

STATUTORY INSTRUMENTS 2005 No. 2.

THE FOOD AND DRUGS (FOOD FORTIFICATION) REGULATIONS, 2005.

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STATUTORY INSTRUMENTS

2005 No. 2.

The Food and Drugs (Food Fortification) Regulations, 2005.

(Under section 41 of the Food and Drugs Act, Cap 278)

IN EXERCISE of the powers conferred on the Minister by section 41 of the Food and Drugs Act, these Regulations are made this 10th day of November, 2004.

1. These Regulations may be cited as the Food and Drugs (Food Fortification) Regulations, 2005.

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

“authorised officer” means a person authorised by the Minister in writing either generally or specifically to act in matters of any specified kind or in any specified matter for the purpose of these Regulations;

“delegated authority” means authority delegated by the Minister to undertake such activities as the Minister may deem fit;

“diluent” means a suitable, inert, food-grade carrier for micronutrients;

“food vehicle” means foodstuff that is selected to carry selected micronutrients;

“fortificant” means the prescribed compound which provides the specified micronutrient;

“fortification” means the addition of one or more micronutrients by means of a fortificant or fortification mix to a foodstuff, whether or not it is normally contained in a foodstuff, for the purpose of preventing or correcting a demonstrated deficiency of one or more micronutrients in the general population or a specific population group of Uganda;

“fortification mix” means a premixed blend of fortificants and diluents formulated to provide specified and determinable amounts of micronutrients;

“guidelines” means guidelines for food fortification issued by the Minister;

“micronutrient” means a natural or synthesised vitamin, mineral, or trace element that is essential for normal growth, development and maintenance of life and of which a deficit will cause characteristic biochemical or physiological changes;

“Minister” means the Minister responsible for health;

“Ministry” means the Ministry responsible for health;

“NDA”, means the National Drug Authority established by the National Drug Policy and Authority Act;

“quality assurance” means the totality of the organised activities undertaken to ensure that a product meets the standards of quality required for its intended use by the consumer;

“quality control” means the measures applied and the steps taken by a manufacturer of foodstuffs to ensure that the correct procedures are being followed and the set criteria are being met in administering fortificants to food vehicles;

“national standard” means a standard produced or adopted by the Uganda National Bureau of Standards for use in Uganda.

3. These Regulations apply to all fortified foodstuffs for human consumption.

4. (1) The Minister shall encourage and promote the fortification of staple foodstuffs and other processed foodstuffs to address identified micronutrient deficiencies in accordance with national standards, prescribed by the Minister.

(2) The Minister shall, monitor the implementation and enforcement of these Regulations.

(3) The guidelines and national standards on food fortification shall serve as the basis for addition of nutrients to foodstuffs to avoid over or under fortification as well as misleading label claims.

(4) The Ministry shall be the owner of the official food fortification logo and shall authorise, regulate and issue guidelines for its application.

5. (1) A person may manufacture, import, or sell foodstuffs identified as fortified food to supply nutrients, which are insufficient in the population.

(2) A person shall not manufacture, import or sell foodstuffs identified as fortified foodstuffs unless the foodstuffs have been fortified in accordance with the national standards, as well as the principles set out in the First Schedule.

(3) The foodstuffs referred to in sub-regulation (2) shall be fortified at a specific stage of production to levels specified in national standards to ensure that the minimum level of the prescribed nutrients are maintained at the time of supply of the foodstuff to the consumer.

6. (1) The fortificants that are allowed for use in fortification of foodstuffs shall be those provided in the guidelines or prescribed in the relevant national standards.

(2) A person who manufactures, imports or supplies a fortificant or fortification mix for the purpose of these Regulations, shall comply with the requirements of the NDA and the requirements set out in the Second Schedule.

(3) Manufacturers of fortified foodstuffs shall use the fortificants or fortification mixes from companies that meet the requirements of the NDA.

7. (1) In addition to the requirements of the national standards for a fortified foodstuff, claims for, or any claims that may imply food fortification, including the use of the official fortification logo as set out in the Third or Fourth schedule shall be reserved only for fortified foodstuffs that are permitted by the Minister and may be displayed on the label or in an advertising or promotional material.

(2) A logo set out in the Third or Fourth Schedule, may be displayed on the label or at the point of sale, or on the shelf and within clear sight of the consumer or used in advertising of the products or promotion and advocacy for the food fortification program.

(3) Where the official logo is used, the format set out in the Third or Fourth Schedule shall be adopted and the logo shall be printed in a prominent position on the main panel in bold print against a contrasting or clear background on all types of packaging material.

(4) The logo shall be visible, legible and indelible.

(5) The design of the logo shall be constructed as set out in the Third or Fourth Schedule.

(6) The logo may be printed in black and white as in facsimile 1 in the Third Schedule or in full colour as in facsimile 2 in the Fourth Schedule.

8. A person manufacturing, importing, selling or distributing fortified foodstuffs shall ensure that the foodstuffs are—

- (a) stored in a cool, well ventilated and dry place which does not at any stage expose it to direct sunlight or excessive humidity;
- (b) not exposed to any form of contamination;
- (c) properly stocked and a stock register with lot numbers and a date of receipt is maintained; and
- (d) transported, kept or stored for sale in the package in which they were originally packaged.

9. (1) The Minister or a delegated authority shall—

- (a) provide for quality assurance, monitoring, and enforcement activities for fortified foodstuffs;
- (b) provide for the examination and analysis of official samples of fortified foodstuffs in a recognised laboratory;
- (c) establish a quality assurance system to check on the quality and safety of any fortified foodstuffs, manufactured, imported or sold in Uganda to ensure compliance with these Regulations; and
- (d) carry out, random on-the-spot checks at—
 - (i) the point of entry for imports;
 - (ii) the factory or warehouse of a fortified foodstuff manufacturer or importer;
 - (iii) wholesale points;
 - (iv) any point of distribution; and
 - (v) consumption level.

(2) Subject to these Regulations, and any other law in force, an authorised officer may, during normal office hours or other reasonable time—

- (a) inspect any factory, commercial concern, shop or store;
- (b) enter any premises or vessel where fortified foodstuffs are manufactured, packed, stored or sold;
- (c) examine and make copies of or acquire any book or records in relation to fortified foodstuffs; and
- (d) interview any person or agent to determine whether these Regulations are complied with.

(3) An authorised officer may impound, stop the manufacture, packing, selling, transporting or any activity related to fortified foodstuffs, where these Regulations have not been complied with.

(4) A person manufacturing, or importing fortified foodstuffs shall establish his or her

own quality assurance system in accordance with the quality assurance system established by the Minister and shall carry out quality assurance activities, which shall include-

- (a) routine instrument and equipment calibration and maintenance checks;
- (b) routine validation of the production procedures and their adequacy;
- (c) routine checks of all raw materials;
- (d) routine checks on the finished products; and
- (e) routine checks on packages and labels.

(5) A person carrying out quality assurance activities shall keep records of the activities which shall specify—

- (a) the batch, lot number and quantity from which the samples were taken for analysis;
- (b) the sample size that was analysed;
- (c) the analysis results and the person who performed the analysis;
- (d) the date, time of inspection and analysis; and
- (e) any other activities that may have been carried out including the nature of activity and its findings.

10. (1) The Minister shall regulate the conduct of promotional and advocacy activities on the use of fortified foods through the food fortification logo and other programs designed to promote nutrition.

(2) Fortified foodstuffs approved by the Minister shall be allowed to use the logo.

11. A person who contravenes a provision of these Regulations commits an offence and shall be liable on conviction to imprisonment not exceeding three months and shall have the items in contravention impounded. The court may order the items to be forfeited, destroyed or disposed of in a manner prescribed by the Minister.

FIRST SCHEDULE.

REGULATION 5(2)

QUALITY CONTROL PRINCIPLES FOR MANUFACTURERS OF FORTIFIED

FOODSTUFFS

A manufacturer of fortified foodstuffs shall—

- (a) keep monthly records of the supplier and amount of fortificants and fortification mixes used every month, and these records shall correspond with the monthly production records;

- (b) ensure that fortificants and fortification mixes are stored under the appropriate conditions to prevent loss of their potency;
- (c) ensure that strict stock rotation procedures are adhered to in order to prevent old stock losing potency and to comply with the shelf life expiry date; and
- (d) ensure that all critical stages of the manufacturing process are monitored to ensure that the correct dosage levels are maintained through the following measures—
SECOND SCHEDULE.
 - (i) checking of fortificants or fortification mix feeders at least once a day to ensure that they are delivering the correct dosage levels;
 - (ii) performing visual checks at least twice in every shift to ensure that fortificants and fortification mixes are being used and that no blockages have occurred as well as keeping record of the visual checks; and
 - (iii) performing spot checks, regularly in accordance with the performance of the fortification process, at least once in every shift, to ensure that the product has been dosed correctly by determining one of the components of a fortificant or fortification mix in accordance with an appropriate analytical method.

REGULATION 6 (2)

QUALITY CONTROL PRINCIPLES FOR MANUFACTURERS, IMPORTERS AND SUPPLIERS OF FORTIFICANTS AND FORTIFICATION MIXES

A manufacturer, importer or supplier of fortificants and fortification mixes shall—

- (a) keep monthly records of the quantities of fortificants and fortification mixes sold to food manufacturers as well as a list of the names and addresses of the purchasers and avail such records to the authorised officer upon request;
- (b) ensure that the quality standards for diluents and fortificants, independently or mixed are in accordance with the standards set out in the latest edition of Food

SECOND SCHEDULE.

Chemicals Codex (FCC), United States Pharmacopoeia, (USP), British Pharmacopoeia (BP), European Pharmacopoeia, (Ph Eur), Merck Index (MI), United States National Formulary (NF), or General principles for use of food additives, Codex Alimentarius, Volume 1;

(c) ensure that each batch of a fortificant and fortification mix for the various food vehicles complies with the fortification standards and is accompanied by a certificate of analysis from a laboratory that has international accreditation for the methods of analysis used;

(d) submit samples of appropriate size of a fortificant and fortification mix every six months, or as and when required, for each type of fortificant or fortification mix to a laboratory that has international accreditation for the methods of analysis used;

(e) keep the analysis report on record and submit a copy of the report to the NDA;

(f) bear the costs of the analysis provided for in paragraph *(d)*.

THIRD SCHEDULE
FOOD FORTIFICATION LOGO

REGULATION 7
(5)

Facsimile 1 (Black and white copy)

1. The texts FORTIFIED FOOD Shall be font type: impact,
and ADDED VALUE upper case
2. The letter F Shall be font type: News 701
BT, upper case, Bold
- 3 Inner circle Gray on black and Black grey white logo

FOURTH SCHEDULE

REGULATION 7(5)

Facsimile 2 (full colour copy)

(a) The texts FORTIFIED FOOD Shall be font type: impact, upper

and ADDED

Shall be font type: News 701 BT VALUE case
upper case, Bold

(b) The letter F

(Pantone, 2755 CVC), C-100%,
cyan, M-100 %, magenta, Y-0%,
yellow, K-9%, black.

(c) Outer circle Blue

M-5%, magenta, Y-79% yellow

(d) Sun Golden Yellow

K-9%, black,

(e) Inner circle Black

BRIG. JIM KATUGUGU MUHWEZI,

FOURTH SCHEDULE

Minister of Health.