

## COMMISSION IMPLEMENTING REGULATION (EU) No 597/2012

of 5 July 2012

**amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substances aluminium ammonium sulphate, fat distillation residues, repellents by smell of animal or plant origin/fish oil and urea**

(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 <sup>(1)</sup>, and in particular Article 13(2)(c) thereof,

Whereas:

(1) The active substances aluminium ammonium sulphate, fat distillation residues, repellents by smell of animal or plant origin/fish oil and urea were included in Annex I to Council Directive 91/414/EEC <sup>(2)</sup> by Commission Directive 2008/127/EC <sup>(3)</sup> in accordance with the procedure provided for in Article 24b of Commission Regulation (EC) No 2229/2004 of 3 December 2004 laying down further detailed rules for the implementation of the fourth stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC <sup>(4)</sup>. Since the replacement of Directive 91/414/EEC by Regulation (EC) No 1107/2009, these substances are deemed to have been approved under that Regulation and are listed in Part A of the Annex to 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 <sup>(5)</sup>.

(2) In accordance with Article 25a of Regulation (EC) No 2229/2004, the European Food Safety Authority (hereinafter 'the Authority') presented to the Commission its views on the draft review reports for aluminium ammonium sulphate <sup>(6)</sup> on 6 December 2011, for fat distillation residues <sup>(7)</sup>, repellents by smell of animal or

plant origin/fish oil <sup>(8)</sup> and urea <sup>(9)</sup> on 16 December 2011. The draft review reports and the views of the Authority were reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 1 June 2012 in the format of the Commission review reports for aluminium ammonium sulphate, fat distillation residues, repellents by smell of animal or plant origin/fish oil and urea.

(3) The Authority communicated its views on aluminium ammonium sulphate, fat distillation residues, repellents by smell of animal or plant origin/fish oil and urea to the notifiers, and the Commission invited them to submit comments on the review reports.

(4) It is confirmed that the active substances aluminium ammonium sulphate, fat distillation residues, repellents by smell of animal or plant origin/fish oil and urea are to be deemed to have been approved under Regulation (EC) No 1107/2009.

(5) In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is necessary to amend the conditions of approval of aluminium ammonium sulphate, fat distillation residues, repellents by smell of animal or plant origin/fish oil and urea. It is, in particular, appropriate to require further confirmatory information as regards those active substances. At the same time certain technical adaptations should be made, in particular the name of the active substances 'Repellents by smell of animal or plant origin/fish oil' and 'fat distillation residues' should be replaced respectively by 'fish oil' and fat distillation residues. The Annex to Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(6) A reasonable period of time should be allowed before the application of this Regulation in order to allow Member States, notifiers and holders of authorisations for plant protection products to meet the requirements resulting from amendment to the conditions of the approval.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

<sup>(1)</sup> OJ L 309, 24.11.2009, p. 1.

<sup>(2)</sup> OJ L 230, 19.8.1991, p. 1.

<sup>(3)</sup> OJ L 344, 20.12.2008, p. 89.

<sup>(4)</sup> OJ L 379, 24.12.2004, p. 13.

<sup>(5)</sup> OJ L 153, 11.6.2011, p. 1.

<sup>(6)</sup> Conclusion on the peer review of the pesticide risk assessment of the active substance aluminium ammonium sulphate, *EFSA Journal* 2012;10(3):2491. Available online: [www.efsa.europa.eu/efsajournal.htm](http://www.efsa.europa.eu/efsajournal.htm)

<sup>(7)</sup> Conclusion on the peer review of the pesticide risk assessment of the active substance fat distillation residues, *EFSA Journal* 2012;10(2):2519. Available online: [www.efsa.europa.eu/efsajournal.htm](http://www.efsa.europa.eu/efsajournal.htm)

<sup>(8)</sup> Conclusion on the peer review of the pesticide risk assessment of the active substance fish oil, *EFSA Journal* 2012;10(2):2546. Available online: [www.efsa.europa.eu/efsajournal.htm](http://www.efsa.europa.eu/efsajournal.htm)

<sup>(9)</sup> Conclusion on the peer review of the pesticide risk assessment of the active substance urea, *EFSA Journal* 2012;10(1):2523. Available online: [www.efsa.europa.eu/efsajournal.htm](http://www.efsa.europa.eu/efsajournal.htm)

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 twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 November 2012.

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

Done at Brussels, 5 July 2012.

*For the Commission*  
*The President*  
José Manuel BARROSO

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## ANNEX

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

(1) Row 219 on the active substance aluminium ammonium sulphate is replaced by the following:

Number	Common name, identification numbers	IUPAC name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
219	Aluminium ammonium sulphate  CAS No 7784-26-1 (dodecahydrate), 7784-25-0 (anhydrous)  CIPAC No 840	Aluminium ammonium sulphate	≥ 960 g/kg (expressed as dodecahydrate)  ≥ 502 g/kg (anhydrous)	1 September 2009	31 August 2019	PART A  Only uses as repellent may be authorised.  PART B  For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on aluminium ammonium sulphate (SANCO/2985/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 June 2012 shall be taken into account.  Conditions of use shall include, where appropriate, risk mitigation measures.  The notifier shall submit confirmatory information as regards:  (a) the impact on the environment of the transformation/dissociation products of aluminium ammonium sulphate;  (b) the risk to non-target terrestrial organisms other than vertebrates and aquatic organisms.  This information shall be submitted to the Member States, the Commission and the Authority by 1 January 2016.'

(\*) Further details on identity and specification of active substance are provided in their review report.

(2) Row 229 on the active substance fat distillation residues is replaced by the following:

Number	Common name, identification numbers	IUPAC name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
229	Fat distillation residues  CAS No: not allocated  CIPAC No 915	Not available	≥ 40 % of cleaved fatty acids  Relevant impurity: Ni maximum 200 mg/kg	1 September 2009	31 August 2019	PART A  Only uses as repellent may be authorised. Fat distillation residues of animal origin must be in compliance with Regulation (EC) No 1069/2009 of the European Parliament and of the Council and Commission Regulation (EU) No 142/2011 (OJ L 54, 26.2.2011, p. 1).

Number	Common name, identification numbers	IUPAC name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
						<p>PART B</p> <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the amended review report on fat distillation residues (SANCO/2610/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 June 2012 shall be taken into account.</p> <p>Conditions of use shall include, where appropriate, risk mitigation measures.</p> <p>The notifier shall submit confirmatory information as regards the specification of the technical material and the analysis of the maximum levels of impurities and contaminants of toxicological concern. This information shall be submitted to the Member States, the Commission and the Authority by 1 May 2013.'</p>

(\*) Further details on identity and specification of active substance are provided in their review report.

(3) Row 248 on the active substance repellents by smell of animal or plant origin/fish oil is replaced by the following:

Number	Common name, identification numbers	IUPAC name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
'248	Fish oil CAS No 100085-40-3 CIPAC No 918	Fish oil	<p>≥ 99 %</p> <p>Relevant impurity:</p> <p>Dioxine max. 6 pg/kg for animal feed</p> <p>Hg max. 0,5 mg/kg feed derived from fish and other sea food processing</p> <p>Cd max. 2 mg/kg feed of animal origin except in feed for domestic pets</p> <p>Pb max. 10 mg/kg</p> <p>PCBs max. 5 mg/kg</p>	1 September 2009	31 August 2019	<p>PART A</p> <p>Only uses as repellent may be authorised. Fish oil must be in compliance with Regulation (EC) No 1069/2009 and Regulation (EU) No 142/2011.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fish oil (SANCO/2629/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 June 2012 shall be taken into account.</p> <p>Conditions of use shall include, where appropriate, risk mitigation measures.</p> <p>The notifier shall submit confirmatory information as regards the specification of the technical material and the analysis of the maximum levels of impurities and contaminants of toxicological concern. This information shall be submitted to the Member States, the Commission and the Authority by 1 May 2013.'</p>

(\*) Further details on identity and specification of active substance are provided in their review report.

(4) Row 257 on the active substance urea is replaced by the following:

Number	Common name, identification numbers	IUPAC name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
'257	Urea  CAS No 57-13-6  CIPAC No 913	Urea	≥ 98 % w/w	1 September 2009	31 August 2019	<p>PART A</p> <p>Only uses as attractant and fungicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on urea (SANCO/2637/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 June 2012 shall be taken into account.</p> <p>Conditions of use shall include, where appropriate, risk mitigation measures.</p> <p>The notifier shall submit confirmatory information as regards:</p> <p>(a) the analysis method for urea and for the impurity biuret;</p> <p>(b) the risk for operators, workers and bystanders.</p> <p>The information set out in point (a) and in point (b) shall be submitted to the Member States, the Commission and the Authority respectively by 1 May 2013 and 1 January 2016.'</p>

(\*) Further details on identity and specification of active substance are provided in their review report.