Meeting

LNFP-1 and 2’-FL – Additional Information Second Discussion Paper

Committee Paper for Discussion - ACNFP/159/03.

Advisory Committee For Novel Foods and Processes.

Application for Authorisation as a Novel Food for LNFP-1 AND 2’-FL

Additional Information from Applicant for review.

Application number RP549.

Issue

The Committee reviewed this application for the first time at the June 2022 meeting. At the February 2023 meeting, members requested further clarification concerning new information provided by the applicant. 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

1. On the 10th February 2021, the FSA received the submission for LNFP-1 and 2’-FL as a novel food from Glycom A/S. The oligosaccharides, LNFP-1 and 2’-FL are manufactured by fermentation with the production micro-organism, followed by a series of purification, isolation and concentration steps to generate the purified novel food ingredient. The oligosaccharides are intended to be used as an ingredient in a number of food products and food supplements.

2. Following a request for information which was reviewed by the Committee on the 8th February 2023, further clarification was sought from the applicant in the following area:

- Production Process

3. The applicant has provided a response to the Committee on this area and the Committee is asked whether this addresses the outstanding question from their request for clarification. 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), and further information (Annexes C and D) are provided.

Applicant's response to request for further information

Production Process

4. In a previous request for information concerning the variability of endotoxin levels in the novel food, the applicant remarked that this was due to continuous improvements in the production process. Members queried this statement as the changes referred to by the applicant were not identified in the application.

5. The applicant has responded by stating that no changes have been made to the fermentation or chemical downstream processes. However, in the full-scale production process described in the dossier, there are sterile filtrations (0.2 µm) at process steps 5A, 6A, 8A and 9A, whereas in the first production batches of novel food, sterile filtration was only conducted at step 8A. This accounted for the improvement in the level of endotoxin detected in the analysis of the product, after the change was implemented.

6. The new information provided by the applicant does not impact on the draft committee advice document already reviewed by the Members because the full-scale production process is described in the safety assessment.

Update to Specification of novel food

7. The applicant has informed the FSA of a slight modification to the L-fucose specification parameter, to 'sum of L-fucose and 2'-fucosyl-lactitol' (Annex C). Certificates of analysis have been provided covering six batches of the novel food (Annex D).

8. In addition, the applicant has made modifications to the internal analytical methods in response to a request by EFSA (Annex C).

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.

ACNFP Secretariat

April 2023

Annexes

Annex A – Request for Information

Annex B – Applicant’s Response to Request for Information

Annex C – Specification of LNFP-I/2’-FL

Annex D – Certificates of analysis for LNFP-I/2’-FL.