HSCS/S6/24/34/3

Health, Social Care and Sport Committee
26 November 2024
34th Meeting, 2024 (Session 6)

Subordinate legislation

Background

1. At this meeting the Committee will consider the following Instruments subject to negative procedure—

   - The Official Controls (Import of High Risk Food and Feed of Non-Animal Origin) Amendment (Scotland) (No. 2) Regulations 2024

   - The Food Safety (Sampling and Qualifications) (Scotland) Amendment Regulations 2024

   - The Feed Additives (Authorisations) and Uses of Feed Intended for Particular Nutritional Purposes (Miscellaneous Amendment) (Scotland) Regulations 2024

The Official Controls (Import of High Risk Food and Feed of Non-Animal Origin) Amendment (Scotland) (No. 2) Regulations 2024 (SSI 2024/324)

Overview

2. The Committee will consider the following Scottish Statutory Instrument (SSI), which is subject to annulment by resolution of the Parliament until 16 December 2024. The Committee is invited to consider the instrument and decide what, if any, recommendations to make.

3. More information about the instrument is summarised below:

Title of instrument: The Official Controls (Import of High Risk Food and Feed of Non-Animal Origin) Amendment (Scotland) (No. 2) Regulations 2024

Laid under: the powers conferred by Article 53(1)(b) 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[1]("Regulation 178/2002"), and Articles 34(6), 47(2)(b) and 54(4)(a) and (b) of Regulation (EU) 2017/625 of the European Parliament and of the Council on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products[2] ("Regulation 2017/625")

Laid on: 7 November 2024

Procedure: Negative

Deadline for committee consideration: 9 December 2024

Deadline for Chamber consideration: 16 December 2024

Commencement: 18 December 2024

Procedure

4. 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.

5. Once laid, the instrument is referred to:

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

[1] EUR 2002/178, as amended by S.I. 2019/641 and S.I. 2020/1504.
[2] EUR 2017/625, as amended by S.I. 2020/1481.

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

6. 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).

7. 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

8. The DPLR Committee considered the instrument on 19 November 2024 and reported on it in its 68th report, 2024. The DPLR Committee made no recommendations in relation to the instrument.

Purpose of the instrument

9. The Policy Note states that the instrument will "amend Commission Implementing Regulation (EU) 2019/1793 imposing temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries."

10. It further states that "this instrument is required to give legislative effect to the Minister's decision with respect to the outcome of a review of Regulation (EU) 2019/1793 which lays down the requirements that apply to certain high risk food and feed commodities of non-animal origin on entry to Great Britain (GB)."

11. 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

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

13. 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.

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

15. 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.

Food Safety (Sampling and Qualifications) (Scotland) Amendment Regulations 2024 (SSI 2024/326)

Overview

16. The Committee will consider the following Scottish Statutory Instrument (SSI), which is subject to annulment by resolution of the Parliament until 16 December 2024. The Committee is invited to consider the instrument and decide what, if any, recommendations to make.

17. More information about the instrument is summarised below:

    Title of instrument: Food Safety (Sampling and Qualifications) (Scotland) Amendment Regulations 2024

    Laid under: Sections 30(9) and 48(1)(b) of the Food Safety Act 1990.

    Laid on: 8 November 2024

    Procedure: Negative

    Deadline for committee consideration: 16 December 2024

    Deadline for Chamber consideration: 17 December 2024

    Commencement: 1 January 2025

Procedure

18. 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.

19. 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.

20. 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).

21. 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

22. The DPLR Committee considered the instrument on 19 November 2024 and reported on it in its 68th report, 2024. The DPLR Committee made no recommendations in relation to the instrument.

Purpose of the instrument

23. The purpose of this instrument is to extend recognition of relevant professional qualifications for Food Examiners to those issued in Switzerland to comply with the UK-Switzerland Recognition of Professional Qualifications (RPQ) Agreement.

24. The instrument amends the Food Safety (Sampling and Qualifications) (Scotland) Regulations 2013, to include a qualification recognised under the Recognition of Professional Qualifications and Implementation of International Recognition Agreements (Amendment) Regulations 2023 ("the Professional Qualification Regulations") in relation to food examination and to futureproof for any future RPQ agreements the UK may enter into, without the need for further amending SSIs.

25. The Professional Qualifications Regulations implement the UK's obligations arising from the RPQ Agreement made between the UK and Switzerland in London on 14 June 2023 and which comes into force on 1 January 2025. The above amendments are necessary to ensure that Scottish legislation complies with the UK's commitments under the UK-Switzerland RPQ Agreement in respect of the mutual recognition of professional qualifications of Food Examiners.

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

Committee consideration

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

28. 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.

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

30. 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.

The Feed Additives (Authorisations) and Uses of Feed Intended for Particular Nutritional Purposes (Miscellaneous Amendment) (Scotland) Regulations 2024 (SSI 2024/330)

Overview

31. The Committee will consider the following Scottish Statutory Instrument (SSI), which is subject to annulment by resolution of the Parliament until 16 December 2024. The Committee is invited to consider the instrument and decide what, if any, recommendations to make.

32. More information about the instrument is summarised below:

Title of instrument: The Feed Additives (Authorisations) and Uses of Feed Intended for Particular Nutritional Purposes (Miscellaneous Amendment) (Scotland) Regulations 2024

Laid under: Articles 9(1), 10(5) and 18A(3) of Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition[3] and section 74A(1) of the Agriculture Act 1970.

Laid on: 8 November 2024

Procedure: Negative

Deadline for committee consideration: 16 December 2024

Deadline for Chamber consideration: 17 December 2024

Commencement: 20 December 2024

Procedure

33. 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.

34. Once laid, the instrument is referred to:

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

[3] EUR 2003/1831 ("Regulation 1831/2003"). Article 9(1) was amended by S.I. 2019/654 and S.I. 2022/377. Article 10(5) was substituted by S.I. 2019/654. Article 18A was inserted by S.I. 2019/654. S.I. 2019/654 was amended by S.I. 2020/1504. Article 2 contains definitions of "prescribe" and "appropriate authority" relevant to the exercise of the powers in Regulation 1831/2003 under which these Regulations are made and was amended by S.I. 2019/654. Article 9(1) applies in relation to renewals in accordance with Article 14.

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

35. 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).

36. 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

37. The DPLR Committee considered the instrument on 19 November 2024 and reported on it in its 68th report, 2024. The DPLR Committee made no recommendations in relation to the instrument.

Purpose of the instrument

38. The policy note states that the purpose of this Scottish Statutory Instrument (SSI) is to implement the decision made by the Minister for Public Health and Women's Health to authorise twenty-five feed additives and one feed for particular nutritional purposes (PARNUT).

39. The SSI authorises the placing on the market and use in Scotland of nine new authorisations, one renewal authorisation, six new use authorisations, three modification authorisations, five renewal and modification authorisations and two renewal, new use and modification authorisations.

40. The instrument also includes transitional provisions for seven existing authorisations and extends to Scotland only.

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

Committee consideration

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

43. 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.

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

45. 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.

Annexe A: Scottish Government Policy Note

THE OFFICIAL CONTROLS (IMPORT OF HIGH RISK FOOD AND FEED OF NON-ANIMAL ORIGIN) AMENDMENT (SCOTLAND) (NO. 2) REGULATIONS 2024

SSI 2024/324

The above instrument was made in exercise of the powers conferred by Article 53(1)(b) of Regulation (EC) No. 178/2002 of the European Parliament and the Council on 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 ("Regulation 178/2002"), and Articles 34(6), 47(2)(b) and 54(4)(a) and (b) of Regulation (EU) 2017/625 of the European Parliament and of the Council on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products and all other powers enabling them to do so. The instrument is subject to negative procedure.

Summary Box

The Official Controls (Import of High Risk Food and Feed of Non-Animal Origin) Amendment (Scotland) (No.2) Regulations 2024 will amend Commission Implementing Regulation (EU) 2019/1793 imposing temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries.

Policy Objectives

This instrument is required to give legislative effect to the Minister's decision with respect to the outcome of a review of Regulation (EU) 2019/1793 which lays down the requirements that apply to certain high risk food and feed commodities of non-animal origin on entry to Great Britain (GB).

The Regulation includes the requirement to review the lists set out in the Annexes on a regular basis in order to take into account new information related to risks and non-compliance and ensure the controls remain proportionate to protect public health.

Following the UK's exit from the EU, this EU Regulation became EU retained EU law, now assimilated law in Scotland (and the rest of GB) along with the requirement for the appropriate authority to review the lists of commodities and their official controls. The appropriate authority are Ministers in Scotland. Food Standards Scotland (FSS) has undertaken the review under its function of developing policy and providing advice relating to matters connected with food safety as provided in section 3 of the Food (Scotland) Act 2015. The review has followed the risk analysis process established by FSS and the Food Standards Agency (FSA). This includes analysis of GB import data which identifies the volume of such imports, sampling results, numbers of consignments found to be non-compliant with GB food and feed safety requirements, expected consumer exposure and the risk it may present to public health. The assessment also considers other intelligence from international authorities and peer review literature.

The Annexes to this legislation contain lists of food and feed commodities of non-animal origin which are either subjected to a temporary increase in official controls, subject to emergency measures or subject to suspension of entry to GB. The decision of the future of the controls in Scotland rests entirely with the Scottish Ministers and the outcome of that decision is the focus of this Scottish Statutory Instrument (SSI). This SSI substitutes, with amendments to Annex 1 and Annex 2 of Regulation (EU) 2019/1793. There are no amendments to Annex 2a of Regulation (EU) 2019/1793. The SSI amends Regulation (EU) 2019/1793 to make consequential provision for sampling and analysis of certain food and feed of non-animal origin for the hazard of pentachlorophenol and dioxins

This instrument will extend to Scotland only. Not progressing this SSI would mean that the Minister's decision would have no legal effect.

UN Convention on the Rights of the Child (Incorporation) (Scotland) Act 2024 Compatibility

In accordance with section 23(2) of the United Nations Convention on the Rights of the Child (Incorporation) (Scotland) Act 2024, the Scottish Ministers certify that, in their view, The Official Controls (Import of High Risk Food and Feed of Non-Animal Origin) Amendment (Scotland)(No.2) Regulations 2024 is compatible with the UNCRC requirements as defined by section 1(2) of the Act.

EU Alignment Consideration

This is the third review of Regulation (EU) 2019/1793 being conducted by the UK. Whilst it is anticipated that UK reviews will generally align with EU controls divergence is possible. However, this would not be due to any proactive policy change. It will be either in relation to our approach to risk analysis which may, on occasion, result in different outcomes to that of the EU and the timing associated with implementation given respective legislative processes.

Consultation

To comply with the requirements of Article 9 of Regulation (EC) 178/2002 of the European Parliament and of the Council laying down general principles and requirements of food law and laying down procedures in matters of food safety, and the requirements of Article 144(7) of Regulation 2017/625, there has been open and transparent public consultation during the preparation and evaluation of this SSI.
A six week public consultation was launched on 14 March 2024 and closed on 25 April 2024 on proposed amendments to items listed in the Annexes of Regulation (EU) 2019/1793. FSS asked for comments from industry, enforcement authorities, consumers and other interested stakeholders on our risk management proposals. The FSA also launched a separate, parallel consultation in England and Wales.

FSS did not receive any responses to the consultation in Scotland whilst the FSA received 8 which have been considered in finalising our recommendations. These included responses from private manufacturer and distribution companies, a Port Health Authority, a Local Authority, food and drink associations and one trade association. Some of the comments were in direct response to the questions posed in the consultation. There were some technical queries about the proposed changes as well as requests to reduce or remove commodities from the proposals.

A full list of those FSS consulted, with the exception of private individuals, who agreed to the release of this information is attached to the consultation page published on Citizen Space.

In line with international transparency commitments set out in the World Trade Organisation (WTO) Sanitary and Phytosanitary (SPS) Agreement, FSS and the FSA notified these proposed SPS changes to WTO members on 20 June 2024. Only one response was received, from the Israel Agricultural Attache. The response sought clarification on Basil and Mint added to the regulation for official controls. FSS and FSA wrote to the Israeli Agricultural Attache providing risk management rationale for adding these commodities to the regulation. No changes to the proposals were made as a result of this response.

There were no changes to the proposals as a result of the public consultation or the WTO Notification and Consultation period. The SSI will amend changes in the Regulation (EU) 2019/1793 whereby one product group will be removed from the scope of controls which includes 7 separate commodities; 4 commodities will be subjected to reduced controls; 2 commodities will be subjected enhanced increased controls; 16 new commodities will be introduced to the annexes to be controlled; CN Code updates are being made to 3 commodities already under control extending the range of commodities that are subject to checks at the border

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 FSA in England and Wales were agreed on.

The instrument substitutes, with amendments, Annex 1 and Annex 2 of Regulation (EU) 2019/1793 based on the outcome of the FSS risk analysis.

Annex 1 contains the list of food and feed of non-animal origin that is subject to a temporary increase in official controls at border control posts (BCPs) or at control points in Great Britain.

The following entries are new listings and have been inserted into Annex 1:

a) Cumin Seeds from India at 10% for Pesticide Residues.
b) Cumin Seeds crushed or ground from India at 10% for Pesticide Residues.
c) Fenugreek leaves from India at 10% for Pesticide Residues.
d) Yardlong Beans from India at 20% for Pesticide Residues.
e) Basil from Israel at 10% for Pesticide Residues.
f) Mint from Israel at 10% for Pesticide Residues
g) Groundnuts paste from Madagascar at 50% for Aflatoxins.
h) Mukunuwenna from Sri Lanka at 10% for Pesticide Residues.
i) Grapefruits from Türkiye at 10% for Pesticide Residues.
j) Sesamum seed from Türkiye at 10% for Salmonella.
k) Tahini and Halva from Türkiye for Sesamum seeds at 10% for Salmonella.

The following entries are new products under existing listings:

a) Mixtures of nuts or dried fruits containing hazelnuts from Georgia.
b) Hazelnut paste from Georgia
c) Hazelnut oil from Georgia.

The following entries have been delisted from Annex 1:

a) Groundnuts (peanuts) in shell from Brazil for Pesticide Residues.
b) Groundnuts (peanuts) shelled from Brazil for Pesticide Residues.

c) Peanut butter from Brazil for Pesticide Residues.
d) Groundnuts (peanuts), otherwise prepared or preserved from Brazil for Pesticide Residues.
e) Oilcake and other solid residue, whether or not ground or in the form of pellets, resulting from the extraction of groundnut oil from Brazil for Pesticide Residues.
f) Groundnut flours and meals from Brazil for Pesticide Residues.
g) Groundnuts paste from Brazil for Pesticide residues.

The following entry has additional CN Codes inserted into Annex 1:

a) Hazelnuts, otherwise prepared or preserved, including mixtures from Georgia for Aflatoxins.

The following entries have CN Code updates under their existing listing to reflect updates to the Tariff website:

a) Granadilla and Passion Fruit from Colombia for Pesticide Residues
b) Bananas from Ecuador for Pesticide Residues

The following entry is a correction to Annex I:

a) Aubergines (Solanum melongena) from Dominican Republic (DO) for pesticide residues - addition of ‘05’ Taric sub-division to specify for the species (Solanum melongena).
b) Tahini and halva from Sesamum seeds from Syria (SY) for Salmonella - addition of CN Codes and Taric sub-division to reflect HMRC changes.
c) Tahini and halva from Sesamum seeds from Türkiye (TR) for Salmonella - addition of CN Codes and Taric sub-division to reflect HMRC changes.

The following entry has been moved from its listing in Annex 1 to Annex 2:

a) Tea whether, or not flavoured from China for Pesticide Residues.

Annex 2, Table 1, contains the list of food and feed of non-animal origin for which special conditions are prescribed governing their entry into Great Britain.

The following entries have been amended in respect of identity and physical checks in Annex 2:

a) Increase from 20% to 30% frequency of identity and physical checks to be performed on Sesamum seeds from India for Salmonella.
b) Decrease from 50% to 30% frequency of identity and physical checks to be performed on Sesamum seed from India for Pesticide Residues.

The following entry is a new listing inserted into Annex 2:

a) Groundnuts paste from Argentina at 5% for Aflatoxins.

The following entries have been transferred from Annex 2 Table 1 to Annex 1:

a) Guar Gum from India at 20% for pentachlorophenol and dioxins.
b) Nutmeg from India at 50% for Aflatoxins.
c) Peppers of the Capsicum Species from India at 20% for Aflatoxins.

Impact Assessment and Financial Effects

A Business and Regulatory Impact Assessment (BRIA) has not been produced for this Regulation. High risk commodities can only be imported through already established BCPs in GB.

Local and Port Health Authorities are likely to have some nominal familiarisation costs associated with the routine updates. Commodities listed in the Annexes to Regulation (EU) 2019/1793 are risk based and therefore relate only to the specified country(s) of origin. Importers may therefore import from other countries across the globe whose products are not identified as high risk and where enhanced import controls do not apply. During the public consultation, no evidence was presented to alter this assessment.

The Minister for Public Health and Women's Health therefore 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
November 2024

Annexe B: Scottish Government Policy Note

POLICY NOTE

THE FOOD SAFETY (SAMPLING AND QUALIFICATIONS) (SCOTLAND) AMENDMENT REGULATIONS 2024

SSI 2024/326

The above instrument was made in exercise of the powers conferred by sections 30(9) and 48(1)(b) of the Food Safety Act 1990. The instrument is subject to negative procedure.

The purpose of this instrument is to extend recognition of relevant professional qualifications for Food Examiners to those issued in Switzerland to comply with the UK- Switzerland Recognition of Professional Qualifications (RPQ) Agreement.

Policy Objectives

The proposed instrument amends the Food Safety (Sampling and Qualifications) (Scotland) Regulations 2013, to include a qualification recognised under the Recognition of Professional Qualifications and Implementation of International Recognition Agreements (Amendment) Regulations 2023 ("the Professional Qualification Regulations") in relation to food examination and to futureproof for any future RPQ agreements the UK may enter into, without the need for further amending SSIs.

The Professional Qualifications Regulations implement the UK's obligations arising from the RPQ Agreement made between the UK and Switzerland in London on 14 June 2023 and which comes into force on 1 January 2025. The above amendments are necessary to ensure that Scottish legislation complies with the UK's commitments under the UK-Switzerland RPQ Agreement in respect of the mutual recognition of professional qualifications of Food Examiners.

UN Convention on the Rights of the Child (Incorporation) (Scotland) Act 2024 Compatibility

The Scottish Ministers have made the following statement regarding children's rights.

In accordance with section 23(2) of the United Nations Convention on the Rights of the Child (Incorporation) (Scotland) Act 2024, the Scottish Ministers certify that, in their view, the Food Safety (Sampling and Qualifications) (Scotland) Amendment Regulations 2024 is compatible with the UNCRC requirements as defined by section 1(2) of the Act.

EU Alignment Consideration

The mutual recognition of professional qualifications was formerly within the competence of the EU, when the UK was a Member State. However, the UK-Switzerland RPQ Agreement was made subsequent to EU exit, and the proposed SSI is consequential to the UK's obligations arising from the RPQ Agreement. This SSI is therefore not directly relevant to the Scottish Government's policy to maintain alignment with the EU.

Consultation

To comply with the requirements of Article 9 of Regulation (EC) 178/2002, Food Standards Scotland invited comments on the proposed amendments from Public Analysts in Scotland from 16 September to 14 October 2024. Information on the consultation was also published on the Food Standards Scotland website. Two responses were received which posed general questions on the subject area rather than expressed views on the policy of implementing the RPQ Agreement in relation to food examiners in Scotland.

Impact Assessments

No Business and Regulatory Impact Assessment was conducted as the changes will impact only a very small number of individual workers. No Data Protection Impact Assessment was conducted as no new data will be collected. Equality and Child Rights and Wellbeing Impact Assessments have been undertaken in line with current Scottish Government requirements. No issues were identified.

Financial Effects

The Minister for Public Health and Women's Health 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
November 2024

Annexe C: Scottish Government Policy Note

THE FEED ADDITIVES (AUTHORISATIONS) AND USES OF FEED INTENDED FOR PARTICULAR NUTRITIONAL PURPOSES (MISCELLANEOUS AMENDMENT) (SCOTLAND) REGULATIONS 2024

SSI 2024/330

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 and section 74A(1) of the Agriculture Act 1970. The instrument is subject to 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 to authorise twenty-five feed additives and one feed for particular nutritional purposes (PARNUT).
- The SSI authorises the placing on the market and use in Scotland of nine new authorisation, one renewal authorisation, six new use authorisation, three modification authorisation, five renewal and modification authorisation and two renewal, new use and modification authorisation.
- This SSI includes transitional provisions for seven existing authorisations.
- This instrument extends 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 by the Scottish Ministers 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 such an authorisation. Regulation (EC) No. 1831/2003 (2003 Regulation) 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.

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 feed products. Assessing animal feed safety in Scotland is the responsibility of Food Standards Scotland (FSS) as the 'feed 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 2003 Regulation 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 2003 Regulation makes provision for the period of authorisation to be automatically extended until the appropriate authority makes a determination. Article 16 of 2003 Regulation 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 Britain1.

PARNUTs are defined in Article 3(o) of Regulation 767/2009 (the 2009 Regulations) as 'feed intended for particular nutritional purposes' which means feed which can satisfy a particular nutritional purpose by virtue of its particular composition or method of manufacture, which clearly distinguishes it from ordinary feed'. In accordance with Regulation (EU) 2020/354, Annex Part B establishes a list (here after referred to as 'the list') of intended uses of feed intended for particular nutritional purposes. In this circumstance, an application has been made to modify an existing entry to the list.

The 2009 Regulations) dictates that PARNUTs may only be marketed if its intended use is included in the list, and it meets the essential nutritional characteristics for the nutritional purpose included in that list. However, due to a mistake introduced into Article 10 of the 2009 Regulations, during the process of fixing deficiencies in EU Law, which gives powers to the Scottish Ministers to prescribe how the list of intended uses may be updated, the Scottish Ministers are unable to use this power to prescribe an update to the list of intended uses. In this instance FSS proposes using the general powers provided in Section 74A (1) and 84(1), Agriculture Act 1970, in respect of the composition of materials for the feeding of animals, to effectively modify the list.

Policy Objectives

This Instrument is required to give legislative effect to the Minister's decision with respect to the authorisation of twenty-five feed additives and one feed for particular nutritional purposes (PARNUT). This instrument authorises the placing on the market and use in Scotland of nine new authorisation, one renewal authorisation, six new use authorisation, three modification authorisation, five renewal and modification authorisation and two renewal, new use and modification authorisation.

This instrument includes transitional provisions for seven feed additives, in accordance with retained 2003 Regulation and Regulation (EC) No. 429/2008. The transitional provisions allow these feed additives to continue to be placed on the market and used until stocks, so labelled, are exhausted. Transitional provisions are required for 6–phytase (EC 3.1.3.26) produced from Komagataella phaffii, Selenised yeast produced from Saccharomyces cerevisiae (CNCM I-3060) inactivated (identification number 3b810), Bacillus velezensis (formerly Bacillus subtilis C-3102) (DSM 15544), Butylated hydroxyanisole (BHA), Copper chelate of hydroxy analogue of methionine, Manganese chelate of hydroxy analogue of methionine, Zinc chelate of hydroxy analogue of methionine. Full transitional provisions can be found in part four of the SSI.

Assessing food and animal feed safety in Scotland is the responsibility of FSS. The Scottish Ministers are responsible for the authorisation of these 25 feed additives and 1 PARNUT in Scotland. The assimilated law provides that authorisations of the relevant animal feed additives and PARNUT's must be prescribed by the Scottish Ministers. This SSI comprises

1 https://data.food.gov.uk/regulated-products/feed_authorisations

the approval by the Scottish Ministers of applications made to them authorising the placing on the market in Scotland of nine new authorisations, six new use only authorisations, one renewal authorisation, two modification authorisations, one modification of a PARNUT, five renewal and modification authorisations. This Instrument extends to Scotland only.

This SSI aligns Scotland with England and Wales and similar EU legislation for these regulated products. FSS and the Food Standards Agency (FSA) have reviewed the European Food Safety Authority (EFSA) opinions along with all supporting documentation for twenty- one of the feed additive authorisations and each formed an independent opinion based on risk assessment and safety conclusions. A safety assessment was not required for one feed additive authorisation as this is for a modification in the authorised owner. The FSS opinion in each case was that the regulated products, as described in the applications, are safe and provide no risk to target species, human health or the environment. A copy of the FSS opinions has been provided and is available at the bottom of the FSS Citizen Space consultation pages here: Consultation on applications for authorisation of regulated products: One feed additive (RP16 Chromium chelate of DL-methionine) - Food Standards Scotland - Citizen Space2 and here: Consultation on applications for authorisation of regulated products: twenty four feed additives and one feed for particular nutritional purposes (PARNUT) for use in animal feed - Food Standards Scotland - Citizen Space3

UN Convention on the Rights of the Child (Incorporation) (Scotland) Act 2024 Compatibility

In accordance with section 23(2) of the United Nations Convention on the Rights of the Child (Incorporation) (Scotland) Act 2024, the Scottish Ministers certify that, in their view, the Feed Additives (Authorisations) and Uses of Feed Intended for Particular Nutritional Purposes (Miscellaneous Amendment) (Scotland) Regulations 2024 is compatible with the UNCRC requirements as defined by section 1(2) of the Act.

EU Alignment Consideration

Following authorisation there will are differences between authorisations in GB and those of the EU, however none of them give rise to any concerns regarding trade or Northern Ireland. Under Windsor Framework arrangements, regulated products authorised in Great Britain (GB) may also be placed on the NI market, provided they are eligible for, and are moved through, the Northern Ireland Retail Movement Scheme (NIRMS). A summary of the specific applications and the way in which their handling will differ to that in the EU is provided below:

Application RP16 chromium chelate of DL-methionine has not been authorised in the EU for consumption by dairy cows. FSS reviewed the information available, including the EFSA opinion, to conclude on the Identity and Characterisation and Safety sections of the dossier. EFSA couldn't conclude on Efficacy and therefore the application was assessed by the FSA Advisory Committee on Animal Feedingstuffs (ACAF). FSS have assessed the available evidence and supports recommending the authorisation of RP16 for consumption by dairy cows. There will be divergence between GB and EU but FSS are content this will not present a barrier to trade.

2 https://consult.foodstandards.gov.scot/regulatory-policy/regulatory-policy-tranche3-single-feed-additive/
3 https://consult.foodstandards.gov.scot/regulatory-policy/regulatory-policy-tranche3-feed-additives/

Application RP26 is proposed to be authorised under different terms to the EU. This is because Saccharomyces cerevisiae (MUCL 39885), has not been authorised for use in cats in the EU. FSS assessed available evidence and supports recommending the authorisation of RP26 for use in cats, there will be divergence between GB and the EU which will require separate labelling for products sold in GB to those sold in the EU. FSS are content this will not present a barrier to trade.

Applications RP140, RP141, RP142 and RP284. FSS have assessed the available evidence and supports recommending the renewal and modification of RP140; the renewal and modification of use of RP141; the authorisation of RP142; and authorisation of new use (extension of species) for RP284 monensin sodium produced by fermentation with Streptomyces cinnamonensis 28682 (NBIMCC 3419) (Coxidin®). Similar applications were submitted to the EU and are ongoing. FSS is content this will not present a barrier to trade.

Application RP222 Selenised yeast Saccharomyces cerevisiae (CNCM I-3060), inactivated (identification number 3b810) is recommended for authorisation of selenium (Se) content from 2000 mg Se/kg to 3500 mg Se/kg. This is a modification of the current feed additive authorisation. If authorised, this would differ from the EU authorisation Implementing Regulation (EU) 2022/1459, which includes two entries one for the existing authorisation with a selenium content of 2000 – 2400 mg Se/kg and one for a new authorisation with selenium content of 3000 – 3500 mg Se/kg. FSS is content this will not present a barrier to trade.

Application RP25. FSS has assessed the available evidence and supports recommending the authorisation of RP25 as a feed additive for all pigs other than sows, suckling and weaned piglets and all minor porcine species. A similar application was submitted to the EU and has been finalised. The application was not made for authorisation as a feed additive for suckling pigs. FSS is content this will not present a barrier to trade.

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, two public consultations were undertaken by FSS during the preparation and evaluation of this SSI. The public consultation for twenty-four feed additives and one PARNUT was open from 22nd April 2024 to 17th June 2024. A second, additional public consultation for one feed additive was open from 5th August 2024 to 2nd September 2024. One response was received. No concerns were raised about the safety of the feed additives and PARNUT and there were no concerns with regards to costs or burdens for the feed industry. A summary of the consultation responses is available here: Consultation on applications for authorisation of regulated products: One feed additive (RP16 Chromium chelate of DL-methionine) - Food Standards Scotland - Citizen Space[4] and here: Consultation on applications for authorisation

4 https://consult.foodstandards.gov.scot/regulatory-policy/regulatory-policy-tranche3-single-feed-additive/

of regulated products: twenty four feed additives and one feed for particular nutritional purposes (PARNUT) for use in animal feed - Food Standards Scotland - Citizen Space5.

Rest of Great Britain

A total of seven consultation responses were received by the FSA: six representing industry and Trade Associations, and one Private Individual. Across the seven 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 consultations, is available here: Consultation on 24 feed additive applications and one application for feed for particular nutritional purposes (PARNUT) for use in animal feed | Food Standards Agency6 and here: Consultation on one feed additive application for use in animal feed | Food Standards Agency7

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 2003 Regulation 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 feed additive authorisations extension of use of feed additives will likely result in the reallocation of wealth from existing to new product lines. A Child Rights and Welfare Impact Assessment (CRWIA) has been carried out with no impact to child rights or welfare found.
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 no financial effects on the Scottish Government, local government or on business.

Food Standards Scotland,
29 October 2024

5 https://consult.foodstandards.gov.scot/regulatory-policy/regulatory-policy-tranche3-feed-additives/
6 https://www.food.gov.uk/news-alerts/consultations/consultation-on-24-feed-additive-applications-and-one-application-for-feed-for-particular-nutritional-purposes-parnut-for-use-in
7 https://www.food.gov.uk/news-alerts/consultations/consultation-on-one-feed-additive-application-for-use-in-animal-feed