directions for use in the English Language;

(v) the proper name, or, if there is no proper name, the common name, of each medicinal ingredient contained therein, except on official drugs, and Patent or Proprietary Medicines;

(vi) an expiry date if applicable or if required by these Regulations; and

(vii) directions as to the type of storage necessary to maintain the potency, efficacy, safety or properties of the drug, if applicable or if required by these Regulations;

*(c)* on the outer label—

(i) a correct statement of net contents in terms of weight, measure, or number; and

(ii) where the drug is intended for parenteral use, the name and proportion of any preservative present therein.

Label on bulk package. [52/1974].

**35.** The label on the bulk package of any drug shall carry—

*(a)* the proper name and standard under which the drug was manufactured; if the standard is contained in any publication listed in the Second Schedule of the Act, the standard shall be stated in full or by the abbreviation provided in the publication;

Second Schedule.

*(b)* the common name of the drug if there is no proper name;

*(c)* the name and address of the manufacturer or distributor of the drug;

*(d)* the lot number or batch number which shall be preceded by the words "lot number" or "lot", "batch number", or "batch" or by an abbreviation of the words "lot" or "batch" where a drug is intended for internal or parenteral use;

*(e)* a correct declaration of net contents in terms of weight, measure or number; and

*(f)* an expiry date, if applicable or if specified by these Regulations; and may carry—

(i) adequate directions for use, in the English language, or a statement of dosages;

(ii) directions on the kind of storage required to maintain the potency, efficacy, safety or properties of the drug.

Drug sold on prescription.

**36.** Regulation 34 does not apply—

*(a)* to the label of a drug sold on a prescription where the label carries—

(i) the name and address of the pharmacist or pharmacy;

(ii) the date and number of the prescription;

(iii) adequate directions for use;

(iv) the name of the person for whom the drug is dispensed or prescribed;

(v) the name of the physician, dentist, or veterinary surgeon, issuing the prescription;

(vi) where the drug is a Third Schedule drug or a controlled drug and unless otherwise directed by the person issuing the prescription, the name of the drug; and

*(b)* to the label of a drug packaged from bulk on the premises where the drug is retailed, if the label carries—

(i) the name of the drug; and

(ii) the name and address of the pharmacist or pharmacy.

Packing cases. [52/1974].

**37.** Regulations 34 and 35 do not apply to packing cases used for the protection of bulk packages of drugs which are in transit for the purpose of import or export.

Name and proportion of drug to be stated on label.

**38.** Notwithstanding regulation 34*(b)*(v), where a Patent or Proprietary Medicine contains a narcotic drug, a Third Schedule drug, or a controlled drug, the name and proportion of such drug shall, subject to regulation 36, be stated on the label.

Label to contain all information.

**39.** Where a package of a drug has only one label, that label shall contain all the information required by these Regulations to be shown on both the inner and outer labels.

Information clearly and prominently displayed.

**40.** All information required by this Part to be carried on a label of a drug shall be clearly and prominently displayed thereon, and readily discernible to the purchaser or consumer under the customary conditions of purchase or use.

Reference to drug.

**41.** No reference, direct or indirect, to the Act, to these Regulations, or to the Ministry of Health, shall be made upon any label or in any advertisement, of a drug unless the reference is a specific requirement of the Act or of these Regulations.

Drug to conform to standard.

**42.** Where by any law in force in Trinidad and Tobago, a standard is prescribed for a drug and that standard is given a name or designation by the law, no person shall use that name or designation on a label, or in any advertisement, of that drug, unless the drug conforms to the standard.

Parenteral, Third Schedule or controlled drugs.

First Schedule.

**43.** Where it is necessary to provide adequate directions for the safe use of parenteral drugs, Third Schedule drugs, or controlled drugs, that are used in the treatment or prevention of any of the diseases, disorders, or abnormal physical states, mentioned in the First Schedule to the Act, the diseases, disorders, or abnormal physical states may be mentioned in the inserts accompanying the drugs, and, to such extent, the drugs are hereby exempted from the provisions of section 4(1) of the Act.

Exemption from section 4(1).

**44.** A drug when distributed in accordance with section 13(2) of the Act is hereby exempted from the provisions of section 4(1) of the Act as regards any inserts accompanying the drug.

Drug in form of tablet.

**45.** (1) No person shall sell a drug in the form of a tablet which is intended to be swallowed whole, unless the tablet disintegrates in not more than 60 minutes when tested by the official method.

(2) Subregulation (1) does not apply to tablets which are represented on the label as being enteric coated, or as having delayed action.

Variations from declared quantity.

**46.** (1) Where the contents of a package of a drug are expressed in terms of weight, measure, or number, no variations from the quantity declared on the label are permitted except, subject to subregulation (2)—

*(a)* variations due exclusively to weighing, measuring, or counting, that occur in packaging conducted in accordance with good commercial practice, which variations are, except where the contents are expressed in terms of number, not to be such that the average content is less than the quantity declared on the label, as determined by the official method;

*(b)* variations due exclusively to differences in the capacity of containers resulting solely from unavoidable difficulties in manufacturing;

*(c)* variations in weight or measure that unavoidably result from the ordinary and customary exposure of the package to evaporation, or to the absorption of water, under normal atmospheric conditions; and

*(d)* where a drug, other than an official drug, consists of several ingredients, the amount of each ingredient so dispensed shall be not less than 90 per cent and not more than 110 per cent of the amount calculated from the label description.

(2) Where the contents of a package of a drug are expressed in terms of minimum weight, measure or number, the contents of the package shall not be less than the minimum expressed.

Caution on label of drug.

**47.** No person shall sell a drug—

*(a)* that contains salicylic acid or its salts, acetylsalicylic acid or its salts, or salicylamide; and

*(b)* that is recommended for children,

unless both the inner and the other labels carry a cautionary statement to the effect that the drug is not to be administered to children under two years of age except on the advice of a physician.

Third Schedule or a controlled drug not to be advertised.

**48.** No person shall advertise to the general public for human use a Third Schedule drug or a controlled drug.

Prohibition.

**49.** The importation and sale of Thalidomide is prohibited.

Second Schedule.

**50.** The provisions of the Second Schedule shall be read as one with this Part.

Contravention or non-compliance with Part III.

**51.** A person who contravenes a provision of this Part is liable on summary conviction to a penalty of three hundred dollars or to imprisonment for three months.

Date Regulations became effective.

**52.** These Regulations have effect from 1st January 1965.

## FIRST SCHEDULE

Regulation 30.
[94/1969
53/1972
105/1974
111/1986
72/1996
192/1999
199/1999
118/2003].

## DIVISION 1—BAKING POWDER

1. Baking Powder shall be a combination of sodium bicarbonate, an acid-reacting material mentioned in paragraph 2, and starch or other neutral material, and shall yield not less than 8 per cent of its weight of carbon dioxide as determined by the official method.

2. The acid-reacting material of baking powder shall be—

*(a)* tartaric acid or its salts or both; or

*(b)* acid salts of phosphoric acids.

## DIVISION 2—FOOD COLOURS

1. In this Division—

*(a)* "pure dye" means the synthetic dye contained in a synthetic food colour;

*(b)* "preparation" means a preparation of one or more synthetic food colours containing less than 15 per cent pure dye and sold for household use in containers of two ounces net or less.

2. (1) A carbonated beverage is adulterated if it contains—

*(a)* saccharin and its salts at levels in excess of 300 parts per million either as the sole sweetening agent or in combination with aspartame;

*(b)* aspartame and its salts at levels in excess of 0.1 per cent either as the sole sweetening agent or in combination with saccharin; or

*(c)* any other synthetic sweetening agent including cyclohexlysulphamic acid and its salts.

(2) The label on any carbonated beverage containing saccharin at levels of 300 parts per million and below shall carry statements to the effect that—

*(a)* the beverage is a diet drink;

*(b)* the beverage is sugar free;

*(c)* the beverage is low-calorie and carbonated;

*(d)* low-calorie drinks are not recommended for use by children;

*(e)* use of the beverage may be hazardous to health.

(3) The label on any carbonated beverage containing aspartame at levels of 0.1 per cent and below shall carry statements to the effect that—

*(a)* the beverage is a diet drink;

*(b)* the beverage is sugar free;

*(c)* the beverage is low-calorie and carbonated;

*(d)* low-calorie drinks are not recommended for use by children;

*(e)* the beverage contains phenylalanine and should not be taken by persons who are suffering from phenylketonuria.

3. No person shall sell a carbonated beverage that contains—

*(a)* saccharin and its salts at levels in excess of 300 parts per million either as the sole sweetening agent or in combination with aspartame;

*(b)* aspartame and its salts at levels in excess of 0.1 per cent either as the sole sweetening agent or in combination with saccharin; or

*(c)* any other synthetic sweetening agent including cyclohexlysulphamic acid and its salts.

4. No person shall sell a colour for use in or upon food that contains more than—

*(a)* two parts per million of arsenic, calculated as arsenic;

*(b)* ten parts per million of lead, calculated as lead, as determined by the official method; or

*(c)* except in the case of iron oxide, a total of 100 parts per million of iron and copper, calculated as iron and copper,

and if other heavy metals are present, the colour shall be deemed to be adulterated.

5. (1) No person shall import a synthetic food colour or a mixture or preparation of synthetic food colours for use in or upon food unless it has been certified by the Minister, or by another agency acceptable to the Minister, that the synthetic food colour or such mixture or preparation of synthetic food colours meets the requirements of paragraph 4, and, if certified by an agency, a copy of the certificate has been submitted to and approved by the Minister.

(2) For the purposes of subparagraph (1), a synthetic food colour or a mixture or preparation of synthetic food colours meets the requirements of paragraph 4 if the provisions thereof will not be contravened in a sale of the synthetic food colour or the mixture or preparation.

6. For the purposes of this Division, the following synthetic food colours shall, subject to paragraph 7, be deemed to be approved by the Minister:

*(a)* food colours certified by the Food and Drug Directorate of Canada;

*(b)* food colours certified by the Food and Drug Administration of the United States of America;

*(c)* colours permitted for use in food in the United Kingdom;

*(d)* synthetic food dyes approved for use in food by the Food and Agriculture Organisation of the United Nations and by the World Health Organisation;

*(e)* synthetic food dyes approved for use in food by the Australian Commonwealth Food Additives Committee.

7. Notwithstanding paragraphs 2, 3 and 6, the Minister may, on the advice of the Food Advisory Committee, withdraw, by notice published in the *Gazette*, approval with respect to any food colour which is toxic or capable of producing toxic effects; and on publication of any such notice, paragraphs 2, 3 and 6 shall cease to apply with respect to that food colour.

## DIVISION 3—DAIRY PRODUCTS

1. The foods referred to in this Division are included within the term "dairy product".

2. Except as provided in this Division, a dairy product that contains a fat other than milk fat is adulterated.

### MILK

3. **Milk or (Whole Milk)** shall be the normal lacteal secretion obtained from the mammary gland of the cow, genus Bos, and shall be free from colostrum, and shall contain—

*(a)* not less than 3.0 per cent of milk fat;

*(b)* not less than 8.5 per cent of milk solids not fat; and

*(c)* not more than 20 parts per million of dirt.

By dirt is meant all matter insoluble in, and foreign to, milk as it leaves the cow's udder.

The milk from animals other than bovine species shall be given a designation appropriate to its source.

4. **Milk Products** shall be products of which the components are exclusively derived from milk, and may contain added substances necessary for manufacture or intended to enrich the natural vitamins and salts in the products if these added substances do not replace, either completely or partly, any constituent whatsoever of milk.

5. **Reconstituted Milk** shall be labelled as such, and shall be a milk product resulting from the combining of milk constituents with water, and shall contain not less than—

*(a)* 3.0 per cent of milk fat; and

*(b)* 8.5 per cent of milk solids not fat.

6. **Milk Fat or Butter Fat** shall be the fat of cow's milk, and shall have—

*(a)* a specific gravity of not less than 0.905 at a temperature of 40°C.;

*(b)* a Reichert-Meissl number not less than 24; and

*(c)* a Polenske number not exceeding 10 per cent of the Reichert-Meissl number, and in no case shall the Polenske number exceed 3.5; and

where the Polenske number exceeds 10 per cent of the Reichert-Meissl number, there shall be deemed to have been an addition to the milk fat of fat other than that of cow's milk.

7. **Sterilised Milk** shall be milk, or a milk product, that has been heated to a temperature of at least 100°C. for a length of time sufficient to kill all the organisms present, and shall be delivered to the consumer in hermetically sealed containers, and shall contain not less than—

*(a)* 3 per cent of milk fat; and

*(b)* 8.5 per cent of milk solids not fat.

8. **Flavoured Sterilised Milk** shall be sterilised milk with cocoa, chocolate, or a flavouring preparation and shall contain not less than—

*(a)* 2.5 per cent of milk fat; and

*(b)* 8.5 per cent of milk solids not fat,

and may contain stabiliser and sugar.

9. **Condensed Milk or Sweetened Condensed Milk** shall be milk, or a milk product, from which water has been evaporated and to which sugar has been added, and shall contain not less than—

*(a)* 28 per cent of milk solids; and

*(b)* 8 per cent of milk fat,

and may contain added vitamin D.

10. **Evaporated Milk or Unsweetened Condensed Milk** shall be milk, or a milk product, from which water has been evaporated, and shall contain not less than—

*(a)* 25.0 per cent of milk solids;

*(b)* 7.5 per cent of milk fat;

and may contain—

*(c)* added vitamin D;

*(d)* disodium phosphate, or sodium citrate, or both, added in a total quantity of not more than 0.1 per cent of the finished product.

11. **Skim Milk (Skimmed Milk)** shall be milk from which all or most of the milk fat has been removed.

12. **Milk Powder, Dry Milk, Dry Whole Milk, Powdered Milk or Powdered Whole Milk** shall be dried milk, and shall contain not less than—

*(a)* 95 per cent of milk solids; and

*(b)* 26 per cent of milk fat,

and may contain added vitamin D.

13. **Skim (Skimmed) Milk Powder, Dry Skim (Skimmed) Milk or Powdered Skim (Skimmed) Milk** shall be dried skim milk and shall contain not less than 95 per cent of milk solids, and may contain added vitamin D.

14. **Partly Skimmed Milk Powder, or Half Cream Milk Powder** shall be dried milk and shall contain not less than—

*(a)* 95 per cent of milk solids; and

*(b)* 13 per cent of milk fat.

15. **Quarter Cream Milk Powder** shall be dried milk not being either dry whole milk or half cream milk powder and shall contain not less than—

*(a)* 95.0 per cent of milk solids; and

*(b)* 8.0 per cent of milk fat.

16. **Pasteurised Milk** shall be milk that has been pasteurised as in paragraph 18 and shall be delivered to the consumer in suitable capped or sealed containers.

17. No milk or milk product shall be labelled "Pasteurised" unless it has been treated in the manner described in paragraph 18.

18. (1) For the purposes of this Division—

"pasteurisation" means the process of heating every particle of milk or milk products either—

*(a)* to a temperature of not less than 62.8°C. (145°F.) holding it at such temperature for a period of not less than 30 minutes, cooling it immediately thereafter to a temperature of 10.0°C. (50°F.) or lower; or

*(b)* to a temperature of not less than 71.7°C. (161°F.) holding it at such temperature for a period of not less than 15 seconds, cooling it immediately thereafter to a temperature of 10.0°C. (50°F.) or lower; and

"pasteurised" shall be construed accordingly.

(2) Pasteurisation shall be carried out under conditions of processing approved by the Director.

19. **Butter** shall be the food, prepared by gathering the milk fat of milk or cream into a mass that may also contain a portion of the other milk constituents not separated in good manufacturing practice, and shall contain—

*(a)* not less than 80 per cent of milk fat; and

*(b)* not more than 16 per cent of moisture,

and may contain salt and food colour.

20. **Cooking Butter** shall be labelled as such, and shall be butter prepared as described in paragraph 19, and shall contain—

*(a)* not less than 80 per cent of milk fat; and

*(b)* not more than 12 per cent of salt; and

*(c)* not more than 0.25 per cent of free fatty acids expressed as butyric acid, and may contain food colour.

21. **Ghee** shall contain not less than 98 per cent of milk fat, without any admixture of other fat.

22. **Ice Cream** shall be the frozen food made from milk or milk products and sweetened with sugar, and shall contain not less than—

*(a)* 8 per cent of fat;

*(b)* 36 per cent of solids;

*(c)* 7.5 per cent of milk solids not fat;

*(d)* 1.8 pounds of solids per Imperial gallon;

and may contain—

*(e)* edible oil or fat;

*(f)* egg;

*(g)* flavouring preparation;

*(h)* cocoa or chocolate syrup;

*(i)* food colour;

*(j)* acid-reducing salts;

*(k)* fruit, nuts, confections; and

*(l)* stabilisers comprising—

(i) not more than 1.0 per cent of gelatin alone; or

(ii) not more than 0.5 per cent of other stabiliser; or

(iii) not more than 0.75 per cent of a mixture of gelatin and other stabilisers, of which the proportion of other stabilisers may not exceed 0.25 per cent.

23. No person shall sell ice cream in which the complete mixture has not been pre-treated or pasteurised immediately before freezing in accordance with conditions approved by the Director.

For the purpose of this paragraph, "pre-treated" means that the complete mixture shall be brought to the boil and cooled in a covered container.

24. **Dairy Ice Cream** shall be ice cream as defined in paragraph 22 except that all the fat therein shall be milk fat only, except such traces as may be introduced by the use as an ingredient of any egg, any flavouring substance or any emulsifying or stabilising agent.

25. **Ultra Heat Treated Milk, or U.H.T. Milk,** shall be milk that has been heated at a temperature of 132.2°C. (270°F.) for a period of not less than one second. The following requirements shall be satisfied in its processing:

*(a)* any apparatus in which the milk is to be heated to and maintained at a temperature of not less than 132.2°C. (270°F.) shall be provided with a device which shall automatically divert the flow of any milk which is not raised to the authorised temperature;

*(b)* any indicating and recording thermometers as the Director shall reasonably consider necessary shall be installed in suitable places in the apparatus in which the milk is treated by the ultra high temperature method so as to indicate the temperatures to which the milk is heated;

*(c)* the records of recording thermometers shall be marked with graduations of 2°F., adequately spaced to give clear readings, and they shall be dated and shall be preserved for a period of not less than three months;

*(d)* a sample of milk taken in accordance with the official method from a batch of milk after treatment by the ultra high temperature method and before delivery to the consumer shall satisfy the colony count test prescribed in the official method;

*(e)* milk which is treated by the ultra high temperature method shall immediately after the treatment be put into sterile containers in which it is to be supplied to the consumer. The containers shall be filled and sealed at the premises at which the treatment has been carried out with such aseptic precautions as will ensure the protection of the milk from risk of contamination;

*(f)* every container in which milk treated by the ultra high temperature method is transported, exposed or offered for sale shall be so closed and securely fastened, either with a cap overlapping the lip of the container or in some other suitable manner approved by the Director, that the container is airtight;

*(g)* every cap closing a container of milk treated by the ultra high temperature method shall be conspicuously and legibly labelled and marked with the words "Ultra Heat Treated Milk" or "U.H.T. Milk", and shall also bear the name and address of the person by whom the milk was put into the container, and, except with the approval of the Director, the cap shall bear no other words. If there is no cap on which the words and the name and address of such person can suitably be marked, they shall be marked within a surrounding line in a prominent position on the container, and except with the approval of the Director, no other words shall be placed within the surrounding line.

## DIVISION 4—EDIBLE OILS AND FATS

1. **Cooking Oil or Edible Oil** shall be a refined product of coconut oil, and shall contain not more than 0.08 per cent of acid expressed as lauric acid, and may contain such other oil as may be approved by the Minister.

2. **Cooking Butter Substitute or Cooking Margarine** shall be labelled as such, and shall contain—

*(a)* not less than 80 per cent of fat; and

*(b)* not more than 12 per cent of salt; and

may contain food colour, preservative and added vitamins.

3. **Margarine** shall be labelled as such and shall contain not less than 80 per cent of fat, and may contain food colour, preservative, salt, and added vitamins.

4. **Phalka Ghee, Ghee Substitute or Vegetable Ghee** shall contain not less than 98 per cent of fat other than animal fat.

5. **Olive Oil** shall be the oil of the fruit of the olive tree and shall have—

*(a)* a specific gravity at 20°/20°C. of not less than 0.910 and not more than 0.918;

*(b)* a refractive index at 40°C. of between 1.4605 and 1.4635;

*(c)* an Iodine value (Hanus) of not less than 78 and not more than 88; and

*(d)* a saponification value of not less than 185 and not more than 195.

6. **Vegetable Fats and Oils** shall be obtained entirely from the botanical source after which they are named, and shall be prepared or processed so as to be dry and sweet in flavour and odour, and may contain Class IV preservative.

7. **Animal Fats and Oils** shall be obtained entirely from animals healthy at the time of slaughter, and shall be prepared or processed so as to be dry and sweet in flavour and odour, and may contain Class IV preservative.

8. **Soya Bean Oil or Soybean Oil** shall be the oil derived from soya beans [the seeds of *Glycine max* (L.) Merr.] and shall have—

*(a)* the following characteristics of identity:

(i) a density at 20°C. relative to water at 20°C. of not less than 0.919 and not more than 0.925;

(ii) a refractive index at 40°C. ($n_D$40°C.) between 1.466 and 1.470;

(iii) an iodine value (Wijs) of not less than 120 and not more than 143;

(iv) a saponification value of not less than 189 and not more than 195 mg. KOH per gram of oil;

(v) a maximum of 1.5 per cent of unsaponifiable matter; and

*(b)* the following characteristics of quality:

(i) the colour, odour, and taste shall be characteristic of soyabean oil with no foreign or rancid odour or taste;

(ii) the maximum acid value shall be 0.6 mg. KOH per gram of oil;

(iii) the maximum peroxide value shall be 10.0 milli-equivalents of oxygen per kilogram of oil.

9. **Peanut Oil, Groundnut Oil, or Arachis Oil** shall be the oil derived from groundnuts ( the seeds of *Arachis hypogaea* L.) and shall have—

*(a)* the following characteristics of identity:

(i) a density at 20°C. relative to water at 20°C. of not less than 0.914 and not more than 0.917;

(ii) a refractive index at 40°C. ($_{nD}$40°C.) between 1.460 and 1.465;

(iii) an iodine value (Wijs) of not less than 80 and not more than 106;

(iv) a saponification value of not less than 187 and not more than 196 mg. KOH per gram of oil;

(v) a maximum of 1.0 per cent of unsaponifiable matter; and

*(b)* the following characteristics of quality:

(i) the colour, odour, and taste shall be characteristic of groundnut oil, with no foreign or rancid odour or taste;

(ii) the acid value shall not be greater than 4.0 mg. KOH per gram of virgin groundnut oil or greater than 0.6 mg. KOH per gram of non-virgin groundnut oil;

(iii) the maximum peroxide value shall be 10.0 milli-equivalents of oxygen per kilogram of oil;

(iv) the minimum percentage of arachidic and higher fatty acids shall be 4.8 per cent when determined by an acceptable method.

10. **Edible Cottonseed Oil** shall be the oil derived from the seeds of various cultivated species of *Gossypium* and shall have—

*(a)* the following characteristics of identity:

(i) a density at 20°C. relative to water at 20°C. of not less than 0.918 and not more than 0.926;

(ii) a refractive index at 40°C. ($n_D$40°C.) between 1.458 and 1.466;

(iii) an iodine value (Wijs) of not less than 99 and not more than 119;

(iv) a saponification value of not less than 189 and not more than 198mg. KOH per gram of oil;

(v) a maximum of 1.5 per cent of unsaponifiable matter;

(vi) a positive Halphen test; and

*(b)* the following characteristics of quality:

(i) the colour, odour, and taste shall be characteristic of edible cottonseed oil, with no foreign or rancid odour or taste;

(ii) the maximum acid value shall be 0.6 mg. KOH per gram of oil;

(iii) the maximum peroxide value shall be 10.0 milli-equivalents of oxygen per kilogram of oil.

11. **Edible Sunflower Seed Oil (or Sunflower Oil or Sunflowerseed Oil)** shall be the oil derived from sunflower seeds (the seeds of *Helianthus annuus*. L.) and shall have—

*(a)* the following characteristics of identity:

(i) a density at 20°C. relative to water at 20°C. of not less than 0.918 and not more than 0.923;

(ii) a refractive index at 40°C. ($n_D$40°C.) between 1.467 and 1.469;

(iii) an iodine value (Wijs) of not less than 110 and not more than 143;

(iv) a saponification value of not less than 188 and not more than 194 mg. KOH per gram of oil;

(v) a maximum of 1.5 per cent of unsaponifiable matter;

*(b)* the following characteristics of quality:

(i) the colour, taste, and odour shall be characteristic of edible sunflowerseed oil, with no foreign or rancid odour or taste;

(ii) the acid value shall not be greater than 4.0 mg. KOH per gram of virgin sunflowerseed oil, or greater than 0.6 mg. KOH per gram of non-virgin sunflowerseed oil;

(iii) the maximum peroxide value shall be 10.0 milli-equivalents of oxygen per kilogram of oil.

12. **Rapeseed Oil (or Rape Oil, or Colza Oil, or Ravison Oil or Sarson Oil)** shall be the oil derived from the seeds of *Brassica campestris* L., *Brassica napus* L., and *Brassica tournefortii* Gouan., and shall have—

*(a)* the following characteristics of identity:

(i) a density at 20°C. relative to water at 20°C. of not less than 0.910 and not more than 0.920;

(ii) a refractive index at 40°C. ($n_D$40°C.) between 1.465 and 1.469;

(iii) an iodine value (Wijs) of not less than 94 and not more than 120;

(iv) a saponification value of not less than 168 and not more than 181 mg. KOH per gram of oil;

(v) a maximum of 2.0 per cent of unsaponifiable matter;

(vi) a Crismer Value of not less than 80 and not more than 85; and

*(b)* the following characteristics of quality:

(i) the colour, taste, and odour shall be characteristic of rapeseed oil, with no foreign or rancid odour or taste;

(ii) the acid value shall be not greater than 4.0 mg. KOH per gram of virgin rapeseed oil, or not greater than 0.6 mg. KOH per gram of non-virgin rapeseed oil;

(iii) the maximum peroxide value shall be 10.0 milli-equivalents of oxygen per kilogram of oil.

13. **Maize Oil (or Corn Oil)** shall be the oil derived from maize germ (the embryos of *Zea mays* L.) and shall have—

*(a)* the following characteristics of identity:

(i) a density at 20°C. relative to water at 20°C. of not less than 0.917 and not more than 0.925;

(ii) a refractive index at 40°C. ($n_D$40°C.) between 1.465 and 1.468;

(iii) an iodine value (Wijs) of not less than 103 and not more than 128;

(iv) a saponification value of not less than 187 and not more than 195 mg. KOH per gram of oil;

(v) a maximum of 2.8 per cent of unsaponifiable matter; and

*(b)* the following characteristics of quality:

(i) the colour, odour, and flavour shall be characteristic of maize oil, with no foreign or rancid odour or taste;

(ii) the acid value shall be not greater than 4.0 mg. KOH per gram of virgin maize oil, or not greater than 0.6 mg. KOH per gram of non-virgin maize oil;

(iii) the maximum peroxide value shall be 10.0 milli-equivalents of oxygen per kilogram of oil.

14. **Sesameseed Oil (or Sesame Oil, or Benne Oil or Ben Oil, or Gingelly Oil, or Till Oil)** shall be the oil derived from sesame seeds ( the seeds of *Sesamum indicum* L.) and shall have—

*(a)* the following characteristics of identity:

(i) a density at 20°C. relative to water at 20°C. of not less than 0.915 and not more than 0.923;

(ii) a refractive index at 40°C. ($_{n_D}$40°C.) between 1.465 and 1.469;

(iii) an iodine value (Wijs) of not less than 104 and not more than 120;

(iv) a saponification value of not less than 187 and not more than 195 mg. KOH per gram of oil;

(v) a maximum of 2.0 per cent of unsaponifiable matter;

(vi) a positive Baudouin test; and

*(b)* the following characteristics of quality:

(i) the colour, odour and flavour shall be characteristic of sesameseed oil, with no foreign or rancid odour or taste;

(ii) the acid value shall be not greater than 4.0 mg. KOH per gram of virgin sesameseed oil, or not greater than 0.6 mg. KOH per gram of non-virgin sesameseed oil;

(iii) the maximum peroxide value shall be 10.0 milli-equivalents of oxygen per kilogram of oil.

15. **Safflowerseed oil (or Safflower oil, or Carthamus Oil or Kurdee Oil)** shall be the oil derived from safflowerseeds (the seeds of *Carthamus tinctorius* L.) and shall have—

*(a)* the following characteristics of identity:

(i) a density at 20°C. relative to water at 20°C. of not less than 0.922 and not more than 0.927;

(ii) a refractive index at 40°C. ($_{n_D}$40°C.) between 1.467 and 1.470;

(iii) an iodine value (Wijs) of not less than 135 and not more than 150;

(iv) a saponification value of not less than 186 and not more than 198 mg. KOH per gram of oil;

(v) a maximum of 1.5 per cent of unsaponifiable matter; and

*(b)* the following characteristics of quality:

(i) the colour, odour and flavour shall be characteristic of safflowerseed oil, with no foreign or rancid odour or taste;

(ii) the maximum acid value shall be 0.6 mg. KOH per gram of safflowerseed oil;

(iii) the maximum peroxide value shall be 10.0 milli-equivalents of oxygen per kilogram of oil.

16. **Mustardseed Oil (or Mustard Oil)** shall be the oil derived from the seeds of the white mustard *(Sinapis alba* L. synonym *Brassica hirta* Moench.), the brown mustard *(Brassica juncea* L. Czern. and Coss.), and of the black mustard *(Brassica nigra* L. Koch.) and shall have—

*(a)* the following characteristics of identity:

(i) a density at 20°C. relative to water at 20°C. of not less than 0.910 and not more than 0.921;

(ii) a refractive index at 40°C. ($_{n_D}$40°C.) between 1.461 and 1.469;

(iii) an iodine value (Wijs) of not less than 92 and not more than 125;

(iv) a saponification value of not less than 170 and not more than 184 mg. KOH per gram of oil;

(v) a maximum of 1.5 per cent of unsaponifiable matter;

(vi) a maximum of 0.4 per cent of allyl isothiocyanate, as determined by an acceptable method; and

*(b)* the following characteristics of quality:

(i) the colour, odour and flavour shall be characteristic of mustardseed oil, with no foreign or rancid odour or taste;

(ii) the acid value shall be not greater than 4.0 mg. KOH per gram of virgin mustardseed oil, or not greater than 0.6 mg. KOH per gram of non-virgin mustardseed oil;

(iii) the maximum peroxide value shall be 10.0 milli-equivalents of oxygen per kilogram of oil.

## DIVISION 5—FLAVOURING PREPARATIONS

1. A flavouring extract or essence shall be a solution in ethyl alcohol, glycerol, or propylene glycol, or any combination of these, of sapid or odorous principles, or both, and shall be derived from the plant after which the flavouring extract or essence is named, and may contain—

*(a)* water;

*(b)* a sweetening agent;

*(c)* food colour; and

*(d)* a Class II or Class IV preservative.

2. Where a flavouring extract or essence is mixed with other flavouring extracts or essences, the label shall carry a statement of the names of all the extracts or essences so mixed and each of those names shall be deemed to comprise the name of the extract or essence.

3. An artificial, imitation, substitute, or synthetic flavouring extract or essence shall be a flavouring extract or essence except that the flavouring principles shall be derived in whole, or in part, from sources other than the aromatic plant after which it is named.

## DIVISION 6—POISONOUS SUBSTANCES IN FOOD

1. No person shall sell any food in a container that may yield to its contents any substance that may be injurious to the health of a consumer of the food.

2. Except as otherwise provided, a food named in the Table herein set forth, which contains in or upon it—

*(a)* any or all of the poisonous or harmful substances listed in the Table in amounts not exceeding the quantities stated therein in parts per million (p.p.m.) for that food, as determined by an acceptable method; and either

*(b)* no other poisonous or harmful substances; or

*(c)* other poisonous or harmful substances in amounts not considered by the Minister likely to be injurious to health,

is hereby exempted from the provision of section 5*(a)* of the Act.

| FOOD | SUBSTANCE | | | |
|---|---|---|---|---|
| | Arsenic p.p.m. | Lead p.p.m. | Copper p.p.m. | Zinc p.p.m. |
| Citric Acid ... ... ... ... ... | 1 | 10 | 50 | 50 |
| Tartaric Acid ... ... ... ... | 1 | 10 | 50 | 50 |
| Cream of Tartar ... ... ... ... | 2 | 20 | 50 | 50 |
| Sodium Bicarbonate ... ... ... ... | 2 | 5 | 50 | 50 |
| Baking Powder ... ... ... ... | 2 | 10 | 50 | 50 |
| PhosphoricAcid ... ... ... ... | 4 | 5 | 30 | 30 |
| Calcium Phosphate ... ... ... ... | 4 | 5 | 30 | 30 |
| Sodium, Potassium and Ammonium Phosphates ... | 4 | 5 | 30 | 30 |
| Sodium and Potassium Nitrates ... ... ... | 1 | 10 | 50 | 50 |
| Sodium Nitrite ... ... ... ... | 1 | 20 | 50 | 50 |
| Marine and Fresh Water Animal Products ... ... | 5 | 10 | 100 | 100 |
| Fresh Fruits ... ... ... ... | 2 | 7 | 50 | 50 |
| Fresh Vegetables ... ... ... ... | 1 | 2 | 50 | 50 |
| Gelatin ... ... ... ... ... | 2 | 7 | 30 | 100 |
| Gelling agents except Gelatin ... ... ... | 2 | 20 | 50 | 200 |
| Dried Herbs and Spices ... ... ... | 5 | 10 | 50 | 50 |
| Apple Juice, Cider, Wine and Beer ... ... | 0.2 | 0.5 | 2 | 5 |
| Fruit Juice except Apple Juice ... ... ... | 0.1 | 0.2 | 2 | 5 |
| Beverages ... ... ... ... ... | 0.1 | 0.2 | 2 | 5 |
| Tea ... ... ... ... ... | 1 | 10 | 150 | 50 |

3. Except as otherwise provided, a food not named in the Table to paragraph 2 which contains in or upon it—

*(a)* not more than—

(i) one part per million of arsenic;

(ii) two parts per million of lead;

(iii) twenty parts per million of copper; or

(iv) fifty parts per million of zinc, as determined by an acceptable method and either;

*(b)* no other poisonous or harmful substances; or

*(c)* other poisonous or harmful substances in amounts not considered by the Minister likely to be injurious to health,

is hereby exempted from the provision of section 5*(a)* of the Act.

## DIVISION 7—PRESERVATIVES

1. For the purposes of this Division—

*(a)* Class I preservatives comprise the following:

(i) ethyl alcohol;

(ii) ascorbic acid, iso-ascorbic acid, and their salts;

(iii) glucose;

(iv) potassium nitrate;
(v) common salt;
(vi) sodium nitrate;
(vii) sodium nitrate in preserved meat only, in an amount not exceeding 200 parts per million of the finished product;
(viii) spices;
(ix) cane sugar;
(x) vinegar;
(xi) wood smoke;
(xii) nisin in canned foods, provided that the cans are hermetically sealed and the foods sufficiently heat processed so as to destroy any clostridium botulinum in the foods or cans, or nisin in canned foods with a $P^H$ of less than 4.5, or in cheese clotted cream;

*(b)* Class II preservatives comprise the following:
(i) benzoic acid, including salts thereof;
(ii) sulphurous acid, including salts thereof;
(iii) sorbic acid, including salts thereof;
(iv) methyl para-hydroxybenzoate;
(v) propyl para-hydroxybenzoate;

*(c)* Class III preservatives comprise the following:
(i) propionic acid, including salts thereof;
(ii) sodium diacetate;
(iii) sorbic acid, including salts thereof;

*(d)* Class IV preservatives comprise the following, whether used with or without a harmless carrier:
(i) gum guaiacum;
(ii) vegetable oils containing tocopherols;
(iii) lecithin;
(iv) citric, tartaric, or ascorbic acid;
(v) monoisopropyl citrate;
(vi) ascorbyl palmitate;
(vii) n-propyl gallate, or n-octyl gallate, or n-dodecyl gallate;
(viii) nordihydroguaiaretic acid;
(ix) butylated hydroxyanisole;
(x) butylated hydroxytoluene.

2. Where any Class II, Class III, or Class IV preservative is sold for use as a preservative for food, the label shall carry adequate directions for use in accordance with the limits prescribed for the preservative in this Division.

3. Notwithstanding regulation 16(1)*(b)*—

*(a)* no label declaration is required for the presence of sulphurous acid or its salts in or upon the following:

(i) sweetening agents;

(ii) beer and stout;

(iii) syrups;

(iv) wine;

(v) confectionery; and

*(b)* no label declaration is required for the presence of a Class III preservative, in or upon the following:

(i) bakery products;

(ii) cheese.

4. No person shall use as a preservative in or upon food, or sell as a preservative for food, any substance other than Class I, Class II, Class III or Class IV preservatives.

5. No person shall sell—

*(a)* benzoic acid or its salts;

*(b)* sulphurous acid or its salts;

*(c)* n-propyl gallate, n-octyl gallate or n-dodecyl gallate;

*(d)* butylated hydroxyanisole;

*(e)* nordihydroguaiaretic acid;

*(f)* butylated hydroxytoluene;

*(g)* methyl para-hydroxybenzoate;

*(h)* propyl para-hydroxybenzoate;

*(i)* nisin,

for use as a preservative for food, unless the label carries a quantitative statement of the amounts of the preservative present.

6. No person shall use in or upon a food more than one Class II preservative.

7. No person shall use in or upon a food, more than—

*(a)* 1,000 parts per million of benzoic acid or its salts, calculated as benzoic acid;

*(b)* 1,000 parts per million of sorbic acid or its salts, calculated as sorbic acid;

*(c)* 1,000 parts per million of methyl para-hydroxybenzoate; or

*(d)* 1,000 parts per million of methyl para-hydroxybenzoate.

8. Except as provided in this Division, no person shall use sulphurous acid or its salts, calculated as sulphur dioxide, in amounts greater than—

*(a)* 100 parts per million in beverages as prepared for consumption;

*(b)* 2,500 parts per million in or upon dried fruits and vegetables; or

*(c)* 500 parts per million in or upon other foods.

9. No person shall use in or upon a food, more than—

*(a)* 2,000 parts per million of propionic acid or its salts, calculated as propionic acid;

*(b)* 3,000 parts per million of sodium diacetate; or

*(c)* 1,000 parts per million of sorbic acid or its salts, calculated as sorbic acid.

10. No person shall use in or upon a food, Class IV preservatives, singly or in combination, including the carrier, in an amount greater than 0.2 per cent of the finished product.

11. No person shall use in or upon a food more than—

*(a)* 0.01 per cent of n-propyl gallate, n-octyl gallate, or n-dodecyl gallate;

*(b)* 0.01 per cent of nordihydroguaiaretic acid;

*(c)* 0.02 per cent of butylated hydroxyanisole;

*(d)* 0.02 per cent of butylated hydroxytoluene; or

*(e)* 0.02 per cent of a combination of not more than three of the Class IV preservatives listed in subparagraphs *(a)*, *(b)*, *(c)* and *(d)*.

12. No person shall use in or upon a food a combination of nordihydroguaiaretic acid and n-propyl gallate or n-octyl gallate or n-dodecyl gallate.

## DIVISION 8—VINEGAR AND DILUTE ACETIC ACID (FOOD GRADE)

1. **Vinegar** shall be the liquid obtained by the acetous fermentation of an alcoholic liquid, and subject to paragraph 7, shall contain not less than 4.0 per cent nor more than 12.0 per cent of acetic acid.

2. **Wine Vinegar** shall be vinegar made from wine, and may contain caramel.

3. **Spirit Vinegar or Alcohol Vinegar, Distilled Molasses Vinegar, White Vinegar or Grain Vinegar** shall be vinegar made from diluted distilled alcohol.

4. **Malt Vinegar** shall be vinegar made from an infusion of malt undistilled prior to acetous fermentation, and may contain other cereals and caramel.

5. **Cider Vinegar or Apple Vinegar** shall be vinegar made from the liquid expressed from apples, and may contain caramel.

6. If any reference is made to the strength of a vinegar by any statement, mark, or device on the label of or in any advertisement of a vinegar, the label shall carry a statement of the strength of the vinegar declared in per cent, and the strength of the vinegar shall be calculated in terms of acetic acid.

7. The maximum limit for the acetic acid content of vinegar does not apply to vinegar sold for manufacturing use only, if the vinegar is so identified by the use of the words, "For Manufacturing Use Only" on the label of the package.

8. Solutions of acetic acid prepared by diluting concentrated or glacial acetic acid with water, with or without the addition of food colour or other material, shall not be sold in any package bearing on the label the word "Vinegar" or the words "Salad Dressing" or any other word or words which may lead the purchaser to believe that the contents consist either wholly or in part of vinegar as defined in paragraph 1.

9. Solutions of acetic acid prepared as described in paragraph 8 shall, subject to paragraph 10, be labelled "Dilute Acetic Acid (Food Grade)" and shall contain not less than 4.0 per cent, nor more than 12.0 per cent of acetic acid.

10. Paragraph 9 does not apply to the preparation and sale in registered pharmacies of acetic acid solutions for medicinal purposes.

## DIVISION 9—FRUIT JUICES

1. **Canned Fruit Juice** shall be the unfermented liquid expressed from sound, ripe, fresh fruit, and may contain—

*(a)* sweetening agent; and

*(b)* a Class II preservative,

and shall be packed in hermetically sealed metal containers.

2. **Canned Grapefruit Juice** shall be the fruit juice obtained from grapefruit, and shall contain, in 100 millilitres measured at a temperature of 20°C.—

*(a)* not less than 9.5 grams of soluble solids before addition of any sweetening agent;

*(b)* not less than 0.3 grams of ash; and

*(c)* not less than 1.0 gram and not more than 2.2 grams of acid calculated as anhydrous citric acid,

and shall be packed in hermetically sealed metal containers.

3. **Canned Orange Juice** shall be the fruit juice obtained from oranges, and shall contain in 100 millilitres measured at a temperature of 20°C.—

*(a)* not less than 10 grams of soluble solids before addition of any sweetening agent;

*(b)* not less than 0.4 grams of ash; and

*(c)* not less than 0.5 grams and not more than 1.9 grams of acid calculated as anhydrous citric acid,

and shall be packed in hermetically sealed metal containers.

4. The label of canned fruit juice shall carry a declaration by name of any added sweetening agent.

## DIVISION 10—COFFEE

1. **Green Coffee, Raw Coffee or Unroasted Coffee** shall be the seed of *Coffea arabica* L., C. liberica Hiern., or *C. robusta* chev., freed from all but a small portion of its spermoderm.

2. **Coffee (Roasted Coffee)** shall be roasted green coffee, and shall contain—

*(a)* no other added or extraneous matter, except added sugar to the extent of not more than 10 per cent;

*(b)* not more than 6 per cent of total ash;

*(c)* not more than 25 per cent of water-soluble extract before addition of any sugar, as determined by an acceptable method.

3. **Instant Coffee** shall be a dried, aqueous extract of pure coffee, and may contain such added carbohydrate material as may be found necessary or desirable for good manufacturing practice.

4. Notwithstanding regulation 17, no person shall sell any coffee containing added sugar in a package unless the package is distinctly labelled with the words "contains added sugar".

## DIVISION 11—SYNTHETIC SWEETENERS

1. For the purpose of this Division, "synthetic sweetener" means a low calorie non-nutritive sweetener which provides little or no energy while having a high intensity sweetening purpose.

2. Subject to paragraph 3, the following synthetic sweeteners shall be deemed to be approved by the Minister:

*(a)* synthetic sweeteners certified by the Food and Drug Directorate of Canada;

*(b)* synthetic sweeteners certified by the Food and Drug Administration of the United States of America;

*(c)* synthetic sweeteners certified for use by the European Union;

*(d)* synthetic sweeteners approved for use in food by the Food and Agriculture Organisation of the United Nations and by the World Health Organisation; and

*(e)* synthetic sweeteners approved by the Codex Alimentaries Commission.

3. (1) The Minister may on his own or on the advice of the Food and Advisory Committee withdraw the approval with respect to any synthetic sweetener which may be hazardous to health.

(2) A withdrawal under subregulation (1) shall be by Notice published in the *Gazette*.

(3) Where a Notice has been published with respect to a synthetic sweetener under these Regulations, an approval with respect to that synthetic sweetener shall cease.

(4) The Minister may, on the advice of the Food Advisory Committee stipulate the proportions and conditions for any synthetic sweetener for use in any food.

(5) For the purpose of this Division "carbonated beverage" means a non-alcoholic beverage that is impregnated with carbon dioxide under pressure and is package for sale in hermetically sealed containers.

(6) A carbonated beverage is adulterated if it contains—

*(a)* saccharin and salts at levels in excess of 300 parts per million either as a sole sweetener or in combination with any other synthetic sweetener(s);

*(b)* aspartame at levels in excess of 1000 parts per million either as a sole sweetener or in combination with any other synthetic sweetener(s);

*(c)* acesulfame potassium at levels in excess of 350 parts per million either as a sole sweetener or in combination with any other synthetic sweetener(s);

*(d)* sucralose at levels in excess of 250 parts per million either as a sole sweetener or in combination with any other synthetic sweetener(s); or

*(e)* any other synthetic sweetener or any combination of synthetic sweetener(s) not approved by the Minister.

4. (1) The label on any carbonated beverage containing saccharin and its salts at levels of 300 parts per million and below either as a sole sweetener or in combination with any other synthetic sweetener(s) shall carry statements to the effect that—

*(a)* the beverage is a diet drink;

*(b)* the beverage is sugar free; and

*(c)* the beverage is low-calorie and carbonated.

(2) The label on any carbonated beverage containing aspartame—

*(a)* at levels of 1000 parts per million and below either as a sole sweetener or in combination with any other synthetic sweetener(s) shall carry statements to the effect that—

(i) the beverage is a diet drink;

(ii) the beverage is sugar free; and

(iii) the beverage is low-calorie and carbonated;

*(b)* shall carry a statement to the effect that the beverage contains phenylalanine and should not be taken by persons who are suffering from phenylketonuria.

(3) The label on any carbonated beverage containing acesulfame potassium at levels 350 parts per million and below either as a sole sweetener or in combination with any other synthetic sweetener(s) shall carry statements to the effect that—

*(a)* the beverage is a diet drink;

*(b)* the beverage is sugar free; and

*(c)* the beverage is low-calorie and carbonated.

(4) The label on any carbonated beverage containing sucralose at levels 250 parts per million and below either as a sole sweetener or in combination with any other synthetic sweetener(s) shall carry statements to the effect that—

*(a)* the beverage is a diet drink;

*(b)* the beverage is sugar free; and

*(c)* the beverage is low-calorie and carbonated low-calorie drinks are not recommended for use by children.

5. No person shall set a carbonated beverage that contains—

*(a)* saccharin and its salts at levels in excess of 300 parts per million either as a sole synthetic sweetener or in combination with any other synthetic sweetener(s);

*(b)* apartame at levels in excess of 1000 parts per million as the sole sweetening agent or in combination with any other synthetic sweetener(s);

*(c)* acesulfame potassium at levels in excess of 350 parts per million either as a sole synthetic sweetener or in combination with any other synthetic sweetener(s);

*(d)* sucralose at levels in excess of 250 parts per million either as the sole sweetening agent or in combination with any other synthetic sweetener(s); or

*(e)* any other synthetics sweetener or any combination of synthetic sweetener(s) not approved by the Minister.

## DIVISION 12—GRAIN AND BAKERY PRODUCTS

**Flour (White Flour)—**

*(a)* shall be the food prepared by the grinding and bolting through cloth having openings not larger than those of woven wire cloth designation "149 microns (No. 100)", of cleaned milling grades of wheat;

*(b)* shall be free from bran coat and germ to such extent that the percentage of ash therein, calculated on a moisture-free basis, does not exceed 1.20 per cent;

*(c)* shall have a moisture content of not more than 15 per cent; and

*(d)* may contain—

(i) malted wheat flour;

(ii) malted barley flour in an amount not exceeding 0.50 per cent of the weight of the flour;

(iii) such other harmless additives as are approved by the Director;

*(e)* shall contain in a harmless carrier in one pound of flour—

(i) not less than 2.0 mg., and not more than 2.5 mg., of thiamine;

(ii) not less than 1.2 mg., and not more than 1.5 mg., of riboflavin;

(iii) not less than 13.0 mg., and not more than 16.5 mg., of iron; and

(iv) not less than 500 mg., and not more than 650 mg., of calcium;

*(f)* and shall be free from the additive Potassium Bromate.

## DIVISION 13—MEAT AND PROCESSED MEAT

1. In this Division—

"accepted method" means any commonly accepted practice used by the various ethnic and religious groups in Trinidad and Tobago or any officially recognised practice for killing animals for the purpose of food;

"animal" means any animal used as food, but does not include marine or fresh water animals;

"filler" means—

*(a)* flour or meal prepared from grain, or from other farinaceous edible vegetable (excluding legumes);

*(b)* bread, biscuits, or bakery products, excluding those made with legumes;

*(c)* milk powder, skim milk powder, butter milk powder, or whey powder;

"type" means the common name denoting the animals from which the food was derived, such as beef, veal, pork, lamb, mutton, goat, poultry and other common names.

2. **Meat** shall be the edible part of the skeletal muscle of an animal which was healthy at the time of slaughter, or muscle that is found in the tongue, heart or oesophagus, with or without the accompanying and overlying fat, together with the portions of bone, skin, sinew, nerve and blood vessels that normally accompany the muscle tissue and are not separated from it in the lips, snout, scalp or ears.

3. **Meat By-product** shall be any edible part of an animal, other than meat, that has been derived from one or more animals, which were healthy at the time of slaughter.

4. **Prepared Meat, or Prepared Meat By-Product** shall be meat or meat by-product respectively whether comminuted or not, to which has been added any other ingredient permitted by these Regulations, or which has been preserved, canned or cooked.

5. Meat, meat by-product or preparations thereof, are adulterated if any of the following substances or class of substance is present therein, or has been added thereto:

*(a)* mucous membranes, any organ or portion of the genital system, black gut, spleens, udders, lungs, or any other organs or portions of an animal that are not commonly sold as an article of food;

*(b)* preservatives, other than Class I preservatives;

*(c)* colour other than caramel.

6. A food that consists wholly or in part of a meat by-product or a prepared meat by-product shall be labelled with—

*(a)* the words "meat by-product"; and

*(b)* the name of the meat by-product.

7. The carcass or any part thereof of an animal used for food shall be obtained from an animal killed by an accepted method.

8. No animal shall be used for food which was affected with disease at the time it was killed.

9. No person shall sell as food the carcass of an animal or any part thereof that was not killed by an accepted method, or of an animal that was affected with disease at the time it was killed.

10. No person shall sell as food, meat, meat by-products, preparations containing meat and meat derivatives obtained, prepared, or manufactured from the carcass of an animal that was not killed by an accepted method, or from an animal that was affected with disease at the time it was killed.

11. Where meat, meat by-product, or preparations thereof are derived from an animal killed by an accepted method associated with a religious or ethnic group, the food shall be labelled appropriately—

*(a)* "Halal", for animals killed by the method accepted by the religion of Islam;

*(b)* "Kosher", for animals killed by the method accepted by the Jewish religion.

12. **Minced (naming the type) Meat or Ground (naming the type) Meat** shall be a comminuted (naming the type) meat preparation, and shall contain not more than 30 per cent of fat, which shall be comprised of fat normally adherent to the meat used, and when the preparation is represented as being lean, it shall contain less than 18 per cent of fat.

13. The preparation known in Trinidad and Tobago as "saw-dust" shall not be sold as minced or ground meat.

14. **Sausage or Sausage Meat** shall be comminuted meat, either fresh or preserved, with added salt and spices, and may contain—

*(a)* animal fat, filler, beef, tripe, liver and fresh animal blood;

*(b)* carbohydrate sweetener;

*(c)* other seasonings (except tomato);

*(d)* harmless lactobacilli cultures;

*(e)* lactic acid starter culture *(Pediococcus cerevisiae);*

*(f)* blood plasma,

and may be enclosed in a casing, with or without subsequent dipping in vinegar, smoking or cooking.

15. Pre-packaged sausages and sausage meats shall be labelled with the type or types of meat that have been used in their manufacture.

16. No person shall sell sausages or sausage meats which contain—

*(a)* less than 75 per cent of meat, as determined by the official method;

*(b)* more than 25 per cent of the meat content in the form of fat, as determined by the official method;

*(c)* a total viable bacterial count of 500,000 micro-organisms per gram, as determined by an acceptable method; or

*(d)* any pathogenic micro-organisms.

17. Notwithstanding paragraphs 15, 16*(a)* and 16*(b)*. **Low Meat (naming the type) Sausages** that contain—

*(a)* less than 75 per cent meat, but not less than 40 per cent meat; and

*(b)* proteinaceous substances such as skim milk powder, butter milk powder, whey powder, soya bean flour, fish protein concentrate, and other proteins approved by the Minister on the advice of the Food Advisory Committee;

may be sold if—

*(c)* the total protein content of the sausage as determined by the official method, is equal to that corresponding to 75 per cent meat, of the type named;

*(d)* the percentage of fat is not greater than 18 per cent as determined by the official method; and

*(e)* the sausages are labelled **"Low Meat (naming the type) Sausage with added Protein"** and the type of protein added is named on the label.

18. Notwithstanding paragraphs 16*(a)*, 16*(b)* and 17, Sausages Canned in Broth, Brine or a Liquid Medium shall contain—

*(a)* not less than 55 per cent of meat, as determined by the official method;

*(b)* not more than 18 per cent of the meat content in the form of fat, as determined by the official method; and

*(c)* not less than 10 per cent of digestible protein, as determined by the official method.

## DIVISION 14—JAMS, JELLIES AND MARMALADES

1. In this Division

"acid ingredient" means citric acid, malic acid, fumaric acid, L-tartaric acid, vinegar, lime juice or lemon juice;

"fruit" means all fruits commonly recognised as human food, and includes ginger, melon, tomato, and rhubarb, but does not include cucumber, chestnut, pumpkin or squash;

"fruit content" means the percentage by weight of the final product which is represented by the total weight of the prepared fruit used for processing;

"prepared fruit" means—

*(a)* in relation to jams and marmalades—

(i) fruit, sound, fresh, freed from stems, calices and seeds (where seeds are not customarily included in the jam or marmalade); or

(ii) the prepared fruit used in making any fruit pulp or puree used in processing to jam or marmalade; and

*(b)* in relation to jellies, the strained fruit juice or nectar used in processing jellies.

2. **(Naming the Fruit)—Jam** shall be the food prepared by processing the edible parts of the fruit named, the pulp of the fruit named, or the preserved named fruit, by boiling with water and sugar to a suitable consistency and shall contain not less than 66 per cent of water-soluble solids as estimated by the refractometer at 20°C. and may contain—

*(a)* that amount of added pectin and acid ingredient that reasonably compensates for any deficiency in the natural pectin content or natural acidity of the named fruit; and

*(b)* Class II preservatives.

3. **(Naming the Citrus Fruit)—Marmalade** shall be the food of jelly-like consistency prepared by boiling together the peel, juice or pulp of the named citrus fruit with sugar and water, and shall contain not less than 65 per cent of water-soluble solids as estimated by the refractometer at 20°C., and may contain—

*(a)* the amount of pectin or acid ingredient which reasonably compensates for any deficiency of the natural acidity or natural pectin content of the named citrus fruit; and

*(b)* Class II preservatives.

4. **(Naming the Fruit)—Jelly** shall be the gelatinous food, free of seeds and pulp, prepared from the named fruit, the juice of the named fruit, a concentrate of the juice of the named fruit, or canned or frozen juice, which has been boiled with water and sugar, and shall contain not less than 65 per cent of water-soluble solids as estimated by the refractometer at 20°C., and may contain—

*(a)* that amount of added pectin and acid ingredient that reasonably compensates for any deficiency in the natural pectin content or natural acidity of the named fruit; and

*(b)* Class II preservatives.

5. No jam, jelly or marmalade shall contain artificial flavour, or any gelling agents other than pectin.

6. Synthetic food colours may only be used as additives in jams, jellies and marmalades made from pineapples, apples or limes.

7. Prepared fruit for preparing jams and marmalades may be used in the form of fruit-pulp or puree which has been canned, frozen, pasteurised, dried, freeze-dried, or preserved with sulphur dioxide.

8. (1) Subject to subparagraph (2), the fruit content of jams, jellies and marmalades shall be stated on the label of every container thereof.

(2) Where the fruit content of jams, jellies or marmalades is greater than or equal to the following standard values for the named fruit products, the word "Standard", instead of the fruit content thereof, may be used on the label of the container—

| | |
|---|---|
| Apple jelly ... ... ... ... | 45 per cent fruit content |
| Apricot jam ... ... ... ... | 40 per cent fruit content |
| Guava jam ... ... ... ... | 45 per cent fruit content |
| Guava jelly ... ... ... ... | 45 per cent fruit content |
| Lime marmalade ... ... ... | 30 per cent fruit content |
| Mixed orange and grapefruit marmalade... | 30 per cent fruit content |
| Mixed raspberry and strawberry jam ... | 40 per cent fruit content |
| Orange jelly... ... ... ... | 30 per cent fruit content |
| Orange marmalade ... ... ... | 30 per cent fruit content |
| Pineapple jam... ... ... ... | 45 per cent fruit content |
| Pineapple jelly... ... ... ... | 45 per cent fruit content |
| Raspberry jam... ... ... ... | 45 per cent fruit content |
| Strawberry jam ... ... ... | 35 per cent fruit content |

9. Jams, jellies and marmalades may contain the following optional ingredients:

*(a)* herbs, spices;

*(b)* essential oils;

*(c)* alcoholic beverages;

*(d)* butter, margarine, or edible vegetable oils added as anti-foaming agents during preparation; or

*(e)* caramel.

10. In preparing jams, jellies and marmalades, dextrose, invert sugar, glucose syrup, dried glucose syrup, or honey may be used in addition to sugar in accordance with good manufacturing practices.

11. Food additives used in preparing jams, jellies and marmalades, including—

anti-foaming agents;

essential oils;

firming agents;

natural fruit flavouring preparations;

pH adjusting agents;

synthetic food colours,

shall be approved by the Director, shall meet specifications accepted or recommended by the Director, and shall be used in such proportions as are recognised as being in conformity with good manufacturing practice, or as indicated by the Director.

12. Jams and jellies manufactured from tropical fruits (other than citrus fruits) and intended for export to countries other than the Caribbean Islands or Guyana shall conform—

*(a)* to the standards of the importing country; or where no such standards exist;

*(b)* to any standard adopted by the Codex Alimentarius Commission for jams or jellies which is not lower than the appropriate standard specified in paragraph 8(2).

13. The provisions of this Division do not apply to cranberry jelly, fruit curd, mincemeat, mint jelly, or to jams, jellies and marmalades containing synthetic sweetening agents, which are labelled with a statement that they are intended for use by diabetics, or with the word "Diabetic".

## DIVISION 15—SWEETENING AGENTS

1. Honey is the sweet substance produced by honey bees *(Apis mellifica)* mainly from the nectars of flowers and blossoms, other sweet exudations from living plants, and other wholesome sweet substances which the bee might naturally collect in the course of its foraging, and shall contain—

*(a)* not more than 23 per cent of moisture;

*(b)* not more than 8 per cent of sucrose;

*(c)* not more than 0.25 per cent of ash.

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2. Notwithstanding regulations 58*(a)* and 64 of the Beekeeping and Bee Products Regulations, the net contents of tin or glass containers of less than ten pounds capacity containing honey shall be marked as required by these Regulations.

3. The registered number of the apiary shall be declared in accordance with the Beekeeping and Bee Products Regulations on the main panel of the label.

## DIVISION 16—LABELLING OF FOOD TO BE USED IN MARKETING TESTS

1. The Director may issue a letter of authorisation, authorising the sale of a quantity of food for the purpose of test marketing within a specified area and for a specified period stated in the letter of authorisation if—

*(a)* the manufacturer or distributor of the food has supplied to the Director the following information:

(i) the purpose for which test marketing of the food is required;

(ii) a description of any proposed variation from the standard of composition and labelling requirements;

(iii) a description of the food including a sample and label;

(iv) adequate data to show that the use of the food will not be detrimental to the health of the purchaser or user;

(v) the quantity of the food to be distributed;

(vi) the period of time required for the distribution;

(vii) the areas designated for the distribution; and

(viii) such other data as the Director may require; and

*(b)* the manufacturer or distributor of the food has agreed—

(i) to describe the food on a label or in an advertisement in a manner that is not false, misleading or deceptive;

(ii) to use such marks or statements on the label as the Director may require;

(iii) to submit to the Director the results of the test marketing, if requested to do so by the Director;

(iv) to withdraw the food from sale, if notified that in the opinion of the Director, it is in the public interest to do so.

2. The Director shall, in any letter of authorisation issued pursuant to paragraph 1, state—

*(a)* the common name of the food to be sold or freely distributed;

*(b)* the name and address of the manufacturer or distributor who intends to distribute the food;

*(c)* the quantity of the food to be distributed;

*(d)* the period of time permitted for the distribution; and

*(e)* the area designated for the distribution.

3. A manufacturer or distributor named in a letter of authorisation issued pursuant to paragraph 1, may within the period of time permitted for the distribution sell or freely distribute a quantity of a food named and described in that letter that does not exceed the quantity specified therein.

4. A sale of a food made in accordance with paragraph 3 is exempt from the provisions of the Act and of these Regulations relating to labelling, except in so far as the Director may require under paragraph 1*(b)*(ii).

## DIVISION 17—KETCHUP

1. **Tomato Ketchup, Tomato Catsup, Tomato Catchup** or a food, the common name of which is a variant of the word "catsup", (hereinafter referred to as "tomato ketchup") shall—

*(a)* be prepared from juice, paste or puree derived from clean, sound, ripe tomatoes of a red or reddish variety, from which the skins and seeds have been removed;

*(b)* be processed by heat; and

*(c)* contain—

(i) vinegar;

(ii) food grade salt;

(iii) seasonings and spices; and

(iv) sweetening agents.

2. (1) A grade may be declared for tomato ketchup.

(2) Where the grade is declared, tomato ketchup shall be labelled "Premium Grade" or "Standard Grade", as the case may be.

(3) Tomato ketchup labelled "Premium Grade" shall have—

*(a)* tomatoes in solid form which amount to not less than 12 per cent by weight;

*(b)* a total of solids which amounts to not less than 33 per cent by weight; and

*(c)* a pH value not exceeding 4.0.

(4) Tomato ketchup labelled "Standard Grade" shall have—

*(a)* tomatoes in solid form which amount to not less than 6 per cent but less than 12 per cent by weight;

*(b)* a total of solids which amounts to not less than 25 per cent but less than 33 per cent by weight; and

*(c)* a pH value not exceeding 4.0.

(5) A Class II preservative and thickening agents may be used in tomato ketchup labelled "Standard Grade".

(6) Whether or not a grade is declared, tomato ketchup shall be of a grade which is not less than that specified for "Standard Grade" in subparagraph (4).

3. Tomato Ketchup shall have no natural or artificial colour, except for the colour imparted by tomatoes.

4. (1) **(Naming the Vegetable or Fruit) Ketchup, Catsup, Catchup** or a food, the common name of which is a variant of the word "catsup", [hereinafter referred to as "(Naming the Vegetable or Fruit) ketchup"] shall—

*(a)* be prepared from a vegetable, fruit or both;

*(b)* be processed by heat;

*(c)* contain—

(i) vinegar;

(ii) food grade salt;

(iii) seasonings and spices; and

(iv) sweetening agents; and

*(d)* have—

(i) a total of solids which amounts to not less than 25 per cent by weight; and

(ii) a pH value not exceeding 4.0.

(2) (Naming the Vegetable or Fruit) ketchup may contain—

*(a)* food colour;

*(b)* a Class II preservative;

*(c)* thickening agents; and

*(d)* tomatoes or tomato products as one of its secondary ingredients.

5. (1) The mould count for ketchup shall not exceed 40 per cent positive microscope fields as determined by the Howard Method.

(2) Yeast cells present in ketchup shall be non-viable.

6. Ketchup shall be free from fly eggs and maggots, except for Drosophila fly, in the case of which, there shall not be more than twenty eggs and one larva or ten eggs and two larvae of Drosophila fly, per 100 grams of ketchup.

## DIVISION 18—IRRADIATED FOOD

1. Irradiated food shall be food which—

*(a)* has been subjected to safe levels of ionising and non-ionising radiation; or

*(b)* contains an ingredient which has been subjected to safe levels of ionising and non-ionising radiation.

2. Sources of irradiation for food shall include—

*(a)* X-rays from sources operated at energy levels of up to 5MeV;

*(b)* gamma rays from the radionuclides $^{60}Co$ and $^{137}Cs$ only, operated at energy levels of up to 5MeV;

*(c)* electrons from sources operated at energy levels of up to 10MeV; and

*(d)* ultra violet radiation operated between the wavelengths 220 and 300 nm, where 90 per cent of the radiation consists of the wavelength 254 nm.

3. The average dose absorbed by a food or ingredient which has been subjected to irradiation shall not exceed—

*(a)* 45 kGy, for sterile foods;

*(b)* 10 kGy, for dried herbs and spices;

*(c)* 3 kGy, for fresh poultry and poultry products;

*(d)* 7 kGy, for frozen poultry and poultry products;

*(e)* 4.5 kGy, for fresh red meats;

*(f)* 7 kGy, for frozen red meats;

*(g)* 3 kGy, for seafoods;

*(h)* 2 kGy, for fresh fruits and vegetables;

*(i)* 1 kGy, for bulbs and tubers; and

*(j)* 1 kGy, for cereals and grains,

where measured by an acceptable method.

4. Where re-irradiation of food or an ingredient is necessary, the total average dose absorbed shall not exceed the levels set out in paragraph 3.

5. A package of irradiated food shall carry the international irradiation symbol, the radura and a statement such as "Food Irradiated", "Irradiated", "Treated with Irradiation" or "Treated by Irradiation" in close proximity to the symbol.

6. (1) Shipping documents in respect of irradiated food, including a bill of lading and an invoice, shall state the location and date of the treatment, the average dose absorbed and a lot number.

(2) The importer, manufacturer or distributor of irradiated food shall retain the shipping documents for a minimum period of one year from the expiry date of the food.

7. A package used for holding food during irradiation shall be—

*(a)* cellophane, coated with nitrocellulose or with vinylidene chloride copolymer;

*(b)* glassine paper;

*(c)* paperboard coated with wax;

*(d)* uncoated polyolefin films;

*(e)* polyolefin films with a coating consisting of acrylonitrile, acrylic acid, taconic acid, methyl acrylate and methyl methacrylate and not less than 85 per cent vinylidene chloride;

*(f)* kraft paper derived from unbleached sulphate pulp;

*(g)* polyethylene terephthalate film;

*(h)* polystyrene film;

*(i)* rubber hydrochloride film;

*(j)* vinylidene chloride-vinyl chloride basic copolymers, consisting of not less than 70 per cent vinylidene chloride;

*(k)* nylon 11;

*(l)* nylon 6; or

*(m)* ethylene-vinyl acetate copolymers.

8. This Division shall not apply to treatments by microwave.

## DIVISION 19—FOOD GRADE SALT

1. This Division shall apply to salt to be used as food.

2. **Food Grade salt** shall—
   *(a)* be white, crystalline, sodium chloride prepared from rock salt, seawater or natural brine;
   *(b)* contain not less than 97 per cent sodium chloride, calculated on a dry weight basis, exclusive of food additives;
   *(c)* contain not less than 99 per cent sodium chloride calculated on a dry weight basis, when sold as pure vacuum salt; and
   *(d)* have a loss on drying, of not more than 0.5 per cent by weight.

3. (1) Food grade salt may contain the food additives specified below—
   *(a)* anticaking agents, that is—
      (i) any of the following coating agents:
         (A) calcium carbonate;
         (B) magnesium carbonate;
         (C) tri-calcium phosphate;
         (D) amorphous silicon dioxide;
         (E) calcium alumino-silicate;
         (F) magnesium alumino-silicate;
         (G) sodium alumino-silicate;
         (H) sodium calcium alumino-silicate; or
         (I) magnesium oxide;
      (ii) any of the following hydrophobic agents:
         (A) aluminium salts of myristic acid, palmitic acid or stearic acid;
         (B) calcium salts of myristic acid, palmitic acid or stearic acid;
         (C) magnesium salts of myristic acid, palmitic acid or stearic acid;
         (D) potassium salts of myristic acid, palmitic acid or stearic acid; or
         (E) sodium salts of myristic acid, palmitic acid or stearic acid; or
      (iii) any of the following crystal modifiers:
         (A) calcium ferrocyanide;
         (B) potassium ferrocyanide; or
         (C) sodium ferrocyanide,

      in an amount not exceeding 0.0010 per cent by weight, calculated as ferrocyanide.

*(b)* nutrients, that is—

(i) sodium fluoride in an amount not less than 0.015 per cent by weight and not more than 0.02 per cent by weight; and

(ii) potassium iodide in an amount not less than 0.006 per cent by weight and not more than 0.01 per cent by weight;

*(c)* propylene glycol in an amount not exceeding 0.03 per cent by weight;

*(d)* ferric ammonium citrate in an amount not exceeding 0.0025 per cent by weight;

*(e)* polyoxyethylene (20) sorbitan mono-oleate in an amount not exceeding 0.0010 per cent by weight, for the production of coarse crystal salt only;

*(f)* sodium alginate in an amount not exceeding 0.0015 per cent by weight, for the production of coarse crystal salt only;

*(g)* dimethyl polysiloxane in an amount not exceeding 0.0010 per cent by weight;

*(h)* polysorbate 80; and

*(i)* any other additives approved by the Director.

(2) Where coating agents and hydrophobic agents are used singly or in combination, the total amount used shall not exceed 2 per cent by weight.

(3) Notwithstanding subparagraph (1)*(a)*(iii), where ferrocyanide is used in the production of dendritic salt, the amount shall not exceed 0.0020 per cent by weight, calculated as ferrocyanide.

4. Naturally occurring contaminants of food grade salt shall not exceed—

*(a)* 0.5 parts per million of arsenic, calculated as arsenic;

*(b)* 0.5 parts per million of cadmium, calculated as cadmium;

*(c)* 2 parts per million of copper, calculated as copper;

*(d)* 16 parts per million of iron, calculated as iron;

*(e)* 2 parts per million of lead, calculated as lead;

*(f)* 0.1 parts per million of mercury, calculated as mercury;

*(g)* 2 per cent of total calcium and magnesium, calculated as calcium; and

*(h)* 0.3 per cent extraneous matter by weight.

5. (1) **Rock salt** shall be crude rock salt or halite obtained from the mining of salt.

(2) **Solar salt** shall be salt prepared by the solar evaporation of sea water or natural brine.

(3) **Granulated salt** shall be salt prepared by the vacuum evaporation of purified brine.

(4) **Table salt** shall be fine, crystalline salt which may contain anticaking agents, crystal modifiers, iodine and fluorine.

(5) **Coarse crystal salt** shall be salt to which food additives have been added to produce coarse crystals of sodium chloride.

(6) **Dendritic salt** shall be salt which has had its crystal habit altered by incorporating sodium ferrocyanide in the brine during vacuum evaporation.

(7) **Flake salt** shall be salt produced by the Grainer process in which the crystals are modified without the use of chemical additives.

6. The label on a package of food grade salt shall carry the statement—

*(a)* "Food grade salt" or "Table salt";

*(b)* "Iodized", where it contains potassium iodide with or without dextrose, sodium bicarbonate or sodium thiosulphate, at the levels set out in paragraph 4(1)*(b)*;

*(c)* "Fluoridated", where it contains levels of sodium fluoride set out in paragraph 4(1)*(b)*; and

*(d)* "Free flowing", where anticaking agents are used.

## DIVISION 20—BREWERY PRODUCTS

1. In this Division—

"hop" means the ripened cones of the female hop plant, humulus lupulus and includes hop extract, hop pellets and pre-isomerised hop extract;

"hop extract" means an extract prepared from the female hop plant in accordance with paragraph 11(1);

"hop pellets" means pellets produced from the female hop plant in accordance with paragraph 11(2) and (3);

"pre-isomerised hop extract" or "pre-isomerised hop pellets" means an extract or hop pellets, as the case may be, prepared from the female hop plant in accordance with paragraph 11(4);

"sugar" means any saccharine substance, saccharine extract or saccharine syrup;

"wort" means any extract or solution convertible into beer;

"yeast" means saccharomyces cerevisiae or saccharomyces carlsbergensis.

2. **Ale** shall be a beverage produced by the fermentation by yeast, of a wort, to which other ingredients may have been added and which has been brewed in such a manner as to have the aroma, flavour and other characteristics that are commonly recognised in ale.

3. **Beer** shall be a beverage produced by the fermentation by yeast, of a wort, to which other ingredients may have been added and which has been brewed in such a manner as to have the aroma, flavour and other characteristics that are commonly recognised in beer.

4. **Lager** or **Lager beer** shall be a beverage produced by the fermentation by yeast, of a wort, which has been stored at cold temperatures during clarification and maturation and brewed in such a manner as to have the aroma, flavour and other characteristics that are commonly recognised in lager or lager beer.

5. **Malta** shall be a beverage produced by combining wort, sugar, hops and carbon dioxide, to which yeast flavour or other flavour may have been added, which has the aroma, flavour and other characteristics that are commonly recognised in malta but which has no alcoholic content by volume when measured by an acceptable method.

6. **Malt liquor** shall be a beverage produced by the fermentation by yeast, of a wort, to which other ingredients may have been added and which has been brewed in such a manner as to have the aroma, flavour and other characteristics that are commonly recognised in malt liquor.

7. **Milk stout** shall be a stout to which lactose has been added.

8. **Porter** shall be a beverage produced by the fermentation by yeast, of a wort, to which other ingredients may have been added and which has been brewed in such a manner as to have the aroma, flavour and other characteristics that are commonly recognised in porter.

9. (1) **Shandy** shall be a beverage containing bright beer, shandy concentrate, sugar, carbon dioxide and water.

(2) **Shandy** shall not contain more than 1.2 per cent alcoholic content by volume.

10. **Stout** shall be a beverage produced by the fermentation by yeast, of a wort, to which other ingredients may have been added and which has been brewed in such a manner as to have the aroma, flavour and other characteristics that are commonly recognised in stout.

11. (1) Hop extract to be used in a brewery product shall be produced by—

*(a)* a process in which carbon dioxide or ethanol is used as a solvent in accordance with good manufacturing practice; or

*(b)* any other method approved by the Director.

(2) Hop pellets to be used in a brewery product shall be produced by hammering or milling hops to a fine powder, running the powder through a high pressure pelletising disc and cooling and vaccum-packing the resulting pellets.

(3) No additives shall be used in producing hop pellets.

(4) Pre-isomerised hop extract or pre-isomerised hop pellets to be used in a brewery product shall be produced by using carbon dioxide or ethanol from which the alpha-acids have been isolated and isomerised with dilute acid and heat.

12. (1) **Near beer, non-alcoholic beer, non-alcoholic ale, non-alcoholic stout** or **non-alcoholic porter,** as the case may be, shall be a brewery product which has an alcoholic content by volume of 0.5 per cent or less.

(2) **Low alcohol beer, low alcohol ale, low alcohol stout** or **low alcohol porter,** as the case may be, shall be a brewery product which has an alcoholic content by volume of more than 0.5 per cent but not more than 1.2 per cent.

(3) **Extra light beer, extra light ale, extra light stout** or **extra light porter,** as the case may be, shall be a brewery product which has an alcoholic content by volume of more than 1.2 per cent but not more than 2.5 per cent.

(4) **Light beer, light ale, light stout** or **light porter,** as the case may be, shall be a brewery product which has an alcoholic content by volume of more than 2.5 per cent but not more than 4.0 per cent.

(5) **Ale, beer, stout** or **porter**, as the case may be, shall be a brewery product which has an alcoholic content by volume of more than 4.0 per cent but not more than 5.5 per cent.

(6) **Strong beer, strong ale, strong stout, strong porter** or **malt liquor,** as the case may be, shall be a brewery product which has an alcoholic content by volume of more than 5.5 per cent but not more than 8.5 per cent.

(7) **Extra strong beer, extra strong ale, extra strong stout, extra strong porter** or **extra strong malt liquor,** as the case may be, shall be a brewery product which has an alcoholic content by volume of more than 8.5 per cent.

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Regulation. [130/1964 94/1969 49/1987].

## SECOND SCHEDULE

### DIVISION 1—THIRD SCHEDULE DRUGS

1. No person shall sell a Third Schedule drug unless he has received a prescription therefor; and the prescription shall show—

*(a)* the name and address of the person for whom the drug may be dispensed;

*(b)* the name and quantity of the drug specified therein;

*(c)* the directions for use given therewith;

*(d)* the date of the prescription; and

*(e)* the signature of the practitioner, who issued the prescription,

and where the signature is not known to the dispenser of the prescription, the signature shall be first verified by him.

2. A record of every prescription for a Third Schedule drug shall be retained by the dispenser thereof for a period of at least two years, and shall show—

*(a)* the name and address of the person named in the prescription;

*(b)* the name and quantity of the drug specified therein;

*(c)* the name of the practitioner who issued the prescription;

*(d)* the date and number of the prescription;

*(e)* the directions for use given therewith.

3. No person shall refill a prescription for a Third Schedule drug unless the practitioner so directs on the prescription, and specifies the number of times that the same may be refilled.

4. No person other than—

*(a)* a practitioner;

*(b)* a drug manufacturer;

*(c)* an importer, wholesaler, jobber, or agent, dealing in drugs;

*(d)* a pharmacist; or

*(e)* a resident of a foreign country while a visitor in Trinidad and Tobago shall import a Third Schedule drug.

5. The provisions of paragraph 1 do not apply to the sale of a Third Schedule drug to—

*(a)* a drug manufacturer;

*(b)* a practitioner;

*(c)* an importer, wholesaler, jobber, or agent, dealing in drugs;

*(d)* a pharmacist;

*(e)* a hospital; or

*(f)* any Department of the Government upon an order signed by the Minister thereof or his duly authorised representative.

6. The provisions of paragraphs 1, 2, 3 and 4, do not apply to a drug listed or described in Part II of the Third Schedule to the Act, if— Third Schedule. Part II.

*(a)* the drug is in a form not suitable for human use; or

*(b)* the main panel of both the inner and the outer labels carries, immediately preceding or following the proprietary, brand, proper, or common name of the drug, the words " Agricultural Use Only", or "Veterinary Drug", or "Veterinary Use Only", or "Not for Human Use", or some other form of words indicating that the drug is not to be used in treating humans.

7. The Minister may, on the advice of the Drug Advisory Committee, add any new drug to the Third Schedule.

8. The Minister may, on the advice of the Drug Advisory Committee, add any drug to the Third Schedule where experience of its use has revealed that there may be a danger to the public health, if the use of that drug without medical advice is allowed to continue. Third Schedule.

9. The addition of a drug to the Third Schedule shall be published by Notice in the *Gazette*, and the addition shall be effective from the date of publication of the Notice.

## DIVISION 2—CONTROLLED DRUGS

1. In this Division—

"controlled drug" means any of the drugs classified as such in paragraph 2 and includes a preparation;

"licence" means a licence issued under paragraph 5;

"licensed dealer" means a medical practitioner, pharmacist or the holder of a licence;

"permit" means a permit issued under paragraph 5;

"preparation" means a drug—

*(a)* that contains more than 5 per cent of barbituric acid or any derivative thereof or any salt thereof; or

*(b)* that contains a controlled drug and one or more other drugs,

in a recognised therapeutic form;

"written order" means an order given in writing, and dated and signed by a person to whom a licensed dealer is permitted to sell or supply a controlled drug pursuant to a written order.

2. For the purposes of this Division the following substances and their salts are classified as controlled drugs:

*(a)* Amphetamine
*(b)* Dexamphetamine
*(c)* Mecloqualone
*(d)* Methamphetamine
*(e)* Methaqualone
*(f)* Methylphenidate
*(g)* Phencyclidine
*(h)* Phenmetrazine
*(i)* Amobarbital
*(j)* Cyclobarbital
*(k)* Glutethimide
*(l)* Pentazocine
*(m)* Pentobarbital
*(n)* Secobarbital
*(o)* Alprazolam
*(p)* Amfepramone
*(q)* Barbital
*(r)* Benzphetamine
*(s)* Bromazepam
*(t)* Camazepam
*(u)* Chlordiazepoxide
*(v)* Clobazam
*(w)* Clonazepam
*(x)* Clorazepate
*(y)* Clotiazepam
*(z)* Cloxazolam
*(aa)* Delorazepam
*(bb)* Diazepam
*(cc)* Estazolam
*(dd)* Ethchlorvynol

*(ee)* Ethinamate
*(ff)* Ethyl loflazepate
*(gg)* Fludiazepam
*(hh)* Flunitrazepam
*(ii)* Flurazepam
*(jj)* Halazepam
*(kk)* Haloxazolam
*(ll)* Ketazolam
*(mm)* Lefetamine
*(nn)* Loprazolam
*(oo)* Lorazepam
*(pp)* Lormetazepam
*(qq)* Mazindol
*(rr)* Medazepam
*(ss)* Meprobamate
*(tt)* Methylphenobarbital
*(uu)* Methyprylon
*(vv)* Nimetazepam
*(ww)* Nitrazepam
*(xx)* Nordazepam
*(yy)* Oxazepam
*(zz)* Oxazolam
*(aaa)* Phendimetrazine
*(bbb)* Phenobarbital
*(ccc)* Phentermine
*(ddd)* Pinazepam
*(eee)* Pipradrol
*(fff)* Prazepam
*(ggg)* Temazepam
*(hhh)* Tetrazepam
*(iii)* Triazolam.

3. Subject to this division no person shall manufacture or sell a controlled drug unless he is a licensed dealer.

4. No person shall import or export a controlled drug unless he is a licensed dealer and has first obtained a permit to do so from the Director.

5. (1) The Director may, on application therefor—

*(a)* issue a licence to any fit and proper person, to sell controlled drugs; or

*(b)* issue a permit to any licensed dealer to import or export a controlled drug.

(2) The provisions of subparagraph (1)*(a)* do not apply to a practitioner or pharmacist.

6. A licence or permit is subject to the condition that the person to whom it is issued, will comply with the provisions of this Division.

7. The Minister may revoke or suspend a licence or a permit issued under this Division if in his opinion the person to whom it is issued, or any person in his employ, has violated or failed to comply with any term or condition thereof or any provision of this Division except that a licence shall not be revoked where the violation is by an employee unless that violation is in connection with controlled drugs in the possession, or under the control, of the licensed dealer.

8. A licence unless it is sooner revoked expires on 31st December next following the day of which it was issued; and where a licence is suspended it has no validity during the period of suspension.

9. A permit is valid only for the importation or exportation in respect of which it is issued.

10. Subject to the terms of his licence and to the provisions of this Division, a licensed dealer may only sell or supply a controlled drug to—

*(a)* another licensed dealer;

*(b)* a hospital.

11. No licensed dealer shall sell or supply a controlled drug to any other licensed dealer unless—

*(a)* he has received a written order therefor from such other licensed dealer; and

*(b)* he has first verified the signature of that other licensed dealer if the signature is unknown to him.

12. No licensed dealer shall sell or supply a controlled drug to a hospital unless—

*(a)* he has first received a written order therefor from the pharmacist in charge of the hospital dispensary or from a physician or dentist authorised by the hospital to sign the order; and

*(b)* he has first verified the signature of that person if the signature is unknown to him.

13. A licensed dealer carrying on the business of a pharmacy, or any pharmacist employed by him for the purposes of that business, may sell a controlled drug to any person if—

*(a)* the drug forms part of the stock in trade of the pharmacy;

*(b)* he has first received a prescription in writing authorising the dispensing of the drug;

*(c)* the prescription has been dated and signed by the practitioner who issued it; and

*(d)* the signature of the practitioner is first verified if the signature is unknown to him.

14. Every licensed dealer, who is a manufacturer, wholesaler, or importer shall keep a separate book or register in which he shall enter or cause to be entered—

*(a)* the name, quantity and form of any controlled drug received by him, the name and address of the person who supplied it and the date on which it was received;

*(b)* the name, quantity and form of any controlled drug sold or supplied, the name and address of the person to whom it was sold or supplied, and the date on which it was sold or supplied;

*(c)* the name and quantity of any controlled drug used in manufacturing, the name and quantity of any controlled drug manufactured, and the date any manufactured controlled drug was placed in stock;

*(d)* the name, quantity and form of any controlled drug he had in stock at the end of each month,

and every required entry shall be made within forty-eight hours of the receipt or disposition of the controlled drug.

15. Every practitioner, and every pharmacist in control of a place of business for the purposes of section 26 of the Pharmacy Board Act, shall keep— Ch. 29:52.

*(a)* bills and invoices of all purchases or consignments of all controlled drugs received by him;

*(b)* a record of the name, quantity and form of any controlled drug sold or supplied, the name and address of the person to whom it was sold or supplied (or if supplied pursuant to a

prescription, the name of the person for whom it was dispensed and the name of the practitioner who issued the prescription), and the date on which it was sold or supplied;

*(c)* a record of the name and quantity of any controlled drug used in manufacturing, the name and quantity of any controlled drug manufactured, and the date any manufactured controlled drug was placed in stock;

*(d)* all controlled drugs under his charge in locked cupboards; and every required entry shall be made within forty-eight hours of the receipt or disposal of the controlled drug.

16. A licensed dealer who carries on the business of a wholesaler dealing in drugs and the business of a pharmacy shall keep separate registers, as required by paragraph 14, in respect of each such business.

17. No pharmacist or practitioner shall refill a prescription for a controlled drug unless the practitioner so directs in the prescription and specifies the number of times it may be refilled and the dates on which it may be refilled.

18. Every pharmacist who dispenses a controlled drug shall initial the prescription therefor; and the pharmacist in control of a pharmacy for the purposes of section 26 of the Pharmacy Board Act, shall maintain a special prescription file in which he shall file or cause to be filed in sequence as to date and number, all written orders and prescriptions for controlled drugs dispensed, sold, or supplied, and such orders and prescriptions shall be kept in the file for a period of at least two years from the date on which they were filled.

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19. Every practitioner who dispenses a controlled drug pursuant to a prescription written by himself or another practitioner shall keep a special prescription file in which he shall file in order as to date all written orders and prescriptions for controlled drugs sold, supplied or dispensed by him.

20. Every licensed dealer (including a practitioner, or pharmacist) shall keep on his premises for a period of at least two years all records that are required to be kept by these Regulations, and the records shall be kept in a manner which will enable an audit thereof to be made at any time.

21. Every licensed dealer shall take all necessary steps to protect controlled drugs in his possession or under his control against loss or theft and shall report to the Director any such loss or theft of a controlled drug within ten days of the discovery thereof.

22. Nothing in this Division prohibits the sale to the Government by a licensed dealer of controlled drugs for its medical supplies but every officer in charge of Government medical supplies shall keep a separate register in which he shall enter or cause to be entered—

*(a)* the name, quantity and form of any controlled drug received by him;

*(b)* the name, quantity and form of any drug distributed or supplied by him to any authorised person or institution.

In this paragraph "authorised person or institution" means any person or institution to whom the officer is authorised by the Chief Medical Officer to distribute the drugs.

## DIVISION 3—NEW DRUGS

1. In this Division—

"appointed day" means the day on which the Act came into operation;

"new drug" means—

*(a)* a drug that contains or consists of a substance whether as an active or inactive ingredient, carrier, coating, excipient, menstruum or other component that has not been imported into Trinidad and Tobago for use as a drug prior to the appointed day;

*(b)* a drug that is a combination of two or more drugs with or without other ingredients, and that has not been imported into Trinidad and Tobago prior to the appointed day in that combination or in the proportion in which those drugs are combined; or

*(c)* a drug, with respect to which the manufacturer prescribes, recommends, proposes or claims a use as a drug, or a condition of use as a drug, including dosage, demonstration or duration of action, and that has not been imported into Trinidad and Tobago prior to the appointed day for that use or condition of use;

"notice of approval" means notice of approval in respect of a new drug given by the Minister pursuant to paragraph 7.

2. (1) No person shall import, sell or advertise for sale a new drug unless—

*(a)* the manufacturer or importer has filed with the Minister in duplicate, a new drug submission in Form C in the Third Schedule in respect of that drug, and paid to the Comptroller

Third Schedule. Form C.

Third Schedule. Form E.

of Accounts the non-refundable registration fee specified in Form E in the Third Schedule for the registration of the new drug; and

*(b)* the Minister has issued to the manufacturer or importer, a notice of approval in respect of the new drug, and the approval has not been withdrawn.

(2) Every new drug submission filed by a manufacturer or importer with the Minister, shall have attached to it the receipt issued by the Comptroller of Accounts in respect of payment of the registration fee.

(3) This regulation shall not apply to a person who has been granted permission by the Minister in accordance with paragraph 12 of this Division.

3. Subject to paragraph 4, a new drug submission in respect of a drug to be imported shall contain—

*(a)* a description of the new drug (including the manufacturer thereof), and a declaration of the proper name, if any, and the name under which it is proposed to be sold;

*(b)* a statement of all the ingredients, the route of administration, the proposed dosage, the claims to be made for the new drug, and the contra-indications and side-effects of the new drug if known, and a description of the pharmaceutical form under which the new drug is to be sold;

*(c)* details of the tests applied to control the potency, purity and safety of the new drug;

*(d)* a draft of every label proposed to be used in connection with the drug;

*(e)* samples of the new drug in the finished pharmaceutical form in which it is to be sold; and

*(f)* such samples of the components of the new drug as the Director may require, and shall include one or more of the following:

(i) a certified copy of a notice of compliance issued to the manufacturer by the Department of National Health and Welfare in Canada;

(ii) a certificate from the Food and Drugs Administration of the Department of Health, Education and Welfare of the United States of America certifying that the new drug is approved for use in the United States of America under the conditions of use recommended

and giving the conditions under which it may be sold in the United States of America;

(iii) a certificate from the Ministry of Health of the United Kingdom certifying that the new drug is approved for use in the United Kingdom under the conditions of use recommended and giving the conditions under which it may be sold in the United Kingdom;

(iv) a certificate from the Department of Health of Australia certifying that the drug is approved for use in Australia and giving the conditions under which it may be sold in Australia; or

(v) a certificate in the English language, respecting the safety of the new drug for conditions of use recommended and giving the conditions under which it may be sold, issued by an official body or Government Department having authority to issue the certificate, such official body or Government Department having experience and facilities for testing the safety of new drugs that are considered by the Minister as adequate to ensure the safety of the new drug under the conditions of use recommended,

but the Minister may accept a submission made in accordance with paragraph 4.

4. The Minister may in his discretion accept a new drug submission that contains information specified in paragraph 3*(a)* to *(f)*, and that includes—

*(a)* detailed reports of the tests made to establish the safety of the new drug for the purpose and under the conditions of use for which it is recommended; and

*(b)* such other information and material as the Minister may in any particular case require.

5. (1) Notwithstanding paragraph 2 but subject to paragraph 12, no person shall import, sell or advertise for sale a new drug in respect of which notice of approval has been given if any material change has been made in—

*(a)* the conditions of use of the drug including the indications for use and the route of administration;

*(b)* its labels;

*(c)* its packaging;

*(d)* the pharmaceutical form in which it is sold;

*(e)* its dosage; or

*(f)* its strength, purity or quality,

which is significantly different from the information contained in the new drug submission filed in respect thereof unless—

*(a)* the manufacturer or importer has filed with the Minister in duplicate a supplement to the new drug submission in Form D in the Third Schedule in respect of a variation of formula, a new claim to that drug, or a new packaging and paid to the Comptroller of Accounts the non-refundable registration fee specified in Form E in the Third Schedule for the registration thereof; and

Third Schedule. Form D.

Third Schedule. Form E.

*(b)* the Minister has issued to the manufacturer or importer a notice of approval in respect of a variation of formula or a new claim to that drug or a new packaging and the approval has not been withdrawn.

(2) Every supplement to a new drug submission filed by a manufacturer or importer with the Minister shall have attached to it the receipt issued by the Comptroller of Accounts in respect of the payment of the registration fee.

6. Where notice of approval in respect of a new drug has been issued to a manufacturer or importer, another manufacturer or importer of the same new drug may provide the Minister with a submission that satisfies the provisions of paragraph 4.

7. The Minister on the recommendation of the Drug Advisory Committee shall, within one hundred and twenty days after the filing of a new drug submission or supplement thereto—

*(a)* notify the person filing the same whether the data and information submitted satisfied the requirements of paragraph 3, 4 or 5; and

*(b)* if those requirements are satisfied and it appears to the Minister after consultation with the Drug Advisory Committee, that the new drug is safe for use as a drug, by Notification signify his approval in respect of that new drug.

8. The Minister may, after consultation with the Drug Advisory Committee, by Notification withdraw approval in respect of a new drug by

sending notice to the manufacturer or importer of that new drug and the withdrawal may be made where—

*(a)* evidence obtained from clinical or other experience, or from tests by new methods or by methods not used before the approval was given, reveals that the new drug is not shown to be safe for the use represented in the submissions in respect of the new drug which were filed with the Minister and on which the approval was based;

*(b)* the submissions in respect of the new drug which were filed with the Minister and on which approval was based, contain any untrue statement of material fact; or

*(c)* the withdrawal is necessary in the interests of public health.

Notice of withdrawal of approval in respect of a new drug shall be published in the *Gazette* and at least one newspaper having daily circulation in Trinidad and Tobago.

9. Where any manufacturer or importer receives any report of any unexpected side effects, injury, toxicity or sensitivity reaction associated with the clinical uses, studies, investigations and tests respecting a new drug, he shall inform the Minister as soon as possible of the side effects, injury, toxicity or sensitivity reaction.

10. Notwithstanding anything to the contrary in this Division, a new drug may be imported for the use of investigators qualified to use the drug for the sole purpose of obtaining clinical and scientific data with respect to its safety, stability, dosage, or efficacy, if—

*(a)* before the importation, the Minister is informed of the identifying name or mark by which the drug may be recognised;

*(b)* both the inner and outer labels on any package of the new drug carry the statement "To Be Used By Qualified Investigators Only";

*(c)* before the sale, the importer ensures that any person to whom the new drug is to be sold is a qualified investigator and has the facilities for the investigation to be conducted by him, and obtains in writing from that person an undertaking that the new drug will be used solely by that person or under his direction;

*(d)* the investigators have written authority from the Minister to carry out the investigation of the new drug and have the facilities for so doing.

11. A person who imports a new drug for the purposes of sale to qualified investigators shall keep accurate records of the sales, and make these records available for inspection on the request of the Minister.

12. Notwithstanding anything to the contrary in this Division, the Minister may grant permission in writing to any person to import any specified quantity of a new drug, for the purpose of enabling that person to make a new drug submission or to file a supplement thereto.

## DIVISION 4—OFFICIAL DRUGS

An official drug labelled as required by regulation 34 shall satisfy the standard mentioned on the label.

## DIVISION 5—ANTIBIOTICS

Ch. 30:02. An antibiotic which is imported, exported, manufactured, dispensed or sold, in accordance with the Antibiotics Act and any Regulations made thereunder is exempted from the provisions of these Regulations.

## DIVISION 6—NARCOTIC DRUGS

27 of 1961. A narcotic drug which is sold, dispensed, imported, exported, or manufactured, in accordance with the Narcotic Control Ordinance and any Regulations made thereunder, is exempted from the provisions of these Regulations except regulation 38.

## DIVISION 7—POISONOUS DRUGS

Ch. 29:52. A poisonous drug which is sold by wholesale or retail, or dispensed in accordance with the Pharmacy Board Act and any Regulations made thereunder is exempt from the provisions of these Regulations.

## DIVISION 8—CONDITIONS, FACILITIES AND CONTROLS FOR DRUG MANUFACTURE

1. For the purposes of this Division—

"drug manufacturer" means any person or firm which manufactures, compounds, or packages a drug for wholesale in the pharmaceutical form in which it is sold by retail to the general public, but does not include a pharmacist or pharmacy manufacturing, or compounding or packaging drugs on the premises where the drugs are sold by retail;

"manufacture" includes mixing, compounding, preparation, and similar physical processes, synthesis or any similar chemical processes and packaging for wholesale, but does not include dividing, sub-dividing, and re-packaging for sale by wholesale or retail.

2. No drug manufacturer shall sell a drug in the finished pharmaceutical form in which it is sold to the general public unless the drug has been manufactured, preserved, stored, labelled and tested under suitable conditions as provided in this Division, and a Certificate to this effect has been issued by the Director, on the advice of the Drug Advisory Committee.

3. For the purposes of paragraph 2, suitable conditions in respect of a drug requires—

*(a)* that the construction, fittings, and furnishings of the area in a building where the drug is manufactured shall be of such material and finish as—

(i) will permit the efficient cleaning of all surfaces;

(ii) will prevent the introduction of extraneous materials into drugs during their manufacture and testing;

(iii) will prevent the migration of dust and its accumulation;

*(b)* that adequate lighting, ventilation, and drainage facilities be provided in the manufacturing area;

*(c)* that all processing and packaging equipment be cleaned following the manufacture of each batch or lot of the drug;

*(d)* in the event parenteral drugs are processed, that all fillings and aseptic processes shall be carried out in a separate and enclosed area designed for the processing and filling of the drugs and operated in a manner that will prevent contamination of the drug compounded and filled;

*(e)* that qualified personnel shall be employed as supervisors in the formulation, processing, testing, packaging and labelling of the drug, and the personnel shall have such technical training as the Director on the advice of the Drug Advisory Committee may deem necessary, having regard to the nature of the duties and the responsibilities involved;

*(f)* that qualified personnel shall be responsible for the maintenance of machinery, equipment and sanitation;

*(g)* that each lot or batch of raw material or bulk material used in manufacturing the drug shall be tested to ensure identity and purity of the raw material or bulk material using tests of pharmacopoeial or equivalent status;

*(h)* that each lot or batch of the drug in finished pharmaceutical form shall be tested to ensure identity, potency and purity, using tests of pharmacopoeial or equivalent status;

*(i)* that each stage of the manufacture be supervised by appropriately qualified personnel;

*(j)* that a system of control shall be used permitting a complete and rapid recall of any batch of the drug from the market;

*(k)* that records shall be kept in form, manner and content satisfactory to the Director showing—

(i) for each batch or lot of the drug—

*(aa)* the tests on the raw or bulk materials used in manufacturing;

*(bb)* the tests on the drug in finished pharmaceutical form;

*(cc)* the name or initials of the qualified personnel supervising each stage of the manufacturing process, and responsible for the tests carried out; and

*(dd)* the lot or batch number assigned to that lot or batch of the drug and the date of manufacture; and

(ii) details of the manufacturing process, tests, procedures, and known hazards and stability of the drug;

*(l)* that adequate protection be given to the personnel engaged in manufacturing or packaging the drug against any hazard arising from contact with the drug or any raw material or processing equipment during the manufacturing or packaging process; and

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*(m)* that the provisions of the Pharmacy Board Act, the Factories Ordinance and the Public Health Ordinance are complied with.

4. The records required by paragraph 3*(k)* shall be kept for a period of five years from the date of testing of the drug, or until the expiry date of the drug, whichever first occurs, and the records shall be made available for inspection by an inspector, and copies shall be made for the information and use of the Director at his request.

5. A sufficient sample of each batch or lot of the drug in finished pharmaceutical form shall be kept by the drug manufacturer under suitable conditions of storage for a period of five years from the date of testing of the drug, or until the expiry date of the drug, whichever first occurs, and the sample shall be submitted to the Director for analysis and examination on his request.

6. A drug manufacturer may be permitted by the Director to dispense with tests, controls, records and samples mentioned in paragraph 3*(g)*, *(h)*, *(j)* and *(k)*, and paragraph 5, where the nature of the drug is such that these tests, controls, records and samples are, in the opinion of the Director, not necessary.

7. A drug manufacturer in a country other than Trinidad and Tobago shall be deemed to have complied with paragraphs 2, 3, 4 and 5, if the manufacturer or importer of a drug or drugs has produced to the Director a certificate concerning the sale, safety, or manufacture of the drug or drugs issued by—

*(a)* the Department of National Health and Welfare of Canada;

*(b)* the Department of Health, Education and Welfare of the United States, or a State or City authority in the United States concerned with health or pharmacy;

*(c)* the Ministry of Health of the United Kingdom;

*(d)* the Department of Health of Australia;

*(e)* any Government Department or official body in other countries issuing such certificates as comply with regulation 10 or paragraph 3*(f)*(v) of Division 3 of this Schedule, which are considered by the Director to show that adequate standards for conditions of drug manufacture are enforced in those countries, in respect of that drug manufacturer. Schedule.

8. A drug manufacturer in Trinidad and Tobago, may, if he does not employ qualified personnel to carry out the tests required by paragraph 3*(f)*(i) and (ii)—

*(a)* import batches or lots of raw or bulk material accompanied by certificates of identity and purity issued by an agency approved by the Director;

*(b)* submit a sample of each batch or lot of the drug in finished pharmaceutical form for testing to the Director, or to an agency or laboratory designated by the Director,

and shall not use any batch or lot of the raw material imported without such certificates nor sell any lot or batch of any drug in finished pharmaceutical form until the results of the tests for that lot or batch have been accepted by the Director.

9. No person shall sell or advertise a new drug manufactured in Trinidad and Tobago that was not manufactured in Trinidad and Tobago before 1st February 1969, unless—

*(a)* the drug manufacturer has filed with the Director in duplicate a New Drug Submission relating to the drug in accordance with paragraphs 10 and 11; and

*(b)* the Minister has issued a Notice of Approval in respect of the drug, and the approval has not been withdrawn.

10. Where a drug manufacturer in Trinidad and Tobago wishes to manufacture for sale a drug that he has not manufactured before 1st February 1969, he shall file with the Director a New Drug Submission in respect of the drug containing—

*(a)* a description of the drug, a declaration of its proper name, if any, the name under which it is proposed to be sold, and the name of the manufacturer;

*(b)* a statement of all the ingredients, the route of administration, the proposed dosage, the claims to be made for the drug, and the contra-indications and side effects of the drug if known, and a description of the pharmaceutical form under which the drug is to be sold;

*(c)* details of the tests applied to control the potency, purity and safety of the drug and of the raw or bulk materials;

*(d)* details of the manufacturing process to be used;

*(e)* a draft of every label proposed to be used in connection with the drug;

*(f)* such samples of the components of the drug as the Director may require;

*(g)* samples of the drug in the finished pharmaceutical form in which it is to be sold;

*(h)* either—

(i) a compilation of published reports of tests made on similar drugs to establish their safety for the purpose and under the conditions of use recommended; or

(ii) detailed reports of tests made to establish the safety of the drug for the purpose and under the conditions of use for which it is recommended; or

(iii) copies of opinions and reports taken from authoritative sources of information concerning the action, hazards, side effects, stability, and safety of the drug or similar drugs made by other manufacturers;

*(i)* such other information and material as the Director in any particular case may require.

11. Paragraphs 10*(b)* and 10*(h)* shall not apply to the manufacture in Trinidad and Tobago of a drug which is included in any of the official publications mentioned in the Second Schedule to the Act if the drug manufacturer complies with the other requirements of paragraph 10.

Second Schedule.

12. The Minister shall, on the recommendation of the Drug Advisory Committee, within one hundred and twenty days after the filing of the New Drug Submission in respect of a drug manufactured in Trinidad and Tobago—

*(a)* notify the person filing the same whether the data and information submitted satisfies the requirements of paragraph 10;

*(b)* if these requirements are satisfied and it appears to the Minister after consultation with the Drug Advisory Committee, that the drug is safe for use as a drug, issue a Notice of Approval in respect of that drug.

13. The Minister may, after consultation with the Drug Advisory Committee, withdraw approval in respect of any drug manufactured in Trinidad and Tobago by sending a notice to the manufacturer of the drug and the withdrawal may be made where—

*(a)* evidence obtained from clinical or other experience, or from tests by new methods or by methods not used before the approval was given, reveals that the drug is shown not to be safe for the use represented in the submissions in respect of the drug which were filed with the Minister and on which the approval was based; or

*(b)* the submissions in respect of the drug which were filed with the Minister and on which approval was based, contain any untrue statement of material fact; or

*(c)* the withdrawal is necessary in the interest of public health.

Notice of withdrawal of approval in respect of a drug shall be published in the *Gazette* and at least one newspaper having daily circulation in Trinidad and Tobago.

14. Where the Minister issues a notice of withdrawal in respect of a drug manufactured in Trinidad and Tobago, the drug manufacturer shall immediately withdraw from the market in Trinidad and Tobago, all batches or lots of that drug at his own expense, and deliver all the lots or batches to the Director.

15. Where any manufacturer receives any report of any unexpected side effects, injury, toxicity or sensitivity reaction associated with the clinical uses, studies, investigations and tests respecting a drug manufactured in Trinidad and Tobago he shall inform the Director as soon as possible of the side effects, injury, toxicity or sensitivity reaction.

16. Notwithstanding paragraph 10, a drug manufacturer may make a small number of batches of a drug that was not manufactured in Trinidad and Tobago before 1st February 1969 for the sole purpose of obtaining scientific data regarding the process of manufacture, or clinical data on the safety, stability, dosage, or efficacy of the drug, provided that—

*(a)* before manufacture the Director is informed of the proposed manufacture, and approves the disposal or use of the drug; and

*(b)* where the drug is to be used in clinical investigation—

(i) before sale or distribution, the Director is informed of the identifying name or mark by which the drug may be recognised;

(ii) both the inner and outer labels on any package of the drug carry the statement "To Be Used By Qualified Investigators Only";

(iii) before sale or distribution, the drug manufacturer ensures that any person to whom the drug is to be sold or distributed is a qualified investigator and has the facilities for the investigation to be conducted by him, and obtains in writing from that person an undertaking that the drug will be used solely by that person or under his direction;

(iv) the investigators have written authority from the Minister on the advice of the Drug Advisory Committee to carry out the investigation of the drug and have the facilities for so doing;

*(c)* the drug manufacturer keeps accurate records of sales and distribution of batches of drugs made for experimental purposes which are sold or distributed to qualified investigators.

## THIRD SCHEDULE

Regulations 6 and 13. [19/1987]. (Regulation 6).

### FORM A

## CERTIFICATE OF APPOINTMENT OF INSPECTOR

*(Section 20 of the Food and Drugs Act)*

This is to certify that *Official Stamp*

Mr. .....
has been appointed as an Inspector under section 20 of the Food and Drugs Act.

..... .....
*Signature of Inspector* *Minister of Health*

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### FORM B

(Regulation 13).

Laboratory No. .....

## CERTIFICATE OF ANALYSIS

*(Under section 30(1) of the Food and Drugs Act)*

I, ....., being a person duly appointed as an analyst under section 20 of the Food and Drugs Act, do hereby certify—

(1) that on the ..... day of ..... 20.....,

I received from ..... a sealed package, which said package was unopened and the seals thereon unbroken;

(2) that I broke the seals and opened the said package and removed therefrom a sample, submitted as a sample of .....

taken from .....

..... of .....;

(3) that I duly analysed or examined the said sample for the purpose of determining if same conformed to the requirements of the Food and Drugs Act and the Regulations thereunder, and I obtained the following results:

As witness my hand this ..... day of ....., 20.....

.....
*Analyst*

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*L.R.O. 1/2009*

(Regulation 2).

**FORM C**

## NEW DRUG SUBMISSION

To: Chief Chemist/Director of Food and Drugs,
Chemistry/Food and Drugs Division,
115, Frederick Street,
Port-of-Spain,
Trinidad.

1. I/We* .....
*(State Name of Importer/Manufacturer/Agent in Trinidad and Tobago)**

of .....
*(State Address)*

hereby make a New Drug Submission for .....
.....
*(State Name of New Drug)*

having its proper name and trade name .....
.....
*(State Proper Name and Trade Name of Drug)*

*Delete as applicable

and with the following ingredients:

| *Chemical Name of Ingredient* | *Quantity Weight or per cent* | *Chemical Name of Ingredient* | *Quantity Weight or per cent* |
|---|---|---|---|
| 1. ..... | ..... | 11. ..... | ..... |
| 2. ..... | ..... | 12. ..... | ..... |
| 3. ..... | ..... | 13. ..... | ..... |
| 4. ..... | ..... | 14. ..... | ..... |
| 5. ..... | ..... | 15. ..... | ..... |
| 6. ..... | ..... | 16. ..... | ..... |
| 7. ..... | ..... | 17. ..... | ..... |
| 8. ..... | ..... | 18. ..... | ..... |
| 9. ..... | ..... | 19. ..... | ..... |
| 10. ..... | ..... | 20. ..... | ..... |

2. I/We* undertake to inform you of any subsequent material changes made in the conditions of use, labelling, packaging, pharmaceutical form, dosage or strength, purity or quality of the New Drug.

3. I/We* undertake to inform you of any report of unexpected side effects, injury, toxicity, sensitivity or other adverse reactions in any way associated with the clinical uses, studies, investigations and tests in respect of the New Drug.

4. I/We* attach in DUPLICATE the information contained in the Note hereunder—

*Delete as applicable

**NOTE**

*(a)* A description of the New Drug (including the manufacturer thereof) and a declaration of the proper name if any and the trade name. ❒

*(b)* A statement of all ingredients, route of administration, dosage, claims to be made for the new drug and the contra-indications and side effects of the drug (if known), and a description of the pharmaceutical form in which it is to be sold. ❒

*(c)* Details of tests applied to control potency, purity and safety of the new drug. ❒

*(d)* Labels and samples of the new drug in its finished pharmaceutical form [Samples for submission may be imported, provided a permit is issued by the Director. If a submission is not made within one hundred and twenty (120) days of import, the samples shall be surrendered to the Director]. ❒

*(e)* Samples of the components of the new drug if required by the Director. [Samples for submission may be imported provided a permit is issued by the Director. If a submission is not made within one hundred and twenty (120) days of import, the samples shall be surrendered to the Director]. ❒

*(f)* Certificates as specified in paragraph 3*(f)* (i)–(v) of Division 3 of the Second Schedule of the Regulations.

CANADA ❒ UNITED KINGDOM ❒ F.D.A. U.S.A. ❒

AUSTRALIA ❒

*(g)* Certificates from State or City authorities in the United States respecting the sale and conditions of sale in the United States.

*(h)* Certificates in the English Language from authorities recognised as having adequate experience and facilities for assessing the safety of new drugs by the Ministries of Health in—

BELGIUM ❒ NETHERLANDS ❒ SWITZERLAND ❒

FRANCE ❒ SWEDEN ❒ DENMARK ❒

**FORM C**—*Continued*

*(i)* Certificates (with English translation) from other authorities in .....

.....

*(j)* Detailed reports of animal tests ❒
and/or

Clinical trials to establish the safety of the new drug.
[Detailed reports may be required by the Drug Advisory Committee if certificates are not available from countries named in paragraphs *(f)*, *(g)* and *(h)* of this Note].

.....
*Importer/Manufacturer/Agent in Trinidad and Tobago**

Date ..... 20.....

*Delete as applicable.

**FORM D**

## SUPPLEMENT TO NEW DRUG SUBMISSION

(Regulation 5).

**VARIATION OF FORMULA/NEW CLAIM/NEW PACKAGING***

To: Chief Chemist/Director of Food and Drugs,
Chemistry/Food and Drugs Division,
115, Frederick Street,
Port-of-Spain.

I/We* .....
*(State Name of Importer/Manufacturer/Agent in Trinidad and Tobago)**

of .....
*(State Address)*

hereby make a supplementary New Drug Submission in DUPLICATE for the drug .....
*(State Name of New Drug)*

in support of the changes indicated below:

| | | | |
|---|---|---|---|
| *(a)* Name/Mark | ❒ | *(f)* Route of administration | ❒ |
| *(b)* Formulation | ❒ | *(g)* Packaging | ❒ |
| *(c)* Conditions of Use | ❒ | *(h)* Label | ❒ |
| *(d)* Indications for Use | ❒ | *(i)* Pharmaceutical form | ❒ |
| *(e)* Dosage | ❒ | *(j)* Any other change | ❒ |

Description of other changes which made the drug different from that in the original New Drug Submission: .....

.....

The following information is attached in support of the changes indicated:

*(a)* Samples of the drug with the changes indicated above in the finished pharmaceutical form in which it is to be sold. ❒
*(b)* Samples of components of the new drug as the Director may require. ❒
*(c)* Certificate of compliance issued to the manufacturer by the authorised Government Agency in the country of origin. ❒
*(d)* Technical literature, describing the changes made to the new drug including tests and results of tests supporting that the quality, potency, efficacy and safety of the new drug are not affected. ❒
*(e)* Any other information that may be required by the Director. ❒

I/We* undertake to inform you of any report of unexpected side effects, toxicity, sensitivity or other adverse reactions associated with the clinical uses, studies, investigations and tests in respect of the new drug or resulting from the material changes made.

Date ..... .....
*Importer/Manufacturer/Agent in Trinidad and Tobago**

*Delete as applicable.

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**FORM E**

## REGISTRATION FEES

(Regulations 2 and 5).

New Drug ..... $750.00

Variation of Formula, New Claim or New Packaging ..... $100.00

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*L.R.O. 1/2009*