Quality Assurance of RUTF and similar products. Future areas of focus!

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For every child
Health, Education, Equality, Protection
ADVANCE HUMANITY
RUTF – Ready to Use Therapeutic Food

- Background on standards applied
- Overview of GMP inspections of manufacturers of therapeutic food
- Current and future trend for the manufacture of RUTF and similar products

UNICEF
Background

- UNICEF is a buyer of Therapeutic Food
- UNICEF is not a normative organisation and we do not want to be seen as one
- UNICEF will refer the available international standards (Codex / ISO 22000) to be applied for production of therapeutic food
- UNICEF/ MSF / WFP common specifications
- UNICEF/ MSF / WFP common questionnaires for products and for manufacturers
Manufacturing standards

Past
- Codex Alimentarius
- ISO 22000 (food safety management)

Future – as above and …
- Any other available information to understand, where food safety risks are found (used as guidance)
Essential References

- Microbial Safety of RUTF (WHO / FAO Technical Meeting Summary March 2013)
- Code of Hygienic Practice for PIF (CAC/RCP 66-2008)
- Control of Salmonella in low moisture foods (www.gmaonline.org)
- www.fda.gov/food/foodsafety
GMP inspections 2010 - 2012

- 23 suppliers (not all is used)
- 26 GMP inspections carried out
- 4 joint GMP inspections with WFP and MSF (2010 and 2012)
- 2 joint GMP inspections with MSF
- 2 joint GMP inspections with US FDA
- 8 suppliers “approved” based on inspection report from MSF or WFP
Future focus areas
Organisation / Hygiene

• Entry procedures to production is too weak. Good hand washing procedures must always be promoted
• It must be clear to staff that they now enter a food production area, where all efforts must be taken to prevent contamination of the food
• Production garments should be suitable and prevent contamination and only be used in the production area
Future focus areas
Quality Management

• Written procedures should be more detailed
• System for handling of corrective and preventive actions (CAPA) should be improved
• HACCP plan must be specific to product
Premises – current situation

- Most are small facilities
- The majority are dedicated to RUTF / RUSF
- Limited in-house QC laboratories
- 2 suppliers use contract manufacturer
- Many suppliers roast their own peanuts or have them processed under contract
- Premises not always designed and constructed to suit operations carried out
Future focus areas
Premises

• Premises must be designed to suit intended purpose and easy to clean
• Hand washing facility at entry to all areas
• Core production area with controlled ventilation to ensure a positive pressure where products are exposed
Future focus areas

Equipment

• Improve control at product changeover
• Cleaning of production equipment must be better controlled. Total removal of water is important. Failures observed several times.
• No or limited metal detection
• Continue focus on “closed” production systems
• Inert gas to be used during all processing steps
Future focus areas
Production procedures - 1

• Apply heat treatment only if relevant and where the impact on finished product stability is carefully considered
• Changes in formulation/manufacturing process must be controlled and well documented
• Improve validation efforts to provide documentation for a uniformity of sub-batches
• Evaluate the relevance of batch definition and size
Future focus areas
Production procedures - 2

• Environmental monitoring
• Environmental monitoring
• Salmonella, Enterobacteriaceae (EB) ....

• Continue focus on batch documentation for dispensing and in-process control (mixing, sealing, printing, residue oxygen in sachets)
Future focus areas
Quality control - 1

• More focus on validation of raw material suppliers
• Improve testing / control of raw materials (as these have a direct impact on quality of the finished product)
• Special attention to peanuts and peanut roasting, soy flour …..(Salmonella, aflatoxin)
• Always receive Certificate of Analysis for raw materials
• Always use full pre-mix and stop adding separate vitamins!
Future focus areas
Quality control - 2

• Improve testing of finished product, so the whole specification are covered at regular intervals

• Out of specification test results. Introduced testing by manufacturers has highlighted issue. Specific problems with Omega 3 / 6 and certain vitamins

• Improve documentation of stability studies

• Prevent oil separation in product
UNICEF & WFP QC testing of supplies

- Pre-delivery inspection will continue
- Focus will be on salmonella, EB and aflatoxins, but we expect the product always comply with the full specification

THANK YOU – Questions?