Committee paper for discussion **ACNFP/147/02**
Advisory Committee for Novel Foods and Processes
Barley Rice Protein – Novel Food Notification – RP19

Issue

1. A notification for the novel food "barley rice protein", has been received under Regulation 2015/2283.

2. The Committee is asked whether there are safety concerns with the proposed use of this novel food in the UK market. The information from the Committee will provide the basis for risk management decisions made by the UK.

Background

3. On the 9 January 2021, the FSA received a notification 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.

4. The FSA has until 4 December 2021 to provide a risk assessment on the safety of the novel food. The FSA requested additional information ahead of the assessment, to which the applicant responded within the allocated time period. The responses provided by the applicant have been included as part of **Annex A**.

5. The notification dossier is attached as **Annex A**. Relevant supporting information is attached as **Annex B.** Both contain confidential information.

This application

Identity of the novel food

6. The applicant describes the product as a powdered mixture of protein from barley (*Hordeum vulgare*) at levels of 0 to 100% and rice (*Oryza sativa*) at levels of 0 to 60%. Barley leaf and grain/seed and rice seed would be the parts used by the applicant to produce the novel food. The ingredients originate from North America and Europe.

Production process

7. A confidential description of the production process was provided, describing how barley rice protein uses primarily mechanical processes to be manufactured. pH adjusting agents, a glucoamylase and a protease for hydrolysis are also used.

Enzymes are deactivated by heat treatment. Additional information on the production process can be found in the applicant's response to the request for information.

Compositional data

8. The application describes the novel food's composition as similar to that of barley and rice, and presents data from five different batches, providing information on proximate analysis (**Table 2.c.1.1.1-1**), heavy metals (**Table 2.c.1.1.2-1**), four batches on microbial contamination (**Table 2.c.1.1.3-1**) and five batches on mycotoxins and secondary metabolites (**Table 2.c.1.2.1-1)**. The applicant claims that no pesticides were detected in any batch.

9. The application shows a table comparing the amino acid profile of 4 production batches of barley rice protein to barley and rice (**Table 2.c.1.2.2-1**).

10. Two stability studies are presented, one under accelerated conditions (40ºC, 75% relative humidity for 24 weeks) and under the intended conditions of use for a certain food type example (0-5ºC). The applicant provided a response on the generic storage conditions for the novel food, describing it would be stored in 20kg paper bags, in dry, ambient temperature. They propose a shelf-life of up to 24 months.

Specifications

11. The applicant provided a specification table for the product (**Table 2.d-1**):

Table 2.d-1 Specifications for Barley Rice Protein

Barley rice protein is an off-white powder, produced by concentration of proteins from a mixture of barley and rice from the mash step of beer production using a series of enzymatic hydrolysis and mechanical purification steps.

Specification Parameter	Specification Limit	Method
Chemical Parameters		
Protein (dry basis)	≥85%	AOAC 990.03; AOAC 992.15
Moisture	<8%	AOAC 925.09
Heavy Metals		
Arsenic	<0.1 mg/kg	AOAC 844-856 (modified)
Cadmium	<0.1 mg/kg	AOAC 844-856 (modified)
Lead	<0.2 mg/kg	AOAC 844-856 (modified)
Mercury	<0.1 mg/kg	AOAC 844-856 (modified)
Microbiological Parameters		
Aerobic plate count	<30,000 CFU/g	AOAC 966.23
Coliforms	<10 CFU/g	AOAC 991.14
Yeast and mould	<50 CFU/g	FDA BAM Chapter 18
Salmonella	Negative in 25g	AOAC-RI 121501
Escherichia coli	<10 CFU/g	AOAC 991.14

Staphylococcus aureus	<10 CFU/g	AOAC 2003,07
Listeria spp.	Negative in 25g	AOAC PTM 081401

AOAC= Association of Official Analytical Chemists; CFU= colony-forming units; FDA BAM= Food and Drug Administration Bacteriological Analytical Manual.

History of use of the novel food ingredient and/or of its source

12. The novel food ingredient barley rice protein has no history of use in the UK. The application describes how the novel ingredient is formed of well known ingredients, barley and rice, and that the amino acid profile of the novel food is significantly similar to both ingredients. According to FAOSTAT, barley was consumed at a rate of 0.48 kg/capita/year and rice at 6.76 kg/capita/year.

Proposed uses and use levels

13. The dossier indicates that barley rice protein is intended to be used as a vegetable protein source in foods except infant formula and follow-on, and provides a table indicating max concentration levels of the novel food as an ingredient in a variety of food products (**Table 2.f.2-1**).

14. The novel food is intended to be used as a substitutional vegetable source of protein, and is compared to rapeseed protein for daily intake and role in the diet. Since it is intended to act as a substitute, it is not expected for barley rice protein to increase the protein daily intake of the UK population. Intake estimated levels are described in **table 2.f.3-1**.

Absorption, distribution, metabolism and excretion

15. The applicant indicates that the novel food is expected to be hydrolysed and digested in a similar manner as other dietary proteins, based on the similarity of composition with rice and barley. They provided studies on digestibility of cooked and uncooked barley and rice in the “nutritional information” section.

Nutritional information

16. The document identifies a conclusion by the NDA EFSA panel stating that “protein intakes between 0.83 and 2.2 g/kg bw/day are considered safe”, and that, given how barley rice protein is intended to substitute other plant-based protein products, it is unlikely that its intake will reach 2.2 g protein/kg bw/day.

17. The applicant acknowledges the presence of anti-nutritional factors such as trypsin inhibitors, phytic acid and phytohaemagglutinins. They claim that the filtration processing and thermal processing steps when producing the novel food are expected to remove natural toxins and antinutritional factors. Additional information is contained within the responses to the FSA request for information document.

18. A confidential study on protein digestibility is presented in the document, concluding that the novel food would be readily digested. Furthermore, a series of

indicators are given to characterise the nutritional value and protein quality evaluation of barley rice protein, based on the two components of the ingredient. A protein efficiency ratio (PER) of 1.5 for rice and 1.7 for barley; a biological value (BV) of 74% for rice and 70% for barley; a net protein utilisation (NPU) of 74% for rice and 62% for barley; a protein digestibility-corrected amino acid score (PDCAAS) of 60% for barley rice protein; a digestible indispensable amino acid score (DIAAS) of 35.7% for infants, 43.3% for children and 51.4% for older children, adolescents and adults.

Toxicological information

19. The document followed a tiered approach to safety evaluation as defined by the International Life Sciences Institute. According to this, traditional animal toxicology studies are not necessary if there is a history of use of the ingredients in foods, if the ingredient is fully characterised, the nutritional implications of the ingredient are fully assessed, and if no biological effects are identified from clinical studies. The applicant concludes that all of these points have been addressed in the dossier and that no further testing is necessary.

Allergenicity

20. The application identifies a series of food allergens present in barley (**Table 2.j-1**), including alpha-amylase inhibitor BMAI-1 precursor (Hor v 15), alpha-amylase (Hor v 16), beta-amylase (Hor v 17), gamma-hordein 3 (Hor v 20), profilin (Hor v 21), and lipid transfer protein (Hor v LTP). Similarly, allergenic proteins in rice such as trpsin alpha-amylase inhibitors, beta-expansin and profilin A are presented (**Table 2.j-2**). The literature evidence presented suggests that allergy to barley and rice is rare and that its frequency varies amongst populations, and the applicant proposes to label the product in accordance with Annex II of Regulation 1169/2011, by which barley is listed as an allergen subject to labelling.

Committee Action Required

- Members are asked whether there are safety concerns with this novel food and/or if additional information is required to assess it.
- The Committee's advice will form the basis for the UK's formal risk assessment for the novel food.

Secretariat

March 2021