EXPLANATORY MEMORANDUM TO

THE FEED ADDITIVES (AUTHORISATIONS) AND USES OF FEED INTENDED FOR PARTICULAR NUTRITIONAL PURPOSES (AMENDMENT OF COMMISSION REGULATION (EU) 2020/354) (ENGLAND) REGULATIONS 2024

2024 No. 1101

1. Introduction

1.1 This explanatory memorandum has been prepared by The Food Standards Agency (FSA) and is laid before Parliament by Command of His Majesty.

2. Declaration

2.1 Minister Andrew Gwynne MP, Parliamentary Under Secretary of State for Public Health and Prevention confirms that this Explanatory Memorandum meets the required standard.

2.2 Dr. James Cooper, Deputy Director of Food Policy at the Food Standards Agency confirms that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Clare Mogford at the Food Standards Agency Email: rpconsultations@food.gov.uk can be contacted with any queries regarding the instrument.

Part One: Explanation, and context, of the Instrument

4. Overview of the Instrument

What does the legislation do?

4.1 This instrument authorises feed additives and one amendment to the list of uses of feed intended for particular nutritional purposes (PARNUT) for use in animal feed in England. These authorisations consist of new authorisations, new use only, renewals (with changes to either the conditions of use, label requirements, formulation and/or for use with different animal species or their sub-groups), and modification only. The Instrument includes transitional arrangements for certain previously authorised feed additives to allow existing stocks to be depleted due to labelling changes and/or conditions of use.

Where does the legislation extend to, and apply?

4.2 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is England and Wales.

4.3 The territorial application of this instrument (that is, where the instrument produces a practical effect) is England only.

5. Policy Context

What is being done and why?

5.1 Feed additives are a regulated product and in order for these products to be made available on the market in England, they are required to go through a formal application process with the FSA. The FSA manage the market authorisation of feed additives and feedstuffs in England and Wales. Food Standards Scotland (FSS) fulfils

the equivalent function in Scotland. Applications for the authorisation of feed additives and one application to amend the PARNUT list were submitted to the FSA. This Instrument makes the necessary changes to the relevant legislation to give effect to a final decision on the authorisations of these feed additives and PARNUT. As the 'appropriate authority', the Secretary of State for Health and Social Care makes decisions on authorisations in relation to England. Applications were received on the joint FSA/FSS application portal for the authorisation of feed additives and one amendment of the PARNUT list. The applications consisted of nine new authorisations, one renewal authorisation, six new use authorisations, three modification authorisation, five renewal and modification authorisations, and two renewal, new use and modification authorisations.

5.2 Ministers in Scotland and Wales have also agreed to the authorisations of the feed additives and PARNUT and will be submitting their own Statutory Instruments in their respective countries.

5.3 Each of the applications have been reviewed by the FSA through an independent safety assessment. The FSA recommendation is that these feed additives and PARNUT list amendment, as described in the application, are safe for the target species, users, consumers and the environment. Copies of the FSA safety assessments are available on the Food Standards Agency website.

5.4 The FSA used the results of the FSA safety assessments to provide the Secretary of State with an opinion on the safety of the applications, with an outline of other relevant factors. Minister Andrew Gwynne (Parliamentary Under Secretary of State for Public Health and Prevention) decided to authorise all products for placement on the market in England. This will result in a change to the legislation.

What was the previous policy, how is this different?

5.5 Prior to EU exit, the EU carried out the authorisation of regulated products, including novel foods, flavourings, food, and feed additives, before being added to or amended in the authorised list and made available on the EU market. During this time, the UK accepted the safety assessments of the European Food Safety Authority (EFSA) in support of authorisation for regulated food and feed products where directly applicable in the UK. The implementation period, during which the UK remained in both the EU customs union and single market, ended on 31 December 2020. On 1 January 2021, assimilated law created consistent practices in certain devolved policy areas across the UK where the four governments agreed it was necessary to maintain UK-wide approaches. New enduring agreements, or 'Common Frameworks', have been developed on how the four countries will work together. As part of the Common Frameworks with the devolved governments, the FSA now works alongside Food Standards Scotland (FSS).

5.6 This Instrument authorises the third set of regulated feed additive products to go through the national authorisation process since the UK left the EU.

5.7 Thirteen of the twenty-five feed additive applications and the PARNUT application were originally submitted to EFSA prior to the end of implementation period on leaving the EU. Each of the feed additive applications that were originally assessed by EFSA has been reviewed by the FSA through an independent safety assessment. The remaining feed additive applications and PARNUT application underwent a full FSA safety assessment.

6. Legislative and Legal Context

How has the law changed?

6.1 The legislative framework for the authorisation of feed additives is set out in assimilated Regulation (EC) 1831/2003 and provides the Secretary of State with powers to set conditions of use on additives for use in animal nutrition[1]. Legislation is in place to regulate the conditions of labelling and packaging for feed additives under Article 16 of Regulation 1831/2003. The feed additives authorised by this Instrument are authorised for a period of ten years following the date that the Instrument comes into force. Feed additive legislation requires such products to be authorised before being placed on the market[2].

6.2 A list of intended uses for feed intended for particular nutritional purposes is set out in the Annex of Regulation (EU) 2020/354[3]. This Instrument utilises sections 74A and 84 of the Agriculture Act 1970 (c. 40) to amend an entry in the list at the Annex of Regulation (EU) 2020/354. The Agriculture Act 1970 powers have been utilised in lieu of Article 10 of Regulation (EC) No 767/2009. Article 10 of Regulation (EC) No 767/2009 is undergoing remedial work due to defective wording rendering the article unusable.

Why was this approach taken to change the law?

6.3 This approach leads to the product being authorised, where there are no safety concerns, whilst the existing legislation is remedied.

7. Consultation

Summary of consultation outcome and methodology

7.1 A public consultation on twenty-four feed additive applications and one PARNUT application [4] was launched by the FSA on 22 April 2024 for a period of eight weeks. An additional consultation on one feed additive application[5] was launched on 5 August 2024 for a period of four weeks. The FSS published its own consultations[6]. Both consultations sought feedback on the proposed terms of authorisation in relation to the feed additives and PARNUT list amendment. In particular, views were sought

[1] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition: https://www.legislation.gov.uk/eur/2003/1831/contents

[2] The FSA maintains a public register of feed additives permitted on the market in Great Britain (GB) and it is available here: https://data.food.gov.uk/regulated-products/landing

[3] Commission Regulation (EU) 2020/354 of 4 March 2020 establishing a list of intended uses of feed intended for particular nutritional purposes and repealing Directive 2008/38/EC: https://www.legislation.gov.uk/eur/2020/354/contents

[4] Consultation on 24 feed additive applications and one application for feed for particular nutritional purposes (PARNUT) for use in animal feed | Food Standards Agency: 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-animal-feed

[5] Consultation on one feed additive application for use in animal feed | Food Standards Agency: https://www.food.gov.uk/news-alerts/consultations/consultation-on-one-feed-additive-application-for-use-in-animal-feed

[6] 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:https://consult.foodstandards.gov.scot/regulatory-policy/regulatory-policy-tranche3-feed-additives/ and Consultation on applications for authorisation of regulated products: One feed additive (RP16 Chromium chelate of DL-methionine) - Food Standards Scotland - Citizen Space: https://consult.foodstandards.gov.scot/regulatory-policy/regulatory-policy-tranche3-single-feed-additive/

on the assessment of the potential impacts set out in the consultation, and further evidence requested on any additional impacts that had not been noted.

7.2 Stakeholders and enforcement authorities were informed of the consultation being launched and were encouraged to comment. This included trade bodies representing stakeholders on animal feed, agriculture and the environment, and trade unions representing stakeholders in the farming industry to ensure a broad spectrum of opinion.

7.3 Key stakeholders whose businesses/organisations who were likely to be affected by or to have an interest in these feed additives and PARNUT list amendment were contacted directly for their feedback. To ensure representation across a broad spectrum of opinion, stakeholders with a range of interests in the regulated products were included.

7.4 The FSA consultation reach was comprehensive, with automatic notifications sent to 27,196 UK-wide subscribers of FSA alerts at the time of launch. Automatic notifications were also issued to FSA subscribers registered to receive updates in relation to national content: 31,129 subscribers to England, 17,526 subscribers to Northern Ireland and 18,451subscribers to Wales. The FSA consultation page received approximately 1016 views.

7.5 For the consultation that was launched on 5 August 2024, automatic notifications were sent to 28599 UK-wide subscribers of FSA alerts at the time of launch. Automatic notifications were also issued to FSA subscribers registered to receive updates in relation to national content – 32,828 subscribers to England, 18,458 subscribers to Northern Ireland and 19,417subscribers to Wales. The FSA consultation page received approximately 908 views.

7.6 Responses were received from a total of six respondents within the UK, including industry and private individuals. Three respondents sent either neutral or supportive responses. One respondent highlighted a minor drafting error within the FSA/FSS consultation documents which was subsequently corrected and implemented into the final recommendation to the Minister. Two respondents had queries regarding the safety of feed additives which had already been addressed in the FSA safety assessments. All other responses either did not directly relate to the consultation launch, or were queries which had already been addressed in the consultation documents. All responses were carefully considered, and a combined summary of responses can be found on each consultation webpage.[7, 8]

8. Applicable Guidance

8.1 The Instrument does not implement or require guidance. This Instrument relates to the authorisation of feed additives and the amendment of one entry to the PARNUT list to be made available on the market in England. These are facilitative measures, and no guidance is required for enforcement authorities.

[7] Consultation on 24 feed additive applications and one application for feed for particular nutritional purposes (PARNUT) for use in animal feed | Food Standards Agency: 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

[8] Consultation on one feed additive application for use in animal feed | Food Standards Agency: https://www.food.gov.uk/news-alerts/consultations/consultation-on-one-feed-additive-application-for-use-in-animal-feed

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 A full Impact Assessment has not been prepared for this Instrument because the regulations are designed to allow authorised feed additives and PARNUTs to be placed on the market in England. The familiarisation costs are expected to be minimal and if applicable, would fall below the de minimis threshold.

Impact on businesses, charities and voluntary bodies

9.2 There is no, or no significant, impact on business, charities or voluntary bodies.

9.3 The legislation does not impact small or micro businesses.

9.4 No specific action is proposed to minimise regulatory burdens on small businesses as it is important all businesses follow food law to ensure consumer and animal safety.

9.5 There is no, or no significant, impact on the public sector.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 Certain feed additives can be subject to post monitoring requirements as part of their terms of authorisation. Such requirements are included in this Instrument for the feed additives which are coccidiostat and histomonostats. This requires the holder of authorisation to carry out a post-market monitoring programme for resistance to bacteria and *Eimeria* spp. Reports containing the outcome of the programme must be submitted to the Secretary of State by 19th December 2033.

10.2 The instrument does not include a statutory review clause as it is a facilitative measure, that does not impose a burden on business. In line with the requirements of the Small Business, Enterprise and Employment Act 2015[9], Minister Andrew Gwynne has made the following statement:

"It is not appropriate to make provision for review in The Feed Additives (Authorisations) and Uses of Feed Intended for Particular Nutritional Purposes (Amendment of Commission Regulation (EU) 2020/354) (England) Regulations."

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

11.1 None.

12. European Convention on Human Rights

12.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

[9] Small Business, Enterprise and Employment Act 2015 (legislation.gov.uk)

13. The Relevant European Union Acts

13.1 This instrument is not made under the European Union (Withdrawal) Act 2018, the European Union (Future Relationship) Act 2020 or the Retained EU Law (Revocation and Reform) Act 2023 ("relevant European Union Acts").