



EUROPEAN  
COMMISSION

Brussels, **XXX**  
SANCO/12773/2014 CIS  
(POOL/G1/2014/12773/12773-EN  
CIS.doc)  
[...](2015) **XXX** draft

**COMMISSION IMPLEMENTING REGULATION (EU) .../...**

**of **XXX****

**concerning the authorisation of potassium iodide, calcium iodate anhydrous and coated  
granulated calcium iodate anhydrous as feed additives for all animal species**

(Text with EEA relevance)

# COMMISSION IMPLEMENTING REGULATION (EU) .../...

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**concerning the authorisation of potassium iodide, calcium iodate anhydrous and coated granulated calcium iodate anhydrous 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<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. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC<sup>2</sup>.
- (2) Potassium iodide and calcium iodate anhydrous were authorised without a time limit by 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 potassium iodide and calcium iodate anhydrous as feed additives for all animal species. Additionally, an application based on Article 10(2) was submitted for the re-evaluation of calcium iodate anhydrous in a film granulated form for all animal species. For the three compounds of iodine, the applicants requested that the 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 published on 19 May 2014<sup>3 4 5 6</sup> that, under the proposed conditions of use, potassium iodide, calcium iodate anhydrous and coated granulated calcium iodate anhydrous do not have an adverse effect on animal health, consumer health or the environment.

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<sup>1</sup> OJ L 268, 18.10.2003, p. 29.

<sup>2</sup> Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).

<sup>3</sup> EFSA Journal 2013; 11(2):3099.

<sup>4</sup> EFSA Journal 2013; 11(2):3100.

<sup>5</sup> EFSA Journal 2013; 11(2):3101.

<sup>6</sup> EFSA Journal 2013; 11(3):3178.

- (5) The Authority further concluded that potassium iodide, calcium iodate anhydrous and coated granulated calcium iodate anhydrous are effective sources of iodine in the respective target species and that no safety concerns would arise for users provided that appropriate protective measures are taken. 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.
- (6) The assessment of potassium iodide, calcium iodate anhydrous and coated granulated calcium iodate anhydrous 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 and preparations should be authorised as specified in the Annex to this Regulation.
- (7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for potassium iodide and calcium iodate anhydrous, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (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 substances and preparations 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*  
*Transitional measures*

Potassium iodide and calcium iodate anhydrous as specified in the Annex and feed containing them, which are produced and labelled before [6 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] in accordance with the rules applicable before [the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] may continue to be placed on the market and used until the existing stocks are exhausted.

*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,

*For the Commission*  
*The President*  
*Jean-Claude JUNCKER*