COMMISSION IMPLEMENTING REGULATION (EU) No 187/2013

of 5 March 2013

amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance ethylene

(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 ethylene 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 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, 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 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 view on the draft review report for ethylene [6] on 16 December 2011. The Authority communicated its view on ethylene to the notifier. The Commission invited it to submit comments on the draft review report for ethylene. The draft review report and the view 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 February 2013 in the format of the Commission review report for ethylene.

(3) It is confirmed that the active substance ethylene is to be deemed to have been approved under Regulation (EC) No 1107/2009.

(4) 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 ethylene. In particular, it is appropriate to modify the requested minimum purity level and to restrict the authorisations to indoor uses by professional users. Furthermore, when the Member States grant authorisations for plant protection products containing ethylene, they shall pay particular attention to the protection of operators, workers and bystanders and to the compliance of ethylene with the required specifications, irrespective of the form in which it is supplied to the user.

(5) 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, the notifier and holders of authorisations for plant protection products containing ethylene 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.

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 February 2014.

(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) European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance ethylene. EFSA Journal 2012;10(1):2508. [43 pp.] doi:10.2903/j.efsa.2012.2508. Available online: www.efsa.europa.eu/efsajournal

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

Done at Brussels, 5 March 2013.

For the Commission
The President
José Manuel BARROSO

ANNEX

In Part A of the Annex to Implementing Regulation (EU) No 540/2011, row 227 on the active substance ethylene is replaced by the following:

Number	Common Name, Identification Numbers	IUPAC Name	Purity [1]	Date of approval	Expiration of approval	Specific provisions
'227	Ethylene CAS No 74-85-1 CIPAC No 839	Ethylene	≥ 90 % Relevant impurity: ethylene oxide, max content 1 mg/kg	1 September 2009	31 August 2019	PART A Only indoor uses as plant growth regulator by professional users 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 ethylene (SANCO/2608/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 February 2013, shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the compliance of ethylene with the required specifications, irrespective of the form in which it is supplied to the user; (b) the protection of operators, workers and bystanders. Conditions of authorisation shall include, where appropriate, risk mitigation measures.'

[1] Further details on identity and specification of active substances are provided in their review reports.