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

Position Paper – Tracers

Summary

- ISDI recommends using a selected number of nutrients as tracers to determine the nutritional suitability of FSMPs over shelf life.
- Most nutrients (all minerals, all macronutrients, all fatty acids, total nucleotides, some vitamins and most of the amino acids) are stable in all conditions and should be excluded from shelf life tests.
- Shelf-life tests for FSMPs should only require a quantitative analysis of a limited number of identified nutrient markers or tracers (i.e. nutrients with higher rates of degradation during shelf life used as tracers or markers to indicate product nutritional suitability and product shelf life)
- The following nutrients as tracers or markers should be used:

PRODUCT	TRACER
Powder FSMPs	Vitamin A
Non acidified liquid and paste FSMPs	Vitamin C, thiamin (and vitamin D for extensively hydrolyzed protein products)

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 purposes¹.

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

Not all nutrients have the same susceptibility to, or rate of, degradation over shelf life. Temperature, light, oxygen, product pH, degree of protein hydrolysis and product moisture can, to differing extent, affect nutrient stability.

FSMPs typically contain a complex blend of macro- and micro-nutrients. However, the shelf life of FSMPs is primarily defined by the nutrients most prone to degradation. While most nutrients remain stable, other nutrients degrade over time and at different speeds (see Table). In non-acidified liquid FSMPs, our study identified 3 nutrients that displayed losses much larger than the others. These 3 nutrients are by decreasing amplitude of losses: vitamin C, thiamin and vitamin D (losses only in products with hydrolyzed proteins). In powder the only nutrient displaying losses was vitamin A.

From a nutritional perspective, it is these more labile nutrients that define and reduce the shelf life of FSMPs. Nutrients with higher rates of degradation during shelf life can therefore be used as tracers or markers to indicate product nutritional suitability and help define product shelf life. If the levels of these more unstable nutrients remain adequate at the end of shelf-life, the levels of the other more stable nutrients will be adequate too.

Conclusion

Typically, therefore, shelf life tests for FSMPs should only require a quantitative analysis of a limited number of identified nutrient tracers. Based on the available results from more than 1400 FSMP shelf-life tests conducted by industry and gathered to build this guidance, most nutrients - all minerals, all macronutrients, all fatty acids, total nucleotides, some vitamins and most of the amino acids - are stable in all conditions and should be excluded from shelf life tests.

ISDI recommends to limit the analyses of nutrient in FSMP shelf-life tests to the following most labile tracers or markers (see Table 2 for additional justification):

PRODUCT	TRACER
Powder FSMPs	Vitamin A
Non acidified liquid and paste FSMPs	Vitamin C, thiamin (and vitamin D for extensively hydrolyzed protein products)

Table: Average percentage of degradation of nutrients after one year in liquid non-acidified FSMPs.

Nutrient	Non-acidified liquid FSMPs	
	20°C	25/30°C
Vitamins		
Pantothenic acid (B5)	stable	-10%
Vitamin C ¹⁾	-20% (with flushing)	-55% (with flushing)
	-46% (no flushing)	-65% (no flushing)
Folic Acid (B9)	-11%	-16%
Thiamin (B1)	-20%	-50%
Vitamin D	Stable with intact proteins	
	-33% (extensively hydrolysed proteins)	
Vitamin B12	-11%	-17%
Vitamin A	Stable	-15%
Sugars		
Total Sugars	-7%	

Other nutrients display no or negligible degradations.