Consumer Product Safety

Consultation Document on Carbaryl, Proposed Re-evaluation Decision PRVD2009-14

Notice to the reader: The online consultation is now closed. Comments and suggestions received during the public consultation period are being considered in the finalization of this document. The final report will be made available as soon as possible.

10 August 2009
HC Pub: 8356
ISBN: 978-1-100-13313-3 (print version)
ISBN: 978-1-100-13314-0 (PDF version)
Catalogue number: H113-27/2009-14E (print version)
Catalogue number: H113-27/2009-14E-PDF (PDF version)

To obtain an electronic copy of the document, Consultation Document on Carbaryl, Proposed Re-evaluation Decision, please contact our publications office.

Should you require further information please contact the Pest Management Information Service.

Summary

Table of Contents

Proposed Re-evaluation Decision for Carbaryl

After a re-evaluation of the insecticide carbaryl, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, is proposing the continued registration of carbaryl products for sale and use in Canada. An evaluation of available scientific information found that, under the proposed conditions of use:

- Certain uses of carbaryl products have value in the food and crop industry and do not pose risks of concern to human health or the environment, that is, commercial products applied in agricultural, non-crop and forestry settings, other than those noted below. As a condition of the continued registration of these uses, new risk-reduction measures are proposed for the labels of carbaryl products. In addition, registrants will be requested to submit information to help refine the current risk assessment.

- The PMRA is seeking additional information on the typical use pattern of carbaryl (for

example, typical rates, number of applications, survey information on critical worker activities, etc.) as well as feedback on the feasibility of proposed mitigation measures such as restricted entry intervals or buffer zones.

- Some uses of carbaryl are proposed for phase-out because they are not supported by the technical registrant. These uses were not included in the risk assessment:
    - indoor pest control uses including greenhouses, residences, food and feed handling establishments and barns and livestock production areas;
    - aerosol products;
    - agricultural dust uses;
    - bran bait application to residential gardens;
    - livestock for food;
    - livestock for non-food;
    - companion animals;
    - granular bait products for ornamental gardens; and
    - applications by hand, spoon and bellygrinder.

- Specific uses of carbaryl products do not meet the current standard for health protection and are proposed for phase-out. These uses are turf, golf courses and sod farms, residential ornamentals, fruit trees and vegetable gardens, tobacco and pick-your-own orchard operations.

The PMRA's pesticide re-evaluation program considers the potential risks as well as value of pesticide products to ensure that they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structures. The re-evaluation draws on data from registrants and other regulatory agencies, published scientific reports and any other relevant information.

This proposal affects all end-use products registered in Canada that contain carbaryl. Once the final re-evaluation decision is made, registrants will be instructed on how to address any new requirements.

This Proposed Re-evaluation Decision is a consultation document[1] that summarizes the science evaluation for carbaryl and presents the reasons for the proposed re-evaluation decision. It also proposes additional risk-reduction measures to further protect human health and the environment.

The information in the Portable Document Format (PDF) version of this document is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessment of carbaryl.

The PMRA will accept written comments on this proposal up to 60 days from the date of publication of this document. Please forward all comments to Publications.

Top of Page

What Does Health Canada Consider When Making a Re-evaluation Decision?

The key objective of the *Pest Control Products Act* is to prevent risks of concern to people and the

environment from the use of pest control products. Health or environmental risk is considered of no concern if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions or proposed conditions of registration[2]. The Act also requires that products have value[3] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies hazard and risk assessment methods as well as policies that are rigorous and modern. These methods consider the unique characteristics of sensitive subpopulations in both humans (for example, children) and organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, as well as on the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Before making a re-evaluation decision on carbaryl, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a Re-evaluation Decision[4] on carbaryl, which will include the decision, the reasons for it, a summary of comments received on the proposed registration decision and the PMRA's response to these comments.

For more details on the information presented in this overview, please refer to the Science Evaluation section of the PDF version of this consultation document.

Top of Page

What Is Carbaryl?

Carbaryl is a broad spectrum Resistance Management Group 1A (carbamate) insecticide that also controls a number of secondary pests. It is applied by both ground and aerial equipment.

Health Considerations

Can Approved Uses of Carbaryl Affect Human Health?

Carbaryl is unlikely to affect human health when used according to the revised label directions, which include additional risk-reduction measures.

Potential exposure to carbaryl may occur through the diet (food and water), by applying the product or by entering treated sites. When assessing health risks, two key factors are considered:

- the dose at which no health effects occur; and
- the levels to which people may be exposed.

The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). The uses considered for continued registration are only those uses for which exposure is well below levels that cause no effects in animal testing.

Toxicology studies on laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose at which no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when carbaryl products are used according to label directions.

The acute toxicity of carbaryl ranged from moderate to high via the oral route of exposure. It was of low acute toxicity via the dermal and inhalation routes of exposure. Carbaryl was mildly irritating

to eyes, but non-irritating to skin and not a skin sensitizer.

Acute over-exposure to carbaryl can inhibit cholinesterase, an enzyme necessary for the normal functioning of the nervous system. This can produce a variety of symptoms in animals and humans including tremors, salivation, and sluggishness. With carbaryl, cholinesterase inhibition can occur rather rapidly with exposure, but this effect has been shown to reverse within hours. No pronounced gender differences were noted in the database.

Based on the weight of evidence, carbaryl was not genotoxic, although carbaryl did cause cancer in mice and rats. However, in rats the tumors occurred at doses that caused severe systemic toxicity such that the cancer risk assessment was based only on the results in the mouse study.

Carbaryl did cause malformations in the fetus when given to pregnant mice, rabbits and dogs (not in rats), but only at high doses that were also toxic to the mother. An effect on offspring survival in the rat was also observed at the same dose that was toxic to the father but not the mother. This suggested sensitivity of the young, although there was no cholinesterase activity assessed. Brain cholinesterase was inhibited in rat fetuses at the same dose as their mothers in a developmental neurotoxicity study, suggesting that fetuses are susceptible to cholinesterase inhibition. However, the lack of detail precluded a definitive assessment of prenatal sensitivity to indirect exposures of carbaryl. In comparison, young rats were found to be more sensitive than adults to brain cholinesterase inhibition from a single direct oral exposure to carbaryl.

Published information suggests that carbaryl can cause other high-dose effects in animals such as immunotoxicity and toxicity to the male reproductive system, but results were considered inconclusive due to the limited nature of the studies. Cholinesterase inhibition occurred at lower doses than the above-noted effects and was considered the most sensitive indicator of toxicity. The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

In light of uncertainty with regards to whether the sensitivity of young animals to brain cholinesterase inhibition was evident upon dermal exposure, extra protective measures were included during the dermal risk assessment to further reduce the allowable level of human exposure to carbaryl.

Risks in Residential and Other Non-Occupational Environments

Residential risks from the use of carbaryl on turf and ornamentals are of concern.

Carbaryl is registered for use on turf, and on residential ornamental and vegetable gardens. Estimates of exposure using the PMRA default approach as well as carbaryl specific biomonitoring data do not achieve the target margin of exposure and/or aggregate risk index for adults and children for all postapplication exposure scenarios and some application scenarios, and are therefore of concern.

Cancer risks are not of concern.

Aggregate risk from exposure incurred by the public at "Pick-Your-Own" orchards is of concern.

"Pick-Your-Own" facilities are considered commercial farming operations that allow public access for harvesting in large-scale fields or orchards treated with commercially labelled carbaryl products. Estimates of exposure that aggregate the dermal exposure incurred during fruit-picking and the dietary exposure from consuming fresh fruit do not reach the target margin of exposure and/or aggregate risk index for orchard crops, and are therefore of concern.

Cancer risks are not of concern.

Occupational Risks from Handling Carbaryl

Most occupational risks are not of concern provided that the proposed protective measures are followed.

Most occupational risks are not of concern for agricultural scenarios provided that additional protective measures are followed. Based on the precautions and directions for use on current carbaryl labels, the non-cancer risk estimates associated with mixing, loading and applying activities did not meet current standards and are of concern to the PMRA. However, the proposed additional protective measures, for example, engineering controls and personal protective equipment, could minimize potential exposure in most cases.

All non-cancer risk estimates for lawn care operators applying carbaryl to residential turf, as well as for golf course and sod farm workers applying carbaryl, did not reach the target margin of exposure and/or aggregate risk index for broadcast treatments even with maximum personal protective equipment and engineering controls, and are therefore of concern.

For commercial workers applying carbaryl to ornamentals, non-cancer risk is not of concern for all application equipment except high pressure handwand.

The majority of uses for agricultural scenarios have margins of exposure that are not of concern, provided that engineering controls or personal protective equipment are used. These measures are needed to minimize potential exposure and protect workers health. For those uses that did not meet the target endpoints, further mitigation or discontinuation/removal of use is proposed.

Cancer risks are not of concern.

Top of Page

Most occupational postapplication risks are not of concern provided that the proposed protective measures are followed.

Postapplication occupational risk assessments consider exposures to workers entering treated sites in agriculture. Most occupational postapplication risks are not of concern if proposed protective measures are followed. Based on the precautions and directions for use on the current product labels for agricultural scenarios, non-cancer postapplication risks to workers performing activities such as thinning, pruning and harvesting of most crops, did not meet current standards and are of concern. However, when the proposed mitigation measures such as lengthened restricted entry intervals and restricting the number of applications are considered, the risks to postapplication workers are not of concern. Some of the proposed restricted entry intervals (up to 51 days) may not be considered agronomically feasible and the PMRA is requesting feedback on this aspect.

Based on the non-cancer risk assessment, the postapplication risks to workers performing high-exposure activities, such as mowing treated turf, and transplanting and harvesting sod, do not meet the target margin of exposure until 26 days after treatment. Risks to workers hand harvesting, pinching, pruning and thinning ornamentals do not meet the target even 30 days after treatment. These restricted entry intervals are not considered agronomically feasible for turf or ornamental garden scenarios.

Cancer risks are not of concern.

Although the risk assessment for the agricultural scenarios identified risks of concern based on the current use pattern, the postapplication non-cancer and cancer risk estimates include a number of conservative (health protective) assumptions that may overestimate exposure, and therefore, risk. The application of the proposed mitigation measures reduces the risk for postapplication activities. Proposed protective measures to reduce worker exposure require consultation with user groups to determine their acceptability to the agricultural community. Additional data such as information on typical use pattern (that is, typical rates, number of applications, survey information on critical worker activities, etc.) may help to refine the current risk assessment and could reduce the proposed restricted entry intervals.

Residues in Water and Food

Carbaryl residues in food are not of concern.

Acute exposure through drinking water exceeds the level of concern based on conservative upper bound estimates from modelling; however exposure is not of concern when available water monitoring data is considered.

Reference doses define levels to which an individual can be exposed over a single day (acute) or lifetime (chronic) and expect no adverse health effects. Generally, dietary exposure from food and water is not of concern if it is less than 100% of the acute reference dose or chronic reference dose (acceptable daily intake). An acceptable daily intake is an estimate of the level of daily exposure to a pesticide residue that, over a lifetime, is believed to have no significant harmful effects.

Human exposure to carbaryl was estimated from residues in treated crops and drinking water, including the most highly exposed sub-population (for example, infants and children one to six years old). Recent data from the Canadian Food Inspection Agency, the United States Department of Agriculture Pesticide Data Program, field trials, processing factors and updated percent crop treated information were used to estimate food residues. As well, information on drinking water was used to estimate both the acute and chronic non-cancer and cancer aggregate exposures and risks. To determine the water contribution, both water modelling results and monitoring data were considered in the assessment.

Short term (acute), long term (chronic) and lifetime cancer exposure estimates were determined for different sub-populations representing different ages, genders and reproductive statues. The maximum degree of refinement possible, based on all available information, was used in both the acute and chronic cancer dietary assessments.

Based on the food contribution only, the acute and chronic exposure estimates for the general population were 29% and 1% of the reference doses, respectively. For the most sensitive population of children aged 1 to 2 years, the acute and chronic exposure estimates were 54% and 2% of the reference doses, respectively. The lifetime cancer risk estimate, based on the Q1* approach, was 6.9×10^{-8} for the general population.

Aggregate exposure to carbaryl (that is, from food and drinking water) represents 2% of the chronic reference dose, while the lifetime cancer risk estimate, based on the Q1* approach, was 7.1×10^{-8} for the general population. As a result, both chronic and cancer risks were below the level of concern of the PMRA.

When using the drinking water modelling data, the acute aggregate exposure estimate for carbaryl for all Canadian population subgroups ranged from 117% to 393% of the acute reference dose for the general population and all infants, respectively. However, the drinking water modelling data is considered an upper bound estimate, based on the conservative assumption that 100% of the watershed is treated. These estimates could be refined with "percent cropped area" data.

In addition, the acute aggregate exposure estimates for carbaryl ranged from 37% to 73% of the acute reference dose for the general population and all infants when using the 95th percentile of the maximum detected concentration from drinking water monitoring data. Although the monitoring data may not capture peak concentrations immediately after use, it is a large data set that contains samples collected over a number of years.

Top of Page

Environmental Considerations

What Happens When Carbaryl Is Introduced Into the Environment?

Carbaryl poses a potential risk to terrestrial and aquatic organismsl; therefore, additional risk-reduction measures need to be observed.

When carbaryl is released into the environment, some of it can be found in soil and surface water. However, carbaryl is rapidly broken down by soil microbes and by chemical reactions in water, and therefore it is not expected to persist in the environment. Laboratory studies indicate that carbaryl is mobile in soil. However, there is no field evidence that the use of this insecticide will result in groundwater contamination, most probably due to the rapid microbiological breakdown of carbaryl in soil.

Carbaryl poses a risk to terrestrial invertebrates, birds and mammals as well as to aquatic organisms like fish, amphibians and invertebrates. In order to minimize the potential exposure to aquatic species from drift, strips of land between the agricultural field and no/a target aquatic areas will be left unsprayed. The width of these spray buffer zones will be specified on the product label. Water monitoring data indicate that carbaryl can occur in runoff. However, the concentrations are low and do not pose a concern for aquatic environments.

Value Considerations

What is the Value of Carbaryl?

In Canada, carbaryl is registered to control a wide range of insect pests including beetles, butterflies, moths, fleas, flies, lice, mites, sawflies, crickets, earwigs, grasshoppers, millipedes, sow bugs, thrips, ticks and cockroaches. It is also registered in Canada for use in apple thinning.

Carbaryl is used on both agricultural and non-agricultural sites including feed crops, industrial oil seed and fibre crops, livestock, greenhouse tobacco seedlings, companion animals, structures, forestry, food crops, turf, lawns and ornamentals.

Carbaryl is important in the resistance management of pests for most uses. Furthermore, for some of the uses for which it is registered, there are few if any other effective registered alternatives.

Top of Page

Proposed Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. The directions include risk-reduction measures to protect human and environmental health. These directions are required by law and must be followed.

Risk-reduction measures are being proposed to address the potential risks identified in this assessment. These measures, in addition to those already identified on existing carbaryl product labels, are designed to further protect human health and the environment. The additional key risk-reduction measures that are being proposed are as follows.

Human Health

- Phase-out of domestic class products and residential applications of commercial products.
- Phase-out of uses on field tobacco, Pick-Your-Own orchard operations, turf, golf courses and sod farms.
- To further protect mixer/loader/applicators: additional protective equipment and the packaging of all carbaryl wettable powder products in water soluble packaging.

- To further protect workers entering treated sites: restrictions on the number of applications, increased application intervals and restricted entry intervals.

- To update the Toxicological Information section on labels: additional information about symptoms and treatment for exposed individuals.

Environment

- To reduce the release of carbaryl into the environment for the protection of aquatic habitats that may contain sensitive species: add label statements, including precautionary statements and spray buffer zones for non-target aquatic habitats.

- To reduce the potential for carbaryl in runoff to adjacent aquatic habitats: add label statements, to include precautionary statements for sites with characteristics that may be conducive to runoff as well as when heavy rain is forecasted.

Top of Page

What Additional Scientific Information Is Being Requested?

The human health risks and risks to the environment were found to be acceptable for certain uses of carbaryl with the addition of mitigation measures. However, the following information is being requested to help refine the risk assessment.

Human Health

- Data code 10.6: The modelled drinking water expected environmental concentrations could be potentially refined with the use of information on percent cropped area.

Next Steps

Before making a re-evaluation decision on carbaryl, the PMRA will consider all comments received from the public in response to this consultation document.

In particular, the PMRA is seeking comments on the feasibility of mitigation measures such as restricted entry intervals or buffer zones and additional information on the typical use pattern of carbaryl (that is, typical rates, number of applications, survey information on critical worker activities, etc.).We would also consider quantitative and/or qualitative data on the economic and social importance of carbaryl to specific industries and information on the viability of alternative chemical and non-chemical pest management practices for the registered site and pest combinations that are proposed for phase-out.

The PMRA will then publish a Re-evaluation Decision, which will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments.

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.

Other Information

At the time that the re-evaluation decision is made, the PMRA will publish an Evaluation Report on

carbaryl in the context of this re-evaluation decision (based on the Science Evaluation section of the PDF version of this document). In addition, the test data on which the decision is based will also be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*

[2] "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*

[3] "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact".

[4] "Decision statement" as required by subsection 28(5) of the Pest Control Products *Act*

Date Modified: 2009-10-19