Consultation on applications for eleven Additives for Use in Animal Feed

Launch date: 7 March 2022

Respond by: 2 May 2022

This consultation will be of most interest to

- Animal feed manufacturers, importers/exporters and retailers
- All feed purchasers, including for food and non-food producing animals
- Trade bodies representing stakeholders on animal feed, agriculture and the environment
- Trade unions representing stakeholders in the farming industry
- Organisations representing consumer interests in the feed and food-chains
- Enforcement Authorities

A list of interested parties is included in Annex A.

Consultation subject and purpose

This consultation is to seek stakeholders' views, comments and feedback in relation to the regulated product applications considered in this document, which have been submitted for authorisation and proposed transitional periods. 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 is stakeholders' opportunity for input on the advice given to Ministers to inform decision making.

The FSA/FSS opinions, and the views gathered through this consultation, will be considered and included alongside those of Officials of the Devolved Governments in Northern Ireland, Scotland and Wales and UK Government Departments other than the FSA to inform Ministers' decision making on whether to authorise the individual feed additives for use in England, Scotland and Wales.

A parallel consultation is being published by FSS.

How to respond

Responses to this consultation should be sent to:
Email: RPconsultations@food.gov.uk
Name: Regulated Products Approvals Team
Division/Branch: Chemical Safety Policy Unit

Details of consultation

In accordance with Retained EU Regulation 1831/2003 (REUL 1831/2003) on feed additives, the applications included in this consultation have been submitted for authorisation.

Eleven feed additives have been submitted for authorisation in each nation of Great Britain (GB), where the decision on authorisation is made by the respective Ministers in England, Scotland and Wales. Protection of public health in relation to the consumption of food and consumer interests in relation to food and feed in the UK is the responsibility of FSA/FSS and the authorisation of regulated products is the responsibility of the relevant appropriate authority of each of the nations of GB.

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. Applications for which transitional arrangements have been proposed are RP130, RP131 and RP1030. Details of the rationale behind these proposals can be found in the introduction to the FSA/FSS opinion. In addition to seeking views on the applications in this consultation, the FSA is also inviting comment on the proposed transitional arrangements for RP130, RP131 and RP1030as outlined in the relevant FSA/FSS opinions.

In respect to Northern Ireland, EU Food Law on feed additives continues to apply under the current terms of the Protocol on Ireland/Northern Ireland (NIP). This means feed additives require authorisation under the EU's authorisation procedures before being placed on the market in Northern Ireland.

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

Introduction

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 following the UK's exit from the EU. Regulated product applications for the GB market, including feed additives, are now subject to the UK's own risk analysis process, with FSA/FSS continuing to provide advice to Ministers (Appropriate Authority) on matters of food safety.

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 below. In order to place new feed additives on the GB market, an application shall be submitted in accordance with REUL 1831/2003. Feed additives are authorised for a ten-year period and can be considered for renewal where an application is re-submitted, at the latest, one-year prior to its expiry. The procedure for each type of application is laid down in REUL 1831/2003 as follows:

- Article 4 application for a new feed additive or a new use of a feed additive
- Article 10 application for re-evaluation of existing feed additives
- Article 13 application for modification of authorisation
- Article 14 application for a renewal of authorisation

Following 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. Details of the individual feed additives are given in the annexes. FSA/FSS advice to Ministers, subject to views

gathered in the consultation, will be to authorise these feed additives on the proposed terms as outlined in the FSA/FSS risk assessment opinions.

In line with FSA/FSS' responsibility to provide advice to Ministers in respect of matters connected with food and feed safety or other interests of consumers in relation to food and feed (sections 6 and 9, Food Standards Act 1999), we have identified factors which may inform Ministerial decision making. The outline of these factors also take into account the impact of any decision ultimately made by Ministers, whether this is to authorise or not. 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.

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 cross-government forums with the Department of Health and Social Care (DHSC), Welsh Government and Scottish Government. The content of this consultation represents the views of FSA/FSS and the factors that FSA/FSS has identified as relevant to these applications. Final advice will be agreed on a four-nation basis before being presented to Ministers.

Impacts

As part of the risk analysis process, FSA/FSS have assessed the impacts that would result from authorisation of these feed additives, should Ministers decide to authorise. 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 food and feed law (i.e. Local Authority Delivery, Health, Environment, Growth, Innovation, Trade, Competition, Consumer Interests or Small and Micro Businesses). The authorisation of these products should generally result in greater market competition supporting growth and innovation in the sector.

Under the provisional common framework for Food and Feed Safety and Hygiene, Northern Ireland continues to have full participation 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.

The majority of Feed Additives included in the consultation have been authorised for use in Northern Ireland, in line with legislation that applies in Northern Ireland, under the Northern Ireland Protocol.

Application RP131 is already on the market, as the application is for renewal, as well as a modification which is being requested for an extrapolation of species that the additive can be used for. The EFSA opinion indicates that the uses proposed for this Feed Additive are safe for use, which aligns to the UK position.

Differential timings and/or decisions in the UK or EU will result in temporarily different rules which may have impacts on what the Feed Additive can be used for. Further detail on this application is available in Annex G.

Engagement and Consultation Process

Details of all validated applications for regulated products are published 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 on the safety of the feed additives which have not been considered below with respect to the intended animal species, consumers (in consumption of animal products), workers/users, stakeholders or 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 the FSA/FSS opinions)?

3. Do you have any views on transitional periods in the withdrawal of existing feed additive authorising legislation proposed for RP130, RP131 and RP1030?

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 2 May 2022. 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.

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

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

Please send response to RPconsultations@food.gov.uk

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

Responses will be shared with FSS.

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,

Mark Bond
Feed Additives Policy Advisor
Chemical Safety Policy Unit

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 across the wider agri-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)
- Pet Food Manufacturers' Association (PFMA)

This is not an exhaustive list.

Annex B: RP15 - Manganese chelate of lysine and glutamic acid as a feed additive for all animal species (Zinpro Animal Nutrition) (new)

Background

In accordance with Article 4 of REUL 1831/2003 on feed additives, application RP15 is submitted for manganese chelate of lysine and glutamic acid (manganese-LG) for a new 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 minerals to animal diets.

The additive is intended to be used in feed for all animal species/categories as a source of manganese (Mn) up to its total maximum content allowed in feed under REUL 1831/2003 at 100 mg Mn/kg complete feed for fish and 150 mg Mn/kg complete feed for all other animal species. The original application to the EU proposed the use of manganese-LG in water for drinking at half of the dose in feed, and whilst considered by the European Food Safety Authority (EFSA), the use of manganese-LG in water was not requested within the GB application, and therefore is not considered further under this authorisation proposal.

Proposed terms of authorisation

The proposed terms of authorisation are outlined in the FSA/FSS opinion, and the opinion has concluded that this product is safe to be authorised on those terms.

Any relevant provisions of retained EU law

Under the requirements of REUL 1831/2003 for feed additives:

1. Article 16: Labelling and packaging requirements.

2. Article 21: Analytical methods have been verified as used for the control of the manganese chelates of lysine and glutamic acid in animal feed. Valid analytical methods exist for:

    - quantification of total manganese in the feed additive, premixtures and feedingstuffs
    - quantification of lysine and glutamic acid in the feed additive

- determining the chelated state of the feed additive

Other legitimate factors identified that Ministers may consider in making decisions

The next step of the authorisation process is for Ministers to make decisions on authorisation. Taking into account the FSA/FSS opinion, Ministers could decide to authorise the product. As the opinion has concluded that the product is safe to be authorised based on the proposed terms, FSA/FSS views are that there are no reasons for Ministers to refuse authorisation unless there are other legitimate factors that might indicate otherwise. In presenting advice and assisting Ministers the FSA and FSS are acting pursuant to their functions under the Food Standards Act 1999 and Food (Scotland) Act 2015. FSA/FSS has not identified any other legitimate factors that would prevent authorisation taking place, so unless the responses to this consultation identify any other legitimate factors Ministers must take into account in making decisions on authorisation, the FSA/FSS advice to Ministers will be to authorise on the proposed terms outlined in the opinion.

Our collective assessment of the other legitimate factors Ministers may consider in making decisions did not identify anything of significance, except for the recent EU authorisation of this feed additive. The other legitimate factors considered included political, economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours.

Manganese chelate of lysine and glutamic acid (manganese-LG) is authorised for use in Northern Ireland, in line with EU legislation that applies in Northern Ireland, under the Northern Ireland Protocol.

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Annex C: RP27 - *Lactobacillus buchneri* DSM 29026 as a silage additive for all animal species (Microferm Limited) (new)

Background

In accordance with Article 4 of REUL 1831/2003 on feed additives, application RP27 is submitted for *Lactobacillus buchneri* DSM 29026 for a new authorisation as a technological feed additive, under the functional group of 'silage additives'. Such feed additives are 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 $5x10^7$ colony-forming units (CFU) per kg forage.

Proposed terms of authorisation

The proposed terms of authorisation are outlined in the FSA/FSS opinion, and the opinion has concluded that this product is safe to be authorised on those terms.

Any relevant provisions of retained EU law

Under the requirements of REUL 1831/2003 for feed additives:

1. Article 16: Labelling and packaging requirements
2. Article 21: Analytical methods have been verified as used for the control of *L. buchneri* DSM 29026 in animal feed. Valid analytical methods exist for:
    - the identification of the bacterial strain *L. buchneri*.
    - the enumeration (bacterial count) of the bacteria in the feed additive.

Other legitimate factors identified that Ministers may consider in making decisions

The next step of the authorisation process is for Ministers to make decisions on authorisation. Taking into account the FSA/FSS opinion, Ministers could decide to

authorise the product. As the opinion has concluded that the product is safe to be authorised based on the proposed terms, FSA/FSS views are that there are no reasons for Ministers to refuse authorisation unless there are other legitimate factors that might indicate otherwise. In presenting advice and assisting Ministers the FSA and FSS are acting pursuant to their functions under the Food Standards Act 1999 and Food (Scotland) Act 2015. FSA/FSS has not identified any other legitimate factors that would prevent authorisation taking place, so unless the responses to this consultation identify any other legitimate factors Ministers must take into account in making decisions on authorisation, the FSA/FSS advice to Ministers will be to authorise on the proposed terms outlined in the opinion.

Our collective assessment of the other legitimate factors Ministers may consider in making decisions did not identify anything of significance, except for the recent EU authorisation of this feed additive. The other legitimate factors considered included political, economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours.

L. buchneri DSM 29026 is authorised for use in Northern Ireland, in line with EU legislation that applies in Northern Ireland, under the Northern Ireland Protocol.

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Annex D: RP65 - Serine protease produced by *Bacillus licheniformis* DSM 19670 as a feed additive for chickens for fattening (RONOZYME® ProAct, RONOZYME® ProAct (CT), RONOZYME® ProAct (L), DSM Nutritional Products (AG)) (new)

Background

In accordance with Article 4 of REUL 1831/2003 on feed additives, application RP65 is submitted for the RONOZYME® ProAct forms for a new authorisation as a zootechnical feed additive, under the functional group of 'digestibility enhancers'. The function of such feed additives is to improve the digestibility of animal diets.

The additive is intended to be used in feed for Chickens for fattening and is proposed for use in coated granulated (ProAct - CT) and liquid (ProAct - L) forms at 15,000 PROT/kg complete feed.*

* [Enzyme activity expressed in PROT units, where "one PROT is the amount of serine protease that liberates one micromole/minute of para-nitroaniline (pNA) from 1 millimolar (mM) Suc-Ala-Ala-Pro-Phe-pNA substrate at pH9 & 37°C].

Proposed terms of authorisation

The proposed terms of authorisation are outlined in the FSA/FSS opinion, and the opinion has concluded that this product is safe to be authorised on those terms.

Any relevant provisions of retained EU law

Under the requirements of REUL 1831/2003 for feed additives:

1. Article 16: Labelling and packaging requirements.
2. Article 21: Analytical methods have been verified as used for the control of serine protease produced by *B. licheniformis* DSM 19670 (RONOZYME® ProAct forms) in animal feed. Valid analytical methods exist for:
    - the quantification of the serine protease activity in the feed additive, premixtures and feedingstuffs.

Other legitimate factors identified that Ministers may consider in making decisions

The next step of the authorisation process is for Ministers to make decisions on authorisation. Taking into account the FSA/FSS opinion, Ministers could decide to authorise the product. As the opinion has concluded that the product is safe to be authorised based on the proposed terms, FSA/FSS views are that there are no reasons for Ministers to refuse authorisation unless there are other legitimate factors that might indicate otherwise. In presenting advice and assisting Ministers the FSA and FSS are acting pursuant to their functions under the Food Standards Act 1999 and Food (Scotland) Act 2015. FSA/FSS has not identified any other legitimate factors that would prevent authorisation taking place, so unless the responses to this consultation identify any other legitimate factors Ministers must take into account in making decisions on authorisation, the FSA/FSS advice to Ministers will be to authorise on the proposed terms outlined in the opinion.

Our collective assessment of the other legitimate factors Ministers may consider in making decisions did not identify anything of significance, except for the recent EU authorisation of this feed additive. The other legitimate factors considered included political, economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours.

Serine protease for Chickens for fattening was previously authorised as a feed additive, under Regulation 1831/2003 (REUL 8/2010) which expired and was removed from the UK market.

Serine protease has since been authorised for use in Northern Ireland, in line with EU legislation that applies in Northern Ireland, under the Northern Ireland Protocol.

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Annex E: RP96 - Pyridoxine hydrochloride (vitamin B_6) as a feed additive for all animal species (DSM Nutritional Products Ltd (Switzerland)) (renewal)

Background

In accordance with Article 14 of REUL 1831/2003 on feed additives, application RP96 is submitted for pyridoxine hydrochloride (Vitamin B_6) for the renewal of 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 feed additives is to provide essential micro-nutrients to animal diets.

Pyridoxine hydrochloride is currently authorised in GB nations for all animal species under Regulation 1831/2003 (REUL 515/2011), whilst a renewal of authorisation was recently concluded in the EU.

Proposed terms of authorisation

The proposed terms of authorisation are outlined in the FSA/FSS opinion, and the opinion has concluded that this product is safe to be authorised on those terms.

Any relevant provisions of retained EU law

Under the requirements of REUL 1831/2003 for feed additives:

1. Article 16: Labelling and packaging requirements
2. Article 21: Analytical methods have been verified as used for the control of pyridoxine hydrochloride (Vitamin B_6) in animal feed. Valid analytical methods exist for:
    - the determination of pyridoxine hydrochloride (Vitamin B_6) in the feed additive, premixtures, feedingstuffs and water.

Other legitimate factors identified that Ministers may consider in making decisions

The next step of the authorisation process is for Ministers to make decisions on authorisation. Taking into account the FSA/FSS opinion, Ministers could decide to authorise the product. As the opinion has concluded that the product is safe to be

authorised based on the proposed terms, FSA/FSS views are that there are no reasons for Ministers to refuse authorisation unless there are other legitimate factors that might indicate otherwise. In presenting advice and assisting Ministers the FSA and FSS are acting pursuant to their functions under the Food Standards Act 1999 and Food (Scotland) Act 2015. FSA/FSS has not identified any other legitimate factors that would prevent authorisation taking place, so unless the responses to this consultation identify any other legitimate factors Ministers must take into account in making decisions on authorisation, the FSA/FSS advice to Ministers will be to authorise on the proposed terms outlined in the opinion.

Our collective assessment of the other legitimate factors Ministers may consider in making decisions did not identify anything of significance, except for the recent EU authorisation of this feed additive, consumer interests and health impacts (outlined below). The other legitimate factors considered included political, economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours.

Consumer interests: Some consumer interest could be generated if this authorisation was refused, due to the loss of a source of vitamin B in products of animal origin for human consumption and maintaining public health.

Health: Animal and human health could be impacted if this application for a critical nutritional feed additive was not authorised. Nutritional feed additives are not applicant-specific, meaning that if the feed additive is not authorised, then no manufacturer could produce this particular nutritional source. Refusal of this feed additive authorisation may have an impact on consumers who eat products of animal origin (e.g. fish, meat or offal).

Pyridoxine hydrochloride (Vitamin B_6) is authorised for use in food, food supplements and as veterinary and human medicinal products.

Pyridoxine hydrochloride (Vitamin B_6) is authorised for use in Northern Ireland, in line with EU legislation that applies in Northern Ireland, under the Northern Ireland Protocol.

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Annex F: RP130 - *Saccharomyces cerevisiae* CNCM I-4407 as a feed additive for calves for rearing (ACTISAF® Sc 47, S.I.Lesaffre, Phileo division) (renewal)

Background

In accordance with Article 14 of REUL 1831/2003 on feed additives, application RP130 is submitted for *Saccharomyces cerevisiae* CNCM I-4407 (ACTISAF® Sc 47) for a renewal of authorisation 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.

S. cerevisiae CNCM I-4407 (ACTISAF® Sc 47) is currently authorised for calves for rearing under Regulation 1831/2003 (REUL 883/2010) in GB under its prior yeast strain name of *S. cerevisiae* NCYC Sc 47. The renewal of authorisation proposes to continue to use a minimum level of use at $1.5x10^9$ colony forming units (CFU)/kg complete feed.

Actisaf® Sc 47 is one of a series of *S. cerevisiae* CNCM I-4407 feed additives from the same applicant which was previously assessed by EFSA and currently authorised as a gut flora stabiliser for multiple target animal species and sub-groups:

- REUL 2020/147: weaned piglets, sows (in order to have a benefit for suckling piglets) and dairy cows
- REUL 2019/899: lambs for fattening, dairy goats, dairy sheep, dairy buffaloes, pigs for fattening (and for horses as a digestibility enhancer)
- REUL 334/2012: rabbits for fattening, non-food producing rabbits
- REUL 316/2003: cattle for fattening

Proposed terms of authorisation

The proposed terms of authorisation are outlined in the FSA/FSS opinion, and the opinion has concluded that this product is safe to be authorised on those terms.

Any relevant provisions of retained EU law

Under the requirements of REUL 1831/2003 for feed additives:

1. Article 16: Labelling and packaging requirements.
2. Article 21: Analytical methods have been verified as used for the control of *S. cerevisiae* CNCM I-4407 (ACTISAF® Sc 47) in animal feed. Valid analytical methods exist for:
    - identification of the yeast strain *S. cerevisiae* CNCM I-4407.
    - enumeration (colony count) of the yeast in the feed additive.

Other legitimate factors identified that Ministers may consider in making decisions

The next step of the authorisation process is for Ministers to make decisions on authorisation. Taking into account the FSA/FSS opinion, Ministers could decide to authorise the product. As the opinion has concluded that the product is safe to be authorised based on the proposed terms, FSA/FSS views are that there are no reasons for Ministers to refuse authorisation unless there are other legitimate factors that might indicate otherwise. In presenting advice and assisting Ministers the FSA and FSS are acting pursuant to their functions under the Food Standards Act 1999 and Food (Scotland) Act 2015. FSA/FSS has not identified any other legitimate factors that would prevent authorisation taking place, so unless the responses to this consultation identify any other legitimate factors Ministers must take into account in making decisions on authorisation, the FSA/FSS advice to Ministers will be to authorise on the proposed terms outlined in the opinion.

Our collective assessment of the other legitimate factors Ministers may consider in making decisions did not identify anything of significance, except for the recent EU authorisation of this feed additive. The other legitimate factors considered included political, economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours.

S. cerevisiae CNCM I-4407 (ACTISAF® Sc 47) is authorised for use in Northern Ireland, in line with EU legislation that applies in Northern Ireland, under the Northern Ireland Protocol.

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Annex G: RP131 - *Bacillus subtilis* ATCC PTA-6737 (*Bacillus velezensis* ATCC PTA-6737) as a feed additive for chickens for fattening, chickens reared for laying, minor poultry species (except for laying), ornamental, sporting and game birds (Kemin Europa N.V.) (renewal, modification and new use)

Background

In accordance with REUL 1831/2003 on feed additives, application RP131 is submitted for *Bacillus velezensis* (ATCC PTA-6737) for a renewal of authorisation (Article 14), modification (Article 13) and a new use (Article 4) for extrapolation of species 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 chickens for fattening, chickens reared for laying, minor poultry species (except for laying), ornamental, sporting and game birds.

Bacillus velezensis (ATCC PTA-6737); formerly identified as *Bacillus subtilis (* (ATCC PTA-6737), is currently authorised for chickens for fattening under Regulation 1831/2003 (REUL 107/2010) and for chickens reared for laying and specified minor avian species (REUL 885/2011).

The new use (extrapolation of species) is proposed to extend to all minor poultry species (except for laying), ornamental, sporting and game birds.

In addition, the applicant requests a modification of authorisation (Article 13) to increase the concentration of the feed additive preparation from 1 x 10^{10} to 8 x 10^{10} colony forming units (CFU) per gram and substitution of the inert carrier from maltodextrin to sodium bicarbonate, without impacting on safety or feed additive function in feed. The minimum effective dose remains unchanged at 1 x 10^{7} CFU/kg complete feed.

Furthermore, the applicant also requests the modification of authorisation under Article 13 in the bacterial strain name of all relevant feed additive authorisations held by the applicant, updating from *B. subtilis* to *B. velezensis*:

- REUL 787/2013 concerning the authorisation of a preparation of *B. subtilis* (ATCC PTA-6737) as a feed additive for turkeys for fattening and turkeys reared for breeding.

- REUL 306/2013 concerning the authorisation of a preparation of *B. subtilis* (ATCC PTA-6737) for weaned piglets and weaned Suidae other than Sus scrofa domesticus.

- REUL 2015/1020 concerning the authorisation of the preparation of *B. subtilis* (ATCC PTA-6737) as a feed additive for laying hens and minor poultry species for laying.

- REUL 2017/2276 concerning the authorisation of the preparation of *B. subtilis* (ATCC PTA-6737) as a feed additive for sows.

Proposed terms of authorisation

The proposed terms of authorisation are outlined in the FSA/FSS opinion, and the opinion has concluded that this product is safe to be authorised on those terms.

Any relevant provisions of retained EU law

Under the requirements of REUL 1831/2003 for feed additives:

1. Article 16: Labelling and packaging requirements.
2. Article 21: Analytical methods have been verified as used for the control of *B. velezensis* (ATCC PTA-6737), formerly *B. subtilis* PB6 in animal feed. Valid analytical methods exist for:
    - identification of the bacterial strain *B. velezensis* (ATCC PTA-6737)
    - enumeration (colony count) of the bacteria in the feed additive

Other legitimate factors identified that Ministers may consider in making decisions

The next step of the authorisation process is for Ministers to make decisions on authorisation. Taking into account the FSA/FSS opinion, Ministers could decide to authorise the product. As the opinion has concluded that the product is safe to be authorised based on the proposed terms, FSA/FSS views are that there are no reasons

for Ministers to refuse authorisation unless there are other legitimate factors that might indicate otherwise. In presenting advice and assisting Ministers the FSA and FSS are acting pursuant to their functions under the Food Standards Act 1999 and Food (Scotland) Act 2015. FSA/FSS has not identified any other legitimate factors that would prevent authorisation taking place, so unless the responses to this consultation identify any other legitimate factors Ministers must take into account in making decisions on authorisation, the FSA/FSS advice to Ministers will be to authorise on the proposed terms outlined in the opinion.

Our collective assessment of the other legitimate factors Ministers may consider in making decisions did not identify anything of significance, except for the recent EU application for authorisation of this feed additive which has not been determined yet. The other legitimate factors considered included political, economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours.

A feed additive application for *B. velezensis* (ATCC PTA-6737) has been submitted for the renewal of authorisation, modification of bacterial name and new use in extrapolation of species.

The EFSA opinions indicate that the uses proposed for this feed additive are safe for use, which aligns to the UK position. A decision on this EU authorisation will be made in due course in line with EU legislation that applies in Northern Ireland, under the Northern Ireland Protocol."

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Annex H: RP161 - *Bacillus licheniformis* DSM 28710 as a feed additive for laying hens, minor poultry species for laying, poultry species for breeding and ornamental birds (B®-Act, Huvepharma NV) (new)

Background

In accordance with Article 4 of REUL 1831/2003 on feed additives, application RP161 is submitted for B-Act® (*Bacillus licheniformis* DSM 28710) for a new authorisation 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.

The additive is intended to be used in feed for laying hens, minor poultry species for laying, poultry species for breeding purposes and ornamental birds at 1.6×10^9 colony forming units (CFU)/kg complete feed.

The additive is currently authorised under Regulation 1831/2003 for the same function in feed:

- REUL 2017/1904 for chickens for fattening and chickens reared for laying,
- REUL 2019/914 for turkeys for fattening, turkeys reared for breeding and minor poultry species for fattening and reared for laying.

Proposed terms of authorisation

The proposed terms of authorisation are outlined in the FSA/FSS opinion, and the opinion has concluded that this product is safe to be authorised on those terms.

Any relevant provisions of retained EU law

Under the requirements of REUL 1831/2003 for feed additives:

1. Article 16: Labelling and packaging requirements.
2. Article 21: Analytical methods have been verified as used for the control of B-Act® (*B. licheniformis* DSM 28710) in animal feed. Valid analytical methods exist for:
    - identification of the bacterial strain *B. licheniformis* DSM 28710.
    - enumeration (colony count) of bacteria in the feed additive.

Other legitimate factors identified that Ministers may consider in making decisions

The next step of the authorisation process is for Ministers to make decisions on authorisation. Taking into account the FSA/FSS opinion, Ministers could decide to authorise the product. As the opinion has concluded that the product is safe to be authorised based on the proposed terms, FSA/FSS views are that there are no reasons for Ministers to refuse authorisation unless there are other legitimate factors that might indicate otherwise. In presenting advice and assisting Ministers the FSA and FSS are acting pursuant to their functions under the Food Standards Act 1999 and Food (Scotland) Act 2015. FSA/FSS has not identified any other legitimate factors that would prevent authorisation taking place, so unless the responses to this consultation identify any other legitimate factors Ministers must take into account in making decisions on authorisation, the FSA/FSS advice to Ministers will be to authorise on the proposed terms outlined in the opinion.

Our collective assessment of the other legitimate factors Ministers may consider in making decisions did not identify anything of significance, except for the recent EU authorisation of this feed additive. The other legitimate factors considered included political, economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours.

B-Act® (*B. licheniformis* DSM 28710) is authorised for use in Northern Ireland, in line with EU legislation that applies in Northern Ireland, under the Northern Ireland Protocol.

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Annex I: RP664 - C*lostridium butyricum* FERM BP-2789 as a feed additive for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding, minor avian species (excluding laying birds), piglets (suckling and weaned) and minor porcine species (suckling and weaned) (Miya-Gold® S, Miyarisan Pharmaceutical Co. Ltd.) (renewal and new use)

Background

In accordance with REUL 1831/2003 on feed additives, application RP664 is submitted for *Clostridium butyricum* FERM BP-2789 (Miya-Gold® S) for a renewal of authorisation (Article 14) and a new use (Article 4) for an extension of species groups 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.

- Renewal of authorisation is requested for chickens and minor avian species reared to the point of lay; turkeys for fattening and turkeys reared for breeding to the point of lay; weaned piglets and minor porcine species (weaned) as collectively authorised under 1831/2003 (REUL 373/2011, REUL 374/2013 and REUL 1108/2014).

- New authorisation is requested for chickens for fattening; suckling piglets and minor porcine species (suckling).

The effective level of use (efficacy) of Miya-Gold® S under existing authorisations is 1.25 x 10^8 colony forming units (CFU) per kg complete feed for turkeys, and 2.5 x 10^8 CFU/kg complete feed for all other species groups.

Proposed terms of authorisation

The proposed terms of authorisation are outlined in the FSA/FSS opinion, and the opinion has concluded that this product is safe to be authorised on those terms.

Any relevant provisions of retained EU law

Under the requirements of REUL 1831/2003 for feed additives:

1. Article 16: Labelling and packaging requirements.
2. Article 21: Analytical methods have been verified as used for the control of *C. butyricum* FERM BP-2789 (Miya-Gold® S) in animal feed. Valid analytical methods exist for:
    - identification of the bacterial strain *C. butyricum* FERM BP-2789
    - enumeration (colony count) of the bacteria in the feed additive.

Other legitimate factors identified that Ministers may consider in making decisions

The next step of the authorisation process is for Ministers to make decisions on authorisation. Taking into account the FSA/FSS opinion, Ministers could decide to authorise the product. As the opinion has concluded that the product is safe to be authorised based on the proposed terms, FSA/FSS views are that there are no reasons for Ministers to refuse authorisation unless there are other legitimate factors that might indicate otherwise. In presenting advice and assisting Ministers the FSA and FSS are acting pursuant to their functions under the Food Standards Act 1999 and Food (Scotland) Act 2015. FSA/FSS has not identified any other legitimate factors that would prevent authorisation taking place, so unless the responses to this consultation identify any other legitimate factors Ministers must take into account in making decisions on authorisation, the FSA/FSS advice to Ministers will be to authorise on the proposed terms outlined in the opinion.

Our collective assessment of the other legitimate factors Ministers may consider in making decisions did not identify anything of significance, except for the recent EU authorisation of this feed additive. The other legitimate factors considered included political, economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours.

C. butyricum FERM BP-2789 (Miya-Gold® S) is authorised for use in Northern Ireland, in line with EU legislation that applies in Northern Ireland, under the Northern Ireland Protocol.

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Annex J: RP808 - 6-phytase produced by *Komagataella phaffii* DSM 32854 as a feed additive for all poultry species, ornamental birds, piglets, pigs for fattening, sows, and minor porcine species for fattening or reproduction (OptiPhos Plus®, Huvempharma EOOD) (new)

Background

In accordance with Article 4 of REUL 1831/2003 on feed additives, application RP808 is submitted for 6-phytase produced by *Komagataella phaffii* DSM 32854 (OptiPhos® Plus) for a new authorisation as a zootechnical feed additive, under the functional group of 'digestibility enhancers'. The function of such feed additives is to improve the digestibility of animal diets.

This current application is proposed for all poultry species, ornamental birds, piglets, pigs for fattening, sows and minor porcine species for fattening or reproduction at 250 FTU*/kg complete feed. OptiPhos® Plus is to be marketed in granular, coated and liquid forms at 5,000 FTU/g

*[FTU = phytase enzyme units, where one FTU is the amount of enzyme that releases 1 micromole of inorganic phosphate from sodium phytate per minute under reaction conditions of pH 5.5 and 37°C.]

Proposed terms of authorisation

The proposed terms of authorisation are outlined in the FSA/FSS opinion, and the opinion has concluded that this product is safe to be authorised on those terms.

Any relevant provisions of retained EU law

Under the requirements of REUL 1831/2003 for feed additives:

1. Article 16: Labelling and packaging requirements.
2. Article 21: Analytical methods have been verified as used for the control of 6-phytase produced by *K. phaffii* DSM 32854 (OptiPhos® Plus) in animal feed. Valid analytical methods exist for:
    - the quantification of the 6-phytase activity in the feed additive, premixtures and feedingstuffs.

Other legitimate factors identified that Ministers may consider in making decisions

The next step of the authorisation process is for Ministers to make decisions on authorisation. Taking into account the FSA/FSS opinion, Ministers could decide to authorise the product. As the opinion has concluded that the product is safe to be authorised based on the proposed terms, FSA/FSS views are that there are no reasons for Ministers to refuse authorisation unless there are other legitimate factors that might indicate otherwise. In presenting advice and assisting Ministers the FSA and FSS are acting pursuant to their functions under the Food Standards Act 1999 and Food (Scotland) Act 2015. FSA/FSS has not identified any other legitimate factors that would prevent authorisation taking place, so unless the responses to this consultation identify any other legitimate factors Ministers must take into account in making decisions on authorisation, the FSA/FSS advice to Ministers will be to authorise on the proposed terms outlined in the opinion.

Our collective assessment of the other legitimate factors Ministers may consider in making decisions did not identify anything of significance, except for the recent EU authorisation of this feed additive. The other legitimate factors considered included political, economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours.

6-phytase produced by *K. phaffii* DSM 32854 (OptiPhos® Plus) is authorised for use in Northern Ireland, in line with EU legislation that applies in Northern Ireland, under the Northern Ireland Protocol.

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Annex K: RP1030 - Decoquinate as a feed additive for chickens for fattening (Deccox®, Zoetis Belgium SA) (re-evaluation)

Background

In accordance with Article 10 of REUL 1831/2003 on feed additives, application RP1030 is submitted for the re-evaluation of decoquinate (Deccox®) as a coccidiostat feed additive, under the category of 'coccidiostats and histomonostats'. 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).

Deccox® (ID code E756) is currently permitted for use for the control of coccidiosis caused by *Eimeria* spp in feed for chickens for fattening at 20-40 mg/kg complete feed under Regulation 1831/2003 (REUL 1289/2004). Of particular relevance, this regulation was amended by REUL 291/2014 on the removal of coccidiostat withdrawal periods and the introduction of maximum residue limits in products of animal origin.

For the submission to GB nations, the applicant proposed a level of use of decoquinate at 20-40 mg/kg in complete feed with consideration of residues in tissues or other products of animal origin. Maintaining a zero withdrawal period required for decoquinate (Deccox®) in feed for chickens for fattening is proposed, as for its existing authorisation.

A separate application (RP419) has been submitted for an Article 13 modification to this authorisation for the addition of Avi-Deccox® 60G which maintains the same active substance and characteristics of decoquinate as for Deccox®and differs only in non-functional characteristics (i.e. diluent used and physical form), without impacting on feed additive function.

Proposed terms of authorisation

The proposed terms of authorisation are outlined in the FSA/FSS opinion, and the opinion has concluded that this product is safe to be authorised on those terms.

Any relevant provisions of retained EU law

Under the requirements of REUL 1831/2003 for feed additives:

1. Article 16: Labelling and packaging requirements.
2. Article 21: Analytical methods have been verified as used for the control of decoquinate (Deccox®) in animal feed. Valid analytical methods exist for:
    - the determination of decoquinate in the feed additive, premixtures and feedingstuffs.
    - the determination of decoquinate in tissues.

Other legitimate factors identified that Ministers may consider in making decisions

The next step of the authorisation process is for Ministers to make decisions on authorisation. Taking into account the FSA/FSS opinion, Ministers could decide to authorise the product. As the opinion has concluded that the product is safe to be authorised based on the proposed terms, FSA/FSS views are that there are no reasons for Ministers to refuse authorisation unless there are other legitimate factors that might indicate otherwise. In presenting advice and assisting Ministers the FSA and FSS are acting pursuant to their functions under the Food Standards Act 1999 and Food (Scotland) Act 2015. FSA/FSS has not identified any other legitimate factors that would prevent authorisation taking place, so unless the responses to this consultation identify any other legitimate factors Ministers must take into account in making decisions on authorisation, the FSA/FSS advice to Ministers will be to authorise on the proposed terms outlined in the opinion.

Our collective assessment of the other legitimate factors Ministers may consider in making decisions did not identify anything of significance, except for the recent EU authorisation of this feed additive. The other legitimate factors considered included political, economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours.

Animal health: Impacts could be anticipated if the authorisation of Deccox® was not renewed. Coccidiostats are crucial feed additives used to maintain the health of animals; particularly poultry species, through the control coccidiosis. The use of different coccidiostats are alternated to maintain their effectiveness (efficacy) and therefore, the

loss of Deccox® would reduce the available range of coccidiostat (active substances) products on the market.

Decoquinate (Deccox®) is authorised for use in Northern Ireland, in line with EU legislation that applies in Northern Ireland, under the Northern Ireland Protocol.

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Annex L: RP419 - Decoquinate as a feed additive for chickens for fattening (Avi-Deccox® 60G, Zoetis Belgium SA) (modification)

Background

In accordance with Article 13 of REUL 1831/2003 on feed additives, application RP419 for Avi-Deccox® 60G is submitted for the modification to the Article 10 re-evaluation of decoquinate (Deccox®) which was also submitted to FSA/FSS under application RP1030.

Avi-Deccox® 60G and Deccox® are coccidiostat feed additives, under the category of 'coccidiostats and histomonostats'. 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).

Avi-Deccox® 60G maintains the same active substance and characteristics of decoquinate as for Deccox® (RP1030) and differs only in the diluent used and its physical form, without impacting on feed additive function.

The new formulation Avi-Deccox® 60G contains micronised decoquinate (60 g/kg complete feed) as the active substance, blended with colloidal silica, silicon dioxide, carboxymethylcellulose sodium (as anticaking/binder agents) and calcium sulphate dihydrate (as a carrier/diluent).

Avi-Deccox® 60G is proposed by the applicant for the identical conditions of use as for Deccox® (RP1030) in the control of coccidiosis caused by *Eimeria* spp in feed for chickens for fattening.

The applicant proposed a level of use of decoquinate in Avi-Deccox® 60G at 20-40 mg/kg in complete feed. As for the existing authorisation of Deccox®, residues in tissues or other products of animal origin and maintaining a zero day withdrawal period in feed for chickens for fattening.

Proposed terms of authorisation

The proposed terms of authorisation are outlined in the FSA/FSS opinion, and the opinion has concluded that this product is safe to be authorised on those terms.

Any relevant provisions of retained EU law

Under the requirements of REUL 1831/2003 for feed additives:

1. Article 16: Labelling, as per the requirements
2. Article 21: Analytical methods have been verified as used for the control of decoquinate (Avi-Deccox® 60G) in animal feed. Valid analytical methods exist for:
    - the determination of decoquinate in feed additive, premixtures and feedingstuffs.
    - the determination of decoquinate in tissues.

Other legitimate factors identified that Ministers may consider in making decisions

The next step of the authorisation process is for Ministers to make decisions on authorisation. Taking into account the FSA/FSS opinion, Ministers could decide to authorise the product. As the opinion has concluded that the product is safe to be authorised based on the proposed terms, FSA/FSS views are that there are no reasons for Ministers to refuse authorisation unless there are other legitimate factors that might indicate otherwise. In presenting advice and assisting Ministers the FSA and FSS are acting pursuant to their functions under the Food Standards Act 1999 and Food (Scotland) Act 2015. FSA/FSS has not identified any other legitimate factors that would prevent authorisation taking place, so unless the responses to this consultation identify any other legitimate factors Ministers must take into account in making decisions on authorisation, the FSA/FSS advice to Ministers will be to authorise on the proposed terms outlined in the opinion.

Our collective assessment of the other legitimate factors Ministers may consider in making decisions did not identify anything of significance, except for the recent EU authorisation of this feed additive. The other legitimate factors considered included political, economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours.

Avi-Deccox® 60G is authorised for use in Northern Ireland, in line with EU legislation that applies in Northern Ireland, under the Northern Ireland Protocol.

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