

Consultation on proposed (provisional) authorisations of four feed additives for use in animal feed

Status: Closed

Date launched: 26 May 2023 Closing date: 9 June 2023

Summary of responses

Consultation on proposed (provisional) authorisations of four feed additives for use in animal feed - Summary of stakeholder responses

Existing authorisation of these compounds expires on 15 July 2023. We have shortened the normal public consultation period to allow the new provisions to apply before existing authorisations expire.

Subject to the outcome of this consultation, FSA will ask ministers to decide on authorisation of these additives for 5 years in accordance with Article 15 of Retained Regulation (EU) 1831/2003.

We are asking for stakeholders' views on the FSA's opinion and the other legitimate factors related to the provisional authorisation of these feed additives (this could include animal health concerns, consumer interests and technical feasibility).

England and Wales

PDF

View FSA opinions cobalt 25 May 2023 as PDF(Open in a new window) (293.6 KB)

How to respond

Please provide responses by 9 June 2023 to: RPconsultations@food.gov.uk

Please state in your response whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents) and in which UK nation you are based.

Any comments received are subject to the same privacy statement as consultations. You can find our Consultations privacy notice here.

Next steps

The views gathered through this consultation will inform FSA advice to Ministers and allow them to decide on authorisations for the individual feed additives used as animal feed in England and Wales.

Following the consultation process responses will be published on our website.

About this feed additive application

We received a single application for authorisation of four cobalt(II) compounds: cobalt(II) acetate tetrahydrate, cobalt(II) carbonate, cobalt(II) carbonate hydroxide (2:3) monohydrate and cobalt(II) sulphate heptahydrate together. This was received with a request for urgent handling.

These feed additives have a long history of safe use, over many decades. The FSA's approach in seeking urgent authorisations is informed by European Food Safety Authority (EFSA) published opinions (2012) on the safety of these feed additives) (see Annex for detail).

Their current authorisation will expire on 15 July 2023. After this date, products containing the additive cannot lawfully be placed on the market, processed, or used unless a further authorisation is issued. There are currently no alternatives to these compounds that could meet nutritional requirements.

We have sufficient evidence to conclude that there is a serious risk that animal health will be negatively and severely impacted (almost immediately) if cobalt was to become unavailable in animal feed. This impact will increase over time. A summary of the evidence is available in the Annex.

Following their proposed provisional (urgent) authorisations, these applications will be subject to full risk assessment as part of the Regulated Products process, details of which can be found here: https://www.food.gov.uk/business-guidance/regulated-products-application-guidance.

Annex

- 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 its association with vitamin B12 for which there is no alternative.
- Most forages (pasture) and feedstuffs fed to ruminants (for example: sheep, cattle) do not
 contain adequate quantities of cobalt to support the ruminant's nutritional requirements
 without the use of cobalt as an additive.
- The differing characteristics of the cobalt compounds (e.g., solubility, authorised concentrations) are required to meet the formulation criteria for the many feed types, from standard rations through to specialised supplements.
- An APHA report on disease surveillance from Q4, 2021 reported cobalt deficiency in 7.8% of animals submitted for post-mortem despite widespread use of cobalt supplementation. Removal is likely to exponentially increase the number of animals affected and negatively impact the national herd and flock.

EU position

EFSA Opinions 2012, No.2791 and No.2727

• The panel recommended restriction of use to ruminants, horses and rabbits, a reduction of the maximum total cobalt and a limit of handling the additive to premixture industry.

- Feeding supplemental cobalt as previously authorised up to the maximum total content allowed is considered safe for all animal species/categories and does not pose safety concerns for consumers.
- The cobalt compounds are considered skin and eye irritants and dermal and inhalatory sensitisers. They have varying dusting potential and considering their toxicological profile, are a hazard when handling. Exposure by inhalation must be avoided.
- Use of cobalt from any source at the maximum concentration in feed will not result in substantial increase of environmental concentrations and are considered effective for ruminants, horses and rabbits.

Industry position

The FSA has informally engaged with stakeholders to understand the impact of these feed additives being unavailable to the market when the existing authorisation expires.

- There is a risk to animal health due to a lack of adequate cobalt if the compounds covered by the proposed authorisation are not available.
- Use of coated cobalt(II) carbonate (the cobalt compound which will remain on the market in GB) cannot replace the compounds in this authorisation as it is insoluble in water, so cannot substitute for use in products requiring water-soluble compounds.
- These cobalt compounds have been widely used for 10 years under the current authorisation with no safety concerns.
- Reformulation of products containing cobalt would carry significant cost to industry and require market withdrawal for 6-20 months while products are developed.
- There is an increased risk of animals developing other mineral deficiencies as these products contain other important minerals and additives.
- Removal of all but one source of cobalt in animal feed presents a high risk to supply chain security.

Further evidence was submitted through AIC and BAFSAM:

PDF

<u>View A Review of Nutritional Supplements currently available on the UK market as PDF(Open in a new window)</u> (377.22 KB)