



Food Safety and Quality Assurance Unit

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WFP shelf life study protocol – Processed food products

Purpose

The purpose of this document is to establish WFP requirements that manufacturers shall meet for determining acceptable product shelf life and storage conditions of processed food products. Conditions of the document are used for audit and technical assessment. Not complying with these requirements may generate critical, major or minor observations and/ or suspension of the supplier.

Scope

Stability studies shall be conducted by the manufacturer on a representative batch of the final product in primary packaging¹, in case of the following events:

- for any new product development or in the absence of shelf-life studies for an existing product. If stability study is not finalised at the time of WFP initial paper assessment or submission, a minimum of 6 months accelerated stability study at 40°C, with factor 2 with testing at time points T0, T1, T2, T3, T6 (months) can be considered and the manufacturer shall commit to initiate and continue the real time stability study and to send reports as soon as preliminary results are available.
- for a change of production site
- for a significant change in production equipment or process (e.g. heat treatment)
- for modification of an existing product:
 - change in primary packaging material
 - change of formulation or major ingredient, such as but not limited to:
 - Raw material
 - Vitamins & and minerals premix
 - Additives, e.g. emulsifier

Requirements

The manufacturer shall demonstrate compliance with the final product specification throughout the shelf-life, on at least 1 representative batch, following the below minimum requirements:

For the complete stability study:

- Reference samples shall be maintained between **2°C to 8°C** for the duration of shelf life
- Minimum two storage conditions shall be followed:
 - Real time condition: **30 °C±2 °C with 65% RH²⁻³** for the duration of the shelf life

¹ A representative batch is a batch manufactured in the same conditions as the commercial batch. Stability studies performed on pilot scale might be accepted, subject to prior approval, and shall be performed on a minimum pilot scale and using a method of manufacture and procedure that simulates the final process to be used for production batches. The final product primary packaging size shall be used. The representative batch (blend) size must be mentioned on the stability reports both in Kg or Metric tons (e.g. batch/blend of 500kg RUTF per pack of 92 grams)

² Monitoring of relative humidity is not mandatory. If the shelf life study is performed in an incubator allowing the control of the relative humidity, then relative humidity must be set at 65% and 75%.

³ Temperature and relative humidity (if applicable) must be regularly controlled and recorded. The record of calibration of incubator(s) shall be available upon request.



- Worst case condition: **40 °C±2 °C with 75% RH²⁻³** for the duration of the shelf life
- with a minimum frequency for the tests: T0, T3, T6, T12, T18 and T24 months and then yearly (when applicable) for both conditions

For the accelerated stability study (when applicable, see scope)⁴

- at 40 °C±2 °C with 75% RH²⁻³
- with a minimum frequency for the tests: T0, T1, T2, T3, T6 and 12 months
- with a Q10 factor 2
- the shelf life predicted using accelerated shelf life study must be validated by completing shelf life study at real time condition.

Laboratory requirements: All the tests shall be performed in ISO17025 accredited laboratories. All the tests performed shall be under the scope of accreditation for the specific product matrix under investigation.

Stability studies must verify the following parameters (with examples that can be used):

Micronutrient stability:

- Minimum two water soluble vitamins (e.g. vitamin C and vitamin B6) shall be tested at every test point. Not applicable for Vegetable oil.
- Minimum one fat soluble (vitamin A) shall be tested at every test point.
- All vitamins and minerals shall at least be tested at T0, T6, T12 months, T24 months and yearly (when applicable).

Absence of microbiological growth: Those mentioned in the specification shall be tested at every test point. RUTF and RUSF do not require testing at every point.

Stability of oils and fatty acids: peroxide value and anisidine value shall be tested at every test point

Organoleptic stability: Organoleptic characteristics shall be tested at every test point, with product as it is intended for consumption.

- **Appearance:** colour, any spots, visible lumps, phase separation, etc.
- **Taste:** acidity, bitterness, sweetness, savoury, cereal like, beany, rancid, stale, etc.
- **Mouthfeel:** grainy, smooth, soft or hard lumps
- **Consistency:** product hardness, visual or touch viscosity; BOSTWICK flow rate to supplement sensory evaluation where applicable

Integrity of the packing materials: Absence of leakage shall be tested at every test point.

- **Sachets (e.g. LNS, SC+, HEB):** absence of leakage under pressure (recommended 25kPa)*a quantitative validated method shall be used
- **Bottles and cans:** absence of leakage when packaging is inverted and squeezed

Integrity of markings: The printing ink must be of food grade standards for the products intended to come in contact with food e.g. RUTF sachets. The markings shall be readable at all test points.

Other parameters: All tests as mentioned in the product specification compulsory list of analysis shall be tested at least at T0, T12 and T24 and yearly (when applicable).

Shelf life study conclusion and report

⁴ Accelerated stability study at 40 °C±2 °C with factor 2 when performed for 6 months, gives potential indication on 12 months shelf life at 30 °C±2 °C.



The report shall include:

- Product / Manufacturer details: product name, product description, ingredient list, address of the manufacturing site
- An introduction with the batch used, the manufacturing date and the 'Best Before' date
- The parameters used for the stability study (storage conditions – temperature and RH)
- The results preferably presented in the form of a summary table, with the specification requirement (acceptance criteria) and time points for all parameters listed in paragraph 2.
- The details on the laboratory(ies) used, its (their) accreditation, and the test methods.
- The conclusion (or the indication based on accelerated studies) based on the obtained results at 30 °C/65% RH, including the justification for the shelf life and recommended storage conditions.
- The report shall be sent at T0 (for the validation of the protocol) and when the results are available at T6 months, T12 months and then yearly until the end of the shelf life.