



WFP shelf-life study protocol – Processed food products

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Scope

This document aims to present the minimum requirements for shelf-life stability study. The study shall be conducted by the manufacturer on at least one representative batch¹ of the finished product in primary packaging, to determine the product shelf life and storage conditions:

- for any **new product development** (or in the absence of shelf-life studies)²
- for a change of **production site**
- for a significant change in **production equipment or process** (e.g., packing line, 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 & minerals premix, additives, e.g., emulsifier
 - change in **supplier for major ingredients**

Suppliers shall ensure that products comply fully with WFP specifications throughout the shelf-life.

1. Minimum requirements in the protocol

The manufacturer shall demonstrate compliance with the end-product specifications throughout the shelf-life, on at least 1 representative batch¹.

Minimum two storage conditions should be followed, with a minimum frequency for the tests: T0, T3, T6, T12, T18 and T25 months and then yearly (when applicable) for both conditions:

¹ A representative batch is a batch manufactured in the **same conditions as the commercial batch** (same **batch size**), manufactured with the **validated formula** and **validated process**. Stability studies performed on pilot scale might be accepted for **preliminary study**, 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 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). **This shall be completed by a commercial batch size study.**

² If stability study is not finalised at the time of initial assessment or submission, the data of a minimum of 6 months of the stability study at 40°C, can be considered. The manufacturer shall continue the real time stability study and send reports when results are available.

- **Recommended conditions:** 30 °C±2 °C with 65% RH³⁻⁴ for the duration of the shelf-life
- **Humanitarian supply chain condition:** 40 °C±2 °C with 75%RH²⁻³ for the duration of the shelf life. In the absence of complete stability study at 30°C, the data of the stability study at 40 °C±2 °C can be used as **accelerated stability study**⁵, with a minimum frequency for the tests: T0, T3 and T6 and when Q10 factor of 2 is considered, based on most thermosensitive vitamin tracer and organoleptic stability. The shelf life predicted using accelerated stability study must be validated by completing shelf-life study at recommended conditions. Additional temperatures conditions to complement the above can be included into the study.

All the tests shall be performed with validated methods, preferably in ISO17025 accredited laboratories.

Stability studies must verify the following parameters:

1.1. Micronutrient stability (only applicable to fortified foods/MNPs)

- Minimum one water soluble vitamin (vitamin C mandatory⁶) and minimum one fat soluble vitamin (vitamin A mandatory) shall be tested at every test point: T0, T3, T6, T12, T18, T25 and then yearly if applicable.
- All vitamins shall at least be tested at T0, T6, T12 months, T25 months and yearly (when applicable).

1.2. Absence of microbiological growth

- Total plate count shall be tested at T0, T12 and T25 at 30 C
- Aw shall be tested at T0, T3, T6, T12 and T25.

1.3. Stability of oils and fatty acids (not applicable to fortified rice and its kernel)

- Peroxide value should be tested at T0, T3, T6, T12, T18, T25. Additionally, for Super Cereal and Super Cereal plus, P-anisidine, TBA and hexanal should be tested.
- For lipid-based products, fatty acids omega 3 and omega 6 content should be tested at T0, T6, T12, T18, T25 and then yearly if applicable.
- When rancidity is perceived during organoleptic test at any point of the study, anisidine value, TBA, hexanal, water activity, and free fatty acids shall be tested to get a complete understanding of the rancid notes.

1.4. Organoleptic stability

Organoleptic characteristics should be tested at T0, T3, T6, T12, T18, T25 and then yearly if applicable, with product as it is intended for consumption. It is the manufacturer's responsibility to establish quantitative criteria for each organoleptic parameter.

³ 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%.

⁴ Temperature and relative humidity (if applicable) must be regularly controlled and recorded. The record of calibration of incubator(s) shall be available upon request.

⁵ For SC/SC+, an additional study under Humanitarian supply chain condition should be performed on opened sachets to simulate SL of product with defective packaging.

⁶ When a food does not contain added vitamin C, another water soluble vitamin shall be used.

For Lipid based Nutrient Supplement and Super Cereal plus products, Annex I provides indicative guidance for establishing an organoleptic tasting protocol with quantitative scale for each parameter⁷.

1.5. Integrity of the packing materials and marking

- Integrity of markings: The markings should be readable at T0, T3, T6, T12, T18, T25 and then yearly if applicable.
- Integrity of the primary packaging material:
 - Prior performing the leak tests, visual inspection of sachets is required: Packaging material must not present any sign of discoloration, demetallization nor delamination. Additionally, the sachets must not be oily.
 - Absence of leakage should be tested at T0, T3, T6, T12, T18, T25 and then yearly if applicable:
 - For sachets (e.g., LNS, SC+, HEB): absence of leakage under pressure (recommended 25kPa), by using a quantitative validated method.
 - For bottles/jerrycans (vegetable oil): absence of leakage when bottles are placed upside down for 24h and gently squeezed.

For other commodities, packaging integrity and marking need to be checked along the entire shelf-life test. Integrity check must be done according to the quality checks performed during packing of the goods.

2. Stability study report

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. Suppliers of specialized nutritious foods (e.g., LNS, SC+, HEB, Date bar) are recommended to utilize the reference template provided in annex II.
- 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.
- The stability study protocol shall be sent prior to starting the study for validation and report shall be shared when the results are available at T6 months, T12 months and then yearly until the end of the shelf life or when requested.

⁷ This is the responsibility of the manufacturer. The annex is only for guidance purposes.

Annex I: [Guidance for establishing organoleptic testing protocol with suggested attributes & rating](#)

Annex II: [Guidance template: Stability study template for Nutritional Products](#)