EXPLANATORY MEMORANDUM TO

THE NOVEL FOODS (AUTHORISATIONS) AND SMOKE FLAVOURINGS (MODIFICATION OF AUTHORISATIONS) (ENGLAND) REGULATIONS 2022

2022 No. 560

1. Introduction

1.1 This explanatory memorandum has been prepared by The Food Standards Agency (FSA) and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 The main purpose of this instrument is as follows:

Novel Foods

2.2 To authorise and update five novel food entries on the list of authorised novel foods, thus allowing them to be placed on the market within England.

2.3 Of the five novel foods to be updated on the list, one update is a change to the specifications and conditions of use of an existing authorised novel food. The remaining four are additions to the list of authorised novel foods, as established in Retained Commission Implementing Regulation (EU) 2017/2470.

Smoke Flavourings

2.4 Authorise the modification of the authorisation holders' names and addresses for five smoke flavouring primary products ("smoke flavourings") to align with companies which currently own these smoke flavourings. This will be reflected on the domestic list of authorised smoke flavourings, as established in Retained Commission Implementing Regulation (EU) No 1321/2013.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument is England and Wales.

4.2 The territorial application of this instrument is England only.

5. European Convention on Human Rights

5.1 As this instrument is subject to the negative resolution procedure and does not amend primary legislation, no statement is required.

6. Legislative Context

Novel Foods

6.1 Novel foods must be authorised before they can be placed on the market. Novel foods are a regulated product and require authorisation in legislation to be available on the market.

6.2 The legislative framework around the authorisation of novel foods is largely contained in the Retained Regulations (EU) 2015/2283, (EU) 2017/2469 and (EU) 2017/2470.

6.3 The Secretary of State for Health and Social Care has accepted the recommendation of the FSA that the five novel food products are safe and can be updated to the authorised novel food list, to allow their use in England.

Smoke Flavourings

6.4 Smoke flavourings are a regulated product. Smoke flavouring authorisations are applicant specific, and the authorisations expire after 10 years. This means that only the listed authorisation holder can apply for the authorisations to be renewed. Renewal applications must be submitted 18 months before the authorisations expires. These smoke flavouring authorisations expire on 1st January 2024.

6.5 The domestic list, Retained Commission Implementing Regulation (EU) No 1321/2013, established the list of authorised smoke flavouring primary products which includes details of the authorisation holders, specifications for each primary products and conditions of use when added to foods. It is, therefore, vital that the domestic list is kept accurate and up to date to ensure transparency and to ensure the current authorisation holders can apply for their authorisations to be renewed.

6.6 Under Article 11 of Retained Regulation (EC) No 2065/2003 on smoke flavourings used or intended for use in or on foods, authorisation holders must apply to the Appropriate Authority for modifications to their existing authorisations. This includes administrative changes such as change of address and authorisation holder.

6.7 This legislation is being made to modify the names and addresses of the authorisation holders in the domestic list.

7. Policy background

What is being done and why?

Novel Foods

7.1 This legislation relates to five novel food products for authorisation and updating the novel foods list. Of the five updates relating to novel foods, one is for an extension of use of an existing authorised novel food, the remaining four are new authorisations. The FSA opinion is that these novel foods products are safe.

7.2 The applications cover novel food products to be used as components in infant follow-on formula. Products one to three in paragraph 7.3 below are human-identical milk oligosaccharides (HiMOs). The manufactured HiMOs are identical in structure to the same molecules present in breast milk. Products four and five in paragraph 7.3 below are Docosahexaenoic Acid (DHA) rich oils derived from marine algae. DHA is mandatory in infant and follow-on formula in the UK under Retained Commission Delegated Regulation (EU) 2016/127.

7.3 The five novel food products are:

- 3'-Sialyllactose (3'-SL) sodium salt
- 6'-Sialyllactose (6'-SL) sodium salt
- 2'-Fucosyllactose/ difucosyllactose mixture (note this consists of a change to the conditions of use and specifications, not a new authorisation)
- Schizochytrium sp. (WZU477) oil
- Schizochytrium sp. (FCC-3204) oil application to:
  - Increase the daily intake of DHA from this source to 1000mg/day; and
  - Extend the use of the authorisation to infant and follow-on formula

7.4 Following this application process the FSA provides the Appropriate Authority with an opinion on the safety of the relevant novel food products, along with an outline of the other relevant factors provided for in the regulations.

7.5 Before leaving the European Union (EU), the United Kingdom (UK) accepted the assessments of the European Food Safety Authority (EFSA) in support of authorisation for regulated food and feed products. EU Food Law on novel foods uses continues to apply in Northern Ireland under the current terms of the Northern Ireland Protocol (NIP). Since the end of the implementation period, Great Britain (GB) has also adopted the same technical guidance and quality assurance processes to make independent GB risk assessments.

7.6 These novel food products were originally submitted to the EFSA prior to the end of the transition period on leaving the EU.

7.7 EFSA has published an opinion on these novel food products, this opinion and all supporting documentation has been reviewed by the FSA in forming an independent opinion based on risk assessment and safety conclusions. The FSA opinion in each case was that the novel food products, as described in the applications, are safe to humans and there are no concerns relating to the environment. A copy of the FSA opinions has been provided and is available here: www.food.gov.uk/news-alerts/consultations/revision-to-the-fsafss-opinions-on-five-novel-foods-authorisation-applications

7.8 All five novel food products have been authorised for use in the EU.

7.9 As part of the common framework agreements with the devolved administrations since the end of the transition period, the FSA has worked alongside Food Standards Scotland (FSS). Ministers in Scotland and Wales have also agreed to the authorisations of the novel food products and will be submitting their own Statutory Instruments in their respective countries.

Smoke Flavourings

7.10 The modification of five authorisation holders' names and addresses, and to amend the domestic list of authorised smoke flavourings, established in Retained Commission Implementing Regulation (EU) 1321/2013.

7.11 Retained Commission Implementing Regulation (EU) 1321/2013 established the domestic list of authorised smoke flavourings and sets out the named authorisation holder for each primary product. The process for modifying authorisations, or for applying for new smoke flavourings, is outlined in Retained Regulation (EC) No 2065/2003.

7.12 Under Article 11 of Retained Regulation (EC) No 2065/2003, authorisation holders must apply to the Appropriate Authority for any modifications to their entry on the domestic list, including any administrative changes, e.g., transfer of ownership, etc.

7.13 In addition, smoke flavourings must undergo a renewal process every 10 years. The current authorisations for smoke flavourings expire on 1st January 2024. Authorisation holders must submit their application for renewal to the Authority (FSA) by 30th June 2022.

7.14 Article 12 (1) of Retained Regulation (EC) No 2065/2003, states that only named authorisation holders can submit an application for renewal. This is because each authorisation assigns to a specific company. The impetus to make these changes at pace is, therefore, driven by the impending renewal submission deadline.

Explanations

What did any law do before the changes to be made by this instrument?

Novel Foods

7.15 The novel food products underwent the same processes before being added to the authorised list and made available on the EU market.

7.16 Following EU exit previously authorised novel food products by the EU continued to be authorised in GB under retained EU law. Directly applicable EU legislation for novel food products has been retained in the UK as retained EU law (REUL). Ministers are empowered under REUL to agree to the authorisation of novel food products.

Smoke Flavourings

7.17 Changes to the domestic list, as was, were enabled by EU legislation. Applications would be made to the competent authority of a Member State, with EFSA and the Commission assessing the application and undertaking the necessary changes as required.

7.18 Following EU exit, directly applicable legislation has been retained, with amendments made to ensure applications for modifications to existing authorisations are made to The Secretary of State for England in their capacity as the Appropriate Authority.

Why is it being changed?

Novel Foods

7.19 Retained EU law on novel foods requires novel foods to be authorised and included on the list of authorised novel foods before being placed on the market.

Smoke Flavourings

7.20 To modify the authorisation holders' details and update the domestic list of authorised smoke flavourings accordingly.

What will it now do?

Novel Foods

7.21 This will authorise and update five novel foods to the list of authorised novel foods, thus allowing them to be placed on the market within England.

Smoke Flavourings

7.22 This will ensure that the domestic list of authorised smoke flavourings is correct and up to date.

8. European Union Withdrawal and Future Relationship

8.1 This instrument does not relate to withdrawal from the European Union / trigger the statement requirements under the European Union (Withdrawal) Act 2018.

9. Consolidation

9.1 This instrument does not involve consolidation and there are no plans to consolidate the relevant legislation at this time.

10. Consultation outcome

Novel Foods

10.1 The public consultation on the novel food products being authorised and updated by this instrument was launched by the FSA and Food Standards Scotland (FSS) on 17th December 2021 and ran for eight weeks.

10.2 This consultation sought views from the public and stakeholders on the proposed novel food products under the specified conditions of use, to consider any relevant provisions under retained EU law and other legitimate factors. This included other evidence further supporting clear, rational and justifiable risk analysis, such as consumer interests, technical feasibility and environmental factors.

10.3 Stakeholders and enforcement authorities were informed of the consultation being launched and were encouraged to comment. This included nutrition associations, scientific advisory committees, health food manufacturers and more to ensure a broad spectrum of opinion.

10.4 The FSA public consultation had a broad reach, through the FSA website, subscription alerts, social media posts and direct contact with key stakeholders. There were 18,165 subscribers to UK wide FSA alerts, and a further 43,900 subscribers to country specific England, Wales and Northern Ireland alerts received automatic notifications.

10.5 The FSS consultation also had an extensive reach, through the FSS website, subscription alerts, social media posts and publication in relevant reports. A link to the consultation was sent to 89 subscribers to novel foods updates, 22 interested parties with Scottish Government and sent directly to local authorities.

10.6 On social media the FSA consultation was shared with 58,300 Twitter followers and 87,200 LinkedIn followers, while the FSS consultation was shared with 5267 Twitter followers and 2095 LinkedIn followers.

10.7 A total of three responses were received to the FSA consultation. FSA consultation attracted responses from industry, non-government organisations (NGOs) and an individual.

10.8 Three responses were received from England, Wales and Northern Ireland. Two responses in support of the authorisations came from the trade association representing specialist nutrition companies in the UK and a private individual. A neutral response was received from a local authority.

10.9 Zero responses were received from the FSS consultation.

10.10 The numbers of responses for both consultations were low in numbers compared to the actual number of stakeholders reached.

10.11 Stakeholders' concerns were carefully considered, advice was sought from the FSA Science, Evidence and Research Directorate to review the scientific responses provided on the FSA/FSS opinion. The responses did not alter the FSA and FSS views on safety.

10.12 The FSA published consultation with responses which can be found here: www.food.gov.uk/news-alerts/consultations/applications-for-six-novel-foods

10.13 The FSS published consultation with responses which can be found here: https://consult.foodstandards.gov.scot/regulatory-policy/publication-of-fss-opinion-and-consultation-on-nf/

10.14 The FSA and the FSS identified a need to revise certain aspects of the terms under which the novel foods products were proposed to be authorised. Three of the novel food applications are now to be two additions to the authorised list of novel foods, rather than as extensions of current authorisations.

10.15 A further update for the novel food consultation was launched by the FSA on 31st March 2022 and the FSS launched a further consultation on 31st March 2022 for two weeks, both to inform the public and stakeholders of the slight amendments.

10.16 Zero additional responses were received to the FSA update and an additional one response was received to the FSS for the additional novel food consultation, bringing a new total of four responses.

10.17 The one further response received in Scotland, was in support of EFSA risk assessments being used. This response was from a local authority.

10.18 Stakeholders' concerns were carefully considered again for this admin change. The responses did not alter the FSA and FSS views on safety.

10.19 The FSA published the update to the novel food consultation which can be found here: https://www.food.gov.uk/news-alerts/consultations/revision-to-the-fsafss-opinions-on-five-novel-foods-authorisation-applications

10.20 FSS published the second consultation with responses which can be found here: https://consult.foodstandards.gov.scot/regulatory-policy/five-nf-revisions-transfer-smoke-flavourings/

Smoke Flavourings

10.21 The FSA undertook a proportionate and targeted approach to consultation that balanced the time-sensitive nature of the changes and its commitment to be open and transparent. The modification of the authorisation holders' details are administrative in nature and have no bearing on the safety of the smoke flavourings or how they are used on the GB market.

10.22 On the 31st March 2022, a consultation was published on the FSA website. A two-week window was given for respondents to comment. The consultation can be found here: https://www.food.gov.uk/news-alerts/consultations/transfer-of-ownership-for-five-smoke-flavouring-authorisations

10.23 As the proposed changes related to very specific changes required to reflect business ownership, direct communication was made with targeted and relevant stakeholders to inform them of the proposed changes to the domestic list.

10.24 Smoke flavourings, in their primary product form, are primarily traded business to business. As the business transactions to transfer ownership had already occurred, businesses buying the smoke flavourings would already be aware of the changes. However, in order to ensure commercial buyers were aware of the upcoming changes to the domestic list, contact was made with relevant industry trade bodies and federations with the request for notice of consultation to be circulated with their members. Contact was acknowledged but no additional comments provided.

10.25 All ten authorisation holders, as listed on the domestic list of Retained Commission Implementing Regulation (EU) No 1321/2013, were also contacted and informed of the pending changes. No direct responses were received.

10.26 No responses were received to the FSA consultation on Smoke Flavourings.

10.27 The FSS public consultation for smoke flavourings was launched for two weeks between 31st March 2022 and 13th April 2022.

10.28 The FSS received three responses. All responses received were from smoke flavouring authorisation holders, one of which highlighted the importance of the changes taking place by 30th June to facilitate renewal applications.

10.29 Stakeholder comments received from the FSS consultation regarding plans to change the authorisation holder details of the five smoke flavouring authorisations were fully considered when providing advice to GB ministers.

10.30 The FSS published consultation with responses can be found here: https://consult.foodstandards.gov.scot/regulatory-policy/five-nf-revisions-transfer-smoke-flavourings/

11. Guidence

11.1 No guidance is being provided. This relates to the addition of novel food products to be made available on the market in England. These are facilitative measures, and no guidance is required for enforcement authorities.

11.2 The FSA will issue a targeted update to local authorities informing them of the updates to the domestic list.

11.3 The FSA publishes guidance on novel food and smoke flavouring authorisations on its website.

11.4 For novel foods please visit: www.food.gov.uk/business-guidance/regulated-products/novel-foods-guidance

11.5 For smoke flavourings please visit www.food.gov.uk/business-guidance/regulated-products/smoke-flavourings-guidance

12. Impact

12.1 There is no, or no significant, impact on business, charities or voluntary bodies.

12.2 There is no, or no significant, impact on the public sector.

12.3 A full Impact Assessment has not been prepared for both parts of this instrument because the regulations are designed to allow authorised novel food products to be

placed on the market in England and for the domestic list of smoke flavourings to be updated with the correct authorisation holder details. As such, no significant impact on business is foreseen with minimal familiarisation costs and, if so, would fall below the de minimis threshold.

12.4 Stakeholders were encouraged to highlight any potential impacts throughout the consultation period and no impacts were raised.

13. Regulating small business

13.1 The instrument will apply to all businesses, small and large.

13.2 The instrument applies equally to all business as principal compliance with agri-food chain legislation does not depend on the size of the business.

13.3 The legislation is to authorise regulated novel food products onto the open market in England. Novel food products are traditionally of interest to large national to international businesses.

13.4 The updating of the domestic list is administrative in nature and is to reflect current ownership of the relevant smoke flavourings. It does not alter the permissions of use for smoke flavourings or reduce the amount of approved smoke flavourings or add additional enforcement measures. Therefore, it should not have any impact on any businesses.

14. Monitoring & review

14.1 No monitoring or review requirements for this instrument.

14.2 This instrument does not include a statutory review clause. In line with the requirements of the Small Business, Enterprise and Employment Act 2015, a review clause is not deemed appropriate considering the legislation is expected to have an economic impact of less than +/- £5 million (net annualised).

15. Contact

15.1 Chris Stockdale at the Food Standards Agency email: Chris.Stockdale@food.gov.uk can be contacted with any queries regarding this instrument.

15.2 Peter Quigley, Deputy Director for Regulatory Services (Interim) at the Food Standards Agency can confirm that this explanatory memorandum meets the required standard.

15.3 Maggie Throup MP, Parliamentary Under-Secretary of State for Vaccines and Public Health at the Department of Health and Social Care can confirm that this explanatory memorandum meets the required standard.