POLICY NOTE

THE FEED ADDITIVES (AUTHORISATIONS) (SCOTLAND) REGULATIONS 2022

SSI 2022/288

The above instrument was made in exercise of the powers conferred by Articles 9(1), 13(6), and 18A(3) of retained Regulation (EC) 1831/2003 on additives for use in animal feed. The instrument is subject to the negative procedure.

Summary Box

The purpose of the instrument is to implement the decision made by the Minister for Public Health, Women's Health & Sport in relation to eleven feed additives, authorising five new feed additives for placing on the market and use in Scotland and renewing, modifying, re-evaluating or extending the authorisation of six others. This instrument also includes transitional arrangements for three existing feed additive authorisations.

Legislative Context

Feed additives are regulated products 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. Feed additives must be authorised before they can be placed on the market and used in Great Britain (GB) and can only be used for the purpose stated in the authorisation. Retained Regulation (EC) 1831/2003 and retained Regulation (EC) 429/2008 set out requirements in relation to the authorisation procedure, conditions of use and labelling of feed additives and their premixtures. These regulations provide the details for submitting an application for feed additives. Feed additives are classified under five broad categories (technological, sensory, nutritional, zootechnical, and coccidiostats and histomonostats), whilst they are further defined within functional groups set out in Annex I of retained Regulation (EC) 1831/2003.

Retained Regulation (EC) 1831/2003 on additives for use in animal nutrition provides Scottish Ministers (and respective Ministers for England and Wales) 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. Article 16 of retained Regulation (EC) 1831/2003 also includes specific labelling and packaging provisions for the feed additives or premixture of additives, whilst Article 17 requires that a GB register of authorised feed additives be established, made available to the public and kept up to date. This register is available here: https://data.food.gov.uk/regulated-products/landing.

Policy Objectives

These Regulations are required to give legislative effect to the Minister's decision with respect to authorisation of eleven feed additives so that they can be used, processed and placed on the market in Scotland. The Regulations will add five new feed additives to the list of authorised feed additives, as well as renewing, modifying, re-evaluating or extending the authorisation of six others as set out in retained Regulation (EC) 1831/2003 on feed additives for use in animal nutrition and in accordance with retained Regulation (EC) 429/2008 on the detailed rules for applications, assessments and authorisations of feed additives. This instrument also includes transitional arrangements for three of the eleven feed additives to allow existing stocks and products on the market to be used up where the criteria of a new authorisation differs from the existing feed additive authorisation.

At the end of EU Exit Implementation Period the UK took on the EU Commission's legal obligation to process applications for the authorisation of regulated food and feed products. Assessing food and feed safety in Scotland is the responsibility of Food Standards Scotland (FSS) as the 'food safety authority'. Risk assessments on the eleven feed additives were initially conducted by the European Food Safety Authority (EFSA), and subsequently quality assured by FSS and the Food Standards Agency (FSA). Furthermore, since 01 April 2021 and the coming into force of the Feed (Transfer of Functions) (Miscellaneous Amendments) (Scotland) Regulation 2020 (SSI 2020/467), FSS is the competent authority for feed in Scotland.

The responsibility for the authorisation of these eleven feed additives rests with Scottish Ministers. The retained law provides that authorisations of the relevant feed additives and the modification of feed additive authorisations must be prescribed by the Scottish Ministers. This Scottish Statutory Instrument (SSI) comprises the authorisations by the Scottish Ministers of applications made to them either for a new feed additive authorisation or the extension, modification, renewal or re-evaluation of a currently authorised feed additive. This instrument applies to Scotland only.

This SSI aligns Scotland with England and Wales and similar EU legislation for these feed additives. All eleven have received favourable opinions from EFSA, with ten of them already authorised by the EU Commission for use in the EU under the same terms of authorisation. The application for *Bacillus velezensis* (ATCC PTA-6737) is currently progressing through the EU authorisation process and has a favourable EFSA opinion. In its Opinion published on 7th March 2022, Food Standards Scotland and the Food Standards Agency concluded that the active agent of *Bacillus subtilis* ATCC PTA-6737 should be taxonomically designated as *Bacillus velezensis* ATCC PTA-6737.

Each EFSA opinion, along with all supporting documentation, has been reviewed by FSS and FSA in forming an independent opinion based on risk assessment and safety conclusions. The FSS/FSA opinion in each case was that the feed additives as described in the applications are safe for the target species, users, consumers and the environment. A copy of the FSS/FSA opinions has been provided and is available at the bottom of the FSS Citizen Space consultation page here: https://consult.foodstandards.gov.scot/regulatory-policy/publication-of-fss-opinion-and-consultation-on-fa/.

As ten of the feed additive applications provided for in this instrument have been authorised for use in the EU under the same conditions, they are also authorised in Northern Ireland, under the terms of the Northern Ireland Protocol. In line with commitments made under the Food and Feed Safety and Hygiene Provisional Common Framework, FSS has worked closely with FSA on these eleven feed additives within the regulated products process. Ministers in England and Wales have also agreed to the authorisations of the feed additives and will be submitting their own Statutory Instruments respectively.

Further information in relation to the lists of authorised feed additives can be obtained from Food Standards Scotland, Pilgrim House, Old Ford Road, Aberdeen, AB11 5RL.

Consultation

In compliance with the requirements of Article 9 of retained Regulation (EC) 178/2002, there has been open and transparent public consultation during the preparation and evaluation of this SSI. The public consultation was open from 07 March 2022 until 02 May 2022. One response was received to the consultation. This response was from a key industry trade body and was supportive of the proposed authorisations. They highlighted no concerns with regards to the safety of the feed additives or with regards to costs or burdens for industry. A summary of the consultation and this response can be found published on Citizen Space here: https://consult.foodstandards.gov.scot/regulatory-policy/publication-of-fss-opinion-and-consultation-on-fa/.
Although there was only one Scottish specific response received by FSS, a further response was received by FSA during their consultation from a UK wide trade association. They were supportive of the proposed authorisations and highlighted no concerns with regards to the safety of the feed additives or with regards to costs or burdens for industry. As this association is UK wide and has Scottish members, its response also has relevance to Scotland. A summary of this response, and FSA's consultation, is available here: https://www.food.gov.uk/news-alerts/consultations/applications-for-eleven-additives-for-use-in-animal-feed.

Impact Assessments
Given the feedback from stakeholders, FSS consider that a specific Business and Regulatory Impact Assessment (BRIA) is not required for these feed additive applications. The costs to businesses are contained in retained Regulation (EC) 1831/2003 on additives for use in animal feed which requires authorisation of feed additives to be placed on the market, as well as of any renewals, modifications, re-evaluations or extensions of existing feed additive authorisations. This SSI gives legislative effect to the Minister's decision and does not introduce any new costs to businesses or industry. No other impact assessments are required.

Financial Effects
The Minister for Public Health, Women's Health & Sport confirms that a BRIA is not necessary as the instrument has no financial effects on the Scottish Government, local government, voluntary bodies or on business.

Monitoring and Review
There is an existing legislative requirement for coccidiostats to be subject to a field monitoring plan and this applies to the two formulations of Decoquinate. This will ensure that it remains effective and does not become resistant to the gut parasites they are intended to control. The authorisation holder must submit a report to the Scottish Ministers at least one-year prior to the authorisation expiry date.

Food and Feed Safety Policy Branch,
Food Standards Scotland,
September 2022