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10 January 2025

Dear Convener,

THE FOOD AND FEED (REGULATED PRODUCTS) (AMENDMENT, REVOCATION, CONSEQUENTIAL AND TRANSITIONAL PROVISION) REGULATIONS 2025

EU EXIT LEGISLATION – PROTOCOL WITH SCOTTISH PARLIAMENT

Thank you for your letter of 7 January 2025.

I have responded to each of the questions posed by the Committee in turn:

The proposed Statutory Instrument (SI) will be made under powers in the Retained EU Law (Revocation and Reform) Act 2023. The Scottish Government has previously indicated to the Parliament that it is opposed on principle to, and does not intend to use, the powers that are available to it in the Act.

1. **Why does the Scottish Government not intend to use the powers in the Retained EU Law (Revocation and Reform) Act 2023, but is content to consent to the UK Government doing so within devolved competence in this SI?**

Scottish Government policy on the use of REUL Act powers is set out in the second bi-annual REUL Act update sent to the Constitution, Europe, External Affairs and Culture Committee on 9 September 2024 https://www.parliament.scot/chamber-and-committees/committees/current-and-previous-committees/session-6-constitution-europe-external-affairs-and-culture-committee/correspondence/2024/second-bi-annual-reul-act-update.

Section of 2 of the update paper highlights that the Scottish Government continues to recognise the value of Common Frameworks as intergovernmental mechanisms for collaboration and co-operation on regulatory policy in a devolved UK, in a manner that respects devolution. As such the entirety of the proposals presented to parliament via this notification have been discussed on a 4-country basis as per the Food and Feed Safety & Hygiene (FFSH) provisional common framework.

Section 3 of the September 2024 update paper confirms there have been other cases where the Scottish Government has consented to REUL Act SIs. The regulated products proposals do not diminish regulatory standards and indeed FSS consider the refreshed regulatory arrangements to be necessary in order to be both more responsive to new and emerging risks, and a better fit with domestic regulatory processes. As the notification sets out, the way in which the EU processes these applications and the way in which those functions were repatriated on EU exit were not quite comparable, and having worked with the "domesticated" version of the EU process, the strong advice from FSS is that the system should indeed be reformed in order to provide for a more responsive, proportionate service to stakeholders which does not take up valuable Parliamentary time unnecessarily.

The Scottish Government will send the third REUL Act update to the Parliament in February 2025 and this will offer a comprehensive update on the position for both SSIs and SIs.

The notification states, "the equivalent EU institutions and European Parliament are equally excluded from scrutinising tertiary legislation by the EU Commission authorising individual regulated product authorisations".

2. **To what extent does the Scottish Government consider this explanation satisfactory given the reduction in parliamentary scrutiny to which the instrument gives effect and considering that the notification also states that "[parliamentary committees] play an important role in scrutinising the exercise of powers by Scottish Ministers in relation to food and feed matters"?**

There is no doubt that parliamentary committees play an important role in scrutinising the exercise of powers by Scottish Ministers in relation to food and feed matters. In the case of regulated products though it should be noted that this is a new development post EU Exit and was introduced as an accommodation of the differences in operation of EU Law and GB regulatory and legislative processes. In GB the current process to prescribe the terms of authorisation in SSIs entails an active parliamentary scrutiny step for which there is no direct parallel in the EU.

Scottish Ministers' decisions on regulated product authorisations are informed by advice from FSS as the independent science and evidence-based food safety authority. FSS provide thorough technical and scientific scrutiny through skilled and experienced risk assessors and expert independent advisory committees. This process aligns with internationally recognised risk analysis principles and ensures that decisions on a food or feed authorisation are based on the assessment of its safety.

Allowing authorisations to come into effect without being prescribed in secondary legislation would result in a level of scrutiny that is proportionate to the regulation of these products which are matters of food and feed safety and highly technical in nature.

FSS is also directly accountable to the Scottish Parliament and the proposal would not diminish the potential for direct Parliamentary scrutiny of its advice to ministers with regard to regulated products.

The notification states that "in relation to Scotland, the instrument also makes consequential amendments to or revocations of certain Scottish Statutory Instruments (SSIs)." The notification further states "Whilst, generally, the Scottish Ministers will not support SIs modifying Acts of the Scottish Parliament, SSIs or wholly devolved, Scotland only UK legislation, Food Standards Scotland and the Scottish Government are satisfied that a sufficient case has been made for the consequential amendment or revocation of a limited number of SSIs in this particular instance."

4. **Please provide further explanation as to why Scottish Government are satisfied in this regard.**

The SSI revocations relate only to regulated product authorisations made by Scottish Ministers since EU Exit which will no longer be required/have effect when administrative lists are established on the coming into force (CIF) of the reform SI. Although the SSIs are being revoked, the legal authorisations themselves will continue to exist by virtue of the reform SI and will be publicly available on a list of authorisations maintained by FSS.

The consequential amendments are minor and technical in nature i.e. removing reference to provisions which will no longer exist.

It is expedient that such minor provisions be made in the same legislative vehicle as the substantive changes in order to ensure clarity when the reform SI comes into force.

5. **Please identify which SSIs these passages refer to.**

Subject to final checks and minor/technical corrections the reform SI does the following:

SSIs revoked (with savings) –

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

The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (Scotland) Regulations 2022

The Feed Additives (Authorisations) (Scotland) Regulations 2022

Reg 5 of The Food and Feed (Miscellaneous Amendments) (Scotland) Regulations 2022

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

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

The Feed Additives (Form of Provisional Authorisations) (Cobalt(II) Compounds) (Scotland) Regulations 2023

The Feed Additives (Authorisations) (Scotland) Regulations 2023

The Food Additives and Novel Foods (Authorisations and Miscellaneous Amendments) and Food Flavourings (Removal of Authorisations) (Scotland) Regulations 2024

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

SSIs with consequential amendments –

The Bread and Flour Regulations 1998
The Specified Sugar Products (Scotland) regulations 2003
The Materials and Articles in Contact with Food (Scotland) Regulations 2012
The Food Additives, Flavourings, Enzymes and Extraction Solvents (Scotland) Regulations 2013
The products Containing meat etc. (Scotland) Regulations 2014
The Novel Foods (Scotland) Regulations 2017

The notification explicitly references the Provisional Food and Feed Safety and Hygiene (FFSH) common framework.

6. **Please provide an update on the latest status of the FFSH common framework and of other common frameworks falling within the Committee's remit, further to correspondence previously received from the then Minister for Public Health, Women's Health and Sport on 30 May 2022.**

Provisional Common Frameworks have been operational across the four governments at official level since December 2020.

At the meeting of the Interministerial Standing Committee (IMSC) on the 3 December 2024, ministers from the four governments agreed that the finalisation of the Common Frameworks should be progressed at pace, with an ambition to secure

four-nation agreement and completion of the current Common Frameworks programme by the end of 2025.

The majority of Frameworks have now been scrutinised by UK legislatures, and the relevant policy teams are progressing with the steps to finalisation within this timeline, including agreeing changes to the Frameworks in response to the recommendations received from legislatures. These include the six Frameworks that have been scrutinised by the Health, Social Care and Sport Committee:

- Common Framework for Food and Feed Safety and Hygiene
- Common Framework for Organs, Tissues and Cells (apart from embryos and gametes)
- Common Framework for Blood Safety and Quality
- Common Framework for Food Compositional Standards and Labelling
- Common Framework for Nutrition Labelling and Compositional Standards
- Common Framework for Public Health Protection and Health Security

Following the sign-off and publication of each finalised Framework, Scottish Ministers will write to the relevant Committees and provide a formal response to their recommendations.

The entirety of the proposals presented to parliament via this notification have been discussed on a 4-country basis as per the FFSH provisional common framework.

7. **Can the Scottish Government explain more about the joint risk analysis process and risk assessment – and how, under the proposed new regime any new information (i) would come to light, and (ii) be reviewed by FSS and FSA?**

The joint risk analysis process[1], which aligns with internationally recognised risk analysis principles, enables FSS and FSA to assess, manage and communicate food and animal feed safety risks, ensuring high standards of food and feed safety and consumer protection are maintained. This process underpins the operation of the FFSH common framework and facilitates a consistent process across the UK.

FSS proactively monitor emerging risks through horizon scanning and intelligence gathering activities. There are many ways in which they receive information. One example is via global networks such as the International Food Safety Authorities Network, where effective exchange of information is provided to react effectively to food safety issues. Another example is through post-market monitoring reports submitted by businesses to the FSS/FSA. FSS will continue to set post-market monitoring requirements within the terms of product authorisations where necessary. Businesses continue to be legally required to report to the FSS/FSA if they have reasons to believe that placing the food or feed product on the market could do harm to consumers.

When FSS receive or become aware of new evidence or information that may have implications for the safety of a product, scientific risk assessors and risk managers

[1] Risk analysis | Food Standards Scotland

consider the quality and relevance of new information against existing evidence to determine if it challenges a previous product safety assessment. This will inform the decision on whether any action may be needed. If there is an immediate food or feed safety risk, FSS take action through their incident management approach.

If FSS/FSA determine that a review of an authorisation is necessary, then they will assess the evidence. If any additional evidence would be useful for that review, then FSS/FSA may request further information from businesses. Following review, advice will be provided to Ministers to inform decisions regarding potentially modifying, suspending or revoking authorisations.

8. **What alternative policy and process models have been considered to reduce resource constraints?**

These two reform proposals were identified as critical to reforming the system. They will immediately relieve pressure on the service and accelerate approval timelines, positively affecting consumer choice and economic growth. The changes will provide substantial efficiency benefits for businesses and will release FSS and FSA resources to focus on new authorisations, including implementation of a more proportionate approach to reviewing products already authorised for sale, focusing on evidence-based safety concerns as they arise rather than being driven by fixed renewal points. These reforms form part of a wider programme of work to modernise the regulatory framework to enable it to keep pace with innovation and emerging technologies, while continuing to safeguard public health.

This programme builds on the recommendations of the Novel Foods Regulatory Framework Review carried out in 2023. Whilst this was an FSA commissioned piece of work, all four countries contributed. The review presented a range of approaches to reform ranging from those within the scope of the current framework to more fundamental options. Following these recommendations, and in light of stakeholder views, alongside taking forward these legislative reforms, FSS and FSA scrutinised the current performance of the market authorisation of regulated products service, implemented a range of continuous improvement measures and identified further actions to improve performance that could be put in place immediately, within the current regulations. These actions, taken forward during 2024, included introducing active management of the caseload, utilising other international regulators' risk assessments and improving guidance and support for applicants.

These reforms and service improvements will make a significant reduction in authorisation timelines, helping new products come to market more quickly, without compromising consumer safety. However, FSS and FSA recognise there is more to be done. They are exploring further changes to reduce delays, and prioritising those that will speed up approval timelines significantly, without compromising safety, transparency and accountability.

9. **Under the proposed new regime, it may appear that more emphasis will have to be placed on businesses reporting to FSS if they believe**

placing a food or feed product on the market could do harm to consumers – how will FSS ensure this requirement is as robust as it can be?

There is already a legal requirement under general food law for all food businesses to report to the FSS/FSA if they have reasons to believe that placing the food or feed product on the market could do harm to consumers, with associated enforcement provisions, and this will not change.

Post-market monitoring requirements will continue to be set within the terms of product authorisations where necessary, including requiring businesses to submit post-market monitoring reports.

For feed additives, food or feed containing, consisting of, or produced from genetically modified organisms (GMOs) and smoke flavourings, where renewal requirements are being removed, this SI widens the range of businesses that the regulator can request information from beyond just authorisation holders and will also now include producers, manufacturers and businesses placing the product on the market.

It is in the interest of businesses to provide this information. The regulator will retain the ability to produce a risk assessment opinion on the available evidence it has, regardless of whether businesses have responded to the request for further information, and take action if necessary to protect consumers that could lead to the authorisation being revoked, suspended or modified.

I hope this additional information is helpful and I look forward to hearing from you following the meeting on 14 January 2025 where this notification will be considered.

Yours sincerely,

Jenni Minto MSP