Explanatory Memorandum to The Novel Foods (Authorisations) and Smoke Flavourings (Modifications of Authorisations) (Wales) Regulations 2022.

This Explanatory Memorandum has been prepared by the Food Standards Agency and is laid before Senedd Cymru in conjunction with the above subordinate legislation and in accordance with Standing Order 27.1.

Deputy Minister's Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (Wales) Regulations 2022.

Lynne Neagle MS
Deputy Minister for Mental Health and Wellbeing
27 May 2022

PART 1

1. Description

1. The purpose of this instrument is

(a) To update the list of authorised Novel Foods (Annex 1 of retained Regulation (EU) 2017/2470) to give legal effect to the decision to authorise the six Novel Food applications and to prescribe the terms under which the Novel Foods are authorised for use in Wales.

(b) To amend the list of authorised smoke flavouring primary products ('smoke flavourings') in the Annex to retained Regulation EU 1321/2013, to change the details of authorisation holders of five of the authorised smoke flavourings.

2. Matters of special interest to the Legislation, Justice and Constitution Committee

2. Corresponding legislation is being made in England and Scotland. The regulations across Great Britain (GB) are due to come-into-force (CIF) on the same dates (18 June for amendments to the list of smoke flavouring authorisation holders and 30 June for the Novel Food authorisations).

3. Legislative background

3. Regulated products are food and feed products which require authorisation before being placed on the market[1].

4. As of 1 January 2021, Great Britain (GB) has been responsible for the risk assessment and authorisation of regulated food and feed products.

5. In Wales, the Food Standards Agency (FSA) is responsible for risk assessing regulated food and feed products, whilst the Welsh Ministers (as the 'appropriate authority' in relation to Wales) make decisions on authorisations.

6. The legislative framework for authorising novel foods is contained within retained Regulation (EU) 2015/2283 on novel foods. Authorisations are enduring. The new novel foods and food uses authorised by this instrument will be added to the Annex to retained Regulation (EU) 2017/2470.

[1] Regulated products include: extraction solvents, feed additives, feed for particular nutritional purposes (PARNUTS), feed detoxification processes, flavourings, food contact materials, food additives, food enzymes, genetically modified food and feed, novel foods and smoke flavourings.

7. The legislative framework for authorising smoke flavourings is contained within retained Regulation (EC) 2065/2003 on smoke flavourings used or intended for use in or on foods. Authorisations are applicant-specific and are valid for ten years. Authorisation holders may apply to renew the authorisation for continued marketing.

8. The authorisations (including the name and addresses of the authorisation holders) are set out in the list of authorised smoke flavourings within the Annex to retained Regulation (EU) 1321/2013.

9. This instrument is subject to the negative procedure.

4. Purpose and intended effect of the legislation

10. This instrument applies in relation to Wales. Corresponding legislation is being made in relation to England and Scotland.

Novel Foods

11. The purpose of Part 2 of, and the Schedules to, this instrument is to update the list of authorised novel foods in the Annex of retained Regulation (EU) 2017/2470 following the Welsh Ministers' determination of six novel food applications in favour of authorisation

12. The six applications cover novel foods to be used as components in infant formula and follow-on formula, as well as a number of other food categories. Three of the novel foods are human-identical milk oligosaccharides (HiMOs). The manufactured HiMOs are identical in structure to the same molecules present in breast milk. They are intended for addition to infant and follow-on formula to more closely replicate breast milk. The other three Novel Foods are Docosahexaenoic acid (DHA) rich oils derived from marine algae. DHA is mandatory in infant and follow-on formula under retained Regulation (EU) 2016/127 supplementing Regulation (EU) 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding. Its inclusion concerns the growth and functional development of the brain in infants. Two applications were requests for authorisation of additional food uses for the same products.

13. Whilst it was a Member State, the UK accepted the assessments of European Food Safety Authority (EFSA) in support of authorisations for regulated food and feed products. Since the end of the transition period, the FSA and Food Standards Scotland (FSS) have adopted the same technical guidance, governance, and quality assurance processes to make independent GB risk assessments. Where EFSA, prior to the end of the transition period, evaluated an application for a product for which an application has also now been made to the GB authorities, FSA/FSS

have decided to make use of the EFSA risk assessment, where this is appropriate, in forming its own independent opinion.

14. All six novel food applications received a positive risk assessment opinion from the FSA. The EFSA risk assessments produced in relation to the applications for the six products while the UK was part of the EU were reviewed by the FSA Science, Evidence and Research Directorate (SERD) to ensure appropriateness for GB. All six novel food applications have since been authorised for use in the European Union/Northern Ireland. The proposed terms of authorisation in Wales are substantively the same as those under which the food products are authorised in the EU/NI.

Smoke Flavourings

15. The purpose of Part 3 of this instrument is to change the details of the authorisation holders of five of the existing authorised smoke flavourings.

16. The changes to the details of authorisation holders are as follows;

- SF-001 'Scansmoke PB 1110' from Azelis Denmark A/S to proFagus GmbH
- SF-002 'Zesti Smoke Code 10' from Mastertaste to Kerry Group Plc.
- SF-005 'SmokEz C-10' from Red Arrow Products Company LLC to Kerry Group Plc.
- SF-006 'SmokEz Enviro-23' from Red Arrow Products Company LLC to Kerry Group Plc.
- SF-007 'TradismokeTM A MAX' from Nactis to J. Rettenmaier & Söhne GmbH + CO KG

5. Consultation and stakeholder engagement

17. On 17 December 2021 the FSA launched a three-country wide consultation in relation to the six novel foods applications. (England, Wales and Northern Ireland). Formal consultation took place for eight weeks, ending on 11 February 2022. A parallel consultation was also launched by Food Standards Scotland (FSS) during this time.

18. A total of three responses were received to the FSA consultation. No responses were received to the FSS consultation. No responses were opposed to authorisation. One response was received from industry – the British Specialist Nutrition Association (BSNA); one from an England-based individual, and one from East of England Trading Standards Association (EETA). No consultation respondents were based in Wales. The FSA made Welsh local authorities (LAs) aware of the consultation prior to launch and sent LAs a link to the consultation once launched.

19. The private individual expressed support, provided that the products do not cause allergenic reactions. BSNA replied to acknowledge and

welcome the work of the FSA and FSS on consulting on these products. EETA raised some queries in response to the questions asked in the consultation. These related to gaining a better understanding around the proposed terms of entry into the novel foods list for one of the HiMO products and a lack of understanding around the maximum usage levels and the impact of this on use in infant formula and foods. EETA also said their members were uncomfortable with novel foods being used in infant formula and requested greater transparency in labelling when genetically modified materials have been used as a processing aid. The FSA and FSS have considered consumer interest in genetically modified organisms but are satisfied that it is not necessary for the novel food authorisation to contain such labelling conditions.

20. As part of the consultation analysis, the FSA/FSS identified revisions required to the FSA/FSS risk assessment opinions for five of the six novel food applications. The revisions were technical and/or administrative in nature and did not affect the safety assessment.

21. On 31 March 2022, the revised novel foods opinions were published on the FSA/FSS websites for an additional two weeks for comment. This two-week period was supplementary to the previous eight-week consultation which closed on 11 February 2022. Key stakeholders and previous respondents to the novel foods consultation were contacted directly to advise of the revised opinions and invite comment.

22. No additional comments were received by the FSA. One additional comment was received by FSS from a local authority who welcomed the use of EFSA risk assessments, where appropriate, to make judgements on product safety.

23. On 31 March 2022, the FSA also published a regulated products update to the website, as part of a stakeholder engagement exercise, making stakeholders aware of the proposed changes to the details of authorisation holders for five authorised smoke flavourings and welcoming any additional comments for a period of two weeks.

24. The FSA did not receive any comments within the two-week period on the proposed changes to the details of the authorisation holders.

25. Stakeholder concerns were thoroughly considered and addressed by the FSA/FSS. Discussions were held on a four-nation basis (FSA, FSA in Wales, FSA in Northern Ireland and FSS), in line with the provisional Food and Feed Safety and Hygiene Common Framework, to address any potential concerns.

26. A summary of the consultation responses, and the FSA subsequent responses has been published on the FSA website.

6. Regulatory Impact Assessment (RIA)

Novel Foods

27. The FSA has assessed the impacts that would result from the authorisation of these novel foods. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e., local authority delivery, health, environment, growth, innovation, trade, competition, consumer interests or small and micro businesses). The FSA did not identify any significant impacts therefore, a full regulatory impact assessment has not been produced.

28. The FSA did identify that the authorisation of these products should generally result in greater market competition supporting growth and innovation in the sector.

Smoke Flavourings

29. The changes to the authorisation holders will not alter the regulatory requirements for marketing or use of the authorised products. The FSA is satisfied that the changes will have no bearing on the safety of the smoke flavourings, or how they are used on the GB market.

30. Stakeholders were encouraged to highlight any potential impacts through the stakeholder engagement exercise and no impacts were raised.

7. Post implementation review

31. Smoke flavourings authorisations are valid for ten years. Renewal applications for all authorised smoke flavourings are expected by the renewal application deadline of 30 June 2022.