EXPLANATORY MEMORANDUM TO

THE FOOD ADDITIVES AND NOVEL FOODS (AUTHORISATIONS AND MISCELLANEOUS AMENDMENTS) AND FOOD FLAVOURINGS (REMOVAL OF AUTHORISATIONS) (ENGLAND) REGULATIONS 2024

2024 No. 685

1. Introduction

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

2. Declaration

2.1 Minister Leadsom, Parliamentary Under Secretary of State for Public Health, Start for Life and Primary Care at the Department of Health and Social Care (DHSC) confirms that this Explanatory Memorandum meets the required standard.

2.2 Rebecca Sudworth, Director of Policy, at the Food Standards Agency confirms that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Susan Roberts at the Foods Standard Agency can be contacted with any queries regarding the instrument by email at susan.roberts@food.gov.uk

Part One: Explanation, and context, of the Instrument

4. Overview of the Instrument

What does the legislation do?

Novels Foods

4.1 This instrument authorises four new novel foods in England, thus allowing them to be distributed, and available on the market, and used in foods in England.

4.2 This instrument also updates the list for authorised novel foods and specifications, to correct identified errors and omissions, relating to two authorised novel foods.

Food additives

4.3 This instrument authorises three food additives in England thus allowing them to be distributed and available on the market and used in foods in England.

4.4 This instrument implements a maximum limit of ethylene oxide for all authorised food additives. Consequently, the existing limit of ethylene oxide for eight food additives will be reduced to align with the new limit.

4.5 This instrument also updates the list for authorised food additives, to make minor technical amendments and correct omissions, relating to two authorised food additives.

Food Flavourings

4.6 This instrument removes the authorisation of twenty-two food flavouring substances in England, thus prohibiting them to be distributed and available on the market and used in foods in England. This instrument also includes a transitional arrangement which

allow foods containing any of the removed food flavourings substances placed on the market before the date that the food flavouring substances removals legally come into force to remain as such, until the date of minimum durability or use-by date.

Where does the legislation extend to, and apply?

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

4.8 The territorial application of this instrument is England only.

5. Policy Context

What is being done and why?

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

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

5.3 As the 'appropriate authority', Minister Leadsom makes decisions on authorisations in relation to England. Applications for the authorisation of four novel food products and three food additives were received on the joint FSA/Food Standards Scotland (FSS) application portal.

5.4 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.

5.5 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.

5.6 In line with the legislative requirements of each regime, the FSA provided the Ministers' Parliamentary Under Secretary of State (Minister for Public Health, Start for Life and Primary Care) 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 regulations for placement on the market in England alongside recommendations to grant the removal of twenty-two flavouring authorisations, the setting of a maximum limit for ethylene oxide, and other consequential amendments. Minister Leadsom agreed to these recommendations.

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

5.8 Ministers in Scotland and Wales 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

5.9 Novel foods are foods that were not used for human consumption to a significant degree within the United Kingdom (UK) or the European Union (EU) before 15 May 1997. This means that the foods do not have a 'history of consumption.'

5.10 This instrument relates to the authorisation of four new novel foods:

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

Food Additives

5.11 This legislation authorises for the first time the production of steviol glycosides using a fermentation process rather than extraction from *Stevia* leaves - steviol glycosides produced by *Yarrowia lipolytica*, (E 960b). 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) - Rebaudioside M, AM and D produced via enzymatic conversion of highly purified steviol glycosides from Stevia leaf extracts.

5.12 Polyglycerol polyricinoleate (PGPR, E 476) 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 extension of use will also allow it in 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.

5.13 It also sets a limit of ethylene oxide for all food additives at 0.1 mg/kg and replaces the limits set in the specification for eight authorised food additives where ethylene oxide is used in their production process and so limits are set to control any residues. Ethylene oxide and its breakdown product 2-chloroethanol are residues/contaminants. On occasion, ethylene oxide has been found to be unavoidably present due to the manufacturing process. These changes follow engagement with industry and balance food safety with giving clarity and consistency to industry and enforcement officers.

Food Flavourings

5.14 This legislation relates to the removal of authorisations for twenty-two food flavourings. These flavouring substances were still under evaluation when added to the list of approved flavourings. 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.

What was the previous policy, how is this different?

5.15 Prior to EU exit the authorisation of regulated products was undertaken by the EU where novel foods, flavourings and food additives underwent authorisation processes before being added/amended to the authorised list and made available on the EU market.

5.16 Following EU exit, previously EU authorised novel foods, flavourings and food additives as set out in directly applicable EU legislation, continued to be authorised in GB under assimilated law.

6. Legislative and Legal Context

How has the law changed?

6.1 Legislation on novel foods (assimilated Regulation 2015/2283), flavourings (assimilated Regulations 1331/2008 and 1334/2008) and food additives (assimilated Regulations 1331/2008 and 1333/2008) requires these products to be authorised and included on their respective lists before being placed on the market. These lists are currently held within the relevant legislation pertaining to each regime. The legislation on novel foods, food additives and food flavourings requires the lists of authorised products set out in legislation to be amended to add or remove permitted substances, or to change the conditions of use for authorised substances.

Why was this approach taken to change the law?

Novel Foods

6.2 Novel foods must be authorised and included on the list established in assimilated Commission Implementing Regulation 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 corrections to errors and omissions that the FSA/FSS has identified in relation to two novel foods on the list.

Food additives

6.3 Food additives must be authorised and included on the list established in assimilated Regulation 1333/2008 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 Regulation 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. This instrument will update the list to allow two new production methods for steviol glycosides and extend the use of an existing food additive. This instrument will set a maximum limit for ethylene oxide in all food additives.

6.4 This instrument will amend assimilated Commission Regulation No 231/2012 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 subcategorises the specifications for E 960c into E 960c(i) for the currently approved production method, and E 960c(ii) for the new method. It updates the Annex with a limit of 0.1 mg/kg for ethylene oxide in all authorised food additives. It reduces the existing limit for ethylene oxide in the specifications for eight food additives in line with the new 0.1 mg/kg limit.

6.5 This instrument will amend assimilated Regulation No 1333/2008 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). It amends the conditions of use for authorised food additives to include E 476 (polyglycerol polyricinoleate) in edible ices at 4,000 mg/kg with the restriction ‘except sorbets’, and in sauces at 8,000mg/kg with the restriction ‘emulsified sauces with a fat content of 20% or more’. It updates the

current authorised level of 4,000 mg/kg with the restriction 'emulsified sauces with a fat content of 20% or less'. All food additives listed under Annex II and III of this Regulation will now need to comply with the new 0.1 mg/kg limit for ethylene oxide.

Food Flavourings

6.6 This instrument will update the list to remove twenty-two food flavourings from assimilated Regulation 1334/2008, thus prohibiting them to be placed on the market within England and used in food in England.

6.7 This instrument contains a transitional measure which allows foods containing any of the removed food flavourings that have been placed on the market before their authorisation was removed to remain on the market until their date of minimum durability or use-by date. The transitional measure includes foods which were exported to the UK before the coming into force date of the legislation. Foods imported into GB containing any of the proposed flavouring substance removals may be marketed until their date of minimum durability or use-by date, provided the importer can demonstrate they were dispatched from the third country concerned and in transit to GB before the entry into force of the proposed removals.

7. Consultation

Summary of consultation outcome and methodology

7.1 The public consultation on the four novel food products, three food additives being authorised; twenty-two food flavourings being removed from authorisation; and a maximum limit of 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.

7.2 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 ethylene oxide in all food additives, we sought views of the potential impacts, and requested evidence on additional impacts that should be considered.

7.3 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.

7.4 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.

7.5 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.

7.6 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.

8. Applicable Guidance

8.1 No guidance is being provided. This relates to the addition of novel food products and food additives to be made available on the market in England. These are facilitative measures, and no guidance is required for enforcement authorities. The FSA will issue a targeted update to local authorities informing them of the updates to the legislation including the changes to the flavourings legislation and the additives specification legislation which will also detail the ethylene oxide changes. Therefore, no specific guidance is required for the changes in flavourings and a limit for ethylene oxide in all food additives.

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 A full Impact Assessment has not been prepared for this instrument because the regulations are designed to allow authorised novel food products and food additives to be placed on the market in England and a new legal limit set for ethylene oxide in all food additives. The familiarisation costs are expected to be minimal and if so, would fall below the de minimis threshold.

9.2 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.

Impact on businesses, charities and voluntary bodies

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

9.4 The legislation applies to activities that are undertaken by small businesses.

9.5 No specific action is proposed to minimise regulatory burdens on small businesses as it is important all businesses follow food law to ensure consumer safety.

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

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 There are no monitoring or review requirements for this instrument. However, related enforcement legislation, Regulation 22 of the Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013 (2013 No. 2210) and Regulation 9 of the Novel Foods (England) Regulations (2018 No. 154) hold a review clause.

10.2 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).

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

11.1 None.

12. European Convention on Human Rights

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

13. The Relevant European Union Acts

13.1 This instrument is not made under the European Union (Withdrawal) Act 2018, the European Union (Future Relationship) Act 2020 or the Retained EU Law (Revocation and Reform) Act 2023 ("relevant European Union Acts").