Consultation on applications for six novel foods

Summary of stakeholder responses

13 May 2022

Introduction

This consultation was launched on 17 December 2021 and closed on 11 February 2022. Food Standards Scotland (FSS) launched a consultation in parallel. This report is a summary of the consultation responses and the FSA's responses to these.

Stakeholders' views were sought in relation to the authorisation of six novel foods, which were submitted for authorisation to be placed on the GB market, in accordance with Retained EU Regulation 2015/2283. In the consultation, four of these applications were for extensions of existing authorisations and two were new applications. The FSA's opinions concerning three of these applications were subsequently amended to proceed with them as new novel foods. Additional revisions have been made to five of the applications, prior to advice being given to Ministers. These do not affect the safety assessments and were published on our website, with comments being invited for a period of two weeks.

The applications on which the consultation originally sought views were:

- Authorisation of two new novel foods:
    - RP8 – 3'-sialyllactose (3'-SL);
    - RP9 – 6'-sialyllactose (6'-SL);

- Extension of the authorised use for four authorised novel foods:
    - RP14 – 2'-fucosyllactose / difucosyllactose mixture;
    - RP87 – DHA-rich algal oil from *Schizochytrium* sp strain WZU477;
    - RP810 – DHA 550 (application to increase the daily intake of DHA from this source to 1000 mg/day);
    - RP811 – DHA 550 (application to extend the use to infant and follow-on formula).

The FSA's opinions were subsequently updated to class the applications and correct the headings of RP8 and RP9 as follows:

- Authorisation of four new novel foods:
    - 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 and RP811 – DHA 550 *Schizochytrium* sp strain FCC-3204.
- Extension of the authorised use and specifications for one authorised novel food:
    - RP14 – 2'-fucosyllactose / difucosyllactose mixture;

Read full details of the revisions to the opinions.

Stakeholders were asked to consider any relevant provisions of retained EU law and factors (for example, consumer interests, technical feasibility and environmental factors) that the Food Standards Agency (FSA) and Food Standards Scotland (FSS) identified as relevant to these applications.

The novel foods and their conditions of use included in this consultation are already authorised for use in Northern Ireland, through the EU's Regulated Products approval process, under the current terms of the Protocol on Ireland/Northern Ireland (NIP).

Consultation reach was comprehensive, with automatic notifications sent to 18,165 UK-wide subscribers of FSA alerts at the time of launch. Automatic notifications were also issued to FSA subscribers registered to receive updates in relation to national content - 20,580 subscribers to England, 11,317 subscribers to Northern Ireland and 12,003 subscribers to Wales. Key stakeholders whose businesses/organisations are likely to be affected by, or to have an interest in, these novel foods were contacted directly for their

feedback. To ensure representation across a broad spectrum of opinion, stakeholders with a range of interests in infant nutrition, were included.

The FSA consultation was also shared with the FSA's 58,300 Twitter and 87,200 LinkedIn followers. The FSA consultation page received approximately 2,100 views.

The update published on 31 March received 151 views.

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

Characteristics of respondents

A total of 3 responses were received to the FSA consultation. One response was from the trade association representing manufacturers of foods for specific groups, one from a Trading Standards Association and the third from a private individual. There were no responses to the parallel FSS consultation. The FSA received no responses to the update published on 31 March, the FSS received one. A list of those who responded can be found at the end of this document.

Summary of responses

The organisation representing industry was in favour of the authorisations. The individual respondent had no concerns, provided there was no issue with allergenicity. The local authority did not express an overall opinion, but responded with a series of questions. These concerned the proposed permitted levels and use of the ingredients in infant formula.

The full text of all responses received to the consultations is given in the tables below, together with our responses to these comments.

Comments received and FSA responses to these

General responses

Comments from the British Specialist Nutrition Association (BSNA)

The British Specialist Nutrition Association would like to acknowledge and welcome this consultation on these six novel foods and the work FSA and FSS are doing in this area. We have no detailed comments on this consultation.

FSA's Response

Comments noted.

Question 1: Do you have any concerns on the safety of the NFs which have not been considered below with respect to the intended consumers, stakeholders or impacts?

Comments from a private individual

I have no objection provided the ingredients do not include any item that is recognised as causing a problem for allergy sufferers, e.g. gluten.

FSA's Response

Comments noted.

The FSA has referred to the opinions of the European Food Safety Agency (EFSA), which took into account potential allergenicity.

With regard to 3'-sialyllactose (3'SL) & 6'-sialyllactose (6'-SL), the two new authorisations, the protein content in the ingredients is low. In addition, the applicant has assessed the allergenic potential of introduced proteins as a result of the genetic modification of the *E. coli* K-12 host (which itself is recognised as non-allergenic) using

the search algorithms provided by the Allergen Online tool (version 17) of the University of Nebraska (FARRP, 2017). No sequence alerts for potential allergenicity were identified and hence the likelihood of allergenic reactions to the novel foods is considered to be low.

Lactose, which some individuals may be intolerant to, is present as a level which is not considered to be clinically significant (3'-SL lactose content is 1.24± 0.64 w/w%, 6'-SL lactose is 2.26± 0.43 w/w%).

We also note generally that all prepacked food requires a food label which must display certain mandatory information. Where a food product contains any of the 14 allergens required to be declared by law, as ingredients, these allergens must be listed and emphasised within the ingredients list.

Comments from East of England Trading Standards Association (EETSA)

The two new applications of NF is [*sic*] authorised for use in Northern Ireland and the remaining four are existing NFs are already approved. The consultation states that the FSA/FSS has had access to all supporting documentation as provided to EFSA for forming the EFSA opinion. Officer's [*sic*] felt without any extensive understanding of the science underpinning these decisions, they would have to rely on expertise of the FSA/FSS and not in a position to raise any safety concerns.

FSA's Response

Comments noted.

Question 2: Do you have any comments or concerns on the impacts in consideration of authorising or not authorising the individual NFs, and if in favour of authorisation, the terms on

which the NFs are authorised (as outlined in the FSA/FSS opinions)?

Comments from East of England Trading Standards Association (EETSA)

There was some confusion over RP8 – 3'-Sialyllactose (3'-SL) Consultation document states for the labelling of food supplements 'Proposed terms for entry to the list of authorised novel foods - should not be consumed by infants and young children' However, the FSA/FSS opinions document states 'The applicant intends to add the NF in a variety of foods, including infant and follow-on formula, foods for infants and toddlers, foods for special medical purposes and food supplements. If 3'-SL is meant to be chemically identical to human breast milk, it was uncertain as to why it could not be used for infants or young children.

FSA's Response

The proposed terms for entry to the list of authorised novel foods excludes the use of 3'-sialyllactose (3'-SL) in food supplements for infants and young children (as stated in Table 1 of Annex A to the consultation document).

This applies to food supplements as defined by Directive 2002/46/EC on food supplements, rather than other foods which may provide a supplemental source of nutrition.

The terms for entry include proposed maximum levels of use. These are based on data provided by the applicant and take into account anticipated daily intake on a body weight basis. The anticipated daily intake of 3'-SL at the maximum proposed use levels is unlikely to exceed the intake level of naturally occurring 3'-SL in breastfed infants on a body weight basis.

Comments from East of England Trading Standards Association (EETSA)

There was also a query that if 3'-SL is so harmless, why would there be maximum limits on doses unless, like some vitamins and minerals there are maximum dosage limits. However, if it is being produced on the basis that it is "human identical" then presumably it would be promoted in in this way. Although it is noted that Infant Formula and Follow-on Formula Regulations prohibit the promotion of formula over breast milk.

FSA's Response

The terms for entry include proposed maximum levels of use. These are based on data provided by the applicant and take into account anticipated daily intake on a body weight basis. The anticipated daily intake of 3'-SL at the maximum proposed use levels is unlikely to exceed the intake level of naturally occurring 3'-SL in breastfed infants on a body weight basis.

Retained Commission Delegated Regulation (EU) 2016/127 on infant formula and follow-on formula does not permit the use of nutrition and health claims in the marketing of infant formula. Any nutrition or health claims used in the marketing of follow-on formula must comply with the provisions of retained Regulation (EC) No 1924/2006 on nutrition and health claims made on foods, and the claims must be listed in the Great Britain Nutrition and Health Claims Register. There are currently no permitted health claims concerning 3'-SL or 6'-SL on the Great Britain Nutrition and Health Claims Register.

Comments from East of England Trading Standards Association (EETSA)

Further feedback was also received about being uncomfortable with novel foods being used in infant formula or follow-on formula.

FSA's Response

The FSA's overarching mission is food we can trust, and we use a scientific, evidence-based approach to ensure food is safe and what it says it is.

Risk assessments on these novel foods were reviewed by the European Food Safety Authority (EFSA). In-house experts at the FSA subsequently reviewed the EFSA opinions and are satisfied in the conclusion that the use of these novel food is safe under the proposed conditions of use for the proposed target populations.

Question 3: Are there any other factors that should be considered by Ministers that have not been highlighted?

Comments from East of England Trading Standards Association (EETSA)

Whilst it is appreciated that if there is no GM material in the end product and therefore no requirement to label the product as GM, it was felt that the consumer should know GM material had been used, in particular, as it may be used in in infant or follow on formula.

Confirmation and validation independently by FSA/FSA Scotland that GM material is a processing aid and to access the science behind this claim.

Review of use of the term GM and inclusion where it is used as a processing aid.

FSA's Response

We support giving consumers choice and recognise that some people will not want to buy or consume GM foods. In the UK, foods must say on their label if they contain or consist of GMOs or contain ingredients produced from GMOs. Foods produced with the help of GM technology do not have to be labelled.

Both 3'-SL and 6'-SL are produced by fermentation of lactose and glucose with a genetically modified strain of *Escherichia coli* K-12 DH1. This is considered a safe and non-pathogenic or toxigenic microorganism, widely used for biotechnology applications. At the end of the production process, the production microorganism is entirely removed from the medium by filtration. The applicants demonstrate that no residual DNA from the production organism is detectable in the novel foods. The GM material meets the definition of 'processing aid' and is not an ingredient in the final product.

Question 4: Do you have any other feedback?

No responses received.

Next Steps

- The next step of the authorisation process is for relevant Ministers in England, Wales and Scotland to make decisions on the authorisation of the six applications.

- The FSA/FSS 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, Statutory Instruments will be prepared in England and Wales (and a Scottish Statutory Instrument in Scotland).

- Regulations in Northern Ireland will not be amended as the novel foods are already authorised for use in Northern Ireland, under the NIP.

List of respondents

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

1. British Specialist Nutrition Association (BSNA)

2. East of England Trading Standards Association (EETSA)