Health, Social Care and Sport Committee

36th Meeting, 2023 (Session 6), Tuesday, 28 November 2023

Subordinate legislation

Note by the clerk

Purpose

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

   - The Food (Scotland) Act 2015 (Compliance Notices) Amendment Regulations 2023
   - The Feed Additives (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

23 November 2023

SSI 2023/337

Title of Instrument: The Food (Scotland) Act 2015 (Compliance Notices) Amendment Regulations 2023

Type of Instrument: Negative

Laid Date: 9 November 2023

Meeting Date: 28 November 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? No

10. The Delegated Powers and Law Reform Committee considered the instrument at its meeting on 21 November 2023 and made no recommendations in relation to this instrument.

Reporting deadline: 11 December 2023

Purpose

11. The purpose of the instrument is to correct an error in the Food (Scotland) Act 2015 (Compliance Notices) Regulations 2023 (SSI 2023 No. 161), specifically to substitute an incorrect reference to regulation 6(2) of the Novel Foods (Scotland) Regulations 2017 with a reference to regulation 4 of those Regulations.

12. The policy note states that the correction will allow Authorised Officers to use compliance notices to deal with breaches of the requirements in the Novel Foods (Scotland) Regulations 2017.

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

SSI 2023/339

Title of Instrument: The Feed Additives (Authorisations) (Scotland) Regulations 2023

Type of Instrument: Negative

Laid Date: 10 November 2023

Meeting Date: 28 November 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? No

14. The Delegated Powers and Law Reform Committee considered the instrument at its meeting on 21 November 2023 and made no recommendations in relation to this instrument.

Reporting deadline: 18 December 2023

Purpose

15. The purpose of the instrument to implement the decision made by the Minister for Public Health and Women's Health on thirteen feed additive applications. It authorises the placing on the market and use in Scotland of ten new feed additives, renews two authorisations with modifications and renews, modifies and authorises a new use for one other additive. This instrument also includes a transitional provision concerning an existing authorisation for one feed additive which is renewed (subject to a modification) by the instrument.

16. The policy note states that the instrument aligns Scotland with England and Wales and with similar EU legislation for these feed additives. It also states that Food Standard Scotland and the Food Standards Agency have concluded that each feed additive as described in the applications are safe for the target species, users, consumers and the environment.

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

ANNEXE A

POLICY NOTE

THE FOOD (SCOTLAND) ACT 2015 (COMPLIANCE NOTICES) AMENDMENT REGULATIONS 2023

SSI 2023/337

The above instrument was made in exercise of the powers conferred by sections 49(1) and (2)(c) and 52 of the Food (Scotland) Act 2015. This instrument is subject to negative procedure.

Summary Box

The purpose of the instrument is made to correct an error in the Food (Scotland) Act 2015 (Compliance Notices) Regulations 2023 (SSI 2023 No. 161), specifically to substitute an incorrect reference to regulation 6(2) of the Novel Foods (Scotland) Regulations 2017 with a reference to regulation 4 of those Regulations.

Policy Objectives

The purpose of the Food (Scotland) Act 2015 (Compliance Notices) Amendment Regulations 2023 is to substitute an incorrect reference to regulation 6(2) of the Novel Foods (Scotland) Regulations 2017 with a reference to regulation 4 of those Regulations. This will allow Authorised Officers (AOs) to use compliance notices to deal with breaches of the requirements in the Novel Foods (Scotland) Regulations 2017.

EU Alignment Consideration

This instrument concerns enforcement measures and is not relevant to the Scottish Government's policy to maintain alignment with the EU.

Consultation

There was no consultation carried out for this instrument. However, FSS had previously consulted from 21 October to 16 December 2021 on our proposal to introduce compliance notices for breaches of the Novel Foods (Scotland) Regulations 2017 along with other food offences as part of the consultation on the Food (Scotland) Act 2015 (Compliance Notices) Regulations 2023.

Impact Assessments

No impact assessment was carried out for this instrument, however a BRIA was previously carried out for the general introduction of Compliance Notices.

Financial Effects

No additional financial effects are foreseen as a result of this instrument.

Food Standards Scotland
November 2023

ANNEXE B

POLICY NOTE

THE FEED ADDITIVES (AUTHORISATIONS) (SCOTLAND) REGULATIONS 2023 SSI 2023/339

The above instrument was made in exercise of the powers conferred by Articles 9(1) and 18A(3) of Regulation (EC) No. 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition. 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 and Women's Health on thirteen feed additive applications. It authorises the placing on the market and use in Scotland of ten new feed additives, renews two authorisations with modifications and renews, modifies and authorises a new use for one other additive. This instrument also includes a transitional provision concerning an existing authorisation for one feed additive which is renewed (subject to a modification) by the instrument. This instrument applies to Scotland only.

Legislative Context

Feed additives are regulated products which may be authorised for specific purposes in animal feed and can have a range of functions including meeting animals' nutritional requirements, improving the quality of feed and food, and improving animals' performance and health. A feed additive must be authorised before it can be placed on the market, processed and used in Great Britain (GB) and can only be used for the purposes stated, and subject to the conditions provided, in an authorisation. The retained Regulation (EC) No. 1831/2003 and Regulation (EC) No. 429/2008 set out the legislative framework for submitting applications for authorisation of feed additives in relation to conditions of use and the labelling and packaging of feed additives and their premixtures. Feed additives are classified under five broad categories (technological, sensory, nutritional, zootechnical, and coccidiostats and histomonostats), and they are further defined within functional groups set out in Annex I of Regulation (EC) No. 1831/2003.

The retained Regulation (EC) No. 1831/2003 provides Scottish Ministers with the power to authorise feed additives and specify conditions for their use. Feed additives authorisations are valid for 10 years following the date that the instrument comes into force. When no decision is taken on the renewal of an authorisation before its expiry date, Article 14 of Regulation (EC) No. 1831/2003 makes provision for the period of authorisation to be automatically extended until the appropriate authority makes a determination. Article 16 of Regulation (EC) No. 1831/2003 makes provision in relation to the labelling and packaging of the feed additives and premixture of additives. Article 17 requires that a GB register of regulated food and feed products for GB which includes feed additives and is available at: Authorised Regulated Food and Feed Products for Great Britain.

Policy Objectives

This instrument is required to give legislative effect to the Minister's decision with respect to the authorisation of thirteen feed additives. This instrument authorises the placing on the market and use in Scotland of ten new feed additives, renews two authorisations with modifications and renews, modifies and authorises a new use for one other additive. This instrument also includes a transitional provision concerning an existing authorisation for one feed additive, which is renewed (subject to a modification) by the instrument, in accordance with retained Regulation (EC) No. 1831/2003 and Regulation (EC) No. 429/2008. The transitional provision is for the feed additive Endo-1,4-beta-xylanase (EC 3.2.1.8), concerning a change in its identification (ID) number from 4a8 to 4a8i. The transitional provision allows for feed additives, premixtures and compound feed and feed materials containing Endo-1,4-beta-xylanase (EC 3.2.1.8) and labelled with ID number 4a8 to continue to be placed on the market and used until stocks, so labelled, are exhausted.

This instrument also revokes retained EU Regulations which are now redundant in GB following the making of this instrument (one European Community Regulation, and various EU Commission Regulations and Implementing Regulations, concerning the authorisation of feed additives together with necessary miscellaneous consequential revocations). The Commission Implementing Regulation (EU) No. 601/2013 concerning the authorisation of cobalt(II) acetate tetrahydrate, cobalt(II) carbonate, cobalt(II) carbonate hydroxide (2:3) monohydrate, cobalt(II) sulphate heptahydrate and coated granulated cobalt(II) carbonate hydroxide (2:3) monohydrate as feed additives is amended as follows: in the Annex, omit the entry for cobalt(II) acetate tetrahydrate (identification number 3b301), the entry for cobalt(II) carbonate (identification number 3b302), the entry for cobalt(II) carbonate hydroxide (2:3) monohydrate (identification number 3b303), the entry for cobalt(II) sulphate heptahydrate (identification number 3b305).

Assessing food and animal feed safety in Scotland is the responsibility of Food Standards Scotland (FSS). The Scottish Ministers are responsible for the authorisation of these thirteen feed additives in Scotland. The retained law provides that authorisations of the relevant feed additives and the modification of feed additive authorisations must be prescribed by the Scottish Ministers. This instrument comprises the authorisations by the Scottish Ministers of applications made to them either for a new feed additive authorisation or the extension, renewal or modification of a currently authorised feed additive. This instrument applies to Scotland only.

This instrument aligns Scotland with England and Wales and with similar EU legislation for these feed additives. FSS and the Food Standards Agency (FSA) have reviewed the European Food Safety Authority (EFSA) opinions along with all supporting documentation concerning the thirteen feed additives and formed an independent opinion based on risk assessment and safety conclusions. The FSS/FSA opinion in each case was that the feed additives as described in the applications are safe for the target species, users, consumers and the environment. 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 second tranche of feed additives - Food Standards Scotland - Citizen Space.

Seven of the additives are authorised as technological additives in the functional group ‘silage additives’, while three are authorised as zootechnical additives in the functional group ‘digestibility enhancers’ and one authorised as a nutritional additive in the functional group of ‘amino acids, their salts and analogues’. 3-nitrooxypropanol (3-NOP) is also authorised as a zootechnical additive. Currently this is the only additive to belong to the functional group ‘substances which favourably affect the environment’.

In line with commitments made under the Food and Feed Safety and Hygiene Provisional Common Framework, FSS has worked closely with FSA on these feed additive authorisations applications within the regulated products process. Ministers in England and Wales have also agreed to the authorisations of the feed additives and will be submitting their own statutory instruments to their respective legislatures.

EU Alignment Consideration
All thirteen feed additives have been authorised for use in the EU. These feed additives have already been approved for use in Northern Ireland (NI), under Windsor Framework arrangements. Twelve of the additives align with relevant EU law, there is no divergence.

The feed additive 3-NOP has been authorised in NI/EU in feed for dairy cows and cows for reproduction, whereas the authorisation in GB is for all ruminants for milk production and reproduction. Based on the studies and evidence provided by the applicant, EFSA concluded that 3-NOP was safe for dairy cows and cows for reproduction but could not extrapolate the margin of safety to all ruminants. Based on further evidence and data requested by the Advisory Committee on Animal Feedingstuffs (ACAF) from the applicant, ACAF could establish a margin of safety and therefore concluded it was safe at the intended inclusion rates for all ruminants. It is unclear whether EFSA received the same further evidence and data from the applicant that was available to ACAF before reaching its conclusion.

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) No. 178/2002, public consultation was undertaken by FSS during the preparation and evaluation of this instrument. The public consultation was open from 25 May 2023 until 20 July 2023. Four responses were received from the consultation. Responses were received from key trade bodies and industry. All were supportive of the proposed authorisations. In brief, the main reasons cited for supporting the authorisations were to avoid disruption between EU and GB trade and resulting health, welfare, and dietary concerns in farm animals, and the importance to trade in avoiding divergence from the EU and NI, due to logistics. No concerns were raised about the safety of the feed additives or with regards to costs or burdens for industry. A summary of the consultation responses is available on Citizen Space: Consultation on applications for authorisation of second tranche of feed additives - Food Standards Scotland - Citizen Space.

Rest of GB
A further seven responses were received by FSA during their consultation from a UK wide trade association. The responses were supportive of the proposed authorisations and highlighted no concerns with regards to the safety of the feed additives or with regards to costs or burdens for industry. As this association is UK wide and has Scottish members, its response also has relevance to Scotland.

Impact Assessments
FSS consider that a specific BRIA (Business and Regulatory Impact Assessment) is not required for these feed additive authorisations. The costs to businesses are contained in Regulation (EC) 1831/2003 on additives for use in animal feed which requires authorisation before feed additives may be placed on the market, as well as of any renewals, modifications, re-evaluations or extensions of existing feed additive authorisations. A full Impact Assessment has not been prepared for this instrument because the regulations are designed to allow authorised feed additives to be placed on the market in Scotland. The familiarisation costs are expected to be minimal, as these feed additive applications are routine or, in the case of 3-NOP, which is the first in its functional group, has been on the market in NI/EU since April 2022. The new feed additive authorisations will likely result in the reallocation of wealth from existing to new product lines. No other impact assessments are required.

Financial Effects
The Minister for Public Health and Women's Health confirms that a BRIA is not necessary as the instrument has minimal financial cost on the Scottish Government, local government or on business.

Matthew Mullen,
Food Standards Scotland,
1st November 2023