Meeting

Isomalto-Oligosaccharides - Additional Information Discussion Paper

Committee Paper for Discussion - ACNFP/163/03

Advisory Committee for Novel Foods and Processes

Application for authorisation as a Novel Food for Isomalto-Oligosaccharides - Additional Information from applicant for review.

Application Number - RP1033

Issue

The Committee reviewed this application for the first time at the February 2023, and again at the June 2023 meeting, where members requested further information. The Committee is invited to consider the response from the applicant and whether it addresses the request for clarification satisfactorily or if further information is required.

A draft Committee Advice document is also provided for review and comment.

Background

1. On the 16th April 2021, the FSA received a submission for the extension of use for isomalto-oligosaccharides (IMOs) as a food ingredient from Bioneutra North America, Inc. IMOs are authorised as a novel food within the UK and the application was seeking to extend the permitted uses. As such the assessment has focused on any impact of the changes proposed by the applicant to the safety of the novel food.

2. IMOs are made by the hydrolysis of starch using an enzyme catalysis reaction, followed by filtration and purification steps to generate either a powder or liquid (syrup) form of the product. The extension of use for IMOs will increase the number of permitted food uses, and include food supplements.

3. The Committee reviewed this dossier for a second time at the 14th June 2023 meeting where further clarification was sought from the applicant in the following area:

- Proposed Uses

4. The Committee is asked whether the applicant's response addresses the outstanding questions from their request for information. To inform the discussion and further development of an opinion, the FSA's requested further information (Annex A) and the applicant's response (Annex B) are provided.

5. At the previous discussion members indicated they were willing to consider a draft of the Committee advice on the safety of the application. This has been prepared and is provide for comment and review in Annex C. It is noted that the section on proposed uses and the associated conclusions will need to be updated in light of the views of the Committee on the applicants response.

Applicant's response to request for further information

Proposed Uses

6. The Committee sought further information in order to understand the role of IMOs in food supplements with respect to the wider diet of groups taking the product and the potential for foreseeable misuse. Members requested that all the proposed formats for the food supplements were identified along with the dose per format and the calorific content per serving.

7. The applicant has updated the proposed use of IMOs in food supplements to a sweetener only. The previous proposed use as a prebiotic fibre in food supplements has been discontinued. The proposed formats of food supplements containing the novel food are chewable food supplements (25 g/100 g) and tablet food supplements (97 g/100 g). Previously, the proposed maximum intake for food supplements was 30 g/day (Annex B: Response to RFI Letter).

8. The applicant notes that the IMOs are no longer the main selling point of food supplements. Therefore, foods and food supplements containing the novel food could be consumed on the same day. The applicant has updated the intake assessment for the extension of use of IMOs using the UK National Diet and Nutrition Survey, 2016-2019 (Annex B: Attachment 1).

9. The applicant states that the total population (all ages) mean and 95th percentile consumer-only intakes of IMOs were reported as 28 and 65 g/person/day, respectively. Teenagers presented the greatest mean intake of IMOs on an absolute basis, at 35 g/day/person, while the highest 95th percentile of IMOs was determined to be 70 g/person/day, as observed in adults (Annex B: Response to RFI Letter).

10. The applicant states that this estimated intake assessment resulted in an overall reduction in the estimated daily intakes by all population groups when compared to those estimates derived from the EFSA Comprehensive database in the original dossier (high-level intakes of up to 113g). The applicant states that estimated intake for IMOs of up to 70 g/day is significantly lower than the clinical trial data that reported doses up to 120 g/day were well tolerated. Based on this information, the applicant considers the novel food is safe for consumers under the intended conditions of use (Annex B: Response to RFI Letter).

11. The Committee noted that in response to the previous RFI question concerning the high exposure of IMOs in certain sub-populations, there was a reference to the recommended levels of carbohydrates in the diet. Members sought further comments from the applicant as to whether there were any safety considerations if all the carbohydrates in a persons diet were in the form of a prebiotic dietary fibre.

12. The applicant states that the novel food is not intended to replace all carbohydrates in the diet, but is proposed to be used a specific range of foods. The estimated mean and 95^{th} percentile intakes of the novel food at up to 35 g/day and 69 g/day, respectively, are considered worse case scenarios (Annex B: Response to RFI Letter).

13. The applicant further states that the novel food is approximately 30% fibre. Based on the revised exposure assessment, the mean and 95^{th} percentile intakes of the fibre would be up to 10.5 g/day and 21 g/day, respectively. The applicant notes that it is highly unlikely that total habitual carbohydrate intakes would be replaced with IMO (Annex B: Response to RFI Letter).

Committee Action Required

- The Committee is asked whether the response from the applicant is sufficient to clarify the data gaps discussed at the last meeting.
- If not, the Committee is asked to indicate what further data is required and the feedback that should be given to the applicant.
- The Committee is also asked to review and comment on the draft output of the Committee advice on the safety.

ACNFP Secretariat

November 2023

Annexes

Annex A – Request for Information

Annex B – Applicant’s Response to Request for Information

Annex C – Draft Committee Advice on the Safety of isomalto-oligosaccharides extension of use