Commission Implementing Regulation (EU) 2015/897 of 11 June 2015 concerning the authorisation of thiamine hydrochloride and thiamine mononitrate as feed additives for all animal species (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2015/897

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concerning the authorisation of thiamine hydrochloride and thiamine mononitrate as feed additives for all animal species

(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) Thiamine hydrochloride and thiamine mononitrate were authorised without a time limit in accordance with Directive 70/524/EEC as feed additives for all animal species. Those products were subsequently entered in the Register of feed additives as existing products, 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, three applications were submitted for the re-evaluation of thiamine hydrochloride and thiamine mononitrate as feed additives for all animal species and, in accordance with Article 7 of that Regulation, for a new use in water for drinking. The applicants requested these additives to be classified in the additive category ‘nutritional additives’. Those applications were 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 opinions of 11 October 2011[(3)] that, under the proposed conditions of use in feed, thiamine hydrochloride and thiamine mononitrate do not have adverse effects on animal health, human health or the environment. The Authority further concluded that thiamine hydrochloride and thiamine mononitrate are effective sources of vitamin B_1 and that no safety concerns would arise for users. 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 additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of thiamine hydrochloride and thiamine mononitrate shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of these substances 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 interested parties 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

The substances specified in the Annex, belonging to the additive category ‘nutritional additives’ and to the functional group ‘vitamins, pro-vitamins and chemically well-defined substances having similar effect’, are authorised as feed additives in animal nutrition subject to the conditions laid down in that Annex.

Article 2

1 The substances specified in the Annex and premixtures containing those substances, which are produced and labelled before 2 January 2016 in accordance with the rules applicable before 2 July 2015 may continue to be placed on the market and used until the existing stocks are exhausted.

2 Compound feed and feed materials containing the substances specified in the Annex which are produced and labelled before 2 July 2016 in accordance with the rules applicable before 2 July 2015 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.

3 Compound feed and feed materials containing the substances specified in the Annex which are produced and labelled before 2 July 2017 in accordance with the rules applicable before 2 July 2015 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

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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2015/897. (See end of Document for details)*

Done at Brussels, 11 June 2015.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2015/897. (See end of Document for details)*

ANNEX

Identification number of the additive	**Name of the holder of the 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 of active substance/kg of complete feedingstuff with a moisture content of 12 % or mg of the active substance/l of water.			
Nutritional additives: Vitamins, provitamins and chemically well-defined substances having similar effect									
3a820		‘Thiamine hydrochloride’ or ‘Vitamin B_1’	*Additive composition* Thiamine hydrochloride *Characterisation of the active substance* Thiamine hydrochloride $C_{12}H_{17}ClN_4OS\#HCl$ CAS No 67-03-8 Thiamine hydrochloride, solid form, produced by chemical synthesis. Purity crieria: min. 98,5 % on anhydrous basis. *Analytical methods*[a]*:* For the characterisation	All animal species	—	—	—	1. In the directions for use of the additive and premixture, indicate the storage and the stability conditions. 2. Thiamine hydrochloride may be used via water for drinking. 3. For safety: breathing protection, safety glasses and gloves shall be	2 July 2025

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

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			of thiamine hydrochloride in the feed additive: — high performance liquid chromatography with UV detection (HPLC-UV) — US Pharmacopeia 32 (‘thiamine hydrochloride’ monograph). For the quantification of thiamine hydrochloride in premixtures: — ion-exchange high performance liquid chromatography coupled to UV detector (HPLC-UV) — VDLUFA Bd. III, 13.9.1, or — reversed phase high performance liquid chromatography coupled				worn during handling.

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