



Special Review Decision

SRD2020-02

# Special Review Decision: Dichlorvos

*Final Decision Document*

*(publié aussi en français)*

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## Special review decision

Pursuant to subsection 17(2) of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) initiated a special review of all registered pest control products containing dichlorvos, based on the European Union regulatory decisions (2007, 2012) to prohibit all uses of dichlorvos in European Union member countries due to human health and environmental concerns (Canada, 2013).

The aspects of concern identified for the special review are potential carcinogenicity of dichlorvos, potential occupational and residential risks, and potential risk to non-target organisms.

Health Canada evaluated the aspects of concern that prompted the special review in accordance with subsection 18(4) of the *Pest Control Products Act*. The proposed special review decision was published for consultation in the Re-evaluation Note REV2018-01, *Special Review of Dichlorvos and Its Associated End-use Products: Proposed Decision for Consultation* (Canada, 2018). Comments and additional information were received during the consultation period. Respondents are listed in Appendix I.

In addition to the consultation on REV2018-01, Health Canada consulted on a proposed re-evaluation decision of dichlorvos in 2017 (PRVD2017-16; Proposed Re-evaluation Decision for Dichlorvos and Its Associated End-use Products; Canada, 2017). Comments and information were received during the consultation of PRVD2017-16.

All comments and information except the comments related to cumulative risk assessment (CRA) received for the proposed special review decision (REV2018-01) are the same as those received for the consultation of the proposed re-evaluation decision (PRVD2017-16).

The final special review decision considered the comments and information received as part of the proposed special review decision. The outcome of the assessment of the aspects of concern, based on the additional information received during the consultation of the REV2018-01 is outlined below:

- **Aspects of concern related to human health:** Health Canada established a new dermal reference value based on a new study. Human health risk assessment was revised using the new dermal reference value, and the comments received during consultation. Revised risk reduction measures are required.
- **Aspects of concern related to the environment:** No comments related to the environmental aspects of concern were received. No changes required to the environmental assessment included in the proposed special review decision.

As the same information (except related to CRA) was received during consultation of the PRVD2017-16 and REV2018-01, details on the updated human health assessment (revised toxicology, occupational and residential risk assessments) and responses to comments (except the response related to CRA) are in RVD2020-08.

Response to comments related to CRA is in Appendix II. In addition, as the label amendments related to the aspects of concern are included in RVD2020-08 (Canada, 2020), they are not listed in detail in this decision document. However, a summary of the required label amendments for the special review is included in Appendix III.

Following an evaluation of the aspects of concern, Health Canada has determined that continued registration of some products containing dichlorvos is considered to be acceptable with the revised label directions.

All pest control products containing dichlorvos that are registered in Canada are subject to this special review decision. Currently registered products containing dichlorvos are listed in Appendix IV.

This document presents the final regulatory decision for the special review of dichlorvos. To comply with this decision, the required amendments (mitigation measures and label updates) must be implemented on all product labels no later than 24 months after the publication date of this decision document. Accordingly, both registrants and retailers will have up to 24 months from the date of this decision document to transition to selling the product with the newly amended labels. Similarly, users will also have the same 24-month period from the date of this decision document to transition to using the newly amended labels, which will be available on the Public Registry. Registrants of the products containing dichlorvos will be informed of the specific requirements affecting their product registration(s) and of the regulatory options available to them.

Products that are cancelled will be phased out following the implementation timeline outlined below.

- One (1) year of sale by registrant from the publication date of this decision document, followed by;
- One (1) year of sale by retailer from the last date of sale by registrant, followed by;
- One (1) year of permitted use from the last date of sale by retailer.

## **Other information**

Any person may file a notice of objection<sup>1</sup> regarding this decision on dichlorvos within 60 days from the date of publication of this Special Review Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides section of Canada.ca (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

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<sup>1</sup> As per subsection 35(1) of the *Pest Control Products Act*.

## Appendix I List of respondents to REV2018-01

List of respondents' affiliations in terms of comments submitted in response to REV2018-01

<b>Category</b>	<b>Respondent</b>	<b>Comments</b>
Non-Governmental Organisation	Ecojustice on behalf of the Canadian Association of Physicians for the Environment, the David Suzuki Foundation, Environmental Defence and Équiterre	Refer Appendix II of this document. Response to comments related to CRA.
Registrant	AMVAC Chemical Corporation	Refer RVD2020-08, Appendix III for the response to other comments related to human health.
Grower group	Canadian Horticulture Council (CHC) on behalf of Canada's greenhouse vegetable growers	

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## Appendix II Comments and responses

The PMRA received comments from stakeholders in response to Re-evaluation Note REV2018-01, *Special Review of Dichlorvos and Its Associated End-use Products: Proposed Decision for Consultation* (Canada, 2018). Comments (related to human health aspects of concern) received as part of the proposed special review decision were the same as those received during the consultation of the proposed re-evaluation decision (PRVD2017-16), except the comments related to organophosphates (OP) cumulative risk assessment (CRA). Response to the comment on CRA is included below. As other comments received as part of the REV2018-01 are the same as the PRVD2017-16, the responses are included in the RVD2020-08 (refer RVD2020-08, Appendix III for the PMRA's responses).

### 1. Comments related to cumulative risk assessment

The commenter indicated the need for conducting a cumulative assessment as part of the REV2018-01, to comply with subsection 19(2)b(i) of the *Pest Control Product's Act*. The comment also specified that the United States Environmental Protection Agency (USEPA) completed a preliminary cumulative effects analysis for organophosphates including dichlorvos in 2002, with an update in 2006. In addition, the commenter expressed the desire to know when the PMRA intends to complete the organophosphate re-evaluations and special reviews, the status of the PMRA's cumulative effects methodology for organophosphates (whether it is completed and will it be consulted with the public), and the timeline for the cumulative assessment of health risks of organophosphates.

#### PMRA response

Health Canada's PMRA agrees that the cumulative assessment of pesticides is an important step in evaluating health risks. The PMRA continues to engage with the international science community, including other Health Canada programs, as well as international regulatory partners such as the EPA, and the European Food Safety Authority, on how to best assess cumulative effects of pesticides.

Following consultation on the proposed cumulative assessment approach (PRO2017-01), the PMRA published its framework for cumulative assessments in the Science Policy Note SPN2018-02 *Cumulative Health Risk Assessment Framework* (April 2018). This document describes the framework and methodology that the PMRA will use for assessing the cumulative health effects of pesticides that have a common mechanism of toxicity, which will also apply to the cumulative risk assessment (CRA) for organophosphate (OP) pesticides.

The PMRA acknowledges that the cumulative assessment for OP pesticides has been completed by the USEPA, as have their re-evaluations of the individual pesticides in the OP group. The USEPA used the Relative Potency Factor method to assess the cumulative risk of OP pesticides, which is described in SPN2018-02. This method is heavily reliant on the quality and availability of appropriate toxicology and exposure data and requires the calculation of a relative potency factor for each individual chemical. This further highlights the importance that the assessment of all of the OP pesticides currently under re-evaluation be complete before initiating the CRA.

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It should be noted that the USEPA indicated no further mitigation was required from cumulative exposure to OPs, as the mitigation put in place for each individual OP pesticide, based on the individual re-evaluations, was sufficient.

In Canada, of the 27 OP pesticides that were originally registered at the time of re-evaluation initiation by the PMRA, more than half are no longer registered. Significant mitigation measures were required for the OPs that were granted continued registration following re-evaluation. Furthermore, extensive mitigation measures are proposed for the remaining OPs for which re-evaluations are to be completed.

Once the final decisions for the remaining individual OPs have been published, the CRA for the OP cluster will be initiated, and will include all of the re-evaluated OP pesticides, OP active ingredients on imported commodities, and any new OP pesticides and uses not captured in the re-evaluations. As indicated above, it is essential that the toxicology and exposure assessments of the individual pesticides be up-to-date prior to undertaking the CRA. This ensures that current information is taken into account in the assessment. In addition, it is important to complete the risk assessments for each of these pesticides in order to mitigate individual chemical risks prior to undertaking a CRA. Failing to mitigate individual chemical risks prior to performing a CRA would unnecessarily complicate a CRA, as well as potentially obscure any drivers of cumulative risk.

Once the initiation of the cumulative assessment for the OPs has been announced, and any requested data has been received, the PMRA will establish a targeted timeline for the consultation on the proposed cumulative assessment and this information will be included in the PMRA's published re-evaluation and special review workplan. In the meantime, the PMRA will continue to monitor the progress and results of other cumulative risk assessments for OP pesticides from other international regulators and will take appropriate action, if needed.

## **2. Other comments related to the health risk assessments**

### **PMRA response**

Please see RVD2020-08, Appendix III for the PMRA's response.



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## Appendix III Summary of the required label amendments (risk reduction measures) related to the aspects of concern

### Human health

To protect human health, the following risk-reduction measures are required for continued registration of dichlorvos in Canada.

#### Cancellation of use:

- Spray application to greenhouse crops (cucumbers, tomatoes and ornamentals), sheds, stables, barns, loafing sheds, pigpens, poultry houses, outdoor areas, and outdoor residential living areas
- Fogging application to dairies, piggeries and barns
- Fogging application for outdoor mosquito control
- Domestic class pest strip use in homes (including garages, attics, crawl spaces), animal and farm buildings, milk rooms, motels, restaurants, food processing plants, industrial and commercial locations, kennels, garbage storage areas and containers, and similar enclosed spaces, or any space that is occupied within four months of application

#### Label amendments:

- For fogging application of the following indoor structures: tobacco storage, poultry houses, food processing plants, industrial plants, warehouses, theatres:
  - Change of classification from Commercial class to RESTRICTED class. The nature of the restriction is for sale to and use by certified applicators only.
  - For use with automated application equipment only.
  - Additional personal protective equipment (PPE) and full ventilation requirement.
  - A restricted-entry interval of 4 days.
- For the current domestic class pest strip product:
  - Change of classification from Domestic class to COMMERCIAL class.
  - For use only in cottages, cabins and trailers, unoccupied for at least four months following application. Not for use in occupied homes.
- For all indoor uses – Applicators are required to post and provide an information sheet to occupants of treated areas (to inform them of the product that was applied, the restricted-entry interval, symptoms of over-exposure, and what to do if they experience these effects).
- For outdoor pest strip (in insect pheromone traps) – additional PPE and use limitations.
- Updated label statements are required to meet current label standards and to clarify use directions and mitigation measures.

## **Environment**

The following precautionary label statement is required:

- A statement to inform the user that dichlorvos is toxic to aquatic organisms.

Uses not supported by manufacturers for re-evaluation and will be removed from all product labels:

- Mushroom houses

## Appendix IV Registered pest control products containing dichlorvos as of 5 march 2020

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
19723	Technical	Amvac Chemical Corporation	Dichlorvos (DDVP) Technique	Liquid	97.7%
11819	Commercial	Gardex Chemicals Ltd.	Gardex Vapona Insecticide Industrial Fogging Solution	Emulsifiable Concentrate	4.65%
16476	Commercial	Gardex Chemicals Ltd.	Gardex Vapona-20 ULV Concentrate	Emulsifiable Concentrate	20%
19680	Commercial	Premier Tech Brighton Ltd.	Pro Professional DDVP-20 Ultra-Low Volume Insecticide	Solution	20%
21222	Commercial	Aberdeen Road Company d/b/a HERCON ENVIRONMENTAL	Vaportape II Insecticidal Strips	Slow-Release Generator	10%
21824	Commercial	Plus (9021-7993 Quebec Inc.)	DICHLORVOS PLUS #1 READY TO USE INSECTICID	Solution	1.8%
23915	Commercial	LOVELAND PRODUCTS CANADA INC.	DDVP 20% Insecticide	Emulsifiable Concentrate	20%
22027	Domestic	Scotts Canada Ltd.	Ortho® Home Defense Max No-Pest Insecticide Strip	Slow-Release Generator	19.2%

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## References

### Published information

<b>PMRA#</b>	<b>Reference</b>
2405939	Canada, 2013. Re-evaluation Note: Special Review Initiation of 23 Active Ingredients. REV2013-06.
2767433	Canada, 2017. Proposed Re-evaluation Decision PRVD2017-16, Dichlorvos and Its Associated End-use Products
2906053	Canada, 2018. Re-evaluation Note REV2018-01, Special Review of Dichlorvos and Its Associated End-use Products: Proposed Decision for Consultation
3090961	Canada, 2020. Re-evaluation Decision: Dichlorvos. RVD2020-08.