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Statement on the safety and efficacy of the feed additive consisting on tragacanth gum for all animal species (Association for International Promotion of Gums)

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 Fašmon 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 Gregoret, Gloria López-Gálvez, Konstantinos Sofianidis, Maria Vittoria Vettori and Matteo Lorenzo Innocenti

Abstract

The additive tragacanth gum is intended to be used as a technological additive (category: technological additive; functional groups: emulsifier, stabiliser, thickener, gelling agent) 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 need for additional information 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 characterisation and identification, the safety for the target species and the efficacy of the additive. 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 tragacanth gum 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, Mojca Fašmon Durjava, Maryline Kouba, 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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Table of contents

Abstract.....	1
1. Introduction.....	4
2. The application dossier	4
3. Conclusions.....	4
4. Documentation as provided to EFSA/Chronology.....	5
Abbreviations.....	5

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 seven 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 A.I.P.G. (Association for International Promotion of Gums)² for re-evaluation of the product tragacanth gum, when used as a feed additive for all animal species (category: technological additive; functional groups: emulsifier, stabiliser, thickener, gelling agent).

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 application. The particulars and documents in support of the application were considered valid by EFSA as of 6 August 2014.

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 tragacanth gum when used under the proposed conditions of use.

2. The application dossier

The present application concerns the product tragacanth gum to be used as a technological additive (functional group: emulsifier, stabiliser, thickener, gelling agent) 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 2 November 2010. This application was received by the EFSA on 11 December 2013. 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. The dossier was considered valid for the start of the assessment on 6 August 2014. The scientific evaluation of the technical dossier started immediately. During the course of the assessment, the working group of technological additives of the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) identified the need for additional information in order to be able to deliver an opinion on the safety and efficacy of this additive. The information requests were sent to the applicant on 28 November 2014 and 2 August 2016, and covered the characterisation and identification, the safety for the target species and the efficacy of the additive. The deadline to provide the information was set to 2 January 2017. The applicant was asked on 18 December 2019 to answer EFSA's request by 31 January 2020, otherwise EFSA intended to finalise the assessment regarding the dossier of reference with the information available. No reply has been received from the applicant.

The European Union Reference Laboratory (EURL) delivered its report on the methods of analysis for this dossier.³

3. Conclusions

Considering the limited data provided in the original dossier and the absence of response from the applicant to the requests from EFSA for additional information, the FEEDAP Panel is not in a position to deliver an opinion on the safety and efficacy of tragacanth gum 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 AIPG Association for International Promotion Of Gums, SonninstraÙe 28, 20097 Hamburg, Germany.

³ The full report is available on the EURL website: <https://ec.europa.eu/jrc/sites/jrcsh/files/finrep-fad-2010-0392-tragacanth%20gum.pdf>

4. Documentation as provided to EFSA/Chronology

Date	Event
11/12/2013	Dossier received by EFSA. Tragacanth gum for all animal species. Submitted by A.I.P.G. Association for International Promotion of Gums.
11/12/2013	Reception mandate from the European Commission
06/08/2014	Application validated by EFSA – Start of the scientific assessment
06/09/2014	Comments received from Member States
28/11/2014	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. <i>Issues: characterisation, efficacy</i>
05/12/2014	Reception of the Evaluation report of the European Union Reference Laboratory for Feed Additives
02/08/2016	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 (Addendum) – Scientific assessment suspended. <i>Issues: safety for target species</i>
27/01/2021	Opinion 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