Health, Social Care and Sport Committee
Tuesday, 21 January 2025
2nd Meeting, 2025 (Session 6)

Note by the Clerk on UK subordinate legislation: consideration of consent notification

Introduction

1. This paper supports the Committee's consideration of a 'type 1' consent notification sent by the Scottish Government relating to the following proposed UK statutory instrument (SI): The Food and Feed (Regulated Products) (Amendment, Revocation, Consequential and Transitional Provision) Regulations 2025 (RP reform SI)

2. The process for the Scottish Parliament's consideration of consent notifications is set out in the SI Protocol. Further details of this process are set out in **Annexe A**.

The Food and Feed (Regulated Products) (Amendment, Revocation, Consequential and Transitional Provision) Regulations 2025 (RP reform SI)

3. On 10 December 2024, the Minister for Public Health and Women's Health wrote to the Committee to give notice of the Scottish Government's proposal to consent to the UK SI. The Scottish Government has also provided an SI notification and a summary notification. These documents are set out in **Annexe B**. The UK Government intends to lay the UK SI on 29 January 2025.

4. The Scottish Government has asked the Committee to respond to the consent notification by 22 January 2025.

5. These Regulations are made under section 14 of the Retained EU Law (Revocation and Reform) Act 2023 (power to revoke or replace).

6. The notification states that the purpose of this instrument is to reform legislation in relation to certain regulated products (RP). RP are certain food and feed products that require authorisation before they can be placed on the market.

7. The instrument amends existing RP legislation to:

   - remove requirements for the periodic renewal of authorisations for three regulated products regimes; and
   - allow authorisations to come into effect following ministerial decision instead of being prescribed by secondary legislation, as is currently the case.

8. There are 12 different RP legislative regimes. The SI amends the following seven RP legislative regimes:

- feed additives,
- food additives,
- enzymes and flavourings,
- food contact materials (FCMs),
- food or feed containing, consisting of or produced from genetically modified organisms (GMOs),
- novel foods, and
- smoke flavourings.

9. The SI does not deal with the following five RP regimes:

- extraction solvents,
- feed detoxification processes,
- irradiated food,
- feed for particular nutritional uses (PARNUTs),
- recycled plastics and regenerated cellulose film (two types of food contact materials).

10. The SI does not apply to these types of regulated product because the approval process they follow is not set out in legislation, does not involve appropriate authority decision making or the legislation that applies to them is not operable or is unlikely to be used in its current form.

11. There is no statutory requirement on the UK Ministers to seek the consent of Scottish Ministers before making this SI. This means that, from a legal point of view, the UK Government could still go ahead with this instrument, whether or not the Scottish Government consents. The UK Government has, however, stated that it does "not intend normally to use the powers under the [REUL Act] in devolved areas without the agreement of the relevant devolved administration. Where a UK Minister intends to exercise the powers in devolved areas we will seek agreement on an SI-by-SI basis".

12. The Health, Social Care and Sport Committee wrote to the Minister for Public Health and Women's Health on 7 January 2025 to seek further clarification on the notification. This correspondence is included at **Annexe C**.

13. The Minister responded to the Committee's correspondence on 10 January 2025. This is included at **Annexe D.**

Next steps

14. If the Committee wishes to approve the proposal to consent to the SI, it may, in doing so, set out in its letter to the Scottish Government any observations or concerns that it thinks are relevant.

15. If the Committee is not content with the proposal, it should include in its letter to the Scottish Government one of the following recommendations:

- That the Scottish Government should not consent to the provision being made in a UK SI and that the Scottish Government should instead take forward an alternative Scottish legislative solution.

- That the Scottish Government should not consent to the provision being made in a UK SI laid solely in the UK Parliament and should instead request that the provision be included in a UK SI laid in both Parliaments under the joint procedure.

- That the provision should not be made at all (that is, that the Scottish Government should not consent to the provision being included in a UK SI, nor should the Scottish Government take forward an alternative Scottish legislative solution).

Clerks to the Committee

January 2025

Annexe A: Process for parliamentary scrutiny of consent notifications in relation to UK statutory instruments

1. The Protocol provides for the Scottish Parliament to scrutinise the Scottish Government's decisions to consent to certain subordinate legislation made by the UK Government: specifically, UK Government subordinate legislation on matters within devolved competence in areas formerly governed by EU law. It sets out a proportionate scrutiny approach and categorises SI notifications as 'type 1' or 'type 2'.

2. Type 2 applies where all aspects of the proposed instrument are clearly technical (e.g., they merely update references in legislation that are no longer appropriate following EU exit) or do not involve a policy decision. These are notified retrospectively, after the Scottish Government has given its consent.

3. All other proposals are type 1. In this case, the Scottish Parliament's agreement is sought before the Scottish Government gives consent to the UK Government making subordinate legislation in this way. Each type 1 notification must be considered by the relevant Committee.

4. **The Committee's role in relation to type 1 notifications is to decide whether it agrees with the Scottish Government's proposal to consent to the UK Government making Regulations within devolved competence, in the manner that the UK Government has indicated to the Scottish Government.**

5. If Members are content for consent to be given, the Committee will write to the Scottish Government accordingly. The Committee may also wish to note any issues in its response or request that it be kept up to date on any relevant developments.

6. If the Committee is not content with the proposal, however, it may recommend that the Scottish Government should not give its consent. In that event, the Scottish Ministers have 14 days under the Protocol to respond to the Committee's recommendation. They could—

   - Agree. If so, the Scottish Ministers would then withhold their consent.
   - Not agree. If so, the Parliament will debate the issue.

7. If the Parliament agrees to the Committee's recommendation that the Scottish Ministers should not consent, the Protocol provides that the Scottish Ministers should "normally not consent" to the UK SI. However, the Protocol also provides that if the Scottish Ministers consider that the Committee's proposed alternative cannot be achieved, they may consent to the UK SI. If so, they must explain why they are doing so to the Scottish Parliament.

Annexe B: Information from Scottish Government

Letter from the Minister for Public Health and Women's Heath

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

EU EXIT LEGISLATION – PROTOCOL WITH SCOTTISH PARLIAMENT

I am writing in relation to the protocol on obtaining the approval of the Scottish Parliament to proposals by the Scottish Ministers to consent to the making of UK secondary legislation affecting devolved areas arising from EU Exit.

That protocol, as agreed between the Scottish Government and then Parliament, accompanied the letter from the then Cabinet Secretary for Government Business and Constitutional Relations, Michael Russell MSP, to the Conveners of the Finance & Constitution and Delegated Powers and Law Reform Committees on 4 November 2020 and replaced the previous protocol that was put in place in 2018.

I attach a Type 1 notification which sets out the details of the SI which the UK Government propose to make and the reasons why I am content that Scottish devolved matters are to be included in this SI. Please note, we are yet to have sight of the final SI and it is not available in the public domain at this stage. We will, in accordance with the protocol, advise you when the final SI is laid and advise you as to whether the final SI is in keeping with the terms of this notification.

I am copying this letter to the Convener of the Delegated Powers and Law Reform Committee.

I look forward to hearing from you by 22 January 2025.

Yours sincerely,

Jenni Minto MSP

HSCS/S6/25/2/1

SI notification

NOTIFICATION TO THE SCOTTISH PARLIAMENT

Name of the SI(s) (if known) or a title describing the policy area

The Food and Feed (Regulated Products) (Amendment, Revocation, Consequential and Transitional Provision) Regulations 2025 (RP reform SI)

Is the notification Type 1 or Type 2

This is a Type 1 notification

A brief overview of the SI (including reserved provision)

The purpose of this instrument is to reform legislation in relation to certain regulated products (RP). RP are certain food and feed products that require authorisation before they can be placed on the market.

RP legislation is amended by this instrument to:

1. remove requirements for the periodic renewal of authorisations for three regulated products regimes; and
2. allow authorisations to come into effect following ministerial decision instead of being prescribed by secondary legislation, as is currently the case.

There are 12 different RP legislative regimes.

The RP reform SI amends 7 RP legislative regimes:

- feed additives,
- food additives,
- enzymes and flavourings,
- food contact materials (FCMs),
- food or feed containing, consisting of or produced from genetically modified organisms (GMOs),
- novel foods, and
- smoke flavourings.

The RP reform SI does not deal with the following 5 RP regimes:

- extraction solvents,
- feed detoxification processes,
- irradiated food,
- feed for particular nutritional uses (PARNUTs),
- recycled plastics and regenerated cellulose film (two types of food contact materials).

The RP reform SI does not apply to these types of regulated product because the approval process they follow is not set out in legislation, does not involve appropriate authority decision making or the legislation that applies to them is not operable or is unlikely to be used in its current form.

In addition, in relation to Scotland, the instrument also makes consequential amendments to or revocations of certain Scottish Statutory Instruments (SSIs). 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.

The RP reform SI is made in exercise of powers contained in sections 14(1), (3), (4) and 20(1) of the Retained EU Law (Revocation and Reform) Act 2023.

The RP reform SI is subject to affirmative procedure and is to be laid in draft on or around 29 January 2025, and is to come into force around 1 April 2025.

Details of the provisions that Scottish Ministers are being asked to consent to.

Summary of the proposals

<u>Removing renewal requirements for authorisation of feed additives, GMOs and smoke flavourings</u>

For the majority of regulated products, once a product is authorised, the holder of the authorisation, e.g. the company that makes that product does not need to apply again for their authorisation to be renewed. Food Standards Scotland (FSS) for Scotland and Food Standards Agency (FSA) for England and Wales – through the joint risk analysis process and risk assessment – reviews any new information that emerges. If there are concerns about safety, they will independently assess any new evidence and retain the ability to review existing authorisations and take action to protect public health.

However, assimilated law (the new name for retained EU law) requires authorisations for GM food and feed, feed additives and smoke flavourings must be renewed (usually) every ten years. Since 2021, there have been no rejections of renewal applications in GB. At the same time, through the risk analysis process, when new evidence about the safety of a product has emerged, FSS and the FSA reviews existing authorisations. For example, titanium dioxide as a food and feed additive is currently being re-evaluated using the UK risk analysis process, based on updated evidence.

Removing the renewals process essentially brings the regulation of these products in line with how we regulate other food and feed products. We retain the power to reconsider any product authorisation at any time. But the way in which we do it would be risk-based, not time-based, and informed by independent assessment of any new scientific evidence about a particular product or its use.

Therefore, the proposed reform would not negatively impact food and feed safety standards. Products subject to renewal requirements have already had their safetyrigorously assessed during their initial authorisation. If new evidence emerges that requires a review of the decision, FSS/FSA will assess the evidence and provide

advice to Ministers to inform decisions regarding potentially modifying, suspending or revoking authorisations.

Currently 20% of the Regulated Products Service caseload is taken up with renewals authorisations. This significantly reduces FSS and FSA's capacity to deal with new product authorisations to a reasonable timeline. A significant number of feed additive renewal applications are expected in the run-up to renewal deadlines in 2027 (300+ over the next two years), meaning that by the end of 2027 over 50% of applications likely to have been received will have been renewal applications.

Without reform this will put considerable strain on both FSS and FSA resources that could significantly impede the authorisation of new products.

The RP reform SI therefore makes the following provision and amendments:

Regulation (EC) No 1831/2003 on feed additives, Regulation (EC) 1829/ 2003 on GMOs and Regulation (EC) 2065/2003 on smoke flavourings are amended to revoke provisions requiring renewal of authorisations after 10 years. So, new authorisations made by Scottish Ministers after the coming into force of the RP reform SI will have no end date or period of validity.

Consequentially, in relation to existing feed additive, GMO and smoke flavouring authorisations, standalone provision is made in the RP reform SI to remove end dates or periods of validity.

For GMOs and feed additives, under Regulation 1829/2003 and 1831/2003 respectively, FSS have existing powers to produce an opinion on an already authorised product which could result in the modification, suspension or revocation of an authorisation and the removal of a product from the market, and this will not change.

For smoke flavourings, Regulation 2065/2003 is amended to create equivalent powers.

Alongside these powers, the RP reform SI makes provision so that FSS can request information from businesses to aid opinion making. Currently under Regulation 1829/2003 and 1831/2003, FSS can seek information about the safety of a GMO or feed additive respectively from the authorisation holder. For GMO, feed additives and smoke flavourings, the SI amends Regulation 1829/2003, 1831/2003 and 2065/2003 respectively so that FSS can also seek information from producers or manufacturers of these products and businesses placing them on the market (who are not otherwise the authorisation holder). Under the amendments to the three legislative regimes, businesses are not obliged to provide the information requested; however, FSS are granted the power to produce an opinion on the basis of the available evidence and this may lead to a recommendation to Scottish Ministers for modification, suspension or revocation of the authorisation depending on the assessment of all available information by FSS.

The RP reform SI makes no change to existing post-market monitoring requirements in GMOs and feed additives. For a small number of current authorisations, there are existing requirements for businesses to submit post market monitoring (PMM) plans

(and post market environmental monitoring (PMEM) plans). The PMM and PMEM requirements in Regulation 18929/2003 and 1831/2003 will continue to apply. Whilst not directly related to renewals, in some cases PMM plans are submitted as part of the renewals application process.

Currently, under Regulation 1829/ 2003 as part of the renewal of authorisation process an authorisation holder must demonstrate that analytical/ detection methods (which allow enforcement authorities and others to detect and identify the transformation event or feed additive in food and feed) are the best available.

Notwithstanding the removal of the renewal requirement for authorisations, the RP reform SI amendments does not make amendment to provision that allows FSS to review future updates to analytical/detection methods to keep up with scientific developments and so the best available methods can be used for surveillance and enforcement purposes.

Under the requirements of general food law (Regulation 178/2002) food businesses continue to be legally required to report to their food safety authorities if they have reasons to believe that placing the food or feed product on the market could do harm to consumers. FSS will make it clear in its guidance to businesses how they can supply FSS with information related to authorisations.

The RP reform SI ensures the ability to modify, suspend and revoke authorisations is in place and consistent across all regimes. The SI amends these provisions in feed additives, GMOs and smoke flavourings as part of the replacement for renewal requirements, and also clarifies the equivalent provisions in legislation regarding food additives, flavourings, food enzymes, FCMs and novel foods.

FSS have the ability to produce an opinion on authorised products and act if necessary to protect consumers. We are aware of a small number of authorisations, for which we have applications for renewal currently in the service, that FSS considers it appropriate to continue reviewing due to emerging evidence or to address data gaps to ensure food or feed safety. Whilst the expiry dates for these authorisations will be removed by the RP reform SI, these products will continue to be subject to administrative review by FSS. We will continue to engage with businesses and provide consumer advice as necessary.

Allowing authorisations to come into effect without being prescribed in secondary legislation.

Following a risk management recommendation from FSS, Scottish Ministers decide whether or not to authorise a new regulated product in Scotland, with the FSA and Ministers in England and Wales fulfilling this same role in the rest of GB. Under the current legislative process, following Ministerial authorisation, a separate SI must be laid in Scotland, Wales, and England to prescribe the terms of authorisation in secondary legislation, which is subject to negative parliamentary procedure.

This reflects the way the relevant assimilated law was retained and modified at the point of EU Exit as part of the cross-government deficiency fixing exercise, which was policy neutral, to ensure legal operability and a functioning statute book. In making these legal fixes it was always recognised that there is no direct equivalence

between EU and GB regulatory and legislative processes, and associated public authority functions, and that a future review would likely be needed.

At EU level, regulated products authorisation functions are delegated to the European Commission via tertiary comitology processes. Following risk assessment by the European Food Safety Authority (EFSA), the Commission will make risk management recommendations that are considered in the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee), consisting of risk managers from Member States who deliver opinions on draft measures the Commission intends to adopt. If approved, the measures will be adopted and tertiary legislation setting out the terms of authorisation is published in the EU Official Journal, which is directly applicable in Member States at the point it comes into force. While there is some variation in the specific comitology procedure that applies to different aspects of regulatory products authorisation processes at EU level, the European Parliament and European Council generally have limited, if any, ability to scrutinise authorisation decisions.

In GB the process to prescribe the terms of authorisation in statutory instruments entails an active parliamentary scrutiny step, for which there is no direct parallel in the EU.

It is recognised that the proposal to remove the need for Scottish SIs will remove the Scottish Parliament's ability to scrutinise the decisions of Scottish Ministers. The Health, Social Care and Sport Committee and the Delegated Powers and Law Reform Committee both play an important role in scrutinising the exercise of powers by Scottish Ministers in relation to food and feed matters.

With respect to regulated products authorisations, parliamentary scrutiny was only introduced at the time of EU Exit as an accommodation of the differences in operation of EU Law and GB regulatory and legislative processes and associated public authority. As noted, the equivalent EU institutions and European Parliament are equally excluded from scrutinising tertiary legislation by the EU Commission authorising individual regulated product authorisations.

Regulated products authorisations are matters of food and feed safety and highly technical. FSS and FSA, as the experts in this area charged with protecting public health, provide thorough technical and scientific scrutiny through skilled and experienced risk assessors and expert independent advisory committees to risk assess individual authorisations and provide a safety opinion from which risk management advice and recommendations are formed. 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. Oversight and final decision-making rests with Ministers.

Removing the need for SIs would therefore result in a level of scrutiny that is proportionate to the regulation of these products, as the terms of authorisations for regulated products are essentially administrative and purely scientific and technical in nature and do not intrinsically need to be set out in legislation. This would also represent a saving of valuable parliamentary time while creating a more efficient process for bringing authorisations into force following a Ministerial decision, without compromising food or feed safety. Published authorisations will contain the same

information that is currently set out in legislation. Proposed authorisations will continue to be subject to scrutiny by science, policy and legal officials before being submitted to Ministers. The process for authorisation of new regulated products will also remain transparent as provided for in assimilated law in this particular area.

FSS is also directly accountable to the Scottish Parliament, and the removal of the need for Scottish SIs would not diminish the potential for direct Parliamentary scrutiny of FSS decisions and advice to Ministers with regard to regulated products.

Therefore, as with renewals, such a change would not reduce regulatory standards or public health protection in Scotland, nor diminish the opportunity for Parliamentary scrutiny of FSS advice.

The process to develop and implement the required statutory instruments takes up to 6 months, including risk management development and legal drafting, which takes up considerable FSS and FSA policy and legal resource, as well as parliamentary time. Removing the need for subordinate legislation to authorise each individual regulated product and moving to an administrative-based approach, underpinned by a statutory duty to publish public lists of authorised products on the FSS and FSA websites along with their terms of authorisation, would bring greater efficiencies to the authorisation process, while also allowing authorised products to reach market faster, for the benefit of consumers and businesses.

This would free up limited FSS and FSA resources to focus on reducing the current caseload of applications within the service, while allowing a more agile and responsive regulatory approach, without impacting on Ministerial decision making or current levels of consumer and public health protection. Eight Scottish SIs have been made since 2021 with no objections raised during parliamentary scrutiny.

The RP SI amends the following regulated products legislation to:

1. revoke the requirement that Ministerial decisions to, authorise, modify authorisations or revoke authorisations, be prescribed in secondary legislation; and
2. place a requirement on FSS, for Scotland, to publish authorisations in an administrative list or register:

    - Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition (Part 2 of the RP reform SI)
    - Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings (Part 3 of the RP reform SI)
    - Regulation (EC) No 1332/2008 of the European Parliament and of the Council on food enzymes, etc. (Part 3)
    - Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives (Part 3)
    - Regulation (EC) No 1334/2008 of the European Parliament and of the Council on flavourings and certain food ingredients with flavouring properties for use in and on foods, etc. (Part 3)

- Regulation (EC) No 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food, etc. (Part 4)
- Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (Part 5)
- Regulation (EU) 2015/2283 on novel foods, etc. (Part 6)
- Regulation (EC) No 2065/2003 of the European Parliament and of the Council on smoke flavourings used or intended for use in or on foods (Part 7)

The RP reform SI does not change the requirement for Scottish Ministers to determine whether a product is authorised or whether an authorisation is modified or revoked (equivalent requirements remain for England and Wales too).

The removal of the requirement that Ministers' determinations are prescribed by secondary legislation will align regulated products with other regulatory systems in the UK i.e. there are comparable authorisation processes for veterinary medicines and plant protection agents (pesticides) that do not require legislation. In both cases, the legislation details the information that must be submitted in an application for a safety assessment to be carried out and the procedure for authorisation. For veterinary medicine, a database is held on the government (VMD) website detailing current, expired and refused authorisations. For pesticides, the legislation details the requirements for a register of approved substances. Similarly, there is a facility on the government (HSE) website where users can search for authorised substances.

Currently existing authorisations for RP products are prescribed in secondary legislation. Prior to EU exit these authorisations were made in EU tertiary regulations (now called assimilated direct legislation) under the legislation listed above. Post- EU exit, authorisations have been prescribed for Scotland in SSIs. The RP reform SI revokes these existing authorisations and preserves their effect as administrative authorisations.

<u>Publication of authorisations</u>
The RP reform SI places an obligation on FSS to publish authorisations made by Scottish Ministers. This takes different forms in the different RP legislative regimes.

In Regulation 1831/2003 on feed additives, there is an existing statutory public register of feed additives. The RP reform SI makes clear that authorisations made by Ministers are to be placed on this existing public register.

In Regulation 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings, there is an existing statutory list for authorised food additives, food enzymes and food flavourings. The RP reform SI amends this Regulation to create an administrative list to be kept by Food Standards Scotland.

In Regulation (EC) No 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food, etc. Currently there is no established list of authorised substances. The RP reform SI creates an administrative list. In Regulation 450/2009 on active and intelligent materials and

articles intended to come into contact with food, all products that are lawfully on the market are provisionally authorised as part of the transitional arrangements when this Regulation came into being in 2009. The RP reform SI amends 450/2009 to allow a period of time to be set within which authorisation holders of products provisionally authorised can apply for full authorisation.

In Regulation 1829/2003 on GMOs, there is an existing statutory public register of feed additives. The RP reform SI makes clear that authorisations made by Ministers are to be placed on this existing public register.

In Regulation (EU) 2015/2283 on novel foods there is an existing statutory list for authorised novel foods. The RP reform SI amends this Regulation to create an administrative list of authorised novel foods in Scotland, to be kept by Food Standards Scotland.

In Regulation (EC) 2065/2003 on smoke flavourings there is an existing statutory list for authorised smoke flavourings. The RP reform SI amends this Regulation to create an administrative list of authorised smoke flavourings in Scotland, to be kept by Food Standards Scotland.

Power to make transitional measures.
Currently as part of the SSI required to modify, suspend or revoke an authorisation in secondary legislation, Ministers can also prescribe any required transitional measures, for example to allow products that conformed with the authorisation before it was modified, suspended or revoked to be placed on the market until stocks are used up. In the absence of the SSI power to do so the RP reform SI confers a power on Ministers as part of their determination on an authorisation to set specific transitional measures which are specifying periods of time within which:

- Existing stocks of the product can be used
- The product can be produced
- The product labelling can be applied

The RP reform SI makes provision that any other, wider transitional measures are required to be made by SSI.

The Food Safety Authority must publish all existing authorisations in the official register or list. The Food Safety Authority does not need to publish any existing/valid transitional measures because they all continue to have effect in legislation.

Consequential amendments
To ensure the continued operability of wider legislation, the instrument makes consequential amendments to relevant legislation having GB extent. This means amending any provisions (including those related to offences and enforcement) where references are made to regulated products regulations, paragraphs or annexes that are being revoked and replaced, to ensure it refers to the relevant replacement.

There are consequential amendments to some enforcement provisions within standard domestic legislation - these are purely consequential and do not expand (or

narrow) the scope of the offence(s) concerned. These amendments ensure that the provisions relating to offences and enforcement reflect the new nature of authorisations (i.e. ministerial decision as point of authorisation followed by the Food Safety Authority updating the official register/list).

Does the SI relate to a common framework or other scheme?

Provisional Food and Feed Safety and Hygiene (FFSH) Common Framework.

Summary of stakeholder engagement/consultation

The FSA, supported by FSS, invited stakeholders with an interest in regulated products to share their insights on the authorisation process through a survey and a follow-up workshop, held on 29 and 30 November 2023.

The workshop built on the results of the survey and explored the challenges and opportunities for several policy features around reform of the regulated products regime. Industry representatives supported the reforms, noting that change to the existing system was needed as it was inefficient and unsupportive of

innovation. They endorsed the need for reform to reduce administrative burdens, without weakening existing food safety standards. The insights obtained informed the proposals subsequently presented in the consultation.

The FSA and FSS conducted a nine-week UK wide public consultation, from 3 April to 5 June 2024, on proposed amendments to the authorisation process for regulated products. Stakeholders were informed of the consultation being launched and were encouraged to comment. Targeted communication included industry trade associations with an interest in regulated products, non- governmental organisations (NGOs) and consumer groups, to ensure a broad spectrum of opinion.

The public consultation had a broad reach, through the FSS and FSA websites, subscription alerts, social media posts and direct contact with key stakeholders. The consultation was shared directly with organisations that have engaged with FSS/FSA about regulated products in general, or a specific regime (e.g. food additives). These organisations, along with members of the FSA's Consumer Forum, were invited to attend online consultation sessions to discuss the proposals.

The reach of the consultation was comprehensive. There were 26,816 subscribers to UK-wide FSA alerts; a further 66,075 subscribers to country specific alerts received automatic notifications. The link to the consultation was posted on the FSA's Facebook, X (formerly Twitter) and LinkedIn pages. These have approximately 120,500, 61,600 and 57,500 followers respectively. FSS shared the consultation with 3,820 LinkedIn followers, 15,913 Facebook followers and

5,555 X followers. The consultation was also shared 103 times via the FSS Stakeholder Engagement Management Service (SEMS). The consultation alert was also sent to enforcement bodies across the UK. Following a press release, the consultation was reported by a number of trade publications.

The consultation page received approximately 3,520 views during the consultation period.

A total of 123 responses were received. Across the 123 respondents, 73 reported being located in England, 17 in Wales, 10 in Scotland and 3 in Northern Ireland (NI). Twenty reported being located outside the United Kingdom (UK). The consultation attracted responses from industry (67), consumers (43), non- governmental organisations (NGOs, 9) and enforcement bodies (4). The number of responses was low compared to the actual number of stakeholders reached.

Overall, there was broad support to both proposals, to remove the requirement for renewals and remove the requirement for authorisations to be prescribed.

Stakeholders' feedback was carefully considered. Based on analysis of responses, there were no identified reasons that would warrant changing the approach. However, there is recognition that some respondents disagreed with the proposals and that there are areas which require additional information, guidance and/or engagement, which will be addressed. General comments regarding the regulated products application process will be taken into account during planned wider reforms.

The FSA/FSS has published the summary of consultation responses which can be found here: www.food.gov.uk/our-work/consultation-on-proposed-reforms-to-the-regulated-products-authorisation-process-summary-of-stakeholder-responses

A note of other impact assessments, (if available)

These reforms will create a more streamlined and effective regulatory regime that keeps pace with innovation in the food industry and will bring benefits to businesses through reduced administrative burdens. Wider impacts include possible increased variety of choice for consumers as new products come to market more quickly, without compromising consumer safety.

A full Impact Assessment has not been prepared for this GB instrument because the annual impact on business is below the de minimis threshold of +/- £5 million EANDCB (equivalent annual net direct cost to business) set for measures being scrutinised at Westminster.

The impact on business, charities or voluntary bodies is positive, including small and micro-businesses, with an equivalent annual net direct benefit to businesses of £254,000.

Indirect benefits to businesses include the reduced lead time in bringing products to market and abolished requirement of the ten-yearly requirement of renewing authorisations for certain products.

The impact on the public sector is an equivalent annual net direct benefit of £1.6m.

Summary of reasons for Scottish Ministers' proposing to consent to UK Ministers legislation

Removing renewal requirements from the three specified regulated products regimes brings them in line with how other food and feed regimes are regulated. The ability to review these authorisations is being retained which allows them to be reassessed if there is any evidence of risk as is currently the case with other regulated products. While implementation of this reform would represent divergence from the EU, a degree of divergence from the EU in the area of regulated products already exists given the differences that can sometimes be seen in applications made, the outcome of risk assessments, and final risk management decisions that are taken, which necessarily restricts the scope for EU alignment. However, we are aware that the EU is also considering reviewing their current renewal requirements for these products.

Removing the need for SIs would result in a level of scrutiny that is proportionate to the regulation of these products, as the terms of authorisations for regulated products are essentially administrative and purely scientific and technical in nature and do not intrinsically need to be set out in legislation. FSS is also directly accountable to the Scottish Parliament, and the removal of the need for Scottish SIs would not diminish the potential for direct Parliamentary scrutiny of FSS decisions and advice to Ministers with regard to regulated products. As the current GB subordinate legislation process is not directly equivalent to EU comitology procedures there are no alignment implications.

Intended laying date (if known) of instruments likely to arise.

The instrument will be laid in draft on or around 29 January 2025

If the Scottish Parliament does not have 28 days to scrutinise Scottish Minister's proposal to consent, why not?

N/A.

Information about any time dependency associated with the proposal.

N/A

Are there any broader governance issues in relation to this proposal, and how will these be regulated and monitored post-withdrawal?

None

Any significant financial implications?

None

Summary notification

HSCS/S6/25/2/1

Title of Instrument The Food and Feed (Regulated Products) (Amendment, Revocation, Consequential and Transitional Provision) Regulations 2025
Proposed laying date at Westminster 29 January 2025
Date by which Committee has been asked to respond 22 January 2025
Power(s) under which SI is to be made Section 14(1), (3), (4)(a), (4)(b) and 20(1) of the Retained EU Law (Revocation and Reform) Act 2023
Categorisation under SI Protocol Type 1
Purpose To remove the requirement for renewal of authorisations every 10 years for feed additives, genetically modified food and feed, and smoke flavourings To remove the requirement to prescribe an authorisation for regulated products in legislation and replacing with the requirement to update an administrative list following Ministerial decision. To make consequential amendments to or revocations of certain Scottish Statutory Instruments
Other information
SG Policy contact: Georgina Finch, Food Standards Scotland Georgina.finch@fss.scot

Annexe C: Correspondence to the Scottish Government

Jenni Minto MSP
Minister for Public Health and Women's Health

7 January 2025

Dear Minister

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

EU EXIT LEGISLATION – PROTOCOL WITH SCOTTISH PARLIAMENT

The Health, Social Care and Sport Committee are due to consider the Food and Feed (Regulated Products) (Amendment, Revocation, Consequential and Transitional Provision) Regulations 2025 (RP reform SI) on 14 January 2025.

In advance of our consideration, it would be helpful if you could provide responses to the following:

Use of enabling powers

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?

Allowing authorisations to come into effect without being prescribed in secondary legislation

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"?

Scottish Statutory Instruments (SSIs)

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

Common Frameworks

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.

Removing renewal requirements for authorisation of feed additives, GMOs and smoke flavourings

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

The Committee would be grateful for a response by midday on **Friday 10 January 2025.**

Yours sincerely,

Clare Haughey MSP

Convener, Health, Social Care and Sport Committee

Annexe D: Correspondence from the Scottish Government

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 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

[1] Risk analysis | Food Standards Scotland

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