COMMISSION IMPLEMENTING REGULATION (EU) No 571/2012

of 28 June 2012

amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substances aluminium silicate, hydrolysed proteins and 1,4-diaminobutane (putrescine)

(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 Article 13(2)(c) thereof,

Whereas:

(1) The active substances aluminium silicate, hydrolysed proteins and 1,4-diaminobutane (putrescine) were included in Annex I to Council Directive 91/414/EEC [2] by Commission Directive 2008/127/EC [3] 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 [4]. 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 [5].

(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 silicate [6], hydrolysed proteins [7] and 1,4-diaminobutane (putrescine) [8] 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 silicate, hydrolysed proteins and 1,4-diaminobutane (putrescine).

(3) The Authority communicated its views on aluminium silicate, hydrolysed proteins and 1,4-diaminobutane (putrescine) to the notifiers, and the Commission invited them to submit comments on the review reports.

(4) It is confirmed that the active substances aluminium silicate, hydrolysed proteins and 1,4-diaminobutane (putrescine) 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 silicate, hydrolysed proteins and 1,4-diaminobutane (putrescine). It is, in particular, appropriate to require further confirmatory information as regards aluminium silicate and hydrolysed proteins. At the same time certain technical adaptations should be made, in particular the name of the active substance 'putrescin (1,4-diaminobutane)' should be replaced by '1,4-diaminobutane (putrescine)'. The Annex to 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,

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.

[1] OJ L 309, 24.11.2009,p. 1.
[2] OJ L 230, 19.8.1991, p. 1.
[3] OJ L 344, 20.12.2008, p. 89.
[4] OJ L 379, 24.12.2004, p. 13.
[5] OJ L 153, 11.6.2011, p. 1.
[6] Conclusion on the peer review of the pesticide risk assessment of the active substance aluminium silicate. EFSA Journal 2012; 10(1):2517. Available online: www.efsa.europa.eu/efsajournal.
[7] Conclusion on the peer review of the pesticide risk assessment of the active substance hydrolysed proteins. EFSA Journal 2012; 10(2):2545. Available online: www.efsa.europa.eu/efsajournal.
[8] Conclusion on the peer review of the pesticide risk assessment of the active substance 1,4-diaminobutane (putrescine). EFSA Journal 2012;10(1):2516. Available online: www.efsa.europa.eu/efsajournal.

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, 28 June 2012.

For the Commission
The President
José Manuel BARROSO

ANNEX

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

(1) Row 220 on the active substance aluminium silicate is replaced by the following:

Number	Common Name, Identification Numbers	IUPAC Name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
'220	Aluminium silicate CAS No 1332-58-7 CIPAC No 841	Not available Chemical name: Aluminium silicate	≥ 999,8 g/kg	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 silicate (SANCO/2603/08) 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. In this overall assessment Member States shall pay particular attention to the operator safety; conditions of use shall include the application of adequate personal and respiratory protective equipment, where appropriate. Conditions of use shall include, where appropriate, risk mitigation measures. The Member States concerned shall ensure that the applicant submits to the Commission confirmatory information as regards: (a) the specification of the technical material, as commercially manufactured, supported by appropriate analytical data; (b) the relevance of the test material used in the toxicity dossier in view of the specification of the technical material. The Member States concerned shall ensure that the applicant submits such information to the Commission by 1 May 2013.'

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

(2) Row 234 on the active substance hydrolysed proteins is replaced by the following:

'Number	Common Name, Identification Numbers	IUPAC Name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
234	Hydrolysed proteins CAS No not allocated CIPAC No 901	Not available	Review report (SANCO/2615/2008)	1 September 2009	31 August 2019	PART A Only uses as attractant may be authorised. Hydrolysed proteins of animal origin must be in compliance with Regulation (EC) No 1069/2009 (**) and Commission Regulation (EU) No 142/2011 (***).

Number	Common Name, Identification Numbers	IUPAC Name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
						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 hydrolysed proteins (SANCO/2615/08) 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. In this overall assessment Member States shall pay particular attention to the operator and worker safety; conditions of use shall include the application of adequate personal protective equipment, where appropriate. Conditions of use shall include, where appropriate, risk mitigation measures. The Member States concerned shall ensure that the applicant submits to the Commission confirmatory information as regards: (a) the specifications of the technical material, as commercially manufactured, supported by appropriate analytical data; (b) the risk to aquatic organisms. The Member States concerned shall ensure that the applicant submits to the Commission the information set out in point (a) by 1 May 2013, the information set out in point (b) by 1 November 2013.

(*) Further details on identity and specification of active substances are provided in their review report.
(**) OJ L 300, 14.11.2009, p. 1.
(***) OJ L 54, 26.2.2011, p. 1.'

(3) Row 245 on the active substance 1,4-diaminobutane (putrescine) is replaced by the following:

Number	Common Name, Identification Numbers	IUPAC Name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
'245	1,4-diaminobutane (putrescine) CAS No 110-60-1 CIPAC No 854	Butane-1,4-diamine	≥ 990 g/kg	1 September 2009	31 August 2019	PART A Only uses as attractant 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 1,4-diaminobutane (putrescine) (SANCO/2626/08) 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.'

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