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

Food Safety and Quality Assurance Unit

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# Technical Expectations – Manufacturing of Fortified Roasted Grain flours

#### Purpose

The purpose of this document is to establish the requirements WFP expects from manufacturers of Fortified Roasted Grain Flours to meet.

Fortified roasted grain flours are flours made of one type of grain (e.g. either maize or wheat) mixed with vitamins and minerals. Addition of other components is not allowed (e.g. sugar, milk, oil, flours from other grains). Roasted flours must have must be cooked in a short time prior to usage and product's consumer group is general population.

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 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<sup>1</sup>

<sup>&</sup>lt;sup>1</sup> 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



- Radionuclide content for the gain coming from Ukraine and Russia (as per IFIA guidance<sup>2</sup>)
- Mycotoxins (aflatoxins, fumonisins, DON, ochratoxin, zeralenon, trichothecenes, etc.), contaminants, ergot, foreign bodies, allergen and pathogens
- Generation of acrylamides due to thermal treatment
- Salmonella risk

### 5. Quality Control:

- Periodical analyses for pesticides and heavy metals should be performed on grain and final product
- Mycotoxins (aflatoxins, fumonisins, DON, ochratoxin, zeralenon) should be tested on deliveries of grain.
- Analyses to be done at least once per shift:
  - Final product: moisture, fat, sensory test, Iron
  - Grain: 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, fat acidity
- Radionuclide content in grain if grain originated from Ukraine and Russia (for the grain) 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)
- In case of continuous mixing 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 roasted flour (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.
- Zoning principles must be applied, with zone prior to roasting to be low risk area and after the roasting high risk.

#### 7. Quality Management and practices

- Validation of the grain cleaning system for toxic seeds and mouldy grain shall be performed
- Validation of grain roasting process should be done for the inactivation of intrinsic enzymes that can affect the shelf life of the roasted flour and for Salmonella control. Validation should be done for each specific grain.
- 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
- Time, temperature and quantity/flow of the roasting conditions should be monitored
- Fortification process shall have following in place

<sup>&</sup>lt;sup>2</sup> http://www.ifia-federation.org/content/wp-content/uploads/Fit-for-Human-Consumption-Bulletin.pdf



- Premix is bought form GAIN approved premix supplier
- Fortification SOP, addition of premix is as per WFP specification
- Daily mass balance of produced grain 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<sup>3</sup>, 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/m²) 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
<20 MT/day	1 week of production, or 500 MT, whichever is lower
>20 MT/day	1 day of production

- Marking on the product shall facilitate traceability up to day of production at minimum (preferably shift, hour/minute and packing line).
- 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

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



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