Meeting

Isomalto-Oligosaccharides (IMOs) Additional Information Discussion Paper

Committee Paper for Discussion - ACNFP/160/01.

Advisory Committee For Novel Foods and Processes.

Application for authorisation as a Novel Food for Isomalto-Oligosaccharides (IMOs) - Additional information from applicant for review.

Application number RP1033.

Issue

The Committee reviewed this application for the first time at the February 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.

Background

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 EU. As such the assessment has focused on any impact of the changes proposed by the applicant to the safety of the novel food.

1. 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.

2. The Committee reviewed this dossier for the first time on the 8th February 2023 where further clarification was sought from the applicant in the following area:

- **Proposed Uses**

3. 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.

4. 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

5. The Committee reviewed the additional proposed uses for the IMOs alongside the current authorised uses. Members queried the purpose of using IMOs as an ingredient in food supplements and are seeking clarification for this intended use.

6. The applicant has stated that the use of IMOs in food supplements is equivalent to the approved food uses, either as a prebiotic dietary fibre [no health claims to be sought by applicant] or as partial/total replacement for sweeteners (Annex B: p1 RFI response letter).

7. The Committee noted the recommendation that food supplements should not be used if other foods with added IMOs are consumed on the same day. Members sought clarification on the risk to consumers of co-consumption of multiple IMO containing foods, as no information was provided to explain why this warning statement was necessary.

8. The applicant has stated that this is a common approach with novel foods as consumers would not be expected to use both sources of IMOs on the same day

over a long period to time. The applicant requests that this recommendation be withdrawn given that there is no perceived risk associated with the estimated cumulative exposure (Annex B: p1 – 2 RFI response letter).

9. The anticipated intake for the extension of use of IMOs indicated high exposure levels in certain sub-populations. For example, in infants and the frail elderly, the high level intakes for the novel food are expected to double from 13 to 27 g/day and 44 to 88 g/day respectively. Members sought clarification concerning the impact of consuming IMOs by vulnerable consumers.

10. The applicant states that the estimated intakes are highly conservative due to the nature of intake assessment noting that there is a large variation in the reported high-level intakes in these population groups: a 5-fold difference in infants (5 to 27 g/day) and ~ 6-fold difference in the very elderly (from 15 to 88 g/day).

11. The applicant continues that this assessment is likely to represent an overestimation of the true high-consumer intakes in the UK population for the following reasons:

(a) the assessment assumes IMO is added to the intended food and beverages at the maximum use levels whereas in reality the levels added will vary depending on the manufacturing process

(b) it is unlikely that IMO will have 100% market penetration across all the proposed food categories.

12. The applicant highlights further reasons to support their position that the proposed uses of IMOs in foods will be safe for consumers (Annex B: p2 – 5 RFI response letter).

Committee Action Required

- The Committee is asked whether the response from the applicant is sufficient to clarify the concerns 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

June 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.