Committee paper for discussion **ACNFP/149/02**

Advisory Committee for Novel Foods and Processes

BARLEY RICE PROTEIN – NOVEL FOOD DOSSIER – RP19

Issue

The Committee reviewed this application for the first time at the April 2021 meeting, and requested further information on which to base their assessment. 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.

Background

1. On the 9 January 2021, the FSA received a dossier from Evergrain for authorisation of barley rice protein, a mixture of protein from barley at levels of 0-100% and rice at levels of 0-60%. The applicant intends to market the product within the food categories: bakery products, breakfast cereals, spreadable fats and dressings, grain products and pastas, snack foods, jam, marmalade and other fruit spreads, candy/confectionery, dairy and dairy imitates, dessert sauces and syrups, meat imitates, soups and soup mixes, savoury sauces, legume-based spreads, nut-based spreads, energy drinks, foods and beverages intended for sportsmen and meal replacements for weight control.

2. The Committee reviewed this application at the 147th ACFNP meeting of April 2021, and concluded that further information be requested from the applicant to inform the safety evaluation of their application. Information was requested on the

    - **Identity and Composition**
    - **Production Process**
    - **ADME/Nutritional information**
    - **Toxicology**
    - **Allergenicity**

3. The FSA's request for further information and the applicant's response are included as **Annexes A** and **B (confidential)**, respectively.

Identity/Composition

4. In reviewing the application further information was requested to characterise the raw material more fully. Questions were raised to clarify the reason for the variability in starting materials and its implications on the product's composition. In their response the applicant describes the brewing process and the origin of the raw material. They also provide proximate analysis information of the starter material as a function of the ratio of rice to barley (Figure 1).

5. The applicant argues that despite the high degree of variability in the ratio of barley to rice, there are no appreciable differences in specific parameters of the starting materials. They state that the production batches presented in the original application demonstrate that the final product contains minimal batch-to-batch variation. They also describe a series of processes of microfiltration and processing that would reduce the risks posed by the ingredient variability.

6. The Committee asked to clarify whether the substance is a protein mix or a protein hydrolysate. The applicant did not explicitly define the food as a hydrolysate, but explained that glucoamylase is used to hydrolyse the starch and a protease to hydrolyse and solubilise the protein fraction, concluding that the product is "produced by selective isolation of the protein fraction of barley and rice".

Production process

7. The applicant was requested to provide further detail on the different steps of the production process, as well as detail on the temperatures to which the product may be exposed. In their response the applicant provided further information on the process and the products in each fraction of the filtration process.

8. The Committee requested information on the enzymatic digestion process, identifying factors such as peptide size, fractions filtered and peptide composition of the final ingredient. The applicant described the molecular weight distribution of the protein fraction in the final product, with the use of Figure 3.

9. The applicant was requested to compare the amino acid profile of the novel ingredient to proteins such as dairy, meat and other relevant, non-plant sources. This was to inform the assessment of the potential for nutritional disadvantage from consuming the novel product in preference to other commonly available sources of protein. A request was also made to clarify their views on the risk to patients with Phenylketonuria.

10. The applicant explained that the aim of the product is to replace other plant-based proteins and not animal-based proteins, arguing that it is very unlikely that the average consumer would replace or substitute all their protein intakes with

Barley Rice Protein. They also expressed that the use of labelling informing of the protein content of the food would allow consumers to self-regulate their exposure to phenylalanine.

ADME/Nutritional information

11. The Committee had previously challenged that the expected consumption of 10.5 g/day suggesting this could be an underestimation. The applicant recalculated the expected consumption based on a total protein intake value of 2.2 g/kg body weight/day. The new calculation estimated expected consumption to be 28 g/day. A worst-case scenario of 77 g/day was also considered by the applicant, but deemed unlikely.

Toxicological information

12. The Committee asked to provide more evidence on the presence of antinutritional factors and potential toxic compounds in the retentate fraction of the product after filtration. The applicant in their response described how the production process includes three pasteurisation steps. They also described, providing references, that treatment steps such as heat, soaking and germination reduce phytate and trypsin inhibitor content.

Allergenicity

13. The Committee requested that if the product was a hydrolysate that allergenicity profile be revisited as this would pose different allergenicity risks to a mixture of proteins. Consideration was requested of the risk to coeliacs from consumption of Barley Rice Protein. The applicant argues that the product contains peptides between 500 Da and 3 Da, indicating that the majority of peptides present in the raw material are readily digested into short peptides to form the protein fraction of the final product.

14. The applicant argues that the majority of allergenic proteins in barley associated with coeliac disease are expected to be readily digested, such that the final product may not present and increased risk to individuals with coeliac disease. They also claim that Barley Rice Protein would be no more or less allergenic than barley, and that products containing the novel food would be appropriately labelled in line with legal requirements.

Committee Action Required

- The Committee is asked whether the response from the applicant is sufficient to complete the risk assessment.
- If not, the Committee is asked to indicate what additional information would be required.

ACNFP Secretariat
August 2021

Annexes attached

Annex A – Request for further information (confidential)

Annex B – Applicant's response to the request for further information (confidential)