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Re-evaluation Note

REV2017-28

Special Review Decision: Carbaryl

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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 carbaryl, based on the 2007 European Commission regulatory decision to prohibit all uses of carbaryl in European Union member countries due to human health and environmental concerns. The PMRA evaluated the aspects of concern that prompted the special review in accordance with the subsection 18(4) of the *Pest Control Products Act*. The proposed special review decision was published for consultation in the Re-evaluation Note REV2016-13, *Special Review of Carbaryl: Proposed Decision for Consultation*. Appendix I summarizes the comments received during the consultation period and provides the PMRA's response to these comments.

Comments received during the consultation process were taken into consideration in making this special review decision, and they did not result in changes to the proposed regulatory decision as described in REV2016-13. Therefore, the PMRA, under the authority of the *Pest Control Products Act*, is confirming the current registration of pest control products containing carbaryl in Canada.

Please refer to the Regulatory Directive DIR2014-01, *Approach to Special Reviews*, for details of the PMRA's special review approach.

Other Information

Any person may file a notice of objection¹ regarding this decision on carbaryl within 45 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 and Pest Management portion of the Canada.ca website, Request a Reconsideration of Decision, or contact the PMRA's Pest Management Information Service.

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

Appendix I Comments and Responses

The PMRA received comments from stakeholders in response to Re-evaluation Note REV2016-13, *Special Review of Carbaryl: Proposed Decision for Consultation*. The PMRA consolidated and summarized the comments related to the aspects of concern of this special review and provides responses below.

1.0 Scope of the Special Review of Carbaryl

1.1 Comment on the information considered by the PMRA for the special review

There is a lack of rigour and limited scope in this special review, many important environmental and human health issues have not been addressed and the PMRA did not assess human health risks as required under the *Pest Control Products Act* such as the use of science-based approach, and, aggregate and cumulative exposure assessments.

PMRA Response

When a special review is initiated under subsection 17(2) (based on the prohibition of all uses of an active ingredient for health or environmental reasons in an Organisation for Economic Co-operation and Development (OECD) member country), the PMRA carries out an analysis of the OECD decision to identify the aspect(s) of concern related to the pest control products (the concern(s) that resulted in the prohibition of the active ingredient in the OECD country). For carbaryl, the aspects of concern that prompted the special review were identified in REV2016-13, and the approach for undertaking the review is described in Regulatory Directive DIR2014-01, *Approach to Special Reviews*. As per DIR2014-01, the PMRA special review evaluation is targeted to address only the aspects of concern that prompted the special review.

The PMRA considered a science based approach in assessing the aspects of concern, and the assessment considered both toxicity and exposure to carbaryl. The aspects of concern related to human health are toxicity of metabolites and potential carcinogenicity of carbaryl. As noted in the REV2016-13, carbaryl metabolism studies indicated that metabolites 4-hydroxycarbaryl and 5-hydroxycarbaryl are minor residues and they are less toxic than carbaryl. Therefore, they are not included as residues of concern in plants.

For assessing risks from potential residues in food or from products used in or around homes and/or schools, the *Pest Control Products Act* requires the application of an additional 10-fold factor to take into account the completeness of the data with respect to the exposure of and toxicity to infants and children, and potential prenatal and postnatal toxicity. A different factor may be determined to be appropriate on the basis of reliable scientific data. For carbaryl the toxicity data were considered complete and the overall level of concern is low. This conclusion is based on the nature and level of concern for the endpoint and the fact that, for certain risk assessments, the endpoint was established from data on the most sensitive subpopulation (post-natal day (PND) 11 pups). Where the endpoint from the most sensitive subpopulation was not used in the risk assessment, the application of other uncertainty factors serves to address residual concerns as noted above. Accordingly, the *Pest Control Products Act* factor is reduced from 10-fold to 1-fold on the basis of these considerations.

The dietary assessments are age specific and incorporate the different eating habits of the population at various stages of life. For example, the assessments take into account differences in children's eating patterns, such as food preferences and the greater consumption of food relative to their body weight when compared to adults. Dietary risk is then determined by combining the exposure and toxicity assessments. For carbaryl, the PMRA conducted acute and chronic dietary exposure assessments considering all registered and imported commodities. Acute aggregate dietary exposure for carbaryl (that is from food and drinking water), represented 41% of the acute reference dose for the general population. While infants were determined to have the highest exposure (107%), the Agency's assessment did not consider this to be of concern due to conservative (high-end) assumptions in the exposure assessment. The aggregate chronic dietary exposure to carbaryl (food and drinking water) represented 2% of the chronic reference dose; the lifetime cancer risk was 7×10^{-8} for the general population. Therefore, the potential risk from aggregate exposure to carbaryl is not of concern.

The *Pest Control Products Act* requires that the PMRA consider the cumulative exposure to pesticides with a common mechanism of toxicity. Carbaryl belongs to the carbamate chemical family. Currently there are a number of carbamate pesticides registered in Canada, once all carbamate pesticides have been re-evaluated, a cumulative risk assessment will be conducted that will consider potential exposure to all chemicals causing toxicity in the same manner.

For assessing the aspects of concern related to the environment (potential risks to non-target terrestrial and aquatic organisms), the PMRA also considered a science-based approach. As outlined in REV2016-13, both toxicity of carbaryl to non-target organisms (beneficial arthropods, birds, mammals and aquatic organisms) and exposure of carbaryl to these organisms were considered in estimating potential risks.

1.2 Comment on pest control products under special review

The proposed special review decision of carbaryl does not examine individual end-use pest control products containing carbaryl as required by the Act.

PMRA Response

Under the *Pest Control Products Act*, a special review of all registered pest control products containing the active ingredient in question is required. Therefore, in this special review, the PMRA considered all registered pest control products (technical, manufacturing concentrate and end-use products) containing carbaryl, and the special review decision is applicable to all registered products. Appendix I of REV2016-13 included the list of registered products containing carbaryl as of 13 July 2016.

2.0 Other Comments

2.1 Comment on the number of incident reports

A comment noted that only six incident reports were received in nine years and questioned the accuracy of the number.

PMRA Response

Since 26 April 2007, registrants have been required by law to report incidents, including adverse effects to human health and the environment, to the PMRA within a set time frame. As described in Regulatory Directive DIR2014-01, *Approach to Special Reviews*, the PMRA special review evaluation of carbaryl focussed on the aspects of concern that prompted the special review.

As noted in the REV2016-13, there were only six incident reports received that were related to the aspects of concern of the special review and the number remains the same as of 13 June 2017.

References

Published Information

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2405939	Canada 2013, Re-evaluation Note REV2013-06, Special Review Initiation of 23 Active Ingredients
2629416	Canada 2016, Re-evaluation Decision RVD2016-02, Carbaryl
2304809	Request for Scientific Assessment of Carbaryl, e-mail from T. MacQuarrie to Fida'a Ali Rawabbeh, Ministry of Agriculture, Jordan, May 6, 2013.
2304815	Request for Scientific Assessment of Carbaryl, e-mail from T. MacQuarrie to S. Nahawi, Ministry of State for Environment Affairs, Syrian Arab Republic, May 6, 2013.
2393042	Section 18(2) Notice of Special Review initiation to FPT members, February 7, 2014.
2558436	European Commission 2006, Final Review report for the active substance carbaryl, September 29, 2006, DACO: 12.5
2558433	European Commission 2007, COMMISSION DECISION of 21 May 2007 concerning the non-inclusion of carbaryl in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance.
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1650855	EFSA 2006, EFSA Scientific Report (2006) 80, Conclusion on the peer review of carbaryl. 12 May 2006
2644467	Joint Meeting on Pesticide Residues in Food, 1970, 1969 Evaluations of Some Pesticide Residues in Food - Carbaryl, DACO: 12.5
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2652830	United States Environmental Protection Agency (USEPA), 2011, Carbaryl Final Work Plan Registration Review, February, 2011

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PMRA Number	Reference
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