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Statement on the safety and efficacy of lignosulphonate of magnesium (Caimabond) for all animal species

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), Vasileios Bampidis, Giovanna Azimonti, Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Mojca Kos Durjava, Maryline Kouba, Marta López-Alonso, Secundino López Puente, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Yolanda Sanz, Roberto Edoardo Villa, Ruud Woutersen, Rosella Brozzi, Jaime Galobart, Lucilla Gregoretti, Gloria López-Gálvez, Matteo Lorenzo Innocenti, Maria-Vittoria Vettori and Konstantinos Sofianidis

Abstract

The additive lignosulphonate of magnesium is intended to be used as a technological additive (functional group: binders) for all animal species. The Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) assessed the data provided by the applicant in the technical dossier. During the course of the assessment, the absence and/or incompleteness of information needed in order to be able to deliver an opinion on the safety and efficacy of this additive was identified and notified to the applicant. The information requested covered the format requirements of the application and the structure of the dossier. The applicant has failed to provide the additional information. Therefore, considering the data provided in the original dossier and the absence of response from the applicant to the requests from EFSA, the FEEDAP Panel is not in a position to deliver an opinion on the safety and efficacy of the additive lignosulphonate of magnesium as a technological additive for all animal species.

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Correspondence: feedap@efsa.europa.eu

Panel members: Giovanna Azimonti, Vasileios Bampidis Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Maryline Kouba, Mojca Kos Durjava, Marta López-Alonso, Secundino López Puente, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Yolanda Sanz, Roberto Edoardo Villa and Ruud Woutersen.

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1. Introduction

Regulation (EC) No 1831/2003¹ establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 10(2) of that Regulation also specifies that for existing products within the meaning of Article 10(1), an application shall be submitted in accordance with Article 7, at the latest one year before the expiry date of the authorisation given pursuant to Directive 70/524/EEC for additives with a limited authorisation period, and within a maximum of 7 years after the entry into force of this Regulation for additives authorised without a time limit or pursuant to Directive 82/471/EEC.

The European Commission received a request from the company CAIMA - Indústria de Celulose, S.A.² for authorisation of the product lignosulphonate of magnesium to be used as a feed additive (category: technological additives; functional group: binders) for all animal species.

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the application to the European Food Safety Authority (EFSA) as an application under Article 10(2) (re-evaluation of an authorised feed additive). EFSA received directly from the applicant the technical dossier in support of this application³. The particulars and documents in support of the application were considered valid by EFSA as of 13 December 2019.

According to Article 8 of Regulation (EC) No 1831/2003, EFSA, after verifying the particulars and documents submitted by the applicant, shall undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5. EFSA shall deliver an opinion on the safety for the target animals, consumer, user and the environment and on the efficacy of the product lignosulphonate of magnesium, for all animal species and categories.

2. The application dossier

The present application concerns the product lignosulphonate of magnesium to be used as a technological additive (functional group: binders) in feed for all animal species.

The European Commission received an application for the use of this product in feed for all animal species on 8 March 2010. This application was received by EFSA on 23 June 2014. EFSA immediately started the verification of the dossier to check whether all the documents and particulars requested in Article 7(3) of Regulation (EC) No 1831/2003 were provided. A substantial amount of information was identified as missing in the technical dossier which would prevent EFSA to start its assessment. A missing information request was sent to the applicant on 1 August 2014 and covered the format requirements of the application and the sections and files of the dossier. In two occasions the applicant requested extensions of the deadline to provide the information, which was eventually set to 31 December 2015 in agreement with the FEED Unit. The applicant indicated its intention to withdraw the application to EFSA (12 January 2016) but has never sent an official request. EFSA requested further clarifications on the status of this request on 5 April 2019. In the absence of a reply, EFSA notified the applicant on 13 December 2019 on its intention to finalise the assessment regarding the dossier of reference with the information available. In the absence of adequate information, the FEEDAP Panel is not in a position to characterise the additive and to assess its safety and efficacy.

EFSA has verified the European Union Reference Laboratory (EURL) report as it relates to the methods used for the control of the lignosulphonate of magnesium in animal feed. The Executive Summary of the EURL report can be found in Annex A.⁴

3. Conclusions

Considering the data provided in the original dossier and the absence of response from the applicant to the requests from EFSA for missing information, the FEEDAP Panel is not in a position to deliver an opinion on the safety and efficacy of the additive lignosulphonate of magnesium as a technological additive for all animal species.

¹ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.

² Rua do Tejo, Constância Sul, 2250-058 Constância, Portugal.

³ EFSA Dossier reference: FAD-2010-0017.

⁴ The full report is available on the EURL website: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

4. Documentation as provided to EFSA/Chronology

Date	Event
31/03/2010	Dossier received by EFSA. CaimaBond (lignosulphonate of magnesium) for all animal species. Submitted by CAIMA - Indústria de Celulose, S.A
23/06/2014	Reception mandate from the European Commission
01/08/2014	Request of missing information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. <i>Issues: format requirements of application, structure of dossier</i>
06/08/2014	Extension of the deadline to provide the missing information was requested by the applicant
21/11/2014	Further extension of the deadline to provide the missing information was requested by the applicant
12/01/2016	Applicant expressed intention to withdraw the application to EFSA
13/12/2019	Application validated by EFSA – Start of the scientific assessment
13/03/2020	Reception of the Evaluation report of the European Union Reference Laboratory for Feed Additives
17/03/2020	Statement adopted by the FEEDAP Panel. End of the Scientific assessment

Abbreviations

EURL European Union Reference Laboratory

FEEDAP EFSA Panel on Additives and Products or Substances used in Animal Feed

Annex A – Executive summary of the evaluation Report on the Analytical Methods submitted in connection with the Application for authorisation of a Lignosulphonate of magnesium according to Regulation (EC) No 1831/2003

In the current application authorisation is sought under Article 10(2) for *lignosulphonate of magnesium* (E565) as a *feed additive* under the category “technological feed additives”, functional group 1(g) “binders” according to the classification system of Annex I of Regulation (EC) No 1831/2003. The authorisation is sought to use the *feed additive* for all animal species and categories.

The Applicant did not include in the dossier any activity definition, purity criteria or minimum content. The Applicant did not specify any conditions of use.

The Applicant did not provide experimental data or an analytical method for the determination of *lignosulphonate of magnesium* in the *feed additive, premixtures, feedingstuffs* and *water*. Furthermore, an unambiguous determination of *lignosulphonate of magnesium* added to *premixtures* and *feedingstuffs* is not achievable experimentally. Therefore, the EURL cannot evaluate nor recommend any method for official control for the determination of *lignosulphonate of magnesium* in the *feed additive, premixtures, feedingstuffs* and *water*.