

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	<i>Lacticaseibacillus rhamnosus</i> (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:
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All animal species	n/a	<p>Minimum level: See Other Provisions at 5.2 below.</p> <p>Maximum level: No maximum</p>
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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

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