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

## Position Paper – Number of Batches

**Summary**

- The shelf life of a product can be determined by the analysis of a single batch

### Introduction

In 2019, following a literature review that emphasized the lack of relevant references and studies, the International Special Dietary Industry (ISDI) launched a multiyear project to develop guidance on shelf-life tests for Food for Special Medical Purpose (FSMP).

The major global manufacturers of FSMPs (Abbott, Fresenius, Nestlé Health Science, Nutricia, Reckitt) participated in the Stability Guidelines Task Force. Available stability data on FSMPs were gathered to be analysed and used to provide recommendations on which nutrients should be included in stability tests to determine the shelf-life of foods for special medical purposes[1].

The data collected comprised 32,798 data points and 1,471 datasets (or recipes) covering more than 70 nutrients. The datasets were categorized into 9 categories (physical state, temperature, humidity, pH of the product, level of protein hydrolysis, presence/absence of fat, adult vs infant FSMP, type of packaging and protective atmosphere) with 29 subcategories. For each nutrient, statistical analyses were performed to identify which factors among these 29 subcategories were responsible for losses and to which extent.

The recommendations applicable to FSMP would be the same for other Foods for Special Dietary Uses (FSDU) that are manufactured in a similar way, such as for example, infant formula or follow-up formula.

### Results

The ISDI project has identified that Foods for Special Medical Purposes (FSMP) product shelf-life can be determined by analysing a single batch because the following processes ensure that different batches of the same product recipe do not present significant differences:

1. The Packaging Validation Standard (ISO/TS 22002-4): Specific prerequisite programs for food packaging manufacturing ensure that the barrier properties of a given packaging do not differ from one pack to the next. The physical-chemical processes responsible for product deterioration and the determination of the product shelf-life



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duration will therefore be qualitatively and quantitatively identical between different manufacturing batches.

2. Manufacturing and hygiene standards: The implementation of Food Good Manufacturing Practices (GMPs) and Hazard Analysis and Critical Control Points (HACCP) ensures that the product composition and properties remain constant across different production batches[1]. The residual and unavoidable small variations in manufacturing between different batches might result in small differences in nutrient content. These differences remain within the legal tolerances and do not affect the shelf life of the product. They might affect the quantity of some nutrients present at the beginning of the shelf life of the product[2], although the relative amplitude of loss of each nutrient over time (expressed as a percentage) between batches will not be significantly different.

## Conclusion

The implementation of these standards guarantees a small inter-batch variability. **Data generated on a single batch are representative of all batches of the recipe and sufficient to define the shelf-life duration of the FSMP. The collection of shelf-life data on several batches is therefore unnecessary**.

[1] See General Principles of Food Hygiene CAC/RCP 1-1969 (link)

[2] Once commercially launched, food manufacturers routinely monitor product composition at batch release



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