**FSS/FSA risk management recommendations on twenty-four feed additives applications and one application for a particular nutritional purposes (PARNUT) for use in animal feed**

Date of publication:

## Document subject and purpose

In this document we publish Food Standards Scotland’s (FSS) risk management recommendations on 24 applications for feed additives, and an application for a particular nutritional purposes (PARNUT) for use in animal feed.

Since the end of the EU exit transition period, the FSS/FSA have adopted technical guidance and quality assurance processes used by the European Food Safety Authority (EFSA) to be able to undertake GB safety assessments for regulated product applications. Further information is available on our website:

<https://www.food.gov.uk/business-guidance/regulated-products-application-guidance>

These risk management recommendations take into account the [opinions](https://www.legislation.gov.uk/eur/2003/1831/article/8) of FSS and FSA, which also considers:

* The safety assessments of FSS and FSA for each application;
* Potential impacts that would result from the authorisation of these feed additives; and
* Other legitimate factors that Scottish Ministers may want to consider before making a decision regarding authorisation.

The final FSS/FSA proposed risk management recommendations that are made to Ministers in Scotland, England and Wales (with Ministers/the Department of Health Permanent Secretary in Northern Ireland being kept informed) will also consider stakeholders’ views received from this consultation.

**Our safety assessment and opinion**

Our risk assessors deliver the science behind our advice. They are responsible for identifying and characterising hazards and risks to health and assessing levels of exposure.

The applications in this consultation have undergone a full safety assessment, including full review of the applicants’ dossiers. The views of the Advisory Committee on Animal Feedingstuffs (ACAF) and the views of the Animal Feed & Feed Additives Joint Expert Group (AFFAJEG) have been taken into account in the FSS/FSA safety assessment for the feed additive applications. The views of the Committees are reflected in the published safety assessments which form the opinions of FSS and the FSA on these applications.

The risk management recommendations will be considered by Scottish Ministers to inform determinations on the authorisation of the feed additives and PARNUT applications in Scotland. The risk management recommendations are being published in parallel with FSA to equally inform Ministers' determination in England and Wales, (with the Department of Health Permanent Secretary in Northern Ireland kept informed).

**Risk management recommendations**

FSS/FSA have made risk management recommendations on the applications for the authorisation of twenty-four feed additives and one PARNUT. The FSS/FSA risk management recommendation for each application is published within a separate annex (linked below), including the regulated product ID number and title of the application. A link to the individual opinion/safety assessments is provided in each Annex.

[Annex A: RP24 - Saccharomyces cerevisiae (MUCL 39885) as a feed additive for weaned piglets (Biosprint®) (Prosol S.p.A.) (renewal)](#_Annex_B:_RP24)

[Annex B: RP25 - Saccharomyces cerevisiae (MUCL 39885) as a feed additive for all pigs and minor porcine species other than sows and piglets (suckling and weaned) (Biosprint®) (Prosol S.p.A.) (new use)](#_Annex_C:_RP25)

[Annex C: RP26 - Saccharomyces cerevisiae (MUCL 39885) as a feed additive for cats and dogs. (Biosprint®) (Prosol S.p.A.) (new use)](#_Annex_D:_RP26)

[Annex D: RP29 – A preparation of Pediococcus acidilactici (CNCM I-4622) as a feed additive for all animal species (Danstar Ferment AG, Switzerland) (new)](#_Annex_E:_RP29)

[Annex E: Monensin sodium produced from Streptomyces cinnamonensis 28682 (NBIMCC 3419) as a feed additive for chickens for fattening, chickens reared for laying and turkeys for fattening (Coxidin®) (Huvepharma NV) (renewal and modification)](#_Annex_F:_RP140)

[Annex F: RP141 - Monensin sodium produced from Streptomyces cinnamonensis 28682 (NBIMCC 3419) as a feed additive for chickens for fattening and turkeys (Coxidin®) (Huvepharma NV) (renewal and modification)](#_Annex_G:_RP141)

[Annex G: RP142 - Monensin sodium produced from Streptomyces cinnamonensis 28682 (NBIMCC 3419) as a feed additive for chickens reared for laying and turkeys reared for breeding (Coxidin®) (Huvepharma NV) (new use)](#_Annex_H:_RP142)

[Annex H: RP185 - 6–phytase (EC 3.1.3.26) produced from Komagataella phaffii (formerly Komagataella pastoris) (DSM 23036) as a feed additive for all avian species and all pigs (OptiPhos®) (Huvepharma EOOD) (renewal, new use and modification)](#_Annex_I:_RP185)

[Annex I: RP222 - Selenised yeast produced from Saccharomyces cerevisiae (CNCM I-3060), inactivated as a feed additive for all animal species (All-Technology (Ireland) Limited) (modification)](#_Annex_J:_RP222)

[Annex J: RP284 - Monensin sodium produced from Streptomyces cinnemonensis 28682 (NBIMCC 3419) as a feed additive for turkeys reared for breeding (Coxidin®) (Huvepharma NV) (new use)](#_Annex_K:_RP284)

[Annex K: RP641 – A preparation of Bacillus velezensis (formerly Bacillus subtilis C-3102) (DSM 15544) as a feed additive for weaned piglets and all avian species (Calsporin®) (Asahi Biocycle Co., Ltd) (renewal, new use and modification)](#_Annex_L:_RP641)

[Annex L: RP1105 – L-histidine monohydrochloride monohydrate produced from Escherichia coli (KCCM 80212) as a feed additive for all animal species (Daesang Europe B.V.) (new)](#_Annex_M:_RP1105)

[Annex M: RP1125 – L-tryptophan produced from Escherichia coli (KCCM 80210) as a feed additive for all animal species (Daesang Europe B.V.) (new)](#_Annex_N:_RP1125)

[Annex N: RP1126 – L-lysine sulphate produced from Corynebacterium glutamicum (KCCM 80227) as a feed additive for all animal species (Daesang Europe B.V.) (new)](#_Annex_O:_RP1126)

[Annex O: RP1198 – Butylated hydroxyanisole (BHA) as a feed additive for cats (FEDIAF) (new)](#_Annex_P:_RP1198)

[Annex P: RP1199 - Part A – L-lysine base (liquid) produced from Corynebacterium glutamicum (KCCM 80183) as a feed additive for all animal species. (CJ Europe GmbH) (new)](#_Annex_Q:_RP1199)

[Annex Q: RP1199 - Part B – L-lysine monohydrochloride (technically pure) produced from Corynebacterium glutamicum (KCCM 80183) as a feed for all animal species (CJ Europe GmbH) (new)](#_Annex_R:_RP1199)

[Annex R: RP1200 – Disodium 5’-guanylate produced from Corynebacterium stationis (KCCM 10530) and Escherichia coli (KFCC 11067) as a feed additive for all animal species (CJ Europe GmbH) (new)](#_Annex_S:_RP1200)

[Annex S: RP1259 – Muramidase (EC 3.2.1.17) produced from Trichoderma reesei (DSM 32338) (Balancius®) as a feed additive for weaned piglets (DSM Nutritional Products Ltd) (new use)](#_Annex_T:_RP1259)

[Annex T: RP1349 - Phytomenadione (Vitamin K1) as a feed additive for horses (JARAZ Enterprises GmbH & Co KG) (new)](#_Annex_U:_RP1349)

[Annex U: RP1386 – Copper chelate of hydroxy analogue of methionine as a feed additive for all animal species (Novus Europe NV) (renewal and modification)](#_Annex_V:_RP1386)

[Annex V: RP1387 – Manganese chelate of hydroxy analogue of methionine as a feed additive for all animal species (Novus Europe NV) (renewal and modification)](#_Annex_W:_RP1387)

[Annex W: RP1388 - Zinc chelate of hydroxy analogue of methionine as a feed additive for all animal species (Novus Europe NV) (renewal and modification)](#_Annex_X:_RP1388)

[Annex X: RP1591 - Fumonisin esterase (EC 3.1.1.87) produced from Komagataella phaffii (DSM 32159) as a feed additive for all species (DSM Nutritional Products Ltd, Switzerland) (new use)](#_Annex_Y:_RP1591)

[Annex Y: RP1654 - Ecobiol® (Bacillus amyloliquefaciens CECT 5940) and Fecinor® (Enterococcus faecium CECT 4515)(Evonik Operations GmbH) (modification) administrative change of authorisation holder](#_Annex_Z:_RP1654)

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

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## 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.

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**Annexes:**

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

**Background**

The FSS/FSA has undertaken a safety assessment of application RP24 for the renewal of use of *Saccharomyces cerevisiae* (MUCL 39885) as a feed additive for weaned piglets. Under this authorisation, the feed additive is marketed in two forms, Biosprint® S in spherical form and Biosprint® G in granular form.

**Safety assessment summary**

The FSS/FSA safety assessment was published on 29 September 2023 and can be found [here](https://www.food.gov.uk/research/research-projects/safety-assessment-rp24-25-26-saccharomyces-cerevisiae-mucl39885-4b1710). The assessment of *S. cerevisiae* (MUCL 39885)shows that the conditions for authorisation in [Article 5](https://www.legislation.gov.uk/eur/2003/1831/article/5) of [Regulation (EC) 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) are satisfied.

The FSS/FSA conclusion on *Saccharomyces cerevisiae* (MUCL 39885) is that:

* *Saccharomyces cerevisiae* (MUCL 39885) 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 feed additive is considered safe for the proposed target species, consumers and the environment.
* *S. cerevisiae* (MUCL 39885) is efficacious for improving faecal consistency in:
	+ All Suidae for reproduction purposes (other than sows) at the proposed dose of 6.4 x 109 CFU/kg (of complete feed with a moisture content of 12%).
	+ Weaned piglets and all Suidae (other than suckling piglets, sows and Suidae for reproduction) at the proposed dose of 3 x 109 CFU/kg.
* On worker safety, the additive is to be considered an eye and skin irritant and a skin and respiratory sensitiser.
* *Saccharomyces cerevisiae* (MUCL 39885) is not suitable for pelleting or heat treating.
* There is no need for specific requirements for a post-market monitoring plan.

**Relevant Legislation**

Legislation in respect of feed additives applies to this application. In particular it is noted that this application must fulfil the following requirements of [Regulation (EC) No 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) for feed additives for use in animal nutrition:

1. [Article 6](https://www.legislation.gov.uk/eur/2003/1831/article/6): Categories of feed additives.
2. [Article 14](https://www.legislation.gov.uk/eur/2003/1831/article/14): Renewal of authorisation.
3. [Article 16](https://www.legislation.gov.uk/eur/2003/1831/article/16/adopted) and [Annex III](https://www.legislation.gov.uk/eur/2003/1831/annex/III/adopted): Labelling and packaging requirements, if authorised.
4. [Article 21](https://www.legislation.gov.uk/eur/2003/1831/article/21): Analytical methods have been verified by the Reference Laboratory as used for the control of *Saccharomyces cerevisiae* (MUCL 39885) in animal feed as detailed in the EURL analytical method evaluation report ([FAD-2009-0028](https://joint-research-centre.ec.europa.eu/publications/fad-2009-0028_en)). Valid analytical methods exist for:
* Enumeration of the active agent *Saccharomyces cerevisiae* (MUCL 39885)
* Identification of the bacterial strain *Saccharomyces cerevisiae* (MUCL 39885)
1. [Annex IV](https://www.legislation.gov.uk/eur/2003/1831/annex/IV/adopted): The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

**FSS/FSA Risk Management Recommendation**

The FSS/FSA risk management is that *Saccharomyces cerevisiae* (MUCL 39885), as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use. The FSS/FSA conclusion is that we are in favour of authorising the feed additive as per [Regulation (EC) 1831/2003 Article 8](https://www.legislation.gov.uk/eur/2003/1831/article/8). The proposed terms of authorisation are set out below.

**Proposed terms of authorisation**

|  |  |
| --- | --- |
| *Additive* | *Saccharomyces cerevisiae* (MUCL 39885) |
| *Identification number*  | 4b1710 |
| *Authorisation holder* | Prosol S.p.A |
| *Additive category* | Zootechnical additive |
| *Functional group* | Gut flora stabilisers |
| *Additive composition* | Preparation of *Saccharomyces cerevisiae* (MUCL 39885) containing a minimum of 1 x 109 Colony Forming Units (CFU)/g |
| *Characterisation of the active substance(s)* | *Viable cells of Saccharomyces cerevisiae* (MUCL 39885) |
| *Analytical method[[1]](#footnote-2)* | For enumeration : Pour plate method CGYE(chloramphenicol, glucose, yeast extract) agar in accordance with BS EN 15789:2021[[2]](#footnote-3)For identification of the yeast strain: Polymerase chain reaction (PCR) method In accordance with DD CEN/TS15790:2008[[3]](#footnote-4) |
| *Species or category of animal*  | * All suidae other than sows
* Cats
* Dogs
 |
| *Maximum age* | Not applicable |
| *Colony forming units (CFU) of additive/kg complete feed with a moisture content of 12%)*  | *Minimum content* | * For all Suidae (other than suckling pigs, sows and Suidae for reproduction): 3 x 109 CFU/kg 3 x 109 CFU/kg
* For all Suidae for reproduction

purposes other than sows: 6.4 x 109 CFU/kg* For cats and dogs: 7 x 1010 CFU/kg
 |
| *Maximum content* | No maximum |
| *Other provisions* | 1. The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture.
 |

**Supplementary information**

* Feed additives are subject to [UK health and safety legislation](https://www.hse.gov.uk/). The safety assessment identified that particular consideration should be given to hazards as a:
* Skin and eye irritant
* Skin and respirator sensitiser
* Categories and definitions of target animals are defined in Annex IV of [Regulation (EC) 429/2008](https://www.legislation.gov.uk/eur/2008/429/contents).
* The FSS/FSA consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in [Regulation (EC) 183/2005](https://www.legislation.gov.uk/eur/2005/183) laying down requirements for feed hygiene and good manufacturing practice.

**Other legitimate factors**

In developing the risk management recommendations, FSS/FSA have had regard to the other legitimate factors (including consumer Interests, political, environmental, societal and technical feasibility) that Scottish Ministers will consider as part of their decision on authorisation.

FSS/FSA have not identified any applicable other legitimate factors to date that would prevent authorisation or affect the conditions of authorisation of this animal feed additive. As noted above, stakeholders and the broader public are equally invited to consider and provide their views on any relevant other legitimate factors as part of the consultation process.

**Impacts**

As part of the risk analysis process, FSS/FSA have assessed the potential impacts that would result from the authorisation of this animal feed additive, should Scottish Ministers decide to authorise, no significant impacts were identified from this authorisation. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

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

**Background**

The FSS/FSA has undertaken a safety assessment of application RP25 for the use of *Saccharomyces cerevisiae* (MUCL 39885) as a feed additive for all pigs other than sows, suckling and weaned piglets and all minor porcine species.  Under this authorisation, the feed additive is marketed in two forms, Biosprint® S in spherical form and Biosprint® G in granular form.

**Safety assessment summary**

The application was evaluated by our independent Advisory Committee on Animal Feedingstuffs (ACAF). The FSS/FSA safety assessment was published on 29 September 2023 and can be found [here](https://www.food.gov.uk/research/research-projects/safety-assessment-rp24-25-26-saccharomyces-cerevisiae-mucl39885-4b1710). The assessment of *S. cerevisiae* (MUCL 39885)shows that the conditions for authorisation in [Article 5](https://www.legislation.gov.uk/eur/2003/1831/article/5) of [Regulation (EC) 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) are satisfied.

The FSS/FSA conclusion on *Saccharomyces cerevisiae* (MUCL 39885) is that:

* *Saccharomyces cerevisiae* (MUCL 39885) 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 feed additive is considered safe for the proposed target species, consumers and the environment.
* *Saccharomyces cerevisiae* (MUCL 39885) is efficacious for improving faecal consistency in:
	+ All Suidae for reproduction (other than sows) at the proposed dose of 6.4x109 CFU/kg of complete feed with a moisture content of 12%.
	+ Weaned piglets and all Suidae (other than suckling piglets, sows and Suidae for reproduction) at the proposed dose of 3x109 CFU/kg of complete feed with a moisture content of 12%.
* On worker safety, the additive is to be considered an eye and skin irritant and should be considered a skin and respiratory sensitiser.
* *Saccharomyces cerevisiae* (MUCL 39885) is not suitable for pelleting or heat treating.
* There is no need for specific requirements for a post-market monitoring plan.

**Relevant Legislation**

Legislation in respect of feed additives applies to this application. In particular it is noted that this application must fulfil the following requirements of [Regulation (EC) No 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) for feed additives for use in animal nutrition:

1. [Article 4](https://www.legislation.gov.uk/eur/2003/1831/article/4): Authorisation for a new or new use of a feed additive.
2. [Article 6](https://www.legislation.gov.uk/eur/2003/1831/article/6): Categories of feed additives.
3. [Article 7](https://www.legislation.gov.uk/eur/2003/1831/article/7): Application for authorisation of a feed additive.
4. [Article 16](https://www.legislation.gov.uk/eur/2003/1831/article/16/adopted) and [Annex III](https://www.legislation.gov.uk/eur/2003/1831/annex/III/adopted): Labelling and packaging requirements apply, if authorised.
5. [Article 21](https://www.legislation.gov.uk/eur/2003/1831/article/21): Analytical methods have been verified by the Reference Laboratory as used for the control of *Saccharomyces cerevisiae* (MUCL 39885) in animal feed as detailed in the EURL analytical method evaluation report ([FAD-2009-0028)](https://joint-research-centre.ec.europa.eu/publications/fad-2009-0028_en). Valid analytical methods exist for:
* Enumeration of the active agent *Saccharomyces cerevisiae* (MUCL 39885)
* Identification of the bacterial strain *Saccharomyces cerevisiae* (MUCL 39885)
1. [Annex IV](https://www.legislation.gov.uk/eur/2003/1831/annex/IV/adopted): The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

**FSS/FSA risk management recommendation**

The FSS/FSA risk management recommendation is that *Saccharomyces cerevisiae* (MUCL 39885), as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use. The FSS/FSA conclusion is that we are in favour of authorising the feed additive as per [Regulation (EC) 1831/2003 Article 8](https://www.legislation.gov.uk/eur/2003/1831/article/8). The proposed terms of authorisation are set out below.

**Proposed terms of authorisation**

|  |  |
| --- | --- |
| *Additive* | *Saccharomyces Cerevisiae* (MUCL 39885) |
| *Identification number*  | 4b1710 |
| *Authorisation holder* | Prosol S.p.A |
| *Additive category* | Zootechnical additive |
| *Functional group* | Gut flora stabilisers |
| *Additive composition* | Preparation of *Saccharomyces cerevisiae* (MUCL 39885) containing a minimum of 1 x 109 Colony Forming Units (CFU)/kg |
| *Characterisation of the active substance(s)* | *Viable cells of Saccharomyces cerevisiae* (MUCL 39885) |
| *Analytical method[[4]](#footnote-5)* | For enumeration : Pour plate method CGYE (chloramphenicol, glucose, yeast extract) agar in accordance with BS EN 15789:2021[[5]](#footnote-6)For identification of the yeast strain: Polymerase chain reaction (PCR) method In accordance with DD CEN/TS15790:2008[[6]](#footnote-7) |
| *Species or category of animal*  | * All suidae other than sows
* Cats
* Dogs
 |
| *Maximum age* | Not applicable |
| *Colony forming units (CFU) of additive/kg complete feed with a moisture content of 12%)*  | *Minimum content* | * For all Suidae (other than suckling pigs, sows and Suidae for reproduction): 3 x 109 CFU/kg
* For all Suidae for reproduction purposes purposes other than sows: 6.4 x 109 CFU/kg
* For cats and dogs: 7 x 1010 CFU/kg
 |
| *Maximum content* | No maximum |
| *Other provisions* | 1. The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture. directions for use of the feed additive and premixture.
 |

**Supplementary information**

* Feed additives are subject to [UK health and safety legislation](https://www.hse.gov.uk/). The safety assessment identified that particular consideration should be given to hazards as a:
* Skin and eye irritant
* Skin and respiratory sensitiser
* Categories and definitions of target animals are defined in Annex IV of [Regulation (EC) 429/2008](https://www.legislation.gov.uk/eur/2008/429/contents).
* The FSS/FSA consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in [Regulation (EC) 183/2005](https://www.legislation.gov.uk/eur/2005/183) laying down requirements for feed hygiene and good manufacturing practice.

**Other legitimate factors**

In developing the risk management recommendations, FSS/FSA have had regard to the other legitimate factors (including consumer Interests, political, environmental, societal and technical feasibility) that Scottish Ministers will consider as part of their decision on authorisation.

FSS/FSA have not identified any applicable other legitimate factors to date that would prevent authorisation or affect the conditions of authorisation of this animal feed additive. As noted above, stakeholders and the broader public are equally invited to consider and provide their views on any relevant other legitimate factors as part of the consultation process.

**Impacts**

As part of the risk analysis process, FSS/FSA have assessed the potential impacts that would result from the authorisation of this animal feed additive, should Scottish Ministers decide to authorise, no significant impacts were identified from this authorisation. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

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

**Background**

The FSS/FSA has undertaken a safety assessment of application RP26 for the use of *Saccharomyces cerevisiae* (MUCL 39885) as a feed additive for cats and dogs. Under this authorisation, the feed additive is marketed in two forms, Biosprint® S in spherical form and Biosprint® G in granular form.

**Safety assessment summary**

The application was evaluated by our independent Advisory Committee on Animal Feedingstuffs (ACAF). The FSS/FSA safety assessment was published on 29 September 2023 and can be found [here](https://www.food.gov.uk/research/research-projects/safety-assessment-rp24-25-26-saccharomyces-cerevisiae-mucl39885-4b1710). The assessment of *S. cerevisiae* (MUCL 39885)shows that the conditions for authorisation in [Article 5](https://www.legislation.gov.uk/eur/2003/1831/article/5) of [Regulation (EC) 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) are satisfied.

The FSS/FSA conclusion on *Saccharomyces cerevisiae* (MUCL 39885) is that:

* *Saccharomyces cerevisiae* (MUCL 39885) 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 additive is safe for the proposed target species, consumers and the environment.
* *Saccharomyces cerevisiae* (MUCL 39885) is efficacious in improving faecal consistency of cats and dogs at the proposed dose of 7x1010 CFU/kg of complete feed with a moisture content of 12%.
* On worker safety, the additive is to be considered an eye and skin irritant and should be considered a skin and respiratory sensitiser.
* *Saccharomyces cerevisiae* (MUCL 39885) is not suitable for pelleting or heat treating.
* There is no need for specific requirements for a post-market monitoring plan.

**Relevant Legislation**

Legislation in respect of feed additives applies to this application. In particular it is noted that this application must fulfil the following requirements of [Regulation (EC) No 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) for feed additives for use in animal nutrition:

1. [Article 4](https://www.legislation.gov.uk/eur/2003/1831/article/4): Authorisation for a new or new use of a feed additive.
2. [Article 6](https://www.legislation.gov.uk/eur/2003/1831/article/6): Categories of feed additives.
3. [Article 7](https://www.legislation.gov.uk/eur/2003/1831/article/7): Application for authorisation of a feed additive.
4. [Article 16](https://www.legislation.gov.uk/eur/2003/1831/article/16/adopted) and [Annex III](https://www.legislation.gov.uk/eur/2003/1831/annex/III/adopted): Labelling and packaging requirements apply, if authorised.

3. [Article 21](https://www.legislation.gov.uk/eur/2003/1831/article/21): Analytical methods have been verified by the Reference Laboratory as used for the control of *Saccharomyces cerevisiae* (MUCL 39885) in animal feed as detailed in the EURL analytical method evaluation report ([FAD-2009-0028)](https://joint-research-centre.ec.europa.eu/publications/fad-2009-0028_en). Valid analytical methods exist for:

* Enumeration of the active agent *Saccharomyces cerevisiae* (MUCL 39885)
* Identification of the bacterial strain *Saccharomyces cerevisiae* (MUCL 39885)
1. [Annex IV](https://www.legislation.gov.uk/eur/2003/1831/annex/IV/adopted): The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

**FSS/FSA risk management recommendation**

The FSS/FSA concluded that S. *cerevisiae* (MUCL 39885), as described in this application, the is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use. The FSS/FSA conclusion is that we are in favour of authorising the feed additive as per [Regulation (EC) 1831/2003 Article 8](https://www.legislation.gov.uk/eur/2003/1831/article/8). The proposed terms of authorisation are set out below.

**Proposed terms of authorisation**

|  |  |
| --- | --- |
| *Additive* | *Saccharomyces Cerevisiae* (MUCL 39885) |
| *Identification number*  | 4b1710 |
| *Authorisation holder* | Prosol S.p.A |
| *Additive category* | Zootechnical additive |
| *Functional group* | Gut flora stabilisers |
| *Additive composition* | Preparation of *Saccharomyces cerevisiae* (MUCL 39885) containing a minimum of 1 x 109 Colony Forming Units (CFU)/kg |
| *Characterisation of the active substance(s)* | *Viable cells of Saccharomyces cerevisiae* (MUCL 39885) |
| *Analytical method[[7]](#footnote-8)* | For enumeration : Pour plate method CGYE(chloramphenicol, glucose, yeast extract) agar in accordance with BS EN 15789:2021[[8]](#footnote-9)For identification of the yeast strain: Polymerase chain reaction (PCR) method In accordance with DD CEN/TS15790:2008[[9]](#footnote-10) |
| *Species or category of animal*  | * All Suidae other than sows
* Cats
* Dogs
 |
| *Maximum age* | Not applicable |
| *Colony forming units (CFU) of additive/kg complete feed with a moisture content of 12%)*  | *Minimum content* | * For all Suidae (other than suckling pigs, sows and Suidae for reproduction): 3 x 109 CFU/kg
* For all Suidae for reproduction purposes other than sows: 6.4 x 109 CFU/kg
* For cats and dogs: 7 x 1010 CFU/kg
 |
| *Maximum content* | No maximum |
| *Other provisions* | 1. The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture.
 |

**Supplementary information**

* Feed additives are subject to [UK health and safety legislation](https://www.hse.gov.uk/). The safety assessment identified that particular consideration should be given to hazards as a:
* Skin and eye irritant
* Skin and respiratory sensitiser
* Categories and definitions of target animals are defined in Annex IV of [Regulation (EC) 429/2008](https://www.legislation.gov.uk/eur/2008/429/contents).
* The FSS/FSA consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in [Regulation (EC) 183/2005](https://www.legislation.gov.uk/eur/2005/183) laying down requirements for feed hygiene and good manufacturing practice.

Other legitimate factors

In developing the risk management recommendations, FSS/FSA have had regard to the other legitimate factors (including consumer Interests, political, environmental, societal and technical feasibility) that Scottish Ministers will consider as part of their decision on authorisation.

FSS/FSA have not identified any applicable other legitimate factors to date that would prevent authorisation or affect the conditions of authorisation of this animal feed additive. As noted above, stakeholders and the broader public are equally invited to consider and provide their views on any relevant other legitimate factors as part of the consultation process.

Impacts

As part of the risk analysis process, FSS/FSA have assessed the potential impacts that would result from the authorisation of this animal feed additive, should Scottish Ministers decide to authorise, no significant impacts were identified from this authorisation. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

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

**Background**

The FSS/FSA has undertaken a safety assessment of application RP29 for the authorisation of use of *Pediococcus acidilactici* (CNCM I-4622) as a feed additive for all animal species.

**Safety assessment summary**

The application was evaluated by our independent Advisory Committee on Animal Feedingstuffs (ACAF). The FSS/FSA safety assessment was published on 29 September 2023 and can be found [here](https://www.food.gov.uk/research/research-projects/safety-assessment-rp29-pediococcus-acidilactici-cncm-i-4622). The assessment of *Pediococcus acidilactici* (CNCM I-4622) shows that the conditions for authorisation in [Article 5](https://www.legislation.gov.uk/eur/2003/1831/article/5) of [Regulation (EC) 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) are satisfied.

The FSS/FSA conclusion on *Pediococcus acidilactici* (CNCM I-4622) is that:

* *Pediococcus acidilactici* (CNCM I-4622) 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 additive may only be used in feed containing the following permitted coccidiostats: halofuginone, robenidine, diclazuril, decoquinate and nicarbazine.
* The additive is safe for the target species, consumers and the environment at the intended concentrations of use.
* *Pediococcus acidilactici* (CNCM I-4622) is efficacious at the proposed dose of 1x109 CFU/kg of complete feed at 12% moisture.
* On worker safety, the additive is to be considered a respiratory sensitiser.
* There is no need for specific requirements for a post-market monitoring plan.

**Relevant Legislation**

Legislation in respect of feed additives applies to this application. In particular it is noted that this application must fulfil the following requirements of [Regulation (EC) No 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) for feed additives for use in animal nutrition:

1. [Article 4](https://www.legislation.gov.uk/eur/2003/1831/article/4): Authorisation for a new or new use of a feed additive.
2. [Article 6](https://www.legislation.gov.uk/eur/2003/1831/article/6): Categories of feed additives.
3. [Article 7](https://www.legislation.gov.uk/eur/2003/1831/article/7): Application for authorisation of a feed additive.
4. [Article 6](https://www.legislation.gov.uk/eur/2003/1831/article/6): Categories of feed additives.
5. [Article 16](https://www.legislation.gov.uk/eur/2003/1831/article/16/adopted) and [Annex III](https://www.legislation.gov.uk/eur/2003/1831/annex/III/adopted): Labelling and packaging requirements apply, if authorised.
6. [Article 21](https://www.legislation.gov.uk/eur/2003/1831/article/21): Analytical methods have been verified by the Reference Laboratory as used for the control of *Pediococcus acidilactici* (CNCM I-4622)in animal feed as detailed in the EURL analytical method evaluation report ([FAD-2013-0031](https://joint-research-centre.ec.europa.eu/publications/fad-2013-0031_en)). Valid analytical methods exist for:
* Enumeration of the active agent *Pediococcus acidilactici* (CNCM I-4622) in the feed additive, premixtures, feed and water.
* Identification of *Pediococcus acidilactici* (CNCM I-4622).
1. [Annex IV](https://www.legislation.gov.uk/eur/2003/1831/annex/IV/adopted): The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

**FSS/FSA risk management recommendation**

The FSS/FSA risk management recommendation is that *P. acidilactici* (CNCM I-4622), as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use. The FSS/FSA conclusion is that we are in favour of authorising the feed additive as per [Regulation (EC) 1831/2003 Article 8](https://www.legislation.gov.uk/eur/2003/1831/article/8). The proposed terms of authorisation are set out below.

**Proposed terms of authorisation**

|  |  |
| --- | --- |
| *Additive* | *Pediococcus acidilactici* (CNCM I-4622) |
| *Identification number*  | 4d1712 |
| *Authorisation holder[[10]](#footnote-11)* | None |
| *Additive category* | Technological additive |
| *Functional group* | Acidity regulator and hygiene condition enhancer |
| *Additive composition* | Solid preparation of *Pediococcus acidilactici* (CNCM I-4622) containing a minimum of 1×109 Colony Forming Units (CFU)/kg  |
| *Characterisation of the active substance(s)* | Viable cells of *Pediococcus acidilactici* (CNCM I-4622). |
| *Analytical method[[11]](#footnote-12)* | For enumeration (colony count) of the feed additive: * Spread plate method using MRS agar in accordance with BS EN 15786:2009[[12]](#footnote-13)

For identification of the bacterial strain: * Pulsed-field gel electrophoresis (PFGE)
 |
| *Species or category of animal*  | All animal species  |
| *Maximum age* | Not applicable |
| *Colony-forming units* (CFU) of additive/kg of complete feed with a moisture content of 12%)  | *Minimum content* |  1x109 CFU/kg |
| *Maximum content* | No maximum |
| *Other provisions* | 1. The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture.
2. To be used only in mash compound feed intended for preparation of liquid feed on farm, or solid feed intended for preparation of liquid feed on farm.
3. If *Pediococcus acidilactici* (CNCM I-4622) 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: halofuginone, decoquinate, robenidine, diclazuril and nicarbazin.
 |

**Supplementary information**

* Feed additives are subject to [UK health and safety legislation](https://www.hse.gov.uk/legislation/).
* The safety assessment identified that particular consideration should be given to hazards as a:
	+ Respiratory sensitiser.
* Categories and definitions of target animals are defined in Annex IV of [Regulation (EC) 429/2008](https://www.legislation.gov.uk/eur/2008/429/contents).
* The FSS/FSA consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in [Regulation (EC) 183/2005](https://www.legislation.gov.uk/eur/2005/183/contents) laying down requirements for feed hygiene and good manufacturing practice.

**Other legitimate factors**

In developing the risk management recommendations, FSS/FSA have had regard to the other legitimate factors (including consumer Interests, political, environmental, societal and technical feasibility) that Scottish Ministers will consider as part of their decision on authorisation.

FSS/FSA have not identified any applicable other legitimate factors to date that would prevent authorisation or affect the conditions of authorisation of this animal feed additive. As noted above, stakeholders and the broader public are equally invited to consider and provide their views on any relevant other legitimate factors as part of the consultation process.

**Impacts**

As part of the risk analysis process, FSS/FSA have assessed the potential impacts that would result from the authorisation of this animal feed additive, should Scottish Ministers decide to authorise, no significant impacts were identified from this authorisation. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

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

**Background**

The FSS/FSA has undertaken a safety assessment of application RP140 for the renewal and modification of use of monensin sodium (carrier: perlite, calcium carbonate) produced by fermentation with *Streptomyces cinnemonensis* 28682 (NBIMCC 3419) (Coxidin®) as a feed additive for chickens for fattening, chickens reared for laying and turkeys for fattening.

**Safety assessment summary**

The application was evaluated by our independent Advisory Committee on Animal Feedingstuffs (ACAF). The FSS/FSA safety assessment was published on 29 September 2023 and can be found [here](https://www.food.gov.uk/research/research-projects/safety-assessment-rp140-141-142-284-monensin-sodium). The assessment of use of monensin sodium (carrier: perlite, calcium carbonate) produced by fermentation with *Streptomyces cinnemonensis* 28682 (NBIMCC 3419) (Coxidin®) shows that the conditions for authorisation in [Article 5](https://www.legislation.gov.uk/eur/2003/1831/article/5) of [Regulation (EC) 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) are satisfied.

The FSS/FSA concluded on monensin sodium (Coxidin®) (carrier: perlite, calcium carbonate) that:

* Monensin sodium is not compatible with tiamulin, erythromycin, oleandomycin and furazolidone.
* The additive is safe for the target species at the proposed dose of 100-125 mg/kg in chickens and 60-100 mg/kg in turkeys.
* There is evidence of safety for consumers at the 6-hour withdrawal mark prior to slaughter.
* The additive is safe for the environment.
* Monensin sodium is efficacious for reducing the impact of coccidia species in chickens and turkeys when used at the proposed doses.
* On worker safety, the additive should be considered irritant to the eyes and highly toxic by inhalation. It is not a skin irritant or sensitiser.
* A post-market monitoring programme shall be carried out by the holder of authorisation for resistance to bacteria and *Eimeria* spp.
* A report containing the outcome of the post market monitoring programme must be submitted to the appropriate authority.

**Relevant Legislation**

Legislation in respect of feed additives applies to this application. In particular it is noted that this application must fulfil the following requirements of [Regulation (EC) No 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) for feed additives for use in animal nutrition:

1. [Article 6](https://www.legislation.gov.uk/eur/2003/1831/article/6): Categories of feed additives.
2. [Article 7:](https://www.legislation.gov.uk/eur/2003/1831/article/7) at the time of application, the applicant must provide a proposal for post-market monitoring (as referred to in [Annex III, section 5 of Regulation (EC) 249/2008](https://www.legislation.gov.uk/eur/2008/429/annex/III), on coccidiostats and histomonostats’).
3. [Article 13](https://www.legislation.gov.uk/eur/2003/1831/article/13): Modification, suspension and revocation of authorisation.
4. [Article 14](https://www.legislation.gov.uk/eur/2003/1831/article/14): For renewals of authorisations, the applicant must send a report on the results of post-market monitoring.
5. [Article 16](https://www.legislation.gov.uk/eur/2003/1831/article/16/adopted) and [Annex III](https://www.legislation.gov.uk/eur/2003/1831/annex/III/adopted): Labelling and packaging requirements apply, if authorised.
6. [Article 21](https://www.legislation.gov.uk/eur/2003/1831/article/21): Analytical methods have been verified by the Reference Laboratory as used for the control of monensin sodium in animal feed as detailed in the EURL analytical method evaluation report ([FAD-2016-0009](https://joint-research-centre.ec.europa.eu/system/files/2017-04/finrep_fad-2016-0009_coxidin.pdf)). Valid analytical methods exist for:
* The quantification of monensin in the feed additive, premixtures, feed materials and compound feed
* The quantification of monensin sodium in chicken and turkey tissues.
1. [Annex IV](https://www.legislation.gov.uk/eur/2003/1831/annex/IV/adopted): The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

**FSS/FSA risk management recommendation**

The FSS/FSA concluded is that monensin sodium (Coxidin®), as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use. The FSS/FSA conclusion is that we are in favour of authorising the feed additive as per [Regulation (EC) 1831/2003 Article 8](https://www.legislation.gov.uk/eur/2003/1831/article/8). The proposed terms of authorisation are set out below.

**Proposed terms of authorisation**

|  |  |
| --- | --- |
| *Additive* | Monensin sodium  |
| *Identification number*  | 51701 |
| *Authorisation holder* | Huvepharma NV |
| *Additive category* | Coccidiostats and histomonostats |
| *Functional group* | No separate functional groups |
| *Additive composition* | Preparation of monensin sodium produced by fermentation with *Streptomyces cinnamonensis* (NBIMCC 3419) in powder form with the below components:* Monensin sodium technical substance: 250g/kg containing:
* Monensin A: 90% minimum
* Monensin A + B: 95% minimum
* Monensin C: 0.2%-0.3%
* Perlite: 150 – 200 g/kg
* Calcium carbonate: 550 – 600 g/kg
 |
| *Characterisation of the active substance(s)* | Monensin sodium technical substance produced by fermentation with *Streptomyces cinnamonensis* (NBIMCC 3419).* Monensin sodium A (C36H61NaO11)
* Monensin sodium B (C35H59NaO11)
* Monensin sodium C (C37H63NaO11)
* CAS No.: 22373-78-0[[13]](#footnote-14)

  |
| *Analytical method[[14]](#footnote-15)* | For the quantification of monensin in the feed additive, premixtures and compound feed:* Reversed phase high performance liquid chromatography using post-column derivatisation coupled to spectrophotometric detection (RP-HPLC-PCD-UV-Vis) in accordance with BS EN ISO 14183:2008[[15]](#footnote-16)

For the quantification of monensin sodium in chicken and turkey tissues: * Reversed phase high performance liquid chromatography coupled to a triple quadrupole mass spectrometer (RP-HPLC-MS/MS) or any equivalent methods.
 |
| *Species or category of animal*  | * Chickens for fattening
* Chickens reared for laying
* Turkeys for fattening
* Turkeys reared for breeding
 |
| *Maximum age* | * Chickens for fattening: None
* Chickens reared for laying, turkeys for fattening and turkeys reared for breeding: 16 weeks
 |
| *Content of monensin (mg/kg of complete feed with a moisture content of 12%)* | *Minimum content* | * Chickens for fattening and reared for laying: 100 mg/kg
* Turkeys for fattening and reared for breeding: 60 mg/kg
 |
| *Maximum content* | * Chickens for fattening and reared for laying: 125 mg/kg
* Turkeys for fattening and reared for breeding: 100 mg/kg
 |
| *Maximum residue limits (MRLs) of monensin sodium in food of animal origin* | * Wet skin and fat: 25 µg/kg
* Wet liver, kidney and muscle: 8 µg/kg
 |
| *Other provisions* | 1. The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture.
2. The additive shall be incorporated in compound feed in the form of a premixture.
3. Monensin sodium shall not be mixed with other coccidiostats.
4. Declaration to be made in the instructions for use: “Dangerous for equines. This feed contains an ionophore. Avoid simultaneous administration with tiamulin and monitor for possible adverse reactions when used concurrently with other medicinal substances.”
5. A post-market monitoring programme must be carried out by the holder of the authorisation for resistance to bacteria and *Eimeria*spp*.*A report containing the outcome of the post market monitoring programme must be submitted to the appropriate authority before 10 years after authorisation[[16]](#footnote-17)
 |

**Supplementary information**

* Feed additives are subject to [UK health and safety legislation](https://www.hse.gov.uk/). The safety assessment identified that particular consideration should be given to hazards as a:
* Eye irritant
* Highly toxic by inhalation
* Categories and definitions of target animals are defined in Annex IV of [Regulation (EC) 429/2008](https://www.legislation.gov.uk/eur/2008/429/contents).
* The FSS/FSA consider a post-market monitoring programme shall be carried out by the holder of authorisation for resistance to bacteria and *Eimeria* spp. In addition to requirements established in [Regulation (EC)183/2005 laying down requirements for feed hygiene](https://www.legislation.gov.uk/eur/2005/183/contents) and good manufacturing practice.  A report containing the outcome of the post market monitoring programme must be submitted to the appropriate authority.

**Other legitimate factors**

In developing the risk management recommendations, FSS/FSA have had regard to the other legitimate factors (including consumer Interests, political, environmental, societal and technical feasibility) that Scottish Ministers will consider as part of their decision on authorisation.

FSS/FSA have not identified any applicable other legitimate factors to date that would prevent authorisation or affect the conditions of authorisation of this animal feed additive. As noted above, stakeholders and the broader public are equally invited to consider and provide their views on any relevant other legitimate factors as part of the consultation process.

**Impacts**

As part of the risk analysis process, FSS/FSA have assessed the potential impacts that would result from the authorisation of this animal feed additive, should Scottish Ministers decide to authorise, No significant impacts were identified from this authorisation. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

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

**Background**

The FSS/FSA has undertaken a safety assessment of application RP141 for the renewal of use and modification of Monensin sodium (Coxidin®) (carrier: perlite, wheat bran) as a feed additive for chickens and fattening turkeys.

**Safety assessment summary**

The application was evaluated by our independent Advisory Committee on Animal Feedingstuffs (ACAF). The FSS/FSA safety assessment was published on 29 September 2023 and can be found [here](https://www.food.gov.uk/research/research-projects/safety-assessment-rp140-141-142-284-monensin-sodium). The assessment of use of Monensin sodium (Coxidin®) (carrier: perlite, wheat bran) shows that the conditions for authorisation in [Article 5](https://www.legislation.gov.uk/eur/2003/1831/article/5) of [Regulation (EC) 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) are satisfied.

The FSS/FSA conclusion on monensin sodium (Coxidin®) (carrier: perlite, wheat bran) is that:

* Monensin sodium is not compatible with tiamulin, erythromycin, oleandomycin and furazolidone.
* The additive is safe for the target species at the proposed dose of 100-125 mg/kg in chickens and 60-100 mg/kg in turkeys.
* There is evidence of safety for consumers at the 6-hour withdrawal mark prior to slaughter.
* The additive is safe for the environment.
* Monensin sodium is efficacious for reducing the impact of coccidia species in chickens and turkeys when used at the proposed doses.
* On worker safety, the additive should be considered irritant to the eyes and highly toxic by inhalation. It is not a skin irritant or sensitiser.
* A post-market monitoring programme shall be carried out by the holder of authorisation for resistance to bacteria and *Eimeria* spp.
* A report containing the outcome of the post market monitoring programme must be submitted to the appropriate authority.

**Relevant Legislation**

Legislation in respect of feed additives applies to this application. In particular it is noted that this application must fulfil the following requirements of [Regulation (EC) No 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) for feed additives for use in animal nutrition:

1. [Article 6](https://www.legislation.gov.uk/eur/2003/1831/article/6): Categories of feed additives.
2. [Article 7:](https://www.legislation.gov.uk/eur/2003/1831/article/7) at the time of application, the applicant must provide a proposal for post-market monitoring (as referred to in [Annex III, section 5 of Regulation (EC) 249/2008](https://www.legislation.gov.uk/eur/2008/429/annex/III), on coccidiostats and histomonostats’).
3. [Article 13](https://www.legislation.gov.uk/eur/2003/1831/article/13): Modification, suspension and revocation of authorisation.
4. [Article 14](https://www.legislation.gov.uk/eur/2003/1831/article/14): For renewals of authorisations, the applicant must send a report on the results of post-market monitoring.
5. [Article 16](https://www.legislation.gov.uk/eur/2003/1831/article/16/adopted) and [Annex III](https://www.legislation.gov.uk/eur/2003/1831/annex/III/adopted): Labelling and packaging requirements apply, if authorised.
6. [Article 21](https://www.legislation.gov.uk/eur/2003/1831/article/21): Analytical methods have been verified by the Reference Laboratory as used for the control of monensin sodium in animal feed as detailed in the EURL analytical method evaluation report ([FAD-2016-0009](https://joint-research-centre.ec.europa.eu/system/files/2017-04/finrep_fad-2016-0009_coxidin.pdf)). Valid analytical methods exist for:
* The quantification of monensin in the feed additive, premixtures, feed materials and compound feed
* The quantification of monensin sodium in chicken and turkey tissues.
1. [Annex IV](https://www.legislation.gov.uk/eur/2003/1831/annex/IV/adopted): The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

**FSS/FSA risk management recommendations**

The FSS/FSA concluded that monensin sodium (Coxidin®), as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use. The FSS/FSA conclusion is that we are in favour of authorising the feed additive as per [Regulation (EC) 1831/2003 Article 8](https://www.legislation.gov.uk/eur/2003/1831/article/8). The proposed terms of authorisation are set out below.

**Proposed terms of authorisation**

|  |  |
| --- | --- |
| *Additive* | Monensin sodium |
| *Identification number*  | 51701 |
| *Authorisation holder* | Huvepharma NV |
| *Additive category* | Coccidiostats and histomonostats |
| *Functional group* | No separate functional groups |
| *Additive composition* | Preparation of monensin sodium produced by fermentation with *Streptomyces cinnamonensis* (NBIMCC 3419) in powder form with the below components:* Monensin sodium technical substance: 250g/kg containing:
* Monensin A: 90% minimum
* Monensin A + B: 95% minimum
* Monensin C: 0.2%-0.3%
* Perlite: 150 – 200 g/kg
* Wheat bran: 550 – 600 g/kg
 |
| *Characterisation of the active substance(s)* |  Monensin sodium technical substance produced by fermentation with *Streptomyces cinnamonensis* (NBIMCC 3419).* Monensin sodium A (C36H61NaO11)
* Monensin sodium B (C35H59NaO11)
* Monensin sodium C (C37H63NaO11)
* CAS No.: 22373-78-0[[17]](#footnote-18)

  |
| *Analytical method[[18]](#footnote-19)* | For the quantification of monensin in the feed additive, premixtures and compound feed: * Reversed phase high performance liquid chromatography using post-column derivatisation coupled to spectrophotometric detection (RP-HPLC-PCD-UV-Vis) in accordance with BS EN ISO 14183:2008[[19]](#footnote-20)

For the quantification of monensin sodium in chicken and turkey tissues:* Reversed phase high performance liquid chromatography coupled to a triple quadrupole mass spectrometer (RP-HPLC-MS/MS) or any equivalent methods.
 |
| *Species or category of animal*  | * Chickens for fattening
* Chickens reared for laying
* Turkeys for fattening
* Turkeys reared for breeding
 |
| *Maximum age* | * Chickens for fattening: None
* Chickens reared for laying, turkeys for fattening and turkeys reared for breeding: 16 weeks
 |
| *Content of monensin(mg/kg of complete feed with a moisture content of 12%)* | *Minimum content* | * Chickens for fattening and reared for laying: 100 mg/kg
* Turkeys for fattening and reared for breeding: 60 mg/kg
 |
| *Maximum content* | * Chickens for fattening and reared for laying: 125 mg/kg
* Turkeys for fattening and reared for breeding: 100 mg/kg
 |
| *Maximum residue limits (MRLs) of monensin sodium in food of animal origin* | * Wet skin and fat: 25 µg/kg
* Wet liver, kidney and muscle: 8 µg/kg
 |
| *Other provisions* | 1. The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture.
2. The additive shall be incorporated in compound feed in the form of a premixture.
3. Monensin sodium shall not be mixed with other coccidiostats.
4. Declaration to be made in the instructions for use: “Dangerous for equines. This feed contains an ionophore. Avoid simultaneous administration with tiamulin and monitor for possible adverse reactions when used concurrently with other medicinal substances.”
5. A post-market monitoring programme must be carried out by the holder of the authorisation for resistance to bacteria and *Eimeria*spp*.*A report containing the outcome of the post market monitoring programme must be submitted to the appropriate authority before 10 years after authorisation[[20]](#footnote-21)
 |

**Supplementary information**

* Feed additives are subject to [UK health and safety legislation](https://www.hse.gov.uk/). The safety assessment identified that particular consideration should be given to hazards as a:
* Eye irritant
* Highly toxic by inhalation
* Categories and definitions of target animals are defined in Annex IV of [Regulation (EC) 429/2008](https://www.legislation.gov.uk/eur/2008/429/contents).
* The FSS/FSA consider a post-market monitoring programme shall be carried out by the holder of authorisation for resistance to bacteria and *Eimeria* spp. In addition to requirements established in [Regulation (EC)183/2005 laying down requirements for feed hygiene](https://www.legislation.gov.uk/eur/2005/183/contents) and good manufacturing practice.  A report containing the outcome of the post market monitoring programme must be submitted to the appropriate authority.

**Other legitimate factors**

In developing the risk management recommendations, FSS/FSA have had regard to the other legitimate factors (including consumer Interests, political, environmental, societal and technical feasibility) that Scottish Ministers will consider as part of their decision on authorisation.

FSS/FSA have not identified any applicable other legitimate factors to date that would prevent authorisation or affect the conditions of authorisation of this animal feed additive. As noted above, stakeholders and the broader public are equally invited to consider and provide their views on any relevant other legitimate factors as part of the consultation process.

**Impacts**

As part of the risk analysis process, FSS/FSA have assessed the potential impacts that would result from the authorisation of this animal feed additive, should Scottish Ministers decide to authorise, no significant impacts were identified from this authorisation. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

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

**Background**

The FSS/FSA has undertaken a safety assessment of application RP142 for the new use (extension of species) of monensin sodium (Coxidin®) (carrier: perlite, wheat bran) as a feed additive for chickens reared for laying and turkeys reared for breeding.

**Safety assessment summary**

The application was evaluated by our independent Advisory Committee on Animal Feedingstuffs (ACAF). The FSS/FSA safety assessment was published on 29 September 2023 and can be found [here](https://www.food.gov.uk/research/research-projects/safety-assessment-rp140-141-142-284-monensin-sodium). The assessment of monensin sodium (Coxidin®) (carrier: perlite, wheat bran) shows that the shows that the conditions for authorisation in [Article 5](https://www.legislation.gov.uk/eur/2003/1831/article/5) of [Regulation (EC) 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) are satisfied.

The FSS/FSA conclusion on monensin sodium (Coxidin®) (carrier: perlite, wheat bran) is that:

* Monensin sodium is not compatible with tiamulin, erythromycin, oleandomycin and furazolidone.
* The additive is safe for the target species at the proposed dose of 100-125 mg/kg in chickens and 60-100 mg/kg in turkeys.
* There is evidence of safety for consumers at the 6-hour withdrawal mark, prior to slaughter.
* The additive is safe for the environment.
* Monensin sodium is efficacious for reducing the impact of coccidia species in chickens and turkeys when used at the proposed doses.
* On worker safety, the additive should be considered irritant to the eyes and highly toxic by inhalation. It is not a skin irritant or sensitiser.
* A post-market monitoring programme shall be carried out by the holder of authorisation for resistance to bacteria and *Eimeria* spp.
* A report containing the outcome of the post market monitoring programme must be submitted to the appropriate authority.

**Relevant Legislation**

Legislation in respect of feed additives applies to this application. In particular it is noted that this application must fulfil the following requirements of [Regulation (EC) No 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) for feed additives for use in animal nutrition:

1. [Article 4](https://www.legislation.gov.uk/eur/2003/1831/article/4): Authorisation for a new or new use of a feed additive.
2. [Article 6](https://www.legislation.gov.uk/eur/2003/1831/article/6): Categories of feed additives.
3. [Article 7:](https://www.legislation.gov.uk/eur/2003/1831/article/7) at the time of application, the applicant must provide a proposal for post-market monitoring (as referred to in [Annex III, section 5 of Regulation (EC) 249/2008](https://www.legislation.gov.uk/eur/2008/429/annex/III), on coccidiostats and histomonostats’).
4. [Article 16](https://www.legislation.gov.uk/eur/2003/1831/article/16/adopted) and [Annex III](https://www.legislation.gov.uk/eur/2003/1831/annex/III/adopted): Labelling and packaging requirements apply, if authorised.
5. [Article 21](https://www.legislation.gov.uk/eur/2003/1831/article/21): Analytical methods have been verified by the Reference Laboratory as used for the control of monensin sodium in animal feed as detailed in the EURL analytical method evaluation report ([FAD-2016-0009](https://joint-research-centre.ec.europa.eu/system/files/2017-04/finrep_fad-2016-0009_coxidin.pdf)). Valid analytical methods exist for:
* The quantification of monensin in the feed additive, premixtures, feed materials and compound feed
* The quantification of monensin sodium in chicken and turkey tissues.
1. [Annex IV](https://www.legislation.gov.uk/eur/2003/1831/annex/IV/adopted): The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

**FSS/FSA risk management recommendations**

The FSS/FSA concluded that monensin sodium (Coxidin®), as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use. The FSS/FSA conclusion is that we are in favour of authorising the feed additive as per [Regulation (EC) 1831/2003 Article 8](https://www.legislation.gov.uk/eur/2003/1831/article/8). The proposed terms of authorisation are set out below.

**Proposed terms of authorisation**

|  |  |
| --- | --- |
| *Additive* | Monensin sodium |
| *Identification number*  | 51701 |
| *Authorisation holder* | Huvepharma NV |
| *Additive category* | Coccidiostats and histomonostats |
| *Functional group* | No separate functional groups |
| *Additive composition* | Preparation of monensin sodium produced by fermentation with *Streptomyces cinnamonensis* (NBIMCC 3419) in powder form with the below components:* Monensin sodium technical substance: 250g/kg containing:
* Monensin A: 90% minimum
* Monensin A + B: 95% minimum
* Monensin C: 0.2%-0.3%
* Perlite: 150 – 200 g/kg
* Wheat bran: 550 – 600 g/kg
 |
| *Characterisation of the active substance(s)* |  Monensin sodium technical substance produced by fermentation with *Streptomyces cinnamonensis* (NBIMCC 3419).* Monensin sodium A (C36H61NaO11)
* Monensin sodium B (C35H59NaO11)
* Monensin sodium C (C37H63NaO11)
* CAS No.: 22373-78-0[[21]](#footnote-22)

  |
| *Analytical method[[22]](#footnote-23)* | For the quantification of monensin in the feed additive, premixtures and compound feed: * Reversed phase high performance liquid chromatography using post-column derivatisation coupled to spectrophotometric detection (RP-HPLC-PCD-UV-Vis) in accordance with BS EN ISO 14183:2008[[23]](#footnote-24)

For the quantification of monensin sodium in chicken and turkey tissues:* Reversed phase high performance liquid chromatography coupled to a triple quadrupole mass spectrometer (RP-HPLC-MS/MS) or any equivalent methods.
 |
| *Species or category of animal*  | * Chickens for fattening
* Chickens reared for laying
* Turkeys for fattening
* Turkeys reared for breeding
 |
| *Maximum age* | * Chickens for fattening: None
* Chickens reared for laying, turkeys for fattening and turkeys reared for breeding: 16 weeks
 |
| *Content of monensin(mg/kg of complete feed with a moisture content of 12%)* | *Minimum content* | * Chickens for fattening and reared for laying: 100 mg/kg
* Turkeys for fattening and reared for breeding: 60 mg/kg
 |
| *Maximum content* | * Chickens for fattening and reared for laying: 125 mg/kg
* Turkeys for fattening and reared for breeding: 100 mg/kg
 |
| *Maximum residue limits (MRLs) of monensin sodium in food of animal origin* | * Wet skin and fat: 25 µg/kg
* Wet liver, kidney and muscle: 8 µg/kg
 |
| *Other provisions* | 1. The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture.
2. The additive shall be incorporated in compound feed in the form of a premixture.
3. Monensin sodium shall not be mixed with other coccidiostats.
4. Declaration to be made in the instructions for use: “Dangerous for equines. This feed contains an ionophore. Avoid simultaneous administration with tiamulin and monitor for possible adverse reactions. when use concurrently with other medicinal substances.”
5. A post-market monitoring programme must be carried out by the holder of the authorisation for resistance to bacteria and *Eimeria*spp*.*A report containing the outcome of the post market monitoring programme must be submitted to the appropriate authority before 10 years after authorisation[[24]](#footnote-25)
 |

**Supplementary information**

* Feed additives are subject to [UK health and safety legislation](https://www.hse.gov.uk/). The safety assessment identified that particular consideration should be given to hazards as a:
* Eye irritant
* Highly toxic by inhalation
* Categories and definitions of target animals are defined in Annex IV of [Regulation (EC) 429/2008](https://www.legislation.gov.uk/eur/2008/429/contents).
* The FSS/FSA consider a post-market monitoring programme shall be carried out by the holder of authorisation for resistance to bacteria and *Eimeria* spp. In addition to requirements established in [Regulation (EC)183/2005 laying down requirements for feed hygiene](https://www.legislation.gov.uk/eur/2005/183/contents) and good manufacturing practice.  A report containing the outcome of the post market monitoring programme must be submitted to the Food Safety Authority.

**Other legitimate factors**

In developing the Risk Management recommendations, FSS/FSA have had regard to the other legitimate factors (including Consumer Interests, Political, Environmental, Societal and Technical Feasibility) that Scottish Ministers will consider as part of their decision on authorisation.

FSS/FSA have not identified any applicable other legitimate factors to date that would prevent authorisation or affect the conditions of authorisation of this animal feed additive. As noted above, stakeholders and the broader public are equally invited to consider and provide their views on any relevant other legitimate factors as part of the consultation process.

**Impacts**

As part of the risk analysis process, FSS/FSA have assessed the potential impacts that would result from the authorisation of this animal feed additive, should Scottish Ministers decide to authorise, no significant impacts were identified from this authorisation. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

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

**Background**

The FSS/FSA has undertaken a safety assessment of application RP185 for the renewal, new use and modification of 6-phytase (EC 3.1.3.26) produced by fermentation with *Komagataella phaffii* (formerly *K. pastoris*) (DSM 23036) as a feed additive for all avian species and all pigs.

**Safety assessment summary**

The application was evaluated by our independent Advisory Committee on Animal Feedingstuffs (ACAF). The FSS/FSA safety assessment was published on 29 September 2023 and can be found [here](https://www.food.gov.uk/research/research-projects/safety-assessment-rp185-6-phytase-from-komagataella-phaffii-dsm-23036). The assessment of 6-phytase (EC 3.1.3.26) shows that the shows that the conditions for authorisation in [Article 5](https://www.legislation.gov.uk/eur/2003/1831/article/5) of [Regulation (EC) 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) are satisfied.

The FSS/FSA concluded on 6-phytase (EC 3.1.3.26) produced by fermentation with *Komagataella phaffii* (DSM 23036) is that:

* The additive is produced by a genetically modified strain of K*. phaffiii* (DSM 23036). The production strain and its recombinant DNA were not detected in the finished feed additive, and no safety concerns were raised with regard to the genetic modification.
* This enzyme is well-characterised and is considered suitable for the qualified presumption of safety (QPS) approach to safety assessment.
* The feed additive is safe for the target species, the consumer and the environment.
* As regards efficacy, previous data could be extrapolated to all avian species and all pigs at the doses proposed by the applicant.
* On worker safety, 6-phytase (EC 3.1.3.26) is a respiratory sensitiser.
* There is no need for specific requirements for a post-market monitoring plan.

**Relevant Legislation**

Legislation in respect of feed additives applies to this application. In particular it is noted that this application must fulfil the following requirements of [Regulation (EC) No 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) for feed additives for use in animal nutrition:

1. [Article 4](https://www.legislation.gov.uk/eur/2003/1831/article/4): Authorisation for a new or new use of a feed additive.
2. [Article 6](https://www.legislation.gov.uk/eur/2003/1831/article/6): Categories of feed additives.
3. [Article 7](https://www.legislation.gov.uk/eur/2003/1831/article/7): Application for authorisation of a feed additive.
4. [Article 13](https://www.legislation.gov.uk/eur/2003/1831/article/13): Modification, suspension and revocation of authorisation.
5. [Article 14](https://www.legislation.gov.uk/eur/2003/1831/article/14): Renewal of authorisation.
6. [Article 16](https://www.legislation.gov.uk/eur/2003/1831/article/16/adopted) and [Annex III](https://www.legislation.gov.uk/eur/2003/1831/annex/III/adopted): Labelling and packaging requirements apply, if authorised.
7. [Article 21](https://www.legislation.gov.uk/eur/2003/1831/article/21): Analytical methods have been verified by the Reference Laboratory as used for the control of 6-phytase (EC 3.1.3.26) in animal feed as detailed in the EURL analytical method evaluation report ([FAD-2016-0019)](https://joint-research-centre.ec.europa.eu/system/files/2016-11/finirep_fad-2016-0019_optiphos.pdf). Valid analytical methods exist for:
* Quantification of phytase activity in the feed additive, premixtures and compound feed.
1. [Annex IV](https://www.legislation.gov.uk/eur/2003/1831/annex/IV/adopted): The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

**FSS/FSA risk management recommendations**

The FSS/FSA concluded that 6-phytase (EC 3.1.3.26), as described in this application, is safe and is not liable to have an adverse effect on target species, environmental safety and human health under the proposed conditions of use. The FSS/FSA conclusion is that we are in favour of authorising the feed additive as per [Regulation (EC) 1831/2003 Article 8](https://www.legislation.gov.uk/eur/2003/1831/article/8). The proposed terms of authorisation are set out below.

**Proposed terms of authorisation**

|  |  |
| --- | --- |
| *Additive* | 6-phytase (EC 3.1.3.26) |
| *Identification number*  | 4a16 |
| *Authorisation holder* | Huvepharma NV |
| *Additive category* | Zootechnical additive |
| *Functional group* | Digestibility enhancers |
| *Additive composition* | Preparation of 6–phytase (EC 3.1.3.26) produced by fermentation with *Komagataella phaffii* (DSM 23036) having a minimum enzyme activity of 4,000 OTU/g in solid form and 8,000 OTU/g in liquid form[[25]](#footnote-26). |
| *Characterisation of the active substance(s)* | * + 6-phytase (EC 3.1.3.26) produced by fermentation with *Komagataella phaffii* (DSM 23036)
* CAS no.: 9001-89-2[[26]](#footnote-27)
* EC (IUBMB) no.: 3.1.3.26[[27]](#footnote-28)
 |
| *Analytical method[[28]](#footnote-29)* | For the quantification of phytase activity in the feed additive, premixtures and compound feed:* Colorimetric method based on the quantification of the inorganic phosphate released by the enzyme from the sodium phytate.
 |
| *Species or category of animal*  | * All avian species
* All porcine species
 |
| *Maximum age* | Not applicable |
| *Content of 6-phytase (EC 3.1.3.26) (units of activity (OTU)/kg of complete feed with a moisture content of 12%)* | *Minimum content* | * All avian species other than turkeys and all porcine species other than piglets: 125 OTU/kg
* Turkeys and piglets: 250 OTU/kg
 |
| *Maximum content* | No maximum level |
| *Other provisions* | 1. The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture.
 |

**Supplementary information**

* Feed additives are subject to [UK health and safety legislation](https://www.hse.gov.uk/). The safety assessment identified that particular consideration should be given to hazards as a:
* Respiratory sensitiser
* Categories and definitions of target animals are defined in Annex IV of [Regulation (EC) 429/2008](https://www.legislation.gov.uk/eur/2008/429/contents).
* The FSS/FSA consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in [Regulation (EC) 183/2005](https://www.legislation.gov.uk/eur/2005/183) laying down requirements for feed hygiene and good manufacturing practice.

**Recommendations of use**

* The recommended maximum dose for all authorised species is 500 OTU/kg\* of complete feed. \*(OTU = phytase units)

**Other legitimate factors**

In developing the Risk Management recommendations, FSS/FSA have had regard to the other legitimate factors (including Consumer Interests, Political, Environmental, Societal and Technical Feasibility) that Scottish Ministers will consider as part of their decision on authorisation.

FSS/FSA have not identified any applicable other legitimate factors to date that would prevent authorisation or affect the conditions of authorisation of this animal feed additive. As noted above, stakeholders and the broader public are equally invited to consider and provide their views on any relevant other legitimate factors as part of the consultation process.

**Impacts**

As part of the risk analysis process, FSS/FSA have assessed the potential impacts that would result from the authorisation of this animal feed additive, should Scottish Ministers decide to authorise, no significant impacts were identified from this authorisation. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

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

**Background**

The FSS/FSA has undertaken a safety assessment of application RP222 for the modification of use of selenised yeast *Saccharomyces cereviisiae* (CNCM I-3060), inactivated as a feed additive for all species.

**Safety assessment summary**

The application was evaluated by our independent Advisory Committee on Animal Feedingstuffs (ACAF). The FSS/FSA safety assessment was published on 29 September 2023 and can be found [here](https://www.food.gov.uk/research/research-projects/safety-assessment-rp222-selenised-yeast-saccharomyces-cerevisiae-cncm-i-3060-inactivated). The assessment of selenised yeast *Saccharomyces cereviisiae* (CNCM I-3060) that the shows that the conditions for authorisation in [Article 5](https://www.legislation.gov.uk/eur/2003/1831/article/5) of [Regulation (EC) 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) are satisfied.

The FSS/FSA concluded on selenised yeast *Saccharomyces cerevisiae* (CNCM I-3060), inactivated that:

* This yeast is well-characterised and is considered suitable for the qualified presumption of safety (QPS) approach to safety assessment.
* The additive remains safe for the target species, consumers and the environment as long as the limits of 0.2 mg Se/kg (supplementation) and 0.5 mg Se/kg (total feed) are not exceeded.
* No demonstration of efficacy was required for the modification of authorisation.
* On worker safety, the additive is hazardous through inhalation and a respiratory sensitiser.
* There is no need for specific requirements for a post-market monitoring plan.

**Relevant Legislation**

Legislation in respect of feed additives applies to this application. In particular it is noted that this application must fulfil the following requirements of [Regulation (EC) No 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) for feed additives for use in animal nutrition:

1. [Article 6](https://www.legislation.gov.uk/eur/2003/1831/article/6): Categories of feed additives.
2. [Article 13](https://www.legislation.gov.uk/eur/2003/1831/article/13): Modification, suspension and revocation of authorisation
3. [Article 16](https://www.legislation.gov.uk/eur/2003/1831/article/16/adopted) and [Annex III](https://www.legislation.gov.uk/eur/2003/1831/annex/III/adopted): Labelling and packaging requirements apply, if authorised.
4. [Article 21](https://www.legislation.gov.uk/eur/2003/1831/article/21): Analytical methods have been verified by the Reference Laboratory as used for the control of selenised yeast *Saccharomyces cerevisiae* (CNCM I-3060), inactivated in animal feed as detailed in the EURL analytical method evaluation report [FAD-2009-0029](https://joint-research-centre.ec.europa.eu/publications/fad-2009-0029-fad-2010-0044_en). Valid analytical methods exist for:
* Determination of selenomethionine in the feed additive
* Determination of total selenium in the feed additive
* Determination of total selenium in premixtures feed materials and compound feed.
1. [Annex IV](https://www.legislation.gov.uk/eur/2003/1831/annex/IV/adopted): The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

**FSS/FSA Risk management recommendation**

The FSS/FSA concluded that selenised yeast *Saccharomyces cereviisiae* (CNCM I-3060), as described in this application, is safe and is not liable to have an adverse effect on all animal species, environmental safety and human health under the proposed conditions of use. The FSS/FSA conclusion is that we are in favour of authorising the feed additive as per [Regulation (EC) 1831/2003 Article 8](https://www.legislation.gov.uk/eur/2003/1831/article/8). The proposed terms of authorisation are set out below.

**Proposed terms of authorisation**

|  |  |
| --- | --- |
| *Additive* | Selenised yeast *Saccharomyces cerevisiae* (CNCM I-3060), inactivated |
| *Identification number*  | 3b810 |
| *Authorisation holder[[29]](#footnote-30)* | None |
| *Additive category* | Nutritional additive |
| *Functional group* | Compounds of trace elements |
| *Additive composition* | Preparation of organic selenium (Se) produced from *Saccharomyces cerevisiae* (CNCM I-3060) containing 2,000 to 3,500 mg Se/kg with the below components:* Organic selenium: 97% minimum of total selenium
* Selenomethionine: 63% minimum of total selenium
 |
| *Characterisation of the active substance(s)* | Selenised yeast *Saccharomyces cerevisiae* (CNCM I-3060) (C5H11NO2Se)· |
| *Analytical method[[30]](#footnote-31)* | For the determination of selenomethionine in the feed additive:· High performance liquid chromatography and inductively coupled plasma mass spectrometry (HPLC-ICPMS) after triple proteolytic digestion* Reversed phase high performance liquid chromatography with UV detection (RP-HPLC-UV)

For determination of total selenium in the feed additive:* Inductively coupled plasma mass

spectrometry (ICPMS) * Inductively coupled plasma atomic

emission spectrometryFor determination of total selenium inpremixtures, compound feed and feed materials:* Hydride generation atomic absorption spectrometry (HGAAS) after microwave digestion in accordance with BS EN 16159:2012[[31]](#footnote-32)
 |
| *Species or category of animal*  | All animal species  |
| *Maximum age* | Not applicable |
| *Content of selenium (mg/kg of complete feed with a moisture content of 12%)* | *Minimum content* | No minimum |
| *Maximum content* | Total selenium: 0.5 mg Se/kg Organic selenium supplementation: 0.2 mg Se/kg |
| *Other provisions* | 1. The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture.
2. The additive shall be incorporated into feed in the form of a premixture.
3. The dusting potential of the additive shall ensure a maximum selenium exposure of 0.2 mg Se/m3.
4. Maximum supplementation with organic selenium 0.2 mg Se/kg of complete feed with a moisture content of 12%
 |

**Supplementary information**

* Feed additives are subject to [UK health and safety legislation](https://www.hse.gov.uk/). The safety assessment identified that particular consideration should be given to hazards as a:
* Respiratory sensitiser
* Risks to users by inhalation
* Categories and definitions of target animals are defined in Annex IV of [Regulation (EC) 429/2008](https://www.legislation.gov.uk/eur/2008/429/contents).
* The FSS/FSA consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in [Regulation (EC) 183/2005](https://www.legislation.gov.uk/eur/2005/183/contents) laying down requirements for feed hygiene and Good manufacturing practice.

**Other legitimate factors**

In developing the Risk Management recommendations, FSS/FSA have had regard to the other legitimate factors (including Consumer Interests, Political, Environmental, Societal and Technical Feasibility) that Scottish Ministers will consider as part of their decision on authorisation.

FSS/FSA have not identified any applicable other legitimate factors to date that would prevent authorisation or affect the conditions of authorisation of this animal feed additive. As noted above, stakeholders and the broader public are equally invited to consider and provide their views on any relevant other legitimate factors as part of the consultation process.

I**mpacts**

As part of the risk analysis process, FSS/FSA have assessed the potential impacts that would result from the authorisation of this animal feed additive, should Scottish Ministers decide to authorise, no significant impacts were identified from this authorisation. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

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

**Background**

The FSS/FSA has undertaken a safety assessment of application RP284 for the new use (extension of species) of monensin sodium (Coxidin®) (carrier: perlite, calcium carbonate) as a coccidiostat and histomonostat feed additive for turkeys reared for breeding.

**Safety assessment summary**

The application was evaluated by our independent Advisory Committee on Animal Feedingstuffs (ACAF). The FSS/FSA safety assessment was published on 29 September 2023 and can be found [here](https://www.food.gov.uk/research/research-projects/safety-assessment-rp140-141-142-284-monensin-sodium). The assessment of monensin sodium (Coxidin®) shows that the conditions for authorisation in [Article 5](https://www.legislation.gov.uk/eur/2003/1831/article/5) of [Regulation (EC) 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) are satisfied.

The FSS/FSA conclusion on monensin sodium (Coxidin®) (carrier: perlite, calcium carbonate) is that:

* Monensin sodium is not compatible with tiamulin, erythromycin, oleandomycin and furazolidone.
* The additive is safe for the target species at the proposed dose of 100-125 mg/kg in chickens and 60-100 mg/kg in turkeys.
* There is evidence of safety for consumers at the 6-hour withdrawal mark.
* The additive is safe for the environment.
* Monensin sodium is efficacious for reducing the impact of coccidia species in chickens and turkeys when used at the proposed doses.
* On worker safety, the additive should be considered irritant to the eyes and highly toxic by inhalation. It is not a skin irritant or sensitiser.
* A post-market monitoring programme shall be carried out by the holder of authorisation for resistance to bacteria and *Eimeria* spp.
* A report containing the outcome of the post market monitoring programme must be submitted to the Food Safety Authority

**Relevant Legislation**

Legislation in respect of feed additives applies to this application. In particular it is noted that this application must fulfil the following requirements of [Regulation (EC) No 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) for feed additives for use in animal nutrition:

1. [Article 4](https://www.legislation.gov.uk/eur/2003/1831/article/4): Authorisation for a new or new use of a feed additive.
2. [Article 6](https://www.legislation.gov.uk/eur/2003/1831/article/6): Categories of feed additives.
3. [Article 7:](https://www.legislation.gov.uk/eur/2003/1831/article/7) at the time of application, the applicant must provide a proposal for post-market monitoring (as referred to in [Annex III, section 5 of Regulation (EC) 249/2008](https://www.legislation.gov.uk/eur/2008/429/annex/III), on coccidiostats and histomonostats’).
4. [Article 16](https://www.legislation.gov.uk/eur/2003/1831/article/16/adopted) and [Annex III](https://www.legislation.gov.uk/eur/2003/1831/annex/III/adopted): Labelling and packaging requirements apply, if authorised.
5. [Article 21](https://www.legislation.gov.uk/eur/2003/1831/article/21): Analytical methods have been verified by the Reference Laboratory as used for the control of monensin sodium in animal feed as detailed in the EURL analytical method evaluation report ([FAD-2016-0009](https://joint-research-centre.ec.europa.eu/system/files/2017-04/finrep_fad-2016-0009_coxidin.pdf)). Valid analytical methods exist for:
* The quantification of monensin in the feed additive, premixtures, feed materials and compound feed
* The quantification of monensin sodium in chicken and turkey tissues.
1. [Annex IV](https://www.legislation.gov.uk/eur/2003/1831/annex/IV/adopted): The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

**FSS/FSA risk management recommendations**

The FSS/FSA concluded that monensin sodium (Coxidin®), as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use. The FSS/FSA conclusion is that we are in favour of authorising the feed additive as per [Regulation (EC) 1831/2003 Article 8](https://www.legislation.gov.uk/eur/2003/1831/article/8). The proposed terms of authorisation are set out below.

**Proposed terms of authorisation**

|  |  |
| --- | --- |
| *Additive* | Monensin sodium  |
| *Identification number*  | 51701 |
| *Authorisation holder* | Huvepharma NV |
| *Additive category* | Coccidiostats and histomonostats |
| *Functional group* | No separate functional groups |
| *Additive composition* | Preparation of monensin sodium produced by fermentation with *Streptomyces cinnamonensis* (NBIMCC 3419) in powder form with the below components:* Monensin sodium technical substance: 250g/kg containing:
* Monensin A: 90% minimum
* Monensin A + B: 95% minimum
* Monensin C: 0.2%-0.3%
* Perlite: 150 – 200 g/kg
* Calcium carbonate: 550 – 600 g/kg
 |
| *Characterisation of the active substance(s)* | Monensin sodium technical substance produced by fermentation with *Streptomyces cinnamonensis* (NBIMCC 3419).* Monensin sodium A (C36H61NaO11)
* Monensin sodium B (C35H59NaO11)
* Monensin sodium C (C37H63NaO11)
* CAS No.: 22373-78-0[[32]](#footnote-33)

  |
| *Analytical method[[33]](#footnote-34)* | For the quantification of monensin in the feed additive, premixtures and compound feed:* Reversed phase high performance liquid chromatography using post-column derivatisation coupled to spectrophotometric detection (RP-HPLC-PCD-UV-Vis) in accordance with BS EN ISO 14183:2008[[34]](#footnote-35)

For the quantification of monensin sodium in chicken and turkey tissues: * Reversed phase high performance liquid chromatography coupled to a triple quadrupole mass spectrometer (RP-HPLC-MS/MS) or any equivalent methods.
 |
| *Species or category of animal*  | * Chickens for fattening
* Chickens reared for laying
* Turkeys for fattening
* Turkeys reared for breeding
 |
| *Maximum age* | * Chickens for fattening: None
* Chickens reared for laying, turkeys for fattening and turkeys reared for breeding: 16 weeks
 |
| *Content of monensin (mg/kg of complete feed with a moisture content of 12%)* | *Minimum content* | * Chickens for fattening and reared for laying: 100 mg/kg
* Turkeys for fattening and reared for breeding: 60 mg/kg
 |
| *Maximum content* | * Chickens for fattening and reared for laying: 125 mg/kg
* Turkeys for fattening and reared for breeding: 100 mg/kg
 |
| *Maximum residue limits (MRLs) of monensin sodium in food of animal origin* | * Wet skin and fat: 25 µg/kg
* Wet liver, kidney and muscle: 8 µg/kg
 |
| *Other provisions* | 1. The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture.
2. The additive shall be incorporated in compound feed in the form of a premixture.
3. Monensin sodium shall not be mixed with other coccidiostats.
4. Declaration to be made in the instructions for use: “Dangerous for equines. This feed contains an ionophore. Avoid simultaneous administration with tiamulin and monitor for possible adverse reactions. when use concurrently with other medicinal substances.”
5. A post-market monitoring programme must be carried out by the holder of the authorisation for resistance to bacteria and *Eimeria*spp*.*A report containing the outcome of the post market monitoring programme must be submitted to the appropriate authority before 10 years after authorisation[[35]](#footnote-36)
 |

**Supplementary information**

* Feed additives are subject to [UK health and safety legislation](https://www.hse.gov.uk/). The safety assessment identified that particular consideration should be given to hazards as a:
* Eye irritant
* Highly toxic by inhalation
* Categories and definitions of target animals are defined in Annex IV of [Regulation (EC) 429/2008](https://www.legislation.gov.uk/eur/2008/429/contents).
* The FSS/FSA consider a post-market monitoring programme shall be carried out by the holder of authorisation for resistance to bacteria and *Eimeria* spp. In addition to requirements established in [Regulation (EC)183/2005 laying down requirements for feed hygiene](https://www.legislation.gov.uk/eur/2005/183/contents) and good manufacturing practice.  A report containing the outcome of the post market monitoring programme must be submitted to the Food Safety Authority.

**Other legitimate factors**

In developing the Risk Management recommendations, FSS/FSA have had regard to the other legitimate factors (including Consumer Interests, Political, Environmental, Societal and Technical Feasibility) that Scottish Ministers will consider as part of their decision on authorisation.

FSS/FSA have not identified any applicable other legitimate factors to date that would prevent authorisation or affect the conditions of authorisation of this animal feed additive. As noted above, stakeholders and the broader public are equally invited to consider and provide their views on any relevant other legitimate factors as part of the consultation process.

**Impacts**

As part of the risk analysis process, FSS/FSA have assessed the potential impacts that would result from the authorisation of this animal feed additive, should Scottish Ministers decide to authorise, no significant impacts were identified from this authorisation. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

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

The FSS/FSA has undertaken a safety assessment of application RP641 for the renewal, modification and new use (extension of species)of a preparation of *Bacillus velezensis (formerly B. subtilis*) (DSM 15544) as a feed additive for weaned piglets and all avian species.

**Safety assessment summary**

The application was evaluated by our independent Advisory Committee on Animal Feedingstuffs (ACAF). The FSS/FSA safety assessment was published on 29 September 2023 and can be found [here](https://www.food.gov.uk/research/research-projects/safety-assessment-rp641-bacillus-velezensis-dsm-15544). The assessment of the preparation of *Bacillus* *velezensis* shows that the conditions for authorisation in [Article 5](https://www.legislation.gov.uk/eur/2003/1831/article/5) of [Regulation (EC) 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) are satisfied.

The FSS/FSA concluded on *Bacillus* *velezensis* (DSM 15544) that:

* *Bacillus* *velezensis* 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 additive is safe for the target species, consumers and the environment.
* Existing conclusions that the additive is efficacious can be extrapolated to include all avian species at the intended concentration of use.
* On worker safety, the additive is a respiratory sensitiser and irritant.
* There is no need for specific requirements for a post-market monitoring plan.

**Relevant Legislation**

Legislation in respect of feed additives applies to this application. In particular it is noted that this application must fulfil the following requirements of [Regulation (EC) No 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) for feed additives for use in animal nutrition:

1. [Article 4](https://www.legislation.gov.uk/eur/2003/1831/article/4): Authorisation for a new or new use of a feed additive
2. [Article 6](https://www.legislation.gov.uk/eur/2003/1831/article/6): Categories of feed additives.
3. [Article 7](https://www.legislation.gov.uk/eur/2003/1831/article/7): Application for authorisation of a feed additive.
4. [Article 13](https://www.legislation.gov.uk/eur/2003/1831/article/13): Modification, suspension and revocation of authorisation.
5. [Article 14](https://www.legislation.gov.uk/eur/2003/1831/article/14): Renewal of authorisation.
6. [Article 16](https://www.legislation.gov.uk/eur/2003/1831/article/16/adopted) and [Annex III](https://www.legislation.gov.uk/eur/2003/1831/annex/III/adopted): Labelling and packaging requirements apply, if authorised.
7. [Article 21](https://www.legislation.gov.uk/eur/2003/1831/article/21): Analytical methods have been verified by the Reference Laboratory as used for the control of *Bacillus velezensis* (DSM 15544) in animal feed as detailed in the EURL analytical method evaluation report [FAD-2019-0013](https://joint-research-centre.ec.europa.eu/publications/fad-2009-0013_en). Valid analytical methods exist for:
* Enumeration of *Bacillus* *velezensis* (DSM 15544) in the feed additive, premixtures and compound feed.
* Identification of the bacterial strain, *Bacillus* *velezensis* (DSM 15544).
1. [Annex IV](https://www.legislation.gov.uk/eur/2003/1831/annex/IV/adopted): The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

**FSS/FSA risk management recommendations**

The FSS/FSA concluded that *Bacillus* *velezensis* (DSM 15544), as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use. The FSS/FSA conclusion is that we are in favour of authorising the feed additive as per [Regulation (EC) 1831/2003 Article 8](https://www.legislation.gov.uk/eur/2003/1831/article/8). The proposed terms of authorisation are set out below.

The proposed change of authorisation holder is administrative and should be reflected in all current authorisations of this feed additive. Similarly the change of the taxonomic strain name from *Bacillus subtilis* to *Bacillus velezensis* (DSM15544) can be supported and reflected in all current authorisations of this feed additive.

**Proposed terms of authorisation**

|  |  |
| --- | --- |
| *Additive*  | *Bacillus velezensis* (DSM 15544)  |
| *Identification number*  | 4b1820  |
| *Authorisation holder* | Asahi Biocycle Co., Ltd  |
| *Additive category*  | Zootechnical additive |
| *Functional group*  | Gut flora stabilisers  |
| *Additive composition*  | Solid preparation of *Bacillus velezensis* (DSM 15544) containing a minimum of 1 x 1010 Colony Forming Units (CFU)/g.  |
| *Characterisation of the active substance(s)*  | Viable spores of *Bacillus velezensis* (DSM 15544).  |
| *Analytical method[[36]](#footnote-37)*  | For enumeration (colony count) of the feed additive:  * spread plate method using tryptone soya agar in all target matrices in accordance with BS EN 15784:2021**[[37]](#footnote-38)**

For identification of the feed additive * Pulsed-field gel electrophoresis (PFGE).
 |
| *Species or category of animal*  | * Weaned piglets
* All avian species

  |
| *Maximum age*  | Not applicable  |
| Colony-forming units (CFU)/kg of complete feed with a moisture content of 12%   | *Minimum content*  |  3x108 CFU/kg |
| *Maximum content*  | No maximum level  |
| *Other provisions*  | 1. The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture.
2. May be used in feed containing the permitted coccidiostats for each avian species.
 |

**Supplementary information**

* Feed additives are subject to [UK health and safety legislation](https://www.hse.gov.uk/). The safety assessment identified that particular consideration should be given to hazards as a:
* Respiratory sensitiser and irritant
* Categories and definitions of target animals are defined in Annex IV of [Regulation (EC) 429/2008](https://www.legislation.gov.uk/eur/2008/429/contents).
* The FSS/FSA consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in [Regulation (EC) 183/2005](https://www.legislation.gov.uk/eur/2005/183) laying down requirements for feed hygiene and good manufacturing practice.

**Other legitimate factors**

In developing the Risk Management recommendations, FSS/FSA have had regard to the other legitimate factors (including Consumer Interests, Political, Environmental, Societal and Technical Feasibility) that Scottish Ministers will consider as part of their decision on authorisation.

FSS/FSA have not identified any applicable other legitimate factors to date that would prevent authorisation or affect the conditions of authorisation of this animal feed additive. As noted above, stakeholders and the broader public are equally invited to consider and provide their views on any relevant other legitimate factors as part of the consultation process.

**Impacts**

As part of the risk analysis process, FSS/FSA have assessed the potential impacts that would result from the authorisation of this animal feed additive, should Scottish Ministers decide to authorise, no significant impacts were identified from this authorisation. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

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

**Background**

The FSS/FSA has undertaken a safety assessment of application RP1105 for the authorisation of use of L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* (KCCM 80212) as a feed additive for all animal species.

**Safety assessment summary**

The FSS/FSA safety assessment was published on 29 September 2023 and can be found [here](https://www.food.gov.uk/research/research-projects/safety-assessment-rp1105-l-histidine). The assessment of the preparation of L-histidine monohydrochloride monohydrate shows that the conditions for authorisation in [Article 5](https://www.legislation.gov.uk/eur/2003/1831/article/5) of [Regulation (EC) 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) are satisfied.

The FSS/FSA conclusion on L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* (KCCM 80212) is that:

* The additiveis produced by a genetically modified strain of *E. coli (KCCM 80212)*. 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 all animal species and consumers of animal products when used to supplement animal diets at appropriate levels
* L-histidine monohydrochloride monohydrate does not pose a risk for the environment.
* The additive is considered an efficacious source of the essential amino acid L-histidine for non-ruminant animal species. For the supplemental L-histidine to be efficacious in ruminants, it would require protection against degradation in the rumen.
* On worker safety, the additive is not a skin or eye irritant but is a skin sensitiser. The additive does represent an inhalation risk for workers handling the product.
* Due to the product's dusting potential and potential endotoxin concentration in the dust, the additive does represent an inhalation risk for workers handling the product. This conclusion was reached by comparing the calculated inhalation exposure of endotoxins per day of 2,300 endotoxin Units against the provisional inhaled endotoxin exposure limit of 900 endotoxin Units, set by the UK Health and Safety Executive (HSE, 2013). A specific provision may be needed in the Terms of Authorisation, if not it will be covered by Health and Safety legislation.
* The FSS/FSA consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in [Regulation (EC) 183/2005](https://www.legislation.gov.uk/eur/2005/183) laying down requirements for feed hygiene and good manufacturing practice.

**Relevant Legislation**

Legislation in respect of feed additives applies to this application. In particular it is noted that this application must fulfil the following requirements of [Regulation (EC) No 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) for feed additives for use in animal nutrition:

1. [Article 4](https://www.legislation.gov.uk/eur/2003/1831/article/4): Authorisation for a new or new use of a feed additive
2. [Article 6](https://www.legislation.gov.uk/eur/2003/1831/article/6): Categories of feed additives.
3. [Article 7](https://www.legislation.gov.uk/eur/2003/1831/article/7): Application for authorisation of a feed additive.
4. [Article 16](https://www.legislation.gov.uk/eur/2003/1831/article/16/adopted) and  [Annex III](https://www.legislation.gov.uk/eur/2003/1831/annex/III/adopted): Labelling and packaging requirements apply, if authorised.
5. [Article 21](https://www.legislation.gov.uk/eur/2003/1831/article/21): Analytical methods have been verified by the Reference Laboratory as used for the control of L-histidine monohydrochloride monohydrate in animal feed as detailed in the EURL analytical method evaluation report [FAD-2020-0016](https://joint-research-centre.ec.europa.eu/publications/fad-2020-0016_en) . Valid analytical methods exist for:
* The quantification of histidine in the feed additive
* The quantification of histidine in premixtures, feed materials and compound feed
* The quantification of histamine in the feed additive.
1. [Annex IV](https://www.legislation.gov.uk/eur/2003/1831/annex/IV/adopted): The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

**FSS/FSA risk management recommendations**

The FSS/FSA risk management recommendation is that L-histidine monohydrochloride monohydrate, as described in this application, is safe and is not liable to have an adverse effect on the target species,environmental safety and human health under the proposed conditions of use. The FSS/FSA conclusion is that we are in favour of authorising the feed additive as per [Regulation (EC) 1831/2003 Article 8](https://www.legislation.gov.uk/eur/2003/1831/article/8). The proposedterms of authorisation are set out below.

**Proposed terms of authorisation**

|  |  |
| --- | --- |
| *Additive*  | L-histidine monohydrochloride monohydrate   |
| *Identification number*  | 3c352i  |
| *Authorisation* holder[[38]](#footnote-39) | None  |
| *Additive category*  | Nutritional additive |
| *Functional group*  | Amino acids, their salts and analogues  |
| *Additive composition*  | L-histidine monohydrochloride monohydrate with a purity criteria not less than 98% as a powder with the following components: * Moisture: 1% maximum
* Histidine: 72% minimum
* Histamine: 100ppm maximum
 |
| *Characterisation of the active substance(s)*  | L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* (KCCM 80212) (C6H12ClN3O3) * CAS no: 5934-29-2[[39]](#footnote-40)
* EINECS no: 611-821-4[[40]](#footnote-41)
 |
| *Analytical method[[41]](#footnote-42)*   | For the quantification of histidine in the feed additive: * High performance liquid chromatography coupled with photometric detection (HPLC-UV) in accordance with BS EN ISO 13903:2005[[42]](#footnote-43)
* Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD)

For the quantification of histidine in premixtures, feed materials and compound feed: * Ion-exchange chromatography coupled to post-column derivatisation and photometric detection (IEC-VIS), [Commission Regulation (EC) No 152/2009](https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32009R0152) laying down the methods of sampling and analysis for the official control of feed (Annex III, F)

For the quantification of histamine in the feed additive: * High performance liquid chromatography coupled with photometric detection (HPLC-UV) in accordance with BS EN ISO 13903:2005
 |
| *Species or category of animal*  | All animal species    |
| *Maximum age*  | Not applicable  |
| *Content of L-histidine monohydrochloride monohydrate (mg/kg of complete feed with a moisture content of 12%)*  | *Minimum content*  | No minimum  |
| *Maximum content*  | No maximum  |
| *Other provisions*  | 1. The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture.
2. L-histidine monohydrochloride monohydrate may be placed on the market and used as an additive consisting of a preparation.
3. The histidine content shall be indicated on the label of the additive and shall contain the following declaration on the label of the additive and premixture:  “The supplementation with L-histidine monohydrochloride monohydrate shall be limited to the nutritional requirements of the target animal, which depends on the environmental conditions, the species, physiological state of the animal, performance level of the animal and level of other amino acids in the diet and level of essential trace elements such as zinc and copper.”
 |

**Supplementary information**

* Feed additives are subject to [UK health and safety legislation](https://www.hse.gov.uk/). The safety assessment identified that particular consideration should be given to hazards as a:
* Skin sensitiser
* Powder where inhalation risks endotoxin exposure
* Categories and definitions of target animals are defined in Annex IV of [Regulation (EC) 429/2008](https://www.legislation.gov.uk/eur/2008/429/contents).
* The FSS/FSA consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in [Regulation (EC) 183/2005](https://www.legislation.gov.uk/eur/2005/183/contents) laying down requirements for feed hygiene and good manufacturing practice.

**Other legitimate factors**

In developing the Risk Management recommendations, FSS/FSA have had regard to the other legitimate factors (including Consumer Interests, Political, Environmental, Societal and Technical Feasibility) that Scottish Ministers will consider as part of their decision on authorisation.

FSS/FSA have not identified any applicable other legitimate factors to date that would prevent authorisation or affect the conditions of authorisation of this animal feed additive. As noted above, stakeholders and the broader public are equally invited to consider and provide their views on any relevant other legitimate factors as part of the consultation process.

**Impacts**

As part of the risk analysis process, FSS/FSA have assessed the potential impacts that would result from the authorisation of this animal feed additive, should Scottish Ministers decide to authorise, no significant impacts were identified from this authorisation. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

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

**Background**

The FSS/FSA has undertaken a safety assessment of application RP1125 for the authorisation of L-tryptophan produced by fermentation with *Escherichia coil* KCCM 80210) as a feed additive for all animal species.

**Safety assessment summary**

The FSS/FSA safety assessment was published on 29 September 2023 and can be found [here](https://www.food.gov.uk/research/research-projects/safety-assessment-rp1125-l-tryptophan). The assessment of the preparation of L-tryptophan shows that the conditions for authorisation in [Article 5](https://www.legislation.gov.uk/eur/2003/1831/article/5) of [Regulation (EC) 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) are satisfied.

The FSS/FSA conclusion on L-tryptophan produced by fermentation with *Escherichia coli* (KCCM 80210) is that:

* The additive is produced from a genetically modified strain of *E. coli* (KCCM 80210).

The production strain and its recombinant DNA were not detected in the finished feed additive, and no safety concerns were raised regarding the genetic modification.

* The feed additive is safe for all non-ruminant animal species. To be safe for ruminants,

 L-tryptophan should be protected against degradation in the rumen.

* No safety concerns were raised for consumers or the environment.
* The additive is considered an efficacious source of the essential amino acid L

tryptophan for non-ruminant species. For L-tryptophan to be efficacious in ruminants, it should be protected from ruminal degradation.

* On worker safety, the additive is not a skin irritant or skin sensitiser. It is an eye irritant.

 Endotoxin activity indicates an inhalation risk for workers handling the product. .

* Due to the product's dusting potential and potential endotoxin concentration in the dust,

the additive does represent an inhalation risk for workers handling the product. This conclusion was reached by comparing the calculated inhalation exposure of endotoxins per day of 2,300 endotoxin Units against the provisional inhaled endotoxin exposure limit of 900 endotoxin Units, set by the UK Health and Safety Executive (HSE, 2013). A specific provision may be needed in the Terms of Authorisation, if not it will be covered by Health and Safety legislation.

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

**Relevant Legislation**

Legislation in respect of feed additives applies to this application. In particular it is noted that this application must fulfil the following requirements of [Regulation (EC) No 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) for feed additives for use in animal nutrition:

1. [Article 4](https://www.legislation.gov.uk/eur/2003/1831/article/4): Authorisation for a new or new use of a feed additive.
2. [Article 6](https://www.legislation.gov.uk/eur/2003/1831/article/6): Categories of feed additives.
3. [Article 7](https://www.legislation.gov.uk/eur/2003/1831/article/7): Application for authorisation of a feed additive.
4. [Article 16](https://www.legislation.gov.uk/eur/2003/1831/article/16/adopted) and [Annex III](https://www.legislation.gov.uk/eur/2003/1831/annex/III/adopted): Labelling and packaging requirements apply, if authorised.
5. [Article 21](https://www.legislation.gov.uk/eur/2003/1831/article/21): Analytical methods have been verified by the Reference Laboratory as used for the control of L-tryptophan in animal feed as detailed in the EURL analytical method evaluation report [FAD-2020-0038](https://joint-research-centre.ec.europa.eu/publications/fad-2020-0038_en). Valid analytical methods exist for:
* The identification of L-tryptophan in the feed additive
* The determination of tryptophan in the feed additive and premixtures
* The determination of tryptophan in feed materials and compound feed.
1. [Annex IV](https://www.legislation.gov.uk/eur/2003/1831/annex/IV/adopted): The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

**FSS/FSA risk management recommendations**

The FSS/FSA risk management recommendation is that L-tryptophan, as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use. The FSS/FSA conclusion is that we are in favour of authorising the feed additive as per [Regulation (EC) 1831/2003 Article 8](https://www.legislation.gov.uk/eur/2003/1831/article/8). The proposedterms of authorisation are set out below.

**Proposed terms of authorisation**

|  |  |
| --- | --- |
| *Additive*  | L-tryptophan  |
| *Identification number*  | 3c440i  |
| *Authorisation holder[[43]](#footnote-44)*  | None  |
| *Additive category*  | Nutritional additive |
| *Functional group*  | Amino acids, their salts and analogues  |
| *Additive composition*  | L-tryptophan with a purity criteria not less than 98% as a powder with the following components:* Moisture content: 1% maximum
* 1,1’-ethylidene-bis-L-tryptophan: 10 mg/kg maximum
 |
| *Characterisation of the active substance(s)*  | L-tryptophan produced by fermentation with *Escherichia coli* (KCCM 80210)  (C11H12N2O2) * CAS no: 73-22-3[[44]](#footnote-45)
* EINECS no: 200-795-6**[[45]](#footnote-46)**
 |
| *Analytical method****[[46]](#footnote-47)*** | For the identification of L-tryptophan in the feed additive:  * Food Chemical Codex "L-tryptophan monograph"[[47]](#footnote-48)

For the determination of tryptophan in the feed additive and premixtures:  * High performance liquid chromatography with fluorescence detection (HPLC-FLD) in accordance with BS EN ISO 13904:20165

For the determination of tryptophan in feed materials and compound feed:  * High performance liquid chromatography with fluorescence detection (HPLC-FLD) in accordance with [Regulation (EC) No 152/2009](https://www.legislation.gov.uk/eur/2009/152/contents) laying down the methods of sampling and analysis for the official control of feed (Annex III, G)
 |
| *Species or category of animal*  | All animal species    |
| *Maximum age*  | Not applicable  |
| *Content of L-tryptophan (mg/kg of complete feed with a moisture content of 12%)*  | *Minimum content*  | No minimum  |
| *Maximum content*  | No maximum  |
| *Other provisions*  | 1. L-tryptophan shall be rumen protected when administered to ruminants.
2. Declaration to be made on the label of the additive and premixture: “The supplementation with L-tryptophan shall take into account all essential and conditionally essential amino acids in order to avoid imbalances.”
 |

**Supplementary information**

* Feed additives are subject to [UK health and safety legislation](https://www.hse.gov.uk/). The safety assessment identified that particular consideration should be given to hazards as a:
* Eye irritant
* Powder where inhalation risks endotoxin exposure
* Categories and definitions of target animals are defined in Annex IV of [Regulation (EC) 429/2008](https://www.legislation.gov.uk/eur/2008/429/contents).
* The FSS/FSA consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in [Regulation (EC) 183/2005](https://www.legislation.gov.uk/eur/2005/183/contents) laying down requirements for feed hygiene and good manufacturing practice.

**Other legitimate factors**

In developing the Risk Management recommendations, FSS/FSA have had regard to the other legitimate factors (including Consumer Interests, Political, Environmental, Societal and Technical Feasibility) that Scottish Ministers will consider as part of their decision on authorisation.

FSS/FSA have not identified any applicable other legitimate factors to date that would prevent authorisation or affect the conditions of authorisation of this animal feed additive. As noted above, stakeholders and the broader public are equally invited to consider and provide their views on any relevant other legitimate factors as part of the consultation process.

I**mpacts**

As part of the risk analysis process, FSS/FSA have assessed the potential impacts that would result from the authorisation of this animal feed additive, should Scottish Ministers decide to authorise, no significant impacts were identified from this authorisation. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

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

**Background**

The FSS/FSA has undertaken a safety assessment of application RP1126 for the authorisation of use of L-lysine sulfphate produced by fermentation with *Corynebacterium glutamicum* (KCCM 80227) as a feed additive for all animal species.

**Safety assessment summary**

The FSS/FSA safety assessment was published on 29 September 2023 and can be found [here](https://www.food.gov.uk/research/research-projects/safety-assessment-rp1126-l-lysine-sulfate). The assessment of the preparation of L-lysine sulphate shows that the conditions for authorisation in [Article 5](https://www.legislation.gov.uk/eur/2003/1831/article/5) of [Regulation (EC) 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) are satisfied.

The FSS/FSA conclusion on L-lysine sulphate produced by fermentation with *Corynebacterium glutamicum* (KCCM 80227) is that:

* This bacterial species is well-characterised and is considered suitable for the qualified presumption of safety (QPS) approach to safety assessment.
* The feed additive is safe for all animal species, consumers users and for the environment.
* L-lysine sulphate is an efficacious source of the essential amino acid L-lysine for non-ruminant animal species. For L-lysine to be as efficacious in ruminants, it should be protected against degradation in the rumen.
* On worker safety, the additive is not a skin or eye irritant or a skin or respiratory sensitiser.
* There is no need for specific requirements for a post-market monitoring plan.

**Relevant Legislation**

Legislation in respect of feed additives applies to this application. In particular it is noted that this application must fulfil the following requirements of [Regulation (EC) No 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) for feed additives for use in animal nutrition:

1. [Article 4](https://www.legislation.gov.uk/eur/2003/1831/article/4): Authorisation for a new or new use of a feed additive.
2. [Article 6](https://www.legislation.gov.uk/eur/2003/1831/article/6): Categories of feed additives.
3. [Article 7](https://www.legislation.gov.uk/eur/2003/1831/article/7): Application for authorisation of a feed additive.
4. [Article 16](https://www.legislation.gov.uk/eur/2003/1831/article/16/adopted) and [Annex III](https://www.legislation.gov.uk/eur/2003/1831/annex/III/adopted): Labelling and packaging requirements apply, if authorised.
5. [Article 21](https://www.legislation.gov.uk/eur/2003/1831/article/21): Analytical methods have been verified by the Reference Laboratory as used for the control of L-lysine sulphate in animal feed as detailed in the EURL analytical method evaluation report [FAD-2020-0082 & FAD-2020-0085](https://joint-research-centre.ec.europa.eu/publications/fad-2020-00820085_en). Valid analytical methods exist for:
* The identification of sulphate in the feed additive
* The quantification of lysine in the feed additives and premixtures containing more than 10% lysine
* The quantification of lysine in premixtures and compound feed.
1. [Annex IV](https://www.legislation.gov.uk/eur/2003/1831/annex/IV/adopted): The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

**FSS/FSA risk management recommendations**

The FSS/FSA concluded that L-lysine sulphate, as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health at the intended concentrations of use. The FSS/FSA conclusion is that we are in favour of authorising the feed additive as per [Regulation (EC) 1831/2003 Article 8](https://www.legislation.gov.uk/eur/2003/1831/article/8). The proposedterms of authorisation are set out below.

**Proposed terms of authorisation**

|  |  |
| --- | --- |
| *Additive*  | L-lysine sulphate  |
| *Identification number*  | 3c324i  |
| *Authorisation holder*  | None  |
| *Additive category*  | Nutritional additive |
| *Functional group*  | Amino acids, their salts and analogues  |
| *Additive composition*  | Granulated preparation of L-lysine sulphate with a minimum of 52% L-lysine, a maximum of 24%sulphate and a maximum moisture content of 4%  |
| *Characterisation of the active substance(s)*  | L-lysine sulphate produced by fermentation with *Corynebacterium* *glutamicum* (KCCM 80227) (C12H28N4O4H2SO4) * CAS Number: 60343-69-3**[[48]](#footnote-49)**
 |
| *Analytical method[[49]](#footnote-50)*  | For quantification of lysine in the feed additive and premixtures containing more than 10% lysine: * Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) in accordance with BS EN ISO 17180:2013[[50]](#footnote-51)

For the identification of sulphate in the feed additive: * European Pharmacopoeia Monograph

 20301[[51]](#footnote-52)For quantification of lysine in premixtures, feed materials and compound feed: * Ion-exchange chromatography

coupled with post-column derivatisation and optical detection (IEC-VIS) inaccordance with [Regulation (EC) 152/2009](https://www.legislation.gov.uk/eur/2009/152/contents) laying down the methods of sampling and analysis for the official control of feed (Annex III, F) For the quantification of lysine in water:* Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) in accordance with BS EN ISO 17180:2013[[52]](#footnote-53).
 |
| *Species or category of animal*  | All animal species    |
| *Maximum age*  | Not applicable  |
| *Content of L-lysine sulphate (mg/kg of complete feed with a moisture content of 12%)*  | *Minimum content*  | No minimum  |
| *Maximum content*  |  10,000 mg/kg |
| *Other provisions*  | 1. The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture.
2. The L-lysine content must be stated on the labelling of the additive.
3. Declaration to be made on the label of the additive and premixture: “The supplementation with L-lysine shall take into account all essential and conditionally essential amino acids in order to avoid imbalances.”
 |

**Supplementary information**

* Feed additives are subject to [UK health and safety legislation](https://www.hse.gov.uk/). The safety assessment identified no specified hazards.
* Categories and definitions of target animals are defined in Annex IV of [Regulation (EC) 429/2008](https://www.legislation.gov.uk/eur/2008/429/contents).
* The FSS/FSA consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in [Regulation (EC) 183/2005](https://www.legislation.gov.uk/eur/2005/183/contents) laying down requirements for feed hygiene and good manufacturing practice.

**Other legitimate factors**

In developing the Risk Management recommendations, FSS/FSA have had regard to the other legitimate factors (including Consumer Interests, Political, Environmental, Societal and Technical Feasibility) that Scottish Ministers will consider as part of their decision on authorisation.

FSS/FSA have not identified any applicable other legitimate factors to date that would prevent authorisation or affect the conditions of authorisation of this animal feed additive. As noted above, stakeholders and the broader public are equally invited to consider and provide their views on any relevant other legitimate factors as part of the consultation process.

**Impacts**

As part of the risk analysis process, FSS/FSA have assessed the potential impacts that would result from the authorisation of this animal feed additive, should Scottish Ministers decide to authorise, no significant impacts were identified from this authorise. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

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

**Background**

The FSS/FSA has undertaken a safety assessment of application RP1198 for the authorisation of butylated hydroxyanisole as a feed additive for cats.

**Safety assessment summary**

The FSS/FSA safety assessment was published on 29 September 2023 and can be found [here](https://www.food.gov.uk/research/research-projects/safety-assessment-rp1198-butylated-hydroxyanisole). The assessment of the preparation of butylated hydroxyanisole (BHA) shows that the conditions for authorisation in [Article 5](https://www.legislation.gov.uk/eur/2003/1831/article/5) of [Regulation (EC) 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) are satisfied.

The FSS/FSA conclusion on butylated hydroxyanisole is that:

* The additive is safe for cats, consumers and the environment at the proposed level of use.
* As BHA is authorised as an antioxidant in food at comparable levels, efficacy in feed does not need to be demonstrated.
* On worker safety, the additive should be considered a skin and eye irritant and a skin sensitiser.
* There is no need for specific requirements for a post-market monitoring plan.

**Relevant Legislation**

Legislation in respect of feed additives applies to this application. In particular it is noted that this application must fulfil the following requirements of [Regulation (EC) No 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) for feed additives for use in animal nutrition:

1. [Article 4](https://www.legislation.gov.uk/eur/2003/1831/article/4): Authorisation for a new or new use of a feed additive.
2. [Article 6](https://www.legislation.gov.uk/eur/2003/1831/article/6): Categories of feed additives.
3. [Article 7](https://www.legislation.gov.uk/eur/2003/1831/article/7): Application for authorisation of a feed additive.
4. [Article 16](https://www.legislation.gov.uk/eur/2003/1831/article/16/adopted) and [Annex III](https://www.legislation.gov.uk/eur/2003/1831/annex/III/adopted): Labelling and packaging requirements apply, if authorised.
5. [Article 21](https://www.legislation.gov.uk/eur/2003/1831/article/21): Analytical methods have been verified by the Reference Laboratory as used for the control of butylated hydroxyanisole (BHA) in animal feed as detailed in the EURL analytical method evaluation report [FAD-2010-0132](https://joint-research-centre.ec.europa.eu/publications/fad-2010-0132_en). Valid analytical methods exist for:
* The quantification of BHA in the feed additive.
* The quantification of BHA in premixtures and compound feed.
1. [Annex IV](https://www.legislation.gov.uk/eur/2003/1831/annex/IV/adopted): The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

**FSS/FSA risk management recommendations**

The FSS/FSA concluded that butylated hydroxyanisole, as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use. The FSS/FSA conclusion is that we are in favour of authorising the feed additive as per [Regulation (EC) 1831/2003 Article 8](https://www.legislation.gov.uk/eur/2003/1831/article/8). The proposed terms of authorisation are set out below.

**Proposed terms of authorisation**

|  |  |
| --- | --- |
| *Additive* | Butylated hydroxyanisole (BHA) |
| *Identification number*  | 1b320 |
| *Authorisation holder[[53]](#footnote-54)* | None |
| *Additive category* | Technological |
| *Functional group* | Antioxidants |
| *Additive composition* | Butylated hydroxyanisole (BHA) with a minimum content of 98.5% in a waxy solid form. |
| *Characterisation of the active substance(s)* | Butylated hydroxyanisole containing a mixture of 2-tert-butyl-4-hydroxyanisole and a minimum of 85% 3-tert-butyl-4-hydroxyanisole (C11H16O2)* CAS no: 25013-16-5[[54]](#footnote-55)
 |
| *Analytical method[[55]](#footnote-56)* | For the quantification of butylated hydroxyanisole in feed additives:* Gas chromatography coupled to flame ionization detection (GC-FID) (FCC7 method)[[56]](#footnote-57)

For the quantification of butylated hydroxyanisole in premixtures and compound feed:* Reversed phase high performance liquid chromatography coupled to ultraviolet-diode-array detection (RP-HPLC-UV-DAD, 285 nm)
 |
| *Species or category of animal*  | Cats  |
| *Maximum age* | Not applicable |
| *Content of Butylated hydroxyanisole (mg/kg of complete feed with a moisture content of 12%)* | *Minimum content* | No minimum |
| *Maximum content* | 150 mg/kg |
| *Other provisions* | 1. The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture.
2. Butylated hydroxyanisole (BHA) can be used in combination with butylated hydroxytoluene (BHT) up to a maximum combined content of 150 mg/kg of complete feed.
 |

**Supplementary information**

* Feed additives are subject to [UK health and safety legislation](https://www.hse.gov.uk/). The safety assessment identified that particular consideration should be given to hazards as a:
* Skin and eye irritant,
* Skin sensitiser
* Categories and definitions of target animals are defined in Annex IV of Regulation (EC) 429/2008.
* The FSS/FSA consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in [Regulation (EC) 183/2005](https://www.legislation.gov.uk/eur/2005/183) laying down requirements for feed hygiene and good manufacturing practice.

**Other legitimate factors**

In developing the Risk Management recommendations, FSS/FSA have had regard to the other legitimate factors (including Consumer Interests, Political, Environmental, Societal and Technical Feasibility) that Scottish Ministers will consider as part of their decision on authorisation.

FSS/FSA have not identified any applicable other legitimate factors to date that would prevent authorisation or affect the conditions of authorisation of this animal feed additive. As noted above, stakeholders and the broader public are equally invited to consider and provide their views on any relevant other legitimate factors as part of the consultation process.

**Impacts**

As part of the risk analysis process, FSS/FSA have assessed the potential impacts that would result from the authorisation of this animal feed additive, should Scottish Ministers decide to authorise, no significant impacts were identified from this authorisation. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

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

**Background**

The FSS/FSA has undertaken a safety assessment of application RP1199 Part A for the authorisation of L-Lysine base (liquid) produced by fermentation with *Corynebacterium glutamicum* (KCCM 80183) as a feed additive for all animal species.

**Safety assessment summary**

The FSS/FSA safety assessment was published on 29 September 2023 and can be found [here](https://www.food.gov.uk/research/research-projects/safety-assessment-rp1199-l-lysine). The assessment of the preparation of L-lysine base (liquid) shows that the conditions for authorisation in [Article 5](https://www.legislation.gov.uk/eur/2003/1831/article/5) of [Regulation (EC) 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) are satisfied.

The FSS/FSA conclusion on L-lysine base (liquid) produced by fermentation with *Corynebacterium glutamicum* (KCCM 80183) is that:

* The additive is produced by a genetically modified strain of  *C. glutamicum* (KCCM 80183). The production strain and its recombinant DNA were not detected in the finished feed additive and no safety concerns were raised with regard to the genetic modification.
* This bacterial species is well-characterised and is considered suitable for the qualified presumption of safety (QPS) approach to safety assessment.
* The additive is safe for the target species, consumers and the environment.
* L-lysine base (liquid) is an efficacious source of the essential amino acid L-lysine for non-ruminant animal species. For the supplemental L-lysine to be as efficacious in ruminants, it should be protected against degradation in the rumen.
* On worker safety, L-lysine is an inhalation hazard and eye irritant.
* There is no need for specific requirements for a post-market monitoring plan.

**Relevant Legislation**

Legislation in respect of feed additives applies to this application. In particular it is noted that this application must fulfil the following requirements of [Regulation (EC) No 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) for feed additives for use in animal nutrition:

1. [Article 4](https://www.legislation.gov.uk/eur/2003/1831/article/4): Authorisation for a new or new use of a feed additive.
2. [Article 6](https://www.legislation.gov.uk/eur/2003/1831/article/6): Categories of feed additives.
3. [Article 7](https://www.legislation.gov.uk/eur/2003/1831/article/7): Application for authorisation of a feed additive.
4. [Article 16](https://www.legislation.gov.uk/eur/2003/1831/article/16/adopted) and [Annex III](https://www.legislation.gov.uk/eur/2003/1831/annex/III/adopted): Labelling and packaging requirements apply, if authorised.
5. [Article 21](https://www.legislation.gov.uk/eur/2003/1831/article/21): Analytical methods have been verified by the Reference Laboratory as used for the control of L-lysine base (liquid) in animal feed as detailed in the EURL analytical method evaluation report [FAD-2019-0016+0028](https://joint-research-centre.ec.europa.eu/publications/fad-2019-00160028_en). Valid analytical methods exist for:
* The quantification of lysine in the feed additive and premixtures containing more than 10% lysine.
* The quantification of lysine in premixtures, feed materials and compound feed.
* The quantification of lysine in water.
1. [Annex IV](https://www.legislation.gov.uk/eur/2003/1831/annex/IV/adopted): The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

**FSS/FSA risk management recommendations**

The FSS/FSA concluded that L-Lysine base (liquid), as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use The FSS/FSA conclusion is that we are in favour of authorising the feed additive as per [Regulation (EC) 1831/2003 Article 8](https://www.legislation.gov.uk/eur/2003/1831/article/8). The proposedterms of authorisation are set out below.

**Proposed terms of authorisation**

|  |  |
| --- | --- |
| Additive  | L-lysine base (liquid) |
| Identification number   | 3c320  |
| Authorisation holder***[[57]](#footnote-58)***  | None  |
| Additive category  | Nutritional additive |
| Functional group  | Amino acids, their salts and analogues |
| Additive composition  | Aqueous solution with a minimum of 50% L-lysine  |
| Characterisation of the active substance(s)  | L-lysine base (liquid) (NH2(CH2)CH(NH2)COOH) produced by fermentation with *Corynebacterium glutamicum* (KCCM 80183)~~.~~ * CAS no: 56-87-1[[58]](#footnote-59)
 |
| Analytical method***[[59]](#footnote-60)***  | For the quantification of lysine in the feed additive and premixtures containing more than 10% lysine: * Ion-exchange chromatography

 coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) in accordance with BS EN ISO17180:2013[[60]](#footnote-61)For the quantification of lysine in premixtures, feed materials and compound feed: * Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS)

in accordance with [Regulation (EC) 152/2009](https://www.legislation.gov.uk/eur/2009/152/contents) (Annex III, F) For the quantification of lysine in water:* Ion exchange chromatography

coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) in accordance with BS EN ISO17180:2013* Ion exchange chromatography

coupled with post-column derivatisation and optical detection (IEC-VIS) in accordance [with Regulation (EC)](https://www.legislation.gov.uk/eur/2009/152/contents)[152/2009](https://www.legislation.gov.uk/eur/2009/152/contents) (Annex III, F) . |
| Species or category of animal   | All animal species |
| Maximum age  | Not applicable  |
| Content of L-lysine (mg/kg of complete feed with a moisture content of 12%)  | Minimum content  | No minimum  |
| Maximum content  | No maximum  |
| Other provisions  | 1. The L-lysine content must be stated on the labelling of the additive.
2. The additive can be used via water for drinking.
3. Declaration to be made on the label of the additive and premixture: “The supplementation with L-lysine, in particular via water for drinking, should take into account all essential and conditionally essential amino acids in order to avoid imbalances.”
 |

**Supplementary information**

* Feed additives are subject to [UK health and safety legislation](https://www.hse.gov.uk/). The safety assessment identified that particular consideration should be given to hazards as a:
	+ eye irritant
	+ inhalation hazard
* Categories and definitions of target animals are defined in Annex IV of [Regulation (EC) 429/2008](https://www.legislation.gov.uk/eur/2008/429/contents).
* The FSS/FSA consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in [Regulation (EC) 183/2005](https://www.legislation.gov.uk/eur/2005/183) laying down requirements for feed hygiene and good manufacturing practice.

**Other legitimate factors**

In developing the Risk Management recommendations, FSS/FSA have had regard to the other legitimate factors (including Consumer Interests, Political, Environmental, Societal and Technical Feasibility) that Scottish Ministers will consider as part of their decision on authorisation.

FSS/FSA have not identified any applicable other legitimate factors to date that would prevent authorisation or affect the conditions of authorisation of this animal feed additive. As noted above, stakeholders and the broader public are equally invited to consider and provide their views on any relevant other legitimate factors as part of the consultation process.

**Impacts**

As part of the risk analysis process, FSS/FSA have assessed the potential impacts that would result from the authorisation of this animal feed additive, should Scottish Ministers decide to authorise, no significant impacts were identified from this authorisation. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

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

**Background**

The FSS/FSA has undertaken a safety assessment of application RP1199 Part B for the authorisation of L-Lysine monohydrochloride produced by fermentation with *Corynebacterium glutamicum* (KCCM 80183) as a feed additive for all animal species.

**Safety assessment summary**

The FSS/FSA safety assessment was published on 29 September 2023 and can be found [here](https://www.food.gov.uk/research/research-projects/safety-assessment-rp1199-l-lysine). The assessment of the preparation of L-lysine monohydrochloride (technically pure) shows that the conditions for authorisation in [Article 5](https://www.legislation.gov.uk/eur/2003/1831/article/5) of [Regulation (EC) 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) are satisfied.

The FSS/FSA conclusion on L-lysine monohydrochloride (technically pure) produced by fermentation with *Corynebacterium glutamicum* (KCCM 80183) is that:

* The additive is produced by a genetically modified strain of C*. glutamicum* (KCCM 80183). The production strain and its recombinant DNA were not detected in the finished feed additive and no safety concerns were raised with regard to the genetic modification.
* This bacterial species is well-characterised and is considered suitable for the qualified presumption of safety (QPS) approach to safety assessment.
* The additive is safe for the target species, consumers and the environment.
* L-lysine monohydrochloride (technically pure) is an efficacious source of the essential amino acid L-lysine for non-ruminant animal species. For the supplemental L-lysine to be as efficacious in ruminants, it should be protected against degradation in the rumen.
* On worker safety, L-lysine is an inhalation hazard and eye irritant.
* There is no need for specific requirements for a post-market monitoring plan.

**Relevant Legislation**

Legislation in respect of feed additives applies to this application. In particular it is noted that this application must fulfil the following requirements of [Regulation (EC) No 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) for feed additives for use in animal nutrition:

1. [Article 4](https://www.legislation.gov.uk/eur/2003/1831/article/4): Authorisation for a new or new use of a feed additive.
2. [Article 6](https://www.legislation.gov.uk/eur/2003/1831/article/6): Categories of feed additives.
3. [Article 7](https://www.legislation.gov.uk/eur/2003/1831/article/7): Application for authorisation of a feed additive.
4. [Article 16](https://www.legislation.gov.uk/eur/2003/1831/article/16/adopted) and [Annex III](https://www.legislation.gov.uk/eur/2003/1831/annex/III/adopted): Labelling and packaging requirements apply, if authorised.
5. [Article 21](https://www.legislation.gov.uk/eur/2003/1831/article/21): Analytical methods have been verified by the Reference Laboratory as used for the control of L-lysine monohydrochloride (technically pure) in animal feed as detailed in the EURL analytical method evaluation report [FAD-2019-0016+0028](https://joint-research-centre.ec.europa.eu/publications/fad-2019-00160028_en). Valid analytical methods exist for:
* The quantification of L-lysine monohydrochloride in the feed additive.
* The quantification of lysine in the feed additive and premixtures containing more than 10% lysine.
* The quantification of lysine in premixtures, feed materials and compound feed.
* The quantification of lysine in water.
1. [Annex IV](https://www.legislation.gov.uk/eur/2003/1831/annex/IV/adopted): The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

**FSS/FSA risk management recommendations**

The FSS/FSA concluded that L-Lysine monohydrochloride, as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use. The FSS/FSA conclusion is that we are in favour of authorising the feed additive as per [Regulation (EC) 1831/2003 Article 8](https://www.legislation.gov.uk/eur/2003/1831/article/8). The proposedterms of authorisation are set out below.

**Proposed terms of authorisation**

|  |  |
| --- | --- |
| Additive  | L-lysine monohydrochloride (technically pure) |
| Identification number   | 3c322ii |
| Authorisation holder***[[61]](#footnote-62)***  | None  |
| Additive category  | Nutritional additive |
| Functional group  | Amino acids, their salts and analogues |
| Additive composition  | Powder of L-lysine monohydrochloride with a minimum of 78% L-lysine and a maximum moisture content of 1.5%. |
| Characterisation of the active substance(s)  | L-lysine monohydrochloride (technically pure) (NH2(CH2)4CH(NH2)COOH) produced by fermentation with *Corynebacterium glutamicum* (KCCM 80183)~~.~~ * CAS no: 657-27-2[[62]](#footnote-63)
 |
| Analytical method***[[63]](#footnote-64)***  | For the identification of L-lysine monohydrochloride in the feed additive:* Food Chemicals Codex “L-lysine

 monohydrochloride monograph”[[64]](#footnote-65)For the quantification of lysine in the feed additive and premixtures containing more than 10% lysine: * Ion-exchange chromatography

coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) in accordance with BS EN ISO17180:2013[[65]](#footnote-66)For the quantification of lysine in premixtures, feed materials and compound feed: * Ion-exchange chromatography

coupled with post-column derivatisation and optical detection (IEC-VIS) in accordance with [Regulation (EC)](https://www.legislation.gov.uk/eur/2009/152/contents)[152/2009](https://www.legislation.gov.uk/eur/2009/152/contents) (Annex III, F) For the quantification of lysine in water:* Ion exchange chromatography

coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) in accordance with BS EN ISO17180:2013* Ion exchange chromatography

coupled with post-column derivatisation and optical detection (IEC-VIS) in accordance with [Regulation (EC)](https://www.legislation.gov.uk/eur/2009/152/contents) [152/2009](https://www.legislation.gov.uk/eur/2009/152/contents) (Annex III, F). |
| Species or category of animal   | All animal species |
| Maximum age  | Not applicable  |
| Content of L-lysine monohydrochloride (mg/kg of complete feed with a moisture content of 12%)  | Minimum content  | No minimum  |
| Maximum content  | No maximum  |
| Other provisions  | 1. The L-lysine content must be stated on the labelling of the additive.
2. The additive can be used via water for drinking.
3. Declaration to be made on the label of the additive and premixture: “The supplementation with L-lysine, in particular via water for drinking, should take into account all essential and conditionally essential amino acids in order to avoid imbalances.”
 |

**Supplementary information**

* Feed additives are subject to [UK health and safety legislation](https://www.hse.gov.uk/). The safety assessment identified that particular consideration should be given to hazards as a:
	+ Eye irritant
	+ Inhalation hazard
* Categories and definitions of target animals are defined in Annex IV of [Regulation (EC) 429/2008](https://www.legislation.gov.uk/eur/2008/429/contents).
* The FSS/FSA consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in [Regulation (EC) 183/2005](https://www.legislation.gov.uk/eur/2005/183) laying down requirements for feed hygiene and good manufacturing practice.

**Other legitimate factors**

In developing the risk management recommendations, FSS/FSA have had regard to the other legitimate factors (including Consumer Interests, Political, Environmental, Societal and Technical Feasibility) that Scottish Ministers will consider as part of their decision on authorisation.

FSS/FSA have not identified any applicable other legitimate factors to date that would prevent authorisation or affect the conditions of authorisation of this animal feed additive. As noted above, stakeholders and the broader public are equally invited to consider and provide their views on any relevant other legitimate factors as part of the consultation process.

**Impacts**

As part of the risk analysis process, FSS/FSA have assessed the potential impacts that would result from the authorisation of this animal feed additive, should Scottish Ministers decide to authorise, no significant impacts were identified from this authorsidered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

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

**Background**

The FSS/FSA has undertaken a safety assessment of application RP1200 for the authorisation of disodium 5’-guanylate produced by fermentation with *Corynebacterium* stationis (KCCM 10530) and *Escherichia coli* (KFCC 11067) as a feed additive for all animal species.

**Safety assessment summary**

The FSS/FSA safety assessment was published on 29 September 2023 and can be found [here](https://www.food.gov.uk/research/research-projects/safety-assessment-rp1200-disodium-5-guanylate). The assessment of the preparation of disodium 5’-guanylate shows that the conditions for authorisation in [Article 5](https://www.legislation.gov.uk/eur/2003/1831/article/5) of [Regulation (EC) 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) are satisfied.

The FSS/FSA conclusion on disodium 5’-guanylate produced by fermentation with *Corynebacterium stationis* (KCCM 10530) and *Escherichia coli* (KFCC 11067) is that:

* The additive is safe for the target species, consumers, users and the environment at the proposed use levels.
* There are concerns on use in drinking water due to hygiene implications.
* The additive is efficacious in contributing to the flavour of feed.
* There is no need for specific requirements for a post-market monitoring plan.

**Relevant Legislation**

Legislation in respect of feed additives applies to this application. In particular it is noted that this application must fulfil the following requirements of [Regulation (EC) No 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) for feed additives for use in animal nutrition:

1. [Article 4](https://www.legislation.gov.uk/eur/2003/1831/article/4): Authorisation for a new or new use of a feed additive.
2. [Article 6](https://www.legislation.gov.uk/eur/2003/1831/article/6): Categories of feed additives.
3. [Article 7](https://www.legislation.gov.uk/eur/2003/1831/article/7): Application for authorisation of a feed additive.
4. [Article 16](https://www.legislation.gov.uk/eur/2003/1831/article/16/adopted) and [Annex III](https://www.legislation.gov.uk/eur/2003/1831/annex/III/adopted): Labelling and packaging requirements apply, if authorised.
5. [Article 21](https://www.legislation.gov.uk/eur/2003/1831/article/21): Analytical methods have been verified by the Reference Laboratory as used for the control of disodium 5’-guanylate (GMP) in animal feed as detailed in the EURL analytical method evaluation report ([FAD-2019-0085](https://joint-research-centre.ec.europa.eu/publications/fad-2019-0085_en)). Valid analytical methods exist for:
* The identification of disodium 5'-guanylate (GMP) in the feed additive.
* The determination of disodium 5'-guanylate (GMP) in the feed additive, premixtures and water .
1. [Annex IV](https://www.legislation.gov.uk/eur/2003/1831/annex/IV/adopted): The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

**FSS/FSA risk management recommendations**

The FSS/FSA concluded that disodium 5’-guanylate, as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use. The FSS/FSA conclusion is that we are in favour of authorising the feed additive as per [Regulation (EC) 1831/2003 Article 8](https://www.legislation.gov.uk/eur/2003/1831/article/8). The proposed terms of authorisation are set out below.

**Proposed terms of authorisation**

|  |  |
| --- | --- |
| *Additive*  | Disodium 5’-guanylate  |
| *Identification number*  | 2b627i  |
| *Authorisation holder[[66]](#footnote-67)* | None  |
| *Additive category*  | Sensory additive |
| *Functional group*  | Flavouring compounds  |
| *Additive composition*  | Powder of disodium 5’-guanylate with a minimum purity criteria of 97%.  |
| *Characterisation of the active substance(s)*  | Hydrated form of disodium 5’-guanylate (GMP) produced by fermentation with *Corynebacterium stationis* (KCCM 10530) and *Escherichia coli* K-12 (KFCC 11067) (C10H12N5Na2O8P) * CAS no: 5550-12-9[[67]](#footnote-68)
* EINECS no: 226-914-1[[68]](#footnote-69)
 |
| *Analytical method[[69]](#footnote-70)*  | For the identification of disodium 5'-guanylate (GMP) in the feed additive:  * FAO JECFA monograph "disodium 5'-guanylate"[[70]](#footnote-71)

For the determination of disodium 5'-guanylate (GMP) in the feed additive, flavouring premixtures and water:  * High performance liquid chromatography coupled to UV detection (HPLC-UV)
 |
| *Species or category of animal*  | All animal species    |
| *Maximum age*  | Not applicable  |
| *Content of Disodium 5’-guanylate (mg/kg of complete feed with a moisture content of 12%)*  | *Minimum content*  | No minimum  |
| *Maximum content*  | See other provisions  |
| *Other provisions*  | 1. The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture.
2. The additive shall be incorporated into the feed in the form of a premixture.
3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance when used alone or in combination with other ribonucleotides to the same level (mg/kg of complete feed with a moisture content of 12%): 50 mg.
4. The functional group, identification number, name and added amount of the active substance shall be indicated on the premixture label where the use level on the label of the premixture would result in exceeding the level of active substance in complete feeding stuff referred to in point 3.
 |

**Supplementary information**

* Feed additives are subject to [UK health and safety legislation](https://www.hse.gov.uk/). The safety assessment for this application identified no specified hazards.
* Categories and definitions of target animals are defined in Annex IV of [Regulation (EC) 429/2008](https://www.legislation.gov.uk/eur/2008/429/contents).
* The FSS/FSA consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in [Regulation (EC) 183/2005](https://www.legislation.gov.uk/eur/2005/183) laying down requirements for feed hygiene and good manufacturing practice.

**Other legitimate factors**

In developing the Risk Management recommendations, FSS/FSA have had regard to the other legitimate factors (including Consumer Interests, Political, Environmental, Societal and Technical Feasibility) that Scottish Ministers will consider as part of their decision on authorisation.

FSS/FSA have not identified any applicable other legitimate factors to date that would prevent authorisation or affect the conditions of authorisation of this animal feed additive. As noted above, stakeholders and the broader public are equally invited to consider and provide their views on any relevant other legitimate factors as part of the consultation process.

**Impacts**

As part of the risk analysis process, FSS/FSA have assessed the potential impacts that would result from the authorisation of this animal feed additive, should Scottish Ministers decide to authorise, no significant impacts were identified from this authorisation. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

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

**Background**

FSS/FSA has undertaken a safety assessment of application RP1259 for the new use (extension of species) of muramidase (EC 3.2.1.17) produced by fermentation with *Trichoderma* *reesei* (DSM 32338) (Balancius® ) as a feed additive for weaned piglets.

**Safety assessment summary**

The FSS/FSA safety assessment was published on 29 September 2023 and can be found [here](https://www.food.gov.uk/research/research-projects/safety-assessment-rp1259-muramidase). The assessment of muramidase (EC 3.2.1.17) (Balancius®) shows that the conditions for authorisation in [Article 5](https://www.legislation.gov.uk/eur/2003/1831/article/5) of [Regulation (EC) 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) are satisfied.

The FSS/FSA conclusion on muramidase (EC 3.2.1.17) produced by fermentation with *Trichoderma reesei* (DSM 32338) (Balancius®) is that:

* The additive is produced by a genetically modified strain of *T. reesei* (DSM 32338). The production strain and its recombinant DNA were not detected in the finished feed additive, and no safety concerns were raised with regard to the genetic modification.
* Muramidase (EC 3.2.1.17) is safe for weaned piglets up to the maximum dose of 65,000 LSU(F)/kg\* complete feed.
* The additive is safe for consumers and the environment.
* It is efficacious in weaned piglets at the minimum dose of 50,000 LSU(F)/kg complete feed.
* On worker safety, the additive should be considered a respiratory sensitiser but is inconclusive on skin and eye irritancy and skin sensitisation.
* There is no need for specific requirements for a post-market monitoring plan.

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

**Relevant Legislation**

Legislation in respect of feed additives applies to this application. In particular it is noted that this application must fulfil the following requirements of [Regulation (EC) No 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) for feed additives for use in animal nutrition:

1. [Article 4](https://www.legislation.gov.uk/eur/2003/1831/article/4): Authorisation for a new or new use of a feed additive.
2. [Article 6](https://www.legislation.gov.uk/eur/2003/1831/article/6): Categories of feed additives.
3. [Article 7](https://www.legislation.gov.uk/eur/2003/1831/article/7): Application for authorisation of a feed additive.
4. [Article 16](https://www.legislation.gov.uk/eur/2003/1831/article/16/adopted) and [Annex III](https://www.legislation.gov.uk/eur/2003/1831/annex/III/adopted): Labelling and packaging requirements apply, if authorised.
5. [Article 21](https://www.legislation.gov.uk/eur/2003/1831/article/21): Analytical methods have been verified by the Reference Laboratory as used for the control of muramidase (EC 3.2.1.17) (Balancius®) in animal feed as detailed in the EURL analytical method evaluation report ([FAD-2017-0046](https://joint-research-centre.ec.europa.eu/publications/fad-2017-0046_en)). Valid analytical methods exist for:
* The quantification of muramidase activity in the feed additive, premixtures, feed materials and compound feed.
1. [Annex IV](https://www.legislation.gov.uk/eur/2003/1831/annex/IV/adopted): The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

**FSS/FSA risk management recommendations**

The FSS/FSA concluded that muramidase (EC 3.2.1.17) as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use. The FSS/FSA conclusion is that we are in favour of authorising the feed additive as per [Regulation (EC) 1831/2003 Article 8](https://www.legislation.gov.uk/eur/2003/1831/article/8). The proposedterms of authorisation are set out below.

**Proposed terms of authorisation**

|  |  |
| --- | --- |
| *Additive*  | Muramidase (EC 3.2.1.17) |
| *Identification number*  | 4d16  |
| *Authorisation holder* | DSM Nutritional Products Ltd  |
| *Additive category*  | Zootechnical   |
| *Functional group*  | Other zootechnical additive |
| *Additive composition*  | Solid and liquid preparations of muramidase (EC 3.2.1.17) produced by fermentation with *Trichoderma reesei* (DSM 32338) having a minimum enzyme activity of 60,000 LSU(F)/g.[[71]](#footnote-72)    |
| *Characterisation of the active substance(s)*  | Muramidase (EC 3.2.1.17) produced by fermentation with *Trichoderma reesei* (DSM 32338) * CAS no: 9001-63-2[[72]](#footnote-73)
* EINECS no: 232-620-4**[[73]](#footnote-74)**
 |
| *Analytical method[[74]](#footnote-75)*  | For the quantification of muramidase in the feed additive, premixtures and compound feed: * Fluorescence-based enzyme assay method that determines the enzyme-catalysed depolymerisation of a fluorescein-labelled peptidoglycan preparation at pH 6.0 and 30 °C.
 |
| *Species or category of animal*  | Weaned piglets    |
| *Maximum age*  | Not applicable  |
| *Content of muramidase (units of activity/kg of complete feed with a moisture content of 12%)*  | *Minimum content*  | 50 000 LSU (F)/kg  |
| *Maximum content*  | 65 000 LSU(F)/kg  |
| *Other provisions*  | 1. The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture.
 |

**Supplementary information**

* Feed additives are subject to [UK health and safety legislation](https://www.hse.gov.uk/). The safety assessment identified that particular consideration should be given to hazards as a:
* Skin and eye irritant
* Skin and respiratory sensitiser
* Categories and definitions of target animals are defined in Annex IV of [Regulation (EC) 429/2008](https://www.legislation.gov.uk/eur/2008/429/contents).
* The FSS/FSA consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in [Regulation (EC) 183/2005](https://www.legislation.gov.uk/eur/2005/183) laying down requirements for feed hygiene and Good manufacturing practice.

**Other legitimate factors**

In developing the Risk Management recommendations, FSS/FSA have had regard to the other legitimate factors (including Consumer Interests, Political, Environmental, Societal and Technical Feasibility) that Scottish Ministers will consider as part of their decision on authorisation.

FSS/FSA have not identified any applicable other legitimate factors to date that would prevent authorisation or affect the conditions of authorisation of this animal feed additive. As noted above, stakeholders and the broader public are equally invited to consider and provide their views on any relevant other legitimate factors as part of the consultation process.

**Impacts**

As part of the risk analysis process, FSS/FSA have assessed the potential impacts that would result from the authorisation of this animal feed additive, should Scottish Ministers decide to authorise, no significant impacts were identified from this authorisation. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

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

**Background**

FSS/FSA has undertaken a safety assessment of application RP1349 for the authorisation of Phytomenadione (Vitamin K1) as a feed additive for horses.

**Safety assessment summary**

The FSS/FSA safety assessment was published on 29 September 2023 and can be found [here](https://www.food.gov.uk/research/research-projects/safety-assessment-rp1349-vitamin-k1). The assessment of Phytomenadione (Vitamin K1) shows that the conditions for authorisation in [Article 5](https://www.legislation.gov.uk/eur/2003/1831/article/5) of [Regulation (EC) 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) are satisfied.

The FSS/FSA conclusion on phytomenadione (Vitamin K1) is that:

* The vitamin is safe for horses, consumers and the environment at the intended concentrations of use.
* The additive is an effective source of Vitamin K1 in horse nutrition.
* On worker safety, phytomenadione is a skin sensitiser but no conclusions could be drawn on skin and eye irritancy and skin sensitisation.
* There is no need for specific requirements for a post-market monitoring plan.

**Relevant Legislation**

Legislation in respect of feed additives applies to this application. In particular it is noted that this application must fulfil the following requirements of [Regulation (EC) No 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) for feed additives for use in animal nutrition:

1. [Article 4](https://www.legislation.gov.uk/eur/2003/1831/article/4): Authorisation for a new or new use of a feed additive.
2. [Article 6](https://www.legislation.gov.uk/eur/2003/1831/article/6): Categories of feed additives.
3. [Article 7](https://www.legislation.gov.uk/eur/2003/1831/article/7): Application for authorisation of a feed additive.
4. [Article 16](https://www.legislation.gov.uk/eur/2003/1831/article/16/adopted) and [Annex III](https://www.legislation.gov.uk/eur/2003/1831/annex/III/adopted): Labelling and packaging requirements apply, if authorised.
5. [Article 21](https://www.legislation.gov.uk/eur/2003/1831/article/21): Analytical methods have been verified by the Reference Laboratory as used for the control of phytomenadione (Vitamin K1) in animal feed as detailed in the EURL analytical method evaluation report ([FAD- 2020-0006](https://joint-research-centre.ec.europa.eu/publications/fad-2020-0006_en)) Valid analytical methods exist for:
* The determination of phytomenadione in the feed additive.
* The determination of phytomenadione in the additive preparation and in complimentary feed.
1. [Annex IV](https://www.legislation.gov.uk/eur/2003/1831/annex/IV/adopted): The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

**FSS/FSA risk management recommendations**

The FSS/FSA concluded that phytomenadione, as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use. The FSS/FSA conclusion is that we are in favour of authorising the feed additive as per [Regulation (EC) 1831/2003 Article 8](https://www.legislation.gov.uk/eur/2003/1831/article/8). The proposedterms of authorisation are set out below.

**Proposed terms of authorisation**

|  |  |
| --- | --- |
| *Additive* | Phytomenadione (Vitamin K1) |
| *Identification number*  | 3a712 |
| *Authorisation holder[[75]](#footnote-76)* | None |
| *Additive category* | Nutritional  |
| *Functional group* | Vitamins, pro-vitamins and chemically well-defined substances having similar effect |
| *Additive composition* | Solid preparation containing a minimum of 4.2% of phytomenadione (Vitamin K1)  |
| *Characterisation of the active substance(s)* | 2-methyl-3-[(E-7R,11R)-3,7,11,15-tetramethylhexadec-2- enyl]naphthalene-1,4-dione (phytomenadione) (C31H46O2)* CAS no: 84-80-0[[76]](#footnote-77)
* EINECS no: 201-564-2[[77]](#footnote-78)

with the following components:* E-phytomenadione: 75% minimum
* E-epoxyphytomenadione: 4% maximum
* Total purity of E-phytomenadione, E-epoxyphytomenadione and Z-phytomenadione isomers: 97% minimum
 |
| *Analytical method[[78]](#footnote-79)* | For the determination of phytomenadione (Vitamin K1) in the feed additive:* High performance liquid chromatography (HPLC) in accordance with the European Pharmacopoeia[[79]](#footnote-80)

For the determination of phytomenadione in the additive preparation and in complimentary feed:* High performance liquid chromatography with fluorescence detection (HPLC-FLD) in accordance with BS EN 14148:2003[[80]](#footnote-81)
 |
| *Species or category of animal*  | Horses  |
| *Maximum age* | Not applicable |
| *Content of phytomenadione (Vitamin K*1**)** *(mg/kg of complete feed with a moisture content of 12%)* | *Minimum content* | No minimum |
| *Maximum content* | No maximum |
| *Other provisions* | 1. The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture.
 |

**Supplementary information**

* Feed additives are subject to [UK health and safety legislation](https://www.hse.gov.uk/). The safety assessment identified that particular consideration should be given to hazards as a:
* Skin and eye irritant
* Skin sensitiser
* Hazard by inhalation
* Categories and definitions of target animals are defined in Annex IV of [Regulation (EC) 429/2008](https://www.legislation.gov.uk/eur/2008/429/contents).
* The FSS/FSA consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in
* [Regulation (EC) 183/2005](https://www.legislation.gov.uk/eur/2005/183) laying down requirements for feed hygiene and good manufacturing practice.

**Other legitimate factors**

In developing the Risk Management recommendations, FSS/FSA have had regard to the other legitimate factors (including Consumer Interests, Political, Environmental, Societal and Technical Feasibility) that Scottish Ministers will consider as part of their decision on authorisation.

FSS/FSA have not identified any applicable other legitimate factors to date that would prevent authorisation or affect the conditions of authorisation of this animal feed additive. As noted above, stakeholders and the broader public are equally invited to consider and provide their views on any relevant other legitimate factors as part of the consultation process.

**Impacts**

As part of the risk analysis process, FSS/FSA have assessed the potential impacts that would result from the authorisation of this animal feed additive, should Scottish Ministers decide to authorise, no significant impacts were identified from this authorisation. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

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

**Background**

FSS/FSA has undertaken a safety assessment of application RP1386 for the renewal and modification of use of copper chelate of hydroxy analogue of methionine as a feed additive for all animal species.

**Safety assessment summary**

The application was evaluated by our independent Advisory Committee on Animal Feedingstuffs (ACAF). The FSS/FSA safety assessment was published on 29 September 2023 and can be found [here](https://www.food.gov.uk/research/research-projects/safety-assessment-rp1386-copper-chelate-of-hydroxy-analogue-of-methionine). The assessment of copper chelate of hydroxy analogue of methionine shows that the conditions for authorisation in [Article 5](https://www.legislation.gov.uk/eur/2003/1831/article/5) of [Regulation (EC) 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) are satisfied.

The FSS/FSA conclusion on copper chelate of hydroxy analogue of methionine is that:

* The additive is safe for the target species, consumers and the environment.
* As its effectiveness (efficacy) has previously been demonstrated and this renewal application does not propose amendments under its existing conditions of authorisation, no further evidence is required.
* On worker safety, the additive is a skin and eye irritant, a skin sensitiser and presents a low risk of respiratory sensitisation.
* There is no need for specific requirements for a post-market monitoring plan.

**Relevant Legislation**

Legislation in respect of feed additives applies to this application. In particular it is noted that this application must fulfil the following requirements of [Regulation (EC) No 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) for feed additives for use in animal nutrition:

1. [Article 6](https://www.legislation.gov.uk/eur/2003/1831/article/6): Categories of feed additives.
2. [Article 13](https://www.legislation.gov.uk/eur/2003/1831/article/13): Modification, suspension and revocation of authorisation.
3. [Article 14](https://www.legislation.gov.uk/eur/2003/1831/article/14): Renewal of authorisation.
4. [Article 16](https://www.legislation.gov.uk/eur/2003/1831/article/16/adopted) and [Annex III](https://www.legislation.gov.uk/eur/2003/1831/annex/III/adopted): Labelling and packaging requirements apply, if authorised.
5. [Article 21](https://www.legislation.gov.uk/eur/2003/1831/article/21): Analytical methods have been verified by the Reference Laboratory as used for the control of copper chelate of hydroxy analogue of methionine in animal feed as detailed in the EURL analytical method evaluation report ([FAD-2007-0012](https://joint-research-centre.ec.europa.eu/publications/fad-2007-0012_en)). Valid analytical methods exist for:
* The quantification of the hydroxy analogue of methionine content in the feed additive,
* The quantification of total copper in the feed additive, premixtures, feed materials and compound feed.
1. [Annex IV](https://www.legislation.gov.uk/eur/2003/1831/annex/IV/adopted): The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

**FSS/FSA risk management recommendations**

The FSS/FSA concluded that copper chelate of hydroxy analogue of methionine, as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use. The FSS/FSA conclusion is that we are in favour of authorising the feed additive as per [Regulation (EC) 1831/2003 Article 8](https://www.legislation.gov.uk/eur/2003/1831/article/8). The proposedterms of authorisation are set out below.

**Proposed terms of authorisation**

|  |  |
| --- | --- |
| *Additive* | Copper chelate of hydroxy analogue of methionine |
| *Identification number*  | 3b410i  |
| *Authorisation holder[[81]](#footnote-82)* | None |
| *Additive category* | Nutritional additive |
| *Functional group* | Compounds of trace elements |
| *Additive composition* | Copper chelate of hydroxy analogue of methionine in solid form containing a minimum of 16% copper and the following components:* (2-hydroxy-4-methylthio) butanoic acid: 78% minimum
* Nickel: 20 ppm maximum
 |
| *Characterisation of the active substance(s)* | Copper chelate of hydroxy analogue of methionine (Cu(CH3S(CH2)2-CH(OH)-COO)2) * CAS no: 292140-30-8[[82]](#footnote-83)
 |
| *Analytical method[[83]](#footnote-84)* | For the quantification of the hydroxy analogue of methionine content in the feed additive: * Titrimetry, potentiometric titration after oxidation reduction reaction.

For the quantification of total copper in the feed additive:* Inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15510[[84]](#footnote-85) or EN 15621[[85]](#footnote-86)) or
* Atomic absorption spectrometry (AAS) in accordance with [Regulation (EC) 152/2009](https://www.legislation.gov.uk/eur/2009/152/contents) laying down the methods of sampling and analysis for official control of feed (Annex IV-C) (ISO 6869[[86]](#footnote-87))

For the quantification of total copper in premixtures: * Inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15510[[87]](#footnote-88) or EN 15621[[88]](#footnote-89)) or
* Atomic absorption spectrometry (AAS) in accordance with [Regulation (EC) 152/2009](https://www.legislation.gov.uk/eur/2009/152/contents) laying down the methods of sampling and analysis for official control of feed (Annex IV-C) (ISO 6869[[89]](#footnote-90)) or
* Inductively coupled plasma mass spectrometry, ICP-MS (EN 17053[[90]](#footnote-91)).

For the quantification of total copper in feed materials and compound feed: * Inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15510 or EN 15621) or
* Atomic absorption spectrometry (AAS) in accordance with [Regulation (EC)152/2009](https://www.legislation.gov.uk/eur/2009/152/contents) laying down the methods of sampling and analysis for official control of feed (Annex IV-C) or ISO 6869) or
* Inductively coupled plasma mass spectrometry, ICP-MS (EN 17053).
 |
| *Species or category of animal*  | All animal species |
| *Maximum age* | Not applicable |
| *Content of copper (Cu) (mg/kg of complete feed with a moisture content of 12%)* | *Minimum content* | No minimum  |
| *Maximum content* | * Bovines before the start of rumination and Ovines: 15 mg/kg (total)
* Other bovines: 30 mg/kg (total)
* Caprines: 35 mg/kg (total)
* Piglets
	+ Suckling and weaned up to 4 weeks after weaning: 150 mg/kg (total)
	+ From 5th week up to 8 weeks after weaning: 100 mg/kg (total)
* Crustaceans: 50 mg/kg (total)
* Other animal species: 25 mg/kg (total)
 |
| *Other provisions* | 1. The additive shall be incorporated into feed in the form of a premixture.
2. The following words shall be included in the labelling:
	* + For feed for sheep if the level of copper in the feed exceeds 10 mg/kg: ‘The level of copper in this feed may cause poisoning in certain breeds of sheep.’
		+ For feed for bovines after the start of rumination if the level of copper in the feed is less than 20 mg/kg: ‘The level of copper in this feed may cause copper deficiencies in cattle grazing pastures with high contents of molybdenum or sulphur.’.
 |

**Supplementary information**

* Feed additives are subject to [UK health and safety legislation](https://www.hse.gov.uk/). The safety assessment identified that particular consideration should be given to hazards as a:
* Skin and eye irritant
* Skin and respiratory sensitiser
* Categories and definitions of target animals are defined in Annex IV of [Regulation (EC) 429/2008](https://www.legislation.gov.uk/eur/2008/429/contents).
* The FSS/FSA consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in [Regulation (EC) 183/2005](https://www.legislation.gov.uk/eur/2005/183) laying down requirements for feed hygiene and good manufacturing practice.

**Other legitimate factors**

In developing the Risk Management recommendations, FSS/FSA have had regard to the other legitimate factors (including Consumer Interests, Political, Environmental, Societal and Technical Feasibility) that Scottish Ministers will consider as part of their decision on authorisation.

FSS/FSA have not identified any applicable other legitimate factors to date that would prevent authorisation or affect the conditions of authorisation of this animal feed additive. As noted above, stakeholders and the broader public are equally invited to consider and provide their views on any relevant other legitimate factors as part of the consultation process.

**Impacts**

As part of the risk analysis process, FSS/FSA have assessed the potential impacts that would result from the authorisation of this animal feed additive, should Scottish Ministers decide to authorise, no significant impacts were identified from this authorisation. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

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

**Background**

FSS/FSA has undertaken a safety assessment of application RP1387 for the renewal and modification of use of manganese chelate of hydroxy analogue of methionine as a feed additive for all animal species.

**Safety assessment summary**

The FSS/FSA safety assessment was published on 29 September 2023 and can be found [here](https://www.food.gov.uk/research/research-projects/safety-assessment-rp1387-manganese-chelate-of-hydroxy-analogue-of-methionine). The assessment of manganese chelate of hydroxy analogue of methionine shows that the conditions for authorisation in [Article 5](https://www.legislation.gov.uk/eur/2003/1831/article/5) of [Regulation (EC) 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) are satisfied.

The FSS/FSA conclusion on manganese chelate of hydroxy analogue of methionine is that:

* The additive is safe for the target species, consumers and the environment at the intended concentrations of use.
* As its effectiveness (efficacy) has previously been demonstrated and this renewal application does not propose amendments under its existing conditions of authorisation, no further evidence is required.
* On worker safety, the additive is not a skin or eye irritant but is a skin sensitiser and presents a low risk of respiratory sensitisation.
* There is no need for specific requirements for a post-market monitoring plan.

**Relevant Legislation**

Legislation in respect of feed additives applies to this application. In particular it is noted that this application must fulfil the following requirements of [Regulation (EC) No 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) for feed additives for use in animal nutrition:

1. [Article 6](https://www.legislation.gov.uk/eur/2003/1831/article/6): Categories of feed additives.
2. [Article 13](https://www.legislation.gov.uk/eur/2003/1831/article/13): Modification, suspension and revocation of authorisation.
3. [Article 14](https://www.legislation.gov.uk/eur/2003/1831/article/14): Renewal of authorisation.
4. [Article 16](https://www.legislation.gov.uk/eur/2003/1831/article/16/adopted) and [Annex III](https://www.legislation.gov.uk/eur/2003/1831/annex/III/adopted): Labelling and packaging requirements apply, if authorised.
5. [Article 21](https://www.legislation.gov.uk/eur/2003/1831/article/21): Analytical methods have been verified by the Reference Laboratory as used for the control of manganese chelate of hydroxy analogue of methionine in animal feed as detailed in the EURL analytical method evaluation report ([FAD-2007-0011](https://joint-research-centre.ec.europa.eu/publications/fad-2007-0011_en)). Valid analytical methods exist for:
* The quantification of the hydroxy analogue of methionine content in the feed additive,
* The quantification of total manganese in the feed additive, premixtures, feed materials and compound feed.
1. [Annex IV](https://www.legislation.gov.uk/eur/2003/1831/annex/IV/adopted): The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

**FSS/FSA risk management recommendations**

The FSS/FSA concluded that manganese chelate of hydroxy analogue of methionine as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use. The FSS/FSA conclusion is that we are in favour of authorising the feed additive as per [Regulation (EC) 1831/2003 Article 8](https://www.legislation.gov.uk/eur/2003/1831/article/8). The proposed terms of authorisation are set out below.

**Proposed terms of authorisation**

|  |  |
| --- | --- |
| *Additive*  | Manganese chelate of hydroxy analogue of methionine  |
| *Identification number*  | 3b510  |
| *Authorisation holder[[91]](#footnote-92)* | None  |
| *Additive category*  | Nutritional additive |
| *Functional group*  | Compounds of trace elements  |
| *Additive composition*  | Manganese chelate of hydroxy analogue of methionine in solid form containing a minimum of 14% manganese and the following components: * (2-hydroxy-4-methylthio) butanoic acid: 76% minimum
* Nickel: 170 ppm maximum
 |
| *Characterisation of the active substance(s)*  | Manganese chelate of hydroxy analogue of methionine  (Mn(CH3S(CH2)2-CH(OH)-COO)2)* CAS no: 292140-32-0[[92]](#footnote-93)
 |
| *Analytical method[[93]](#footnote-94)*  | For the quantification of the hydroxy analogue of methionine content in the feed additive: * Titrimetry, potentiometric titration after oxidation reduction reaction

For the quantification of total manganese in the feed additive, premixtures, feed materials and compound feed: * Atomic Absorption Spectrometry (AAS) in accordance with Commission [Regulation (EC) No 152/2009](https://www.legislation.gov.uk/eur/2009/152/contents) laying down the methods of sampling and analysis for official control of feed or BS EN ISO 6869:2001[[94]](#footnote-95) or
* Inductively coupled plasma atomic emission spectrometry, (ICP-AES) in accordance with BS EN 15510:2017[[95]](#footnote-96) or
* Inductively coupled plasma atomic emission spectrometry after pressure digestion (ICP-AES) in accordance with BS EN 15621:2017 [[96]](#footnote-97)

For the quantification of total manganese in feed materials and compound feed: * Atomic Absorption Spectrometry (AAS) in accordance with Commission [Regulation (EC) No 152/2009](https://www.legislation.gov.uk/eur/2009/152/contents) laying down the methods of sampling and analysis for official control of feed (Annex IV-C)
* Inductively coupled plasma atomic emission spectrometry, ICP-AES in accordance with BS EN 15510:2017[[97]](#footnote-98) or
* Inductively coupled plasma atomic emission spectrometry after pressure digestion, ICP-AES in accordance with BS EN 15621:2017[[98]](#footnote-99)
 |
| *Species or category of animal*  | All animal species  |
| *Maximum age*  | Not applicable  |
| *Content of manganese (Mn) (mg/kg of complete feed with a moisture content of 12%)*  | *Minimum content*  | No minimum  |
| *Maximum content*  | * Fish: 100 mg/kg (total)
* Other animal species: 150 mg/kg (total)
 |
| *Other provisions*  | 1. The additive shall be incorporated into feed in the form of a premixture.
2. Manganese chelate of hydroxy analogue of methionine may be placed on the market and used as an additive consisting of a preparation.
 |

**Supplementary information**

* Feed additives are subject to [UK health and safety legislation](https://www.hse.gov.uk/). The safety assessment identified that particular consideration should be given to hazards as a:
* Skin sensitiser
* Risk to users by inhalation
* Categories and definitions of target animals are defined in Annex IV of [Regulation (EC) 429/2008](https://www.legislation.gov.uk/eur/2008/429/contents).
* The FSS/FSA consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in [Regulation (EC) 183/2005](https://www.legislation.gov.uk/eur/2005/183) laying down requirements for feed hygiene and good manufacturing practice.

**Other legitimate factors**

In developing the Risk Management recommendations, FSS/FSA have had regard to the other legitimate factors (including Consumer Interests, Political, Environmental, Societal and Technical Feasibility) that Scottish Ministers will consider as part of their decision on authorisation.

FSS/FSA have not identified any applicable other legitimate factors to date that would prevent authorisation or affect the conditions of authorisation of this animal feed additive. As noted above, stakeholders and the broader public are equally invited to consider and provide their views on any relevant other legitimate factors as part of the consultation process.

**Impacts**

As part of the risk analysis process, FSS/FSA have assessed the potential impacts that would result from the authorisation of this animal feed additive, should Scottish Ministers decide to authorise, no significant impacts were identified from this authorisation. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

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

**Background**

FSS/FSA has undertaken a safety assessment of application RP1388 for the renewal and modification of use of zinc chelate of hydroxy analogue of methionine as a feed additive for all animal species.

**Safety assessment summary**

The FSS/FSA safety assessment was published on 29 September 2023 and can be found [here](https://www.food.gov.uk/research/research-projects/safety-assessment-rp1388-zinc-chelate-of-hydroxy-analogue-of-methionine). The assessment of zinc chelate of hydroxy analogue of methionine shows that the conditions for authorisation in [Article 5](https://www.legislation.gov.uk/eur/2003/1831/article/5) of [Regulation (EC) 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) are satisfied.

The FSS/FSA conclusion on zinc chelate of hydroxy analogue of methionine is that:

* The additive is safe for the target species, consumers and the environment.
* As its effectiveness (efficacy) has previously been demonstrated and this renewal application does not propose amendments under its existing conditions of authorisation, no further evidence is required.
* On worker safety, the additive is not a skin or eye irritant but is a skin sensitiser and poses a risk to users by inhalation.
* There is no need for specific requirements for a post-market monitoring plan.

**Relevant Legislation**

Legislation in respect of feed additives applies to this application. In particular it is noted that this application must fulfil the following requirements of [Regulation (EC) No 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) for feed additives for use in animal nutrition:

1. [Article 6](https://www.legislation.gov.uk/eur/2003/1831/article/6): Categories of feed additives.
2. [Article 13](https://www.legislation.gov.uk/eur/2003/1831/article/13): Modification, suspension and revocation of authorisation.
3. [Article 14](https://www.legislation.gov.uk/eur/2003/1831/article/14): Renewal of authorisation.
4. [Article 16](https://www.legislation.gov.uk/eur/2003/1831/article/16/adopted) and [Annex III](https://www.legislation.gov.uk/eur/2003/1831/annex/III/adopted): Labelling and packaging requirements apply, if authorised.
5. [Article 21](https://www.legislation.gov.uk/eur/2003/1831/article/21): Analytical methods have been verified by the Reference Laboratory as used for the control of zinc chelate of hydroxy analogue of methionine in animal feed as detailed in the EURL analytical method evaluation report ([FAD-2007-0010](https://joint-research-centre.ec.europa.eu/publications/fad-2007-0010_en)). Valid analytical methods exist for:
* The quantification of the hydroxy analogue of methionine content in the feed additive.
* The quantification of total zinc in the feed additive, premixtures, feed materials and compound feed.
1. [Annex IV](https://www.legislation.gov.uk/eur/2003/1831/annex/IV/adopted): The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

**FSS/FSA risk management recommendations**

The FSS/FSA concluded that zinc chelate of hydroxy analogue of methionine, as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use. The FSS/FSA conclusion is that we are in favour of authorising the feed additive as per [Regulation (EC) 1831/2003 Article 8](https://www.legislation.gov.uk/eur/2003/1831/article/8). The proposed terms of authorisation are set out below.

**Proposed terms of authorisation**

|  |  |
| --- | --- |
| *Additive* | Zinc chelate of hydroxy analogue of methionine |
| *Identification number*  | 3b610 |
| *Authorisation holder[[99]](#footnote-100)* | None |
| *Additive category* | Nutritional additive |
| *Functional group* | Compounds of trace elements |
| *Additive composition* | Zinc chelate of hydroxy analogue of methionine in solid form containing a minimum of 17% zinc and the following components.* (2-hydroxy-4-methylthio) butanoic acid: 79% minimum
* Nickel: 1.7 ppm maximum
 |
| *Characterisation of the active substance(s)* | Zinc chelate of hydroxy analogue of methionine (Zn(CH3S(CH2)2-CH(OH)-COO)2)* CAS no: 292140-29-5[[100]](#footnote-101)
 |
| *Analytical method[[101]](#footnote-102)* | For the quantification of the hydroxy analogue of methionine content in the feed additive: * Titrimetry, potentiometric titration after oxidation reduction reaction.

For the quantification of total zinc in the feed additive:* Inductively coupled plasma atomic emission spectrometry, (ICP-AES) in accordance with BS EN 15510:2017[[102]](#footnote-103) or BS EN 15621:2017 [[103]](#footnote-104) or
* Atomic absorption spectrometry, (AAS) in in accordance with [Regulation (EC) No 152/2009](https://www.legislation.gov.uk/eur/2009/152/contents) laying down the methods of sampling and analysis for official control of feed or BS EN ISO 6869:2001[[104]](#footnote-105)

For the quantification of total zinc in premixtures:* Inductively coupled plasma atomic emission spectrometry, (ICP-AES) in accordance with BS EN 15510:2017[[105]](#footnote-106) or BS EN 15621:2017 [[106]](#footnote-107) or
* Atomic absorption spectrometry, (AAS) in in accordance with [Regulation (EC) No 152/2009](https://www.legislation.gov.uk/eur/2009/152/contents) laying down the methods of sampling and analysis for official control of feed or BS EN ISO 6869:2001[[107]](#footnote-108) or
* Inductively coupled plasma mass spectrometry (ICP-MS) in accordance with BS EN 17053:2018[[108]](#footnote-109).

For the quantification of total zinc in feed materials and compound feed:* Inductively coupled plasma atomic emission spectrometry, (ICP-AES) in accordance with BS EN 15510:2017[[109]](#footnote-110) or BS EN 15621:2017 [[110]](#footnote-111) or
* Atomic absorption spectrometry, (AAS) in in accordance with [Regulation (EC) No 152/2009](https://www.legislation.gov.uk/eur/2009/152/contents) (annex IV-C) laying down the methods of sampling and analysis for official control of feed or BS EN ISO 6869:2001[[111]](#footnote-112)
* Inductively coupled plasma mass spectrometry ICP-MS in accordance with BS EN 17053[[112]](#footnote-113)
 |
| *Species or category of animal*  | All animal species |
| *Maximum age* | Not applicable |
| *Content of Zinc (Zn) (mg/kg of complete feed with a moisture content of 12%)* | *Minimum level* | No minimum |
| *Maximum level* | * Dogs and cats: 200 mg/kg (total)
* Salmonids and milk replacers for calves: 180 mg/kg (total)
* Piglets, sows, rabbits and all fish other than salmonids: 150 mg/kg (total)
* Other animal species and categories: 120 mg/kg (total)
 |
| *Other provisions* | 1. The additive shall be incorporated into feed in the form of a premixture.
2. Zinc chelate of hydroxy analogue of methionine may be placed on the market and used as an additive consisting of a preparation.
 |

**Supplementary information**

* Feed additives are subject to [UK health and safety legislation](https://www.hse.gov.uk/). The safety assessment identified that particular consideration should be given to hazards as a:
	+ Skin sensitiser
	+ Risk to users by inhalation
* Categories and definitions of target animals in Annex IV of [Regulation (EC) 429/2008](https://www.legislation.gov.uk/eur/2008/429/contents).
* The FSS/FSA consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in [Regulation (EC) 183/2005](https://www.legislation.gov.uk/eur/2005/183) laying down requirements for feed hygiene and good manufacturing practice.

**Other legitimate factors**

In developing the Risk Management recommendations, FSS/FSA have had regard to the other legitimate factors (including Consumer Interests, Political, Environmental, Societal and Technical Feasibility) that Scottish Ministers will consider as part of their decision on authorisation.

FSS/FSA have not identified any applicable other legitimate factors to date that would prevent authorisation or affect the conditions of authorisation of this animal feed additive. As noted above, stakeholders and the broader public are equally invited to consider and provide their views on any relevant other legitimate factors as part of the consultation process.

**Impacts**

As part of the risk analysis process, FSS/FSA have assessed the potential impacts that would result from the authorisation of this animal feed additive, should Scottish Ministers decide to authorise, no significant impacts were identified from this authorisation. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

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

**Background**

FSS/FSA has undertaken a safety assessment of application RP1591 for the authorisation of fumonisin esterase (EC 3.1.1.87) produced by fermentation with *Komagataella* *phaffii* (DSM 32159) as a feed additive for all species.

**Safety assessment summary**

The FSS/FSA safety assessment was published on 29 September 2023 and can be found [here](https://www.food.gov.uk/research/research-projects/safety-assessment-rp1591-fumonisin-esterase). The assessment of fumonisin esterase (EC 3.1.1.87) shows that the conditions for authorisation in [Article 5](https://www.legislation.gov.uk/eur/2003/1831/article/5) of [Regulation (EC) 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) are satisfied.

The FSS/FSA conclusion on fumonisin esterase (EC 3.1.1.87) produced by fermentation with *Komagataella phaffii* (DSM 32159) is that:

* The additive is produced by a genetically modified strain of K*. phaffii* (DSM 32159). The production strain and its recombinant DNA were not detected in the finished feed additive, and no safety concerns were raised with regard to the genetic modification.
* This yeast is well-characterised and is considered suitable for the qualified presumption of safety (QPS) approach to safety assessment.
* The additive is safe for the target species, consumers and the environment under the proposed conditions of use.
* The additive has the capacity to degrade fumonisins in fermenting feed (with a fumonisin content within the guidance limits) when used at the minimum recommended dose of 40 U/kg feed however, efficacy has only been demonstrated in maize based silages.
* On worker safety, the additive is non-irritant to skin and eyes, is not a dermal sensitiser, not toxic by inhalation and the respiratory exposure is low however, a risk of sensitisation via the respiratory route cannot be excluded.
* There is no need for specific requirements for a post-market monitoring plan.

**Relevant Legislation**

Legislation in respect of feed additives applies to this application. In particular it is noted that this application must fulfil the following requirements of [Regulation (EC) No 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) for feed additives for use in animal nutrition:

1. [Article 4](https://www.legislation.gov.uk/eur/2003/1831/article/4): Authorisation for a new or new use of a feed additive.
2. [Article 6](https://www.legislation.gov.uk/eur/2003/1831/article/6): Categories of feed additives.
3. [Article 7](https://www.legislation.gov.uk/eur/2003/1831/article/7): Application for authorisation of a feed additive.
4. [Article 16](https://www.legislation.gov.uk/eur/2003/1831/article/16/adopted) and [Annex III](https://www.legislation.gov.uk/eur/2003/1831/annex/III/adopted): Labelling and packaging requirements apply, if authorised.
5. [Article 21](https://www.legislation.gov.uk/eur/2003/1831/article/21): Analytical methods have been verified by the Reference Laboratory as used for the control of fumonisin esterase (3.1.1.87) in animal feed as detailed in the EURL analytical method evaluation report ([FAD-2017-0005](https://joint-research-centre.ec.europa.eu/publications/fad-2017-0005_en)). Valid analytical methods exist for:
* The quantification of fumonisin esterase activity in the feed additive, premixtures and compound feed.
1. [Annex IV](https://www.legislation.gov.uk/eur/2003/1831/annex/IV/adopted): The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

**FSS/FSA risk management recommendations**

The FSS/FSA concluded that fumonisin esterase (EC 3.1.1.87), as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use. The FSS/FSA conclusion is that we are in favour of authorising the feed additive as per [Regulation (EC) 1831/2003 Article 8](https://www.legislation.gov.uk/eur/2003/1831/article/8). The proposed terms of authorisation are set out below.

**Proposed terms of authorisation**

|  |  |
| --- | --- |
| *Additive*  | Fumonisin esterase (EC 3.1.1.87) |
| *Identification number*  | 1m03i |
| *Authorisation holder****[[113]](#footnote-114)***  | None  |
| *Additive category*  | Technological additive |
| *Functional group*  | Substances for reduction of the contamination of feed by mycotoxin: fumonisins.  |
| *Additive composition*  | * Preparation of fumonisin esterase (EC 3.1.1.87) produced by fermentation with *Komagataella phaffii* (DSM 32159) having a minimum enzyme activity of 3000 U/g[[114]](#footnote-115)
 |
| *Characterisation of the active substance(s)*  | Fumonisin esterase (EC 3.1.1.87) produced by *Komagataella phaffii (*DSM 32159) * EC (IUBMB) No: 3.1.1.87
 |
| *Analytical method[[115]](#footnote-116)* | For the determination of fumonisin esterase activity: * High performance liquid chromatography coupled with a tandem mass spectrometry (HPLC-MS/MS) method based on the quantification of the tricarboxylic acid released from the action of the enzyme on fumonisin B1 at pH 8.0 and 30 ºC.
 |
| *Species or category of animal*  | All animal species  |
| *Maximum age*  | Not applicable  |
| *Units of activity/kg of fresh material*  | *Minimum content*  | 40 U/kg |
| *Maximum content*  | No maximum  |
| *Other provisions*  | 1. The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture.
2. The additive is only allowed in maize-based silages.
 |

**Supplementary information**

* Feed additives are subject to [UK health and safety legislation](https://www.hse.gov.uk/). The safety assessment identified that particular consideration should be given to hazards as a:
	+ Respiratory sensitiser
* Categories and definitions of target animals are defined in Annex IV of [Regulation (EC) 429/2008](https://www.legislation.gov.uk/eur/2008/429/contents).
* The FSS/FSA consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in [Regulation (EC) 183/2005](https://www.legislation.gov.uk/eur/2005/183) laying down requirements for feed hygiene and good manufacturing practice.

**Recommended use**

Fumonisin esterase (EC 3.1.1.87) is recommended at a maximum dose of 300 U/kg of fresh material.

**Other legitimate factors**

In developing the Risk Management recommendations, FSS/FSA have had regard to the other legitimate factors (including Consumer Interests, Political, Environmental, Societal and Technical Feasibility) that Scottish Ministers will consider as part of their decision on authorisation.

FSS/FSA have not identified any applicable other legitimate factors to date that would prevent authorisation or affect the conditions of authorisation of this animal feed additive. As noted above, stakeholders and the broader public are equally invited to consider and provide their views on any relevant other legitimate factors as part of the consultation process.

**Impacts**

As part of the risk analysis process, FSS/FSA have assessed the potential impacts that would result from the authorisation of this animal feed additive, should Scottish Ministers decide to authorise, no significant impacts were identified from this authorisation. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

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

**Background**

In accordance with [Article (13) of Regulation (EC) 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/article/13) on feed additives, application RP1654 is submitted for administrative amendments to be made to change the authorisation holder. The administrative amendments requested are with current authorisations that remain applicable to Great Britain.

*Enterococcus faecium* (CECT 4515) is currently authorised under the Regulation in feed for:

* Weaned piglets [Regulation (EU) 961/2017](https://www.legislation.gov.uk/eur/2017/961)

*Bacillus amyloliquefaciens* (CECT 5940) is currently authorised under the Regulation in feed for:

* Chickens for fattening and chickens for laying [Regulation (EU) 1395/2020](https://www.legislation.gov.uk/eur/2020/1395)

The applicant requests modification of authorisations in accordance with [Article (13) of Regulation (EC) 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/article/13) to amend the name of the holder of authorisation from Evonik Nutrition & Care GmbH to Evonik Operations GmbH.

**Safety assessment summary**

The proposed change of the terms of authorisation is administrative in nature. Therefore the FSS/FSA do not require new assessments of the additives.

**Relevant Legislation**

Legislation in respect of feed additives applies to this application. In particular it is noted that this application must fulfil the following requirements of [Regulation (EC) No 1831/2003](https://www.legislation.gov.uk/eur/2003/1831/contents) for feed additives for use in animal nutrition:

1. [Article 13:](https://www.legislation.gov.uk/eur/2003/1831/article/13) Modification, suspension and revocation of authorisation.

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

**Background**

FSS/FSA has undertaken a safety assessment of application RP658 to amend entry number 60, ‘reduction of the risk of mild fever and subclinical hypocalcaemia’, of Part B of the Annex to [Regulation (EU) 2020/354](https://www.legislation.gov.uk/eur/2020/354/contents) establishing a list of intended uses of feed intended for particular nutritional purposes.

**Safety assessment summary**

The application was evaluated by our independent Advisory Committee on Animal Feedingstuffs (ACAF). The FSS/FSA safety assessment was published on 29 September 2023 and can be found [here](https://www.food.gov.uk/research/research-projects/safety-assessment-rp658-reduction-of-the-risk-of-milk-fever-and-subclinical-hypocalcaemia-in-dairy-cows). The assessment of the application to modify entry number 60, ‘reduction of the risk of mild fever and subclinical hypocalcaemia’ shows that the conditions for authorisation in [Regulation (EU) 2020/354](https://www.legislation.gov.uk/eur/2020/354/contents) which establishes a list of intended uses of feed intended for particular nutritional purposes (PARNUT) are satisfied.

The FSS/FSA concluded that the modification of entry number 60, ‘reduction of the risk of milk fever and subclinical hypocalcaemia’ that a modification of the entry to include DCAD levels between -200 and 100 mEq/kg dry matter would not pose any additional risks to the target species and would be expected to improve efficacy.

**Relevant Legislation**

Legislation in respect of feed additives applies to this application. In particular it is noted that this application must fulfil the following requirements of [Regulation (EC) 767/2009](https://www.legislation.gov.uk/eur/2009/767) on the placing on the market and use of feed:

1. [Article 9](https://www.legislation.gov.uk/eur/2009/767/article/9): The marketing of feed intended for particular nutritional purposes apply.
2. [Article 10](https://www.legislation.gov.uk/eur/2009/767/article/10): The application procedure applies.

Under the requirements of [Regulation (EU) 2020/354](https://www.legislation.gov.uk/eur/2020/354/introduction#:~:text=%281%29%20The%20placing%20on%20the%20market%20and%20use,accordance%20with%20Article%2010%20of%20the%20said%20Regulation.) for feed for particular nutritional purposes:

1. [Article 1](https://www.legislation.gov.uk/eur/2020/354/article/1): The marketing of feed may only be marketed if the general provisions and the intended use are complied with.
2. [Annex Part B](https://www.legislation.gov.uk/eur/2020/354/annex): The general provisions and list of intended uses must be complied with, where applicable for the individual PARNUT authorisation.

**FSS/FSA Risk management recommendation**

The FSS/FSA concluded that the modification of entry number 60 of the Regulation, ‘Reduction of the risk of milk fever’ and subclinical hypocalcaemia’ as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed intended use. The FSS/FSA conclusion is that we are in favour of authorising the feed additive as per [Regulation (EC) 767/2009 Article 10](https://www.legislation.gov.uk/eur/2009/767/article/10). The proposedterms of authorisation are set out below.

**Proposed terms of authorisation**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Entry number   | Particular nutritional purpose  | Essential nutritional characteristics   | Species   | Labelling declarations   | Recommended length of time   | Other Provisions   |
| 60   | Reduction of the risk of milk fever and subclinical hypocalcaemia  | Low cations/anions ratio.   For the total ration:  Minimum acidification via feed for particular nutritional purpose: 100 mEq/kg dry matter.  Objective: Range from negative DCAD values to <200 DCAD[[116]](#footnote-117)  Or  | Dairy Cows   | * Calcium
* Phosphorus

Magnesium * Sodium
* Potassium
* Chlorides
* Sulphur
 | From 3 weeks before calving until calving   | Indicate in the instructions for proper use “stop feeding after calving”   |

**Other legitimate factors**

In developing the Risk Management recommendations, FSS/FSA have had regard to the other legitimate factors (including Consumer Interests, Political, Environmental, Societal and Technical Feasibility) that Scottish Ministers will consider as part of their decision on authorisation.

FSS/FSA have not identified any applicable other legitimate factors to date that would prevent authorisation or affect the conditions of authorisation of this animal feed additive. As noted above, stakeholders and the broader public are equally invited to consider and provide their views on any relevant other legitimate factors as part of the consultation process.

**Impacts**

As part of the risk analysis process, FSS/FSA have assessed the potential impacts that would result from the authorisation of this animal feed additive, should Scottish Ministers decide to authorise, no significant impacts were identified from this authorisation. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

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1. Details of the analytical methods set out in the document referenced “D06/FSQ/CVH/CMP/mdr/ARES (2010)58412” and last updated on 6 June 2016 are available at: <https://joint-research-centre.ec.europa.eu/publications/fad-2009-0028_en>. [↑](#footnote-ref-2)
2. BS EN 15789:2021 *“Animal feeding stuffs. Methods of sampling and analysis. Detection and enumeration of Saccharomyces cerevisiae used as feed additive”.* Published by the British Standards Institution on 30th November 2021 (ISBN 978 0 580 99832 4) and available at: [https://knowledge.bsigroup.com](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021R0733). [↑](#footnote-ref-3)
3. DD CEN/TS:15790:2008 “Animal Feeding Stuffs – PCR typing of probiotic strains of Sacccharomyces cerevisiae (yeast)”. Published by the British Standards Institution on 31st January 2009 (ISBN 978 0 580 61806 2). Available from the British Standards Institution [https://knowledge.bsigroup.com](https://knowledge.bsigroup.com/) [↑](#footnote-ref-4)
4. Details of the analytical methods set out in the document referenced “D06/FSQ/CVH/CMP/mdr/ARES (2010)58412” and last updated on 6 June 2016 are available at: <https://joint-research-centre.ec.europa.eu/publications/fad-2009-0028_en>. [↑](#footnote-ref-5)
5. BS EN 15789:2021 *“Animal feeding stuffs. Methods of sampling and analysis. Detection and enumeration of Saccharomyces cerevisiae used as feed additive”.* Published by the British Standards Institution on 30th November 2021 (ISBN 978 0 580 99832 4) and available at: [https://knowledge.bsigroup.com](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021R0733). [↑](#footnote-ref-6)
6. DD CEN/TS:15790:2008 “Animal Feeding Stuffs – PCR typing of probiotic strains of Sacccharomyces cerevisiae (yeast)”. Published by the British Standards Institution on 31st January 2009 (ISBN 978 0 580 61806 2). Available from the British Standards Institution [https://knowledge.bsigroup.com](https://knowledge.bsigroup.com/) [↑](#footnote-ref-7)
7. Details of the analytical methods set out in the document referenced “D06/FSQ/CVH/CMP/mdr/ARES (2010)58412” and last updated on 6 June 2016 are available at: <https://joint-research-centre.ec.europa.eu/publications/fad-2009-0028_en>. [↑](#footnote-ref-8)
8. BS EN 15789:2021 *“Animal feeding stuffs. Methods of sampling and analysis. Detection and enumeration of Saccharomyces cerevisiae used as feed additive”.* Published by the British Standards Institution on 30th November 2021 (ISBN 978 0 580 99832 4) and available at: [https://knowledge.bsigroup.com](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021R0733). [↑](#footnote-ref-9)
9. DD CEN/TS:15790:2008 “Animal Feeding Stuffs – PCR typing of probiotic strains of Sacccharomyces cerevisiae (yeast)”. Published by the British Standards Institution on 31st January 2009 (ISBN 978 0 580 61806 2). Available from the British Standards Institution [https://knowledge.bsigroup.com](https://knowledge.bsigroup.com/) [↑](#footnote-ref-10)
10. There is no requirement to include the name of the holder of this authorisation as this authorisation does not fall within the scope of Article 9(5) of Regulation (EC) 1831/2003. [↑](#footnote-ref-11)
11. Details of the analytical methods set out in the document referenced “JRC.D.5/SFB/CvH/JO /mds/Ares” and last updated on 6 June 2016 are available at: <https://joint-research-centre.ec.europa.eu/publications/fad-2013-0031_en>. [↑](#footnote-ref-12)
12. BS EN 15876:2021*“Animal feeding stuffs. Methods of sampling and analysis. Detection and enumeration of Pediococcus spp. used as feed additive”*. Published by the British Standards Institution on 30th November 2021 (ISBN 978 0 539 24219 5) and available at: <https://knowledge.bsigroup.com>. [↑](#footnote-ref-13)
13. This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service https://cas.org/cas-data/cas-registry. [↑](#footnote-ref-14)
14. Details of the analytical methods set out in the document referenced “JRC F.5/CvH/MGH /mds/Ares” and last updated on 27 April 2017 are available at: <https://joint-research-centre.ec.europa.eu/publications/fad-2016-0009_en> [↑](#footnote-ref-15)
15. **BS EN ISO 1**4183**:20**08***“Animal feeding stuffs.*** *Determination of monensin, Narasin and salinomycin contents. Liquid chromatographic method using post-column derivitization****”*. Published by the British Standards Institution on** 24**th** January **20**06 **(ISBN 978 0 5**806**2**9556**) and available at:** <https://knowledge.bsigroup.com>**.** [↑](#footnote-ref-16)
16. “appropriate authority” refers to:

(i)the Secretary of State in relation to England;

(ii)the Welsh Ministers in relation to Wales;

(iii) the Scottish Ministers in relation to Scotland. [↑](#footnote-ref-17)
17. This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service <https://cas.org/cas-data/cas-registry>. [↑](#footnote-ref-18)
18. Details of the analytical methods set out in the document referenced “JRC F.5/CvH/MGH /mds/Ares” and last updated on 27 April 2017 are available at: <https://joint-research-centre.ec.europa.eu/publications/fad-2016-0009_en>. [↑](#footnote-ref-19)
19. **BS EN ISO 1**4183**:20**08***“Animal feeding stuffs.*** *Determination of monensin, Narasin and salinomycin contents. Liquid chromatographic method using post-column derivitization****”*. Published by the British Standards Institution on** 24**th** January **20**06 **(ISBN 978 0 5**806**2**9556**) and available at:** [https://knowledge.bsigroup.com](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021R0733)**.** [↑](#footnote-ref-20)
20. “appropriate authority” refers to:

(i)the Secretary of State in relation to England;

(ii)the Welsh Ministers in relation to Wales;

(iii) the Scottish Ministers in relation to Scotland. [↑](#footnote-ref-21)
21. This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service <https://cas.org/cas-data/cas-registry>. [↑](#footnote-ref-22)
22. Details of the analytical methods set out in the document referenced “JRC F.5/CvH/MGH /mds/Ares” and last updated on 27 April 2017 are available at: <https://joint-research-centre.ec.europa.eu/publications/fad-2016-0009_en>. [↑](#footnote-ref-23)
23. **BS EN ISO 1**4183**:20**08***“Animal feeding stuffs.*** *Determination of monensin, Narasin and salinomycin contents. Liquid chromatographic method using post-column derivitization****”*. Published by the British Standards Institution on** 24**th** January **20**06 **(ISBN 978 0 5**806**2**9556**) and available at:** [https://knowledge.bsigroup.com](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021R0733)**.** [↑](#footnote-ref-24)
24. “appropriate authority” refers to:

(i)the Secretary of State in relation to England;

(ii)the Welsh Ministers in relation to Wales;

(iii) the Scottish Ministers in relation to Scotland. [↑](#footnote-ref-25)
25. 1 OTU is the amount of enzyme that catalyses the release of 1 µmol of inorganic phosphate per minute from 5.1mM sodium phytate in pH 5.5 citrate buffer at 37ºC, measured as the blue P-molybdate complex colour at 820 nm. [↑](#footnote-ref-26)
26. This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service <https://cas.org/cas-data/cas-registry> [↑](#footnote-ref-27)
27. This is the identification number allocated by the International Union of Biochemistry and Molecular Biology (IUBMB) https://iubmb.org. [↑](#footnote-ref-28)
28. Details of the analytical methods set out in the document referenced “JRC F.5/CvH/MGH /mds/Ares” and last updated on 17 November 2016 are available at: <https://joint-research-centre.ec.europa.eu/publications/fad-2016-0019_en>. [↑](#footnote-ref-29)
29. There is no requirement to include the name of the holder of this authorisation as this authorisation does not fall within the scope of [Article 9(5) of Regulation (EC) 1831/2003](https://www.legislation.gov.uk/european/regulation/2003/1831). [↑](#footnote-ref-30)
30. Details of the analytical methods set out in the document referenced “JRC.DG.D.6/CvH/PRO/AG/ARES(2011)255176” and last updated on 6th June 2016 are available at: <https://joint-research-centre.ec.europa.eu/publications/fad-2009-0029-fad-2010-0044_en>. [↑](#footnote-ref-31)
31. BS EN 16159:2012 *“Animal feeding stuffs. Determination of selenium by hydride generation atomic absorption spectrometry (HGAAS) after microwave digestion (digestion with 65 % nitric acid and 30 % hydrogen peroxide)”*. Published by the British Standards Institution on 29th February 2012 (ISBN 978 0 580 66997 2) and available at: <https://knowledge.bsigroup.com>. [↑](#footnote-ref-32)
32. This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service https://cas.org/cas-data/cas-registry. [↑](#footnote-ref-33)
33. Details of the analytical methods set out in the document referenced “JRC F.5/CvH/MGH /mds/Ares” and last updated on 27 April 2017 are available at: <https://joint-research-centre.ec.europa.eu/publications/fad-2016-0009_en> [↑](#footnote-ref-34)
34. **BS EN ISO 1**4183**:20**08***“Animal feeding stuffs.*** *Determination of monensin, narasin and salinomycin contents. Liquid chromatographic method using post-column derivitization****”*. Published by the British Standards Institution on** 24**th** January **20**06 **(ISBN 978 0 5**806**2**9556**) and available at:** <https://knowledge.bsigroup.com>**.** [↑](#footnote-ref-35)
35. “appropriate authority” refers to:

(i)the Secretary of State in relation to England;

(ii)the Welsh Ministers in relation to Wales;

(iii) the Scottish Ministers in relation to Scotland. [↑](#footnote-ref-36)
36. Details of the analytical methods set out in the document referenced “D08/FSQ/CVH/CMP/mds/ARES (2009)347415” and last updated on 6 June 2016 are available at: <https://joint-research-centre.ec.europa.eu/publications/fad-2009-0013_en>. [↑](#footnote-ref-37)
37. BS EN 15784:2021 *“Animal feeding stuffs. Methods of sampling and analysis. Detection and enumeration of Bacillus spp. used as feed additive”*. Published by the British Standards Institution on 30th November 2021 (ISBN 978 0 539 24209 6) and available at: https://knowledge.bsigroup.com. [↑](#footnote-ref-38)
38. There is no requirement to include the name of the holder of this authorisation as this authorisation does not fall within the scope of [Article 9(5) of Regulation (EC) 1831/2003](https://www.legislation.gov.uk/european/regulation/2003/1831). [↑](#footnote-ref-39)
39. This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service <https://cas.org/cas-data/cas-registry> [↑](#footnote-ref-40)
40. The EINECS number is given in the European Inventory of Existing Commercial Substances, as published in O.J. No. C146A, 15.6.90, p.1. [↑](#footnote-ref-41)
41. Details of the analytical methods set out in the document referenced “JRC F.5/CvH/ZE/AS/Ares” and last updated on 16th October 2020 are available at: <https://joint-research-centre.ec.europa.eu/publications/fad-2020-0016_en>. [↑](#footnote-ref-42)
42. BS EN ISO 13903:2005 *“Animal feeding stuffs. Determination of amino acids content”*. Published by the British Standards Institution on 24th October 2005 (ISBN 0 580 46218 8) and available at: https://knowledge.bsigroup.com. [↑](#footnote-ref-43)
43. There is no requirement to include the name of the holder of this authorisation as this authorisation does not fall within the scope of Article 9(5) of Regulation [(EC) 1831/2003](https://www.legislation.gov.uk/european/regulation/2003/1831). [↑](#footnote-ref-44)
44. This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service https://cas.org/cas-data/cas-registry [↑](#footnote-ref-45)
45. The EINECS number is given in the European Inventory of Existing Commercial Substances, as published in O.J. No. C146A, 15.6.90, p.1. [↑](#footnote-ref-46)
46. Details of the analytical methods set out in the document referenced “JRC F.5/CvH/ZE/AS/Ares” and last updated on 19 December 2020 are available at: <https://joint-research-centre.ec.europa.eu/publications/fad-2020-0038_en> [↑](#footnote-ref-47)
47. Food Chemicals Codex (FCC), 13th edition (Method: FCC L-tryptophan monograph published). Published by the United States Pharmacopeial Convention on 1st March 2022 (ISSN 2153-1455) and available at: <https://www.foodchemicalscodex.org>. [↑](#footnote-ref-48)
48. This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service https://cas.org/cas-data/cas-registry [↑](#footnote-ref-49)
49. Details of the analytical methods set out in the document referenced “JRC F.5/CvH/ZE/AS/Ares” and last updated on 2 July 2021 are available at the following address: <https://joint-research-centre.ec.europa.eu/publications/fad-2020-00820085_en> [↑](#footnote-ref-50)
50. BS EN ISO 17180:2013 “Animal feeding stuffs. Determination of lysine, methionine and threonine in commercial amino acid products and premixtures”. Published by the British Standards Institution on 30th April 2013 (ISBN 978 0 580 76077 8) and available at: https://knowledge.bsigroup.com. [↑](#footnote-ref-51)
51. European Pharmacopoeia, Monograph (Identification reactions of ions and functional groups – sulphates). Published online by the European Directorate for the Quality of Medicines and Healthcare on 1st January 2024 and available at: <https://pheur.edqm.eu/home>. [↑](#footnote-ref-52)
52. BS EN 17053:2018 *“Animal feeding stuffs. Methods of sampling and analysis. Determination of trace elements, heavy metals and other elements in feed by ICP-MS (multi-method)”.* Published by the British Standards Institution on 28th February 2018 (ISBN 978 0 580 94471 0) and available at: [BS EN ISO 17180:2013 | 30 Apr 2013 | BSI Knowledge (bsigroup.com)](https://knowledge.bsigroup.com/products/animal-feeding-stuffs-determination-of-lysine-methionine-and-threonine-in-commercial-amino-acid-products-and-premixtures?version=standard) [↑](#footnote-ref-53)
53. There is no requirement to include the name of the holder of this authorisation as this authorisation does not fall within the scope of Article 9(5) of Regulation (EC) 1831/2003. [↑](#footnote-ref-54)
54. This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service <https://cas.org/cas-data/cas-registry>. [↑](#footnote-ref-55)
55. Details of the analytical methods are set out in the document referenced “JRC.D.5/CvH/SB/ag/ARES(2012)40826” and last updated on 6 June 2016 and available at: <https://joint-research-centre.ec.europa.eu/publications/fad-2010-0132_en>. [↑](#footnote-ref-56)
56. Food Chemicals Codex (FCC), 13th edition (Method: BHA-FCC V1 monograph \_ published). Published by the United States Pharmacopeial Convention on 1st March 2022 (ISSN 2153-1455) and available at: [https://www.foodchemicalscodex.org](https://www.foodchemicalscodex.org/). [↑](#footnote-ref-57)
57. There is no requirement to include the name of the holder of this authorisation as this authorisation does not fall within the scope of Article 9(5) of Regulation (EC) 1831/2003 [↑](#footnote-ref-58)
58. This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service <https://cas.org/cas-data/cas-registry>. [↑](#footnote-ref-59)
59. Details of the analytical methods are set out in the document referenced “JRC F.5/CvH/SB/AS/Ares” and last updated on 27 January 2020 and available at: <https://joint-research-centre.ec.europa.eu/publications/fad-2019-00160028_en>. [↑](#footnote-ref-60)
60. BS EN ISO 17180:2013 “Animal feeding stuffs. Determination of lysine, methionine and threonine in commercial amino acid products and premixtures”. Published by the British Standards Institution on 30th April 2013 (ISBN 978 0 580 76077 8) and available at: https://knowledge.bsigroup.com. [↑](#footnote-ref-61)
61. There is no requirement to include the name of the holder of this authorisation as this authorisation does not fall within the scope of Article 9(5) of Regulation (EC) 1831/2003 [↑](#footnote-ref-62)
62. This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service <https://cas.org/cas-data/cas-registry>. [↑](#footnote-ref-63)
63. Details of the analytical methods are set out in the document referenced “JRC F.5/CvH/SB/AS/Ares” and last updated on 27 January 2020 and available at: <https://joint-research-centre.ec.europa.eu/publications/fad-2019-00160028_en>. [↑](#footnote-ref-64)
64. Food Chemicals Codex (FCC), 13th edition (method: FCC L-lysine monohydrochloride monograph published). Published by the United States Pharmacopeial Convention on 1st March 2022 (ISSN 2153-1455) and available at: [https://www.foodchemicalscodex.org](https://www.foodchemicalscodex.org/)/. [↑](#footnote-ref-65)
65. BS EN ISO 17180:2013 “Animal feeding stuffs. Determination of lysine, methionine and threonine in commercial amino acid products and premixtures”. Published by the British Standards Institution on 30th April 2013 (ISBN 978 0 580 76077 8) and available at: <https://knowledge.bsigroup.com>. [↑](#footnote-ref-66)
66. There is no requirement to include the name of the holder of this authorisation as this authorisation does not fall within the scope of Article 9(5) of Regulation (EC) 1831/2003 [↑](#footnote-ref-67)
67. This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service <https://cas.org/cas-data/cas-registry>. [↑](#footnote-ref-68)
68. The EINECS number is given in the European Inventory of Existing Commercial Substances, as published in O.J. No. C146A, 15.6.90, p.1. [↑](#footnote-ref-69)
69. Details of the analytical methods are set out in the document referenced “JRC F.5/CvH/ZE/AS/Ares” and last updated on 16 October 2020 and available at: <https://joint-research-centre.ec.europa.eu/publications/fad-2019-0085_en>. [↑](#footnote-ref-70)
70. FAO JECFA Combined Compendium of Food Additive Specifications, “Disodium 5’-guanylate”. Published by the Food and Agriculture Organisation of the United Nations and last updated (Web version) August 2011 (ISBN 92-5-105569-6) and available at: <http://www.fao.org>. [↑](#footnote-ref-71)
71. 1 LSU(F) is defined as the amount of enzyme that increases the fluorescence of 12.5 µg/ml fluorescein-labelled peptidoglycan per minute at pH 6.0 and 30 ºC by a value that corresponds to the fluorescence of approximately 0.06 nmol fluorescein isothiocyanate isomer. [↑](#footnote-ref-72)
72. This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service <https://cas.org/cas-data/cas-registry>. [↑](#footnote-ref-73)
73. The EINECS number is given in the European Inventory of Existing Commercial Substances, as published in O.J. No. C146A, 15.6.90, p.1. [↑](#footnote-ref-74)
74. Details of the analytical methods are set out in the document referenced “JRC F.5/CvH/SB/AS/Ares” and last updated on 2 March 2018 and available at: <https://joint-research-centre.ec.europa.eu/publications/fad-2017-0046_en>. [↑](#footnote-ref-75)
75. There is no requirement to include the name of the holder of this authorisation as this authorisation does not fall within the scope of Article 9(5) of Regulation (EC) 1831/2003. [↑](#footnote-ref-76)
76. This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service <https://cas.org/cas-data/cas-registry>. [↑](#footnote-ref-77)
77. The EINECS (European INventory of Existing Commercial chemical Substances) number as published in O.J. No. C146A, 15.6.90, p.1. [↑](#footnote-ref-78)
78. Details of the analytical method is set out in the document referenced “JRC F.5/CvH/SB/AS/Ares” and last updated on 17 February 2021, available at <https://joint-research-centre.ec.europa.eu/publications/fad-2020-0006_en>. [↑](#footnote-ref-79)
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81. There is no requirement to include the name of the holder of this authorisation as this authorisation does not fall within the scope of Article 9(5) of Regulation (EC) 1831/2003. [↑](#footnote-ref-82)
82. This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service <https://cas.org/cas-data/cas-registry>. [↑](#footnote-ref-83)
83. Details of the analytical methods are set out in the document referenced “D08-FSQ(2007)D/29104” and last updated on 6 June 2016 and available at[: https://joint-research-centre.ec.europa.eu/publications/fad-2007-0012\_en](../Mel%20and%20Kaila%20review%20of%20policy%20instructions%2026.1.24/%3A%20https%3A/joint-research-centre.ec.europa.eu/publications/fad-2007-0012_en). [↑](#footnote-ref-84)
84. BS EN 15510:2017 - TC *“Animal feeding stuffs. Methods of sampling and analysis. Determination of calcium, sodium, phosphorus, magnesium, potassium, iron, zinc, copper, manganese, cobalt, molybdenum and lead by ICP-AES”.* Published by the British Standards Institution on 31st August 2017 (ISBN 978 0 539 09335 3) and available at: <https://knowledge.bsigroup.com.> [↑](#footnote-ref-85)
85. BS EN 15621:2017 *“Animal feeding stuffs. Methods of sampling and analysis. Determination of calcium, sodium, phosphorus, magnesium, potassium, sulphur, iron, zinc, copper, manganese and cobalt after pressure digestion by ICP-AES”.* Published by the British Standards Institution on 31st August 2017 (ISBN 978 0 580 94543 4) and available at: <https://knowledge.bsigroup.com>. [↑](#footnote-ref-86)
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91. There is no requirement to include the name of the holder of this authorisation as this authorisation does not fall within the scope of Article 9(5) of Regulation (EC) 1831/2003. [↑](#footnote-ref-92)
92. This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service <https://cas.org/cas-data/cas-registry>. [↑](#footnote-ref-93)
93. Details of the analytical methods are set out in the document referenced “D08-FSQ(2007)D/29224” and last updated on 6 June 2016 and available at[: https://joint-research-centre.ec.europa.eu/publications/fad-2007-0011\_e](https://joint-research-centre.ec.europa.eu/publications/fad-2007-0011_en)n [↑](#footnote-ref-94)
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100. This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service <https://cas.org/cas-data/cas-registry>. [↑](#footnote-ref-101)
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104. BS EN ISO 6869:2001 *“Animal feeding stuffs. Determination of the contents of calcium, copper, iron, magnesium, manganese, potassium, sodium and zinc. Method using atomic absorption spectrometry”.* Published by the British Standards Institution on 15th March 2001 (ISBN 0 580 36933 1) and available at: <https://knowledge.bsigroup.com>. [↑](#footnote-ref-105)
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107. BS EN ISO 6869:2001 *“Animal feeding stuffs. Determination of the contents of calcium, copper, iron, magnesium, manganese, potassium, sodium and zinc. Method using atomic absorption spectrometry”.* Published by the British Standards Institution on 15th March 2001 (ISBN 0 580 36933 1) and available at: <https://knowledge.bsigroup.com>. [↑](#footnote-ref-108)
108. BS EN 17053:2018 *“Animal feeding stuffs. Methods of sampling and analysis. Determination of trace elements, heavy metals and other elements in feed by ICP-MS (multi-method)”.* Published by the British Standards Institution on 28th February 2018 (ISBN 978 0 580 94471 0) and available at: <https://knowledge.bsigroup.com>. [↑](#footnote-ref-109)
109. BS EN 15510:2017 - TC *“Animal feeding stuffs. Methods of sampling and analysis. Determination of calcium, sodium, phosphorus, magnesium, potassium, iron, zinc, copper, manganese, cobalt, molybdenum and lead by ICP-AES”.* Published by the British Standards Institution on 31st August 2017 (ISBN 978 0 539 09335 3) and available at: [https://knowledge.bsigroup.com.](https://knowledge.bsigroup.com) [↑](#footnote-ref-110)
110. BS EN 15621:2017 *“Animal feeding stuffs. Methods of sampling and analysis. Determination of calcium, sodium, phosphorus, magnesium, potassium, sulphur, iron, zinc, copper, manganese and cobalt after pressure digestion by ICP-AES”.* Published by the British Standards Institution on 31st August 2017 (ISBN 978 0 580 94543 4) and available at: <https://knowledge.bsigroup.com>. [↑](#footnote-ref-111)
111. BS EN ISO 6869:2001 *“Animal feeding stuffs. Determination of the contents of calcium, copper, iron, magnesium, manganese, potassium, sodium and zinc. Method using atomic absorption spectrometry”.* Published by the British Standards Institution on 15th March 2001 (ISBN 0 580 36933 1) and available at: <https://knowledge.bsigroup.com>. [↑](#footnote-ref-112)
112. BS EN 17053:2018 *“Animal feeding stuffs. Methods of sampling and analysis. Determination of trace elements, heavy metals and other elements in feed by ICP-MS (multi-method)”.* Published by the British Standards Institution on 28th February 2018 (ISBN 978 0 580 94471 0) and available at: <https://knowledge.bsigroup.com>. [↑](#footnote-ref-113)
113. There is no requirement to include the name of the holder of this authorisation as this authorisation does not fall within the scope of Article 9(5) of Regulation (EC) 1831/2003. [↑](#footnote-ref-114)
114. 1 U is the enzymatic activity that releases 1 µmol tricarboxylic acid per minute from 100 µM fumonisin B1 in 20 mM Tris-Cl buffer pH 8.0 with 0.1 mg/ml bovine serum albumin at 30 ºC. [↑](#footnote-ref-115)
115. Details of the analytical methods are set out in the document referenced “JRC F.5/CvH/MGH /mds/Ares” and last updated on 18 May 2017 and available at: <https://joint-research-centre.ec.europa.eu/publications/fad-2017-0005_en>. [↑](#footnote-ref-116)
116. DCAD (mEq/kg dry matter) = (Na+K) - (Cl+S)  [↑](#footnote-ref-117)