Explanatory Memorandum to The Food Additives and Novel Foods (Authorisations and Miscellaneous Amendments) and Food Flavourings (Removal of Authorisations) (Wales) Regulations 2024.

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.

Minister's Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of The Food Additives and Novel Foods (Authorisations and Miscellaneous Amendments) and Food Flavourings (Removal of Authorisations) (Wales) Regulations 2024.

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Minister for Mental Health and Early Years
07 June 2024

PART 1

1. Description

1. The purpose of this instrument is to:

- Give legal effect to the Welsh Ministers' determination of the applications for authorisation of four novel foods and three food additives in favour of authorisation.

- Update the list for authorised novel foods and specifications to correct identified errors and omissions relating to two authorised novel foods.

- Update the list for authorised food additives, to make minor technical amendments and correct omissions, relating to two authorised food additives.

- Implement a general maximum residue limit of ethylene oxide across all authorised food additives. Consequently, the existing permitted limits of ethylene oxide in the existing authorisations for eight food additives are removed.

- Remove the authorisation of twenty-two food flavouring substances in Wales, thus prohibiting them being available on the market and used in food in Wales.

- Provide a transitional arrangement for any existing stocks of those food flavourings, or food containing them to continue to be placed on the market and used in other food.

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

2. This instrument makes minor corrections within the existing legislation for authorised novel foods and food additives - including corrections we committed to making in the Welsh Government's response to technical scrutiny points raised by the Legislation, Justice and Constitution Committee in their report on the Food Additives, Food Flavourings, and Novel Foods (Authorisations) and Food and Feed (Miscellaneous Amendments) (Wales) Regulations 2023. These amendments can be found in Regulation 2 and Schedule 1, paragraph 6 of this Instrument.

3. Legislative background

<u>Authorisation of 7 regulated products applications</u>

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

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. As the 'appropriate authority', Welsh Ministers make decisions on authorisations in relation to Wales.

6. Applications for the authorisation of four novel food products, three food additives and the removal of authorisation of twenty-two food flavourings were received on the joint FSA/Food Standards Scotland (FSS) application portal.

7. Before leaving the EU, the UK accepted the safety assessments of the European Food Safety Authority (EFSA) in support of authorisation for regulated food and feed products where directly applicable in the UK. Since the end of the implementation period, GB has also adopted the same technical guidance and quality assurance processes to make independent GB safety assessments. After the end of the transition period on 31 December 2020 assimilated law created consistent practices in certain devolved policy areas across the UK where the four governments agreed it was necessary to maintain UK-wide approaches. New enduring agreements, or 'Common Frameworks', on how the four countries will work together in these policy areas have been developed.

8. The FSA safety assessments detail in each case that the novel foods and food additives (new additives or changes in use), as described in the applications, are safe for humans. Copies of the FSA safety assessments are available on the Food Standards Agency website.

9. The FSA provided the Welsh Ministers with the safety assessments. In addition, to assist in their decision making, the FSA also provided an outline of the other relevant factors provided for in the relevant assimilated Regulations for placing on the market in Wales of the 7 new regulated products, alongside recommendations for the removal of authorisations for the twenty-two flavouring substances, the setting of a maximum residue limit for ethylene oxide, and other consequential amendments. The Welsh Ministers agreed to these recommendations.

10. This Instrument makes the necessary changes to the relevant legislation.

11. Ministers in England and Scotland have also agreed to the recommendations and will be making their own Statutory Instruments in their respective countries. Further detail on the Policy areas is provided below.

Novel foods

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

    This instrument will authorise four new novel foods:

    - Cetylated fatty acids
    - Partially hydrolysed protein from spent barley (*Hordeum vulgare)* and rice (*Oryza sativa)*
    - Lacto-*N*-fucopentaose I (LNFP-I) and 2'-fucosyllactose (2'-FL) mixture
    - 3-fucosyllactose (3-FL) (produced by a derivative strain of *Escherichia coli* K-12 DH1)

13. Novel foods must be authorised and included on the list established in assimilated Commission Implementing Regulation (EU) 2017/2470 before they can be placed on the market or used. This instrument will update the list to add four new novel foods and implement necessary corrections identified by FSA/FSS in relation to existing entries for two novel foods on the list.

Food Additives

14. Food additives are substances (not normally consumed as a food in itself and not normally used as a characteristic ingredient in 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.

15. Food additives must be authorised and included on the list established in assimilated Regulation (EC) No 1333/2008 of the European Parliament and of the Council before they can be placed on the market or used. The list also sets out conditions of use such as which types of foods they can be added to and maximum permitted levels. Every food additive must have a specification set out in assimilated Commission Regulation (EU) No 231/2012 and separate specifications are needed for each authorised production method for a food additive. Authorisation is also required for changes in use of permitted food additives and changes to production methods of permitted food additives.
16. This Instrument authorises for the first time the production of steviol glycosides using a fermentation process rather than extraction from Stevia leaves – E 960b steviol glycosides produced by *Yarrowia lipolytica*. It will be used in the same foods and at the same levels as other authorised steviol glycosides (E 960a and E 960c). It also authorises a new enzymatic method (different enzymes) to make steviol glycosides - E 960c(ii) - Rebaudioside M, AM and D

produced via enzymatic conversion of highly purified steviol glycosides from Stevia leaf extracts. The existing E 960c becomes E 960c(i).

17. E 476 Polyglycerol polyricinoleate is an authorised emulsifier that is used to aid the mixture of fat and oil in products such a spreadable fats and emulsified sauces. The instrument extends the permitted usesto include ice-creams and frozen yoghurts (edible ices) and emulsified sauces at a higher use level. It provides an emulsion structure which allows products to be formulated using healthier, low saturated fat oils and lower sugar levels.

18. The instrument also sets a maximum residue limit of ethylene oxide for all food additives at a level of 0.1 mg/kg. Existing (higher) limits are removed from specifications for eight authorised food additives where ethylene oxide may be present due to their production process. On occasion, ethylene oxide has been found to be unavoidably present in other additives due to changes in the manufacturing process. These changes follow engagement with industry and balance food safety with giving clarity and consistency to industry and enforcement officers.

19. This instrument will:

- Amend assimilated Regulation (EC) No 1333/2008 of the European Parliament and of the Counci. Firstly, to add E 960b to the list of authorised food additives under the same food categories and use levels currently set for existing steviol glycosides (E 960a and E 960c). Secondly, it authorises a new use for E 476 (polyglycerol polyricinoleate) - in edible ices at 4,000 mg/kg with the restriction ‘except sorbets’.It increases the maximum level for E 476 in ‘emulsified sauces with a fat content of 20% or more’ to 8,000 mg/kg . It maintains the current authorised level of 4,000 mg/kg for ‘emulsified sauces with a fat content of 20% or less’.
- Amend assimilated Commission Regulation (EU) No 231/2012. Firstly, it amends the Annex to introduce a maximum residue limit of 0.1 mg/kg for ethylene oxide in all authorised food additives (or mixtures thereof). It removes the existing (higher) specific permitted limits for ethylene oxide in the specifications for eight food additives to bring them in line with the new general 0.1 mg/kg limit. Secondly, to add a new specification for E 960c(ii) (Rebaudisodie M, AM and D produced via enzymatic conversion of highly purified steviol glycosides from Stevia leaf extracts), and E 960b (steviol glycosides from fermentation [*Yarrowia lipolytica*]). It renumbers the specification for the existing E 960c to E 960c(i) (for the currently approved production method) and introduces a new specification for E 960c(ii) (for the new method).

<u>The removal of twenty-two food flavourings</u>

20. Flavourings are used to add a new taste or odour to a food or to modify the existing taste or odour of a food.

21. This instrument will update the list to remove twenty-two food flavourings from assimilated Regulation (EC) No 1334/2008 of the European Parliament and of the Council, thus prohibiting them to be placed on the market within Wales and used in food in Wales.

22. These flavouring substances were still under evaluation when the list of approved flavourings was established in 2012. There is a footnote next to each of these flavourings in the approved list to indicate that the evaluation is ongoing. The flavourings industry has since decided not to support work to deliver additional information to finalise their safety evaluation and has requested the removal of these twenty-two flavourings from the list of approved products.

23. This instrument contains a transitional measure which allows the removed food flavourings, or food containing them that were in present in the United Kingdom, and were or could lawfully have been place on the marked in Great Britain t before their authorisation was removed to remain on the market (and be used in other food) until their date of minimum durability or use-by date. The transitional measure includes flavourings and food which were in transit to Great Britain before the coming into force date of the legislation. Such flavourings or food containing them that could lawfully have been imported into GB and placed on the market may be marketed (or used in other food) until their date of minimum durability or use-by date.

4. Purpose and intended effect of the legislation

24. The purpose of this legislation is to, in relation to Wales: authorise the placing on the market of the four novel food products and three food additives, remove of authorisation of twenty-two food flavourings, and set maximum residue limit of ethylene oxide being applied in all authorised food additives.

25. This instrument applies in relation to Wales. Corresponding legislation has been made in England and Scotland. The legislation will come into force across Great Britain on 28 June 2024.

26. This instrument is subject to the negative procedure.

5. Consultation

27. The public consultation on the authorisation of the four novel food products, the authorisation of the three food additives, the removal of authorisation of twenty-two food flavouring substances, and the introduction of a maximum residue limit for ethylene oxide being applied in all authorised food additives was launched by the FSA on 02 February 2024 for a period of eight weeks. A parallel consultation was run by FSS.

28. The consultation sought feedback on the proposed terms of authorisation in relation to the four novel food and three food additive applications. In particular, we sought views on our assessment of the potential impacts set out in the consultation and requested further evidence on any additional impacts that had not been noted. In relation to the application to remove the authorisation of twenty-two food flavouring substances and the proposal to set a limit for residues of ethylene oxide in all food additives, we sought views of the potential impacts, and requested evidence on additional impacts that should be considered.

29. 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. Key stakeholders whose businesses/organisations are likely to be affected by or to have an interest in these novel foods, flavourings and food additives, were contacted directly for their feedback. To ensure representation across a broad spectrum of opinion, stakeholders with a range of interests in the regulated products were included.

30. The FSA consultation reach was comprehensive, with automatic notifications sent to 37,272 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 – 30,672 subscribers to England, 17,249 subscribers to Northern Ireland and 18,154 subscribers to Wales. The FSA consultation had a reach of 61,400 on X (formerly known as Twitter) and 120,000 LinkedIn followers. The FSA consultation page received approximately 2,418 views.

31. All responses were carefully considered with no significant changes to the FSA Recommendations being made in response to comments received during the consultation. Minor refinements to the suggested labelling designations for three novel foods were made considering comments received.

32. The FSA published the consultation responses on the FSA website.

33. Responses to the FSS consultation can be found on the FSS website.

6. Regulatory Impact Assessment (RIA)

34. The FSA has assessed the impacts that would result from the authorisation of these feed additives. 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. This is in line with the policy set out in the Welsh Ministers' code of practice for carrying out regulatory impact assessments for subordinate legislation.

35. 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.

36. Whilst we are removing the authorisation for some flavourings, the UK flavouring industry have informed the FSA that these are not used in food in the UK and so there will be no significant impact on businesses.