Final Review report for the active substance *Pepino mosaic virus strain CH2 isolate 1906*

Finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 29 May 2015 in view of the approval of *Pepino mosaic* virus strain CH2 isolate 1906 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 *Pepino mosaic* virus strain CH2 isolate 1906, 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 30 July 2012 an application from De Ceuster NV, hereafter referred to as the applicant, for the approval of the active substance *Pepino mosaic* virus strain CH2 isolate 1906 for use in plant protection products. The authorities of Belgium indicated to the Commission on 10 January 2013 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 *Pepino mosaic* virus strain CH2 isolate 1906 was distributed to the Member States, the European Food Safety Authority (EFSA) and the Commission.

Thereupon, Belgium 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.

Belgium submitted that draft assessment report to the Commission and EFSA on 8 January 2014.

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1. Does not necessarily represent the views of the Commission.
On 27 January 2014, 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 and that there was no need to conduct an expert consultation.

According to the provisions of Article 12(2) of the Regulation, EFSA sent to the Commission its conclusion on the risk assessment [Conclusion on the peer review of the pesticide risk assessment of the active substance *Pepino mosaic* virus strain CH2 isolate 1906 (approved: 18 December 2014)]\(^3\).

This conclusion refers to background document A (draft assessment report including its final addendum) 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 *Pepino mosaic* virus strain CH2 isolate 1906. The Commission referred the draft review report to the applicant for commenting and to the Standing Committee on Plants, Animals, Food and Feed for examination on 20 March 2015. The draft review report was finalised in the meeting of the Standing Committee on 29 May 2015.

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) 2015/1176\(^4\) concerning the approval of *Pepino mosaic* virus strain CH2 isolate 1906 as active substance under Regulation (EC) No 1107/2009, and to assist the Member States in decisions on individual plant protection products containing *Pepino mosaic* virus strain CH2 isolate 1906 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 II, 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

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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.

3. **Overall conclusion in the context of Regulation (EC) No 1107/2009**

The overall conclusion from the evaluation is that it may be expected that plant protection products containing *Pepino mosaic* virus strain CH2 isolate 1906 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 *Pepino mosaic* virus strain CH2 isolate 1906 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 summary of representative uses evaluated (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.

The following reference values have been finalised as part of this evaluation:

- Considering all the available information, EFSA did not find it necessary to derive toxicological reference values for *Pepino mosaic* virus strain CH2 isolate 1906.

With particular regard to residues, as this virus is not pathogenic to humans, and will not produce any toxin, it can be concluded that the consumer risk assessment is not needed. A quantitative risk assessment is not necessary.

For the same reasons, no exposure estimates for operators, workers and bystanders are needed. However, Member States shall pay particular attention to the protection of operators and workers, taking into account that all microorganisms should be regarded as potential sensitizers.

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.
The criteria as listed in point 5 of Annex II (low-risk active substances) as regards the classification of an active substance in accordance with Regulation (EC) No 1272/2008 do not apply to *Pepino mosaic* virus strain CH2 isolate 1906 as microorganisms in general are not covered by this Regulation.

With regard to the other criteria the following can be stated:

- 'Persistence' and 'Bioaccumulation' are not appropriate terms to be used for microorganisms. They are in general naturally occurring and multiplying and therefore we do not expect an important risk.

- *Pepino mosaic* virus strain CH2 isolate 1906 does not fulfil the interim criteria to be considered as an endocrine disruptor. *Pepino mosaic* virus strain CH2 isolate 1906 is not classified (microorganisms in general are not covered by Regulation (EC) No 1272/2008) and no toxic effects to endocrine organs have been observed as a result of the use of plant protection products containing *Pepino mosaic* virus strain CH2 isolate 1906.

- No neurotoxic or immunotoxic effects have been observed as a result of the use of plant protection products containing *Pepino mosaic* virus strain CH2 isolate 1906.

Therefore, *Pepino mosaic* virus strain CH2 isolate 1906 can 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 *Pepino mosaic* virus strain CH2 isolate 1906 is given in Appendix I.

*Pepino mosaic* virus isolate CH2 isolate 1906 is deposited in GenBank, under accession number JN835466 and it is a wild-type mild strain isolated from a commercial crop of tomatoes in Belgium.

The active substance used for manufacturing of the formulated product shall have a minimum concentration of $5 \times 10^5$ viral genome copies/µL.

It has been established that for the active substance notified by the applicant none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern. However, 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.
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 Pepino mosaic virus strain CH2 isolate 1906.**

Only the use in greenhouses may be authorised.

On the basis of the representative uses evaluated (as listed in Appendix II), the following issue has been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:

Member States shall pay particular attention to:
- the protection of operators and workers, taking into account that *Pepino mosaic* virus strain CH2 isolate 1906 is to be considered, as any microorganisms, 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 on the basis of the EFSA Conclusions.

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 11).

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 *Pepino mosaic* virus strain CH2 isolate 1906.
APPENDIX I

Main identity

**PEPINO MOSAIC VIRUS STRAIN CH2 ISOLATE 1906**

<table>
<thead>
<tr>
<th>Name of the organism:</th>
<th><em>Pepino mosaic</em> virus strain CH2 isolate 1906</th>
</tr>
</thead>
<tbody>
<tr>
<td>Taxonomy:</td>
<td>Family: Alphaflexiviridae</td>
</tr>
<tr>
<td></td>
<td>Genus: potexvirus</td>
</tr>
<tr>
<td>Species, subspecies, strain:</td>
<td><em>Pepino mosaic</em> virus strain CH2 isolate 1906</td>
</tr>
<tr>
<td>Identification / detection:</td>
<td>Sequencing of complete genome: genome composed of a 6410 nucleotide long, single stranded RNA with 5 Open Reading Frames (ORF): ORF1 encodes a 164-k Da RNA dependent polymerase ORF2-4 form the PepMV triple (gene block TGB) ORF5 codes for a 25-k Da coat protein (CP) Best method for detection, identification and differentiation of genotypes is TaqMan real-time quantitative reverse transcription PCR (RT-qPCR). To unambiguously identify the mild CH2 isolate 1906, the sequence of part of TGB and CP regions has to be determined.</td>
</tr>
<tr>
<td>Culture collection:</td>
<td>The strain is deposited in GenBank, under accession number JN835466</td>
</tr>
<tr>
<td>Minimum and maximum concentration of the MPCA used for manufacturing of the formulated product (viable granules; g/kg):</td>
<td>PMV-01 formulation contains: &gt;5×10⁵ genome copies /µL product</td>
</tr>
<tr>
<td>Is the MPCA genetically modified; if so provide type of modification</td>
<td><em>Pepino mosaic</em> virus strain CH2 isolate 1906 is a natural wild-type.</td>
</tr>
</tbody>
</table>
## APPENDIX II

### Summary of representative uses evaluated

**PEPINO MOSAIC VIRUS STRAIN CH2 ISOLATE 1906**

<table>
<thead>
<tr>
<th>Crop and/or situation (a)</th>
<th>Zone</th>
<th>Product code or name</th>
<th>F G or I (b)</th>
<th>Pests or Group of pests controlled (c)</th>
<th>Formulation</th>
<th>Application</th>
<th>Application rate per treatment</th>
<th>PHI (days) (l)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tomatoes</td>
<td></td>
<td>PMV-01</td>
<td>G</td>
<td><em>Pepino mosaic virus CH2 strain</em></td>
<td>SC</td>
<td>Low volume Spraying</td>
<td>Seedlings, as soon as possible after planting, at the latest before the first tomato cluster flourishes from</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Northerm Central Southern</td>
<td></td>
<td></td>
<td></td>
<td>&gt;5x10^5 viral genome copies per µL</td>
<td></td>
<td>6.7x10^11 viral genome copies/hL in case of 4L product and 300L/ha to 25x10^11 viral genome copies/hL in case of 8L product and 160L water/ha</td>
<td>NA</td>
</tr>
</tbody>
</table>

(a) For crops, the EU and codex classifications (both) should be used; where relevant, the situation should be described (e.g. fumigation of a structure)

(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)

(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds

(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(e) GCPF codes - Crop Life Technical Monograph No 2, 1989

(f) All abbreviations used must be explained

(g) Method, e.g. high volume spraying, spreading, dusting, drench

(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used must be indicated

(i) Viable granules = colony forming units and g/kg or g/L

(j) Growth stage at 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

(k) Indicate the minimum and maximum number of application possible under practical conditions of use

(l) PHI - minimum pre-harvest interval

(m) Remarks may include: Extent of use/economic importance/restrictions