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**Consultation on revisions to the Food Standards Scotland (FSS) opinion on five novel foods applications for authorisation and transfer of authorisation holder for five smoke flavourings**

**Summary of stakeholder responses**

16 May 2022

**Introduction**

This consultation was launched on 31March 2022 and closed on 13 April 2022. The Food Standards Agency (FSA) also released [an update](https://www.food.gov.uk/news-alerts/consultations/revision-to-the-fsafss-opinions-on-five-novel-foods-authorisation-applications) in parallel. This report is a summary of the FSS consultation responses and replies to these.

This consultation sought stakeholders’ views in relation to the authorisation of five novel food applications, which were submitted for authorisation to be placed on the GB market, in accordance with Retained EU Regulation 2015/2283. Stakeholder’s views were also sought regarding transfer of authorisation holder for five smoke flavourings.

This consultation followed an [original consultation](https://consult.foodstandards.gov.scot/regulatory-policy/publication-of-fss-opinion-and-consultation-on-nf/) on six novel foods applications for authorisation. In the original consultation, four of the novel food applications were extensions of use for an existing authorisations and two were new applications. Following the initial consultation, FSS and the FSA identified a need to revise five of the opinions, prior to advice being given to Minsters. The changes were identified through initial drafting discussions with lawyers, ahead of Scottish Statutory Instrument and Statutory Instrument drafting (should Ministers move to authorise). The changes relate to the way in which the authorisations would be entered on the list of authorised novel foods (retained Regulation (EC) 2017/2470).  The proposed changes do not affect the safety assessment of the novel foods. However, in the interests of transparent policymaking, FSS launched this second two-week consultation inviting public comment.

FSS’s opinions concerning three of these applications have been subsequently amended to proceed with them as new applications. As a result, in this second consultation five of the novel food applications were new applications and one was an extension of use for an existing authorisation. Additional minor revisions were made to the title of two of the applications, prior to advice being given to Ministers.

FSS’s opinions have been subsequently updated to reclassify the applications and correct the headings of RP8 and RP9 as follows:

* Authorisation of five new novel foods applications:
  + RP8 – 3’-sialyllactose (3’-SL) sodium salt;
  + RP9 – 6’-sialyllactose (6’-SL) sodium salt;
  + RP87 – DHA-rich algal oil from *Schizochytrium* sp strain WZU477;
  + RP810 – DHA 550 *Schizochytrium* sp strain (FCC-3204) (application to increase the daily intake of DHA from this source to 1000 mg/day);
  + RP811 – DHA 550 *Schizochytrium* sp strain (FCC-3204) (application to extend the use to infant and follow-on formula).
* Extension of the authorised use for one authorised novel food:
  + RP14 – 2’-fucosyllactose / difucosyllactose mixture;

Full details of the revisions to the opinions can be found [here](https://consult.foodstandards.gov.scot/regulatory-policy/five-nf-revisions-transfer-smoke-flavourings/).

Stakeholders were asked to consider any relevant provisions of retained EU law and factors (e.g. consumer interests, technical feasibility and environmental factors) that FSS and the FSA identified as relevant to these applications.

The novel foods and their conditions of use included in this consultation are currently authorised for use in Northern Ireland, in line with legislation that applies there, under the Northern Ireland Protocol.

The reach of this consultation was comprehensive, achieved through subscription alerts, social media posts and directly contacting stakeholders. This consultation was sent to 88 subscribers. Key stakeholders whose businesses/organisations are likely to be affected by, or to have an interest in, the novel foods and the smoke flavouring transfers of authorisation holder were contacted directly for their feedback. To ensure representation across a broad spectrum of opinion, stakeholders with an interest in infant nutrition, were included. This consultation generated 279 impressions on Twitter, 116 impressions on LinkedIn and 940 impressions on Facebook.

FSS is grateful to those who responded. The comments, together with FSS’s responses to these, are set out in the tables below.

**Characteristics of respondents and summary of responses**

This second consultation received 4 responses. 1 of these was regarding the novel foods and agreed with the risk assessment procedure. This was an anonymous response.

The remaining 3 responses were regarding the transfer of authorisation holders for five smoke flavourings, acknowledging the transfers. 1 response raised a minor concern regarding timescales. 2 of these were anonymous and 1 was from Kompozíció Kft, a smoke flavouring business operator.

A list of those who responded can be found below.

# **Summary of substantive comments and FSS response**

**Specific responses**

Question 1: Do you have any comments, concerns or other feedback regarding the amendments to the FSS opinions on the five novel food applications? Please specify which opinion(s) you are commenting on.

| Respondent | Comment | FSS Responses |
| --- | --- | --- |
| Anonymous | In agreement that we should make use of the EFSA risk assessment, where appropriate to make judgment on the safety of the products. | Comments noted. |
| Anonymous | Acknowledged | This question concerns novel food applications, but your comments are noted regarding the smoke flavouring transfers of authorisation holder. |
| Kompozíció Kft. | We accept these minor modifications regarding to the ownership of authorisations. | This question concerns novel food applications, but your comments are noted regarding the smoke flavouring transfers of authorisation holder. |

Question 2: Do you have any comments, concerns or any other feedback regarding the transfer of authorisation holder for the five smoke flavourings? Please specify which transfer(s) you are commenting on.

|  |  |  |
| --- | --- | --- |
| Respondent | Comment | FSS Response |
| Kompozíció Kft. | We accept these minor modifications regarding to the ownership of authorisations. | Comments noted. |
| Anonymous | Comment is given with respect to the transfer from the current authorisation holder to the new authorisation holder as well as in general.  The transfer of the holdership should happen sufficiently early enough before the 30 June 2022, so that the dossier for the re-authorization can be handed in by the new authorization holder. | Comment noted. We are currently planning for these transfers to be complete before the 30th of June 2022. |
| Anonymous | Acknowledged | Comments noted. |

Question 3: Do you have any other feedback?

|  |  |  |
| --- | --- | --- |
| Respondent | Comment | FSS Response |
| Kompozíció Kft. | We accept these minor modifications regarding to the ownership of authorisations. | Comments noted. |

**Next Steps**

* The next step of the authorisation process is for relevant Ministers in Scotland, England and Wales to make decisions on the authorisation of the novel foods.
* The FSS/FSA risk assessment opinions on these applications concluded that the products are safe to be authorised based on the proposed terms of authorisation. No reasons to change the advice that these novel foods should be authorised have been identified during the consultation process.  On that basis, the final advice to respective Ministers will be to authorise these novel foods on the proposed terms of authorisation.
* Should Ministers move to authorise, a Scottish Statutory Instrument will be prepared in Scotland, while a Statutory Instrument is prepared in England and Wales.
* Regulations in Northern Ireland will not be amended as the novel foods are already authorised for use in Northern Ireland, in line with EU legislation that applies in Northern Ireland, under the Northern Ireland Protocol.

**List of Respondents**

This list does not include those respondents who asked for their response to be kept confidential or responses from individuals.

1. Kompozíció Kft.