EXPLANATORY MEMORANDUM TO

THE FEED ADDITIVES (AUTHORISATIONS) (ENGLAND) REGULATIONS 2023

2023 No. 1196

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. Purpose of the instrument

2.1 This instrument authorises thirteen feed additives in England, allowing them to be distributed and available on the market in England. Of the thirteen authorisations, ten consist of new authorisations, and three renewals (with changes either to the conditions of use, label requirements, formulation and / or for use with different animal species or their sub-groups). The instrument also includes transitional arrangements for one previously authorised feed additive to allow existing stocks to be depleted.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

4. Extent and Territorial Application

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

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

5. European Convention on Human Rights

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

6. Legislative Context

6.1 Feed additives are a type of regulated product and require authorisation in legislation to be available on the market.

6.2 The legislative framework for the authorisation of feed additives is set out in retained Regulation (EC) No. 1831/2003 ('Regulation 1831/2003') and provides the Secretary of State with powers to set conditions for the use of the feed additive. Regulation 1831/2003 is available here: https://www.legislation.gov.uk/eur/2003/1831/contents

6.3 The feed additives authorised by this instrument are authorised for a period of 10 years following the date that the instrument comes into force.

6.4 Legislation is in place to regulate the conditions of labelling and packaging for feed additives under Article 16 of Regulation 1831/2003.

6.5 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.

7. Policy background

What is being done and why?

7.1 Regulated Products require authorisation in legislation to be available on the market and are required to go through a formal application process with the FSA. Following this application process the FSA advises the Secretary of State which additives it recommends should be approved along with specific conditions of use.

7.2 Applications for the authorisation of thirteen feed additive products have been submitted to the FSA, consisting of ten new authorisations and three renewals (with changes either to the conditions of use, label requirements, formulation and / or for use with different animal species or their sub-groups).

7.3 The FSA and Food Standards Scotland (FSS) have carried out a risk analysis on all applications and have provided the Secretary of State with an opinion on the safety of the applications, along with an outline of the other relevant factors provided for in the regulations for placement on the market in England.

7.4 Prior to EU exit, the UK accepted the assessments of the European Food Safety Authority (EFSA) in support of authorisation for regulated food and feed products. Since the end of the implementation period, FSA has also adopted the same technical guidance and quality assurance processes to make independent risk assessments.

7.5 As part of the Food and Feed Safety and Hygiene Provisional Common Framework agreement with the devolved administrations since the end of the transition period, the FSA has worked alongside the FSS. Ministers in Scotland and Wales have also agreed to the authorisations of the feed additives and will be submitting their own Statutory Instruments in their respective countries. These Feed Additives have already been approved for use in Northern Ireland, under Windsor Framework arrangements.

7.6 All thirteen feed additives within 12 applications were originally submitted to the EFSA prior to the end of the transition period on leaving the EU.

7.7 For twelve feed additives, EFSA had published their opinion prior to the GB risk assessment starting. The FSA/FSS reviewed each opinion, along with all supporting documentation, when forming its independent safety assessment. The thirteenth feed additive, 3-Nitrooxypropanol (referred to as '3-NOP') is the first application published which underwent a full FSA/FSS safety assessment.

7.8 3-NOP is an innovative feed additive, designed to reduce methane production in ruminants (e.g., cows, sheep) that has the potential to contribute to UK carbon net-zero targets.

7.9 All of the applications have been authorised for use in the EU. As a result of stakeholder engagement post-consultation, it was considered necessary to include transitional arrangements for Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* (CBS 114044) to minimise market impacts following identification code changes, which are provided on product labels. Endo-1,4-beta-xylanase (EC 3.2.1.8) is a feed additive intended to improve the digestibility of animal diets.

7.10 It should be noted that for 3-NOP, there is minor divergence in the terms of the EU and GB authorisations. This is because 3-NOP has been authorised in NI/EU in feed specifically for dairy cows and cows for reproduction whereas the proposed authorisation in GB is for all ruminants for milk production and reproduction.

7.11 A copy of the FSA/FSS risk management recommendations has been provided and is available here: https://www.food.gov.uk/our-work/fsafss-opinions-on-twelve-applications-for-feed-additives-summary

7.12 The Secretary of State for Health and Social Care has accepted the recommendation of the FSA that the thirteen feed additives are safe for the target species, users, consumers and the environment, and to allow their use in England.

7.13 This will be the second set of regulated feed additive products to go through the national authorisation process since the UK left the EU.

Explanations

What did any law do before the changes to be made by this instrument?

7.14 Prior to EU exit, the authorisation of regulated products were within the scope of EU legislation where feed additives underwent authorisation processes before being added/amended to the authorised register and made available on the EU market.

7.15 Following EU exit, previously EU authorised feed additives continued to be authorised in GB under retained EU law (REUL). Directly applicable EU legislation for these feed additives has been retained in the UK as REUL. Ministers are empowered under REUL to agree to the authorisation of feed additives for placing on the GB market.

Why is it being changed?

7.16 The only change is to authorise these feed additives for placing on the market in England. Legislation is the only route for regulated products, including feed additives to be available on the market in England.

What will it now do?

7.17 This instrument will permit the specified feed additives to be placed on the market in England.

8. European Union Withdrawal and Future Relationship

8.1 This instrument does not relate to withdrawal from the European Union / trigger the statement requirements under the European Union (Withdrawal) Act.

9. Consolidation

9.1 This instrument does not consolidate any legislation and there are no plans to consolidate the relevant legislation at this time.

10. Consultation outcome

10.1 The public consultation on the feed additives being authorised by this instrument was launched by the FSA on 25 May 2023 and lasted for eight weeks.

10.2 This consultation sought views from the public and stakeholders on the proposed feed additives under the specified conditions of use, to consider any relevant provisions

under retained EU law and other legitimate factors. This included other evidence further supporting clear, rational and justifiable risk analysis, such as consumer interests, technical feasibility and environmental factors. Consideration was given to the provision of transitional arrangements for 6-phytase (EC 3.1.3.26) produced by *Trichoderma reesei* (CBS 122001) to minimise market impacts of this feed additive between existing and new authorisations where conditions of use and labelling have changed.

10.3 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.

10.4 The FSA public consultation had a broad reach, through the FSA website, subscription alerts, social media posts and direct contact with key stakeholders. There were 34,420 subscribers to UK wide FSA alerts. The consultation was also shared with the FSA's 61,200 X (formerly Twitter) and 109,609 LinkedIn followers. The FSA consultation page received approximately 326 views from 25 May 2023 – 20 July 2023.

10.5 A total of seven responses were received, from England, Wales and Northern Ireland, including responses from trade associations of whom represent in excess of 250 members and businesses with an interest in animal feed/feed additives. Five responses were supportive, and one response did not directly apply to the applications that were being consulted on, other than a general response to the consultation launch. The other response was from a company that highlighted some minor drafting errors within the FSA/FSS opinion and proposed amendments to be considered for future consultation documents.

10.6 The FSA has published the consultation with responses which can be found here: https://www.food.gov.uk/news-alerts/consultations/consultation-on-twelve-applications-for-feed-additives-for-use-in-animal-feed

10.7 The FSS also published its own consultation, and the responses can be found here: https://consult.foodstandards.gov.scot/regulatory-policy/regulatory-policy-tranche2-feed-additives/

11. Guidance

11.1 No guidance is being provided. This relates to thirteen feed additives to be made available on the market in England. These are facilitative measures, and no guidance is required for enforcement authorities.

11.2 The FSA will issue a targeted update to local authorities informing them of the authorisations and will update the GB Feed Additives Register.

12. Impact

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

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

12.3 A full Impact Assessment has not been prepared for this instrument because the regulations are designed to allow authorised feed additives to be placed on the market in England. The familiarisation costs are expected to be minimal and if so, would fall below the de minimis threshold as these feed additive applications are routine or, in

the case of 3-NOP, which is the first in its functional group, has been on the market in NI/EU since April 2022.

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses.

13.2 No specific action is proposed to minimise regulatory burdens on small businesses.

14. Monitoring & review

14.1 There are no monitoring or review requirements for this instrument.

14.2 This instrument does not include a statutory review clause. Pursuant to section 31(2)(a) of the Small Business, Enterprise and Employment Act 2015, the Parliamentary Under Secretary of State for Primary Care and Public Health has determined that it would not be appropriate to make provision in this instrument for a review clause considering the legislation is expected to have an economic impact of less than +/- £5 million (net annualised).

14.3 Other factors include the requirement in legislation for the feed additive authorisation to be limited to a 10-year period only. For authorisations to be renewed, an updated application must be submitted to FSA/FSS at least one-year prior to their expiry date. These applications are further scrutinised for safety and efficacy of the feed additive before going through the same authorisation procedure for their renewal.

15. Contact

15.1 Subrata Dey at the Food Standards Agency phone: 07356 101059 email: subrata.dey@food.gov.uk can be contacted with any queries regarding the instrument.

15.2 Sarah Houghton, Deputy Director for Regulatory Services at the Food Standards Agency can confirm that this Explanatory Memorandum meets the required standard.

15.3 Neil O'Brien MP, Parliamentary Under-Secretary at the Department of Health and Social Care confirm that this Explanatory Memorandum meets the required standard.