

Supply Division

Supply Chains for Children



GMP inspection observations, complaints and
sampling and testing results 2022 – 2023
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Code of Hygienic Practice for Low Moisture Foods CAC/RCP 75-2015, rev 2016

ISO 22000 / 2018 or FSSC 22000

- Dedicated facilities for low moisture foods
- HVAC system – positive pressure
- Clear zoning system
- Dry cleaning
- Environmental Monitoring Program
- Change Control system
- Contamination control / heat treatment
- Foreign matter detection at sachet level

Personnel

- Training of internal auditors needs improvements – focus on low moisture foods
- Temporary workers is still widely used – even in critical production areas
- Limit the number of staff in critical areas
- Lack of induction training and health check of new staff in the packaging area.

Quality Management System

- 3rd party certification of quality system is expected in cases where regulatory oversight do not exist. Many now have FSSC 22000 certification
- Handling of non-conforming materials needs improvement – potential impact on other batches
- Investigation reports have generally been good for companies where EB/pathogens are identified. Identification of the root cause is still an issue for the EB cases
- Serious complaints not recorded in complaint file

Facilities

- Logical flow of materials and staff
- Surfaces smooth and easy to clean (with special focus on dry cleaning). Tiles not acceptable.
- Debugging of secondary packaging done in warehouse
- Cleaning room needs to be separated from production area
- Peanut roasting – separation between clean and “dirty” area
- Issues with balancing of the HVAC system
- Dust extraction where powders are handled
- Serious powder issue

Equipment

- Heat treatment (fully or partial)
- Qualification of equipment and validation of process parameters
- Equipment designed to facilitate dry cleaning
- Dead legs needs to be eliminated
- Protect against contamination (exposed foil)
- Foreign matter detection on final RUTF sachet is achieved (new lines not approved without detection on sachets). If metal detection is used, then complementation with filter is needed. X-ray should be considered a CCP
- Leakage testing is in-adequate. Microleaks are a concern as even 100 % inspection do not eliminate it

Operation

- Dry cleaning is required
- Limited controlled wet cleaning (no production should take place when water is introduced). High water pressure applications not allowed
- Environmental monitoring is implemented by most companies, but some need to clearly implement zone 1, 2, 3 and 4 and trend the different zones
- Is it designed to detect contamination? Zero detection of EB is a major concern. Add random sampling
- Testing for salmonella in zone 2, 3 and 4 is needed or need more focus
- Maintenance: clear procedure / formal assessment before restart of production

Documentation

- Procedures needs to be reviewed, updated and approved at regular intervals
- Control of changes in formulation and production processes. Remember to use approved procedure
- Electronic recording in ERP system do not match the date, when the task were performed
- Retention times for longer than 3 years is needed
- Protocols and associated reports to be approved by QA.

Batch documentation

- The various operating parameters needs to be documented
- CCP monitoring – e.g. print out, when a “kill step” is used. Ensure that the set limits are followed
- Reconciliation of used raw and packaging materials needs to be compared with yield of finished product
- “Rework” documentation to be improved

Quality Assurance

- Evaluation of suppliers needs to be improved
- Audit of key suppliers are needed (e.g. peanuts or peanut paste, milk powders, oil mixtures)
- Supplier audits clearly impacted by Covid-19. Now it is back to normal business
- CpK and process controls needs to be implemented. Webinar arranged by USAID
- Internal audit not done as scheduled
- Too little focus on low moisture food during internal audit. Just reference to ISO 22000 standard

Quality Control

- More than yearly analysis (number of nutrients and mixes) needed for RUTF and RUSF (companies can still improve their knowledge on compliance with the finished product specification)
- Trend analysis and OOS results needs better CAPA and maybe adjustment of the product formula
- At least one tracer vitamin or mineral should be tested per shift (no pooling). Single minerals added needs to be tested
- Not the whole batch included in the finish product sampling
- In-sufficient control at raw material receipt
- Participate in proficiency testing for Salmonella

Micronnutrient Tablets

- Manufacturing site needs to comply with WHO GMP Guidelines
- Training of staff
- Validation of manufacturing process (3 identical batches) – consistency
- Written agreement with 3. party manufacturers – all responsibilities needs to be defined inclusive finished product testing and release
- Supplier qualification
- Suitability of equipment
- Stability study min 12 months data

Summary of market complaints 2022 - 2023

- Leaking sachets – poor sealing – paste
- Microleaks - oil
- “batch marking” print on sachets can be erased
- Weak shipper cartons
- Shelf life extension from 2 to 3 years
- Poor palletization

SALMONELLA OVERVIEW OF RUTF/RUSF PRODUCTS - 2022

No. of batches tested	No. of Salmonella positive sample	Cases	Root cause
657	3 +	(multiple found by manufacturer)	soy flour / water incident
		3	soy flour

SALMONELLA OVERVIEW OF RUTF/RUSF PRODUCTS - 2023

No. of batches tested	No. of Salmonella positive sample	Cases	Root cause
852	3	1	New Blender which was contaminated due to contaminated water
		2	investigation on going/ root cause could be peanut paste

OVERVIEW OF EB RESULTS 2022

No. of batches tested	No. of samples tested for EB	EB. < 10 per sample	EB. 10 - 100 per sample	Root cause	EB. > 100 per sample	Root cause
657	6570	6567	2	Bag roll alignment activity	1	Bag roll alignment activity

OVERVIEW OF EB RESULTS 2023

No. of batches tested	No. of samples tested for EB	EB. < 10 per sample	EB. 10 - 100 per sample	Cases	Root cause	EB. > 100 per sample	Cases	Root cause
852	8520	8507	9	1	NA	4	1	270 cfu/g. No root cause has been found.
				1	40 cfu/g. No root cause has been found.		1	240 cfu/g. No root cause has been found.
				1	inefficient cleaning before production		1	150 cfu/g. No root cause has been found.
				1	20 cfu/g. No root cause has been found.		1	250 cfu/g. no root cause has been found by manufacturer. Re-tested by UNICEF and Salmonella was detected.
				1	maintenance intervention on the packaging line A			
				1	73 cfu/g. Maintenance activity as potential root cause			
				3	2 cases: PCR Pump tubing as potential root cause 1 case: poor maintenance			

OVERVIEW OF AFLATOXIN RESULTS 2022

No. of batches tested	Aflatoxins > 10 ppb	Aflatoxins 2 - 10 ppb	Cases	Root cause
321	0	8	7	Some of the portion of Blanched Peanut lots had aflatoxin elevated levels

OVERVIEW OF AFLATOXIN RESULTS 2023

No. of batches tested	Aflatoxins > 10 ppb	Aflatoxins 2 - 10 ppb	Root cause
408	0	5	investigation on-going

F75 / F100 overview 2022

F75 OVERVIEW 2022				
No. of tested batches	Salmonella Absence	Salmonella Presence	Cronobacter spp. Absence	Cronobacter spp. Presence
58	58	0	58	0

F100 OVERVIEW 2022				
No. of tested batches	Salmonella Absence	Salmonella Presence	Cronobacter spp. Absence	Cronobacter spp. Presence
44	44	0	44	0

F75 / F100 overview 2023

F75 OVERVIEW 2023				
No. of tested batches	Salmonella Absence	Salmonella Presence	Cronobacter spp. Absence	Cronobacter spp. Presence
90	90	0	90	0

F100 OVERVIEW 2023						
No. of tested batches	Salmonella Absence	Salmonella Presence	Cronobacter spp. Absence	Cronobacter spp. Presence	Cases	Root cause
45	45	0	43	2	1	on-going investigation.
					1	breakdown maintenance

UNICEF analytical testing for nutrition products 2022 / 2023

A review of the nutrition test results in 2022 and 2023 showed that there were no major observations.

Minor deviations observed were due to analytical uncertainty which had no impact on the quality and use of the products.



Oil leakage results for RUTF products - 2022 / 2023

No. of tested batches	No. of batches leakage found total	No. of batches rejected	Cases	Root cause
124	30	4	3	tailings on the sealing jaws caused the horizontal sealing to be weak
			4	NA
			3	NA