FSA/FSS opinions on twelve applications for feed additives for use in animal feed

FSA/FSS opinions on twelve applications for feed additives: Summary

These opinions take into account the safety assessments for each application and potential impacts that would result from the authorisation of these feed additives.

Document subject and purpose

In this document we publish the Food Standards Agency (FSA)/ Food Standards Scotland (FSS) opinions on twelve applications for feed additives for use in animal feed. These opinions take into account the safety assessments for each application, as well as potential impacts that would result from the authorisation of these feed additives, and other legitimate factors that Ministers may want to consider before making a decision regarding authorisation.

Our safety assessment process

Our risk assessors deliver the science behind our advice. They are responsible for identifying and characterising hazards and risks to health and assessing levels of exposure. Where the European Food Safety Authority (EFSA) had commenced an assessment of an application prior to the end of the transition period for the UK exiting the EU (applications in Annexes A to L), the FSA/FSS safety assessors will take the EFSA opinion into account as part of its safety assessment, where it has been published by EFSA. For applications in this consultation, the FSA/FSS have had access to all supporting documentation that was provided to EFSA for the purposes of forming its opinion as this information was provided to the FSA/FSS by the applicant. After safety assessment, the FSA/FSS have agreed with EFSA conclusions in its opinions.

Application for Annex M, RP1059 3-nitrooxypropanol (3-NOP) (Bovaer® 10), has undergone a full FSA/FSS safety assessment, including full review of the applicant dossier for ruminants (animals that chew the cud) for milk production and for reproduction. The views of the Animal Feed and Feed Additives Joint Expert Group (AFFAJEG) and the Advisory Committee on Animal Feedingstuffs (ACAF) have been taken into account in the FSA/FSS safety assessment for this application.

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

The FSA/FSS opinion for each feed additive is published within a separate annex, including the regulated product ID number and title of the application. A link to the individual safety

assessments is provided in each annex.

Annex A: RP215 - Endo-1,4-beta-xylanase produced by Trichoderma reesei

RP215 - Endo-1,4-beta-xylanase produced by Trichoderma reesei as a feed additive for all poultry species, piglets (suckling and weaned), pigs for fattening and minor porcine species.

Annex A: RP215 - Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by Trichoderma reesei (CBS 143953, previously deposited as ATCC 5588) as a feed additive for all poultry species, piglets (suckling and weaned), pigs for fattening and minor porcine species (Danisco Xylanase 40000 G/L) (Danisco (UK) Limited) (renewal, modification and new use)

Background

Name of applicant:

Danisco (UK) Ltd (trading as Danisco Animal Nutrition)

Address of applicant:

PO Box 777
Marlborough
Wiltshire
SN8 1XN
United Kingdom

FSA/ FSS Safety Assessment

FSA/FSS has undertaken a safety assessment of application RP215 for the renewal, modification and extension of use of endo-1,4-beta-xylanase (EC 3.2.1.8) (Xylanase 40000 G/L) produced by *Trichoderma reesei* (CBS 143953), previously deposited as ATCC 5588) as a feed additive for poultry and pigs, from Danisco Animal Nutrition.

FSA/FSS has reviewed the EFSA opinion (EFSA Journal 2021;0(0):6539) and confirm that it is adequate for UK considerations and therefore a full safety assessment of this application was not performed by FSA/FSS. Please see the earlier section titled ‘Our safety assessment process’ to understand how and when we make use of EFSA opinions.

The FSA/FSS opinion is that endo-1,4-beta-xylanase (EC 3.2.1.8) (Xylanase 40000 G/L), 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 proposed terms of authorisation are set out below.

Any relevant provisions of Retained EU Law

Under the requirements of Retained EU Regulation 1831/2003 (‘the Regulation’) for feed additives:

1. Article 16 and points 1(a) and 1(b) of Annex III: Labelling and packaging requirements apply, if authorised.
2. Article 21: Analytical methods have been verified by the European Reference Laboratory as used for the control of Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by Trichoderma reesei (CBS 143953) in animal feed as detailed in the EURL analytical method evaluation report (FAD-2010-0007). Valid analytical methods exist for: the quantification of endo-1,4-beta-xylanase activity in the feed additive, premixtures, feed materials and compound feed.
3. Annex IV: The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

Proposed terms of authorisation

1: Additive details

Additive category	(4) Zootechnical additives
Functional group	(a) Digestibility enhancers
Feed additive	Endo-1,4-beta-xylanase (EC 3.2.1.8)
ID No	4a11
Target species	All poultry species, piglets (suckling and weaned), pigs for fattening and minor porcine species.
Authorisation Holder	Danisco (UK) Limited
Authorisation period	10 years from the date of authorisation

2: Additive composition

Preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by fermentation with *Trichoderma reesei* (CBS 143953) with a minimum activity of 40 000 U/g

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

Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by fermentation with *Trichoderma reesei* (CBS 143953)

- EC (IUBMB) no: 3.2.1.8
- CAS no: 9025-57-4
- EINECS no: 232-800-2

4: Conditions of use

Species or category of animal	Maximum age	Content of endo-1,4-beta-xylanase (units of activity/kg of complete feed with a moisture content of 12%)
All poultry species	n/a	Minimum level: 625 U Maximum level: No maximum?
Piglets (suckling and weaned), pigs for fattening and minor porcine species	n/a	Minimum level: 2 000 U Maximum level: No maximum?

5: Other Provisions

1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated.

6: Analytical methods

For quantification of endo-1,4-beta-xylanase activity in the feed additive, premixtures, feed materials and compound feed:
Colorimetric method measuring water soluble dye released by action of endo-1,4-beta-xylanase from azurine cross-linked wheat arabinoxylan substrate.

One Unit is the amount of enzyme which releases 0.48 micromoles (?mol) of reducing sugar (xylose equivalent) per minute from wheat arabinoxylan at pH 4,.2 and 50°C.

Other relevant information (separate to terms of authorisation)

1: 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, respiratory sensitiser.
- major animal species and their subgroups are defined in Annex IV of Retained EU Regulation 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 Retained EU Regulation 183/2005 ‘Feed Hygiene Regulation’ and Good Manufacturing Practice.

2: Recommendations

For use in feed rich in starch and non-starch polysaccharides (mainly beta- arabinoxylans).

Annex B: RP263 – Lacticaseibacillus rhamnosus as a feed additive for all animal species

FSA/FSS has undertaken a safety assessment of application RP263 for the use of Lacticaseibacillus rhamnosus (IMI 507023) as a feed additive for all animal species, from All-Technology (Ireland) Limited.

Annex B: RP263 – *Lacticaseibacillus rhamnosus* (formerly *Lactobacillus rhamnosus*) (IMI 507023) as a feed additive for all animal species (All-Technology (Ireland) Limited) (new)

Background

Name of applicant:

All-Technology (Ireland) Limited

Address of applicant:

Sarney
Summerhill Road
A86X006
Dunboyne
Co. Meath
Ireland

FSA/ FSS Safety Assessment

FSA/FSS has undertaken a safety assessment of application RP263 for the use of *Lacticaseibacillus rhamnosus* (IMI 507023) as a feed additive for all animal species, from All-Technology (Ireland) Limited.

FSA/FSS has reviewed the EFSA opinion (EFSA Journal 2021;19(7):6700) and confirmed that it is adequate for UK considerations and, therefore, a full safety assessment of this application was not performed by FSA/FSS. Please see the earlier section titled ‘Our safety assessment process’ to understand how and when we make use of EFSA opinions.

The FSA/FSS opinion is that *Lacticaseibacillus rhamnosus* (IMI 507023), as described in this application, is safe and is not liable to have an adverse effect on the target species, worker safety, environmental safety and human health at the intended concentrations of use. The proposed terms of authorisation are set out below.

Any relevant provisions of retained EU law

Under the requirements of the Regulation for feed additives:

1. Article 16 and points 1(c), 1(e) and 2 of Annex III: Labelling and packaging requirements apply, if authorised.
2. Article 21: Analytical methods have been verified by the European Reference Laboratory as used for the control of *Lacticaseibacillus rhamnosus* (IMI 507023) in animal feed as detailed in the EURL analytical method evaluation report (FAD-2020-0075). Valid analytical methods exist for:

- the identification of the bacterial strain *L. rhamnosus* (IMI 507023)
- the enumeration (bacterial count) of the bacteria in the feed additive.

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

Proposed terms of authorisation

1: Additive details

Additive category	(1) Technological additives
Functional group	(k) Silage additives
Feed additive	*Lacticaseibacillus rhamnosus* (IMI 507023)
ID No	1k21701
Target species	All animal species

Authorisation period	10 years from the date of authorisation

2: Additive composition

Solid preparation of *Lacticaseibacillus rhamnosus* (IMI 507023) containing a minimum of 1 x 1010 CFU/g additive.

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

Viable cells of *Lacticaseibacillus rhamnosus* (IMI 507023).

4: Conditions of use

Species or category of animal	Maximum age	Colony-forming units of the additive/kg of fresh material:
All animal species	n/a	Minimum level: See Other Provisions at 5.2 below. Maximum level: No maximum

5: Other Provisions

1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated.
2. Minimum content of the additive when used without combination with other micro-organisms as silage additives: 1 x 109 CFU/kg of easy and moderately difficult to ensile fresh material.

6: Analytical methods

For enumeration (colony count) of the feed additive:
Spread plate method on MRS agar (BS EN 15787:2021)

For identification of bacterial strain:
Pulsed Field Gel Electrophoresis (PFGE)

Other relevant information (separate to terms of authorisation)

1: 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.
- Definitions of silage, in accordance with Retained EU Regulation 429/2008:
  - Easy to ensile forage: >3 % soluble carbohydrates in fresh material.
  - Moderately difficult to ensile forage: 1.5-3.0% soluble carbohydrates in fresh material.
  - Difficult to ensile forage: <1.5 % soluble carbohydrates in the fresh material.

- Major animal species and their subgroups are defined in Annex IV of Retained EU Regulation 429/2008.

2: Recommendations

Lacticaseibacillus rhamnosus (IMI 507023) may be applied to fresh material (forage) as a solid preparation or aqueous solution.

Annex C: RP267 - Pediococcus pentosaceus as a feed additive for all animal species

Pediococcus pentosaceus (IMI 507024) as a feed additive for all animal species (All-Technology (Ireland) Limited) (new)

Background

Name of applicant:

All-Technology (Ireland) Limited

Address of applicant:

Sarney
Summerhill Road
A86X006
Dunboyne
Co. Meath
Ireland

FSA/FSS Safety Assessment

FSA/FSS has undertaken a safety assessment of application RP267 for the use of *Pediococcus pentosaceus* (IMI 507024) as a feed additive for all animal species, from All-Technology (Ireland) Limited.

FSA/FSS has reviewed the EFSA opinion (EFSA Journal 2021;19(7):6701) and confirms that it is adequate for UK considerations and, therefore, a full safety assessment of this application was not performed by FSA and FSS. Please see the earlier section titled ‘Our safety assessment process’ to understand how and when we make use of EFSA opinions.

The FSA/FSS opinion is that *Pediococcus pentosaceus* (IMI 507024), as described in this application, is safe and is not liable to have an adverse effect on the target species, worker safety, environmental safety and human health at the intended concentrations of use. The proposed terms of authorisation are set out below.

Any relevant provisions of retained EU law

Under the requirements of the Regulation for feed additives:

1. Article 16 and points 1(c), 1(e) and 2 of Annex III: Labelling and packaging requirements apply, if authorised.
2. Article 21: Analytical methods have been verified by the European Reference Laboratory as used for the control of *Pediococcus pentosaceus* (IMI 507024) in animal feed as detailed in the EURL analytical method evaluation report (FAD-2020-0076). Valid analytical methods exist for:

- the identification of the bacterial strain *P. pentosaceus* (IMI 507024)
- the enumeration (bacterial count) of the bacteria in the feed additive

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

Proposed terms of authorisation

1: Additive details

Additive category	(1) Technological additives
Functional group	(k) Silage additives
Feed additive	*Pediococcus pentosaceus* (IMI 507024)
ID No	1k21016
Target species	All animal species
Authorisation period	10 years from the date of authorisation

2: Additive composition

Solid preparation of *Pediococcus pentosaceus* (IMI 507024) containing a minimum of 1 x 1010 CFU/g additive.

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

Viable cells of *Pediococcus pentosaceus* (IMI 507024).

4: Conditions of use

Species or category of animal	Maximum age	Colony-forming units of the additive/kg of fresh material:
All animal species	n/a	Minimum level: See Other Provisions at 5.2 below. Maximum level: No maximum?

5: Other Provisions

1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated.
2. Minimum content of the additive when used without combination with other micro-organisms as silage additives: 1 x 109 CFU/kg of easy and moderately difficult to ensile

fresh material.

6: Analytical methods

For enumeration (colony count) of the feed additive:
Spread plate method on MRS agar (BS EN 15786:2021)

For identification of bacterial strain:
Pulsed Field Gel Electrophoresis (PFGE)

Other relevant information (separate to terms of authorisation)

1. **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.
- Definitions of silage, in accordance with Retained EU Regulation 429/2008:
  - Easy to ensile forage: >3 % soluble carbohydrates in fresh material.
  - Moderately difficult to ensile forage: 1.5-3.0% soluble carbohydrates in fresh material.
  - Difficult to ensile forage: <1.5 % soluble carbohydrates in the fresh material.
- Major animal species and their subgroups are defined in Annex IV of Retained EU Regulation 429/2008.

2: Recommendations

Pediococcus pentosaceus (IMI 507024) may be applied to fresh material (forage) as a solid preparation or aqueous solution.

Annex D: RP270 - Pediococcus pentosaceus as a feed additive for all animal species

Annex D: RP270 - Pediococcus pentosaceus (IMI 507025) as a feed additive for all animal species (All-Technology (Ireland) Limited) (new)

Background

Name of applicant:

All-Technology (Ireland) Limited

Address of applicant:

Sarney
Summerhill Road

A86X006
Dunboyne
Co. Meath
Ireland

FSA/FSS Safety Assessment

FSA/FSS has undertaken a safety assessment of application RP270 for the use of *Pediococcus pentosaceus* (IMI 507025) as a feed additive for all animal species, from All-Technology (Ireland) Limited.

FSA/FSS has reviewed the EFSA opinion (EFSA Journal 2021;19(7):6702) and confirms that it is adequate for UK considerations and therefore a full safety assessment of this application was not performed. Please see the earlier section titled 'Our safety assessment process' to understand how and when we make use of EFSA opinions.

The FSA/FSS opinion is that *Pediococcus pentosaceus* (IMI 507025), as described in this application, is safe and is not liable to have an adverse effect on the target species, worker safety, environmental safety and human health at the intended concentrations of use. The proposed terms of authorisation are set out below.

Any relevant provisions of retained EU law

Under the requirements of the Regulation for feed additives:

1. Article 16 and points 1(c), 1(e) and 2 of Annex III: Labelling and packaging requirements apply, if authorised.
2. Article 21: Analytical methods have been verified by the European Reference Laboratory as used for the control of *Pediococcus pentosaceus* (IMI 507025) in animal feed as detailed in the EURL analytical method evaluation report (FAD-2020-0077). Valid analytical methods exist for:

- the identification of the bacterial strain *P. pentosaceus* (IMI 507025)
- the enumeration (bacterial count) of the bacteria in the feed additive

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

Proposed terms of authorisation

1: Additive details

Additive category	(1) Technological additives
Functional group	(k) Silage additives
Feed additive	*Pediococcus pentosaceus* (IMI 507025)
ID No	1k21017
Target species	All animal species
Authorisation period	10 years from the date of authorisation

2: Additive composition

Solid preparation of *Pediococcus pentosaceus* (IMI 507025) containing a minimum of 1 x 1010 CFU/g additive.

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

Viable cells of *Pediococcus pentosaceus* (IMI 507025)

4: Conditions of use

Species or category of animal	Maximum age	Colony-forming units of the additive/kg of fresh material:
All animal species	n/a	Minimum level: See Other Provisions at 5.2 below Maximum level: No maximum

5: Other Provisions

1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated.?
2. Minimum content of the additive when not combined with other micro-organisms as silage additives: 1 x 109 CFU/kg of easy and moderately difficult to ensile fresh material.

6: Analytical methods

For enumeration (colony count) of the feed additive:
Spread plate method on MRS agar (BS EN 15786:2021)

For identification of bacterial strain:
Pulsed Field Gel Electrophoresis (PFGE)

Other relevant information (separate to terms of authorisation)

1: 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.
- Definitions of silage, in accordance with Retained EU Regulation 429/2008:
  - Easy to ensile forage: >3 % soluble carbohydrates in fresh material.
  - Moderately difficult to ensile forage: 1.5-3.0% soluble carbohydrates in fresh material.
  - Difficult to ensile forage: <1.5 % soluble carbohydrates in the fresh material.
- Major animal species and their subgroups are defined in Annex IV of Retained EU Regulation 429/2008.

2: Recommendations

Pediococcus pentosaceus (IMI 507025) may be applied to fresh material (forage) as a solid preparation or aqueous solution.

Annex E: RP271 - Lactiplantibacillus plantarum as a feed additive for all animal species

Annex E: RP271 - Lactiplantibacillus plantarum (formerly Lactobacillus plantarum) (IMI 507026) as a feed additive for all animal species (All-Technology (Ireland) Limited) (new)

Background

Name of applicant:

All-Technology (Ireland) Limited

Address of applicant:

Sarney
Summerhill Road
A86X006
Dunboyne
Co. Meath
Ireland

FSA/FSS Safety Assessment

FSA/ FSS has undertaken a safety assessment of application RP271 for the use of *Lactiplantibacillus plantarum* (IMI 507026) as a feed additive for all animal species, from All-Technology (Ireland) Limited.

FSA/FSS has reviewed the EFSA opinion (EFSA Journal 2021;19(7):6703) and confirm that it is adequate for UK considerations and therefore a full safety assessment of this application was not performed by FSA and FSS. Please see the earlier section titled ‘Our safety assessment process’ to understand how and when we make use of EFSA opinions.

It is the FSA/FSS opinion that *Lactiplantibacillus plantarum* (IMI 507026), as described in this application, is safe and is not liable to have an adverse effect on the target species, worker safety, environmental safety and human health at the intended concentrations of use. The proposed terms of authorisation are set out below.

Any relevant provisions of retained EU law

Under the requirements of the Regulation for feed additives:
1. Article 16 and points 1(c), 1(e) and 2 of Annex III: Labelling and packaging requirements apply, if authorised.
2. Article 21: Analytical methods have been verified by the European Reference Laboratory as used for the control of *Lactiplantibacillus plantarum* (IMI 507026) in animal feed as detailed in the EURL analytical method evaluation report (FAD-2020-0078). Valid analytical methods exist for:

- the identification of the bacterial strain *L. plantarum* (IMI 507026)

- the enumeration (bacterial count) of the bacteria in the feed additive

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

Proposed terms of authorisation

1: Additive details

Additive category	(1) Technological additives
Functional group	(k) Silage additives
Feed additive	*Lactiplantibacillus plantarum* (IMI 507026)
ID No	1k21601
Target species	All animal species
Authorisation period	10 years from the date of authorisation

2: Additive composition

Solid preparation of *Lactiplantibacillus plantarum* (IMI 507026) containing a minimum of 1 x 1010 CFU/g additive

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

Viable cells of *Lactiplantibacillus plantarum* (IMI 507026)

4: Conditions of use

Species or category of animal	Maximum age	Colony-forming units of the additive/kg of fresh material:
All animal species	n/a	Minimum level: See Other Provisions at 5.2 below Maximum level: No maximum?

5: Other Provisions

1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated.?
2. Minimum content of the additive when not combined with other micro-organisms as silage additives: 1 x 109 CFU/kg of easy and moderately difficult to ensile fresh material.?

6: Analytical methods

For enumeration (colony count) of the feed additive:
Spread plate method on MRS agar (BS EN 15787:2021)

For identification of bacterial strain:
Pulsed Field Gel Electrophoresis (PFGE)

Other relevant information (separate to terms of authorisation)

1: 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.
- Definitions of silage, in accordance with Retained EU Regulation 429/2008:
  - Easy to ensile forage: >3 % soluble carbohydrates in fresh material.
  - Moderately difficult to ensile forage: 1.5-3.0% soluble carbohydrates in fresh material.
  - Difficult to ensile forage: <1.5 % soluble carbohydrates in the fresh material.
- Major animal species and their subgroups are defined in Annex IV of Retained EU Regulation 429/2008.

2: Recommendations

Lactiplantibacillus plantarum (IMI 507026) may be applied to fresh material (forage) as a solid preparation or aqueous solution.

Annex F: RP272 – Lactiplantibacillus plantarum as a feed additive for all animal species

Annex F: RP272 – Lactiplantibacillus plantarum (formerly Lactobacillus plantarum) (IMI 507027) as a feed additive for all animal species (All-Technology (Ireland) Limited) (new)

Background

Name of applicant:

All-Technology (Ireland) Limited

Address of applicant:

Sarney
Summerhill Road
A86X006
Dunboyne
Co. Meath
Ireland

FSA/FSS Safety Assessment

FSA/FSS has undertaken a safety assessment of application RP272 for the use of *Lactiplantibacillus plantarum* (IMI 507027) as a feed additive for all animal species, from All-Technology (Ireland) Limited

FSA/FSS has reviewed the EFSA opinion (EFSA Journal 2021;19(7):6704) and confirm that it is adequate for UK considerations and therefore a full safety assessment of this application was not performed by FSA and FSS. Please see the earlier section titled 'Our safety assessment process' to understand how and when we make use of EFSA opinions.

It is the FSA/FSS opinion that *Lactiplantibacillus plantarum* (IMI 507027), as described in this application, is safe and is not liable to have an adverse effect on the target species, worker safety, environmental safety and human health at the intended concentrations of use. The proposed terms of authorisation are set out below.

Any relevant provisions of retained EU law

Under the requirements of the Regulation for feed additives:

1. Article 16 and points 1(c), 1(e) and 2 of Annex III: Labelling and packaging requirements apply, if authorised.
2. Article 21: Analytical methods have been verified by the European Reference Laboratory as used for the control of *Lactiplantibacillus plantarum* (IMI 507027) in animal feed as detailed in the EURL analytical method evaluation report (FAD-2020-0079). Valid analytical methods exist for:

- The identification of the bacterial strain *L. Plantarum* (IMI 507027)
- the enumeration (bacterial count) of the bacteria in the feed additive

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

Proposed terms of authorisation

1: Additive details

Additive category	(1) Technological additives
Functional group	(k) Silage additives
Feed additive	*Lactiplantibacillus plantarum* (IMI 507027)
ID No	1k21602
Target species	All animal species
Authorisation period	10 years from the date of authorisation

2: Additive composition

Solid preparation of *Lactiplantibacillus plantarum* (IMI 507027) containing a minimum of 1 x 1010 CFU/g additive

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

Viable cells of *Lactiplantibacillus plantarum* (IMI 507027)

4: Conditions of use

Species or category of animal	Maximum age	Colony-forming units of the additive/kg of fresh material:
All animal species	n/a	Minimum level: See Other Provisions at 5.2 below Maximum level: No maximum?

5: Other Provisions

1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated.?
2. Minimum content of the additive when not combined with other micro-organisms as silage additives: 1 x 109 CFU/kg of easy and moderately difficult to ensile fresh material.?

6: Analytical methods

For enumeration (colony count) of the feed additive:
Spread plate method on MRS agar (BS EN 15787:2021)

For identification of bacterial strain:
Pulsed Field Gel Electrophoresis (PFGE)

Other relevant information (separate to terms of authorisation)

1: 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.
- Definitions of silage, in accordance with Retained EU Regulation 429/2008:
    - Easy to ensile forage: >3 % soluble carbohydrates in fresh material.
    - Moderately difficult to ensile forage: 1.5-3.0% soluble carbohydrates in fresh material.
    - Difficult to ensile forage: <1.5 % soluble carbohydrates in the fresh material.
- Major animal species and their subgroups are defined in Annex IV of Retained EU Regulation 429/2008.

2: Recommendations

Lactiplantibacillus plantarum (IMI 507027) may be applied to fresh material (forage) as a solid preparation or aqueous solution.

Annex G: RP273 - Lactiplantibacillus plantarum as a feed additive for all animal species

Annex G: RP273 - Lactiplantibacillus plantarum (formerly Lactobacillus plantarum) (IMI 507028) as a feed additive for all animal species (All-Technology (Ireland) Limited) (new)

Background

Name of applicant:

All-Technology (Ireland) Limited

Address of applicant:

Sarney
Summerhill Road
A86X006
Dunboyne
Co. Meath
Ireland

FSA/FSS Safety Assessment

FSA/FSS has undertaken a safety assessment of application RP273 for the use of I (IMI 507028) as a feed additive for all animal species, from All-Technology (Ireland) Limited.

FSA/FSS has reviewed the EFSA opinion (EFSA Journal 2021;19(7):6705) and confirm that it is adequate for UK considerations and therefore a full safety assessment of this application was not performed by FSA and FSS. Please see the earlier section titled ‘Our safety assessment process’ to understand how and when we make use of EFSA opinions.

It is the FSA/FSS opinion that I (IMI 507028), as described in this application, is safe and is not liable to have an adverse effect on the target species, worker safety, environmental safety and human health at the intended concentrations of use. The proposed terms of authorisation are set out below.

Any relevant provisions of retained EU law

Under the requirements of the Regulation for feed additives:

1. Article 16 and points 1(c), 1(e) and 2 of Annex III: Labelling and packaging requirements apply, if authorised.
2. Article 21: Analytical methods have been verified by the European Reference Laboratory as used for the control of *Lactiplantibacillus plantarum* (IMI 507028) in animal feed as detailed in the EURL analytical method evaluation report (FAD-2020-0080). Valid analytical methods exist for:

- the identification of the bacterial strain *L. plantarum* (IMI 507028).
- the enumeration (bacterial count) of the bacteria in the feed additive.

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

Proposed terms of authorisation

1: Additive details

Additive category	(1) Technological additives
Functional group	(k) Silage additives
Feed additive	*Lactiplantibacillus plantarum* (IMI 507028)
ID No	1k21603
Target species	All animal species
Authorisation period	10 years from the date of authorisation

2: Additive composition

Solid preparation of *Lactiplantibacillus plantarum* (IMI 507028) containing a minimum of 1 x 1010 CFU/g additive

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

Viable cells of *Lactiplantibacillus plantarum* (IMI 507028)

4: Conditions of use

Species or category of animal	Maximum age	Colony-forming units of the additive/kg of fresh material:
All animal species	n/a	Minimum level: See Other Provisions at 5.2 below Maximum level: No maximum

5: Other Provisions

1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated.
2. Minimum content of the additive when not combined with other micro-organisms as silage additives: 1 x 109 CFU/kg of easy and moderately difficult to ensile fresh material.

6: Analytical methods

For enumeration (colony count) of the feed additive:
Spread plate method on MRS agar (BS EN 15787:2021)

For identification of bacterial strain:
Pulsed Field Gel Electrophoresis (PFGE)

Other relevant information (separate to terms of authorisation)

1: 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.
- Definitions of silage, in accordance with Retained EU Regulation 429/2008:
    - Easy to ensile forage: >3 % soluble carbohydrates in fresh material.
    - Moderately difficult to ensile forage: 1.5-3.0% soluble carbohydrates in fresh material.

    - Difficult to ensile forage: <1.5 % soluble carbohydrates in the fresh material.
- Major animal species and their subgroups are defined in Annex IV of Retained EU Regulation 429/2008.

2: Recommendations

Lactiplantibacillus plantarum (IMI 507028) may be applied to fresh material (forage) as a solid preparation or aqueous solution.

Annex H: RP687 - Lactiplantibacillus plantarum as a feed additive for all animal species

Annex H: RP687 - Lactiplantibacillus plantarum (formerly Lactobacillus plantarum) (DSM 26571) as a feed additive for all animal species (Chr. Hansen A/S) (new)

Background

Name of applicant:

Chr. Hansen A/S

Address of applicant:

10-12 Boege Allé
2970
Hoersholm
Denmark

FSA/FSS Safety Assessment

FSA/FSS has undertaken a safety assessment of application RP687 for the use of *Lactiplantibacillus plantarum* (DSM 26571) as a feed additive for all animal species, from Chr. Hansen A/S.

FSA/FSS has reviewed the EFSA opinion (EFSA Journal 2021;19(10):6898) and confirm that it is adequate for UK considerations and therefore a full safety assessment of this application was not performed by FSA and FSS. Please see the earlier section titled ‘Our safety assessment process’ to understand how and when we make use of EFSA opinions.

It is the FSA/FSS opinion that *Lactiplantibacillus plantarum* (DSM 26571), as described in this application, is safe and is not liable to have an adverse effect on the target species, worker safety, environmental safety and human health at the intended concentrations of use. The proposed terms of authorisation are set out below.

Any relevant provisions of retained EU law

Under the requirements of the Regulation for feed additives:

1. Article 16 and points 1(c), 1(e) and 2 of Annex III: Labelling and packaging requirements apply, if authorised.
2. Article 21: Analytical methods have been verified by the European Reference Laboratory as used for the control of *Lactiplantibacillus plantarum* (DSM 26571) in animal feed as detailed in the EURL analytical method evaluation report (FAD-2019-0091). Valid analytical methods exist for:

- The identification of the bacterial strain *L. Plantarum* (DSM 26571)
- the enumeration (bacterial count) of the bacteria in the feed additive.

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

Proposed terms of authorisation

1: Additive details

Additive category	(1) Technological additives
Functional group	(k) Silage additives
Feed additive	*Lactiplantibacillus plantarum* (DSM 26571)
ID No	1k1604
Target species	All animal species
Authorisation period	10 years from the date of authorisation

2: Additive composition

Solid preparation of *Lactiplantibacillus plantarum* (DSM 26571) containing a minimum of 1 x 1011 CFU/g additive.

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

Viable cells of *Lactiplantibacillus plantarum* (DSM 26571)

4: Conditions of use

Species or category of animal	Maximum age	Colony-forming units of the additive/kg of fresh material:
All animal species	n/a	Minimum level: See Other Provisions at 5.2 below Maximum level: No maximum

5: Other Provisions

1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated.
2. Minimum content of the additive when not combined with other micro-organisms as silage additives: 1 x 108 CFU/kg of easy, moderately difficult and difficult to ensile fresh material.

6: Analytical methods

For enumeration (colony count) of the feed additive:
Spread plate method on MRS agar (BS EN 15787:2021)

For identification of bacterial strain:
Pulsed Field Gel Electrophoresis (PFGE)

Other relevant information (separate to terms of authorisation)

1: 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.
- Definitions of silage, in accordance with Retained EU Regulation 429/2008:
  - Easy to ensile forage: >3 % soluble carbohydrates in fresh material.
  - Moderately difficult to ensile forage: 1.5-3.0% soluble carbohydrates in fresh material.
  - Difficult to ensile forage: <1.5 % soluble carbohydrates in the fresh material.
- Major animal species and their subgroups are defined in Annex IV of Retained EU Regulation 429/2008.

Annex I: RP954 - Endo-1,4-beta-xylanase produced by Trichoderma reesei as a feed additive for piglets (weaned), chickens for fattening, chickens reared for laying, turkeys for fattening and turkeys reared for breeding

Annex I: RP954 - Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by Trichoderma reesei (CBS 114044) as a feed additive for piglets (weaned), chickens for fattening, chickens reared for laying, turkeys for fattening and turkeys reared for breeding (Econase® XT) (Roal Oy) (renewal)

Background

Name of applicant:

Roal Oy

Address of applicant:

Tykkimäentie 15b
05200
Rajamäki
Finland

FSA/FSS Safety Assessment

FSA/FSS has undertaken a safety assessment of application RP954 for the renewal of use of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* (CBS 114044) (Econase® XT) as a feed additive for piglets (weaned), chickens for fattening, chickens reared for laying, turkeys for fattening and turkeys reared for breeding, from Roal Oy.

FSA/FSS has reviewed the EFSA opinions (EFSA Journal 2021;19(2):6458 and EFSA Journal 2019;17(11):5880) and confirms that it is adequate for UK considerations and, therefore, a full safety assessment of this application was not performed. Please see the earlier section titled 'Our safety assessment process' to understand how and when we make use of EFSA opinions.

The FSA/FSS opinion is that endo-1,4-beta-xylanase (EC 3.2.1.8) (Econase® XT), as described in this application, is safe and is not liable to have an adverse effect on the target species, worker safety, environmental safety and human health at the intended concentrations of use. The proposed terms of authorisation are set out below.

Any relevant provisions of retained EU law

Under the requirements of the Regulation for feed additives:

1. Article 16 and points 1(a) and 1(b) of Annex III: Labelling and packaging requirements apply, if authorised.
2. Article 21: Analytical methods have been verified by the European Reference Laboratory as used for the control of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 114044) (Econase® XT) in animal feed as detailed in the EURL analytical method evaluation report (FAD-2018-0071). Valid analytical methods exist for:

- the quantification of endo-1,4-beta-xylanase in the feed additive, premixtures, feed materials and compound feed

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

Proposed terms of authorisation

1: Additive details

Additive category	(4) Zootechnical additives
Functional group	(a) digestibility enhancers
Feed additive	Endo-1,4-beta-xylanase (EC 3.2.1.8)
ID No	4a8
Target species	Piglets (weaned), chickens for fattening, chickens reared for laying, turkeys for fattening and turkeys reared for breeding
Authorisation Holder	Roal Oy
Authorisation	10 years from the date of authorisation period

2: Additive composition

Preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by fermentation with *Trichoderma reesei* (CBS 114044) having a minimum activity of 1.6 x 105 BXU/g for both solid and liquid forms:

Form	Activity (BXU = endo-1,4-beta-xylanase units)*
Solid (P) forms	800 000 BXU/g (new formulation) 160 000 BXU/g (new formulation) 4 000 000 BXU/g
Liquid (L) forms	160 000 BXU/g (new formulation) 400 000 BXU/g

*[Enzyme activity expressed in birchwood xylanase units (BXU), where one BXU is the amount of enzyme which liberates 1 nanomole of reducing sugars as xylose from birch xylan per second at pH 5.3, and 50°C.

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

Endo-1,4-beta-xylanase produced by fermentation of *Trichoderma reesei* (CBS 114044)

- EC (IUBMB) number: 3.2.1.8
- EINECS number: 232-800-2
- CAS number: 9025-57-4

4: Conditions of use

Species or category of animal	Maximum age	Content of endo-1,4-beta-xylanase (units of activity/kg of complete feed with a moisture content of 12%)
Chickens for fattening, chickens reared for laying	n/a	Minimum level: 8,000 BXU Maximum level: No Maximum
Turkeys for fattening, turkeys reared for breeding	n/a	Minimum level: 16,000 BXU Maximum level: No Maximum
Piglets (weaned)	n/a	Minimum level: 24,000 BXU Maximum level: No Maximum

5: Other Provisions

1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.

6: Analytical methods

For the quantification of endo-1,4-beta-xylanase in the feed additive and premixtures: Colorimetric method based the enzymatic reaction of endo-1,4-beta-xylanase on the birch xylan substrate at pH 5.3 and 50°C.

For the quantification of endo-1,4-beta-xylanase in feed materials and compound feed: Colorimetric method based the enzymatic reaction of endo-1,4-beta-xylanase on the azurine cross-linked wheat arabinoxylan substrate at pH 5.3 and 50°C.

Other relevant information (separate to terms of authorisation)

1: 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.
- for use in feed for piglets (weaned) up to 35 kg body weight.
- Major animal species and their subgroups are defined in Annex IV of Retained EU Regulation 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 Retained EU Regulation 183/2005 ‘Feed Hygiene Regulation’ and Good Manufacturing Practice.

2: Recommendations

For use in compound feed rich in non-starch polysaccharides, mainly arabinoxylans (e.g., containing more than 20% wheat).

Annex J: RP955 - 6-phytase produced by Trichoderma reesei as a feed additive for all pigs and poultry

Annex J: RP955 - 6-phytase (EC 3.1.3.26) produced by Trichoderma reesei (CBS 122001) as a feed additive for all pigs and poultry (Finase® EC) (Roal Oy) (renewal)

Background

Name of applicant:

Roal Oy

Address of applicant:

Tykkimäentie 15b

05200

Rajamäki

Finland

FSA/FSS Safety Assessment

FSA/FSS has undertaken a safety assessment of application RP955 for the renewal of use of 6? phytase (EC 3.1.3.26) produced by *Trichoderma reesei* (CBS 122001) (Finase® EC) as a feed additive for pigs and poultry, from Roal Oy.

FSA/FSS has reviewed the EFSA opinion (EFSA Journal 2020;18(12):6336) and confirm that it is adequate for UK considerations and therefore a full safety assessment of this application was not performed by FSA and FSS. Please see the earlier section titled ‘Our safety assessment process’ to understand how and when we make use of EFSA opinions.

It is the FSA/FSS opinion that 6-phytase (EC 3.1.3.26) (Finase® EC), as described in this application, is safe and is not liable to have an adverse effect on the target species, worker safety, environmental safety and human health at the intended concentrations of use. The proposed terms of authorisation are set out below.

Any relevant provisions of retained EU law

Under the requirements of the Regulation for feed additives:

1. Article 16 and points 1(a) and 1(c) of Annex III: Labelling and packaging requirements apply, if authorised.

2. Article 21: Analytical methods have been verified by the European Reference Laboratory as used for the control of 6-phytase produced by *Trichoderma reesei* (CBS 122001) in animal feed as detailed in the EURL analytical method evaluation report (FAD-2008-0040). Valid analytical methods exist for:

- the quantification of 6-phytase activity in the feed additive, premixtures, feed materials and compound feed.

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

Proposed terms of authorisation

1: Additive details

Additive category	(4) Zootechnical additives
Functional group	(a) Digestibility enhancers
Feed additive	6-phytase (EC 3.1.3.26)
ID No	4a12
Target species	All pigs and poultry
Authorisation Holder	Roal Oy
Authorisation period	10 years from the date of authorisation

2: Additive composition

Preparation of 6-phytase (EC 3.1.3.26) produced by *Trichoderma reesei* (CBS 122001) having a minimum activity of 4 x 10? PPU/g for the solid form and 5 x 10^3 PPU/g for the liquid forms:

Form	Activity (PPU = phytase units)*
Solid form	40 000 PPU/g
Liquid forms	5 000 PPU/g (new formulation) 10 000 PPU/g

* Enzyme activity is expressed in PPU units, where one PPU is the amount of enzyme which liberates 1 micromole (?mol) of inorganic phosphate from sodium phytate per minute at pH 5.0 and 37°C]

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

6-phytase (EC 3.1.3.26) produced by?fermentation with *Trichoderma reesei*? (CBS 122001)

- EC (IUBMB) no: 3.1.3.26
- CAS no: 9001-89-2
- EINECS no: 232-630-9

4: Conditions of use

Species or category of animal?	Maximum age?	Content of 6-phytase?(units of activity/kg of complete feed with a moisture content of 12%)?
Pigs Poultry for fattening, poultry for breeding.	n/a	Minimum level: 250 PPU Maximum level:?No maximum
Poultry for laying	n/a	Minimum level: 125 PPU Maximum level:?No maximum

5: Other provisions

1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.?

6: Analytical methods

For the quantification of phytase activity in the feed additive, premixtures, feed materials and compound feed:??

Colorimetric method quantifying the activity of 6-phytase by measuring released inorganic phosphate from sodium phytate by analysing the colour formed by reduction of a phosphomolybdate complex.

7:?Transition?period?arrangements

As regards the feed additive composition, minor improvements were made during manufacturing which do not affect safety, however it is our view that it is appropriate to provide transitional periods to meet new requirements (i.e., on labelling).

A proposal for transitional?arrangements?is?set out?below?for the existing?feed additive? authorisation for pigs and poultry?(where all pig and poultry sub-groups?are?defined as food-producing animals).

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

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

Other relevant information (separate to terms of authorisation)

1: 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.
- major animal species and their subgroups are defined in Annex IV of Retained EU Regulation 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 Retained EU Regulation 183/2005 ‘Feed Hygiene Regulation’ and Good Manufacturing Practice.

2: Recommendations

- The maximum recommended level of 6-phytase in all species/ categories is 1,000 PPU/kg complete feed.
- For use in feed containing more than 0.23% phytin-bound phosphorus.? ?

Annex K: RP1052a - L-lysine monohydrochloride produced by Corynebacterium glutamicum as a feed additive for all animal species

Annex K: RP1052a - L-lysine monohydrochloride produced by Corynebacterium glutamicum (KCCM 80216 or KCTC 12307BP) as a feed additive for all animal species (Daesang Europe B.V.) (new)?

Background

Name of applicant:

Daesang Europe B.V.

Address of applicant:

Van Heuven Goedhartlaan 935

1181 LD

Amstelveen

The Netherlands

FSA/FSS Safety Assessment

FSA/ FSS has undertaken a safety assessment of application RP1052a for the use of L-lysine monohydrochloride produced by fermentation with *Corynebacterium glutamicum* (KCCM 80216 or KCTC 12307BP) as a feed additive for all animal species, from Daesang Europe B.V.

FSA/FSS has reviewed the EFSA opinions (EFSA Journal 2020;18(12):6334 and EFSA Journal 2020;18(12):6333) and confirm that they are adequate for UK considerations and therefore a full safety assessment of this application was not performed by FSA and FSS. Please see the earlier section titled ‘Our safety assessment process’ to understand how and when we make use of EFSA opinions.

It is the FSA/FSS opinion that L-lysine monohydrochloride additive, as described in this application, is safe and is not liable to have an adverse effect on the target species, worker safety, environmental safety and human health at the intended concentrations of use. The proposed terms of authorisation are set below.

Any relevant provisions of retained EU law

Under the requirements of the Regulation for feed additives:

1. Article 16 and point 1(d) of Annex III: Labelling and packaging of feed additives and premixtures

2. Article 21: Analytical methods have been verified by the European Reference Laboratory as used for the control of L-lysine monohydrochloride in animal feed as detailed in the EURL analytical method evaluation reports (FAD-2020-0008).

- Valid analytical methods exist for: the identification of L-lysine monohydrochloride in the feed additive
- the quantification of L-lysine in the feed additive, premixtures, feed materials, compound feed and water.

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

Proposed terms of authorisation

1: Additive details

Category	Details
Additive category	(3) Nutritional feed additives

Category	Details
Functional group	(c) Amino acids, their salts and analogues
Feed additive	L?lysine monohydrochloride
ID No	3c327
Target species	All animal species
Authorisation Holder	Daesang Europe B. V.
Authorisation period	10 years from the date of authorisation

2: Additive composition

Component???	Contents???
L-lysine monohydrochloride (technically pure)	Powder with a minimum of 78% L-lysine and a maximum moisture content of 1.5%.?

3: Characterisation / identification of the active substance

L-lysine monohydrochloride produced by fermentation with *Corynebacterium glutamicum* (KCCM 80216 or KCTC 12307BP).

- L-lysine monohydrochloride (C?H??ClN?O?)
- CAS no: 657-27-2
- EINECS no: 211-519-9

4: Conditions of use

Species or category of animal?	Maximum age?	Content of L-lysine monohydrochloride (mg/kg of complete feed with a moisture content of 12%)?
All animal species?	n/a	Minimum level: No minimum? Maximum level:?No maximum?

5: Other Provisions

1. The lysine content shall be indicated on the labelling of the additive.
2. L-lysine monohydrochloride (technically pure) may be placed on the market and used as an additive consisting of a preparation.

6: Analytical methods

For the identification of L-lysine monohydrochloride in the feed additive:

Food Chemical Codex "L-lysine monohydrochloride monograph".

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) – BS EN ISO 17180:2013.

For the quantification of lysine in premixtures, feed materials and compound feed:

Ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) - Annex III, F of Retained EU Regulation 152/2009 (Determination of Amino Acids (Except Tryptophan)).

For the quantification of lysine in water:

The EURL considered the following methods for the potential determination of lysine in water (as for other authorised sources of lysine):

- Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) - BS EN ISO 17180:2013.; or
- Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS) - Annex III, F of Retained EU Regulation 152/2009 (Determination of Amino Acids (Except Tryptophane)).

Other relevant information (separate to terms of authorisation)

1: Supplementary information

- Feed additives are subject to UK health and safety legislation. The safety assessment identified no specified hazards.
- Major animal species and their subgroups are defined in Annex IV of Retained EU Regulation 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 Retained EU Regulation 183/2005 ‘Feed Hygiene Regulation’ and Good Manufacturing Practice.

Annex L: RP1052b - L-lysine base (liquid) produced by Corynebacterium glutamicum as a feed additive for all animal species?

Annex L: RP1052b - L-lysine base (liquid) produced by Corynebacterium glutamicum (KCCM 80216 or KCTC 12307BP) as a feed additive for all animal species (Daesang Europe B.V.) (new) ?

Background?

Name of applicant:

Daesang Europe B.V.

Address of applicant:

Van Heuven Goedhartlaan 935

1181 LD

Amstelveen

The Netherlands

FSA/FSS Safety Assessment

FSA/ FSS has undertaken a safety assessment of application RP1052b for the use of L-lysine base (liquid) produced by fermentation with *Corynebacterium glutamicum* (KCCM 80216 or KCTC 12307BP) as a feed additive for all animal species, from Daesang Europe B. V.

FSA/FSS has reviewed the EFSA opinions (EFSA Journal 2020;18(12):6334 and EFSA Journal 2020;18(12):6333) and confirm that they are adequate for UK considerations and therefore a full safety assessment of this application was not performed by FSA and FSS. Please see the earlier section titled ‘Our safety assessment process’ to understand how and when we make use of EFSA opinions.

The FSA/FSS opinion is that L-lysine base (liquid) additive, as described in this application, is safe and is not liable to have an adverse effect on the target species, worker safety, environmental safety and human health at the intended concentrations of use. The proposed terms of authorisation are set below.

Any relevant provisions of retained EU law

Under the requirements of the Regulation for feed additives:

1. Article 16 and point 1(d) of Annex III: Labelling and packaging of feed additives and premixtures

2. 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 reports (FAD-2020-0008). Valid analytical methods exist for:

- the quantification of L-lysine in the feed additive, premixtures, feed materials, compound feed and water.

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

Proposed terms of authorisation

1: Additive details

Category	Details
Additive category	(3) Nutritional feed additives
Functional group	(c) Amino acids, their salts and analogues

Category	Details
Feed additive	L?lysine base (liquid)
ID No	3c326
Target species	All animal species
Authorisation Holder	Daesang Europe B. V.
Authorisation period	10 years from the date of authorisation

2: Additive composition

Component???	Contents???
L-lysine base (liquid)	Aqueous solution with a minimum of 50% L-lysine

3: Characterisation / identification of the active substance

L-lysine base (liquid) produced by fermentation with Corynebacterium glutamicum (KCCM 80216 or KCTC 12307BP).

- L-lysine (C?H??N?O?)
- CAS no: 56-87-1
- EINECS no: 200-294-2

4: Conditions of use

Species or category of animal?	Maximum age?	Content of L-lysine (mg/kg of complete feed with a moisture content of 12%)?
All animal species?	n/a	Minimum level: No minimum? Maximum level:?No maximum?

5: Other Provisions

1. The lysine content shall be indicated on the labelling of the additive.
2. L-lysine base (liquid) may be placed on the market and used as an additive consisting of a preparation.

6: Analytical methods

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) – BS EN ISO 17180:2013.

For the quantification of lysine in premixtures, feed materials and compound feed:

Ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) - Annex III, F of Retained EU Regulation 152/2009 (Determination of Amino Acids (Except Tryptophane)).

For the quantification of lysine in water:

The EURL considered the following methods for the potential determination of lysine in water (as for other authorised sources of lysine):

- Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) - BS EN ISO 17180:2013.; or
- Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS) - Annex III, F of Retained EU Regulation 152/2009 (Determination of Amino Acids (Except Tryptophan)).

Other relevant information (separate to terms of authorisation)

1: Supplementary information

Feed additives are subject to UK health and safety legislation. The safety assessment identified no specified hazards.

Major animal species and their subgroups are defined in Annex IV of Retained EU Regulation 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 Retained EU Regulation 183/2005 ‘Feed Hygiene Regulation’ and Good Manufacturing Practice.

Annex M: RP1059 - 3-nitrooxypropanol as a feed additive for ruminants for milk production and for reproduction

Annex M: RP1059 - 3-nitrooxypropanol as a feed additive for ruminants for milk production and for reproduction (Bovaer® 10) DSM Nutritional Products Ltd., Switzerland (new)

Background

Name of applicant:

DSM Nutritional Products Ltd., in Switzerland

Address of applicant:

Wurmigsweg 576

4303

Kaiseraugst

Switzerland

FSA/FSS Safety Assessment:

FSA/FSS has undertaken a safety assessment of?application RP1059 for the use of 3-nitrooxypropanol (3-NOP) (Bovaer® 10) as a feed additive for ruminants (for example, cattle, sheep, goats) for milk production and for reproduction, from DSM Nutritional Products Ltd., Switzerland.

The application was evaluated by our independent Animal Feed and Feed Additives Joint Expert Group (AFFAJEG) and the Advisory Committee on Animal Feedingstuffs (ACAF). The FSA/FSS safety assessment was published on 31 March 2023 and can be found here. The assessment of 3-nitrooxypropanol shows that the conditions for authorisation in Article 5 of the Regulation are satisfied.

The FSA/FSS opinion is that 3-nitrooxypropanol, 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 and under the proposed terms of authorisation. The proposed terms of authorisation are set out below.

Any relevant provisions of retained EU law

Under the requirements of the Regulation for feed additives:?

1. Article 16 and points 1(a) of Annex III: Labelling and packaging?requirements apply, if authorised.

2. Article 21: Analytical methods have been verified by the European Reference Laboratory (EURL) as used for the control of 3-nitrooxypropanol in animal feed as detailed in the EURL analytical method evaluation report (FAD-2019-0057). FSA/FSS?has?reviewed?the (EURL) evaluation report and determined the analytical method as appropriate for official controls for this feed additive. Valid analytical methods exist for:

- the quantification of 3-nitrooxypropanol activity in the feed additive, premixtures, feed materials and compound feed.

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

Conclusions from the Safety Assessment:

The FSA/FSS?conclusion?on?3-nitrooxypropanol (Bovaer® 10) is that:??

- the additive is safe for the proposed target species under the conditions of use at a maximum dose of 200 mg/kg of dry matter.
- the feed additive is considered safe for consumers and the environment.
- 3-nitrooxypropanol is considered efficacious for reducing methane production in ruminants when fed daily at the proposed dose.
- On worker safety, the additive is to be considered an eye and skin irritant but not a skin sensitiser and a respiratory sensitiser.

Proposed terms of authorisation:

1:?Additive details

Category	Details
Additive category??	(4) Zootechnical
Functional group??	(c) Substances which favourably affect the environment
Feed additive??	3-nitrooxypropanol
ID No??	4c1
Target species??	Ruminants for milk production and reproduction
Authorisation Holder?	DSM Nutritional Products Ltd., Switzerland
Authorisation period??	10 years from the date of?authorisation?

2: Additive composition

Component???	Contents???
3-nitrooxypropanol	Preparation with a minimum of 10% of 3-nitrooxypropanol 0.4% of particles with diameter < 50µm

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

- 3-nitrooxypropanol (Propan-1,3-diol-mononitrate) (C?H?NO?)
- CAS no: 100502-66-7.

4: Conditions of use

Species or category of animal???	Maximum age???	Content of?3-nitrooxypropanol (mg/kg of complete feed?with a moisture content of 12%)?
Ruminants for milk production and for reproduction	n/a	Minimum level: 53 Maximum level: 88

5:?Other?Provisions?

1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.
2. The additive shall be incorporated into feed in the form of a premixture.

6:?Analytical?methods?

For quantification of 3-nitrooxypropanol in the feed additive, premixtures, feed materials and compound feed:

Reversed phase high performance liquid chromatography with spectrophotometric detection (HPLC-UV).

Other relevant information (separate to terms of authorisation)

1: Supplementary information

- Feed additives are subject to UK health and safety legislation. The risk assessment identified that particular consideration should be given to hazards as a:

- skin and eye irritant

- respiratory sensitiser.

- The FSA/FSS consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in Retained EU Regulation 183/2005 ‘Feed Hygiene Regulation’ and Good Manufacturing Practice.
- Main animal species and their subgroups are defined in Annex IV of Retained EU Regulation 429/2008.

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