

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<sup>(1)</sup>, 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<sup>(2)</sup>. 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<sup>(3)</sup> that, under the proposed conditions of use, potassium alginate and sodium alginate do not have an adverse effect on animal health, human health

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*Changes to legislation: There are currently no known outstanding effects for the  
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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.

### *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



ANNEX

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

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							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 with personal
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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.
			Other non- food- producing animals Fish	—	—	—	<p>1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</p> <p>2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from</p>

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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 be used with personal protective equipment, including breathing protection.
1d402	Potassium alginate	<i>Additive composition</i> Potassium alginate Powder form <i>Characterisation of the active substance</i> Potassium alginate (≥ 89,2 %) (C <sub>6</sub> H <sub>7</sub> KO <sub>6</sub> ) <sub>n</sub> CAS No: 9005-36-1	Cats and dogs	—	—	35 200	1.	4 In November 2028, the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment

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	<p><i>Analytical method<sup>a</sup></i> For the identification of potassium alginate in the feed additive: The potassium alginate monograph, FAO JECFA Combined Compendium of Food Additive Specifications — Monograph No 1 (2006)</p>		<p>shall be indicated.</p> <p>2. The mixture of different sources of alginates shall not exceed the permitted maximum content in complete feedingstuffs.</p> <p>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</p>
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								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.
<b>Technological additives: thickeners</b>								
1d401	Sodium alginate	<i>Additive composition</i> Sodium alginate Powder form <i>Characterisation of the active substance</i> Sodium alginate (≥ 90,8 %) (C <sub>6</sub> H <sub>7</sub> NaO <sub>6</sub> ) <sub>n</sub> <i>Analytical method<sup>a</sup></i> For the identification of sodium alginate in the feed	Cats and dogs	—	—	35 200	1.	4 In November 2028 directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.

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	additive: — The sodium alginate monograph, FAO JECFA Combined Compendium of Food Additive Specifications — Monograph No 1 (2006)					2. The mixture of different sources of alginates shall not exceed the permitted maximum content in 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
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ANNEX

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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.
			Other non-food-producing animals Fish	—	—	—	<p>1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</p> <p>2. For users of the additive</p>

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1d402	Potassium alginate	<p><i>Additive composition</i>                  Potassium alginate Powder form  <i>Characterisation of the active substance</i>                  Potassium alginate (≥ 89,2 %) (C<sub>6</sub>H<sub>7</sub>KO<sub>6</sub>)<sub>n</sub>                  CAS No: 9005-36-1  <i>Analytical method<sup>a</sup></i>                  For the identification of potassium alginate in the feed additive:                  The potassium alginate monograph, FAO JECFA Combined Compendium of Food Additive Specifications — Monograph No 1 (2006)</p>	Cats and dogs	—	—	35 200	<p>1.</p> <p>2.</p> <p>3.</p>	<p>4                  In November 2028, the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</p> <p>The mixture of different sources of alginates shall not exceed the permitted maximum content in complete feedingstuffs.</p> <p>For users of the additive and premixtures, feed business operators</p>
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								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 with personal protective equipment, including breathing protection.
<b>Technological additives: gelling agents</b>								
1d401	Sodium alginate	<i>Additive composition</i> Sodium alginate	Cats and dogs	—	—	35 200	1.	4 In November 2028 directions

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	<p>Powder form  <i>Characterisation of the active substance</i>                  Sodium alginate                  (≥ 90,8 %) (C<sub>6</sub>H<sub>7</sub>NaO<sub>6</sub>)<sub>n</sub>  <i>Analytical method<sup>a</sup></i>                  For the identification of sodium alginate in the feed additive: —                  The sodium alginate monograph, FAO JECFA Combined Compendium of Food Additive Specifications —                  Monograph No 1 (2006)</p>				<p>for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</p> <p>2. The mixture of different sources of alginates shall not exceed the permitted maximum content in complete feedingstuffs.</p> <p>3. For users of the additive and premixtures, feed business operators shall establish operational procedures</p>
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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 protection.
			Other non-food-producing animals Fish	—	—	—	1. In the directions for use of the additive and

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								procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection.
1d402	Potassium alginate	<i>Additive composition</i> Potassium alginate Powder form <i>Characterisation of the active substance</i> Potassium alginate (≥ 89,2 %) (C <sub>6</sub> H <sub>7</sub> KO <sub>6</sub> ) <sub>n</sub> CAS No: 9005-36-1 <i>Analytical method<sup>a</sup></i> For the identification of potassium alginate in the feed additive: The potassium alginate monograph, FAO JECFA	Cats and dogs	—	—	35 200	1.	4 November 2028 In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.
							2.	The mixture of different sources of alginates shall not exceed the

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	<p>Combined Compendium of Food Additive Specifications — Monograph No 1 (2006)</p>				<p>3.</p>	<p>permitted maximum content in complete feedingstuffs.  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</p>
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								premixtures shall be used with personal protective equipment, including breathing protection.
<b>Technological additives: binders</b>								
1d401	Sodium alginate	<i>Additive composition</i> Sodium alginate Powder form <i>Characterisation of the active substance</i> Sodium alginate (≥ 90,8 %) (C <sub>6</sub> H <sub>7</sub> NaO <sub>6</sub> ) <sub>n</sub> <i>Analytical method<sup>a</sup></i> For the identification of sodium alginate in the feed additive: — The sodium alginate monograph, FAO JECFA Combined Compendium of Food Additive Specifications — Monograph No 1 (2006)	Cats and dogs	—	—	35 200	1.	4 In November 2028, directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.
							2.	The mixture of different sources of alginates shall not exceed the permitted maximum content in

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							with personal protective equipment, including breathing protection.
		Other non- food- producing animals Fish	—	—	—	1.	In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.
						2.	For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks

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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	<i>Additive composition</i> Potassium alginate Powder form <i>Characterisation of the active substance</i> Potassium alginate (≥ 89,2 %) (C <sub>6</sub> H <sub>7</sub> KO <sub>6</sub> ) <sub>n</sub>	Cats and dogs	—	—	35 200	1.	4 In November 2028, the directions for use of the additive and premixtures, the storage conditions and stability to

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	<p>CAS No: 9005-36-1 <i>Analytical method<sup>a</sup></i> For the identification of potassium alginate in the feed additive: The potassium alginate monograph, FAO JECFA Combined Compendium of Food Additive Specifications — Monograph No 1 (2006)</p>					<p>heat treatment shall be indicated.</p> <p>2. The mixture of different sources of alginates shall not exceed the permitted maximum content in complete feedingstuffs.</p> <p>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</p>
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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) *EFSA Journal* 2017; 15(7):4945.

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