Consultation on applications for thirteen feed additive authorisations for use in animal feed

Summary of stakeholder responses

12 October 2023

Introduction

This consultation was issued on 25 May 2023 and closed on 20 July 2023.

Food Standards Scotland (FSS) launched a consultation in parallel which can be found on the FSS website. This report is a summary of the consultation responses, the main themes identified and the FSA's responses to these.

Stakeholders' views were sought in relation to the authorisation of thirteen feed additives, consisting of new authorisations, modifications, and/or renewal of existing authorisations, which were submitted for authorisation to be placed on the GB market in accordance with Retained EU Regulation 1831/2003 (REUL 1831/2003) 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, to one previously authorised feed additive (RP955 - 6-phytase (EC 3.1.3.26)) to allow for existing stocks to be exhausted where the criteria of a new authorisation differs from the existing feed additive authorisation.

The applications on which the consultation sought views were**:**

Authorisation of one renewal, modification and new use feed additive:

- RP215 - Endo-1,4-beta-xylanase (EC 3.2.1.8)

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)
- RP1052a - L-lysine base (liquid) produced by *Corynebacterium glutamicum* (KCCM 80216 or KCTC 12307BP)
- RP1052b - L-lysine monohydrochloride produced by *Corynebacterium glutamicum* (KCCM 80216 or KCTC 12307BP)
- RP1059 – 3-nitrooxypropanol as a feed additive for ruminants for milk production and for reproduction

Authorisation of two renewal feed additives:

- RP954 - Endo-1,4-beta-xylanase (EC 3.2.1.8)
- RP955 - 6-phytase (EC 3.1.3.26)

The feed additives included in this consultation are currently authorised for use in Northern Ireland.

Stakeholders were requested to feedback any comments on the scope of the proposed feed additive authorisations and other legitimate factors (for example, consumer interests, technical feasibility and environmental factors) that the FSA and FSS identified as relevant to these applications.

The consultation reach was comprehensive, with automatic notifications sent to 34,420 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 – 28,214 subscribers to England, 15,768 subscribers to Northern Ireland and 16,618 subscribers to Wales. 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 across the wider agri-sector were contacted directly for feedback on this consultation.

The FSA consultation was also shared with the FSA's 61,200 Twitter and 109,609 LinkedIn followers. The FSA consultation page received approximately 326 views from 25/5/23-20/7/23.

The FSA is grateful to all those who responded. The comments, together with the FSA's responses to these, are set out in Table 1 below.

Characteristics of respondents

A total of seven consultation responses were received: six from representatives of industry including the British Association of Feed Supplement and Additive Manufacturers (BAFSAM), and one from a company. BAFSAM is a trade association representing manufacturers and processors of animal feed additives, speciality feed ingredients, premixtures and feed supplement products in the UK and Ireland. BAFSAM state that they can be considered to represent a significant portion of the UK feed additive industry which are directly involved or impacted by the regulated products process for feed additives. A response was also received from the Agricultural Industries Confederation (AIC) who have a broad reach across the agri-sector also submitted a duplicate response to the parallel FSS consultation. These two trade associations with over 250 members collectively represent key sub-sectors within the agri-supply industry including animal feed There was a total of four responses to FSS including two from Scotland only Associations. Across the seven respondents, the majority gave their location as UK-wide or England, with only one respondent from the EU.

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

Summary of responses

Seven responses were received, all representing industries. Five responses were supportive and one response did not directly apply to the applications that were being consulted on, other than a general response to the consultation launch.

One response was submitted by a representative of the applicant seeking authorisation, highlighting minor drafting errors within the FSA/FSS opinion and proposed text amendments to be considered for future consultation documents.

The main concerns raised related to the terminology referred to in the FSA/FSS opinion document for the feed additive RP955 – 6-phytase (EC 3.1.3.26) and their 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) to be placed on the EU market. The FSA 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, it is not our intention to recommend to the Minister that this information is included in legislation.

There are no other relevant provisions of EU law or legitimate factors were identified by the respondents.

The number of responses was low in comparison with actual numbers of stakeholders reached due to the collated responses from members of the industry trade associations (for example, BAFSAM, AIC) which represent the majority of businesses with an interest in animal feed/feed additives.

Our responses to stakeholders' comments are set out in Table 1 below.

Table 1: Summary of substantive comments

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

Number	Main theme of response	Summary of Stakeholders' Comments	FSA's Response
1	Support for authorisations	Respondents commenting on behalf of industry were in support of the authorisations. The main reasons cited were a lack of safety concerns, the potential for disruption to trade and resulting health, welfare, and dietary concerns in farm animals if animal feed additives are not authorised. One respondent expressed their reassurance on the judgement and independence of the FSA safety assessment, providing further assurance to consumer confidence. On the RP1059 feed additive application for 3-Nitrooxypropanol (3-NOP, Bovaer® 10), respondents were in favour of the significant methane reduction (up to 28%) produced by ruminants cited in independent trials worldwide and the potentially huge environmental benefits to combat global warming as well as the potentially positive contribution towards the UK's carbon net zero targets. 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.	Comments noted. We note these suggestions and will consider them in shaping the process in future.

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2	Safety for the user/worker	One respondent raised their concerns over the rationale for including particle size in the specifications for 3-NOP citing that the user/worker safety (PPE) is well-covered by other legislation.	Comments noted. FSA/FSS provide all key details in the Consultation drawn out from the safety assessment. Whilst particle size does inform on user/worker safety, it is also appropriate to include in the legislation as a characteristic of the composition of 3-NOP.
3	Refinement of the consultation document(s)	On RP954 and RP955, one respondent flagged minor drafting errors and proposed text amendments within the consultation document. Feedback provided on the recommended use level of 6-phytase (RP955) outlined that this recommended level is not listed within the EU regulation for this feed additive.	Comments noted We note these minor errors and will consider suggestions in shaping the process in future. Whilst our consultation provides all key information drawn out from the relevant EFSA opinion; as the recommended use level

Number	Main theme of response	Summary of Stakeholders' Comments	FSA's Response
			does not hold a legal basis, it will not be included within the GB Statutory Instruments under UK law.
4	Animal Productivity/ Performance	One respondent raised concerns about the ability to assess the known or anticipated effects in particular to feed additive 3-NOP (RP1059) and how this should be captured in the Veterinary Medicines Directorate (VMD) adverse reaction reporting system. However, the respondent recognises the wider effects than just immediate reactions, including those related to the quality of animal products or animal productivity, and is therefore in favour of the authorisation of this feed additive.	Comments noted. We note these suggestions and will consider them in shaping the process in future.

Number	Main theme of response	Summary of Stakeholders' Comments	FSA's Response
5	Trade impact	On RP1059, 3-nitrooxypropanol one respondent noted the desirability of consistent use of the feed additive across the UK.	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 relevant Ministers in England, Wales and Scotland to make decisions on authorisation of the twelve feed applications (containing thirteen feed additives). In the absence of Ministers in Northern Ireland, the Northern Ireland Department of Health Permanent Secretary will be informed of the recommendation to authorise.

The FSA/FSS 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 these feed additives should be recommended for authorisation have been identified during the consultation process. On that basis, the final FSA/FSS advice to Ministers will be to authorise these feed additives on the proposed terms of authorisation outlined in the FSA/FSS opinions.

Should Ministers move to authorise, Statutory Instruments will be prepared in England and Wales (and a Scottish Statutory Instrument in Scotland) in line with the terms of authorisation previously outlined in the FSA/FSS opinion.

Regulations in Northern Ireland will not be amended as the feed additives are already authorised for use in Northern Ireland.

List of respondents

1. British Retail Consortium (BRC)
2. UK Pet Food
3. National Farmers' Union Cymru
4. AB Vista
5. Agricultural Industries Confederation (AIC)
6. National Farmers' Union
7. British Association of Feed Supplement and Additive Manufacturers (BAFSAM) United Kingdom