



Food Safety and Quality Assurance Unit

August 2024

Technical Expectations – Manufacturing of Fortified Wheat Flour

Purpose

The purpose of this document is to establish the requirements WFP expects from manufacturers of fortified wheat flour 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. *Certification*

As of 01.06.2021 all international wheat flour 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. *Compliance with WFP specifications and contract conditions*

Supplier has to incorporate all requirements of WFP specifications and contract conditions in its QM system.

3. *Quality Management and Certification:*

Company shall have verified HACCP Plan that includes following PrP's as per ISO/TS22002-1 (among others):

- Pest Management
- Foreign Bodies management
- HACCP plan should include (among other risks):
 - Risk of toxic seeds contamination
 - Risk of over-fortification¹
 - Radionuclide content for the wheat coming from Ukraine and Russia (as per IFIA guidance²)
 - Mycotoxins, contaminants, ergot, foreign bodies, allergen and pathogens
- Quality Control plan shall include at minimum
 - Periodical analyses of water used in contact with food (wheat 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 wheat or miller) shall be in case of:
 - Wheat coming in vessel - one test per vessel of wheat (aggregate sample)
 - Wheat 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, ash, wet gluten, sensory test, Iron
 - Wheat: toxic seeds
 - Other analyses to be included in the QC plan: protein content, gluten index, Hagberg Falling number, fat acidity, Zeleny index, moisture content, gluten index
 - Radionuclide content if wheat in case of wheat originated from Ukraine and Russia (for the wheat)

Analyses shall be performed as per QC Plan.

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.ifa-federation.org/content/wp-content/uploads/Fit-for-Human-Consumption-Bulletin.pdf>



4. *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, smaller than 2 mm sieve size, preferably 1mm or less.
- Laboratory equipment for determination of Fe content in flour (e.g. ICheck or other validated device and method), moisture content (oven method), ash (furnace method)
- 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.

5. *Quality Management and practices*

- Validation of the wheat cleaning system for toxic seeds 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
- 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 flour 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 requirements³, and shall be re-tested in case of change of equipment, premix concentration, process practices
 - Temperature controlled storage for sensitive Raw Materials (premix)

6. *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.

7. *Batch definition + Coding/Labeling + 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).

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



- Technical solution as using ink jet printer with food grade ink are acceptable for daily/per shift/weekly change of the traceability information.
8. 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, ash, wet gluten and Fe)
 - Any other documents/analysis mentioned in this document or documents to which this document refers to, upon WFP request
 9. 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
 - CCP Monitoring records

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