

10 March 2025

Shelf Life Determination of Foods for Special Medical Purposes (FSMP)

Position Paper – Analysis Frequency

Summary

- Shelf life duration can be appropriately defined on the sole basis of real-time results obtained, at a minimum, at the beginning and end of shelf life. In such cases, the obtention of results at intermediate times is not mandatory.

ISDI identified the following aspects in relation to the analysis frequency necessary for the shelf-life determination of Foods for Special Medical Purposes (FSMP) products.

Real-time shelf-life tests

Shelf-life duration can be appropriately defined on the sole basis of real-time results obtained, at a minimum, at the beginning and end of shelf life. Results at intermediate times are not mandatory.

If real-time data at end of shelf life are not available, intermediate real-time data can be used to define an initial shorter, or preliminary, shelf life. Significant changes in sensory properties, physical properties and nutrient content in real-time (non-accelerated) conditions typically require longer than 3 months to materialise, so a frequency of analysis less than three months is not necessary.

Accelerated shelf-life tests

Data generated in a single accelerated temperature study may be sufficient to establish product shelf life if the appropriate correlation between accelerated and available real-time stability data is established on the most unstable nutrients by predictive mathematical modelling.

The frequency and scope of analyses should be defined on a case-by-case basis and based on the market temperature zone and product type.

The temperature and humidity conditions for conducting shelf life tests are discussed in the ISDI Position “Shelf Life Determination of Foods for Special Medical Purposes (FSMP) products – Focus on the Temperature & Climatic Zones factors”.

Conclusion

Shelf-life duration can be appropriately defined on the sole basis of real-time results obtained, at a minimum, at the beginning and end of shelf life. In such cases, the obtention of results at intermediate times is not mandatory.