# Commission Implementing Regulation (EU) 2015/861 of 3 June 2015 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) 2015/861

## of 3 June 2015

## 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[(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) Potassium iodide and calcium iodate anhydrous were authorised without a time limit by Directive 70/524/EEC as amended by Commission Regulation (EC) No 1459/2005[(3)]. 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[(4)(5)(6)(7)] 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.

(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*

**Amendment to Regulation (EC) No 1459/2005**

In the Annex to Commission Regulation (EC) No 1459/2005, the entries ‘Potassium iodide’ and ‘calcium iodate anhydrous’, related to the element E 2 Iodine-I, are deleted.

*Article 3*

**Transitional measures**

1 Potassium iodide and calcium iodate anhydrous which were authorised by Directive 70/524/EEC and premixtures containing them, which are produced and labelled before 24 December 2015 in accordance with the rules applicable before 24 June 2015 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 specified in paragraph 1 which are produced and labelled before 24 June 2016 in accordance with the rules applicable before 24 June 2015 may continue to be placed on the market and used until the existing stocks

are exhausted. As regards feed intended for non-food producing animals, the time period for production and labelling referred to in the first sentence shall end 24 June 2017.

*Article 4*

**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, 3 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) 2015/861. (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 |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Element (I) in mg/kg of complete feed with a moisture content of 12 % | | | |
| Category of nutritional additives. Functional group: compounds of trace elements | | | | | | | | | |
| 3b201 | — | Potassium iodide | *Additive composition*<br>Potassium iodide and calcium stearate, as powder, with a minimum content of 69 % iodine<br>*Characterisation of the active substance*<br>Potassium iodide<br>Chemical formula: KI<br>CAS number: 7681-11-0<br>*Analytical methods*[a]<br>For the determination of Potassium iodide in the feed additive:<br>— Titrimetry — Food Chemicals Codex | All species | — | — | Equines: 4 (total)<br>Ruminants for milk production and laying hens: 5 (total)<br>Fish: 20 (total)<br>Other species or categories of animals: 10 (total) | 1. The additive shall be incorporated into compound feed in form of a premixture.<br>2. Potassium iodide may be placed on the market and used as an additive consisting of a preparation.<br>3. Protective measures shall be taken according to national regulations implementing Union legislation on health and safety | 24 June 2025 |

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| | | | monograph;<br>or<br>— Titrimetry — European Pharmacopoeia monograph (Eur.Ph. 6 01/2008:0186).<br>For the quantification of total potassium in the feed additive:<br>— Atomic Absorption Spectrometry, AAS (EN ISO 6869:2000);<br>or<br>— Inductively Coupled Plasma Atomic Emission Spectrometry, ICP-AES (EN 15510:2007).<br>For the quantification of total iodine in premixtures, feed materials and compound feed:<br>— Inductively Coupled Plasma Mass Spectrometry, ICP-MS (EN 15111:2007). | | at work including Council Directives 89/391/EEC[b], 89/656/EEC[c], 92/85/EEC[d] and 98/24/EC[e]. Appropriate protective gloves, respiratory and eye protection according to Council Directive 89/686/EEC[f] shall be worn during handling.<br>4. In the directions for use of the additive and premixture indicate the storage and stability conditions.<br>5. The recommended maximum content of total iodine in complete |