Consultation pack on twelve applications for feed additives for use in animal feed

This consultation seeks stakeholders' views, comments and feedback in relation to the regulated product applications considered in this document.
PDF
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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 key stakeholders is provided in Annex A.

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, and/ or 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 the Food Standards Agency (FSA) and Food Standards Scotland (FSS) have identified as relevant to these applications. This consultation provides the opportunity for stakeholders' views to be taken into account, to inform Ministers in England and Wales, before they make a decision on the authorisation of the feed additives included in this consultation. A parallel consultation is being published by FSS.

The FSA/FSS opinions take into account the FSA/FSS safety assessments. Links to these safety assessments are provided in the FSA/FSS opinions document.

The FSA/ FSS opinions, the safety assessments and the views gathered through this consultation will be provided to Ministers to inform their decision-making on whether to authorise the individual feed additives for use as animal feed in England, Scotland and Wales.

Details of the consultation

Introduction

In order to be placed on the market, applications for the authorisation of regulated products must be submitted in Great Britain (GB), where the decision on authorisation is made by the respective Ministers in England, Scotland 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.

The FSA and FSS have been working together to ensure that the high standard of food and feed safety and consumer protection in the UK continues. This is in line with FSA/FSS responsibility to provide advice to Ministers in respect of matters connected with food safety or other interests of consumers in relation to food (section 6 and 9, Food Standards Act 1999 and section 3, Food (Scotland) Act 2015).

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 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.

Our 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 transition period for the UK exiting the EU (applications in Annexes B to M), the FSA/FSS safety assessors will take the EFSA opinion into account as part of its safety assessment, where it has been published by EFSA. For applications in this consultation, the FSA/FSS 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 the FSA/FSS by the applicant. After safety assessment, the FSA/FSS have agreed with EFSA conclusions in its opinions.

Application for Annex N, RP1059 3-nitrooxypropanol (3-NOP) (Bovaer® 10), has undergone a full FSA/FSS safety assessment, including full review of the applicant dossier for ruminants (animals that chew the cud) 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 FSA/FSS safety assessment for this application.

Following 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. 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), Welsh Government and Scottish Government. Final advice will be agreed on a four-nation basis before being presented to Ministers.

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

Subject of this consultation

In accordance with Retained EU Regulation 1831/2003 (‘the Regulation’) on additives for use in animal nutrition, the applications included in this consultation have been submitted for a new authorisation, new use, renewal, or modification.

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'. To place new feed additives on the GB market, an application must be submitted in accordance with the Regulation. 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 the Regulation as follows:

- 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 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 (EC 3.1.3.26) produced by *Trichoderma reesei* (CBS 122001). In addition to seeking views on the applications in this consultation, the FSA is also inviting comment on the proposed transitional arrangements for RP955 outlined in Annex K.

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

Each feed additive authorisation is considered within a separate annex, including the regulated product ID number and title of the application:

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 growing porcine species (Danisco Xylanase 40000 G/L), (Danisco (UK) Limited) (renewal, modification and new use) 16

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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) 23

Annex I: RP687 - *Lactiplantibacillus plantarum* (formerly *Lactobacillus plantarum*) (DSM 26571) as a feed additive for all animal species (Chr. Hansen A/S) (new) 24

Impacts

As part of the risk analysis process, FSA/FSS have assessed the potential impacts that would result from the authorisation of these feed additives, should Ministers decide to authorise. FSA/FSS' 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'. 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. environmental, trade, and consumer interests). 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, 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 with 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 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 build a more

sustainable food and feed system and contribute to UK net zero carbon emissions.

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 RP1059 3-nitrooxypropanol (Bovaer® 10). As the usage of this is a commercial decision for individual dairy producers, the opportunity to reduce methane production through this product would be an indirect benefit under the Better Regulation Framework.

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 has reported that there are 7850 dairy producers in GB (footnote) (as of October 2022) and 2.65 million dairy cows over 12 months of age (footnote) (as of Dec 2021). The large potential market for this feed additive means there is likely to be an indirect economic impact associated with this authorisation.

Trade Impacts

Eleven out of the twelve applications are already authorised in the 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.

RP954 Endo1,4-beta-xylanase (3.2.1.8) produced by *Trichoderma reesei* (CBS 114044) (Econase® XT) 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 (3.2.1.8) 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 for milk production and for reproduction, however the target species for the Northern Ireland / EU authorisation is for dairy cows and cows for reproduction only. 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.

Supplementary information on feed additives

Where dossiers for existing feed additives were submitted to the EU by the deadlines set out in the Regulation, 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) of the Regulation on existing feed additives on renewal of authorisations.

Feed additives are classified under five broad categories, as outlined in Article 6 of the Regulation, and further defined for specific functions in 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 either a substance, a micro-organism or a preparation as described in Article 2(2)(a) of the Regulation.

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 all animal species, or for major species or defined sub-groups (for example, poultry or chickens for laying), as defined in Annex IV of Retained EU Regulation 429/2009. In addition, 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 Retained EU Regulation 429/2009.

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 primarily intended to 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, based on significant change between the existing and new authorisation.

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' 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/or maximum content are referenced on this basis where applicable.

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).

Engagement and Consultation Process

Details of all valid applications for regulated products are published monthly on the Register of Regulated Product Applications, on the Food Standards Agency website.

Stakeholders are invited to consider the questions posed below in relation to any relevant provisions of retained EU law and other legitimate factors.

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

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?

Responses

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

How to respond

Please respond to the consultation via the online survey. If this is not possible, you can email a response to: RPconsultations@food.gov.uk

Please indicate which application(s)/product(s) you are responding about by using the following subject line for your response:

Response to [insert RP number(s)] feed additives consultation

If responding by email, please state in your response whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents) and in which nation you are based.

Responses from Wales should also be sent using the steps outlined above, as all comments received will be shared with FSA in Wales.

A summary of responses to this consultation will be published by the Food Standards Agency within 12 weeks of the consultation closing.

For information on how the FSA handles your personal data, please refer to the Consultation privacy notice.

Responses will be shared with Ministers in England, Scotland and Wales

Further information

If you require a more accessible format of this document, please send details to the named contact for responses to this consultation and your request will be considered.

This consultation has been prepared in accordance with HM Government consultation principles.

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

Yours,

Regulated Products Approvals Team,
Regulated Services

Annex A: List of interested parties

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 in animal nutrition and the wider agriculture sector will be contacted directly for feedback on this consultation:

- Agricultural Industries Confederation (AIC)
- British Association of Feed Supplement and Additive Manufacturers (BAFSAM)
- British Equestrian Trade Association (BETA)
- Grain and Feed Trade Association (GAFTA)
- National Office of Animal Health (NOAH)
- Northern Ireland Grain Trade Association (NIGTA)
- UK Pet Food (previously the Pet Food Manufacturers Association (PFMA))

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 growing porcine species (Danisco Xylanase 40000 G/L), (Danisco (UK) Limited) (renewal, modification and new use)

Background

In accordance with Retained EU Legislation 1831/2003 (‘the Regulation’) on feed additives, application RP215 is submitted for the enzyme preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) 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 the Regulation in feed for:

- Chickens for fattening, laying hens, ducks and turkeys for fattening (Retained EU Regulation 9/2010)
- Weaned piglets and pigs for fattening (Retained EU Regulation 528/2011)
- Minor poultry species other than ducks (Retained EU Regulation 1021/2012)

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.

FSA/FSS opinion

The FSA/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 Food Standards Agency website:

- FSA/FSS opinions on twelve applications for feed additives for use in animal feed
- Safety assessments of twelve feed additive applications

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 the Regulation 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.

FSA/FSS opinion

The FSA/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 Food Standards Agency website:

- FSA/FSS opinions on twelve applications for feed additives for use in animal feed
- Safety assessments of twelve feed additive applications

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 the Regulation 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.

FSA/FSS opinion

The FSA/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 Food Standards Agency website:

- FSA/FSS opinions on twelve applications for feed additives for use in animal feed
- Safety assessments of twelve feed additive applications

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 the Regulation 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.

FSA/FSS opinion

The FSA/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 Food Standards Agency website:

- FSA/FSS opinions on twelve applications for feed additives for use in animal feed
- Safety assessments of twelve feed additive applications

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 the Regulation 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.

FSA/FSS opinion

The FSA/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 Food Standards Agency website:

- FSA/FSS opinions on twelve applications for feed additives for use in animal feed
- Safety assessments of twelve feed additive applications

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 the Regulation on feed additives, application RP272 is submitted for 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.

FSA/FSS opinion

The FSA/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 Food Standards Agency website:

- FSA/FSS opinions on twelve applications for feed additives for use in animal feed
- Safety assessments of twelve feed additive applications

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 the Regulation 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.

FSA/FSS opinion

The FSA/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 Food Standards Agency website:

- FSA/FSS opinions on twelve applications for feed additives for use in animal feed
- Safety assessments of twelve feed additive applications

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 the Regulation on feed additives, application RP687 is submitted for 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.

FSA/FSS opinion

The FSA/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 Food Standards Agency website:

- FSA/FSS opinions on twelve applications for feed additives for use in animal feed
- Safety assessments of twelve feed additive applications

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 the Regulation 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 the Regulation (Retained EU Regulation 902/2009) 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.

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 the regulation below, although its authorisation expired in November 2021. A separate application has been submitted as a new authorisation to replace:

- Retained EU Regulation 1110/2011 as amended under Retained EU Regulation 2018/1569 for use in feed for laying hens, minor poultry species and pigs for fattening.

*[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.

FSA/FSS opinion

The FSA/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 Food Standards Agency website:

- FSA/FSS opinions on twelve applications for feed additives for use in animal feed
- Safety assessments of twelve feed additive applications

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 the Regulation 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 (EC 3.1.3.26) produced by *T. reesei* (CBS 122001) (Finase® EC) is currently authorised under the Regulation for the same function in feed, where this current application collectively seeks the renewal of:

- Retained EU Regulation 277/2010 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.
- Retained EU Regulation 891/2010 for use in feed for turkeys.
- Retained EU Regulation 886/2011 for use in feed for sows.

FSA/FSS opinion

The FSA/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 Food Standards Agency website:

- FSA/FSS opinions on twelve applications for feed additives for use in animal feed
- Safety assessments of twelve feed additive applications

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 the Regulation 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.

FSA/FSS opinion

The FSA/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 Food Standards Agency website:

- FSA/FSS opinions on twelve applications for feed additives for use in animal feed
- Safety assessments of twelve feed additive applications

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 the Regulation 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.

FSA/FSS opinion

The FSA/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 Food Standards Agency website:

- FSA/FSS opinions on twelve applications for feed additives for use in animal feed
- Safety assessments of twelve feed additive applications

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 the Regulation 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 UK net zero targets.

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

FSA/FSS opinion

The FSA/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 Food Standards Agency website:

- FSA/FSS opinions on twelve applications for feed additives for use in animal feed
- Safety assessments of twelve feed additive applications