Commission Implementing Regulation (EU) No 608/2012 of 6 July 2012 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substances denathonium benzoate, methyl nonyl ketone and plant oils/spearmint oil (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 608/2012

of 6 July 2012

amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substances denathonium benzoate, methyl nonyl ketone and plant oils/spearmint oil

(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 denathonium benzoate, methyl nonyl ketone and plant oils/ spearmint oil 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 denathonium benzoate[(6)], methyl nonyl ketone[(7)] on 2 December 2011 and for plant oils/spearmint oil[(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 denathonium benzoate, methyl nonyl ketone and plant oils/spearmint oil.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) No 608/2012. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(3) The Authority communicated its views on denathonium benzoate, methyl nonyl ketone and plant oils/spearmint oil to the notifiers, and the Commission invited them to submit comments on the review reports.

(4) It is confirmed that the active substances denathonium benzoate, methyl nonyl ketone and plant oils/spearmint oil 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 denathonium benzoate, methyl nonyl ketone and plant oils/spearmint oil. It is, in particular, appropriate to require further confirmatory information as regards methyl nonyl ketone. The use of plant oils/spearmint oil should be restricted to postharvest treatment of potatoes.

(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.

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, 6 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 226 on the active substance denathonium benzoate is replaced by the following

Number	Common Name, Identification Numbers	IUPAC Name	Purity[a]	Date of approval	Expiration of approval	Specific provisions
'226	Denathonium benzoate CAS No 3734-33-6 CIPAC No 845	Benzyldiethyl[2,6-xylylcarbamoyl]methyl]benzoate	≥ 775 g/kg	1 September 2009	31 August 2019	PART A Only uses as repellent may be authorised. PART B In assessing applications to authorise plant protection products containing denathonium benzoate for uses other than brushing with automatic rolling equipment in forestry, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and

a Further details on identity and specification of active substance are provided in their review report.

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						information is provided before such an authorisation is granted. 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 denathonium benzoate (SANCO/2607/2008) 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. In this overall assessment Member States must pay

a Further details on identity and specification of active substance are provided in their review report.

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						particular attention to the protection of the operators. Authorised conditions of use must prescribe the application of adequate personal protective equipment. Conditions of use shall include, where appropriate, risk mitigation measures.'

a Further details on identity and specification of active substance are provided in their review report.

(2) Row 238 on the active substance methyl nonyl ketone is replaced by the following:

Number	Common Name, Identification Numbers	IUPAC Name	Purity[a]	Date of approval	Expiration of approval	Specific provisions
'238	Methyl nonyl ketone CAS No 112-12-9 CIPAC No 846	Undecan-2-one	≥ 975g/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

a Further details on identity and specification of active substance are provided in their review report.