COMMITTEE PAPER FOR DISCUSSION **ACNFP/113/1**

ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES

REFINED OIL FROM THE SEEDS OF BUGLOSSOIDES ARVENSIS

ISSUE

At the September meeting, the Committee was satisfied with the applicant's responses to its earlier questions. The Committee is now asked to consider a draft opinon for this novel ingredient and finalise its advice for recommending a post-market monitoring scheme.

Background

1. The Committee reviewed this application for the first time in June 2013 (ACNFP/111/2) and raised questions relating to production process details, human study data, toxicology studies and optional processing steps. At the September meeting, the Committee considered the applicant.s responses to its questions (ACNFP/112/1) and did not highlight any outstanding safety concerns. The Secretariat agreed to draft an opinon for the Committee's consideration at the November meeting (**Annex A**: Protect: Policy).

2. While the Committee's risk assessment did not highlight any safety concerns relating to the novel ingredient or its known constituents, the Committee remained mindful that neither the novel ingredient nor its source has a history of consumption anywhere in the world. The Committee therefore discussed the possibility of recommending some type of post-market monitoring scheme (such as adverse effects monitoring) following EU authorisation and it was agreed that this issue will be explored further before deciding on a particular recommendation, for inclusion in the Committee's opinion.

3. Introducing a <u>mandatory</u> postmarket monitoring scheme is ultimately a risk management decision that would have to be agreed by the UK Competent Authority and the other 27 EU Member States. To date, mandatory post-market monitoring requirements have been imposed on two novel foods:

    - **Phytosterol esters** (approved in 2000 for use in yellow fat spreads): the applicant was required to present data on consumption patterns for spreads with added phytosterol esters, in order to confirm the assumption that

consumption levels would be similar to existing spreads and that consumption would be restricted to the target group.

- **Lycopene** (approved in 2009 for use in a range of foods): authorisations were issued to a group of applicants with a requirement for each company to provide information, on an annual basis, on the lycopene-containing products that were launched on the EU market. This information will be used as part of a general review of lycopene safety and exposure from all sources (food colouring, food supplements, dietary sources and novel ingredient). This requirement was introduced as there were indications that some consumers might exceed the ADI that had previously been set for the food additive uses of lycopene.

4. From a risk assessment perspective, the Committee will wish to explain the reasoning for introducing the concept for this application, and how the information resulting from any post-market monitoring might be used.

5. One option would be for the Committee to consider a recommendation, addressed to the applicant, to closely monitor adverse reaction reports. Many food and food supplement manufacturers already operate such reporting systems, and ensuring that consumers can easily report any reactions to buglossoides oil would provide early warning of any unanticipated effects.

COMMITTEE ACTION REQUIRED

6. The Committee is asked:

    - whether it is content to recommend approval of Technology Crops International's refined Buglossoides oil; and

    - to review the draft opinion and indicate any amendments it wishes to make, including its views on the need for post-market monitoring.

Secretariat
November 2013

Annexes attached:

Annex A- Draft opinion (Protect-Policy)