EXPLANATORY MEMORANDUM TO

THE FOOD ADDITIVES, FOOD FLAVOURINGS AND NOVEL FOODS (AUTHORISATIONS) (ENGLAND) REGULATIONS 2023

2023 No. 334

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. Purpose of the instrument

Novel Foods

2.1 Novel foods are food that was 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 don't have a 'history of consumption'.

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

Food Flavourings

2.3 This instrument authorises one new food flavouring in England, thus allowing it to be distributed and available on the market and used in foods in England.

Food Additives

2.4 This instrument authorises one food additive in England, thus allowing it to be distributed and available on the market and used in foods in England. This authorisation is for a new production method of an existing authorised food additive (steviol glycoside E 960), which has resulted in a change to its name and E number This instrument also includes transitional arrangements for the food additive labelling update, due to the change in name and E number, to allow for existing stocks of labels that contain the food additive to be depleted.

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 extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is England and Wales.

4.2 The territorial application of this instrument (that is, where the instrument produces a practical effect) is England only.

5. European Convention on Human Rights

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

6. Legislative Context

6.1 Novel foods, food flavourings and food additives are regulated products that need to be included on legislative lists of authorised products before being placed on the market or used in foods.

Novel Foods

6.2 Novel foods must be authorised and included on the list established in Retained Commission Implementing Regulation 2017/2470 before they can be placed on the market or used. This instrument will update the list to add one novel food and extend the authorised uses of a second novel food.

6.3 The Secretary of State for Health and Social Care has taken account of the opinion of the FSA that the novel foods do not pose a risk to human health and are safe for the uses. They decided to update the list of authorised novel foods to allow their use in England.

Food Flavourings

6.4 Food flavourings must be authorised and included on the list established in Retained Regulation 1334/2008 before they can be placed on the market or used in food. This instrument will update the list to add one new food flavouring.

6.5 The Secretary of State for Health and Social Care has taken account of the opinion of the FSA that the food flavouring does not pose a risk to human health and is safe for the uses. They decided to update the list of authorised food flavourings to allow its use in England.

Food Additives

6.6 Food additives must be authorised and included on the list established in Retained Regulation 1333/2008 before they can be placed on the market or used. This instrument will update the list to add a new food additive and add a new specification to reflect the new production method for a food additive (E960 steviol glycosides).

6.7 The Secretary of State for Health and Social Care has taken account of the opinion of the FSA that the food additive does not pose a risk to human health and is safe for the uses. They decided to update the list of authorised food additives to allow its use in England.

7. Policy background

What is being done and why?

7.1 Regulated Products require authorisation in legislation to be available on the market. Applications for the authorisation of two novel food products, one flavouring and one food additive were received by the FSA. The FSA carried out a risk analysis and provided the Secretary of State with an opinion on the safety along with an outline of the other relevant factors provided for in the regulations, who decided to authorise the products for placement on the market in England. This will mean a change to the legislation.

7.2 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.

7.3 The novel foods, food flavouring and food additive applications were received by EFSA and the European Commission prior to the end of the transition period on leaving the EU.

7.4 EFSA has published opinions on the novel foods, flavouring and food additive, these opinions and 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, flavouring and food additive, as described in the applications, are safe for humans and there are no concerns relating to the environment. A copy of the FSA opinions has been provided and are available here:

Assessment of the safety of Vitamin D2 Mushroom (Agaricus bisporus) powder as a novel food ingredient | Food Standards Agency[1]

Assessment of the safety of the extended uses of UV-treated Baker's yeast (S. cerevisiae) as a novel food | Food Standards Agency[2]

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[3]

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[4]

7.5 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.

7.6 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 authorisation of the two novels foods, food flavouring and food additive and will be making their own Statutory Instruments in their respective countries.

Novel Foods

7.7 This instrument relates to two novel foods. The authorisation of vitamin D2 mushroom (agaricus bisporus) powder as a new novel food and the extension of use for an existing authorised novel food, UV-treated baker's yeast (saccharomyces

[1] https://www.food.gov.uk/research/novel-and-non-traditional-foods-additives-and-processes/assessment-of-the-safety-of-vitamin-d2-mushroom-agaricus-bisporus-powder-as-a-novel-food-ingredient
[2] https://www.food.gov.uk/research/novel-and-non-traditional-foods-additives-and-processes/assessment-of-the-safety-of-the-extended-uses-of-uv-treated-bakers-yeast-s-cerevisiae-as-a-novel-food
[3] https://www.food.gov.uk/research/novel-and-non-traditional-foods-additives-and-processes/assessment-of-new-flavouring-substance-3-1-35-dimethylisoxazol-4-ylmethyl-1h-pyrazol-4-yl-1-3-hydroxybenzylimidazolidine-24
[4] https://www.food.gov.uk/research/novel-and-non-traditional-foods-additives-and-processes/assessment-for-the-application-for-a-change-in-the-steviol-glycoside-specification-in-great-britain-to-include-a-new

cerevisiae). The FSA opinion is that these novel foods are safe for the uses under the conditions of use.

7.8 The authorisations cover novel food products to be used in a variety of foods and categories such as foods for special medical purposes (FSMPs) and in food supplements.

Flavourings

7.9 This legislation relates to an authorisation for a new food flavouring. 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. The FSA opinion is the food flavouring is safe.

Food Additives

7.10 This legislation relates to a new production method of an existing authorised food additive, which has resulted in a change to its name and E number for labelling purposes to allow the consumer to differentiate between the additives made with the existing and new production method (E 960 will become E 960a and the new additive is E 960c). The FSA opinion is that the food additive is safe.

7.11 This food additive is authorised for use as a permitted low-calorie, high intensity sweetener. The new authorisation will include a new method for the production of this food additive.

Explanations

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

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

Why is it being changed?

7.13 Retained EU law on novel foods, flavourings and food additives requires novel foods, flavourings and food additives to be authorised and included on the list of authorised novel foods before being placed on the market.

What will it now do?

Novel Foods

7.14 This instrument will update the list of authorised novel foods within Retained Commission Implementing Regulation 2017/2470 to add the new novel food and the extended uses and will amend the specification for the existing novel food, thus allowing them to be placed on the market and used in foods within England.

Flavourings

7.15 This instrument will update the list of authorised flavourings within Retained Regulation 1334/2008 to include the new food flavouring authorisation, thus allowing it to be placed on the market within England and used in food in England.

Food Additives

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

7.17 The authorisation of a new production method of an existing authorised food additive (steviol glycoside E 960) has resulted in a consequential change to its name and E number. This instrument contains a transitional measure which allows the 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.

7.18 This instrument will update the list of authorised food additives to correct two typographical errors relating to the E number for an additive (Advantame).

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.

9. Consolidation

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

10. Consultation outcome

10.1 The first public consultation on the two novel food products, one flavouring and one additive being authorised and updated by this instrument was launched by the FSA and the FSS ran a parallel consultation on 17th October 2022 and ran for eight weeks.

10.2 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.

10.3 The consultations sought views from the public and stakeholders on the proposed two novel foods, one food flavouring and one food additive 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. Consideration was made to the provision of transitional arrangements to minimise market impacts between existing and new authorisations where conditions of use have changed.

10.4 Stakeholders and enforcement authorities were informed of both consultations 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.

10.5 The FSA public consultations had a broad reach, through the FSA website, subscription alerts, social media posts and direct contact with key stakeholders. There were 31,073 subscribers to UK wide FSA alerts, and a further 54,329 subscribers to country specific England, Wales and Northern Ireland alerts received automatic notifications

10.6 The consultations were also shared with the FSA's 60,034 Twitter and 98,141 LinkedIn followers. The FSA consultation page received approximately 608 views.

10.7 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.

10.8 The FSA published consultations with responses which can be found here:

Consultation on applications for authorisation of miscellaneous regulated products: two novel foods, one flavouring and one food additive[5]

Applications for authorisation of miscellaneous regulated products: one novel food and one food additive[6]

10.9 The FSS published consultations with responses which can be found here (Please note that the error and omission for the novel food was not present within FSS's first consultation:

Consultation on applications for authorisation of two novel foods, one food additive and one food flavouring[7]

Consultation on the amendment to the specification of one food additive[8]

11. Guidance

11.1 No guidance is being provided. This relates to the addition of novel food products, a food flavouring and a food additive 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.

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 this instrument because the regulations are designed to allow authorised novel food products, food flavourings and food additives to be placed on the market in England. The familiarisation costs are expected to be minimal 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.

[5] https://www.food.gov.uk/news-alerts/consultations/consultation-on-applications-for-authorisation-of-miscellaneous-regulated-products-two-novel-foods-one-flavouring-and-one-food

[6] https://www.food.gov.uk/news-alerts/consultations/applications-for-authorisation-of-miscellaneous-regulated-products-one-novel-food-and-one-food-additive

[7] https://consult.foodstandards.gov.scot/regulatory-policy/miscellaneous-amendment/

[8] https://consult.foodstandards.gov.scot/regulatory-policy/amendment-of-miscellaneous-consultation/

13. Regulating small business

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

13.2 No specific action is proposed to minimise regulatory burdens on small 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 Natalie Watson at the Food Standards Agency email: Natalie.Watson@food.gov.uk or phone: 07870362654 can be contacted with any queries regarding this instrument.

15.2 Natasha Smith/James Cooper, Deputy Directors of Food Policy at the Food Standards Agency email: CooperSmithJobShare@food.gov.uk can confirm that this explanatory memorandum meets the required standard.

15.3 Neil O'Brien, Parliamentary Under-Secretary of State for Primary Care and Public Health at the Department of Health and Social Care can confirm that this explanatory memorandum meets the required standard.