

ADOPTED: 25 January 2017

doi: 10.2903/j.efsa.2017.4710

Safety of cassia gum as a feed additive for dogs and cats based on a dossier submitted by Glycomer GmbH

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP),
Guido Rychen, Gabriele Aquilina, Giovanna Azimonti, Vasileios Bampidis,
Maria de Lourdes Bastos, Georges Bories, Andrew Chesson, Pier Sandro Cocconcelli,
Gerhard Flachowsky, Boris Kolar, Maryline Kouba, Secundino López Puente,
Marta López-Alonso, Alberto Mantovani, Baltasar Mayo, Fernando Ramos, Maria Saarela,
Roberto Edoardo Villa, Robert John Wallace, Pieter Wester, Anne-Katrine Lundebye,
Carlo Nebbia, Derek Renshaw, Matteo Lorenzo Innocenti and Jürgen Gropp

Abstract

The additive cassia gum consists mainly of high-molecular weight polysaccharides composed primarily of a linear chain of 1,4- β -D-mannopyranose units with 1,6-linked α -D-galactopyranose units. In 2014, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) delivered an opinion on the safety and efficacy of cassia gum. The FEEDAP Panel concluded, based on positive findings observed in a bacterial reverse mutation test with a semirefined cassia gum (about 70 mg anthraquinones/kg) but not with purified semirefined cassia gum that meets the specification as a food additive (< 0.5 mg anthraquinones/kg), that only purified semirefined cassia gum that meets the specifications of cassia gum as a food additive can be considered safe for cats and dogs, at a maximum content of 1.5% cassia gum (15,000 mg/kg feed) in dry matter, corresponding to 1.32% (13,200 mg/kg feed) in a standardised complete feed with 12% water content. The FEEDAP Panel also concluded that cassia gum should be regarded as a skin and respiratory sensitiser and as a potential irritant to skin and eyes. Following this opinion, the European Commission gave the possibility to the applicant to submit complementary information on the safety for all animal species. No new data were submitted to address the potential of the additive to exert mutagenic effects, and therefore, the FEEDAP Panel is not in the position to modify the conclusions reached in the previous opinion.

© 2017 European Food Safety Authority. *EFSA Journal* published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

Keywords: cassia gum, safety, tolerance, anthraquinone, dogs, cats

Requestor: European Commission

Question number: EFSA-Q-2016-00644

Correspondence: feedap@efsa.europa.eu

Panel members: Gabriele Aquilina, Giovanna Azimonti, Vasileios Bampidis, Maria de Lourdes Bastos, Georges Bories, Andrew Chesson, Pier Sandro Coconcelli, Gerhard Flachowsky, Jürgen Gropp, Boris Kolar, Maryline Kouba, Secundino López Puente, Marta López-Alonso, Alberto Mantovani, Baltasar Mayo, Fernando Ramos, Guido Rychen, Maria Saarela, Roberto Edoardo Villa, Robert John Wallace and Pieter Wester.

Acknowledgements: The Panel wishes to thank the members of the Working Group on Technological additives, including Anne-Katrine Lundebye, Carlo Nebbia and Derek Renshaw, for the preparatory work on this scientific opinion.

Suggested citation: EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen G, Aquilina G, Azimonti G, Bampidis V, Bastos ML, Bories G, Chesson A, Coconcelli PS, Flachowsky G, Kolar B, Kouba M, López Puente S, López-Alonso M, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Lundebye A-K, Nebbia C, Renshaw D, Innocenti ML and Gropp J, 2017. Scientific Opinion on the safety of cassia gum as a feed additive for dogs and cats based on a dossier submitted by Glycomer GmbH. *EFSA Journal* 2017;15(2):4710, 6 pp. doi:10.2903/j.efsa.2017.4710

ISSN: 1831-4732

© 2017 European Food Safety Authority. *EFSA Journal* published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

This is an open access article under the terms of the [Creative Commons Attribution-NoDerivs License](https://creativecommons.org/licenses/by/4.0/), which permits use and distribution in any medium, provided the original work is properly cited and no modifications or adaptations are made.



The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.



Table of contents

Abstract.....	1
1. Introduction.....	4
1.1. Background and Terms of Reference as provided by the requestor.....	4
1.2. Additional information.....	4
2. Data and methodologies.....	4
2.1. Data.....	4
2.2. Methodologies.....	4
3. Assessment.....	5
3.1. Safety for the target species.....	5
3.2. User safety.....	6
4. Conclusions.....	6
Documentation provided to EFSA.....	6
References.....	6
Abbreviations.....	6

1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1831/2003¹ establishes the rules governing the Community authorisation of additives for use in animal nutrition and, in particular, Article 9 defines the terms of the authorisation by the Commission.

The applicant, Glycomer, is seeking a Community authorisation of Cassia Gum as a technological additive for dogs and cats (Table 1).

Table 1: Description of the substances

Category of additive	Technological additives
Functional group of additive	Gelling agent
Description	Cassia Gum
Target animal category	Cats, dogs
Applicant	Glycomer GmbH
Type of request	New opinion

On 29 October 2014, the Panel on Additives and Products or Substances used in Animal Feed of the European Food Safety Authority ("Authority"), in its opinion on the safety and efficacy of the product, considered that only purified semi-refined cassia gum that meets the specifications of cassia gum as a food additive can be considered safe for cats and dogs.

The Commission gave the possibility to the applicant to submit complementary information in order to complete the assessment and to allow a revision of the Authority's opinion.

The Commission has now received new data on Cassia Gum.

In view of the above, the Commission asks the Authority to deliver a new opinion on Cassia Gum as a technological additive for dogs and cats based on the additional data submitted by the applicant.

1.2. Additional information

The additive cassia gum is currently authorised as a technological additive, not needed functional groups gelling agent, thickeners, emulsifying and stabilising agent for use in food for dogs and cats, with a maximum content of 17,600 mg/kg complete feed.

The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) issued four opinions on the safety and efficacy of cassia gum for dogs and cats (EFSA FEEDAP Panel, 2014a,b,c,d).

The EFSA Panel on Food additives, flavourings, processing aids and materials in contact with food (AFC) issued an opinion on cassia gum as a food additive (EFSA, 2006) and concluded that the use of cassia gum complying with the newly defined specifications (anthraquinones content < 0.5 mg/kg) as an additive for the proposed food uses is not of safety concern.

The additive has been assessed by the Joint FAO/WHO Expert Committee on Food Additive (JECFA, 2010) and was considered safe for use in food.

2. Data and methodologies

2.1. Data

The present assessment is based on the data submitted by the applicant in the form of additional information² following a previous application on the same product.³

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety of cassia gum is in line with the principles laid down in Regulation (EC) No 429/2008.

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 Dossier reference: FAD-2016-0043.

³ Dossier reference: FAD-2010-0186.

3. Assessment

Cassia gum is described in Regulation (EC) No 231/2012, which lays down the specification for food additives.⁴ It is the ground, purified endosperm of the seeds of *Cassia tora* and *Cassia obtusifolia* (Leguminosae) containing less than 0.05% *Cassia occidentalis*. It consists mainly of high-molecular weight polysaccharides composed primarily of a linear chain of 1,4- β -D-mannopyranose units with 1,6-linked α -D-galactopyranose units. The ratio of mannose to galactose is given as about 5:1; the concentration of galactomannans is > 75%, of acid-insoluble matter is < 2%, of protein is < 7%, of total ash is < 1.2% and of lead is < 1 mg/kg; the viscosity is < 500 mPa·s. Specifications of cassia gum as a food additive give a maximum content of total anthraquinones of 0.5 mg/kg (detection limit). The applicant, in the original application, did not provide any information on the concentrations of anthraquinones in the feed additive.

As feed additive, cassia gum is intended to be used as a gelling agent in complete feed for cats and dogs with moisture content higher than 20%. The applicant proposes a maximum content of 4,000 mg cassia gum/kg complete feed (moisture \leq 12%).

In its previous opinion (EFSA FEEDAP Panel, 2014b), the FEEDAP Panel concluded that only purified (isopropanol extraction) semirefined cassia gum that meets the specifications of cassia gum as a food additive (< 0.5 mg anthraquinones/kg) can be considered safe for cats and dogs. Moreover, the Panel concluded that cassia gum is regarded as a skin and respiratory sensitiser and as a potential irritant to skin and eyes.

The applicant did not submit any new data, only argumentations to challenge the previous EFSA opinion.

3.1. Safety for the target species

In its previous opinion (EFSA FEEDAP Panel, 2014a,b,c,d), the FEEDAP Panel noted that:

- 1) positive findings were observed in a bacterial reverse mutation test with a semirefined cassia gum (about 70 mg anthraquinones/kg) but not with the purified semirefined cassia gum (following the specifications of cassia gum as a food additive: < 0.5 mg anthraquinones/kg);
- 2) in one 90-day study in dog and one 90-day study in cats, 2.5% semirefined cassia gum in the diet was tolerated by dogs and cats;

and, therefore, concluded that only purified semirefined cassia gum that meets the specifications of cassia gum as a food additive (< 0.5 mg anthraquinones/kg) can be considered safe for cats and dogs, at a maximum content of 1.5% cassia gum (15,000 mg/kg feed) in dry matter (DM), corresponding to 1.32% (13,200 mg/kg feed) in a standardised complete feed with 12% water content.

The applicant has challenged these conclusions on the basis that the analytical method applied to the purified semirefined cassia gum is likely to have substantially underestimated the total anthraquinone content. The Panel is not in the position to accept or reject this interpretation, that refers to the method of analysis used to characterise the purified cassia gum applied for as a food additive, assessed by the AFC Panel (EFSA, 2006), and not to the product under assessment. However, the FEEDAP Panel notes that this cassia gum with low anthraquinone content was obtained after an additional purification step by isopropanol extraction and thus differs from the material under application. Only for this purified product, the bacterial reverse mutation test did not raise genotoxic concern. The Panel was not in a position to conclude on the safety of cassia gum with an anthraquinone content higher than 0.5 mg/kg since the cassia gum under assessment (anthraquinones < 70 mg/kg) gave a positive response in a valid bacterial reverse mutation test (Organisation for Economic Co-operation and Development (OECD) No 471: bacteria reverse mutation test, 1983).⁵

The applicant, in this latest submission, did not address the genotoxic potential of semirefined cassia gum under assessment. Consequently, the Panel has no basis on which to modify its previous conclusion.

⁴ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council.

⁵ The more recent version (Organisation for Economic Co-operation and Development (OECD) No 471: bacteria reverse mutation test, 1997) adds only two bacterial strains (TA102, *Escherichia coli* WP2) and a more detailed description of the experimental protocol.

3.2. User safety

The applicant has not provided new data that would lead the Panel to revise the conclusions reached in its previous opinion.

4. Conclusions

No new data on the genotoxic potential of the semirefined cassia gum under assessment have been submitted. The FEEDAP Panel is therefore not in the position to conclude on the safety of cassia gum under assessment and reiterates that only purified (isopropanol extracted) semirefined cassia gum that meets the specifications of cassia gum as a food additive (< 0.5 mg anthraquinones/kg) can be considered safe for cats and dogs. The FEEDAP Panel also reiterates its previous conclusion that cassia gum should be regarded as a skin and respiratory sensitiser and as a potential irritant to skin and eyes.

Documentation provided to EFSA

- 1) Cassia gum for dogs and cats. Supplementary information. July 2016. Submitted by Glycomer GmbH.

References

- EFSA (European Food Safety Authority), 2006. Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) related to an application on the use of cassia gum as a food additive. *EFSA Journal* 2006;4(12):389, 16 pp. doi:10.2903/j.efsa.2006.389
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2014a. Scientific Opinion on the safety and efficacy of cassia gum for dogs and cats based on a dossier submitted by Intercolloid (UK) Ltd. *EFSA Journal* 2014;12(11):3901, 15 pp. doi:10.2903/j.efsa.2014.3901
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2014b. Scientific Opinion on the safety and efficacy of cassia gum for dogs and cats based on a dossier submitted by Glycomer GmbH. *EFSA Journal* 2014;12(11):3899, 16 pp. doi:10.2903/j.efsa.2014.3899
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2014c. Scientific Opinion on the safety and efficacy of cassia gum (Galactogum) for dogs and cats based on a dossier submitted by Galacto Naturstoffe GmbH. *EFSA Journal* 2014;12(11):3900, 15 pp. doi:10.2903/j.efsa.2014.3900
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2014d. Scientific Opinion on the safety and efficacy of cassia gum (Diagum CS) for dogs and cats based on a dossier submitted by Lubrizol Advance Materials Europe B.V.B.A. *EFSA Journal* 2014;12(11):3902, 16 pp. doi:10.2903/j.efsa.2014.3902
- JECFA (Joint FAO/WHO Expert Committee on Food Additive), 2010. Safety evaluation of certain food additives. Seventy-first meeting of the Joint FAO/WHO. WHO Food Additives Series 62, Geneva, 2010. Available online: <http://www.inchem.org/documents/jecfa/jecmono/v62je01.pdf>

Abbreviations

AFC	EFSA Panel on Food additives, flavourings, processing aids and materials in contact with food
DM	dry matter
FAO	Food Agricultural Organization
FEEDAP	Panel on Additives and Products or Substances used in Animal Feed
JECFA	The Joint FAO/WHO Expert Committee on Food Additives
OECD	Organisation for Economic Co-operation and Development
WHO	World Health Organization