# POLICY NOTE

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

## SSI 2024/330

The above instrument was made in exercise of the powers conferred by Articles 9(1) and 18A(3) of Regulation (EC) No. 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition and section 74A(1) of the Agriculture Act 1970. The instrument is subject to negative procedure.

**Summary Box**

- The purpose of this Scottish Statutory Instrument (SSI) is to implement the decision made by the Minister for Public Health and Women's Health to authorise twenty-five feed additives and one feed for particular nutritional purposes (PARNUT).
- The SSI authorises the placing on the market and use in Scotland of nine new authorisation, one renewal authorisation, six new use authorisation, three modification authorisation, five renewal and modification authorisation and two renewal, new use and modification authorisation.
- This SSI includes transitional provisions for seven existing authorisations.
- This instrument extends to Scotland only.

## Legislative Context

Feed additives are regulated products which may be authorised for specific purposes in animal feed and can have a range of functions including meeting animals' nutritional requirements, improving the quality of feed and food, and improving animals' performance and health. A feed additive must be authorised by the Scottish Ministers before it can be placed on the market, processed and used in Great Britain (GB) and can only be used for the purposes stated, and subject to the conditions provided, in such an authorisation. Regulation (EC) No. 1831/2003 (2003 Regulation) and Regulation (EC) No. 429/2008 set out the legislative framework for submitting applications for authorisation of feed additives in relation to conditions of use and the labelling and packaging of feed additives and their premixtures. Feed additives are classified under five broad categories (technological, sensory, nutritional, zootechnical, and coccidiostats and histomonostats), and they are further defined within functional groups set out in Annex I of Regulation (EC) No. 1831/2003.

At the end of the Implementation Period, the UK inherited the European Commission's (EC) legal obligation to process applications for the authorisation of regulated feed products. Assessing animal feed safety in Scotland is the responsibility of Food Standards Scotland (FSS) as the 'feed safety authority'. FSS and the Food Standards Agency (FSA) assess GB-wide regulated products applications jointly through the GB regulated products application service, and make recommendations to Ministers. The authorisation of these products for placing on the market in Scotland rests entirely with the Scottish Ministers.

The 2003 Regulation provides Scottish Ministers with the power to authorise feed additives and specify conditions for their use. Feed additives authorisations are valid for 10 years following the date that the instrument comes into force. When no decision is taken on the renewal of an authorisation before its expiry date, Article 14 of 2003 Regulation makes

provision for the period of authorisation to be automatically extended until the appropriate authority makes a determination. Article 16 of 2003 Regulation makes provision in relation to the labelling and packaging of the feed additives and premixture of additives. Article 17 requires that a GB register of regulated food and feed products for GB which includes feed additives and is available at: Authorised Regulated Food and Feed Products for Great Britain[1].

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

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

**Policy Objectives**

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

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

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

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

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

This SSI aligns Scotland with England and Wales and similar EU legislation for these regulated products. FSS and the Food Standards Agency (FSA) have reviewed the European Food Safety Authority (EFSA) opinions along with all supporting documentation for twenty-one of the feed additive authorisations and each formed an independent opinion based on risk assessment and safety conclusions. A safety assessment was not required for one feed additive authorisation as this is for a modification in the authorised owner. The FSS opinion in each case was that the regulated products, as described in the applications, are safe and provide no risk to target species, human health or the environment. A copy of the FSS opinions has been provided and is available at the bottom of the FSS Citizen Space consultation pages here: Consultation on applications for authorisation of regulated products: One feed additive (RP16 Chromium chelate of DL-methionine) - Food Standards Scotland - Citizen Space[2] and here: Consultation on applications for authorisation of regulated products: twenty four feed additives and one feed for particular nutritional purposes (PARNUT) for use in animal feed - Food Standards Scotland - Citizen Space[3]

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

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

**EU Alignment Consideration**

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

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

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

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

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

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

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

Aligning with relevant EU policy maintains and advances fair trade, competition and access to EU markets for industry and agricultural services.

**Consultation**

*Scotland*

To comply with the requirements of Article 9 of Regulation (EC) 178/2002, two public consultations were undertaken by FSS during the preparation and evaluation of this SSI. The public consultation for twenty-four feed additives and one PARNUT was open from 22nd April 2024 to 17th June 2024. A second, additional public consultation for one feed additive was open from 5th August 2024 to 2nd September 2024. One response was received. No concerns were raised about the safety of the feed additives and PARNUT and there were no concerns with regards to costs or burdens for the feed industry. A summary of the consultation responses is available here: Consultation on applications for authorisation of regulated products: One feed additive (RP16 Chromium chelate of DL-methionine) - Food Standards Scotland - Citizen Space[4] and here: Consultation on applications for authorisation

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

of regulated products: twenty four feed additives and one feed for particular nutritional purposes (PARNUT) for use in animal feed - Food Standards Scotland - Citizen Space[5]

*Rest of Great Britain*

A total of seven consultation responses were received by the FSA: six representing industry and Trade Associations, and one Private Individual. Across the seven respondents, all gave their location as UK-wide. As all respondents are UK wide, their response also has relevance to Scotland. A summary of the responses, and FSA's consultations, is available here: Consultation on 24 feed additive applications and one application for feed for particular nutritional purposes (PARNUT) for use in animal feed | Food Standards Agency[6] and here: Consultation on one feed additive application for use in animal feed | Food Standards Agency[7]

**Impact Assessments**
FSS consider that a specific Business and Regulatory Impact Assessment (BRIA) is not required for these authorisations. The costs to businesses are contained in 2003 Regulation which both require authorisations before products may be placed on the market or for extensions/modifications of use of current authorisations. This SSI gives legislative effect to the Minister's decision and does not introduce any new costs to businesses or industry. The new feed additive authorisations extension of use of feed additives will likely result in the reallocation of wealth from existing to new product lines. A Child Rights and Welfare Impact Assessment (CRWIA) has been carried out with no impact to child rights or welfare found. No other impact assessments are required.

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

Food Standards Scotland,
29 October 2024

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