COMMISSION IMPLEMENTING REGULATION (EU) 2017/157

of 30 January 2017

renewing the approval of the active substance thiabendazole in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011

(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 20(1) thereof,

Whereas:

(1) The approval of the active substance thiabendazole, as set out in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ([2]), expires on 30 June 2017.

(2) An application for the renewal of the inclusion of thiabendazole in Annex I to Council Directive 91/414/EEC ([3]) was submitted in accordance with Article 4 of Commission Regulation (EU) No 1141/2010 ([4]) within the time period provided for in that Article.

(3) The applicant submitted the supplementary dossiers required in accordance with Article 9 of Regulation (EU) No 1141/2010. The application was found to be complete by the rapporteur Member State.

(4) The rapporteur Member State prepared a renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority (hereinafter 'the Authority') and the Commission on 28 May 2013.

(5) The Authority communicated the renewal assessment report to the applicant and to the Member States for comments and forwarded the comments received to the Commission. The Authority also made the supplementary summary dossier available to the public.

(6) On 23 October 2014, the Authority communicated to the Commission its conclusion ([5]) on whether thiabendazole can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented the draft review report for thiabendazole to the Standing Committee on Plants, Animals, Food and Feed on 20 March 2015.

(7) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. Those approval criteria are therefore deemed to be satisfied.

([1]) OJ L 309, 24.11.2009, p. 1.
([2]) 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]) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).
([4]) Commission Regulation (EU) No 1141/2010 of 7 December 2010 laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council Directive 91/414/EEC and establishing the list of those substances (OJ L 322, 8.12.2010, p. 10).
([5]) EFSA Journal 2015;12(11):3880. Available online: www.efsa.europa.eu

(8) It is therefore appropriate to renew the approval of thiabendazole.

(9) The risk assessment for the renewal of the approval of thiabendazole is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing thiabendazole may be authorised. It is therefore appropriate not to maintain the restriction for uses as a fungicide.

(10) In accordance with Article 14(1) 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 include certain conditions. It is, in particular, appropriate to require further confirmatory information.

(11) In accordance with Article 20(3) of Regulation (EC) No 1107/2009, in conjunction with Article 13(4) thereof, the Annex to Implementing Regulation (EU) No 540/2011 should be amended accordingly.

(12) Commission Implementing Regulation (EU) 2016/549 [1] extended the approval period of thiabendazole until 30 June 2017 in order to allow the renewal process to be completed before the expiry of the approval of that substance. However, given that a decision on renewal has been taken ahead of that date, this Regulation should apply from 1 April 2017.

(13) 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

Renewal of the approval of active substance

The approval of the active substance thiabendazole, as specified in Annex I, is renewed subject to the conditions laid down in that Annex.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

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

Article 3

Entry into force and date of application

This Regulation shall enter into force the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 April 2017.

[1] Commission Implementing Regulation (EU) 2016/549 of 8 April 2016 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances bentazone, cyhalofop butyl, diquat, famoxadone, flumioxazine, DPX KE 459 (flupyrsulfuron-methyl), metalaxyl-M, picolinafen, prosulfuron, pymetrozine, thiabendazole and thifensulfuron-methyl (OJ L 95, 9.4.2016, p. 4).

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

Done at Brussels, 30 January 2017.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
Thiabendazole CAS No 148-79-8 CIPAC No 323	2-(thiazol-4-yl) benzimidazole	≥ 985 g/kg	1 April 2017	31 March 2032	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 thiabendazole, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of operators and consumers, — the protection of groundwater, — the control of waste water from post-harvest uses. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit by 31 March 2019 to the Commission, the Member States and the Authority confirmatory information regarding Level 2 tests as currently indicated in the OECD Conceptual Framework investigating the potential for endocrine-mediated effects of thiabendazole.

(1) Further details on identity and specification of active substance are provided in the review report.

ANNEX II

The Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) in Part A, entry 17 on thiabendazole is deleted;

(2) in Part B, the following entry is added:

	Common Name, Identification Numbers	IUPAC Name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
'105	Thiabendazole CAS No 148-79-8 CIPAC No 323	2-(thiazol-4-yl) benzimidazole	≥ 985 g/kg	1 April 2017	31 March 2032	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 thiabendazole, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of operators and consumers, — the protection of groundwater, — the control of waste water from post-harvest uses. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit by 31 March 2019 to the Commission, the Member States and the Authority confirmatory information regarding Level 2 tests as currently indicated in the OECD Conceptual Framework investigating the potential for endocrine-mediated effects of thiabendazole.'

(*) Further details on identity and specification of active substance are provided in the review report.