Commission Implementing Regulation (EU) No 637/2012 of 13 July 2012 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substances iron sulphate, repellents by smell of animal or plant origin/tall oil crude and repellents by smell of animal or plant origin/tall oil pitch (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 637/2012

of 13 July 2012

amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substances iron sulphate, repellents by smell of animal or plant origin/tall oil crude and repellents by smell of animal or plant origin/tall oil pitch

(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 iron sulphate, repellents by smell of animal or plant origin/tall oil crude and repellents by smell of animal or plant origin/tall oil pitch 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 iron sulphate[(6)], repellents by smell of animal or plant origin/tall oil crude[(7)] and repellents by smell of animal or plant origin/tall oil pitch[(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

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) No 637/2012. 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*

the Commission review reports for iron sulphate, repellents by smell of animal or plant origin/tall oil crude and repellents by smell of animal or plant origin/tall oil pitch.

(3) The Authority communicated its views on iron sulphate, repellents by smell of animal or plant origin/tall oil crude and repellents by smell of animal or plant origin/tall oil pitch to the notifiers, and the Commission invited them to submit comments on the review reports.

(4) It is confirmed that the active substances iron sulphate, repellents by smell of animal or plant origin/tall oil crude and repellents by smell of animal or plant origin/tall oil pitch 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 iron sulphate, repellents by smell of animal or plant origin/tall oil crude and repellents by smell of animal or plant origin/tall oil pitch. It is, in particular, appropriate to require further confirmatory information as regards those active substances.

(6) The Annex to Regulation (EU) No 540/2011 should therefore be amended accordingly.

(7) 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.

(8) 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

Member States shall in accordance with Regulation (EC) No 1107/2009, where necessary, amend or withdraw existing authorisations for plant protection products containing repellents by smell of animal or plant origin/tall oil crude as active substances in order to comply with the Annex to this Regulation by 1 May 2013.

Article 3

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.

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Done at Brussels, 13 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 235 on the active substance iron sulphate is replaced by the following:

Number	Common Name, Identification Numbers	IUPAC Name	Purity[a]	Date of approval	Expiration of approval	Specific provisions
'235	*Iron sulphate*: Iron(II)sulphate anhydrous: CAS No 7720-78-7 Iron(II)sulfate monohydrate: CAS No 17375-41-6 Iron(II)sulfate heptahydrate: CAS No 7782-63-0 CIPAC No 837	Iron(II)sulphate or iron(II)sulfate or iron(II)sulfate anhydrous: CAS No 7720-78-7 Iron(II)sulfate monohydrate: CAS No 17375-41-6 Iron(II)sulfate heptahydrate: CAS No 7782-63-0	Iron(II)sulfate anhydrous: ≥ 350 g/kg total iron. Relevant impurities: arsenic, 18 mg/kg cadmium, 1,8 mg/kg chromium, 90 mg/kg lead, 36 mg/kg mercury, 1,8 mg/kg expressed on the basis of the anhydrous variant	1 September 2009	31 August 2019	PART A Only uses as herbicide 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 amended review report on iron sulphate (SANCO/2616/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on

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

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						1 June 2012 shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the risk for operator; — the risk to children/ residents playing on treated turf; — the risk to surface waters and to aquatic organisms. Conditions of use shall include, where appropriate, risk mitigation measures and the application of adequate personal protective equipment.

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