# FOOD AND DRUGS REGULATIONS

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Reg. 10/1977

# FOOD AND DRUGS REGULATIONS

*made under section 25*

## PART I
## ADMINISTRATION

Citation.

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

Interpretation.

**2.** In these Regulations –

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

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

"declared" means written on the label attached to or

accompanying the food, drug or substance in respect of which the declaration is required, in letters of the prescribed size;

"Government Analyst" includes the Commissioner of Food and Drugs;

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

"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, drug, cosmetic or device to which the label relates, is for sale;

"official method" means a method of analysis or examination designated as such by the Government Analyst 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;

"parts per million" means part by weight per million parts by weight except where otherwise stated;

"per cent" means per cent by weight (weight in weight) except where otherwise stated;

"potable water" means water which is clear, colourless, wholesome and free from any pathogenic micro-organism, and chemical contaminant.

Prescribing standards of composition.

**3.** (1) 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.

(2) Where a standard referred to in paragraph (1) is prescribed, no person shall use that standard on any label or in any advertisement of a food, drug, cosmetic or device unless that food, drug, cosmetic or device conforms to the standard prescribed.

Copies of method of analysis to be furnished by Government.

**4.** The Government Analyst shall upon request furnish copies of official methods, and within a reasonable time indicate that a method submitted to him for his ruling is acceptable or otherwise.

Advertisement to comply with Act, and Regulations.

**5.** (1) No person shall advertise any food, drug, cosmetic or device unless such advertisement complies with the requirements of the Act and these Regulations.

(2) Unless specifically required to do so by a written law, no label or advertisement of a food, drug, cosmetic or device shall either directly or indirectly make reference to the Act, these Regulations, the Analyst Department or the Ministry of Health.

Approval to advertise.

**6.** (1) No person shall advertise any drug unless he has first been granted approval in writing by the Government Analyst to do so, and such approval has not been withdrawn at the time of publication of the advertisement.

(2) The Government Analyst may refuse to grant approval, or may withdraw the approval granted in respect of any advertisement by notifying in writing the applicant for the approval or the person to whom the approval was granted, as the case may be, where –

(a) he has reasonable grounds to believe

that the application on which approval in respect of any such advertisement was granted, contained false or misleading statements; or

(b) the advertisement in respect of which approval was given, does not comply with the requirements of these Regulations.

(3) If the Government Analyst refuses to grant approval or withdraws the approval granted in respect of an advertisement the applicant or the person to whom the approval was granted may, within fourteen days after being notified of the refusal or withdrawal, appeal therefrom to the Minister.

(4) The Minister, acting on the advice of the Drug Advisory Committee, may overrule or confirm the refusal or withdrawal and whatever is decided the Government Analyst shall notify the applicant or the person to whom the approval was granted of that decision.

Information on label.

**7.** (1) Any information required by these Regulations to be included on a label of a food, drug, cosmetic or device shall be –

(a) clearly and prominently displayed on the label, and

(b) readily discernible to the public under the customary conditions of purchase and use.

(2) For the purposes of paragraph (1), the name by which any food, drug, cosmetic or device is generally known

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 articles, conjunctions and prepositions, is in identical type and identically displayed.

Information to be in durable characters etc.

**8.** All information required by these Regulations to be declared shall be in durable characters, and in bold-faced capital letters written in such colour or colours as to afford a distinct contrast with the background.

Certificate of appointment of inspector. Form A, Part 1 of First Schedule.

**9.** A certificate furnished to an inspector pursuant to section 20 of the Act, shall be in the form set out as Form A in Part I of the First Schedule.

Photographs of premises and articles.

**10.** 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 insanitary conditions.

Samples to be taken of imported food, drug, cosmetic or device.

**11.** (1) Where an inspector by virtue of section 22 of the Act takes samples of a food, drug, cosmetic or device he shall not permit the food, drug, cosmetic or device to be cleared of customs until the Government Analyst has consented thereto.

(2) The inspector shall transmit as soon as practicable the samples taken under paragraph (1) to an analyst for analysis or examination and the analyst shall submit a certificate in accordance with regulation 15 to the Government Analyst.

(3) The Government Analyst shall send a report of the analysis or examination to the Commissioner-General of the Revenue Authority and a copy thereof to the importer

of the food drug, cosmetic or device.

Admission of food, drug, etc., constitutes violation of Act.

**12.** (1) Where a food, drug, cosmetic or device sought to be admitted into Guyana, would, if sold in Guyana, constitute a violation of the Act or these Regulations, the food, drug, cosmetic or device may be admitted into Guyana 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.

(2) 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, shall be forfeited to the State and disposed of as the Minister may direct, except that the Minister may extend the time for complying with the conditions specified *or* for exporting the said goods.

Certificate for imported food, drug, etc.

**13.** 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 such 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.

**14.** (1) When taking a sample pursuant to section 21 of the Act, an inspector shall, after procuring a suitable quantity of the article in question, notify the owner thereof or the person from whom the sample was obtained of his

intention to submit the sample or a part thereof to an analyst for analysis or examination.

(2) Where, in the opinion of the inspector, division of the procured quantity –

(a) would not interfere with analysis or examination he shall –

(i) divide the quantity into three parts;

(ii) identify the three parts as the owner's portion, the sample, and the duplicate sample and where only one part bears the label, that part shall be identified as the sample;

(iii) seal each part in such a manner that it cannot be opened without breaking the seal; and

(iv) deliver the part identified as the owner's portion to the owner or the person from whom the sample was obtained, submit the sample to an analyst for analysis or examination and retain the duplicate sample for future comparison or verification; or

(b) would interfere with analysis or examination he shall –

(i) identify the entire quantity as the sample;

(ii) seal the sample in such a manner that it cannot be opened without breaking the seal, and

(iii) submit the sample to an analyst for analysis or examination.

(3) Where the owner or the person from whom the sample was obtained objects, to the procedure followed by an inspector under paragraph (2) (b) at the time the sample was obtained, the inspector shall follow the procedure set out in paragraph (2) (a) if the owner or the person from whom the sample was obtained, supplies at his own expense a sufficient quantity of the article.

Certificate of analyst Form B Part I of First Schedule.

**15.** 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 Part I of the First Schedule.

Fees to be paid for analysis by members of the public. Part II of First Schedule.

**16.** Where a member of the public requests the analysis of any food, drug or cosmetic, the fees to be paid for such analysis shall be as specified in the tariff of fees set out in Part II of the First Schedule.

## PART II
## FOODS

Interpretation.

**17.** In this Part –

"alcoholic beverage" means a liquid food containing ethyl

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alcohol in such amount so as to make it liable to duty under the Tax Act and includes spirits, liqueurs, wines, malt liquors, cider, perry, champagne and spirit compounds used as foods, but does not include a flavouring preparation or a liquid food in which ethyl alcohol is used as a preservative;

"artificial (non-nutritive) sweetening agent" means any chemical compound which is sweet to the taste but does not include sugar or other carbohydrate or polyhydric alcohols;

"baked confectionery" means any solid or semi-solid food suitable for human consumption without any further preparation or processing 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;

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

"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 semisolid food suitable for human consumption without further preparation or processing and which is 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;

"close proximity" means with reference to the common name, immediately adjacent to the common name without any intervening printed, written or graphic matter;

"common name" means –

Part IV of Second Schedule.

(a) the name printed in bold type as set out in Part IV of the Second Schedule;

(b) where the name is not printed in bold type, 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

(c) where the name of the food consists of the names generally known of two or more of its principal ingredients, the names of these ingredients generally known arranged in descending order of proportion by weight, which may be separated by conjunctions or prepositions;

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

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

"container" includes any form of packaging of food for sale as a single item, whether by way of wholly or partly enclosing the food or by way of attaching the food to some article, and in particular includes a wrapper or confining brand;

"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;

Part IV of Second Schedule

"flavouring preparation" includes any food for which a standard is provided in Division 8 of Part IV of the Second Schedule;

"food additive" means any substance including any source of radiation, 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) any nutritive material that is used, recognised or commonly sold as an article or ingredient of food;

(b) vitamins, minerals nutrients, or amino-acids unless added for flavourings;

(c) spices, seasonings, flavouring preparations, 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;

Part I of Second Schedule.

"food colour" means those colours permitted for use in or upon food by Part I of the Second Schedule;

"ingredients" means any substance including a food additive used in the manufacture or 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;

"pre-packaged" means packaged or made up in advance ready for retail sale in a wrapper or container and where any food, drug, cosmetic or device packaged or made up in a wrapper or container is found on any premises where such food, drug, cosmetic or device packaged, kept or stored for sale, the food, drug,

cosmetic or device shall be deemed to be pre-packaged unless the contrary is proved;

Part II of Second Schedule

"preservative" means a substance classified as such in Part II of the Second Schedule;

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"proof spirit" means proof spirit as defined in the Customs Act;

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

"retail sale" means any sale to a person buying otherwise than for the purpose of re-sale, but does not include a sale to a caterer for the purposes of his catering business, or a sale to a manufacturer for the purposes of his manufacturing business;

"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 detained 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 suitable for human consumption without further preparation or processing and which is composed principally of sugar with or without the addition of edible oil or fats, milk products, gelatin, edible gums, nuts, fruits, natural or synthetic flavours, food additives, food colours or preserved fruit and in cludes 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 purpose 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 before its dispensing or supplying the food.

Labelling of food and information to be carried on label.

**18.** (1) No person shall sell a food unless a label is applied to the food in compliance with these Regulations.

(2) Except as otherwise provided by this Part, the label applied to a food shall carry –

(a) on the main panel

(i) the brand or trade name, if any, of the food;
(ii) the common name of the food; and
(iii) a correct declaration of the net contents in terms of weight, volume or number in accordance with the usual practice in describing the food;

(b) on any panel

(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 of or the person preparing the food and its country of preparation or origin;

Part II of Second Schedule

(iii) a declaration by name of any Class II, Class III or Class IV preservative as set forth in Part II of the Second Schedule, that is added to the food;

(iv) a declaration of any food colour that is added to the food except a food listed in regulation 22;

(v) a declaration of any flavouring preparation that is added to a food except a food listed in regulation 24;

(vi) the expiry date or date mark required by these Regulations;

(vii) storage instructions required by these Regulations;

(viii) any other statement required to be declared by these Regulations; and

(c) on any panel (including the panel at the bottom of the package) the batch

number, lot number or registration number as may be required by these Regulations.

(3) The declaration required by paragraph (2) (b) shall not be placed on the bottom of any food or on a panel on the bottom of the package of any food.

(4) For the purposes of paragraph (2) (a), 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 force of these Regulations.

(5) Any new glass bottles used for packaging carbonated beverages or liquid dairy products shall, on the expiration of two years from the coming into force of these Regulations, bear clearly and legibly as a label fired on the body of the bottle, the name and address of the manufacturer and a statement of net contents as prescribed by paragraph (2) (a) (iii).

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

(7) The declaration of net contents required by paragraph (2) (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, stating the date when the variation becomes effective, made by the Minister.

(8) 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.

(9) The list of ingredients required by paragraph (2) (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.

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

(11) 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 good manufacturing practice, added water shall be declared as an ingredient.

(12) 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) for 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);

vegetables 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 as set out in Part II of the Second Schedule;
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 as set out in Part II of the Second Schedule);
stabilisers;
thickening agents;
vegetable or edible gums;

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

(14) Where a 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.

(15) The declarations required by paragraph (2) shall be made in English except where a label is applied to a package of food in a country the official language of which is not English the declarations so required shall appear in English on any panel except the bottom of the package.

Common name of animal to be used in declaration.

**19.** 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 any declaration required by these Regulations.

Declaration as to net contents.

**20.** Notwithstanding regulation 18 (2) (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 (57 grams) or the volume of net contents is less than two fluid ounces (57 millilitres);

(b) eggs, fresh fruit or fresh vegetables packed in transparent, colourless and flexible materials where the egg, fruit or vegetable is customarily sold by number, or if sold by weight by multiples of one pound or of half a kilogram except 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;

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

Exceptions to list of ingredients.

**21.** (1) Notwithstanding regulation 18(2) (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 (57 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) baked confectionery and sugar confectionery;

(g) blood pudding;

(h) gelatin desserts;

(i) alcoholic beverages;

(j) Angostura aromatic bitters;

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

(l) packages containing less than two fluid ounces (57 millilitres) or two ounces (57 grants) of food where the largest dimension of the package is less than two inches or 50 millimetres.

(2) If the label or any package of food mentioned in paragraph (1) contains any statement which relates to an ingredient of the food other than the brand, trade or common name of the food or any other statement required by these Regulations, then the label shall have included thereon a full list of ingredients as required by regulation 18(2) (b) (i) –

Label declaration not required for food colour added to certain foods.

**22.** Notwithstanding regulation 18(2) (b) (iv), no label declaration label is required to indicate –

(a) the presence of food colour added in the following foods –

(i) bakery products, except brown bread;
(ii) butter, margarine, shortening;
(iii) cheese and processed cheese;
(iv) baked confectionery and sugar confectionery;
(v) gelatine desserts;
(vi) ice cream, water ices and

milk ices;
(vii) icing sugar;
(viii) liqueurs, alcoholic cordials and Angostura aromatic bitters;
(ix) sherbets; and
(x) carbonated beverages;

(b) the presence of caramel as a food colour in the following foods –

(i) fermented beverages exempt from duty under the Tax Act;
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(ii) sauces;
(iii) spirits, except gin;
(iv) vinegar;
(v) wine; and
(vi) dilute acetic acid (food grade).

Label declaration not required for sulphur dioxide etc.

**23.** (1) Notwithstanding regulation 18 (2) (b) (iii), no label declaration is required to indicate –

(a) 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, washed grey sugar;
(iv) confectionery;
(v) malt liquors;
(vi) wines;

(vii) syrups; or
(viii) shrimp;

Part II of Second Schedule.

(b) the presence of Class III preservatives as set out in Part II of the Second Schedule, in or upon –

(i) bread;
(ii) bakery products;
(iii) cheese, processed cheese, processed cheese products; or
(iv) wines;

Part II of Second Schedule.

(2) Class I preservatives as set out in Part II of the Second Schedule, shall be declared by name as if they were ingredients of a food.

Label declaration not required for artificial or imitation preparation.

**24.** Notwithstanding regulation 18(2) (b) (v), no label declaration is required to indicate the presence of artificial or imitation flavouring preparation added 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 "fruit juice";

(f) carbonated beverages;

(g) flavoured skim milk, flavoured

malted milk or flavoured, malted milk products; or

(h) sugar confectionery.

Labelling of food commonly sold in normal and dried state.

**25.** (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) Paragraph (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.

Food prepared by adding water.

**26.** 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.

Food sold pre-packaged.

**27.** Where a food is sold pre-packaged by retail as a mixture of ingredients, dry or otherwise, and is intended to be made into another food for human consumption by the addition of any food or substance other than water, the name of the substance required to be added shall be mentioned on the label preceded by such words as "Add", "Needs" or "Mixed With", in close proximity to the common name of the mixture of the ingredients sold.

Labelling of food containing artificial sweetener.

**28.** A food containing an artificial sweetener or its salts shall carry on the label the name of the artificial sweetener, and a statement to the effect that it contains a non-nutritive artificial sweetener.

## ALCOHOLIC BEVERAGES

Labelling of alcoholic beverages.

**29.** The following provisions apply in the labelling and advertising of alcoholic beverages –

(a) 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 that name is generally recognized as being associated with that distinctive type of alcoholic beverage.

(b) 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 that country, may only be applied to an alcoholic beverage produced in another country if the common name is

preceded by name or adjective in identical lettering, indicating the true country or locality of origin.

(c) The word "wine" may only be applied as a common name to –

(i) undistilled fermented alcoholic beverages prepared from a fruit ingredient consisting only of fresh or preserved grapes;

(ii) undistilled fermented alcoholic beverages prepared from a fruit ingredient other than grapes or prepared wholly or principally from a fruit.

(d) Where an undistilled fermented alcoholic beverage is –

(i) prepared from a fruit ingredient consisting of fruit grown in a territory of the Caribbean Community the label shall, on a conspicuous part thereof, show an accurate description of the fruit and the territory from which it was grown;

(ii) prepared wholly or principally from a fruit, grain, tuber, stem or any other part of a plant the label shall show the common name of the plant followed by

the word "wine".

(e) The common name "non-alcoholic wine" shall not be applied to any food, except an unfermented grape juice sold as a sacramental wine for religious use which, though not an alcoholic beverage, resembles it.

(f) The label of distilled spirits or liqueurs shall carry a statement of the alcoholic strength of the spirits or liqueurs in terms of any of the following –

(i) percentage of alcohol by volume;

(ii) degrees Gay-Lussac (°G.L.);

(iii) degrees proof spirit or per cent proof spirit;

(iv) degrees or per cent U.S. proof; or

(v) in any other term authorised by the Minister.

(g) The common names "brandy", "rum", "gin" or "vodka", shall not be applied to any 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).

(h) In the case of spirit compounds, a declaration of the minimum alcoholic strength in terms of percentage proof

spirit shall be made on the label in a form of words such as "not less than X% proof spirit".

(i) The word "vintage" shall not be used in connection with any wine or brandy which is not prepared by fermentation of freshly gathered grapes in the place in which they are grown but the word "vintage" may be used in connection with cider.

(j) The common names referred to in paragraphs (a) and (b) may be in a language other than English, but shall be printed in the English alphabet with accepted accent marks.

## FOOD FROM VENDING MACHINE

Sale of food from vending machine.

**30.** (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 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.

Food sold unpackaged etc.

**31.** (1) Regulation 18 does not apply to a food that is –

(a) weighed or measured in or counted into a package the presence of the purchaser, or weighed, measured or

counted in the presence of the purchaser before being packaged or weighed, measured or counted in the presence of the purchaser;

(b) sold in bulk or packaged from bulk at the place where the food is retailed unless that package bears a statement, mark or device describing the ingredients or the substances contained therein the name of the food and the net contents of the package.

Bulk containers.

**32.** Notwithstanding regulation **18,** a bulk container of a food or a food additive shall carry a label which label may carry any or all of the following –

(a) the common name of the food;

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

(c) the net contents of the bulk container;

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

(e) any batch or lot number, date mark, expiry date or registration number required by these Regulations; or

(f) any storage instructions required by these Regulations.

Package

**33.** Notwithstanding regulation 18(2), a package

containing food additive etc.

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 Government Analyst may consider necessary to ensure, its safe use, in accordance with the Act, regulations made thereunder or with good 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.

Variations of content of a package of

**34.** (1) Subject to paragraph (2), where the contents of a package of food are expressed in terms of weight, measure

food. or number, no variation below the quantity declared on the label is permitted except –

(a) variations due exclusively to differences in the capacity of containers resulting solely from unavoidable difficulties in manufacturing, but no greater variation is permitted because of the design of the containers than is usual in the case of containers of similar capacity that can be manufactured so as to be of approximately uniform capacity; and

(b) 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.

(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.

Labelling of artificial food.

**35.** 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 such food; and

(b) be in identical type and be identically

displayed with such name.

Inner and outer labels.

**36.** 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.

## ADULTERATION OF FOOD

Adulteration of food.

**37.** (1) Subject to paragraph 2, a food is adulterated if any of the following substances or classes of substances are present therein or have been added thereto –

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

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

(c) synthetic sweetening agents other than saccharin or its salts;

(d) iso-propyl alcohol;

(e) synthetic food colours in a proportion greater than 0.03 per cent of the weight of the food when prepared for consumption as directed, or as it is usually consumed (except in food colour preparations as specified in Part I of the Second Schedule);

Part I of Second Schedule.

(f) dihydrosafrole;

(g) isosafrole;

(h) safrole;

(i) cottonseed flour that contains more than four hundred and fifty parts per million of free gossypol;

(j) fatty acids and their salts containing toxic factors;

(k) oil of American sassafras from *Sassafras albidum* (Nutt), Nees;

(l) oil and Brazilian sassafras from *Ocotea Cymbarum* H.B.K.;

(m) oil of Camphor sassafras from Cinnamomum camphorum Sieb; or

(n) oil of micranthum from Cinnamomum micranthum Hayata.

(2) Notwithstanding paragraph (1) –

(i) a food is not adulterated by reason only that it contains not more than 0.3 per cent mineral oil, if good manufacturing practices require the use of mineral oil;

(ii) chewing gum is not adulterated by reason only that it contains a paraffin wax base;

(iii) fresh fruits and vegetables, except turnips, are not adulterated by reason only that they are coated

with not more than 0.3 per cent paraffin wax and petrolatum, if good manufacturing practices require the use of such coating; and

(iv) turnips and cheese are not adulterated by reason only that they are coated with paraffin wax in accordance with good manufacturing practice.

Food injurious to health.

**38.** No person shall prepare, pack, store or transport any food intended for sale in any manner which renders it injurious to health, or which injuriously affects its nutritive properties, or which renders it unwholesome, nor shall a person sell any food which has become injurious to health, which has had its nutritive properties injuriously affected, or which has become unwholesome.

Container blown of punctured, etc.

**39.** No person shall sell any canned food the container of which is blown or punctured, or any frozen food which has been thawed in the package and subsequently refrozen.

Water as ingredient.

**40.** No person shall use water other than potable water as an ingredient in the manufacture or preparation of any food.

Use of preservatives. Part II of Second Schedule.

**41.** (1) No person shall use as a preservative in or upon food or sell as a preservative for food, any substance other than those classified in Part II of the Second Schedule as Class I, Class II, Class III or Class IV preservatives, respectively.

Part II of Second

(2) Where any Class II, Class III or Class IV preservative, as the case may be, is sold for use on food, the

Schedule.

label thereof shall include adequate directions for use in accordance with the limits prescribed for that preservative in Part II of the Second Schedule.

## POISONOUS SUBTANCES IN FOOD

Food in container.

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

Specified poisonous substances Part III of Second Schedule.

**43.** Notwithstanding section 5(a) of the Act, the foods specified in Part III of the Second Schedule may contain in or upon them any or all of the poisonous substances specified in that Part opposite to that food 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 no other poisonous or harmful substances or other poisonous or harmful substances in amounts not considered by the Government Analyst likely to be injurious to health.

Food not specified in Part III of Second Schedule.

**44.** Notwithstanding section 5(a) of the Act and subject to regulation 45, a food not specified in Part III of the Second Schedule may contain in or upon it not more than –

(a) one part per million of arsenic,

(b) two parts per million of lead,

(c) twenty parts per million of copper, or

(d) fifty parts per million of zinc,

as determined by an acceptable method and no other poisonous or harmful substance or other poisonous or harmful substances in amounts not considered by the Government Analyst likely to be injurious to health.

Standard for food Part IV Second Schedule.

**45.** There is prescribed in Part IV of the Second Schedule standards for food and only those ingredients set out in relation to the prescribed standard shall be used in a food.

## PART III
## DRUGS

Interpretation.

**46.** In this Part –

"antibiotic" means any drug or combination of drugs such as those declared by order made under the Antibiotics Act, which is prepared from certain micro-organisms, or which formerly was prepared from micro-organisms but is now made synthetically and which possesses inhibitory action on the growth of other micro-organisms;

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"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 repackaged 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 generally known, or the name by which the drug is generally known in Guyana;

"controlled drug" means any of the drugs classified as such in regulation 88 and includes a preparation;

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"dangerous drug" means, any of the substances mentioned as such in the Dangerous Drugs Ordinance;

"dentist" means a person who is registered as a dentist under any law for the time being in force in Guyana;

"expiration date" or "expiry 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;

"'licence" means a licence issued under regulation 90(1) (a);

"licensed dealer" means a practitioner, a pharmacist or the holder of a licence;

"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 Guyana for use as a drug before 1st January, 1977;

(b) a drug that is a combination of two or more drugs with or without other ingredients, and that has not been imported into Guyana before 1st January, 1977 in that combination or in the proportion in which those drugs are combined;

(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 Guyana before 1st January, 1977 for that use or condition of use; or

(d) any other drug that the Minister may specify;

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

(a) in this Part, or

Second Schedule of Act.

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

"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 of Act.

(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 and Poisons Board;

"permit" means a permit issued under regulation 90(1) (b);

c. 36:07 "pharmacist" means a person who is registered as a pharmacist under the Pharmacy Practitioners Act;

"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 duly qualified medical practitioner under any law for the, time being in force in Guyana;

"practitioner" means a person who is registered as a duly qualified medical practitioner under any law for the time being in force in Guyana and includes a dentist

or a 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 shall 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 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 Adapted Name Council of the United States Pharmacopeial Convention as the adopted name of the drug;

(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 of Act.

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

Third Schedule of Act.

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

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

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"veterinary surgeon" means a person who is registered as a veterinary surgeon under the Animal Diseases Act;

"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.

Labelling of drugs.

**47.** No person shall sell a drug unless a label is applied to the drug in compliance with these Regulations.

Information to be carried on label.

**48.** (1) Except as otherwise provided by this Part, the label applied to a drug shall carry on the main panel of both the inner and the outer labels –

Second Schedule of Act.

(a) 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 stated; or

(b) if there is no proper name, the common name.

(2) In addition to paragraph (1) –

(a) the inner and outer labels of a drug shall show –

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

(ii) the address of the manufacturer or distributor of the drug, unless the immediate container of the drug contains 0.2 of a fluid ounce or five millilitres or less, in which case the address need not be shown, 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 labels on Patent or Proprietary Medicines;

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

(v) a quantitative list of the medicinal ingredients contained in the drug' by

their proper names or, if they have no proper names, by their common names, except labels on official drugs and Patent or Proprietary Medicines;

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

(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; and

(b) the outer label of a drug shall show –

(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.

**49.** The label on a bulk package of any drug -

(a) shall show –

(i) the proper name and 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

Second Schedule of Act.

abbreviation therein stated;

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

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

(iv) 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";

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

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

(b) may show –

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

(ii) directions as to this type of storage necessary to maintain the potency, efficacy, safety or properties of the drug.

Label of drug sold on prescription.

**50.** Regulation 48 does not apply –

(a) to the label of a drug sold on prescription if the label shows –

(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 practitioner 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 shows –

(i) the name of the drug; and

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

Packing cases.

**51.** Regulations 48 and 49 do not apply to packing cases used for the protection of bulk packages of drugs that are in transit for the purpose of import or export.

Patent or Proprietary Medicine containing dangerous drug etc.

**52.** Notwithstanding regulation 48 (2) (a) (v) where a Patent or Proprietary Medicine contains a dangerous drug, a Third Schedule drug, or a controlled drug, the name and proportion of such drug shall, subject to regulation 50 be stated on the label.

Package of drug with one label.

**53.** 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.

Cautionary phrase.

**54.** The label of every pre-packaged drug shall include the cautionary phrase prominently displayed and readily discernible — "keep out of the reach of children".

Standard prescribed.

**55.** Where a written law prescribes a standard for a drug and gives a name or designation to that standard, no person shall use that name or designation on a label or in any advertisement of that drug unless the drug conforms with the standard.

Diseases, disorders etc. mentioned in Inserts Third Schedule drug. First Schedule of Act.

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

Exemption of inserts accompanying drug.

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

Variations of contents of a package of a drug.

**58.** (1) Subject to paragraph (2), where the contents of a drug are expressed in terms of weight, measure or number, no variations from the quantity declared on the label are permitted except –

(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 methods;

(b) variations due exclusively to differences in the capacity of containers resulting solely from un-avoidable 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) Notwithstanding paragraph (1), 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.

Drug with salicylic acid etc.

**59.** (1) No person shall sell a drug containing –

(a) salicylic acid or its salts, acetylsalicylic acid or its salts or salicylamide, unless, where the drug is recommended for children, both the inner and outer labels shall carry cautionary statements 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;

(b) hyoscine (scopolamine) or its salts, unless both the inner and outer labels carry a cautionary statement to the effect that the drug is not to be used by persons suffering from glaucoma, or where the drug causes blurring of the vision or pressure pain within the eye;

(c) phenacetin, either singly or in combination with other drugs, unless its label carries the following statement –

"Caution: May be injurious if taken in large doses or for a long time. Do not exceed the recommended dose without consulting a physician." and

(d) any other substance that requires a cautionary statement as determined by the Minister acting on the advice of the Drug Advisory Committee.

(2) Paragraph (1) does not apply to any preparation containing a drug that is required by anyone to be sold on prescription, or for parenteral or injectable use.

Sale of corticosteriod drug.

**60.** (1) No person shall sell a corticosteroid drug for ophthalmic use unless –

(a) the outer label or the package insert carries, as part of the directions for use, the following statements –

"Contraindications"

Viral diseases of the cornea and conjunctiva;
Tuberculosis of the eye;
Fungal diseases of the eye;
Acute purulent untreated infections of the eye, which, like other diseases caused by micro-organisms, may be masked or enhanced by the presence of the steroid.

Side Effects

Extended ophthalmic use of corticosteroid drugs may cause increased intraocular pressure in certain individuals and in those diseases causing thinning of the cornea, perforation has been known to occur";

and

(b) the inner label carries the statements required by paragraph (1) (a) or instructions to see the outer label or package insert for information about contraindications and side effects.

(2) Paragraph (1) does not apply to a corticosteroid drug that is dispensed by a pharmacist pursuant to a prescription.

(3) No person shall disseminate to a practitioner promotional literature about corticosteroid drugs for ophthalmic use unless the statements required by paragraph (1) (a) are included in that literature.

(4) Paragraphs (1) and (3) do not apply to a drug sold solely for veterinary use.

Tablet disintegration times.

**61.** (1) No person shall sell a drug in the form of a tablet, the label of which indicates that it carries an enteric coating or a coating designed to have a similar purpose, unless the tablet –

(a) does not disintegrate when exposed to simulated gastric juice for 60 minutes; and

(b) disintegrates in not more than an additional 60 minutes in simulated intestinal juice when tested by the official method.

(2) Where a standard of disintegration has not been prescribed for a drug in any of the publications listed in

Second Schedule of Act.

the Second Schedule to the Act or in paragraph (1), no person shall sell a drug in the form of a tablet that is intended to be swallowed whole, unless the tablet disintegrates in more than 60 minutes when tested by the official method.

(3) Paragraphs (1) and (2) do not apply with respect to tablets the drug in which has been demonstrated by an acceptable method to the satisfaction of the Government Analyst to be available to the body.

(4) Paragraph (2) does not apply in respect of tablets that are represented on the label as releasing the drug at timed intervals or in sustaining quantities over a period of time.

Thalidomide.

**62.** No person shall import or sell or advertise for sale Thalidomide.

Third Schedule Drug and controlled drug.

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

## THIRD SCHEDULE DRUGS

Third Schedule Drug to be sold by prescription.

**64.** No person shall sell a Third Schedule Drug unless he has received a prescription therefor and such 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 such signature is not known to the dispenser of the prescription, the signature shall be first verified by him.

Record of prescription for Third Schedule Drug.

**65.** 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 there in;

(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.

Dispenser to retain prescription.

**66.** Every prescription shall be retained by the dispenser for a period of at least two years unless marked for refill and on the final refill the prescription shall be retained for a period of at least two years from the date of the final refill.

Refilling a prescription.

**67.** (1) No person shall refill a prescription for a Third Schedule Drug unless the practitioner so directs and no person shall refill such a prescription more times than the number of times prescribed by the practitioner.

(2) The person refilling a prescription for a Third Schedule Drug shall record on the original prescription therefor, the following information respecting each refilling of a prescription:

(a) the date of refill;

(b) the quantity of drug dispensed; and

(c) his name.

Importation of Third Schedule Drug.

**68.** No person other than –

(a) a practitioner;

(b) a licensed drug manufacturer;

(c) a licensed importer of drugs whose business is under the personal control of a pharmacist;

(d) a pharmacist; or

(e) the Government Analyst,

shall import a Third Schedule Drug.

Sale of Third Schedule Drug to licensed drug manufacturer etc.

**69.** (1) Regulation 64 does not apply to the sale of a Third Schedule Drug to –

(a) a licensed drug manufacturer;

(b) practitioner;

(c) a licensed importer of drugs whose business is under the personal control

of a pharmacist;

(d) a pharmacist;

(e) a hospital with a pharmacist;

(f) a Department of the Government upon receipt of a written request signed by the Minister thereof or his duly authorised representative; or

(g) any person, upon receipt of a written request by the Government Analyst.

(2) Where a person makes a sale authorised by paragraphs (1)(f) and (1)(g) he shall retain the written request for the drug for a period of at least two years from the date of filling the request.

Licensed importer of drugs not to sell or transfer Third Schedule Drug.

**70.** No licensed importer of drugs, whose business is under the personal control of a pharmacist, shall sell or transfer any Third Schedule Drug to any person other than a practitioner or a pharmacist and the importer shall keep a record of such sale and transfer.

Drug listed in Part II of Third Schedule of Act.

**71.** Regulations 64, 65, 66, 67 and 68 do not apply to a drug listed or described in Part II of the Third Schedule to the Act, if –

(a) the drug is in a form not suitable for human use; or

(b) the main panels of both the inner and the outer labels carry, 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.

Disinfectant germicide or antiseptic.

**72.** A drug represented for use primarily as a disinfectant, germicide or antiseptic, shall carry on both the inner and outer labels of a package –

(a) the chemical name and proportion or amount of each drug contained therein;

(b) the batch number;

(c) directions for use;

(d) the words “For External use only” or “For Internal use only” whichever are applicable;

(e) for preparations of phenolic type of natural oils other than soaps and ointments, a statement of the phenol co-efficient of the preparation as determined by the official method;

(f) for preparations containing available chlorine, a statement of the percentage of the available chlorine content.

Aminopyrine or dipyrone.

**73.** (1) No person shall sell aminopyrine or dipyrone (a derivative of aminopyrine) for oral or parenteral use, unless –

(a) the inner label carries the statement:

"WARNING: Fatal agranulocytosis may be associated with the use of aminopyrine or dipyrone. It is essential that adequate blood studies be made.

(See enclosed warnings and precautions)" and

(b) the outer label or the package insert carries the following statements:

"WARNING: Fatal and even serious agranulocytosis is known to occur after the administration of aminopyrine or dipyrone. Fatal agranulocytosis has occurred after short term, intermittent and prolonged therapy with the drugs. Therefore, the use of these drugs should be as brief as possible. Bearing in mind the possibility that such reactions may occur, aminopyrine or dipyrone should be used only when other less potentially dangerous agents are ineffective.

PRECAUTIONS: It is essential that frequent white blood cell counts and differential counts be made during

treatment with these drugs. However, it is emphasized that agranulocytosis[1] may occur suddenly without prior warning. The drug should be discontinued at the first evidence of any alteration of the blood count or sign of agranulocytosis, and the patient should be instructed to discontinue use of the drug at the first indication of sore throat or sign of other infection in the mouth or throat (pain, swelling, tenderness, ulceration).

(2) No person shall disseminate to a practitioner promotional literature about aminopyrine or dipyrone unless the statement specified in paragraph (1) are included in such literature.

(3) Paragraphs (1) and (2) do not apply to preparations containing aminopyrine or dipyrone that are dispensed by a pharmacist pursuant to a prescription, or sold for veterinary use only.

Coated tablets containing potassium salts.

**74.** (1) No person shall sell coated tablets containing potassium salts with or without thiazide diuretics, unless the inner label thereof or the package insert carries the following statement –

"WARNING: A probable association exists between the use of coated tablets containing potassium salts, with or without thiazide diuretics and the incidence of serious small bowel ulceration. Such preparations should be used only when adequate dietary supplementation is not practical, and should be discontinued if abnormal pain, distention, nausea,

vomiting or gastrointestinal bleeding occur."

(2) No person sell disseminate to a practitioner promotional literature about coated tablets containing potassium salts, with and without thiazide diuretics unless the statement specified in paragraph (1) is included in such literature.

(3) Paragraph (1) and (2) do not apply to coated tablets containing potassium salts with or without thiazide diuretics that are dispensed by a pharmacist pursuant to a prescription or sold for veterinary use only.

Antibiotic preparation for treatment of cattle.

**75.** A person may sell an antibiotic preparation for the treatment of cattle if –

(a) the preparation is not to be used for lactating cattle and the inner and outer labels of the preparation carry a statement to that effect; or

(b) where the preparation may be used for lactating cattle -

(i) there has been submitted, on request, to the Government Analyst acceptable evidence to show the period of time that must elapse after the last treatment with the preparation, in order that the milk from treated lactating animals shall not contain residues of antibiotics and that period does not exceed 96 hours;

(ii) the main panel of the outer label of the preparation and either the inner

label or a packaging insert describing the antibiotic preparation carries the words:

"WARNING: MILK TAKEN FROM TREATED ANIMALS WITHIN.... HOURS AFTER THE LATEST TREATMENT WITH AN INTRAMAMMARY MEDICATION SHALL NOT BE USED IN FOOD."; and

(iii) the blank on the label is filled in with the true figure.

Substance with oestrogenic activity.

**76.** No person shall sell any substance having oestrogenic activity for administration to poultry which may be consumed as food.

Drug recommended to be administered to animal.

**77.** (1) The Government Analyst may require the manufacturer of a drug recommended for administration to animals which may be consumed as food –

(a) to file with him in respect of that drug a submission, in form and content satisfactory to the Government Analyst, describing in detail, tests carried out to determine that no residues of the drug, except residues within the limits prescribed by these Regulations remain in meat, meat by-products, eggs or milk from animals to which the drug has been administered; and

(b) to print on the main panel of the outer

label of a drug recommended for administration to animals which may be consumed as food and either the inner label or a packaging insert describing the drug, a warning that meat, meat-products, eggs or milk from animals to which the drug has been administered cannot be sold for consumption as food if they are obtained within such time after administration as may be specified by the Government Analyst.

(2) No manufacturer shall sell a drug in respect of which the Government Analyst has required a warning to be printed pursuant to paragraph (1) (b), unless the manufacturer has complied with that requirement.

**NEW DRUGS**

New drug.

**78.** (1) No person shall import, sell or advertise for sale a new drug unless –

(a) he has a licence, that is in force, issued by the Minister in respect of the importation or sale, as the case may be, of that new drug; and

(b) he has paid the licence fee of one hundred dollars.

(2) An application for the issue of a licence to import, or sell a new drug shall be submitted in duplicate in writing to the Minister setting forth –

(a) a description of the new drug including the name and address of 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 list of all the ingredients stated quantitatively, the specifications for the ingredients, the route of administration, the proposed dosage, the claims to be made for the new drug, any known contraindications and side-effects of the new drug and a description of the pharmaceutical dosage form in which the new drug is to be sold;

(c) a description of the plant and equipment to be used in manufacturing, processing and packaging the new drug;

(d) details of the method of manufacture and the controls to be used in manufacturing, processing and packaging the new drug;

(e) details of the tests conducted to control the potency, purity, stability and safety of the new drug;

(f) detailed reports of the tests made to establish the safety of the new drug for the purpose and under the conditions of use recommended;

(g) substantial evidence of the clinical effectiveness of the new drug for the purpose and under the conditions of use recommended;

(h) a draft of every label, package insert, product brochure and file card proposed to be used in connection with the drug;

(i) samples of the new drug in the finished pharmaceutical form in which it is to be sold;

(j) such samples of the components of the new drug as the Government Analyst may require; and

(k) 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 Drug 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 new drug is approved for use in Australia under the conditions of use recommended 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 such certificate, such official body or Government Department having the 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.

(3) The Minister may in his discretion, refuse to issue a licence or may issue a licence although the application therefor does not comply with paragraph (2) (k) but is accompanied by –

(a) information set forth in subparagraphs (a) to (j) of paragraph (2); and

(b) such other information and material as the Minister may require.

Material change in new drug.

**79.** (1) Where a material change is made to a new drug in respect of –

(a) the strength, purity or quality thereof;

(b) the pharmaceutical dosage form in which it is sold;

(c) the conditions of use, including indications for use and the route of administration;

(d) the dosage; or

(e) the label,

a person who has a licence to import or sell that drug shall cease to do so until he obtains a new licence for that changed drug.

(2) An application for the issue of a new licence shall state fully and accurately the details of the changes made and the manner in which the new drug is affected by the change.

Licence previously issued.

**80.** Where a person wishes to import, sell or advertise for sale, a new drug in respect of which a licence has been previously issued to another applicant, that person shall make a separate application in accordance with regulation 78.

Issue of Licence.

**81.** The Minister on the recommendation of the Drug Advisory Committee shall, within one hundred and twenty days after the filing of an application for the issue of a licence to import or sell a new drug, notify the applicant whether or not his application is approved and, if approved, may issue a licence to the applicant.

Withdrawal of licence.

**82.** (1) The Minister may, after consultation with the Drug Advisory Committee, by notice withdraw a licence to import or sell a new drug and shall notify the person to whom the licence has been issued of the withdrawal.

(2) The withdrawal of a licence 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 licence was issued, reveals that the new drug is not shown to be safe for the use represented in the application made to the Minister in respect of that new drug and on which the licence was issued;

(b) the information submitted to the Minister in relation to that new drug and on which the licence was issued, contained or was based on untrue statement of material fact; or

(c) it is necessary in the public interest.

(3) The notice mentioned in paragraph (1) shall be published in a daily newspaper printed and circulating in Guyana.

Reporting effects of new drug.

**83.** Where a person receives any report of any unexpected side-effects, injury, toxicity or sensitivity reaction associated with the clinical uses, studies, investigations and tests respecting any new drug, he shall immediately inform the Government Analyst thereof, furnishing him with the full information available.

New drug for use of investigators.

**84.** (1) Notwithstanding anything to the contrary in these Regulations, a new drug may be imported for the use of investigators for the sole purpose of obtaining clinical and scientific data with respect to its safety, stability, dosage or efficiency, if –

(a) the investigators have written authority from the Minister on the advice of the Drug Advisory Committee to carry out investigations on the new drug and have the facilities for so doing;

(b) before the importation, the Minister is informed of the identifying name or mark by which the new drug may be recognized;

(c) both the inner and outer labels on any package of such new drug carry the statement "To Be Used For Investigational Purposes Only";

(d) before the sale, the importer ensures that any person to whom the new

drug is to be sold has written authority from the Minister to conduct investigations relating to that new drug, and obtains in writing from that person an undertaking that the new drug will be used solely by him or under his direction for investigational purposes.

(2) A person who imports a new drug for the purpose of sale to any other person authorized by the Minister to carry out investigations in relation to that new drug, shall keep accurate records of such sales, and shall make these records available for inspection by inspectors duly designated under the Act.

Permission to import new drug to be used as sample.

**85.** Notwithstanding anything to the contrary in these Regulations, the Minister may grant permission in writing to any person to import a specified quantity of a new drug, for submission as a sample with an application for the issue of a licence in respect of that new drug.

Emergency licence.

**86.** Notwithstanding any other provision in these Regulations, the Minister may grant an emergency licence to a practitioner for the importation of a new drug, the application for which does not comply with the requirements of these Regulations, if that drug is required for the treatment of an urgent case, and the Minister is satisfied that it is in the best interest of the patient for whom the drug is intended, that the importation is effected without delay.

## PART IV
## CONTROLLED DRUGS

Interpretation.

**87.** In this Part "preparation" means a drug that contains –

(a) more than 5 per cent of barbituric acid, any derivative thereof or any salt thereof; or

(b) a controlled drug and one or more other drugs, in a recognised therapeutic form.

Controlled drugs.

**88.** For the purposes of this Part the following substances are classified as controlled drugs –

(a) Amphetamine and its salts;

(b) Barbituric acid and its salts and derivatives;

(c) Chenopodium oil;

(d) Coumarin;

(e) N, N-Diethyltryptamine (DET) and its salts;

(f) 3-(1, 2 – dimenthylheptyl) – 1 – hydroxyl –7, 8, 9, 10—tetrahydro—6, 6, 9—trimethyl—6H—dibenzo [b,d] pyran (DMHP) and its salts;

(g) N, N-Dimethyltrytamine (DMT) and its salts;

(h) Dinitrobenzene;

(i) Lysergic acid diethylamide (LSD or Lysergide) and its salts;

(j) Mescaline and its salts;

(k) Methamphetamine and its salts and derivatives;

(l) 3—Methyl - 4, 5 - methylenedioxy - amphetamine (MMDA) and its salts;

(m) 4-Methyl -- 2, 5 – dimenthoxyamphetamine (STP) (DOM) and its salts;

(n) 1 – Methyl—d—lysergic acid (+)—1—hydroxy—2—butylamide (Methysergide) and its salts;

(o) N-Methyl—3—piperidyl benzilate (LBJ) and its salts;

(p) 3, 4—Methylenedioxyamphetamine (MDA) and its salts;

(q) Parahexyl and its salts;

(r) Psilocine and its salts;

(s) Psilocybine and its salts;

(t) Tetrahydrocannabinol and its isomers.

Manufacture and sale etc. of controlled drug.

**89.** (1) Subject to this Part, no person, except a licensed dealer shall –

(a) manufacture or sell a controlled drug; or

(b) import or export a controlled drug

unless he first obtained a permit to do so from the Minister.

(2) An application for the issue -

(a) of a licence to be a licensed dealer shall be in the form set out as Form A in the Third Schedule, and

Form A Third Schedule.

(b) of a permit to a licensed dealer shall be in the form set out as Form B in the Third Schedule.

Form B Third Schedule

Issue of licence to licensed dealer.

**90.** (1) The Minister may, upon application thereof –

Form C Third Schedule.

(a) issue a licence in the form set out as Form C in the Third Schedule, to any person who, in the opinion of the Minister, is qualified to be a licensed dealer, to manufacture or sell a controlled drug; or

(b) issue a permit in the form set out as From D in the Third Schedule to any licensed dealer to import or export a controlled drug subject to such terms and conditions as he may think fit.

Form D Third Schedule.

(2) Paragraph (1) (a) does not apply to a practitioner or a pharmacist.

(3) A fee of twenty five dollars is payable by the applicant in respect of each licence or permit, as the case may be, issued under paragraph (1).

(4) A licence issued under paragraph (1) (a) shall, unless it is sooner revoked, expire on the 31st day of

December next following the date on which it was issued and may be renewed by the Minister on the appropriate application being made to the Minister in respect thereof.

(5) A permit issued under paragraph (1) (b) is valid only for the particular importation or exportation in respect of which it was issued.

Revocation or suspension of licence or permit.

**91.** (1) The Minister may revoke or suspend a licence or a permit issued pursuant to regulation 90(1) 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 of such licence or permit or any provision of these Regulations.

(2) Where a licence has been suspended it has no validity during the period of suspension.

Condition of licence or permit.

**92.** A licence or permit issued under regulation 90 is subject to the condition that the person to whom it is issued shall comply with these Regulations.

Sale or supply of controlled drug.

**93.** Subject to the terms and conditions of his licence and to the requirements of these Regulations a licensed dealer may only sell or supply a controlled drug –

(a) to another licensed dealer, if he receives written order therefor from such dealer and he verifies the signature affixed to the order before supplying same; and

(b) to a hospital, if he receives a written order signed by a pharmacist or a practitioner or other official duly authorised by the hospital to sign

such an order, and he verifies the signature and fixed to the order before supply same.

Conditions as to sale or supply of controlled drug by licensed dealer or pharmacist.

**94.** (1) A licensed dealer who is a pharmacist carrying on the business of a pharmacy, or any pharmacist employed by him for the purposes of that business, may sell or supply 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 that drug;

(c) the prescription has been dated and signed by the practitioner who issued it and includes his full name and address; and

(d) the signature of the practitioner is verified before effecting the sale or the supply.

(2) A pharmacist shall not repeat a prescription for a controlled drug unless the practitioner issuing the original prescription specifies therein the number of times it may be repeated, and the intervals at which it may be repeated.

Register to be kept for controlled drugs.

**95.** (1) Every licensed dealer and every pharmacist in control of a place of business carrying on the business of a pharmacy shall keep separate register in relation to controlled drugs, in which he shall enter or cause to be entered within forty eight hours of every receipt or dispensation of any

controlled drug, the following –

(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, the date on which it was sold or supplied, and if supplied pursuant to a prescription, the name and address of the person for whom it was prescribed and the name and address of the practitioner who issued the prescription;

(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; and

(d) the name, quantity and form of any controlled drug in his stock at the end of each month.

(2) A licensed dealer in both the business of a wholesaler dealing in drugs and the business of a pharmacy, shall keep separate registers as required by paragraph (1), in relation to each business.

(3) Every licensed dealer and every pharmacist shall keep on his premises full and complete records concerning receipts and disposals of controlled drugs in separate files, in sequence as to number and date, for a period of at least two years from the date on which each transaction took place and the records shall be kept in a manner that will enable an audit thereof to be made at any time.

Protection of controlled drugs.

**96.** 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 Minister any such loss or theft of a controlled drug within ten days of the discovery of such loss or theft.

Officer in charge of medical supplies to keep separate register.

**97.** (1) Nothing in these Regulations 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.

(2) In this regulation "authorised person or institution" means any person or institution to whom the officer is authorised by the Chief Medical Officer to distribute such drugs.

## PART V
## COSMETICS

Interpretation.

**98.** In this Part "pre-packaged product" means any product that is packaged in such a manner that it is ordinarily sold to or used or purchased by a consumer without being repackaged.

Labelling of cosmetics.

**99.** No person shall sell a cosmetic unless a label is applied to the cosmetic in compliance with these Regulations.

Package of cosmetic with only one label.

**100.** Where a cosmetic 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.

Inner label of cosmetic.

**101.** Subject to these Regulations, the inner label of a cosmetic shall carry –

(a) the name of the manufacturer or distributor of the cosmetic and the address of his principal place of business;

(b) the identity of the cosmetic in terms of its common or generic name or in terms of its function, unless the identity is obvious; and

(c) the batch number or lot number.

Outer label of cosmetic.

**102.**(1) Where a cosmetic is a pre-packaged product produced or manufactured for use by a commercial or industrial enterprise or institution or is not a pre-packaged product the label applied to it shall carry on the outer label a declaration of the net contents of the cosmetic –

(a) by volume, when the product is a liquid or gas or is viscous; or

(b) by weight, when the product is solid unless it is the established trade practice to show the net contents of the product by numerical count or by linear area or cubic measurement, in which case, the declaration shall be in accordance with the established trade practice.

(2) A declaration of the net contents of a cosmetic mentioned in paragraph (1) need not appear on the outer label of –

(a) a package of perfume or toilet water, the net contents of which does not exceed four fluid ounces (114 millilitres);

(b) a package of liquid cosmetic, other than perfume or toilet water, the net contents of which does not exceed one fluid ounce (28.4 millilitres);

(c) a package of toilet bar soap, the net contents of which does not exceed two ounces (57 grams); or

(d) a package of solid cosmetic, other than toilet bar soap, the net contents of which does not exceed one ounce (28.4 grams).

Claim respecting action of cosmetic.

**103.**(1) No manufacturer shall, on any label or in any advertisement for a cosmetic make any claim respecting –

(a) the ability of the product or any ingredient thereof to influence the chemistry of the skin, hair or teeth; or

(b) product formulation, manufacture or performance that would imply that the user of the product will not suffer injury to health

unless the manufacturer is in possession of evidence validating the claim.

(2) The manufacturer shall upon request furnish the Government Analyst with the evidence referred to in paragraph (1).

No symbol or statement to imply cosmetic compounded in accordance with prescription.

**104.**(1) No person shall sell a cosmetic if any label or advertisement of the cosmetic contains any symbol or statement that implies that the cosmetic has been compounded in accordance with a prescription.

(2) Paragraph (1) does not apply to a cosmetic dispensed by a pharmacist pursuant to a prescription.

Cosmetic recommended for removing stains from teeth.

**105.** No person shall sell a cosmetic recommended for removing stains from the teeth that has a measure of acidity greater than that represented by a pH of 4.

Cosmetic containing coal tar dye etc.

**106.**(1) No person shall sell a cosmetic for use in the area of the eye that contains any coal tar dye, coal tar dye base or coal tar dye intermediate.

(2) For the purpose of paragraph (1), "area of the eye" means the area bounded by the supraorbital and infraorbital ridges and includes the eyebrows, the skin underlying the eyebrows, the eyelids, the eyelashes, the conjunctival sac of the eye, the eyeball and the soft tissue that lies below the eye and within the infraorbital ridge.

Cosmetic containing estrogenic substance.

**107.** No person shall sell a cosmetic that contains an estrogenic substance unless that cosmetic is dispensed by a pharmacist pursuant to a prescription.

Cosmetic representing an avoidable hazard.

**108.** (1) No person shall sell a cosmetic representing an avoidable hazard unless the inner and outer labels carry adequate directions for use.

(2) For the purpose of paragraph (1), "avoidable hazard" means a threat of injury to the health of the user of a cosmetic that can be –

(a) predicted from the composition of the cosmetic, the toxicology of the ingredients and the site of application thereof;

(b) reasonably anticipated during normal use; and

(c) eliminated by specified limitations on the usage of the cosmetic.

Hair dye containing paraphenyl-enediamine.

**109.** No person shall sell a hair dye that contains paraphenylenediamine or other coal tar dye base or coal tar dye intermediate unless –

(a) both the inner and the outer labels thereof carry the following warning:

"**CAUTION**: This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows. To do so may cause blindness."

(b) Instructions to the following effect, accompany each package of the hair dye:

(i) the preparation may cause serious inflammation of the skin in some persons and a preliminary test should always be carried out to determine whether or not special sensitivity exists; and

(ii) to make the test, a small area of skin behind the ear or upon the inner surface of the forearm should be cleansed, using either soap and water or alcohol, and a small quantity of the hair dye as prepared for use should be applied to the area and allowed to dry. After twenty-four hours, the area should be washed gently with soap and water. If no irritation or inflammation is apparent, it is usually assumed that no hypersensitivity to the

dye exists. The test should, however, be carried out before each application. On no account should the hair dye be used for dyeing eyebrows or eyelashes as severe inflammation of the eye or even blindness may result.

Deodorant for use in genital area.

**110.** A deodorant that is intended for use in the genital area and that is sold in a pressurized container shall carry the following information on both its inner and outer labels:

"**DIRECTIONS**: For external use only. Use sparingly and not more than once daily. Spray external skin surface while holding nozzle at least 8 inches from skin."

"**CAUTION**: Do not apply internally or to broken, irritated or itching skin. Do not use when wearing a sanitary napkin. Discontinue use immediately if a rash or irritation develops. Consult a physician if the rash or irritation persists or if there is any unusual odour or discharge at any time."

Manufacturer of cosmetic to furnish list to the Government Analyst.

**111.** Upon written request of the Government Analyst, a manufacturer of a cosmetic shall furnish to him –

(a) a quantitative list of the ingredients contained in the cosmetic;

(b) complete information concerning any one or all of the ingredients contained in the cosmetic; and

(c) adequate amount of samples, of any ingredients used in the manufacture of the cosmetic.

## PART VI
## DEVICES

Labelling of device.

**112.** No person shall sell a device unless a label is applied to the device in compliance with these Regulations.

Information to be carried on label.

**113.** Subject to this Part, the label applied to a package containing a device shall show –

(a) the name and address of the manufacturer or distributor of the device;

(b) the name of the device;

(c) the batch number or lot number of the device;

(d) list of the contents of the package and the number of complete units contained therein; and

(e) adequate directions for use of the device.

Package of device with only one label.

**114.** Where a package containing a device has only one label that label shall contain all the information required by this Part to be shown on both the inner and outer labels.

## PART VII
## CONDITIONS AND FACILITIES FOR MANUFACTURE OF FOOD, COSMETIC OR DEVICE

Food, cosmetic and device to be manufactured in a building constructed in accordance with good manufacturing practice.

**115.** No manufacturer shall sell a food, cosmetic or device unless –

(a) the food, cosmetic or device has been manufactured, packaged and stored –

(i) in a building the construction, fittings and furnishings of which are of such material and finishing as accord with good manufacturing practices, permit the efficient cleaning of all surfaces and prevent migration of dust and the introduction of extraneous material into the food, cosmetic or device;

(ii) in a building that is maintained in a clean, sanitary and orderly condition free from vermin, infestation, accumulated waste or debris;

(iii) under the supervision of persons who have had such training as the Government Analyst considers satisfactory having regard to the duties and responsibilities involved;

(b) each batch or lot of the raw material

used in the manufacture of the food, cosmetic or device has been tested for identity and purity; and

(c) each batch or lot of the finished food, cosmetic or device has been tested for identity and purity.

## PART VIII
## CONDITIONS, FACILTIES AND CONTROLS FOR DRUG MANUFACTURE

Interpretation.

**116.** In this Part –

"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 such 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.

Sale of drug in finished pharmaceutical form.

**117.** (1) 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, packaged, preserved, stored, labelled and tested under suitable conditions as provided in this Part, and a Certificate to this effect has been issued by the Government Analyst, on the advice of the Drug Advisory Committee.

(2) For the purposes of paragraph (1) "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 ready and 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, in

in accordance with good pharmaceutical practices;

(b) that the premises used for the processing, testing, finishing, distribution and storage of the drug, and all auxiliary facilities, shall be maintained in a clean, sanitary and orderly condition, free from vermin, infestation, accumulated waste or debris;

(c) that adequate lighting, ventilation and drainage facilities shall be provided in the manufacturing area;

(d) that all processing and packaging

equipment shall be cleaned following the manufacture of each batch or lot of the drug;

(e) 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 such drugs and operated in a manner that will prevent contamination of the drug compounded and filled;

(f) that qualified persons shall be employed as supervisors in the formulation, processing, testing, packaging and labelling of the drug, and such persons shall have such technical training as the Government Analyst on the advice of the Drug Advisory Committee may deem necessary, having regard to the nature of the duties and the responsibilities involved;

(g) that qualified persons shall be responsible for the maintenance of machinery, equipment and sanitation;

(h) that each batch or lot of raw material or bulk material used in manufacturing the drug shall be tested to ensure identity and purity of such raw material or bulk material using tests of pharmacopoeial or equivalent status;

(i) that each batch or lot of the drug in finished pharmaceutical form shall be tested to ensure identity, potency and purity, using tests of pharmacopoeial or equivalent status;

(j) that each stage of the manufacture shall be supervised by appropriately qualified persons;

(k) that a system of control shall be applied which will permit a complete and rapid recall of any batch of the drug from the market;

(l) that records shall be maintained relating to each drug, in a form, manner and content satisfactory to the Government Analyst showing –

(i) for each batch or lot of the drug –

(A) the tests carried out on the raw or bulk materials used in the manufacturing of the drags;

(B) the tests carried out on the drugs in finished pharmaceutical form;

(C) the names or initials of the qualified persons supervising each stage of the manufacturing process and responsible for the tests carried out; and

(D) the batch or lot number assigned to that batch or lot of the drug and the date of manufacture.

(ii) details of the manufacturing process;

(iii) the quality controls applied;

(iv) all information received pertaining to the quality or hazards of any drug;

(v) the results of tests to determine the stability of each drug; and

(vi) the measures taken to ensure the recall of unsatisfactory batches or lots of drugs from the market.

(m) that adequate protection shall be given to the persons 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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1953 Ed.
c. 95:02.

(n) that the provisions of the Pharmacy and Poisons Ordinance, the Public Health Ordinance and the Factories Act are complied with.

(3) The records required by paragraph (2) (1)

shall be kept for a period of five years from the date of testing of each batch or lot of each drug or until the expiry date of that drug, whichever first occurs, and such records shall be made available for inspection by an inspector, and copies shall be made for the information and use of the Government Analyst at his request.

Sample of drug in finished pharmaceutical form to be kept by manufacturer.

**118.** 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 such sample shall be submitted to the Government Analyst for analysis and examination on his request.

Dispensation.

**119.** A drug manufacturer may be permitted by the Government Analyst to dispense with tests, controls, records and samples mentioned in paragraphs (2) (h), (2) (i), (2) (k) and (2)(1) of regulation 117, and regulation 118, where the nature of the drug is such that these tests, controls, records and samples are, in the opinion of the Government Analyst, not necessary.

Manufacturer not in Guyana.

**120.** A drug manufacturer in a country other than Guyana shall be deemed to have complied with regulations 117 and 118, if the manufacturer or importer of a drug has produced to the Government Analyst a certificate concerning the sale, safety or manufacture of the drug issued by –

(a) the Department of National Health and Welfare of Canada;

(b) the Department of Health, Education and Welfare of the United States of America, or a State or City Authority in the United States of America

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 complying with regulation 13 or paragraph (2) (k) (v) of regulation 78, and indicating to the satisfaction of the Government Analyst that adequate standards for conditions of drug manufacture are enforced in those countries, in respect of that drug manufacturer.

Drug manufacturer not employing qualified persons.

**121.** If a drug manufacturer in Guyana does not employ qualified persons to carry out the tests required by paragraphs (2) (h) and (2) (i) of regulation 117 he may –

(a) import batches or lots of raw or bulk material accompanied by certificates of identity and purity issued by an Agency approved by the Government Analyst;

(b) submit a sample of each batch or lot of the drug in finished pharmaceutical form for testing to the Government Analyst, or to an agency or laboratory designated by the Government Analyst,

and shall not use any batch or lot of such raw material imported without such certificates nor sell any batch or lot of any drug in finished pharmaceutical form until the results of the tests for the batch or lot have been accepted by the Government Analyst.

Sale or advertisement of new drug manufactured in Guyana.

**122.** No person shall sell or advertise a new drug manufactured in Guyana that was not manufactured in Guyana before 1st June, 1977, unless –

(a) he has a licence that is in force, issued by the Minister in respect of the sale or manufacture, as the case may be, of that new drug; and

(b) he has paid a licence fee of one hundred dollars.

Application for issue of licence for new drug to be manufact-ured in Guyana.

**123.** Where a drug manufacturer in Guyana wishes to manufacture for sale a drug that he has not manufactured before 1st June, 1977 he shall apply to the Minister for the issue of a licence in respect of such drug setting forth –

(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 and address 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 contraindications 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, stability and safety of the drug and of the raw bulk material;

(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 Government Analyst may require;

(g) samples of the drug in the finished pharmaceutical form in which it is to be sold;

(h) one of the following –

(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;

(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;

(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 Government Analyst may require.

Drug included in publications mentioned in Second Schedule to Act.

**124.** Paragraphs (b) and (h) of regulation 123 do not apply to the manufacturer in Guyana 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 or regulation 123.

Issue of licence to manufacture a new drug in Guyana.

**125.** (1) The Minister on the recommendation of the Drug Advisory Committee shall, within one hundred and twenty days after the filing of an application for the issue of a licence to manufacture a new drug in Guyana notify the applicant whether or not his application is approved, and if approved, may issue a licence to the applicant.

Fourth Schedule.

(2) The licence shall be in the form set out in the Fourth Schedule.

Withdrawal of licence to manufacture new drug.

**126.** A licence to manufacture a new drug in Guyana may be withdrawn in like manner and for like reason as set out in regulation 82.

Drug to be withdrawn upon issue of notice of

**127.** Where the Minister issues a notice of withdrawal in respect of any drug manufactured in Guyana, the drug manufacturer shall immediately withdraw from the market in

withdrawal.

Guyana all batches or lots of that drug at his own expense and deliver all such batches or lots to the Government Analyst.

Reporting effects of drug manufactured in Guyana.

**128.** 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 Guyana he shall immediately inform the Government Analyst, furnishing him with the full information available.

Manufacturing of drug to obtain scientific data.

**129.** Notwithstanding regulation 123, a drug manufacturer may make a small number of batches of a drug that was not manufactured in Guyana before 1st June, 1977 for the sole purpose of obtaining scientific data regarding the process of manufacture or clinical data on the safety, stability, dosage, or efficacy of such drug, if only –

(a) before the manufacture of the drug the Minister is informed of the proposed manufacture, and approves the disposal or use of it;

(b) where the drug is to be used in clinical investigation –

(i) the investigators have written authority from Minister on the advice of the Drug Advisory Committee to carry out the investigation of the drug and have the facilities for so doing;

(ii) before the sale or distribution of it, the Minister is informed of the identifying name or mark by

which the drug may be recognized;

(iii) both the inner and outer labels on any package of such drug carry the statement "To Be Used for Investigational Purposes Only";

(iv) before the sale or distribution of it, the drug manufacturer ensures that any person to whom the drug is to be sold or distributed has written authority from the Minister to conduct investigations relating to that drug, and obtains in writing from that person an undertaking that the drug will be used solely by him or under his direction for investigational purposes; and

(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 any person who has written authority from the Minister to conduct investigations relating to such drugs.

Premises to be licensed.

**130.** (1) No food, drug, cosmetic or device shall be manufactured in any premises unless there is in force a licence to indicate that the premises for the manufacturing of the food, drug, cosmetic or device and the conditions and facilities for the manufacture comply with regulations 115 or 117.

(2) An application for a licence and a renewal

thereof shall be made to the Government Analyst, accompanied by a fee of twenty-five dollars and shall state information satisfactory to the Government Analyst in respect of –

(a) the name and address of the person making application for the licence;

(b) the address and description of the premises where the whole or any part of the manufacture of the food, drug, cosmetic or device is carried out;

(c) the proper name of the food, drug, cosmetic or device in respect of which an application for a licence is made;

(d) the name, training and qualifications for the personnel employed in the manufacture of the food, drug, cosmetic or device.

(3) As a condition of the issuance and continuation of a licence, the Government Analyst may require the manufacturer to furnish samples of any materials used in the manufacture of the food/drug, cosmetic or device or samples of the finished food, drug, cosmetic or device to ensure that the food, drug, cosmetic or device is not unsafe for use.

Fourth Schedule.

(4) A licence shall be in the form set out in the Fourth Schedule.

Manufacturer to keep records.

**131.** Every manufacturer shall –

(a) keep records in a satisfactory form

respecting the manufacture of the food, cosmetic or device manufactured by him;

(b) make these records available to the Government Analyst upon request; and

(c) notify the Government Analyst immediately of any deficiency concerning the quality or safety of food, cosmetic or device manufactured by him.

**Official Drugs**

Official drugs.

**132.** An official drug labelled as required by regulation 48 shall satisfy the standard mentioned on the label.

**Antibiotics**

Antibiotics c. 34:02.

**133.** An antibiotic which is imported, exported, manufactured, dispensed or sold in accordance with the Antibiotic Act is exempted from these Regulations.

**Dangerous Drugs**

Dangerous drugs Cap. 142 1953 Ed.

**134.** A dangerous drug which is sold, dispensed, imported, exported or manufactured, in accordance with the Dangerous Drugs Ordinance is exempted from these Regulations except regulation 52.

Offences and penalties. [Reg. 5/1983]

## PART IX
## OFFENCES AND PENALTIES

**135.** (1) A person who contravenes or fails to comply with any of these Regulations shall be guilty of an offence.

(2) For the avoidance of doubt it is hereby declared that the section 33 of the Act shall apply to any offence referred to in paragraph (1).

## FIRST SCHEDULE

### PART I

### REGULATION 9

### FORM A

### CERTIFICATE OF APPOINTMENT OF INSPECTOR

**Food and Drugs Act**
**(Cap. 34:03)**

In exercise of the powers conferred upon me by sections 20 of the Food and Drugs Act, Cap. 34:03, I hereby

appoint .....as an Inspector for the purposes of the Act.

Photograph

.....

Signature of Inspector

.....
Minister of Health

_____

**FORM B**

Certificate No. .....

**CERTIFICATE OF ANALYSIS**
**FOOD AND DRUGS ACT**

**(Cap. 34:03)**
**(Under section 30(1) of the Food and Drugs Act, Cap. 34:03)**

I, ..... having been appointed as an analyst under the Food and Drugs Act, Cap. 34:03. do hereby certify:

(1) That on the ..... day of ..... 20.....I received from ..... a sealed package;

(2) That I broke the seals, opened the said package and removed there from a sample, submitted as a sample of ..... taken from ..... of .....; and

(3) That I analysed/examined *the said sample and/or * I directed the analysis/examination of the said sample for

the purposes of the Food and Drugs Act, Cap. 34:03, and that I obtained the following results –

OBSERVATIONS:

.....

Analyst

Date:

*Cross out as applicable

## PART II
## TARIFF OF FEES

### ARTICLES OF FOOD, DRUGS, COSMETICS AND DEVICES

1. Complete analysis of milk
2. Analysis of milk for dirt or preservative.
3. Analysis of butter, margarine, ghee or lard.
4. Chemical analysis of ice-cream, ice-cream mixes
5. Determination of the proportion of fat in milk
6. Identification and determination of the proportion of fat in butter, ghee, lard or margarine
7. Test for rancidity in butter
8. General analysis of bread, flour, tea, coffee, mustard, pepper, ginger, turmeric, condensed milk, butter, margarine, ghee, cheese, lard, etc., with an opinion as to purity or otherwise
9. Examination of any article of food or drink for the presence of arsenic, copper, iron, lead, tin or zinc
10. Examination for each additional element of 9
11. Moisture in any foodstuff
12. Analysis for one component of any drug or drug preparation with an opinion as to its purity, etc.
13. Analysis for each additional constituent of 12
14. Complete microbiological examination of any food,

cosmetic, drug or drug preparation
15. Analysis for one constituent of any kind of food, drug, cosmetic or therapeutic device containing any medicament not mentioned above
16. Analysis for each additional constituent
17. Determination of proof spirit except item 18
18. Determination of proof spirit in wines, malt, liquors or "unobscured" spirits
19. Determination of proof spirit and obscuration in coloured rums
20. Microscopical examination of a food or drug

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## SECOND SCHEDULE

### PART I
### FOOD COLOURS

1. In this Part –

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

"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. No person shall sell for use in or upon food any colour except the following –

(a) natural colours being cochineal, vegetable colours and vegetable colour extractives, or their colouring

principles whether isolated from natural sources or produced synthetically;

(b) caramel;

(c) specially purified charcoals, carbon blacks, iron oxide and titanium dioxide;

(d) synthetic food colour approved by the Minister.

3. No person shall sell a food having in or upon it any added colour except the following –

(a) natural colours being cochineal, vegetable colours and vegetables colour extractives, or their colouring principles whether isolated from natural sources or produced synthetically;

(b) caramel;

(c) specially purified charcoals, carbon blacks, iron oxide and titanium dioxide;

(d) synthetic food colours approved by the Minister.

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

(a) 2 parts per million of arsenic,

calculated as arsenic;

(b) 10 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 such synthetic food colours 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 purpose 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 purpose of this Part, 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, by notice withdraw approval with respect to any food colour which is toxic or capable of producing toxic effects, and on publication of such notice paragraphs 2, 3 and 6 cease to apply with respect to that food colour.

## PART II
## PRESERVATIVES

1. (1) The following preservatives are Class I preservatives for the purpose of this Part –

(a) Ethyl alcohol;
(b) Ascorbic acid, isoascorbic acid and their salts;
(c) Dextrose;
(d) erythorbic acid and its salts;
(e) glucose;

(f) potassium nitrate;
(g) common salt;
(h) sodium nitrate;
(i) spices;
(j) sugar;
(k) vinegar;
(l) wood smoke; and
(m) nisin in canned foods, if the cans are hermetically sealed and the foods sufficiently heat processed so as to destroy any Clostribium botulium in the foods or cans, or nisin in canned foods with pH of less than 4.5 or in clotted cream.

(2) Notwithstanding subparagraph (1), sodium nitrate or potassium nitrate is a Class I preservative in relation to preserved meats if used in quantities not exceeding 200 parts per million of the finished product.

2. (1) The following preservatives are Class II preservatives for the purposes of this Part –

(a) benzoic acid, including the salts thereof;
(b) sulphurous acid, including the salts thereof;
(c) sorbic acid, including the salts thereof;
(d) methyl para-hydroxybenzorate; and
(e) propyl para-hyroxybenzoate.

(2) No person shall use more than one Class II preservatives in or upon any food, except in the case of methyl para-hydroxybenzoate and propyl para-hydrox-benzoate, where a mixture of both may be used.

(3) No person shall use in or upon any food more than –

(a) 1,000 parts per million of benozoic 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 propyl para-hydroxybenzoate.

(4) No person shall use sulphurous acid or its salts calculated as sulphur dioxide, in amounts greater than –

(a) 100 parts per million in beverages prepared for consumption in accordance with label directions;
(b) 2,500 parts per million in or upon dried fruits and vegetables; or
(c) 500 parts per million in or upon other foods.

3. (1) The following preservatives are Class III preservatives for the purposes of this Part –

(a) propionic acid, including the salts thereof;
(b) sodium diacetate; and
(c) sorbic acid, including the salts thereof.

(2) 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.

4. (1) The following preservatives are Class IV preservatives for the purposes of this Part –

(a) gum guaiacum;
(b) vegetable oils containing tocopherols;
(c) lecithin;
(d) citric, tartaric, or ascorbic acid;
(e) monoisopropyl citrate;
(f) ascorbyl palmitate;
(g) n-propyl gallate, or n-octyl gallate, or n-dodecyl gallate;
(h) butylated hydroxyanisole;
(i) butylated hydroxytoluene; and
(j) nordihydroguaiartic acid.

(2) No person shall sell a food containing –

(a) any combination of Class IV preservatives that includes both nordihydroguaiaretic acid and propyl gallate or n-octyl gallate or n-dodecyl gallate;

(b) any combination of Class IV preservatives, including the substances in which they are dissolved, in an amount greater than 0.2 per cent of the finished product;

(c) a combination of Class IV preservatives that includes more than three of the following preservatives –

(i) butylated hyroxyanisole;
(ii) butylated hydroxytoluene;
(iii) propyl gallate, n-octyl gallate or n-dodecyl gallate;

(d) any combination of the Class IV preservatives listed in sub-subparagraph (c) in an amount greater than 0.02 per cent of the finished product.

5. (1) No person shall sell –

(a) benzoic acid, including the salts thereof;
(b) sulphurous acid, including the salts thereof;
(c) n-propyl gallate, n-octyl gallate or n-dodecyl gallate;
(d) butylated hydroxyanisole;
(e) butylated hydroxtoluene;
(f) methyl para-hydroxybenzoate;
(g) propyl para-hydroxybenzoate;
(h) nisin; or
(i) nordihydroguaiaretic acid,

for use as a preservatives for food unless the label of each package includes a quantitative declaration of each of the preservatives present.

## PART III
## Poisonous substances permitted

| FOOD | Arsenic parts per million | Lead parts per million | Copper parts per million | Zinc parts per million | Fluorine parts per million |
|---|---|---|---|---|---|
| Aluminium compounds | 3 | 10 | 50 | 50 | 2 |
| Apple juice, cider, wine and beer | 0.2 | 0.5 | 2 | 5 | 2 |
| Baking powder | 2 | 10 | 50 | 50 | 10 |
| Calcium phosphate | 4 | 5 | 30 | 30 | 30 |
| Citric acid | 1 | 10 | 50 | 50 | 2 |
| Cream of tartar | 2 | 20 | 50 | 50 | 2 |
| Dried herbs and spices | 5 | 10 | 50 | 50 | 20 |
| Edible bone meal | 1 | 10 | 20 | 150 | 650 |
| Fish protein | 3.5 | 0.5 | - | - | 150 |
| Fresh fruits | 2 | 7 | 50 | 50 | 2 |
| Fresh vegetables | 1 | 2 | 50 | 50 | 2 |
| Fruit juice except apple juice | 0.1 | 0.2 | 2 | 5 | 1 |
| Gelatin | 2 | 7 | 30 | 100 | 60 |
| Gelling agents except gelatin | 2 | 20 | 50 | 200 | 2 |
| Liver | 1 | 2 | 150 | 100 | 2 |
| Marine and fresh water animal products | 5 | 10 | 100 | 100 | 25 |
| Phosphoric acid | 4 | 5 | 30 | 30 | 20 |
| Sodium bicarbonate | 2 | 5 | 50 | 50 | 2 |
| Sodium and potassium nitrates | 1 | 10 | 50 | 50 | 2 |
| Sodium nitrite Sodium, potassium and ammonium phosphates | 4 | 5 | 30 | 30 | 20 |
| Tartaric acid | 1 | 10 | 50 | 50 | 2 |
| Tea | 1 | 10 | 150 | 50 | 100 |
| Beverages as consumed and bottled water | 0.1 | 0.2 | 2 | 5 | 2 |

## PART IV

## STANDARDS PRESCRIBED FOR FOOD

### DIVISION 1

### BAKING POWDER

1. BAKING POWDER shall be a combination of sodium bicarbonate, an acid-reacting material mentioned in paragraph 2, starch or other neutral material, may contain an anti-caking agent and shall yield –

(a) not less than 8 per cent of its weight of available carbon dioxide; and

(b) not more than 1.5 per cent of its weight of residual carbon dioxide, as determine by the official method.

2. The acid-reacting material of baking powder shall be one or any combination of –

(a) tartaric acid or its salts or both;
(b) acid salts of phosphoric acid;
(c) lactic acid or its salts;
(d) acid compounds of aluminium.

### DIVISION 2
### CARBONATED BEVERAGES

1. For the purposes of this Division "carbonated beverage" means a non-alcoholic beverage that is impregnated with carbon dioxide under pressure and is sold in hermetically sealed containers.

2. A carbonated beverage is adulterated if it contains any synthetic sweetening agent including saccharin and its salts and cyclohexylsulphamic acid and its salts.

3. No person shall sell a carbonated beverage that contains saccharin cyclohexylsulphamic acid, or their salts.

## DIVISION 3

## 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.** The commercial article known as **GROUND COFFEE** or **COFFEE** or **ROASTED COFFEE** shall be the product obtained by roasting and grinding raw coffee. It shall contain–

(a) no other added or extraneous matter; except added sugar to the extent of not more that 10 per cent;
(b) not more than 6 per cent of total ash;
(c) not more than 14 per cent of crude fibre;
(d) not more than 25 per cent of water-soluble extract before addition of any sugar, as determined by an acceptable method; and
(e) not less than 0.75 per cent and not more than 1.5 per cent of caffeine.

**3.** INSTANT COFFEE shall be a dried aqueous

extract of pure coffee, and may contain such added carbonhydrate material as may be found necessary or desirable for good manufacturing practice.

**4.** The percentage of caffeine that has been removed from coffee from which a decaffeinted coffee or decaffeinated instant coffee has been made shall be shown on the principal display panel followed by the word "of caffeine removed" and the decaffeinated coffee or decaffeinated instant coffee shall not contain any ingredients other than those allowed by these Regulations.

**5.** Notwithstanding regulation 31, no person shall sell any coffee containing added sugar in a package unless such package is distinctly labelled with the words "contains added sugar".

## DIVISION 4
## CURRY POWDER

**CURRY POWDER** shall be any combination of turmeric with spices and seasoning, and shall contain –

(a) not more than 5 per cent salt;
(b) not less than 85 per cent of spices, aromatic seeds and herbs; and
(c) not more than 10 parts per million of lead as determined by the official method.

## DIVISION 5

## DAIRY PRODUCTS

1. The foods referred to in this Division are included within the term "diary 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 per cent milk fat;
(b) not less than 8.5 per cent of milk solids, not fat; and
(c) not more than twenty parts per million of dirt.

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

4. (1) Milk is adulterated if it fails to conform to the Freezing Point Test which is the official method.

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

5. An inspector may, in any case where a sample of milk is likely to deteriorate before it is delivered to the Analyst Department, add a preservative to each portion into which the sample has been divided in pursuance of the normal procedure for taking samples under the Act and -

(a) in such a case, he shall write on the label of each portion into which the sample has been divided the words "preserved for anaylsis"; and

(b) the composition of the milk sold to the inspector shall be taken to be composition of the milk found by analysis after due allowance has been made for the presence of the preservatives in the milk.

**6.** No person shall sell milk for manufacture into dairy products if it contains more than –

(a) 2,000,000 bacteria in 0.035 of a fluid ounce (1 millilitre); or

(b) 0.00007 of an ounce (2 milligrams) of sediment per 16 fluid ounces (454.6 millilitres);

as determined by the official method.

**7.** No manufacturer shall purchase milk for manufacture or manufacture milk into other dairy products if he has reason to believe it does not meet the requirements of paragraph 6.

**8. 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.

**9. RECONSTITUTED MILK** shall be labelled as such, and shall be a milk product resulting from the combining of milk constituents with water, shall contain not less than –

(a) 3.0 per cent of milk fat; and
(b) 8.5 per cent of milk solids not fat;

and may contain added vitamin A.

**10. 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 Reichet-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.

**11. STERILIZED 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) 3.0 per cent of milk fat; and
(b) 8.5 per cent of milk solids not fat.

**12. FLAVOURED STERILIZER MILK** shall be sterilized 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.

**13. 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) 28.0 per cent of milk solids; and
(b) 8.0 per cent of milk fat;

and may contain added vitamin D.

**14. 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; and
(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; and
(e) an emulsifying agent, if such addition is declared on the label.

**15. SKIM MILK (SKIMMED MILK)** –

(a) shall be milk from which all or most of the milk fat has been removed;
(b) shall contain not more than 0.1 per cent milk fat; and

(c) may contain –
(i) added vitamin A; and
(ii) added vitamin D.

**16. MILK POWDER, DRY MILK, DRY WHOLE MILK POWDER- EDMILK** or **POWDERED WHOLE MILK** shall be dried milk, and shall contain not less than –

(a) 95.0 per cent of milk solids; and
(b) 26.0 per cent of milk fat;

and may contain added vitamin D.

**17. SKIM (SKIMMED) MILK POWDER, DRY SKIM (SKIMMED) MILK** or **POWDERED SKIM (SKIMMED) MILK** shall be dried skim milk and shall contain –

(a) not less than 95.0 per cent of milks solids; and

(b) not less than 2000 International Units and not more than 2500 International Units added vitamin A per 3.52 ounces (100 grams);

and may contain –

(c) an antifoaming agent; and

(d) added vitamin D.

**18. PARTLY SKIMMED MILK POWDER** or **HALF CREAM MILK POWDER** shall be dried milk and shall contain not less than –

(a) 95.0 per cent of milk solids; and

(b) 13.0 per cent milk fat.

**19. 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.

**20. PASTEURISED MILK** shall be milk that has been pasteurised as in paragraph 22 and shall be delivered to the consumer in suitably capped or sealed containers.

**21.** No milk or milk product shall be labelled "pasteurised" unless it has been treated in the manner described in paragraph 22.

**22.** (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.

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

**23. BUTTER**

(a) 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;

(b) shall be free from any rancid taste or odour;

(c) shall have an acid value of not more than 2.

(d) shall contain not less than 80 per cent of milk fat and not more than 16 per cent of moisture; and

(e) may contain salt and food colour.

**24. COOKING BUTTER**

(a) shall be labelled as such and shall be butter prepared as described in paragraph 23;

(b) shall contain not less than 80 per cent of milk fat and not more than 12 per cent of salt;

(c) shall have an acid value of not more than 2; and

(d) may contain food colour.

**25. GHEE,** which shall be free from any rancid taste

or odour, shall contain not less than 98 per cent of milk fat, without any mixture of other fat, and shall have an acid value of not more than 2.

**26. ICE CREAM**

(a) shall be the frozen food made from milk or milk products and sweetened with sugar;

(b) may contain –
- (i) edible oil or fat;
- (ii) egg,
- (iii) flavouring preparation,
- (iv) cocoa or chocolate syrup,
- (v) food colour,
- (vi) acid-reducing salts,
- (vii) fruit, nuts, confections, and
- (viii) stabilisers comprising not more than 1.0 per cent of gelatine alone, or not more than 0.5 per cent of other stabiliser, or not more than 0.75 per cent of a mixture of gelatine and other stabilisers, of which the proportion of other stabilisers may not exceed 0.25 per cent;

(c) shall contain not less than –

- (i) 8.0 per cent of fat,
- (ii) 36.0 per cent of solids,
- (iii) 7.5 per cent of milk solids not fat, and
- (iv) 1.8 pounds (817 grams) of solids per Imperial gallon (4.546 litres); and

(d) shall contain not more than –

(i) 100,000 bacteria in 0.035 of an ounce (1 gram), and

(ii) 10 coliform organisms in 0.035 of an ounce (1 gram); as determined by the official method.

**27.** (1) 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 Government Analyst.

(2) 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.

**28. DIARY ICE-CREAM** shall be ice-cream as defined in paragraph 26, but 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.

## DIVISION 6

DRESSING AND SEASONING

1. **MAYONNAISE, MAYONNAISE DRESSING** or **MAYONNAISE SALAD DRESSING**,

(a) shall be a combination of –

(i) vegetable oil;
(ii) whole egg or egg yolk, in liquid,

frozen or dried form; and

(iii) vinegar, acetic acid (food grade), lime juice or lemon juice;

(b) may contain –

(i) water;
(ii) salt;
(iii) a sweetening agent;
(iv) spice or other seasoning except turmeric or saffron;
(v) citric, tartaric or lactic acid;
(vi) a sequestering agent; and

(c) shall contain not less than 65 per cent vegetable oil.

**2. SALAD DRESSING**

(a) shall be a combination of –

(i) vegetable oil;
(ii) whole egg or egg yolk, in liquid, frozen or dried form;
(iii) vinegar, acetic acid (food grade), lime juice or lemon juice; and
(iv) cereal;

(b) may contain –

(i) water;
(ii) salt;
(iii) a sweetening agent;
(iv) spice or other seasoning;
(v) an emulsifying agent;
(vi) citric, tartaric or lactic acid;

(vii) a sequestering agent; and
(viii) a Class II preservative specified in Part II of the Second Schedule; and

(c) shall contain not less than 35 per cent of vegetable oil.

## DIVISION 7

## EDIBLE OILS AND FATS

**1. CRUDE** (raw, virgin or unrefined) **COCONUT OIL** shall be the product obtained by expression and/or solvent extraction from the kernel (copra) of the coconut of Cocos nucifera (Linn). It shall have the colour, odour and taste characteristic of crude coconut oil and shall be free from admixture with other oils and fats.

**2. REFINED COCONUT OIL** shall be crude coconut oil which has been neutralized, bleached, deodorized, coloured, flavoured with food additives or otherwise treated, and shall have –

(a) a density of 30°C. relative to water at 30°C. of not less than 0.915 and not more than 0.927;
(b) a refractive index at 40°C. n 40°C. between 1.488 and 1.450;
(c) an iodine value (Wijs) of not less than 7.5 and not more than 10.5;
(d) a saponification value of not less than 248 and not more than 264;
(e) a maximum of 0.5 per cent of unsaponifiable matter; and
(f) not more than 0.10 per cent of free fatty

acids expressed as lauric acid in the case of oil sampled from a manufacturer, and not more than 0.15 per cent in the case of oil sampled from a retailer.

**3. COOKING OIL** or **EDIBLE OIL** shall refined coconut oil and may contain such other oil as may be approved by the Minister.

**4. 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.

**5. MARGARINE s**hall be labelled as such, and shall contain –

(a) not less than 80 per cent of fat;
(b) not more than 16 per cent of water; and
(c) not less than 2680 International Units and not more than **3320** International Units added vitamin A in 3.52 ounces (100 grams),

and may contain food colour, preservative, salt and added vitamin D.

**6. PHALKA GHEE, GHEE SUBSTITUTE** or **VEGETABLE GHEE** shall contain not less than 98 per cent of fat other than animal and may contain Class IV preservatives as specified in Part II of the Second Schedule.

**7. LARD** shall be the rendered fat from fresh, clean,

sound fatty tissues from swine *(Sus scrofa* in good health, at the time of slaughter and may contain lard stearine or hydrogenated lard, Class IV preservatives specified in Part II of the Second Schedule and not more than one per cent of substances resulting from the rendering process, other than fatty acids and fat.

**8. SHORTENING,** other than butter or lard, shall be the semi-solid food prepared from fats, oils or combination of fats and oils and may be processed by hydrogenation and may contain –

(a) Class IV preservatives specified in Part II of the Second Schedule; and
(b) an antifoaming agent.

**9. VEGETABLE FATS AND OILS** shall be fats and oils 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 preservatives specified in Part II of the Second Schedule and an antifoaming agent.

**10. ANIMAL FATS AND OILS** shall be fats and oils 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 preservatives specified in Part II of the Second Schedule and an antifoaming agent.

**11. CORN OIL** or **MAIZE 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 30°C. relative to water at 30°C. of not less than 0.913 and not more than 0.920;
(ii) a refractive index at 40°C. (n 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;
(v) a maximum of 2.8 per cent: of unsaponifiable matter; and

(b) the following characteristics of quality –

(i) the colour, odour, and taste 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 for virgin maize oil, or not greater than 0.6 for non-virgin maize oil;
(iii) the maximum peroxide value shall be 10.0 milliequivalents of peroxide oxygen in 2.2 pounds (1 kilogram) of oil.

**12. COTTONSEED OIL** shall be the oil derived from the seeds of various cultivated species of *Gossypium,* may contain oxystearin and shall have –

(a) the following characteristic of identity –

(i) a density at 30°C. relative to water at 30°C. of not less than 0.910 and not more than 0.920;
(ii) a refractive index at 40°C. (n 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 198;

(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 cottonseed oil, with no foreign or rancid odour or taste;

(ii) the maximum acid value shall be 0.6;

(iii) the maximum peroxide value shall be 10.0 milliequivalents of peroxide oxygen in 2.2 pounds (1 kilogram) of oil.

**13. 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 30°C. relative to water at 30°C. of not less than 0.907 and not more than 0.910;

(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 valule of not less

than 170 and not more than 184;

(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 taste 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 for virgin mustardseed oil, or not greater than 0.6 for non-virgin mustardseed oil;

(iii) the maximum peroxide value shall be 10.0 milliequivalents of peroxide oxygen in 2.2. pounds (1 kilogram) of oil.

**14. OLIVE OIL** shall be the oil of the fruit of the olive tree *(Olea europaea* L), and shall have –

(a) a density of 20 °C, relative to water at 20 °C. of not less than 0.910 and not more than 0.918;

(b) a refractive index at 40°C. (n 40°C.) 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.

**15. 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 30°C. relative to water at 30° C. of not less than 0.909 and not more than 0.913:
(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;
(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 ground nut oil. with no foreign or rancid odour or taste;
(ii) the acid value shall not be greater than 4.0 for virgin ground nut oil, or not greater than 0.6 for non-virgin ground nut oil;
(iii) the maximum peroxide value shall be 10.0 milliequivalents of peroxide oxygen in 2.2 pounds (1 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.

**16. RAPESEED OIL, TURNIP RAPE OIL, COLZA OIL, RAVISON OIL, TORIA 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;
(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, odour and taste 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 for virgin rapeseed oil, or not greater than 0.6 for non-virgin rapeseed oil;
(iii) the maximum peroxide value shall be 10.0 milliequivalents of peroxide oxygen in 2.2 pounds (1 kilogram)

of oil.

**17. SAFFLOWERSEED OIL, SAFFLOWER OIL. CARTHAMUS OIL** or **KURDEE OIL** shall be the oil derived from safflower seeds (the seeds of *Carthamus tinctorius* L.) and shall have –

(a) the following characteristics of identity –
  (i) a density at 30°C. relative to water at 30°C. of not less than 0.915 and not more than 0.920;
  (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;
  (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 safflowerseed oil, with no foreign or rancid odour or taste;
  (ii) the maximum acid value shall be 0.6;
  (iii) the maximum peroxide value shall be 10.0 milliequivalents of peroxide oxygen in 2.2 pounds (1 kilogram) of oil.

**18. SESAMESEED OIL, SESAME OIL, BENNE OIL, BEN OIL, GINGELLY OIL, TILLIE 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 30°C. relative to water at 30°C. of not less than 0.915 and not more than 0.919;
(ii) a refractive index at 40°C. (n 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;
(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 taste 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 for virgin sesameseed oil. or not greater than 0.6 for non-virgin sesameseed oil;
(iii) the maximum peroxide value shall be 10.0 milliequivalents of peroxide oxygen in 2.2 pounds (1 kilogram) of oil.

**19. SOYA BEAN OIL** or **SOYBEAN OIL** shall be the oil derived from soya beans (the seeds of *Glycine max* (L.) Merr.), may contain oxystearin and shall have –

(a) the following characteristics of identity –

(i) a density at 30°C. relative to water at 30°C. of not less than 0.917 and not more than 0.921;
(ii) a refractive index at 40˚C. (n 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;
(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 soya bean oil with no foreign or rancid odour or taste;
(ii) the maximum acid value shall be 0.6;
(iii) the maximum peroxide value shall be 10.0 milliequivalents of peroxide oxygen in 2.2 pounds (1 kilogram) of oil.

**20. SUNFLOWER SEED OIL, 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 30°C. relative to water at 30°C. of not less than 0.915 and not more than 0.920;
(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 saponificationvalue of not less than 188 and not more than 194;

(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 sunflowerseed oil, with no foreign or rancid odour or taste;

(ii) the acid value shall not be greater than 4.0 for virgin sunflowerseed oil, or not greater than 0.6 for non-virgin sunflowerseed oil;

(iii) the maximum peroxide value shall be 10.0 milliequivalents of peroxide oxygen in 2.2 pounds (1 kilogram) of oil.

## DIVISION 8
## 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 specified in Part II of the Second Schedule.

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 9

## FRUIT JUICES

1. **FRUIT JUICE** shall be the unfermented liquid expressed from sound, ripe, fresh fruit, and may contain –

(a) a sweetening agent; and
(b) a Class II preservative specified in Part II of the Second Schedule;

and shall be packed in hermetically sealed containers.

2. **GRAPEFRUIT JUICE** shall be the fruit juice obtained from grape fruit, and shall contain, in 3.5 fluid ounces (100 millilitres) measured at a temperature of 20°C. –

(a) not less than 0.33 of an ounce (9.5

grams) of soluble solids before addition of any sweetening agent;

(b) not less than 0.01 of an ounce (0.3 gram) of ash, and

(c) not less than 0.035 of an ounce (1.0 gram) and not more than 0.077 of an ounce (2.2 grains) of acid calculated as anhydrous citric acid;

and shall be packed in hermetically sealed containers.

3. **ORANGE JUICE** shall be the fruit juice obtained from oranges, and shall contain in 3.5 fluid ounces (100 millilitres) measured at a temperature of 20°C. –

(a) not less than 0.35 of an ounce (10 grams) of soluble solids before addition of any sweetening agent;

(b) not less than 0.014 of an ounce (0.4 gram) of ash; and

(c) not less than 0.017 of an ounce (0.5 gram) and not more than 0.066 of an ounce (1.9 grams) of acid calculated as anhydrous citric acid;

and shall be packed in hermetically sealed containers.

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

## DIVISION 10

## GRAIN AND BAKERY PRODUCTS

**1. 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 "150 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 14 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; and
(iii) such other harmless additives as are approved by the Government Analyst; and

(e) shall contain in a harmless carrier in one pound (453.6 grams) of flour –

(i) not less than 0.00007 of an ounce (2.0 milligrams), and not more than 0.000087 of an ounce (2.5 milligrams) of thiamine;

(ii) not less than 0.00004 of an ounce (1 .2 milligrams), and not more than 0.00005 of an ounce (1.5 milligrams.) of riboflavin;

(iii) not less than 0.00056 of an ounce (16.0 milligrams), and not more than 0.0007 of an ounce (20.0 milligrams) of niacin or niacinamide;

(iv) not less than 0.00045 of an ounce (13.0 milligrams), and not more than 0.00058 of an ounce (16.5 milligrams) of iron; and

(v) not less than 0.017 of an ounce (500 milligrams), and. not more than 0.023 of an ounce (650 milligrams) of calcium.

2. **COMPOSITE 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 "150 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 14 per cent; and

(d) may contain –

(i) malted wheat flour;
(ii) cassava flour;
(iii) rice flour;
(iv) yam flour;
(v) soya flour;
(vi) such other harmless additives as are approved by the Government Analyst; and

(e) shall contain in a harmless carrier in one pound (453.6 grams) of flour –

(i) not less than 0.00007 of an ounce (2.0 milligrams), and not more than 0.000087 of an ounce (2.5 milligrams) of thiamine;
(ii) not less than 0.00004 of an ounce (1.2 milligrams), and not more than 0.00005 of an ounce (1.5 milligrams) of riboflavin;
(iii) not less than 0.00056 of an ounce (16.0 milligrams), and not more than 0.0007 of an ounce (20.0 milligrams) of niacin or niacinamide;
(iv) not less than 0.00045 of an ounce (13.0 milligrams), and not more than 0.00058 of an ounce (16.5 milligrams) of iron; and
(v) not less than 0.017 of an ounce (500 milligrams), and not more than 0.023 of an ounce (650 milligrams) of calcium.

## DIVISION 11

## JAMS, JELLIES AND MARMALADES

1. In this Division –

"acid ingredient" means citric acid, malic acid, furmaric 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 or 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 30°C. (86°F), 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) a Class II preservative specified in Part II of the Second Schedule.

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 30°C. (86°F), 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) a Class II preservative specified in Part II of the Second Schedule.

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 60 per cent of water-soluble solids as estimated by the refractometer at 30°C. (86°F) uncorrected for insoluble solids, 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) a Class II preservative specified in Part II of the Second Schedule.

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, freezer-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 percent 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 antifoaming 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 –

antifoaming agents;
essential oils;
firming agents;
natural fruit flavouring preparations;
pH adjusting agents;
synthetic food colours;

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

12. Jams and jellies manufactured from tropical fruits (other than citrus fruits) and intended for export to countries other than the territories of the Caribbean Community shall conform to the standards of the importing country, or where no such standards exist, 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 12

## MEAT AND PROCESSED MEAT

1. In this Division –

"accepted method" means any commonly accepted and officially recognised practice including that of certain religious groups used in killing animals for the purpose of food;

"animal" means any animal used as food, but does not include marine and 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 meat of the animals from which the food was derived, such as beef, goat, lamb, mutton, pork, poultry, veal and other common names.

2. **MEAT** shall be the edible part of the skeleton muscle of an animal which was healthy at the time of slaughter, or muscle that is found in the tongue, heart or oesophagus, and may contain 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 process of dressing, but does not include muscle found 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, and in the case of prepared hams, shoulders, butts, picnics and backs, may contain gelatin.

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 preservative, specified in Part II of the Second Schedule;

(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 and the carcass of which has been inspected by the proper authority and approved as being fit for human consumption.

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 group, the food shall be labelled appropriately –

(a) "Halal", where the meat used is from animals killed by the method accepted by the Islam religion;

(b) "Kosher", where the meat used is from animals killed by the method accepted by the Jewish religion.

12. No person shall sell as food meat from an animal to which diethylstilbestrol has been administered as a growth promotant.

13. **MINCED** or **GROUND BEEF** shall be comminuted beef meat and shall contain not more than 30 per cent of fat, which shall be comprised of the fat normally adherent to the beef used, and where the product is represented as being lean, it shall contain not more than 15

per cent of fat.

14. **SAUSAGE** or **SAUSAGE MEAT** shall be fresh or preserved comminuted meat, to which has been 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;

(g) meat binder,

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 or 500.000 micro-organisms in 0.035 of an ounce (1 grams as determined by an acceptable method; or

(d) any pathogenic micro-organisms.

## DIVISION 13

## PEANUT BUTTER

**PEANUT BUTTER**

(a) shall be the product prepared by grinding shelled, roasted and wholesome peanuts and may contain–

(i) salt;
(ii) sugar;
(iii) emulsifiers;
(iv) antioxidants, Class IV preservatives specific in Part II of the Second Schedule;
(v) stabilizers;
(vi) peanut oil;

the total of which shall not be more than ten per cent;

(b) shall contain –

(i) not less than forty-eight per cent and not more than fifty-five per cent fat;
(ii) not more than 0.35 of an ounce (10 milligrams) of water-insoluble

inorganic residue per 3.5 ounces (100 grams) of peanut butter; and

(c) shall be aflatoxin negative.

## DIVISION 14

## 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 bees might naturally collect in the course of its foraging, and shall contain –

(a) not more than 23.0 per cent of moisture;

(b) not more than 8.0 per cent of sucrose;

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

2. **SUGAR** shall be the food chemically known as sucrose and shall contain not less than 99.8 per cent sucrose.

3. **REFINED, GRANULATED WHITE CRYSTAL SUGAR** shall contain not less than 98.5 per cent sucrose by polarisation.

4. **YELLOW CRYSTAL** or **DEMERARA CRYSTAL SUGAR** shall contain not less than 94.0 per cent sucrose by polarisation and not more than 1.5 per cent mineral and organic matter other than sugar.

5. **DARK CRYSTAL** or **REFINERY CRYSTAL**

**SUGAR** shall contain not less than 94.0 per cent sucrose by polarisation and not more than 2.5 per cent mineral and organic matter other than sugar.

6. **ICING SUGAR** shall be powdered sugar and may contain –

(a) food colour; and

(b) either not more than 5.0 per cent starch or not more than 1.5 per cent of an anticaking agent.

## DIVISION 15

## TOMATO PRODUCTS

1. **TOMATO KETCHUP** or **CATSUP**.

(a) shall be the heat processed product made from the liquid obtained from red, ripe, sound and wholesome tomatoes or concentrate with skins, seeds and other coarse or hard substances removed, or from concentrate obtained from the liquid and shall contain –

(i) vinegar or acetic acid (food grade);
(ii) salt;
(iii) onion, garlic, spices or other condiments;
(iv) sugar, invert sugar or dextrose; and
(v) not less than 6.0 per cent by

weight of natural tomato soluble solids as determined by an acceptable method.

(b) may contain –

(i) a Class II preservative specified in Part II of the Second Schedule;
(ii) added food colour; and
(iii) an approved thickening agent; and

(c) shall not contain any other vegetable substance

2. **TOMATO PASTE** shall be the heat processed product made by evaporating a portion of the water from tomatoes or sound tomato trimmings, may contain salt and a Class II preservative specified in Part II of the Second Schedule and shall contain not less than 24.0 per cent natural tomato soluble solids as determined by an acceptable method.

3. **TOMATO PUREE** shall be the heat processed product made from whole, ripe tomatoes, trimmings from whole tomatoes, with the skins and seeds removed, concentrated to yield a product which contains not less than 8.0 per cent but less than 24.0 per cent natural tomato soluble solids and may contain salt and a Class II preservative specified in Part II of the Second Schedule. The concentration of the natural tomato soluble solids shall be declared on the label.

## DIVISION 16

## 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, 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 whole apples, apple parts or apple culls 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, provided that such vinegar is so identified by the use of the words "For Manufacturing Use Only" on the label of the

package, if in package form, and upon all documents pertaining to the vinegar.

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 and 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.

reg.89(2)(a)

## THIRD SCHEDULE

### FORM A
### APPLICATION FOR LICENCE
### FOOD AND DRUGS ACT

**(Cap. 34:03)**

**CONTROLLED DRUGS**

Application to manufacture/sell* a Controlled Drug

I, .....
of ..... apply to

become a licensed dealer of the following controlled drugs –

.....
Signature

Dated this day of 20

*Cross out as applicable.

———

**FORM B**

**APPLICATION FOR PERMIT**

**FOOD AND DRUGS ACT**

**(Cap. 34:03)**

**CONTROLLED DRUGS**

**Application to Import/Export* - Controlled Drugs**

I, .....of
.....

apply to import/export* the following controlled drugs –

.....
Signature

Dated this day of 20
*Cross out as applicable.

———

**FORM C**

**LICENCE TO MANUFACTURE OR SELL A CONTROLLED DRUG**

**FOOD AND DRUGS ACT**

**(Cap. 34:03)**

**CONTROLLED DRUGS**

LICENCE NO:

Licence is hereby granted to .....
..... of .....
.....
to manufacture/sell* the following controlled drugs –

Exact .....
Description .....

of drug to .....

be manufactured .....

sold* .....

Quantity of .....

Drugs to be .....

Manufactured/ .....

Sold* .....

subject to the conditions specified in Part IV of the Food and

Drugs Regulations, Cap. 34:03 (sub. leg.) from the date hereof until 31st December, 20 (inclusive).

Dated this day of 20

.....
Minister of Health

OFFICIAL STAMP

*Cross out as applicable.

———

**FORM D**

**PERMIT**

**FOOD AND DRUGS ACT**

**(Cap. 34:03)**

**CONTROLLED DRUGS**

Permit to Import or Export a Controlled Drug

PERMIT NO:

Permission is hereby issued to licensed dealer
.....

to import/export* the following controlled drugs –

subject to the conditions specified in Part IV of the Food and

Drugs Regulations, Cap. 34:03, from the date hereof until the* 31 December, 20 (inclusive).

Dated this day of 20

.....
Minister of Health

OFFICIAL STAMP

*Cross out as applicable

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**FOURTH SCHEDULE**

**LICENCE OF PREMISES**

**FOOD AND DRUGS ACT**

**(Cap. 34:03)**

Licence to Manufacture a Food/Drug/Cosmetic/Device*

LICENCE NO:

Licence is hereby granted to .....
of .....
to manufacture the following Food/Drug/Cosmetic/Device*

Exact description .....

of Food/Drug/ .....

Cosmetic/Device* .....

subject to the conditions specified in the Food and Drugs Regulations,

Dated this day of 20

.....
Government Analyst

OFFICIAL STAMP

*Cross out as applicable