FSA/FSS risk management recommendations on 24 feed additives applications and one application for feed for particular nutritional purposes (PARNUT) for use in animal feed

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Document subject and purpose

In this document we publish the Food Standards Agency (FSA)/Food Standards Scotland (FSS) risk management recommendations on 24 applications for feed additives, and one application for feed for particular nutritional purposes (PARNUT).

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

Our risk assessors deliver the science behind our advice and publish their safety assessments, links to which are available within each recommendation annex. Risk assessors are responsible for identifying and characterising hazards and risks to health and assessing levels of exposure.

The risk management recommendations consider the safety assessments (which represent the opinion of the FSA and FSS for each application) as well as potential impacts that may result from the authorisation of these feed additive and PARNUT applications. They also consider other legitimate factors that ministers may want to consider before making a decision on authorisation of these applications.

The final FSA/FSS risk management recommendations that are made to ministers in England, Wales, Scotland and Northern Ireland are published within a separate annex for each application and will also consider stakeholders' views received from this consultation.

The FSA/FSS risk management recommendations on 24 applications for feed additives, and one application for feed for particular nutritional purposes (PARNUT).

Annex A: RP24 - *Saccharomyces cerevisiae* (MUCL 39885) (renewal)

Annex B: RP25 - *Saccharomyces cerevisiae* (MUCL 39885) (new use)

Annex C: RP26 - *Saccharomyces cerevisiae* (MUCL 39885) (new use)

Annex D: RP29 - *Pediococcus acidilactici* (CNCM I-4622) (new)

Annex E:RP140 - Monensin sodium (Coxidin®) (renewal and modification)

Annex F: RP141 - Monensin sodium (Coxidin®) (renewal and modification)

Annex G: RP142 - Monensin sodium (Coxidin®) (new use)

Annex H: RP185 - 6-phytase (EC 3.1.3.26) (renewal, new use and modification)

Annex I: RP222 - Selenised yeast *Saccharomyces cerevisiae* (CNCM I-3060), inactivated (modification)

Annex J: RP284 - Monensin sodium (Coxidin®) (new use)

Annex K: RP641 - *Bacillus velezensis* (formerly *Bacillus subtilis*) (DSM 15544) (renewal, new use and modification)

Annex L: RP1105 - L-histidine monohydrochloride monohydrate (new)

Annex M: RP1125 - L-tryptophan (new)

Annex N: RP1126 - L-lysine sulphate (new)

Annex O: RP1198 - Butylated hydroxyanisole (BHA) (new)

Annex P: RP1199 - Part A – L-lysine base (liquid) (new)

Annex Q: RP1199 - Part B – L-lysine monohydrochloride (new)

Annex R: RP1200 - Disodium 5'-guanylate (new)

Annex S: RP1259 - Muramidase (EC 3.2.1.17) (new use)

Annex T: RP1349 - Phytomenadione (Vitamin K_1) (new)

Annex U: RP1386 - Copper chelate of hydroxy analogue of methionine (renewal and modification)

Annex V: RP1387 - Manganese chelate of hydroxy analogue of methionine (renewal and modification)

Annex W: RP1388 - Zinc chelate of hydroxy analogue of methionine (renewal and modification)

Annex X: RP1591 - Fumonisin esterase (EC 3.1.1.87) (new use)

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 RP658 - A modification of entry number 60 of the PARNUT regulation, 'Reduction of the risk of milk fever and subclinical hypocalcaemia'

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

Safety assessment conclusion

The FSA/FSS 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.

The FSA/FSS safety assessment was published on 29 September 2023 and can be found here: Safety Assessment RP24-25-26 *Saccharomyces Cerevisiae* MUCL39885 - 4B1710 | Food Standards Agency

The assessment of Saccharomyces cerevisiae (MUCL 39885) shows that the conditions for authorisation in Article 5 of assimilated Regulation (EC) 1831/2003 are satisfied.

The FSA/FSS 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 purposes (other than sows) at the proposed dose of 6.4 x 10^9 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 10^9 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 assimilated Regulation (EC) 1831/2003 ('the Regulation') for feed additives:

1. Article 6: Categories of feed additives.
2. Article 14: Renewal of authorisation
3. Article 16 and Annex III: Labelling and packaging requirements apply, if authorised.
4. Article 21: Analytical methods have been verified by the European 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). Valid analytical methods exist for:
   - Enumeration of the active agent *S. cerevisiae* (MUCL 39885)
   - Identification of the bacterial strain *S. cerevisiae* (MUCL 39885)
5. Annex IV: The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

FSA/FSS Risk management recommendation

The FSA/FSS risk 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 FSA/FSS conclusion is that we are in favour of authorising the feed additive as per article 8 of assimilated Regulation (EC) 1831/2003. The proposed terms of authorisation are set out below.

Combined proposed terms of authorisation RP24, RP25 and RP26

Combined proposed terms of authorisation	RP24, RP25, RP26
Additive	*Saccharomyces Cerevisiae* (MUCL 39885)
Identification number	4b1710
Authorisation holder	Prosol S.p.A
Additive category	Zootechnical additives
Functional group	Gut flora stabilisers
Additive composition	Preparation of *Saccharomyces cerevisiae* (MUCL 39885) containing a minimum of 1 x 10^9 Colony Forming Units (CFU)/g
Characterisation of the active substance(s)	Viable cells of *Saccharomyces cerevisiae* (MUCL 39885)
Analytical method[1]	For enumeration: Pour plate method CGYE (chloramphenicol, glucose, yeast extract) agar in accordance with BS EN 15789:2021[2] For identification of the yeast strain: Polymerase chain reaction (PCR) method in accordance with DD CEN/TS15790:2008[3]
Species or category of animal	All suidae other than sows Cats Dogs
Maximum age	Not applicable

[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: European Commission Joint Research Centre.

[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 30 November 2021 (ISBN 978 0 580 99832 4).

[3] DD CEN/TS:15790:2008 "Animal Feeding Stuffs – PCR typing of probiotic strains of Saccharomyces cerevisiae (yeast)". Published by the British Standards Institution on 31 January 2009 (ISBN 978 0 580 61806 2).

Combined proposed terms of authorisation	RP24, RP25, RP26
Minimum content of Colony forming units (CFU) of additive/kg complete feed with a moisture content of 12%	For all Suidae (other than suckling pigs, sows and Suidae for reproduction) 3×10^9 CFU/kg For all Suidae for reproduction purposes other than sows: 6.4×10^9 CFU/kg For cats and dogs: 7×10^{10} CFU/kg
Maximum content of Colony forming units (CFU) of additive/kg complete feed with a moisture content of 12%	No maximum
Other provisions	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. The safety assessment identified that particular consideration should be given to hazards as a:
  - skin and eye irritant
  - skin and respiratory sensitiser.
- Main animal species and their subgroups are defined in Annex IV of assimilated Regulation (EC) 429/2008.
- The FSA/FSS consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in assimilated Regulation (EC) 183/2005 laying down requirements for feed hygiene and good manufacturing practice.

Other legitimate factors

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

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

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)

Safety assessment conclusion

The FSA/FSS has undertaken a safety assessment of application RP25 for the new 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.

The FSA/FSS safety assessment was published on 29 September 2023 and can be found here: Safety Assessment RP24-25-26 *Saccharomyces Cerevisiae* MUCL39885 - 4B1710 | Food Standards Agency

The assessment of *Saccharomyces cerevisiae* (MUCL 39885) shows that the conditions for authorisation in article 5 assimilated Regulation (EC) 1831/2003 are satisfied.

The FSA/FSS 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 6.4 x 10^9 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 10^9 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 assimilated Regulation (EC) 1831/2003 ('the Regulation') for feed additives:

1. Article 4 and 7: Authorisation for a new or new use of a feed additive.
2. Article 6: Categories of feed additives.
3. Article 16 and Annex III: Labelling and packaging requirements apply, if authorised.
4. Article 21: Analytical methods have been verified by the European 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). Valid analytical methods exist for:

- Enumeration of the active agent *Saccharomyces cerevisiae* (MUCL 39885)
- Identification of the bacterial strain *Saccharomyces cerevisiae* (MUCL 39885)

5. Annex IV: The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

FSA/FSS Risk management recommendation

The FSA/FSS 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 FSA/FSS conclusion is that we are in favour of authorising the feed additive as per article 8 of assimilated Regulation (EC) 1831/2003. The proposed terms of authorisation are set out below.

Combined proposed terms of authorisation RP24, RP25 and RP26

Combined proposed terms of authorisation	RP24, RP25, RP26
Additive	*Saccharomyces Cerevisiae* (MUCL 39885)
Identification number	4b1710
Authorisation holder	Prosol S.p.A
Additive category	Zootechnical additives
Functional group	Gut flora stabilisers
Additive composition	Preparation of *Saccharomyces cerevisiae* (MUCL 39885) containing a minimum of 1 x 10^9 Colony Forming Units (CFU)/g
Characterisation of the active substance(s)	Viable cells of *Saccharomyces cerevisiae* (MUCL 39885)
Analytical method[4]	For enumeration: Pour plate method CGYE (chloramphenicol, glucose, yeast extract) agar in accordance with BS EN 15789:2021[5] For identification of the yeast strain: Polymerase chain reaction (PCR) method in accordance with DD CEN/TS15790:2008[6]
Species or category of animal	All Suidae other than sows Cats Dogs
Maximum age	Not applicable

[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: European Commission Joint Research Centre.

[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 30 November 2021 (ISBN 978 0 580 99832 4).

[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 31 January 2009 (ISBN 978 0 580 61806 2).

Combined proposed terms of authorisation	RP24, RP25, RP26
Minimum content of Colony forming units (CFU) of additive/kg complete feed with a moisture content of 12%)	For all Suidae (other than suckling pigs, sows and Suidae for reproduction) 3×10^9 CFU/kg For all Suidae for reproduction purposes other than sows: 6.4×10^9 CFU/kg For cats and dogs: 7×10^{10} CFU/kg
Maximum content of Colony forming units (CFU) of additive/kg complete feed with a moisture content of 12%)	No maximum
Other provisions	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. The safety assessment identified that particular consideration should be given to hazards as a:
    - skin and eye irritant
    - skin and respiratory sensitiser.
- Main animal species and their subgroups are defined in Annex IV of assimilated Regulation (EC) 429/2008.
- The FSA/FSS consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in assimilated Regulation (EC) 183/2005 laying down requirements for feed hygiene and good manufacturing practice.

Other legitimate factors

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

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

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

Safety assessment conclusion

The FSA/FSS has undertaken a safety assessment of application RP26 for the use of *Saccharomyces cerevisiae* (MUCL 39885) as a feed additive for cats and dogs.

The assessment of *Saccharomyces cerevisiae* (MUCL 39885) shows that the conditions for authorisation in article 5 in of assimilated Regulation (EC) 1831/2003 are satisfied.

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

- *S. 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.
- *S. cerevisiae* (MUCL 39885) is efficacious in improving faecal consistency of cats and dogs at the proposed dose of $7x10^{10}$ CFU/kg of complete 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.
- *S. 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 assimilated Regulation (EC) 1831/2003 ('the Regulation') for feed additives:

1. Article 4 and 7: Authorisation for a new or new use of a feed additive
2. Article 6: Categories of feed additives.

3. Article 16 and Annex III: Labelling and packaging requirements apply, if authorised.
4. Article 21: Analytical methods have been verified by the European 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). Valid analytical methods exist for:

- Enumeration of the active agent *S. cerevisiae* (MUCL 39885)
- Identification of the bacterial strain *S. cerevisiae* (MUCL 39885)

5. Annex IV: The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

FSA/FSS Risk management recommendation

The FSA/FSS 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 FSA/FSS conclusion is that we are in favour of authorising the feed additive as per article 8 of assimilated Regulation (EC) 1831/2003. The proposed terms of authorisation are set out below. The proposed terms of authorisation are set out below.

Combined proposed terms of authorisation RP24, RP25 and RP26

Combined proposed terms of authorisation	RP24, RP25, RP26
Additive	*Saccharomyces Cerevisiae* (MUCL 39885)
Identification number	4b1710
Authorisation holder	Prosol S.p.A
Additive category	Zootechnical additives
Functional group	Gut flora stabilisers
Additive composition	Preparation of *Saccharomyces cerevisiae* (MUCL 39885) containing a minimum of 1 x 10^9 Colony Forming Units (CFU)/g
Characterisation of the active substance(s)	Viable cells of *Saccharomyces cerevisiae* (MUCL 39885)
Analytical method[7]	For enumeration: Pour plate method CGYE (chloramphenicol, glucose, yeast extract) agar in accordance with BS EN 15789:2021[8] For identification of the yeast strain: Polymerase chain reaction (PCR) method in accordance with DD CEN/TS15790:2008[9]
Species or category of animal	All Suidae other than sows Cats Dogs
Maximum age	Not applicable

[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: European Commission Joint Research Centre.

[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).

[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 31 January 2009 (ISBN 978 0 580 61806 2).

Combined proposed terms of authorisation	RP24, RP25, RP26
Minimum content of Colony forming units (CFU) of additive/kg complete feed with a moisture content of 12%	For all Suidae (other than suckling pigs, sows and Suidae for reproduction) 3×10^9 CFU/kg For all Suidae for reproduction purposes other than sows: 6.4×10^9 CFU/kg For cats and dogs: 7×10^{10} CFU/kg
Maximum content of Colony forming units (CFU) of additive/kg complete feed with a moisture content of 12%	No Maximum
Other provisions	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. The safety assessment identified that particular consideration should be given to hazards as a:
    - skin and eye irritant
    - skin and respiratory sensitiser
- Main animal species and their subgroups are defined in Annex IV of assimilated Regulation (EC) 429/2008.
- The FSA/FSS consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in assimilated Regulation (EC) 183/2005 laying down requirements for feed hygiene and good manufacturing practice.

Other legitimate factors

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

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

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

Safety assessment conclusion

The FSA/FSS 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.

The FSA/FSS safety assessment was published on 29 September 2023 and can be found here: Safety Assessment RP29 Pediococcus Acidilactici CNCM I-4622 | Food Standards Agency

The assessment of *Pediococcus acidilactici* (CNCM I-4622) shows that the conditions for authorisation in article 5 of Regulation (EC) 1831/2003 are satisfied.

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

- *P. 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.
- *P. acidilactici* (CNCM I-4622) is efficacious at the proposed dose of $1x10^9$ 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 assimilated Regulation (EC) 1831/2003 ('the Regulation') for feed additives:

1. Article 4 and 7: Authorisation for a new or new use of a feed additive

2. Article 6: Categories of feed additives.
3. Article 16 and Annex III: Labelling and packaging requirements apply, if authorised.
4. Article 21: Analytical methods have been verified by the European 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). Valid analytical methods exist for:

    - Enumeration of the active agent *P. acidilactici* (CNCM I-4622) in the feed additive, premixtures, feed and water.
    - Identification of *P. acidilactici* (CNCM I-4622).

FSA/FSS Risk management recommendation

The FSA/FSS 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 FSA/FSS conclusion is that we are in favour of authorising the feed additive as per article 8 of assimilated Regulation (EC) 1831/2003. The proposed terms of authorisation are set out below.

Proposed terms of authorisation RP29

Proposed terms of authorisation	RP29
Additive	*Pediococcus acidilactici* (CNCM I-4622)
Identification number	4d1712
Authorisation holder[10]	None
Additive category	Technological
Functional group	Acidity regulator and hygiene condition enhancer
Additive composition	Solid preparation of *Pediococcus acidilactici* (CNCM I-4622) containing a minimum of 1×10^{10} Colony Forming Units (CFU)/g
Characterisation of the active substance(s)	Viable cells of *Pediococcus acidilactici* (CNCM I-4622).
Analytical method[11]	For enumeration (colony count) of the feed additive: Spread plate method using MRS agar in accordance with BS EN 15786:2009[12] For identification of the bacterial strain: Pulsed-field gel electrophoresis (PFGE)
Species or category of animal	All animal species
Maximum age	Not applicable
Minimum content of Colony-forming units (CFU) of additive/kg of complete feed with a moisture content of 12%	$1x10^9$ CFU/kg

[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.

[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: European Commission Joint Research Centre.

[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 30 November 2021 (ISBN 978 0 539 24219 5).

Proposed terms of authorisation	RP29
Maximum content of Colony-forming units (CFU) of additive/kg of complete feed with a moisture content of 12%	No maximum
Other provisions	The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture. To be used only in mash compound feed intended for preparation of liquid feed on farm, or solid feed materials intended for preparation of liquid feed on farm. If *Pediococcus acidilactici* (CNCM I-4622) is to be used in feed containing coccidiostats, this feed additive is only 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.
- The safety assessment identified that particular consideration should be given to hazards as a: Respiratory sensitiser.
- Main animal species and their subgroups are defined in Annex IV of assimilated Regulation (EC) 429/2008.
- The FSA/FSS consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in assimilated Regulation (EC) 183/2005 laying down requirements for feed hygiene and good manufacturing practice.

Other legitimate factors

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

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

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

Safety assessment conclusion

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

The FSA/FSS safety assessment was published on 29 September 2023 and can be found here: Safety Assessment RP140-141-142-284 Monensin Sodium | Food Standards Agency.

The assessment of monensin sodium (Coxidin®) (carrier: perlite, calcium carbonate) shows that the conditions for authorisation in article 5 of assimilated of Regulation (EC) 1831/2003 are satisfied.

The FSA/FSS 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 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[13].

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 assimilated Regulation (EC) 1831/2003 ('the Regulation') for feed additives:

1. Article 6: Categories of feed additives.
2. Article 13: Modification of authorisation
3. Article 14: for renewals of authorisations, the applicant must send a report on the results of post-market monitoring.
4. Article 16 and point (a) of Annex III: Labelling and packaging requirements apply, if authorised.
5. Annex IV: The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.
6. Article 21: Analytical methods have been verified by the European 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). 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.

FSA/FSS Risk management recommendation

The FSA/FSS risk management recommendation 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

[13] "appropriate authority" refers to: the Secretary of State in relation to England; the Welsh Ministers in relation to Wales; the Scottish Ministers in relation to Scotland.

conditions of use. The FSA/FSS conclusion is that we are in favour of authorising the feed additive as per article 8 of assimilated Regulation (EC) 1831/2003. The proposed terms of authorisation are set out below.

Combined proposed terms of authorisation RP140 and RP284

Combined proposed terms of authorisation	RP140 and RP284
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

Combined proposed terms of authorisation	RP140 and RP284
Characterisation of the active substance(s)	Monensin sodium technical substance produced by fermentation with *Streptomyces cinnamonensis* (NBIMCC 3419). Monensin sodium A ($C_{36}H_{61}NaO_{11}$) Monensin sodium B ($C_{35}H_{59}NaO_{11}$) Monensin sodium C ($C_{37}H_{63}NaO_{11}$) CAS No.: 22373-78-0[14]
Analytical method[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[16] For the quantification of monensin sodium in chicken and turkey tissues: Reversed phase

[14] This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service.

[15] 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: European Commission Joint Research Centre

[16] BS EN ISO 14183:2008 "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 January 2006 (ISBN 978 0 580 62955 6).

Combined proposed terms of authorisation	RP140 and RP284
	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
Minimum content of monensin (mg/kg of complete feed with a moisture content of 12%)	Chickens for fattening and reared for laying: 100 mg/kg Turkeys for fattening and reared for breeding: 60 mg/kg
Maximum content of monensin (mg/kg of complete feed with a moisture content of 12%)	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

Combined proposed terms of authorisation	RP140 and RP284
Other provisions	The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture. The additive shall be incorporated in compound feed in the form of a premixture. Monensin sodium shall not be mixed with other coccidiostats. 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." 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[17] before 10 years after authorisation.

[17] "appropriate authority" refers to:

- the Secretary of State in relation to England
- the Welsh Ministers in relation to Wales
- the Scottish Ministers in relation to Scotland

Supplementary information

- Feed additives are subject to UK health and safety legislation. The safety assessment identified that particular consideration should be given to hazards as a:
    - eye irritant
    - highly toxic by inhalation.
- Main animal species and their subgroups are defined in Annex IV of assimilated Regulation (EC) 429/2008.
- The FSA/FSS 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 assimilated Regulation (EC)183/2005 laying down requirements for feed hygiene and good manufacturing practice.

Other legitimate factors

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

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

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)

Safety assessment conclusion

The FSA/FSS 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 for fattening and turkeys.

The FSA/FSS safety assessment was published on 29 September 2023 and can be found here: Safety Assessment RP140-141-142-284 Monensin Sodium | Food Standards Agency

The assessment of monensin sodium (Coxidin®) (carrier: perlite, wheat bran) shows that the conditions for authorisation in article 5 of assimilated Regulation (EC) 1831/2003 are satisfied.

The FSA/FSS 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[18]

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 assimilated Regulation (EC) 1831/2003 ('the Regulation') for feed additives:

1. Article 6: Categories of feed additives.
2. Article 13: Modification of authorisation
3. Article 14: for renewals of authorisations, the applicant must send a report on the results of post-market monitoring.
4. Article 16 and Annex III: Labelling and packaging requirements apply, if authorised.
5. Article 21: Analytical methods have been verified by the European 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). 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.
6. Annex IV: The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

FSA/FSS Risk management recommendation

The FSA/FSS risk management recommendation is that monensin sodium (Coxidin®), as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use. The FSA/FSS conclusion is that we are in favour of authorising the feed additive

[18] "appropriate authority" refers to: the Secretary of State in relation to England; the Welsh Ministers in relation to Wales; the Scottish Ministers in relation to Scotland.

as per article 8 of assimilated Regulation (EC) 1831/2003. The proposed terms of authorisation are set out below:

Combined proposed terms of authorisation RP141 and RP142

Combined proposed terms of authorisation	RP141 and RP142
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 ($C_{36}H_{61}NaO_{11}$) Monensin sodium B ($C_{35}H_{59}NaO_{11}$) Monensin sodium C ($C_{37}H_{63}NaO_{11}$) CAS No.: 22373-78-0[19]

[19] This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service.

Combined proposed terms of authorisation	RP141 and RP142
Analytical method[20]	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[21] 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

[20] 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: European Commission Joint Research Centre.

[21] BS EN ISO 14183:2008 "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 January 2006 (ISBN 978 0 580 62955 6).

Combined proposed terms of authorisation	RP141 and RP142
Minimum content of monensin (mg/kg of complete feed with a moisture content of 12%)	Chickens for fattening and reared for laying: 100 mg/kg Turkeys for fattening and reared for breeding: 60 mg/kg
Maximum content of monensin (mg/kg of complete feed with a moisture content of 12%)	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	The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture. The additive shall be incorporated in compound feed in the form of a premixture. Monensin sodium shall not be mixed with other coccidiostats. 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.” 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

Combined proposed terms of authorisation	RP141 and RP142
	submitted to the appropriate authority[22] before 10 years after authorisation

Supplementary information

- Feed additives are subject to UK health and safety legislation. The safety assessment identified that particular consideration should be given to hazards as a:
    - eye irritant
    - highly toxic by inhalation.
- Main animal species and their subgroups are defined in Annex IV of assimilated Regulation (EC) 429/2008.
- The FSA/FSS consider 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[22]
- In addition to requirements established in assimilated Regulation (EC)183/2005 laying down requirements for feed hygiene and good manufacturing practice.

Other legitimate factors

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

The FSA/FSS have not identified any applicable other legitimate factors to date that would prevent authorisation or affect the conditions of authorisation of this animal

[22] "appropriate authority" refers to: the Secretary of State in relation to England, the Welsh Ministers in relation to Wales, the Scottish Ministers in relation to Scotland.

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

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)

Safety assessment conclusion

The FSA/FSS 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.

The FSA/FSS safety assessment was published on 29 September 2023 and can be found here: Safety Assessment RP140-141-142-284 Monensin Sodium | Food Standards Agency

The assessment of monensin sodium (Coxidin®) shows that the conditions for authorisation in article 5 of assimilated Regulation (EC)1831/2003 are satisfied.

The 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[23]

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 assimilated Regulation (EC) 1831/2003 ('the Regulation') for feed additives:

1. Article 4: Authorisation for a new or new use of a feed additive
2. Article 6: Categories of feed additives.
3. Article 7: at the time of application, the applicant must provide a proposal for post-market monitoring (as referred to in paragraph 5.5 of Annex III to assimilated Regulation (EC) 429/2008, on 'coccidiostats and histomonostats')
4. Article 16 and Annex III: Labelling and packaging requirements apply, if authorised.
5. Article 21: Analytical methods have been verified by the European 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). 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.
6. Annex IV: The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

FSA/FSS Risk management recommendation

The FSA/FSS risk management recommendation 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

[23] "appropriate authority" refers to: the Secretary of State in relation to England; the Welsh Ministers in relation to Wales; the Scottish Ministers in relation to Scotland.

of use. The FSA/FSS conclusion is that we are in favour of authorising the feed additive as per article 8 of assimilated Regulation (EC) 1831/2003. The proposed terms of authorisation are set out below.

Combined proposed terms of authorisation RP141 and RP142

Combined proposed terms of authorisation	RP141 and RP142
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 ($C_{36}H_{61}NaO_{11}$) Monensin sodium B ($C_{35}H_{59}NaO_{11}$) Monensin sodium C ($C_{37}H_{63}NaO_{11}$) CAS No.: 22373-78-0[24]

[24] This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service.

Combined proposed terms of authorisation	RP141 and RP142
Analytical method[25]	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[26] 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

[25] 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: European Commission Joint Research Centre.

[26] BS EN ISO 14183:2008 "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 January 2006 (ISBN 978 0 580 62955 6).

Combined proposed terms of authorisation	RP141 and RP142
Minimum content of monensin(mg/kg of complete feed with a moisture content of 12%)	Chickens for fattening and reared for laying: 100 mg/kg Turkeys for fattening and reared for breeding: 60 mg/kg
Maximum content of monensin (mg/kg of complete feed with a moisture content of 12%) Minimum 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	The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture. The additive shall be incorporated in compound feed in the form of a premixture. Monensin sodium shall not be mixed with other coccidiostats. 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." 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[27] before 10 years after authorisation.

[27] "appropriate authority" refers to: the Secretary of State in relation to England; the Welsh Ministers in relation to Wales; the Scottish Ministers in relation to Scotland.

Supplementary information

- Feed additives are subject to UK health and safety legislation. The safety assessment identified that particular consideration should be given to hazards as a:
    - eye irritant
    - highly toxic by inhalation.
- Main animal species and their subgroups are defined in Annex IV of assimilated Regulation (EC) 429/2008.
- The FSA/FSS 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 assimilated Regulation (EC)183/2005 laying down requirements for feed hygiene and good manufacturing practice.

Other legitimate factors

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

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

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)

Safety assessment conclusion

The FSA/FSS 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.

The FSA/FSS safety assessment was published on 29 September 2023 and can be found here: Safety Assessment RP185 6-Phytase from Komagataella Phaffii DSM 23036 | Food Standards Agency.

The assessment of 6-phytase (EC 3.1.3.26) produced by fermentation with *Komagataella phaffii* shows that the conditions for authorisation in article 5 in assimilated Regulation (EC) 1831/2003 are satisfied.

The FSA/FSS conclusion 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 assimilated Regulation (EC) 1831/2003 ('the Regulation') for feed additives:

1. Article 4 and Article 7: Authorisation for a new or new use of a feed additive.
2. Article 6: Categories of feed additives.
3. Article 13: Modification of authorisation.
4. Article 14: Renewal of authorisation.
5. Article 16 and Annex III: Labelling and packaging requirements apply, if authorised.
6. Article 21: Analytical methods have been verified by the European 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). Valid analytical methods exist for:
    - quantification of phytase activity in the feed additive, premixtures, and compound feed.
7. Annex IV: The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

FSA/FSS Risk management recommendation

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

Proposed terms of authorisation RP185

Proposed terms of authorisation	RP185
Additive	6-phytase (EC 3.1.3.26)
Identification number	4a16
Authorisation holder	Huvepharma NV

Proposed terms of authorisation	RP185
Additive category	Zootechnical additives
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[28].
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[29] EC (IUBMB) no.: 3.1.3.26[30]
Analytical method[31]	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

[28] 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.

[29] This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service.

[30] This is the identification number allocated by the International Union of Biochemistry and Molecular Biology (IUBMB).

[31] 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: European Commission Joint Research Centre.

Proposed terms of authorisation	RP185
Minimum content of 6-phytase (EC 3.1.3.26) (units of activity (OTU)/kg of complete feed with a moisture content of 12%)	All avian species other than turkeys and all porcine species other than piglets: 125 OTU/kg Turkeys and piglets: 250 OTU/kg
Maximum content of 6-phytase (EC 3.1.3.26) (units of activity (OTU)/kg of complete feed with a moisture content of 12%)	No maximum level
Other provisions	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. The safety assessment identified that particular consideration should be given to hazards as a:

- Respiratory sensitizer.
- Main animal species and their subgroups are defined in Annex IV of assimilated Regulation (EC) 429/2008.
- The FSA/FSS consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in assimilated Regulation 183/2005 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, the FSA/FSS have had regard to other legitimate factors (including Consumer Interests, Political, Environmental,

Societal and Technical Feasibility) that ministers will consider as part of their decision on authorisation.

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

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)

Safety assessment conclusion

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

The FSA/FSS safety assessment was published on 29 September 2023 and can be found here: Safety Assessment RP222 Selenised Yeast *Saccharomyces Cerevisiae* CNCM I-3060 Inactivated | Food Standards Agency.

The assessment of selenised yeast *Saccharomyces cerevisiae* (CNCM I-3060), inactivated shows that the conditions for authorisation in article 5 of assimilated Regulation (EC) 1831/2003 are satisfied.

The FSA/FSS conclusion on selenised yeast *Saccharomyces cerevisiae* (CNCM I-3060), inactivated is 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 assimilated Regulation (EC) 1831/2003 ('the Regulation') for feed additives:

1. Article 6: Categories of feed additives.
2. Article 13: Modification of authorisation.
3. Article 16 and Annex III: Labelling and packaging requirements apply, if authorised.
4. Article 21: Analytical methods have been verified by the European 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. 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.
5. Annex IV: The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

FSA/FSS Risk management recommendation

The FSA/FSS risk management recommendation is that selenised yeast *Saccharomyces cerevisiae* (CNCM I-3060), inactivated as described in this application, is safe and is not liable to have an adverse effect on all animal species, environmental safety and human health under the proposed conditions of use. The FSA/FSS conclusion is that we are in favour of authorising the feed additive as per article 8 of assimilated Regulation (EC) 1831/2003. The proposed terms of authorisation are set out below.

Proposed terms of authorisation RP222

Proposed terms of authorisation	RP222
Additive	Selenised yeast *Saccharomyces cerevisiae* (CNCM I-3060), inactivated
Identification number	3b810
Authorisation holder[32]	None
Additive category	Nutritional additives
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)	Selenomethionine produced by *Saccharomyces cerevisiae* (CNCM I-3060) ($C_5H_{11}NO_2Se$)
Analytical method[33]	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:

[32] 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.

[33] 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 6 June 2016 are available at: European Commission Joint Research Centre.

Proposed terms of authorisation	RP222
	Inductively coupled plasma mass spectrometry (ICPMS) Inductively coupled plasma atomic emission spectrometry For determination of total selenium in premixtures, compound feed and feed materials: Hydride generation atomic absorption spectrometry (HGAAS) after microwave digestion in accordance with BS EN 16159:2012[34]
Species or category of animal	All animal species
Maximum age	Not applicable
Minimum content of selenium (mg/kg of complete feed with a moisture content of 12%)	No minimum
Maximum content of selenium (mg/kg of complete feed with a moisture content of 12%)	Total selenium: 0.5 mg Se/kg
Other provisions	The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture. The additive shall be incorporated into feed in the form of a premixture.

[34] 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 29 February 2012 (ISBN 978 0 580 66997 2).

Proposed terms of authorisation	RP222
	The dusting potential of the additive shall ensure a maximum selenium exposure of 0.2 mg Se/m3. 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. The safety assessment identified that particular consideration should be given to hazards as a:
    - respiratory sensitiser
    - risk by inhalation.
- Main animal species and their subgroups are defined in Annex IV of assimilated Regulation (EC) 429/2008.
- The FSA/FSS consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in assimilated Regulation (EC)183/2005 laying down requirements for feed hygiene and good manufacturing practice.

Other legitimate factors

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

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

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

Safety assessment conclusion

The FSA/FSS has undertaken a safety assessment of application RP284 for the new use (extension of species) of monensin sodium produced from *Streptomyces cinnamonensis* 28682 (NBIMCC 3419) (Coxidin®) (carrier: perlite, calcium carbonate) as a coccidiostat and histomonostat feed additive for turkeys reared for breeding.

The FSA/FSS safety assessment was published on 29 September 2023 and can be found here: Safety Assessment RP140-141-142-284 Monensin Sodium | Food Standards Agency.

The assessment of monensin sodium (Coxidin®) (carrier: perlite, calcium carbonate) shows that the conditions for authorisation in article 5 in assimilated Regulation (EC) 1831/2003 are satisfied.

The FSA/FSS 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 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[35]

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 assimilated Regulation (EC) 1831/2003 ('the Regulation') for feed additives:

1. Article 4: Authorisation for a new or new use of a feed additive.
2. Article 6: Categories of feed additives.
3. Article 7: at the time of application, the applicant must provide a proposal for post-market monitoring (as referred to in paragraph 5.5 of Annex III to assimilated Regulation (EC) 429/2008, on 'coccidiostats and histomonostats')
4. Article 16 and Annex III: Labelling and packaging requirements apply, if authorised.
5. Article 21: Analytical methods have been verified by the European 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). 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.
6. Annex IV: The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

FSA/FSS Risk management recommendation

The FSA/FSS risk management recommendation is that monensin sodium (Coxidin®), as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use. The FSA/FSS conclusion is that we are in favour of authorising the feed additive

[35] "appropriate authority" refers to: the Secretary of State in relation to England; the Welsh Ministers in relation to Wales; the Scottish Ministers in relation to Scotland.

as per article 8 of assimilated Regulation (EC) 1831/2003. The proposed terms of authorisation are set out below.

Combined proposed terms of authorisation RP140 and RP284

Combined terms of authorisation	RP140 and RP284
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 ($C_{36}H_{61}NaO_{11}$) Monensin sodium B ($C_{35}H_{59}NaO_{11}$) Monensin sodium C ($C_{37}H_{63}NaO_{11}$) CAS No.: 22373-78-0[36]

[36] This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service.

Combined terms of authorisation	RP140 and RP284
Analytical method[37]	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[38] 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
Minimum content of monensin (mg/kg of complete feed with a moisture content of 12%)	Chickens for fattening and reared for laying: 100 mg/kg

[37] 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: European Commission Joint Research Centre

[38] BS EN ISO 14183:2008"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 January 2006 (ISBN 978 0 580 62955 6).

Combined terms of authorisation	RP140 and RP284
	Turkeys for fattening and reared for breeding: 60 mg/kg
Maximum content of monensin (mg/kg of complete feed with a moisture content of 12%)	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	The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture. The additive shall be incorporated in compound feed in the form of a premixture. Monensin sodium shall not be mixed with other coccidiostats. 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." 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[39] before 10 years after authorisation

[39] "appropriate authority" refers to: the Secretary of State in relation to England; the Welsh Ministers in relation to Wales; the Scottish Ministers in relation to Scotland.

Supplementary information

- Feed additives are subject to UK health and safety legislation. The safety assessment identified that particular consideration should be given to hazards as an:
    - eye irritant
    - highly toxic by inhalation.
- Main animal species and their subgroups are defined in Annex IV of assimilated Regulation (EC) 429/2008.
- The FSA/FSS 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 assimilated Regulation (EC)183/2005 laying down requirements for feed hygiene and good manufacturing practice.

Other legitimate factors

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

The FSA/FSS 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, FSA/FSS have assessed the potential impacts that would result from the authorisation of this animal feed additive, should ministers decide to authorise. No significant impacts were identified. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The

authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

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

Safety assessment conclusion

The FSA/FSS 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* C-3102) (DSM 15544) as a feed additive for weaned piglets and all avian species.

The FSA/FSS safety assessment was published on 29 September 2023 and can be found here: Safety Assessment RP641 Bacillus Velezensis DSM 15544 | Food Standards Agency.

The assessment of *Bacillus velezensis (formerly B. subtilis* C-3102) (DSM 15544) shows that the conditions for authorisation in article 5 of assimilated Regulation (EC) 1831/2003 are satisfied.

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

- *B. 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 assimilated Regulation (EC) 1831/2003 ('the Regulation') for feed additives:

1. Article 4 and Article 7: Authorisation for a new or new use of a feed additive.
2. Article 6: Categories of feed additives.
3. Article 13: Modification of authorisation

4. Article 14: Renewal of authorisation
5. Article 16 and Annex III: Labelling and packaging requirements apply, if authorised.
6. Article 21: Analytical methods have been verified by the European 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. Valid analytical methods exist for:
    - Enumeration of *B. velezensis* (DSM 15544) in the feed additive, premixtures and compound feed.
    - Identification of the bacterial strain, *B. velezensis* (DSM 15544).
7. Annex IV: The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

FSA/FSS Risk management recommendation

The FSA/FSS risk management recommendation is that *B. velezensis* (DSM 15544), as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use. The FSA/FSS conclusion is that we are in favour of authorising the feed additive as per article 8 of assimilated Regulation (EC) 1831/2003. 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 RP641

Proposed terms of authorisation	RP641
Additive	*Bacillus velezensis* (DSM 15544)
Identification number	4b1820
Authorisation holder	Asahi Biocycle Co., Ltd
Additive category	Zootechnical additives
Functional group	Gut flora stabilisers
Additive composition	Solid preparation of *Bacillus velezensis* (DSM 15544) containing a minimum of 1 x 10^{10} Colony Forming Units (CFU)/g.
Characterisation of the active substance(s)	Viable spores of *Bacillus velezensis* (DSM 15544).
Analytical method[40]	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[41]

[40] 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: European Commission Joint Research Centre.

[41] 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 30 November 2021 (ISBN 978 0 539 24209 6).

Proposed terms of authorisation	RP641
	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
Minimum content of colony-forming units (CFU)/kg of complete feed with a moisture content of 12%	$3x10^8$ CFU/kg
Maximum content of colony-forming units (CFU)/kg of complete feed with a moisture content of 12%	No maximum level
Other provisions	The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture. 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. The safety assessment identified that particular consideration should be given to hazards as a:
    - respiratory sensitiser and irritant.
- Main animal species and their subgroups are defined in Annex IV of assimilated Regulation (EC) 429/2008.

- The FSA/FSS consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in assimilated Regulation (EC) 183/2005 laying down requirements for feed hygiene and good manufacturing practice.

Other legitimate factors

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

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

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)

Safety assessment conclusion

The FSA/FSS 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.

The FSA/FSS safety assessment was published on 29 September 2023 and can be found here: Safety Assessment RP1105 L-Histidine | Food Standards Agency.

The assessment of L-histidine monohydrochloride monohydrate shows that the conditions for authorisation in Article 5 of assimilated Regulation (EC) 1831/2003 are satisfied.

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

- The additive is 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 deemed 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 covered by Health and Safety legislation.
- There is no basis to propose specific requirements for a post-market monitoring plan other than those established in assimilated Regulation (EC)183/2005 'Feed Hygiene Regulation' 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 assimilated Regulation (EC) 1831/2003 ('the Regulation') for feed additives:

1. Article 4 and Article 7: Authorisation for a new or new use of a feed additive.
2. Article 6: Categories of feed additives.
3. Article 16 and Annex III: Labelling and packaging requirements apply, if authorised.
4. Article 21: Analytical methods have been verified by the European 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 . 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.
5. Annex IV: The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

FSA/FSS Risk management recommendation

The FSA/FSS 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 FSA/FSS conclusion is that we are in favour of authorising the feed additive as per article 8 of assimilated Regulation (EC) 1831/2003. The proposed terms of authorisation are set out below.

Proposed terms of authorisation RP1105

Proposed terms of authorisation	RP1105
Additive	L-histidine monohydrochloride monohydrate
Identification number	3c352i
Authorisation holder[42]	None
Additive category	Nutritional additives
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

[42] 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.

Proposed terms of authorisation	RP1105
Characterisation of the active substance(s)	L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* K-12 (KCCM 80212) ($C_6H_{12}ClN_3O_3$) CAS no: 5934-29-2[43] EINECS no: 611-821-4[44]
Analytical method[45]	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[46] Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD)

[43] This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service

[44] 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.

[45] 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: the European Commission Joint Research Centre.

[46] 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.

Proposed terms of authorisation	RP1105
	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 laying down the methods of sampling and analysis for the official control of feed (Annex III. F) (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
Minimum content of L-histidine monohydrochloride monohydrate (mg/kg of complete feed with a moisture content of 12%)	No minimum
Maximum content of L-histidine monohydrochloride monohydrate (mg/kg of	No maximum

Proposed terms of authorisation	RP1105
complete feed with a moisture content of 12%)	
Other provisions	The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture. L-histidine monohydrochloride monohydrate may be placed on the market and used as an additive consisting of a preparation. 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 depend on the species, the physiological state of the animal, the performance level of the animal, the environmental conditions, the level of other amino acids in the diet and the level of essential trace elements such as copper and zinc”

Supplementary information

- Feed additives are subject to UK health and safety legislation. The safety assessment identified that particular consideration should be given to hazards as a:
    - skin sensitiser
    - powder where inhalation risks endotoxin exposure.

- Main animal species and their subgroups are defined in Annex IV of assimilated Regulation (EC) 429/2008.
- The FSA/FSS consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in assimilated Regulation (EC) 183/2005 laying down requirements for feed hygiene and good manufacturing practice.

Other legitimate factors

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

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

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

Safety assessment conclusion

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

The FSA/FSS safety assessment was published on 29 September 2023 and can be found here: Safety Assessment RP1125 L-Tryptophan | Food Standards Agency

The assessment of L-tryptophan produced by fermentation with *Escherichia coli* (KCCM 80210) shows that the conditions for authorisation in article 5 of assimilated Regulation (EC) 1831/2003 are satisfied.

The FSA/FSS 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.
- 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 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 assimilated Regulation (EC) 1831/2003 ('the Regulation') for feed additives:

1. Article 4 and Article 7: Authorisation for a new or new use of a feed additive.
2. Article 6: Categories of feed additives.
3. Article 16 and Annex III: Labelling and packaging requirements apply, if authorised.
4. Article 21: Analytical methods have been verified by the European 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. 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.
5. Annex IV: The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

FSA/FSS Risk management recommendation

The FSA/FSS 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 FSA/FSS conclusion is that we are in favour of authorising the feed additive as per article 8 of assimilated Regulation (EC) 1831/2003. The proposed terms of authorisation are set out below.

Proposed terms of authorisation RP1125

Proposed terms of authorisation	RP1125
Additive	L-tryptophan
Identification number	3c440i
Authorisation holder[47]	None
Additive category	Nutritional
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) ($C_{11}H_{12}N_2O_2$) CAS no: 73-22-3[48] EINECS no: 200-795-6[49]

[47] 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.

[48] This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service

[49] 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.

Proposed terms of authorisation	RP1125
Analytical method[50]	For the identification of L-tryptophan in the feed additive: Food Chemical Codex "L-tryptophan monograph"[51] 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 13904:2016[5] For the determination of tryptophan in feed materials and compound feed: High performance liquid chromatography with fluorescence detection (HPLC-FLD) in accordance with http:// /COMMISSION REGULATION (EC) No 152/2009 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

[50] 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: the European Commission Joint Research Centre

[51] Food Chemicals Codex (FCC), 13th edition (Method: FCC L-tryptophan monograph published). Published by the United States Pharmacopeial Convention on 1 March 2022 (ISSN 2153-1455) and available at the Food Chemicals Codex (FCC).

Proposed terms of authorisation	RP1125
Minimum content of L-tryptophan (mg/kg of complete feed with a moisture content of 12%)	No minimum
Maximum content of L-tryptophan (mg/kg of complete feed with a moisture content of 12%)	No maximum
Other provisions	L-tryptophan shall be rumen protected when administered to ruminants. 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. The safety assessment identified that particular consideration should be given to hazards as an:
    - eye irritant
    - powder where inhalation risks endotoxin exposure.
- Main animal species and their subgroups are defined in Annex IV of assimilated Regulation (EC) 429/2008.
- The FSA/FSS consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in assimilated Regulation (EC) 183/2005 laying down requirements for feed hygiene and good manufacturing practice.

Other legitimate factors

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

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

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)

Safety assessment conclusion

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

The FSA/FSS safety assessment was published on 29 September 2023 and can be found here: Safety Assessment RP1126 L-Lysine Sulfate | Food Standards Agency

The assessment of L-lysine sulphate produced by fermentation with *Corynebacterium glutamicum* (KCCM 80227) shows that the conditions for authorisation in Article 5 of assimilated Regulation (EC) 1831/2003 are satisfied.

The FSA/FSS 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 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 assimilated Regulation (EC) 1831/2003 ('the Regulation') for feed additives:

1. Article 4 and Article 7: Authorisation for a new or new use of a feed additive.

2. Article 6: Categories of feed additives.
3. Article 16 and Annex III: Labelling and packaging requirements apply, if authorised.
4. Article 21: Analytical methods have been verified by the European 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. 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.
5. Annex IV: The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

FSA/FSS Risk management recommendation

The FSA/FSS risk management recommendation is that L-lysine sulphate, as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health at the intended concentrations of use. The FSA/FSS conclusion is that we are in favour of authorising the feed additive as per article 8 of assimilated Regulation (EC) 1831/2003. The proposed terms of authorisation are set out below.

Proposed terms of authorisation RP1126

Proposed terms of authorisation	RP1126
Additive	L-lysine sulphate
Identification number	3c324i
Authorisation holder	None
Additive category	Nutritional
Functional group	Amino acids, their salts and analogues

Proposed terms of authorisation	RP1126
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) ($C_{12}H_{28}N_4O_4 \cdot H_2SO_4$) CAS Number: 60343-69-3[52]
Analytical method[53]	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 ISO 17180:2013[54] For the identification of sulphate in the feed additive: European Pharmacopoeia Monograph 20301[55]

[52] This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service.

[53] 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: European Commission Joint Research Centre

[54] 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 30 April 2013 (ISBN 978 0 580 76077 8).

[55] European Pharmacopoeia, Monograph (Identification reactions of ions and functional groups – sulphates). Published online by the European Directorate for the

Proposed terms of authorisation	RP1126
	For 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 COMMISSION REGULATION (EC) No 152/2009 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.
Species or category of animal	All animal species
Maximum age	Not applicable
Minimum content of L-lysine sulphate (mg/kg of complete feed with a moisture content of 12%)	No minimum
Maximum content of L-lysine sulphate (mg/kg of	10,000 mg/kg

Quality of Medicines and Healthcare on 1 January 2024 and available at: European Pharmacopoeia.

Proposed terms of authorisation	RP1126
complete feed with a moisture content of 12%)	
Other provisions	The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture. The L-lysine content must be stated on the labelling of the additive. Declaration to be made on the label of the additive and premixture: "The supplementation with L-lysine 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. The safety assessment identified no specified hazards.
- Main animal species and their subgroups are defined in Annex IV of assimilated Regulation (EC) 429/2008.
- The FSA/FSS consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in assimilated Regulation (EC) 183/2005 laying down requirements for feed hygiene and good manufacturing practice.

Other legitimate factors

In developing the risk management recommendations, the FSA/FSS have had regard to other legitimate factors (including Consumer Interests, Political, Environmental,

Societal and Technical Feasibility) that ministers will consider as part of their decision on authorisation.

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

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

Safety assessment conclusion

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

The FSA/FSS safety assessment was published on 29 September 2023 and can be found here: Safety Assessment RP1198 Butylated Hydroxyanisole | Food Standards Agency

The assessment of butylated hydroxyanisole (BHA) shows that the conditions for authorisation in article 5 of assimilated Regulation (EC) 1831/2003 are satisfied.

The FSA/FSS conclusion on butylated hydroxyanisole (BHA) is that:

- The additive is safe for cats, users, 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 assimilated Regulation (EC) 1831/2003 ('the Regulation') for feed additives:

1. Article 4 and Article 7: Authorisation for a new or new use of a feed additive.
2. Article 6: Categories of feed additives.
3. Article 16 and Annex III: Labelling and packaging requirements apply, if authorised.
4. Article 21: Analytical methods have been verified by the European 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. Valid analytical methods exist for:

- the quantification of butylated hydroxyanisole (BHA) in the feed additive
- the quantification of butylated hydroxyanisole (BHA) in premixtures and compound feed.

5. Annex IV: The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

FSA/FSS Risk management recommendation

The FSA/FSS risk management recommendation is that butylated hydroxyanisole (BHA), as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use. The FSA/FSS conclusion is that we are in favour of authorising the feed additive as per article 8 of assimilated Regulation (EC) 1831/2003. The proposed terms of authorisation are set out below.

Proposed terms of authorisation RP1198

Proposed terms of authorisation	RP1198
Additive	Butylated hydroxyanisole (BHA)
Identification number	1b320
Authorisation holder[56]	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 (BHA) containing a mixture of 2-tert-butyl-4-hydroxyanisole and a minimum of 85% 3-tert-butyl-4-hydroxyanisole ($C_{11}H_{16}O_2$)

[56] 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.

Proposed terms of authorisation	RP1198
	CAS no: 25013-16-5[57]
Analytical method[58]	For the quantification of butylated hydroxyanisole (BHA) in feed additives: Gas chromatography coupled to flame ionization detection (GC-FID) (FCC7 method)[59] For the quantification of butylated hydroxyanisole (BHA)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
Minimum content of Butylated hydroxyanisole (mg/kg of complete feed with a moisture content of 12%)	No minimum
Maximum content of Butylated hydroxyanisole (mg/kg of complete feed with a moisture content of 12%)	150 mg/kg

[57] 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.

[58] 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.

[59] 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.

Proposed terms of authorisation	RP1198
Other provisions	The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture. 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. The safety assessment identified that particular consideration should be given to hazards as a:
  - skin and eye irritant,
  - skin sensitiser.
- Main animal species and their subgroups are defined in Annex IV of assimilated Regulation (EC) 429/2008.
- The FSA/FSS consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in assimilated Regulation (EC) 183/2005 laying down requirements for feed hygiene and good manufacturing practice.

Other legitimate factors

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

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

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)

Safety assessment conclusion

The FSA/FSS 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.

The FSA/FSS safety assessment was published on 29 September 2023 and can be found here: Safety Assessment RP1199 L-Lysine | Food Standards Agency

The assessment of L-lysine base (liquid) produced by fermentation with *Corynebacterium glutamicum* (KCCM 80183) shows that the conditions for authorisation in article 5 of assimilated Regulation (EC) 1831/2003 are satisfied.

The FSA/FSS 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 assimilated Regulation (EC) 1831/2003 ('the Regulation') for feed additives:

1. Article 4 and Article 7: Authorisation for a new or new use of a feed additive.
2. Article 6: Categories of feed additives.
3. Article 16 and Annex III: Labelling and packaging requirements apply, if authorised.
4. Article 21: Analytical methods have been verified by the European 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. 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.
5. Annex IV: The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

FSA/FSS Risk management recommendation

The FSA/FSS risk management recommendation is that L-lysine base (liquid), as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use. The FSA/FSS conclusion is that we are in favour of authorising the feed additive as per Article 8 of assimilated Regulation (EC) 1831/2003. The proposed terms of authorisation are set out below.

Proposed terms of authorisation RP1199 Part A

Proposed terms of authorisation	RP1199 Part A
Additive	L-lysine base (liquid)
Identification number	3c320
Authorisation holder[60]	None
Additive category	Nutritional
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) ($NH_2(CH_2)CH(NH_2)COOH$) produced by fermentation with *Corynebacterium glutamicum* (KCCM 80183). CAS no: 56-87-1[61]
Analytical method[62]	For the quantification of lysine in the feed additive and premixtures containing more than 10% lysine:

[60] 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

[61] This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service.

[62] 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.

Proposed terms of authorisation	RP1199 Part A
	Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) in accordance with BS EN ISO 17180:2013[63] For 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 Commission Regulation (EC) No 152/2009 laying down the methods of sampling and analysis for the official control of feed (Annex III, F) (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 Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS) in accordance with Commission Regulation (EC) No 152/2009 laying down the methods of sampling and analysis for the official control of feed (Annex III, F) (Annex III, F)

[63] 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 30 April 2013 (ISBN 978 0 580 76077 8).

Proposed terms of authorisation	RP1199 Part A
Species or category of animal	All animal species
Maximum age	Not applicable
Minimum content of L-lysine (mg/kg of complete feed with a moisture content of 12%)	No minimum
Maximum content of L-lysine (mg/kg of complete feed with a moisture content of 12%)	No maximum
Other provisions	The L-lysine content must be stated on the labelling of the additive. The additive can be used via water for drinking. 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. The safety assessment identified that particular consideration should be given to hazards as an:
    - eye irritant
    - inhalation hazard.
- Main animal species and their subgroups are defined in Annex IV of assimilated Regulation (EC) 429/2008.

The FSA/FSS consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in assimilated Regulation (EC)

183/2005 laying down requirements for feed hygiene and good manufacturing practice.

Other legitimate factors

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

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

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)

Safety assessment conclusion

The FSA/FSS 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.

The FSA/FSS safety assessment was published on 29 September 2023 and can be found here: Safety Assessment RP1199 L-Lysine | Food Standards Agency.

The assessment of L-lysine monohydrochloride produced by fermentation with *Corynebacterium glutamicum* (KCCM 80183) shows that the conditions for authorisation in Article 5 of assimilated Regulation (EC) 1831/2003 are satisfied.

The FSA/FSS 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 assimilated Regulation (EC) 1831/2003 ('the Regulation') for feed additives:

1. Article 4 and Article 7: Authorisation for a new or new use of a feed additive.
2. Article 6: Categories of feed additives.
3. Article 16 and Annex III: Labelling and packaging requirements apply, if authorised.
4. Article 21: Analytical methods have been verified by the European 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. 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.
5. Annex IV: The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

FSA/FSS Risk management recommendation

The FSA/FSS risk management recommendation is that L-lysine monohydrochloride, as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use. The FSA/FSS conclusion is that we are in favour of authorising the feed additive as per article 8 of assimilated Regulation (EC) 1831/2003. The proposed terms of authorisation are set out below.

Proposed terms of authorisation RP1199 Part B

Proposed terms of authorisation	RP1199 Part B
Additive	L-lysine monohydrochloride (technically pure)
Identification number	3c322ii
Authorisation holder[64]	None
Additive category	Nutritional
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) ($NH_2(CH_2)_4CH(NH_2)COOH$) produced by fermentation with *Corynebacterium glutamicum* (KCCM 80183). CAS no: 657-27-2[65]

[64] 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

[65] This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service.

Proposed terms of authorisation	RP1199 Part B
Analytical method[66] 13	For the identification of L-lysine monohydrochloride in the feed additive: Food Chemicals Codex "L-lysine monohydrochloride monograph"[67] 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 ISO 17180:2013[68] 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 Commission Regulation (EC) No 152/2009 laying down the methods of sampling and analysis for the official control of feed (Annex III, F) F)

[66] 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: European Commission Joint Research Centre.

[67]Food Chemicals Codex (FCC), 13th edition (method: FCC L-lysine monohydrochloride monograph published). Published by the United States Pharmacopeial Convention on 1 March 2022 (ISSN 2153-1455) and available at: Food Chemicals Codex/.

[68] 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 30 April 2013 (ISBN 978 0 580 76077 8).

Proposed terms of authorisation	RP1199 Part B
	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 Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS) in accordance with Commission Regulation (EC) No 152/2009 laying down the methods of sampling and analysis for the official control of feed (Annex III, F) F)
Species or category of animal	All animal species
Maximum age	Not applicable
Minimum content of L-lysine monohydrochloride (mg/kg of complete feed with a moisture content of 12%)	No minimum
Maximum content of L-lysine monohydrochloride (mg/kg of complete feed with a moisture content of 12%)	No maximum
Other provisions	The L-lysine content must be stated on the labelling of the additive. The additive can be used via water for drinking. Declaration to be made on the label of the additive and premixture: “The supplementation

Proposed terms of authorisation	RP1199 Part B
	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. The safety assessment identified that particular consideration should be given to hazards as an:
    - eye irritant
    - inhalation hazard.
- Main animal species and their subgroups are defined in Annex IV of assimilated Regulation (EC) 429/2008.
- The FSA/FSS consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in assimilated Regulation (EC) 183/2005 laying down requirements for feed hygiene and good manufacturing practice.

Other legitimate factors

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

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

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)

Safety assessment conclusion

The FSA/FSS 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.

The FSA/FSS safety assessment was published on 29 September 2023 and can be found here: Safety Assessment RP1200 Disodium 5'-Guanylate | Food Standards Agency

The assessment of disodium 5'-guanylate produced by fermentation with *Corynebacterium stationis* (KCCM 10530) and *Escherichia coli* (KFCC 11067) shows that the conditions for authorisation in Article 5 of assimilated are satisfied.

The FSA/FSS 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, 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 assimilated Regulation (EC) 1831/2003 ('the Regulation') for feed additives:

1. Article 4 and Article 7: Authorisation for a new or new use of a feed additive.
2. Article 6: Categories of feed additives.

3. Article 16 and Annex III: Labelling and packaging requirements apply, if authorised.
4. Article 21: Analytical methods have been verified by the European 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). 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, flavouring premixtures and water
5. Annex IV: The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

FSA/FSS Risk management recommendation

The FSA/FSS risk management recommendation is that disodium 5'-guanylate, as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use. The FSA/FSS conclusion is that we are in favour of authorising the feed additive as per article 8 of assimilated Regulation (EC) 1831/2003. The proposed terms of authorisation are set out below.

Proposed terms of authorisation RP1200

Proposed terms of authorisation	RP1200
Additive	Disodium 5'-guanylate
Identification number	2b627i
Authorisation holder[69]	None
Additive category	Sensory
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) ($C_{10}H_{12}N_5Na_2O_8P$) CAS no: 5550-12-9[70] EINECS no: 226-914-1[71]

[69] 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

[70] This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service.

[71] 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.

Proposed terms of authorisation	RP1200
Analytical method[72]	For the identification of disodium 5'-guanylate (GMP) in the feed additive: FAO JECFA monograph "disodium 5'-guanylate"[73] 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
Minimum content of Disodium 5'-guanylate (mg/kg of complete feed with a moisture content of 12%)	No minimum
Maximum content of Disodium 5'-guanylate (mg/kg of complete feed	See other provisions

[72] 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: European Commission Joint Research Centre.

[73] 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).

Proposed terms of authorisation	RP1200
with a moisture content of 12%)	
Other provisions	The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture. The additive shall be incorporated into the feed in the form of a premixture. 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. 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. The safety assessment identified no specified hazards.
- Main animal species and their subgroups are defined in Annex IV of assimilated Regulation (EC) 429/2008.

- The FSA/FSS consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in assimilated Regulation (EC) 183/2005 laying down requirements for feed hygiene and good manufacturing practice.

Other legitimate factors

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

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

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

Safety assessment conclusion

FSA/FSS 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.The FSA/FSS safety assessment was published on 29 September 2023 and can be found here: Safety Assessment RP1259 Muramidase | Food Standards Agency.

The assessment of Muramidase (EC 3.2.1.17) produced by fermentation with *Trichoderma reesei* (DSM 32338) (Balancius®) shows that the conditions for authorisation in article 5 of assimilated Regulation (EC) 1831/2003 are satisfied.

The FSA/FSS 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 assimilated Regulation (EC) 1831/2003 ('the Regulation') for feed additives:

1. Article 4 and Article 7: Authorisation for a new or new use of a feed additive.
2. Article 6: Categories of feed additives.
3. Article 16 and Annex III: Labelling and packaging requirements apply, if authorised.
4. Article 21: Analytical methods have been verified by the European 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). Valid analytical methods exist for:
    - the quantification of muramidase activity in the feed additive, premixtures, feed materials and compound feed.
5. Annex IV: The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

FSA/FSS Risk management recommendation

The FSA/FSS risk management recommendation is that Muramidase (EC 3.2.1.17) as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use. The FSA/FSS conclusion is that we are in favour of authorising the feed additive as per article 8 of assimilated Regulation (EC) 1831/2003. The proposed terms of authorisation are set out below.

Proposed terms of authorisation RP1259

Proposed terms of authorisation	RP1259
Additive	Muramidase (EC 3.2.1.17)
Identification number	4d16

Proposed terms of authorisation	RP1259
Authorisation holder	DSM Nutritional Products Ltd
Additive category	Zootechnical additives
Functional group	Other zootechnical
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.[74]
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[75] EINECS no: 232-620-4[76]

[74] 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.

[75] This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service.

[76] 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.

Proposed terms of authorisation	RP1259
Analytical method[77]	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
Minimum content of muramidase (units of activity/kg of complete feed with a moisture content of 12%)	50 000 LSU (F)/kg
Maximum content of muramidase (units of activity/kg of complete feed with a moisture content of 12%)	65 000 LSU(F)/kg
Other provisions	The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture.

[77] 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: European Commission Joint Research Centre.

Supplementary information

- Feed additives are subject to UK health and safety legislation. The safety assessment identified that particular consideration should be given to hazards as a:
  - Skin and eye irritant
  - Skin and respiratory sensitiser
- Main animal species and their subgroups are defined in Annex IV of assimilated Regulation (EC) 429/2008.
- The FSA/FSS consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in assimilated Regulation (EC) 183/2005 laying down requirements for feed hygiene and good manufacturing practice.

Other legitimate factors

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

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

Annex T: RP1349 Phytomenadione (Vitamin K_1) as a feed additive for horses (JARAZ Enterprises GmbH & Co. KG) (new)

Safety assessment conclusion

FSA/FSS has undertaken a safety assessment of application RP1349 for the authorisation of Phytomenadione (vitamin K_1) as a feed additive for horses.

The FSA/FSS safety assessment was published on 29 September 2023 and can be found here: Safety Assessment RP1349 Vitamin K1 | Food Standards Agency.

The assessment of Phytomenadione (vitamin K_1) shows that the conditions for authorisation in article 5 in assimilated Regulation (EC) 1831/2003 are satisfied.

The FSA/FSS conclusion on phytomenadione (vitamin K_1) 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 K_1 in horse nutrition.
- On worker safety, phytomenadione is a skin sensitiser but no conclusions could be drawn on skin and eye irritancy and skin sensitsation.
- 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 assimilated Regulation (EC) 1831/2003 ('the Regulation') for feed additives:

1. Article 4 and Article 7: Authorisation for a new or new use of a feed additive.
2. Article 6: Categories of feed additives.
3. Article 16 and Annex III: Labelling and packaging requirements apply, if authorised.
4. Article 21: Analytical methods have been verified by the European Reference Laboratory as used for the control of phytomenadione (vitamin K_1) in animal feed as detailed in the EURL analytical method evaluation report (FAD- 2020-0006)
   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.

5. Annex IV: The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

FSA/FSS Risk management recommendation

The FSA/FSS risk management recommendation is that Phytomenadione, as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use. The FSA/FSS conclusion is that we are in favour of authorising the feed additive as per article 8 of assimilated Regulation (EC) 1831/2003. The proposed terms of authorisation are set out below.

Proposed terms of authorisation RP1349

Proposed terms of authorisation	RP1349
Additive	Vitamin K_1 (Phytomenadione)
Identification number	3a712
Authorisation holder[78]	None
Additive category	Nutritional
Functional group	Vitamins, pro-vitamins and chemically well-defined substances having similar effect
Additive composition	Produced by chemical synthesis Solid preparation containing a minimum of 4.2% of phytomenadione (vitamin K_1)
Characterisation of the active substance(s)	2-methyl-3-[(E-7R,11R)-3,7,11,15-tetramethylhexadec-2- enyl] naphthalene-1,4-dione (phytomenadione) ($C_{31}H_{46}O_2$) CAS no: 84-80-0[79]

[78] 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.

[79] This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service.

Proposed terms of authorisation	RP1349
	EINECS no: 201-564-2[80] 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[82]	For the determination of phytomenadione (vitamin K_1) in the feed additive: High performance liquid chromatography (HPLC) in accordance with the European Pharmacopoeia[83] For the determination of phytomenadione in the additive preparation and in complimentary feed: High performance liquid chromatography

[80] The EINECS (European Inventory of Existing Commercial chemical Substances) number as published in O.J. No. C146A, 15.6.90, p.1.

[82] 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 European Commission Joint Research Centre.

[83] European Pharmacopoeia, Monograph (Phytomenadione). Published online by the European Directorate for the Quality of Medicines and Healthcare on 1st January 2024 and available at: European Pharmacopoeia.

Proposed terms of authorisation	RP1349
	with fluorescence detection (HPLC-FLD) in accordance with BS EN 14148:2003[84]
Species or category of animal	Horses
Maximum age	Not applicable
Minimum content of phytomenadione (vitamin $K_{1)}$ (mg/kg of complete feed with a moisture content of 12%)	No minimum
Maximum content of phytomenadione (vitamin $K_{1)}$ (mg/kg of complete feed with a moisture content of 12%)	No maximum
Other provisions	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. The safety assessment identified that particular consideration should be given to hazards as a:
  - Skin and eye irritant
  - Skin sensitiser
  - Hazard by inhalation
- Main animal species and their subgroups are defined in Annex IV of assimilated Regulation (EC) 429/2008.

[84] BS EN 14148:2003 "Foodstuffs. Determination of vitamin K1 by HPLC". Published by the British Standards Institution on 25 July 2003 (ISBN 0 580 42317 4).

- The FSA/FSS consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in assimilated Regulation (EC)183/2005 laying down requirements for feed hygiene and good manufacturing practice.

Other legitimate factors

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

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

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

Safety assessment conclusion

FSA/FSS 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.

The FSA/FSS safety assessment was published on 29 September 2023 and can be found here: Safety Assessment RP1386 Copper Chelate of Hydroxy Analogue of Methionine | Food Standards Agency

The assessment of copper chelate of hydroxy analogue of methionine shows that the conditions for authorisation in article 5 of assimilated Regulation (EC) 1831/2003 are satisfied.

The FSA/FSS 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 assimilated Regulation (EC) 1831/2003 ('the Regulation') for feed additives:

1. Article 6: Categories of feed additives.
2. Article 13: Modification of authorisation.
3. Article 14: Renewal of authorisation.
4. Article 16 and Annex III: Labelling and packaging requirements apply, if authorised.

5. Article 21: Analytical methods have been verified by the European 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). 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.
6. Annex IV: The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

FSA/FSS Risk management recommendation

The FSA/FSS risk management recommendation is that copper chelate of hydroxy analogue of methionine, as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use. The FSA/FSS conclusion is that we are in favour of authorising the feed additive as per article 8 of assimilated Regulation (EC) 1831/2003. The proposed terms of authorisation are set out below.

Proposed terms of authorisation RP1386

Proposed terms of authorisation	RP1386
Additive	Copper chelate of hydroxy analogue of methionine
Identification number	3b410i
Authorisation holder[85]	None
Additive category	Nutritional
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 $(Cu(CH_3S(CH_2)_2\text{-}CH(OH)\text{-}COO)_2)$ CAS no: 292140-30-8[86]
Analytical method[87]	For the quantification of the hydroxy analogue of methionine content in the feed additive: Titrimetry, potentiometric titration after oxidation reduction reaction.

[85] 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.

[86] This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service.

[87] 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: European Commission Joint Research Centre.

Proposed terms of authorisation	RP1386
	For the quantification of total copper in the feed additive: 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 laying down the methods of sampling and analysis for official control of feed (Annex IV-C) (ISO 6869[88)] For the quantification of total copper in premixtures: Inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15510[89] or EN 15621[90]) or

[88] 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 15 March 2001 (ISBN 0 580 36933 1).

[89] 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 31 August 2017 (ISBN 978 0 580 94543 4).

[90] BS EN 15621:2017 "Animal feeding stuffs. Methods of sampling and analysis. Determination of calcium, sodium, phosphorus, magnesium, potassium, sulphur, iron,

Proposed terms of authorisation	RP1386
	Atomic absorption spectrometry (AAS) in accordance with Regulation (EC) 152/2009 laying down the methods of sampling and analysis for official control of feed (Annex IV-C) (ISO 6869[91]) or Inductively coupled plasma mass spectrometry, ICP-MS (EN 17053[92]). For the quantification of total copper in compound feed/feed materials: Inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15510 or EN 15621) or Atomic absorption spectrometry, AAS (Commission Regulation (EC) No 152/2009 laying down the methods of sampling and

zinc, copper, manganese and cobalt after pressure digestion by ICP-AES". Published by the British Standards Institution on 31 August 2017 (ISBN 978 0 580 94543 4).

[91] 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 15 March 2001 (ISBN 0 580 36933 1).

[92] 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 28 February 2018 (ISBN 978 0 580 94471 0).

Proposed terms of authorisation	RP1386
	analysis for the 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
Minimum content of copper (Cu) (mg/kg of complete feed with a moisture content of 12%)	No minimum
Maximum content of copper (Cu) (mg/kg of complete feed with a moisture content of 12%)	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	The additive shall be incorporated into feed in the form of a premixture. 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

Proposed terms of authorisation	RP1386
	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. The safety assessment identified that particular consideration should be given to hazards as a:
    - Skin and eye irritant
    - Skin and respiratory sensitiser
- Main animal species and their subgroups are defined in Annex IV of assimilated Regulation (EC) 429/2008.
- The FSA/FSS consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in assimilated Regulation (EC) 183/2005 laying down requirements for feed hygiene and good manufacturing practice.

Other legitimate factors

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

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

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

Safety assessment conclusion

FSA/FSS 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.

The FSA/FSS safety assessment was published on 29 September 2023 and can be found here: Safety Assessment RP1387 Manganese Chelate of Hydroxy Analogue of Methionine | Food Standards Agency.

The assessment of manganese chelate of hydroxy analogue of methionine shows that the conditions for authorisation in article 5 of assimilated Regulation (EC) 1831/2003 are satisfied.

The FSA/FSS 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 assimilated Regulation (EC) 1831/2003 ('the Regulation') for feed additives:

1. Article 6: Categories of feed additives.

2. Article 13: Modification of authorisation.
3. Article 14: Renewal of authorisation.
4. Article 16 and Annex III: Labelling and packaging requirements apply, if authorised.
5. Article 21: Analytical methods have been verified by the European 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). 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.
6. Annex IV: The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

FSA/FSS Risk management recommendation

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

Proposed terms of authorisation RP1387

Proposed terms of authorisation	RP1387
Additive	Manganese chelate of hydroxy analogue of methionine
Identification number	3b510

Proposed terms of authorisation	RP1387
Authorisation holder[93]	None
Additive category	Nutritional
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 $(Mn(CH_3S(CH_2)_2\text{-}CH(OH)\text{-}COO)_2)$ CAS no: 292140-29-5[94]
Analytical method[95]	For the quantification of the hydroxy analogue of methionine content in the feed additive: Titrimetry, potentiometric titration after oxidation reduction reaction;

[93] 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.

[94] This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service.

[95] 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: European Commission Joint Research Centren

Proposed terms of authorisation	RP1387
	For the quantification of total manganese in the feed additive and premixtures: Atomic Absorption Spectrometry, AAS (EN ISO 6869[96]); or Inductively Coupled Plasma – Atomic Emission Spectrometry, ICP-AES (EN 15510[97]); or Inductively Coupled Plasma – Atomic Emission Spectrometry after pressure digestion, ICP-AES (EN 15621[98]); For the quantification of total manganese in feed materials and compound feed:

[96] 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 15 March 2001 (ISBN 0 580 36933 1).

[97] 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 31 August 2017 (ISBN 978 0 539 09335 3).

[98] 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 31 August 2017 (ISBN 978 0 580 94543 4).

Proposed terms of authorisation	RP1387
	Atomic Absorption Spectrometry, AAS (Regulation (EC) No 152/2009 laying down the methods of sampling and analysis for the official control of feed (Annex IV-C) Inductively Coupled Plasma – Atomic Emission Spectrometry, ICP-AES (EN 15510); or Inductively Coupled Plasma – Atomic Emission Spectrometry after pressure digestion, ICP-AES (EN 15621).
Species or category of animal	All animal species
Maximum age	Not applicable
Minimum content of manganese (Mn) (mg/kg of complete feed with a moisture content of 12%)	No minimum
Maximum content of manganese (Mn) (mg/kg of complete feed with a moisture content of 12%)	Fish: 100 mg/kg (total) Other animal species: 150 mg/kg (total)
Other provisions	The additive shall be incorporated into feed in the form of a premixture.

Proposed terms of authorisation	RP1387
	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. The safety assessment identified that particular consideration should be given to hazards as a:
    - skin sensitiser
    - risk to users by inhalation
- Main animal species and their subgroups are defined in Annex IV of assimilated Regulation (EC) 429/2008.
- The FSA/FSS consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in assimilated Regulation (EC) 183/2005 laying down requirements for feed hygiene and good manufacturing practice.

Other legitimate factors

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

The FSA/FSS 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, FSA/FSS have assessed the potential impacts that would result from the authorisation of this animal feed additive, should ministers

decide to authorise. No significant impacts were identified. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

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

Safety assessment conclusion

FSA/FSS 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.

The FSA/FSS safety assessment was published on 29 September 2023 and can be found here: Safety Assessment RP1388 Zinc Chelate of Hydroxy Analogue of Methionine | Food Standards Agency

The assessment of zinc chelate of hydroxy analogue of methionine shows that the conditions for authorisation in article 5 of assimilated Regulation (EC) 1831/2003 are satisfied.

The FSA/FSS 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 assimilated Regulation (EC) 1831/2003 ('the Regulation') for feed additives:

1. Article 6: Categories of feed additives.
2. Article 13: Modification of authorisation.
3. Article 14: Renewal of authorisation.

4. Article 16 and Annex III: Labelling and packaging requirements apply, if authorised.
5. Article 21: Analytical methods have been verified by the European 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). 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.

6. Annex IV: The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

FSA/FSS risk management recommendations

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

Proposed terms of authorisation RP1388

Proposed terms of authorisation	RP1388
Additive	Zinc chelate of hydroxy analogue of methionine
Identification number	3b610
Authorisation holder[99]	None
Additive category	Nutritional
Functional group	Compounds of trace elements

[99] 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.

Proposed terms of authorisation	RP1388
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 ($Zn(CH_3S(CH_2)_2\text{-}CH(OH)\text{-}COO)_2$) CAS no: 292140-29-5[100]
Analytical method[101]	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 (EN 15510[102] or EN 15621) or

[100] This is a reference to the CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service.

[101] Details of the analytical methods are set out in the document referenced "D08-FSQ(2007)D/29110" and last updated on 6 June 2016 and available at: European Commission Joint Research Centre.

[102] BS EN 15510:2017 - TC "Animal feeding stuffs. Methods of sampling and analysis. Determination of calcium, sodium, phosphorus, magnesium, potassium, iron, zinc,

Proposed terms of authorisation	RP1388
	Atomic absorption spectrometry, AAS (ISO 6869) For the quantification of total zinc in premixtures: Inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15510 or EN 15621[103]) or Atomic absorption spectrometry, AAS (ISO 6869[104]) or Inductively coupled plasma mass spectrometry, ICP-MS (EN 17053[105]);

copper, manganese, cobalt, molybdenum and lead by ICP-AES". Published by the British Standards Institution on 31 August 2017 (ISBN 978 0 539 09335 3).

[103] 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 31 August 2017 (ISBN 978 0 580 94543 4).

[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 15 March 2001 (ISBN 0 580 36933 1).

[105] 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

Proposed terms of authorisation	RP1388
	For the quantification of total zinc 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) laying down the methods of sampling and analysis for the official control of feed No 152/2009 (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
Minimum level of Zinc (Zn) (mg/kg of complete feed with a moisture content of 12%)	No minimum
Maximum level of Zinc (Zn) (mg/kg of complete feed with a moisture content of 12%)	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)

(multi-method)". Published by the British Standards Institution on 28 February 2018 (ISBN 978 0 580 94471 0).

Proposed terms of authorisation	RP1388
	Other animal species: 120 mg/kg (total)
Other provisions	The additive shall be incorporated into feed in the form of a premixture. 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. The safety assessment identified that particular consideration should be given to hazards as a:
    - Skin sensitiser
    - Risk to users by inhalation
- Main animal species and their subgroups are defined in Annex IV of assimilated Regulation (EC) 429/2008.
- The FSA/FSS consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in assimilated Regulation (EC) 183/2005 laying down requirements for feed hygiene and good manufacturing practice.

Other legitimate factors

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

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

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)

Safety assessment conclusion

FSA/FSS 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. The FSA/FSS safety assessment was published on 29 September 2023 and can be found here: Safety Assessment RP1591 Fumonisin Esterase | Food Standards Agency.

The assessment of fumonisin esterase (EC 3.1.1.87) produced by fermentation with *Komagataella phaffii* (DSM 32159) shows that the conditions for authorisation in article 5 of assimilated Regulation (EC) 1831/2003 are satisfied.

The FSA/FSS 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 assimilated Regulation (EC) 1831/2003 ('the Regulation') for feed additives:

1. Article 4 and Article 7: Authorisation for a new or new use of a feed additive.
2. Article 6: Categories of feed additives.
3. Article 16 and Annex III: Labelling and packaging requirements apply, if authorised.
4. Article 21: Analytical methods have been verified by the European 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). Valid analytical methods exist for:

- The quantification of fumonisin esterase activity in the feed additive, premixtures and compound feed.

5. Annex IV: The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

FSA/FSS Risk management recommendation

The FSA/FSS risk management recommendation is that fumonisin esterase (EC 3.1.1.87), as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use. The FSA/FSS conclusion is that we are in favour of authorising the feed additive as per article 8 of assimilated Regulation (EC) 1831/2003. The proposed terms of authorisation are set out below.

Proposed terms of authorisation RP1591

Proposed terms of authorisation	RP1591
Additive	Fumonisin esterase (EC 3.1.1.87)

Proposed terms of authorisation	RP1591
Identification number	1m03i
Authorisation holder[106]	None
Additive category	Technological
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[107]
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[108]	For the determination of fumonisin esterase activity: High performance liquid chromatography coupled with a tandem mass spectrometry (HPLC-MS/MS) method based on the

[106] 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.

[107] 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.

[108] 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: European Commission Joint Research Centre.

Proposed terms of authorisation	RP1591
	quantification of the tricarboxylic acid released from the action of the enzyme on fumonisin B_1 at pH 8.0 and 30 ºC.
Species or category of animal	All animal species
Maximum age	Not applicable
Minimum content of units of activity/kg of fresh material	40 U/kg
Maximum content of units of activity/kg of fresh material	No maximum
Other provisions	The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture. The use of the additive is only allowed in maize based silages.

Supplementary information

- Feed additives are subject to UK health and safety legislation. The safety assessment identified that particular consideration should be given to hazards as a:
    - respiratory sensitiser.
- Main animal species and their subgroups are defined in Annex IV of assimilated Regulation (EC) 429/2008
- The FSA/FSS consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in assimilated Regulation (EC) 183/2005 laying down requirements for feed hygiene and good manufacturing practice.

Recommendations of 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, the FSA/FSS have had regard to other legitimate factors (including Consumer Interests, Political, Environmental, Societal and Technical Feasibility) that ministers will consider as part of their decision on authorisation.

The FSA/FSS 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, FSA/FSS have assessed the potential impacts that would result from the authorisation of this animal feed additive, should ministers decide to authorise. No significant impacts were identified. The impacts considered

included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

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

Background

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

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

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

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

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

The applicant requests modification of authorisation (in accordance with article 13 of assimilated Regulation (EC) 1831/2003) to amend the name of the holder of authorisation from Evonik Nutrition & Care GmbH to Evonik Operations GmbH.

FSA/FSS opinion

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

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

Safety assessment conclusion

FSA/FSS 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 assimilated Regulation (EU) 2020/354 establishing a list of intended uses of feed intended for particular nutritional purposes.

The application was evaluated by our independent experts and their assessment of the application to modify entry number 60 is that the conditions for authorisation in assimilated Regulation (EU) 2020/354 ('the Regulation') which establishes a list of intended uses of feed intended for particular nutritional purposes ('PARNUT') are satisfied.

The FSA/FSS safety assessment was published on 29 September 2023 and can be found here: Safety Assessment RP658 Reduction of the Risk of Milk Fever and Subclinical Hypocalcaemia in Dairy Cows | Food Standards Agency

The FSA/FSS opinion is that the modification of entry number 60 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 proposed terms of authorisation are set out below.

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 assimilated Regulation (EC) 767/2009:

1. Article 9: the marketing of feed intended for particular nutritional purposes applies.
2. Article 10: the application procedure applies.

Legislation in respect of feed additives applies to this application. In particular it is noted that this application must fulfil the following requirements of:

1. Article 1: the marketing of feed may only be marketed if the general provisions and the intended use are complied with.
2. Annex: The general provisions and list of intended uses must be complied with, where applicable for the individual PARNUT authorisation.

FSA/FSS risk management recommendation

The FSA/FSS risk management recommendation on the application to modify the first row 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. The FSA/FSS conclusion is that we are in favour of this modification per article 10 of assimilated Regulation (EC) 767/2009.

Proposed terms of authorisation RP658

Proposed terms of authorisation	RP658
Entry number	60
Particular nutritional purpose	Reduction of the risk of milk fever and subclinical hypocalcaemia
Essential nutritional characteristics	Low cations/anions ratio. For the total ration: Minimum acidification via feed for particular nutritional purpose: 100 mEq/kg dry matter. Objective: Range from negative DCAD values to <200 DCAD[109] Or
Species	Dairy Cows

[109] DCAD (mEq/kg dry matter) = (Na+K) - (Cl+S)

Proposed terms of authorisation	RP658
Labelling declarations	Calcium Phosphorus Magnesium Sodium Potassium Chlorides Sulphur
Recommended length of time	From 3 weeks before calving until calving
Other Provisions	Indicate in the instructions for proper use “stop feeding after calving”

Note rest of rows under entry 60 are to remain as is.

Other legitimate factors

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

The FSA/FSS 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, FSA/FSS have assessed the potential impacts that would result from the authorisation of this animal feed additive, should ministers decide to authorise. No significant impacts were identified. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The

authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.

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