Commission Implementing Regulation (EU) 2020/1293 of 15 September 2020 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance azadirachtin (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1293

of 15 September 2020

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

(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) Commission Implementing Directive 2011/44/EU[(2)] included azadirachtin as an active substance in Annex I to Council Directive 91/414/EEC[(3)].

(2) In accordance with Regulation (EC) No 1107/2009, active substances included in Annex I to Directive 91/414/EEC 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[(4)].

(3) The approval of the active substance azadirachtin, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, was restricted to the use as insecticide.

(4) In accordance with Article 7(1) of Regulation (EC) No 1107/2009, on 27 February 2012 Trifolio-M GmbH, one of the producers of the active substance, submitted an application to the designated Rapporteur Member State, Germany, seeking an amendment to the conditions of approval of azadirachtin in order to allow its use as acaricide. The application was found to be admissible by the designated Rapporteur Member State.

(5) The designated Rapporteur Member State assessed the new use of the active substance azadirachtin in relation to the potential effects on human and animal health and the environment in accordance with the provisions of Article 4 of Regulation (EC) No 1107/2009, and prepared an addendum to the draft assessment report and additional report which was submitted to the European Food Safety Authority (‘the Authority’) and the Commission on 10 January 2013.

Changes to legislation: Commission Implementing Regulation (EU) 2020/1293 is up to date with all changes known to be in force on or before 29 March 2022. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

(6) In accordance with Article 12(1) of Regulation (EC) No 1107/2009, the Authority circulated the addendum to the draft assessment report and additional report to the applicant and to the Member States for comments and made it available to the public. In accordance with Article 12(3) of Regulation (EC) No 1107/2009, additional information was requested from the applicant. Germany evaluated the additional information and submitted a revised addendum to the draft assessment report and additional report to the Commission and to the Authority on 19 September 2017.

(7) On 14 September 2018, the Authority communicated to the Commission its conclusion[(5)] on whether the new use of the active substance azadirachtin can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented the draft addendum to the review report for azadirachtin and a draft Regulation to the Standing Committee on Plants, Animals, Food and Feed on 19 May 2020.

(8) The applicant was invited to submit comments on the addendum to the review report.

(9) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance that, when the plant protection product is used as an acaricide, the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate to withdraw the restriction for the use of azadiracthin as an insecticide only.

(10) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(11) 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

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with the Annex to this Regulation.

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.

***Changes to legislation:** Commission Implementing Regulation (EU) 2020/1293 is up to date with all changes known to be in force on or before 29 March 2022. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

Done at Brussels, 15 September 2020.

For the Commission

The President

Ursula VON DER LEYEN