# THE FOOD AND DRUGS ACT

## REGULATIONS
*(under section 21)*

## The Food and Drugs Regulations, 1975

L.N. 65/75
90B/93
160/93
20C/98
55/2003
37A/2010
2A/2013
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*(under section 21)*

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*(Made by the Minister on the 3rd day of March, 1975)*

[*4th August, 1975*]

L.N. 65/75
*Amdts:*
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### PART I. *Definitions*

**1.** These Regulations may be cited as the Food and Drugs Regulations, 1975. Citation.

**2.** In these Regulations, unless the context otherwise requires— Interpretation.

"can" means any hermetically sealed container;

"cubic centimeter" and its abbreviated form "cc" shall be interchangeable with the term "milliliter" and its abbreviated form "ml";

"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;

"ice" means the product obtained by freezing potable water which has been kept, stored and delivered under such hygienic conditions as to prevent contamination;

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

"main panel" means the principal label affixed to the package or container identifying its contents by stating the name of the food, drug, cosmetic or device, the ingredients, weight, manufacturer, place of manufacture and such other information as may be required by these Regulations;

"official method" means a method of analysis or examination designated as such by the Minister 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 and free from any pathogenic micro-organism;

PART II. *Foods, Drugs, Cosmetics and Devices*

*Division 1. General*

**3.**—(1) A person shall not 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 any enactment, no label or advertisement shall either directly or indirectly make reference to the Ministry of Health and Environmental Control or these Regulations.

**4.**—(1) A person shall not advertise any drug unless he has first been granted approval in writing by the Minister to do so, and such approval has not been withdrawn at the time of publication of the advertisement.

(2) The Minister 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 approval was granted, at the case may be, in cases 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.

**5.**—(1) Any information required by these Regulations to be included on a label shall be clearly and prominently displayed thereon, so as to be readily discernible to the public under normal conditions of purchase and of 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.

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

*Division II. Food*

**7.** In this Division—

"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;

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

"close proximity" means with reference to a common name, written or graphic matter placed immediately adjacent to that common name;

"common name" means with reference to a food, the name by which the food is generally known;

"food additive" means any substance, including any source of radiation, the use of which results, or may reasonably be expected to result, in it or its by-products becoming a part of or affecting the characteristics of a food excepting—

(*a*) any nutritive material that is used, recognized, or commonly sold as an article or ingredient of food;

(*b*) vitamins, minerals, and amino acids unless added for flavourings;

(*c*) spices, seasoning, flavouring preparations essential oils, oleoresins and natural extractives;

(*d*) pesticides;

(*e*) food packaging materials and components thereof; and

(*f*) drugs recommended for administration to animals that may be a source of food for human beings;

"unstandardized food" means any food for which a standard has not been prescribed.

**8.** A person shall not 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.

**9.** A person shall not 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.

**10.** A person shall not use water other than potable water as an ingredient in the manufacture or preparation of any food.

*Labelling*

**11.**—(1) A person shall not sell a package of food which is not labelled or which bears a label that does not comply with the provisions of these Regulations.

(2) The provisions of paragraph (1) shall not apply to food packaged from bulk on the premises where that food is retailed, so, however, that where any food so packaged bears any statement, mark or device regarding the ingredients or the substances contained therein other than the name of the food, the name and address of the retailer and the net contents, it shall be labelled as required by the Act.

**12.**—(1) Unless otherwise specifically provided in these Regulations, every package of food offered for sale shall bear a label stating legibly and conspicuously in conformity with regulations 5 and 6—

(*a*) on the main panel—

(i) the brand name or trade name, if any; and

(ii) the common name of the food; and

(iii) a statement of the weight, volume, number or measure of contents; and

(*b*) on the remainder of the label—

(i) a declaration of added colour, if present; and

(ii) the name and address of the manufacturer, packer, importer, vendor or of any person who assumes the responsibilities of the manufacturer, packer, importer or vendor and indicates in conjunction with his name and address that he is not the manufacturer, packer, importer or vendor.

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