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SAVING LIVES
CHANGING LIVES

Food Safety and Quality Assurance Unit

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Technical Expectations – Manufacturing of Super Cereal & Super Cereal Plus

Purpose

The purpose of this document is to guide existing and new suppliers of Super Cereal and Super Cereal Plus in the equipment, regulatory and quality management requirements to ensure Total Quality Management in production of these two products. Non-complying may generate minor, major or critical observations during the audit/assessment.

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.
   Clear a FSSC 22000 audit (latest version), with additional minimum requirements from WFP as required. Audit will be conducted by WFP selected external certified company, irrespective of supplier's existing certification. If the supplier does not have a pre-existing certification, they will be able to receive the certification at the end of this exercise.

   Company should have updated repository of relevant food safety regulations and standards such as Codex, national regulation, EU regulation, recipient countries regulation

   Codex for hygiene standards in low-moisture foods (CXC 75) will be applicable. Link here. Most importantly:
   - Zoning;
   - product air contact; and
   - environmental monitoring programme

2. ***Manufacturing Site***
   - Registration
     - Super Cereal Plus – Registered as baby food manufacturer
     - Super Cereal – Manufacturer of foods for special dietary needs

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 SC/SC+ consistent quality.

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 SC/SC+ must ensure effective implementation of following PRP
   - Pest control program
   - 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, corn, rice, soya and any other raw materials
- Risk of over-fortification[1]
- Risk of allergens (cross-contamination from nuts, soy, sesame type formulations etc.)

5. Toxic seeds risk and management should be in vendor specifications. Should also be included in the Super Cereal manufacturer's HACCP Plan (Risk Analysis)
   - The risk assessment for each vendor should be detailed, such as risk related with origin of grain, grain cleaning equipment, performance.

6. *Quality Control*

- Minimum in-process tests expected from the supplier include:
  - Granulation
  - Pre-extrusion mixing rate of the grains or grain flours
  - Protein
  - Moisture
  - One traceable Vitamin or Mineral spot check (e.g. iCheck for Iron)
  - Temperature control of the product at the time of packing

  An in-process, properly calibrated, Near Infra-Red equipment is recommended, but not mandatory
- The supplier needs to have an Internal laboratory for critical tests during final release
  - One hygiene tracer at minimum – example, Enterobacteriaceae
  - Product viscosity (Bostwick or equivalent)
  - Proximate – Protein, Fat
  - Moisture
  - Mycotoxin ELISA test kits or equivalent
  - Packaging Material tests (leak tester)
  - O2 measurement (Super cereal plus)
- Salmonella – at an outsourced ISO-17025 certified lab, with a proficiency tested method. This is for approval of each batch of finished product
- RING Tests with accredited international lab or participation in a proficiency testing programme at least once a year for all analysis performed within the internal lab.
- Water needs to be tested systematically as defined in the risk analysis
- Environmental Monitoring Programme
  - Ref: Codex 75 – Zoning, Environment, Equipment cleaning, air quality, people, water, shoes, cleaning equipment
  - Do not test salmonella or pathogens for product contact surfaces
  - Salmonella. Can be tested internally but at a stand alone facility that does not come in contact with food. It need to be validated with external etc. Never to release food.
  - EB
  - Any exceptional release outside defined accepted specifications at any point within the production process (including final batch release), should have a proper authorization.

7. *Equipment and Production Requirements*

[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

- Any air coming into contact with product after extrusion needs to be filtered, preferably using HEPA Filtration. Filtration effectiveness should be validated for microbiological clearance.
  - High risk areas need to have positive air flow and dust filtration is mandatory. Examples could include dumping stations for milk powder, sugar etc. Identification of risk for each areas within the processing facility
  - Any Pneumatics in the plant should be completely sealed, and the air suction point should have filtered air coming in.

- Manufacturing from raw agricultural products to Final product has to be in-site. No sub-contracting for processing of cereals and beans, or any part of the process is allowed.
  Only exception is de-hulling of soyabeans used for Super Cereal Plus, where the suppliers cleaning has to be validated, and should include all "grain cleaning requirements" mentioned under point 7.

- Minimum critical equipment requirements. Validation of the equipment with evidenced proof, at least once every year or 40,000 MT, whichever comes first.
  - Grain Cleaning equipment
    - Destoning
    - Aspirator
    - Sieving
    - Sortex machine
  - Pre-extrusion Grinding
  - Extruder
    - Should be a CCP with validated for microbial load reduction
    - preferably twin screw extruder for both products
    - Minimum Requirements:
      - Super Cereal - Single screw extruder;
      - Super Cereal Plus - Wet extrusion, with preconditioner
    - An alternate to extrusion will be drum drying, validated as a CCP for both products.

- Final Vitamin and Mineral Mixing (Coefficient of Variation, link here)
- Drying with hot air – continuous, not batch, to avoid microbiology uptake
- Sifting post final grinding
- Packing machines
  - 1.5 kg to 3kg at minimum
  - Brick pack packaging machine must be used [2]
- Vacuum leak tester
- Nitrogen flushing or vacuum in the packaging
- Metal Detection / X-Ray at the finished product after final primary packing
  - Should be a validated CCP
- Temperature controlled storage for sensitive Raw Materials (premix, milk powder etc.)
- Online printer (e.g. laser, ink jet printer) for printing traceability information on the individual sachets (food grade ink required) and transport boxes
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8. *Quality Management and Practices*

- Water used in the facility

[2] Example of brick pack packaging machine: https://reformpack.net/carousel-brick-pack-machine/ *(WFP do not promote the use of this particular brand)*

- Water used in the facility should be minimal and only where necessary. This should be controlled as per Codex for hygiene in low moisture foods (CXC-75)
- Water filtration system is necessary for all food coming in contact with the product
- Drainage should be as per CXC-75. No water accumulation, such as steam condensation, is allowed in the production areas.
- Statutory requirements should be available on-site and compliance should be demonstrated for water pre-filtration
- Cleaning has to be validated after every cleaning through environment monitoring programme
- Controlled wet cleaning, including disinfection after every wet cleaning; and subsequent drying, before validation
- CIP is not allowed, all equipment should be opened up, cleaned and disinfected

- 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

9. *Packaging*

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.

Validation process of new packaging supplier or new packaging material

WFP must be informed of any major packaging changes (e.g. new packaging supplier, new material composition, new production process at a packaging supplier)

a. Primary packaging

The scope of the validation process for primary packaging include new primary packaging supplier and major modifications in the packaging material (e.g. new composition, new production process).
As a minimum, the food manufacturer must validate the following parameters:

- Physical visit at the primary packaging supplier to validate packaging quality controls
- Packaging testing by an external laboratory to validate :
    - technical parameters listed on the certificate of analysis: WVTR, OTR, bond strength, seal strength, optical density (non-exhaustive list)
    - technical parameters that can impact machineability on the packing line: coefficient of friction, hot tack
- Small scall machine trial (minimum equivalent to 30min a nominal speed): registration of the film, packaging integrity (vacuum leak test and dye penetrant test), visual validation (good registration, no wrinkles)

b. Finished product[3]

Transit test that is representative from humanitarian supply chain must be performed for new WFP supplier and when packaging is significantly modified (e.g. material composition).
Is intended by humanitarian supply chain:

- Land and sea transport
- Storage/transport at high altitude (minimum 2000m)

[3] Applicable for WFP international suppliers. For local suppliers, WFP recommends to perform a road test with a pallet of goods on challenging road.

- Multiple handling
- Static and dynamic stacking
- Minimum 500 cartons

WFP recommends the tests to be performed as per ISTA 3A or ASTM D4169-22 DC 3 + DC 17 + DC 13 or equivalent. Test can be performed without the support of an accredited laboratories if agreed upon with WFP.[4]

Packaging quality controls

a. Super cereals in 25kg packaging:

- Controls at reception
  - Visual inspection of the outer bag and inner liner:
    - No puncture and no damage of inner liner
    - Sealing quality of the inner liner
    - Bottom stitching quality (no puncture of the inner liner)
  - Measure of thickness of the inner liner
  - Grammage of the PP woven bag (outer bag)
  - Check compliance of CoA from packaging supplier against WFP specification
  - Compliance and quality of pre-printed information
- In line controls:
  - Top stitching quality
  - Sealing quality (stitching must be done above the sealing)
  - Visibility of printed traceability information
  - Weight of the bags
- Release controls:
  - Drop test

c. Super Cereal and Super Cereal Plus in smaller packaging (e.g. 1.5kg to 3kg packs):

- Controls at reception:
  - Check food grade certificate and CoA (including WVTR and OTR for laminate and ECT for cartons)
  - Visually inspect the design (carton, metallized flexible material)
  - Measure the thickness of the metallized flexible material and grammage of cartons
  - Reject primary packaging received with foreign object or torn/exposed condition

- In-line controls:
  - Weight the box (filled) - every 2h
  - Check readability of printed traceability information – every 2h
  - Headspace measurement: collect 10 sachets randomly (from different fillers) every hour
  - Measure residual O2 in the sachet (<5%)
  - Sealing quality and integrity (visually) – every 1 h, collect 30 sachets (from different fillers) and record the defects (and take picture of major defects)[5]

[4] If the transit test isn't performed by an accredited laboratory, at least 500 cartons must be tested and to be loaded on a truck for 100km from supplier's factory to point A, then 100km from point A back to supplier's factory, including storage at minimum 2500m high.

[5] According to "packaging defects" available in WFP technical expectation: docs.wfp.org/api/documents/WFP-0000156789/download/

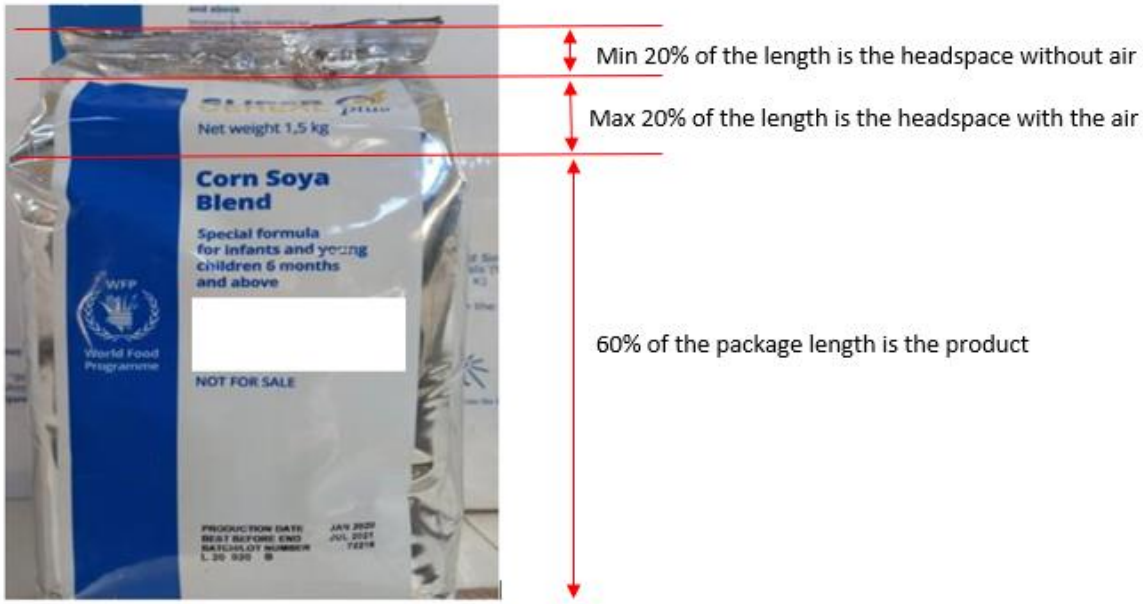
- Leak test shall be performed during the packing process, at least every hour (depending on the speed of the line) on 3 sachets per line.[6] If at least one sachet does not pass the test, additional tests must be performed on sachets (recommended 10) produced since the previous test. If issue is confirmed, production must be stopped and immediate corrective actions on the line must be taken until the leak test is passed.
- Dye penetrant test[7] shall be performed at least once at the beginning of the production and after 4h of production on 5 sachets taken randomly from the production line. If at least one sachet does not pass the test (micro channel in sealing area, pin holes), 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

- Release controls:
  - Check readability of printed traceability information
  - Online printing [8](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.
  - Visual inspection against standard.[2] A document with pictures of examples of "good" and "bad" sachets (sealing quality, alignment, ink-jet information…) must be displayed next to each packing machine
  - Drop test (see annex)
  - Residual air/gas in the headspace[9]
  - Use following templates for reporting and tracking the performance: https://docs.wfp.org/api/documents/WFP-0000156830/download/

The control of the headspace is very important for sachets of SC and SC+. The amount of residual air/nitrogen in the headspace should be reduced to the minimum to avoid bulging or swelling of the bag. Sufficient headspace free of air/nitrogen should be left in the bag to compensate for changes in pressure caused by transport of the product to high altitudes (e.g. 2.000 meters and 0.8 bar of absolute pressure externally) or changes in temperatures or external air pressure (e.g. change form 20°C to 40°C, increases the internal pressure by 0,07 bar). Swollen bags are prone to bursting during the transport and manipulation.
Producer must implement controls to keep the residual gas at minimum and validate the control limits. Producer must also ensure that carton boxes are meeting WFP requirements and are strong enough to withstand a challenging supply chain and protect sachets from bursting.

Example of a sachet with optimized residual air in the headspace:

[6] For vacuum leak testing or bubble leak testing the desired pressure is –25kPa and the value less than desired pressure is –20kPa. The pressure must be hold for 1min.
7 The dye penetrant test should be done to assess the quality of the top, bottom and longitudinal seal areas as well as any micro holes that can be present on the sachet.
[8] 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)
[9] Headspace is the part of the package not filled with the product. The headspace can be partially filled with gas (oxygen/nitrogen) or empty (vacuum). Top part of the package should be squeezed to leave no air inside and this squeezed part should be measured (required value: 5-6 cm) (see picture).



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.

Primary packaging:

a) Inspection of primary packaging manufacturers:

Food manufacturer shall perform a technical visit to each primary packaging supplier to approve new suppliers and minimum every 2 years

Food manufacturer shall ask their primary packaging suppliers to perform a self-assessment and the guideline provided by WFP can be used for this purpose.

b) Primary packaging material:

The production and composition of the metallized flexible material plays an important role in the integrity of the final packaging.

The adhesive used for the lamination must provide enough flexibility to avoid cracks in the material that can occur during handling.

The grammage of the adhesive must be well defined and controlled by the supplier.

The sequence of the lamination process must also be done in a way that the metallized side is never in direct contact with the lamination cylinders.

Pre-conditioning of primary packaging manufacturers:

Primary packaging material must be pre-conditioned, for at least 35h before the production, in conditions (temperature and relative humidity) similar to conditions in production area (considered as ambient temperature and controlled relative humidity).

10. ***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 a day of production

11. ***Quality Assurance to be shared with WFP for each delivery***
    - Proof of purchase and CoA for the premix.
    - Any other documents/analysis mentioned in this document or documents to which this document refers to, upon WFP request
    - Proof of RM Purchase for each raw material, including packaging material and QM
    - QC for RM, in-process & Final product
    - QC or Certificate of Conformity on Packaging Material
    - Trend analyses for the KPIs
    - HACCP documents, such as, CCP monitoring records
    - Final product release certification from the company, per batch, as per company protocol

12. ***QA documents to be shared after the first delivery to WFP***
    - Status on the corrective and preventive action (CAPA) implementation of deviation/assessment, if applicable.
    - 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

13. ***Stability Study***

    Stability study for each type of product being produced for WFP as per WFP shelf-life guidance. Any change in production processes, suppliers, ingredients, packaging, should be addressed in the change management protocol and a clear definition of triggers new shelf-life study should be included.

14. ***Minimum Personnel Structure***
    - Team Composition
        - QA Manager
        - Under QA, Lab/QC Manager. One QC person at least should be trained to be able to identify toxic seeds.
        - Factory Manager
        - Under FM, Production Manager
        - Under PM, Clear Structure for shift leaders for production and packaging.

    - The CVs should meet Job Description requirements

15. ***Traders***

    Preferably, WFP works directly with manufacturers of these foods. However, in certain circumstances, working with traders is allowed. Roles and responsibilities need to be clarified in that case.

- The entire responsibility of production, from sourcing raw materials to release of finished product should be with the manufacturers.

- In case the trader is responsible for purchase of certain raw materials, such as vitamin and mineral premix, they have to be treated as a supplier and supplier management, control of raw materials etc. should apply to them the same way.
  - Approval of the trader's suppliers needs to be verified by the manufacturer. For example, if the trader is responsible for packaging material sourcing, the packaging material suppliers should be approved by the trader only after specific consent and capability assessment by the manufacturer

- In case the trader is responsible for final shipment to WFP, responsibility of traceability, loading etc. need to be clearly specified and shared between the two entities.

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 ± 5°)
- **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 ± 5°)
- **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 ± 1% of that which would be achieved by a free fall.
There shall be no rupture or loss of contents as a result of the test (the required minimum number of units to be checked with drop test is 3 cartons per 500mt). If only the carton is damaged, it shall be replaced.