

FSS opinions on feed additive applications for use in animal feed

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## Document subject and purpose

In this document we publish Food Standards Scotland’s (FSS) opinions on applications for 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 Scottish Ministers may want to consider before making a decision regarding authorisation.

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

The FSS opinion for each feed additive is published within a separate annex, including the regulated product ID number and title of the application. Links to the individual safety assessments are provided in each Annex.

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

**Matthew Mullen**

**Policy Officer**

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**Food Standards Scotland**

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**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 digestibility enhancer 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

**FSS/FSA Safety Assessment**

FSS/FSA 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.

FSS/FSA has reviewed the EFSA opinion ([**EFSA Journal 2021;**0(0):6539](https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2021.6539)) and confirm that it is adequate for UK considerations and therefore a full safety assessment of this application was not performed by FSS/FSA.

The FSS/FSA 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 REUL 1831/2003 for feed additives:

1. [Article 16](https://www.legislation.gov.uk/eur/2003/1831/article/16/adopted) and points 1(a) and 1(b) of [Annex III:](https://www.legislation.gov.uk/eur/2003/1831/annex/III/adopted) Labelling and packaging requirements apply, if authorised.
2. [Article 21](https://www.legislation.gov.uk/eur/2003/1831/article/21): Analytical methods have been verified by the European Reference Laboratory as used for the control of Endo-1,4-beta-xylanaseproduced by  *Trichoderma reesei* (CBS 143953) in animal feed as detailed in the EURL analytical method evaluation report ([FAD-2010-0007](https://joint-research-centre.ec.europa.eu/publications/fad-2010-0007_en)). Valid analytical methods exist for:

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

1. [Annex IV](https://www.legislation.gov.uk/eur/2003/1831/annex/IV/adopted): The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

**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 (μmol) 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](https://www.legislation.gov.uk/eur/2008/429/annex/IV) of REUL 429/2008.
* The FSS/FSA consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in REUL 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).

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**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

**FSS/FSA Safety Assessment**

FSS/FSA 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.

FSS/FSA has reviewed the EFSA opinion ([**EFSA Journal 2021;**19(7):6700](https://www.efsa.europa.eu/en/efsajournal/pub/6700)) and confirmed that it is adequate for UK considerations and, therefore, a full safety assessment of this application was not performed by FSS/FSA. Please see the earlier section titled ‘[Our safety assessment process](#Bookmark1)’ to understand how and when we make use of EFSA opinions.

The FSS/FSA 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 REUL 1831/2003 for feed additives:

1. [Article 16](https://www.legislation.gov.uk/eur/2003/1831/article/16/adopted) and points 1(c), 1(e) and 2 of [Annex III](https://www.legislation.gov.uk/eur/2003/1831/annex/III/adopted): Labelling and packaging requirements apply, if authorised.
2. [Article 21](https://www.legislation.gov.uk/eur/2003/1831/article/21): Analytical methods have been verified by the European Reference Laboratory as used for the control of *L*a*cticaseibacillus rhamnosus* (IMI 507023) in animal feed as detailed in the EURL analytical method evaluation report ([FAD-2020-0075](https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2020-0075007800790080?search&form-return)). 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.

1. [Annex IV:](https://www.legislation.gov.uk/eur/2003/1831/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 REUL 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](https://www.legislation.gov.uk/eur/2008/429/annex/IV) of REUL 429/2008

**2: Recommendations**

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

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**Annex C: RP267 - *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

**FSS/FSA Safety Assessment**

FSS/FSA 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.

FSS/FSA has reviewed the EFSA opinion ([**EFSA Journal 2021;**19(7):6701](https://www.efsa.europa.eu/en/efsajournal/pub/6701)) and confirms that it is adequate for UK considerations and, therefore, a full safety assessment of this application was not performed by FSS and FSA. Please see the earlier section titled ‘[Our safety assessment process](#Bookmark1)’ to understand how and when we make use of EFSA opinions.

FSS/FSA 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 REUL 1831/2003 for feed additives:

1. [Article 16](https://www.legislation.gov.uk/eur/2003/1831/article/16/adopted) and points 1(c), 1(e) and 2 of [Annex III](https://www.legislation.gov.uk/eur/2003/1831/annex/III/adopted): Labelling and packaging requirements apply, if authorised.
2. [Article 21](https://www.legislation.gov.uk/eur/2003/1831/article/21): Analytical methods have been verified by the European Reference Laboratory as used for the control of *P*e*diococcus pentosaceus (I*MI 507024) in animal feed as detailed in the EURL analytical method evaluation report ([FAD-2020-0076](https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2020-00760077?search&form-return)). 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

1. [Annex IV](https://www.legislation.gov.uk/eur/2003/1831/annex/IV/adopted): The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

### 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 REUL 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](https://www.legislation.gov.uk/eur/2008/429/annex/IV) of REUL 429/2008.

**2: Recommendations**

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

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**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

**FSS/FSA Safety Assessment**

FSS/FSA 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.

FSS/FSA has reviewed the EFSA opinion ([**EFSA Journal 2021;**19(7):6702](https://www.efsa.europa.eu/en/efsajournal/pub/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 section titled ‘Our safety assessment process’ in the Consultation Letter to understand how and when we make use of EFSA opinions.

The FSS/FSA 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 REUL 1831/2003 for feed additives:

1. [Article 16](https://www.legislation.gov.uk/eur/2003/1831/article/16/adopted) and points 1(c), 1(e) and 2 of [Annex III](https://www.legislation.gov.uk/eur/2003/1831/annex/III/adopted): Labelling and packaging requirements apply, if authorised.
2. [Article 21](https://www.legislation.gov.uk/eur/2003/1831/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](https://joint-research-centre.ec.europa.eu/publications/fad-2020-00760077_en)). 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

1. [Annex IV](https://www.legislation.gov.uk/eur/2003/1831/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 1010CFU/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 REUL 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](https://www.legislation.gov.uk/eur/2008/429/annex/IV) of REUL 429/2008.

**2: Recommendations**

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

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**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

**FSS/FSA Safety Assessment**

FSS/FSA 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.

FSS/FSA has reviewed the EFSA opinion ([**EFSA Journal 2021;**19(7):6703](https://www.efsa.europa.eu/en/efsajournal/pub/6703)) and confirm that it is adequate for UK considerations and therefore a full safety assessment of this application was not performed by FSS and FSA. Please see the section titled ‘Our safety assessment process’ in the Consultation Letter to understand how and when we make use of EFSA opinions.

It is the FSS/FSA 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 REUL 1831/2003 for feed additives:

1. [Article 16](https://www.legislation.gov.uk/eur/2003/1831/article/16/adopted) and points 1(c), 1(e) and 2 of [Annex III](https://www.legislation.gov.uk/eur/2003/1831/annex/III/adopted): Labelling and packaging requirements apply, if authorised.
2. [Article 21](https://www.legislation.gov.uk/eur/2003/1831/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](https://joint-research-centre.ec.europa.eu/publications/fad-2020-0075007800790080_en)). 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

1. [Annex IV](https://www.legislation.gov.uk/eur/2003/1831/annex/IV/adopted): The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

### 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 1010CFU/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 REUL 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](https://www.legislation.gov.uk/eur/2008/429/annex/IV) of REUL 429/2008.

**2: Recommendations**

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

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**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

**FSS/FSA Safety Assessment**

FSS/FSA 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

FSS/FSA has reviewed the EFSA opinion ([**EFSA Journal 2021;**19(7):6704](https://www.efsa.europa.eu/en/efsajournal/pub/6704)) and confirm that it is adequate for UK considerations and therefore a full safety assessment of this application was not performed by FSS and FSA. Please see the section titled ‘Our safety assessment process’ in the Consultation Letter to understand how and when we make use of EFSA opinions.

It is the FSS/FSA 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 REUL 1831/2003 for feed additives:

1. [Article 16](https://www.legislation.gov.uk/eur/2003/1831/article/16/adopted) and points 1(c), 1(e) and 2 of [Annex III](https://www.legislation.gov.uk/eur/2003/1831/annex/III/adopted): Labelling and packaging requirements apply, if authorised.
2. [Article 21](https://www.legislation.gov.uk/eur/2003/1831/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](https://joint-research-centre.ec.europa.eu/publications/fad-2020-0075007800790080_en?search=&form-return=)). Valid analytical methods exist for:

* The identification of the bacterial strain *L. Plantarum* (IMI507027)
* the enumeration (bacterial count) of the bacteria in the feed additive

1. [Annex IV](https://www.legislation.gov.uk/eur/2003/1831/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 1010CFU/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 REUL 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](https://www.legislation.gov.uk/eur/2008/429/annex/IV) of REUL 429/2008

**2: Recommendations**

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

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**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

**FSS/FSA Safety Assessment**

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

FSS/FSA has reviewed the EFSA opinion ([**EFSA Journal 2021**;19(7):6705](https://www.efsa.europa.eu/en/efsajournal/pub/6705)) and confirm that it is adequate for UK considerations and therefore a full safety assessment of this application was not performed by FSS and FSA. Please see the section titled ‘Our safety assessment process’ in the Consultation Letter to understand how and when we make use of EFSA opinions.

It is the FSS/FSA opinion that *Lactiplantibacillus plantarum* (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 REUL 1831/2003 for feed additives:

1. [Article 16](https://www.legislation.gov.uk/eur/2003/1831/article/16/adopted) and points 1(c), 1(e) and 2 of [Annex III](https://www.legislation.gov.uk/eur/2003/1831/annex/III/adopted): Labelling and packaging requirements apply, if authorised.
2. [Article 21](https://www.legislation.gov.uk/eur/2003/1831/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](https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2020-0075007800790080?search&form-return)). 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](https://www.legislation.gov.uk/eur/2003/1831/annex/IV/adopted): The general conditions of use must be complied with, where applicable for the individual feed additive authorisation

### 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 REUL 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](https://www.legislation.gov.uk/eur/2008/429/annex/IV) of REUL 429/2008

**2: Recommendations**

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

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**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

**FSS/FSA Safety Assessment**

FSS/FSA 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.

FSS/FSA has reviewed the EFSA opinion ([**EFSA Journal 2021;**19(10):6898](https://www.efsa.europa.eu/en/efsajournal/pub/6898)) and confirm that it is adequate for UK considerations and therefore a full safety assessment of this application was not performed by FSS and FSA. Please see the section titled ‘Our safety assessment process’ in the Consultation Letter to understand how and when we make use of EFSA opinions.

It is the FSS/FSA 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 REUL 1831/2003 for feed additives:

1. [Article 16](https://www.legislation.gov.uk/eur/2003/1831/article/16/adopted) and points 1(c), 1(e) and 2 of [Annex III](https://www.legislation.gov.uk/eur/2003/1831/annex/III/adopted): Labelling and packaging requirements apply, if authorised.
2. [Article 21](https://www.legislation.gov.uk/eur/2003/1831/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](https://joint-research-centre.ec.europa.eu/publications/fad-2019-0091_en)). 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:](https://www.legislation.gov.uk/eur/2003/1831/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 REUL 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](https://www.legislation.gov.uk/eur/2008/429/annex/IV) of REUL 429/2008.

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**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

**FSS/FSA Safety Assessment**

FSS/FSA has undertaken a safety assessment of application RP954 for the renewal of use of endo-1,4-beta-xylanase (EC 3.2.1.8) (Econase® XT) 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, from Roal Oy.

FSS/FSA has reviewed the EFSA opinions ([**EFSA Journal 2021;**19(2):6458](https://www.efsa.europa.eu/en/efsajournal/pub/6458) and [**EFSA Journal 2019**;17(11):5880](https://www.efsa.europa.eu/en/efsajournal/pub/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](#Bookmark1)’ to understand how and when we make use of EFSA opinions.

The FSS/FSA 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 REUL 1831/2003 for feed additives:

1. [Article 16](https://www.legislation.gov.uk/eur/2003/1831/article/16/adopted) and points 1(a) and 1(b) of [Annex III](https://www.legislation.gov.uk/eur/2003/1831/annex/III/adopted): Labelling and packaging requirements apply, if authorised.
2. [Article 21](https://www.legislation.gov.uk/eur/2003/1831/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](https://joint-research-centre.ec.europa.eu/publications/fad-2018-0071_en)). 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](https://www.legislation.gov.uk/eur/2003/1831/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 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 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 |

**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](https://www.legislation.gov.uk/eur/2008/429/annex/IV) of REUL 429/2008.
* The FSS/FSA consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in REUL 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).

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**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

**FSS/FSA Safety Assessment**

FSS/FSA 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.

FSS/FSA has reviewed the EFSA opinion ([**EFSA Journal 2020;**18(12):6336](https://www.efsa.europa.eu/en/efsajournal/pub/6336)) and confirm that it is adequate for UK considerations and therefore a full safety assessment of this application was not performed by FSS and FSA. Please see the section titled ‘Our safety assessment process’ in the Consultation Letter to understand how and when we make use of EFSA opinions.

It is the FSS/FSA 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 REUL 1831/2003 for feed additives:

1. [Article 16](https://www.legislation.gov.uk/eur/2003/1831/article/16/adopted) and points 1(a) and 1(c) of [Annex III](https://www.legislation.gov.uk/eur/2003/1831/annex/III/adopted): Labelling and packaging  requirements apply, if authorised.
2. [Article 21](https://www.legislation.gov.uk/eur/2003/1831/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-2008-00](https://joint-research-centre.ec.europa.eu/publications/fad-2008-0040_en?search=&form-return=)40). Valid analytical methods exist for:

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

1. [Annex IV](https://www.legislation.gov.uk/eur/2003/1831/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 104 PPU/g for the solid form and 5 x 103 PPU/g for the liquid forms:

|  |  |
| --- | --- |
| **Form** | **Activity (PPU = phytase units)[[1]](#footnote-2)** |
| Solid form | 40 000 PPU/g |
| Liquid forms | 5 000 PPU/g (new formulation)  10 000 PPU/g |

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

6-phytase 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](https://www.legislation.gov.uk/eur/2008/429/annex/IV) of REUL 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 REUL 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.

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**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

**FSS/FSA Safety Assessment**

FSS/FSA 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.

FSS/FSA has reviewed the EFSA opinions ([**EFSA Journal 2020;**18(12):6334](https://www.efsa.europa.eu/en/efsajournal/pub/6334) and [**EFSA Journal 2020**;18(12):6333](https://www.efsa.europa.eu/en/efsajournal/pub/6333)) and confirm that they are adequate for UK considerations and therefore a full safety assessment of this application was not performed by FSS and FSA. Please see the section titled ‘Our safety assessment process’ in the Consultation Letter to understand how and when we make use of EFSA opinions.

It is the FSS/FSA 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 REUL 1831/2003 for feed additives:

1. [Article 16](https://www.legislation.gov.uk/eur/2003/1831/article/16/adopted) and point 1(d) of [Annex III](https://www.legislation.gov.uk/eur/2003/1831/annex/III/adopted): Labelling and packaging of feed additives and premixtures
2. [Article 21](https://www.legislation.gov.uk/eur/2003/1831/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](https://joint-research-centre.ec.europa.eu/publications/fad-2020-0008_en)). 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.

1. [Annex IV](https://www.legislation.gov.uk/eur/2003/1831/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 |
| **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 (C6H15ClN2O2)
* 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) - REUL 152/2009 ([Annex III, F](https://www.legislation.gov.uk/eur/2009/152/annex/III)).

**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) - REUL 152/2009 ([Annex III, F](https://www.legislation.gov.uk/eur/2009/152/annex/III))

**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](https://www.legislation.gov.uk/eur/2008/429/annex/IV) of REUL 429/2008
* The FSS/FSA consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in REUL 183/2005 ‘Feed Hygiene Regulation’ and Good Manufacturing Practice.

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**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

**FSS/FSA Safety Assessment**

FSS/FSA 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.

FSS/FSA has reviewed the EFSA opinions ([**EFSA Journal 2020;**18(12):6334](https://www.efsa.europa.eu/en/efsajournal/pub/6334) and [**EFSA Journal 2020**;18(12):6333](https://www.efsa.europa.eu/en/efsajournal/pub/6333)) and confirm that they are adequate for UK considerations and therefore a full safety assessment of this application was not performed by FSS and FSA. Please see the section titled ‘Our safety assessment process’ in the Consultation Letter to understand how and when we make use of EFSA opinions.

The FSS/FSA 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 REUL 1831/2003 for feed additives:

1. [Article 16](https://www.legislation.gov.uk/eur/2003/1831/article/16/adopted) and point 1(d) of [Annex III](https://www.legislation.gov.uk/eur/2003/1831/annex/III/adopted): Labelling and packaging of feed additives and premixtures
2. [Article 21](https://www.legislation.gov.uk/eur/2003/1831/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](https://joint-research-centre.ec.europa.eu/publications/fad-2020-0008_en)). Valid analytical methods exist for:

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

1. [Annex IV](https://www.legislation.gov.uk/eur/2003/1831/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 |
| **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 (C6H14N2O2)
* 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) - REUL 152/2009 ([Annex III, F](https://www.legislation.gov.uk/eur/2009/152/annex/III)).

**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) - REUL 152/2009 ([Annex III, F](https://www.legislation.gov.uk/eur/2009/152/annex/III)).

**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](https://www.legislation.gov.uk/eur/2008/429/annex/IV) of REUL 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 REUL 183/2005 ‘Feed Hygiene Regulation’ and Good Manufacturing Practice.

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# 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., Switzerland

**Address of applicant:**

Wurmigsweg 576

4303

Kaiseraugst

Switzerland

**FSS/FSA Safety Assessment**

FSS/FSA 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 FSS/FSA safety assessment was published on 31st March 2023 and can be found [here](https://www.food.gov.uk/research/outcome-of-assessment-of-3-nitrooxypropanol-3-nop-summary). The assessment of 3-nitrooxypropanol shows that the conditions for authorisation in Article 5 of REUL 1831/2003 are satisfied.

The FSS/FSA 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 REUL 1831/2003 for feed additives:

1. [Article 16](https://www.legislation.gov.uk/eur/2003/1831/article/16/adopted) and points 1(a) of [Annex III](https://www.legislation.gov.uk/eur/2003/1831/annex/III/adopted): Labelling and packaging requirements apply, if authorised.
2. [Article 21](https://www.legislation.gov.uk/eur/2003/1831/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](https://joint-research-centre.ec.europa.eu/publications/fad-2019-0057_en)). FSS/FSA 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](https://www.legislation.gov.uk/eur/2003/1831/annex/IV): The general conditions of use must be complied with, where applicable for the individual feed additive authorization.

**Conclusions from the Safety Assessment:**

The FSS/FSA 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 additives |
| **Functional group** | (c) Substances which favourably affect the environment |
| **Feed additive** | 3-nitrooxypropanol (Bovaer® 10) |
| **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 |
| **Chemical-physical specifications** | |
| Particle size distribution | 0.4% of particles with diameter < 50µm |

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

* 3-nitrooxypropanol (Propan-1,3-diol-mononitrate) (C3H7NO4)
* 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 safety assessment identified that particular consideration should be given to hazards as a:
  + skin and eye irritant
  + respiratory sensitiser.
* The FSS/FSA consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in REUL 183/2005 ‘Feed Hygiene Regulation’ and Good Manufacturing Practice.
* Main animal species and their subgroups are defined in [Annex IV](https://www.legislation.gov.uk/eur/2008/429/annex/IV) of REUL 429/2008.

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1. Enzyme activity is expressed in PPU units, where one PPU is the amount of enzyme which liberates 1 micromole (μmol) of inorganic phosphate from sodium phytate per minute at pH 5.0 and 37°C] [↑](#footnote-ref-2)