Health, Social Care and Sport Committee

12th Meeting, 2023 (Session 6), Tuesday, 28 March 2023

Subordinate legislation

Note by the clerk

Purpose

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

   - The Genetically Modified Food and Feed (Authorisations and Modifications of 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 this instrument.

Clerks to the Committee

23 March 2023

SSI 2023/059

Title of Instrument: The Genetically Modified Food and Feed (Authorisations and Modifications of Authorisations) (Scotland) Regulations 2023

Type of Instrument: Negative

Laid Date: 2 March 2023

Meeting Date: 28 March 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 14 March 2023 and made no recommendations in relation to this instrument.

11. In its report the Committee welcomed that regulation 22 of SSI 2023/59 corrects an error identified by the Committee in SSI 2022/137, the Genetically Modified Food and Feed (Authorisations) (Scotland) Regulations 2022.

Reporting deadline: 24 April 2023

Purpose

12. The purpose of the instrument is to implement the decision made by the Minister for Public Health, Women's Health & Sport to:

    - modify the authorisation holders' details for 51 previously authorised Genetically Modified Organisms (GMOs)
    - to authorise six GM food and feed products for placement on the market in Scotland, and
    - renew the authorisation for two GM food and feed products for placement on the market in Scotland.

13. The instrument also amends The Genetically Modified Food and Feed (Authorisations) (Scotland) Regulations 2022, providing minor corrections for authorisations.

14. The policy note states that this instrument 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. The Scottish Government has further confirmed that the terms of authorisation for the GMOs in The Genetically Modified Food and Feed (Authorisations and Modifications of Authorisations) (Scotland) Regulations 2023 are the same as the terms of authorisation in the EU/NI.

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

16. A copy of Food Standards Scotland's consultation and summary of stakeholder responses is available on the Food Standards Scotland website: *Consultation on applications for eight genetically modified organisms (GMOs) for food and feed uses and for the change of authorisation holder for fifty-one authorised GMOs.*

Annexe A

POLICY NOTE

THE GENETICALLY MODIFIED FOOD AND FEED (AUTHORISATIONS AND MODIFICATIONS OF AUTHORISATIONS) (SCOTLAND) REGULATIONS 2023

SSI 2023/59

The above instrument was made in exercise of the powers conferred by Articles 7(3), 9(2), 11, 19(3), 21(2), 23 and 35 of Regulation (EC) No. 1829/2003 of the European Parliament and of the Council on genetically modified (GM) food and feed. The instrument is subject to negative procedure.

Summary Box

The purpose of the instrument is to implement the decision made by the Minister for Public Health, Women's Health & Sport to modify the authorisation holders' details for 51 previously authorised Genetically Modified Organisms (GMOs) and to authorise six and renew the authorisation for two GM food and feed products for placement on the market in Scotland.

Policy Objectives

The instrument is required to give legislative effect to the Minister's decision with respect to the modification of authorisation holders' details for 51 GMOs and the authorisation of eight GM food and feed products, either for placing on the market in Scotland or for the renewal of their use on the market. This SSI also amends The Genetically Modified Food and Feed (Authorisations) (Scotland) Regulations 2022, providing minor corrections for authorisations contained therein.

At the end of the Implementation Period the UK inherited the EU Commission's 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'. The European Food Safety Authority (EFSA) previously developed technical guidance on the requirements of applications and these generally remain relevant as FSS' approach is based on EU processes.

The authorisation of these regulated 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 comprises the authorisations by the Scottish Ministers of applications made to them either for a new authorisation or renewal of an authorisation for GM food and feed and applications made to modify authorisation holders' details for previously authorised GMOs. This instrument will apply to Scotland only.

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 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, there has been open and transparent public consultation during the preparation and evaluation of this SSI. The consultation ran from 12 October 2022 to 6 December 2022 and attracted 199 visitors, resulting in the survey being accessed 63 times.

There were nine responses to the consultation, of which three were in support and six were opposed to the authorisations. Those in support included businesses and trade associations, while those in opposition were private individuals and not for profit organisations. Concerns were raised around issues such as risk assessments for regulated products and the potential effects of GMO consumption on health and the environment, including potential for increased use of herbicides. Conversely, trade associations raised concerns around the significant impact of the feed deficit pending a decision on authorisation, given the reliance of the feed industry in Scotland on GMO feed. Responses both for and against authorisation were low in numbers compared to actual numbers of stakeholders reached.

Stakeholder concerns were analysed in detail and addressed. Based on the science and evidence, the responses did not alter FSS views. A summary of the consultation responses and the main themes identified in these have been published on the consultation page on Citizen Space alongside FSS consideration of each of the themes. A list of those consulted, with the exception of private individuals, and who agreed to the release of this information is attached to the consultation report published on Citizen Space.

Impact Assessments

FSS consider that a specific (Business and Regulatory Impact Assessment) BRIA is not required for these regulated products authorisations. The costs to businesses are contained in the Regulation (EC) No. 1829/2003 of the European Parliament and of the Council on GM food and feed which requires authorisation for GMOs to be placed on the market. 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. Two out of the eight GMOs authorised in this SSI are renewals and the collective impact is expected to be minimal. The new authorisations would likely result in reallocation of wealth from existing to new product lines. The consultation has explored perceived impacts with industry which have been reviewed by FSS and responded to as outlined above. No other impact assessments are required.

Financial Effects

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

Food Standards Scotland
February 2023