Commission Implementing Regulation (EU) 2019/1947 of 22 November 2019 concerning the authorisation of cassia gum as a feed additive for cats and dogs (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2019/1947

of 22 November 2019

concerning the authorisation of cassia gum as a feed additive for cats and dogs

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC⁽²⁾.
- (2) Cassia gum was authorised without a time limit in accordance with Directive 70/524/ EEC as a feed additive for cats and dogs⁽³⁾. This additive was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1) (b) of Regulation (EC) No 1831/2003.
- In accordance with Article 10(2) of Regulation (EC) No 1831/2003 four applications were submitted for the re-evaluation of cassia gum as a feed additive for cats and dogs. The applicants requested this additive to be classified in the additive category 'technological additives' and in the functional group 'gelling agents'. Those applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003. Subsequently, three of those applications were withdrawn by the respective applicants for authorisation.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 29 October 2014⁽⁴⁾, 25 January 2017⁽⁵⁾ and 27 November 2018⁽⁶⁾ that, only purified (isopropanol extraction) semi-refined cassia gum that meets the specifications of cassia gum as a food additive⁽⁷⁾ (< 0,5 mg anthraquinones/kg) does not have an adverse effect on animal health at a maximum content of 13 200 mg/kg of complete feed with 12 % moisture content. It also concluded that the additive is regarded as a skin and respiratory sensitiser and as potential irritant to skin and eyes. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. It further concluded that

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the mutagenicity of the existing semi-refined cassia gum in the market, as described in the application cannot be excluded. The Authority further concluded that cassia gum has the potential to be effective as gelling agent when used together with carrageenan in feeds with a moisture content higher than 20 %. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the methods of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

- (5) The assessment of cassia gum shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied, provided that the specifications as a food additive are met. Accordingly, the use of the additive should be authorised as specified in the Annex to this Regulation.
- (6) Therefore, cassia gum as an existing product which does not comply with the specifications as a food additive, as well as feed containing it, should be withdrawn from the market. For practical reasons however, a limited period should be allowed for the withdrawal from the market of the existing stocks of the additive and feed containing it in order to enable operators to prepare themselves to meet the new requirements resulting from the authorisation.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The additive specified in the Annex, belonging to the additive category 'technological additives' and to the functional group 'gelling agents', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Transitional measures

- The feed additive cassia gum which is produced and labelled before 16 December 2019 in accordance with the rules applicable before 16 December 2019 may continue to be placed on the market and used until 16 March 2020.
- 2 Premixtures containing the feed additive referred to in paragraph 1 which are produced and labelled before 16 March 2020 in accordance with the rules applicable before 16 December 2019 may continue to be placed on the market and used until 16 June 2020.
- 3 Compound feed and feed materials containing the feed additive referred to in paragraph 1 or premixtures referred to in paragraph 2 which are produced and labelled before 16 June 2020 in accordance with the rules applicable before 16 December 2019 may continue to be placed on the market and used until 16 December 2020.

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Article 3

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 22 November 2019.

For the Commission

The President

Jean-Claude JUNCKER

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ANNEX

Identific	at#Acchditive	Compos	it ism ecies	Maximu	mMinimu	mMaximu	mOther	End of
number		chemica	l or	age	content	content	provisio	nsperiod
of the		formula	category		mg of ad	ditive/	•	of
additive		descript	io a f		kg of cor			authorisation
		analytic	alanimal		feedings			
		method			with a m			
					content o	of 12 %		
Additive	category:	technolog	ical additi	ves. Func	tional grou	up: gelling	agents	
1f499	Cassia	Additive	Dogs			13 200	1.	The: 12.2029
	gum	compositi	<i>G</i> ats					additive
		Preparation	n					shall
		of						be
		purified						only
		endosperi	n					used
		of						in
		Cassia						complete
		tora,						feed
		Cassia						having
		obtusifoli						a
		(Legumin	osae)					moisture
		containin	g					content
		less than						>
		0,05 %						20
		Cassia						%
		occidenta						in
		Anthraqu	inones					combination
		(total) <						with
		0,5 mg/						carrageenan
		kg						(representing
		Powder						at
		form						least
		Characte	risation					25
		of active						%
		substance	:					of
		Mainly						the
		1,4-β-D-						amount
		mannopy	ranose					of .
		units						cassia
		with						gum
		1,6-						used).
		linked						For
		α-D-						users
		galactopy	ranose					of
		units.						the

- a Details of the analytical methods are available at the following address of the Reference Laboratory for Feed Additives: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports
- b FAO JECFA Combined Compendium of Food Additive Specifications, 'Cassia Gum', Monograph No 10 (2010) http://www.fao.org/fileadmin/user_upload/jecfa_additives/docs/monograph10/additive-513-m10.pdf
- c Commission Directive 2010/67/EU of 20 October 2010 amending Directive 2008/84/EC laying down specific purity criteria on food additives other than colours and sweeteners (OJ L 277, 21.10.2010, p. 17).

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Ratio			additive
mannose			and
to			premixtures,
galactose			feed
is 5:1.			business
Galactomann	ans		operators
> 75 %	uns		shall
Analytical			establish
method ^a :			operational
For the			procedures
determination	,		and
of cassia	1		organisational
gum			measures
in feed			to
additive:			address
FAO			potential
JECFA			risks
monograph			resulting
No			from
10 ^b as			their
referred			use.
in			Where
Commission			those
Directive			risks
2010/67/			cannot
EU ^e			be
EU			eliminated
			or
			reduced
			to
			a
			minimum
			by
			such
			procedures
			and
			measures,
			the
			additive
			and
			premixtures
			shall
			be
			used
			with
			personal
			protective

a Details of the analytical methods are available at the following address of the Reference Laboratory for Feed Additives: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

b FAO JECFA Combined Compendium of Food Additive Specifications, 'Cassia Gum', Monograph No 10 (2010) http://www.fao.org/fileadmin/user_upload/jecfa_additives/docs/monograph10/additive-513-m10.pdf

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			equipme including skin, eyes and breathing
			breathing protection

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- b FAO JECFA Combined Compendium of Food Additive Specifications, 'Cassia Gum', Monograph No 10 (2010) http://www.fao.org/fileadmin/user_upload/jecfa_additives/docs/monograph10/additive-513-m10.pdf
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- (1) OJ L 268, 18.10.2003, p. 29.
- (2) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).
- (3) Commission Directive 93/55/EEC of 25 June 1993 amending Council Directive 70/524/EEC concerning additives in feedingstuffs (OJ L 206, 18.8.1993, p. 11).
- (4) EFSA Journal 2014; 12(11):3899, 3900, 3901 and 3902
- (5) EFSA Journal 2017; 15(2):4709 and 4710
- (6) EFSA Journal 2019;17(1):5528.
- (7) 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 (OJ L 83, 22.3.2012, p. 1).

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