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Consultation on applications for the authorisation of thirteen feed additives for use in animal feed

Summary of stakeholder responses

21st August 2023

# Introduction

The consultation on thirteen feed additives was launched on behalf of the Minister for Public Health and Women’s Health on 25th May 2023 and closed on 20th July 2023. The Food Standards Agency (FSA) launched a consultation in parallel.

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

Stakeholders’ views were sought in relation to the authorisation of thirteen feed additives, which were submitted for authorisation to be placed on the market in Great Britain (GB), in accordance with retained Regulation (EU) 1831/2003 ([REUL 1831/2003](https://www.legislation.gov.uk/eur/2003/1831)) as laid out in the following articles:

• Article 4, application for a new authorisation or new use of a feed additive;

• Article 13, application for modification of authorisation;

• Article 14, application for a renewal of authorisation.

The consultation also introduced proposals for transitional arrangements for RP955 - 6-phytase (EC 3.1.3.26) produced by *Trichoderma reesei* (CBS 122001) to allow for existing stocks of the additive to be exhausted.

The applications on which the consultation sought views were:

* Authorisation of ten new feed additives:
  + RP263 – *Lacticaseibacillus rhamnosus* (formerly *Lactobacillus rhamnosus*) (IMI 507023)
  + RP267 - *Pediococcus pentosaceus* (IMI 507024)
  + RP270 - *Pediococcus pentosaceus* (IMI 507025)
  + RP271 - *Lactiplantibacillus plantarum* (formerly *Lactobacillus plantarum*) (IMI 507026)
  + RP272 - *Lactiplantibacillus plantarum* (formerly *Lactobacillus plantarum*) (IMI 507027)
  + RP273 - *Lactiplantibacillus plantarum* (formerly *Lactobacillus plantarum*) (IMI 507028)
  + RP687 - *Lactiplantibacillus plantarum* (formerly *Lactobacillus plantarum*) (DSM 26571)
  + RP1052 (Part 1) - L-lysine base (liquid) produced by *Corynebacterium glutamicum* (KCCM 80216 or KCTC 12307BP)
  + RP1052 (Part 2) - L-lysine monohydrochloride produced by *Corynebacterium glutamicum* (KCCM 80216 or KCTC 12307BP)
  + RP1059 – 3-nitrooxypropanol (Bovaer® 10)
* Renewal, modification and new use
  + RP215 - Endo-1,4-beta-xylanase (EC 3.2.1.8) RP215 - Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* (CBS 143953, previously deposited as ATCC 5588)
* Renewal of use for two existing additives
  + RP954 - Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* (CBS 114044)
  + RP955 - 6-phytase (EC 3.1.3.26) produced by *Trichoderma reesei* (CBS 122001)

Stakeholders were asked to consider any relevant provisions of retained European Union (EU) law and other legitimate factors (for example, consumer interests, technical feasibility and environmental factors) that FSS and the FSA identified as relevant to these applications.

The consultation had extensive reach, achieved through subscription alerts, social media posts and publication in relevant reports. A link to the consultation was sent to 139 subscribers to Feed Additive updates. The consultation was also made available to 32 local authorities via the monthly enforcement report. Key stakeholders whose businesses/organisations are likely to be affected by, or to have an interest in feed additives were contacted directly for their feedback.

The consultation was also shared with the FSS’s 5,498 Twitter followers, 15,133 Facebook followers and 3,317 LinkedIn followers. The posts for the consultation made on all platforms generated a total of 921 impressions and 3 engagements. The consultation received 156 visitors, resulting in the survey being accessed 43 times.

FSS are grateful to those who responded. The comments, together with FSS’s responses to these, are set out below.

**Characteristics of respondents**

Four responses were received from trade bodies and industry.

A list of those who responded can be found at the end of this document.

**Summary of responses**

The responses received were supportive of the authorisations. One response from industry highlighted minor drafting errors in the FSS/FSA opinion and proposed text amendments to be considered going forward.

The main concerns raised related to the terminology referred to in the FSS/FSA opinion document for the feed additive RP955 – 6-phytase (EC 3.1.3.26) and its maximum recommended usage levels. The respondent believed that there should be no maximum level of usage applied as noted in Regulation (EU) 2021/982 for 6-phytase (EC 3.1.3.26). FSS has carefully considered the comments received and the views expressed. Legal minimum levels for enzymes such as 6-phytase are set out in legislation to ensure effective use whilst recommended levels hold no legal basis. Whilst EFSA recommendations have been presented within the consultation package, such recommendations will not be laid out in UK law.

The full text to the responses received to the consultation is given below, together with our response to these comments.

# Table 1: Summary of substantive comments

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

|  | Main theme of response | Summary of Stakeholders’ Comments | FSS Response |
| --- | --- | --- | --- |
|  |  |  |  |
| 1 | Support for authorisations | Respondents 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.  The RP1059 – 3-nitrooxypropanol (3-NOP, Bovaer® 10) application states a reduction in methane production when added to ruminants feed. One respondent would like to see more studies carried out. | Comments noted.  We note these suggestions and will consider them in shaping the process in future.  FSS/FSA provided key details in the consultation from the safety assessment. These findings support the statement that 3-NOP can be efficacious for reducing methane production in ruminants when fed daily at the proposed dose. The safety assessment presented three *in vitro* studies, two meta-analyses, and three long term dairy cow efficacy trials. The AFFAJEG concluded that these studies showed the additive can be considered to be efficacious for reducing methane production in ruminants when used on a daily basis. |
| 2 | Refinement of the consultation document(s) | One response highlighted several discrepancies in the wording of RP954 & RP955 between the FSS and FSA consultations.  While also highlighting that both applications are referred to as bacteria, despite these feed additives not being of bacterial origin and not being produced during fermentation with bacteria.  One response noted that both FSS and FSA have stated a maximum recommended level of 1,000 PPU/kg for 6-phytase. However, the table on proposed conditions of use included states there are no maximum levels of 6-phytase. | Comments noted.  Whilst the EFSA recommendations have been presented within the consultation package, recommended use level does not hold a legal basis, it will not be included in UK law. |
| 3 | Future considerations | One response focused on the need to integrate RP1059 and similar feed additives into emissions calculations and monitoring. | We note these suggestions and will consider them in shaping the process in future.  Upon publication FSS will communicate with colleagues In the appropriate departments. |
| 4 | Trade Economic considerations | One response highlighted the discrepancy in approving RP1059 for all ruminants for milk production and reproduction whereas the EU authorisation is for dairy cows and cows for reproduction only. The respondent was concerned that this may impact the competitive position of foods produced from ruminants given feeds with RP1059 in GB. | Comments noted.  We note these suggestions and will consider them in shaping the process in future. |

# Next Steps

* The next step of the authorisation process is for the Minister to make decisions on the authorisation of the thirteen additives.
* The FSS risk assessment opinions on these applications concluded that the products are safe to be authorised based on the proposed terms of authorisation. No reasons to change the advice that the feed additives should be authorised have been identified during the consultation process. On that basis, the final advice to respective Ministers in Scotland, England and Wales will be to authorise these feed additives on the proposed terms of authorisation. The Permanent Secretary in Northern Ireland will be informed of the final recommendations.
* 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)

Quality Meat Scotland

National Farmers Union (NFU)

AB Vista on behalf of Roal OY