FSA/FSS opinions of applications for eleven Additives for Use in Animal Feed

Date of publication: 7 March 2022

Document subject and purpose

In this document we publish the Food Standards Agency (FSA)/Food Standards Scotland (FSS) opinions, following the quality assurance of risk assessments conducted by the European Food Safety Authority (EFSA), of eleven Feed Additives for use in animal nutrition as outlined in the annexes.

The opinions will be considered by Ministers to inform decision-making on whether to authorise the individual feed additives for use in England, Scotland and Wales.

This opinion is being published in parallel with FSS.

Comments and feedback

If you wish to comment on the FSA/FSS opinions, feedback should be sent to:

Email: RPconsultations@food.gov.uk
Name: Regulated Products Approvals Team
Division/Branch: Chemical Safety Policy Unit

Please state, in your comment, whether you are commenting as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents) and in which country you are based.

Please indicate which application(s)/opinion(s) you are commenting on by using the following subject line for your response:

Comment on [insert RP number(s)] Feed Additives FSA/FSS opinion

Comments will be shared with FSS.

Comments will be published and made available to the public and Ministers.

Document details

In accordance with Retained EU Regulation 1831/2003 (REUL 1831/2003) on feed additives, the feed additives included in this document 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 (Appropriate Authority) in England, Scotland and Wales. Protection of public health in relation to the consumption of food and feed 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.

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.

Whilst it was a Member State of the EU, the UK accepted the assessments of EFSA in support of authorisations for regulated food and feed products. Since the end of the transition period, FSA/FSS have adopted equivalent technical guidance and quality assurance processes to make independent GB risk assessments. Where EFSA, prior to the end of the transition period, evaluated an application for a product for which an application is now made to GB, FSA/FSS has decided to make use of the EFSA risk assessment, where this is appropriate, in forming its own independent opinion. Therefore, FSA/FSS risk assessors have reviewed the EFSA opinions for the products included in this document in the context of intended GB use and have concluded that the intended uses are safe. FSA/FSS has had access to all supporting documentation as provided to EFSA for forming the EFSA opinion.

Supplementary information on feed additives

Where dossiers for existing feed additives were submitted to the EU by the deadlines set out in REUL 1831/2003 and the decision on their authorisation was not concluded prior to

any expiry date where set, the feed additives may remain on the market until concluded. Refer to Article 10(6) on existing feed additives and Article 14(4) on renewal of authorisations.

Feed additives are classified under five broad categories, and further defined for specific functions, as outlined in Annex I of REUL 1831/2003. The categories are:

1. Technological (for example, preservatives or gelling agents)
2. Sensory (colourants or flavourings)
3. Nutritional (for example, vitamins and trace elements)
4. Zootechnical, 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 American Type Culture Collection (ATCC).

Feed additives may be authorised for all animal species or for major species or defined sub-groups (for example, poultry or chickens for laying) as defined in Annex IV of REUL 429/2008. In addition, species groups may be extrapolated to minor species (for example, minor poultry such as geese) or other animal groups requested within the application (for example, game birds). ‘Minor species’ refers to food-producing animals other than bovines (dairy and meat animals, including calves), sheep (meat animals), pigs, chickens (including laying hens), turkeys and fish belonging to the *Salmonidae*, as defined in Article 1 of REUL 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 and are not intended to directly enter the food-chain (for example, sows for reproduction or turkeys reared for breeding).

Transitional arrangements may be applied where the criteria of a new authorisation differs from the existing feed additive authorisation, which allows existing stocks and products on the market to be used up. Transitional arrangements are only referenced in

the Annexes below where applicable, based on significant change between the existing and new authorisation.

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

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

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

The FSA/FSS opinion for each feed additive is published within a separate annex, including the regulated product ID number and title of the application (Ctrl+Click to follow link):

Further information

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

Yours,

Mark Bond
Feed Additives Policy Advisor
Chemical Safety Policy Unit

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

FSA/FSS has reviewed the European Food Safety Authority (EFSA) risk assessment opinion and confirm that FSA/FSS agree with the safety conclusions outlined. FSA/FSS has had access to all supporting documentation as provided to the EFSA for forming the EFSA opinion. Therefore, the information on which this opinion is based can be found in the EFSA opinion as detailed below. There has been no additional information received by FSA/FSS since the publication date of the EFSA opinion, therefore, the appropriateness of the EFSA opinion is maintained. Following the principles outlined in the introduction for making use of the EFSA opinion, the FSA/FSS opinion is that the feed additive, as described in this application, is safe.

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 EFSA below, the use of manganese-LG in water was not requested within the GB application, and therefore is not considered further under this authorisation proposal.

EFSA Risk Assessment:

EFSA has published its risk assessments and opinions, and the European Reference Laboratory (EURL) analytical method evaluation report has been published, which FSA/FSS has reviewed:

- EFSA Journal No.6454 (2021): Safety of the feed additive consisting of manganese chelates of lysine and glutamic acid for all animal species (Zinpro Animal Nutrition).
- EFSA Journal No.6001 (2020): Safety and efficacy of manganese chelates of lysine and glutamic acid as feed additive for all animal species.
- EFSA Journal No.1956 (2010): Statement on the use of feed additives authorised/applied for use in feed when supplied via water.
- EURL analytical method evaluation report (FAD-2018-0009). FSA/FSS determined the analytical method as appropriate for official controls for this feed additive.

Conclusions from EFSA Risk Assessment:

EFSA (2020, 2021) concluded on manganese-LG that:

- it is safe for chickens for fattening at 150 mg Mn/kg complete feed, with a margin of safety of 5.5. This conclusion can be extrapolated to all animal species and categories provided that the maximum authorised levels of manganese in feed are not exceeded.
- it is safe for consumers of tissues and products (for example, meat, milk or eggs) from animals fed the feed additive up to the maximum permitted limit of manganese in feed.
- on worker safety, this feed additive poses a risk during handling to workers and users by inhalation from the manganese and nickel content of manganese-LG. Nickel is also a recognised skin sensitiser and its highest content in the feed additive was determined at 4 mg/kg complete feed. Therefore, the feed additive is considered as a skin and respiratory sensitiser. The feed additive is also an irritant to the eyes but not to the skin.
- it is intended to be a substitute for other authorised manganese feed additives and will not further increase the environmental burden of manganese.
- it is effective (efficacious) in chickens for fattening and this conclusion can be extrapolated/extended to other species and their sub-group categories.
- the simultaneous use in both feed and water should be avoided. EFSA did not recommend the use of manganese compounds via water for drinking.
- there is no need for specific requirements for a post-market monitoring plan.

Proposed terms of authorisation:

1: Additive details

Category	**Details**
Additive category	(3) Nutritional feed additive
Functional group	(b) Compounds of trace elements
Feed additive	Manganese chelate of lysine and glutamic acid
ID No	3b509

Category	Details
Target species	All animal species
Authorisation period	10 years from the date of authorisation

Main animal species and their subgroups are defined in Annex IV of REUL 429/2008

2: Additive composition

A preparation of chelates of manganese with lysine and chelates of manganese with glutamic acid in a ratio of 1:1 as a powder with the below components.

Component	Contents
manganese	15-17%
lysine	20-21.5%
glutamic acid	22-24%
moisture	3.5% maximum
nickel	4 ppm maximum

3: Characterisation / identification of the active substance(s)

- Manganese-2,6-diaminohexanoic acid, chloride and hydrogen sulphate salt $C_6H_{19}ClN_2O_8SMn$
- Manganese-2-aminopentanedioic acid, sodium and hydrogen sulphate salt $C_5H_{10}NNaO_9SMn$

4: Conditions of use

Species or category of animal	Maximum age	Content of element (Mn) in mg/kg of complete feed with a moisture content of 12%)
Fish	n/a	Minimum level: No minimum Maximum level: 100 (total)
All other animal species	n/a	Minimum level: No minimum Maximum level: 150 (total)

5: Other Provisions

1. The additive shall be incorporated into the feed in form of a premixture.
2. Worker/user safety considerations, particularly identified for personal protection for:
    a. Nickel content
    b. Skin and respiratory sensitiser
    c. Eye irritant

6: Analytical methods

For quantification of total manganese in the feed additive, premixtures and feedingstuffs:

- Inductively Coupled Plasma-Atomic Emission Spectrometry after pressure digestion (ICP-AES) –EN15621; or
- Atomic Absorption Spectrometry (AAS) –ISO6869; or
- Inductively Coupled Plasma-Atomic Emission Spectrometry, (ICP-AES) –EN 15510 *(for premixtures and feedingstuffs only)*; or
- Inductively Coupled Plasma-Mass Spectrometry (ICP-MS)–EN 17053 *(for premixtures and feedingstuffs only)*; or
- Atomic Absorption Spectrometry (AAS) – Retained EU Regulation 152/2009 *(for feedingstuffs only)*

For the quantification of lysine and glutamic acid in the feed additive:

- Ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) –ISO 13903

For determination of the chelated form of the feed additive:

- Mid-infrared (IR) spectrometry together with the determination of the content of the trace element and lysine and glutamic acid in the feed additive

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

FSA/FSS has reviewed the European Food Safety Authority (EFSA) risk assessment opinion and confirm that FSA/FSS agree with the safety conclusions outlined. FSA/FSS has had access to all supporting documentation as provided to the EFSA for forming the EFSA opinion. Therefore, the information on which this opinion is based can be found in the EFSA opinion as detailed below. There has been no additional information received by FSA/FSS since the publication date of the EFSA opinion, therefore, the appropriateness of the EFSA opinion is maintained. Following the principles outlined in the introduction for making use of the EFSA opinion, the FSA/FSS opinion is that the feed additive, as described in this application, is safe.

EFSA Risk Assessment:

EFSA has published its risk assessment and opinion, qualified presumption of safety, and the European Reference Laboratory (EURL) analytical method evaluation report has been published, which FSA/FSS has reviewed:

- EFSA Journal No.6159 (2020): Safety and efficacy of *Lactobacillus buchneri* DSM 29026 as a silage additive for all animal species
- EFSA Qualified presumption of safety (QPS)
- EURL analytical method evaluation report (FAD-2018-0093). FSA/FSS determined the analytical method as appropriate for official controls for this feed additive.

Conclusions from EFSA Risk Assessment:

EFSA (2020) concluded on *Lactobacillus buchneri* DSM 29026 that:

- this bacterial species is well-characterised and is considered suitable for the qualified presumption of safety (QPS) approach to safety assessment.
- no acquired antimicrobial resistance determinants of concern were detected.

- the use of this bacterial strain as a silage additive is considered safe for animal species, for consumers of products from animals fed the treated silage and for the environment.

- at a minimum concentration of 5 x 10^7 colony-forming units (CFU) per kg forage, *L. buchneri* DSM 29026 may improve silage from easy and moderately difficult to ensile forage material.

- on worker safety, in the absence of data, no conclusions could be drawn on the potential of the additive to be a skin or eye irritant, or skin sensitiser. Given the proteinaceous nature of the active agent, the additive should be considered a respiratory sensitiser.

Proposed terms of authorisation:

1: Additive details

Category	**Details**
Additive category	(1) Technological feed additive
Functional group	(k) Silage additives (to ensile easy and moderately difficult to ensile forage materials)
Feed additive	*Lactobacillus buchneri* DSM 29026
ID No	1k20759
Target species	All animal species
Authorisation period	10 years from the date of authorisation

Main animal species and their subgroups are defined in Annex IV of REUL 429/2008

Definitions of silage, in accordance with Retained EU Regulation 429/2008:

- Easy to ensile forage: >3 % soluble carbohydrates in fresh material.
- Moderately difficult to ensile forage: 1.5-3.0% soluble carbohydrates in fresh material.

2: Additive composition

Preparation of *Lactobacillus buchneri* DSM 29026 containing a minimum of 2×10^{10} CFU/g additive

3: Characterisation / identification of the active substance

Viable cells of *Lactobacillus buchneri* DSM 29026

4: Conditions of use

Species or category of animal	**Maximum age**	**Content of *Lactobacillus buchneri* DSM 29026 (CFU of additive/kg of fresh material):**
All animal species	n/a	Minimum level: See Other Provisions Maximum level: No maximum

5: Other Provisions

1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated.
1. Minimum content of the additive when not combined with other micro-organisms as silage additives: 5×10^7 CFU/kg of easy and moderately difficult to ensile fresh material.
2. Worker/user safety considerations, particularly identified for personal protection for:
    a. Skin and respiratory sensitiser
    b. Skin and eye irritant

6: Analytical methods:

For enumeration (colony count) of the feed additive:

Spread plate method on MRS agar (EN 15787)

For identification of bacterial strain:

Pulsed Field Gel Electrophoresis (PFGE)

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Annex C: 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)

FSA/FSS has reviewed the European Food Safety Authority (EFSA) risk assessment opinion and confirm that FSA/FSS agree with the safety conclusions outlined. FSA/FSS has had access to all supporting documentation as provided to the EFSA for forming the EFSA opinion. Therefore, the information on which this opinion is based can be found in the EFSA opinion as detailed below. There has been no additional information received by FSA/FSS since the publication date of the EFSA opinion, therefore, the appropriateness of the EFSA opinion is maintained. Following the principles outlined in the introduction for making use of the EFSA opinion, the FSA/FSS opinion is that the feed additive, as described in this application, is safe.

EFSA Risk Assessment:

EFSA has published its risk assessment and opinion, and the European Reference Laboratory (EURL) analytical method evaluation report has been published, which FSA/FSS has reviewed:

- EFSA Journal No.6448 (2021): Safety and efficacy of a feed additive consisting of serine protease produced by *Bacillus licheniformis* DSM 19670 (Ronozyme® ProAct) for chickens for fattening (DSM Nutritional Products Ltd)
- EURL analytical method evaluation report (FAD-2019-0010). FSA/FSS determined the analytical method as appropriate for official controls for this feed additive.

Conclusions from EFSA Risk Assessment:

EFSA (2021) concluded on *Bacillus licheniformis* DSM 19670 (Ronozyme® ProACT) that:

- the serine protease is produced by a genetically modified strain of *B. licheniformis* DSM 19670. The production strain and its recombinant DNA were not detected in the intermediate or finished feed additive and no safety concerns were raised with regard to the genetic modification.

- the feed additive is safe for chickens for fattening, and no concerns were raised with regard for consumers and for the environment.
- *B. licheniformis* DSM 19670 (RONOZYME® ProAct) has the potential to be effective at 15,000 PROT/kg* complete feed for chickens for fattening when used in proposed coated granulated (ProAct - CT) and liquid (ProAct - L) forms.
- on worker safety, the feed additive is not an eye irritant but should be considered a skin irritant, whilst no conclusions could be drawn on its potential to be a skin sensitiser in the absence of data. Given the proteinaceous nature of the active agent, the additive should be considered a respiratory sensitiser.
- there is no need for specific requirements for a post-market monitoring plan.

* [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 pH 9 & 37°C].

Proposed terms of authorisation:

1: Additive details

Category	Details
Additive category	(4) Zootechnical feed additive
Functional group	(a) Digestibility enhancers
Feed additive	Serine protease
ID No	4a13
Target species	Chickens for fattening
Authorisation Holder	DSM Nutritional Products Ltd
Authorisation period	10 years from the date of authorisation

Main animal species and their subgroups are defined in Annex IV of REUL 429/2008

2: Additive composition

Solid and liquid preparation of serine protease (EC 3.4.21.-)

- Produced by *Bacillus licheniformis* DSM 19670
- Having a minimum activity of 75,000 PROT/g

3: Characterisation / identification of the active substance(s)

- Serine protease (EC 3.4.21.-) produced by Bacillus licheniformis DSM 19670.
- CAS number: 37259-58-8 (serine protease)
- EINECS number: 253-431-3
- IUB number: 3.4.21-[1]

4: Conditions of use

Species or category of animal	**Maximum age**	**Content of Serine protease (Units of activity/kg of complete feed with a moisture content of 12%)**
Chickens for fattening	n/a	Minimum level: 15,000 PROT/kg Maximum level: No maximum

5: Other Provisions

1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.
2. Worker/user safety considerations, particularly identified for personal protection for:
    a. Skin and respiratory sensitiser
    b. Skin irritant

6: Analytical methods

For the quantification of the serine protease activity in the feed additive, premixtures, compound feed and feed materials:

Colourimetric method based on the enzymatic reaction of serine protease on the Suc-Ala-Ala-Pro-Phe-pNA substrate.

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

FSA/FSS has reviewed the European Food Safety Authority (EFSA) risk assessment opinion and confirm that FSA/FSS agree with the safety conclusions outlined. FSA/FSS has had access to all supporting documentation as provided to the EFSA for forming the EFSA opinion. Therefore, the information on which this opinion is based can be found in the EFSA opinion as detailed below. There has been no additional information received by FSA/FSS since the publication date of the EFSA opinion, therefore, the appropriateness of the EFSA opinion is maintained. Following the principles outlined in the introduction for making use of the EFSA opinion, the FSA/FSS opinion is that the feed additive, as described in this application, is safe.

EFSA Risk Assessment:

EFSA has published its risk assessment and opinion, the use of feed additives in water, and the European Reference Laboratory (EURL) analytical method evaluation report has been published, which FSA/FSS has reviewed:

- EFSA Journal No.6289 (2020): Assessment of the application for renewal of authorisation of pyridoxine hydrochloride (vitamin B_6) as a feed additive.
- EFSA Journal No.1956 (2010): Statement on the use of feed additives authorised/applied for use in feed when supplied via water.
- EURL analytical method evaluation report (FAD-2010-0139). FSA/FSS determined the analytical method as appropriate for official controls for this feed additive.

Since this concerns a renewal application, the EFSA opinion refers to the original EFSA risk assessment that FSA/FSS has also reviewed where necessary.

Conclusions from EFSA Risk Assessment:

EFSA (2021) concluded on pyridoxine hydrochloride (Vitamin B_6) that:

- the composition of the additive and conditions of use for the species/categories for which the additive is authorised have not been modified, and that there is no evidence to reconsider the conclusions reached in previous assessments.

- under the current authorised conditions of use in feed and water, pyridoxine hydrochloride (Vitamin B_6) is safe for the target species, consumers and the environment.
- as its effectiveness (efficacy) has previously been demonstrated under its existing authorisation, no further evidence is required.
- on worker safety, this feed additive is not a skin or eye irritant and is not a skin sensitiser. Pyridoxine hydrochloride may cause skin (photo-) sensitisation and in the absence of inhalation toxicity studies, adverse respiratory effects cannot be fully excluded.
- there is no need for specific requirements for a post-market monitoring plan.

Proposed terms of authorisation:

1: Additive details

Category	Details
Additive category	(3) Nutritional feed additive
Functional group	(a) Vitamins, pro-vitamins and chemically well-defined substances having similar effect
Feed additive	Pyridoxine hydrochloride (Vitamin B_6)
ID No	3a831
Target species	All animal species
Authorisation period	10 years from the date of authorisation

Main animal species and their subgroups are defined in Annex IV of REUL 429/2008

2: Additive composition

Component	Contents
Purity criteria	not less than 98.5%

3: Characterisation / identification of the active substance(s)

- Pyridoxine hydrochloride: $C_8H_{11}NO_3 \cdot HCl$
- CAS no:58-56-0
- EINECS no:200-386-2

4: Conditions of use

Species or category of animal	Maximum age	Content of Pyridoxine HCl (Vitamin B_6) (mg of additive/kg of complete feedingstuff with a moisture content of 12%)
All animal species	n/a	Minimum level: No minimum Maximum level: No maximum

5: Other Provisions

1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment and in water shall be indicated.
2. Pyridoxine hydrochloride (vitamin B_6) may be used via water for drinking.
3. Worker/user safety considerations, particularly identified for personal protection for:
    a. Skin sensitiser (photo-sensitiser)
    b. Respiratory sensitiser/irritant

6: Analytical methods

As pyridoxine hydrochloride (Vitamin B_6) is permitted in water, it is appropriate to introduce the verified analytical method specifically for the determination of this feed additive in water.

For the determination of pyridoxine hydrochloride (Vitamin B_6) in the feed additive:

Titration with perchloric acid (Ph. Eur. 10th edition, monograph 0245).

For the determination of pyridoxine hydrochloride (Vitamin B_6) in premixtures:

Reversed phase High Performance Liquid Chromatography coupled to UV detector (RP-HPLC-UV) - VDLUFA Bd.III, 13.9.1 method.

For the determination of pyridoxine hydrochloride (Vitamin B_6) in feedingstuffs and water:

Reversed phase High Performance Liquid Chromatography coupled to fluorescence detector (RP-HPLC-FLD) – method based on EN14164:2008.

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

FSA/FSS has reviewed the European Food Safety Authority (EFSA) risk assessment opinion and confirm that FSA/FSS agree with the safety conclusions outlined. FSA/FSS has had access to all supporting documentation as provided to the EFSA for forming the EFSA opinion. Therefore, the information on which this opinion is based can be found in the EFSA opinion as detailed below. There has been no additional information received by FSA/FSS since the publication date of the EFSA opinion, therefore, the appropriateness of the EFSA opinion is maintained. Following the principles outlined in the introduction for making use of the EFSA opinion, the FSA/FSS opinion is that the feed additive, as described in this application, is safe.

EFSA Risk Assessment:

EFSA has published its risk assessment and opinion, qualified presumption of safety, and the European Reference Laboratory (EURL) analytical method evaluation report has been published, which FSA/FSS has reviewed:

- EFSA Journal No.6167 (2020): Assessment of the application for renewal of the authorisation of Actisaf® Sc 47 (*Saccharomyces cerevisiae* CNCM I-4407) as a feed additive for calves for rearing.
- EFSA Qualified presumption of safety (QPS)
- EURL analytical method evaluation report (FAD-2010-0038). FSA/FSS determined the analytical method as appropriate for official controls for this feed additive.

Since this concerns a renewal application, the EFSA opinion refers to the original EFSA risk assessment that FSA/FSS has also reviewed where necessary.

Conclusions from EFSA Risk Assessment:

EFSA (2020) concluded on *Saccharomyces cerevisiae* CNCM I-4407 (ACTISAF® Sc 47) that:

- *S. cerevisiae* CNCM I-4407 was previously identified as *S. cerevisiae* NCYC Sc 47 under its existing authorisation for use in feed for calves for rearing.
- this feed additive is currently on the market and this renewal remains unchanged for the intended target species (calves for rearing) and minimum use level of $1.5x10^9$ colony-forming units (CFU) per kg complete feed.
- *S. cerevisiae* is well-characterised and is considered by EFSA to be suitable for the qualified presumption of safety (QPS) approach to safety assessment.
- *S. cerevisiae* (ACTISAF® Sc 47) remains safe for calves for rearing, consumers and the environment under the existing authorised conditions of use.
- as its effectiveness (efficacy) has previously been demonstrated under its existing authorisation, no further evidence is required.
- on worker safety, the feed additive is not a skin or eye irritant and is unlikely to pose a risk by inhalation. In the absence of data, no conclusions could be drawn on the potential of the additive to be a skin sensitiser.
- there is no need for specific requirements for a post-market monitoring plan.

Proposed terms of authorisation:

1: Additive details

Category	Details
Additive category	(4) Zootechnical feed additive
Functional group	(b) Gut flora stabilisers
Feed additive	*Saccharomyces cerevisiae* CNCM I-4407 (ACTISAF® Sc 47)
ID No	4b1702
Target species	Calves for rearing
Authorisation Holder	S.I. Lesaffre
Authorisation period	10 years from the date of authorisation

Main animal species and their subgroups are defined in Annex IV of REUL 429/2008

2: Additive composition

Component	**Contents**
Solid form preparation of *Saccharomyces cerevisiae* CNCM I-4407	containing a minimum of 5×10^9 CFU/g

3: Characterisation / identification of the active substance

Viable dried cells of *Saccharomyces cerevisiae* CNCM I-4407

4: Conditions of use

Species or category of animal	**Maximum age**	**Content of *Saccharomyces cerevisiae* CNCM I-4407 (CFU/kg of complete feedingstuff with a moisture content of 12%)**
Calves for rearing	n/a	Minimum level: 1.5×10^9 CFU/kg Maximum level: No maximum

5: Other Provisions

1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.
2. Worker/user safety considerations, particularly identified for personal protection for:
    a. Skin sensitiser

6: Analytical methods

For enumeration (colony count):

Pour plate method using CGYE (yeast extract glucose chloramphenicol) agar EN 15789.

For identification of yeast strain:

Polymerase chain reaction (PCR) method CEN/TS 15790

7: Transition period arrangements

A proposal for transitional arrangements is set out below for the existing feed additive authorisation for calves for rearing (where all cow sub-groups are defined as food-producing animals).

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 to be 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 for **food-producing animals**

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Annex F: 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)

FSA/FSS has reviewed the European Food Safety Authority (EFSA) risk assessment opinion and confirm that FSA/FSS agree with the safety conclusions outlined. FSA/FSS has had access to all supporting documentation as provided to the EFSA for forming the EFSA opinion. Therefore, the information on which this opinion is based can be found in the EFSA opinion as detailed below. There has been no additional information received by FSA/FSS since the publication date of the EFSA opinion, therefore, the appropriateness of the EFSA opinion is maintained. Following the principles outlined in the introduction for making use of the EFSA opinion, the FSA/FSS opinion is that the feed additive, as described in this application, is safe.

Furthermore, in stating this opinion, the FSA/FSS accept the international redesignation from *Bacillus subtilis* to *Bacillus velezensis*. This redesignation is proposed to be reflected in the authorisation for this feed additive and in the following 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.

EFSA Risk Assessment:

EFSA has published its risk assessment and opinion, qualified presumption of safety, and the European Reference Laboratory (EURL) analytical method evaluation report has been published, which FSA/FSS has reviewed:

- EFSA Journal No.6280 (2020): Safety and efficacy of *Bacillus subtilis* PB6 (*Bacillus velezensis* ATCC PTA-6737) as a feed additive for chickens for fattening, chickens reared for laying, minor poultry species (except for laying purposes), ornamental, sporting and game birds. (To note: EFSA refer to *B. subtilis PB6 which* is a trade name for *B. subtilis* and where ATCC PTA-6737 refers to the strain ID code deposited in an internationally recognised Culture Collection).

- EFSA Qualified presumption of safety (QPS)

- EURL analytical method evaluation report (FAD-2008-0039). FSA/FSS determined the analytical method as appropriate for official controls for this feed additive.

Since this concerns a renewal application, the EFSA opinion refers to the original EFSA risk assessment that FSA/FSS has also reviewed where necessary.

Conclusions from EFSA Risk Assessment:

EFSA (2020) concluded on *B. velezensis* (ATCC PTA-6737) that:

- in previous risk assessments undertaken, that this bacterial strain is safe and effective (efficacious), as authorised under the regulations listed above.

- this bacterial strain was originally identified as *B. subtilis* (PB6) and recognises its redesignation to *B. velezensis*.

- this bacterial strain is well-characterised and is considered suitable for the qualified presumption of safety (QPS) approach to safety assessment.

- risk assessment consideration was taken in context of the proposed increase in concentration of the feed additive (stock) product from 1×10^8 to 8×10^8 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. The

final level of the feed additive incorporated into feed remains unchanged at a minimum content of 1 x 10^7 CFU/kg complete feed.

- *B. velezensis* (ATCC PTA-6737) is presumed safe for the target species, consumers of products derived from animals fed the additive (for example, meat or eggs) and the environment.

- the effectiveness (efficacy) of *B. velezensis* (ATCC PTA-6737) has previously been demonstrated under its existing authorisations in feedingstuffs for chickens for fattening and chickens reared for laying at the level of 1 x 10^7 CFU/kg complete feed. Further evidence is not required and this conclusion for efficacy can be extrapolated to minor poultry species (except for laying), ornamental, sporting and game birds.

- on worker safety, the additive is not a skin/eye irritant or a skin sensitiser and exposure via inhalation is unlikely.

- there is no need for specific requirements for a post-market monitoring plan.

Proposed terms of authorisation:

1: Additive details

Category	Details
Additive category	(4) Zootechnical feed additive
Functional group	(b) Gut flora stabilisers
Feed additive	*Bacillus velezensis* (ATCC PTA-6737)
ID No	4b1823
Target species	Chickens for fattening, chickens reared for laying, minor poultry species (except for laying), ornamental, sporting and game birds.
Authorisation Holder	Kemin Europa N.V.
Authorisation period	10 years from the date of authorisation

Main animal species and their subgroups are defined in Annex IV of REUL 429/2008

2: Additive composition

Component	Contents
Preparation of *Bacillus velezensis* ATCC PTA-6737	containing a minimum of 8×10^{10} CFU/g additive

3: Characterisation / identification of the active substance)

Viable spores of *Bacillus velezensis* (ATCC PTA-6737)

4: Conditions of use

Species or category of animal	**Maximum age**	**Content of *Bacillus velezensis (ATCC PTA-6737)* (CFU/kg of complete feedingstuff with a moisture content of 12%)**
Chickens for fattening, chickens reared for laying, minor poultry species (except for laying), ornamental, sporting and game birds	n/a	Minimum level: 1×10^7 CFU/kg Maximum level: No maximum

5: Other Provisions

1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.
2. If *Bacillus velezensis* (ATCC PTA-6737) is to be used in feed containing coccidiostats, this feed additive is allowed in feed for specified animal species containing coccidiostats under the individual authorisation criteria for: lasalocid, maduramycin, monensin, narasin, salinomycin, decoquinate, robenidine, diclazuril and narasin/nicarbazin (last entry as combined use only).
3. Worker/user safety considerations, particularly identified for personal protection for:
    - No specified hazards

6: Analytical methods

For enumeration (colony count):

Spread plate method using tryptone soya agar with pre-heat treatment of feed samples.

For identification of bacterial strain:

Pulsed-field gel electrophoresis (PFGE).

7: Transition period arrangements

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**

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Annex G: 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)

FSA/FSS has reviewed the European Food Safety Authority (EFSA) risk assessment opinion and confirm that FSA/FSS agree with the safety conclusions outlined. FSA/FSS has had access to all supporting documentation as provided to the EFSA for forming the EFSA opinion. Therefore, the information on which this opinion is based can be found in the EFSA opinion as detailed below. There has been no additional information received by FSA/FSS since the publication date of the EFSA opinion, therefore, the appropriateness of the EFSA opinion is maintained. Following the principles outlined in the introduction for making use of the EFSA opinion, the FSA/FSS opinion is that the feed additive, as described in this application, is safe.

EFSA Risk Assessment:

EFSA has published its risk assessment and opinion, qualified presumption of safety, and the European Reference Laboratory (EURL) analytical method evaluation report has been published, which FSA/FSS has reviewed:

- EFSA Journal No.6449 (2021): Safety and efficacy of the feed additive consisting of *Bacillus licheniformis* DSM 28710 (B-Act®) for laying hens, minor poultry species for laying, poultry species for breeding purposes and ornamental birds (HuvePharma N.V.).
- EFSA Qualified presumption of safety (QPS)
- EURL analytical method evaluation report (FAD-2015-0016). FSA/FSS determined the analytical method as appropriate for official controls for this feed additive.

Conclusions from EFSA Risk Assessment:

EFSA (2021) concluded on *Bacillus licheniformis* DSM 28710 (B-Act®) that:

- it is considered by EFSA to be suitable for the qualified presumption of safety (QPS) approach to safety assessment.

- in addition, the bacterial strain does not harbour acquired antimicrobial resistance genes or has toxigenic potential, and therefore is presumed safe for the target species, consumers and the environment.

- the additive has the potential to be effective (efficacious) at 1.6 x 10^9 colony-forming units (CFU) per kg complete feed for laying hens. This same dose has previously been demonstrated as efficacious in chickens and turkeys for fattening and may be extrapolated to minor poultry species for laying, poultry species for breeding and for ornamental birds.

- the compatibility of B-Act® (*B. licheniformis* DSM 28710) with coccidiostats as previously assessed, apply to the current application provided that the maximum authorised concentrations of the coccidiostats for the target species are equal or lower than those for chickens for fattening.

- on worker safety, B-Act® (*B. licheniformis* DSM 28710) is considered a respiratory sensitiser, whilst no conclusions could be drawn on the potential for skin and eye irritation or skin sensitisation.

- there is no need for specific requirements for a post-market monitoring plan.

Proposed terms of authorisation:

1: Additive details

Category	**Details**
Additive category	(4) Zootechnical feed additive
Functional group	(b) Gut flora stabilisers
Feed additive	*Bacillus licheniformis* DSM 28710
ID No	4b1828
Target species	Laying hens, minor poultry species for laying, poultry species for breeding and ornamental birds
Authorisation Holder	HuvePharma NV
Authorisation period	10 years from the date of authorisation

Main animal species and their subgroups are defined in Annex IV of REUL 429/2008

2: Additive composition

Component	Contents
Solid form preparation of *Bacillus licheniformis* DSM 28710	containing a minimum of 3.2×10^9 CFU/g of additive

3: Characterisation / identification of the active substance

Viable spores of *Bacillus licheniformis* DSM 28710

4: Conditions of use

Species or category of animal	Maximum age	Content of *Bacillus licheniformis* DSM 28710 (CFU/kg of complete feedingstuff with a moisture content of 12%)
Laying hens, minor poultry species for laying, poultry species for breeding and ornamental birds	n/a	Minimum level: 1.6×10^9 CFU/kg Maximum level: No maximum

5: Other Provisions

1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.
2. If *B. licheniformis* DSM 28710 is to be used in feed containing coccidiostats, this feed additive is allowed with the following permitted coccidiostats under the individual authorisation criteria for: diclazuril and lasalocid A sodium.
3. Worker/user safety considerations, particularly identified for personal protection for:
    a. Skin and respiratory sensitiser
    b. Skin and eye irritant

6: Analytical methods

For enumeration (colony count) in the additive, premixture and feedingstuffs:

Spread plate method EN 15784

For identification of bacterial strain:

Pulsed-field gel electrophoresis (PFGE)

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Annex H: RP664 - *Clostridium 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)

FSA/FSS has reviewed the European Food Safety Authority (EFSA) risk assessment opinion and confirm that FSA/FSS agree with the safety conclusions outlined. FSA/FSS has had access to all supporting documentation as provided to the EFSA for forming the EFSA opinion. Therefore, the information on which this opinion is based can be found in the EFSA opinion as detailed below. There has been no additional information received by FSA/FSS since the publication date of the EFSA opinion and prior to conclusion of our own risk assessment review, therefore, the appropriateness of the EFSA opinion is maintained. Following the principles outlined in the introduction for making use of the EFSA opinion, the FSA/FSS opinion is that the feed additive, as described in this application, is safe.

EFSA Risk Assessment:

EFSA has published its risk assessment and opinion, and the European Reference Laboratory (EURL) analytical method evaluation report has been published, which FSA/FSS has reviewed:

- EFSA Journal No.6450 (2021): Safety and efficacy of the feed additive consisting of *Clostridium butyricum* FERM BP-2789 (Miya-Gold® S) 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 (Miyarisan Pharmaceutical Co. Ltd.).
- EURL analytical method evaluation report (FAD-2010-0005). FSA/FSS determined the analytical method as appropriate for official controls for this feed additive.

Since this concerns a renewal application, the EFSA opinion refers to the original EFSA risk assessment that FSA/FSS has also reviewed where necessary.

Conclusions from EFSA Risk Assessment:

EFSA (2021) concluded on *Clostridium butyricum* FERM BP-2789 (Miya-Gold® S) that:

- its use for chickens for fattening was previously permitted on the market, although its authorisation expired, and is submitted as a new use.
- Miya-Gold® S remains safe for the animal species and their sub-groups, for consumers and the environment under the current and previously authorised conditions of use.
- the effectiveness (efficacy) of Miya-Gold® S has previously been demonstrated in feed under its existing authorisations and the conditions of use for these target species have not been modified for:
    - weaned piglets and weaned minor porcine species; in chickens reared for laying and minor avian species (excluding laying birds) at a minimum of 2.5 x 10^8 colony-forming units (CFU) per kg complete feed
    - turkeys for fattening and turkeys reared for breeding at a minimum of 1.25 x 10^8 CFU/kg complete feed.
- further evidence on efficacy is not required and conclusons on its effectiveness can be extrapolated to chickens for fattening, suckling piglets and suckling minor porcine species at the level of 2.5 x 10^8 CFU/kg complete feed.
- Miya-Gold® S is compatible with the following coccidiostats: decoquinate, diclazuril, lasalocid, maduramicin ammonium, narasin, narasin/nicarbazin, monens in sodium, robenidine, salinomycin sodium and semduramicin sodium.
- on worker safety, Miya-Gold® S is not a skin or eye irritant, whilst no conclusions were drawn on its potential as a respiratory sensitiser.
- there is no need for specific requirements for a post-market monitoring plan.

Proposed terms of authorisation:

1: Additive details

Category	Details
Additive category	(4) Zootechnical feed additive
Functional group	(b) Gut flora stabilisers
Feed additive	*Clostridium butyricum* (FERM BP-2789)
ID No	4b1830
Target species	Chickens for fattening; chickens reared for laying, turkeys for fattening and turkeys reared for breeding, minor avian species (excluding laying birds) piglets (suckling and weaned) and minor porcine species (suckling and weaned)
Authorisation Holder	Miyarisan Pharmaceutical Co Ltd
Authorisation period	10 years from the date authorisation

Main animal species and their subgroups are defined in Annex IV of REUL 429/2008

Dossier submitted by Pen & Tec Consulting SLU as representatives for the authorisation holder (Miyarisan Pharmaceutical Co. Ltd.)

2: Additive composition

Component	Contents
Solid form preparation of *Clostridium butyricum* (FERM BP-2789)	containing a minimum of 5×10^8 CFU/g additive

3: Characterisation / identification of the active substance

Viable spores of *Clostridium butyricum* FERM BP-2789

4: Conditions of use

Species or category of animal	**Maximum age**	**Content of *Clostridium butyricum* FERM BP-2789 (CFU/kg of complete feedingstuff with a moisture content of 12%)**
Turkeys for fattening; Turkeys reared for breeding	n/a	Minimum level: 1.25 x 10^8 CFU/kg Maximum level: No maximum
Chickens for fattening; chickens reared for laying, minor avian species (excluding laying birds) piglets (suckling and weaned) and minor porcine species (suckling and weaned) porcine species (suckling and weaned)	n/a	Minimum level: 2.5 x 10^8 CFU/kg Maximum level: No maximum

5: Other Provisions

1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.
2. If *Clostridium butyricum* (FERM BP-2789) is to be used in feed containing coccidiostats, this feed additive is allowed in feed for specified animal species for coccidiostats under the individual authorisation criteria for: decoquinate, diclazuril, lasalocid, maduramicin ammonium, monensin sodium, narasin, narasin/nicarbazin (as combined use), robenidine, salinomycin sodium and semduramicin sodium.
3. Worker/user safety considerations, particularly identified for personal protection for:
    - Respiratory sensitiser

6: Analytical methods

For enumeration (colony count):

Pour plate method based on ISO 15213 standard

For identification of bacterial strain:

Pulsed-field gel electrophoresis (PFGE)

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Annex I: 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®, Huvepharma EOOD) (new)

FSA/FSS has reviewed the European Food Safety Authority (EFSA) risk assessment opinion and confirm that FSA/FSS agree with the safety conclusions outlined. FSA/FSS has had access to all supporting documentation as provided to the EFSA for forming the EFSA opinion. Therefore, the information on which this opinion is based can be found in the EFSA opinion as detailed below. There has been no additional information received by FSA/FSS since the publication date of the EFSA opinion, therefore, the appropriateness of the EFSA opinion is maintained. Following the principles outlined in the introduction for making use of the EFSA opinion, the FSA/FSS opinion is that the feed additive, as described in this application, is safe.

EFSA Risk Assessment:

EFSA has published its risk assessments and opinions, qualified presumption of safety, and the European Reference Laboratory (EURL) analytical method evaluation report has been published, which FSA/FSS has reviewed:

- EFSA Journal No.6141 (2020): Safety and efficacy of OptiPhos® PLUS for poultry species for fattening, minor poultry species reared for breeding and ornamental birds.
- EFSA Journal No.6161 (2020): Safety and efficacy of OptiPhos® PLUS (6 phytase) for laying hens, turkeys for breeding, chickens for breeding, minor poultry species for egg production purposes and breeding.
- EFSA Journal No.6204 (2020): Safety and efficacy of OptiPhos® PLUS for suckling and weaned piglets, pigs for fattening, sows, other minor pig species for fattening and other minor reproductive pig species.
- EFSA Qualified presumption of safety (QPS)
- EURL analytical method evaluation report (FAD-2019-0052). FSA/FSS determined the analytical method as appropriate for official controls for this feed additive.

Conclusions from EFSA Risk Assessment:

EFSA (2020) concluded on 6-phytase produced by *Komagataella phaffii* DSM 32854 (OptiPhos® Plus) that:

- 6-phytase is produced by a genetically modified yeast strain of *K. phaffii*, which is well-characterised and is considered suitable to the qualified presumption of safety (QPS) approach to safety assessment when used for enzyme production. The genetic modification of the production strain does not give rise to safety concerns and viable cells of the production strain and its DNA were not detected in the finished feed additive.

- the additive is safe for the proposed target species under the conditions of use, with a wide margin of safety of over 100-fold for chickens for fattening and this conclusion on safety is extrapolated to all species and sub-groups requested in this application. The feed additive is also considered safe for consumers and the environment.

- OptiPhos® Plus has the potential to be effective (efficacious) in increasing phosphorus utilisation in the studied target avian and porcine species at 250 FTU/kg* in complete feed in the proposed granular, coated and liquid forms. This same conclusion can be extrapolated to the minor avian and porcine species proposed under this application.

- on worker safety, OptiPhos® Plus is a skin sensitiser, although not a skin irritant. No conclusions could be drawn on the feed additive as an eye irritant, and given the proteinaceous nature of the active substance, it is to be considered as a respiratory sensitiser.

- there is no need for specific requirements for a post-market monitoring plan.

* [(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:

1: Additive details

Category	Details
Additive category	(4) Zootechnical feed additive
Functional group	(a) Digestibility enhancers
Feed additive	6-phytase (EC 3.1.3.26)
ID No	4a32
Target species	All poultry species, ornamental birds, piglets, pigs for fattening, sows, and minor porcine species for fattening or reproduction
Authorisation Holder	Huvepharma EOOD
Authorisation period	10 years from the date of authorisation

Main animal species and their subgroups are defined in Annex IV of REUL 429/2008

2: Additive composition

Preparation of 6-phytase (EC 3.1.3.26) produced by *K. phaffii* (DSM 32854).

Form	Minimum activity (FTU = phytase units)
Granular form	5 000 FTU/g
Coated form	5 000 FTU/g
Liquid form	5 000 FTU/g

3: Characterisation / identification of the active substance

6-phytase (EC 3.1.3.26) produced by fermentation with *Komagataella phaffii* DSM 32854

4: Conditions of use

Species or category of animal	Maximum age	Content of 6-phytase (units of activity/kg of complete feedingstuff with a moisture content of 12%)
All poultry species; ornamental birds; piglets; pigs for fattening; sows; minor porcine species for fattening or reproduction	n/a	Minimum level: 250 FTU Maximum level: No maximum

5: Other Provisions

1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.
2. Worker/user safety considerations, particularly identified for personal protection for:
    a. Skin and respiratory sensitiser
    b. Eye irritant

6: Analytical methods

For the quantification of phytase activity in the feed additive:

Colorimetric method based on the enzymatic reaction of phytase on the phytate – VDLUFA 27.1.4.

For the quantification of phytase activity in premixtures:

Colorimetric method based on the enzymatic reaction of phytase on the phytate - VDLUFA 27.1.3.

For the quantification of phytase activity in feed materials and compound feed:

Colorimetric method based on the enzymatic reaction of phytase on the phytate – EN ISO 30024

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

FSA/FSS has reviewed the European Food Safety Authority (EFSA) risk assessment opinion and confirm that FSA/FSS agree with the safety conclusions outlined. FSA/FSS has had access to all supporting documentation as provided to the EFSA for forming the EFSA opinion. Therefore, the information on which this opinion is based can be found in the EFSA opinion as detailed below. There has been no additional information received by FSA/FSS since the publication date of the EFSA opinion, therefore, the appropriateness of the EFSA opinion is maintained. Following the principles outlined in the introduction for making use of the EFSA opinion, the FSA/FSS opinion is that the feed additive, as described in this application, is safe.

For the submission to GB nations, the applicant proposed a level of use of decoquinate at 20-40 mg/kg in complete feed. Residues in tissues or other products of animal origin were proposed for liver and skin/fat (1,000 µg/kg); kidney (800 µg/kg) and muscle (500 µg/kg), with no withdrawal period required for decoquinate (Deccox®) in feed for chickens for fattening, as for its existing authorisation.

The composition of Deccox® contains micronised decoquinate (60 g/kg complete feed) as the active substance, blended with colloidal silica, soybean oil and wheat middlings as a carrier.

A separate application (RP419) has been submitted for (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 of the feed additive (different diluent and physical form).

EFSA Risk Assessment:

EFSA has published its risk assessments and opinions, and the European Reference Laboratory (EURL) analytical method evaluation report has been published, which FSA/FSS has reviewed:

- EFSA Journal No.5541 (2019): Safety and efficacy of Deccox® (decoquinate) for chickens for fattening.

- EFSA Journal No.6453 (2021): Efficacy of the feed additive consisting of decoquinate (Deccox®) for use in chickens for fattening (Zoetis Belgium SA).
- EURL analytical method evaluation reports (FAD-2013-0034). FSA/FSS determined the analytical method as appropriate for official controls for this feed additive.

Since this concerns a re-evaluation of an existing feed additive (Article 10 application), the EFSA opinion refers to the original EFSA risk assessment that FSA/FSS has also reviewed where necessary.

Conclusions from EFSA Risk Assessment:

EFSA (2019, 2021) concluded on Deccox® (decoquinate) that:

- it is effective in controlling coccidiosis (protozoa/parasite gut infection) in chickens for fattening at a minimum dose of 30 mg/kg complete feed.
- decoquinate is safe for chickens for fattening at the highest proposed concentration in complete feed of 40 mg/kg with a margin of safety of 5-10 times this maximum proposed level.
- this feed additive is safe for the consumer under the proposed conditions of use and no withdrawal period is required to ensure consumer safety. In addition, no maximum residue limits were considered necessary.
- decoquinate does not have antibacterial action and is not genotoxic or carcinogenic.
- only bentonite was identified in context of relevant interactions with other additives or veterinary drugs.
- decoquinate used in chickens for fattening up to the highest proposed dose of 40 mg/kg complete feed does not pose a risk for terrestrial, aquatic compartment and sediment. No risk is expected for secondary poisoning or for groundwater contamination.

- on worker safety, Deccox® is not a skin or eye irritant and has no sensitisation potential, whilst inhalation risk for users is considered negligible as inhalation toxicity and exposure are very low.

- on post-market monitoring, for field monitoring of *Eimeria* spp. resistance to decoquinate should be undertaken by the holder of authorisation.

Proposed terms of authorisation:

1: Additive details

Category	Details
Additive category	(5) Coccidiostats and Histomonostats
Functional group	n/a
Feed additive	Decoquinate (Deccox®)
ID No	51756i
Target species	Chickens for fattening
Authorisation Holder	Zoetis Belgium SA
Authorisation period	10 years from the date of authorisation

Main animal species and their subgroups are defined in Annex IV of REUL 429/2008

2: Additive composition

Component	Contents
Decoquinate	60.0 g/kg
Refined deodorised soya oil	28.5 g/kg
Colloidal silica	0.6 g/kg
Wheat middlings	q.s. 1 kg

3: Characterisation / identification of the active substance

Decoquinate: (Ethyl 6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylate)

- Chemical Formula: $C_{24}H_{35}NO_5$

- CAS No: 18507-89-6

Related impurities:

- Methyl-6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylate: < 1.0%

- 6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylic acid: < 0.5%
- Diethyl-4-decycloxy-3-ethoxyanilinomethylenemalonate: < 0.5%

4: Conditions of use

Species or category of animal	**Maximum age**	**Content of Decoquinate (Deccox®) (mg/kg of complete feedingstuff with a moisture content of 12%):**
Chickens for fattening	n/a	Minimum level: 30 mg/kg Maximum level: 40 mg/kg

Minimum level raised from 20 mg/kg based on EFSA conclusions on efficacy.

5: Other Provisions

1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.
2. The additive shall be incorporated in compound feedingstuffs in the form of a premixture.
3. Decoquinate shall not be mixed with other coccidiostats.
4. Decoquinate shall not be used in feed containing bentonite
5. Post-market monitoring programmes shall be carried out by the holder of authorisation for resistance to bacteria and *Eimeria* spp.
6. Worker/user safety considerations, particularly identified for personal protection:
    - No specified irritant/sensitiser hazards

6: Analytical methods

For the quantification of decoquinate in the feed additive, premixtures and feedingstuffs:

Reversed-Phase High Performance Liquid Chromatography with fluorescence detection (RP-HPLC-FL) – EN 16162

For the quantification of decoquinate in tissues:

Reversed-Phase High Performance Liquid Chromatography coupled to a triple quadrupole mass spectrometer (RP-HPLC-MS/MS).

7: Transition period arrangements

Proposal: Feed containing this feed additive may to 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 preparation or feed containing the feed additive to be produced and labelled within six months after the date of this authorisation
- Longer transitional arrangements for feed additives intended for food-producing animals only are not suggested for this cocidiostat feed additive (Decoquinate - Deccox®). Such medicated feeds are not manufactured with an extended shelf-life and the composition of Deccox® has not changed from its existing authorisation (only minimum content in feed, impacting shorter term labelling and stocks).

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

FSA/FSS has reviewed the European Food Safety Authority (EFSA) risk assessment opinion and confirm that FSA/FSS agree with the safety conclusions outlined. FSA/FSS has had access to all supporting documentation as provided to the EFSA for forming the EFSA opinion. Therefore, the information on which this opinion is based can be found in the EFSA opinion as detailed below. There has been no additional information received by FSA/FSS since the publication date of the EFSA opinion, therefore, the appropriateness of the EFSA opinion is maintained. Following the principles outlined in the introduction for making use of the EFSA opinion, the FSA/FSS opinion is that the feed additive, as described in this application, is safe.

Avi-Deccox® 60G maintains the same active substance and characteristics of decoquinate as for Deccox®, and differs only in non-functional characteristics (i.e. diluent used and its physical form). Consequently, the risk assessment of Avi-Deccox® 60G is most recently based on the existing opinion for decoquinate undertaken for Deccox® (RP1030). EFSA previously published its risk assessment on Avi-Deccox® 60G in 2014 in comparison to Deccox® and its common active substance decoquinate.

The new formulation as 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 gut infection (coccidiosis) caused by protozoa/ parasites (i.e *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 were proposed for liver and skin/fat (1,000 µg/kg); kidney (800 µg/kg) and muscle (500 µg/kg) and in maintaining a zero day withdrawal period in feed for chickens for fattening.

EFSA published its initial risk assessment on Avi-Deccox® 60G in 2014 in comparison to Deccox®, and is considered further under more recent EFSA Opinions for Deccox® due to the common active substance of decoquinate.

EFSA Risk Assessment:

EFSA has published its risk assessments and opinions, and the European Reference Laboratory (EURL) analytical method evaluation report has been published, which FSA/FSS has reviewed:

- EFSA Journal No.3905 (2014): Scientific Opinion on the modification of the terms of authorisation of Avi-Deccox® 60G (decoquinate) for chickens for fattening.
- EFSA Journal No.5541 (2019): Safety and efficacy of Deccox® (decoquinate) for chickens for fattening.
- EFSA Journal No.6453 (2021): Efficacy of the feed additive consisting of decoquinate (Deccox®) for use in chickens for fattening (Zoetis Belgium SA).
- EURL analytical method evaluation report (FAD-2014-0014). FSA/FSS determined the analytical method as appropriate for official controls for this feed additive.

Since this concerns a modification application, the EFSA opinion refers to the original EFSA risk assessment that FSA/FSS has also reviewed where necessary.

Conclusions from EFSA Risk Assessment:

EFSA (2014) concluded on **Avi-Deccox® 60G** that:

- it also contains the same active substance decoquinate at the same concentration 60g/kg (6%) complete feed as for the existing authorisation of Deccox® and its re-evaluation under RP1030.
- the difference between Avi-Deccox® 60G and Deccox® relates solely to the inert carrier (calcium sulphate dihydrate and wheat middlings respectively), and their physical forms (granulated and powdered respectively). These differences will not affect the safety for the target species, consumer, user and environment with respect of the assessment of Deccox® (decoquinate).

- Avi-Deccox® 60G is equivalent to Deccox® in terms of the capacity of the feed additive to control coccidiosis in chickens.

As for the application to GB nations RP1030 for **Deccox®**, EFSA (2019, 2021) concluded on the common active substance decoquinate that:

- it is effective in controlling coccidiosis in chickens for fattening at a minimum dose of 30 mg/kg complete feed.
- decoquinate is safe for chickens for fattening at the highest proposed concentration in complete feed of 40 mg/kg complete feed with a margin of safety of 5-10 times this maximum proposed level.
- this feed additive is safe for the consumer under the proposed conditions of use and no withdrawal period is required to ensure consumer safety. In addition, no maximum residue limits were considered necessary.
- decoquinate does not have antibacterial action and is not genotoxic or carcinogenic.
- only bentonite was identified in context of relevant interactions with other additives or veterinary drugs.
- decoquinate used in chickens for fattening up to the highest proposed dose of 40 mg/kg complete feed does not pose a risk for terrestrial, aquatic compartment and sediment. No risk is expected for secondary poisoning or for groundwater contamination.
- on worker safety, decoquinate (Deccox®) is not a skin or eye irritant and has no sensitisation potential, whilst inhalation risk for users is considered negligible as inhalation toxicity and exposure are very low.
- on post-market monitoring, for field monitoring of *Eimeria* spp. resistance to decoquinate should be undertaken by the holder of authorisation.

Proposed terms of authorisation:

1: Additive details

Category	Details
Additive category	(5) Coccidiostats and Histomonostats
Functional group	n/a
Feed additive	Decoquinate (Avi-Deccox® 60G)
ID No	51756ii
Target species	Chickens for fattening
Authorisation Holder	Zoetis Belgium SA
Authorisation period	10 years from the date of authorisation

Main animal species and their subgroups are defined in Annex IV of REUL 429/2008

2: Additive composition

Component	Contents
Decoquinate	60.0 g/kg
Colloidal silica	0.6 g/kg
Silicon dioxide	4.0 g/kg
Carboxymethylcellulose sodium	30.0 g/kg
Calcium sulphate dihydrate	q.s. ad 1,000 g

3: Characterisation / identification of the active substance

Decoquinate: (Ethyl 6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylate)

- Chemical Formula: $C_{24}H_{35}NO_5$
- CAS No: 18507-89-6

Related impurities:

- Methyl-6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylate: < 1.0%
- 6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylic acid: < 0.5%
- Diethyl-4-decycloxy-3-ethoxyanilinomethylenemalonate: < 0.5%

4: Conditions of use

Species or category of animal	Maximum age	Content of Decoquinate (Avi-Deccox®) (mg/kg of complete feedingstuff with a moisture content of 12%):
All requested species	n/a	Minimum level: 30 mg/kg Maximum level: 40 mg/kg

Minimum level raised from 20 mg/kg based on EFSA conclusions on efficacy.

5: Other Provisions

1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated
2. The additive shall be incorporated in compound feedingstuffs in the form of a premixture
3. Decoquinate shall not be mixed with other coccidiostats
4. Decoquinate shall not be used in feed containing bentonite
5. Post-market monitoring programmes shall be carried out by the holder of authorisation for resistance to bacteria and *Eimeria* spp.
6. Worker/user safety considerations, particularly identified for personal protection:
    - No specified irritant/sensitiser hazard

6: Analytical methods

For the quantification of decoquinate in the feed additive, premixtures and feedingstuffs:

Reversed-Phase High Performance Liquid Chromatography with fluorescence detection (RP-HPLC-FL) – EN 16162.

For the quantification of decoquinate in tissues:

Reversed-Phase High Performance Liquid Chromatography coupled to a triple quadrupole mass spectrometer (RP-HPLC-MS/MS) or any other analytical method complying with the requirements set by Retained EU Decision 2002/657

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