Application for consultation to determine the status of a novel food, pursuant to Article 4(2) of the above Regulation

Mung bean protein
Recipient Member State: UK Food Standards Agency (FSA)

Name and description of the novel food concerned:

The food is an isolate of mung bean (Vigna radiata) flour in which a series of mechanical processing steps removes some of the fat and carbohydrate fractions. The resulting protein rich product consistent with the Codex standard for vegetable protein products. It is intended to be used as an alternative protein powder in a range of health food products.

The dossier highlights no suggestion that this should not be considered as food. No medicinal or drugs considerations were highlighted. No information is highlighted to suggest that the isolate is performing a technical function in the food and therefore should be considered as an additive. The purpose appears to be solely to replace proteins from other sources for example in vegan and vegetarian products.

Status – Novel food

Novel food category (where applicable):

(iv) food consisting of, isolated from or produced from plants or their parts, except when the food has a history of safe food use within the Union and is consisting of, isolated from or produced from a plant or a variety of the same species obtained by:

— traditional propagating practices which have been used for food production within the Union before 15 May 1997;

Reasons statement:

History of consumption

It is clear mung beans (Vigna radiata) have a history of consumption. Mung beans were previously known as Phaseolus aureus and the two names can be considered as synonymous. The change in nomenclature is parts of wider taxonomic changes explained in the further literature provided the applicant. Powdered forms of mung bean / mung bean flour have been used in the EU prior to 1997. Information is provided in the dossier to substantiate that significant history of consumption for the source material. There is no history of consumption for the isolate directly.

Composition

The key issue that the dossier focusses on is to what extent the mung bean protein isolate is different to mung bean flour and arguing therefore the existing history of consumption for mung beans should apply.
The isolate is produced by mechanical process that separates the protein and fibre / starch and utilises pH adjustments and ionic adjusting agents as part of the process. The product is pasteurised before being spray dried.

Information on the composition of the product was provided by the applicant. The proximate analysis confirms that the fat, moisture and carbohydrate fractions of the flour are reduced in the process.

The applicant has explained that the product is on the market outside the EU since November 2017 (Asia and the USA) in the form of a liquid egg substitute containing 12g of the ingredient per serving. No adverse events have been reported in relation to the over 30,000 servings that have been sold.

**Intake**

The product is intended for use in a wide range of products including crackers, beverages and snacks. It is intended to replace other protein sources in products. The applicant has undertaken an assessment to consider the exposure for consumers for consuming the product as compared to eating a 120g portion of mung beans. The applicant suggests the level of addition of the protein ingredient is between 3-20% of the final product, which is less than the ~24% protein in the portion of mung beans.

**Conclusion**

An enquiry on the novel food status from the applicant was considered by the UK under Regulation 258/97. The UK had reached a view based on the evidence provided and after discussion with Member State colleagues. The initial view was that for the reasons below it would be considered a novel food;

- A history of consumption had not been demonstrated for the isolate
- That the final product was different from the starting material and that there may be differences in exposure because of the concentration of the protein component.
- The extraction was selective, in that the protein as a whole had been concentrated relative to the starting material although only by three times the starting level.

The UK reviewed the information from a comparative perspective and arrived at an opinion of not novel.

After further discussion with EU counterparts at the January 2019 Novel Foods Working Group Meeting, the UK agreed to review the information and reconsider its original decision of novel status. **The UK therefore regards the Mung bean protein isolate as novel.** The decision has been made on the basis that there is not a significant history of consumption for the isolate and the proposed food is consequently deemed novel.