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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) 2018/523

of 28 March 2018

amending Regulation (EU) No 37/2010 to classify the substance fluazuron as regards its maximum residue limit

(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 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and the Council ([1]), and in particular Article 14 in conjunction with Article 17 thereof,

Having regard to the opinion of the European Medicines Agency formulated by the Committee for Medicinal Products for Veterinary Use,

Whereas:

(1) Article 17 of Regulation (EC) No 470/2009 requires that the maximum residue limit ('MRL') for pharmacologically active substances intended for use in the Union in veterinary medicinal products for food-producing animals or in biocidal products used in animal husbandry is established in a Regulation.

(2) Table 1 of the Annex to Commission Regulation (EU) No 37/2010 ([2]) sets out the pharmacologically active substances and their classification regarding MRLs in foodstuffs of animal origin.

(3) Fluazuron is already included in that table as an allowed substance for bovine species, applicable to muscle, fat, liver and kidney, excluding animals producing milk for human consumption.

(4) An application for the extension of the existing entry for fluazuron to fin fish has been submitted to the European Medicines Agency ('EMA').

(5) The EMA, based on the opinion of the Committee for Medicinal Products for Veterinary Use, has recommended the establishment of an MRL for fluazuron in fin fish.

(6) According to Article 5 of Regulation (EC) No 470/2009, EMA is to consider using MRLs established for a pharmacologically active substance in a particular foodstuff for another foodstuff derived from the same species, or MRLs established for a pharmacologically active substance in one or more species for other species.

(7) The EMA has considered that the extrapolation of the entry for fluazuron to tissues of all ruminants except ovine species and to bovine milk is appropriate.

([1]) OJ L 152, 16.6.2009, p. 11.
([2]) 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).

(8) Regulation (EU) No 37/2010 should therefore be amended accordingly.

(9) It is appropriate to grant the stakeholders concerned a reasonable period of time to take measures that may be required to comply with the new MRL.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EU) No 37/2010 is amended as set out in the Annex to this Regulation.

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*.

It shall apply from 3 June 2018.

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

Done at Brussels, 28 March 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

In Table 1 of the Annex to Regulation (EU) No 37/2010, the entry for the substance 'fluazuron' is replaced by the following:

Pharmacologically active Substance	Marker residue	Animal Species	MRLs	Target Tissues	Other Provisions (according to Article 14(7) of Regulation (EC) No 470/2009)	Therapeutic Classification
'Fluazuron	Fluazuron	All ruminants except bovine and ovine	200 µg/kg 7 000 µg/kg 500 µg/kg 500 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption	Antiparasitic agents/Agents (acting) against ectoparasites'
		Bovine	200 µg/kg 7 000 µg/kg 500 µg/kg 500 µg/kg 200 µg/kg	Muscle Fat Liver Kidney Milk	NO ENTRY	
		Fin fish	200 µg/kg	Muscle and skin in natural proportions	NO ENTRY	

COMMISSION IMPLEMENTING REGULATION (EU) 2018/524

of 28 March 2018

amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances *Bacillus subtilis* (Cohn 1872) Strain QST 713, identical with strain AQ 713, clodinafop, clopyralid, cyprodinil, dichlorprop-P, fosetyl, mepanipyrim, metconazole, metrafenone, pirimicarb, *Pseudomonas chlororaphis* strain: MA 342, pyrimethanil, quinoxyfen, rimsulfuron, spinosad, thiacloprid, thiamethoxam, thiram, tolclofos-methyl, triclopyr, trinexapac, triticonazole and ziram

(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 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ([1]), and in particular the first paragraph of Article 17 thereof,

Whereas:

(1) Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ([2]) sets out the active substances deemed to have been approved under Regulation (EC) No 1107/2009.

(2) The approval periods of the active substances mepanipyrim, *Pseudomonas chlororaphis* Strain: MA 342, quinoxyfen, thiacloprid, thiram and ziram were last extended by Commission Implementing Regulation (EU) 2016/2016 ([3]). The approval periods of those substances will expire on 30 April 2018.

(3) The approval periods of the active substances *Bacillus subtilis* (Cohn 1872) Strain QST 713, identical with strain AQ 713, clodinafop, metrafenone, pirimicarb, rimsulfuron, spinosad, thiamethoxam, tolclofos-methyl and triticonazole were extended by Commission Implementing Regulation (EU) No 487/2014 ([4]). The approval periods of those substances will expire on 30 April 2018.

(4) The approval periods of the active substances clopyralid, cyprodinil, fosetyl, pyrimethanil and trinexapac were extended by Commission Implementing Regulation (EU) No 678/2014 ([5]). The approval periods of those substances will expire on 30 April 2018.

(5) The approval periods of the active substances dichlorprop-P, metconazole and triclopyr were extended by Commission Implementing Regulation (EU) No 878/2014 ([6]). The approval periods of those substances will expire on 30 April 2018.

(6) Applications for the renewal of the approval of the substances referred to in recitals 2 to 5 were submitted in accordance with Commission Implementing Regulation (EU) No 844/2012 ([7]).

([1]) OJ L 309, 24.11.2009, p. 1.

([2]) Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

([3]) Commission Implementing Regulation (EU) 2016/2016 of 17 November 2016 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances acetamiprid, benzoic acid, flazasulfuron, mecoprop-P, mepanipyrim, mesosulfuron, propineb, propoxycarbazon, propyzamide, propiconazole, Pseudomonas chlororaphis Strain: MA 342, pyraclostrobin, quinoxyfen, thiacloprid, thiram, ziram, zoxamide (OJ L 312, 18.11.2016, p. 21).

([4]) Commission Implementing Regulation (EU) No 487/2014 of 12 May 2014 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances Bacillus subtilis (Cohn 1872) Strain QST 713, identical with strain AQ 713, clodinafop, metrafenone, pirimicarb, rimsulfuron, spinosad, thiamethoxam, tolclofos-methyl and triticonazole (OJ L 138, 13.5.2014, p. 72).

([5]) Commission Implementing Regulation (EU) No 678/2014 of 19 June 2014 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances clopyralid, cyprodinil, fosetyl, pyrimethanil and trinexapac (OJ L 180, 20.6.2014, p. 11).

([6]) Commission Implementing Regulation (EU) No 878/2014 of 12 August 2014 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances dichlorprop-P, metconazole and triclopyr (OJ L 240, 13.8.2014, p. 18).

([7]) Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

(7) Due to the fact that the assessment of the substances has been delayed for reasons beyond the control of the applicants, the approvals of those active substances are likely to expire before a decision has been taken on their renewal. It is therefore necessary to extend their approval periods.

(8) In view of the aim of the first paragraph of Article 17 of Regulation (EC) No 1107/2009, as regards cases where the Commission will adopt a Regulation providing that the approval of an active substance referred to in the Annex to this Regulation is not renewed because the approval criteria are not satisfied, the Commission will set the expiry date at the same date as before this Regulation or at the date of the entry into force of the Regulation providing that the approval of the active substance is not renewed, whichever date is later. As regards cases where the Commission will adopt a Regulation providing for the renewal of an active substance referred to in the Annex to this Regulation, the Commission will endeavour to set, as appropriate under the circumstances, the earliest possible application date.

(9) Taking into account that the approvals of the active substances expire on 30 April 2018, this Regulation should enter into force as soon as possible.

(10) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(11) 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

Part A of the Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the third 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, 28 March 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Part A of the Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) in the sixth column, expiration of approval, of row 73, Thiram, the date is replaced by '30 April 2019';

(2) in the sixth column, expiration of approval, of row 74, Ziram, the date is replaced by '30 April 2019';

(3) in the sixth column, expiration of approval, of row 82, Quinoxyfen, the date is replaced by '30 April 2019';

(4) in the sixth column, expiration of approval, of row 89, *Pseudomonas chlororaphis* Strain: MA 342, the date is replaced by '30 April 2019';

(5) in the sixth column, expiration of approval, of row 90, Mepanipyrim, the date is replaced by '30 April 2019';

(6) in the sixth column, expiration of approval, of row 92, Thiacloprid, the date is replaced by '30 April 2019';

(7) in the sixth column, expiration of approval, of row 123, Clodinafop, the date is replaced by '30 April 2019';

(8) in the sixth column, expiration of approval, of row 124, Pirimicarb, the date is replaced by '30 April 2019';

(9) in the sixth column, expiration of approval, of row 125, Rimsulfuron, the date is replaced by '30 April 2019';

(10) in the sixth column, expiration of approval, of row 126, Tolclofos-methyl, the date is replaced by '30 April 2019';

(11) in the sixth column, expiration of approval, of row 127, Triticonazole, the date is replaced by '30 April 2019';

(12) in the sixth column, expiration of approval, of row 129, Clopyralid, the date is replaced by '30 April 2019';

(13) in the sixth column, expiration of approval, of row 130, Cyprodinil, the date is replaced by '30 April 2019';

(14) in the sixth column, expiration of approval, of row 131, Fosetyl, the date is replaced by '30 April 2019';

(15) in the sixth column, expiration of approval, of row 132, Trinexapac, the date is replaced by '30 April 2019';

(16) in the sixth column, expiration of approval, of row 133, Dichlorprop-P, the date is replaced by '30 April 2019';

(17) in the sixth column, expiration of approval, of row 134, Metconazole, the date is replaced by '30 April 2019';

(18) in the sixth column, expiration of approval, of row 135, Pyrimethanil, the date is replaced by '30 April 2019';

(19) in the sixth column, expiration of approval, of row 136, Triclopyr, the date is replaced by '30 April 2019';

(20) in the sixth column, expiration of approval, of row 137, Metrafenone, the date is replaced by '30 April 2019';

(21) in the sixth column, expiration of approval, of row 138, *Bacillus subtilis* (Cohn 1872) Strain QST 713, identical with strain AQ 713, the date is replaced by '30 April 2019';

(22) in the sixth column, expiration of approval, of row 139, Spinosad, the date is replaced by '30 April 2019';

(23) in the sixth column, expiration of approval, of row 140, Thiamethoxam, the date is replaced by '30 April 2019'.

CORRIGENDA

Corrigendum to Commission Implementing Regulation (EU) 2018/483 of 22 March 2018 on the minimum selling price for skimmed milk powder for the 18th partial invitation to tender within the tendering procedure opened by Implementing Regulation (EU) 2016/2080

(Official Journal of the European Union L 81 of 23 March 2018)

On page 9, recital (3):

for: '(3) The measures provided for in this Regulation are in accordance with the opinion of the Committee for the Common Organisation of the Agricultural Markets,',

read: '(3) The Committee for the Common Organisation of the Agricultural Markets has not delivered an opinion within the time limit laid down by its Chair,'.

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