Commission Implementing Regulation (EU) 2017/1506 of 28 August 2017 renewing the approval of the active substance maleic hydrazide 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)

COMMISSION IMPLEMENTING REGULATION (EU) 2017/1506

of 28 August 2017

renewing the approval of the active substance maleic hydrazide 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) Commission Directive 2003/31/EC[(2)] included maleic hydrazide as an active substance in Annex I to Council Directive 91/414/EEC[(3)].

(2) Active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 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 maleic hydrazide, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 October 2017.

(4) An application for the renewal of the approval of maleic hydrazide was submitted in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012[(5)] within the time period provided for in that Article.

(5) The applicant submitted the supplementary dossiers required in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The application was found to be complete by the rapporteur Member State.

(6) 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 ('the Authority') and the Commission on 30 April 2015.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/1506. 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*

(7) 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.

(8) On 29 April 2016 the Authority communicated to the Commission its conclusion[6] on whether maleic hydrazide can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented the draft renewal report for maleic hydrazide to the Standing Committee on Plants, Animals, Food and Feed on 6 October 2016.

(9) The applicant was given the opportunity to submit comments on the draft renewal report.

(10) It has been established with respect to one or more representative uses of at least one plant protection product containing maleic hydrazide that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate to renew the approval of maleic hydrazide.

(11) The risk assessment for the renewal of the approval of maleic hydrazide is based on a limited number of representative uses, which, however, do not restrict the uses for which plant protection products containing maleic hydrazide may be authorised. It is therefore appropriate to remove the restriction for use only as a growth regulator.

(12) 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, however, necessary to include certain conditions and restrictions. It is, in particular, appropriate to set a maximum level for the toxicologically relevant impurity hydrazine in the active substance as manufactured, at the level considered safe by the Authority, which is 0,028 mg/kg.

(13) It is however appropriate to allow sufficient time for the producers to implement necessary manufacturing processes and controls as regards that maximum level.

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

(15) 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 the active substance

The approval of the active substance maleic hydrazide is renewed as set out in Annex I.

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/1506. 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*

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 on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 November 2017 except for the provision concerning hydrazine content specified in column ‘Purity’ of the table in Annex I, which shall apply from 1 November 2018.

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

Done at Brussels, 28 August 2017.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/1506. 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*

ANNEX I

Common Name,Identification Numbers	**IUPAC Name**	**Purity**[a]	**Date of approval**	**Expiration of approval**	**Specific provisions**
Maleic hydrazide CAS No 123-33-1 CIPAC No 310	6-hydroxy-2H-pyridazin-3-one	≥ 979 g/kg Until 1 November 2018, the impurity hydrazine shall not exceed 1 mg/kg in the technical material. From 1 November 2018, the impurity hydrazine shall not exceed 0,028 mg/kg in the technical material.	1 November 2017	31 October 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 renewal report on maleic hydrazide, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of consumers, — the operator and worker safety; the conditions of the use should include the application

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