

COMMISSION IMPLEMENTING REGULATION (EU) 2015/418

of 12 March 2015

amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance Z-13-hexadecen-11-yn-1-yl acetate

(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 substance Z-13-hexadecen-11-yn-1-yl acetate was 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 (⁴). Since the replacement of Directive 91/414/EEC by Regulation (EC) No 1107/2009, this substance is deemed to have been approved under that Regulation and is listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 (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 view on the draft review report for Z-13-hexadecen-11-yn-1-yl acetate (⁶) on 18 December 2013. The Authority communicated its view on Z-13-hexadecen-11-yn-1-yl acetate to the notifier.
- (3) The Commission invited the notifier to submit comments on the draft review report for Z-13-hexadecen-11-yn-1-yl acetate. The draft review report and the view of the Authority were reviewed by the Member States and the Commission within the Standing Committee on Plants, Animals, Food and Feed and finalised on 12 December 2014 in the format of the Commission review report for Z-13-hexadecen-11-yn-1-yl acetate.
- (4) It is confirmed that the active substance Z-13-hexadecen-11-yn-1-yl acetate is 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 Z-13-hexadecen-11-yn-1-yl acetate. In particular, it is appropriate to require further confirmatory information.
- (6) The Annex to Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (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

Amendment to Implementing Regulation (EU) No 540/2011

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) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

(³) Commission Directive 2008/127/EC of 18 December 2008 amending Council Directive 91/414/EEC to include several active substances (OJ L 344, 20.12.2008, p. 89).

(⁴) 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 (OJ L 379, 24.12.2004, p. 13).

(⁵) 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).

(⁶) Conclusion on the peer review of the pesticide risk assessment of the active substance Z-13-hexadecen-11-yn-1-yl acetate. EFSA Journal 2014; 12(12):3526. Available online: www.efsa.europa.eu/efsajournal.htm

*Article 2***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, 12 March 2015.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX

In Part A of the Annex to Implementing Regulation (EU) No 540/2011, row 258 on the active substance Z-13-hexadecen-11-yn-1-yl acetate is replaced by the following:

Number	Common Name, Identification Numbers	IUPAC Name	Purity	Date of approval	Expiration of approval	Specific provisions
'258	Z-13-hexadecen-11-yn-1-yl acetate CAS No 78617-58-0 CIPAC: 974	Z-13-hexadecen-11-yn-1-yl acetate	≥ 75 %	1 September 2009	31 August 2019	<p>PART A</p> <p>Only uses as attractant 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 Z-13-hexadecen-11-yn-1-yl acetate (SANCO/2649/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed 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> <ul style="list-style-type: none"> (1) the specification of the technical material, as commercially manufactured including information on any relevant impurities; (2) exposure risk assessment for operators, workers and bystanders; (3) environmental fate and behaviour of the substance; (4) exposure risk assessment for non-target organisms. <p>The notifier shall submit to the Commission, the Member States and the Authority the information set out in point (1) by 30 June 2015 and the information set out in points (2), (3) and (4) by 31 December 2016.'</p>