

	<p>PRODUCT SPECIFICATIONS SHEET</p> <p>High Energy Biscuits 2.0</p>	<p>Author: A Fleet</p> <p>Revision: ARF, MEFB</p> <p>Version: 4.0</p> <p>Date: 15.11.2019</p>
---	---	---

1. General Description:

High Energy Biscuits (HEB) are biscuits high in energy and protein and supplemented with a premix of vitamins and minerals.

2. Intended use:

HEB 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 during which 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 a complement food ration (such as snacks) to provide vitamins and minerals in regions/population where diet is subject to nutritional deficiencies. HEB 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: 450 kcal minimum

Protein: 10.0-15.0g (N x 6.25)

Fat: 15.0g minimum

Sugar (total): 10.0-15.0g

Fiber (crude): 2.3g maximum

Ash (total): 3.5g maximum

Vitamin and Mineral premix content per 100g finished product:

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 6.0 kg/MT of finished product.

Premix Requirement

Vitamin A as Retinol: 824.6mcg as palmitate CWS
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 cyanocobalamin SD
Biotin: 20.7mcg as Biotin
Vitamin D: 10mcg as cholecalciferol CWS/beadlet
Vitamin E: 7.4mg as alpha or dl- tocopherol equivalent CWS
Calcium: 174mg as calcium carbonate

Label* HEB 2.0 per 100g

500mcg
0.9mg
0.9mg
8mg
4mg
1mg
180mcg
1.8mcg
20mcg
5mcg
7mg
250mg

Iron: 8.6mg as ferrous fumarate, ferric pyrophosphate or NA EDTA	10mg
Zinc: 5.7mg as zinc sulphate	8mg
Iodine: 147.7mcg as potassium iodate	120mcg
Phosphorus 46.9mg as calcium phosphate	167mg

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.

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

International Standards:

High Energy Biscuits shall comply, except when specified otherwise in this long term agreement (LTA), with the following guidelines or standards of Codex Alimentarius:

- Guidelines on Formulated Supplementary Foods for Older Infants and Young Children, CAC/GL 08-1991 of the Codex Alimentarius. http://www.fao.org/input/download/standards/298/CXG_008e.pdf
- Code of Hygienic Practice for Low Moisture Foods CAC/RCP 66 - 2008 of the Codex Alimentarius; http://www.fao.org/input/download/standards/13921/CXP_075e_2015.pdf
- Recommended International Code of Practice: General Principles of Food Hygiene CAC/RCP 1-1969 Rev 4 - 2003 including Annex Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its application.
<https://www.mhlw.go.jp/english/topics/importedfoods/guideline/dl/04.pdf>
- General principles for addition of essential nutrients to foods: CAC/GL 09-1987 (amended 1989, 1991), of the Codex Alimentarius.
http://www.fao.org/input/download/standards/299/CXG_009e_2015.pdf

5.Processing:

Requirements to Raw materials:

HEB shall be manufactured from fresh and high-quality raw materials, HEB shall be free from foreign materials and substances which represent a hazard to health. HEB 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 HEB to ensure the quality protein
- Added Sugar: Max.15 g/100g of biscuit

Standards for raw materials:

- Wheat flour: Codex STAN 152-1985.
http://www.fao.org/input/download/standards/50/CXS_152e.pdf
- Soy flour/soy protein: Codex STAN 171-1989 (for soy) or Codex STAN 175-1989 (for soy protein).
http://www.fao.org/input/download/standards/56/CXS_171e.pdf and
http://www.fao.org/input/download/standards/325/CXS_175e.pdf
- Sugar: to Codex STAN 212-1999.
http://www.fao.org/input/download/standards/338/CXS_212e_u.pdf
- Skimmed milk powder: Codex STAN 207-1999
http://www.fao.org/input/download/standards/333/CXS_207e.pdf

-Shortening must be prepared from oil that conform to Codex STAN 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.

https://mvo.nl/media/voedselveiligheid/codex_standard_named_vegetable_oils.pdf

-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.

Notes:

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

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

Requirements to additives:

- Lecithin shall be in proportion as specified in the Codex STAN 074-1981.

http://www.fao.org/input/download/standards/290/cxs_074e.pdf

- Raising (SODA) agent as specified in the Codex STAN 074-1981, the maximal value is determined by the GMP principles.

- Artificial flavoring agents are not allowed except ethyl vanillin and vanillin: 7mg/100g.

- Other additives must comply with Codex STAN 192-1995 and Codex STAN 074-1981.

http://www.fao.org/gsfonline/docs/CXS_192e.pdf AND

http://www.fao.org/input/download/standards/290/cxs_074e.pdf

Vitamins and mineral premix:

HEB shall include a premix consisting of the vitamins and minerals described on the product specification. The mineral and vitamin premix(es) cannot be produced by the HEB 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 of these suppliers are approved by UNICEF. HEB 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 together.

Additionally, the premix shall:

-Be delivered to the processor of HEB with a complete Certificate of Analysis.

-Be stored as recommended by premix manufacturers.

See Annex 1 for a reference table of premix fortification.

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 <http://foodqualityandsafety.wfp.org>

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
- Hazard Analysis Critical Control Point program

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:

Microorganisms acceptable limits:

Standard plate count: Max 10,000cfu per g
Mesophyllic aerobic bacteria: Max 10,000cfu per g
Coliforms: Max 10cfu per g
Escherichia coli: Absent in 10g
Salmonella: Absent in 25g
Staphylococcus aureus: <10cfu per g
Bacillus cereus: Max 10cfu per g
Enterobacter sakazakii: Absent in 10g
Yeasts and moulds: Max 100cfu per g

Additional Requirements

Organoleptic: HEB shall have a pleasant smell and palatable taste.
Broken biscuits: not be more than 5.0% (by weight).
Weight: one biscuit should weigh between 5g and 10g.
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.

7. Control of contaminants:

HEB 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 contaminant testing at least once per year.

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 CODEX STAN 193-1995

Heavy Metals:

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

Arsenic (As): <0.10ppm

Cadmium (Cd): <0.10ppm

Lead (Pb): <0.02ppm

Mercury (Hg): <0.20ppm

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

Other contaminants:

Free from radioactivity

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

Suppliers shall have to check the quality of their product and guarantee that HEB 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.

7. Packaging:**7.1 Primary packaging:**

HEB 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 HEBs from moisture as well as from vitamin and fat degradation throughout their shelf life.

Sachets shall be:

- 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 OPP 20micron/PR 3C/DRY/VMCPP 25micron packages.
 - 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. The minimum requirements are:
 - WVTR <0.05 g/m².day (38°C/90% RH) (ASTM F1249-06 or equivalent)
 - OTR < 0.05 cc/m².day (23°C/50% RH) (ASTM D-3985 or equivalent)
 - Reverse printing is mandatory
- Typically, a laminate composed of (PET or OPP) + (alu 7) + (PP) (total typical thickness 62mic +/-3) or equivalent can be used.

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 cardboard should weight approximately 10kg. Cardboard strength requirements : preferably tested by compression test. Individual packages shall be packed in a 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 CODEX STAN 1- 1985. http://www.fao.org/input/download/standards/32/CXS_001e.pdf

Primary labelling:

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

List of ingredients in descending order and declaration of allergens

Product name "High Energy Biscuits"

Nutritional value per 100 g.

Manufacturing date (month/year)

Best before date (month/year)

Nutritional information per 100g

This product contains no lard

Not for sale

Additional marking as per LTA agreement

Net weight

Best before end: month + year
Production lot/batch
Country of origin
Name and address of the supplier

Secondary labeling:

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

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

Month and year of production

Full name or code of the production enterprise

Ingredients, nutritional information

Best before end: month + year

Production lot/batch

Country of origin

Name and address of the supplier Additional marking is as per LTA agreement.

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 source 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 HEBs 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 Revision 7, July 2019*. 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 % (AOAC 925.10, 2002)

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: 10-15g/100g (AOAC 981.10)

Fat Min. 15.0 g/100g (AOAC 963.15, 2000)

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)

Safety

Vitamin A-Retinol 500 – 850 mcg/100g (AOAC 960.45)

Iron Min. 10 mg/100g (AOAC 945.40)

Aerobic mesophilic bacteria Max. 10,000 cfu/g ICC No 125 (AACC 42-11)

Coliforms Max. 10 cfu/g (AOAC 2005.03)

Escherichia coli Absent in 10 g (AOAC 991.14)

Salmonella absent in 25 g (AACC 42-25B)

Staphylococcus aureus <10 cfu/g (AACC 42-30B)

Bacillus cereus Max. 10 cfu/g (AOAC 980.31)

Yeasts and moulds Max. 100 cfu/g (ICC No 146)

Aflatoxin M1 < 0.5 ppb (AACC 45-16; ISO 14501/IDF 171:2007 or ISO 14674/IDF190:2005)