Summary of stakeholder responses: Consultation on applications for authorisation of feed additives and one feed for particular nutritional purposes (PARNUT)(Autumn 2024)

Consultation on applications for authorisation of feed additives and one feed for particular nutritional purposes (PARNUT).

Introduction

This document presents a summary of responses from two public consultations. The first consultation, Consultation on 24 feed additive applications and one application for feed for particular nutritional purposes (PARNUT) for use in animal feed, which ran from 22 April to 17 June 2024, covered twenty-four feed additive applications and one application for feed for particular nutritional purposes (PARNUT) for use in animal feed.

The additional consultation, Consultation on one feed additive application for use in animal feed, ran for a shorter period but focused on a single feed additive application. This took place from 5 August to 1 September 2024, resulting in a total of 25 feed additive applications considered and one PARNUT.

Food Standards Scotland (FSS) launched both consultations in parallel with FSA.

During both consultations, stakeholders provided their views on the feed additive applications. These consisted of nine new authorisations; six new use only; one renewal of authorisation; two feed additive modifications and one PARNUT modification; five renewals with modification; and two applications for renewal and new use with modification.

The applications on which the consultations sought views were:

New authorisation of nine feed additive applications:

- RP16 - Chromium chelate of DL-methionine (Availa® Cr) (identification number GB4d0001)
- RP29 – Pediococcus acidilactici (CNCM I-4622) (identification number 4d1712)
- RP1105 – L-histidine monohydrochloride monohydrate by fermentation with Escherichia coli K-12(KCCM 80212) (identification number 3c352i)
- RP1125 – L-tryptophan produced by fermentation with Escherichia coli (KCCM 80210) (identification number 3c440i)
- RP1126 – L-lysine sulphate produced by fermentation with Corynebacterium glutamicum (KCCM 80227) (identification number 3c324i)
- RP1198 – Butylated hydroxyanisole (identification number 1b320)

- RP1199 Part A - L-lysine base (liquid) produced by fermentation with Corynebacterium glutamicum (KCCM 80183) (identification number 3c320) and RP1199 Part B – L-lysine monohydrochloride (technically pure) produced by fermentation with Corynebacterium glutamicum (KCCM 80183) (identification number 3c322ii)
- RP1200 – Disodium 5’-guanylate produced by fermentation with Corynebacterium stationis (KCCM 10530) and Escherichia coli K-12(KFCC 11067) (identification number 2b627i)
- RP1349 – Phytomenadione (Vitamin K1) (identification number 3a712)

Authorisation of six new use only feed additive applications (extension of species):

- RP25 – Saccharomyces cerevisiae (MUCL 39885) (identification number 4b1710)
- RP26 – Saccharomyces cerevisiae (MUCL 39885) (identification number 4b1710)
- RP142 – Monensin sodium (carrier: perlite, wheat bran) (identification number 50701)
- RP284 - Monensin sodium (carrier: perlite, calcium carbonate) (identification number 51701)
- RP1259 - Muramidase (EC 3.2.1.17) produced by Trichoderma reesei (DSM 32338) (identification number 4d16)
- RP1591 - Fumonisin esterase (EC 3.1.1.87) produced by fermentation with Komagataella phaffii (DSM 32159) (identification number 1m03i)

One renewal of authorisation of feed additive application:

- RP24 – Saccharomyces cerevisiae (MUCL 39885) (identification number 4b1710)

Authorisation of five feed additive applications for renewal with modification:

- RP140 – Monensin sodium (carrier: perlite, calcium carbonate) produced by fermentation with Streptomyces cinnamonensis 28682 (NBIMCC 3419) (identification number 51701)
- RP141 – Monensin sodium (carrier: perlite, wheat bran) produced by fermentation with Streptomyces cinnamonensis 28682 (NBIMCC 3419) (identification number 51701)
- RP1386 – Copper chelate of hydroxy analogue of methionine (identification number 3b410i)
- RP1387 – Manganese chelate of hydroxy analogue of methionine (identification number 3b510)
- RP1388 – Zinc chelate of hydroxy analogue of methionine (identification number 3b610)

Authorisation of two feed additive applications for renewal and new use (extension of species) with modification:

- RP185 - 6-phytase (EC 3.1.3.26) produced by fermentation with Komagataella phaffii (DSM 23036) (identification number 4a16)
- RP641 - Bacillus velezensis (formerly Bacillus subtilis) (DSM 15544) (identification number 4b1820)

Authorisation of two feed additive applications for modification only:

- RP222 - selenised yeast produced by fermentation with Saccharomyces cerevisiae (CNCM I-3060), inactivated (identification number 3b810)
- RP1654 - Enterococcus faecium (CECT 4515) (identification number 4b1822) and Bacillus amyloliquefaciens (CECT 5940) (identification number 4b1713)

Authorisation of one feed for particular nutritional purposes (PARNUT) application for modification only:

- RP658 - A modification of entry number 60. ‘Reduction of the risk of milk fever and subclinical hypocalcaemia’ of Part B of the Annex to assimilated Regulation (EU) 2020/35

Stakeholders were encouraged to consider any relevant provisions of assimilated law (footnote 1) and other legitimate factors (for example, consumer interests, technical feasibility and environmental factors) that the FSA and FSS identified as relevant to these applications.

Consultation reach

Direct feedback was sought from key stakeholders whose businesses or organisations could be impacted by the feed additives and PARNUT. Feedback was also sought from a diverse range of stakeholders with interests in regulated products, including businesses, associations, professional bodies, and local authorities.

Eight-week consultation

The consultation reach was comprehensive, with automatic notifications sent to 27,196 UK-wide subscribers of FSA alerts at the time of launch. Automatic notifications were also issued to FSA subscribers registered to receive updates in relation to national content: 31,129 subscribers to England, 17,526 subscribers to Northern Ireland and 18,451 subscribers to Wales.
The FSA consultation page received approximately 1,016 views from 22/04/2024-17/06/2024.

Additional consultation on application RP16

Automatic notifications were sent to 28,599 UK-wide subscribers of FSA alerts at the time of launch. Automatic notifications were also issued to FSA subscribers registered to receive updates in relation to national content – 32,828 subscribers to England, 18,458 subscribers to Northern Ireland and 19,417 subscribers to Wales.
The FSA consultation page received approximately 908 views from 5/8/2024 - 1/9/2024.
The consultations were also announced on social channels. The FSA has a reach of 61.7k followers on X (formerly known as Twitter) and 122,671 LinkedIn followers.

Characteristics of respondents

Responses were received from combined total of six respondents: five representing industry and one private individual. Across the six respondents, all gave their location as within the UK. FSS received one response to their consultation from a private individual. A list of those who responded can be found at the end of this document.

Summary of responses

The number of responses was low in comparison with actual numbers of stakeholders reached. There were no other relevant provisions of assimilated law or legitimate factors identified by the respondents.

The comments from both consultations, together with the FSA's responses to these, are set out below.

Summary of substantive comments

The responses to the consultation across all six respondents have been analysed and the main themes identified. The FSA's responses to the comments made are included below.

1. Neutral or support for authorisations

Main theme of response: Neutral or support for authorisations 1(a)

Summary of Stakeholders' Comments: Two of the respondents sent neutral feedback

FSA's Response: Thank you for your response.

Main theme of response: Neutral or support for authorisations 1(b)

Summary of Stakeholders' Comments: One of the respondents expressed support for this consultation.

FSA's Response: Thank you for your response.

2. Refinement of the consultation document(s)

Main theme of response: Refinement of the consultation document(s).

Summary of Stakeholders' Comments: On RP24, RP25 and RP26, one of the respondents highlighted that the consultation document incorrectly stated that the feed additive is safe for pelleting or heat treating, whereas our safety assessment concluded that the feed additive is not suitable for pelleting or heat treating. The respondent clarified that the feed additive is not suitable for pelleting or heat treating.

FSA's Response: Thank you for your response. Following consultation, we will amend the text in 'Other Provisions' within our Terms of Authorisation and recommendation to outline that, in the directions for use of the additive and premixtures, the storage conditions shall be indicated (removing reference to pelleting and stability to heat treatment).

3. Transitional arrangements

Main theme of response: Transitional arrangements.

Summary of Stakeholders' Comments: Two of the respondents requested transitional periods to allow for labelling to be updated and existing stocks to be sold to minimise waste.

FSA's Response: Thank you for your response. Transitional periods have already been included in the FSA risk management recommendation.

4. Trade and divergence

Main theme of response: Trade and divergence.

Summary of Stakeholders' Comments: One of the respondents noted that trade impacts had been identified and there would be divergences between GB and EU approvals. As such, they proposed that FSA/FSS must maintain links to EU legislation so that businesses can cross-reference the GB and EU terms of authorisation and identify differences.

FSA's Response: Thank you for your response. The FSA does not include EU legislation updates on the GB Feed Additive Register. Background on placing a regulated product on the market can be found here: Background on placing a regulated product on the market - Food Standards Agency). The guidance outlines how the FSA refers to the importance of EU legislation when ascertaining what products are permitted in Northern Ireland.

5. Reform

Main theme of response: Reform consultation.

Summary of Stakeholders' Comments: Two of the respondents referenced their support for initial reforms to the regulated products authorisation process, proposed in a recent FSA/FSS consultation.

FSA's Response: Thank you for your response. Following Board agreement and the consultation earlier this year, new UK Government ministers have confirmed they are content to proceed with our two initial market authorisation reform proposals to remove renewal requirements for authorised regulated products and allow authorisations to come into effect following ministerial decisions in England, Wales and Scotland, and then be published in an official register or list, rather than by secondary legislation. We are now prioritising delivery of this work and the FSA and Food Standards Scotland's response to the Spring 2024 public consultation on the proposals has now been published. Subject to UK Government decisions on legislative timetabling, we hope to introduce legislation for these proposals in early 2025.

6. Concerns over safety of animal species and consumer

Main theme of response: Concerns over safety of animal species and consumer.

Summary of Stakeholders' Comments: On RP16, two respondents shared their opinions that feed additives were unnecessary and that natural products should be used rather than seeking profit. One of the respondents expressed their view that there may be long term effects on children.

FSA's Response: Thank you for your comments. Possible impacts to human health are considered as part of the safety assessment, as published in the consultation.

Next Steps

The next step of the authorisation process is for relevant ministers in England, Wales and Scotland to make decisions on the authorisation of 25 feed additive applications and one PARNUT application, consisting of: nine new authorisations; six new use only; one renewal of authorisation; five renewals with modification; two feed additive modification only and one PARNUT modification only; and two renewal and new use with modification.
The FSA/FSS safety assessments on these applications concluded that the products are safe to be authorised based on the proposed terms of authorisation.

There have been no other identified reasons to change the advice on these applications as a result of the consultation process. On that basis, the final FSA/FSS advice to ministers will be to authorise these applications on the proposed terms of authorisation for each application.

Should ministers agree to authorise, Statutory Instruments will be prepared in England and Wales (and a Scottish Statutory Instrument in Scotland) in line with the proposed terms of authorisation.

List of respondents

- ADM
- Agricultural Industries Association (AIC)
- CJ do Brasil Industria Comercio de Produtos Alimentícios Ltda.
- UK Pet Foods
- Prosol S.P.A.
- Private individuals

1. Directly applicable EU legislation no longer applies in GB. EU legislation, retained when the UK exited the EU, was assimilated on 31 December 2023. References to any legislation with ‘EU’ or ‘EC’ in the title [e.g. Regulation (EU) 2015/2283 or Regulation (EC) 1333/2008] should now be regarded as assimilated law where applicable to GB. Assimilated law is published on legislation.gov.uk. References to ‘Retained EU Law’ or ‘REUL’ should now be regarded as references to assimilated law.