Explanatory Memorandum to The Food Additives, Food Flavourings, and Novel Foods (Authorisations) and Food and Feed (Miscellaneous Amendments) (Wales) Regulations 2023.

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 Food Additives, Food Flavourings, and Novel Foods (Authorisations) and Food and Feed (Miscellaneous Amendments) (Wales) Regulations 2023.

Lynne Neagle MS
Deputy Minister for Mental Health and Wellbeing
22 March 2023

PART 1

1. Description

1. The purpose of this instrument is to:
    - give legal effect to the Welsh Minister's determination of the applications for authorisation of 2 novel foods, 1 food additive and 1 flavouring for food use in favour of authorisation.
    - correct two typographical errors where the incorrect E number has been ascribed to a food additive within the retained food additives legislation.
    - address three technical scrutiny points concerning the Food and Feed (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2022 identified by the Legislation, Justice and Constitution Committee.

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

2. The Food and Feed (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2022 were laid before and approved by resolution of the Senedd. They were made on 15 December 2022 and came into force on 31 December 2022.

3. This instrument makes correcting amendments to three Welsh statutory instruments (see Part 5 of this instrument) to address technical scrutiny points (numbers 2, 3 and 5) identified in the Legislation, Justice and Constitution Committee's report (SL(6)291) on the Food and Feed (Miscellaneous Amendments (Wales) (EU Exit) Regulations 2022. The two other technical scrutiny points identified in that report were addressed prior to publication of that statutory instrument.

3. Legislative background

Authorisation of 4 regulated products applications

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

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

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

[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. Novel foods are foods which was not used for human consumption to a significant degree in the UK or European Union (EU) before 15 May 1997. This means that the foods don't have a 'history of consumption'.

8. Novel foods must be authorised by inclusion on the list established in retained Commission Implementing Regulation 2017/2470 before they can be placed on the market. The legislative framework for authorising novel foods is contained within retained Regulation 2015/2283 on novel foods. If a novel food has been authorised, that authorisation is enduring. Once granted, there is no requirement to renew these authorisations. This instrument will update the list to add one novel food and extend the authorised uses of a second novel food.

9. Food additives are substances (not normally consumed as a food in itself and not normally used as a characteristic ingredient of food) added to food to perform a specific technological function, such as making food look or taste better, and extending the storage and shelf-life of food. Additives are used as colours, preservatives, antioxidants and sweeteners among other functions.

10. Food additives must be authorised by inclusion on the list established in Retained Regulation 1333/2008 before they can be placed on the market or used. The legislative framework for authorising food additives is contained within retained Regulation 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings. If a food additive has been authorised, that authorisation is enduring. Once granted, there is no requirement to renew these authorisations. This instrument will update the list to add a new food additive and will amend retained Regulation 231/2012 to add a new specification for that food additive.

11. Flavourings are used to add a new taste or odour to a food or to modify the existing taste or odour of a food. A commercial flavouring is often a complex mixture of different substances selected to provide the desired flavour.

12. Food flavourings must be authorised by inclusion on the list established in Retained Regulation 1334/2008 before they can be placed on the market or used in food. The legislative framework for authorising food flavourings is contained within retained Regulation 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings. If a flavouring has been authorised, that authorisation is enduring. Once granted, there is no requirement to renew these authorisations. This instrument will update the list to add one new food flavouring.

<u>Miscellaneous Amendments</u>

13. Retained Regulation 1333/2008 contains lists of approved additives and their accompanying E number. Two historical typographical errors have been identified within Annex 2 to retained Regulation 1333/2008. Within Annex 2, the food additive Advantame has twice been allocated the incorrect E number (E 960). The correct E number for Advantame is E 969.

Amendments concerning the Food and Feed (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2022

14. As detailed within section 2 of this document, the Legislation, Justice and Constitution Committee's report (SL(6)291) on the Food and Feed (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2022 identified five technical scrutiny points.

15. Two points were resolved prior to publication of the instrument. The remaining three points are addressed by the amendments to three Welsh statutory instruments made by Part 5 of this instrument.

16. This instrument is subject to the negative procedure.

4. Purpose and intended effect of the legislation

Authorisation of 4 regulated products applications

17. This legislation will authorise, in relation to Wales, the placing on the market of two novel foods, one food additive and one flavouring.

18. Of the two novel food authorisations, one is the authorisation of a new novel food, and one is an extension of the authorised uses for an existing novel food.

Novel Foods

19. This instrument will authorise two novel foods

20. The first is an extension of use for an existing authorised novel food, UV-treated baker's yeast (saccharomyces cerevisiae).

21. The second is the authorisation of a new novel food - Vitamin D2 Mushroom Powder (Agaricus Bisporus).

Food Additive

22. This instrument will update the list of authorised food additives to authorise a new production method for E 960 steviol glycosides, an existing food additive and effect a consequential name change and E number. The additive from the new production method is included as a new entry, with the designation E 960c. The existing additive is renamed and given the designation E960a. This instrument will also add a new specification for the new production method of the food additive within Retained Regulation 231/2012 thus allowing it to be placed on the market.

23. In order to minimise disruption to business, this instrument contains a transitional measure which allows the existing food additive and foods containing it to continue to be labelled with the previous name or E number for a

period of 18 months to allow for existing stocks of packaging and labels to be depleted.

Food Flavouring

24. This instrument will authorise Food Flavouring 3-(1((3,5-dimethylisoxazol-4-yl)methyl)-1*H*-pyrazol-4-yl)-1-(3-hydroxybenzyl)imidazolidine-2,4-dione (new authorisation). This food flavouring reduces the bitterness of certain foods such as cocoa and green tea and, therefore, allows the use of less sugar or sweetener in food products containing it. It also improves the overall flavour profile of food.

25. Whilst it was a Member State, the United Kingdom (UK) accepted the assessments of the European Food Safety Authority (EFSA) in support of authorisation for regulated food and feed products. 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.

26. Where, prior to the end of the transition period, EFSA evaluated an application for a product for which an application has also now been made to GB authorities, FSA/FSS have decided to make use of the EFSA risk assessment, where this is appropriate, in forming its own independent opinion.

27. The novel foods, food flavouring and food additive applications were received European Commission prior to the end of the transition period. All four applications received a positive risk assessment opinion, published by EFSA.

28. These opinions alongside all supporting documentation have 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 foods, food additive, and food flavouring, as described in the applications, are safe for humans and there are no concerns relating to the environment. A copy of the FSA opinions are available here:

    Novel Foods

- Assessment of the safety of Vitamin D2 Mushroom (Agaricus bisporus) powder as a novel food ingredient | Food Standards Agency
- Assessment of the safety of the extended uses of UV-treated Baker's yeast (S. cerevisiae) as a novel food | Food Standards Agency

    Food Additive

- Assessment for the Application for a change in the Steviol Glycoside Specification in Great Britain to Include a New Manufacturing Method for Steviol Glycosides Including Rebaudioside M. | Food Standards Agency

    Food Flavouring

- Assessment of new Flavouring Substance 3-(1-((3,5-dimethylisoxazol-4-yl)methyl)-1H-pyrazol-4-yl)-1-(3-hydroxybenzyl)imidazolidine-2,4-dione | Food Standards Agency

29. The novel foods, flavouring and food additive have been authorised for use in the EU. EU Food Law on novel foods, food additives and food flavourings continues to apply to food manufactured in Northern Ireland.

30. Corresponding legislation has been made in England and Scotland. The regulations authorising the regulated products across Great Britain (GB) will come into force on 15 May 2023. Part 5 of this instrument comes into force on 14 April 2023.

Miscellaneous Amendments

31. This instrument will also correct two incorrect references within Annex 2 of retained Regulation 1333/2008. The correct E number for Advantame is E 969. The two occasions where it has incorrectly been referred to as E 960 will be corrected.

Amendments concerning the Food and Feed (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2022

32. This instrument will also make minor correcting amendments to 3 Welsh statutory instruments to address minor errors identified by the Legislation Justice and Constitution Committee in their report on the Food and Feed (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2022.

33. This instrument applies in relation to Wales.

5. Consultation

Authorisation of 4 regulated products applications

34. On 17 October 2022 the FSA launched a consultation in England and Wales on the other legitimate factors relevant to the two novel foods, one flavouring and one food additive applications for authorisation or extension for food and feed uses. Formal consultation took place for eight weeks, ending on 11 December 2022. A parallel consultation was also launched by Food Standards Scotland (FSS) during this time.

35. A second, short, focussed public consultation was launched relating to one novel food and the food additive on 23rd January 2023 and ran for two weeks. The reason for this additional consultation was to address an error and omissions within the first public consultation. The FSS also launched an additional consultation for the food additive.

36. A total of four positive consultation responses to the first consultation were received: all from industry. Respondents gave their location as UK-wide or England. Two positive responses were received to the second consultation. A summary of the consultation responses, and the FSA subsequent responses has been published on the FSA website.

37. The FSA made Welsh local authorities (LAs) aware of the consultation and sent LAs a link to the consultation once launched. Furthermore, the FSA made key Welsh stakeholders aware of the consultation when launched, and updated Welsh stakeholders again one week prior to the consultation closing.

38. Stakeholder responses have been thoroughly considered and addressed by the FSA/FSS. Discussions regarding consultation responses were held on a four-nation basis (FSA in Wales, England, Northern Ireland and FSS), in line with the provisional Food and Feed Safety and Hygiene Common Framework. No stakeholder responses altered the FSA's recommendation to the Welsh Ministers.

Miscellaneous Amendments

39. Correction of the two additional and erroneous references to E 960 is required to complete the necessary amendments for the authorisation of the food additives E 960a and E 960c, and to correct the relevant entries for E 969 Advantame. No additional consultation was required beyond that mentioned above.

Food and Feed (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2022

40. The FSA in Wales undertook a four-week consultation between the 4 August 2022 and the 1 September 2022 on "proposed changes to Welsh law in relation to EU Directives on animal feed, food contact materials and extraction solvents". A summary of the consultation responses has been published on the FSA's website. The corrections made by instrument fall within the scope that consultation.

6. Regulatory Impact Assessment (RIA)

Authorisation of 4 regulated products applications

41. The FSA has assessed the impacts that would result from the authorisation of these novel foods, food additive and flavouring. 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 and small and micro businesses). The FSA did not identify any significant impacts therefore, a full regulatory impact assessment has not been produced.

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

Miscellaneous Amendments

43. An impact assessment was not produced in relation to the miscellaneous minor corrections made by this instrument as they concern minor technical amendments required to change the wording of the law rather than its purpose or effect.