Consultation on applications for eleven additives for use in animal feed

Summary of stakeholder responses

[20 June 2022]

Introduction

This consultation was launched on 7 March 2022 and closed on 2 May 2022. Food Standards Scotland (FSS) launched a consultation in parallel. This report is a summary of the consultation responses and the FSA's responses to these.

Stakeholders' views were sought in relation to the authorisation of eleven feed additives, which were submitted for authorisation to be placed on the GB market, in accordance with Retained EU Regulation 1831/2003. The consultation was for new products, renewals, re-evaluation, modifications and new uses of existing feed additives, as outlined below. The consultation also introduces proposals for transitional arrangements 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 new feed additives:
    - RP15 - Manganese chelate of lysine and glutamic acid
    - RP27 - *Lactobacillus buchneri* DSM 29026
    - RP65 - Serine protease produced *by Bacillus licheniformis* DSM 19670
    - RP161 - *Bacillus licheniformis* DSM

- RP808 - 6-phytase produced by *Komagataella phaffii* DSM 32854

- Renewal of authorisation for two feed additives:
  - RP96 - Pyridoxine hydrochloride (vitamin B6)
  - RP130 - *Saccharomyces cerevisiae* CNCM I-4407
- Renewal and a new use of one feed additive:
  - RP664 - *Clostridium butyricum* FERM BP-2789
- Renewal, modification and a new use of one feed additive:
  - RP131 - *Bacillus subtilis* ATCC PTA-6737 (*Bacillus velezensis* ATCC PTA-6737)
- Re-evaluation of one feed additive:
  - RP1030 – Decoquinate
- Modification of one feed additive:
  - RP419 - Decoquinate

The feed additives and their conditions of use included in this consultation are already authorised for use in Northern Ireland, through the EU's Regulated Products approval process, under the terms of the Protocol on Ireland/Northern Ireland (NIP).

Stakeholders were asked to consider any relevant provisions of retained EU law and factors (e.g. consumer interests, technical feasibility and environmental factors) that the Food Standards Agency (FSA) and Food Standards Scotland (FSS) identified as relevant to these applications.

Consultation reach was comprehensive, with automatic notifications sent to 18,165 UK-wide subscribers of FSA alerts at the time of launch. 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 58,300 Twitter and 87,200 LinkedIn followers, with 822 and 2211 impressions respectively. The FSA consultation page received approximately 1146 views and the consultation details (pdf) were accessed 189 times.

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

Characteristics of respondents

The consultation received a single response, from the British Association of Feed Supplement and Additive Manufacturers (BAFSAM). BAFSAM is the British Association of Feed Supplement and Additive Manufacturers, 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.

A response was also received after the consultation closed, from the Agricultural Industries Confederation (AIC), a trade association with over 230 members that represents several sectors within the agri-supply industry (including animal feed, fertilisers and seed). These two organisations are representative of the majority of the feed industry through their members and are the largest stakeholders for this industry. AIC submitted a duplicate response to the parallel FSS consultation; there were no additional responses to FSS.

Summary of responses

The full text of the response received to the consultation is given below, together with our responses to these comments. Due to the limited number of responses received, we have set out our responses in full.

British Association of Feed Supplement and Additive Manufacturers' (BAFSAM) Comments

The British Association of Feed Supplement and Additive Manufacturers (BAFSAM) welcomes the publication of the first 11 feed additive consultations by the FSA.

We would like to make the following specific comments:

- We are pleased to see the pragmatic approach taken by the FSA in taking into account the EFSA opinions for these additives. We would welcome an approach

which considers as relevant, opinions by other authoritative bodies such as EFSA and the FDA as well as harmonised guidance such as that being developed by the ICCF.

- In terms of transition periods, we note that the FSA is proposing similar ones to EFSA. Feedback from our members indicates that for changes to additives submitted for renewal or where the conditions of use have changed as part of a re-authorisation, transition periods which reflect the shelf-life of the additive would be appropriate. For many feed additives, the shelf-life is typically 12 months and premixtures and compound feed containing the feed additive may be used for up to 24 months. There are particular instances, for example for flavouring premixtures or pet foods, where shelf-lives would be relatively long and a case by case approach would be appreciated.
- We recognise that the FSA has had to set up the regulated products process and that this has taken time. However, we would welcome the development of transparent timeframes and more clarity in the position of applications in the review process. We also hope that detailed minutes can be made available from Scientific Committee meetings in a timely manner. In particular, BAFSAM is keen to engage fully with the FSA as its develops and updates the risk analysis process. Many of our members have a great deal of experience of submitting feed additive applications and can contribute the industry perspective on the authorisation process and practical implications of the data requirements. We would discourage any adoption of the transparency regulation on the basis that the administrative burden has become a significant barrier with in our view, no appreciable gain in the quality of the data set or safety evaluation.
- Lastly, we would like to take this opportunity to repeat previous feedback that the FSA regulated products database for feed additives is an excellent resource.

FSA's Response

Comments noted.

Use of opinions from other bodies (EFSA, FDA etc.) for non-pipeline authorisations

Whilst out of scope of the consultation, these comments have been noted.

Transition periods reflecting the shelf-life of the additive (and subsequent compound feed)

We note that BAFSAM were content with the proposed transition periods in this instance. the need for the length of any transition periods will continue to be considered on a case by case basis taking into account some of the technical issues raised.

Transparent timeframes and clarity of status of applications

The Register of Regulated Product Applications is publicly available and lists all those applications which have been validated, showing their current stage in the application process. The Regulated Products Application Service is continuing to develop its processes and anticipates making further improvements later this year.

Publication of minutes from Scientific Committees

We understand the importance of providing an open record of committee proceedings. Currently, meeting minutes are agreed by members at the following committee meeting. However, although minutes will be published, the process, level of detail and timing for publication is still being discussed.

Engagement with BAFSAM in development of the risk analysis process

We recognise the expertise held within industry on the preparation of these complex feed additive applications for authorisation. Our aim is to undertake meaningful engagement with our stakeholders throughout the decision making process.

Adoption of the transparency regulation

Whilst not the subject of this consultation, these comments have been noted.

Agricultural Industries Confederation (AIC) answers to questions posed

AIC provided comments in answer to two of the questions posed in the consultation. One of the questions asked whether the respondent has any concerns as to the safety of

the feed additives which have not been considered within the consultation, to which AIC responded that they do not have any such concerns.

In response to the question requesting comments or concerns on the impact of authorising or not authorising the individual feed additives and, if in favour of authorisation, the terms of authorisation as outlined in the FSA/FSS opinions, AIC stated they are mindful that EU Exit results in inevitable divergence in the composition of GB and EU Registers of Feed Additives and that, in order to minimise any negative impacts of such divergence AIC is in favour of these proposed authorisations. They commented that they consider it of vital importance to the UK livestock feed sector that a wide range of safe and effective additives remain available to the industry.

FSA's Response

Comments noted.

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 the eleven applications.

- The FSA/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 these feed additives should be authorised have been identified during the consultation process. On that basis, the final advice to respective Ministers will be to authorise these feed additives on the proposed terms of authorisation.

- Should Ministers move to authorise, Statutory Instruments will be prepared in England and Wales (and a Scottish Statutory Instrument in Scotland).

- Regulations in Northern Ireland will not be amended as the feed additives are already authorised for use in Northern Ireland, under the NIP. This is with the exception of RP131 which, as indicted in the consultation, is pending a decision on

EU authorisation of the extension of use. The EFSA opinions do indicate that the uses proposed for this feed additive are safe for use, which aligns to the UK position.

List of respondents

1. British Association of Feed Supplement and Additive Manufacturers (BAFSAM)

2. Agricultural Industries Confederation (AIC)