Commission Implementing Regulation (EU) 2016/1095 of 6 July 2016 concerning the authorisation of Zinc acetate dihydrate, Zinc chloride anhydrous, Zinc oxide, Zinc sulphate heptahydrate, Zinc sulphate monohydrate, Zinc chelate of amino acids hydrate, Zinc chelate of protein hydrolysates, Zinc chelate of glycine hydrate (solid) and Zinc chelate of glycine hydrate (liquid) as feed additives for all animal species and amending Regulations (EC) No 1334/2003, (EC) No 479/2006, (EU) No 335/2010 and Implementing Regulations (EU) No 991/2012 and (EU) No 636/2013 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2016/1095

of 6 July 2016

concerning the authorisation of Zinc acetate dihydrate, Zinc chloride anhydrous, Zinc oxide, Zinc sulphate heptahydrate, Zinc sulphate monohydrate, Zinc chelate of amino acids hydrate, Zinc chelate of protein hydrolysates, Zinc chelate of glycine hydrate (solid) and Zinc chelate of glycine hydrate (liquid) as feed additives for all animal species and amending Regulations (EC) No 1334/2003, (EC) No 479/2006, (EU) No 335/2010 and Implementing Regulations (EU) No 991/2012 and (EU) No 636/2013

(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) The zinc compounds Zinc acetate dihydrate, Zinc oxide, Zinc sulphate heptahydrate, Zinc sulphate monohydrate, Zinc chelate of amino acids hydrate and Zinc chelate of glycine hydrate were authorised without a time limit by Commission Regulations (EC) No 1334/2003[(3)] and (EC) No 479/2006[(4)] in accordance with Directive 70/524/EEC. These 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, applications were submitted for the re-evaluation of Zinc acetate dihydrate, Zinc oxide, Zinc sulphate heptahydrate, Zinc sulphate monohydrate, Zinc chelate of amino acids hydrate and Zinc chelate of glycine hydrate as feed additives for all animal species. Additionally, in accordance with Article 7 of that Regulation, an

application was submitted for Zinc chloride anhydrous as feed additive for all animal species. The applicants requested that those additives be classified in the additive category 'nutritional additives'. The 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 1 February 2012[(5)], 8 March 2012[(6)], 23 May 2012[(7)], 15 November 2012[(8)], 12 September 2013[(9)] and 12 March 2015[(10)] that, under the proposed conditions of use, Zinc acetate dihydrate, Zinc chloride anhydrous, Zinc oxide, Zinc sulphate heptahydrate, Zinc sulphate monohydrate, Zinc chelate of amino acids hydrate and Zinc chelate of glycine hydrate do not have an adverse effect on animal and human health and that no safety concerns for users would arise provided that appropriate protective measures are taken.

(5) With respect to the impacts on the environment, in particular the drainage and run-off of zinc to surface water, the Authority recommended in its opinion of 8 April 2014[(11)] to decrease significantly the maximum contents of zinc in complete feed for several target species. However, in order not to risk not meeting the physiological needs of animals also in special life periods or any other negative impacts on animal health, the decrease of zinc contents recommended by the Authority should not be introduced in one step. With the objective of further reductions, feed business operators and research institutes should be encouraged to collect new scientific data about the physiological needs of the different animal species.

(6) The Authority further concluded that Zinc acetate dihydrate, Zinc chloride anhydrous, Zinc oxide, Zinc sulphate heptahydrate, Zinc sulphate monohydrate, Zinc chelate of amino acids hydrate and Zinc chelate of glycine hydrate are effective sources of zinc. Considering the chemical characteristics of Zinc chelate of amino acids, the Authority recommends its splitting into the following two groups: Zinc chelate of amino acids hydrate and Zinc chelate of protein hydrolysates. Moreover, for Zinc chelate of glycine hydrate two different forms have been assessed, a solid and a liquid one. 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.

(7) The assessment of Zinc acetate dihydrate, Zinc chloride anhydrous, Zinc oxide, Zinc sulphate heptahydrate, Zinc sulphate monohydrate, Zinc chelate of amino acids hydrate, Zinc chelate of protein hydrolysates, Zinc chelate of glycine hydrate (solid) and Zinc chelate of glycine hydrate (liquid) 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.

(8) As a result of the granting authorisation for 'Zinc acetate dihydrate', 'Zinc oxide', 'Zinc sulphate heptahydrate', 'Zinc sulphate monohydrate', 'Zinc chelate of amino acids hydrate' and 'Zinc chelate of glycine hydrate' by this Regulation, the entries on these substances in Regulations (EC) No 479/2006 and (EC) No 1334/2003 are obsolete and should therefore be deleted.

(9) Commission Regulation (EU) No 335/2010[(12)] and Commission Implementing Regulations (EU) No 991/2012[(13)] and (EU) No 636/2013[(14)] authorised several zinc compounds as nutritional feed additives. In order to take into account the conclusions of the Authority in its opinion of 8 April 2014, which were also the scientific basis for the provisions concerning the total zinc content in compound feed for the additives authorised by this Regulation and which are mainly referring to the environmental impact of feed supplementation with zinc, it is appropriate to align the maximum contents of zinc in Regulation (EU) No 335/2010 and Implementing Regulations (EU) No 991/2012 and (EU) No 636/2013 with the provisions of this Regulation as regards the zinc content in compound feed. Regulations (EU) No 335/2010 and Implementing Regulations (EU) No 991/2012 and (EU) No 636/2013 should therefore be amended accordingly.

(10) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for Zinc acetate dihydrate, Zinc oxide, Zinc sulphate heptahydrate, Zinc sulphate monohydrate, Zinc chelate of amino acids hydrate and Zinc chelate of glycine hydrate and the zinc compounds authorised by Regulation (EU) No 335/2010 and Implementing Regulations (EU) No 991/2012 and (EU) No 636/2013, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(11) 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 substances specified in the Annex, belonging to the additive category ‘nutritional additives’ and to the functional group ‘compounds of trace elements’, are authorised as additives in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Amendment to Regulation (EC) No 1334/2003

In the Annex to Regulation (EC) No 1334/2003, from the entry E6 on the element Zinc-Zn the following additives: ‘Zinc acetate dihydrate’, ‘Zinc oxide’, ‘Zinc sulphate heptahydrate’, ‘Zinc sulphate monohydrate’, ‘Zinc chelate of amino acids hydrate’, and their chemical formulas and descriptions are deleted.

Article 3

Amendment to Regulation (EC) No 479/2006

In the Annex to Regulation (EC) No 479/2006, the entry E6 on the additive 'Zinc chelate of glycine hydrate' is deleted.

Article 4

Amendment to Regulation (EU) No 335/2010

In the Annex to Regulation (EU) No 335/2010, in the line 3b6.10 the eighth column is replaced by the following:

Dogs and cats: 200 (total)

Salmonids and milk replacers for calves: 180 (total)

Piglets, sows, rabbits and all fish species other than salmonids: 150 (total)

Other species and categories: 120 (total).

Article 5

Amendment to Implementing Regulation (EU) No 991/2012

In the Annex to Implementing Regulation (EU) No 991/2012, in the line 3b609 the eighth column is replaced by the following:

Dogs and cats: 200 (total)

Salmonids and milk replacers for calves: 180 (total)

Piglets, sows, rabbits and all fish species other than salmonids: 150 (total)

Other species and categories: 120 (total).

Article 6

Amendment to Implementing Regulation (EU) No 636/2013

In the Annex to Commission Implementing Regulation (EU) No 636/2013, in the line 3b611 the eighth column is replaced by the following:

Dogs and cats: 200 (total)

Salmonids and milk replacers for calves: 180 (total)

Piglets, sows, rabbits and all fish species other than salmonids: 150 (total)

Other species and categories: 120 (total).

Article 7

Transitional measures

1 Zinc acetate dihydrate, Zinc oxide, Zinc sulphate heptahydrate, Zinc sulphate monohydrate, Zinc chelate of amino acids hydrate and Zinc chelate of glycine hydrate and the zinc compounds authorised by Regulation (EU) No 335/2010 and Implementing Regulations (EU) No 991/2012 and (EU) No 636/2013 and premixtures containing them, which are produced and labelled before 27 January 2017 in accordance with the rules applicable before 27 July 2016 may continue to be placed on the market and used until the existing stocks are exhausted.

2 Feed materials and compound feed containing the substances referred to in paragraph 1 which are produced and labelled before 27 July 2017 in accordance with the rules applicable before 27 July 2016 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 Feed materials and compound feed containing the substances referred to in paragraph 1 which are produced and labelled before 27 July 2018 in accordance with the rules applicable before 27 July 2016 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 8

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, 6 July 2016.

For the Commission

The President

Jean-Claude JUNCKER