EXPLANATORY MEMORANDUM TO

THE FEED ADDITIVES (AUTHORISATIONS) (ENGLAND) REGULATIONS 2022

2022 No. 1129

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 eleven feed additives in England, allowing them to be distributed and available on the market in England. Of the eleven authorisations, five consist of new authorisations and six consist of renewals (with and without changes to the conditions of use, formulation and for use with different animal species or their sub-groups). This instrument also includes transitional arrangements for three previously authorised feed additives to allow for 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 the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

6. Legislative Context

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

6.2 Feed additives are classified under five broad categories (Technological, Sensory, Nutritional, Zootechnical and Coccidiostats & Histomonostats), and further defined for specific functions, as outlined in Annex I of Retained Regulation (EC) No 1831/2003 (Regulation 1831/2003) https://www.legislation.gov.uk/eur/2003/1831/annex/I.

6.3 The legislative framework for the authorisation of feed additives is set out in Regulation 1831/2003 and provides the Secretary of State with powers to set conditions for the use of the feed additive.

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

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

6.6 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 This instrument relates to eleven feed additive applications consisting of five new authorisations and six renewals (with and without changes to the conditions of use, formulation and extending the use to different animal species or their sub-groups).

7.2 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.

7.3 Following this application process the FSA advises the Secretary of State of which feed additives it recommends should be approved along with specific conditions of use.

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

7.5 As part of the common framework agreements with the devolved administrations since the end of the transition period, the FSA has worked alongside Food Standards Scotland (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.

7.6 Before leaving the EU, the UK accepted the assessments of the European Food Safety Authority (EFSA) in support of authorisation for regulated food and feed products. EU Food Law on Feed Additives continues to apply in Northern Ireland under the current terms of the Northern Ireland Protocol (NIP). Since the end of the implementation period, GB has also adopted the same technical guidance and quality assurance processes to make independent GB risk assessments.

7.7 The eleven feed additives were originally submitted to the EFSA prior to the end of the transition period on leaving the EU.

7.8 The EFSA has published an opinion on each of these feed additives and each opinion, along with all supporting documentation has been reviewed by the FSA in forming an independent opinion based on risk assessment and safety conclusions. The 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 FSA opinions has been provided and is available here: www.food.gov.uk/sites/default/files/media/document/Feed%20Additives%20FSAFSS%20Opinions.pdf.

7.9 All these current feed additive applications have been authorised for use in the EU, with the exception of *B. velezensis* (formerly *B. subtilis*) ATCC PTA-6737 which is currently progressing through the EU authorisation process.

7.10 This will be the first 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?

7.11 Prior to EU exit the authorisation of regulated products was under EU legislation where feed additives underwent the same processes before being added/amended to the authorised register and made available on the EU market.

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

Why is it being changed?

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

What will it now do?

7.14 This instrument will permit the 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 7th March 2022 and ran 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 made to the provision of transitional arrangements to minimise market impacts 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 18,808 subscribers to UK wide FSA alerts.

10.5 A total of two responses were received, from England, Wales and Northern Ireland, both in support of the authorisations. The first response was from the British Association of Feed Supplement and Additive Manufacturers and the second from the Agricultural Industries Confederation (AIC). The two organisations are trade associations and are representative of the majority of the feed industry through their members and are the largest stakeholders for this industry. Both were generally in favour of authorisation. AIC also noted the importance of a wide range of feed remaining available to the industry. Zero responses were received against authorisation.

10.6 The numbers of responses for the consultation were low compared to the actual number of stakeholders reached via these two major trade associations with direct interests in animal feed and feed additives.

10.7 The FSA published consultation with responses which can be found here: www.food.gov.uk/news-alerts/consultations/applications-for-eleven-additives-for-use-in-animal-feed.

10.8 The FSS also ran a consultation, the published consultation with responses can be found here: https://consult.foodstandards.gov.scot/regulatory-policy/publication-of-fss-opinion-and-consultation-on-fa/.

11. Guidance

11.1 No guidance is being provided. This relates to eleven 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.

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 is an existing legislative requirement for cocciodiostats 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 Secretary of State at least one-year prior to the authorisation expiry date.

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 Vaccines 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 Katy Williams at the Food Standards Agency email: katy.williams@food.gov.uk or phone: 07817958610 can be contacted with any queries regarding this instrument.

15.2 Peter Quigley, 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, Parliamentary Under-Secretary of State at the Department of Health and Social Care can confirm that this explanatory memorandum meets the required standard.