

# PRODUCT EVALUATION FINDINGS

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# Product Evaluation-2022/2023

|                          | Tender                                    | Dossier/product | Recommended | Under Review |
|--------------------------|-------------------------------------------|-----------------|-------------|--------------|
| <b>Antianemia (2022)</b> | Iron 60 mg Folic Acid 400 mcg (10x10 tab) | 8               | 4           | 1            |
|                          | Iron 60 mg Folic Acid 2800 mcg (100 tab)  | 6               | 2           | 1            |
|                          | Iron 60 mg (100 tab)                      | 7               | 3           | 1            |
|                          | Folic acid 5 mg (1000 tab)                | 10              | 3           | 1            |
|                          | Ferrous sulphate liq. 125 mg/ml (30 ml)   | 5               | 1           | 1            |
| <b>RUTF (2022)</b>       | RUTF (Contd. Review....)                  |                 | 4           |              |
| <b>LNS(2022)</b>         | LNS-SQ                                    | 8               | 2           | 1            |
|                          | PLW                                       | 7               | 1           | 4            |
| <b>MMS (2022)</b>        | MMS (100 tabs/bot)                        | 8               | 2           | 3            |
|                          | MMS (Blis, 30 tab)                        | 8               | 2           | 2            |
| <b>RUTF(2023)</b>        | RUTF (Standard)                           | 30              | 18          | 12           |
|                          | RUTF -Soy                                 | 3               | 1           | 2            |
|                          | RUTF-Chickpea                             | 3               | 1           | 2            |
|                          | RUTF-Oat                                  | 1               |             | 1            |
|                          | RUTF-Rice/Lentil                          | 1               |             | 1            |

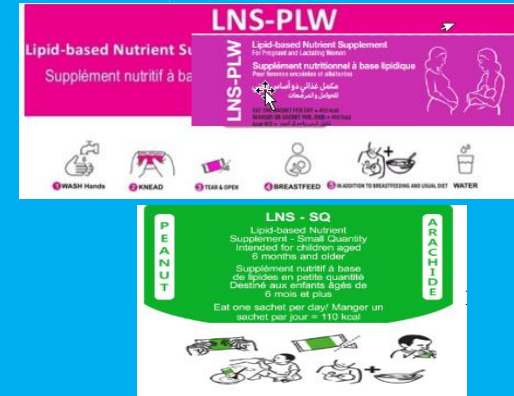
# Antianemia & MMS

- Production standard- Food supplements ( Pharma )
- Process validation not completed
- CoPP requirement
- PIL and labeling requirement
- Stability Study as per ICH guidelines
  - ✓ Test zone requirement
  - ✓ Different pack/size, pilot/bench top batch size
  - ✓ Product appearance change, gas formation in blister pack
  - ✓ Dissolution test requirement
  - ✓ Different API sources and lack of corresponding stability study
- Pending GMP verification



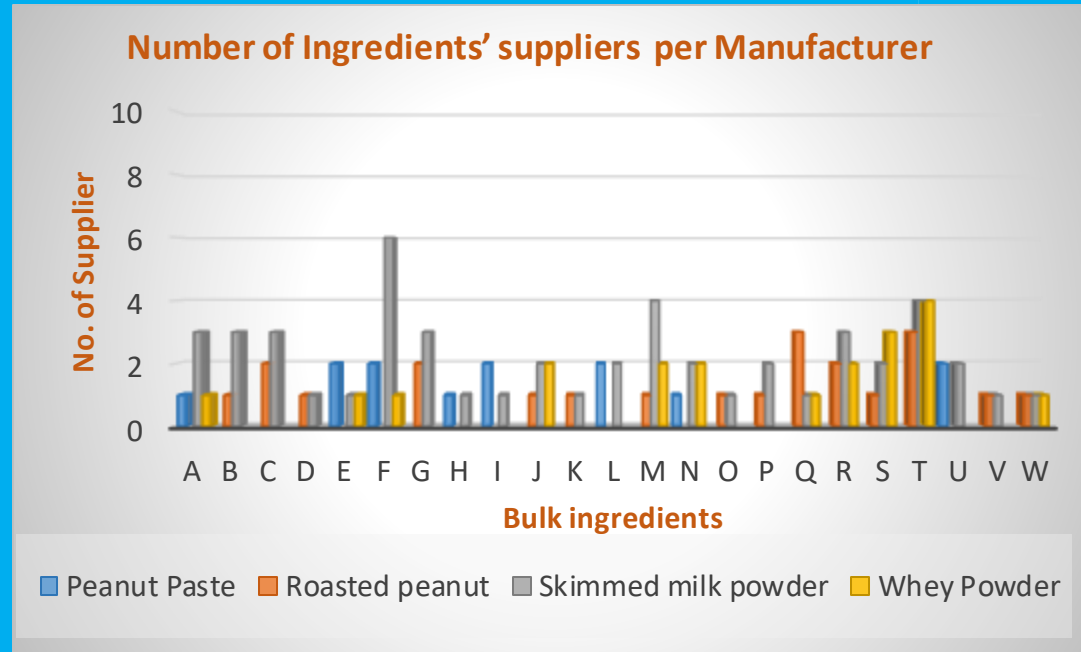
# LNS-SQ & LNS-PLW

- No product developed yet
- Nutritional profile
  - ✓ PDCAAS (protein digestibility score)
  - ✓ n-3 FA level, Vitamins and minerals
- Packaging and labeling requirement
- Stability study
  - product consistency & appearance (oil separation)
  - Vitamin stability e.g., Vitamin A and Vitamin C



# RUTF-Raw Materials-Source

- ✓ Supplier validation protocol
- ✓ Specification, COA (suppliers/internal)
- ✓ Risk Assessment of raw materials, sampling plan and quality control
- ✓ Do supplier's COA, Internal COA and set specification match?
- ✓ Heat treatment of raw materials, Validated heat treatment
- ✓ Selection of right origin and ingredients to reach the PDCAAS, n-3/n-6 ratio



- **Higher Variation in source .....Higher the risk**
- **Stringent Supplier validation and periodic monitoring or continuous monitoring??? Food safety Risk????**

# Process Validation

- ❖ HACCP Plan, Process flow, OPRPs and CCPs
- ❖ Mixing validation (CV), SOP mixing, trending of nutrients
- ❖ Packaging integrity and validation (Composition, COA)
- ❖ Labeling requirements validation (Sachet and Carton)
- ❖ Stability requirements and protocol (IA stability requirements)
- ❖ Quality and safety Certificates : FSSC 22000 V5.1 (18), BRC (2 ), ISO 22000:2018 (2)
- ❖ Heat treatment validation (???)

## Environmental monitoring

- ☐ SOP cleaning (dry cleaning, wet cleaning, detergent & disinfection)
- ☐ Trending microbials swabs and settle plate
- ☐ Plant layout, zoning, man, material and air flow



# Formulation Validation

## Formulation

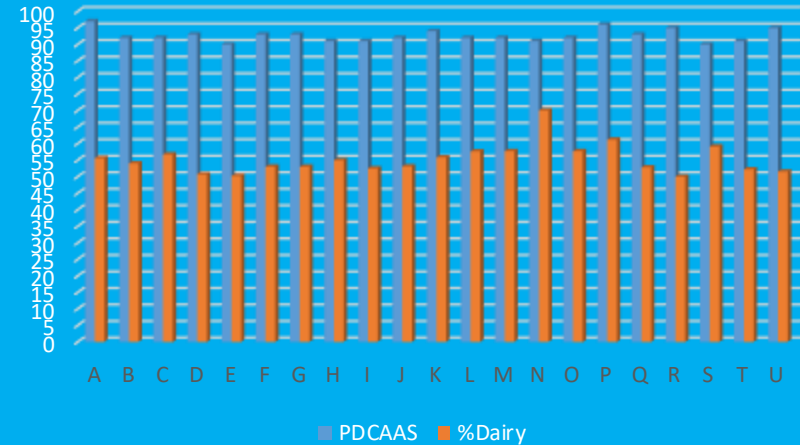
- Suppliers meet PDCAAS, dairy % requirement, N-3/n-6 requirements
- Variation
  - ✓ Selection of ingredient origin
  - ✓ Processing (roasted peanut, paste, skimmed milk, whey powder, protein isolate)
  - ✓ amino acids (Lysine, methionine and Cysteine)
  - ✓ palm oil, canola oil, flaxseed oil, soy oil, coconut oil

## Organoleptic

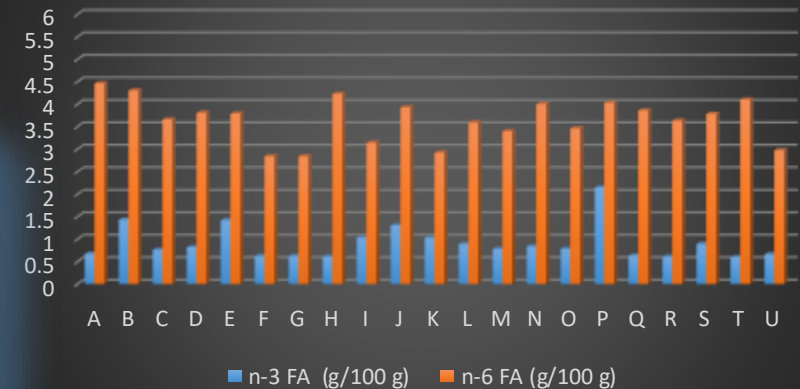
- ❖ Smooth, homogenous, pleasant sweet and milky taste and light brown in color
- ❖ Hard texture and oil separation
- ❖ Non homogenous and gritty product



PDCCAS, Dairy % in RUTF per Supplier



n-3/n-6 level in RUTF per RUTF supplier



# Next Steps-RUTF

- Continuous development (formulation, processes, plant)
- Commercial sample, COA from commercial batch
- Start stability study to the commercial batch and update periodically
- Periodic renewal of quality and safety certification
- Change control- update



Nutrition

# Thank You