Final Review report for the active substance **Mild Pepino Mosaic Virus VC1**
Finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 24 January 2017
in view of the approval of Mild Pepino Mosaic Virus isolate VC1 as active substance in accordance with Regulation (EC) No 1107/2009

1. **Procedure followed for the evaluation process**

This review report has been established as a result of the evaluation of the new active substance Mild Pepino Mosaic Virus isolate VC1, made in the context of the work provided for in Articles 7 to 13 of Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, with a view to the possible approval of this substance for the use in plant protection products.

In accordance with the provisions of Article 7 of that Regulation, the authorities of Belgium received on 2 December 2013 an application from Valto BV, hereafter referred to as the applicant, for the approval of the active substance Mild Pepino Mosaic Virus isolate VC1 for use in plant protection products. The authorities of the Netherlands indicated to the Commission on 30 June 2014 the results of their examination of the completeness of the dossier satisfying the requirements of Article 8, according to the provisions of Article 9 of the Regulation. Subsequently, and in accordance with the requirements of Article 9(3), a dossier on Mild Pepino Mosaic Virus isolate VC1 was distributed to the Member States, the European Food Safety Authority (EFSA) and the Commission.

Thereupon, the Netherlands as rapporteur Member State started the detailed examination of the dossier provided by the applicant. According to the provisions of Article 11, the rapporteur Member State shall prepare and submit to the Commission and EFSA within twelve months a report (the draft assessment report), assessing whether the active substance can be expected to meet the criteria provided for in Article 4 of the Regulation.

The Netherlands submitted that draft assessment report to the Commission and EFSA on 10 November 2015.

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1. Does not necessarily represent the views of the Commission.
On 15 December 2015, EFSA circulated the draft assessment report to Member States and the applicant and, in addition, organised a public consultation on it, in line with the provisions of Article 12(1) of the Regulation.

EFSA organised a consultation to review the draft assessment report and the comments received thereon (peer review) in accordance with the provisions of Article 12(2) and 12(3). In this framework, EFSA decided to request additional information from the applicant.

According to the provisions of Article 12(2) of the Regulation, EFSA sent to the Commission its conclusion on the risk assessment [Peer review of the pesticide risk assessment of the active substance Mild Pepino Mosaic Virus isolate VC1 (approved: 18 November 2016)]3. This conclusion refers to background document A (draft assessment report) and background document B (EFSA peer review report).

According to the provisions of Article 13 of that Regulation, the Commission produced a draft review report and a draft Regulation on Mild Pepino Mosaic Virus isolate VC1. The Commission referred the draft review report to the applicant for commenting on 1 December 2016 and on 6 December 2016 to the Standing Committee on Plants, Animals, Food and Feed, for final examination. The draft review report was finalised in the meeting of the Standing Committee on 24 January 2017.

The present review report contains the conclusions of the final examination by the Standing Committee. Given the importance of the conclusion of EFSA, and the comments and clarifications submitted after the conclusion of EFSA (background document C), these documents are also considered to be part of this review report.

2. Purposes of this review report

This review report, including the background documents and appendices hereto, has been developed and finalised in support of Commission Implementing Regulation (EU) 2017/4084 concerning the approval of Mild Pepino Mosaic Virus isolate VC1 as active substance under Regulation (EC) No 1107/2009, and to assist the Member States in decisions on individual plant protection products containing Mild Pepino Mosaic Virus isolate VC1 they have to take in accordance with the provisions of that Regulation, and in particular the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011.

This review report provides also for the evaluation required under part I, Section A.2(b) of the above mentioned uniform principles, as well as under several specific sections of chapter B of these principles. In these sections it is provided that Member States, in evaluating applications and granting authorisations, shall take into account the information concerning the requirements of Regulation (EU) No 544/2011, submitted for the purpose of approval of the active substances, as well as the result of the evaluation of those data.


In accordance with the provisions of Article 10 of Regulation (EU) No 188/2011, this review report will be made available to the public.

The information in this review report is, at least partly, based on information which is confidential and/or protected under the provisions of Regulation (EC) No 1107/2009. It is therefore recommended that this review report would not be accepted to support any registration outside the context of that Regulation, e.g. in third countries, for which the applicant has not demonstrated to have regulatory access to the information on which this review report is based.


The overall conclusion from the evaluation is that it may be expected that plant protection products containing Mild Pepino Mosaic Virus isolate VC1 will fulfil the safety requirements laid down in Article 4(1) – (3) of Regulation (EC) No 1107/2009. This conclusion is however subject to compliance with the particular requirements in sections 4, 5, 6 and 7 of this report, as well as to the implementation of the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011, for each Mild Pepino Mosaic Virus isolate VC1 containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of the uses which were proposed and supported by the data submitter and mentioned in the list of uses supported by available data (attached as Appendix II to this review report).

Extension of the use pattern beyond those described above will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the requirements of Article 29(1) of Regulation (EC) No 1107/2009 and of the uniform principles laid down in Regulation (EU) No 546/2011.

On the basis of studies conducted by the applicant and on studies published in the open scientific literature, the review concluded that, as there are no adverse effects observed from the exposure to Mild Pepino Mosaic Virus isolate VC1, there is no need for establishing toxicological reference values.

With particular regard to residues, a further investigation of residues and consumer exposure is not necessary, in the absence of the need for toxicological reference values. The review concludes that it is appropriate to include Mild Pepino Mosaic Virus isolate VC1 in Annex IV to Regulation (EC) No 396/2005.

The review has identified several acceptable exposure scenarios for operators, workers and bystanders, which require however to be confirmed for each plant protection product in accordance with the relevant sections of the above mentioned uniform principles.

The review has also concluded that under the proposed and supported conditions of use there are no unacceptable effects on the environment, as provided for in Article 4(3)(e) of Regulation (EC) No 1107/2009, provided that certain conditions are taken into account as detailed in section 6 of this report.
Mild Pepino Mosaic Virus isolate VC1 does not meet any of the criteria listed in point 5 of Annex II to Regulation (EC) No 1107/2009. Taking into account that Mild Pepino Mosaic Virus isolate VC1 is a virus that is not pathogenic or infective to humans, is in general naturally occurring and does not constitute a distinct risk to any compartment of the environment, it is concluded that Mild Pepino Mosaic Virus isolate VC1 shall be considered a low risk active substance in accordance with Article 22 of Regulation (EC) No 1107/2009.

4. **Identity and Physical/chemical properties**

The main identity of Mild Pepino Mosaic Virus isolate VC1 is given in Appendix I.

The isolate is deposited at the culture collection of the German Collection of Micro-organisms and Cell Cultures (DMZ), Germany, under the reference number DSM 26973.

The minimum initial population in the MPCA (microbial pest control agent) shall be $1.5 \times 10^{11}$ virus particles per mL (10 mg/L).

It has been established that for the active substance notified by the applicant Valto BV the impurity nicotine is of toxicological relevance and shall be below 0.1 mg/L in the technical grade of the MPCA.

Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall 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.

5. **Endpoints and related information**

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011, the most important endpoints were identified during the evaluation process. These endpoints are listed in the conclusion of EFSA, and in section 3 of this report.

6. **Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing Mild Pepino Mosaic Virus isolate VC1**

Only the use in greenhouses may be authorised.

Member States shall pay particular attention to:

- the protection of operators and workers, taking into account that Mild Pepino Mosaic Virus isolate VC1 is to be considered, as any microorganism, a potential sensitizer;
- 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.
Conditions of use shall include risk mitigation measures, where appropriate.

7. **List of studies to be generated**

No further studies were identified which were at this stage considered necessary in relation to the approval of Mild Pepino Mosaic Virus isolate VC1 under the current approval conditions.

Some endpoints however may require the generation or submission of additional studies to be submitted to the Member States in order to ensure authorisations for use under certain conditions.

A complete list of studies to be generated, still ongoing or available but not peer reviewed can be found in the relevant part of the EFSA Conclusion (page 12).

8. **Information on studies with claimed data protection**

For information of any interested parties, the rapporteur Member State will keep available a document which gives information about the studies for which the sole data submitter has claimed data protection and which during the evaluation process were considered as essential with a view to approval under Regulation (EC) No 1107/2009. This information is only given to facilitate the operation of the provisions of Article 62 of Regulation (EC) No 1107/2009 in the Member States. It is based on the best information available but it does not prejudice any rights or obligations of Member States or operators with regard to its uses in the implementation of the provisions of Article 62 of Regulation (EC) No 1107/2009 and neither does it commit the Commission.

9. **Updating of this review report**

The information in this report may require to be updated from time to time in order to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 13, 21, 38, 44, 56 of Regulation (EC) No 1107/2009. Any such adaptation will be finalised in the Standing Committee on Plants, Animals, Food and Feed, in connection with any amendment of the approval conditions for Mild Pepino Mosaic Virus isolate VC1.
## APPENDIX I

### Main identity

**MILD PEPINO MOSAIC VIRUS ISOLATE VC1**

<table>
<thead>
<tr>
<th>Name of the organism</th>
<th><em>Pepino mosaic virus</em></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Taxonomy</strong></td>
<td>potex viruses</td>
</tr>
<tr>
<td>Species, subspecies, strain:</td>
<td>Genus: <em>Potexvirus</em>&lt;br&gt;Family: <em>Alphaflexiviridae</em>&lt;br&gt;Order: <em>Tymovirales</em></td>
</tr>
<tr>
<td><strong>Identification</strong></td>
<td>ELISA&lt;br&gt;qRT-PCR&lt;br&gt;bioassay (infectivity on tomato)</td>
</tr>
<tr>
<td><strong>Culture collection</strong></td>
<td>German Collection of Micro-organisms and Cell Cultures (DSMZ)&lt;br&gt;Reference no. DSM 26973.</td>
</tr>
<tr>
<td>Minimum and maximum concentration of the MPCA used for manufacturing of the formulated product (cfu; g/kg):</td>
<td>10-50 mg/L&lt;br&gt;1.5x10^{11} to 7.5x10^{11} virus particles/mL</td>
</tr>
<tr>
<td>Identity and content of relevant impurities, additives, contaminating organisms in the technical grade of MPCA:</td>
<td>Nicotine &lt; 0.1mg/L</td>
</tr>
<tr>
<td>Is the MCPA genetically modified; if so provide type of modification:</td>
<td>no</td>
</tr>
</tbody>
</table>
## APPENDIX II

List of uses supported by available data

### MILD PEPINO MOSAIC VIRUS ISOLATE VC1

<table>
<thead>
<tr>
<th>Use No.</th>
<th>Member state(s)</th>
<th>Crop and/or situation</th>
<th>Pests or Group of pests controlled</th>
<th>Method/Kind</th>
<th>Application</th>
<th>Max. number (min. interval between applications)</th>
<th>Application rate</th>
<th>PHI (days)</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>All</td>
<td>Solanum lycopersicum (tomato)</td>
<td>Pepino mosaic virus</td>
<td>Downward Spraying (12-15 bar)</td>
<td>Young tomato plants (BBCH 13-51, 10-30 cm high) Jan-Dec</td>
<td>a) 1 per crop cycle b)* 8 per 12 months (8 crop cycles per year)</td>
<td>a) 70 L product / ha per appl. b) 560 L product / ha per season</td>
<td>-</td>
<td>e.g. g safener/synergist per ha</td>
</tr>
</tbody>
</table>

V10 is applied in combination with 800 grams of carborundum per 100 litres of spray liquid.
<table>
<thead>
<tr>
<th>Use-No.</th>
<th>Member state(s)</th>
<th>Crop and/or situation (crop destination / purpose of crop)</th>
<th>Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)</th>
<th>Application</th>
<th>Application rate</th>
<th>PHI (days)</th>
<th>Remarks:</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>All</td>
<td><em>Solanum lycopersicum</em> (tomato)</td>
<td><em>Pepino mosaic virus</em></td>
<td>G</td>
<td>Rubbing individual plants</td>
<td>a) 1 per crop cycle</td>
<td>a) 0.8 L product / ha per appl.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>a) 0.02 g a.s./ha per application</td>
<td>0.02 g a.s.2/ha per crop cycle</td>
<td>b) 6.4 L product / ha per 12 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.02 g a.s.1/ha per application</td>
<td>0.16 g a.s.2/ha per season</td>
<td>8 L/ha per appl.</td>
</tr>
</tbody>
</table>

*The product is applied once per tomato plant. The product can be applied at tomato plant propagation or after transplant to tomato production greenhouses, as long as the application takes place before BBCH 51. Plant propagation companies can have up to 8 productions per 12 months. Tomato producing companies have 1-3 crops per year.*
Remarks columns:
1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions