EXPLANATORY MEMORANDUM TO

THE FEED ADDITIVES (FORM OF PROVISIONAL AUTHORISATIONS) (COBALT(II) COMPOUNDS) (ENGLAND) REGULATIONS 2023

2023 No. 689

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 provides the form and content of provisional authorisation for four feed additives in England that require urgent authorisation to protect animal welfare. The feed additives will be authorised for ruminants with a functional rumen (cattle, sheep), equidae (horses), lagomorphs (rabbits, hares), rodents, herbivore reptiles and zoo mammals.

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 in legislation to be available on the market. Authorisations are generally for a period of 10 years.

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.

6.3 A provisional authorisation of up to 5 years, may be issued by the Secretary of State if the feed additive is needed to protect animal welfare. This is the first time that this power has been used. Before a provisional authorisation can be issued, the form must be set out in regulation (Article 15 of Regulation 1831/2003).

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

6.5 Article 17 of Regulation 1831/2003 requires the FSA to maintain 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 the provisional authorisation of four Cobalt compounds as feed additives under Article 15 of Regulation 1831/2003. The Secretary of State for Health and Social Care has accepted the recommendation of the FSA to urgently authorise these feed additives on a provisional basis, enabling their continued use in England.

7.2 The current feed additive authorisations for these Cobalt compounds will expire in GB on 15 July 2023. Once authorisation has expired, products containing the additive cannot lawfully be placed on the market, processed, or used. Without intervention, this will disrupt supply to the GB market.

7.3 These additives, which have a long history of safe use, are essential to maintaining animal welfare and there is a serious risk that animal health will be negatively and severely impacted if Cobalt was to become unavailable as a feed additive. This impact will increase over time as there are currently no alternatives to these compounds that could meet nutritional requirements.

7.4 FSA considered evidence presented in the application, the previous European Food Safety Authority's opinion following risk assessment and evidence provided by stakeholders and through public consultation. Due to the urgency of the situation, it was not possible to conduct a full risk assessment of these feed additives. As part of its regulated products process, the FSA will undertake a full risk assessment of the new application of these feed additives.

7.5 As part of the common framework agreements with the devolved administrations since the end of the transition period, the FSA has worked on a four-country basis. Relevant Ministers in Scotland and Wales have also agreed to prescribe the form and content of the provisional authorisations. Each nation will submit their own statutory instruments in their respective countries.

7.6 Under current operating arrangements for Northern Ireland (NI), businesses seeking authorisation of a feed additive to be placed on the NI market will continue to follow EU rules. The EU is currently considering an urgent application but there is a risk this will not be in place when the current authorisation expires.

Explanations

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

7.7 Although a power existed to issue a provisional authorisation, it was not possible to do so without prescribing regulations concerning the form of the provisional authorisation.

Why is it being changed?

7.8 Urgent authorisation is needed to maintain market supply and protect animal welfare and therefore the form of provisional authorisation must be prescribed.

7.9 There are five authorised Cobalt compounds on the GB market that are essential to maintaining animal welfare. Authorisations of four of these additives expire on 15 July 2023.

7.10 The remaining authorised Cobalt compound will not meet all animals' nutritional needs as it is insoluble and contains low levels of Cobalt so is not suitable for many types of application. Cobalt deficiency in animals (particularly ruminants) results in loss of appetite, severe emaciation and, if left untreated, death.

What will it now do?

7.11 This instrument prescribes the form and content of the provisional authorisations enabling four Cobalt compounds 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 involve consolidation and there are no plans to consolidate the relevant legislation at this time.

10. Consultation outcome

10.1 A two-week public consultation was issued in England and Wales. This was considered proportionate given the urgent need for authorisation. Prior to the public consultation, the FSA and Food Standards Scotland (FSS) engaged extensively with stakeholders and industry on the risks associated with the removal of these four Cobalt compounds from the market.

10.2 The Agricultural Industries Confederation (AIC) and the British Association of Feed Supplements and Additive Manufacturers (BAFSAM) provided strong evidence in support of the four Cobalt authorisations. This evidence was published by FSA as a component of the public consultation. The AIC and BAFSAM outlined that Cobalt supplementation is at its height from March to November and is administered 3-weekly to young animals in spring/summer and sheep/cattle during summer/autumn. As most forages and feedstuffs fed to ruminants do not contain adequate quantities of Cobalt to support the ruminant's nutritional requirements, FSA veterinarians estimate that without the use of Cobalt as an additive this would lead to death of animals within 3-12 months.

10.3 The FSA public consultation had a broad reach, through the FSA subscription alerts, social medial posts and direct contact with key stakeholders. There were 34,170 subscriptions to UK-wide FSA alerts.

10.4 A total of fourteen consultation responses were received from trade bodies, non-governmental organisations, and other government departments. All were supportive of the proposal to secure an urgent authorisation and recognised the negative impact on animal health if these additives were removed from the GB market.

10.5 The FSA published consultation with responses can be found at the following website: https://www.food.gov.uk/news-alerts/consultations/consultation-on-proposed-provisional-authorisations-of-four-feed-additives-for-use-in-animal-feed.

11. Guidance

11.1 No guidance is being provided. 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 this authorisation and will update the GB Register of Feed Additives.

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 continue to be placed on the market in England. The familiarisation costs are expected to be minimal, if anything, and so, would fall below the *de minimis* threshold.

13. Regulating small business

13.1 The legislation introducing the form and content of authorisation is a facilitative measure that supports business and applies to activities that are undertaken by small businesses.

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

14. Monitoring & review

14.1 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 because the provisional authorisation are limited to a period of 5 years.

15. Contact

15.1 Amanda Blackler at the Food Standards Agency Telephone: 07855 514792 or email: Amanda.Blackler@food.gov.uk can be contacted with any queries regarding the instrument.

15.2 Natasha Smith or James Cooper Deputy Directors for Food Policy at the Food Standards Agency can confirm that this Explanatory Memorandum meets the required standard.

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