

Explanatory Memorandum to The Feed Additives (Form of Provisional Authorisations) (Cobalt(II) Compounds) (Wales) Regulations 2023

This Explanatory Memorandum has been prepared by the Food Standards Agency and is laid before Senedd Cymru in conjunction with the above subordinate legislation and in accordance with Standing Order 27.1.

Deputy Minister's Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of The Feed Additives (Form of Provisional Authorisations) (Cobalt(II) Compounds) (Wales) Regulations 2023

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Deputy Minister for Mental Health and Wellbeing
22 June 2023

PART 1

1. Description

1. The purpose of this instrument is to prescribe the form of the urgent provisional authorisation of four cobalt(II) trace compounds (“cobalt compounds”) as animal feed additives.

2. Matters of special interest to the Legislation, Justice and Constitution Committee

2. None.

3. Legislative background

3. Regulated products are food and feed products which require authorisation before being placed on the market¹.
4. As of 1 January 2021, Great Britain (GB) has been responsible for the risk assessment and authorisation of regulated food and feed products.
5. In Wales, the Food Standards Agency (FSA) is responsible for risk assessing regulated food and feed products. As the ‘appropriate authority’, Welsh Ministers, make decisions on authorisations in relation to Wales.
6. Feed additives are substances, micro-organisms or preparations (other than feed materials and premixtures) which are intentionally added to feed or water to perform one or more specific functions (noted below).
 - (a) Technological additives (e.g. preservatives)
 - (b) Sensory additives (e.g. flavourings and colourings)
 - (c) Nutritional additives (e.g. vitamins and minerals)
 - (d) Zootechnical additives (e.g. enzyme and micro-organisms used to favourably affect the performance of animals in good health)
 - (e) Coccidiostats and histomonostats (to control gut parasites)
7. The legislative framework for authorising feed additives is largely contained within retained Regulation (EC) 1831/2003 (Regulation 1831/2003) on additives for use in animal nutrition. This Regulation provides the Welsh Ministers with powers to approve and set the conditions of use for feed additives.

¹ Regulated products include: extraction solvents, feed additives, feed for particular nutritional purposes (PARNUTS), feed detoxification processes, flavourings, food contact materials, food additives, food enzymes, genetically modified food and feed, novel foods and smoke flavourings.

8. Where urgent authorisation of a feed additive is needed to ensure the protection of animal welfare, Article 15 of Regulation 1831/2003 establishes that:

“In specific cases where urgent authorisation is needed to ensure the protection of animal welfare, the appropriate authority may provisionally authorise the use of an additive for a maximum period of five years. The authorisation is to be in a form prescribed by the appropriate authority.”
9. This Article allows for urgent provisional authorisations to be made administratively. Welsh Ministers, in their capacity as the ‘appropriate authority’ have granted the provisional authorisations of the four feed additives. This took place on 20 June 2023.
10. In addition, Article 15 requires any provisional authorisation/s to be in a form prescribed (by regulations made by statutory instrument) by the appropriate authority. This Instrument sets out the form of these authorisations.
11. Legislation is in place to regulate the conditions of labelling and packaging for feed additives under Article 16 of Regulation 1831/2003.
12. The FSA, on behalf of the Welsh Ministers, will update the register of authorised feed additives, as required by Article 17 of Regulation 1831/2003. The register can be accessed at <https://data.food.gov.uk/regulated-products/landing>.
13. This instrument is subject to the negative procedure.

4. Purpose and intended effect of the legislation

14. The purpose of this instrument is to prescribe the form of these urgent provisional authorisations .
15. Cobalt is an essential trace element that is used to meet the nutritional demands for ruminants, horses and to a lesser extent other animal species due to its association with vitamin B12. Cobalt is typically added to feed because the British pasture (soil) doesn’t contain sufficient cobalt to support livestock, especially sheep.
16. This instrument relates to four Cobalt(II) Compounds:
 - cobalt(II) acetate tetrahydrate
 - cobalt(II) carbonate
 - cobalt(II) carbonate hydroxide (2:3) monohydrate
 - cobalt(II) sulphate heptahydrate

17. These cobalt compounds were previously assessed and were considered safe for use in the authorised form, by the European Food Safety Authority (EFSA) when the UK was still a member State of the European Union. The 2012 EFSA opinions can be found below:
- For cobalt(II) acetate tetrahydrate, cobalt(II) carbonate hydroxide (2:3) monohydrate, and cobalt(II) sulphate heptahydrate – please visit <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2012.2791>
 - For cobalt(II) carbonate please visit <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2012.2727>
18. These cobalt compounds have been on the market since 1970 and the FSA has no evidence that they are unsafe.
19. Feed additives authorisations are granted for 10-year periods but can be renewed by application. An application for renewal must be made one year prior to the expiration of the existing authorisation.
20. The existing authorisations for these four cobalt compounds will expire in GB on 15 July 2023. Due to industry oversight, no application for renewal was made by the statutory deadline of 14 July 2022. A new application for authorisation of all four cobalt compounds was submitted in November 2022. There is insufficient time to progress this application through the full regulated products assessment process and for legislation to come into force prior to the expiry of the existing authorisations.
21. Without action to undertake urgent provisional authorisation under the relevant available powers, the four cobalt compounds in question would no longer be lawfully available on the market in GB from 15 July 2023.
22. Following extensive engagement and consultation with stakeholders and industry, there is compelling evidence to conclude there is a serious risk that animal welfare will be negatively and severely impacted (almost immediately) if these cobalt compounds were to become unavailable in animal feed. There are currently no alternatives to these water- soluble compounds that could meet nutritional requirements.
23. By administrative decision made on 20 June 2023 pursuant to Article 15 of Regulation 1831/2003, to ensure the protection of animal welfare, the Welsh Ministers have provisionally authorised the four cobalt compounds in the terms set out in this instrument.
24. The provisional authorisation takes effect as of the expiry of the existing authorisations, and is for a period of 5 years. This will enable these four compounds to remain on the GB market pending the determination of the full application for authorisation that is currently progressing through the normal full Regulated Products approval process in line with the statutory requirements of this regime- including risk assessment and full consultation.

25. Corresponding provisional authorisations and legislation has been made in England and Scotland.

5. Consultation

26. Article 9 of retained Regulation (EC) No. 178/2002 provides that there must be open and transparent public consultation during the preparation, evaluation and revision of food law, except in urgent circumstances.

27. In order to be satisfied that the urgent provisional authorisation of these four feed additives is necessary to protect animal welfare, the FSA and FSS have engaged extensively with targeted stakeholders and industry on the risks associated with the removal from the market of these four cobalt compounds. All have returned compelling evidence as to the importance of these authorised products remaining on the market.

28. Responses received from 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. In brief, cobalt deficiency in animals (particularly ruminants) results in loss of appetite, reduced growth rate, severe emaciation, weakness, anaemia and decreased fertility, milk and wool production. The UK feed trade associations mentioned above have indicated 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 industry estimates that without the use of cobalt as an additive this would lead to death of animals within 3-12 months. This information can be accessed at

<https://www.food.gov.uk/sites/default/files/media/document/Soluble%20Co%28I%29%20salts%20are%20essential%20for%20the%20production%20of%20supplement%20products.pdf>

29. In addition, the FSA undertook a two-week consultation running from 26 May 2023 to 09 June 2023. This was published on the FSA website and circulated to targeted UK stakeholders and Local Authorities (LAs) directly. Furthermore, the FSA made key Welsh stakeholders aware of the consultation when launched and updated them again one week prior to the consultation closing. The consultation can be accessed at <https://www.food.gov.uk/news-alerts/consultations/consultation-on-proposed-provisional-authorisations-of-four-feed-additives-for-use-in-animal-feed>

30. A total of 14 consultation responses were received from trade bodies, non-governmental organisations (NGOs), and other government departments (OGDs) representing interests across the UK. All 14

responses received were supportive of the proposal to secure an urgent authorisation, recognising the negative impact on animal health if these additives were removed from the GB market and consequential impacts.

31. A summary of the consultation responses, and the FSA subsequent responses has been published on the FSA website.

6. Regulatory Impact Assessment (RIA)

32. A full RIA has not been prepared for this instrument because the purpose of the urgent provisional authorisations are to enable the four authorised feed additives to remain on the market in Wales for a limited period pending the determination of full applications for re-authorisation. The familiarisation costs are expected to be minimal. This is in line with the policy set out in the Welsh Ministers' code of practice for carrying out regulatory impact assessments for subordinate legislation.

7. Post implementation review

33. The four cobalt compounds have been provisionally authorised for a period of 5 years commencing on 15 July 2023, pending the determination of the application for the full re-authorisation of the four additives. The provisional authorisations and this instrument will be revoked once the full application has been determined.