Commission Implementing Regulation (EU) No 161/2013 of 21 February 2013 concerning the authorisation of a preparation of sodium hydroxide as a feed additive for cats, dogs and ornamental fish (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 161/2013

of 21 February 2013

concerning the authorisation of a preparation of sodium hydroxide as a feed additive for cats, dogs and ornamental fish

(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) A preparation of Sodium hydroxide, CAS number 1310-73-2, was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for use on cats and dogs by Commission Directive 86/525/EEC[(3)]. That preparation was subsequently entered in the Community Register of feed additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.

(3) 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 hydroxide, CAS number 1310-73-2, as a feed additive for cats and dogs and, in accordance with Article 7 of that Regulation, for a new use for ornamental fish, requesting that additive to be classified in the additive category ‘technological additives’. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 11 September 2012[(4)] that, taking into account the fact that this additive was already authorised for food use with the same function and under the proposed conditions of use, sodium hydroxide does not have an adverse effect on animal health, and that its function in feed is essentially the same as in food as acidity regulator and therefore no further demonstration of efficacy is necessary. It concluded that no safety concerns would arise for users provided that appropriate protective measures are taken. It also

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 161/2013. (See end of Document for details)*

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.

(5) The assessment of sodium hydroxide shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this preparation should be authorised as specified in the Annex to this Regulation.

(6) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation, it is appropriate to allow a transitional period for the disposal of existing stocks of additive, pre-mixtures and compound feed containing it, as authorised by Directive 86/525/EEC.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

The preparation specified in the Annex, belonging to the additive category ‘technological additives’ and to the functional group ‘acidity regulators’, is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

The additive specified in the Annex and premixtures containing it which are produced and labelled before 14 March 2014 in accordance with the rules applicable before 14 March 2013 may continue to be placed on the market and used until the existing stocks are exhausted.

Compound feed containing the additive specified in the Annex which is produced and labelled before 14 March 2015 in accordance with the rules applicable before 14 March 2013 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 3

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, 21 February 2013.

For the Commission

The President

José Manuel BARROSO

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 161/2013. (See end of Document for details)*

ANNEX

Identification number of the additive	**Name of the holder of authorisation**	**Additive**	**Composition, chemical formula, description, analytical method**	**Species or category of animal**	**Maximum age**	**Minimum content**	**Maximum content**	**Other provisions**	**End of period of authorisation**
						mg/kg of complete feedingstuff with a moisture content of 12 %			
Category of technological additives. Functional group: acidity regulators									
1j524	—	Sodium hydroxide	*Additive composition* Sodium hydroxide min. 50 % w/w (water solution) *Characterisation of the active substance* Sodium hydroxide ≥ 98,0 % total alkali (calculated as NaOH) NaOH CAS No.: 1310-73-2 Produced by chemical synthesis *Method of Analysis*[a] Determination of sodium hydroxide	—	—	—	—	1. For safety: breathing protection, eye protection, gloves and protective clothing shall be used during handling. 2. For use: the resulting total sodium concentration in feed shall not compromise the overall electrolyte balance.	14 March 2023

a Details of the analytical methods are available at the following addresses: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx and http://www.fao.org/ag/jecfa-additives/details.html?id=400