International Special Dietary Foods Industries

10 March 2025

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

Position Paper – FSMPs differing by their flavour or presence or absence of Fibre

Summary

Statistical analysis of the shelf-life data of Foods for Special Medical Purposes (FSMPs) collected by the industry indicates that different flavours or the presence or absence of fibre in the same recipe have no impact on the stability of nutrients. ISDI, therefore, considers that it is not relevant nor required to conduct distinct shelf-life tests for recipes that only differ by their flavours or by the presence or absence of fibre.

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.

As part of this work, a specific statistical analysis (see Annex for details on the statistical method used) was performed to study the effect on the stability of nutrients and included among the factors considered the different flavours or the absence or presence of fibre in the same recipe.

Results

The studied flavours were: chocolate, coffee, fruit flavours, vanilla and no flavour. Flavours did not have a significant effect on any of the studied nutrients. None of the 2 by 2 effect was significant at an alpha level of 0.01 (to account for multiplicity).

No difference in stability of the studied nutrients was detected between recipes that only differ by the presence or absence of fibre. Nutrients were qualified as stable based on conservative

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limits. Nutrients were qualified as stable if the losses after one year were lower than 5% for macronutrients; less than 7.5% for fatty acids and less than 10% for vitamins & minerals, amino acids & nucleotides. All of the 95% confidence intervals of the effect of fibre are within the stability limit defined for the nutrient so affiliated recipes with or without fibre can be considered statistically equivalent if the stability limit is considered as the equivalence margin.

Table: List of studied nutrients (i.e. the nutrients with sufficient data per physical state - i.e. with at least 10 affiliated recipes i.e. recipes differing only by their flavours or by the presence or absence of fibre):

Type of nutrients	Nutrients
Macronutrients	Carbohydrates, Fat, Protein
Vitamins and others	Vitamin A, B6, B12, C, D, E, K, beta-carotene, folic acid, pantothenic acid, choline, biotin, riboflavin, niacin, thiamine
Minerals	Calcium, copper, iron, magnesium, manganese, phosphorus, potassium, sodium, zinc, chloride, iodine, fluoride*, chromium*, molybdenum, selenium
Fatty acids	Alpha-linolenic acid, linoleic acid, polyunsaturated fatty acids PUFA, saturated fatty acids, monounsaturated fatty acids
Amino acids	Alanine, arginine, aspartic acid, glutamic acid, glycine, leucine, lysine, methionine, phenylalanine, proline, serine, threonine, tyrosine, valine, isoleucine, cystine*, histidine, tryptophan

*Effect of fibre on these nutrients was not studied by lack of data.

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Examples

We show here as examples the results obtained on vitamin C, the most unstable nutrient in liquid FSMPs, vitamin A and E.

Figure 1 Effect of flavours (A vs B) on the degradation rate of vitamin C at 1 year in liquid FSMP (p value=0,1659)

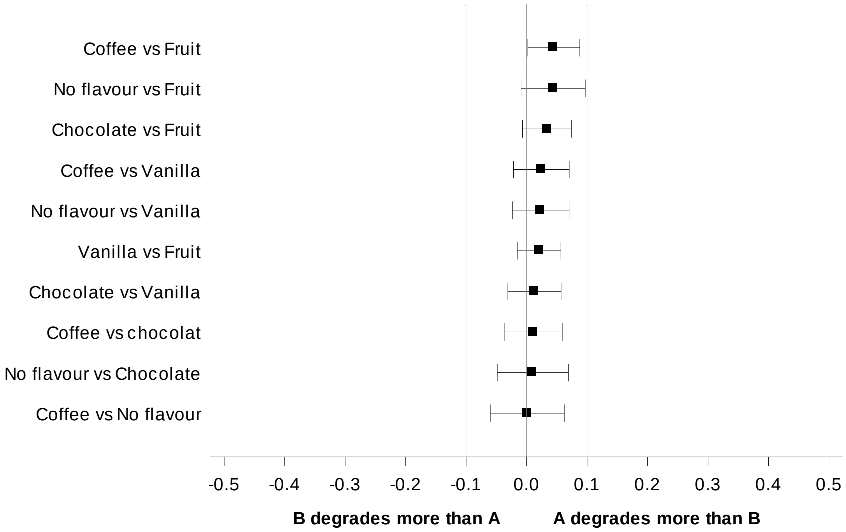

Figure 2 Effect of flavours (A vs B) on degradation rate of vitamin A at 1 year in liquid FSMP (p value=0,8116)

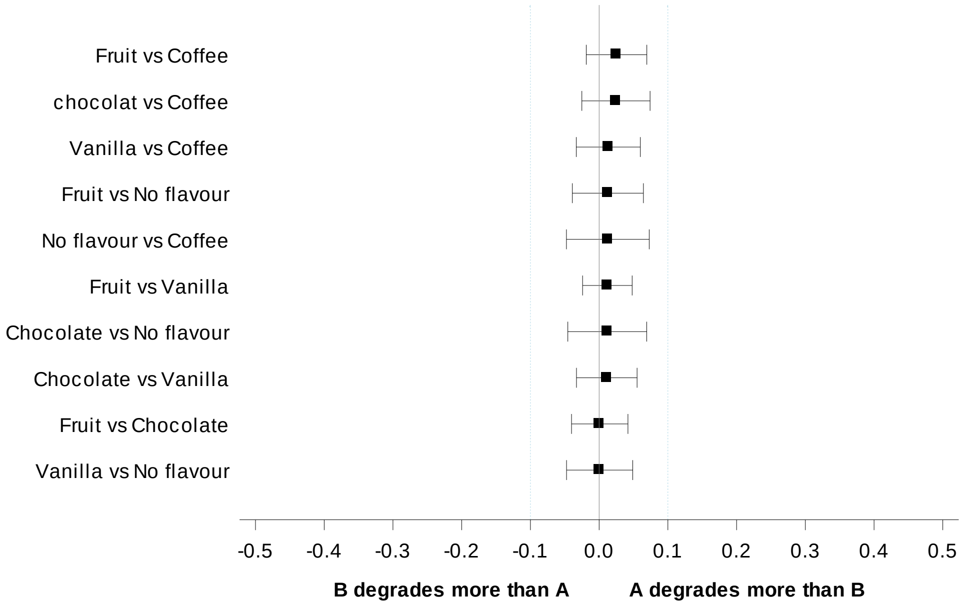

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Figure 3 Effect of flavours (A vs B) on degradation rate of vitamin E at 1 year in liquid FSMP (p value=0,6773)

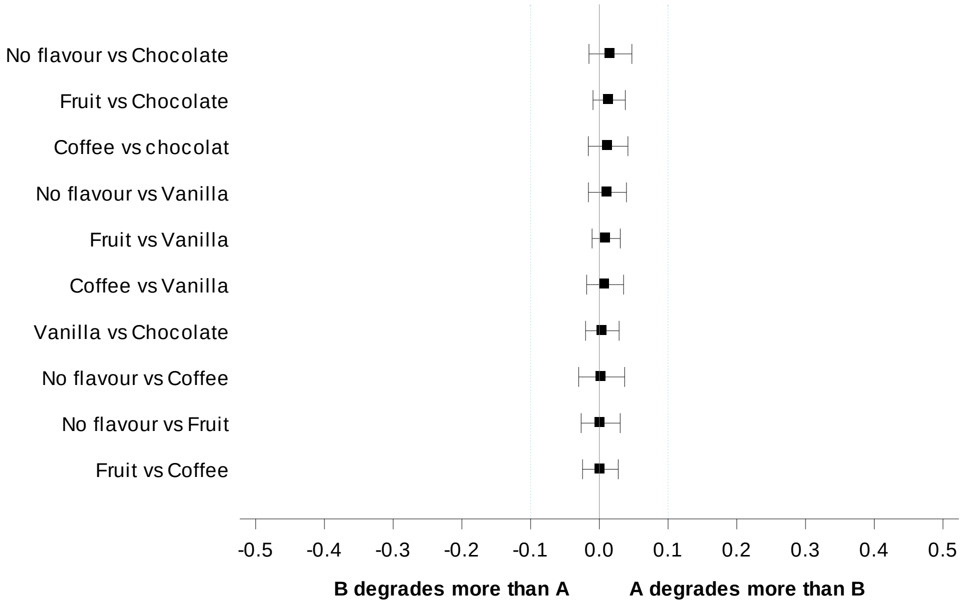

Figure 41: Vitamin C - Liquid - Effect of fibre on degradation rate of vitamin C at 1 year in liquid FSMP (p value= 0,1568)

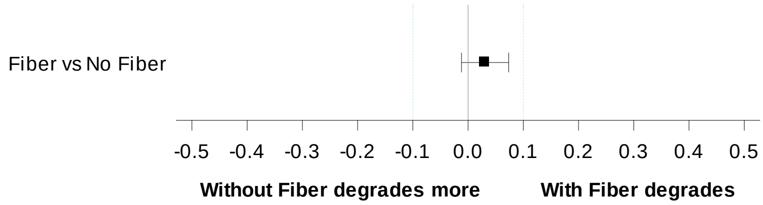

Figure 52: Vitamin A - Liquid - Effect of fibre on degradation rate of vitamin A at 1 year in liquid FSMP (p value= 0,4703)

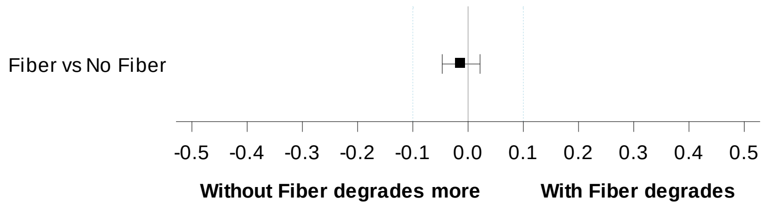

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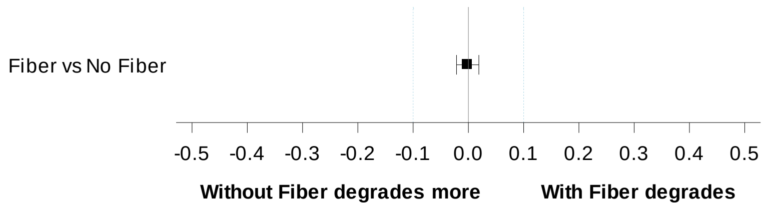
Figure 63: Vitamin E - Liquid - Effect of fibre on degradation rate of vitamin A at 1 year in liquid FSMP (p value= 0,9021)



Conclusion

Since flavours and fibre did not impact the stability of nutrients, it is not relevant nor required to conduct distinct shelf-life tests on FSMP products that only differ by their flavour or the presence or absence of fibre.

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Annex – Statistical Analysis

The full statistical analyses of the shared stability data were outsourced to SOCAR Research (SOCAR) a third party statistical provider. As part of this work, a specific statistical analysis was performed on the stability data of affiliated recipes. Affiliated recipes are recipes that only differ by a single parameter such as flavour or the absence or presence of fibre.

The impact of these specific single differences on the degradation rate of nutrients in the affiliated recipes was analysed using a three-level organizational model with a random slope nested by record ID (level 2) and Affiliated ID (level 3). The three-level organizational model enabled the grouping of the data available not only by record ID as the random effect but also by an upper affiliation ID nest.

The affiliation ID identified a group of records from the same recipe code and with the same characteristics related to physical state, age, fat content, type of protein hydrolysis, nitrogen flushed, pH, storage humidity, packaging type and packaging size and storage temperature. This analysis was performed for each nutrient and physical state (i.e. liquid, powder, paste) with sufficient data in at least 10 affiliation IDs. Only data for liquid recipes was used in the analysis of affiliated recipes due to the limited number of available data. This is not seen as an issue, since the main analysis had shown that powder products were generally stable and the only nutrient which was unstable was Vitamin A.

The goal of the analysis of the affiliated recipes was to show the equivalence on degradation rate for different values of the variable of interest. For example, to show equivalence on degradation rate across the different flavours. In order to show no effect of the variable of interest, the 95% confidence interval of the difference was compared with the stability limit (used as the equivalence margin). Nutrients were qualified as stable based on conservative limits. Nutrients were qualified as stable if the losses after one year were lower than 5% for macronutrients; less than 7.5% for fatty acids and less than 10% for vitamins & minerals, amino acids & nucleotides. In order to show equivalence, the 95% confidence interval must have been within the limit of the equivalence margin. In order to show a significantly relevant effect beyond the stability limits, the effect P value must be below 0,05 and the 95% confidence interval must exceed the limit of the equivalence margin. For fiber and flavour analysis, the estimate and 95% confidence interval of the effect difference between all possible 2 by 2 categories at 1 year (for liquid) was used for the statistical comparison.

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