

Official Journal of the European Union

L 220



English edition

Legislation

Volume 58

21 August 2015

Contents

II *Non-legislative acts*

REGULATIONS

- ★ **Commission Implementing Regulation (EU) 2015/1413 of 10 August 2015 entering a name in the register of protected designations of origin and protected geographical indications (Ogulinski kiseli kupus/Ogulinsko kiselo zelje (PDO))** 1
- ★ **Commission Implementing Regulation (EU) 2015/1414 of 20 August 2015 amending Implementing Regulation (EU) No 136/2012 concerning the authorisation of sodium bisulphate as feed additive for pets and for non-food producing animals ⁽¹⁾** 3
- ★ **Commission Implementing Regulation (EU) 2015/1415 of 20 August 2015 concerning the authorisation of astaxanthin as a feed additive for fish, crustaceans and ornamental fish ⁽¹⁾** 7
- ★ **Commission Implementing Regulation (EU) 2015/1416 of 20 August 2015 concerning the authorisation of sodium bisulphate as feed additive for all animal species ⁽¹⁾** 11
- ★ **Commission Implementing Regulation (EU) 2015/1417 of 20 August 2015 concerning the authorisation of diclazuril as a feed additive for rabbits for fattening and for breeding (holder of the authorisation Huvepharma NV) ⁽¹⁾** 15
- Commission Implementing Regulation (EU) 2015/1418 of 20 August 2015 establishing the standard import values for determining the entry price of certain fruit and vegetables 18

Corrigenda

- ★ **Corrigendum to Commission Implementing Regulation (EU) 2015/1409 of 19 August 2015 establishing the standard import values for determining the entry price of certain fruit and vegetables (OJ L 219, 20.8.2015)** 20

⁽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) 2015/1413

of 10 August 2015

entering a name in the register of protected designations of origin and protected geographical indications (Ogulinski kiseli kupus/Ogulinsko kiselo zelje (PDO))

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs ⁽¹⁾, and in particular Article 52(2) thereof,

Whereas:

- (1) Pursuant to Article 50(2)(a) of Regulation (EU) No 1151/2012, Croatia's application to register the name 'Ogulinski kiseli kupus'/'Ogulinsko kiselo zelje' was published in the *Official Journal of the European Union* ⁽²⁾.
- (2) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, the name 'Ogulinski kiseli kupus'/'Ogulinsko kiselo zelje' should therefore be entered in the register,

HAS ADOPTED THIS REGULATION:

Article 1

The name 'Ogulinski kiseli kupus'/'Ogulinsko kiselo zelje' (PDO) is hereby entered in the register.

The name specified in the first paragraph denotes a product in Class 1.6. Fruit, vegetables and cereals, fresh or processed, as listed in Annex XI to Commission Implementing Regulation (EU) No 668/2014 ⁽³⁾.*Article 2*This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.⁽¹⁾ OJ L 343, 14.12.2012, p. 1.⁽²⁾ OJ C 115, 10.4.2015, p. 20.⁽³⁾ Commission Implementing Regulation (EU) No 668/2014 of 13 June 2014 laying down rules for the application of Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs (OJ L 179, 19.6.2014, p. 36).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 10 August 2015.

*For the Commission,
On behalf of the President,
Phil HOGAN
Member of the Commission*

COMMISSION IMPLEMENTING REGULATION (EU) 2015/1414**of 20 August 2015****amending Implementing Regulation (EU) No 136/2012 concerning the authorisation of sodium bisulphate as feed additive for pets and for non-food producing animals****(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 13(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 or modifying such authorisation.
- (2) The use of sodium bisulphate was authorised for 10 years for pets and other non-food producing animals by Commission Implementing Regulation (EU) No 136/2012 ⁽²⁾.
- (3) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted requesting a modification on the conditions of use. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The application concerns a modification of the conditions of use for pets and other non-food producing animals requesting to modify the content of the additive in the complete feedingstuff.
- (5) The European Food Safety Authority concluded in its opinion of 22 May 2014 ⁽³⁾ that, under the proposed conditions of use, the previous content of sodium bisulphate as acidity regulator and as flavouring compound should be modified by new data received.
- (6) In order to allow for the use of sodium bisulphate under the new proposed conditions, it is appropriate to amend Implementing Regulation (EU) No 136/2012.
- (7) The assessment of sodium bisulphate shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this preparation should be authorised as specified in the Annexes to this Regulation.
- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (9) 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

Annex I to Implementing Regulation (EU) No 136/2012 shall be replaced by the Annex I to this Regulation.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Implementing Regulation (EU) No 136/2012 of 16 February 2012 concerning the authorisation of sodium bisulphate as feed additive for pets and other non-food producing animals (OJ L 46, 17.2.2012, p. 33).

⁽³⁾ EFSA Journal 2014; 12(6):3731.

Article 2

Annex II to Implementing Regulation (EU) No 136/2012 shall be replaced by the Annex II to this Regulation.

Article 3

The substance specified in the Annex, and feed containing it, which are produced and labelled before 10 September 2017 in accordance with the rules applicable before 10 September 2015 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 4

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, 20 August 2015.

For the Commission

The President

Jean-Claude JUNCKER

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
						mg/kg of complete feedingstuff with a moisture content of 12 %			
Category of technological additives. Functional group: acidity regulators									
1j514ii	—	Sodium bisulphate	<i>Additive composition</i> Sodium bisulphate: ≥ 95,2 % <i>Characterisation of the active substance</i> Sodium bisulphate CAS No 7681-38-1 NaHSO ₄ Na 19,15 % SO ₄ 80,01 % Produced by chemical synthesis <i>Method of Analysis</i> ⁽¹⁾ Determination of sodium hydrogen sulphate in feed additives: titrimetric method based on the determination of total soluble acidity of sodium bisulphate against a standard sodium hydroxide solution.	Pets and other non-food producing animals other than cats and mink	—	—	4 000	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. 2. For safety: breathing protection, eye protection and gloves shall be used during handling. 3. The total content of sodium bisulphate must not exceed the maximum permitted levels in complete feedingstuff established for each relevant species	8 March 2022
				Cats			20 000		
				Mink			10 000		

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

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
						mg/kg of complete feedingstuff with a moisture content of 12 %			
Category of sensory additives. Functional group: flavouring compounds									
1j514ii	—	Sodium bisulphate	<i>Additive composition</i> Sodium bisulphate: ≥ 95,2 % <i>Characterisation of the active substance</i> Sodium bisulphate CAS No 7681-38-1 NaHSO ₄ Na 19,15 % SO ₄ 80,01 % Produced by chemical synthesis <i>Method of Analysis</i> ⁽¹⁾ Determination of sodium hydrogen sulphate in feed additives: titrimetric method based on the determination of total soluble acidity of sodium bisulphate against a standard sodium hydroxide solution.	Pets and other non-food producing animals other than cats and mink	—	—	4 000	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. 2. For safety: breathing protection, eye protection and gloves shall be used during handling. 3. The total content of sodium bisulphate must not exceed the maximum permitted levels in complete feedingstuff established for each relevant species.	8 March 2022
				Cats			20 000		
				Mink			10 000		

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

COMMISSION IMPLEMENTING REGULATION (EU) 2015/1415
of 20 August 2015
concerning the authorisation of astaxanthin as a feed additive for fish, crustaceans and ornamental fish

(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) Astaxanthin was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for salmon, trout and ornamental fish. That product was subsequently entered in the Register of feed additives as an existing product, 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, two applications were submitted for the re-evaluation of astaxanthin and its preparations as a sensory additive for salmon, trout and ornamental fish, and, in accordance with Article 7 of that Regulation, for a new use for crustaceans and for fish other than salmon and trout. The applicants requested this additive to be classified in the additive category '*sensory additives*'. Those 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 of 20 May 2014 ⁽³⁾ that, under the proposed conditions of use in feed, astaxanthin does not have an adverse effects on animal health, human health or the environment. The Authority also concluded that astaxanthin is efficacious in colouring the flesh of fish, the epidermis of crustaceans and the skin of ornamental fish. It further concluded that no safety concerns would arise for users. 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.
- (5) The assessment of astaxanthin shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this substance should be authorised as specified in the Annex to this Regulation. Maximum contents should be set up for astaxanthin.
- (6) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (7) 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

The substance specified in the Annex, belonging to the additive category '*sensory additives*' and to the functional group '*colourants*' is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

⁽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⁾ EFSA Journal 2014; 12(6):3724 and EFSA Journal 2014; 12(6):3725.

Article 2

1. The substance specified in the Annex and premixtures containing that substance, which are produced and labelled before 10 March 2016 in accordance with the rules applicable before 10 September 2015 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the substance specified in the Annex which are produced and labelled before 10 September 2016 in accordance with the rules applicable before 10 September 2015 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for fish.
3. Compound feed and feed materials containing the substance specified in the Annex which are produced and labelled before 10 September 2017 in accordance with the rules applicable before 10 September 2015 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for ornamental fish.

Article 3

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, 20 August 2015.

For the Commission
The President
Jean-Claude JUNKER

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
						mg/kg of active substance of complete feedingstuff with a moisture content of 12 %			

Category of sensory additives. Functional group: a. colourants (ii) substances which, when fed to animals, add colours to food of animal origin

2a161j	—	Astaxanthin	<i>Additive composition</i> Astaxanthin	Fish	—	—	100	1. Astaxanthin may be placed on the market and used as an additive consisting of a preparation. 2. In the directions for use of the additive and premixtures, indicate the stability and storage conditions. 3. The mixture of astaxanthin with other carotenoids and xanthophylls shall not exceed 100 mg/kg of complete feed (moisture content 12 %). 4. For safety: breathing protection, safety glasses and gloves shall be worn during handling.	10 September 2025
			Triphenylphosphine oxide (TPPO) ≤ 100 mg/kg Dichloromethane ≤ 600 mg/kg <i>Characterisation of the active substance</i> Astaxanthin $C_{40}H_{52}O_4$ CAS No: 7542-45-2 Astaxanthin, solid form, produced by chemical synthesis Purity criteria: — Assay (expressed as astaxanthin): min 96 % of total colouring matters. — Carotenoids other than astaxanthin: max 5 % of total colouring matters. <i>Method of Analysis</i> ⁽¹⁾ — For the quantification of Astaxanthin in the feed additive preparation: spectrophotometry at 431 nm. — For the quantification of Astaxanthin in the premixtures and feedingstuffs: Normal Phase High Performance Liquid Chromatography coupled to visible detection (NP-HPLC-VIS, 470 nm).	Crustaceans	—	—	100		

⁽¹⁾ Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>.

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
						mg/kg of active substance of complete feedingstuff with a moisture content of 12 %			
Category of sensory additives. Functional group: a. colourants (iii) substances which favourably affect the colour of ornamental fish or birds									
2a161j	—	Astaxanthin	<i>Additive composition</i> Astaxanthin Triphenylphosphine oxide (TPPO) ≤ 100 mg/kg Dichloromethane ≤ 600 mg/kg <i>Characterisation of the active substance</i> Astaxanthin C ₄₀ H ₅₂ O ₄ CAS No: 7542-45-2 Astaxanthin, solid form, produced by chemical synthesis Purity criteria: — Assay (expressed as astaxanthin): min 96 % of total colouring matters. — Carotenoids other than astaxanthin: max 5 % of total colouring matters. <i>Method of Analysis</i> ⁽¹⁾ — For the quantification of Astaxanthin in the feed additive preparation: spectrophotometry at 431 nm. — For the quantification of Astaxanthin in the premixtures and feedingstuffs: Normal Phase High Performance Liquid Chromatography coupled to visible detection (NP-HPLC-VIS, 470 nm).	Ornamental fish	—	—	100	1. Astaxanthin may be placed on the market and used as an additive consisting of a preparation. 2. In the directions for use of the additive and premixtures, indicate the stability and storage conditions. 3. The mixture of astaxanthin with other carotenoids and xanthophylls shall not exceed 100 mg/kg of complete feed (moisture content 12 %). 4. For safety: breathing protection, safety glasses and gloves shall be worn during handling.	10 September 2025

⁽¹⁾ Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>.

COMMISSION IMPLEMENTING REGULATION (EU) 2015/1416
of 20 August 2015
concerning the authorisation of sodium bisulphate as feed additive 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.
- (2) The use of sodium bisulphate was authorised for 10 years for pets and other non-food producing animals by Commission Implementing Regulation (EU) No 136/2012 ⁽²⁾.
- (3) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of sodium bisulphate. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The application concerns the authorisation of sodium bisulphate as a feed additive for all animal species, to be classified in the additive categories 'technological additives'.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinions of 11 October 2011 ⁽³⁾ and of 22 May 2014 ⁽⁴⁾ that, under the proposed conditions of use, sodium bisulphate does not have an adverse effect on animal health, human health or the environment, and that its use is considered efficacious as preservative and acidity regulator for all animal species. The Authority does not consider that there is a need for specific requirement of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (6) The assessment of sodium bisulphate shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this preparation should be authorised as specified in the Annexes to this Regulation.
- (7) 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

The substance specified in Annex I, belonging to the additive category 'technological additives' and to the functional group 'preservatives', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Implementing Regulation (EU) No 136/2012 of 16 February 2012 concerning the authorisation of sodium bisulphate as feed additive for pets and other non-food producing animals (OJ L 46, 17.2.2012, p. 33).

⁽³⁾ EFSA Journal 2011; 9(11):2415.

⁽⁴⁾ EFSA Journal 2014; 12(6):3731.

Article 2

The substance specified in Annex II, belonging to the additive category 'technological additives' and to the functional group 'acidity regulators', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 3

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, 20 August 2015.

For the Commission

The President

Jean-Claude JUNKER

ANNEX I

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
						mg/kg of complete feedingstuff with a moisture content of 12 %			
Category of technological additives. Functional group: preservatives									
1j514ii	—	Sodium bisulphate	<i>Additive composition</i> Sodium bisulphate: ≥ 95,2 % <i>Characterisation of the active substance</i> Sodium bisulphate CAS No 7681-38-1 NaHSO ₄ Na 19,15 % SO ₄ 80,01 % Produced by chemical synthesis <i>Method of Analysis</i> ⁽¹⁾ Determination of sodium hydrogen sulphate in feed additives: titrimetric method based on the determination of total soluble acidity of sodium bisulphate against a standard sodium hydroxide solution.	All animal species other than cats and mink	—	—	4 000	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. 2. For safety: breathing protection, eye protection and gloves shall be used during handling. 3. The total content of sodium bisulphate must not exceed the maximum permitted levels in complete feedingstuff established for each relevant species.	10 September 2025
				Cats			20 000		
				Mink			10 000		

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

ANNEX II

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
						mg/kg of complete feedingstuff with a moisture content of 12 %			
Category of technological additives. Functional group: acidity regulators									
1j514ii	—	Sodium bisulphate	<i>Additive composition</i> Sodium bisulphate: ≥ 95,2 % <i>Characterisation of the active substance</i> Sodium bisulphate CAS No 7681-38-1 NaHSO ₄ Na 19,15 % SO ₄ 80,01 % Produced by chemical synthesis <i>Method of Analysis</i> ⁽¹⁾ Determination of sodium hydrogen sulphate in feed additives: titrimetric method based on the determination of total soluble acidity of sodium bisulphate against a standard sodium hydroxide solution.	All animal species other than cats, mink, pet and other non-food producing animals	—	—	4 000	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. 2. For safety: breathing protection, eye protection and gloves shall be used during handling. 3. The total content of sodium bisulphate must not exceed the maximum permitted levels in complete feedingstuff established for each relevant species.	10 September 2025

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

COMMISSION IMPLEMENTING REGULATION (EU) 2015/1417**of 20 August 2015****concerning the authorisation of diclazuril as a feed additive for rabbits for fattening and for breeding (holder of the authorisation Huvepharma NV)****(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.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of a preparation of diclazuril. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) That application concerns the authorisation of diclazuril, CAS number 101831-37-2, as a feed additive for rabbits for fattening and for breeding, to be classified in the additive category 'coccidiostats and histomonostats'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 10 December 2014 ⁽²⁾ that, under the proposed conditions of use, diclazuril does not have an adverse effect on animal health, human health or the environment and is effective in controlling coccidiosis in rabbits for fattening and for breeding. It considers that there is a need for specific requirements of post-market monitoring to verify the resistance to *Eimeria* spp. The Authority also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) The assessment of diclazuril, CAS number 101831-37-2, shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.
- (6) 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 preparation specified in the Annex belonging to the additive category 'coccidiostats and histomonostats', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

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

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2015; 13(1):3968.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 20 August 2015.

For the Commission

The President

Jean-Claude JUNKER

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	Maximum Residue Limits (MRLs) in the relevant foodstuffs of animal origin
						mg of active substance/kg of complete feeding stuff with a moisture content of 12 %				
Coccidiostats and histomonostats										
51775	Huve-pharma NV	Diclazuril 0,5 g/100 g (Coxiril)	<i>Additive composition</i> Preparation of: Diclazuril: 5 g/kg. Starch: 15 g/kg. Wheat meal: 700 g/kg. Calcium carbonate: 280 g/kg. <i>Characterisation of the active substance</i> Diclazuril, C₁₇H₉Cl₃N₄O₂, (±)-4-chlorophenyl[2,6-dichloro-4-(2,3,4,5-tetrahydro-3,5-dioxo-1,2,4-triazin-2-yl)phenyl]acetonitrile, CAS number: 101831-37-2. Impurity D ⁽¹⁾: ≤ 0,1 %. Any other single impurity: ≤ 0,5 %. Total impurities: ≤ 1,5 %. <i>Analytical method</i> ⁽²⁾ For determination of diclazuril in feed: reversed-phase high performance liquid chromatography (HPLC) using Ultraviolet detection at 280nm (Commission Regulation (EC) No 152/2009 ⁽³⁾).	Rabbits	—	1	1	1. The additive shall be incorporated in compound feed in the form of a premixture. 2. Diclazuril shall not be mixed with other coccidiostats. 3. For safety: breathing protection, glasses and gloves shall be used during handling. 4. Use prohibited at least two days before slaughter. 5. A post market monitoring programme concerning the resistance to Eimeria spp. shall be carried out by the holder of authorisation during the latter part of the period of the authorisation.	10 September 2025	Commission Regulation (EU) No 37/2010 ⁽⁴⁾ (— 2 500 µg diclazuril/kg of wet liver. — 1 000 µg diclazuril/kg of wet kidney. — 150 µg diclazuril/kg of wet muscle. — 300 µg diclazuril/kg of wet skin/fat.)

⁽¹⁾ European Pharmacopoeia monograph 1718 (Diclazuril for Veterinary use).

⁽²⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>.

⁽³⁾ Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).

⁽⁴⁾ Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).

COMMISSION IMPLEMENTING REGULATION (EU) 2015/1418**of 20 August 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, 20 August 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	MA	156,5
	ZZ	156,5
0709 93 10	TR	124,7
	ZZ	124,7
0805 50 10	AR	126,2
	BO	154,5
	CL	153,9
	UY	144,0
	ZA	149,9
	ZZ	145,7
	ZZ	145,7
0806 10 10	EG	238,9
	TR	167,5
	US	339,9
	ZZ	248,8
0808 10 80	AR	234,3
	BR	97,6
	CL	147,4
	NZ	152,0
	US	110,0
	UY	141,9
	ZA	122,1
	ZZ	143,6
	ZZ	143,6
	ZZ	143,6
0808 30 90	AR	155,3
	CL	135,1
	CN	85,3
	NZ	109,3
	TR	132,9
	ZA	119,6
	ZZ	122,9
0809 30 10, 0809 30 90	MK	79,3
	TR	126,3
	ZZ	102,8
0809 40 05	BA	42,6
	IL	99,6
	MK	36,8
	XS	57,7
	ZZ	59,2

⁽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'.

CORRIGENDA**Corrigendum to Commission Implementing Regulation (EU) 2015/1409 of 19 August 2015
establishing the standard import values for determining the entry price of certain fruit and
vegetables**

(Official Journal of the European Union L 219 of 20 August 2015)

On page 7, in the Annex:

for: 'EG 253,2',

read: 'EG 235,2'.

