Commission Implementing Regulation (EU) 2018/1533 of 12 October 2018 concerning the authorisation of sodium alginate as a feed additive for cats, dogs, other non-food-producing animals and fish and potassium alginate as a feed additive for cats and dogs (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1533

of 12 October 2018

concerning the authorisation of sodium alginate as a feed additive for cats, dogs, other non-food-producing animals and fish and potassium alginate 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.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of potassium alginate.
- (3) Article 10 of Regulation (EC) No 1831/2003 provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC⁽²⁾. Sodium alginate was authorised without a time limit by Directive 70/524/EEC as feed additive for fish, pets and other non-food-producing animals. The additive was subsequently entered in the Register of feed additives as existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.
- (4) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of sodium alginate as feed additive for pets and other non-food-producing animals and fish.
- (5) The applications concern the authorisation of potassium alginate as a feed additive for cats and dogs, and sodium alginate as a feed additive for cats, dogs, other non-food-producing animals and fish, to be classified in the additive category 'technological additives'. Those applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (6) The European Food Safety Authority ('the Authority') concluded in its opinion of 5 July 2017⁽³⁾ that, under the proposed conditions of use, potassium alginate and sodium alginate do not have an adverse effect on animal health, human health

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1533. (See end of Document for details)

or the environment. The Authority also concluded that the potassium alginate and sodium alginate concerned are effective as stabilisers, thickeners, gelling agents and binders. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

- (7) The assessment of the additives concerned shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of additives should be authorised as specified in the Annex to this Regulation.
- (8) 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 additives specified in the Annex, belonging to the additive category 'technological additives' and to the functional group 'stabilisers', 'thickeners', 'gelling agents' and 'binders' are authorised as additives in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Transitional measures

Sodium alginate specified in the Annex and premixtures containing that additive, which are produced and labelled before 4 May 2019 in accordance with the rules applicable before 4 November 2018 may continue to be placed on the market and used until the existing stocks are exhausted.

Feed materials and compound feed containing sodium alginate specified in the Annex which are produced and labelled before 4 November 2019 in accordance with the rules applicable before 4 November 2018 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food producing animals.

Feed materials and compound feed containing sodium alginate specified in the Annex which are produced and labelled before 4 November 2020 in accordance with the rules applicable before 4 November 2018 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1533. (See end of Document for details)

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, 12 October 2018.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1533. (See end of Document for details)

ANNEX

Identific number of the additive	a <i>t</i> Aodditive	chemical formula, descripti analytica	l or category o o f	age	mMinimum content mg of ad kg of cor feedings	content ditive/ nplete tuff	End of nsperiod of authorisatio
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a Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

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				protective equipment, including breathing protection.
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							their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall
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				reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection.
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				and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing
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Technol	ogical addi	tives: binde	P FC			premixtures shall be used with personal protective equipment, including breathing protection.
1d401	Sodium alginate	Additive compositi Sodium alginate Powder form Character of the active substance Sodium alginate (≥ 90,8 % (C ₆ H ₇ Nac Analytical method ^a For the identificat of sodium alginate in the feed additive: The sodium alginate monograp FAO JECFA Combined Compend of Food Additive Specificat Monograp No 1 (2006)	Cats and alogs cisation D ₆)n din ion ions ions		35 200	A INovember the 28 directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. The mixture of different sources of alginates shall not exceed the permitted maximum content in

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				complete feedingstuffs.
			3.	For
				users
				of
				the
				additive
				and
				premixtures,
				feed
				business
				operators
				shall establish
				operational
				procedures
				and
				organisational
				measures
				to
				address
				potential
				risks
				resulting
				from
				their
				use. Where
				those
				risks
				cannot
				be
				eliminated
				or
				reduced
				to
				a
				minimum
				by
				such procedures
				and
				measures,
				the
				additive
				and
				premixtures
				shall
				be
				used

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Other non-food-producing animals					with personal protective equipment, including breathing protection.
of the additive and premixture the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixture feed business operators shall establish operational procedures and procedures and		non- food- producing		2.	In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential

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							resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection.
1d402	Potassium alginate	Additive compositi Potassium alginate Powder form Character of the active substance Potassium alginate $(\geq 89,2\%)$ (C_6H_7KO)	n risation n		35 200	1.	A INovember the 28 directions for use of the additive and premixtures, the storage conditions and stability to

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CAS		heat
No:		treatment
9005-36-1		shall
Analytical		be
method ^a		indicated.
For the		
identification	2.	The
of		mixture
		of
potassium		different
alginate in the		sources
feed		of
additive:		alginates
The		shall
		not
potassium		exceed
alginate		the
monograph, FAO		permitted
		maximum
JECFA Combined		content
		in
Compendium of Food		complete
Additive		feedingstuffs.
Specifications —	3.	For
Monograph No 1		users
(2006)		of
(2000)		the
		additive
		and
		premixtures,
		feed
		business
		operators
		shall
		establish
		operational
		procedures
		and
		organisational
		measures
		to
		address
		potential
		risks
		resulting
		from
		their
		use.
		Where
		those

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

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1		I		risks
				1
				cannot
				be
				eliminated
				or
				reduced
				to
				a
				minimum
				by
				such
				procedures
				and
				measures,
				the
				additive
				and
				premixtures
				shall
				be
				used
				with
				personal
				protective
				equipment,
				including
				breathing
				protection.
				protection.

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

- (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) EFSA Journal 2017; 15(7):4945.

Changes to legislation:

There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1533.