

COMMISSION IMPLEMENTING REGULATION (EU) 2021/917**of 7 June 2021****approving the low-risk active substances *Pepino Mosaic Virus*, EU strain, mild isolate Abp1 and *Pepino Mosaic Virus*, CH2 strain, mild isolate Abp2 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 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 13(2) in conjunction with Article 22(1) thereof,

Whereas:

- (1) In accordance with Article 7(1) of Regulation (EC) No 1107/2009, Abiopep Plant Health S.L. submitted to Spain on 27 November 2017 an application for the approval of the active substances *Pepino Mosaic Virus*, EU strain, mild isolate Abp1 and *Pepino Mosaic Virus*, CH2 strain, mild isolate Abp2.
- (2) In accordance with Article 9(3) of that Regulation, Spain, as rapporteur Member State, notified the applicant, the other Member States, the Commission and the European Food Safety Authority ('the Authority') on 15 February 2018 of the admissibility of the application.
- (3) On 22 July 2019, the rapporteur Member State submitted a draft assessment report to the Commission with a copy to the Authority, assessing whether these active substances can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (4) The Authority complied with Article 12(1) of Regulation (EC) No 1107/2009.
- (5) On 22 October 2019, the Authority communicated to the applicant, the Member States and the Commission its conclusion ⁽²⁾ on whether the active substances *Pepino Mosaic Virus*, EU strain, mild isolate Abp1 and *Pepino Mosaic Virus*, CH2 strain, mild isolate Abp2 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.
- (6) On 25 January 2021, the Commission presented to the Standing Committee on Plants, Animals, Food and Feed a review report and a draft Regulation regarding *Pepino Mosaic Virus*, EU strain, mild isolate Abp1 and *Pepino Mosaic Virus*, CH2 strain, mild isolate Abp2.
- (7) The applicant was given the possibility to submit comments on the review report.
- (8) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substances, 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. It is therefore appropriate to approve *Pepino Mosaic Virus*, EU strain, mild isolate Abp1 and *Pepino Mosaic Virus*, CH2 strain, mild isolate Abp2.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ EFSA (European Food Safety Authority), 2021. Conclusion on the peer review of the pesticide risk assessment of the active substances *Pepino Mosaic Virus*, EU strain, mild isolate Abp1 and *Pepino Mosaic Virus*, CH2 strain, mild isolate Abp2. EFSA Journal 2021;19(1):6388, 16 pp. doi:10.2903/j.efsa.2021.6388. Available online: www.efsa.europa.eu.

- (9) The Commission further considers that *Pepino Mosaic Virus*, EU strain, mild isolate Abp1 and *Pepino Mosaic Virus*, CH2 strain, mild isolate Abp2 are low-risk active substances pursuant to Article 22 of Regulation (EC) No 1107/2009. *Pepino Mosaic Virus*, EU strain, mild isolate Abp1 and *Pepino Mosaic Virus*, CH2 strain, mild isolate Abp2 are not substances of concern and they fulfil the conditions set out in point 5.2 of Annex II to Regulation (EC) No 1107/2009. Taking into account the assessment by the rapporteur Member State and the Authority, as regards the intended uses in permanent greenhouses (soil-bound and hydroponics), *Pepino Mosaic Virus*, EU strain, mild isolate Abp1 and *Pepino Mosaic Virus*, CH2 strain, mild isolate Abp2 are microorganisms which are expected to have a low risk for humans, animals and the environment. *Pepino mosaic virus* infection and its replication are known to be very specific to some plants (*Solanaceae* family) and have not been reported to occur in other organisms. No critical areas of concern were identified, and the two strains are unlikely to have a potential of toxicity, infectivity and pathogenicity. For these reasons, only general mitigation measures should be taken for operators and workers.
- (10) It is therefore appropriate to approve *Pepino Mosaic Virus*, EU strain, mild isolate Abp1 and *Pepino Mosaic Virus*, CH2 strain, mild isolate Abp2 as low-risk substances.
- (11) 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 include certain conditions.
- (12) 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.
- (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

Approval of the active substances

The active substances *Pepino Mosaic Virus*, EU strain, mild isolate Abp1 and *Pepino Mosaic Virus*, CH2 strain, mild isolate Abp2 are approved subject to the conditions laid down in Annex I.

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, 7 June 2021.

For the Commission
The President
Ursula VON DER LEYEN

⁽³⁾ 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).

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
Pepino Mosaic Virus, EU strain, mild isolate Abp1	Not applicable	<p>The impurity nicotine shall not exceed the following values in the technical material:</p> <p>max. 0,005 mg/L in Abp1 TK</p> <p>max. 3,87 x 10⁻⁵ mg/kg in MPCP</p> <p>(Nicotine has been reported to be present in tomato plants, therefore, as the microbial pest control agent (MPCA) is produced in tomato plants, nicotine is present as a consequence of the production method).</p>	28 June 2021	28 June 2036	<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 <i>Pepino Mosaic Virus</i>, EU strain, mild isolate Abp1 and <i>Pepino Mosaic Virus</i>, CH2 strain, mild isolate Abp2, and in particular Appendices I and II thereto, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>a) the strict maintenance of environmental conditions and quality control analysis during the manufacturing process to be assured by the producer, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 ⁽²⁾;</p> <p>b) the protection of operators and workers, taking into account that microorganisms are per se considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p>

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

⁽²⁾ https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_phys-chem-ana_microbial-contaminant-limits.pdf

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
Pepino Mosaic Virus, CH2 strain, mild isolate Abp2	Not applicable	<p>The impurity nicotine shall not exceed the following values in the technical material:</p> <p>max. 0,007 mg/L in Abp2 TK</p> <p>max. 3,87 x 10⁻⁵ mg/kg in MPCP</p> <p>(Nicotine has been reported to be present in tomato plants, therefore, as the microbial pest control agent (MPCA) is produced in tomato plants, nicotine is present as a consequence of the production method).</p>	28 June 2021	28 June 2036	<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 <i>Pepino Mosaic Virus</i>, EU strain, mild isolate Abp1 and <i>Pepino Mosaic Virus</i>, CH2 strain, mild isolate Abp2, and in particular Appendices I and II thereto, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>a) the strict maintenance of environmental conditions and quality control analysis during the manufacturing process to be assured by the producer, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 ⁽²⁾;</p> <p>b) the protection of operators and workers, taking into account that microorganisms are per se considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p>

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

⁽²⁾ https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_phys-chem-ana_microbial-contaminant-limits.pdf.

ANNEX II

In Part D of the Annex to Implementing Regulation (EU) No 540/2011, the following entries are added:

No	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
'29	<i>Pepino Mosaic Virus</i> , EU strain, mild isolate Abp1	Not applicable	<p>The impurity nicotine shall not exceed the following values in the technical material:</p> <p>max. 0,005 mg/L in Abp1 TK</p> <p>max. $3,87 \times 10^{-5}$ mg/kg in MPCP</p> <p>(Nicotine has been reported to be present in tomato plants, therefore, as the microbial pest control agent (MPCA) is produced in tomato plants, nicotine is present as a consequence of the production method).</p>	28 June 2021	28 June 2036	<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 <i>Pepino Mosaic Virus</i>, EU strain, mild isolate Abp1 and <i>Pepino Mosaic Virus</i>, CH2 strain, mild isolate Abp2, and in particular Appendices I and II thereto, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>a) the strict maintenance of environmental conditions and quality control analysis during the manufacturing process to be assured by the producer, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 ⁽²⁾.</p> <p>b) the protection of operators and workers, taking into account that microorganisms are per se considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate'</p>

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

⁽²⁾ https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_phys-chem-ana_microbial-contaminant-limits.pdf.

No	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
'30	<i>Pepino Mosaic Virus</i> , CH2 strain, mild isolate Abp2	Not applicable	<p>The impurity nicotine shall not exceed the following values in the technical material:</p> <p>max. 0,007 mg/L in Abp2 TK</p> <p>max. 3,87 x 10⁻⁵ mg/kg in MPCP</p> <p>(Nicotine has been reported to be present in tomato plants, therefore, as the microbial pest control agent (MPCA) is produced in tomato plants, nicotine is present as a consequence of the production method).</p>	28 June 2021	28 June 2036	<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 <i>Pepino Mosaic Virus</i>, EU strain, mild isolate Abp1 and <i>Pepino Mosaic Virus</i>, CH2 strain, mild isolate Abp2, and in particular Appendices I and II thereto, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>a) the strict maintenance of environmental conditions and quality control analysis during the manufacturing process to be assured by the producer, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 ⁽²⁾.</p> <p>b) the protection of operators and workers, taking into account that microorganisms are per se considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate'</p>

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

⁽²⁾ https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_phys-chem-ana_microbial-contaminant-limits.pdf.