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Legislation

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Contents

[1] Text with EEA relevance

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

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:

(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.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).
([3]) Commission Regulation (EC) No 1459/2005 of 8 September 2005 amending the conditions for authorisation of a number of feed additives belonging to the group of trace elements (OJ L 233, 9.9.2005, p. 8).
([4]) EFSA Journal 2013; 11(2):3099.
([5]) EFSA Journal 2013; 11(2):3100.
([6]) EFSA Journal 2013; 11(2):3101.
([7]) 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

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

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* 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: — Titrimetry — Food Chemicals Codex monograph; or — Titrimetry — 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 — Inductively Coupled Plasma Atomic Emission Spectrometry, ICP-AES (EN 15510:2007).	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)	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. 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 89/686/EEC (6) shall be worn during handling. 4. In the directions for use of the additive and premixture indicate the storage and stability conditions.	24 June 2025

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 %			
			For the quantification of total iodine in premixtures, feed materials and compound feed: — Inductively Coupled Plasma Mass Spectrometry, ICP-MS (EN 15111:2007).					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.	
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: $Ca(IO_3)_2$ CAS number: 7789-80-2 *Analytical methods* (1) 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)	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

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 %			
			— Inductively Coupled Plasma Atomic Emission Spectrometry, ICP-AES (EN 15510:2007). For the quantification of total iodine in premixtures, feed materials and compound feed: — Inductively Coupled Plasma Mass Spectrometry, ICP-MS (EN 15111:2007).					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.	
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: $Ca(IO_3)_2$ 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)	1. For user safety: breathing protection, safety glasses and gloves shall be worn during handling. 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.	24 June 2025

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 %			
			Analytical methods (1) 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 — Inductively Coupled Plasma Atomic Emission Spectrometry, ICP-AES (EN 15510:2007). For the quantification of total iodine in premixtures, feed materials and compound feed: — Inductively Coupled Plasma Mass Spectrometry, ICP-MS (EN 15111:2007).					

(1) 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
(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).

COMMISSION IMPLEMENTING REGULATION (EU) 2015/862

of 3 June 2015

establishing the standard import values for determining the entry price of certain fruit and vegetables

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ([1]),

Having regard to Commission Implementing Regulation (EU) No 543/2011 of 7 June 2011 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sectors ([2]), and in particular Article 136(1) thereof,

Whereas:

(1) Implementing Regulation (EU) No 543/2011 lays down, pursuant to the outcome of the Uruguay Round multilateral trade negotiations, the criteria whereby the Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex XVI, Part A thereto.

(2) The standard import value is calculated each working day, in accordance with Article 136(1) of Implementing Regulation (EU) No 543/2011, taking into account variable daily data. Therefore this Regulation should enter into force on the day of its publication in the *Official Journal of the European Union*,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 136 of Implementing Regulation (EU) No 543/2011 are fixed in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day 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,
On behalf of the President,
Jerzy PLEWA
Director-General for Agriculture and Rural Development

([1]) OJ L 347, 20.12.2013, p. 671.
([2]) OJ L 157, 15.6.2011, p. 1.

ANNEX

Standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)

CN code	Third country code (1)	Standard import value
0702 00 00	AL	46,1
	MA	77,9
	MK	71,9
	TN	138,3
	TR	80,1
	ZZ	82,9
0707 00 05	AL	34,4
	MK	40,6
	ZZ	37,5
0709 93 10	TR	70,0
	ZZ	70,0
0805 50 10	AR	109,6
	BO	145,2
	BR	107,1
	TR	67,0
	ZA	166,3
	ZZ	119,0
0808 10 80	AR	93,1
	BR	100,6
	CL	138,8
	NZ	131,1
	US	219,4
	ZA	132,9
	ZZ	136,0
0809 10 00	TR	288,5
	ZZ	288,5
0809 29 00	US	507,5
	ZZ	507,5

(1) Nomenclature of countries laid down by Commission Regulation (EU) No 1106/2012 of 27 November 2012 implementing Regulation (EC) No 471/2009 of the European Parliament and of the Council on Community statistics relating to external trade with non-member countries, as regards the update of the nomenclature of countries and territories (OJ L 328, 28.11.2012, p. 7). Code 'ZZ' stands for 'of other origin'.

DIRECTIVES

COMMISSION DELEGATED DIRECTIVE (EU) 2015/863

of 31 March 2015

amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, ([1]) and in particular Article 6(3) thereof,

Whereas:

(1) Directive 2011/65/EU lays down rules on the restriction of the use of hazardous substances in electrical and electronic equipment (EEE) with a view to contributing to the protection of human health and the environment, including the environmentally sound recovery and disposal of waste EEE.

(2) Directive 2011/65/EU prohibits the use of lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE) in electrical and electronic equipment placed on the Union market. Annex II to that Directive lists those restricted substances.

(3) The risks to human health and the environment arising from the use of Hexabromocyclododecane (HBCDD), Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP) and Dibutyl phthalate (DBP) should be considered a priority in the periodic review of the list of restricted substances in Annex II. With a view to further restrictions, the substances that were subject to previous assessments should be re-investigated.

(4) In accordance with Article 6(1) of Directive 2011/65/EU, interested parties, including economic operators, recyclers, treatment operators, environmental organisations and employee and consumer associations, have been consulted and a thorough assessment has been performed.

(5) Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP) and Diisobutyl phthalate (DIBP) are substances of very high concern (SVHC). DIBP is a substance that can be used as a substitute for DBP and was subject to previous assessments performed by the Commission. The available evidence indicates that those four substances, when used in EEE, can have a negative impact on recycling and on human health and the environment during EEE waste management operations.

(6) Substitutes that have less negative impacts are available for DEHP, BBP, DBP and DIBP in most EEE. The use of those substances in EEE should therefore be restricted. DEHP, BBP and DBP are already restricted through entry 51 of Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council, ([2]) so that toys containing DEHP, BBP or DBP in a concentration greater than 0,1 % by weight of the plasticised material, calculated for the three phthalates cumulatively, cannot be placed on the EU market. In order to avoid double regulation, the restriction through entry 51 of Annex XVII to that Regulation shall therefore continue to be the only restriction applicable to DEHP, BBP and DBP in toys.

([1]) OJ L 174, 1.7.2011, p. 88.

([2]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

(7) In order to facilitate transition and to mitigate possible socioeconomic impacts, an appropriate transition period should be granted, which will allow economic operators to apply for exemptions from the substance restrictions in accordance with Article 5 of Directive 2011/65/EU. The longer innovation cycles for medical devices and monitoring and control instruments should be taken into account while determining the transitional period. The restriction of the use of DEHP, BBP, DBP and DIBP should therefore apply to medical devices, including in vitro medical devices, and monitoring and control instruments, including industrial monitoring and control instruments, from 22 July 2021.

(8) Any adaptation of Annex III or IV to Directive 2011/65/EU to exempt applications in relation to DEHP or DBP should take place in a manner which, in order to avoid double regulation and unnecessary burden, ensures coherence with the administration of any authorisation granted under Regulation (EC) No 1907/2006 in relation to the incorporation of those substances in EEE. Operators considering whether to apply for exemptions under Directive 2011/65/EU should be aware that such exemptions may cover the entire life cycle of the EEE, including the manufacturing phase.

(9) Directive 2011/65/EU should therefore be amended accordingly,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex II to Directive 2011/65/EU is replaced by the text in the Annex to this Directive.

Article 2

1. Member States shall adopt and publish, by 31 December 2016 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from 22 July 2019.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 31 March 2015.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

'ANNEX II

Restricted substances referred to in Article 4(1) and maximum concentration values tolerated by weight in homogeneous materials

Lead (0,1 %)

Mercury (0,1 %)

Cadmium (0,01 %)

Hexavalent chromium (0,1 %)

Polybrominated biphenyls (PBB) (0,1 %)

Polybrominated diphenyl ethers (PBDE) (0,1 %)

Bis(2-ethylhexyl) phthalate (DEHP) (0,1 %)

Butyl benzyl phthalate (BBP) (0,1 %)

Dibutyl phthalate (DBP) (0,1 %)

Diisobutyl phthalate (DIBP) (0,1 %)

The restriction of DEHP, BBP, DBP and DIBP shall apply to medical devices, including *in vitro* medical devices, and monitoring and control instruments, including industrial monitoring and control instruments, from 22 July 2021.

The restriction of DEHP, BBP, DBP and DIBP shall not apply to cables or spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of EEE placed on the market before 22 July 2019, and of medical devices, including *in vitro* medical devices, and monitoring and control instruments, including industrial monitoring and control instruments, placed on the market before 22 July 2021.

The restriction of DEHP, BBP and DBP shall not apply to toys which are already subject to the restriction of DEHP, BBP and DBP through entry 51 of Annex XVII to Regulation (EC) No 1907/2006.'

CORRIGENDA

Corrigendum to Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EEC

(Official Journal of the European Union L 10 of 14 January 2006)

On page 47, Annex I, paragraph 2(b):

for: '(b) avian influenza viruses with an intravenous pathogenicity index in six-week old chickens greater than 1.2;2;',

read: '(b) avian influenza viruses with an intravenous pathogenicity index in six-week old chickens greater than 1.2;',

on page 59, Annex IX, paragraph 5(c)(ii):

for: '(ii) originate from hatching eggs satisfying the conditions set out in point (a) of paragraph 2, point (a) of paragraph 3 or point (a) of paragraph 4;',

read: '(ii) originate from hatching eggs satisfying the conditions set out in point (a) of paragraph 3;'.

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