

Brussels, **XXX**
SANCO/12773/2014 Rev. 1 ANNEX
CIS (POOL/G1/2014/12773/1277R1-EN
ANNEX CIS.doc)
[...](2015) **XXX** draft

ANNEX 1

ANNEX

to the

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

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

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	<p>Additive composition:</p> <p>Potassium iodide and calcium stearate, as powder, with a minimum content of 69 % iodine</p> <p>-----</p> <p>Characterisation of the active substance:</p> <p>Potassium iodide</p> <p>Chemical formula: KI</p> <p>CAS number: 7681-11-0</p> <p>-----</p> <p>Analytical methods⁽¹⁾:</p> <p>For the determination of Potassium iodide in the feed additive:</p> <ul style="list-style-type: none">- Titrimetry - Food Chemicals Codex monograph; or- Titrimetry - European Pharmacopoeia monograph (Eur.Ph. 6 01/2008:0186). <p>For the quantification of total potassium in the feed additive:</p> <ul style="list-style-type: none">- Atomic Absorption Spectrometry, AAS (EN ISO 6869:2000); or- Inductively Coupled Plasma Atomic Emission Spectrometry, ICP-AES (EN 15510:2007). <p>For the quantification of total iodine in premixtures, feed materials and compound feed:</p> <ul style="list-style-type: none">- Inductively Coupled Plasma Mass	All species	-	-	Equines: 3 (total) Ruminants for milk production and laying hens: 5 (total) Fish: 20 (total) Dogs: 4 (total) Cats: 5 (total) Other species or categories of animals: 10 (total)	<ol style="list-style-type: none">1. The additive shall be incorporated into compound feed in form of a premixture.2. The additive 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 Council Directives 89/391/EEC⁽²⁾, 89/656/EEC⁽³⁾, 92/85/EEC⁽⁴⁾ and 98/24/EC⁽⁵⁾. Appropriate protective gloves, respiratory and eye protection according to Council Directive	10 years from the date of entry into force of this Regulation <i>[To be completed by the Service responsible for the publication]</i>

			Spectrometry, ICP-MS (EN 15111:2007).					<p>89/686/EEC⁽⁶⁾ shall be worn during handling.</p> <p>4. Declarations to be made on the labelling of the additive, premixture and complementary feed:</p> <ul style="list-style-type: none"> - Storage and stability conditions. - "In case of a low content of goitrogen substances in the diet, the total iodine content in complete feed shall not exceed 2 mg/kg for ruminants for milk production and 3 mg/kg for laying hens." 	
3b202	-	Calcium iodate anhydrous	<p>Additive composition: Calcium iodate anhydrous, as powder, with a minimum content of 63,5 % iodine</p> <p>-----</p> <p>Characterisation of the active substances: Chemical formula: $\text{Ca}(\text{IO}_3)_2$ CAS number: 7789-80-2</p> <p>-----</p> <p>Analytical methods⁽¹⁾: For the determination of Calcium iodate in the feed additive:</p> <ul style="list-style-type: none"> - Titrimetry - Food Chemicals Codex 	All species	-	-	<p>Equines: 3 (total)</p> <p>Ruminants for milk production and laying hens: 5 (total)</p> <p>Fish: 20 (total)</p> <p>Dogs: 4 (total)</p> <p>Cats: 5 (total)</p> <p>Other species or categories of animals:</p>	<ol style="list-style-type: none"> 1. The additive shall be incorporated into a compound feed in form of a premixture. 2. The additive may be placed on the market and used as an additive consisting of a preparation. 3. Protective measures shall be taken according to 	<p>10 years from the date of entry into force of this Regulation</p> <p><i>[To be completed by the Service responsible for the publication]</i></p>

			<p>monograph; or</p> <ul style="list-style-type: none"> - Titrimetry - European Pharmacopoeia monograph (Eur.Ph. 6 01/2008:20504). <p>For the quantification of total calcium in the feed additive:</p> <ul style="list-style-type: none"> - Atomic Absorption Spectrometry, AAS (EN ISO 6869:2000); or - Inductively Coupled Plasma Atomic Emission Spectrometry, ICP-AES (EN 15510:2007). <p>For the quantification of total iodine in premixtures, feed materials and compound feed:</p> <ul style="list-style-type: none"> - Inductively Coupled Plasma Mass Spectrometry, ICP-MS (EN 15111:2007). 				10 (total)	<p>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.</p> <p>4. Declarations to be made on the labelling of the additive, premixture and complementary feed:</p> <p>"In case of a low content of goitrogen substances in the diet, the total iodine content in complete feed shall not exceed 2 mg/kg for ruminants for milk production and 3 mg/kg for laying hens."</p>	
3b203	-	Coated granulated	<p>Additive composition:</p> <p>Coated granulated preparation of calcium</p>	All species	-	-	Equines: 3 (total)	1. For user safety: breathing	10 years from the

		calcium iodate anhydrous	<p>iodate anhydrous with an iodine content of 1 - 10 %</p> <p>Coating agents and dispersants (choice of polyoxyethylene (20) sorbitan monolaurate (E432), glycerol polyethyleneglycol ricinoleate (E484), polyethyleneglycol 300, sorbitol (E420ii), and maltodextrin): < 5 %.</p> <p>Feed materials (calcium magnesium carbonate, calcium carbonate, corn cobs) as granulating agents.</p> <p>Particles < 50 µm: < 1,5%</p> <p>-----</p> <p>Characterisation of the active substance:</p> <p>Chemical formula: $\text{Ca}(\text{IO}_3)_2$</p> <p>CAS number: 7789-80-2</p> <p>-----</p> <p>Analytical methods⁽¹⁾:</p> <p>For the determination of Calcium iodate in the feed additive:</p> <ul style="list-style-type: none"> - Titrimetry - Food Chemicals Codex monograph; or - Titrimetry - European Pharmacopoeia monograph (Eur.Ph. 6 01/2008:20504). <p>For the quantification of total calcium in the feed additive:</p> <ul style="list-style-type: none"> - Atomic Absorption Spectrometry, AAS (EN ISO 6869:2000); or - Inductively Coupled Plasma Atomic Emission Spectrometry, ICP-AES (EN 15510:2007). <p>For the quantification of total iodine in premixtures, feed materials and compound feed:</p> <ul style="list-style-type: none"> - Inductively Coupled Plasma Mass Spectrometry, ICP-MS (EN 15111:2007). 				<p>Ruminants for milk production and laying hens: 5 (total)</p> <p>Fish: 20 (total)</p> <p>Dogs: 4 (total)</p> <p>Cats: 5 (total)</p> <p>Other species or categories of animals: 10 (total)</p>	<p>protection, safety glasses and gloves shall be worn during handling.</p> <p>2. Declarations to be made on the labelling of the additive, premixture and complementary feed:</p> <p>"In case of a low content of goitrogen substances in the diet, the total iodine content in complete feed shall not exceed 2 mg/kg for ruminants for milk production and 3 mg/kg for laying hens."</p>	<p>date of entry into force of this Regulation</p> <p><i>[To be completed by the Service responsible for the publication]</i></p>
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⁽¹⁾ Details of the analytical methods are available at the following address of the European Union Reference Laboratory:
http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx

- (²) Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p. 1).
- (³) Council Directive 89/656/EEC of 30 November 1989 on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace (OJ L 393, 30.12.1989, p. 18).
- (⁴) Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (OJ L 348, 28.11.1992, p. 1).
- (⁵) Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (OJ L 131, 5.5.1998, p. 11).
- (⁶) Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment (OJ L 399, 30.12.1989, p. 18).