Re-evaluation Decision RVD2018-05

Methomyl and Its Associated End-use Products

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Re-evaluation Decision

Under the authority of the *Pest Control Products Act*, all registered pesticides must be regularly re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to meet current health and environmental safety standards and continue to have value. The re-evaluation considers data and information from pesticide manufacturers, published scientific reports and other regulatory agencies. The PMRA applies internationally accepted risk assessment methods as well as current risk management approaches and policies.

Methomyl is effective as both a contact and systemic insecticide in agriculture, forestry and as a granular bait in barns, poultry houses, feedlots and kennels. There are seven products containing methomyl that are currently registered in Canada under the authority of the *Pest Control Products Act*, including two technical grade active ingredients, four commercial class end-use products and one restricted class end-use product.

This document presents the re-evaluation decision[1] for methomyl. All products containing methomyl that are registered in Canada are subject to this re-evaluation decision. This re-evaluation decision was consulted on as Proposed Re-evaluation Decision PRVD2016-02, *Methomyl*.[2]The 90 day consultation period ended on 14 April 2016. The PMRA received comments relating to the health, value and environmental risk assessments. These comments and new data/information resulted in revisions to some parts of the risk assessments (see the Science Evaluation) and subsequently changes to the proposed regulatory decision as described in PRVD2016-02. Appendix II of this document summarizes the comments received and provides the PMRA's response.

Regulatory Decision for Methomyl

The PMRA has completed the re-evaluation of methomyl. Under the authority of the *Pest Control Products Act*, the PMRA is granting continued registration of products containing methomyl for sale and use in Canada. An evaluation of available scientific information found that some uses of methomyl products do not present unacceptable risks to human health or the environment when used according to the conditions of registration, including amended label directions. Certain uses of methomyl are no longer supported by the registrant and will be removed from the labels. Label amendments, as summarized below and listed in Appendix III, are required for all end-use products.

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

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

Risk Mitigation Measures

Registered pesticide product labels include specific direction for use. Directions include risk mitigation measures to protect human health and the environment and must be followed by law.

Human Health

To protect the general population from dietary exposure, the following risk-reduction measures are required for continued registration of methomyl in Canada:

- Removal of uses no longer supported by the registrant (apple, barley, canola, flax, lettuce, oat, potato, snap bean, tomato, tobacco, wheat, balsam fir and spruce in farm woodlots and rights-of-way)
- Permit only a single yearly application at a maximum application rate of 459 g a.i./ha on succulent shelled peas only, 563 g a.i./ha on sweet corn, 698 g a.i./ha on Brussels sprouts, and 486 g a.i./ha on broccoli, cabbage and cauliflower.
- Restrict the timing of application on broccoli, Brussels sprouts, cabbage, cauliflower and sweet corn to occur before mid-August.
- 12 hour restricted-entry interval for the restricted-class product.

Environment

- Advisory statements to inform users that methomyl is toxic to non-target organisms including bees, beneficial insects, birds, mammals, aquatic invertebrates, fish and amphibians.
- Advisory statements to minimise spray drift to areas where bees might be present.
- Advisory statements to inform users of conditions that may favour run-off and leaching.
- Spray buffer zones to protect aquatic habitats from drift.
- A statement advising that methomyl could potentially reach groundwater, particularly in areas where soils are permeable and/or the depth to the water table is shallow.

Next Steps

To comply with this decision, the required mitigation measures must be implemented on all products labels sold by registrants no later than 24 months after the publication date of this decision document. Appendix I lists the products containing methomyl that are registered under the authority of the *Pest Control Products Act*.

Other Information

Any person may file a notice of objection[3] regarding this decision on methomyl within 60 days from the date of publication of this Re-evaluation 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.

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

Science Evaluation Update

1.0 Revised Health Risk Assessment

1.1 Toxicology Assessment for Methomyl

The human health risk assessment for methomyl was published in PRVD2016-02. Comments from the registrant were received during the consultation process. Overall, the comments did not have any impact on the toxicology assessment. Appendix II summarizes the comments and provides the PMRA's response to these comments.

1.2 Dietary Exposure and Risk Assessment

The dietary assessment for methomyl was published in the PRVD2016-02. The PMRA had proposed the cancellation of all food and feed uses and the revocation of all Canadian MRLs due to dietary risks of concern. Based on the comments received, the dietary risk assessment was revised to include only the food commodities that continue to be supported in Canada as a result of the re-evaluation of methomyl (that is, broccoli, Brussels sprouts, cabbage, cauliflower, sweet corn and succulent shelled peas), as well as crops for which there are MRLs for import purposes (that is, blueberry, celery and citrus fruits). Residues for all other commodities, including imports, were set at zero. In addition, revised highly refined drinking water estimates were generated, which were modelled based on a single application occurring before mid-August for all crops except succulent shelled peas, and two applications occurring between April and May for Christmas trees (see Section 1.2.3).

Sufficient information was available to adequately assess the dietary exposure and risk to methomyl. Acute and chronic dietary (food and drinking water) exposure and risk assessments for methomyl were conducted using the Dietary Exposure Evaluation Model - Food Commodity Intake Database™ (DEEM-FCID™; Version 4.02, 05-10-c) program, which incorporates food consumption data from the National Health and Nutrition Examination Survey/What We Eat in America (NHANES/WWEIA) dietary survey for the years 2005-2010 available through Centers for Disease Control and Prevention's National Center for Health Statistics. For more information on dietary risk, see Appendix IV.

The acute and chronic exposure estimates are considered to be highly refined (more precise) as monitoring residues, percent crop treated, experimental processing factors and domestic/import data were used to the extent possible.

1.2.1 Acute Dietary Exposure and Risk Assessment

The acute dietary risk from food and drinking water was calculated considering the highest ingestion of methomyl that would be likely on any one day, and using food and water consumption, and food and water residue values. The expected intake of residues is compared to the acute reference dose (ARfD), which is the dose at which an individual could be exposed on any given day and expect no adverse health effects. When the estimated exposure is less than the ARfD, the acute dietary exposure is not of concern.

The acute probabilistic risk assessment was conducted for the general population and all subpopulations using available residue monitoring data from the United States Department of Agriculture's Pesticide Data Program (USDA PDP) for broccoli, Brussels sprouts, cabbage, cauliflower, sweet corn, succulent shelled peas, blueberries, celery and citrus fruits. In addition, the following inputs were incorporated where available: percent crop treated (PCT) information in Canada and in the United States; 100% crop treated for commodities for which no PCT information was available; available information on domestic production and import supply; and available experimental processing factors. Drinking water contribution to the exposure was accounted for by direct incorporation of the estimated environmental concentrations (EECs) distribution, obtained from water modelling (see Section 1.2.3) into the dietary exposure evaluation model (DEEM).

The acute dietary (food and drinking water) exposure estimates at the 99.9th percentile for the general population and all subpopulations ranged from 15% to 78% of the ARfD, and therefore are not of concern. Drinking water contribution accounted for 37% of the total acute exposure for the most exposed subpopulation. The detailed results are presented in Appendix IV.

1.2.2 Chronic Dietary Exposure and Risk Assessment

The average residue values from USDA's PDP monitoring data and average PCT estimates from Canada and the US were used to conduct a refined dietary risk assessment for broccoli, Brussels sprouts, cabbage, cauliflower, sweet corn, succulent shelled peas, blueberries, celery and citrus fruits. The chronic dietary risk was estimated by incorporating food and drinking water directly in the assessment using average food residues and the average EEC value of 4.4 µg a.i./L for drinking water (see Section 1.2.3).

The chronic dietary (food and drinking water) exposure estimates for the general population and all subpopulations ranged from 9% to 48% of the ADI, and therefore are not of concern. Drinking water contribution accounted for 98% of the total chronic exposure for the most exposed subpopulation. The detailed results are presented in Appendix IV.

1.2.3 Exposure from Drinking Water

Residues of methomyl in potential drinking water sources were estimated from modelling, as described below.

1.2.3.1 Concentrations in Drinking Water

Refined EECs were calculated using the Pesticides in Water Calculator (PWC 1.52) model. Modelled crops were Brussels sprouts, broccoli, cabbage, cauliflower, succulent shelled peas and corn. The application rates modelled were a single application of 486 and 698 g a.i./ha for Brussels sprouts and 486 g a.i./ha for broccoli, cabbage and cauliflower. The application rate used for succulent shelled peas was a single application of 459 g a.i./ha, and a single application of 563 g a.i./ha was used for corn. The modelling used application dates ranging from May through October for succulent shelled peas, from May through mid-August for Brussels sprouts, broccoli, cabbage, cauliflower and corn. Modelling was also conducted for uses on Christmas trees, using two applications of 486 g a.i./ha and initial application dates between April and May. More information is provided in Appendix V.

1.2.3.2 Drinking Water Exposure and Risk Assessment

Drinking water exposure estimates were combined with food exposure estimates, with EEC values incorporated directly into the dietary (food and drinking water) assessments (see Sections 1.2.1 and 1.2.2).

1.3 Occupational Exposure and Risk Assessment

No comments specific to the occupational risk assessment were received. The occupational risk assessment was updated based on the revised use pattern.

As a result of these changes, certain mitigation measures proposed in PRVD2016-02 are no longer required. See Appendix III for label amendments.

2.0 Revised Environmental Risk Assessment

The newly revised label supports only a reduced list of crops. With the exception of the use on Christmas trees for which the use directions remain the same, the revised use directions for the supported crops include reduced application rates (698 g a.i./ha for cole crops, 459 g a.i./ha for succulent shelled peas, and 563 g a.i./ha for corn) and limits application to ground based equipment. Overall, exposure to spray drift is therefore reduced for terrestrial and aquatic species compared to the previously registered uses. Similarly, surface water concentrations from runoff were also recalculated for the revised use pattern based on updated methods and the reduced use rates.

The environmental risk based on the new use pattern showed exceedance of the level of concern and identified a potential risk of adverse effects to non-target terrestrial and aquatic organisms including bees, beneficial insects, birds, mammals, aquatic invertebrates, fish and amphibians. In order to mitigate the risk to aquatic systems, spray buffer zones were re-calculated and range from 5-45 m for ground application. Additional mitigation measures are included on the label to reflect the revised use patterns as listed in Appendix III.

3.0 Maximum Residue Limits for Methomyl in Food

In general, when the re-evaluation of a pesticide has been completed, the PMRA intends to update Canadian MRLs and to remove MRLs that are no longer supported. MRLs for pesticides in/on food are specified by Health Canada's PMRA under the authority of the *Pest Control Products Act*.

Canadian MRLs for methomyl are currently specified for apples (0.5 ppm), blueberries (6 ppm), cabbages (5 ppm), celery (0.5 ppm), citrus fruits (1 ppm), grapes (4 ppm), lettuce (2 ppm), strawberries (1 ppm) and sweet corn kernels plus cob with husks removed (0.1 ppm). As a result of methomyl re-evaluation, the PMRA will:

- maintain the current MRLs for blueberries, cabbages, celery, citrus fruits and sweet corn kernels plus cob with husks removed;
- establish MRLs based on field trial studies for broccoli, Brussels sprouts, cauliflower and succulent shelled peas;
- replace the current Canadian MRLs for apples, grapes, lettuce and strawberries with risk-based MRLs at the LOQ of the CFIA enforcement method; and
- establish risk-based MRLs at the LOQ of the CFIA enforcement method for all non-registered food commodities.

List of Abbreviations

µg	microgram(s)
ADI	acceptable daily intake
a.i.	active ingredient
ARfD	acute reference dose
bw	body weight
CFIA	Canadian Food Inspection Agency
DEEM	Dietary Exposure Evaluation Model
EEC	estimated environmental concentration
g	gram(s)
ha	hectare(s)
K_{oc}	Organic-Carbon Partition Coefficient
K_d	Soil-Water Partition Coefficient
kg	kilogram(s)
L	litre(s)
LEACHM	Leaching Estimation and Chemistry Model
LOQ	limit of quantitation
mg	milligram(s)
MRL	maximum residue limit
NAFTA	North American Free Trade Agreement
NHANES/WWEIA	National Health and Nutrition Examination Survey/What We Eat in America
NIOSH	National Institute for Occupational Safety and Health
OECD	Organisation for Economic Co-operation and Development
PCT	percent crop treated
PMRA	Pest Management Regulatory Agency
ppm	parts per million
PRZM/EXAMS	Pesticide Root Zone Model/Exposure Analysis Modeling System
PRZM-GW	Pesticide Root Zone Model for Ground Water
PWC	Pesticide in Water Calculator
REI	restricted-entry interval
SFO	Single First Order
STORET	STOrage and RETrieval water quality monitoring database
US	United States
USDA PDP	United States Department of Agriculture's Pesticide Data Program
USEPA	United States' Environmental Protection Agency

Appendix I

Table 1 Registered commercial and/or restricted class uses of methomyl in Canada as of 3 August 2017

Site(s)	Pest(s)	Formulation Type	Application Methods and Equipment	Application Rate		Maximum Number of Applications per Year
				Product (g product/ha)	Active ingredient rate (g a.i./ha)	
Broccoli	Cabbage looper, imported cabbageworm, diamondback moth	Soluble powder in water soluble bag	Ground equipment: hydraulic sprayers	270-540	236-486	1
Brussels sprouts	Cabbage looper, imported cabbageworm, diamondback moth			270-540	236-486	1
Brussels sprouts	Slugs (larvae of grey garden slugs)			775	698	
Cabbage	Cabbage looper, imported cabbageworm, diamondback moth			270-540	236-486	1
Cauliflower	Cabbage looper, imported cabbageworm, diamondback moth			270-540	236-486	1
Sweet corn	Aphids			430-620	387-558	1
	Brown marmorated stink bug (suppression)			625	563	
	Corn earworm			430-625	378-563	
	European corn borer			625	563	
Succulent shelled pea	Alfalfa looper, pea aphid and brown marmorated stinkbug (suppression)			510	459	1
Structural-indoor and outdoor (non-residential)	Blow fly, eye gnat, flesh fly, house fly, little house fly, flies (general)	Granular	Shaker can/bait station	250 g/100m^2	2.5 g/100m^2	Not stated

Table 2 Products containing methomyl that are registered in Canada[4] as of 27 February 2018

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
10868	Restricted	E.I. Du Pont Canada Company	Lannate Toss-N-Go Insecticide	Soluble Powder	Methomyl 90%
29457	Technical Grade Active Ingredient	E.I. Du Pont Canada Company	DuPont Methomyl Technical	Solid	Methomyl 99.7%
32442		Sinon Corporation	Sinon Methomyl Technical		Methomyl 99.3%
29428	Commercial	Engage Animal Health Corporation	Fatal Attraction Fly Bait	Granular	Methomyl 1%; (Z)-9-tricosene 0.025%
25358		Farnam Companies Inc.	Blue Streak Fly Bait		
24969		Troy Biosciences Inc.	Stimukil Fly Bait		
15176		Wellmark International	Starbar Premium Fly Bait		Methomyl 1%; (Z)-9-tricosene 0.049%

[4] Excluding discontinued products or products with a submission for discontinuation as of 27 February 2018 based upon the PMRA's Electronic Pesticide Regulatory System (e-PRS) database

Appendix II Comments and Responses

In response to the consultation document PRVD2016-02, *Methomyl*, the following comments were received:

1.0 Comments Related to the Health Risk Assessments

1.1 Comments Related to Toxicology

In response to the consultation on PRVD2016-02, comments related to the toxicology assessment were received from the registrant

1.1.1 Comment

The presented findings for published literature studies in the genotoxicity section of the assessment were incorrect and the overall weight of evidence indicates that methomyl does not have genotoxic potential.

PMRA Response
The positive genotoxicity studies that the PMRA obtained from the literature and included in PRVD2016-02 for methomyl were the PMRA Nos. 1585238, 1585239 and 1585240. The in vitro cytotoxicity study that was conducted by Guanggang et al. (2013) and cited in the received comment was not previously reviewed by the PMRA and, as such, was not included in PRVD for methomyl. The PMRA re-examined the positive genotoxicity studies that were summarized in PRVD2016-02 and concluded that these positive in vitro and in vivo studies did not have any significant methodological issues and adequate study details (including product purity) were provided. Therefore, they were considered acceptable for risk assessment purposes. However, in light of the negative results obtained for carcinogenicity studies conducted with mice and rats, the significance of these positive genotoxicity studies from the published literature is minimal and no further analysis is warranted at this time.

1.1.2 Comment

Based on the strength and breadth of the methomyl database, as well as the depth of information known about the mode of action, pharmacokinetics, pharmacodynamics, rapid recovery of the enzyme and the significant use history for the active ingredient, the use of a 10× assessment factor for interspecies variability is overly conservative and should be refined to 3× to better reflect the data set available. This refinement of the interspecies factor would result in a composite uncertainty factor of 30× which would account for the uncertainties in extrapolation from rats and other mammals to humans and for uncertainties regarding the sensitivity among humans.

PMRA Response
In risk assessment, the interspecies uncertainty factor of 10-fold is applied as a default to account for uncertainties when extrapolating toxicity data from animals to humans. Chemical-specific adjustment factors can be used in risk assessment to provide a method for the incorporation of relevant quantitative data on interspecies or intraspecies differences in either the toxicokinetics or toxicodynamics by modifying the relevant default uncertainty factor.

Human-derived data, such as pharmacokinetic data, are important for consideration of either interspecies differences or human variability, along with comparable in vitro studies conducted in both animal and human tissues.

To justify a reduction of the interspecies uncertainty factor, the registrant presented a relatively brief summary discussing the severity of effect, mode of action and metabolic and pharmacokinetic differences. The registrant concluded that there were no observed differences between species with respect to the rate and extent of metabolism and the rate of elimination. Based on this information, the registrant stated that a basis exists for a chemical-specific adjustment factor for methomyl, taking into account what is known about the metabolism and similarity across species. While the PMRA agrees with the registrant with regards to metabolism being similar across the species that were examined, it should be noted that only rats and monkeys were exposed to methomyl in pharmacokinetic studies. There is insufficient toxicokinetic data available for humans exposed to methomyl.

The registrant presented a table that compared the findings from seven different acute neurotoxicity studies and stated that this table demonstrated the “many similarities with respect to the most sensitive effect of cholinesterase inhibition among the species, sexes and across age groups within species”. In examining this table, it was apparent that six of the seven studies examined rats, while only one study involved humans. Consistent with SPN2016-01, *Restricted Use of Human Studies with Pesticides for Regulatory Purposes* the latter study was not considered by the PMRA, as it was a systemic toxicity study. Notwithstanding the PMRA’s policy on human studies, the human study could only examine erythrocyte cholinesterase activity. This is a significant limitation given that the most sensitive endpoint throughout the methomyl database was brain cholinesterase inhibition. Based on the available information, the PMRA has determined that these seven acute neurotoxicity studies are insufficient to make any conclusions with regards to the similarities between species.

The pharmacokinetic and pharmacodynamic data that is currently available for humans is insufficient to alleviate uncertainties in extrapolating from rats to humans. Therefore, given the lack of appropriate data to attain confidence in this adjustment of uncertainty factors, the interspecies factor of 10-fold will remain.

1.1.3 Comment

The data available for methomyl provides evidence to support the concept of reversibility throughout the day and the use of the eating occasion analysis since there was no need to account for a cumulative effect over a 24-hour period.

PMRA Response

Throughout the database for methomyl, the most severe toxic effects were noted following a single bolus dose, such as what is administered in acute toxicity studies, as the full dose was administered at one time. In dietary studies, much higher daily doses were tolerated, as animals were exposed to the total daily dose over an extended period of time and the rapid recovery of cholinesterase inhibition lessened the observed toxicity. The PMRA agrees that the observed neurotoxic effects noted in toxicity studies appear to be reversible when they occur at sublethal doses.

Given this knowledge it is possible that the acute toxicity studies may overestimate the effects that would be observed if the entire daily dose was administered over multiple, but brief exposure periods.

To help support their claim that cholinesterase inhibition is quickly reversed following exposure to methomyl, the registrant discussed a study that was not available to the PMRA. In this study, the regeneration kinetics for rat and human cholinesterase activity were compared in vitro. The registrant concluded that the human enzyme was slightly more sensitive to cholinesterase inhibition compared to the rat and was slower to regenerate. The registrant did point out that the source of the human cholinesterase enzyme was acetylcholinesterase from erythrocytes, while the source of the rat enzyme was whole blood hemolysate which was said to be a mixture of acetyl and butyryl cholinesterase. Given the examination of different cholinesterase enzymes, this study is not ideal for drawing conclusions other than to indicate that reversal of cholinesterase inhibition was demonstrated in both rats and humans.

In the registrant-submitted document, a table was presented that compared the findings from six different acute neurotoxicity studies conducted with rats. It can be concluded from these available acute neurotoxicity studies that recovery is relatively rapid in rats following exposure to methomyl. However, based on the available data, it is unclear as to when recovery of cholinesterase inhibition actually occurs post-dosing, as the presented studies demonstrated a significant range in recovery time. In some of the rat studies conducted with gavage dosing, recovery of cholinesterase activity was reported to occur between 1.5 and 3 hours post-dosing in PND11 male and female pups, while adult rats recovered by 4 hours post-dosing. By the dietary route of exposure, recovery was not determined, as samples were only collected at 1 and 2 hours following a two-hour feed. In a time-course study conducted with adult male rats, it was stated in the table that brain cholinesterase activity was still statistically significantly inhibited up to 24 hours post-dosing. The PMRA has reviewed this time-course study and concluded that brain and erythrocyte cholinesterase activity was significantly inhibited 90 minutes post-dosing. However, by 180 minutes post-dosing, erythrocyte and brain cholinesterase activity, while statistically different from control values, had recovered sufficiently that the slight decreases were no longer considered to be toxicologically significant. Therefore, based on the available study results, the time for recovery of erythrocyte and brain cholinesterase inhibition in rats is between 1.5 to 4 hours following exposure to methomyl. The registrant reported that USEPA concluded that brain and erythrocyte half-lives from the rodent data (adults and pups) “were consistently between 0.5 and 1 hour”. The registrant did not report on the recovery half-lives associated with each of the rat studies in their table of acute neurotoxicity studies, nor did they provide any details as to how USEPA derived their half-lives.

In the absence of this information, the PMRA will employ a conservative approach and use the upper end of the recovery range (that is, 4 hours) for rats exposed to a single dose of methomyl in lieu of an estimated half-life for any eating occasion analysis.

The human acute neurotoxicity study included in the registrant-submitted table reportedly had a recovery of erythrocyte cholinesterase by 4-6 hours following exposure to methomyl. The registrant reported that USEPA concluded that recovery half-lives in this study were "highly variable and somewhat dependent on dose, resulting in half-life confidence intervals between 0.6 and approximately 6 hours". Given that the most sensitive endpoint noted in the database for methomyl was brain cholinesterase activity and it was not possible to measure this in the human study, there is uncertainty with regards to the estimate of human recovery. Consistent with SPN2016-01, the human study was not considered by the PMRA for risk assessment as it was a systemic toxicity study; however, the reported results do add support to using the upper range of recovery (that is, 4 hours) from the acute rat studies in any eating occasion analysis undertaken for the risk assessment of methomyl.

1.2 Comments Related to Dietary Exposure

In response to the consultation on PRVD2016-02, comments that related to the dietary exposure assessment were received from the registrant, the Canadian Horticulture Council and the New Brunswick Department of Agriculture, Aquaculture and Fisheries.

1.2.1 Comment

Regarding the chronic and acute probabilistic dietary exposure and risk assessment, the consumption data and monitoring residue data do not reflect the most current data available.

PMRA Response
A revised dietary exposure assessment was conducted using the Dietary Exposure Evaluation Model - Food Commodity Intake Database™ (DEEM-FCID™; Version 4.02, 05-10-c) program which incorporates food consumption data from the NHANES/WWEIA dietary survey for the years 2005-2010 available through the Centers for Disease Control and Prevention's National Center for Health Statistics. Residues for all food commodities included in the revised dietary exposure assessment were from the most recent available USDA PDP.

1.2.2 Comment

As Canada is a nation with a significant amount of imported produce, the PMRA has creatively addressed exposure due to imported produce. However, the methodology is unnecessarily conservative due to lack of available data. The PMRA should employ a more realistic process to account for the dietary risk from imported produce.

PMRA Response
The dietary exposure assessment was revised to include updated percent domestic and percent import supply estimates.

1.2.3 Comment

Some of the commodities driving the extreme high end of the acute dietary exposure distribution have few or no methomyl detects in the monitoring data.

PMRA Response
The registrant no longer supports the use of methomyl on apples in Canada and grapes are no longer registered in the US; therefore, these two commodities, which were significant contributors to dietary exposure in the PRVD2016-02 assessment, were removed from the revised dietary exposure assessment.

1.2.4 Comment

Based on the rapid degradation of methomyl and strength of data showing no lasting effects in vivo, a sub-24 hour time frame is appropriate for the acute dietary assessment on an eating occasion basis.

PMRA Response
The reversibility of methomyl is discussed in Appendix II, Section 1.1 *Comments Related to Toxicology*. Although the reported results add support to using the upper range of recovery (4 hours) from the acute rat studies, since no risks of concern were identified based on the revised dietary risk assessment, the eating occasion analysis was not required at this time.

1.2.5 Comment

The PMRA has included grapes as part of the dietary risk assessment. Uses on grapes have been removed in Canada and the US (most significant exporting country for grapes to Canada). This is a significant contributor to dietary risk for children and infants and should be corrected in the risk assessment. The PMRA should re-evaluate the risk assessment taking into consideration the proposed changes to the use pattern.

PMRA Response
A revised dietary exposure assessment was conducted reflecting this change. The revised dietary assessment includes only the crops that continue to be supported in Canada as a result of the re-evaluation of methomyl (that is, broccoli, Brussels sprouts, cabbage, cauliflower, sweet corn, peas as well as Christmas trees, which can also contribute to levels in drinking water), as well as crops for which there are MRLs for import purposes (that is, blueberry, celery and citrus fruits).

1.2.6 Comment

Regarding use on peas, methomyl is an important control option for Alfalfa Looper, although application may not be required every year.

PMRA Response
Peas (dry and succulent) were included in the revised dietary assessment. Since no risks of concern were identified, and adequate US crop field trial data for succulent peas were submitted to the Agency in order to specify a Canadian MRL for this crop, the use of methomyl on succulent shelled peas continues to be supported in Canada as a single application at the maximum application rate of 459 g a.i./ha. The label will be revised accordingly.

1.2.7 Comment

Methomyl is an important pesticide option for vegetable producers in New Brunswick, including sweet corn and cabbage production. Other commodities have transitioned away from this product and are less reliant on its registration.

PMRA Response
Sweet corn and cabbage were included in the revised dietary assessment; since no risks of concern were identified in the revised health risk assessment, the uses on sweet corn and cabbage continue to be supported in Canada as a single application at the maximum application rate of 563 g a.i./ha and 486 g a.i./ha, respectively.

2.0 Comments Pertaining to the Value Assessment

In response to the consultation on PRVD2016-02, value comments were received from the registrant, the Canadian Horticulture Council and the New Brunswick Department of Agriculture, Aquaculture and Fisheries.

2.1 Comment

Modifications to the use pattern for Lannate Toss-n-go Insecticide were proposed by the registrant along with revocation of specific MRLs, in order to retain a subset of food uses for Canadian growers.

Respondents also stated that methomyl is an important component of pest control in the production of Cole crops (that is, broccoli, cabbage, cauliflower and Brussels sprouts), sweet corn and peas. It has value both as an effective insecticide to control listed pests, and as a rotational product for resistance management purposes.

PMRA Response
Refinement of the risk assessments resulted in the retention of the use of methomyl on Cole crops (that is, broccoli, cabbage, cauliflower and Brussels sprouts), sweet corn and peas, at a seasonal application of one per year. For Cole crops and sweet corn, the latest application date of August 15 was added as a mitigation measure. The retention of methomyl provides farmers the option of including methomyl in their pest management program.

3.0 Comments Pertaining to the Environmental Assessment

In response to the consultation on PRVD2016-02, comments that related to the environmental assessment were received from the registrant.

3.1.1 Comment

As documented on page 105 of PRVD2016-02, the PMRA included exposure from a subset of labelled crops in the modelling. Only four crops with the highest maximum annual use patterns were included in modelling of methomyl (apples, lettuce, sweet corn, and wheat/barley/rye). Future assessments should include the full range of relevant scenarios and uses, as it provides a more complete picture of variability of exposures, and identifies potential refinement opportunities. Because of the suggested label changes, the final decision should reflect relevant scenarios for the proposed remaining use patterns.

PMRA Response
The PMRA has updated the water modelling based on the revised use patterns for cole crops, corn and peas. Also, modelling on Christmas trees was conducted in order to capture all uses retained following the re-evaluation.

3.1.2 Comment

Environmental fate parameters (Page 106) have not been calculated with the latest NAFTA kinetics package. Adsorption K_{oc}: 0.236 mg/L is actually the K_d value and should be entered as such in models. Regarding the aerobic soil biotransformation half-life, it is un-clear what 8 half-lives were used to calculate the model input. The anaerobic aquatic biotransformation half-life is listed as stable. The registrant suggests using a multiplier on the anaerobic soil metabolism single value of 14 days as conservative method for providing an input parameter, rather than assuming this process to be stable.

PMRA Response
Modelling has been updated to use a K_d of 0.235, rather than a K_{oc}. Four aerobic soil half-lives were used for modelling and were calculated with the current NAFTA tool or its predecessor. All half-lives came from the SFO (exponential) model. The 80% confidence bound on the mean, as used by USEPA, was used to calculate a half-life for modelling of 13.3 days.

3.1.3 Comment

Regarding the modeling discussion as presented in Page 106-109: In the Level 2 and Refined Level 2 Modeling, PRZM/EXAMS was used to estimate surface drinking water concentrations. It is unclear, as documented, which model versions were used. Surface water modeling tools have since been updated, and Pesticide Water Calculator (PWC) is the most current tool for estimating surface water drinking water concentrations. Modeling should be updated to use the latest tool. In Level 2 Modeling, LEACHM was used to estimate groundwater concentrations. PRZM-GW is the latest tool used for calculation of drinking water concentrations from groundwater, and modeling should be updated.

PMRA Response
All water modelling was redone for the new scenarios, using PWC v1.52.

3.1.4 Comment

Standard environmental fate parameterization used by PRZM-GW (declining degradation with depth) does not represent methomyl degradation patterns observed in the real world. Model revisions should include a representation of more realistic degradation patterns based on available data, focused field studies, and correspond with the noted lack of accumulation observed in monitoring data of groundwater.

PMRA Response
The PMRA did not have any reliable data for degradation of methomyl with depth, so this was not accounted for in the revised water modelling. The assessment of methomyl determined that it has a potential to leach to groundwater. In Canada, the monitoring database is limited and conclusions regarding the potential exposure of humans to methomyl in groundwater cannot be drawn from this data. Available monitoring data from the United States indicates that methomyl is detected infrequently in groundwater and at low concentrations. Data that would allow the use of these results in the Canadian drinking water assessment are not available. It is unclear if the samples were collected from wells that were in methomyl use areas. Therefore, it is not possible to determine if the non-detects were a result of no use or no movement to groundwater. As a result, the PMRA relied on modelled EECs to estimate exposure in drinking water.

3.1.5 Comment

Regarding documentation, it is unclear which regional scenarios were used to calculate estimated drinking water concentrations in surface and ground water for a given crop at Level 2 and Refined Level 2. For example, surface water EECs are provided for Quebec Reservoir and the lettuce use rate. However, there is no lettuce scenario for Quebec. The same situation occurs for sweet corn in British Columbia and Alberta. It is also unclear why certain crops were not modeled where scenarios do exist. For example, there is a Quebec apples scenario that was not included. In future assessments, the registrant requests a more explicit definition of input assumptions, model versions, and scenario details that are utilized in any evaluation report. This can be achieved by providing either a more detailed appendices (new tool sets provide a detailed report ready input/output summary) or could be facilitated by providing electronic run files.

PMRA Response
The revised water modelling was done on crop-specific scenarios for cole crops, corn, peas and Christmas trees.

3.1.6 Comment

The dugout environment is no longer included in drinking water assessments and should be removed from future assessments. Additionally, the cole crop vegetables remaining on the label are generally not grown in areas of dugout hydrology.

PMRA Response
The dugout scenario was not used for the revised water modelling.

3.1.7 Comment

Surface water estimates utilized an excessively conservative assumption that 100% of the small watershed area is cropped and treated with methomyl (on the same day). While assuming 100% cropped area follows the PMRA guidance and provides a screening level assessment, actual Percent Cropped Area (PCA) should be included in refined modeling to obtain more realistic EECs in drinking water.

PMRA Response
A percent cropped area was not used to modify model results because a percent cropped area would be applied only to surface water EECs. For methomyl, the EECs from groundwater modelling were more important to the risk assessment, and therefore lower EECs for surface water would not affect the outcome.

3.2 Comments Related to Water Monitoring

3.2.1 Comment

Extensive groundwater monitoring data available on methomyl clearly shows a lack of chronic exposure, but groundwater predictions indicate some level of risk based on the model results. Monitoring data provides enough evidence to conclude that methomyl does not pose a chronic risk to human health in groundwater.

PMRA Response
The assessment of methomyl determined that it has a potential to leach to groundwater. In Canada, the monitoring database is limited and conclusions regarding the potential exposure of humans to methomyl in groundwater cannot be drawn. Available monitoring data from the United States indicates that methomyl is detected infrequently in groundwater and at low concentrations. Data that would allow the use of these results in the Canadian drinking water assessment are not available. It is unclear if the samples were collected from wells that were in methomyl use areas therefore, it is not possible to determine if the non-detects were a result of no use or no movement to groundwater. As a result, the PMRA relied on modelled EECs to estimate exposure in drinking water.

3.2.2 Comment

The high concentrations in the STORET database reference (Page 108 of the PRVD) were investigated further by the registrant. The registrants review concluded that the high concentrations are not relevant to current or proposed legal labeled uses and requests that based on the analysis only samples potentially relevant to drinking water be considered in the assessment.

PMRA Response
Levels of pesticides detected in surface water are directly related to the frequency and timing of monitoring in relation to pesticide application and runoff events. Therefore, timing and frequency of sampling is likely to be the most important factor influencing the concentration detected and the frequency of detections. Samples are often taken at arbitrary time intervals (once a month, once a week) and are unlikely to capture the absolute maximum concentration of methomyl. In addition, information on the use of methomyl in the area of sampling is in general sparse or not available. For these reasons, the acute risk assessment was based on the results of modelling. Eliminating the STORET data from the monitoring analysis would not affect the outcome of the current assessment.

3.2.3 Comment

The listing of monitoring data could be improved by evaluating monitoring programs for surface drinking water supplies in Canada to better categorize source type (river, lake, reservoir) and relationship to agricultural lands.

PMRA Response
The PMRA acknowledges that the addition of information regarding the water sources in the summary tables (such as Table 3.2-1 in the PRVD 2016-02) would assist in interpretation of the data. During the analysis, the PMRA does consider this information when determining if the monitoring data are relevant to the drinking water assessment. This suggestion will be considered in future water monitoring assessments.

Appendix III Label Amendments for End-use Products Containing Methomyl

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the label statements provided below.

Statements To Protect Human Health

1. **Commercial Class Products**

a. Under TOXICOLOGICAL INFORMATION, **add:**

"Methomyl is a carbamate which is a cholinesterase inhibitor. Typical symptoms of overexposure to cholinesterase inhibitors include malaise, muscle weakness, dizziness and sweating. Headache, salivation, nausea, vomiting, abdominal pain and diarrhea are often prominent. A life-threatening poisoning is signified by loss of consciousness, incontinence, convulsions and respiratory depression with a secondary cardiovascular component. Treat symptomatically. If exposed, plasma and red blood cell cholinesterase tests may indicate degree of exposure (baseline data are useful). However, if a blood sample is taken several hours after exposure, it is unlikely that blood cholinesterase activities will be depressed, due to rapid reactivation of cholinesterase. Atropine, only by injection, is the preferable antidote. Do not use pralidoxime. In cases of severe acute poisoning, use antidotes immediately after establishing an open airway and respiration. With oral exposure, the decision of whether to induce vomiting or not should be made by an attending physician."

b. Under PRECAUTION STATEMENTS, **add**, as applicable:

"THIS PRODUCT IS NOT TO BE USED INSIDE OR AROUND HOMES, OR ANY OTHER PLACE WHERE CHILDREN OR PETS ARE LIKELY TO BE PRESENT."

"Wear cotton coveralls over a long-sleeved shirt, long pants, shoes plus socks and chemical-resistant gloves."

2. **Restricted Class Product (Reg. No. 10868)**

a. Under PRECAUTION STATEMENTS,

i. add:

"Apply only when the potential for drift to areas of human habitation or areas of human activity (houses, cottages, schools and recreational areas) is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings."

ii. **replace**:

"Wear coveralls over a long-sleeved shirt and long pants, chemical resistant gloves, socks, chemical resistant footwear, goggles or face shield, and either a respirator with a

NIOSH/MSHA/MHSE approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH/MSHA/BHSE approved canister approved for pesticides during mixing, loading, application, clean-up and repair."

with:
"Wear coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, socks, chemical resistant footwear, goggles or face shield, and a respirator with a NIOSH-approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH-approved canister approved for pesticides during mixing, loading, application, clean-up and repair."

iii. **add**:
Handheld Application: "For mechanically-pressurized handguns: Do not handle more than 2.36 kg ai in a day (485 L at the rate of 0.486 kg a.i./ha and spray volume of 100 L/ha). These restrictions are in place to minimize exposure to individual applicators. Application may need to be performed over multiple days or using multiple applicators."

b. Under DIRECTIONS FOR USE,

i. **add**:
"For outdoor use only."

"DO NOT enter or allow worker entry into treated areas during the Restricted Entry Interval (REI) of 12 hours."

"DO NOT apply methomyl on broccoli, Brussels sprouts, cabbage, cauliflower and sweet corn after August 15th to reduce the potential for this product to enter groundwater."

"**DO NOT GRAZE OR HARVEST FOR LIVESTOCK FEED**"

ii. **Remove** all text and the tables associated with REIs (page 11).

c. In the minor use box labelled "NOTE TO USER: READ THE FOLLOWING BEFORE USING THIS PRODUCT FOR THE INDICATED SPECIAL USE APPLICATIONS" on page 12, **remove** text and table related to REIs and **add**:

"For outdoor use only."

"DO NOT enter or allow worker entry into treated areas during the Restricted Entry Interval (REI) of 12 hours."

"DO NOT apply methomyl on sweet corn after August 15th to reduce the potential for this product to enter groundwater."

4. **Commercial and Restricted Class Products**

a. Under DIRECTIONS FOR USE, **add**:
"Not for use in residential areas. Residential areas are defined as sites where bystanders including children may be potentially exposed during or after application. This includes around homes, school, parks, playgrounds, playing fields, public buildings or any other areas where the general public including children could be exposed."

b. Under PRECAUTIONS, **add**:
"May be fatal if swallowed, inhaled or absorbed through the skin or eyes."

Statements To Protect The Environment

1. Restricted Class Products

a. Add to ENVIRONMENTAL HAZARDS:

Toxic to aquatic organisms. Observe buffer zones specified under DIRECTIONS FOR USE.

Toxic to birds and small wild mammals. Any spilled or exposed granules must be incorporated into the soil or otherwise cleaned-up from the soil surface.

Toxic to bees. Bees can be exposed to direct treatment, drift, or residues on flowering crops or weeds.

DO NOT apply this product to flowering crops if bees are visiting the treatment area. Minimize spray drift to reduce harmful effects on bees in habitats close to the application site.

Toxic to certain beneficial insects. Minimize spray drift to reduce harmful effects on beneficial insects in habitats next to the application site such as hedgerows and woodland. Integrated Pest Management (IPM) users should use precaution to avoid application of methomyl insecticide coinciding with the presence of beneficial invertebrates.

This product demonstrates the properties and characteristics associated with chemicals detected in ground water. The use of methomyl insecticide in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination.

To reduce runoff from treated areas into aquatic habitats avoid application to areas with a moderate to steep slope, compacted soil, or clay.

Avoid application when heavy rain is forecast.

Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.

b. Add to DIRECTIONS FOR USE:

Airblast application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** direct spray above plants to be treated. Turn off outward pointing nozzles at row ends and outer rows. **DO NOT** apply when wind speed is greater than 16 km/h at the application site as measured outside of the treatment area on the upwind side.

Buffer zones:

Use of the following spray methods or equipment **DO NOT** require a buffer zone: hand-held or backpack sprayer and spot treatment.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Buffer Zone Table

Method of application	**Crop**		**Buffer Zones (metres) Required for the Protection of:**			
			Freshwater Habitat of Depths:		**Estuarine/Marine Habitats of Depths:**	
			Less than 1 m	**Greater than 1 m**	**Less than 1 m**	**Greater than 1 m**
Airblast	Balsam fir and spruce in Christmas tree plantations	Early growth stage	45	35	25	15
		Late growth stage	35	25	15	5
Ground boom	Cole crops		25	10	5	3
	Corn		20	10	5	3
	Peas		15	10	4	2

For tank mixes, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture and apply using the coarsest spray (ASAE) category indicated on the labels for those tank mix partners.

ADDITIONAL LABEL STATEMENTS

Restricted Class Product (Reg. No. 10868)

1. **Remove** the following uses: balsam fir and spruce in farm woodlots and rights-of-way, apples, barley, canola, flax, lettuce, oats, potatoes, snap beans, tobacco, tomato, and wheat.

2. Under Restricted Uses -Directions For Use (page 6), **replace**:
"LANNATE® Toss-N-Go® Insecticide is a dry powder contained within a water-soluble bag, to be dissolved in water for application by ground or air equipment. Use air application only where recommended. Use only in commercial plantings; do not use in home plantings"

with:

"LANNATE® Toss-N-Go® Insecticide is a dry powder contained within a water-soluble bag, to be dissolved in water for application by ground equipment. Use only in commercial plantings."

3. Under Application (page 6), **replace**:
"Apply at the recommended rates when insects first appear. Apply at 5 to 7 day intervals. Apply the low rates on small plants, small insects and light infestations of insects. Early morning or late evening sprays are recommended"

with:

"Apply at the recommended rates when insects first appear. Apply the low rates on small plants, when insects are small in size and light infestations of insects. Early morning or late evening sprays are recommended."

4. Under Ground Application (page 6), **replace**:
"Use sufficient water to obtain thorough, uniform coverage. Suggested water volumes for conventional ground applications are: 250 to 850 L/ha for broccoli, cauliflower, Brussel sprouts, cabbage, lettuce, tomatoes, and potatoes; 100 L/ha for flax and canola; 100 to 350 L/ha for wheat, oats, barley, snapbeans and peas; 240 to 900 L/ha for sweet corn; 200 to 450 L/ha for tobacco. Rates per hectare for apples are based on using a volume of 3000 litres per hectare"

with:

"Ground application: Use sufficient water to obtain thorough, uniform coverage. Suggested water volumes for conventional ground applications are: 250 to 850 L/ha for broccoli, cauliflower, Brussel sprouts and cabbage; 100 to 350 L/ha for succulent shelled peas; and 240 to 900 L/ha for sweet corn."

5. **Remove** the following statements (page 6):
"Aerial Application: Apply only by fixed-wing or rotary aircraft equipment, which has been functionally and operationally calibrated for the atmospheric conditions of the area and the application rates and conditions of this label. Label rates, conditions and precautions are product specific. Read and understand the entire label before opening this product. Apply only at the rate

recommended for aerial application on this label. Where no rate for aerial application appears for the specific use, this product cannot be applied by any type of aerial equipment. Ensure uniform application. To avoid streaked, uneven or overlapped application, use appropriate marking devices.

Use Precautions:
Apply only when meteorological conditions at the treatment site allow for complete and even crop coverage. Apply only under conditions of good practice specific to aerial application as outlined in the National Aerial Pesticide Application Manual, developed by the Federal/Provincial/Territorial Committee on Pest Management and Pesticides.

Do not apply to any body of water. Avoid drifting of spray onto any body of water or other non-target areas. Specified buffer zones should be observed. Coarse sprays are less likely to drift, therefore, avoid combinations of pressure and nozzle type that will result in fine particles (mist). Do not apply during periods of dead calm or when wind velocity and direction pose a risk of spray drift. Do not spray when the wind is blowing towards a nearby sensitive crop, garden, terrestrial habitat (such as shelter-belt) or aquatic habitat.

Operator Precautions:
Do not allow the pilot to mix chemicals to be loaded onto the aircraft. Loading of premixed chemicals with a closed system is permitted. It is desirable that the pilot have communication capabilities at each treatment site at the time of application. The field crew and the mixer/loaders must wear chemical resistant gloves, coveralls and goggles or face shield during mixing/loading, cleanup and repair. Follow the more stringent label precautions in cases where the operator precautions exceed the generic label recommendations on the existing ground boom label. All personnel on the job site must wash hands and face thoroughly before eating and drinking. Protective clothing, aircraft cockpit and vehicle cabs must be decontaminated regularly."

6. Under Product Specific Precautions (page 7), **replace**:
"Read and understand the entire label before opening this product. If you have questions, call the manufacturer at 1-800-667-3925 or obtain technical advice from the distributor or your provincial agricultural representative. Application of this specific product must meet and/or conform to the following: Pilot should not assist in the mixing and loading operations. Apply a minimum of 22.5 L of water per hectare"

with:

"Read and understand the entire label before opening this product. If you have questions, call the manufacturer at 1-800-667-3925 or obtain technical advice from the distributor or your provincial agricultural representative."

7. **Replace** the Crop method of Application table (Page 7), with the following table:

Site (s)	Pest (s)	Product Rate (grams product / ha)	Maximum Number of Application per Year	PHI	Application instructions
Broccoli	Cabbage looper, imported cabbageworm, diamondback moth	270-540	1	7	Ground application only. Use only in commercial plantings. Latest application date is August 15. Maximum one application/year. Use sufficient water to obtain thorough, uniform coverage. Suggested water volumes for conventional ground applications are: 250 to 850 L/ha for broccoli, cauliflower, Brussel sprouts and cabbage. Applications timing for cabbage looper, imported cabbageworm, diamondback moth: Apply at the recommended rates when insects first appear. Apply the low rates on small plants, when insects are small in size and light infestations of insects. Early morning or late evening sprays are recommended. Application timing for slugs (larvae of grey garden slug): use sufficient water volumes to obtain good coverage. Make application late in the evening.
Brussels sprouts	Cabbage looper, imported cabbageworm, diamondback moth	270-540	1	7	
Brussels sprouts	Slugs (larvae of grey garden slugs)	775		30	
Cabbage	Cabbage looper, imported cabbageworm, diamondback moth	270-540	1	1	
Cauliflower	Cabbage looper, imported cabbageworm, diamondback moth	270-540	1	7	
Sweet corn	Aphids	430-620	1	3	Ground application only. Latest application date is August 15. Maximum one application/year. Use sufficient water to obtain thorough, uniform coverage. Suggested water volumes for conventional ground applications are: 240 to 900 L/ha. Aphids: Apply during hot weather. Corn earworm: Application to begin when 25% of the ears show silk. Direct sprays to the silks. European corn borer: Application to begin when egg masses begin to hatch, but no later than when the first feeding damage is seen on leaves. Sprays should be directed into the whorl of the plant. After tassels appear, direct spray at the ear zone. In areas where the second generation borers may be a problem, late plantings should be treated before tassels are visible. Latest
	Corn earworm	430-625			
	European corn borer	625			

Site (s)	Pest (s)	Product Rate (grams product / ha)	Maximum Number of Application per Year	PHI	Application instructions
					timing of application is early silk stage.
Succulent shelled pea	Alfalfa looper, pea aphid	510	1	1	Ground application only. Maximum one application/year. Use sufficient water to obtain thorough, uniform coverage. Suggested water volumes for conventional ground applications are: 100 to 350 L/ha for succulent shelled peas. Apply when insects first appear. Apply the low rates on small plants, when insects are small in size and light infestations of insects. Early morning or late evening sprays are recommended.

8. **Remove** the following (page 11):
"* Do not apply to Early MacIntosh, Wealthy or Summer Glo Apple varieties. Do not graze livestock in orchard for 10 days after treatment.
** Pilot should not assist in the mixing and loading operations. Apply a minimum of 22.5 L water per ha.
*** LANNATE ® Toss-N-Go® Insecticide may be applied with a sucker control agent. Use on limited acreage until safety to crop is determined.
**** Consult Canadian or Provincial Forestry Service for timing and spray concentrations."

9. In the minor use box labelled "NOTE TO USER: READ THE FOLLOWING BEFORE USING THIS PRODUCT FOR THE INDICATED SPECIAL USE APPLICATIONS" on page 11,
   a. Replace "For control of brown marmorated stink bug in apples and suppression of brown marmorated stink bug in peas, wheat, oats, barley, snap beans, sweet corn and tomatoes"

   with:

   "For suppression of brown marmorated stink bug in succulent shelled peas and sweet corn."
   b. In the Crop method of application table, **remove** the following crops from the table: apples, wheat, oats, barley, snap beans, and tomatoes.
   c. Replace column titled: "Crop/Method of application G-Ground A-Air"
   with: "Crop/Method of application Ground Only"
   d. In the "Max Number of Applications per Year" column for sweet corn, **replace** "3" **with** "1" and **add** "Latest application date is August 15."
   e. Under the Crop/Method of Application table, **replace**:
   "Apply when insects first appear. Continue applications at 5-7 day intervals if monitoring indicates the need. * Do not apply to Early MacIntosh, Wealthy or Summer Glo Apple

varieties. Do not graze livestock in orchard for 10 days after treatment. ** Pilot should not assist in the mixing and loading operations. Apply a minimum of 22.5 L water per ha"

with:

"Apply when insects first appear."

10. **Remove** the following text from page 13, "Aerial application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply when wind speed is greater than 16 km/h at flying height at the site of application. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) fine classification.

    To reduce drift caused by turbulent wingtip vortices, the nozzle distribution along the spray boom length **MUST NOT** exceed 65 % of the wing- or rotorspan."

11. Remove reference to Aerial application in the buffer zone table on page 13.

Appendix IV Dietary Exposure and Risk Estimates for Methomyl*

Table 1 Summary of Acute Dietary Exposure and Risk from Methomyl

Population Subgroup	Acute Dietary (99.9^{h} percentile)[1]			
	Food only		Food + Water	
	Exposure (mg/kg bw)	%ARfD	Exposure (mg/kg bw)	%ARfD
General Population	0.000158	23	0.000181	26
All Infants (< 1 year old)	0.000448	64	0.000506	72
Children 1-2 years old	0.000534	76	0.000547	78
Children 3-5 years old	0.000389	56	0.000364	52
Children 6-12 years old	0.000238	34	0.000235	34
Youth 13-19 years old	0.000087	12	0.000108	15
Adults 20-49 years old	0.000095	16	0.000118	17
Adults 50-99 years old	0.000186	27	0.000197	28
Females 13-49 years old	0.000108	16	0.000128	18

[1]Acute Reference Dose (ARfD) of 0.0007 mg/kg bw.

Table 2 Summary of Chronic Dietary Exposure and Risk from Methomyl

Population Subgroup	Chronic Dietary[1]			
	Food only		Food + Water	
	Exposure (mg/kg bw/day)	%ADI	Exposure (mg/kg bw/day)	%ADI
General Population	0.000002	0.2	0.000090	13
All Infants (< 1 year old)	0.000002	0.3	0.000334	48
Children 1-2 years old	0.000006	0.8	0.000128	18
Children 3-5 years old	0.000004	0.6	0.000103	15
Children 6-12 years old	0.000002	0.3	0.000076	11
Youth 13-19 years old	0.000001	0.1	0.000064	9
Adults 20-49 years old	0.000001	0.1	0.000089	13
Adults 50+ years old	0.000002	0.2	0.000087	13
Females 13-49 years old	0.000001	0.2	0.000088	13

[1]Acceptable Daily Intake (ADI) of 0.0007 mg/kg bw/day.

* Based on revised use pattern.

Appendix V Environmental Exposure Estimates for Methomyl

The following sections review the estimated environmental concentrations (EECs) of methomyl resulting from water modelling based on the revised use pattern.

Methomyl was modelled for use on cole crops, peas, corn and Christmas trees. Application information and the main environmental fate parameters used in the models are summarized in the table below.

Table 1 Major groundwater and surface water model inputs for assessment of methomyl

Parameter	Cole crops	Peas	Corn	Christmas Trees
Application Information				
Maximum rate each application (g a.i./ha)	486 and 698	459	563	486
Maximum number of applications per year	1	1	1	2
Initial application dates	May to mid-August	May to October	May to mid-August	April and May
Method of application	Foliar spray	Foliar spray	Foliar spray	Foliar spray
Environmental Fate Characteristics				
Hydrolysis half-life at pH 7 (days)	378	378	378	378
Photolysis half-life in water (days)	1	1	1	1
Adsorption K_d (mL/g)	0.24	0.24	0.24	0.24
Aerobic soil biotransformation half-life (days)	13.3	13.3	13.3	13.3
Aerobic aquatic biotransformation half-life (days)	5	5	5	5
Anaerobic aquatic biotransformation half-life (days)	stable	stable	stable	stable

2.2 Aquatic Ecoscenario Assessment: Level 1 Modelling

For Level 1 aquatic ecoscenario assessment, estimated environmental concentrations (EECs) of methomyl from runoff into a receiving water body were simulated using the Pesticide in Water Calculator (PWC) model. The PWC model simulates pesticide runoff from a treated field into an adjacent water body and the fate of a pesticide within that water body. For the Level 1 assessment, the water body consists of a 1 ha wetland with an average depth of 0.8 m and a drainage area of 10 ha. A seasonal water body was also used to assess the risk to amphibians, as

a risk was identified at the screening level. This water body is essentially a scaled down version of the permanent water body noted above, but having a water depth of 0.15 m.

Five or six crop-specific regional scenarios were modelled to represent different regions of Canada. A range of initial application dates was modelled for each crop-scenario case. Table 1 lists the application information and the main environmental fate characteristics used in the simulations.

The EECs are for the portion of the pesticide that enters the water body via runoff only; deposition from spray drift is not included. The models were run for 50 years for all scenarios.

The EECs are calculated from the model output from each run as follows. For each year of the simulation, PWC calculates peak (or daily maximum) and time-averaged concentrations. The time-averaged concentrations are calculated by averaging the daily concentrations over five time periods (96-hour, 21-day, 60-day, 90-day, and 1 year). The 90th percentiles for the peak and 21 day averaging period are reported as the EECs for that period.

The largest EECs of all selected runs of a given crop are reported in Table 2 below.

Table 2 Level 1 aquatic ecoscenario modelling EECs (µg a.i./L) for methomyl in a water bodies 0.8 m and 0.15m deep, ignoring spray drift

Crop	EEC (µg a.i./L)			
	0.8 m water depth		0.15 m water depth	
	Peak	21-day	Peak	21-day
Brussels sprouts (0.486 g a.i./ha)	47	18	252	64
Brussels sprouts (0.698 g a.i./ha)	68	26	362	92
Corn (0.563 g a.i./ha)	95	33	505	117
Peas (0.459 g a.i./ha)	67	23	359	82
Christmas Trees (2 × 496 g a.i./ha)	8.0	3.9	43	12.1

References

Published Information

Human Health

PMRA Document Number	Reference
Toxicology	
1585238	1994. Genotoxic effects of the carbamate insecticide, methomyl. I. In vitro studies with pure compound and the technical formulation, “Lannate 25”. Environmental and Molecular Mutagenesis, 23(4): 306-311. DACO: 4.5.4
1585239	1994. Genotoxic effects of the carbamate insecticide, methomyl. II. In vivo studies with pure compound and the technical formulation, “Lannate 25”. Environmental and Molecular Mutagenesis, 24(3): 235-242. DACO: 4.5.4
1585240	1997. Assessment of the ability of propoxur, methomyl, and aldicarb, three carbamate insecticides, to induce micronuclei in vitro in cultured Chines hamster ovary cells and in vivo in BALB/c mice. Environmental and Molecular Mutagenesis, 29(4): 386-393. DACO: 4.5.4