Meeting

Dry Cacaofruit Cascara Discussion Paper

Committee Paper for Discussion - ACNFP/168/07

Advisory Committee For Novel Foods and Processes

Application for Authorisation of Dry Cacaofruit Cascara as a Novel Food.

Application Number RP1484

Issue

An application has been received under the novel food authorisation process (regulation 2015/2283 as retained in UK law) for Dry Cacaofruit Cascara.

The Committee is asked to advice on whether the available data provides an adequate basis for a risk assessment, and whether the novel food is safe and not nutritionally disadvantageous under the proposed use and use levels. To support the evaluation a draft Committee Advice Document has been prepared.

Background

1. In March 2022, the FSA received the submission for Dry Cacaofruit Cascara from Cabosse Naturals N.V. The novel food is the outer husk of the cacao fruit that has been emptied off the cacao beans, cleaned, dried and ground into a powder. It is proposed to be used as an ingredient in various foods and beverages for the general population.

2. The application dossier is attached as Annex A, the annexes to the dossier attached as Annex B and subsequent information requested ahead of the review in Annex C. All annexes contain confidential information.

This Application

Identification

3. The novel food is the outer husk of the cacao fruit that houses the cacao beans. This husk, referred to as cascara is further processed into a powder once the contents have been removed for chocolate production.

4. Taxonomy of the novel food and more details of the identity is provided in Annex A: 1.1.

Production Process

5. The production process for this novel food is described in summary in the Committee Advice Document and in detail in the dossier (Annex A: 1.2), with a flow chart provided. A non-confidential summary is also provided. HACCP has not been provided with justification and brief outline of mitigation of risks in the two requests for further information (Annex C).

6. Annex C also contains the requests made to the applicant in the initial assessment in relation to the production process where more detailed processing of the novel food was requested and provided (two RFI responses and supplementary annexes). GMP certificates and raw material information are provided (Annex B: Annex 4).

Composition

7. The applicant has provided analytical data for five independently manufactured batches of the dry novel food. Analysis was performed by accredited laboratories with certifications provided. Summary of the compositional data is in Annex A: 1.3, and all associated supplementary data provided (Annex B: Annexes 2).

Stability

8. The applicant carried out stability tests under conditions of 20°C for 24 months More detail of the study can be found in Annex B: Annex 6. A 24-month shelf life has been proposed.

Specification

9. The applicant has provided specification of the dry powdered novel food based on the composition of the product, as well as measured levels of microbiological contaminants. These were assessed using internationally recognised methods (Annex B: Annexes 2). The applicant concludes from the compositional analysis that the product consistently meets the proposed specifications for the novel food.

History of Use

10. The applicant has performed literature studies on the novel food details of which are in Annex A: 1.5 and references in Annex B: Annexes 3.

Proposed Used and Intake

11. The applicant states the target population for this novel food is the general population (Annex A: 1.6).

12. The food is to be marketed as an ingredient for various food categories primarily for sugar substitution and sensory improvement with maximum use levels provided. Supplementary information for this section can also be found in Annex B: Annexes 3.

13. The applicant states there are no concerns for combined intakes neither for undesirable substances related to the novel food.

Absorption, distribution, metabolism and excretion

14. No ADME studies were performed nor instigated. The applicant states that dry cacaofruit cascara contains components that are regularly digested and absorbed hence the novel food was not considered to give rise to safety concern (Annex A: 1.7).

Nutritional information

15. Proximate analysis was performed on five non-consecutive batches, with the applicant exploring the nutritional profile based on the novel foods’ composition and the implications of factors such as antinutrients (Annex A: 1.8).

Toxicological information

16. A bacterial reverse mutation test and an *in vitro* micronucleus test following Good Laboratory Practice (GLP) and performed in line with OECD test guidelines (471 and 487 respectively) were undertaken on the novel food with the reports provided (Annex B: Annexes 3).

17. A repeated-dose oral toxicity study in rats was also undertaken on the novel food. No concerns were raised (Annex B: Annexes 3).

18. Other toxicology information (chronic toxicity, carcinogenicity and human studies) was considered but based on the results from the aforementioned studies showing no adverse effects, the applicant deemed it unsuitable for further investigation (Annex B: 1.9).

Allergenicity

19. The applicant has considered the allergenicity potential of the novel food particularly from risk of cross-reactivity. A detailed summary can be found in Annex A: 1.10 and detailed reports in Annex B: Annexes 3. No concerns have been raised on allergenicity.

Committee Action Required

- The Committee is asked whether the available data provide a satisfactory basis for evaluating the safety of this novel food ingredient?
- If so, the Committee is asked whether it is content to recommend approval of the novel food as an ingredient to be added to the range of foods specified?
- If not, the Committee is asked to indicate what additional data would be required?

ACNFP Secretariat

August 2024

Annexes

Annex A - Dossier

Annex B - Annexes to the dossier

Annex C - Request for further information and response