Meeting

Akkermansia Muciniphila from the Akkermansia Company SA Additional Information

Committee Paper for Discussion - ACNFP/167/04

Advisory Committee For Novel Foods and Processes

Application for Akkermansia Muciniphila as a Novel Food from the Akkermansia Company SA (Previously A-Mansia Biotech SA).

Application Number RP1468

Issue

The application for pasteurised cells of Akkermansia muciniphila was reviewed in April and June 2023. Queries were raised on identity, production, composition, and specification, as well as proposed use. 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.

Introduction

1. An application was submitted to the Food Standards Agency in April 2021 by The Akkermansia Company SA (previously A-Mansia Biotech SA), for the authorisation of Pasteurised Akkermansia muciniphila (pasteurised cells of the bacterial species Akkermansia muciniphila) as a food supplement and as an ingredient in foods with special medical purposes (FSMPs), under the assimilated novel foods regulation (EU) 2015/2283.

2. This product has been authorised for use in the European Union (EU) as a food supplement and as an ingredient of foods with special medical purposes (FSMPs)

under regulation (EU) 2015/2283. It has yet to be assessed for authorisation in Great Britain.

3. Akkermansia muciniphila is a human gut commensal, non-motile, non-spore forming, elliptical bacterium. The species accounts for between 1% and 5% of healthy intestinal microbiota.

4. The applicant’s intention is to market Akkermansia muciniphila as a freeze-dried powder containing a minimum of 2.5x1010 total cells per gram and <500 viable cells per gram (<500cfu/g). This number of viable cells represent <0.000002% of total Akkermansia muciniphila cells in the final product. It is intended for use in food supplements at up to 5x1010 cells/day in the healthy population, excluding pregnant or lactating women.

5. The application was previously considered at the April and June 2023 meetings where queries were raised on:

- Identity,
- Production
- Composition
- Specification
- Proposed use

6. A draft Committee Advice Document is attached as Annex A for comments by members.

7. Copies of the applicant’s responses to the FSA’s Requests for Further Information are provided in Annex B and Annex C, which includes supplemental information to the RFI responses. Annexes B and C both contain confidential information.

This application

Identity and composition

8. Following Committee review, further information was sought on the analyses used to confirm the identity of the bacterium at various stages of the production process including the finished final product. The applicant has responded with further information on the methods and protocols used.

- The Committee are asked if the applicant’s response sufficiently demonstrates the identity of the bacterium used during the production process and within the final novel food product? As well as whether the novel food complies with the specification.
- The Committee are also asked to advise on which risks, if any, are associated with the virulence factors and antimicrobial resistance genes identified in the bioinformatic analyses? Furthermore, which evidence supports the conclusions that the identified virulence factors and antimicrobial resistance genes are not a safety concern?

Production process

9. Further information was sought under the production process section of the novel food dossier, surrounding the analysis of risks and how they are managed by the applicant. Further information has since been provided, seeking to demonstrate that critical control points have been identified and are managed appropriately to ensure that specific hazards are addressed.

- Considering the information provided, the Committee are asked to advise whether the information indicates there are additional risks in the process that need to be managed?
- Members are also asked if sufficient information has been provided to inform the risk assessment of the novel food?

Composition and specification

10. Queries were raised during the review of the dossier on batch-to-batch variation and to what extent this is reflected in the specification. It was noted that not all the batch data provided indicated that the specification for viable cells were met. As such the effectiveness of the specification in controlling their product quality was explored.

11. It was noted that the specification for this novel food sets the number of viable cells at 500 colony forming units per gram (<500cfu/g). This differs from that identified by European Food Safety Authority (EFSA) in their scientific opinion of Akkermansia muciniphila, which suggests a proposed limit on the number of viable Akkermansia muciniphila cells to be less than 10 colony forming units (<10cfu/g). In order to prevent possible adverse effects on gut barrier integrity and balance of the microbiota in susceptible people.

12. The applicant has now provided justification for setting specification limits at the levels proposed. This includes information for how the specification is used in managing their production process.

- The Committee are asked whether the response provides the information needed to ensure the specification is appropriate in characterising and managing identified risks for the novel food?
- The difference with the level of viable cells proposed in this application of 500 CFU per gram to that recommended by EFSA of 10 CFU/g was noted. Members advice is sought on whether the proposed specification for viable cells is justified to support the safety of the novel food under the proposed conditions of use?
- Advice is also sought on how any difference in scientific thinking on the viable cells point should be captured in the assessment.

Proposed Use

13. The Committee explored how the product would be presented within the food category ‘Foods with Special Medical Purposes’. Queries were also raised on the reasoning for inclusion of Children aged 12 to 18 within the target population for the novel food and how this would be managed. In response information on the types of food product intended for market have been given and the applicant provides clarification for the target population.

- The Committee are therefore asked whether the necessary evidence has been presented to support the safety of the novel food for the target population identified by the applicant?
- Does the assessment need to comment on any risks for vulnerable consumers?

Toxicology

14. In developing the CAD the following questions were raised by the Secretariat on which Committee advice is sought.

- Based on the evidence presented and the previous views of the committee is appropriate to identify a toxicological point of departure for this novel food? If not, what factors should influence the identification of a safe upper intake?
- If a point of departure can be identified how should the evidence from the 90- day study and the human study be weighted in the Committee’s view?

Committee Action Required

- The Committee is asked to note the response from the applicant and is asked whether the responses from the applicant are sufficient to complete the risk assessment.
- If so, the Committee are also asked to review and provide comments on the draft Committee Advice Document attached as Annex A.
- If not, The Committee is asked to indicate what additional data would be required and if there are additional issues to be explored to complete the assessment.

Secretariat
June 2024

Annexes:

Annex A – Draft Committee Advice Document
Annex B – RFI questions and applicants response following the 159th ACNFP meeting
Annex C – RFI questions and applicants response following the 160th ACNFP meeting