



Food Safety and Quality Assurance Unit, February 2024

Technical Expectations – Manufacturing of Fortified Biscuits (FBs)

Background

Fortified Biscuits are a strategic product for WFP to use during the initial response to a rapid-onset emergency such as an earthquake or a flood. In addition to their primary use, they are also used to support people in refugee and IDP camps, and in school feeding programs to address chronic hunger and malnutrition. WFP pre-positions contingency stock of Fortified Biscuits for immediate response to a rapid-onset emergency.

Fortified Biscuits are shelf-stable, ready-to-eat foods, allowing for easy maintenance of emergency stockpiles. In a school-feeding context, they are ideal for environments with limited cooking facilities or when transitioning from 'no foods provided' to 'school meals'.

For Fortified Biscuits supplies to be sustainable, production must be operationally feasible from a manufacturing standpoint, while ensuring the safety of food during the entirety of its shelf-life. The manufacturing equipment required to produce Fortified Biscuits are comparable to similar products such as tea biscuits or shortbread cookies, but with a longer shelf life of minimum 18 months. Suppliers are not expected to maintain a dedicated FB production facility. Likewise, suppliers should not depend solely on FB production for WFP to manage costs or maintain operations. FB costs should be affordable and in line with the costs of manufacturing similar products.

Purpose

WFP technical requirements provide a technical guide for better understanding WFP's expectations of quality, safety and process control for manufacturing these foods, and are in addition to WFP specifications for FB. Conditions of the document are used for the audit purposes and technical assessment. Not complying with these requirements may generate critical, major or minor observations and/or suspension of the supplier.

Requirements

1. **Manufacturing Standards and Quality Management Certification**

The appropriate standards to refer to for raw materials, premixes, ingredients, packaging and the finished product are included in the [finished product technical specification](#).

All FB suppliers shall have FSSC 22000 or equivalent (IFS/BRC/SQF) certification in place. Not complying with this request may result in suspension of the supplier from WFP roster.

2. **Manufacturing Site**

The manufacturer shall upon request forward a copy of the Manufacturing License for the products issued by its National Regulatory Authority.

3. **Compliance with WFP Specifications and Contract Conditions**

The Manufacturer must incorporate all requirements of WFP specification and contract conditions in their quality management system. The manufacturer must establish its own finished product specification and clearly state the amount and frequency of testing required for consistent quality of the final product.



4. **Pre-requisite Programmes and HACCP**

The manufacturer shall have verified HACCP Plan that includes pre-requisite programs (PRPs) as per ISO/TS22002-1 and [Codex general principles of food hygiene](#).

Among others, the manufacturer of FB must ensure effective implementation of following PRPs:

- Pest control programme
- Personnel hygiene
- Cleaning and sanitation
- Maintenance program
- Foreign bodies management

HACCP plan should include (among other risks):

- Risk of toxic or noxious seed contamination through wheat flour (Or from wheat flour supplier)
- Risk of over-fortification¹
- Risk of Acrylamide²
- Risk of allergens (cross-contamination from nuts, soy, sesame type formulations etc.)
- Use of potable water, utilities should be part of HACCP plan
- 3-MCPD and GE

5. **Quality Control**

- Incoming wheat flour shall be examined per delivery/batch for at least fat acidity, gluten (dry/wet), moisture, ash and parameters checked during physical inspection.
- Incoming fat/biscuit shortening shall be examined per delivery/batch for at least FFA, POV, melting point, moisture and physical inspection.
- Perform inspection and testing of other incoming raw and packaging materials according to a pre-defined quality plan.
- Analyses to be done at least once per shift for final product which include moisture, water activity, FFA, POV, ash, sensory (taste, odor, color and appearance), net contents, dimensions, codification quality, sealing quality and leak test.
- Periodical analyses of water used in contact with food (dough mixing) and for hygiene, as defined by the risk analysis in the factory. Analyses of water should include microbiological parameters and heavy metals.
- Quality control checks associated with food safety shall be performed as per HACCP plan.
- Supplier shall have in place a statistical process control concept in place documenting product and packaging compliance. More frequent testing may also be needed in the startup phase in order to document that the product, packaging and net weight, packaging integrity comply with the finished product specification.
- All raw materials, premix and packaging materials shall have certificate of analysis (COA). Also, certificate of compliance for food grade packaging material (CoC) shall be made available. All materials shall only be sourced/procured from approved vendors. The CoA can also be generated upon reception after internal testing.
- Periodical analyses for contaminants (melamine, Aflatoxin M1), pesticides and heavy metals for critical ingredients and finished product.
- In order to verify that FBs comply with the product specification, unless otherwise specified in the product technical specification, a complete testing analysis (including all macro- and micronutrients, microbiological and other contaminants) of the finished product should be conducted at least once per year.

¹ Over-fortification may cause health issues at the consumer, please see WHO document here https://www.who.int/ipcs/highlights/full_report.pdf?ua=1

² https://www.fooddrinkeurope.eu/uploads/publications_documents/FoodDrinkEurope_Acrylamide_Toolbox_2019.pdf



- Document all reports on quality control data into log sheets and/or in available digital system and shall be traceable in case of any food incident situation.

6. Equipment and Production Requirements

- Sieving and/or Sifting system for wheat flour, sugar and other powdered materials where necessary to screen materials for foreign materials.
- Sugar grinder and flour sifter (pre/post stage) must be equipped with set of strong magnets.
- Sieving/filtration system for fat/biscuit shortening, liquid glucose/invert syrup and other liquid/solid ingredients where necessary.
- Treatment and/or filtration system for potable water used during wet dough mixing process.
- Metal/X-ray detector with sensibility to detect Fe, Non-Fe, SS and/or glass as final defense line against foreign object. The detector should be installed after primary packaging is completed.
- Bulk storage tanks for flour, sugar, fat and potable water must have lid closure system. All accessories (pipes, filters and tools) shall be kept under hygienic conditions.
- Equipment with temporary repairs, rusted surfaces, leaky parts and dead ends not acceptable.
- Proper fixture for lightings and false sealing structure to avoid risk of falling on product/process.
- Rotary moulder and production aid tools shall be kept on elevated stands with protective cover.
- Monitoring and measuring devices for weight & temperature reading shall be functional.
- Separate lock and control room for chemicals used in cleaning, sanitation, hygiene, utilities, printing and pest control. Dedicated location for food grade materials and clearly labelled.
- Laboratory equipment for determination of moisture content (oven method/infrared moisture analyzer), ash (furnace method), FFA, POV, protein and fat (titration equipment), water activity (water activity analyzer), seal check (leak tester) and other small equipment as per quality plan.
- Production and laboratory scales shall be checked for accuracy daily before production and shall be calibrated by an external calibration company regularly with certification.
- Temperature controlled room for premix (storage conditions as per premix supplier instructions, usually below 25°C).
- Ink jet printer for printing traceability information on the individual sachets (food grade ink required) and transport boxes (secondary packaging)

7. Quality Management and Practices

- Validation of sieving and/or sifting systems used for dry and liquid materials.
- Validation of heat killing step i.e. baking zone – validation of core temperature to kill pathogens.
- Validation of homogeneous mixing of micronutrient, measuring coefficient of variation
- Quarantine materials and products not meeting quality requirement and clearly marked.
- Periodic assessment of upstream suppliers and reporting incidents for corrective actions.
- Releasing batch only after clearance by the internal laboratory and quality assurance practices.
- Rework is not permitted except if supplier has quality and food safety controls in place for the storage, handling, traceability, reprocessing (mixing and heat treatment) to ensure that reprocessing of the rework will not affect quality, safety, composition, shelf life and sensory acceptability of the finished product. The use of biscuit rework is maximum 2% of the same batch. Perform validation test for the use of rework and to define their internal controls accordingly. The supplier shall also include use of rework in their HACCP risk assessment.
- Document change management and revise HACCP Plan accordingly, change shall be carried out in a manner that does not compromise on finished product specification.
- Keeping retention samples of finished product till end of labelled shelf life.
- Fortification process shall have following in place
 - Premix is bought from GAIN approved premix supplier
 - Fortification SOP, addition of premix is as per WFP specification
 - Daily mass balance of produced FBs and premix used



- CV is performed at least once to validate the process, as per WFP requirements³
- Temperature controlled storage for sensitive raw materials (premix, milk powder, flavors etc.)

8. Packaging

9. Packaging specification with demonstrated performance against WFP specification. Controls at reception shall be performed and food contact material certificate for primary packaging shall be made available.

a) *Controls at reception*

- o Check compliance against WFP specification of food grade certificate and certificate of analysis from packaging suppliers (including WVTR and OTR for laminate and ECT for cartons)
- o Measure thickness of the metallized flexible material and grammage of cartons
- o Visual inspection of the design/markings (carton, metallized flexible material ...)
- o Primary packaging received with foreign object or torn/exposed condition shall be rejected.

b) *In-line controls*⁴

- o Weight of the box (filled)
- o Check readability of online printing of dates and batch number
- o Visual inspection of the seal needs to be performed at least every 30 minutes (30 packages per packing line), Statistics on seal defects should be kept, with categorization of the defects (e.g. minor, major, critical).⁵
- o Leak test shall be performed during the packing process, at least every hour (depending on the speed of the line) on 3 sachets per line.⁶ If at least one sachet does not pass the test, additional tests must be performed on sachets (recommended 10) produced since the previous test. If issue is confirmed, production must be stopped and immediate corrective actions on the line must be taken until the leak test is passed.
- o Sealing quality shall be checked during the packing process. The minimum seal strength of longitudinal and transversal seal of sachets produced online shall be 10N/15mm (test speed 100mm/min)⁷
- o Highly recommended: Penetrant red test to be performed for microleak detections twice per shift (at shift handover and in the middle) on 3 sachets (depending on the speed of the machine). If issue is confirmed, production must be stopped and immediate corrective actions on the line must be taken until the leak test is passed.

c) *Release controls*

- o A document with pictures of examples of "good" and "bad" sachets (sealing quality, alignment, ink-jet information...) must be displayed next to each packaging machine

³ <https://foodqualityandsafety.wfp.org/it/food-fortification-and-coefficient-of-variation-cv-calculation>

⁴ WFP developed an Excel file that can be used to facilitate recording of quality checks: <https://docs.wfp.org/api/documents/WFP-0000156826/download/>

⁵ WFP developed a guidance on classification of defect, available here: <https://docs.wfp.org/api/documents/WFP-0000150009/download/>

⁶ For vacuum leak testing or bubble leak testing the minimum pressure is -25kPa. The pressure must be hold for 1 min.

⁷ WFP developed a guidance to support Improvement of sealing quality of flexible packaging, available here: <https://docs.wfp.org/api/documents/WFP-0000156321/download/>



- Traceability markings, such as date and batch number on the pack & on the box must be checked
- Online printing (e.g. laser, ink-jet) adhesion shall be tested during the packing process and segregation and/or rejection of sachets with double code/faded/erasable printing shall be done.
- Drop test on boxes (see annex)

Use of new primary or secondary packaging materials:

- WFP must be informed
- Validation trial must be performed on the line and quality parameters assessed and validated

Shelf life of packaging material:

Every packaging item (flexible laminate, carton box, bottle, cap, bag....) must have a shelf life that is recommended by the packaging supplier. Similarly, clear definition of storage conditions to preserve packaging integrity and properties before productions should be provided by packaging supplier and applied by food manufacturer in its premises. Shelf life of packaging and storage conditions must be reflected in raw material packaging specifications available at food manufacturer premises.

Traceability information printed on sachet:

WFP recommends the use of laser coding on sachets to print production date/best before end/lot number because it is more durable than other printing technologies (e.g. ink-jet)

Inspection of primary packaging manufacturers:

Food manufacturer shall perform a technical visit to each primary packaging supplier to approve new suppliers and revisit at least once every 2 years.

Food manufacturer shall ask their primary packaging suppliers to perform a self-assessment against the guideline provided by WFP.

10. *Batch definition + Coding/Labelling + Traceability*

- Marking of the product (primary and secondary packaging) shall facilitate tracing at least up to date of production and preferably more (e.g. time, packing machine)
- Each lot should be completely traceable to each raw material used
- Each lot should be released only after clearance by the internal laboratory and quality assurance practices.
- The Packing List prepared for WFP, as well as stuffing of containers/loading trucks must facilitate traceability up to the day of production and packing line

11. *Quality Assurance to be shared with WFP for each delivery*

- Proof of purchase and CoA for the premix.
- CoA for the final product.
- Any other documents/analysis mentioned in this document or documents to which this document refers to, upon WFP request

12. *QA documents to be shared after the first delivery to WFP*

- Status on the corrective and preventive action (CAPA) implementation of deviation/assessment.
- CV for the premix (if not provided during the audit).
- Confirmation of starting shelf-life study for WFP product, if not already done.
- Critical Control Point (CCP) monitoring records

Timeline – Above documents to be submitted within 21 calendar days of completion of production



12.1 Process Control documentation

- CV
- %age broken biscuits
- %age packaging defects (by defect)
- Sealing temperature
- Baking temperature
- Baking time
- Key QC trend analysis (protein, Vitamin tracer, moisture)

13. ***Shelf-Life and Storage***

Fat oxidation is the limiting factor impacting FB shelf-life. Lipid oxidation is considered the main cause of the deterioration of food products with a high fat content such FBs. Lipid oxidation is associated with the formation of off-odor and off-flavor that compromise the acceptability of the products, as well as impact the nutritional quality of the foods. Please refer to the shelf-life study protocol.

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Annex – Drop test protocol:

Drop test shall be performed as per principles of ISO 2248/ASTM D5276 (or equivalent), with following sequence on the same carton:

- **Edge dropping:** carton is dropped from a height of 460mm on 1 edge (the angle between a prescribed surface of the package and the horizontal surface $\pm 5^\circ$)
- **Corner dropping:** carton is dropped from a height of 460mm on 1 corner (the angle between a prescribed surface of the package and the horizontal surface $\pm 5^\circ$)
- **Face dropping:** carton is dropped from a height of 460mm on 1 face (2° maximum angle between the impacting face and the horizontal surface)

The velocity at impact shall be within $\pm 1\%$ of that which would be achieved by a free fall.

There should be no rupture of cartons (dent cartons are acceptable), no rupture of tape and no loss of content

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