**Consultation on applications for authorisation of feed additives for use in animal feed**

**Consultation Summary Page**

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| **Date consultation launched:** | **Closing date for responses:** |
| 25th May 2023 | 20th July 2023 |

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| **Who will this consultation be of most interest to?**This consultation will be of most interest to: * Animal feed manufacturers, importers/exporters and retailers
* All feed purchasers, including for food and non-food producing animals
* Trade bodies representing stakeholders on animal feed, agriculture and the environment
* Trade unions representing stakeholders in the farming industry
* Organisations representing consumer interests in the feed and food-chains
* Enforcement Authorities

A list of interested parties is included in [Annex A.](#_Annex_A:_List)  |

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| **Consultation subject and purpose**This consultation seeks stakeholders’ views, comments and feedback in relation to the regulated product applications considered in this document, which have been submitted for new authorisation, renewal or modification of existing authorisations. We ask stakeholders to consider any relevant provisions of retained EU law and other legitimate factors (other evidence further supporting clear, rational and justifiable risk analysis, such as consumer interests, technical feasibility and environmental factors), including those that Food Standards Scotland (FSS) and the Food Standards Agency (FSA) have identified as relevant to these applications. This consultation provides the opportunity for stakeholders’ views to be taken into account, to inform Ministers in Scotland, before they make a decision on the authorisation of the feed additives included in this consultation. A parallel consultation is being published by the FSA. |

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| The FSS/FSA opinions take into account the FSS/FSA safety assessments. Links to these safety assessments are provided in the FSS/FSA opinions document. The FSS/FSA opinions, the safety assessments and the views gathered through this consultation will be considered and included alongside those of officials across FSS, the FSA, Devolved Administrations and other UK Government Departments in order to inform Scottish Ministers’ decision-making on whether to authorise, or renew or modify the existing authorisations of the feed additives for use in Scotland. |

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| **Responses to this consultation** |
| If you wish to comment on the applications in this consultation, all responses should be submitted through the Citizen Space entry, where the questions can be answered and other feedback given. | **Contact details**Matthew MullenPolicy OfficerFood and Feed Safety Regulatory PolicyFood Standards Scotlandmatthew.mullen@fss.scotClaire MoniSenior Policy AdvisorFood and Feed Safety Regulatory PolicyTel: 01224 285158Mobile: 07780 955741 | **Postal address**Food Standards ScotlandFourth FloorPilgrim HouseOld Ford RoadAberdeenAB11 5RL |

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| **Is a Business & Regulatory Impact Assessment (BRIA) included with this consultation?**  | Yes [ ]  | No [x]   |

### Consultation on the second tranche of regulated product applications for feed additives and other legitimate factors

Details of Consultation

Introduction

In order to be placed on the market applications for the authorisation of regulated products such as feed additives must be submitted in GB, where the decision on authorisation is made by the respective Ministers in Scotland, England and Wales. This is a function that was previously carried out at a European Union (EU) level. Regulated product applications for the GB market, including feed additives, are now subject to the UK’s own risk analysis process.

FSS and the FSA have been working together to ensure that the high standard of food and feed safety and consumer protection in Scotland and the rest of the UK continues. This is in line with FSS’/FSA’s responsibility to provide advice to Ministers in respect of matters connected with food safety or other interests of consumers in relation to food (section 3, [Food (Scotland) Act 2015](https://www.legislation.gov.uk/asp/2015/1/contents) and sections 6 and 9, [Food Standards Act 1999](https://www.legislation.gov.uk/ukpga/1999/28/contents)).

Under current operating arrangements for Northern Ireland, businesses seeking a new authorisation for a regulated feed product to be placed on the Northern Ireland market will continue to follow EU rules. From Autumn 2023, the Windsor agrifood Framework will allow UK public health standards to apply for retail goods moved via the agrifood green lane and placed on the NI market. Therefore, goods moving via this route containing GB authorised products will be able to be placed on the NI market.

FSS/FSA risk assessors deliver the science behind our advice. They are responsible for identifying and characterising hazards and risks to health and assessing levels of exposure. Where the European Food Safety Authority (EFSA) had commenced an assessment of an application prior to the end of the EU Exit transition period, FSS/FSA risk assessors will take the EFSA opinion into account as part of its safety assessment, where it has been published by EFSA. For the applications in this consultation, FSS/FSA have had access to all supporting documentation that was provided to EFSA for the purposes of forming its opinion as this information was provided to FSS/FSA by the applicant.

The application for RP1059 3-nitrooxypropanol (3-NOP) (Bovaer® 10) (Annex N), has undergone a full FSS/FSA safety assessment, including a full review of the applicant dossier for ruminants (animals that chew the cud)[[1]](#footnote-1) for milk production and for reproduction. The views of the Animal Feed and Feed Additives Joint Expert Group (AFFAJEG) and the Advisory Committee on Animal Feedingstuffs (ACAF) have been taken into account in the FSS/FSA safety assessment for this application.

Following the safety assessment, this consultation seeks to gather stakeholders’ views on the proposed regulated product authorisations.

Ministers in all four nations have agreed to a [provisional common framework for Food and Feed Safety and Hygiene](https://www.gov.uk/government/publications/food-and-feed-safety-and-hygiene-provisional-common-framework). This consultation has been developed under the commitments to collaborative four-nation working set out in this Framework. As such, this consultation has been developed through relevant cross-government forums with the Department of Health and Social Care (DHSC), Scottish Government and Welsh Government. Final advice will be agreed on a four-nation basis before being presented to Ministers.

This consultation letter and the FSS/FSA opinions document present the views of FSS/FSA and the factors that FSS/FSA have identified as relevant to these applications, including the potential impact of any decision made by Ministers. Stakeholders are invited to use this opportunity to comment on these factors or highlight any additional factors that should be brought to the attention of Ministers before a final decision is made.

Following the consultation, the next step of the authorisation process is for relevant Ministers in Scotland, England and Wales to make decisions on authorisation (with Ministers in Northern Ireland kept informed), taking into account the FSS/FSA opinions, any relevant provisions of retained EU law and any other legitimate factors, including those raised during the consultation process.

Subject of Consultation

In accordance with the retained [EU Regulation (REUL) 1831/2003 on additives for use in animal nutrition](https://www.legislation.gov.uk/eur/2003/1831/contents), the applications included in this consultation have been submitted for new authorisation, new use, renewal or modification of use.

Feed additives are substances, micro-organisms or preparations (other than feed materials and premixtures) which are intentionally added to feed or water to perform, in particular, one or more specific functions, as outlined in the section titled ['Supplementary information on feed additives'](#_Supplementary_information_on). To place new feed additives on the GB market, an application must be submitted in accordance with REUL 1831/2003. Feed additives are authorised for a ten-year period. Authorisations can be considered for renewal where an application is re-submitted, at the latest, one-year prior to the authorisation’s expiry date. The procedure for each type of application is laid down in REUL 1831/2003 as follows:

* Article 4, application for a new authorisation or for a new use of a feed additive;
* Article 13, application for modification of authorisation;
* Article 14, application for a renewal of authorisation.

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 application for which transitional arrangements have been proposed is RP955 6-phytase produced by *Trichoderma reesei* (CBS 122001). In addition to seeking views on the applications in this consultation, FSS is also inviting comment on the proposed transitional arrangements for RP955 outlined in Annex J of the FSS/FSA opinions document.

This consultation concerns twelve applications for (thirteen) feed additives. Details of each application are given in the annexes of this consultation letter and in the FSS/FSA opinions document.

Each application is considered within a separate annex, including the regulated product ID number and title of the application (click to follow link):

* [Annex A: List of interested parties](#_Annex_A:_List_1) 19
* [Annex B: RP215 - Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by Trichoderma reesei (CBS 143953, previously deposited as ATCC 5588) as a digestibility enhancer for all poultry species, piglets (suckling and weaned), pigs for fattening and minor porcine species (Danisco Xylanase 40000 G/L), (Danisco (UK) Limited) (renewal, modification and new use)](#_Annex_B:_RP15)  20
* [Annex C: RP263 - *Lacticaseibacillus rhamnosus* (formerly *Lactobacillus rhamnosus*) (IMI 507023) as a feed additive for all animal species (All-Technology (Ireland) Limited) (new)](#_Annex_C:_RP27) 22
* [Annex D: RP267 - *Pediococcus pentosaceus* (IMI 507024) as a feed additive for all animal species (All-Technology (Ireland) Limited) (new)](#_Annex_D:_RP65) 23
* [Annex E: RP270 - *Pediococcus pentosaceus* (IMI 507025) as a feed additive for all animal species (All-Technology (Ireland) Limited) (new)](#_Annex_E:_RP96)  24
* [Annex F: RP271 - *Lactiplantibacillus plantarum* (formerly *Lactobacillus plantarum*) (IMI 507026) as a feed additive for all animal species (All-Technology (Ireland) Limited) (new)](#_Annex_F:_RP130)  25
* [Annex G: RP272 - *Lactiplantibacillus plantarum* (formerly *Lactobacillus plantarum*) (IMI 507027) as a silage additive for all animal species (All-Technology (Ireland) Limited) (new)](#_Background) 26
* [Annex H: RP273 - *Lactiplantibacillus plantarum* (formerly *Lactobacillus plantarum*) (IMI 507028) as a silage additive for all animal species (All-Technology (Ireland) Limited) (new)](#_Annex_H:_RP161) 27
* [Annex I: RP687 - *Lactiplantibacillus plantarum* (formerly *Lactobacillus plantarum*) (DSM 26571) as a silage additive for all animal species (Chr. Hansen A/S) (new)](#_Annex_I:_RP664 - Clostridium butyri) 28
* [Annex J: RP954 - Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* (CBS 114044) as a feed additive for piglets (weaned), chickens for fattening, chickens reared for laying, turkeys for fattening and turkeys reared for breeding (Econase® XT) (Roal Oy) (renewal)](#_Annex_J:_RP808) 29
* [Annex K: RP955 - 6-phytase (EC 3.1.3.26) produced by *Trichoderma reesei* (CBS 122001) as a feed additive for all pigs and poultry (Finase® EC) (Roal Oy) (renewal)](#_Annex_K:_RP955) 31
* [Annex L: RP1052a - L-lysine monohydrochloride produced by *Corynebacterium glutamicum* (KCCM 80216 or KCTC 12307BP) as a feed additive for all animal species (Daesang Europe B.V.) (new))](#_Annex_L:_RP419)  32
* [Annex M: RP1052b - L-lysine base (liquid) produced by *Corynebacterium glutamicum* (KCCM 80216 or KCTC 12307BP) as a feed additive for all animal species (Daesang Europe B.V.) (new)](#_Annex_M:_RP1052b) 33
* [Annex N: RP1059 – 3-nitrooxypropanol as a feed additive for ruminants for milk production and for reproduction (Bovaer® 10) (DSM Nutritional Products Ltd., Switzerland) (new)](#_Annex_N:_RP1059)  34

Impacts

As part of the risk analysis process, FSS/FSA have assessed the potential impacts that would result from authorisation of these feed additives, should Ministers decide to authorise. FSS’/FSA’s assessment of the proposals identified potential positive impacts on the environment from the authorisation of RP1059 3-nitrooxypropanol (Bovaer® 10); these are outlined under ‘[Other legitimate factors](#_Other_legitimate_factors)’. For the rest of the applications, no significant impacts were identified. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. local authority delivery, health, environment, growth, innovation, trade, competition, consumer interests or small and micro businesses). The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

Under the [provisional common framework for Food and Feed Safety and Hygiene](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/934750/food-and-feed-safety-and-hygiene-proposed-common-framework-command-paper-web-accessible.pdf), Northern Ireland continues to fully participate in the risk analysis processes concerning food and feed safety. This reflects Northern Ireland’s integral role within the UK and ensures that any decision made fully considers the potential impacts on the whole of the UK. Eleven of the twelve feed additive applications included in the consultation have been authorised for use in Northern Ireland, in line current operating arrangements.

Application RP954 concerns Endo-1,4 beta-xylanase produced by *Trichoderma reesei* (CBS 114044) (Econase® XT), which requires renewal of authorisation in the EU, and therefore in Northern Ireland. The EU has not yet made a decision on the renewal of authorisation for this feed additive, which is currently authorised and already on the market in Northern Ireland under its previous authorisation. Differential timings and/or decisions in the UK or EU may result in temporarily different rules in Northern Ireland and GB which may have impacts on what the feed additive can be used for across the UK. Further detail on this application is available in Annex J.

### Other legitimate factors

We have considered a range of other legitimate factors that Scottish Ministers may wish to consider in making decisions about these feed additives (including environmental, trade and consumer interests). A summary of the impacts identified, notably for RP1059 3-nitrooxypropanol (Bovaer® 10), is outlined below.

**Environmental Impacts**

RP1059 3-nitrooxypropanol (Bovaer® 10) is an innovative feed additive that has the potential to reduce methane production in ruminants under the proposed conditions of use, to contribute to UK net zero carbon emissions, and build a more sustainable food and feed system.

The usage of RP1059 3-nitrooxypropanol (Bovaer® 10) is a commercial decision for individual dairy producers, therefore the scale of the benefits from a reduction in methane production is currently unknown as we do not have a clear understanding of how many businesses will begin using the additive.

**Economic Impacts**

The use of RP1059 3-nitrooxypropanol (Bovaer® 10) will be a voluntary commercial decision.

The major use for RP1059 3-nitrooxypropanol (Bovaer® 10) will be in feed for dairy cows. For context, the Agriculture and Horticulture Development Board[[2]](#footnote-2) has reported that there are 7850 dairy producers in GB, 819 of whom are based in Scotland (as of October 2022) and 1.86 million dairy cows, with 174,000 in Scotland (as of Dec 2021). Therefore, there is likely to be an indirect economic impact of authorising this feed additive.

**Trade Impacts**

Eleven out of the twelve applications are already authorised in the EU. GB authorisation of these products will facilitate trade through alignment with Northern Ireland/EU.

The application submitted to the EU to renew RP954 Endo-1,4-beta-xylanase(3.2.1.8) produced by *Trichoderma reesei* (CBS 114044) (Econase® XT) has not been concluded for Northern Ireland/EU markets but is currently permitted under its previous authorisation. This will impact on manufacturers in not being able to market the full range of stock formulations of the feed additive until renewed in Northern Ireland/EU.

**Feed/Local Authority Delivery**

Eleven out of the twelve applications are already authorised in the EU, and if the applications in this consultation are authorised in GB, there will be reduced burdens for local authority inspections and enforcement, with GB becoming aligned with Northern Ireland/EU.

RP954 Endo1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 114044) is currently authorised for use in Northern Ireland under its existing authorisation, in line with current operating arrangements.  Minor divergence in labelling for RP954 Endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 114044) (Econase® XT) may add to a minor burden for local authority inspections and enforcement due to the new range of stock formulations only available in Great Britain until it is renewed in Northern Ireland/EU.

The target species for RP1059 3-nitrooxypropanol (Bovaer®) in GB is all ruminants, however the target species for the Northern Ireland/EU authorisation is dairy cows and cows for reproduction. This difference in target species between an authorisation of RP1059 3-nitrooxypropanol (Bovaer®) in GB and its current authorisation in Northern Ireland/EU may add burdens for local authority inspections and enforcement.

**Consumer interests**

FSS monitors consumers’ attitudes regarding a range of food-related issues through our [Food in Scotland consumer tracker survey](https://www.foodstandards.gov.scot/publications-and-research/nutrition-research/consumer-attitudes-to-food). This survey provides feedback on consumer attitudes to food issues such as safety and authenticity, diet and nutrition and sustainability within the food environment.

### Supplementary information on feed additives

Where dossiers for existing feed additives were submitted to the EU by the deadlines set out in REUL 1831/2003, and the decision on their authorisation was not concluded prior to any expiry date where set, the feed additives may remain on the market until concluded. Refer to [Article 14(4)](https://www.legislation.gov.uk/eur/2003/1831/article/14) of REUL 1831/2003 on existing feed additives on renewal of authorisations.

Feed additives are classified under five broad categories, as outlined in [Article 6](https://www.legislation.gov.uk/eur/2003/1831/article/6) of REUL 1831/2003, and further defined for specific functions in [Annex I](https://www.legislation.gov.uk/eur/2003/1831/annex/I).

The categories are:

1. Technological additives (for example, silage additives or preservatives)
2. Sensory additives (colourants or flavourings)
3. Nutritional additives (for example, amino acids and trace elements)
4. Zootechnical additives, to perform specialised functions (for example, improving digestibility of feed)
5. Coccidiostats and Histomonostats, to control gut parasites

Feed additives are defined as “substances, micro-organisms or preparations, other than feed material and premixtures, which are intentionally added to feed or water in order to perform, in particular, one or more of the functions mentioned in Article 5(3) [of REUL 1831/2003]”.

Microorganisms (for example, bacteria, yeast or fungi) are identified by a unique ID code relating to their deposition into an internationally recognised Culture Collection; for example, the National Collection of Industrial, Food and Marine Bacteria (NCIMB) in the UK or the American Type Culture Collection (ATCC).

Feed additives may be intended for target animal species, or for major species or defined sub-groups (for example, poultry or chickens for laying), as defined in [Annex IV of REUL 429/2008](https://www.legislation.gov.uk/eur/2008/429/annex/IV). According to [Article 7(5) of REUL 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/article/7), species groups may be extrapolated to minor species (for example, minor poultry such as ducks or geese) or other animal groups requested within an application (for example, game birds). ‘Minor species’ refers to food-producing animals other than bovines (dairy and meat animals, including calves), sheep (meat animals), pigs, chickens (including laying hens), turkeys and fish belonging to *Salmonidae*, as defined in [Article 1(2) of REUL 429/2008](https://www.legislation.gov.uk/eur/2008/429/article/1).

Animals may be intended for direct human consumption (for example, pigs for fattening or turkeys for fattening), whilst there are additional animal sub-groups for breeding purposes only which are not intended to directly enter the food-chain (for example, sows for reproduction or turkeys reared for breeding).

Transitional arrangements may be applied; for example, where the criteria of a new authorisation differs from the existing feed additive authorisation, to allow existing stocks and products on the market to be used up. Transitional arrangements are only referenced where applicable.

Transitional periods stated for relevant applications are proposed to be staggered in time for feed additives, or premixtures and compound feed, to allow their sequential use to exhaust stocks of the individual feed types. Transitional periods to exhaust stocks of finished feed for non-food-producing animals are longer in duration than for food-producing animals, due to extended product shelf-life and high-volume labelling runs, such as for pet food.

Reference to complete feed herein refers to the equivalent of compound feed which, due to its composition, is sufficient for the animals’ daily ration. This term used throughout is standardised to complete feed with a moisture content of 12%, and where minimum and maximum content are referenced on this basis.

Proposals for renewal of authorisations below may include additional information compared to the existing authorisation that, in itself, does not constitute a modification of authorisation. For example, characterisation of the feed additive may be more explicitly described, such as reference to a solid preparation or viable cells, but was applicable in the existing authorisation. Further refinements in text have also become standardised; for example the labelling for storage and heat stability (under ’Other provisions’ section).

Requirements in retained EU legislation

Requirements in retained EU legislation are given within the annexes.

Engagement and Consultation Process

Details of all valid applications for regulated products are published monthly on the Register of Regulated Product Applications, available [here](https://www.food.gov.uk/risk-analysis/register-of-regulated-product-applications).

Stakeholders are invited to consider the questions below.

Following the consultation process responses will be published and made available to stakeholders and Ministers.

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| Questions asked in this consultation:1. Do you have any concerns in relation to the safety of these feed additives which have not been considered below with respect to the intended animal species, consumers (in consumption of animal products), workers/users or environmental impacts?
2. Do you have any comments or concerns on the impacts, in consideration of authorising or not authorising the individual feed additives, and if in favour of authorisation, the terms on which the feed additives are authorised (as outlined in this consultation)?
3. Do you have any comments on the proposed transitional arrangements for RP955 6-phytase (EC 3.1.3.26) produced by *Trichoderma reesei* (CBS 122001)?
4. Are there any other factors that should be considered by Ministers that have not been highlighted?
5. Do you have any other feedback?
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Responses

This consultation will run for 8 weeks. Responses are required by close of 20th July 2023.

Please state in your response via the questionnaire:

* Whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents);
* Which application(s)/product(s) you are commenting on;
* If you give us permission to quote your name or organisation in the publication of the results.

All responses to this consultation will be published by Food Standards Scotland within 3 months of the consultation closing. All responses should be sent through the Citizen Space entry for this consultation. Reponses will be shared with the FSA and Ministers.

Further information

If you require a more accessible format of this document, such as in Braille or in another language, please send details to the named contact for responses to this consultation and your request will be considered. Please let us know if you need paper copies of the consultation documents.

Please feel free to pass this document to any other interested parties, or send us their full contact details and we will arrange for a copy to be sent to them direct.

This consultation has been prepared taking account of the Consultation Criteria. The Consultation Criteria from the [HM Code of Practice on Consultation](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/100807/file47158.pdf) should be included in each consultation and they are listed below:

**The Seven Consultation Criteria**

 **Criterion 1** **— When to consult**

 *Formal consultation should take place at a stage when there is scope to influence the policy outcome.*

 **Criterion 2** **—** **Duration of consultation exercises**

 *Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible.*

 **Criterion 3 —** **Clarity of scope and impact**

 *Consultation documents should be clear about the consultation process, what is being proposed, the scope to influence and the expected costs and benefits of the proposals.*

 **Criterion 4** **—** **Accessibility of consultation exercises**

 *Consultation exercises should be designed to be accessible to, and clearly targeted at, those people the exercise is intended to reach.*

 **Criterion 5 —** **The burden of consultation**

 *Keeping the burden of consultation to a minimum is essential if consultations are*

 *to be effective and if consultees’ buy-in to the process is to be obtained.*

 **Criterion 6 —** **Responsiveness of consultation exercises**

 *Consultation responses should be analysed carefully and clear feedback should be provided to participants following the consultation.*

 **Criterion 7** **—** **Capacity to consult**

 *Officials running consultations should seek guidance in how to run an effective consultation exercise and share what they have learned from the experience.*

Criterion 2 states that *Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible*. This consultation has been shortened to **8 weeks** for the following reasons:

* All 11 cases included within the second tranche draft recommendations are considered routine and should not raise undue concern with consumers, industry or businesses.
* Of the 11 cases, 10 have already been ratified into EU legislation.
* FSS risk management recommendations are based on FSS/FSA review of EFSA opinions.
* Consulting for 12 weeks will place undue pressure on adhering to legislative deadlines for authorisations.
* Delivering authorisations efficiently will demonstrate that processes previously completed by the EU can be delivered at pace post EU Exit, aligning processes' timelines to facilitate authorisation processes for GB businesses with stakes in EU markets.
* It is considered that, in this instance, an 8-week consultation period allows ample time for comments from stakeholders.
* It is important to aim for consistency across the 4 countries wherever possible. 10 authorisations have in this consultation already been authorised by the EU and by extension approved for use in Northern Ireland.
* With dual applications, regulation of products should keep pace with the EC.
* Any delay could create an uneven playing field for GB businesses and affect GB-NI trade.

The Code of Practice states that an Impact Assessment should normally be published alongside a formal consultation. An impact assessment was not required for this consultation.

Queries

If you have any queries relating to this consultation please contact the person named on page 2, who will be able to respond to your questions.

GDPR, publication of personal data and confidentiality of responses

The European General Data Protection Regulation (GDPR) replaces the Data Protection Directive 95/46/EC and was developed to harmonize data privacy laws across Europe. The Data Protection Act (the DPA) 2018 applies GDPR standards and  transposes the EU Data Protection Directive 2016/680 (Law Enforcement Directive) into domestic UK law. In accordance with the GDPR, we are required to provide a privacy notice in relation to this public consultation. Food Standards Scotland will be known as the “Controller” of the personal data provided to us. We need to collect this information to allow us to effectively carry out our official duties of policy development and for the purposes of record keeping. In responding to this consultation, you have consented to provide this information to us but are able to withdraw your consent at any time by getting in touch with us.

Personal information will be stored on Scottish Government servers and cloud based services have been procured and assessed against the national cyber security centre cloud security principles. Personal information will not be used for any purpose other than in relation to consultations. Personal information will be stored for as long as necessary to carry out the above functions and for five years from receipt in accordance with our retention policy. No third parties have access to your personal data unless the law allows them to do so.

You have a right to see the information we hold on you by making a request in writing to the email address below. If at any point you believe the information we process on you is incorrect you can request to have it corrected. If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data not in accordance with the law you can complain to the Information Commissioner’s Office (ICO). Our Data Protection Officer in the FSS is the Head of Corporate Services who can be contacted at the following email address: dataprotection@fss.scot.

 In accordance with the principle of openness, our office in Pilgrim House in Aberdeen will hold a copy of the completed consultation as per our retention policy. FSS will not publish anything without your consent. If you have any queries please email: dataprotection@fss.scot or return by post to the address given on page 2.

In accordance with the provisions of Freedom of Information Act (Scotland) 2002/Environmental Information (Scotland) Regulations 2004, all information contained in your response may be subject to publication or disclosure. If you consider that some of the information provided in your response should not be disclosed, you should indicate the information concerned, request that it is not disclosed and explain what harm you consider would result from disclosure. The final decision on whether the information should be withheld rests with FSS. However, we will take into account your views when making this decision.

Any automatic confidentiality disclaimer generated by your IT system will not be considered as such a request unless you specifically include a request, with an explanation, in the main text of your response.

A detailed Privacy Policy is available on our [website](https://www.foodstandards.gov.scot/privacy), that explains how FSS will safeguard and process any personal identifiable information that we collect from you in relation to this consultation.

**Comments on the consultation process itself**

We are interested in what you thought of this consultation and would therefore welcome your general feedback on both the consultation package and overall consultation process. If you would like to help us improve the quality of future consultations, please feel free to share your thoughts with us by sending an email to openness@fss.scot or return by post to the address given on page 2.

Thank you on behalf of Food Standards Scotland for participating in this public consultation.

Matthew Mullen

Policy Officer

Feed Safety and Hygiene Policy

Food Standards Scotland

Annex A: List of interested parties

Key stakeholder trade associations who have an interest in feed additives across the wider sector will be contacted directly for feedback on this consultation:

Agricultural Industries Confederation

Agricultural Industries Confederation Scotland

British Association of Feed Supplement and Additive Manufacturers

British Equestrian Trade Association

Grain and Feed Trade Association

National Beef Association

National Farmers Union of Scotland

National Sheep Association Scotland

National Office of Animal Health

Pet Food Manufacturers' Association

Royal Highland and Agricultural Society of Scotland

Scottish Quality Crops

Scottish Wholesale Association

Scottish Corn Trade Association

This is not an exhaustive list.

Annex B: RP215 - Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* (CBS 143953, previously deposited as ATCC 5588) as a feed additive for all poultry species, piglets (suckling and weaned), pigs for fattening and minor porcine species (Danisco Xylanase 40000 G/L) (Danisco (UK) Limited) (renewal, modification and new use)

Background

In accordance with REUL 1831/2003 on feed additives, application RP215 is submitted for the enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 143953, previously deposited as ATCC 5588) (Danisco Xylanase 40000 G/L) for a renewal of authorisation (Article 14), modification (Article 13) and a new use (Article 4) for extrapolation of species as a zootechnical additive, under the functional group of ‘digestibility enhancers’. The function of such feed additives is to improve the digestibility of animal diets.

An application was submitted for the feed additive authorisation for all poultry species, suckling piglets, weaned piglets, pigs for fattening & minor growing porcine species.

Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *T. reesei* (ATCC 5588) (Danisco Xylanase 40000 G/L) is currently authorised under Regulation 1831/2003 in feed for:

* Chickens for fattening, laying hens, ducks and turkeys for fattening ([REUL 9/2010](https://www.legislation.gov.uk/eur/2010/9/contents))
* Weaned piglets and pigs for fattening ([REUL 528/2011](https://www.legislation.gov.uk/eur/2011/528))
* Minor poultry species other than ducks ([REUL 1021/2012](https://www.legislation.gov.uk/eur/2012/1021/contents))

The new use (extrapolation of species) is proposed to extend to all poultry species and to suckling piglets and minor growing porcine species.

In addition, the applicant requests a modification of authorisation (Article 13) to reduce the minimum content from 1,250 Units/kg complete feed to 625 Units/kg complete feed for turkeys for fattening.

FSS/FSA Opinion

The FSS/FSA opinion, which includes a link to the safety assessment and details of the proposed terms of authorisation of the feed additive, can be found on the consultation page.

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Annex C: RP263 - *Lacticaseibacillus rhamnosus* (formerly *Lactobacillus rhamnosus*) (IMI 507023) as a feed additive for all animal species (All-Technology (Ireland) Limited) (new)

Background

In accordance with Article 4 of REUL 1831/2003 on feed additives, application RP263 is submitted for the preparation of *Lacticaseibacillus rhamnosus* (formerly *Lactobacillus rhamnosus*) (IMI 507023) for a new authorisation as a technological additive under the functional group of ‘silage additives’. The function of such feed additives is intended to improve the production, fermentation of, and/or aerobic stability of silage in the preparation of animal feed and are not intended to be added directly to feed at the time of consumption by animals.

The additive is intended to be used in feed for all animal species/categories to improve the aerobic stability of easy and moderately difficult to ensile forage materials. This silage additive is proposed at a minimum concentration of 1 x 109 colony-forming units (CFU) per kg fresh material.

FSS/FSA Opinion

The FSS/FSA opinion, which includes a link to the safety assessment and details of the proposed terms of authorisation of the feed additive, can be found on the consultation page.

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Annex D: RP267 - *Pediococcus pentosaceus* (IMI 507024) as a feed additive for all animal species (All-Technology (Ireland) Limited) (new)

**Background**

In accordance with Article 4 of REUL 1831/2003 on feed additives, application RP267 is submitted for the preparation of *Pediococcus pentosaceus* (IMI 507024) for a new authorisation as a technological additive under the functional group of ‘silage additives’. The function of such feed additives is intended to improve the production, fermentation of, and/or aerobic stability of silage in the preparation of animal feed and is not intended to be added directly to feed at the time of consumption by animals.

The additive is intended to be used in feed for all animal species/categories to improve the aerobic stability of easy and moderately difficult to ensile forage materials. This silage additive is proposed at a minimum concentration of 1 x 109 colony-forming units (CFU) per kg fresh material.

FSS/FSA Opinion

The FSS/FSA opinion, which includes a link to the safety assessment and details of the proposed terms of authorisation of the feed additive, can be found on the consultation page.

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Annex E: RP270 - *Pediococcus pentosaceus* (IMI 507025) as a feed additive for all animal species (All-Technology (Ireland) Limited) (new)

**Background**

In accordance with Article 4 of REUL 1831/2003 on feed additives, application RP270 is submitted for the preparation of *Pediococcus pentosaceus* (IMI 507025) for a new authorisation as a technological additive under the functional group of ‘silage additives’. The function of such feed additives is intended to improve the production, fermentation of, and/or aerobic stability of silage in the preparation of animal feed and are not intended to be added directly to feed at the time of consumption by animals.

The additive is intended to be used in feed for all animal species/categories to improve the aerobic stability of easy and moderately difficult to ensile forage materials. This silage additive is proposed at a minimum concentration of 1 x 109 colony-forming units (CFU) per kg fresh material.

FSS/FSA Opinion

The FSS/FSA opinion, which includes a link to the safety assessment and details of the proposed terms of authorisation of the feed additive, can be found on the consultation page.

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Annex F: RP271 - *Lactiplantibacillus plantarum* (formerly *Lactobacillus plantarum*) (IMI 507026) as a feed additive for all animal species (All-Technology (Ireland) Limited) (new)

**Background**

In accordance with Article 4 of REUL 1831/2003 on feed additives, application RP271 is submitted for the preparation of *Lactiplantibacillus plantarum* (formerly *Lactobacillus plantarum*) (IMI 507026) for a new authorisation as a technological additive under the functional group of ‘silage additives’. The function of such feed additives is intended to improve the production, fermentation of, and/or aerobic stability of silage in the preparation of animal feed and are not intended to be added directly to feed at the time of consumption by animals.

The additive is intended to be used in feed for all animal species/categories to improve the aerobic stability of easy and moderately difficult to ensile forage materials. This silage additive is proposed at a minimum concentration of 1 x 109 colony-forming units (CFU) per kg fresh material.

FSS/FSA Opinion

The FSS/FSA opinion, which includes a link to the safety assessment and details of the proposed terms of authorisation of the feed additive, can be found on the consultation page.

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Annex G: RP272 - *Lactiplantibacillus plantarum* (formerly *Lactobacillus plantarum*) (IMI 507027) as a feed additive for all animal species (All-Technology (Ireland) Limited) (new)

**Background**

In accordance with Article 4 of REUL 1831/2003 on feed additives, application RP272 is submitted the preparation of *Lactiplantibacillus plantarum* (formerly *Lactobacillus plantarum*) (IMI 507027) for a new authorisation as a technological additive under the functional group of ‘silage additives’. The function of such feed additives is intended to improve the production, fermentation of, and/or aerobic stability of silage in the preparation of animal feed and are not intended to be added directly to feed at the time of consumption by animals.

The additive is intended to be used in feed for all animal species/categories to improve the aerobic stability of easy and moderately difficult to ensile forage materials. This silage additive is proposed at a minimum concentration of 1 x 109 colony-forming units (CFU) per kg fresh material.

FSS/FSA Opinion

The FSS/FSA opinion, which includes a link to the scientific opinion and details of the proposed terms of authorisation of the feed additive, can be found on the consultation page.

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Annex H: RP273 - *Lactiplantibacillus plantarum* (formerly *Lactobacillus plantarum*) (IMI 507028) as a feed additive for all animal species (All-Technology (Ireland) Limited) (new)

**Background**

In accordance with Article 4 of REUL 1831/2003 on feed additives, application RP273 is submitted for the preparation of *Lactiplantibacillus plantarum* (formerly *Lactobacillus plantarum*) (IMI 507028) for a new authorisation as a technological additive under the functional group of ‘silage additives’. The function of such feed additives is intended to improve the production, fermentation of, and/or aerobic stability of silage in the preparation of animal feed and are not intended to be added directly to feed at the time of consumption by animals.

The additive is intended to be used in feed for all animal species/categories to improve the aerobic stability of easy and moderately difficult to ensile forage materials. This silage additive is proposed at a minimum concentration of 1 x 109 colony-forming units (CFU) per kg fresh material.

FSS/FSA Opinion

The FSS/FSA opinion, which includes a link to the safety assessment and details of the proposed terms of authorisation of the feed additive, can be found on the consultation page.

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Annex I: RP687 - *Lactiplantibacillus plantarum* (formerly *Lactobacillus plantarum*) (DSM 26571) as a feed additive for all animal species (Chr. Hansen A/S) (new)

**Background**

In accordance with Article 4 of REUL 1831/2003 on feed additives, application RP687 is submitted the preparation of *Lactiplantibacillus plantarum (*formerly *Lactobacillus plantarum*) (DSM 26571) for a new authorisation as a technological additive under the functional group of ‘silage additives’. The function of such feed additives is intended to improve the production, fermentation of, and/or aerobic stability of silage in the preparation of animal feed and are not intended to be added directly to feed at the time of consumption by animals.

The additive is intended to be used in feed for all animal species/categories to improve the aerobic stability of easy, moderately difficult and difficult to ensile forage materials. This silage additive is proposed at a minimum concentration of 1 x 108 colony-forming units (CFU) per kg fresh material.

FSS/FSA Opinion

The FSS/FSA opinion, which includes a link to the safety assessment and details of the proposed terms of authorisation of the feed additive, can be found on the consultation page.

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Annex J: RP954 - Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* (CBS 114044) as a feed additive for piglets (weaned), chickens for fattening, chickens reared for laying, turkeys for fattening and turkeys reared for breeding (Econase® XT) (Roal Oy) (renewal)

**Background**

In accordance with Article 14 of REUL 1831/2003 on feed additives, application RP954 is submitted for the enzyme preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* (CBS 114044) (Econase® XT) for renewal of authorisation as a zootechnical additive under the functional group of ’digestibility enhancers’. The function of such feed additives is to improve the digestibility of animal diets.

Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *T. reesei* (CBS 114044) (Econase® XT) is currently authorised under REUL 1831/2003 [(REUL 902/2009](https://www.legislation.gov.uk/eur/2009/902/contents)) for weaned piglets, chickens for fattening, chickens reared for laying, turkeys for fattening and turkeys reared for breeding. Under this authorisation, the feed additive is marketed in two forms, as a solid (P) and liquid (L) with activities of 4,000,000 and 400,000 BXU/g additive, respectively[[3]](#footnote-3).

The current application for renewal proposes new stock formulations at lower concentrations in solid form (at 160,000, 800,000 BXU/g) and liquid form at 160,000 BXU/g, although the minimum level added to feed remains the same.

This feed additive was also previously authorised for use in feed under [REUL 1110/2011](https://www.legislation.gov.uk/eur/2011/1110/contents), although its authorisation expired in November 2021. A separate application has been submitted as a new authorisation to replaceREUL 1110/2011 as amended under [REUL 2018/1569](https://www.legislation.gov.uk/eur/2018/1569) for use in feed for laying hens, minor poultry species and pigs for fattening.

FSS/FSA Opinion

The FSS/FSA opinion, which includes a link to the safety assessment and details of the proposed terms of authorisation of the feed additive, can be found on the consultation page.

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Annex K: RP955 - 6-phytase (EC 3.1.3.26) produced by *Trichoderma reesei* (CBS 122001) as a feed additive for all pigs and poultry (Finase® EC) (Roal Oy) (renewal)

**Background**

In accordance with Article 14 of REUL 1831/2003 on feed additives, application RP955 is submitted for the enzyme preparation of 6‐phytase (EC 3.1.3.26) produced by *Trichoderma reesei* (CBS 122001) (Finase® EC) for a renewal of authorisation as a zootechnical additive under the functional group of ‘digestibility enhancers’. The function of such feed additives is to improve the digestibility of animal diets.

6-phytase produced by *T. reesei* (CBS 122001) (Finase® EC) is currently authorised under REUL 1831/2003 for the same function in feed, where this current application collectively seeks the renewal of :

* [REUL 277/2010](https://www.legislation.gov.uk/eur/2010/277?view=extent#extent%3Dwales) for use in feed for poultry for fattening and breeding other than turkeys for fattening, for poultry for laying and for pigs other than sows.
* [REUL 891/2010](https://www.legislation.gov.uk/eur/2010/891) for use in feed for turkeys.
* [REUL 886/2011](https://www.legislation.gov.uk/eur/2011/886) for use in feed for sows.

FSS/FSA Opinion

The FSS/FSA opinion, which includes a link to the safety assessment and details of the proposed terms of authorisation of the feed additive, can be found on the consultation page.

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Annex L: RP1052a - L-lysine monohydrochloride produced by *Corynebacterium glutamicum* (KCCM 80216 or KCTC 12307BP) as a feed additive for all animal species (Daesang Europe B.V.) (new)

**Background**

In accordance with Article 4 of REUL 1831/2003 on feed additives, application RP1052a is submitted for the substance L-lysine monohydrochloride produced by fermentation with *Corynebacterium glutamicum* (KCCM 80216 or KCTC 12307BP) for a new authorisation as a nutritional additive under the functional group of ‘amino acids, their salts and analogues’. The function of such feed additives is to provide essential micro-nutrients to animal diets.

L-lysine monohydrochloride produced by *Corynebacterium glutamicum* (KCCM 80216 or KCTC 12307BP) is proposed for use in feed for all animal species, with no minimum or maximum content.

FSS/FSA Opinion

The FSS/FSA opinion, which includes a link to the safety assessment and details of the proposed terms of authorisation of the feed additive, can be found on the consultation page.

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Annex M: RP1052b - L-lysine base (liquid) produced by *Corynebacterium glutamicum* (KCCM 80216 or KCTC 12307BP) as a feed additive for all animal species (Daesang Europe B.V.) (new)

**Background**

In accordance with Article 4 of REUL 1831/2003 on feed additives, application RP1052b is submitted for the substance L-lysine base (liquid) produced by fermentation with *Corynebacterium glutamicum* (KCCM 80216 or KCTC 12307BP) for a new authorisation as a nutritional additive under the functional group of ‘amino acids, their salts and analogues’. The function of such feed additives is to provide essential micro-nutrients to animal diets.

L-lysine base (liquid) produced by *Corynebacterium glutamicum* (KCCM 80216 or KCTC 12307BP) is proposed for use in feed for all animal species, with no minimum or maximum content.

**FSS/FSA Opinion**

The FSS/FSA opinion, which includes a link to the safety assessment and details of the proposed terms of authorisation of the feed additive, can be found on the consultation page.

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Annex N: RP1059 – 3-nitrooxypropanol as a feed additive for ruminants for milk production and for reproduction (Bovaer® 10) (DSM Nutritional Products Ltd., Switzerland) (new)

**Background**

In accordance with Article 4 of REUL 1831/2003 on feed additives, application RP1059 is submitted for 3-nitrooxypropanol (3-NOP) (Bovaer® 10) for a new authorisation as a zootechnical additive, under the functional group of ‘substances which favourably affect the environment’. This innovative feed additive is designed to interrupt methane production in ruminants (animals that chew the cud, for example cows). Such feed additives have the potential to contribute to net zero targets.

3-nitrooxypropanol (Bovaer®) is proposed for use in all ruminants for milk production and for reproduction.

**FSA/FSS Opinion**

The FSS/FSS opinion, which includes a link to the safety assessment and details of the proposed terms of use of the feed additive, can be found on the consultation page.

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1. [Supplying and using animal by-products as farm animal feed - GOV.UK (www.gov.uk)](https://www.gov.uk/guidance/supplying-and-using-animal-by-products-as-farm-animal-feed) [↑](#footnote-ref-1)
2. [GB producer numbers | AHDB](https://ahdb.org.uk/dairy/GB-producer-numbers) [↑](#footnote-ref-2)
3. Enzyme activity expressed in birchwood xylanase units (BXU), where one BXU is the amount of enzyme which liberates 1 nanomole of reducing sugars as xylose from birch xylan per second at pH 5.3, and 50°C. [↑](#footnote-ref-3)