

COMMISSION IMPLEMENTING REGULATION (EU) No 1089/2013

of 4 November 2013

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

(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) and Article 78(2) thereof,

Whereas:

(1) The active substance kieselgur (diatomaceous earth) 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 kieselgur (diatomaceous earth) on 22 June 2012. The Authority communicated its view on kieselgur (diatomaceous earth) to the notifier. The Commission invited it to submit comments on the draft review report for kieselgur (diatomaceous earth). 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 the draft review report was finalised on 3 October 2013 in the format of the Commission review report for kieselgur (diatomaceous earth).

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Council Directive 91/414/EEC of 15 July 1991 on the placing on the market of plant protection products (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).

(3) It is confirmed that the active substance kieselgur (diatomaceous earth) 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. It is, in particular, appropriate to require further confirmatory information.

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

(6) Member States should be provided with time to amend or withdraw authorisations for plant protection products containing kieselgur (diatomaceous earth).

(7) For plant protection products containing kieselgur (diatomaceous earth), where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, this period should expire at the latest eighteen months after the date of entry into force of the Regulation.

(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

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.

Article 2

Transitional measures

Member States shall in accordance with Regulation (EC) No 1107/2009, where necessary, amend or withdraw existing authorisations for plant protection products containing kieselgur (diatomaceous earth) as active substance by 25 May 2014.

*Article 3***Grace period**

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall be as short as possible and shall expire by 25 May 2015 at the latest.

*Article 4***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, 4 November 2013.

For the Commission

The President

José Manuel BARROSO

ANNEX

In Part A of the Annex to Implementing Regulation (EU) No 540/2011, row 236 on the active substance kieselgur (diatomaceous earth) is replaced by the following:

Number	Common name, Identification numbers	IUPAC name	Purity	Date of approval	Expiration of approval	Specific provisions
'236	Kieselgur (diatomaceous earth) CAS No 61790-53-2 CIPAC No 647	Kieselgur (no IUPAC name) Diatomaceous earth Amorphous silicon dioxide Silica Diatomite	The product consists of 100 % diatomaceous earth. Maximum 0,1 % of particles of crystalline silica with diameter below 50 µm	1 September 2009	31 August 2019	<p>PART A</p> <p>Only indoor uses as insecticide and acaricide by professional users 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 kieselgur (diatomaceous earth) (SANCO/2617/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2013 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the safety of operators and workers. Conditions of use shall include the application of adequate personal and respiratory protective equipment. Where necessary, conditions of use shall prohibit the presence of workers after application of the product concerned for a period appropriate in view of the risks caused by that product.</p> <p>The Member States concerned shall ensure that the notifiers submit, by 25 November 2015, to the Commission, the Member States and the Authority information concerning the inhalation toxicity to confirm the occupational limits of kieselgur (diatomaceous earth).'</p>