FOOD, DRUGS AND CHEMICAL SUBSTANCES (GENERAL) REGULATIONS, 1978

ARRANGEMENT OF REGULATIONS

Regulation

FOOD, DRUGS AND CHEMICAL SUBSTANCES (GENERAL) REGULATIONS, 1978

[L.N. 105/1978, L.N. 228/1978, L.N. 190/1988.]

REGULATIONS UNDER SECTION 28

1. Citation

These Regulations may be cited as the Food, Drugs and Chemical Substances (General) Regulations, 1978 and shall come into operation on the 1st May, 1979.

[L.N. 228/1978.]

2. Interpretation

In these Regulations, unless the context otherwise requires—

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

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

"official method" means a method of analysis or examination, designated as such by the Minister, for use in the carrying into effect the provisions of the Act;

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

3. Official methods to be furnished

The Minister shall, upon request by any person, furnish official methods.

4. Manner of designating lot or batch number

Where a lot or batch number is required by any regulations made under the Act to appear on any article, container, package, or label, it shall be preceded by one of the following designations—

(a) "lot number" or "batch number";

(b) "lot no." or "batch no.";

(c) "lot" or "batch"; or

(d) "L" or "B".

5. Names of reference

(1) Where any food, drug, cosmetic, device, or chemical substance has more than one name, whether common or proper, a reference to that food, drug, cosmetic, device, or chemical substance by any of its names shall be deemed to be a reference to it by all its names.

(2) The term "cubic centimetre" and its abbreviation "*cc*" shall, wherever applicable, be deemed to be interchangeable with the term "millilitre" and its abbreviation "*ml*".

6. Statement, information, etc., on label

(1) Any statement, information, or declaration that is required by any regulations made under the Act to appear on the label of any food, drug, cosmetic, device, or chemical substance shall be in the English language in addition to any other language which may appear thereon.

(2) The English language type size shall be equivalent to, or greater than, the type size used for any other language and shall be displayed on the main panel.

7. Information on label to be prominently displayed and readily discernible

Any information appearing on a label of any food, drug, cosmetic, device, or chemical substance shall be—

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

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

8. Importation of food, etc., in violation of the Act prohibited

(1) Subject to regulation 9, no person shall import into Kenya any food, drug, cosmetic, device, or chemical substance where an authorized officer is satisfied, after the examination or analysis of a sample thereof in accordance with subsection (11) of section 30 of the Act, that the sale of such an article in Kenya would be a violation of the Act or any regulations made thereunder.

(2) Where an authorized officer finds, as a result of an examination or analysis, that any food, drug, cosmetic, device, or chemical substance should not be admitted into Kenya, he shall forthwith send a copy of the report of analysis or examination to the Commissioner of Customs and Excise and to the importer of the food, drug, cosmetic, device, or chemical substance.

9. Certain prohibited articles to be admitted for specified purposes

(1) Where any food, drug, cosmetic, device, or chemical substance sought to be imported into Kenya would, if sold in Kenya, constitute a violation of the Act or any of the regulations made thereunder, it may be admitted into Kenya for the purposes of relabelling or reconditioning under the supervision of an authorized officer.

(2) Where the relabelling or reconditioning under paragraph (1) is not satisfactorily carried out within three months and where the conditions specified in the public analyst's report are not complied with, the food, drug, cosmetic, device, or chemical substance shall be exported out of Kenya to a destination disclosed to the authorized officer.

(3) Where the food, drug, cosmetic, device, or chemical substance is not exported within three months, it shall be forfeited to the Government and shall be disposed of in such manner as the Minister may direct; but the Minister may extend the period for complying with the provisions of paragraph (2).

10. Export of food, etc., in violation of the Act prohibited

(1) No person shall export out of Kenya any food, drug, cosmetic, other than a food, drug, device or chemical substance exported under regulation 9, unless an export health certificate in such form as may be prescribed is issued by an authorized officer.

(2) An authorised officer may require—

(a) any food, drug, cosmetic, device or chemical substance to be examined or analysed in accordance with subsection (11) of section 30 of the Act; and

(b) any other relevant information, before issuing an export health certificate.

(3) A fee of five hundred shillings shall be payable for every Export Health Certificate issued under this Regulation.

[L.N. 190/1988, s. 2.]

11. Procedure for taking samples and form of certificate of analysis

(1) Where an authorized officer takes a sample pursuant to section 30 of the Act, he shall notify the owner thereof or the person from whom the sample was obtained of his intention to submit the sample to the public analyst for analysis or examination; and—

(a) where, in his opinion, division of the procured quantity of the sample would not interfere with the analysis or examination he shall—

(i) divide the quantity into two parts;

(ii) identify the two parts as the owner's portion and the 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 and forward the sample to the public analyst for analysis or examination; or

(b) where, in his opinion, division of the procured quantity of the sample would interfere with analysis or examination he shall—

(i) identify the entire quantity as the sample;

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

(iii) forward the sample to the public analyst for analysis or examination.

(2) The public analyst's certificate specifying the result of his analysis or examination of a sample sent to him by an authorised officer in accordance with paragraph (1) of this Regulation shall be in the form set out in the Schedule to these Regulations.

SCHEDULE

[Regulation 10.]

CERTIFICATE OF ANALYSIS OR EXAMINATION

I, ..., a public Analyst appointed under the provisions of the Food, Drugs and Chemical Substances Act (Cap. 254), hereby certify that the seal on the sample of ..... received by me on the ..... was unbroken.

I further certify that the sample has been analysed by me or under my direction and the result of analysis is as follows—

.....

.....

.....

and I am of the opinion that .....

.....

.....

Given under my hand this ..... day of ....., 20 .....

.....

*Public Analyst**

Full Address .....

* *Name to be typed or printed.*
