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Safety of cassia gum as a feed additive for dogs and cats based on a dossier submitted by Intercolloid (UK) Ltd

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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. Following this opinion, the European Commission gave the possibility to the applicant to submit complementary information in order to complete the assessment on the safety for all animal species. The new data submitted, describing a reproduction study in cats, do not address the potential of the additive to exert mutagenic effects, and do not allow conclusions to be drawn on the safety of semirefined cassia gum with an anthraquinone content higher than the one specified for the use as a food additive (< 0.5 mg/kg). The FEEDAP Panel is not in the position to modify the conclusions reached in the previous opinion.

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

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1. Introduction

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

Regulation (EC) No 1831/2003[1] 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, Intercolloid (UK) Ltd, 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 (E499)
Target animal category	Cats and dogs
Applicant	Intercolloid (UK) Ltd
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 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, 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 information[2] 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 and the relevant guidance documents: Guidance on technological additives (EFSA FEEDAP Panel, 2012a), Technical guidance: Tolerance and efficacy studies in target animals (EFSA FEEDAP Panel, 2011a), Technical Guidance for assessing the safety of

[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.

feed additives for the environment (EFSA, 2008a), Guidance for the preparation of dossiers for the re-evaluation of certain additives already authorised under Directive 70/524/EEC (EFSA, 2008b), Guidance for the preparation of dossiers for additives already authorised for use in food (EFSA FEEDAP Panel, 2012b) and Guidance on the assessment of additives intended to be used in pets and other non-food-producing animals (EFSA FEEDAP Panel, 2011b).

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 a 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 ≤ 12%).

In its previous opinion (EFSA FEEDAP Panel, 2014a), the FEEDAP Panel 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.

The applicant has submitted new data to support the safety of cassia gum with higher anthraquinones content for the target species.

3.1. Safety for the target species

In its previous opinion (EFSA FEEDAP Panel, 2014), 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, in the current application, did not address the genotoxicity potential of semirefined cassia gum. Instead, in order to support the safety of cassia gum with a higher level of anthraquinones, a study in cats performed in 1997 was provided.[5]

This study, briefly described below, showed several limitations. The cassia gum used in the study was not satisfactorily characterised. According to the applicant, the cassia gum used in this study had a concentration of anthraquinones of approximately 70 mg/kg, based on the assumption that the test item would not have contained more than 10 mg chrysophanic acid/kg, since this was the specified content of cassia 4 years before study start. However, no analytical certificates were provided to support this claim. The nutritive value of the diets administered to the cats could only be estimated. Moreover, several limitations in the description and reporting of the study were identified (e.g. number of animals included in the trial vs observations reported).

A total of 30 female cats, between 1 and 7 years of age, were grouped into two adjacent rooms with 15 cats each. They were fed canned diets with and without 0.3% cassia gum (corresponding to 1.9% in DM). The first 4 weeks of feeding were considered by the study authors as a prefeed period. Thereafter, cats with behavioural signs of oestrus were mated (at least 4 times preferably within a

[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] Technical dossier/0113_2011_Trial_2472.

single day). Three weeks after mating, the queens were checked for gestation by ultrasound. Fifty-five days after mating, pregnant queens were caged individually and remained there throughout lactation (6 weeks). Feed intake was measured daily and body weight weekly; at parturition, litter details and queen and kitten birth weights were recorded. At the beginning of the trial, blood samples were collected from all the queens and at the end of the trial from all the queens and the kittens.

Throughout the trial food intake was high but there was a high incidence of vomiting and loose faeces occurring on both diets. This was thought to be due to the relatively low energy content of both diets, resulting in relatively high food intakes. Diet composition was not given and analytical data on dietary nutrient concentration was not provided. However, from different statements in the text and some tabulated figures it is assumed[6] that the diet(s) contained about 15.8% DM and about 4,000 kcal energy/kg DM and that, consequently, the DM intake during the premating period was rather low (< 40 g/cat and day) compared to a standard figure of 60 g/adult cat. Data of the lactation period could not be taken for comparison, since (i) the number of queens is not stated, (ii) the body weight (bw) of queens is not given and (iii) feed intake is indicated as 'mean total food intake during lactation (g)' and as 'mean peak food intake (g/kg bw)'.

The number of queens is given with 15 per group, the 'number mated' with 19 for the cassia and 21 for the control group. The number of pregnant cats was 10 in the cassia and 8 in the control group; however, fertility (percentage of pregnant cats) was 42% and 38%, respectively, and referring to the pregnant cats to the number of mated which is higher than the panel of cats in the study. Data from eight litters per group were compared (10 litters had to be expected for the cassia group), body weight of queens during lactation is given for eight animals of the cassia group, but only for six of the control group.

The results can be described briefly. Both groups had a similar performance throughout the trial. Kitten birth weights were slightly higher in the control compared to the cassia gum group. However, these differences were not significant. Weight gain during pregnancy was normal on both diets and 90% of day old kittens survived to weaning. There were no obvious abnormalities in the kittens produced and their development appeared normal. At the end of trial, blood results were not significantly different between the queens and their kittens fed the different diets, with the exception of cholesterol levels being higher in kittens fed the cassia diet (7.37 vs 5.66 mmol/L, $p < 0.005$). Cholesterol levels were also higher in the queens fed the cassia diet, but this did not reach statistical significance. The white blood cell counts in the treated queens was higher (50.3×10^9/L) than in control queens (18.5×10^9/L); statistical analysis was not available.

Considering the limitations described above (test substance not characterised, the report is incomplete, essential data are lacking, and the few findings described are ambiguous), this study is of limited value to support the safety for the target species.

The applicant made reference to an unpublished report of a reproduction study in dogs (Hynds et al., 1995). However, since the report was not made available, the FEEDAP Panel cannot assess it.

4. Conclusions

Considering that no new data on the genotoxic potential of the semirefined cassia gum with an anthraquinone content higher than the one specified for the use as food additive (< 0.5 mg/kg), and the limitations in the study conducted in cats, the FEEDAP Panel is not in a position to modify its previous conclusion. Therefore, the FEEDAP Panel reiterates 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, corresponding to 1.32% (13,200 mg/kg feed) in a standardised complete feed with 12% water content.

[6] From a sentence 'the test diet contained cassia at a level of 0.3% on a fresh matter basis (equivalent to 1.9 g/400 kcal, or 1.9 g/100 g dry matter', it can be concluded that (i) the dry matter content of the diet was 15.8% (0.3/1.9 × 100), (ii) the energy content (gross?, metabolisable?) was 4,000 kcal/kg DM (400/100 × 1,000). Another sentence gives the 'predicted' energy concentration of the cassia containing diet with 61.85 kcal/100 g and 66.2 and 66.7 kcal/100 g for the two batches of control diet. The average energy content of the diets would be 64.9 kcal/100 g, corresponding to 4,108 kcal/kg DM (649/0.158). Taking these figures for an interpretation of the data of the premating period (Table 1 of the report: mean body weight/cat of both groups: 3,326 g, mean daily feed intake/cat of both groups: 224 g, mean daily energy intake per kg bw of both groups: 42 kcal), the daily DM intake was 35.4 g. The energy intake was 139.7 kcal/cat (42 × 3.326) equal to 3.94 (139.7/35.4) kcal/g feed DM. This energy concentration is approximately confirmed also by data reported for the lactation period (Table 3).

Documentation provided to EFSA

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Abbreviations

AFC	EFSA Panel on Food additives, flavourings, processing aids and materials in contact with food
bw	body weight
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
WHO	World Health Organization