Health, Social Care and Sport Committee

13th Meeting, 2023 (Session 6), Tuesday, 18 April 2023

Subordinate legislation

Note by the clerk

Purpose

1. This paper invites the Committee to consider the following negative instrument:

   - The Food Additives, Food Flavourings and Novel Foods (Authorisations) (Scotland) Regulations 2023

Procedure for negative instruments

2. Negative instruments are instruments that are "subject to annulment" by resolution of the Parliament for a period of 40 days after they are laid. This means they become law unless they are annulled by the Parliament. All negative instruments are considered by the Delegated Powers and Law Reform Committee (on various technical grounds) and by the relevant lead committee (on policy grounds).

3. Under Rule 10.4, any member (whether or not a member of the lead committee) may, within the 40-day period, lodge a motion for consideration by the lead committee recommending annulment of the instrument.

4. If the motion is agreed to by the lead committee, the Parliamentary Bureau must then lodge a motion to annul the instrument to be considered by the Parliament as a whole. If that motion is also agreed to, the Scottish Ministers must revoke the instrument.

5. If the Parliament resolves to annul an SSI then what has been done under authority of the instrument remains valid but it can have no further legal effect. Following a resolution to annul an SSI the Scottish Ministers (or other responsible authority) must revoke the SSI (make another SSI which removes the original SSI from the statute book.) Ministers are not prevented from making another instrument in the same terms and seeking to persuade the Parliament that the second instrument should not be annulled.

6. Each negative instrument appears on the Health, Social Care and Sport Committee's agenda at the first opportunity after the Delegated Powers and Law Reform Committee has reported on it. This means that, if questions are asked or concerns raised, consideration of the instrument can usually be continued to a later meeting to allow the Committee to gather more information or to invite a Minister to give evidence on the instrument. Members should however note that, for scheduling reasons, it is not *always* possible to continue an instrument to the following week. For this reason, if any Member has significant concerns about a negative instrument, they are encouraged to make this known to the clerks in advance of the meeting.

7. In many cases, the Committee may be content simply to note the instrument and agree to make no recommendations on it.

Guidance on subordinate legislation

8. Further guidance on subordinate legislation is available on the Delegated Powers and Law Reform Committee's web page at: http://www.scottish.parliament.uk/parliamentarybusiness/CurrentCommittees/delegated-powers-committee.aspx

Recommendation

9. The Committee is invited to consider any issues which it wishes to raise in relation to these instruments.

Clerks to the Committee

13 April 2023

SSI 2023/78

Title of Instrument: The Food Additives, Food Flavourings and Novel Foods (Authorisations) (Scotland) Regulations 2023

Type of Instrument: Negative

Laid Date: 16 March 2023

Meeting Date: 18 April 2023

Minister to attend meeting: No

Motion for annulment lodged: No

Drawn to the Parliament's attention by the Delegated Powers and Law Reform Committee? Yes.

10. The Delegated Powers and Law Reform Committee considered the instrument at its meeting on 28 March 2023 and made no recommendations in relation to this instrument.

Reporting deadline: 8 May 2023

Purpose

11. The purpose of the instrument is to authorise a new food additive, a new food flavouring and a new novel food to be placed on the market in Scotland.

12. It also authorises new conditions of use and changes to the specification of an existing novel food.

13. The policy note states that this SSI aligns Scotland with England and Wales as well as with similar EU legislation for these products, all of which have now been authorised by the EU Commission.

14. A copy of the Scottish Government's Policy Note is included in **Annexe A**.

15. Full details of the Food Standards Scotland Consultation and summary of responses can be accessed here: Consultation on applications for authorisation of two novel foods, one food additive and one food flavouring - - Citizen Space

ANNEXE A

POLICY NOTE

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

SSI 2023/78

The above instrument was made in exercise of the powers conferred by Articles 7(5) and 14A(2)(b) of Regulation (EC) No. 1331/2008 of the European Parliament and of the Council of establishing a common authorisation procedure for food additives, food enzymes and food flavourings and Article 12(1) of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel 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.
The instrument is subject to negative procedure.

Summary Box

The purpose of this instrument is to implement the decision made by the Minister for Public Health, Women's Health & Sport on four regulated food product applications. It authorises the placing on the market in Scotland of a new food additive, a new food flavouring and a new novel food. It also authorises new conditions of use and changes to the specification of an existing novel food.

Policy Objectives
The instrument is required to give legislative effect to the Minister's decision with respect to four regulated food products authorisations.

It amends the domestic list of food additives approved for use in foods set out in Annex 2 to Regulation (EC) No.1333/2008 to add the food additive enzymatically produced steviol glycosides (E 960c). It also amends the name and E-number of the existing food additive steviol glycosides (E 960) to steviol glycosides from Stevia (E 960a), allowing the consumer to differentiate between the additives made with the existing and new production methods. The instrument will also update the Annex to Commission Regulation (EU) No. 231/2012 to re- name the existing specification for steviol glycosides (E 960) and add a new specification for enzymatically produced steviol glycosides (E 960c).

The instrument will add the new food flavouring (3-(1-((3,5-dimethylisoxazol-4-yl)methyl)- 1H-pyrazol-4-yl)-1-(3-hydroxybenzyl)imidazolidine-2,4-dione) to the list of authorised food flavourings and source materials set out in Annex 1 to Regulation (EC) No. 1334/2008

The instrument will also amend Commission Implementing Regulation (EU) 2017/2470 to add the new novel food vitamin D_2 mushroom powder to the list of authorised novel foods provided for there. Further, it will amend the entry in that list

for the existing novel food UV- treated baker's yeast (Saccharomyces cerevisiae) to provide for additional conditions of use and a revised specification.
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. The retained law obligates the Scottish Ministers to prescribe authorisation of the relevant regulated product in law, which is the focus of this Scottish Statutory Instrument (SSI).

This SSI aligns Scotland with England and Wales as well as with similar EU legislation for these products, all of which have now been authorised by the EU Commission.

Consultation
To comply with the requirements of Article 9 of Regulation (EC) No. 178/2002 there has been open and transparent public consultation during the preparation and evaluation of this SSI.

The initial consultation ran from 17 October 2022 to 11 December 2022 and attracted 190 visitors, resulting in the survey being accessed 28 times. There was one response to the initial consultation, which was in support of the authorisations. The response was from industry within Scotland and no concerns were raised.

The additional consultation ran from 23 January 2023 to 6 February 2023 and attracted 125 visitors, resulting in the survey being accessed 16 times. There were no responses to the additional consultation.

Summaries of the consultation responses and replies to these were published on the consultation pages on Citizen Space for both the initial and the additional consultations. A list of those who replied to the consultation and who agreed to publication of their details and response was included in these summaries published on Citizen Space.

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 decisions and does not in itself introduce any new costs to the individual businesses or industry as a whole. The new authorisations would likely

result in reallocation of wealth from existing to new product lines. No other impact assessments are required.

Financial Effects
The Minister for Public Health, Women's Health & Sport confirms that no BRIA is necessary as the instrument has no financial effects on the Scottish Government, local government or on business.

Food Standards Scotland
9 March 2023