Health, Social Care and Sport Committee

18th Meeting, 2022 (Session 6), Tuesday 17 May 2022

Subordinate legislation

Note by the clerk

Purpose

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

   Genetically Modified Food and Feed (Authorisations) (Scotland) Regulations 2022

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

12 May 2022

SSI 2022/137

Title of Instrument: Genetically Modified Food and Feed (Authorisations) (Scotland) Regulations 2022

Type of Instrument: Negative

Laid Date: 21 April 2022

Meeting Date: 17 May 2022

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.

Reporting deadline: 23 May 2022

Purpose

10. The instrument authorises five new types of genetically modified maize and soybean products for use in food and animal feed sold in Scotland. It also renews authorisation for continuing use of four genetically modified maize products.

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

12. Section 28(2) of the Interpretation and Legislative Reform (Scotland) Act 2010 sets out that a negative SSI must be laid before the Scottish Parliament at least 28 days before the instrument comes into force. This instrument breaches the 28 day rule. Reasons for this breach are detailed in a letter to the Presiding Officer, attached at Annexe B.

Delegated Powers and Law Reform Committee Consideration

13. The Delegated Powers and Law Reform Committee considered this at their meeting on 10 May 2022, and agreed to draw this instrument to the attention of the Parliament under the general reporting ground in respect of an error in paragraphs 4(2) of schedules 3, 4 and 7. The document reference number is incorrectly stated to be EURL-VL-0417VP rather than EURL-VL-03/12VP.

14. In response to correspondence from the Committee, the Scottish Government acknowledged that there is a referencing error in the instrument but does not propose to correct this.

15. A copy of the correspondence can be found in **Annex B.**

Annexe A

POLICY NOTE

The Genetically Modified Food and Feed (Authorisations) (Scotland) Regulations 2022
SSI 2022/137

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 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 authorise five and renew the authorisation for four genetically modified (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 authorisation of nine GM food and feed products, either for placing on the market in Scotland or for the renewal of their use in the market.

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 genetically modified food and feed. 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. Not progressing this SSI would mean that the Minister's decision to authorise would have no legal effect. Not signing the SSI would also lead to divergence across GB and the EU, creating an unequal footing within the UK and disruptions for imports, exports and enforcement bodies as Northern Ireland operates under EU legislation under the terms of the Northern Ireland Protocol. Additionally, due to the United Kingdom Internal Market Act, if the SSI is not progressed the product could still be put on the market across GB.

All relevant information on the authorisation of the products will be entered in the register of genetically modified food and feed referred to in Article 28(1) of Regulation 1829/2003.

The authorisations made by this instrument will be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article (1) and Article 15(1)(e) of retained Regulation (EC) 1946/2003 on transboundary movements of genetically modified organisms.

Further information including in relation to the register or the information notified pursuant to the Cartagena Protocol, can be obtained from Food Standards Scotland, Pilgrim House, Old Ford Road, Aberdeen, AB 11 5RL.

Consultation

To comply with the requirements of Article 9 of Regulation (EC) 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 30 November 2021 to 25 January 2022 and attracted 245 visitors, resulting in the survey being accessed 126 times.

There were 37 responses to the consultation, of which four were in support and 33 were opposed to the authorisation of these products. Those in support included private individuals and trade associations, while those in opposition were mainly private individuals. Concerns were raised around a number of issues, including the adequacy of the risk assessments, the effects of the consumption of GMO on human health, and environmental impacts including potential for increased use of herbicides. Conversely, trade associations raised concerns around the potential for trade disruption and rising feed prices during the current feed supply deficit. 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. Discussions were held on a four-nation basis, in line with the provisional Food and Feed Safety and Hygiene Common Framework, to address any devolved concerns and ensure alignment. The views of FSS and the Food Standards Agency in England and Wales were agreed on through discussion of feedback and responses within cross-government forums with the Scottish Government, the Department of Health and Social Care, and the Welsh Government. 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 genetically modified 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. Since four out of the nine GMOs authorised in this SSI are renewals, the 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 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
19 April 2022

Annexe B

Genetically Modified Food and Feed (Authorisations) (Scotland) Regulations 2022 (SSI 2022/137)

On 28 April 2022, the Committee asked the Scottish Government:

The instrument implements a decision to authorise five, and to renew authorisation for four, products containing genetically modified organisms to be placed on the market in Scotland. Regulation 3 gives effect to schedules 1 – 9 of the instrument which set out the scope, extent and requirements of authorisation for the use of specified genetically modified organisms including the methods to be used to detect the genetically modified substance in food and food ingredients, feed and other products.

Paragraphs 4(2) of schedules 3 and 7 relate to authorisations involving GM maize MON 87427 and specify the method to be used in detecting this substance in products. Both paragraphs refer to the following document entitled "Event-specific Method for the Quantification of Maize MON 87427 Using Real-time PCR", reference "EURL-VL-0417VP" as the one in which the relevant method is described. However, that reference number relates to the document also specified in para 4(2) of schedule 2 which prescribes the method for detection of GM maize MZIR098.

1. Please confirm whether the document references for "Event-specific Method for the Quantification of Maize MON 87427 Using Real-time PCR" in paragraphs 4(2) of schedules 3 and 7 should be to EURL-VL-03/12VP rather than EURL-VL-0417VP.

1. Please confirm whether any corrective action is proposed, and if so, what action and when.

On 2 May 2022, the Scottish Government responded:

1. Thank you for bringing this to our attention. It is correct that the document references for "Event-specific Method for the Quantification of Maize MON 87427 Using Real-time PCR" in paragraphs 4(2) of schedules 3 and 7 should be to EURL-VL-03/12VP rather than EURL-VL-0417VP.

2. We have considered whether there should be any corrective action.

When the whole title of the document, as it appears in the instrument, "*Event-specific Method for the Quantification of Maize MON 87427 Using Real-time PCR", reference "EURL-VL-04/17VP*", is searched, the correct reference document for GM Maize 87427 is reached, that being the document with reference number EURL-VL-03/12VP.

When the reference number "*EURL-VL-04/17VP*" alone is searched this leads to the document for GM Maize MZIR098. The title of the document,

“Event-specific Method for the Quantification of maize MZIR098 by Real-time PCR” we consider, makes it immediately obvious for someone searching for the detection method for MON 87427 that this is incorrect.

Whilst paragraph 4(2) of schedules 3 and 7 cite the incorrect document reference number, the fact that the correct document title is listed in full and appears when a search is carried out (even with the incorrect reference number), we think, still allows the reader to find the correct reference document easily. Therefore, we are not proposing any corrective action.