Consultation pack on 24 feed additive applications and one application for feed for particular nutritional purposes (PARNUT)

This consultation seeks stakeholders' views, comments and feedback in relation to the regulated product applications considered in this document, which have been submitted for authorisation. These applications have been submitted for new, new use only, modifications and renewal with or without modifications of existing authorisations of feed additives and one feed for particular nutritional purposes (PARNUT).

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

Key stakeholders

The following 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)

This is not an exhaustive list.

Consultation subject and purpose

This consultation seeks stakeholders' feedback on the regulated product applications considered in this document. These applications have been submitted for:

- new authorisations (eight feed additives)
- new use only (six feed additives)
- renewal of authorisation (one feed additive)

- modification (two feed additives and one PARNUT)
- renewal and modification (five feed additives)
- renewal, new use and modification (two feed additives)

The Food Standards Agency (FSA) and Food Standard Scotland (FSS) risk management recommendations, the safety assessments and the views gathered through this consultation will be shared with the ministers in England, Scotland, Wales and Northern Ireland to support their decision making.

A parallel consultation is being published by FSS to support ministers in their decision making in Scotland.

Details of the consultation

Introduction

To be placed on the market in Great Britain (GB), applications for the authorisation of regulated products must be submitted in GB. The decision on authorisation is made by respective ministers in England, Wales and Scotland, with the Minister of Health for Northern Ireland kept informed.

The provisional common framework for Food and Feed Safety and Hygiene is a non-statutory arrangement between the UK government and devolved administrations to establish common approaches to policy areas where powers have returned from the EU within areas of devolved competence. This consultation has been developed under the commitments to collaborative four-nation working set out in this framework.

Final recommendations will be agreed on a four-nation basis before being presented to ministers. The FSA and FSS have been working together to ensure the continued high standard of food and feed safety and consumer protection in the UK. This is in line with FSA/FSS responsibility to provide recommendations to ministers on matters connected with food and feed safety or other consumer food interests (sections 6 and 9 of the Food Standards Act 1999 and section 3 of the Food Act 2015 in Scotland).

Regulated product applications for the GB market, including feed additives and feed for particular nutritional purposes (PARNUTs), are subject to the UK's risk analysis process.

FSA/FSS adopted technical guidance and quality assurance processes used by the European Food Safety Authority (EFSA) to be able to undertake GB risk assessments for regulated product applications. Please see the links within each annex to the individual safety assessments.

Our risk assessors deliver the science behind our advice. They are responsible for identifying and characterising hazards and risks to health and assessing exposure levels. The feed additive applications have undergone an FSA/FSS safety assessment, including a review of the applicant's dossier and supplementary information. Following the safety assessments, this consultation seeks to gather stakeholders' views on the proposed feed additive authorisations.

This consultation and the FSA/FSS risk management recommendations document present the recommendations 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, ministers in England, Scotland and Wales will make decisions on authorisation, with the Minister of Health for Northern Ireland kept informed. They will consider the FSA/FSS recommendation, any relevant provisions of assimilated law, and any other legitimate

factors, including those raised during the consultation process.

Subject of this consultation

In accordance with assimilated law on feed additives for use in animal feed, the applications included in this consultation have been submitted for a new authorisation, new use only, modification, and renewal with or without modification of existing authorisation.

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

- Article 4 and Article 7 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

In accordance with Article 9 of assimilated Regulation (EC) 767/2009, feed intended for particular nutritional purposes may only be marketed in GB if its intended use is included in the list of intended uses established in accordance with Article 10 of the same regulation, and it meets the essential nutritional characteristics for the nutritional purpose included in that list.

Assimilated Regulation (EU) 2020/354 establishes a list of intended uses of feed intended for particular nutritional purposes.

In accordance with Article 10 of assimilated Regulation (EC) 767/2009, an application to modify an entry in the list is included in this consultation.

Transitional arrangements

Transitional arrangements may be necessary for modification applications under Article 13 of assimilated Regulation (EC) 1831/2003 and renewal applications where Article 14(2)(d) of assimilated Regulation (EC) 1831/2003, a proposal for amending or supplementing the conditions of the original authorisation applies. The proposed changes may affect the labelling requirements under Article 16 of the assimilated Regulation (EC 1831/2003) and it is therefore necessary to provide transitional arrangements to protect animal welfare by ensuring the continued use, for a limited period, of existing products to allow for existing stock to be exhausted.

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.

The consultation provides detail on proposals for transitional arrangements which are outlined below:

RP185, 6–phytase (EC 3.1.3.26) produced from *Komagataella phaffii* (formerly *Komagataella pastoris*) (DSM 23036) as a feed additive for all avian species and all pigs (OptiPhos®) (Huvepharma EOOD) (renewal, new use and

modification)

As regards the change in nomenclature and the extension of species to include all avian and porcine species, it is our view that it is appropriate to provide transitional periods to meet new labelling requirements. In all cases the changes are not considered to have any immediate impact on animal or human safety thus justifying the use of a suitable transition provision.

A proposal for transitional arrangements is set out below for the existing feed additive authorisation.

Proposal: Feed containing this additive may continue to be placed on the market and used under the conditions of its prior authorisation until existing stocks are exhausted where:

- the feed additive, premixture, compound feed and feed materials containing the feed additive is produced and labelled within six months from the date of this authorisation.

RP222 – Selenised yeast produced from *Saccharomyces cerevisiae* (CNCM I-3060), inactivated as a feed additive for all animal species (All-Technology (Ireland) Limited) (modification)

As regards the modification to the conditions of authorisation and composition of the additive, it is our view that it is appropriate to provide transitional periods to meet new labelling requirements. In all cases the changes are not considered to have any immediate impact on animal or human safety thus justifying the use of a suitable transition provision.

Proposal: Feed containing this additive may continue to be placed on the market and used under the conditions of its prior authorisation until existing stocks are exhausted where:

- the **feed additive or premixture** containing the feed additive is produced and labelled within **six months** from the date of this authorisation.
- **compound feed and feed materials** containing this feed additive to be produced and labelled within **twelve months** from the date of this authorisation when intended for food-producing animals.
- **compound feed and feed materials** containing this feed additive to be produced and labelled within **twenty-four months** from the date of this authorisation when intended for non-food-producing animals.

RP641 *Bacillus velezensis* (formerly *Bacillus subtilis* C-3102) (DSM 15544) as a feed additive for weaned piglets and all avian species (Calsporin®) (Asahi Biocycle Co., Ltd) (renewal, new use and modification)

As regards the change in nomenclature and the extension of species to include all avian species, it is our view that it is appropriate to provide transitional periods to meet new labelling requirements. In all cases the changes are not considered to have any immediate impact on animal or human safety thus justifying the use of a suitable transition provision.

Proposal: Feed containing this additive may continue to be placed on the market and used under the conditions of its prior authorisation until existing stocks are exhausted where:

- the **feed additive or premixture** containing the feed additive is produced and labelled within **six months** from the date of this authorisation.
- **compound feed and feed materials** containing this feed additive to be produced and labelled within **twelve months** from the date of this authorisation when intended for food-producing animals.

- **compound feed and feed materials** containing this feed additive to be produced and labelled within **twenty-four months** from the date of this authorisation when intended for non-food-producing animals.

RP1198 – Butylated hydroxyanisole (BHA) as a feed additive for cats (FEDIAF) (new)

This new authorisation is more descriptive than the previous authorisation and is allocated a new identification number. It is our view that it is appropriate to provide transitional periods to meet new labelling requirements. In all cases the changes are not considered to have any immediate impact on animal or human safety thus justifying the use of a suitable transition provision.

Proposal: Feed containing this additive may continue to be placed on the market and used under the conditions of its prior authorisation until existing stocks are exhausted where:

- the **feed additive or premixture** containing the feed additive is produced and labelled within **six months** from the date of this authorisation.
- **compound feed and feed materials** containing this feed additive to be produced and labelled within **twenty-four months** from the date of this authorisation.

RP1386 – Copper chelate of hydroxy analogue of methionine produced by Novus Europe NV

As regards the modification to the conditions of authorisation and composition of the additive, and the modification of the identification number, it is our view that it is appropriate to provide transitional periods to meet new labelling requirements. In all cases the changes are not considered to have any immediate impact on animal or human safety thus justifying the use of a suitable transition provision.

Proposal: Feed containing this additive may continue to be placed on the market and used under the conditions of its prior authorisation until existing stocks are exhausted where:

- the **feed additive or premixture** containing the feed additive is produced and labelled within **six months** from the date of this authorisation.
- **compound feed and feed materials** containing this feed additive to be produced and labelled within **twelve months** from the date of this authorisation when intended for food-producing animals.
- **compound feed and feed materials** containing this feed additive to be produced and labelled within **twenty-four months** from the date of this authorisation when intended for non-food-producing animals.

RP1387 – Manganese chelate of hydroxy analogue of methionine produced by Novus Europe NV

As regards the modification to the conditions of authorisation and composition of the additive, and the modification of the identification number, it is our view that it is appropriate to provide transitional periods to meet new labelling requirements. In all cases the changes are not considered to have any immediate impact on animal or human safety thus justifying the use of a suitable transition provision.

Proposal: Feed containing this additive may continue to be placed on the market and used under the conditions of its prior authorisation until existing stocks are exhausted where:

- the **feed additive or premixture** containing the feed additive is produced and labelled within **six months** from the date of this authorisation.
- **compound feed and feed materials** containing this feed additive to be produced and labelled within **twelve months** from the date of this authorisation when intended for food-producing animals.
- **compound feed and feed materials** containing this feed additive to be produced and labelled within **twenty-four months** from the date of this authorisation when intended for non-food-producing animals.

RP1388 – Zinc chelate of hydroxy analogue of methionine produced by Novus Europe NV

As regards the modification to the conditions of authorisation and composition of the additive, and the modification of the identification code, it is our view that it is appropriate to provide transitional periods to meet new labelling requirements. In all cases the changes are not considered to have any immediate impact on animal or human safety thus justifying the use of a suitable transition provision.

Proposal: Feed containing this additive may continue to be placed on the market and used under the conditions of its prior authorisation until existing stocks are exhausted where:

- the **feed additive or premixture** containing the feed additive is produced and labelled within **six months** from the date of this authorisation.
- **compound feed and feed materials** containing this feed additive to be produced and labelled within **twelve months** from the date of this authorisation when intended for food-producing animals.
- **compound feed and feed materials** containing this feed additive to be produced and labelled within **twenty-four months** from the date of this authorisation when intended for non-food-producing animals.

Supplementary information on feed for particular nutritional purposes

Feed for particular nutritional purposes (PARNUTs), also known as the specific nutritional needs of animals whose process of assimilation, absorption or metabolism is, or could be, temporarily or irreversibly impaired and who can therefore benefit from the ingestion of feed appropriate to their condition. PARNUTs can satisfy a specific nutritional purpose through a particular composition or method of production.

The annex of assimilated Regulation (EU) 2020/354 establishes a list of intended uses of feed intended for particular nutritional purposes.

List of Annexes

This consultation concerns 24 feed additive applications and one PARNUT. Details of each application are given in the annexes and in the FSA/FSS risk management recommendations document.

Each authorisation is considered within a separate annex, each authorisation details the regulated product ID number and title of the application:

Annex A: RP24 - *Saccharomyces cerevisiae* (MUCL 39885) as a feed additive for weaned piglets (Biosprint®) (Prosol S.p.A.) (renewal)

Annex B: RP25 - *Saccharomyces cerevisiae* (MUCL 39885) as a feed additive for all pigs and minor porcine species other than sows and piglets (suckling and weaned) (Biosprint®) (Prosol S.p.A.) (new use)

Annex C: RP26 - *Saccharomyces cerevisiae* (MUCL 39885) as a feed additive for cats and dogs (Biosprint®) (Prosol S.p.A.) (new use)

Annex D: RP29 - *Pediococcus acidilactici* (CNCM I-4622) as a feed additive for all animal species (Danstar Ferment AG (Switzerland) as a feed additive for all animal species (new)

Annex E: RP140 - Monensin sodium produced from *Streptomyces cinnamonensis* 28682 (NBIMCC 3419) as a feed additive for chickens for fattening, chickens reared for laying and turkeys for fattening (Coxidin®) (Huvepharma NV) (renewal and modification)

Annex F: RP141 - Monensin sodium produced from *Streptomyces cinnamonensis* 28682 (NBIMCC 3419) as a feed additive for chickens for fattening and turkeys (Coxidin®) (Huvepharma NV) (renewal and modification)

Annex G: RP142 - Monensin sodium produced from *Streptomyces cinnamonensis* 28682 (NBIMCC 3419) as a feed additive for chickens reared for laying and turkeys reared for breeding (Coxidin®) (Huvepharma NV) (new use)

Annex H: RP185 - 6–phytase (EC 3.1.3.26) produced from *Komagataella phaffii* (formerly *Komagataella pastoris*) (DSM 23036) as a feed additive for all avian species and all pigs (OptiPhos®) (Huvepharma EOOD) (renewal, new use and modification).

Annex I: RP222 - Selenised yeast produced from *Saccharomyces cerevisiae* (CNCM I-3060), inactivated as a feed additive for all animal species (All-Technology (Ireland) Limited) (modification)

Annex J: RP284 - Monensin sodium produced from *Streptomyces cinnamonensis* 28682 (NBIMCC 3419) as a feed additive for turkeys reared for breeding (Coxidin®) (Huvepharma NV) (new use)

Annex K: RP641 - *Bacillus velezensis* (formerly *Bacillus subtilis* C-3102) (DSM 15544) as a feed additive for weaned piglets and all avian species (Calsporin®) (Asahi Biocycle Co., Ltd) (renewal, new use and modification)

Annex L: RP1105 - L-histidine monohydrochloride monohydrate produced from *Escherichia coli* (KCCM 80212) as a feed additive for all animal species (Daesang Europe B.V.) (new)

Annex M: RP1125 - L-tryptophan produced from *Escherichia coli* (KCCM 80210) as a feed additive for all animal species (Daesang Europe B.V.) (new)

Annex N: RP1126 - L-lysine sulphate produced from *Corynebacterium glutamicum* (KCCM 80227) as a feed additive for all animal species (Daesang Europe B.V.) (new)

Annex O: RP1198 - Butylated hydroxyanisole (BHA) as a feed additive for cats (FEDIAF) (new)

Annex P: RP1199 Part A - L-lysine base (liquid) produced from *Corynebacterium glutamicum* (KCCM 80183) as a feed additive for all animal species. (CJ Europe GmbH) (new)

Annex Q: RP1199 Part B - L-lysine monohydrochloride (technically pure) produced from *Corynebacterium glutamicum* (KCCM 80183) as a feed for all animal species (CJ Europe GmbH) (new)

Annex R: RP1200 - Disodium 5’-guanylate produced from *Corynebacterium stationis* (KCCM 10530) and *Escherichia coli* (KFCC 11067) as a feed additive for all animal species (CJ Europe GmbH) (new)

Annex S: RP1259 - Muramidase (EC 3.2.1.17) produced from *Trichoderma reesei* (DSM 32338) as a feed additive for weaned piglets (Balancius®) (DSM Nutritional Products Ltd) (new use)

Annex T: RP1349 - Phytomenadione (vitamin K1) as a feed additive for horses (JARAZ Enterprises GmbH & Co. KG) (new)

Annex U: RP1386 - Copper chelate of hydroxy analogue of methionine as a feed additive for all animal species (Novus Europe NV) (renewal and modification)

Annex V: RP1387 - Manganese chelate of hydroxy analogue of methionine as a feed additive for all animal species (Novus Europe NV) (renewal and modification)

Annex W: RP1388 - Zinc chelate of hydroxy analogue of methionine as a feed additive for all animal species (Novus Europe NV) (renewal and modification)

Annex X: RP1591 - Fumonisin esterase (EC 3.1.1.87) produced from *Komagataella phaffii* (DSM 32159) as a feed additive for all species (DSM Nutritional Products Ltd, Switzerland) (new use)

Annex Y: RP1654 - Administrative change of authorisation holder (Evonik Operations GmbH) (modification)

Annex Z: RP658 - Modification of entry number 60 of the PARNUT regulation, ‘Reduction of the risk of milk fever and subclinical hypocalcaemia’ as a feed for particular nutritional purposes for dairy cows (Prince Agri Products, Inc) (modification)

Impacts

As part of the risk analysis process, the FSA/FSS have assessed the potential impacts that may result should ministers decide to authorise these feed applications. Our collective assessment of the proposals did not identify any significant impacts. The impacts considered included those most frequently identified as potential impacts when introducing or amending 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, Northern Ireland continues to fully participate in the risk analysis processes concerning 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.

Impact for Northern Ireland

In October 2023, the Windsor Framework was implemented providing a unique set of arrangements to support the flow of agrifood retail products from GB to Northern Ireland. These goods can meet the same standards applied in the rest of the UK in public health, marketing (including labelling) and organic foods when moving through the Northern Ireland Retail Movement Scheme (NIRMS). The scheme extends to some pet food. PARNUTs and feed additives, whether being used to produce compound feeds or being directly fed to livestock, would not meet the definition of pre-packed retail goods intended for the final consumer, so would not be able to benefit from the scheme. However, if goods remain in Northern Ireland, traders can benefit from the Movement Assistance Scheme to recoup costs associated with certification.

In Northern Ireland, feed additives used in qualifying Northern Ireland goods will be able to be placed on the market in GB, in line with the Government's steadfast commitment to ensuring Northern Ireland's unfettered access to the GB market.

Other Legitimate Factors

We have considered a range of other legitimate factors that ministers may wish to consider in making decisions about these applications including political, economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours. Our collective assessment of the other legitimate factors did not identify anything of major significance. However, for the applications within this consultation, our collective assessment of these did identify the following issues of note:

Trade Impacts

Application RP26 – *Saccharomyces cerevisiae* (MUCL 39885), has not been authorised for use in cats in the EU. The FSA/ FSS assessed available evidence and supports recommending the authorisation of RP26 for use in cats, there will be divergence between GB and the EU which will require separate labelling for products sold in GB to those sold in the EU.

Application RP140 and RP284 – The FSA/FSS have assessed the available evidence and supports recommending the renewal and modification of RP140 and authorisation of new use (extension of species) for RP284 monensin sodium produced from *Streptomyces cinnamonensis* 28682 (NBIMCC 3419) (Coxidin®). A similar application was submitted to the EU and is ongoing.

Application RP141 and RP142 – The FSA/FSS have assessed the available evidence and supports recommending the renewal and modification of use of RP141 and authorisation of RP142 monensin sodium produced from *Streptomyces cinnamonensis* 28682 (NBIMCC 3419) (Coxidin®). A similar application was submitted to the EU and is ongoing.

Application RP222 – Selenised yeast *Saccharomyces cerevisiae* (CNCM I-3060), inactivated (identification number 3b810) is recommended for authorisation of selenium (Se) content from 2000 mg Se/kg to 3500 mg Se/kg. This is a modification of the current feed additive authorisation.

If authorised, this would differ from the EU authorisation Implementing Regulation (EU) 2022/1459, which includes two entries one for the existing authorisation which a selenium content of 2000 – 2400 mg Se/kg and one for a new authorisation of selenium content of 3000 – 3500 mg Se/kg. authorisation of selenium content of 3000 – 3500 mg Se/kg.

Application RP25 – The FSA/FSS have assessed the available evidence and supports recommending the authorisation of RP25 as a feed additive for all pigs other than sows, suckling and weaned piglets and all minor porcine species. A similar application was submitted to the EU and has been finalised. The application was not made for authorisation as a feed additive for suckling pigs.

Feed / Local Authority Delivery

Twenty out of the twenty-four feed additive applications are already authorised in the EU, and if authorised in GB, will reduce burdens for local authority inspections and enforcement for these feed additives. Conversely, if GB authorises feed additives not yet authorised in the EU, divergence may add burdens for local authority inspections and enforcement until the feed additives are authorised in the EU due to the new range of stock formulations only available in GB until they are authorised in the EU. Divergence between GB and the EU may require separate

labelling for products sold in GB to those sold in the EU.

Supplementary information on feed additives

Where applications for already authorised feed additives were submitted to the EU by the deadlines set out in assimilated Regulation (EC) 1831/2003, and the decision on the renewal of the authorisation was not concluded prior to any expiry date set, the feed additives affected shall remain on the market until the appropriate authority make a determination on the renewals. "Appropriate authority" means, in relation to England, the Secretary of State; in relation to Wales, the Welsh Ministers; and in relation to Scotland, the Scottish Ministers. Please refer to Article 14 (4) of assimilated Regulation (EC) 1831/2003 in respect of renewal of authorisations for more information.

Feed additives are classified under five broad categories, as outlined in Article 6 of assimilated Regulation (EC) 1831/2003 in respect of renewal of authorisations for more information. Feed additives are classified under five broad categories, as outlined in Article 6 of assimilated Regulation (EC) 1831/2003, and further defined for specific functions in Annex I to assimilated Regulation (EC) 1831/2003.

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.

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 produced from genetically modified strains of microorganisms; however, the production strains and their DNA were not detected in the finished feed additives. As a result, the feed additives do not require the traceability conditions specified by GMO legislation.

The applications that have used GM strains in processing which were not detected in the finished feed are as follows:

- **RP185 -** 6–phytase (EC 3.1.3.26) produced from *Komagataella phaffii* (formerly *Komagataella pastoris*) (DSM 23036) as a feed additive for all avian species and all pigs (OptiPhos®) (Huvepharma EOOD) (renewal, new use and modification).
- **RP1105 -** L-histidine monohydrochloride monohydrate produced from *Escherichia coli* (KCCM 80212) as a feed additive for all animal species (Daesang Europe B.V.) (new)
- **RP1125 -** L-tryptophan produced from *Escherichia coli* (KCCM 80210) as a feed additive for all animal species (Daesang Europe B.V.) (new)
- **RP1199 Part A -** L-lysine base (liquid) produced from *Corynebacterium glutamicum* (KCCM 80183) as a feed additive for all animal species. (CJ Europe GmbH) (new)
- **RP1199 Part B -** L-lysine monohydrochloride (technically pure) produced from *Corynebacterium glutamicum* (KCCM 80183) as a feed for all animal species (CJ Europe GmbH) (new)
- **RP1259 -** Muramidase (EC 3.2.1.17) produced from *Trichoderma reesei* (DSM 32338) as a feed additive for weaned piglets (Balancius®) (DSM Nutritional Products Ltd) (new use)

- **RP1591 -** Fumonisin esterase (EC 3.1.1.87) produced from *Komagataella phaffii* (DSM 32159) as a feed additive for all species (DSM Nutritional Products Ltd, Switzerland) (new use)

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 to assimilated Regulation (EC) 429/2008. 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), as stated in Article 7(5) of assimilated Regulation (EC) 1831/2003. '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 assimilated Regulation (EC) 429/2008

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).

Reference to complete feed refers to the equivalent of compound feed which, due to its composition, is sufficient for the animal's 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, unless otherwise specified. 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.

We invite stakeholders to consider the questions posed below in relation to any relevant legislation 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. Regarding RP1105 L-histidine monohydrochloride monohydrate produced from *Escherichia coli* (KCCM 80212) as a feed additive for all animal species and RP1125 L-tryptophan produced from *Escherichia col*i (KCCM 80210) as a feed additive for all animal species: Do you have any comments on whether any labelling should be included in the terms of authorisation in relation to the products' dusting potential and potential endotoxin concentration in the dust, and the associated inhalation risk for workers handling the product, or whether this is sufficiently included in existing Health and Safety legislation?
3. 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 proposed terms of which the feed additives are authorised (as outlined in this consultation)?

4. Do you have any comments on the proposed transitional arrangements for:

- **RP185 -** 6-phytase (EC 3.1.3.26)
- **RP222 -** Selenised yeast *Saccharomyces cerevisiae* (CNCM I-3060) inactivated
- **RP641 -** *Bacillus velezensis* (DSM 15544)
- **RP1198 -** Butylated hydroxyanisole (BHA)
- **RP1386 -** Copper chelate of hydroxy analogue of methionine
- **RP1387 -** Manganese chelate of hydroxy analogue of methionine
- **RP1388 -** Zinc chelate of hydroxy analogue of methionine produced by Novus Europe NV.

- Or whether transitional provisions are needed on any other applications in this consultation?

5. Are there any other factors that should be considered by ministers that have not been highlighted?

6. Do you have any other feedback? Please consider any relevant legislation and other legitimate factors which may support clear, rational and justifiable risk analysis.

Responses

This consultation will run for eight weeks. Responses are required by midnight of 17 June 2024.

How to respond

Please respond to the consultation via the link to 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 be sent using the steps outlined above, all comments received will be shared with the FSA in Wales.

A summary of responses to this consultation will be published on the FSA website 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, Wales and Northern Ireland.

Further information

If you require a more accessible format of this document, please contact our helpline: 0330 332 7149 open 9.00 until 17.00, Monday to Friday or Submit an online enquiry 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,
The Regulated Products Approvals Team,
Regulated Services

Annex A-H: RP24, RP25, RP26, RP29, RP140, RP141, RP142, RP185

Annex A: RP24 – *Saccharomyces cerevisiae* (MUCL 39885) as a feed additive for weaned piglets (Biosprint®) (Prosol S.p.A.) (renewal)

Background

In accordance with Article 14 of assimilated Regulation (EC) 1831/2003 on feed additives, application RP24 is submitted for *Saccharomyces cerevisiae* (MUCL 39885) (Biosprint®) for renewal of authorisation as a zootechnical additive under the functional group of 'gut flora stabilisers'. The function of such feed additives is to have a positive effect on gut micro-organisms to maintain animal health and performance.

An application was submitted for renewal of the feed additive authorisation for weaned piglets.

The additive *Saccharomyces cerevisiae* (MUCL 39885) is proposed at a minimum of 1×10^9 colony forming units (CFU)/g. Under this authorisation, the feed additive is marketed in two forms, Biosprint® S in spherical form and Biosprint® G in granular form.

Saccharomyces cerevisiae (MUCL 39885) is currently authorised for use in feed for:

- weaned piglets (assimilated Regulation (EU) 170/2011)
- sows (assimilated Regulation (EU) 2020/1094)
- dairy cows and horses (assimilated Regulation (EU) 2020/1096)
- minor ruminant species for fattening and dairy production (assimilated Regulation (EU) 2016/104)

FSA/FSS risk management recommendation

The FSA/FSS opinion is that *Saccharomyces cerevisiae* (MUCL 39885), as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use.

The FSA/FSS risk management recommendations, 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 risk management recommendations
- Safety Assessment RP24-25-26 Saccharomyces Cerevisiae (MUCL39885)

Annex B: RP25 - *Saccharomyces cerevisiae* (MUCL 39885) as a feed additive for all pigs and minor porcine species other than sows and piglets (suckling and weaned) (Biosprint®) (Prosol S.p.A.) (new use)

Background

In accordance with Article 4 of assimilated Regulation (EC) 1831/2003 and Article 7 of assimilated Regulation (EC) 1831/2003 on feed additives, application RP25 is submitted for *Saccharomyces*

cerevisiae (MUCL 39885) (Biosprint®) for a new use of authorisation as a zootechnical additive under the functional group of 'gut flora stabilisers'. The function of such feed additives is to have a positive effect on gut micro-organisms to maintain animal health and performance.

This additive is already permitted in sows and weaned piglets. The applicant requested an additional authorisation for all pigs (other than sows, weaned piglets and suckling piglets and minor porcine species at a proposed minimum of 3×10^9 colony forming units (CFU)/g. The safety assessment considered the available evidence including extrapolating from the existing uses on sows and considered that this supports use of this feed additive in the following categories:

- for all Suidae (other than suckling pigs, sows and Suidae for reproduction) 3×10^9 CFU/kg
- for all Suidae for reproduction purposes other than sows: 6.4×10^9 CFU/kg

Under this authorisation, the feed additive is marketed in two forms, Biosprint® S in spherical form and Biosprint® G in granular form.

Saccharomyces cerevisiae (MUCL 39885) is currently authorised for use in feed for:

- weaned piglets (Regulation 170/2011)
- sows (assimilated Regulation (EU) 2020/1094)
- dairy cows and horses (assimilated Regulation (EU) 2020/1096)
- minor ruminant species for fattening and dairy production (assimilated Regulation (EU) 2016/104)

FSA/FSS risk management recommendation

The FSA/FSS opinion is that *Saccharomyces cerevisiae* (MUCL 39885), as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use.

The FSA/FSS risk management recommendations, 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 risk management recommendation – add links
- Safety Assessment RP24-25-26 Saccharomyces Cerevisiae (MUCL39885)

Annex C: RP26 - *Saccharomyces cerevisiae* (MUCL 39885) as a feed additive for cats and dogs. (Biosprint®) (Prosol S.p.A.) (new use)

Background

In accordance with Article 4 of assimilated Regulation (EC) 1831/2003 and Article 7 of assimilated Regulation (EC) 1831/2003 on feed additives, application RP26 is submitted for *Saccharomyces cerevisiae* (MUCL 39885) (Biosprint®) for a new use of authorisation as a zootechnical additive under the functional group of 'gut flora stabilisers'. The function of such feed additives is to have a positive effect on gut micro-organisms to maintain animal health and performance.

The additive *Saccharomyces cerevisiae* (MUCL 39885) is proposed at a minimum of 1×10^9 colony forming units (CFU)/g for cats and dogs. Under this authorisation, the feed additive is marketed in two forms, Biosprint® S in spherical form and Biosprint® G in granular form.

Saccharomyces cerevisiae (MUCL 39885) is currently authorised for use in feed for:

- weaned piglets (assimilated Regulation (EU) 170/2011)
- sows (assimilated Regulation (EU) 2020/1094)
- dairy cows and horses (assimilated Regulation (EU) 2020/1096)
- minor ruminant species for fattening and dairy production (assimilated Regulation (EU) 2016/104)

FSA/FSS risk management recommendation

The FSA/FSS opinion is that *Saccharomyces cerevisiae* (MUCL 39885), as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use.

The FSA/FSS safety assessment and details of the proposed terms of use of the feed additives can be found on the Food Standards Agency website:

- FSA/FSS risk management recommendation – add links
- Safety Assessment RP24-25-26 Saccharomyces Cerevisiae (MUCL39885)

Annex D: RP29 – A preparation of *Pediococcus acidilactici* (CNCM I-4622) as a feed additive for all animal species (Danstar Ferment AG, Switzerland) (new)

Background

In accordance with Article 4 of assimilated Regulation (EC) 1831/2003 and Article 7 of assimilated Regulation (EC) 1831/2003 on feed additives, application RP29 is submitted for a preparation of *Pediococcus acidilactici* (CNCM I-4622) for a new authorisation as a technological additive under the functional groups ‘acidity regulator’ and ‘hygiene condition enhancer’. The function of such feed additives is to adjust the pH of feed and increase lactic acid concentration in feed respectively.

The additive *Pediococcus acidilactici* (CNCM I-4622) is proposed to be used at a minimum of 1 x 10^9 (colony forming units (CFU)/kg of complete feed with a moisture content of 12%) for all animal species.

Pediococcus acidilactici (CNCM I-4622) is currently authorised for use in feed for:

- All porcine species for fattening and for breeding, other than sows; all avian species as a gut flora stabiliser (assimilated Regulation (EU) 2020/151))

FSA/FSS risk management recommendation

The FSA/FSS opinion is that *Pediococcus acidilactici* (CNCM I-4622), as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use.

The FSA/FSS safety assessment and details of the proposed terms of use of the feed additives can be found on the Food Standards Agency website:

- FSA/FSS risk management recommendations
- Safety Assessment RP29 Pediococcus Acidilactici (CNCM I-4622)

Annex E: RP140 - Monensin sodium produced from *Streptomyces cinnamonensis* 28682 (NBIMCC 3419) as a feed additive for chickens for

fattening, chickens reared for laying and turkeys for fattening (Coxidin®) (Huvepharma NV) (renewal and modification)

Background

In accordance with Article 13 and Article 14 of assimilated Regulation (EC) 1831/2003 on feed additives, application RP140 is submitted for monensin sodium (carrier: perlite, calcium carbonate) produced by fermentation with *Streptomyces cinnamonensis* 28682 (NBIMCC 3419) (Coxidin®) for a renewal of authorisation as a coccidiostat and histomonostat feed additive, and for the modification of the withdrawal period for chickens for fattening and laying. The function of such feed additives is to maintain the health of animals through the control of gut infections (i.e., coccidiosis caused by protozoa/parasites (e.g., Eimeria species)).

Monensin sodium (Coxidin®) using perlite and calcium carbonate as carriers is proposed for use at an inclusion level of 100 – 125 mg/kg in chickens for fattening and chickens reared for laying up to 16 weeks of age, and at an inclusion level of 60 – 100 mg/kg in turkeys for fattening up to 16 weeks of age.

Perlite is present in the active substance from its use as a filtration aid to which is added calcium carbonate as a carrier to standardise the material. Perlite was previously named as a constituent in the original authorisation; we therefore continue this approach in this consultation.

Monensin sodium (Coxidin®) is currently authorised for use in feed for:

- chickens reared for laying (assimilated Regulation (EU) 140/2012)
- chickens for fattening and turkeys (assimilated Regulation (EC) 109/2007)

Of particular relevance, the authorisation of monensin sodium (Coxidin®) for chickens for fattening and turkeys was amended by assimilated Regulation (EC) 1095/2008 and introduced maximum residue limits in products of animal origin. The authorisation was further amended by assimilated Regulation (EU) 495/2011 as regards the composition of the feed additive.

A separate application, RP284, has been submitted for a new use for turkeys reared for breeding, which maintains the same active substance, characteristics and feed additive function.

FSA/FSS risk management recommendation

The FSA/FSS opinion is that monensin sodium produced from *Streptomyces cinnamonensis* 28682 (NBIMCC 3419), as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use.

The applicant requested a reduction in the withdrawal period from 1 day to 0 days for chickens for fattening and laying. Risk managers have considered the safety assessment and section 5 of the Guidance on the assessment of the safety of feed additives for the consumer that states that an experimental withdrawal up to 12 hours is considered a practical zero-day withdrawal, and recommend a reduction as requested by the applicant with extension of this recommendation to turkeys for fattening and breeding.

The FSA/FSS safety assessment and details of the proposed terms of use of the feed additives can be found on the Food Standards Agency website:

- FSA/FSS risk management recommendations
- Safety Assessment RP140-141-142-284 Monensin Sodium

Annex F: RP141 - Monensin sodium produced from *Streptomyces cinnamonensis* 28682 (NBIMCC 3419) as a feed additive for chickens for fattening and turkeys (Coxidin®) (Huvepharma NV) (renewal and modification)

Background

In accordance with Article 13 and Article 14 of assimilated Regulation (EC) 1831/2003 on feed additives, application RP141 is submitted for monensin sodium (carrier: perlite, wheat bran) produced by fermentation with *Streptomyces cinnamonensis* 28682 (NBIMCC 3419) (Coxidin®) for a renewal of authorisation as a coccidiostat and histomonostat feed additive, and for the modification of the withdrawal period for chickens for fattening. The function of such feed additives is to maintain the health of animals through the control of gut infections i.e., coccidiosis caused by protozoa/parasites (e.g., Eimeria species).

Monensin sodium (Coxidin®) using perlite and wheat bran as a carrier is proposed for use at an inclusion level of 100 – 125 mg/kg in chickens for fattening, and at an inclusion level of 60 –100 mg/kg in turkeys for fattening up to 16 weeks of age.

Perlite is present in the active substance from its use as a filtration aid to which is added wheat bran as a carrier to standardise the material. Perlite was previously named as a constituent in the original authorisation; we therefore continue this approach in this consultation.

Monensin sodium (Coxidin®) is currently authorised for use in feed for:

- Chickens for fattening and turkeys (assimilated Regulation (EC) 109/2007)

Of particular relevance, the authorisation of monensin sodium (Coxidin®) for chickens for fattening and turkeys was amended by assimilated Regulation (EC) 1095/2008 and introduced maximum residue limits in products of animal origin. The authorisation was further amended by assimilated Regulation (EU) 495/2011 as regards the composition of the feed additive.

FSA/FSS risk management recommendation

The FSA/FSS opinion is that monensin sodium (Coxidin®), as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use.

The applicant requested a reduction in the withdrawal period from 1 day to 0 days. Risk managers have considered the safety assessment and section 5 of the Guidance on the assessment of the safety of feed additives for the consumer states that an experimental withdrawal up to 12 hours is considered a practical zero-day withdrawal and recommend a reduction as requested by the applicant with extension of this recommendation to turkeys for fattening and breeding.

The FSA/FSS safety assessment and details of the proposed terms of use of the feed additives can be found on the Food Standards Agency website:

- FSA/FSS risk management recommendations
- Safety Assessment RP140-141-142-284 Monensin Sodium

Annex G: RP142 - Monensin sodium produced from *Streptomyces cinnamonensis* 28682 (NBIMCC 3419) as a feed additive for chickens reared for laying and turkeys reared for breeding (Coxidin®) (Huvepharma NV) (new

use)

Background

In accordance with Article 4 and Article 7 of assimilated Regulation (EC) 1831/2003 on feed additives, application RP142 is submitted for monensin sodium (carrier: perlite, wheat bran) produced by fermentation with *Streptomyces cinnamonensis* 28682 (NBIMCC 3419) (Coxidin®) for a new use (extension of species) of authorisation as a coccidiostat and histomonostat feed additive. The function of such feed additives is to maintain the health of animals through the control of gut infections (i.e., coccidiosis caused by protozoa/parasites (e.g., Eimeria species).

Monensin sodium (Coxidin®) using perlite and wheat bran as a carrier is proposed for use at an inclusion level of 100 –125 mg/kg in chickens reared for laying up to 16 weeks of age, and at an inclusion level of 60 –100 mg/kg in turkeys reared for breeding up to 16 weeks of age.

Perlite is present in the active substance from its use as a filtration aid to which is added wheat bran as a carrier to standardise the material. Perlite was previously named as a constituent in the original authorisation; we therefore continue this approach in this consultation.

Monensin sodium (Coxidin®) is currently authorised for use in feed for:

- chickens for fattening and turkeys (assimilated Regulation (EU) 109/2007)

The applicant has requested extension in use from ‘chickens for fattening’ and ‘turkeys for fattening’ to include ‘chickens reared for laying’ and ‘turkeys reared for breeding’, intending to expand the renewal request of application RP141. Whilst assimilated Commission Regulation (EC) No. 109/2007 simply refers to turkeys, in practice this means ‘turkeys for fattening’.

Of particular relevance, the authorisation of Monensin sodium (Coxidin®) for chickens for fattening and turkeys was amended by assimilated Regulation (EC) 1095/2008 and introduced maximum residue limits in products of animal origin. The authorisation was further amended by assimilated Regulation (EC) 495/2011 as regards the composition of the feed additive.

FSA/FSS risk management recommendation

The FSA/FSS opinion is that monensin sodium (Coxidin®), as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use.

The FSA/FSS safety assessment and details of the proposed terms of use of the feed additives can be found on the Food Standards Agency website:

- FSA/FSS risk management recommendations
- Safety Assessment RP140-141-142-284 Monensin Sodium

Annex H: RP185 - 6–phytase (EC 3.1.3.26) produced from *Komagataella phaffii* (formerly *Komagataella pastoris*) (DSM 23036) as a feed additive for all avian species and all pigs (OptiPhos®) (Huvepharma EOOD) (Renewal, new use and modification)

Background

In accordance with Article 4, Article 7, Article 13 and Article 14 of assimilated Regulation (EC) 1831/2003 on feed additives, application RP185 is submitted for the enzyme preparation of 6-

phytase (EC 3.1.3.26) produced by fermentation with *Komagataella phaffii* (formerly *Komagataella pastoris*) (DSM 23036) for renewal of authorisation and a new use (extension of species) with modification, as a zootechnical feed additive under the functional group of 'digestibility enhancers'. The function of such feed additives is to enhance the digestibility of animal diets.

An application was submitted for the feed additive authorisation for all avian species and all pigs.

The preparation of 6-phytase (EC 3.1.3.26) produced from K. phaffii (DSM 23036) (OptiPhos®) is currently authorised for use in feed for:

- chickens for fattening, chickens reared for laying, laying hens, other avian species other than turkeys for fattening and turkeys reared for breeding, sows, turkeys for fattening, turkeys reared for breeding, pigs for fattening, piglets (weaned) (assimilated Regulation (EU) 2020/2121)
- fish (assimilated Regulation (EU) 2017/2274)

The new use (extrapolation of species) is proposed to extend to all avian species and all pigs.

The additive is proposed for use with a minimum activity of 4,000 OTU/g* in solid form and 8,000 OTU/g in liquid form. * 1 OTU is the amount of enzyme that catalyses the release of one micromole of inorganic phosphate per minutes form 5.1 mM sodium phytate in pH 5.5 citrate buffer at 37º C, measured as the blue phosphorus-molybdate complex colour at 820nm.

The application is also submitted for a modification of the authorised product name from '*Komagataella pastoris*' to the specific strain 'Komagataella phaffi'.

FSA/FSS risk management recommendation

The FSA/FSS opinion is that 6-phytase (EC 3.1.3.26), as described in this application, is safe and is not liable to have an adverse effect on target species, environmental safety and human health under the proposed conditions of use.

The FSA/FSS safety assessment and details of the proposed terms of use of the feed additives can be found on the Food Standards Agency website:

- FSA/FSS risk management recommendations
- Safety Assessment RP185 6-Phytase from Komagataella Phaffii (DSM 23036)

Annex I-Q: RP222, RP284, RP641, RP1105, RP1125, RP1126, RP1198, RP1199 Part A and Part B

Annex I: RP222 - Selenised yeast produced from *Saccharomyces cerevisiae* (CNCM I-3060), inactivated as a feed additive for all animal species (All-Technology (Ireland) Limited) (modification)

Background

In accordance with Article 13 of assimilated Regulation (EC) 1831/2003 on feed additives, application RP222 is submitted for selenised yeast produced from *Saccharomyces cerevisiae* (CNCM I-3060), inactivated, for a modification of authorisation as a nutritional feed additive under the functional group of compounds of trace elements. The function of such feed additives is to provide essential micro-nutrients to animal diets.

An application was submitted for modification (increase of selenium content) of the feed additive requesting selenium (Se) content from 2000 mg Se/kg to 3500 mg Se/kg.

Selenised yeast produced from *Saccharomyces cerevisiae* (CNCM I-3060), inactivated, is currently authorised for use in feed for:

- All animal species (assimilated Regulation (EU) 2019/804)

FSA/FSS risk management recommendation

The FSA/FSS opinion is that selenised yeast Saccharomyces cereviisiae (CNCM I-3060), inactivated, as described in this application, is safe and is not liable to have an adverse effect on all animal species, environmental safety and human health under the proposed conditions of use.

The FSA/FSS safety assessment and details of the proposed terms of use of the feed additives can be found on the Food Standards Agency website:

- FSA/FSS risk management recommendations
- Safety Assessment RP222 Selenised Yeast Saccharomyces Cerevisiae (CNCM I-3060), inactivated

Annex J: RP284 - Monensin sodium produced from *Streptomyces cinnamonensis* 28682 (NBIMCC 3419) as a feed additive for turkeys reared for breeding (Coxidin®) (Huvepharma NV) (new use)

Background

In accordance with Article 4 and Article 7 of assimilated Regulation (EC) 1831/2003 on feed additives, application RP284 is submitted for monensin sodium (carrier: perlite, calcium carbonate) produced by fermentation with *Streptomyces cinnamonensis* 28682 (NBIMCC 3419) (Coxidin®) for a new use (extension of species) of authorisation as a coccidiostat and histomonostat feed additive. The function of such feed additives is to maintain the health of animals through the control of gut infections (i.e., coccidiosis caused by protozoa/parasites (e.g., Eimeria species).

Monensin sodium using calcium carbonate and perlite as a carrier is submitted at an inclusion level 60 –100 mg/kg in turkeys reared for breeding up to 16 weeks of age.

Perlite is present in the active substance from its use as a filtration aid to which is then added calcium carbonate as a carrier to standardise the material. Perlite was previously named as a constituent in the original authorisation; we therefore continue this approach in this consultation.

Monensin sodium (Coxidin®) is currently authorised use in feed for:

- chickens reared for laying (assimilated Regulation (EC) 140/2012)
- chickens for fattening and turkeys (assimilated Regulation (EC) 109/2007)

The applicant has requested extension in use from ‘chickens for fattening’ and ‘turkeys for fattening’ to include ‘turkeys reared for breeding’, intending to expand the renewal request of application RP140. Whilst assimilated Commission Regulation (EC) 109/2007 simply refers to turkeys in practice this means ‘turkeys for fattening’.

Of particular relevance, the authorisation of Coxidin® for chickens for fattening and turkeys was amended by assimilated Regulation (EC) 1095/2008 and introduced maximum residue limits in

products of animal origin. The authorisation was further amended by assimilated Regulation (EU) 495/2011 as regards the composition of the feed additive.

FSA/FSS risk management recommendation

The FSA/FSS opinion is that monensin sodium (Coxidin®), as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use.

The FSA/FSS safety assessment and details of the proposed terms of use of the feed additives can be found on the Food Standards Agency website:

- FSA/FSS risk management recommendations
- Safety Assessment RP140-141-142-284 Monensin Sodium

Annex K: RP641 – A preparation of *Bacillus velezensis* (formerly *Bacillus subtilis* C-3102) (DSM 15544) as a feed additive for weaned piglets and all avian species (Calsporin®) (Asahi Biocycle Co., Ltd) (renewal, new use and modification)

Background

In accordance with Article 4, Article 7, Article 13 and Article 14 of assimilated Regulation (EC) 1831/2003 on feed additives, application RP641 is submitted for a preparation of *Bacillus velezensis* (formerly *Bacillus subtilis* C-3102) (DSM 15544) (Calsporin®) for renewal of authorisation, modification, and a new use (extrapolation of species) in accordance with as a zootechnical feed additive under the functional group of gut flora stabilisers. The function of such feed additives is to have a positive effect on gut micro-organisms to maintain animal health and performance.

An application was submitted for the feed additive authorisation for weaned piglets and all avian species.

Bacillus velezensis (formerly *Bacillus subtilis* C-3102) (DSM 15544) is currently authorised for use in feed for:

- chickens for fattening (assimilated Regulation (EU) 2019/893)
- weaned piglets (assimilated Regulation (EU) 333/2010)
- chickens reared for laying, turkeys, minor avian species and other ornamental and game birds (assimilated Regulation (EU) 184/2011)
- laying hens and ornamental fish (assimilated Regulation (EU) 2016/897)
- sows, suckling piglets, dogs (assimilated Regulation (EU) 2017/2312)
- pigs for fattening (assimilated Regulation (EU) 2018/1081)

The new use (extrapolation of species) is proposed to extend to all avian species.

In addition, the applicant requests a modification of authorisation (in accordance with Article 13 of assimilated Regulation (EC) 1831/2003 to reduce the minimum content from 5×10^8 to 3×10^8 colony forming units (CFU)/kg of complete feed with a moisture content of 12% for chickens reared for laying and to change the taxonomic strain name from *Bacillus subtilis* to *Bacillus velezensis* (DSM15544) (the latter being relevant for all existing authorisations of this feed additive) .

The applicant also requests that the name of authorisation holder is updated from ‘Asahi Calpis Wellness Co. Ltd. (represented by Pen & Tec Consulting S.L.U)’ to ‘Asahi Biocycle Co., Ltd, (represented by Pen & Tec Consulting S.L.U., now trading as Argenta)’ for all authorisations of this feed additive.

FSA/FSS risk management recommendation

The FSA/FSS opinion is that *Bacillus velezensis* (DSM 15544), as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use.

The FSA/FSS safety assessment and details of the proposed terms of use of the feed additives can be found on the Food Standards Agency website:

- FSA/FSS risk management recommendations
- Safety Assessment RP641 Bacillus Velezensis (DSM 15544)

Annex L: RP1105 - L-histidine monohydrochloride monohydrate produced from *Escherichia coli* (KCCM 80212) as a feed additive for all animal species (Daesang Europe B.V.) (new)

Background

In accordance with Article 4 and Article 7 of assimilated Regulation (EC) 1831/2003 on feed additives, application RP1105 is submitted for L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* (KCCM 80212) for a new authorisation as a nutritional feed 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.

An application was submitted for the feed additive authorisation for all animal species.

L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* (KCCM 80212) is proposed without minimum or maximum concentrations of the additive.

FSA/FSS risk management recommendation

The FSA/FSS opinion is that L-histidine monohydrochloride monohydrate, as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use.

The FSA/FSS safety assessment and details of the proposed terms of use of the feed additives can be found on the Food Standards Agency website:

- FSA/FSS risk management recommendations
- Safety Assessment RP1105 L-Histidine

Annex M: RP1125 - L-tryptophan produced from *Escherichia coli* (KCCM 80210) as a feed additive for all animal species. (Daesang Europe B.V.) (new)

Background

In accordance with Article 4 and Article 7 of assimilated Regulation (EC) 1831/2003 on feed additives, application RP1125 is submitted for L-tryptophan produced by fermentation with *Escherichia coli* (KCCM 80210) for a new authorisation as a nutritional feed 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.

An application was submitted for the feed additive authorisation for all animal species.

L-tryptophan produced by fermentation with *Escherichia coli* (KCCM 80210) is proposed for use without minimum or maximum concentrations of the additive.

FSA/FSS risk management recommendation

The FSA/FSS opinion is that L-tryptophan, as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use.

The FSA/FSS safety assessment and details of the proposed terms of use of the feed additives can be found on the Food Standards Agency website:

- FSA/FSS risk management recommendations
- Safety Assessment RP1125 L-Tryptophan

Annex N: RP1126 - L-lysine sulphate produced from *Corynebacterium glutamicum* (KCCM 80227) as a feed additive for all animal species. (Daesang Europe B.V.) (new)

Background

In accordance with Article 4 and Article 7 of assimilated Regulation (EC) 1831/2003 on feed additives, application RP1126 is submitted for L-lysine sulphate produced by fermentation with *Corynebacterium glutamicum* (KCCM 80227) for a new authorisation as a nutritional feed 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.

An application was submitted for the feed additive authorisation for all animal species.

L-lysine sulphate produced by fermentation with *Corynebacterium glutamicum* (KCCM 80227) is proposed for use at a maximum of 10,000 mg additive/kg of lysine in complete feed with a moisture content of 12%.

FSA/FSS risk management recommendation

The FSA/FSS opinion is that L-lysine sulphate, as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health at the intended concentrations of use.

The FSA/FSS safety assessment and details of the proposed terms of use of the feed additives can be found on the Food Standards Agency website:

- FSA/FSS risk management recommendations
- Safety Assessment RP1126 L-Lysine Sulfate

Annex O: RP1198 - Butylated hydroxyanisole (BHA) as a feed additive for cats (FEDIAF) (new)

Background

In accordance with Article 4 and Article 7 of assimilated Regulation (EC) 1831/2003 on feed additives, application RP1198 is submitted for butylated hydroxyanisole (BHA) for a new authorisation as a technological feed additive under the functional group of antioxidants. Such feed additives are intended to prolong the storage life of feed by protecting them against deterioration caused by oxidation. authorisation as a technological feed additive under the functional group of antioxidants. Such feed additives are intended to prolong the storage life of feed by protecting them against deterioration caused by oxidation.

BHA is currently authorised for use in feed for:

- all animal species except cats (assimilated Regulation (EU) 2020/1399)

Whilst this feed additive is currently authorised for use in cats, this authorisation is maintained through article 10(1) and (3) of assimilated Regulation (EC) 1831/2003 (in accordance with the conditions specified in Directive 70/524/EEC and its implementing measures). The authorisation is only maintained pending the necessary legislation under article 10(5) of assimilated Regulation (EC) 1831/2003 requiring its removal from the market. This new authorisation application has been made in light of the afore mentioned pending legislation under article 10(5).

FSA/FSS risk management recommendation

The FSA/FSS opinion is that butylated hydroxyanisole (BHA), as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use.

The FSA/FSS safety assessment and details of the proposed terms of use of the feed additives can be found on the Food Standards Agency website:

- FSA/FSS risk management recommendations
- Safety Assessment RP1198 Butylated Hydroxyanisole (BHA)

Annex P: RP1199 Part A - L-lysine base (liquid) produced from *Corynebacterium glutamicum* (KCCM 80183) as a feed additive for all animal species. (CJ Europe GmbH) (new)

Background

In accordance with Article 4 and Article 7 of assimilated Regulation (EC) 1831/2003 on feed additives, application RP1199 Part A is submitted for L-lysine base (liquid) produced by fermentation with *Corynebacterium glutamicum* (KCCM 80183) for a new authorisation as a nutritional feed 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.

An application was submitted for the feed additive authorisation for all animal species.

L-lysine base (liquid) produced by fermentation with *Corynebacterium glutamicum* (KCCM 80183) is proposed without minimum or maximum concentrations of the additive.

FSA/FSS risk management recommendation

The FSA/FSS opinion is that L-lysine base (liquid), as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use.

The FSA/FSS safety assessment and details of the proposed terms of use of the feed additives can be found on the Food Standards Agency website:

- FSA/FSS risk management recommendations
- Safety Assessment RP1199 L-Lysine

Annex Q: RP1199 Part B - L-lysine monohydrochloride (technically pure) produced from *Corynebacterium glutamicum* (KCCM 80183) as a feed for all animal species (CJ Europe GmbH) (new)

Background

In accordance with Article 4 and Article 7 of assimilated Regulation (EC) 1831/2003 on feed additives, application RP1199 Part B is submitted for L-lysine monohydrochloride (technically pure) produced by fermentation with *Corynebacterium glutamicum* (KCCM 80183) for a new authorisation as a nutritional feed 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.

An application was submitted for the feed additive authorisation for all animal species.

L-lysine monohydrochloride (technically pure) produced by fermentation with *Corynebacterium glutamicum* (KCCM 80183) is proposed without minimum or maximum concentrations of the additive.

FSA/FSS risk management recommendation

The FSA/FSS opinion is that L-lysine monohydrochloride, as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use.

The FSA/FSS safety assessment and details of the proposed terms of use of the feed additives can be found on the Food Standards Agency website:

- FSA/FSS risk management recommendations
- Safety Assessment RP1199 L-Lysine

Annex R-Z: RP1200, RP1259, RP1349, RP1386, RP1387, RP1388, RP1591, RP1654, RP658

Annex R: RP1200 - Disodium 5’-guanylate produced from *Corynebacterium stationis* (KCCM 10530) and *Escherichia coli* (KFCC 11067) as a feed additive for all animal species (CJ Europe GmbH) (new)

Background

In accordance with Article 4 and Article 7 of assimilated Regulation (EC) 1831/2003 on feed additives, application RP1200 is submitted for disodium 5’-guanylate produced by fermentation with *Corynebacterium stationis* (KCCM 10530) and *Escherichia coli* (KFCC 11067) for a new authorisation as a sensory feed additive under the functional group of flavouring compounds. The function of such feed additives is to increase feed smell or palatability.

An application was submitted for the feed additive authorisation for all animal species.

Disodium 5’-guanylate (GMP) is currently authorised for use in feed for:

- All animal species where produced by ribonucleic acid (RNA) hydrolysis (assimilated Regulation (EU) 2018/238)

FSA/FSS risk management recommendation

The FSA/FSS opinion is that Disodium 5’-guanylate, as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use.

The FSA/FSS safety assessment and details of the proposed terms of use of the feed additives can be found on the Food Standards Agency website:

- FSA/FSS risk management recommendations
- Safety Assessment RP1200 Disodium 5’-Guanylate

Annex S: RP1259 - Muramidase (3.2.1.17) produced from *Trichoderma reesei* (DSM 32338) as a feed additive for weaned piglets (Balancius®) (DSM Nutritional Products Ltd) (new use)

Background

In accordance with Article 4 and Article 7 of assimilated Regulation (EC) 1831/2003 on feed additives, application RP1259 is submitted for muramidase (3.2.1.17) produced by fermentation with *Trichoderma reesei* (DSM 32338) (Balancius®) for a new use authorisation as a zootechnical feed additive under the functional group of other zootechnical additives. The function of such feed additives is to improve feed efficiencies and animal performance.

An application was submitted for a new use (extension of species) authorisation for weaned piglets. The additive is marketed in solid (GT) and liquid (L) forms each and is proposed with a minimum activity of 60,000 LSU(F)/g*. The feed additive is intended to be used as a minimum level of 50000 LSU(F)/kg and a maximum of 65 000 LSU(F)/kg in complete feed with a moisture content of 12%.

Muramidase (3.2.1.17) produced by T. reesei (DSM 32338) (Balancius®, previously Lysozyme®) is currently authorised for use in feed for:

- Chickens for fattening, minor poultry species for fattening (assimilated Regulation (EU) 2019/805)
- Chickens reared for breeding, turkeys for fattening, turkeys reared for breeding, and other poultry species reared for breeding (assimilated Regulation (EU) 2020/163)

* 1 LSU(F) is defined as the amount of enzyme that increases the fluorescence of 12.5 µg/ml fluorescein-labelled peptidoglycan per minute at pH 6.0 and 30°C by a value that corresponds to the fluorescence of approximately 0.06 nmol fluorescein isothiocyanate isomer.

FSA/FSS risk management recommendation

The FSA/FSS opinion is that Muramidase (EC 3.2.1.17) as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use.

The FSA/FSS safety assessment and details of the proposed terms of use of the feed additives can be found on the Food Standards Agency website:

- FSA/FSS risk management recommendations
- Safety Assessment RP1259 Muramidase

Annex T: RP1349 – Phytomenadione (vitamin K1) as a feed additive for horses (JARAZ Enterprises GmbH & Co. KG) (new)

Background

In accordance with Article 4 and Article 7 of assimilated Regulation (EC) 1831/2003 on feed additives, application RP1349 is submitted for phytomenadione (vitamin K1) for a new authorisation as a nutritional feed additive under the functional group of vitamins, pro-vitamins and chemically well-defined substances having similar effect. The function of such additives is to provide essential micro-nutrients to animal diets.

An application was submitted for the feed additive authorisation for horses.

Phytomenadione (vitamin K1) is proposed for use without minimum or maximum concentrations of the additive.

FSA/FSS risk management recommendation

The FSA/FSS opinion is that Phytomenadione, as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use.

The FSA/FSS safety assessment and details of the proposed terms of use of the feed additives can be found on the Food Standards Agency website:

- FSA/FSS risk management recommendations
- Safety Assessment RP1349 Vitamin K1

Annex U: RP1386 - Copper chelate of hydroxy analogue of methionine as a feed additive for all animal species (Novus Europe NV) (renewal and modification)

Background

In accordance with Article 13 and Article 14 of assimilated Regulation (EC) 1831/2003 on feed additives, application RP1386 is submitted for copper chelate of hydroxy analogue of methionine for a renewal and modification of authorisation as a nutritional feed additive under the functional group of compounds of trace elements. The function of such feed additives is to provide essential micro-nutrients to animal diets.

An application was submitted for the feed additive authorisation for all animal species.

Copper chelate of hydroxy analogue of methionine is currently authorised for use in feed for:

- All animal species (assimilated Regulation (EU) 349/2010)

The application referred to modifications in the manufacturing process so that the additive no longer contains mineral oil. As a result, the applicant proposed a modification of the specification to better reflect the variability of the material. The ID number has also been updated. No changes are proposed for the maximum concentrations of the additive specific to target species.

FSA/FSS risk management recommendation

The FSA/FSS opinion is that copper chelate of hydroxy analogue of methionine, as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use.

The FSA/FSS safety assessment and details of the proposed terms of use of the feed additives can be found on the Food Standards Agency website:

- FSA/FSS risk management recommendations
- Safety Assessment RP1386 Copper Chelate of Hydroxy Analogue of Methionine

Annex V: RP1387 - Manganese chelate of hydroxy analogue of methionine as a feed additive for all animal species (Novus Europe NV) (renewal and modification)

Background

In accordance with Article 13 and Article 14 of assimilated Regulation (EC) 1831/2003 on feed additives, application RP1387 is submitted for manganese chelate of hydroxy analogue of methionine for a renewal of authorisation as a nutritional feed additive under the functional group of compounds of trace elements. The function of such feed additives is to provide essential micro-nutrients to animal diets.

An application was submitted for the feed additive authorisation for all animal species.

Manganese chelate of hydroxy analogue of methionine is currently authorised for use in feed for:

- All animal species (assimilated Regulation (EU) 350/2010)

The application referred to modifications in the manufacturing process so that the additive no longer contains mineral oil. As a result, the applicant proposed new specifications to better reflect the variability of the material. Analytical method(s) have been updated to reflect more modern techniques as appropriate. The ID number has also been adapted.

FSA/FSS risk management recommendation

The FSA/FSS opinion is that Manganese chelate of hydroxy analogue of methionine as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use.

The FSA/FSS safety assessment and details of the proposed terms of use of the feed additives can be found on the Food Standards Agency website:

- FSA/FSS risk management recommendations
- Safety Assessment RP1387 Manganese Chelate of Hydroxy Analogue of Methionine

Annex W: RP1388 - Zinc chelate of hydroxy analogue of methionine as a feed additive for all animal species (Novus Europe NV) (renewal and modification)

Background

In accordance with Article 13 and Article 14 of assimilated Regulation (EC) 1831/2003 on feed additives, application RP1388 is submitted for zinc chelate of hydroxy analogue of methionine for a renewal and modification of authorisation as a nutritional feed additive under the functional group of compounds of trace elements. The function of such feed additives is to provide essential micro-nutrients to animal diets.

An application was submitted for the feed additive authorisation for all animal species.

Zinc chelate of hydroxy analogue of methionine is currently authorised for use in feed for:

- All animal species (assimilated Regulation (EU) 335/2010)

The application referred to modifications in the manufacturing process so that the additive no longer contains mineral oil. As a result, the applicant proposed new specifications to better reflect the variability of the material. The ID number has been adapted to reflect that in the EU in format.

FSA/FSS risk management recommendation

The FSA/FSS opinion is that zinc chelate of hydroxy analogue of methionine, as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use.

The FSA/FSS safety assessment and details of the proposed terms of use of the feed additives can be found on the Food Standards Agency website:

- FSA/FSS risk management recommendations
- Safety Assessment RP1388 Zinc Chelate of Hydroxy Analogue of Methionine

Annex X: RP1591 - Fumonisin esterase (EC 3.1.1.87) produced from *Komagataella phaffii* (DSM 32159) as a feed additive for all animal species (DSM Nutritional Products Ltd, Switzerland) (new use)

Background

In accordance with Article 4 and Article 7 of assimilated Regulation (EC) 1831/2003 on feed additives, application RP1591 is submitted for fumonisin esterase (EC 3.1.1.87) produced by fermentation with Komagataella phaffii (DSM 32159) for a new use (extension of species) of authorisation as a technological feed additive under the functional group of substances for reduction of the contamination of feed by mycotoxins: fumonisins. The function of such feed additives are intended to reduce mycotoxin contamination in animal feed.

An application was submitted for the feed additive authorisation for all animal species.

Fumonisin esterase (EC 3.1.1.87) produced by fermentation with K. phaffii (DSM 32159) is currently authorised for use in feed for:

- All pigs and all poultry species assimilated Regulation (EU) 2018/1568)

FSA/FSS risk management recommendation

The FSA/FSS opinion is that Fumonisin esterase (EC 3.1.1.87), as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use.

The FSA/FSS safety assessment and details of the proposed terms of use of the feed additives can be found on the Food Standards Agency website:

- FSA/FSS risk management recommendations
- Safety Assessment RP1591 Fumonisin Esterase

Annex Y: RP1654 - Ecobiol® (Bacillus amyloliquefaciens CECT 5940) and Fecinor® (Enterococcus faecium CECT 4515) (Evonik Operations GmbH) (modification) administrative change of authorisation holder

Background

In accordance with Article 13 of assimilated Regulation (EC) 1831/2003 on feed additives, application RP1654 is submitted for administrative amendments to be made to change the authorisation holder. The administrative amendments requested are with current authorisations that remain applicable to Great Britain.

Enterococcus faecium (CECT 4515) is currently authorised for use in feed for:

- Weaned piglets (assimilated Regulation (EU) 2017/961)

Bacillus amyloliquefaciens (CECT 5940) is currently authorised for use in feed for:

- Chickens for fattening and chickens for laying (assimilated Regulation (EU) 2020/1395)

The applicant requests modification of authorisations to amend the name of the holder of authorisation from ‘Evonik Nutrition & Care GmbH’ to ‘Evonik Operations GmbH’.

FSA/FSS risk management recommendation

The FSA/FSS are satisfied that the administrative changes do not require new assessments of the additives.

Annex Z: RP658 Modification of entry number 60 of the PARNUT regulation, ‘Reduction of the risk of milk fever and subclinical hypocalcaemia’ as a feed for particular nutritional purposes for dairy cows (Prince Agri Products, Inc) (modification)

Background

In accordance with Article 9 of assimilated Regulation (EC) 767/2009 on feed for particular nutritional purposes (PARNUT), application RP658 is submitted to modify the entry number 60 ‘Reduction of the risk of milk fever and subclinical hypocalcaemia’ of part B of the annex to assimilated Regulation 2020/354 establishing a list of intended uses of feed intended for particular nutritional purposes (PARNUT).

Section one of the current entry 60 of Part B of the Annex to assimilated Regulation 2020/354 contains the following essential nutritional characteristics:
Low cations/anions ratio
For the total ration:

- Minimum acidification via feed for particular nutritional purpose: 100 mEq/kg dry matter
- Objective: 0 < DCADs (mEq/kg dry matter) < 100

DCAD (mEq/kg dry matter) = (Na + K) – (Cl + S) The new proposal is to adapt this to provide dietary cation-anion difference (DCAD) at a minimum of -200 mEq/kg and a maximum of 100mE/kg of dry matter for the total ration.

FSA/FSS risk management recommendation

The FSA/FSS opinion is that the modification of entry number 60 of Part B of the Annex to assimilated Regulation 2020/354, ‘Reduction of the Risk of Milk Fever and Subclinical Hypocalcaemia’ as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health at the intended concentrations of use.

The FSA/FSS safety assessment and details of the proposed terms of use of the feed additives can be found on the Food Standards Agency website:

- FSA/FSS risk management recommendations
- Safety Assessment RP658 Reduction of the Risk of Milk Fever and Subclinical Hypocalcaemia in Dairy Cows