Meeting

Xanthobacter sp. SoF1 Cells Further Information

Committee Paper for Discussion - ACNFP/174/04

Advisory Committee For Novel Foods and Processes

Application for authorisation as a novel food for Xanthobacter sp. SoF1 Cells

Application Number - RP1326

Issue

The Committee reviewed this application for the first time at the February 2025 meeting. Members advised further information was needed to support the assessment of the novel food. The Committee are invited to consider the response from the applicant and whether this addresses the requests for information satisfactorily.

The draft Committee Advice Document (CAD) has been updated with the applicant’s response to support the review of this novel food application. Members are asked to consider the CAD, with reference to the questions below, and provide comments.

If further information is required, the Committee’s advice is sought to clarify the remaining data gaps and the impact this has on the safety assessment of the novel food.

Background

1. In November 2021, the FSA received the submission for Solar Foods Oy for Solein®. The novel food is the dried microbial cells of non-genetically modified *Xanthobacter* sp. SoF1 and is intended to be used as a source of protein used in

breakfast cereals, noodles, bakery wares, processed egg and egg products, salad dressings, soups and broths, flavoured drinks, and protein products.

2. The Committee conducted a review of the application for the first time at the February 2025 meeting.

3. The Committee advised further data to be sought to support the progression of the review of this full novel food application. The applicant has provided additional information in the following areas:

- Identity.
- Production Process.
- Compositional information.
- Specification.
- Proposed uses and anticipated intake.
- Nutritional information.
- Toxicological information.

4. The updated draft CAD is attached as Annex A. The application dossier and the annexes to the dossier are attached as Annexes B and C, respectively. These contain confidential information. The FSA's request for further information (RFI) and the applicant's response to the RFI are included as Annexes D and E, respectively. These also contain confidential information.

Outstanding considerations for this application

5. To conclude the safety assessment for the novel food under the proposed conditions of use, Members are asked to identify the remaining data gaps. The CAD has been updated with the applicant's response to the queries raised following the previous review by the Committee. Where further data is requested, Members are asked to clarify the impact of the missing data on the safety assessment.

6. The Committee is asked to review the questions raised in the CAD on the identity of the novel food, production process, proposed use, nutritional information, and toxicological information, with respect to the information provided by the applicant. Members are then requested to consider the extent to which the applicant's response addresses these data gaps.

7. Identity: Information was previously requested on the taxonomy of the microorganism, the presence of AMR genes, pathogenicity and virulence factors,

and the production of secondary metabolites. Members views are sought as to whether the response addresses the information gaps.

8. Production process: Members requested information on the development of the master cell stock, the stability of the bacterial cell line and the critical control points in the production process. Comments are sought from the Committee as to whether this information addresses the issues raised.

9. Compositional information: Members views are sought on the updated information concerning the dietary fibre components in the novel food, and the content of uric acid, in the context of potential health concerns in consumers.

10. Proposed use: Members views are sought on the updated intake assessment for the novel food with respect to the content of iron and manganese present, and the protein quality of the novel food.

11. Toxicological information: The Committee previously identified the NOAEL for the novel food as the high dose. Members are asked to provide comments on how this information informs the margin of exposure and the assessment of the safety the novel food under the proposed conditions of use.

Committee Action Required

- The Committee is asked whether the response from the applicant is sufficient to address the issues raised by the Committee at the last meeting and reach a conclusion on the novel food.
- If not, the Committee is asked to indicate what further data is required to complete the review of the novel food. Members are also requested to clarify the impact of the missing data on the assessment.

ACNFP Secretariat

November 2025

Annexes

ACNFP-174-04-Annex A – Draft Committee Advice Document

ACNFP-174-04-Annex B – Dossier and References [Confidential]

ACNFP-174-04-Annex C – Annexes [Confidential]

ACNFP-174-04-Annex D – Request for Information (RFI)

ACNFP-174-04-Annex E – Response to RFI