COMMITTEE PAPER FOR DISCUSSION **ACNFP/127/08**
ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES

PHYTOSTEROLS FROM XI'AN HEALTHFUL BIOTECHNOLOGY

ISSUE

The Committee reviewed this application for the first time at the January teleconference and requested further information on which to base their assessment. Members are invited to consider the response from the applicant and whether it considers substantial equivalence has been demonstrated.

Background

1. Under Article 3(4) of the Novel Foods Regulation (EC) 258/97, the Chinese company Xi'an Healthful Biotechnology has requested an opinion from the UK Competent Authority (CA) on the equivalence of their phytosterols with phytosterols sold by Archer Daniels Midland (ADM), for use in the same range of products

2. A non confidential version of the dossier was subject to a 21 day public consultation. This ended on the 2nd February 2017 and no comments were received on this application.

3. At the January teleconference Members requested further information in a number of areas

    a) Specifications

    b) Effect of the production process applied to the novel food

    c) Toxicology

    d) Intakes of the novel ingredient

4. A letter outlining the concerns raised with the applicant is provided in **Annex A**. The applicant has now provided a response to the Committee's questions **Annex B** with two appendices to provide supporting information.

a) Specification of the novel food

5. The Committee had commented that as that from the information provided it was difficult to determine the composition of the Xi'an Healthful Biotechnology product and therefore whether it was substantially equivalent. They asked for further information on the product and for this to be presented in a way that allows easy comparison. They also asked for the chromatograms to be labelled in such a way to allow ease of analysis.

6. The applicant has provided further information on the terms used in the dossier and suggested that the information provided previously from the compositional analysis can be represented. The Secretariat are seeking further clarification from the applicant on this and this will be shared with the Committee as soon as it is available. They have also provided a labelled chromatogram to support the data already presented.

b) Effect of the production process applied to the novel food

7. The Committee requested further information on the production process in particular any catalysts used in the process. They requested comments from the applicant on the rationale for the heavy metal contaminants analysed in order to ensure relevant metals had been tested for in the assessment. The applicant has responded to this with further information and a more detailed flow diagram in an appendix. They have commented and are undertaking further analysis for potential residues from the catalyst. This has yet to be received and is expected shortly.

8. The Committee also sought more information on the source material both in terms of the plant species used and the geographic origin. In response the applicant has explained that they produce products from two source materials soya and tall oil depending on the specifications of their client. The applicant suggests that it is the soya source phytosterol product that they are seeking substantial equivalence for in this application.

c) Toxicological information on the novel food

9. The Committee sought clarification on relevance of the toxicological studies presented in the dossier to the novel ingredient under assessment. In response the applicant has clarified that a number of studies included in the dossier were those from previous authorisations intended to show that the toxicity of phytosterol esters similar to theirs had been evaluated previously. The applicant has provided further information on studies undertaken on their novel ingredient and the results the applicant suggests support the safety of their novel ingredient.

d) Intakes of the novel ingredient

10. The Committee also sought an explanation from the applicant on how they would ensure that they were not extending the exposure to phytosterols by authorising this product. The applicant in response suggests that they will be using the phytosterol ester in line with the authorisation and that the intention is that their product be used as an alternative to other phytosterol products authorised for use by product manufacturers in the EU.

COMMITTEE ACTION REQUIRED

a) The Committee is asked whether the response from the applicant is sufficient to address the questions raised in January 2017.

b) If not, the Committee is asked to indicate what feedback should be given to the applicant.

Secretariat
January 2017

Annexes attached:

Annex A – Letter providing feedback to the applicant from the January teleconference of the ACNFP members

Annex B - The applicant's response to the request for further information.