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Registration Decision

RD2018-19

Pepino mosaic virus, strain CH2, isolate 1906 and PMV-01

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Registration Decision Statement¹ for *Pepino Mosaic Virus*, strain CH2, isolate 1906 and PMV-01

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting registration for the sale and use of *Pepino mosaic virus*, strain CH2, isolate 1906 and PMV-01, containing the technical grade active ingredient *Pepino mosaic virus*, strain CH2, isolate 1906, to protect greenhouse tomatoes against *Pepino mosaic virus* (PepMV).

This decision is consistent with the Proposed Registration Decision PRD2018-12, *Pepino mosaic virus*, strain CH2, isolate 1906 and PMV-01, which contains a detailed evaluation of the information submitted in support of this registration. The evaluation found that, under the approved conditions of use, the health and environmental risks and the value of the pest control product(s) are acceptable. See Appendix I for a summary of comments received during the consultation process as well as Health Canada's response to these comments.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2018-12, *Pepino mosaic virus*, strain CH2, isolate 1906 and PMV-01) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (hc.pmra.info-arla.sc@canada.ca).

Any person may file a notice of objection² regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides section of the Canada.ca website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

¹ "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

² As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Comments and Responses

1. Comments on

Verification of the identity of *Pepino mosaic virus*, strain CH2, isolate 1906 vs other strains of *Pepino mosaic virus* during manufacturing.

Response

Acceptable methodologies for detection of the active ingredient, *Pepino mosaic virus*, strain CH2, isolate 1906, were submitted by the applicant. *Pepino mosaic virus*, strain CH2, isolate 1906 can be identified to the isolate level by nucleotide sequence determination.

2. Comments on

Product purity and potential microbial contamination. A published peer review of the European Food Safety Authority pesticide risk assessment of *Pepino mosaic virus*, strain CH2, isolate 1906 was provided (EFSA, 2015) that indicated that microbial contamination was found in the batch analysis provided for the EU evaluation.

Response

The quality assurance procedures used to limit contaminating microorganisms during the manufacture of *Pepino mosaic virus*, strain CH2, isolate 1906 (technical grade active ingredient) and PMV-01 are acceptable. These procedures include good hygienic practices for the maintenance, sanitation and cleaning of all laboratories and sterilization of all equipment used in the manufacturing process.

The absence of human pathogens and below-threshold levels of contaminating microorganisms were shown in the microbial screening of batches of *Pepino mosaic virus*, strain CH2, isolate 1906 (technical grade active ingredient) by using standard methods for detecting and enumerating microbial contaminants of concern. In addition, all batches of *Pepino mosaic virus*, strain CH2, isolate 1906 (technical grade active ingredient) must conform to the limits set out in the Organisation for Economic Co-operation and Development (OECD) issue paper on microbial contaminants for microbial pest control products [ENV/JM/MONO(2011)43].”

3. Comments on

The evidence that the product protects against other aggressive strains of PepMV and the statistical significance.

Response

The applicant provided four efficacy studies performed against other aggressive strains, two on the EU strain, one on the US1 strain and one on mixed infections. The standard error of the mean was used to determine differences between treatments.

This information, along with scientific rationales, indicate that PMV-01 is effective against aggressive strains in addition to the CH2 strain.

4. Comments on

Paragraph '1.4 Mode of Action' of PRD2018-12, *Pepino mosaic virus*, strain CH2, isolate 1906 and PMV-01 states: "Cross-protection is considered effective when similarities in nucleotide sequence between PepMV strains is 90% or more". It is known that EU and US1 strains share only 80-85% similarity with the CH2 strain. This includes CH2 isolate 1906 of PMV-01.

Response

While similarity of nucleotide sequences between mild and aggressive virus strains is the principal determinant of the effectivity of cross protection by a mild virus strain-based disease management tool, similarity in coat proteins also plays a role. Although RNA similarity between the EU and CH2 strains is 80-85%, the applicant also provided evidence that the amino acid sequences in coat proteins between these two strains were highly similar. This information, considered in combination with the results of efficacy studies, collectively indicates that PMV-01 would be expected to provide an adequate level of protection to plants infected with the EU strain.

5. Comments on

Published evidence (Vermunt and Kaarsemaker, 2017) indicating that attenuated CH2 alone is not effective against other aggressive strains.

Response

The applicant submitted information consisting of trial results and scientific rationales, which demonstrated that PMV-01 provides an adequate level of protection against aggressive strains other than CH2 as well as a mixed infection of two aggressive strains.

References provided by commenter:**PMRA****Document****Number****Reference**

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| 2937910 | EFSA (European Food Safety Authority), 2015. Conclusion on the peer review of the pesticide risk assessment of the active substance <i>Pepino mosaic virus</i> strain CH2 isolate 1906. EFSA Journal 2015;13(1):3977, 25 pp. doi:10.2903/j.efsa.2015.3977 |
| 2937915 | Adrianus M.W. Vermunt and Rudolfus C. Kaarsemaker, 2017. Multi-genotype cross-protection against <i>Pepino mosaic virus</i> in tomato. Crop Protection 96:116-122. |