RP687 Assessment of the application for the feed additive Lactiplantibacillus plantarum DSM 26571 for all animal species

Maes o ddiddordeb ymchwil: Research projects
Statws y prosiect: Wedi'i gwblhau
Cod prosiect: RP 687
Awduron: Risk Assessment Unit Science, Evidence and Research Division, FSA
Cynhaliwyd gan: Risk Assessment Team Science Division, FSS
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1.Executive summary

The FSA/ FSS have undertaken a safety assessment of application RP 687 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. In line with the principles for making use of EFSA opinions in their decision making on regulated products, the FSA/FSS opinion is that the conclusions of the EFSA opinion are valid for the UK and therefore *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.

2.Background and purpose of review

EFSA Journal 2021;19(10):6898 **Question number**: EFSA-Q-2020-00279
In accordance with Retained EU Regulation 1831/2003 on feed additives, the application RP 687 for the use of *Lactiplantibacillus plantarum* DSM 26571 as a feed additive for all animal species, from Chr. Hansen A/S has been submitted for authorisation in each nation of Great Britain (GB).

Whilst it was a Member State of the EU, the UK accepted the assessments of EFSA in support of authorisations for regulated food and feed products. Since the end of the transition period, FSA/ FSS has adopted equivalent technical guidance and quality assurance processes to make independent GB safety assessments.

A number of applications have been received by GB where EFSA, prior to the end of the transition period, evaluated an application for the product. FSA/FSS has decided to make use of the EFSA risk assessment, where this is appropriate, in forming its own independent opinion. Therefore, FSA/FSS safety assessors have reviewed the EFSA opinions for the application below in the context of intended GB use and have concluded that the intended uses are safe.

In reviewing the output of the EFSA risk assessment the reviewers have verified that the standard approach as outlined in the relevant guidance has been followed and the arguments made are consistent with the data summarised. Consideration has been given to the processes undertaken

to ensure the outcome is robust and whether there are and aspects that would require further review such as specific issues for the countries of the UK. The result of the assessment is that the EFSA scientific opinion is adequate also for UK considerations. Therefore, a full safety assessment has not been performed by FSA/ FSS.

3.Details of the EFSA assessment

Methodology applied in the EFSA opinion

EFSA FEEDAP guidance: Guidance on studies concerning the safety of use of the additive for users/workers **(2012)**, Guidance on the identity, characterisation and conditions of use of feed additives **(2017a)**, Guidance on the characterisation of microorganisms used as feed additives or as production organisms **(2018a)**, Guidance on the assessment of the safety of feed additives for the target species **(2017b)**, Guidance on the assessment of the efficacy of feed additives **(2018b)**, Guidance on the assessment of the safety of feed additives for the consumer **(2017c)**, Guidance on the assessment of the safety of feed additives for the environment **(2019)** and principles in Regulation (EC) No 429/2008 and the relevant guidance documents.

3.1 Source/organism

The additive is a preparation containing viable cells of *Lactiplantibacillus plantarum* DSM 26571.

3.2 Genetic modification step

Not relevant.

3.3 Specification

Information provided on the identity, composition and specifications of the bacteria does not raise safety concerns (the published version is redacted whilst confidentiality claims are determined. This is for information relating to the preparation of the inoculum).

3.4 Exposure assessment

Not relevant

3.5 Toxicological data

Data for skin / eye irritation and skin sensitisation were provided for the additive under application and did not raise any safety concerns. There are no specific data on respiratory tract effects however, given the proteinaceous nature of the active agent, the additive should be considered to be a respiratory sensitiser.

However, for assessing the safety for the user of the additive, the active agent is the principal concern provided that other components do not introduce safety issues. For this specific product, the cryoprotectant/carrier material used in the preparation of the final formulation does not introduce additional risks.

4. EFSA assessment and conclusions

The species *L. plantarum* is considered by EFSA to be suitable for the Qualified Presumption of Safety (QPS) approach. the identity of the strain has been established as *L. plantarum* and the antibiotic resistance qualification met. Consequently, *Lactiplantibacillus plantarum* DSM 26571 is

considered safe for the target species, consumers of products from animals fed treated silage and the environment.

5. Caveats and uncertainties

The addition of *Lactiplantibacillus plantarum* DSM 26571 at a minimum concentration of 1 × 108 CFU/kg has the potential to improve the preservation of nutrients from easy, moderately difficult and difficult to ensile forage material.

6. FSA Conclusion on reliability and applicability

The application has been assessed in line with the applicable guidance (although it should be noted the FEEDAP guidance differs in approach to all other EFSA guidance on toxicological testing and does not provide the best 3Rs approach) and is partially based on considerations of detailed proprietary information available to the Panel, whilst this is only briefly summarised this description is consistent with the conclusions. The QPS principles used for the assessment of the microorganism are well established and widely used. The conclusions are appropriate and consistent within the identified caveats and uncertainties and would be applicable to the UK.

7. Outcome of assessment

FSA/FSS has reviewed the EFSA opinion and consider it adequate also for UK considerations. Therefore, a full safety assessment of this application was not performed by the FSA and FSS. FSA/FSS has had access to all supporting documentation as provided to EFSA for forming the EFSA opinion. FSA/FSS agree with the safety conclusions outlined in the opinion.

Following the principles outlined in the background for making use of the EFSA opinion, the FSA/FSS opinion is 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.

8. References

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012. Guidance on studies concerning the safety of use of the additive for users/workers. EFSA Journal 2012;10(1):2539, 5 pp. https://doi.org/10.2903/j.efsa.2012.2539

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2017a. Guidance on the identity, characterisation and conditions of use of feed additives. EFSA Journal 2017;15(10):5023, 12 pp. https://doi.org/10.2903/j.efsa.2017.5023

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2017b. Guidance on the assessment of the safety of feed additives for the target species. EFSA Journal 2017;15(10):5021, 19 pp. https://doi.org/10.2903/j.efsa.2017.5021

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2017c. Guidance on the assessment of the safety of feed additives for the consumer. EFSA Journal 2017;15(10):5022, 17 pp. https://doi.org/10.2903/j.efsa.2017.5022

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2018a. Guidance on the characterisation of microorganisms used as feed additives or as

production organisms. EFSA Journal 2018;16(3):5206, 24 pp. https://doi.org/10.2903/j.efsa.2018.5206

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2018b. Guidance on the assessment of the efficacy of feed additives. EFSA Journal 2018;16(5):5274, 25 pp. https://doi.org/10.2903/j.efsa.2018.5274

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2019. Guidance on the assessment of the safety of feed additives for the environment. EFSA Journal 2019;17(4):5648, 78 pp. https://doi.org/10.2903/j.efsa.2019.5648