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Consultations on applications for the authorisation of twenty-five feed additive applications and one application for feed for particular nutritional purposes (PARNUT)

Summary of stakeholder responses

14th October 2024

# **Introduction**

This report is a summary of the Food Standards Scotland’s (FSS) consultation results and the FSS responses to these.

The first consultation, which ran from April 22 to June 17 2024, covered twenty-four feed additives and one application for feed for particular nutritional purposes (PARNUT) for use in animal feed. The second shorter four week consultation focused on a single feed additive application and took place from August 5 to September 1 2024. In total 26 feed additives have been considered. The first consultation can be found [here](https://consult.foodstandards.gov.scot/regulatory-policy/regulatory-policy-tranche3-feed-additives/) and the second consultation can be found [here](https://consult.foodstandards.gov.scot/regulatory-policy/regulatory-policy-tranche3-single-feed-additive/). These consultations were carried out on behalf of the Minister for Public Health and Women’s Health. The Food Standards Agency (FSA) also launched both consultations in parallel.

Stakeholders’ views were sought in relation to the authorisation of twenty-five additives, which were submitted for authorisation to be placed on the market in Great Britain (GB), in accordance with [Regulation (EU) 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) on additives for use in animal nutrition. The authorisation of one PARNUT in accordance with [Regulation (EU) 2020/354](https://www.legislation.gov.uk/eur/2020/354/contents) [(Annex Part B)](https://www.legislation.gov.uk/eur/2020/354/annex) which establishes a list (here after referred to as ‘the list’) of intended uses of feed intended for particular nutritional purposes. In this circumstance, an application has been made to modify an existing entry to the list.

[Regulation (EC) 767/2009](https://eur03.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.legislation.gov.uk%2Feur%2F2009%2F767%2Farticle%2F9&data=05%7C02%7C%7Ca23f4bd9c3de4dd1423408dcdc87639a%7C8a1c50f901b74c8aa6fa90eb906f18e9%7C0%7C0%7C638627721291028883%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C0%7C%7C%7C&sdata=MfXr6DtF69JXExd5WAtdydApD7vtzWi635ubCHE30LA%3D&reserved=0) dictates that a PARNUT may only be marketed if its intended use is included in the list, and it meets the essential nutritional characteristics for the nutritional purpose included in that list. However, due to ineffective EU exit amendments to these regulations made by [The Animal Feed (Amendment) (EU Exit) Regulations 2019](https://eur03.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.legislation.gov.uk%2Fuksi%2F2019%2F654%2Fregulation%2F99&data=05%7C02%7C%7C3e5940d8d21a4c8f8f3708dcd3d41e56%7C8a1c50f901b74c8aa6fa90eb906f18e9%7C0%7C0%7C638618155211311694%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C0%7C%7C%7C&sdata=1Gr7GUtzrKFhwcx0Yqgp7SHEbGXKeKYmNDuflGtsXUI%3D&reserved=0) the powers of Article 10 of Regulation (EC) 767/2009 have been rendered unusable. Work is underway to remedy this issue however it is anticipated that this will take a considerable amount of time.

In this instance FSS propose using the general powers provided in [Section 74A (1), Agriculture Act 1970](https://eur03.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.legislation.gov.uk%2Fukpga%2F1970%2F40%2Fsection%2F74A&data=05%7C02%7C%7C3e5940d8d21a4c8f8f3708dcd3d41e56%7C8a1c50f901b74c8aa6fa90eb906f18e9%7C0%7C0%7C638618155211320536%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C0%7C%7C%7C&sdata=6D%2BErCpzWS2AKkvdcSH7RCemjTRuwPH4Fm%2FrO8Y2bdQ%3D&reserved=0) , in respect of the composition of materials for the feeding of animals, to effectively modify the list. This proposal has not been made with a view to utilising these Agriculture Act powers for PARNUT purposes going forwards, instead it is suggested to enable the continuation of the aforementioned remedy work, with the defective legislation being amended after this instrument has been laid.

The regulated product applications for authorisation on which the consultations sought views were:

**New authorisation of nine feed additives:**

* 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 from *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)

**Authorisation of six new use only feed additives (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 from *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 additives:**

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

**Authorisation of five feed additives 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 additives 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 additives 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) 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) 2020/354](https://www.legislation.gov.uk/eur/2020/354/contents)

The consultation also introduced proposals for transitional arrangements for:

* RP185, 6–phytase (EC 3.1.3.26) produced by fermentation with *Komagataella phaffii* (formerly *Komagataella pastoris*) (DSM 23036) (identification number 4a16)
* RP222 - Selenised yeast produced by fermentation with *Saccharomyces cerevisiae* (CNCM I-3060) inactivated (identification number 3b810)
* RP641 - *Bacillus velezensis* (formerly *Bacillus subtilis* C-3102) (DSM 15544) (identification number 4b1820)
* RP1198 - Butylated hydroxyanisole (identification number 1b320)
* 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)

Stakeholders were asked to consider any relevant provisions of assimilated law and other legitimate factors (e.g. consumer interests, technical feasibility and environmental factors) that FSS and the FSA identified as relevant to these applications.

The consultations had comprehensive reach, achieved through subscription alerts, social media posts and publication in relevant reports. A link to the first consultation was sent to 230 subscribers to updates. A link to the second consultation was sent to 62 subscribers to updates. Key stakeholders whose businesses/organisations are likely to be affected by or to have an interest in these feed additives and a PARNUT, were contacted directly for their feedback. To ensure representation across a broad spectrum of opinion, stakeholders with a range of interests in the regulated products were included.

The first consultation was also shared with the FSS 5,556 X (formerly known as Twitter) followers, 15,000 Facebook followers and 3,814 LinkedIn followers. The posts for this consultation made on all platforms generated a total of 399 impressions and 6 engagements. The consultation received 76 visitors, resulting in the survey being accessed 15 times. The second consultation was shared on the same social media platforms. The posts for this consultation generated a total of 1651 impressions and 56 engagements. The consultation received 79 visitors, resulting in the survey being accessed 28 times.

FSS are grateful to those who responded.

**Characteristics of respondents**

FSS received one response from the first consultation and zero responses from the second consultation. The FSA received seven responses from trade bodies and industry for both consultations. Five responses from the first consultation and two from the second consultation.

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. The responses received were supportive of the authorisations. One response to FSS from industry referred to the increasing amount of applications, the time taken to authorise applications within the regulated products process and the potential impacts to trade with Northern Ireland and the EU.

The full text to the responses received to the consultations by FSS/FSA are given below, together with FSS/FSA response to these comments.

# Table 1: Summary of substantive comments

The responses to the consultation have been analysed and the main themes identified. FSS/FSA responses to the comments made are included in the table below.

|  | Main theme of response | Summary of Stakeholders’ Comments | FSS / FSA Response |
| --- | --- | --- | --- |
|  |  |  |  |
| 1 | Support for authorisations | Respondent(s) commenting on behalf of industry and trade bodies were in support of the authorisations. The main reasons cited were disruption between EU and GB trade and resulting health, welfare, and dietary concerns in farm animals if animal feed additives are not authorised, and the importance to trade in avoiding divergence from the EU and Northern Ireland, due to logistics. Whilst being supportive of the authorisations being consulted on, concerns were raised over the speed of authorisations and the need to avoid a situation where feed additive approvals lag behind those of other key exporting and importing nations.  | Thank you for your comments. We note these suggestions and will consider them in shaping the process in future.   |
| 2 | Refinement of the consultation document(s) | On RP24, RP25 and RP26, one respondent 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.  | 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 stability to heat treatment).  |
| 3 | Transitional provisions   | Two respondents requested for transitional periods to allow for labelling to be updated and existing stocks to be sold to minimise waste.  | Transitional periods are listed in the FSS risk management recommendation.  |
| 4 | Trade and divergence  | One respondent noted that trade impacts had been identified and there would be divergences between GB and EU approvals. As such, they proposed that FSS/FSA must maintain links to EU legislation so that businesses can cross-reference GB and EU terms of authorisation and identify differences.  | FSS does not include EU legislation updates on the GB Feed Additive Register. However, 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)](https://www.food.gov.uk/business-guidance/placing-a-regulated-product-on-the-market#placing-your-product-on-the-northern-ireland-market) The guidance outlines how FSS refers to the importance of EU legislation when ascertaining what products are permitted in Northern Ireland.   |
| 5 | Reform | Two respondents referenced their support for initial reforms to the regulated products authorisation process, proposed in a recent FSS/FSA consultation.  | 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 Scotland, England and Wales, and then be published in an official register or list, rather than by secondary legislation. We are now prioritising delivery of this work, FSS and the FSA 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 GB-wide legislation for these proposals in early 2025.   For these changes to apply in Scotland and Wales, the agreement of Scottish and Welsh Ministers to a GB Statutory Instrument will be needed along with the consent of the respective parliaments.  |
| 6 | Concerns over safety of animal species and consumer | 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. | 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 the Minister to make decisions on the authorisation of the twenty-five feed additives and one PARNUT.
* The FSS risk assessment opinions 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 during the consultation process. On that basis, the final FSS advice to the Scottish Ministers will be to authorise these feed additives on the proposed terms of authorisation.
* In Northern Ireland, the Minister of Health will be informed of the recommendation to authorise.
* Should the Minister move to authorise, a Scottish Statutory Instrument will be prepared in line with the terms of authorisation (Annex C) which accompanies the Ministerial Recommendation Submission.

# **List of Respondents**

* The Agricultural Industries Confederation (AIC)
* ADM
* CJ do Brasil Industria Comercio de Produtos Alimentícios Ltda.
* UK Pet Foods
* Prosol S.P.A.