PRODUCT SPECIFICATION SHEET

Fortified Biscuits-CAR 100x100 g

Version no: 1.0
Material No: S000837
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Revised by: AF, MCR
Date: 05.12.2023

1. General Description

Fortified Biscuits are biscuits high in energy and protein and supplemented with a premix of vitamins and minerals. There are 100 packages weighing 100 g each, for a total of 10.00 kg net.

2. Intended use

Fortified biscuits are intended for general food distribution, school feeding and use in emergencies. This ready-to-eat food is used to cover urgent needs in the acute phase of an emergency in which a population is not able to cook due to a lack of access to basic facilities (clean water, cooking equipment, etc.). Their use is also extended to complement food rations (such as snacks) to provide vitamins and minerals in regions/populations where the diet is subject to nutritional deficiencies. Fortified biscuits can also be used to prevent micronutrient deficiency in young and school age children.

3. Target population

General population and school aged children in an emergency context.

4. Technical Specifications

Nutritional composition per 100g of product

Moisture content: 4.5% maximum
Nutritional value: it shall contain the following nutritional value per 100g dry matter
Energy: 430 kcal/1799 kJ minimum
Protein: 10.0 g (N x 6.25) minimum
Fat: 15.0 g minimum
Sugar (total): Max 15 g
Fiber (crude): Max 2.3 g
Ash (total): Max 3.5 g

Vitamins and minerals per 100g Fortified biscuits

Vitamin A as Retinol:500-850mcg
Vitamin B1: Min 0.9mg

Vitamin B2: Min 0.9mg
Niacin: Min 8mg
Pantothenic acid: Min 4mg
Vitamin B6: Min 1mg
Folic acid: Min 180mcg
Vitamin B12: Min 1.8mcg
Biotin: Min 20mcg
Vitamin D: Min 5mcg
Vitamin E: Min 7mg
Calcium: Min 250mg
Iron: 10-17 mg
Zinc: Min 8mg
Iodine: Min 120mcg
Phosphorus: Min 167mcg

Note: Variable levels of micronutrients (i.e., iron, zinc, calcium etc.) are naturally present in raw materials may lead variable of micronutrients in finished product. The product should meet UNICEF's specification for all parameters through-out the shelf-life.

International Standards

Fortified Biscuits shall comply with the following guidelines or standards of Codex Alimentarius:

1. CAC/GL 08-1991; Guidelines on Formulated Supplementary Foods for Older Infants and Young Children
2. CAC/RCP 75-2015; Code of Hygienic Practice for Low Moisture Foods
3. CAC/RCP 1-1969; Recommended International Code of Practice: General Principles of Food Hygiene including Annex Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its application
4. CAC/GL 09-1987; General principles for addition of essential nutrients to foods

5. Processing

5.1 Requirements for raw materials

Fortified biscuits shall be manufactured from fresh and high-quality raw materials and shall be free from foreign materials and substances which represent a hazard to health. Fortified biscuits shall be free from excessive moisture, insect damage and fungal contamination and shall comply with all relevant national food laws and standards.

The product formulation shall be based on supplier experience and must include

-Dry Skimmed Milk: Min. 4.0 g/100g of fortified biscuits to ensure quality protein
-Added Sugar: Max. 15 g/100g of biscuit

Standards for raw materials

1. CXS 152-1985: Standard for Wheat flour
2. CXS 171-1989: Standard for Soy flour or CXS 175-1989: Standard for soy protein
3. CXS 212-1999: Standard for Sugar
4. CXS 207-1999: Skimmed milk powder
5. CXS 210- 1999: Standard for named vegetable oils. Shortening must be prepared from oil that conform to CXS 210-1999, must be controlled for trans fatty acids according to national or international standards and must contain only antioxidants that comply with Codex and relevant regulations
6. Other raw materials need to comply with Codex or relevant regulations

Raw materials shall be stored under dry, ventilated, and hygienic conditions. Only safe insecticides (i.e., phosphine) may be used for fumigation control. Where needed, fumigation shall be performed by certified operators.

- Note

Milk and milk powder: determination of aflatoxin M1 content, clean up by immune-affinity chromatography and determination by HPLC and Thin Layer Chromatography

5.2 Requirements to additives

1. Lecithin shall be in proportion as specified in the CXS 74-1981: Standard for processed cereal-based foods for infants and young children
2. Raising (soda) agent as specified in the CXS 74-1981: the maximum value is determined by GMP principles
3. Artificial flavoring agents are not allowed except for ethyl vanillin and vanillin: 7mg/100g
4. Other additives must comply with CXS 192-1995: General standards for food additives and CXS 74-1981 Standard For Processed Cereal-Based Foods For Infants and Young Children

5.3 Vitamins and mineral premix

Fortified biscuits shall include a premix consisting of the vitamins and minerals described in the product specification. The mineral and vitamin premix(es) must not be produced by the fortified biscuits manufacturer itself and must be supplied only from suitably qualified premix facilities. Suppliers should implement an effective food safety and quality management system for the premix, including supplier approval and premix quality control.

A list of suppliers of sources of premix is available at: http://gpf.gainhealth.org/suppliers/current-suppliers. However, not all these suppliers are approved by UNICEF. Fortified biscuits suppliers must validate their premix supplier to ensure the quality of the premix facility on its own merit. Vitamin and mineral forms used must be soluble and easily absorbed. The added minerals should be water-soluble and should not form insoluble components when mixed.

Additionally, the premix shall:
-Be delivered to the processor of fortified biscuits with a complete Certificate of Analysis.

-Be stored as recommended by premix manufacturers.

As an example, the manufacturer can use the below reference table for fortification to provide the following net micronutrient supplement per 100g of biscuit. The premix addition rate for this example is approximately 7.0 kg/MT of finished product.

Premix Requirement (Added/100 g Final product (+/-10%))

Vitamin A as Retinol: 824.6mcg as palmitate CWS or beadlet
Vitamin B1: 1mg as thiamine mononitrate
Vitamin B2: 1.2mg as riboflavin
Niacin: 5.9mg as nicotinamide
Pantothenic acid: 4.9mg as calcium d-pantothenate
Vitamin B6: 1.1mg as pyridoxine hydrochloride
Folic acid: 243mcg as folic acid
Vitamin B12: 2.2mcg as Vitamin B12 0.1% or 1% spray dried
Biotin: 20.7mcg as Biotin
Vitamin D: 10mcg as cholecalciferol CWS or beadlet
Vitamin E: 7.4mg as alpha or dl- tocopherol equivalent CWS
Calcium: 174.1 mg as calcium carbonate; Calcium Phosphate
Iron: 8.6mg as 5.6 g from ferric pyrophosphate + 3 g from NA EDTA
Zinc: 5.7mg as zinc sulphate
Iodine: 147.7mcg as potassium iodate
Phosphorus: 46.9mg as calcium phosphate

**Note: The column for added nutrient means added micronutrient premix. The variable amount considers some losses (process, storage) and the higher valued on the labelling takes consideration of inherent contribution from raw materials on top of premix added.*

5.4 Homogeneity of micronutrients

Theoretical calculations indicate that a mixing system with a Coefficient of Variation of 10% using iron/vitamin A as the indicator element, will enable product to meet the above variation target on 95%, provided that all conditions of mixing are rigorously applied. The guide for these calculations is showed at

https://docs.wfp.org/api/documents/WFP-0000145318/download/

6. Food safety and risk assessment at manufacturing premises

For compliance with Codex standards the processor must be able to demonstrate by principle and practice the adoption, implementation and recording of:

-Good Manufacturing Practices (GMP)

-Good Hygiene Practices (GHP)

-Hazard Analysis Critical Control Point program (HACCP)

The manufacturer must be registered under national food law as a processor of foods for human consumption.

6.1 Hygiene

It is recommended that the products covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the Recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1-1969), and other Codes of Practice recommended by the Codex Alimentarius Commission which are relevant to these products.

The product should comply with any microbiological criteria established in accordance with the Principles for the Establishment and application of microbiological Criteria for Foods (CAC/GL 21-1997)
To the extent possible in good manufacturing practice, the products shall be free from objectionable matter. When tested by appropriate methods of sampling and examination, the products:

-shall be free from micro-organisms in amounts which may represent a hazard to health
-shall be free from parasites which may represent a hazard to health; and
-shall not contain any substance originating from micro-organisms in amounts which may represent a hazard to health.

6.2 Microbiology

The following levels of microbiological contamination in the finished product shall not be exceeded:

Acceptable microbial limits

Total plate count: Max 10,000 cfu per g
Total Coliform bacteria: Max 10 cfu per g
Escherichia coli: Absent in 10g
Salmonella: Absent in 25g
Staphylococcus aureus: <10 cfu per g
Bacillus cereus: Max 10 cfu per g

Enterobacter sakazakii: Absent in 10g
Yeasts and moulds: Max 100 cfu per g

6.3 Additional Requirements

Organoleptic: Fortified biscuits shall have a typical colour, pleasant smell and palatable taste.
Broken biscuits: not be more than 5.0% (by weight).
Weight: one biscuit should weigh between 5g and 10 g.
Peroxide value: shall not be above 10 meq/kg fat.
Shelf life: 12 months minimum, 24 months preferred.
Shelf life is from date of manufacture when stored dry at ambient temperatures prevalent in the country of destination, protected from direct sunlight.

6.4 Control of contaminants

Fortified biscuits shall be free from objectionable matter; shall not contain any substances originating from micro-organisms or any other poisonous or deleterious substances, heavy metals, or pesticide residues, in amounts which may represent a hazard to health.
Manufacturers should control for contaminants with their finished goods testing program, including a full list of contaminants testing at least once per year.

6.4.1 Mycotoxins

The product shall comply with those maximum mycotoxin limits established by the Codex Alimentarius Commission for this commodity. Maximum level of aflatoxin M1:< 0.5 ppb, as per reference CXS 193-1995: General standard for contaminants and toxins in food and feed.

6.4.2 Heavy Metals

The product shall be free from heavy metals in amounts which may represent a hazard to health.

Arsenic (As): <0.10 ppm
Cadmium (Cd:) < 0.20 ppm
Lead (Pb): < 0.20 ppm
Mercury (Hg): <0.10 ppm

6.4.3 Pesticide residues

The product shall comply with those maximum residue limits established by the Codex Alimentarius Commission for this commodity.
The product shall be prepared with special care under good manufacturing practices, so that residues of those pesticides which may be required in the production, storage or processing of

the raw materials or the finished food ingredient do not remain, or, if technically unavoidable, are reduced to the maximum extent possible.

These measures shall consider the specific nature of the products concerned and the specific population group for which they are intended.

Carbamate: <10ppb
Organochlorine: <10ppb
Organophosphorus: <10ppb
Pyrethroid: < 10ppb

6.4.4 Other contaminants

-Free from radioactivity

-Free from Genetically Modified Organisms (GMO) (if required by the recipient country).

-Suppliers shall check the quality of their product and guarantee that fortified biscuits is fit for human consumption.

-Melamine: max 2.5mg/kg, as per applicable reference COMMISSION REGULATION (EU) No 594/2012 of 5 July 2012 amending Regulation (EC) 1881/2006
https://www.fsai.ie/uploadedFiles/Reg594_2012.pdf

-Acrylamide: Levels should be managed as per COMMISSION REGULATION (EU) 2017/2158 with a reference level of max 350 mcg/kg of finished product.

https://www.fsai.ie/uploadedFiles/Reg2017_2158.pdf

7. Packaging

7.1 Primary packaging

Fortified biscuits shall be packaged in food-grade flexible sachets, hermetically sealed and robust enough to withstand multiple handling & transport and protect the product throughout its shelf life. Sachet material shall not represent a hazard for infants and young children when sachets are opened and put in contact with the mouth.

Each single unit package must contain from 50 to 100 grams of biscuits or as per otherwise specified in the LTA. Weight and quantity tolerance must meet the International Organization of Legal Metrology International Recommendation OIML R 874.

It is the responsibility of the manufacturers to select a packaging material that will protect the fortified biscuits from moisture as well as from vitamin and fat degradation throughout their shelf life.

Sachets shall be

- Packed in food grade materials compliant with the last amendments of national regulations in the country of production

-Biscuits should be packed in protective packaging suitable to maintain minimum 12 months shelf life. For example, metalized laminate PET/met PET/PE (Total typical thickness 70 mic +/- 3)

-Optimized shape to avoid space loss in the sachets and cartons

-Properly sealed (test example: ASTM F2338 – 09, ASTM D3078 – 02 or equivalent)

-The sachets must be placed in an appropriate way in the carton box during the packing process to avoid packaging & product damage.

-The laminate must include a high barrier layer to highly reduce permeability of oxygen and water vapor. Example of Applicable standard and test for barrier properties:

-WVTR <1.5 g/m2.day (38°C/90% RH) (ASTM F1249-13 or equivalent)

-OTR < 1.5 cc/m2.day (23°C/50% RH) (ASTM F192714 or equivalent)

-optical density = 2 (ASTM D 1003 or equivalent)

-Reverse printing is mandatory

7.2 Secondary packaging

Individual packages shall be packed in strong cardboard cartons suitable for multiple handling. N.B. About 15-20 bags of silica gel of at least 1g each should be placed in each container to absorb moisture. In addition, craft paper should be laid to all sides of the container. A full carton should weight approximately 10kg. Cardboard strength requirements : preferably tested by compression test. Individual packages shall be packed in strong cardboard and cartons should be suitable for multiple handling.

As a guidance, cartons shall be

-New, manufactured from well-constructed double walled corrugated board

-With an edge crush resistance of 60ECT = 60 lbs/in eq 11 kN/m (ISO 3037) and a specific weight of 700 to 1000 grams per square meter, fully filled for maximum strength.

-The fluting must be vertical, supporting the load.

-The carton should be plain brown, dimensions adjusted to the load.

-No stapling will be accepted.

8. Labelling

The labelling of the product covered by the provision of this specification shall comply with CXS 1-1985: General standard for the labelling of prepackaged foods.

8.1 Primary labelling

Primary labeling shall include the following information in English, French and Spanish or Arabic (labelling in local languages might also be required):

-List of ingredients in descending order and declaration of allergens

-Product name “Fortified Biscuits”

-Fortified food

-Nutritional value per 100 g.

-Production lot/batch

-Manufacturing date (month/year)

-Best before date (month/year)

-This product contains no lard.

-**Not for sale or exchange** in bold

-Net weight

-Country of origin

-Name and address of the supplier

-The Statement "*It is strongly recommended to start breastfeeding immediately after birth, exclusively breastfeed during the first 6 months and continue until at least 24 months*".

8.2 Secondary labeling

Cartons shall be marked in English, French and Spanish or Arabic (labelling in local languages might also be required) with the following information in letters measuring 1.0 to 1.5cm on the cartons:

-Fortified Biscuits
-Fortified food

-Net weight and gross weight (total net weight of all primary packages in the carton)

- Production lot/batch

-Month and year of production

-Best before end

-Name and address of the supplier

-Country of origin

-**Not for sale or exchange** in bold

-Additional marking as per LTA agreement.

9. Storage

The product must be stored under dry, ventilated, and hygienic conditions away from direct sunlight and far from all sources of contaminations. Ideally, the product should be best stored up to 30°C.

10. Shelf life and stability

Unless stated otherwise in the LTA, the fortified biscuits must have a minimum 12-month shelf-life (preferably 24 months shelf life) when stored in temperatures up to 30°C. The supplier should conduct shelf-life studies to confirm shelf-life as per Interagency stability study requirements for nutritional products (unicef.org). As a minimum, parameters to examine include: sensory, moisture, water activity of the finished product, lipid stability (peroxide and anisidine values), Vitamin A, and packaging performance.

- Notes

Given that the potential supplier will have the flexibility to work on continuous improvement with UNICEF and other technical partners, lower shelf-life, but not less than 12-month will be accepted, provided that such shelf-life has been the result of changes in the formula and packaging as instructed and agreed upon with the agency.

11. Analytical requirements

The manufacturer should conduct a complete analysis of the finished product to verify that the finished product is manufactured in a homogeneous and consistent content. ALL parameters included in this specification sheet should be tested at least once a year.

Analytical CoA Requirements per Batch

A Certificate of Analysis (CoA) should be issued and forwarded prior to each shipment or order collection for each batch provided. This certificate must mention the laboratory name, methods of analysis, laboratory variability ranges for each nutrient, specifications, and targets for all the criteria below, to be applied to the finished product after primary packaging or anytime thereafter up to the point when the primary packaging is opened. The batch cannot be released if there is a failure to meet the following criteria:

List of compulsory tests and reference method for statements and CoA requirements per batch: (Reference method cited should be the latest version and can be equivalent)

Physico-chemical

Moisture content Max: 4.5 % (AACC 44-15.02, ISO 712, AOAC 925.10)
Organoleptic (smell, taste, color), Typical color, pleasant smell and palatable taste. Sensory
Broken biscuits Max.: 5.0 % broken (by weight) Visual inspection
GMO cereal (Only if required) < 0.9 % of GMO material in total cereal DNA Quantitative PCR (ISO 21570)

Nutrient

Protein (N x 6.25): Min. 10g/100g (AOAC 992.23 EN ISO 16634-2)
Fat: Min. 15.0 g/100g (ISO 11085)
Sugar (total): 10.0-15.0 g/100g (AOAC 920.189)
Crude fibre: Max. 2.3 g/100g (AOAC 962.09)
Ash (total): Max. 3.5 g/100g (ISO 2171.2000)
Peroxide value: Max. 10 meq/kg fat (AOAC 965.33)
Vitamin A-Retinol: 500 – 850 mcg/100g (AOAC 2012.10 2014 UNI EN 12823)
Iron: Min. 10 mg/100g (AOAC 2015.06 EN 15763:2010)

Safety

Total plate count: Max. 10,000 cfu/g (ISO 4833-1 ICC No 125 AACC 42-11.01)
Total Coliforms: Max. 10 cfu/g (ISO 4832 AOAC 2005.03 AACC 45-15.02)
Escherichia coli: Absent in 10 g (AOAC 991.14)
Salmonella: absent in 25 g (ISO 6579-1 AACC 42-25.03)
Staphylococcus aureus: <10 cfu/g (EN ISO 6888-2 AACC 42- 30.04)
Bacillus cereus: Max. 10 cfu/g (ISO 7932 AOAC 980.31)
Yeasts and moulds: Max. 100 cfu/g (ISO 21527-2 ICC No 146 AACC 42-50.02)
Aflatoxin M1: < 0.5 ppb (AACC 45-16; ISO 14501/IDF 171:2007 or ISO 14674/IDF190:2005)

Useful Resources

1. Contaminants Reference Table
2. Stability study template for Nutritional Products
3. Interagency Requirements for stability study
4. Interagency Specialised Food Manufacturer Quality Questionnaire.
5. Interagency Specialised food Product Questionnaire
6. Technical Requirements for Nutritional Products
7. docs.wfp.org/api/documents/WFP-0000153256/download/

FOR MORE INFORMATION

CPHHQ-SD- Nutrition Supplies |sd.nutritionsupplies@unicef.org