

	QA Specialised food	Ref MSF: QA-NFOS-IA-I.1.3-5 Date of issue: 18/11/2011 Revision: 7 08/04/2019
	INTERAGENCY REQUIREMENTS FOR STABILITY STUDY	

1. Scope

This document aims to present the minimum requirements for the stability study report. Stability studies shall be conducted by the manufacturer on the end product in primary packaging¹, to determine the product shelf life and storage conditions:

- 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 initial 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, T4, T6 (months) will be considered and the manufacturer shall commit to 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
 - emulsifier

2. Minimum requirements in the protocol

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

- For the real time stability study:
 - at 30°C±2°C with 65%RH²⁻³ for the duration of the shelf life, and
 - at 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 temperatures
- For the accelerated stability study (when applicable, see paragraph 1)
 - at 40°C±2°C with 75%RH²⁻³
 - with a minimum frequency for the tests: T0, T1, T2, T3 and T6 months
 - with a factor 2

All the tests shall be performed in ISO17025 accredited laboratories. All the tests performed shall be under the scope of accreditation for this product matrix.

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

- **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

¹ The exactly same primary packaging shall be used (25 kg bags can be replaced by 1 kg pack with similar properties: same material and sealing).

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.

IA REQUIREMENTS FOR STABILITY STUDY

- All vitamins and minerals shall at least be tested at T0, T12 months, T24 months and yearly (when applicable).
- **Absence of microbiological growth:** at the beginning and the end of the study
- **Stability of oils and fatty acids** (peroxide value, anisidine value)
- **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)
- **Integrity of markings**

3. Stability study report

The report shall include:

- **An introduction** with the batch used, the manufacturing date and the 'Best Before' date
- **The parameters** used for the stability study (temperature, and RH if applicable)
- **The results** preferably presented in the form of a summary table, with the specifications (acceptance criteria) for at least all parameters listed in paragraph 2.
- The details on the laboratory(ies) used and it (their) accreditation, and the test methods shall appear.
- **The conclusion** (or temporary conclusion) based on the obtained results, 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.