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Statement on the safety and efficacy of Shellac for all animal species

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Abstract

The additive Shellac is intended to be used as a technological additive (functional group: stabiliser) 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 description of the additive/efficacy, and safety 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 request from EFSA, the FEEDAP Panel is not in a position to deliver an opinion on the safety and efficacy of the additive Shellac as a technological additive for all animal species.

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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 4(1) of that Regulation lays down that any person seeking authorisation for a feed additive or for a new use of a feed additive shall submit an application in accordance with Article 7.

The European Commission received a request from the company Stroeever GmbH & Co. KG² for authorisation of the product Shellac to be used as a feed additive (category: technological additives; functional group: stabiliser) 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 4(1) (authorisation of a feed additive or new use of a feed additive). EFSA received directly from the applicant the technical dossier in support of this application.³ The particulars and documents in support of the application were considered valid by EFSA as of 01 December 2011.

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 Shellac, for all animal species and categories.

2. The application dossier

The present application concerns the product Shellac to be used as a technological additive (functional group: stabiliser) 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 11 November 2010. This application was received by EFSA on 19 January 2011. 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 1 December 2011. The scientific evaluation of the technical dossier started immediately. During the course of the assessment, the working group on 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 request was sent to the applicant on 19 March 2012 and covered the description of the additive, its safety and efficacy. In one occasion, the applicant requested an extension of the deadline to provide the information, which was eventually set to 29 June 2012. On 3 March 2020, EFSA notified the applicant its intention to finalise the assessment regarding the dossier of reference.

The European Union Reference Laboratory (EURL) delivered its report on the methods of analysis for this dossier.⁴

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 the additive Shellac as a technological additive for all animal species.

4. Documentation as provided to EFSA/Chronology

Date	Event
26/05/2011	Dossier received by EFSA. Shellac for all animal species. Submitted by Stroeever GmbH & Co. KG
19/01/2011	Reception mandate from the European Commission

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 Association Management & Regulatory Services Ltd, on behalf of SSB Stroeever GmbH, Kerkweide 27, 2265DM Leidschendam, The Netherlands.

³ EFSA Dossier reference: FAD-2011-0022.

⁴ The full report is available on the EURL website: <https://ec.europa.eu/jrc/sites/jrcsh/files/FinRep-FAD-2011-0022.pdf>

Date	Event
01/12/2011	Application validated by EFSA – Start of the scientific assessment
01/03/2012	Comments received from Member States
21/02/2012	Reception of the Evaluation report of the European Union Reference Laboratory for Feed Additives
19/03/2012	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: description of the additive, safety and efficacy</i>
03/03/2020	Scientific assessment re-started
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