Revision to the FSA/FSS opinions on five novel foods authorisation applications

The FSA and FSS recently consulted on six novel food applications for the Great Britain (GB) market. However, revisions to five of these opinions have subsequently been proposed, prior to advice being given to Ministers. While the proposed changes do not affect the safety assessment, stakeholder feedback remains crucial to the process of transparent policymaking. Hence, we are making stakeholders aware of these revisions.

Important

We welcome any additional comments on the minor amendments to the FSA/FSS' opinions on the novel foods applications outlined below. Comments should be provided within 2 weeks of the date of this publication and any comments received are subject to the same privacy statement as consultations, details of which can be found in our consultations privacy notice.

Comments should be emailed to: RPconsultations@food.gov.uk

About the novel foods

Our consultation on six novel foods applications was published on the FSA website on 17 December 2021 and ran for 8 weeks. This consultation has now closed and the next step is to provide advice to UK Ministers on authorisation of these novel foods.

However, we have identified a need to revise certain aspects of the terms under which the novel foods are proposed to be authorised. It is necessary that these revisions are made before advice is provided to Ministers and, as part of the FSA's commitment to open and transparent policy making, it is important that stakeholders are made aware of these changes and are given the chance to comment.

Taking into account the safety assessment of these novel foods, it is necessary to progress three of the applications as new additions to the authorised list of novel foods, rather than as extensions of current authorisations. This was also the conclusion made during the EU authorisation of these products, which are already authorised in Northern Ireland under the current terms of the Protocol on Ireland/Northern Ireland (NIP). The rationale behind this decision is highlighted in the revised opinions, which have been amended accordingly. The FSA/FSS opinions have also been revised to correct the headings for two of the applications.

Summary of revisions to novel foods opinions

- RP8 – 3'-sialyllactose (3'-SL): heading revised to refer to sodium salt;
- RP9 – 6'-sialyllactose (6'-SL): heading revised to refer to sodium salt;
- RP14 – 2'-fucosyllactose / difucosyllactose mixture: no change;

- RP87 – DHA-rich algal oil from Schizochytrium sp strain WZU477: change from extension of use to new authorisation;
- RP810 – DHA 550 (application to increase the daily intake of DHA from this source to 1000 mg/day in food supplements): change from extension of use to new authorisation for oil from Schizochytrium sp. strain FCC-3204. Under 'Proposed uses and use levels', the conditions of use are now presented in a table format; the batch analysis has been omitted from the Specifications table and the parameter p-anisidine added;
- RP811 – DHA 550 (application to extend the use to infant and follow-on formula): change from extension of use to new authorisation for oil from Schizochytrium sp. strain FCC-3204. Under 'Proposed uses and use levels', the conditions of use are now presented in a table format; the batch analysis has been omitted from the Specifications table and the parameter p-anisidine added.

Details of these changes and the rationales are included in the revised opinions document:

Scientific Opinions

Updated 31 March 2022:

PDF
View FSA and FSS novel food opinions as PDF(Open in a new window) (492.82 KB)

Additional requirements relating to labelling of food supplements

Furthermore, it is proposed that the following provision is put in place relating to application RP810:

- Labelling of food supplements containing Schizochytrium sp. (FCC-3204) oil shall bear a statement that they should not be consumed by infants and children under 3 years of age.

This is based on the intended use of the novel food in food supplements proposed by the applicant. The risk assessment was based on the proposed target population for use in food supplements, and as such the risk assessment conclusions do not conclude on the safety of the novel food to be used in food supplements for infants and children under 3 years of age. It is therefore necessary for the novel food to be labelled accordingly to reflect this, when used in food supplements.

Next steps

Following revision of the FSA and FSS opinions, any feedback to these revisions will be considered, along with the consultation responses, when finalising advice to UK Ministers.