Commission Implementing Regulation (EU) 2017/406 of 8 March 2017 approving the low-risk active substance Mild Pepino Mosaic Virus isolate VX1, 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) 2017/406

of 8 March 2017

approving the low-risk active substance Mild Pepino Mosaic Virus isolate VX1, 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 22(1) in conjunction with Article 13(2) thereof,

Whereas:

(1) In accordance with Article 7(1) of Regulation (EC) No 1107/2009 the Netherlands received on 2 December 2013 an application from Valto BV for the approval of the active substance Mild Pepino Mosaic Virus isolate VX1. In accordance with Article 9(3) of that Regulation, the Netherlands, as rapporteur Member State, notified the applicant, the other Member States, the Commission and the European Food Safety Authority (hereinafter 'the Authority') on 30 June 2014 of the admissibility of the application.

(2) On 10 November 2015 the rapporteur Member State submitted a draft assessment report to the Commission with a copy to the Authority, assessing whether that active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

(3) The Authority complied with Article 12(1) of Regulation (EC) No 1107/2009. In accordance with Article 12(3) of Regulation (EC) No 1107/2009, it requested that the applicant supply additional information to the Member States, the Commission and the Authority. The assessment of the additional information by the rapporteur Member State was submitted to the Authority in the format of an updated draft assessment report on 8 September 2016.

(4) On 18 November 2016 the Authority communicated to the applicant, the Member States and the Commission its conclusion[(2)] on whether the active substance Mild Pepino

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Mosaic Virus isolate VX1 can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority made its conclusion available to the public.

(5) On 6 December 2016, the Commission presented to the Standing Committee on Plants, Animals, Food and Feed the review report for Mild Pepino Mosaic Virus isolate VX1 and a draft Regulation providing that Mild Pepino Mosaic Virus isolate VX1 is approved.

(6) The applicant was given the possibility to submit comments on the review report.

(7) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance, and in particular the uses which were examined and detailed in the review report, 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. It is therefore appropriate to approve Mild Pepino Mosaic Virus isolate VX1.

(8) 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, however, necessary to include certain conditions and restrictions.

(9) The Commission further considers that Mild Pepino Mosaic Virus isolate VX1 is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. Mild Pepino Mosaic Virus isolate VX1 is not a substance of concern and fulfils the conditions set in point 5 of Annex II to Regulation (EC) No 1107/2009. Mild Pepino Mosaic Virus isolate VX1 is a naturally occurring plant virus strain. A plant virus does not replicate outside the plant cell and the virus does not have a cellular structure and does not produce metabolites. It is not pathogenic to humans or animals. The additional exposure of humans, animals and the environment by the uses approved under Regulation (EC) No 1107/2009 is expected to be negligible compared to natural exposure.

(10) It is therefore appropriate to approve Mild Pepino Mosaic Virus isolate VX1 as a low-risk substance. In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011[(3)] should 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

Approval of active substance

The active substance Mild Pepino Mosaic Virus isolate VX1, as specified in Annex I, is approved subject to the conditions laid down in that Annex.

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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

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, 8 March 2017.

For the Commission

The President

Jean-Claude JUNCKER

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ANNEX I

Common Name, Identification Numbers	**IUPAC Name**	**Purity**[a]	**Date of approval**	**Expiration of approval**	**Specific provisions**
Mild Pepino Mosaic Virus isolate VX1 Reference number DSM 26974 in the German Collection of Micro-organisms and Cell Cultures (DSMZ)	Not applicable	Nicotine < 0,1 mg/L	29 March 2017	29 March 2032	Only the use in greenhouses may be authorised. 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 Mild Pepino Mosaic Virus isolate VX1, 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 workers, taking into account that Mild Pepino Mosaic Virus isolate VX1 is to be considered, as any

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