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

SAVING LIVES
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Food Safety and Quality Assurance Unit

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Technical Expectations – Manufacturing of Fortified Vegetable oils

Purpose

The purpose of this document is to establish the requirements WFP expects from manufacturers of fortified vegetable oils 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 vegetable oil 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.
   Unless otherwise specified TBHQ should be added to oil as an antioxidants, within limits of Standard For Named Vegetable Oils CXS 210-1999.

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
   - Management of purchased materials
   - Product recall procedures
   - Pest Management
   - Foreign Bodies management

   HACCP plan should include (among other risks):
   - Risk of over-fortification[1]
   - Risk of over-dosage of antioxidants

[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

- Radionuclide content for the raw material (crude oil/oil seeds) coming from Ukraine and Russia (as per IFIA guidance[2])
- Contamination of crude oil in case production is not made directly from seeds[3]
- Chemical contamination: mineral oil, pesticide residues, dioxine and PCB's, PAH's, hexane (in crude seed oil), aflatoxin (groundnut oil), zearalenone (maize germ oil), 3-MCPD + glycidyl esters, gossypol (cottonseed oil),
- Risk of migration from packaging

5. ***Quality Control:***

- Periodical analyses of water used in contact with food and for hygiene. Analyses of water should include microbiological parameters and heavy metals.
- Periodical analyses for contaminants and chemicals listed under point 4.
- Analyses to be done at least once per day:
  - Final product: sensory, moisture, FFA, peroxide, vitamin A
- Other analyses to be included in the QC plan: insoluble impurities, soap content, melting point, saponification, iodine value, unsaponifiable matter, refractive index, relative density, vitamin D, metal contamination (pro-oxidants), antioxidants.
- Radionuclide content in seeds/crude in case of raw material originated from Ukraine or Russia

Analyses shall be performed as per QC Plan.

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

Manufacturer shall have:

- Premix doser with minimum level sensor and automatic stop/start/alarm to avoid over-fortification and under-fortification. Other designs are acceptable if they have prevention for over-fortification and under-fortification.
- Magnet or metal detector should be at the end of the line
- Filter should be at the end of the line, measurement of pressure should be done
- Laboratory equipment for determination of vitamin A content in oil (e.g. ICheck or other validated device and method), moisture content, FFA and peroxide
- Temperature controlled room for storage of vitamin and mineral premix (storage conditions as per premix supplier instructions, usually below 25°C).
- Ink jet printer for printing traceability information on the bottles (food grade inks) and cartons.

7. ***Quality Management and practices***

- Each batch shall be released only after clearance by the internal laboratory and quality assurance practices.
- Quarantine materials and products not meeting quality requirement and clearly marked.
- Periodic assessment of upstream suppliers and reporting incidents for corrective actions.
- 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 form GAIN approved premix supplier
  - Fortification SOP, addition of premix is as per WFP specification

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

[3] E.g. In case of crude oil transport via ships- previous cargoes are checked by comparing a ship's logbook with the EU or FOSFA List of Acceptable Previous Cargo, taking into account the construction material of the ship's tanks. This activity is normally performed by an independent superintendent.

- Daily mass balance of produced oil and premix used
- Vitamin A analysis is done once per day
- 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[4], 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 specifications 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:

- Check compliance against WFP specification of food grade certificate (primary packaging, including: cap, bottle, inner seal…) and certificate of analysis from packaging suppliers (e.g. wall thickness for bottles, mechanical performance, ECT for cartons). As per required in the packaging specification under paragraph 7, some documentations are required from suppliers for every delivery .
- Measure grammage of cartons
- Visual inspection of the design/marking (carton, label …)
- Primary packaging received with foreign object or torn/exposed condition shall be rejected.

b) *In-line controls*

- There should be sensors on the filling line to detect presence and good sealing of the inner seal (when relevant) and proper closure of caps
- Leak test: once per shift, 3 bottles must be placed upside down for min 1h and gently squeezed to identify any potential leakage
- Weight of the box (filled)
- Check readability of online printing of dates and batch number (ink jet)

c) Release controls

- Visual inspection of the goods

Shelf life of packaging material:

Every packaging item (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 production 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.

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

- Batch size limitation

Production Capacity	Batch Size
0-500 MT/day	1 day of production max
> 500 MT/day	1 shift (8 hours) of production max

- 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)

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

- 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

2. ***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 content, FF, peroxide and vitamin A)
    - Any other documents/analysis mentioned in this document or documents to which this document refers to, upon WFP request

3. ***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

4. ***Shelf-Life and Storage***

    A shelf stability study should be performed as per : Stability studies need to be conducted on the final product to confirm the product shelf life (wfp.org)