II

(Non-legislative acts)

REGULATIONS

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:


(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.

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.

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.

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.

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
## Category of nutritional additives. Functional group: compounds of trace elements

<table>
<thead>
<tr>
<th>Identification number of the additive</th>
<th>Name of the holder of authorisation</th>
<th>Additive</th>
<th>Composition, chemical formula, description, analytical method</th>
<th>Species or category of animal</th>
<th>Maximum content</th>
<th>Minimum content</th>
<th>Other provisions</th>
<th>End of period of authorisation</th>
</tr>
</thead>
</table>
| 3b201 | — | Potassium iodide | Additive composition  
Potassium iodide and calcium stearate, as powder, with a minimum content of 69 % iodine  
Characterisation of the active substance  
Potassium iodide  
Chemical formula: KI  
CAS number: 7681-11-0  
Analytical methods (1)  
For the determination of Potassium iodide in the feed additive:  
— Titrmetry — Food Chemicals Codex monograph; or  
— Titrmetry — European Pharmacopoeia monograph (Eur.Ph. 6 01/2008:0186).  
For the quantification of total potassium in the feed additive:  
— Atomic Absorption Spectrometry, AAS (EN ISO 6869:2000); or  
Ruminants for milk production and laying hens: 5 (total)  
Fish: 20 (total)  
Other species or categories of animals: 10 (total) | 1. The additive shall be incorporated into compound feed in form of a premixture.  
2. Potassium iodide may be placed on the market and used as an additive consisting of a preparation.  
4. In the directions for use of the additive and premixture indicate the storage and stability conditions. | 24 June 2025 |
<table>
<thead>
<tr>
<th>Identification number of the additive</th>
<th>Name of the holder of authorisation</th>
<th>Additive</th>
<th>Composition, chemical formula, description, analytical method</th>
<th>Species or category of animal</th>
<th>Maximum age</th>
<th>Minimum content</th>
<th>Maximum content</th>
<th>Other provisions</th>
</tr>
</thead>
</table>
| 3b202                                | —                                   | Calcium iodate anhydrous | Additive composition  
Calcium iodate anhydrous, as powder, with a minimum content of 63.5% iodine  
Characterisation of the active substances  
Chemical formula: Ca(IO₃)₂  
CAS number: 7789-80-2  
Analytical methods (*)  
For the determination of Calcium iodate in the feed additive:  
— Titrimetry — Food Chemicals Codex monograph; or  
— Titrimetry — European Pharmacopoeia monograph (Eur.Ph. 6 01/2008:20504).  
For the quantification of total calcium in the feed additive:  
— Atomic Absorption Spectrometry, AAS (EN ISO 6869:2000); or | All species | — | — | Equines: 4 (total)  
Ruminants for milk production and laying hens: 5 (total)  
Fish: 20 (total)  
Other species or categories of animals: 10 (total) | 5. The recommended maximum content of total iodine in complete feed for:  
— equines is 3 mg/kg,  
— dogs is 4 mg/kg,  
— cats is 5 mg/kg,  
— ruminants for milk production is 2 mg/kg and  
— laying hens 3 mg/kg. |

1. The additive shall be incorporated into a compound feed in form of a premixture.  
2. Calcium iodate anhydrous may be placed on the market and used as an additive consisting of a preparation.  
3. Protective measures shall be taken according to national regulations implementing Union legislation on health and safety at work including Directives 89/391/EEC, 89/656/EEC, 92/85/EEC and 98/24/EC. Appropriate protective gloves, respiratory and eye protection according to Directive 89/686/EEC shall be worn during handling. | 24 June 2025 |
<table>
<thead>
<tr>
<th>Identification number of the additive</th>
<th>Name of the holder of authorisation</th>
<th>Additive</th>
<th>Composition, chemical formula, description, analytical method</th>
<th>Species or category of animal</th>
<th>Maximum age</th>
<th>Minimum content</th>
<th>Maximum content</th>
<th>Other provisions</th>
<th>End of period of authorisation</th>
</tr>
</thead>
</table>
|                                      | 3b203                              | Coated granulated calcium iodate anhydrous | Additive composition  
Coated granulated preparation of calcium iodate anhydrous with an iodine content of 1 — 10 %  
Coating agents and dispersants (choice of polyoxyethylene (20) sorbitan monolaurate (E432), glycerol polyethyleneglycol ricinoleate (E484), polyethyleneglycol 300, sorbitol (E420ii), and maltodextrin): < 5 %.  
Feed materials (calcium magnesium carbonate, calcium carbonate, corn cobs) as granulating agents.  
Particles < 50 μm: < 1,5 %  
Characterisation of the active substance  
Chemical formula: Ca(IO₃)₂  
CAS number: 7789-80-2 | All species | — | — | Equines: 4 (total)  
Ruminants for milk production and laying hens: 5 (total)  
Fish: 20 (total)  
Other species or categories of animals: 10 (total) | 4. The recommended maximum content of total iodine in complete feed for:  
— equines is 3 mg/kg,  
— dogs is 4 mg/kg,  
— cats is 5 mg/kg,  
— ruminants for milk production is 2 mg/kg and  
— laying hens 3 mg/kg. | 24 June 2025 |
|                                      |                                    | —        | —                                             | —                           | —                 | —               | —               | 2. The recommended maximum content of total iodine in complete feed for:  
— equines is 3 mg/kg,  
— dogs is 4 mg/kg,  
— cats is 5 mg/kg,  
— ruminants for milk production is 2 mg/kg and  
— laying hens 3 mg/kg. | —               | —                 | —               | —               | — |
<table>
<thead>
<tr>
<th>Identification number of the additive</th>
<th>Name of the holder of authorisation</th>
<th>Additive</th>
<th>Composition, chemical formula, description, analytical method</th>
<th>Species or category of animal</th>
<th>Maximum age</th>
<th>Minimum content</th>
<th>Maximum content</th>
<th>Other provisions</th>
<th>End of period of authorisation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td><em>Analytical methods (†)</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>For the determination of Calcium iodate in the feed additive:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>— Titrimetry — Food Chemicals Codex monograph; or</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>— Titrimetry — European Pharmacopoeia monograph (Eur.Ph. 6 01/2008:20504).</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>For the quantification of total calcium in the feed additive:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>— Atomic Absorption Spectrometry, AAS (EN ISO 6869:2000); or</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>For the quantification of total iodine in pre-mixtures, feed materials and compound feed:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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