World Food Programme
Programme Alimentaire Mondial
Programa Mundial de Alimentos
برنامج الأغذية العالمي

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Food Safety and Quality Assurance Unit

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Technical Expectations – Manufacturing of Fortified Maize meal

Purpose

The purpose of this document is to establish the requirements WFP expects from manufacturers of fortified maize meal to meet.
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.

   As of 01.06.2021 all international maize meal suppliers shall have FSSC22000 certificate or equivalent (IFS/BRC). Not complying with this request may result in the suspension of the supplier from WFP's 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***
   Supplier has to incorporate all requirements of WFP specifications and contract conditions in its QM system.

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 must ensure effective implementation of following PRPs
   - Pest Management
   - Foreign Bodies management

   HACCP plan should include (among other risks):
   - Risk of toxic seeds contamination
   - Risk of over-fortification[1]
   - Radionuclide content for the maize coming from Ukraine and Russia (as per IFIA guidance[2])
   - Mycotoxins (aflatoxins, fumonisins, DON, ochratoxin, zeralenon, trichothecenes, etc.), contaminants, ergot, foreign bodies, allergen and pathogens

[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] http://www.ifia-federation.org/content/wp-content/uploads/Fit-for-Human-Consumption-Bulletin.pdf

- Microbial growth during the tempering stage

5. ***Quality Control:***
   - Periodical analyses of water used in contact with food (maize tempering) and for hygiene. Analyses of water shall include microbiological parameters and heavy metals.
   - Periodical analyses for pesticides and heavy metals shall be performed on maize and final product based on risk analysis
   - Mycotoxins (aflatoxins, fumonisins, DON, ochratoxin, zeralenon) shall be tested on deliveries of maize.
     - Minimum testing frequency (supplier of maize or miller) shall be in case of:
       - Maize coming in vessel - one test per vessel of maize (aggregate sample)
       - Maize coming through land transport - at least one test each 10.000 MT (aggregate sample)
   - Analyses to be done at least once per shift:
     - Final product: moisture, fat, sensory test, Iron
     - Maize: toxic seeds, grain grading (especially moldy grains percentage)
   - Other analyses to be included in the QC plan for final product: granulation, peroxide value, TPC, yeast and moulds)
   - Radionuclide content in maize if maize originated from Ukraine and Russia (for the maize)

   Analyses shall be performed as per QC Plan.

6. ***Equipment and production requirements***

   Manufacturer shall have:
   - Cleaning system that can remove toxic seeds (especially Datura spp. seeds)
   - Premix feeder with minimum level sensor and automatic stop/start/alarm to avoid over-fortification and under-fortification.
   - The mixing conveyer (mixing of added premix) that is at least 4 meters long.
   - Entoleter (egg crusher) installed at the end of the line
   - Magnet or metal detector should be at the end of the line
   - Mesh/sieve/filter before bagging
   - Laboratory equipment for determination of Fe content in maize meal (e.g. ICheck or other validated device and method), moisture content (oven method), mycotoxin analysis equipment (e.g. ELISA, lateral flow assays, etc.)
   - Temperature controlled room for storage of vitamin and mineral premix (storage conditions as per premix supplier instructions, usually below 25°C).
   - Ink jet printer with the food grade ink, for printing traceability information on the bags.

7. ***Quality Management and practices***
   - Validation of the maize cleaning system for toxic seeds and mouldy grain shall be performed
   - Each batch shall be released only after clearance by the internal laboratory and quality assurance practices.
   - Rework: Allowed for semi-finished product based on risk analysis. Clear SOP & documentation required.
   - Recycle/Reprocess: No recycling or reprocessing of finished product/end product
   - Tempering time should be recorded
   - SOP for cleaning of the tempering silo should be present and cleaning should be recorded.
   - Fortification process shall have following in place
     - Premix is bought form GAIN approved premix supplier
     - Fortification SOP, addition of premix is as per WFP specification
     - Daily mass balance of produced maize meal and premix used
     - Fe analysis is done once per shift

- Visual monitoring of the dosing system is done at least once per shift
- CV is performed at least once to validate the process, as per WFP requirements[3], and shall be re-tested in case of change of equipment, premix concentration, process practices
- Temperature controlled storage for sensitive Raw Materials (premix)

8. *Packaging*

- Packaging material shall have food contact material certificate (including inks and additives)
- Grammage (grams/m^2) of PP woven bags shall be checked at reception of every packaging batch as well as the compliance with WFP requirements available on the packaging specification
- Stitching quality shall be checked during packing process
- Drop test shall be performed during the packing process
- 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.

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

- Batch size limitation

Production Capacity	Batch Size
<100 MT/day	1 week of production, or 500 MT, whichever is lower
100-500 MT/day	1 day of production
> 500 MT/day	1 shift (8 hours) of production

- Marking on the product shall facilitate traceability up to the level specified above (week, day or a shift).
- Technical solution as using ink jet printer with food grade ink are acceptable for daily/per shift/weekly change of the traceability information.

10. *Documents to be shared with WFP for each delivery (and first)*

- Proof of purchase and CoA for the premix
- CoA for the final product (including at least moisture, aflatoxin and Fe)
- Any other documents/analysis mentioned in this document or documents to which this document refers to, upon WFP request

11. *Documents to be shared after the first delivery to WFP*

- Status on the CAPA implementation
- 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 Points (CCP) Monitoring records

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

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