Meeting

3-FL – Additional Information Discussion Paper

Committee Paper for Discussion - ACNFP/157/02

Advisory Committee for Novel Foods and Processes

Application for Authorisation as a Novel Food for 3-FL - Additional Information from applicant for review.

Application number RP1202

Issue

The Committee reviewed this application for the first time at the June 2022 meeting and requested further information on which to base their assessment of the novel food. Members are invited to consider the response from the applicant and whether it addresses the requests for information satisfactorily or if further information is required.

1. At the last meeting the Committee requested that the Secretariat draft an assessment output for this novel food for consideration, subject to the applicant's response to the request for further information addressing the outstanding question. The Committee is invited to consider the draft assessment output for this novel food in Annex A.

Background

2. On the 27th July 2021, the FSA received the submission for 3-FL from Glycom A/S. The oligosaccharide, 3-FL**,** is 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 oligosaccharide is intended to be used as an ingredient in a number of food products and food supplements.

3. The Committee reviewed the 3-FL dossier at a ACNFP meeting on 8th June 2022, where they identified an area requiring further clarification to assess the safety of the novel food and its proposed use. Information was requested on the

- **Composition**

4. The applicant has provided a response to the Committee on this area and the Committee is asked whether this addresses the outstanding questions on the dossier. To inform the discussion and further development of an opinion, the FSA's requested further information (Annex B) and the applicant's response (Annex C) are provided. The applicant has also provided a copy of a published p aper by Townsend et al (2007) concerning the level of endotoxins in powdered infant milk formula (Annex D). This annex was also provided for ACNFP 157/01.

Composition

5. The Committee remarked that the analytical data shows the presence of gram negative endotoxins in low quantities in the finished products. Members noted, however, that there was a marked variability in the content of these endotoxins between different batches of the novel food ingredient. Given the potential for adverse effects in vulnerable consumers, the Committee Members requested that the applicant provide further clarification concerning the variability in endotoxin levels in the novel food ingredients.

6. The applicant has responded by stating that the most likely reason for variability in the residual endotoxin levels is the continuous improvement during upscaling and refinement of the production process. The most recent batch has reported levels of <0.0003 EU/mg. The applicant expects future batches of the novel food to have levels of endotoxin close to most recent one reported.

7. The applicant has amended the data in Table 2.b.1.6-3 in the dossier because some values were reported for the wrong batches.

8. The applicant has assessed the potential exposure of endotoxins in the novel food ingredients to vulnerable consumers. The content of endotoxins reported in infant milk products by Townsend et al (2007) was compared to the calculated exposure level in infants from 3-FL at the recommended intake level. Based on this information, the calculated levels of endotoxins from 3-FL, 17 – 45 times lower than the levels reported in 53 out 75 milk powder products.

9. The applicant remarks that seven other human milk oligosaccharide products have already been reviewed and approved for the UK market with a specification of 10 EU/mg for residual endotoxins.

10. The applicant concludes by stating that based on the existing approvals of other milk oligosaccharides, the analytical data from batches of the novel food ingredients showing low levels of endotoxins, and the specification limit for 3- FL, there is no additional safety risk to vulnerable consumers.

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 assessment for this novel food.

ACNFP Secretariat December 2022

Annexes

Annex A – Draft Output for 3-FL

Annex B – Request for Information

Annex C – Applicant’s Response to Request for Information

Annex D – Copy of Published Paper by Townsend et al, 2007