Health, Social Care and Sport Committee
Tuesday 18 June 2024
20th Meeting, 2024 (Session 6)

Note by the Clerk on the Food Additives and Novel Foods (Authorisations and Miscellaneous Amendments) and Food Flavourings (Removal of Authorisations) (Scotland) Regulations 2024 (SSI 2024/156)

Overview

1. At this meeting, the Committee will consider the following Scottish Statutory Instrument (SSI), which is subject to annulment by resolution of the Parliament until 11 September 2024. The Committee is invited to consider the instrument and decide what, if any, recommendations to make.

2. More information about the instrument is summarised below:

   Title of instrument: The Food Additives and Novel Foods (Authorisations and Miscellaneous Amendments) and Food Flavourings (Removal of Authorisations) (Scotland) Regulations 2024 (SSI 2024/156)

   Laid under: Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings, and Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001

   Laid on: 30 May 2024

   Procedure: Negative

   Deadline for committee consideration: 9 September 2024 (Advisory deadline for any committee report to be published)

   Deadline for Chamber consideration: 11 September 2024 (Statutory 40-day deadline for any decision whether to annul the instrument)

   Commencement: 28 June 2024

Procedure

3. Under the negative procedure, an instrument is laid after it is made, and is subject to annulment by resolution of the Parliament for a period of 40 days beginning on the day it is laid.

4. Once laid, the instrument is referred to:

   - the Delegated Powers and Law Reform (DPLR) Committee, for scrutiny on various technical grounds, and

   - a lead committee, whose remit includes the subject-matter of the instrument, for scrutiny on policy grounds.

5. Any MSP may propose, by motion, that the lead committee recommend annulment of the instrument. If such a motion is lodged, it must be debated at a meeting of the Committee, and the Committee must then report to the Parliament (by the advisory deadline referred to above).

6. If there is no motion recommending annulment, the lead committee is not required to report on the instrument.

Delegated Powers and Law Reform Committee consideration

7. The DPLR Committee considered the instrument on 11 June 2024 and reported on it in its 41st report, 2024. The DPLR Committee made no recommendations in relation to the instrument.

Purpose of the instrument

8. The purpose of the instrument is to implement the decision made by the Minister for Public Health and Women's Health in relation to eight regulated food product applications. It authorises the placing on the market in Scotland of four new novel foods, authorises a new production method for two food additives and a new use for one other food additive, and authorises the removal of twenty two food flavouring substances. The instrument also provides a maximum limit for residues of ethylene oxide in all food additives and corrections of minor technical errors and omissions are made in two existing novel foods and two existing food additives authorisations.

9. The Policy Note accompanying the instrument is included in Annexe A. It includes a summary of consultation undertaken on the instrument, impact assessments carried out, and the anticipated financial effects.

Committee consideration

10. So far, no motion recommending annulment has been lodged.

11. Members are invited to consider the instrument and decide whether there are any points they wish to raise. If there are, options include:

    - seeking further information from the Scottish Government (and/or other stakeholders) through correspondence, and/or

- inviting the Minister (and/or other stakeholders) to attend the next meeting to give evidence on the instrument.

It would then be for the Committee, at the next meeting, to consider the additional information gathered and decide whether to make recommendations in relation to the instrument.

12. If members have no points to raise, the Committee should note the instrument (that is, agree that it has no recommendations to make).

13. However, should a motion recommending annulment be lodged later in the 40-day period, it may be necessary for the Committee to consider the instrument again.

Clerks to the Committee
June 2024

Annexe A: Scottish Government Policy Note

POLICY NOTE

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

SSI 2024/156

The above instrument was made in exercise of the powers conferred by Articles 7(4) and (5) and 14A(2)(b) of Regulation (EC) No. 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings and Articles 12(1) and 32A(3)(b) of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, amending Regulation (EU) No. 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No. 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No. 1852/2001, and all other powers enabling them to do so. The instrument is subject to the negative procedure.

Summary Box

The purpose of this Scottish Statutory Instrument (SSI) is to implement the decision made by the Minister for Public Health and Women's Health in relation to eight regulated food product applications. It authorises the placing on the market in Scotland of four new novel foods, authorises a new production method for two food additives and a new use for one other food additive, and authorises the removal of twenty two food flavouring substances. This instrument also provides a maximum limit for residues of ethylene oxide in all food additives and corrections of minor technical errors and omissions are made in two existing novel foods and two existing food additives authorisations. This instrument extends to Scotland only.

Legislative Context

At the end of the Implementation Period the UK inherited the European Commission's (EC) legal obligation to process applications for the authorisation of regulated food and feed products. Assessing food and animal feed safety in Scotland is the responsibility of Food Standards Scotland (FSS) as the 'food safety authority'. FSS and the Food Standards Agency (FSA) assess GB-wide regulated products applications jointly through the GB regulated products application service, and make recommendations to Ministers. The authorisation of these products for placing on the market in Scotland rests entirely with the Scottish Ministers.

Novel foods are regulated products which include any food that was not used for human consumption to a significant degree within the EU or the United Kingdom before 15 May 1997. Following the UK's exit from the EU, novel foods must be authorised domestically before they can be placed on the market and used in Great Britain (GB) and can only be used for the purpose stated in the authorisation. Regulation (EU) No. 2015/2283 sets out the legislative framework for submitting applications for authorisation of novel foods in relation to conditions of use.

Food additives are regulated products which are defined as any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods. Following the UK's exit from the EU, food additives must be authorised domestically before they can be placed on the market and used in GB and can only be used for the purpose stated in the authorisation. Regulation (EC) No. 1331/2008 sets out the legislative framework for submitting applications for authorisation of food additives in relation to conditions of use and the labelling and packaging of food additives. Chapter IV of Regulation (EC) No. 1333/2008 also includes specific labelling and packaging provisions for the food additives. Every food additive must, also, have a specification set out in Regulation (EU) No. 231/2012 and separate specifications are needed for each authorised production method for a food additive.

Food flavourings are regulated products which include products not intended to be consumed as such, which are added to food in order to impart or modify odour and/or taste and made or consisting of the following categories: flavouring substances, flavouring preparations, thermal process flavourings, smoke flavourings, flavour precursors or other flavourings or mixtures thereof. Following EU exit, food flavourings must be authorised domestically before they can be placed on the market and used in GB and can only be used for the purpose stated in the authorisation. Regulation (EC) No. 1331/2008 sets out the legislative framework for submitting applications for authorisation of food flavourings in relation to conditions of use and the labelling and packaging of food flavourings. Chapter IV of Regulation (EC) No. 1334/2008 also includes specific labelling and packaging provisions for the food additives.

Regulation (EU) No. 2015/2283 provides Scottish Ministers (and respective Ministers for England and Wales) with the power to authorise novel foods and specify conditions for their use. Regulation (EC) No. 1333/2008 provides Scottish Ministers (and respective Ministers for England and Wales) with the power to authorise food additives and specify their conditions of use. Regulation (EC) No. 1334/2008 provides Scottish Ministers (and respective Ministers for England and Wales) with the power to authorise food flavourings and specify their conditions of use. Article 6 of Regulation (EU) No. 2015/2283 and Article 7 of Regulation (EC) No. 1331/2008 require that a GB register of regulated food and feed products for GB which includes novel foods, food additives and food flavourings and is available at: https://data.food.gov.uk/regulated-products/landing.

Policy Objectives

This Instrument is required to give legislative effect to the Minister's decision with respect to the authorisation of the food additives and novel foods, the removal of food flavouring authorisations, the limit for ethylene oxide in all food additives and the technical amendments.

This Instrument adds four new novel foods to the domestic list of novel foods authorised to be placed on the market within Great Britain and make amendments to two existing novel food authorisations.

This Instrument also modifies and/or authorises two new production methods for a food additive and a new use for one other food additive. This Instrument will, also, amend Regulation (EU) No. 231/2012 to add a new specification for E 960c(ii) (Rebaudioside 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 introducing a maximum limit of 0.1 mg/kg for residues of 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. 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.

This Instrument amends 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’.

This Instrument updates the domestic list of food flavourings to remove twenty-two food flavourings from Regulation (EC) No. 1334/2008, thus prohibiting them to be placed on the market within Scotland and used in food in Scotland. It also includes a transitional measure which allows those flavourings, and foods containing them, to remain on the market, and be added to other foods, if present in the UK or in transit to GB before the authorisation is removed. Foods to which they are added may also be lawfully placed on the market, and used, until their 'best before' or 'use by' date.

The responsibility for the authorisation of these regulated product applications rests with Scottish Ministers. The assimilated law provides that authorisations of the relevant novel foods, food additives and food flavourings must be prescribed by the Scottish Ministers. This SSI comprises the approval by the Scottish Ministers of applications made to them authorising the placing on the market in Scotland of four new novel foods, authorises a new production method for two food additives and a new use for one other food additive, and authorises the removal of twenty two food flavouring substances. This Instrument extends to Scotland only.

This SSI aligns Scotland with England and Wales and similar EU legislation for these regulated products. Food Standards Scotland (FSS) and the Food Standards Agency (FSA) have reviewed the European Food Safety Authority (EFSA) opinions along with all supporting documentation for the four novel foods, three food additives, the removal of twenty two food flavouring authorisations and the limit for ethylene oxide in all food additives and formed an independent opinion based on risk assessment and safety conclusions. The FSS/FSA opinion in each case was that the regulated products, as described in the applications, are safe for consumers. A copy of the

FSS/FSA opinions has been provided and is available at the bottom of the FSS Citizen Space consultation page here: Consultation on applications for authorisation of miscellaneous regulated products: four novel foods, three food additives, removal of twenty- two food flavouring authorisations, and a proposal to set a limit for ethylene oxide in food additives - Food Standards Scotland - Citizen Space: https://consult.foodstandards.gov.scot/regulatory-policy/publication-of-regulatory-policy-tranche3-misc/

EU Alignment Consideration

In the EU, three of the novel foods (Partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*), Cetylated Fatty Acids, and 3-fucosyllactose) and one of the food additives (E 476) have been authorised, the twenty two food flavouring authorisations have been removed, and the new limit of ethylene oxide limit in all food additives has been introduced. All the above have already been approved for use in Northern Ireland (NI), under Windsor Framework arrangements. Authorisations for two of the novel foods and one food additive do not align with relevant EU law.

The novel food 3-fucosyllactose (3-FL) has an additional labelling requirement in the EU authorisation, that food supplements should not be consumed by infants (children under 12 months) and children (children aged 1 year to 3 years), however, the safety assessment states that the absorption of 3-FL from consumption of the novel food is not expected to differ from the intake of human milk oligosaccharides following infant consumption of breast milk. Therefore, this was not expected to pose a safety concern for infants (children under 12 months) or other age groups. Risk managers have not identified any other factors to implement a general restriction to infants (children under 12 months) and children (children aged 1 year to 3 years); the additional labelling requirement for the GB authorisation is proposed to be “For infants (children under 12 months) and young children (children aged 1 year to 3 years), food supplements are not intended to be used if breast milk or other foods with added 3- fucosyllactose are consumed on the same day.” There are also differences between the specification and proposed uses for the GB authorisation versus the EU authorisation. These differences are justified because the safety assessment determined that the information provided is sufficient for the specification of 3-FL, and appropriately characterises the novel food seeking authorisation. Additionally, the applications for EU and GB authorisation are applications made by two different applicants, to two independent regulators in two different jurisdictions. They have each been subject to the independent risk assessment and risk management process in the jurisdiction in which they were made, differences are therefore inevitable, especially when we are assessing things on a different basis (i.e. the levels in the separate applications are different).

The novel food cetylated fatty acids has a ‘Maximum Level’ of 1.6g per day, in the EU authorisation, whereas GB’s ‘Maximum Level’ is 2.1g per day. The FSS/FSA safety assessment concluded that 2.1g per day of cetylated fatty acids is safe. Both GB and EU have calculated the margin of safety for the substance based on the data from the toxicological study using their standard methodology. Both calculations are valid given the data presented. How the values were calculated were explained in the relevant safety assessments. The difference between the GB and EU assessments related to which dose was chosen as the No Observed Adverse Effect

Level (NOAEL) and which safety factors were applied to identify the maximum dose. There are differences between the specification for the GB authorisation versus the EU authorisation. These differences are justified because the safety assessment determined that the information provided is sufficient for the specification of the cetylated fatty acids and appropriately characterises the novel food seeking authorisation. We believe that the differences between the EU authorised specification and the proposed GB specification occurred during the risk management stage in the EU and we are therefore unable to comment on why these amendments were made.

For the food additive Rebaudioside M, AM and D produced via enzymatic conversion of highly purified steviol glycosides from stevia leaf extracts, although there will be a divergence from the EU authorisation and the GB authorisation there are no significant differences. In the GB authorisation we have one combined specification to cover rebaudiosides D, M and AM, whilst the Commission had 3 separate specifications for each of these rebaudiosides. The parameters and limits are identical between the EU and GB specifications apart from the fact that in the GB specification a particle size limitation wasn't considered necessary by the AEJEG or the applicant which the FSA and FSS agreed with. There was a minor error in the EU specification as the genetically modified strains of *E. coli* should be pSK041 not pSK401 as stated.

For the food additive polyglycerol polyricinoleate (PGPR, E 476), as part of the legislation for the EU approval of the extension of use, changes to the specifications for E 476, E 422 and E 475 were included in the Regulation. These changes will not be included in the authorisation of RP217 as discussions with industry are needed before setting new numerical limits for glycidyl fatty acid esters to ensure that there is no significant impact on FBOs who use these food additives.

The corrections to exemptions/restrictions for steviol glycosides and polyols in Regulation (EC) No. 1333/2008 will result in a difference between EU and GB legislation for the wording for E 960a – E 960c within category 05.2 (Other confectionery including breath freshening microsweets) and Polyols. This correction is not intended to change the conditions of use of steviol glycosides (E 960a and E 960c), but to ensure consistency with how sandwich spreads are described.

The novel food lacto-*N*-fucopentaose I (LNFP-I) and 2'-fucosyllactose (2'-FL) mixture and the food additive Steviol glycosides produced by *Yarrowia lipolytica* have not yet been authorised in the EU.

Aligning with relevant EU policy maintains and advances fair trade, competition and access to EU markets for industry and agricultural services.

Consultation

Scotland

To comply with the requirements of Article 9 of Regulation (EC) 178/2002, public consultation was undertaken by FSS during the preparation and evaluation of this SSI. The public consultation was open from 02 February 2024 until 29 March 2024. No responses were received.

Rest of Great Britain

A total of fifteen consultation responses were received by the FSA: four representing industry, six Trade Associations, one Non-Government Organisation/Professional Body, one Non– Government Organisation (with close links to Government), one Independent Public Health Nutrition Charity, one Local Authority/consumer protection organisation and one Private Individual. Across the 15 respondents, all gave their location as UK-wide. As all respondents are UK wide, their response also has relevance to Scotland. A summary of the responses, and FSA's consultation, is available here: https://www.food.gov.uk/our-work/summary-of-stakeholder-responses-consultation-on-applications-for-authorisation-of-miscellaneous-regulated-products-spring-2024.

Impact Assessments

FSS consider that a specific Business and Regulatory Impact Assessment (BRIA) is not required for these authorisations. The costs to businesses are contained in Regulation (EU) 2015/2283 and Regulation (EC) 1331/2008 which both require authorisations before products may be placed on the market or for extensions/modifications of use of current authorisations. This SSI gives legislative effect to the Minister's decision and does not introduce any new costs to businesses or industry. The new novel food authorisations and new production methods and extension of use of food additives will likely result in the reallocation of wealth from existing to new product lines. No other impact assessments are required. Whilst we are removing the authorisation for some flavourings, the UK flavouring industry have informed FSS/FSA that these are not used in food in the UK and so there will be no significant impact on businesses.

Financial Effects

The Minister for Public Health and Women's Health confirms that a BRIA is not necessary as the instrument has no financial effects on the Scottish Government, local government or on business.

Evangelos Katsoulis
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Food Standards Scotland,
24 May 2024