COMMITTEE PAPER FOR DISCUSSION **ACNFP/132/07**

ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES
HOVENIA DULCIS FRUIT EXTRACT - DOSSIER 163

ISSUE

1. The German Competent Authority (CA) has prepared an initial assessment report on an application for *Hovenia dulcis* fruit extract under the Novel Foods Regulation (EC) No 258/97. The extract is to be sold in food supplements.

2. The Committee is asked whether it agrees with the initial opinion and whether it would like to make any further comments on this application. The Committee's advice will form the basis for the UK's formal response to the Commission.

Background

3. On 30 October the European Commission forwarded the initial opinion of the German Competent authority on an application made by Hovenia dulcis AB under Article 4 of the Regulation for *Hoodia dulcis* fruit extract. They view that as the applicant has not provided the further information required the application to place the product on the market should be refused.

4. The Commission has requested the views of Member States on the German CA's negative initial opinion. Member States have until 28 December to submit any comments and/or reasoned objections to the German opinion.

5. The German Initial Assessment Report is attached as **Annex A** and the application dossier is attached as **Annex B. Annex A and B** contain protected information.

This application

6. The applicant is seeking authorisation for *Hovenia dulcis* fruit extract. The extract is to be sold in food supplements with a recommended intake of 4-6 capsules; this corresponds to an intake of between 1640 and 2460 mg of extract per day. The product is not intended for children, pregnant women and nursing mothers.

7. The German CA is proposing a negative opinion for this dossier on the basis that the applicant has had three opportunities to provide the data requested and this has not been provided. The German CA considers that the applicant has not

responded to the deficiencies in the application namely insufficient characterisation of the novel ingredient, no evidence of the safe use of the product as a food in non-EU countries, and that the toxicological data did not clearly relate to the product applied for.

8. Based on the information the applicant has provided the novel food is a hot water extract of *Hovenia dulcis* fruit that is dried and then further purified using alcohol solvents in the EU where it is repackaged into food supplements. *Hovenia dulcis* has been consumed outside Europe particularly in Asia but has not been consumed in the EU and therefore is considered as novel.

9. The German CA has indicated concerns with the specification of the product. They felt more detailed analysis of the flavonoid component was needed and as a result taxifolin, myricetin, quercetin and dihydromyricetin have been added to the specification. They also indicated that in their view the specification for dihydromyricetin was too high when compared to the levels seen in the 6 batches tested. The primary concern was whether the material was appropriately characterised to understand the relevance of the toxicological data provided.

10. While the initial opinion indicates that no shelf life data is provided. The applicant makes comparison between the composition of the product produced in Korea verses the product purified and packaged in the EU. A study suggesting a 2 year shelf life of the powdered product produced in Korea is indicated in the German opinion. Studies have not been provided on the shelf life of the use subject to the authorisation as a food supplement.

11. The applicant has not provided an intake assessment for the novel food nor is an explanation of the dose selected provided. The suggestion is that the product does not replace other components in the diet and is therefore not nutritionally disadvantageous.

12. Information is provided on the use of the novel ingredient in populations outside of the EU namely in Korea, China and Taiwan. The applicant references data that suggest 5.2% Korean adults use the product, which approximately 2.5 million people. The German CA comments that while data on use of the fruit is provided this does not give an indication of quantities consumed to support the safety of the product.

13. The key concern of the German CA is in relation to the toxicological data. While they are keen to point out that they do not expect the product to be unsafe the data to establish safety has not been provided. No human studies have been provided. The information identified from literature on consumption of the product in humans was largely efficacy studies of potential beneficial effects on the liver particularly in processing alcohol. The studies while not suggesting adverse effects were not intended to capture parameters needed to establish a NOAEL.

14. Several toxicological studies in rats were provided one of which allowed identification of a NOAEL of 1 200 mg/kg/bw per day. The applicant has indicated that the same material was used, as they have sought authorisation. The German CA highlights that evidence of the composition of the test material in these studies was not provided and so their relevance to the assessment cannot be determined.

15. The applicant has not undertaken any studies to assess the allergenicity of the novel ingredient. A literature search has been undertaken which suggested that no allergy to the fruit had been seen in the populations consuming the fruit.

COMMITTEE ACTION REQUIRED

- Members are asked whether they agree with the initial negative opinion from the German CA, and whether they wish to make any comments on the application.
- The Committee's advice will form the basis for the UK's formal response to the opinion of the German CA.

Secretariat
November 2017

Annexes attached:

Annex A Application dossier for the approval of the *Hovenia dulcis.*

Annex B Initial Opinion of the German Authority – Official Sensitive