INTERAGENCY (IA) NEW REQUIREMENTS FOR STABILITY STUDY

for
Specialized Foods / FSMPs
(Foods for Special Medical Purposes)

Part 1

- ❑ When stability study is needed?
- ❑ Type of stability studies
- ❑ Stability batch size & RH
- ❑ Stability testing parameters
- ❑ Stability reports / reporting

Part 2

- ❑ Vitamin A levels in RUTF-stability reports and PDI (Pre Delivery Inspections)
- ❑ Possible key interventions to maintain Vitamin A levels

New Requirements for Stability Studies

Key Topics

When Stability Study is needed (1/2)

- For any new product development or
- in the absence of shelf-life studies for an existing product.
- If stability study is not finalized at the time of initial assessment or submission,
  - a minimum of 6 months accelerated stability study at 40°C, with factor 2
  - and the manufacturer shall commit to continue the real time stability study and to send reports as soon as preliminary results are available.

When Stability Study is needed (2/2)

Also, when there is a,

- ❑ change of production site
- ❑ significant change in production equipment or process (e.g. heat treatment)
- ❑ modification of an existing product
- ❑ change in primary packaging material
- ❑ change of formulation or major ingredient, such as, but not limited to:
  i. raw material
  ii. vitamins & minerals premix
  iii. emulsifier
- ❑ change in supplier-only for vitamins & minerals premix and Vitamin A*

* MSF & UNICEF additional requirement

- Real time (long term) stability study should be conducted :
  - at 30°C±2°C with 65% RH (if applicable) for the duration of the shelf life, and
  - at 40°C±2°C with 75% RH (if applicable) for the duration of the shelf life
- Testing period and time points:
  - minimum testing frequency : T0, T3, T6, T12, T18 and T24 months and then yearly for both temperatures
- Stability should be conducted on, at least 1 representative batch (prefer 2 batches*)

* UNICEF additional requirement

INTERAGENCY REQUIREMENTS FOR STABILITY STUDY

Type of stability studies required

For Real Time Stability Study

Minimum protocol requirements

- Accelerated stability study should be conducted :
  - at 40°C±2°C with 75% RH (if applicable)
- Testing period and time points:
  - minimum testing frequency : T0, T1, T2, T3 and T6 months
- Stability should be conducted on, at least 1 representative batch (prefer 2 batches*)

* UNICEF additional requirement

INTERAGENCY REQUIREMENTS FOR STABILITY STUDY

Type of stability studies required

For Accelerated Stability Study

Minimum protocol requirements

Stability Batch Size

Minimum requirements

- Stability batch should be,
  - Commercial batch size (Preferred*)
  - Process validated (Preferred*)
  - Produced with the same vitamins & minerals premix and / or Vitamin A, source to be used in the commercial finished product
  - Manufactured ONLY by the product manufacturer
  - Pilot scale batch MAY be accepted, subject to prior approval only
  - For Pilot scale batch-method of manufacture and procedure MUST simulate the final process to be used for production batches

* UNICEF additional requirement

INTERAGENCY REQUIREMENTS FOR STABILITY STUDY

Relative Humidity (RH)

Minimum requirements

- Monitoring of relative humidity is not mandatory
- If the shelf life study is performed in an incubator
  - ✓ Relative humidity must be set at 65% and 75%.
  - ✓ **RH** (Relative Humidity) can vary ±5%*
- Temperature and relative humidity (if applicable) must be regularly controlled and recorded.
- The record of calibration of incubator(s) shall be available upon request.

* UNICEF additional requirement

- All the tests shall be performed in ISO17025 accredited laboratories (Preferred)
- Stability studies must verify the following parameters
  - Micronutrient stability:
    - ✓ Minimum 1 water soluble vitamin (vitamin C mandatory) shall be tested at every test point
    - ✓ Minimum 1 fat soluble vitamin shall be tested at every test point (Vitamin A* mandatory)
    - ✓ All vitamins shall at least be tested at T0, T12, T18*, T24 months and yearly (when applicable).
    - ✓ All minerals shall at least be tested at T0, T12, T24 months and yearly (when applicable).

* MSF & UNICEF additional requirement

Stability Testing Parameters *(1/2)*

Minimum testing requirements

- Microbial testing:
  at the beginning and the end of the study (every 6 months Preferred*)
- Stability of oils and fatty acids (peroxide value, anisidine value, moisture content) ***
- Organoleptic stability: taste (rancidity, acidity/bitterness, sweetness/savoury, etc), odour, product consistency and behaviour (absence of phase separation…) ***
- Integrity of the packing materials (absence of leakage & availability of seal opening notch)***
- Integrity of markings- (printing ink must be of food grade standards for the products intended to come in contact with food e.g. RUTF sachets*).

***At all testing points*

* MSF & UNICEF additional requirement

Stability Testing Parameters (2/2)

Minimum testing requirements

INTERAGENCY REQUIREMENTS FOR STABILITY STUDY

Stability Study Reports *(1/2)*

Minimum reporting requirements

Stability Reports should include,

- ❑ Product name and mfg. site address
- ❑ Mfg. date, expiry and stability study start date
- ❑ Pack size (primary pack) & batch number
- ❑ Batch size in number of primary packs and/or blend size in kg or Metric (M tons)
- ❑ Storage conditions (temperature, and RH (if applicable)

INTERAGENCY REQUIREMENTS FOR STABILITY STUDY

Stability Study Reports *(2/2)*

Minimum reporting requirements

- Testing Parameters (Physical, Chemical, Vitamins, Minerals and Microbial)
- Specifications (acceptance criteria) for all parameters and test methods/reference
- Testing laboratory information
- Conclusion & storage requirements (based on the results)
- The report shall be sent at T0 (for the validation of the protocol), T6, T12 months and then yearly until the end of the shelf life.

Stability Report – Reference/ Dummy Template

Company Logo		Name of the Company		Page No: 1 of 4

Product Name					
Product Mfg site (Name & address					
Primary Pack size	e.g. 92 gm sac	Primary Packing Material			
Mfg. Date	DDMMYYY	**Expiry Date**	DDMMYYY	**Stability Start**	DDMMYYYY
Batch /Lot Number		**Batch Size (Kg and /M. ton)**	e.g. 500kg /MTON	**Batch Size (No. of Primary pack units)**	
Storage Conditions	e.g. 30^0C or 40^0C ±2^0C		**Relative Humidity**	e.g. 65 % or 75 % ± 5%	

Parameters	Specification	Method/ Specification Reference	T0	T3	T6	T12	T18	T24	T36
Physical									
Chemical									
Vitamins									
Minerals									
Microbiology									

Testing Labs Info/ Accredition	

Result Discussion:	

Conclusion & Storage Requirements (Based on results)	

Stability Data Trend for Nutrition Products

Results from RUTF tender 2019

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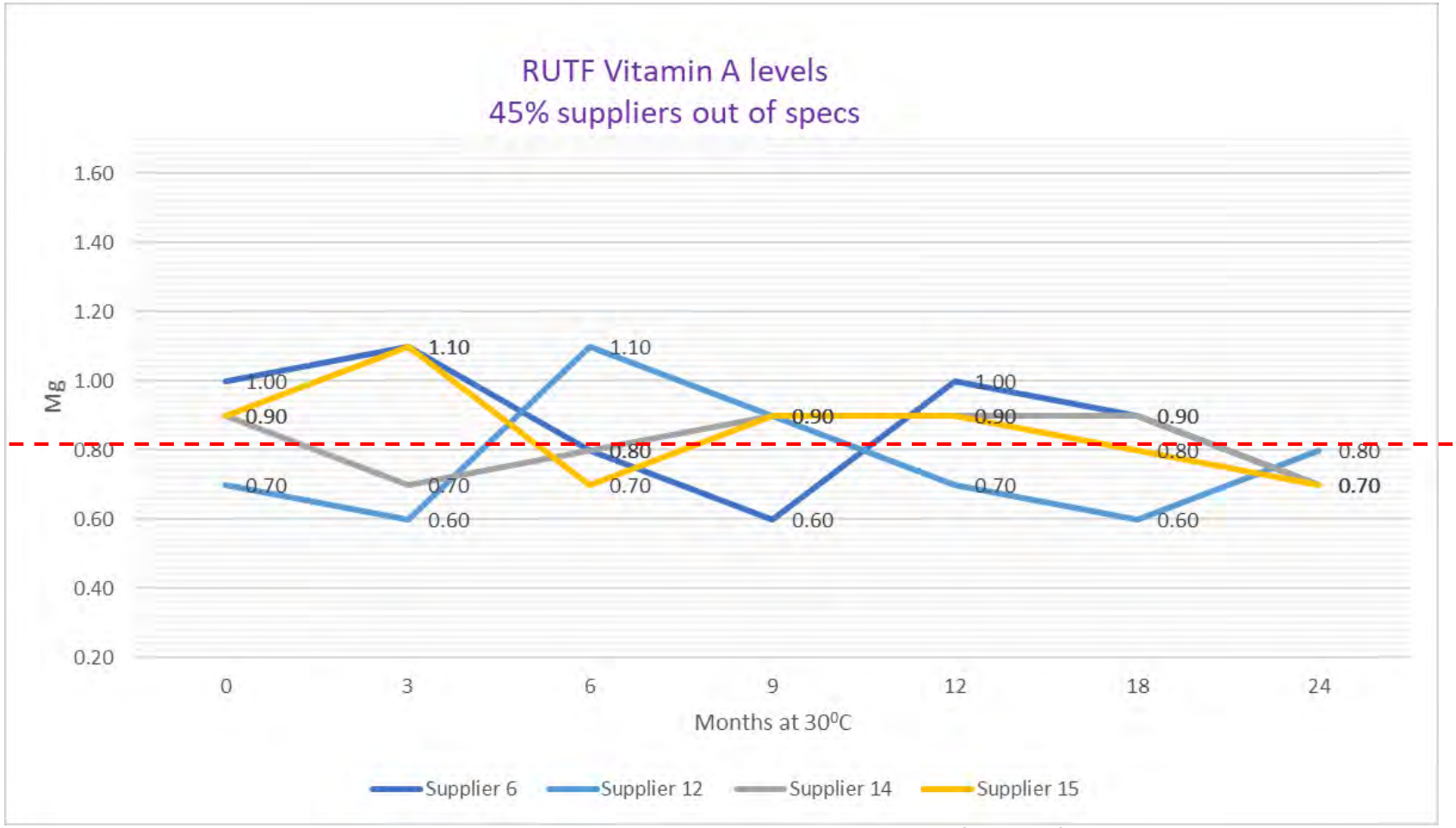
RUTF Vitamin A levels during stability testing- RUTF tender 2019

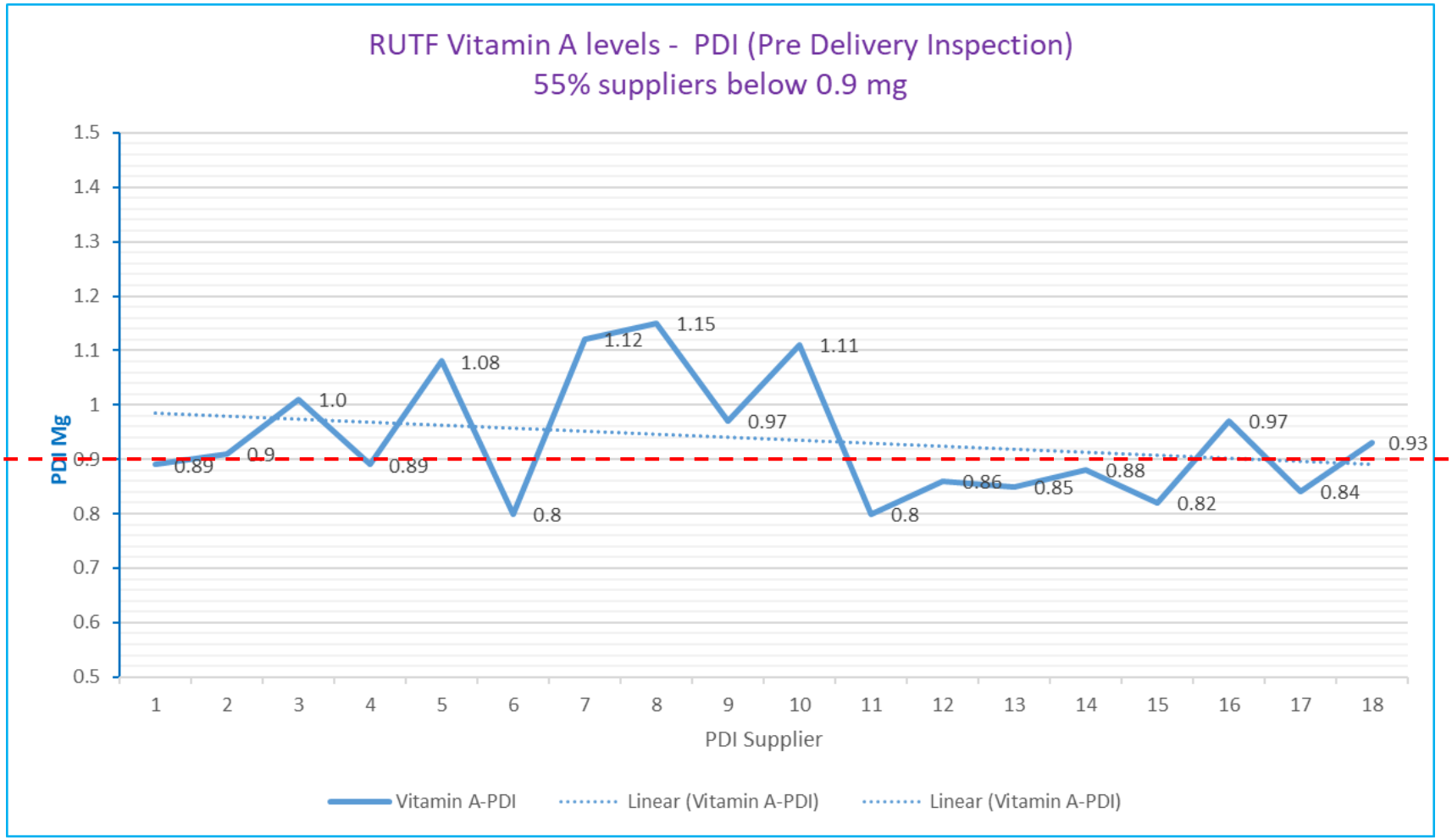
Suppliers- Monthly Interval Trend



Ref: Data on file- Stability reports- RUTF Tender 2019
9 suppliers were considered based on their completeness and reporting of stability data for minimum 18 - 24 months

RUTF- Vitamin A Levels during Pre - Delivery Inspection (PDI)-2018

Fresh stocks inspected before dispatch



Ref: Data on File- UNICFE PDI 2018

- Testing of Vitamin A levels in Premix,
  - on goods receipt
  - if stored more than a month
  - before using in manufacturing process
- Testing of Vitamin A levels in RUTF
  - After Batch release/ post production
    - Aim for maximum specified limit levels. e.g. RUTF – 1.1 mg /100 grams (limit 0.8-1.1 grams)
- Process validation of commercial batches
- Storage of Premix and Finished product at recommended storage conditions

INTERAGENCY REQUIREMENTS FOR STABILITY STUDY

Harnessing Vitamin A levels

Possible key interventions *to maintain Vitamin A levels*

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Thank You