Consultation pack on one feed additive application for use in animal feed

This consultation seeks stakeholders' views, comments and feedback in relation to the regulated product application considered in this document, which has been submitted for authorisation.

This consultation will be of most interest to:

- animal feed manufacturers, importers/exporters and retailers
- all feed purchasers, including for food- and non-food-producing animals
- trade bodies representing stakeholders on animal feed, agriculture and the environment
- trade unions representing stakeholders in the farming industry
- organisations representing consumer interests in the feed and food-chains
- Enforcement Authorities

Key stakeholders

The following key stakeholder trade associations which are represented across all four nations of the UK who have a strong interest in feed additives and their use in animal nutrition and the wider agriculture sector will be contacted directly for feedback on this consultation:

- Agricultural Industries Confederation (AIC)
- British Association of Feed Supplement and Additive Manufacturers (BAFSAM)
- British Equestrian Trade Association (BETA)
- Grain and Feed Trade Association (GAFTA)
- National Office of Animal Health (NOAH)
- Northern Ireland Grain Trade Association (NIGTA)
- UK Pet Food (previously the Pet Food Manufacturers' Association)

This is not an exhaustive list.

Consultation subject and purpose

This consultation seeks stakeholders' feedback on the regulated product applications considered in this document. This application has been submitted for a new authorisation.

The Food Standards Agency (FSA) and Food Standard Scotland (FSS) risk management recommendation, the safety assessment and the views gathered through this consultation will be shared with the ministers in England, Scotland, Wales to support their decision making with the Minister of Health for Northern Ireland kept informed.

A parallel consultation is being published by FSS to support ministers in their decision making in Scotland.

Details of the consultation

Introduction

To be placed on the market in Great Britain (GB), applications for the authorisation of regulated products must be submitted in GB. The decision on authorisation is made by respective ministers in England, Wales and Scotland, with the Minister of Health for Northern Ireland kept informed.

The provisional common framework for Food and Feed Safety and Hygiene is a non-statutory arrangement between the UK government and devolved administrations to establish common approaches to policy areas where powers have returned from the EU within areas of devolved competence. This consultation has been developed under the commitments to collaborative four-nation working set out in this framework. Final recommendations will be agreed on a four-nation basis before being presented to ministers. The FSA and FSS have been working together to ensure the continued high standard of food and feed safety and consumer protection in the UK. This is in line with FSA/FSS responsibility to provide recommendations to ministers on matters connected with food and feed safety or other consumer food interests (sections 6 and 9 of the Food Standards Act 1999 and section 3 of the Food Act 2015 in Scotland).

Regulated product applications for the GB market, including feed additives are subject to the UK's risk analysis process.

FSA/FSS adopted technical guidance and quality assurance processes used by the European Food Safety Authority (EFSA) to be able to undertake GB risk assessments for regulated product applications. Please see the link for the individual safety assessment.

Our risk assessors deliver the science behind our advice. They are responsible for identifying and characterising hazards and risks to health and assessing exposure levels. This feed additive application has undergone an FSA/FSS safety assessment, including a review of the applicant's dossier and supplementary information. Following the safety assessment, this consultation seeks to gather stakeholders' views on the proposed feed additive authorisation.

This consultation and the FSA/FSS risk management recommendation document present the recommendation of the FSA/FSS and the factors that the FSA/FSS have identified as relevant to this application, including the potential impact of any decision made by ministers. Stakeholders are invited to use this opportunity to comment on these factors or highlight any additional factors that should be brought to the attention of ministers before a final decision is made.?

Following the consultation, ministers in England, Scotland and Wales will make decisions on authorisation, with the Minister of Health for Northern Ireland kept informed. They will consider the FSA/FSS recommendation, any relevant provisions of assimilated law, and any other legitimate factors, including those raised during the consultation process.

Subject of this consultation

In accordance with assimilated law on feed additives for use in animal feed, the application included in this consultation has been submitted for a new authorisation.

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, as outlined in the section titled 'Supplementary information on feed additives'.?To place feed additives on the GB market, an application must be submitted in accordance with assimilated Regulation (EC) 1831/2003. Feed additives are authorised for a ten-year period. The procedure for this application is laid down in assimilated Regulation (EC) 1831/2003 under Article

4 and Article 7 application for a new authorisation or new use of a feed additive.

Impacts

As part of the risk analysis process, the FSA/FSS have assessed the potential impacts that may result should ministers decide to authorise this feed additive application. Our collective assessment of the proposals did not identify any significant impacts. The impacts considered included those most frequently identified as potential impacts when introducing or amending feed law (i.e., local authority delivery, health, environment, growth, innovation, trade, competition, consumer interests or small and micro-businesses). The authorisation of this product should generally result in greater market competition, supporting growth and innovation in the sector.

Under the provisional common framework for food and feed safety and hygiene, Northern Ireland continues to fully participate in the risk analysis processes concerning feed safety. This reflects Northern Ireland's integral role within the UK and ensures that any decision made fully considers the potential impacts on the whole of the UK.

Impact for Northern Ireland

In October 2023, the Windsor Framework was implemented providing a unique set of arrangements to support the flow of agrifood retail products from GB to Northern Ireland. These goods can meet the same standards applied in the rest of the UK in public health, marketing (including labelling) and organic foods when moving through the Northern Ireland Retail Movement Scheme (NIRMS). The scheme extends to some pet food. PARNUTs and feed additives, whether being used to produce compound feeds or being directly fed to livestock, would not meet the definition of pre-packed retail goods intended for the final consumer, so would not be able to benefit from the scheme. However, if goods remain in Northern Ireland, traders can benefit from the Movement Assistance Scheme to recoup costs associated with certification.

In Northern Ireland, feed additives used in qualifying Northern Ireland goods will be able to be placed on the market in GB, in line with the Government's steadfast commitment to ensuring Northern Ireland's unfettered access to the GB market.

Other legitimate factors

We have considered a range of other legitimate factors that ministers may wish to consider in making decisions about this application including political, economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours. Our collective assessment of the other legitimate factors did not identify anything of major significance. However, for the application within this consultation and our collective assessment of this application, we did identify the following issues of note:

Trade impacts

Application RP16 – chromium chelate of DL-methionine has not been authorised in the EU for consumption by dairy cows. The FSA/FSS have assessed the available evidence and supports recommending the authorisation of RP16 for consumption by dairy cows, there will be divergence between GB and EU.

Supplementary information on feed additives

Feed additives are classified under five broad categories, as outlined in Article 6 of assimilated Regulation (EC) 1831/2003 , and further defined for specific functions in Annex I to assimilated

Regulation (EC) 1831/2003. The categories are:

1. Technological additives (for example, silage additives or preservatives)
2. sensory additives (colourants or flavourings)
3. nutritional additives (for example, amino acids and trace elements)
4. zootechnical additives, to perform specialised functions (for example, improving digestibility of feed)
5. Coccidiostats and histomonostats, to control gut parasites.

Microorganisms (for example, bacteria, yeast or fungi) are identified by a unique ID code relating to their deposition into an internationally recognised culture collection; for example, the National Collection of Industrial, Food and Marine Bacteria (NCIMB) in the UK or the American Type Culture Collection (ATCC).

Feed additives may be produced from genetically modified strains of microorganisms; however, the production strains and their DNA were not detected in the finished feed additive. As a result, the feed additive does not require the traceability conditions specified by GMO legislation.

Feed additives may be intended for all animal species, or for major species or defined sub-groups (for example, poultry or chickens for laying), as defined in Annex IV to assimilated Regulation (EC) 429/2008. In addition, species groups may be extrapolated to minor species (for example, minor poultry such as ducks or geese) or other animal groups requested within an application (for example, game birds), as stated in Article 7(5) of assimilated Regulation (EC) 1831/2003. 'Minor species' refers to food-producing animals other than bovines (dairy and meat animals, including calves), sheep (meat animals), pigs, chickens (including laying hens), turkeys and fish belonging to Salmonidae, as defined in Article 1(2) of assimilated Regulation (EC) 429/2008.

Animals may be intended for direct human consumption (for example, pigs for fattening or turkeys for fattening), whilst there are additional animal sub-groups for breeding purposes only which are not intended to directly enter the food-chain (for example, sows for reproduction or turkeys reared for breeding).

Reference to complete feed refers to the equivalent of compound feed which, due to its composition, is sufficient for the animal's daily ration. This term used throughout is standardised to complete feed with a moisture content of 12%, and where minimum and maximum content are referenced on this basis, unless otherwise specified. Proposals for renewal of authorisations below may include additional information compared to the existing authorisation that, in itself, does not constitute a modification of authorisation. For example, characterisation of the feed additive may be more explicitly described, such as reference to a solid preparation or viable cells but was applicable in the existing authorisation. Further refinements in text have also become standardised; for example, the labelling for storage and heat stability (under 'Other provisions' section).

Engagement and consultation process

Details of all valid applications for regulated products are published monthly on the Register of Regulated Product Applications on the Food Standards Agency website.

We invite stakeholders to consider the questions posed below in relation to any relevant legislation and other legitimate factors.

Following the consultation process, responses will be published and made available to stakeholders and ministers.

Questions asked in this consultation:

1. Do you have any concerns in relation to the safety of this?feed additive which have not been considered below?with respect to the intended animal species, consumers (in consumption of animal products), workers/users or environmental impacts?
2. Do you have any comments or concerns on the impacts, in consideration of authorising or not authorising this feed additive? If in favour of authorisation, do you have any comments on the proposed terms of this feed additive if authorised (as outlined in this consultation)?
3. Are there any other factors that should be considered by ministers that have not been highlighted?
4. Do you have any other feedback? Please consider any relevant legislation and other legitimate factors which may support clear, rational and justifiable risk analysis.

Responses

This consultation will run for 4 weeks. Responses are required by midnight of 1 September 2024.

How to respond

Please respond to the consultation via the online survey. If this is not possible, you can email a response to: RPconsultations@food.gov.uk

If responding by email, 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 nation you are based.

Responses from Wales should be sent using the steps outlined above, all comments received will be shared with the FSA in Wales.

Within three months of a consultation ending, we aim to publish on the FSA website a summary of responses received.

For information on how the FSA handles your personal data, please refer to the Consultation privacy notice.

Responses will be shared with ministers in England, Scotland, Wales and Northern Ireland.??

Further information

If you require a more accessible format of this document, please contact our helpline: 0330 332 7149 open 9.00 until 17.00, Monday to Friday or Submit an online enquiry for responses to this consultation and your request will be considered.

This consultation has been prepared in accordance with HM Government consultation principles.

Thank you on behalf of the Food Standards Agency for participating in this public consultation.

Yours,

The Regulated Products Approvals Team,

Strategy and Regulatory Compliance Directorate

Annex A: RP16 -?Chromium chelate of DL-methionine?as a feed additive for dairy cows (Availa® Cr) (Zinpro Animal Nutrition (Europe), Inc.) (new)

Background

In accordance with Article 4 of assimilated Regulation (EC) 1831/2003 on feed additives, application RP16 is submitted for chromium chelate of DL-methionine (Availa® Cr) for a new authorisation as a zootechnical feed additive under the functional group of ‘other zootechnical’ (as set out at paragraph 4(d) of Annex I to assimilated Regulation (EC) 1831/2003). The function of this feed additive is to increase milk yield in dairy cows.

An application was submitted for the feed additive authorisation for dairy cows.

Chromium chelate of DL-methionine is proposed for use at a minimum of 0.2 mg/kg and a maximum of 0.5 mg/kg of chromium in complete feed with a moisture content of 12%.

FSA/FSS risk management recommendation

The FSA/FSS risk management recommendation is that chromium chelate of DL- methionine (Availa®Cr), as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use.

The FSA/FSS safety assessment and details of the proposed terms of use of the feed additives can be found on the Food Standards Agency website:

FSA/FSS recommendation

Safety assessment