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Clare Haughey MSP
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17 February 2025

Dear Clare,

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 31 January 2025 detailing the committee's agreement to the provision of consent to the above GB SI.

In the letter you provide a list of points that were raised in the meeting. I am writing to address those points and do so, in turn, below.

Potential for divergence of alignment with the EU in this area.

We know the EU is also considering whether changes need to be made to renewals. For example, the EU Commission evaluation of feed additives regulation which was published in February 2024 concluded that the 10-year authorisation periods are considered too short which discourages industry from investing resources in developing new feed additives. As with any developments in the EU, the Scottish

Government (SG) and Food Standards Scotland (FSS) will continue to monitor and review our approach as necessary in line with SG alignment policy.

The potential for the removal of the requirement of parliamentary approval for authorisations for new products before they can be placed on the market.

Extensive and robust technical and scientific scrutiny is undertaken before a recommendation is reached on whether a product is safe to be authorised for sale prior to that decision being implemented by an SSI

Removing the need for SSIs 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, 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.

The requirement for an SSI to give effect to an authorisation decision on regulated products was only introduced on EU Exit. Other regulatory regimes in the UK do not have a SSI or equivalent requirement, for example veterinary medicines and pesticides. Bringing the service more into line with these regimes offers a more proportionate and flexible regulatory system, better utilising parliamentary time.

The resource implications for Food Standards Scotland of undertaking continuous review.

Currently 22% of the Regulated Products Service caseload is taken up with renewals authorisations. This significantly reduces FSS' 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 into the service will have been renewal applications. These reforms go some way towards helping the regulator maintain a steady state. Without reform this will put considerable strain on FSS that could significantly impede the authorisation of new products, unless there was a substantial increase in resource. FSS anticipate a minimum of a threefold increase in resource to this area to maintain steady state if these reforms do not proceed.

Removing the renewals process essentially brings the regulation of these products in line with how other food and feed products are regulated. FSS retain the power to reconsider any product authorisation at any time. But the way in which they 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. Freeing up resource also means that FSS and FSA could strengthen their approach to risk analysis and

assessment in the future, building capacity for monitoring risks, horizon scanning and post-market surveillance.

Therefore, the proposed reform would not negatively impact food and feed safety standards. Products subject to renewal requirements have already had their safety rigorously assessed during their initial EU 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.

The rationale and implications, including in terms or resources and the scrutiny role of parliament, of the proposed change of procedure for bringing the relevant authorisations into effect from one involving secondary legislation that would be subject to scrutiny by the Committee to a process of direct ministerial decisions that would no longer be subject to such scrutiny.

Much of this is addressed in my response above. The Committee will also know that FSS is a non-Ministerial public body which answers directly to the Scottish Parliament.

Applications for regulated food products go through a rigorous risk analysis process which is open and transparent for public scrutiny. FSS/FSA publish and regularly update two registers which set out the applications in the market authorisations service, and the issues going through the risk analysis process which allows for public scrutiny. FSS/FSA publish the scientific opinion once a risk assessment is complete. In addition, the terms of authorisation for a product are consulted on publicly and responses taken into consideration before making a recommendation on whether or not the Minister should agree to authorise.

The Reform SI does not change the level of technical and scientific scrutiny or the openness and transparency of the risk analysis process prior to making an authorisation recommendation for a product.

The Committee asks the Scottish Government and Food Standards Scotland to give a commitment that they will provide a regular update, perhaps on a quarterly basis, on any authorisations brought into effect by ministerial decision, that may be of particular relevance or significance to the Committee's remit.

As you know, Food Standards Scotland lays its annual reports in Parliament. Given the nature of regulated products and the length of time required to assess and provide recommendations, often applications are batched, and we may only see one or two batches reach the end of that process in a year. That being the case, it would seem the most suitable way of keeping Parliament and the Committee updated on decisions in this area would be via those annual reports. Currently those reports already contain some limited information on regulated products, and this could possibly be expanded to provide links to the latest authorisations.

FSS officials will look into this further and consider the best and most proportionate way to address the Committee request.

Yours sincerely,

Jenni Minto MSP