Proposed Re-evaluation Decision PRVD2016-02

Methomyl

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Overview

Proposed Re-evaluation Decision for Methomyl

Health Canada's Pest Management Regulatory Agency (PMRA) has now completed the risk and value assessments for methomyl. This revised assessment is based on consideration of the comments and submitted data in response to REV2009-02, changes to the use pattern outlined in REV2010-08 and any regulatory changes in other countries. Under the authority of the *Pest Control Products Act*, the PMRA is proposing continued registration of certain uses of methomyl in Canada.An evaluation of available scientific information found that:

- Non-food uses of methomyl continue to have value and do not present an unacceptable risk to human health or the environment, when used according to revised label directions. Non-food uses include application to balsam fir and spruce in Christmas tree plantations, farm woodlots and rights-of-way, and as granular baits in barns, poultry houses, feedlots and kennels.
- Based on the human health risk assessment,food and feed uses of methomyl, including use on tobacco,are being proposed for cancellation and all established maximum residue limits (MRLs) for methomyl are proposed for revocation.

This proposal affects all end-use products containing methomyl registered in Canada. Once the final re-evaluation decision is made, the 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 methomyl 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 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 assessment of methomyl.

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 (please see contact information indicated on the cover page of this document).

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

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

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[2] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use of or exposure to the product under its conditions or proposed conditions of registration. 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, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management section of Health Canada's website.

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

What is Methomyl?

Methomyl is a carbamate insecticide, used to control a broad range of insect pests on a wide variety of sites including forests and woodlots, ornamental spruce and fir trees, terrestrial feed and food crops, industrial oilseed and fibre crops, and structures (in other words, farm buildings). It is applied using conventional ground and aerial application equipment by farmers, farm workers and professional applicators.

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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".

Health Considerations

Can Approved Uses of Methomyl Affect Human Health?

Non-food uses of methomyl are unlikely to affect your health when used according to the revised label directions. Based on the human health risk assessment, all food and feed uses of methomyl, including use on tobacco, are being proposed for cancellation.

Potential exposure to methomyl may occur through the diet (in other words, food and drinking water), when applying the product or by entering treated sites. When assessing health risks, two key factors are considered: the levels at which no health effects occur in animal testing 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). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

In laboratory animals, the technical grade active ingredient methomyl was of high acute toxicity by the oral route. It was of low acute toxicity dermally and of moderate toxicity through inhalation exposure. Methomyl was non-irritating to eyes and skin, but highly toxic via the eyes. Methomyl did not cause an allergic skin reaction.

Short- and long-term (lifetime) animal toxicity tests were assessed for the potential of methomyl to cause neurotoxicity, immunotoxicity, chronic toxicity, cancer, reproductive and developmental toxicity, and various other effects. The most sensitive endpoint used for risk assessment was the effect on the nervous system (decreased cholinesterase activity). When methomyl was given to young animals, effects on cholinesterase activity indicated that the young were more sensitive to methomyl than the adult animal. The risk assessment takes this sensitivity into account in determining the allowable level of human exposure to methomyl.

Residues in Water and Food

Based on the human health risk assessment, all food and feed uses of methomyl, including use on tobacco, are being proposed for cancellation.

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 drinking water is acceptable if it is less than 100% of the acute reference dose or chronic reference dose (acceptable daily intake). An acceptable daily intake (ADI) 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 methomyl was calculated based on residues in treated crops and drinking water. Exposure was determined for the general population, as well as various subpopulations including children. Residue estimates in food were mostly based on monitoring data from the United States Department of Agriculture (USDA) Pesticide Data Program as well as the Canadian Food Inspection Agency (CFIA) National Chemical Residue Monitoring Program. Residues in drinking water were based on modelling data.

Acute risk concerns were identified from exposure to food only as well as exposure from drinking water only. The acute exposure from food was 79% of the acute reference dose for the general population and ranged from 47% to 211% for the various subpopulations. Of note, acute exposures were 174, 211 and 152% for infants (less than 1 years of age), children aged 1 to 2 years, and children aged 3 to 5 years, respectively. Acute exposure from drinking water exceeded 100% of the acute reference dose for the general population and all subpopulations. Chronic exposure from food only was less than 8% of the ADI for the general population and all subpopulations. Chronic exposure from drinking water exceeded 100% of the ADI for one population subgroup: infants at 158% of the ADI.

Aggregate risk due to exposure from both food and drinking water combined was not assessed, as potential concerns were identified from the individual pathways of exposure.

The *Food and Drugs Act* prohibits the sale of adulterated food; that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act.* Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in/on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Canadian MRLs for methomyl are currently established for apple, blueberry, cabbage, celery, citrus fruit, grape, lettuce, strawberry and sweet corn kernel plus cob with husks removed. Residues in all other agricultural commodities, including those approved for treatment in Canada but without a specific MRL, are regulated under subsection B.15.002(1) of the Food and Drugs Regulations, which requires that residues not exceed 0.1 ppm. Additional details regarding MRLs can be found in the Science Evaluation section of this consultation document. Since all food uses of methomyl are being proposed for cancellation, established MRLs for methomyl are being proposed for revocation. This will ensure that residues in food do not pose any health risk concerns.

Risks in Residential and Other Non-Occupational Environments

Residential risks are not of concern.

As methomyl is currently registered for use on apple trees, potential residential exposure may occur following application by commercial applicators to apple trees in residential areas. No residential risks of concern were identified for this use. Since all food and feed uses are proposed for cancellation, this scenario is not expected to occur.

Potential exposure may also occur from “Pick Your Own” facilities or commercial farming operations that allow public access for harvesting in large-scale fields or orchards treated with commercially labelled methomyl products. However, since all food uses are proposed for cancellation, exposure in Pick Your Own facilities is not expected to occur and was not included in this assessment.

Occupational Risks

Occupational risks to handlers are not of concern provided additional risk reduction measures are observed.

Occupational risk assessments for handlers consider exposure to workers who mix, load and apply methomyl. For the uses proposed for continued registration (in other words, application to balsam fir and spruce in Christmas tree plantations, farm woodlots and rights-of-way, and as granular baits in barns, poultry houses, feedlots and kennels), handler risks are not of concern with risk mitigation measures. These measures include personal protective equipment and limits on amount of product handled per day. These measures are needed to minimize potential exposure and protect workers’ health.

Postapplication risks are not of concern provided additional risk reduction measures are observed.

Postapplication occupational risk assessments consider exposures to workers entering treated sites. For the uses proposed for continued registration, postapplication risks are not of concern. A restricted-entry interval of 12 hours is required for postapplication activities that may occur following application to balsam fir and spruce in Christmas tree plantations, farm woodlots and rights-of-way.

Environmental Considerations

What Happens When Methomyl Is Introduced into the Environment?

When used according to the label directions, methomyl is not expected to pose an unacceptable risk to the environment.

Methomyl can enter non-target terrestrial and aquatic habitats through spray drift and can enter aquatic habitats through run-off and leaching. It is slightly persistent in some soils, but is not expected to accumulate over time. Methomyl is soluble in water and can move through the soil profile, and potentially reach ground water. In aquatic environments, methomyl is non-persistent and does not accumulate. It is not likely to accumulate in plant and animal tissues.

Under controlled laboratory conditions, methomyl can be toxic to some non-target species such as bees, beneficial insects, birds, wild mammals, aquatic invertebrates, amphibians and fish.

If methomyl is used at labelled application rates without any risk reduction measures, it may cause adverse effects in the organisms listed above. Therefore, mitigation measures are required in order to reduce potential exposure of non-target organisms and reduce environmental risks.

When methomyl is used in accordance with the label and the mitigation measures have been applied, the reduced environmental exposure is deemed adequate and the risk is considered to be acceptable.

Value Considerations

What is the Value of Methomyl?

Methomyl is absorbed by the host plant in addition to providing contact action.

Methomyl is effective in two ways: (a) as a contact insecticide, killing target insects upon direct contact, and (b) as an insecticide that works by killing target insects upon ingestion of treated plants. Methomyl is absorbed and transported throughout the plant, imparting protection to the entire plant. It is effective against insects with piercing-sucking mouthparts, such as aphids and thrips, since it moves within the vascular tissues where aphids feed and into cells where thrips feed.

Methomyl is effective for the control of pests such as:

- chewing insects once they enter the host plants: corn earworm and European corn borer larvae tunnel into the midrib of the leaf and migrate into the stalk of the plant, or husk of the ear
- insects, such as thrips, beet armyworm and slugs that hide within the developing plant leaves while feeding and are protected from direct contact with insecticidal sprays

Methomyl has a unique application method for the control of slugs on Brussels sprouts.

There are few registered alternatives to methomyl for control of slugs on this crop. Methomyl is registered to control slugs on Brussels sprouts as a spray. In contrast, the alternative active ingredients to methomyl are formulated for use as baits, which may not be as effective when alternate food sources are available, such as when crops are mature.

Methomyl is of value for pest management in agriculture in Canada.

There are no viable alternatives to methomyl for the control of beet webworm and clover cutworm on canola in Eastern Canada. Resistance management is a concern for these pests in Western Canada since deltamethrin (MoA group 3) is the only registered alternative active ingredient to methomyl and is registered for this use in Western Canada only.

There are few viable alternatives to methomyl for the control of alfalfa looper on peas and canola; bertha armyworm on flax; and for the control of thrips on barley, oats and wheat.

Methomyl (MoA group 1A) is required for rotation with insecticides with a different mode of action to delay the development of resistance. Examples are as follows:

- Acetamiprid (MoA group 4) is the only viable alternative active ingredient to methomyl for the control of aphids on sweet corn
- Chlorantraniliprole (MoA group 28) is the only active ingredient with local systemic available for rotation with methomyl for the control of corn earworm on sweet corn

Proposed Measures to Minimize Risk

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

Risk mitigation measures affecting the use pattern of methomyl were implemented in REV2010-08. These included (a) removal of the use of methomyl on strawberries and in residential areas and parks, as these uses were no longer supported by the registrant, (b) clarification of the maximum number of applications per season, and (c) inclusion of restricted-entry intervals.

Based on the health risk assessment, the PMRA proposes to cancel all food and feed uses of methomyl. Consequently, all MRLs are proposed for revocation. Continued registration with additional risk mitigation measures is proposed for non-food uses: application to balsam fir and spruce in Christmas tree plantations, farm woodlots and rights-of-way, and granular baits in barns, poultry houses, feedlots and kennels.

Risk reduction measures are being proposed to address potential risks identified in this assessment. These measures, in addition to those already identified on existing methomyl product labels, are designed to further protect human health and the environment. The following additional key risk-reduction measures are being proposed for non-food uses of methomyl.

Additional Key Risk Reduction Measures

Human Health

To protect mixer/loader/applicators:

- Ensure they wear additional personal protective equipment.
- Limit the amount of product used per day when using mechanically pressurized handguns.

To protect workers entering treated sites:

- A Restricted-entry interval of 12 hours for balsam fir and spruce in Christmas tree plantations, farm woodlots and rights-of-way.

To protect the general public and bystanders:

- A statement clarifying that bait products are limited to agricultural use (in other words, not for use in residential areas).
- A statement to promote best management practices to minimize human exposure from spray drift or spray residues resulting from drift.

To reduce the potential for accidental ingestion of granular bait products:

- A statement clarifying that bait products should not be used where children or pets are likely to be present.

Environment

- Advisory statements to inform users that methomyl is toxic to non-target organisms including bees, beneficial insects, birds, mammals, aquatic invertebrates, fish, frogs and other amphibians.
- Advisory statements to minimize 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

Before making a final re-evaluation decision on methomyl, the PMRA will consider any comments received from the public in response to this consultation document.[4] A science-based approach will be applied in making a final decision on methomyl. The PMRA will then publish a Re-evaluation Decision[5] that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA response to these comments.

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

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

Science Evaluation

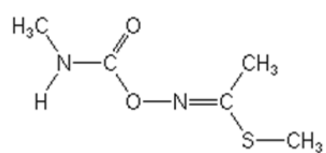
1.0 Introduction

Methomyl is a broad spectrum carbamate insecticide belonging to the resistance management mode of action (MoA) Group 1A, making it an acetylcholinesterase inhibitor. It works by contact and stomach action.

Following the re-evaluation announcement for methomyl, E.I. Dupont Canada Company, the registrant of the technical grade active ingredient (TGAI) and primary data provider in Canada indicated that it intends to continue to support all uses included on the labels of Commercial Class and/or Restricted Class end-use products (EPs), except for use in residential areas, municipal parks and on strawberries.

2.0 The Technical Grade Active Ingredient, Its Properties and Uses

2.1 Identity of the Technical Grade Active Ingredient

Common Name		Methomyl
Function		Insecticide
Chemical Family		Carbamate
Chemical Name		
1	**International Union of Pure and Applied Chemistry (IUPAC)**	*S*-methyl (*EZ*)-*N*-(methylcarbamoyloxy)thioacetimidate
2	**Chemical Abstracts Service (CAS)**	Methyl *N*-[[(methylamino)carbonyl]oxy]ethanimidothioate
CAS Registry Number		16752-77-5
Molecular Formula		$C_5H_{10}N_2O_2S$
Structural Formula		
Molecular Weight		162.2

Registration Number	Purity of the Technical Grade Active Ingredient (%)
19139	98.7
29457	99.7

Based on the manufacturing process used, impurities of human health or environmental concern as identified in the *Canada Gazette*, Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25), including TSMP Track 1 substances, are not expected to be present in the product.

2.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Result
Vapour pressure at 25°C	0.72 mPa
Ultraviolet (UV)/visible spectrum	Not expected to absorb at λ > 350 nm
Solubility in water at 25°C	57.9 g/L
n-Octanol/water partition coefficient	log K_{ow} = 0.093
Dissociation constant	Not applicable since methomyl does not have a dissociable moiety.

2.3 Description of Registered Methomyl Uses

Appendix I lists all methomyl products that were registered as of 17 July 2014 under the authority of the *Pest Control Products Act*, excluding those products that are to be discontinued, or for which a submission to discontinue the product registration has been received by the PMRA. Appendix II lists all of the uses for which methomyl is registered.

Uses of methomyl belong to the following use-site categories: forests and woodlots, industrial oilseed crops and fibre crops, terrestrial feed crops, terrestrial food crops, outdoor ornamentals (spruce and fir trees) and structural (farm buildings).

3.0 Human Health

3.1 Toxicology Summary

A detailed review of the toxicological database for the technical grade active ingredient, methomyl, was conducted. The database is complete and consists of the full array of toxicity studies currently required for hazard assessment purposes. All of these toxicity studies were conducted in accordance with the accepted international testing protocols and Good Laboratory Practice at that time. The scientific quality of the data is high and the database is considered adequate to define the majority of the toxic effects that may result from exposure to methomyl.

Pharmacokinetic studies in the rat and monkey showed that methomyl was rapidly absorbed and predominantly eliminated in the urine and expired air with a minimal amount excreted in the feces. Methomyl did not appear to accumulate appreciably in tissues. Excretion patterns did not appear to be significantly influenced by species, sex, dose level or duration of dosing. There are three metabolic pathways for methomyl: i) the displacement of the S-methyl moiety by glutathione and enzymic transformation to give the mercapturic derivative, ii) hydrolysis releasing methomyloxime, which is rapidly broken down to carbon dioxide and iii) in vivo isomerization of syn-methomyl to the anti-methomyl isomer, which upon hydrolysis produces anti-methomyloxime. This metabolite may then undergo a Beckman rearrangement and elimination reaction to form acetonitrile.

In acute toxicity studies in rats, methomyl was highly toxic by the oral route, moderately toxic via the inhalation route and of low toxicity by the dermal route of administration. Acute toxic effects, consistent with N-methyl carbamates, included tremors, salivation, miosis, incoordination, lethargy and breathing difficulties. Methomyl was non-irritating to rabbit eyes and skin, but highly toxic via the eyes. Methomyl did not cause skin sensitization in guinea pigs.

Methomyl consistently demonstrated clinical signs of toxicity indicative of anticholinesterase activity. This effect on cholinesterase activity was noted in various species throughout the database and reflected the mode of action of the N-methyl carbamate class of chemicals. When reviewing the toxicity studies for methomyl, a notable difference was observed between the effects of gavage and dietary dosing. Greater cholinergic toxicity with gavage dosing was attributed to higher peak exposures than those obtained in dietary studies. Clinical signs and cholinesterase inhibition were rarely seen in dietary studies because of the rapid reversibility that likely occurred during periods of feeding. Rats tolerated chronic dietary dose levels that were equivalent to or even exceeded the LD_{50} in acute gavage studies. Repeat-dose dietary administration pointed to an effect on erythropoiesis. Anemia and/or pathology of the spleen and bone marrow were noted across species (rat, mouse and dog). Comparison of the dietary short and long-term studies in the rat did not suggest a pronounced increase in toxicity with increased duration of dosing. No pronounced gender or species differences were apparent.

Administration of methomyl to hens in an acute delayed neurotoxicity study illustrated no evidence of delayed neurotoxicity. In an acute neurotoxicity study in the rat, cholinesterase inhibition was observed at the earliest sampling timepoint of 30 minutes after acute dosing, returning to normal by 24 hours, with clinical signs of tremors occurring at higher doses. Published studies confirmed that peak cholinesterase inhibition occurred 15-30 minutes following acute oral exposures. In a subchronic neurotoxicity study in the rat, clinical signs associated with neurotoxicity were more pronounced than levels of cholinesterase inhibition. No neuropathology findings were noted in the database.

Numerous studies were available on the mutagenic potential of methomyl. Tests included gene mutation, DNA damage studies, and structural chromosome aberrations along with other mutagenic mechanisms. Methomyl did not show mutagenicity or cause primary DNA damage in bacterial or mammalian cells in vitro. It did show an increase in micronuclei and chromosomal aberrations in human lymphocytes in vitro. Positive results were also obtained for DNA damage in vivo in the mouse. Methomyl, however, did not show evidence of carcinogenicity in the mouse or rat.

Methomyl is a metabolite of thiodicarb and is structurally related to it. Thiodicarb is a pesticide classified as a B2 probable human carcinogen by USEPA. However, thiodicarb is not a degradate of methomyl, thus tempering this concern. Two animal metabolites of methomyl of potential concern are acetamide and acetonitrile. Acetamide was classified as a group C possible human carcinogen by USEPA. EPA concluded that acetamide in the diet was not a carcinogenic hazard since i) the conversion rate of methomyl to acetamide was low (~2-3%), therefore residue levels should be low, ii) the carcinogenicity studies with methomyl were negative, iii) methomyl is comprised of 98.7% syn-isomer and 0.092% anti-isomer; syn-isomer must be converted to anti-isomer before acetamide is formed, and iv) acetamide induced liver tumours in rats only when administered at very high dosages (in other words, > 1000 mg/kg bw/day). USEPA also concluded that acetonitrile in the diet was not a carcinogenic hazard because it is volatile, residues are small, it has little or no cancer potential and its toxicity was accounted for in the negative methomyl carcinogenicity studies. Lastly, it was shown in the literature that synthesized nitrosomethomyl was mutagenic in vitro and was capable of producing stomach tumours in rats. However, when methomyl was incubated with nitrite and macerated meat under simulated stomach conditions, there was no evidence that nitrosomethomyl was formed. In summary, methomyl was not considered to pose a carcinogenic risk to humans based on the available data.

The multi-generation reproduction study, with reduced weight gains in the parents and offspring at the lowest dose tested, did not show sensitivity of the young. Birth weights were reduced at levels causing maternal toxicity, which included reduced weight gain and food intake in both parental generations and anemia and some clinical signs (body tics) in the first generation. More severe effects were noted at the highest dose in parents (clinical signs) and offspring (increased stillborn and decreased pup survival). Developmental toxicity studies in rats and rabbits did not show evidence of sensitivity of the young following in utero exposure. The pronounced difference between gavage and dietary dosing was evident in the rat developmental toxicity studies, with an approximate 10-fold higher toxicity via gavage dosing. Malformations were noted in the rat gavage study, but only at levels causing severe maternal toxicity including death. Studies in rabbits did not elicit any teratogenic effects, but clinical signs indicating neurotoxicity were visible at high doses. An increase in variations was seen in rabbit fetuses, but only at a maternally toxic dose. Although sensitivity of the young was not seen in the reproduction and developmental toxicity studies, it should be noted that cholinesterase activity (identified in most neurotoxicity studies as the most sensitive endpoint) was not assessed in these studies.

To address the uncertainty associated with sensitivity of the young, a comparative cholinesterase assay was performed in rats, assessing erythrocyte and brain cholinesterase activity in pups and young adults following acute exposure. Toxicologically significant effects were observed at the lowest dose tested in both populations, with sensitivity demonstrated in the younger population. Benchmark dosing analysis confirmed the relative sensitivity for brain cholinesterase inhibition in the pup when compared to adults, the pup being approximately three times more sensitive than the adult. Therefore, the young were considered to be the most sensitive population.

Results of the toxicology studies conducted on laboratory animals with methomyl, along with the toxicology endpoints for use in the human health risk assessment, are summarized in Tables 1 and 2 of Appendix III.

3.1.1 *Pest Control Products Act* Hazard Characterization

For assessing risks from potential residues in food or from products used in or around homes or schools, the *Pest Control Products Act* requires the application of an additional 10-fold factor to threshold effects. This factor should take into account the completeness of the data with respect to the exposure of, and toxicity to, infants and children as well as potential pre- and post-natal toxicity. A different factor may be determined to be appropriate on the basis of reliable scientific data.

With respect to the completeness of the toxicology database as it pertains to the exposure of and toxicity to infants and children, data of high quality was available for methomyl. The database included one developmental toxicity study in rats, one developmental toxicity study in rabbits, a multi-generation reproduction study in rats, and a comparative cholinesterase assay in juvenile and young adult rats.

With respect to identified concerns relevant to the assessment of risk to infants and children, the prenatal developmental toxicity studies in rats and rabbits provided no indication of increased susceptibility of fetuses to in utero exposure. In the rat developmental study, malformations occurred at levels causing severe maternal toxicity including death. While malformations are considered serious, the degree of concern is tempered by the accompanying maternal toxicity. It is recognized that maternal toxicity of such severity could, in and of itself, bring about adverse consequences in the young. Studies in rabbits did not elicit any teratogenic effects, but clinical signs indicating neurotoxicity were visible at high-dose levels. An increase in fetal variations was seen in the rabbit developmental study, but only at a maternally toxic dose. In the multigeneration reproduction study, severe effects were noted at the highest dose level, both in the parents (reduced weight gain, food consumption and clinical signs) and in the offspring (increased stillborn and decreased pup survival).

Although developmental and reproductive toxicity studies did not indicate an increased sensitivity of the young in rat or rabbit species, based on in utero exposures, the assessment of cholinesterase inhibition was lacking. The comparative cholinesterase assay indicated increased sensitivity of juveniles when compared with young adults. Effects on cholinesterase activity levels in the young were not assessed following in utero or lactational (in other words, "indirect") exposures, therefore it is not known whether sensitivity is present via these exposure routes as well. In absence of these data, it is assumed that these subpopulations (fetuses or nursing pups) would demonstrate at most, a comparable degree of sensitivity to that observed in directly dosed young animals. The rapid reactivation of cholinesterase activity associated with methomyl, combined with the placental or lactational transfer necessary for the young to be exposed, makes it unlikely that a higher degree of sensitivity would be observed in the indirectly exposed animal compared to the directly exposed young animal. Therefore, the use of the point of departure for cholinesterase inhibition in the directly dosed young animal for risk assessment is expected to address concerns relating to indirect exposures.

In summary, with regards to the *Pest Control Products Act* factor, the toxicity data are considered complete and the overall level of concern is low. This conclusion is based on the nature and level of concern for the endpoint and the fact that, for certain risk assessments, the endpoint was established from data on the sensitive subpopulation. Where the endpoint from the sensitive subpopulation was not used in the risk assessment, the application of other uncertainty factors serves to address residual concerns as noted above. Accordingly, the *Pest Control Products Act* factor can be reduced to onefold on the basis of these considerations.

Cancer Assessment

There was no evidence of carcinogenicity and therefore, no cancer risk assessment was necessary.

3.2 Dietary Risk Assessment

In a dietary exposure assessment, the PMRA determines how much pesticide residue, including residues in milk and meat, may be ingested with the daily diet. Exposure to methomyl from potentially treated imported foods is also included in the assessment. These dietary assessments are age-specific and incorporate the different eating habits of the population at various stages of life. For example, the assessments take into account differences in children's eating patterns, such as food preferences and the greater consumption of food relative to their body weight when compared to adults. Dietary risk is then determined by comparing the exposure to the dietary reference dose. High toxicity may not indicate high risk if the exposure is low. Similarly, there may be risk from a pesticide with low toxicity if the exposure is high.

The PMRA considers limiting use of a pesticide when risk exceeds 100% of the reference dose. PMRA's Science Policy Note SPN2003-03, *Assessing Exposure from Pesticides, a User's Guide*, presents detailed acute and chronic risk assessment procedures.

In situations where the need to mitigate dietary exposure has been identified, the following options are considered. Dietary exposure from Canadian agricultural uses can be mitigated through changes in the use pattern. Revisions of the use pattern may include such actions as reducing the application rate or the number of seasonal applications, establishing longer pre-harvest intervals, and/or removing uses from the label. In order to quantify the impact of such measures, new residue chemistry studies that reflect the revised use pattern would be required. These data would also be required in order to amend MRLs to the appropriate level. Imported commodities that have been treated also contribute to the dietary exposure and are routinely considered in the risk assessment. The mitigation of dietary exposure that may arise from treated imports is generally achieved through the amendment or establishment of MRLs.

Residue estimates used in the dietary exposure assessment may be conservatively based on the MRLs or the field trial data representing the residues that may remain on food after treatment at the maximum label rate. Surveillance data representative of the national food supply may also be used to derive a more accurate estimate of residues that may remain on food when it is purchased. These include data from the Canadian Food Inspection Agency (CFIA) National

Chemical Residue Monitoring Program and the United States Department of Agriculture (USDA) Pesticide Data Program (PDP). Percentage of crop treated information, food supply data, and experimental processing factors are also included in the assessment when available.

For methomyl, the majority of residue estimates were based on monitoring data from CFIA and USDA. Several samples had detectable residues. A value equal to half of the average limit of detection (LOD) of methomyl was assumed for samples with non-detectable residues, with true zeroes incorporated to account for the percent of crop not treated. For commodities with no monitoring data (dried pulse), anticipated residues from field trial data were used. For commodities with no monitoring data and/or field trial data available (hop, pecan, peppermint and pomegranate), residues were assumed at the general maximum residue limit of 0.1 ppm. The use of monitoring data, percent crop treated information, food supply data, and experimental processing factors resulted in an overall highly refined dietary exposure assessment for methomyl. Although monitoring data are generally assumed to provide more refined estimates of exposure than field trial data, monitoring data may be highly uncertain if most samples are non-detect, the analytical methodology has relatively high limits of detection, and the percentage of crop treated is high. This was the case for methomyl, but still represented the best data available to conduct a refined exposure assessment.

Acute and chronic dietary exposure and risk assessments were conducted using the Dietary Exposure Evaluation Model – Food Commodity Intake Database^{TM} (DEEM-FCID^{TM}, Version 2.14), which uses food consumption data from the USDA Continuing Surveys of Food Intakes by Individuals from 1994 to 1996 and 1998.

The dietary exposure to methomyl was previously assessed in 2005 at a refined level using monitoring residue data from the USDA PDP and the CFIA National Chemical Residue Monitoring Program. The refinement included the use of percent crop treated information and available experimental processing factors. The results of this assessment were included in the preliminary risk and value assessment of methomyl (REV2009-02) published in 2009. At that time, potential dietary risk concerns were identified along with residue chemistry data gaps. Interim label changes, requested as mitigation measures by the PMRA, were described in REV2010-08. As a result, changes to the use pattern were implemented and residue chemistry data were submitted by the registrant to address the identified data deficiencies. Changes to the use pattern included voluntary cancellation of the use on strawberries.

The submitted residue chemistry studies were reviewed (see Appendix V) and deemed adequate. However, some data are still outstanding. Nonetheless, sufficient information was available from the submitted studies and from foreign reviews to characterize the residue chemistry of methomyl and to conduct a dietary risk assessment.

The present dietary risk assessment is a significant update of the 2005 assessment. The assessment was updated by taking into account all implemented changes in the use pattern (including any regulatory changes in other countries) and by using the most recent monitoring data available at the time of re-evaluation (PDP 2008-2009 and CFIA 2008-2010), available percentage crop treated information, and incorporating revised drinking water concentrations obtained from modelling. Moreover, the exposure estimates were compared to revised toxicology reference doses.

For more information on dietary risk estimates or residue chemistry information used in the dietary assessment, see Appendices IV, V and VI. The PMRA response to comments on the preliminary dietary risk assessment (REV2009-02) is in Appendix VIII.

3.2.1 Determination of Acute Reference Dose

General Population (Including Pregnant Women, Infants and Children)

To estimate acute dietary risk (1 day), the acute comparative cholinesterase assay in young rats was selected for risk assessment. In place of a no observed adverse effect level (NOAEL), a benchmark dose level ($BMDL_{10}$) of 0.07 mg/kg bw was determined in post natal day (PND) 11 pups based on inhibition of brain cholinesterase activity. This value was selected since it is based on the most sensitive endpoint available in the database, occurred following a single exposure, is derived from a susceptible population (in other words, the young) and is protective of other neurological and systemic effects. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability have been applied. An additional uncertainty factor for lack of a NOAEL was not required since bench mark dosing analysis was performed. As discussed in the *Pest Control Products Act* Hazard Characterization section, the *Pest Control Products Act* factor has been reduced to onefold. **The composite assessment factor (CAF) is 100.**

The ARfD is calculated according to the following formula:

$$\text{ARfD (gen. pop)} = \frac{BMDL_{10}}{CAF} = \frac{0.07 \text{ mg/kg bw}}{100} = 0.0007 \text{ mg/kg bw of methomyl}$$

The acute reference dose (ARfD) is considered protective of all populations including infants and children.

3.2.2 Acute Dietary Exposure and Risk Assessment

Acute dietary risk is calculated considering the highest ingestion of methomyl that would be likely on any one day, and using food consumption and food residue values. A probabilistic procedure allowed all possible combinations of consumption and residue levels to be combined to estimate a distribution of the amount of methomyl residue that might be consumed individually in a day. A value representing the high end (99.9th percentile) of this distribution is compared to the ARfD, which is the dose at which an individual could be exposed on any given day and expect no adverse health effects. When the expected intake of residues is less than the ARfD, then acute dietary risk is not of concern.

Acute risk concerns were identified from exposure to food only. The acute exposure was 79% of the acute reference dose for the general population and ranged from 47 to 211% for the various subpopulations. Of note, acute exposures were 174 211 and 152% for infants (less than 1 years of age), children aged 1 to 2 years, and children aged 3 to 5 years, respectively.

The PMRA conducted further analysis to determine risk drivers and possible mitigation measures for the acute dietary exposure. As previously discussed, the assessment was highly refined from use of food surveillance data, percent crop treated information and experimental processing factors. For samples with non-detectable residues, PMRA generally assumes one-half the detection limit. However, PMRA may consider conducting a sensitivity analysis in which non-detects are assumed to have true zero residues. In this case, when true zero residues were assumed for non-detect samples, the acute exposure for children was still calculated to be above 100% of the acute reference dose. Therefore, it was concluded that non-detects had no significant impact on the exposure estimates. For commodities on methomyl labels (but with no specific MRLs) for which monitoring data was not available, appropriate field trial data were used when available. Otherwise, the general MRL of 0.1 ppm was assumed. The impact of these assumptions on the risk estimates was minimal. For children, the most exposed population subgroup, residues in grape and apple commodities were the most significant sources of exposure. However, even if these two commodities are removed, the acute exposure for children was calculated as still being of concern (specifically, > 100% ARfD) due to contributions from other commodities.

3.2.3 Determination of Acceptable Daily Intake

General Population (Including Pregnant Women, Infants and Children)

To estimate dietary risk of repeat exposure, the acute comparative cholinesterase study in young rats was selected for risk assessment. In place of a NOAEL, a $BMDL_{10}$ of 0.07 mg/kg bw was determined in PND 11 pups based on inhibition of brain cholinesterase activity. The quick acting and reversible nature of cholinesterase inhibition is considered as justification to default to the acute point of departure, which is lower than the subchronic or chronic NOAELs. In the case of methomyl, long-term daily exposures are considered as multiple acute exposures, each causing transient inhibition of cholinesterase with resulting potential toxicity. Uncertainty factors of 10-fold for interspecies extrapolation as well as 10-fold for intraspecies variability were used to derive the ADI.
An additional uncertainty factor for lack of a NOAEL was not required since bench mark dosing analysis was performed. As discussed in the *Pest Control Products Act* Hazard Characterization section, the *Pest Control Products Act* factor has been reduced to onefold. **The composite assessment factor (CAF) is 100.**

The ADI is calculated according to the following formula:

$$ADI = \frac{BMDL_{10}}{CAF} = \frac{0.07 \text{ mg/kg bw/day}}{100} = 0.0007 \text{ mg/kg bw/day of methomyl}$$

This value was considered to be protective of all populations including infants and children.

3.2.4 Chronic Dietary Exposure and Risk Assessment

The chronic dietary risk was calculated by using the average consumption of different foods and the average residue values on those foods. This expected intake of residues was then compared to the ADI. When the expected intake of residues is less than the ADI, then chronic dietary risk is not of concern.

Chronic exposure from food only was less than 8% of the ADI for the general population and all subpopulations, and is not of concern.

3.3 Exposure from Drinking Water

3.3.1 Concentrations in Drinking Water

Concentrations of methomyl in Canadian drinking water sources were modelled using Pesticide Root Zone Model/Exposure Analysis Modelling System (PRZM/EXAMS) for surface water and Leaching Estimation and Chemistry Model (LEACHM) for groundwater. Refined (Level 2) drinking water concentrations were calculated using crop specific input parameters and reassessing the fate input parameters to choose less conservative values than in a previous Level 1 assessment. The modelling results indicate that methomyl has the potential to leach into groundwater and run-off to surface water.

Methomyl was previously assessed for risks to drinking water in 2005 and 2009, both at Level 1 and Level 2. The current Level 2 modelling incorporates new use patterns and some new fate data. Eight (for surface water) and four (for groundwater) initial application dates between early May and late July were modelled. The model was run for 50 years for all scenarios. The largest estimated environmental concentrations (EECs) of all selected runs are reported in Table 1, which follows.

Table 1 Level 2 Estimated Environmental Concentrations of Methomyl in Potential Drinking Water Sources

Crop	Groundwater EEC (µg a.i./L)		Surface Water EEC(µg a.i./L)					
			Reservoir (P.E.I.)		Reservoir (Que.)		Dugout	
	Daily[1]	Yearly[2]	Daily[3]	Yearly[4]	Daily[3]	Yearly[4]	Daily[3]	Yearly[4]
Lettuce (field), 3 x 0.9 kg a.i./ha, at 5-day intervals	17	16	123	4.8	66	1.9	100	6.1
Sweet corn, 3 x 0.5625 kg a.i./ha, at 2-day intervals	N/M[5]	N/M[5]	83	3.3	N/M[5]	N/M[5]	67	4.0

Notes

1 90th percentile of daily average concentrations.
2 90th percentile of yearly average concentrations.
3 90th percentile of yearly peak concentrations.
4 90th percentile of yearly average concentrations.
5 Not modelled.

The surface water modelling estimates were further refined using regional scenarios and weather information in consideration of specific information and use patterns for the following crops: lettuce, apples, small grains and corn. Results are tabulated in Table 2.

See Appendix XI for details on concentrations in drinking water.

Table 2 Refined Level 2 Estimated Environmental Concentrations of Methomyl in Potential Drinking Water Sources

Crop	Surface Water Estimated Environmental Concentrations (µg a.i./L)													
	Reservoir (B.C.)		Reservoir (Alta.)		Reservoir (Ont.)		Reservoir (Que.)		Reservoir (N.S.)		Reservoir (Sask.)		Dugout (Sask.)	
	Daily[1]	Yearly[2]	Daily[1]	Yearly[2]	Daily[1]	Yearly[2]	Daily[1]	Yearly[2]	Daily[1]	Yearly[2]	Daily[1]	Yearly[2]	Daily[1]	Yearly[2]
Lettuce (field), 3 x 0.9 kg a.i./ha, at 5-day intervals	N/M[3]	N/M[3]	N/M[3]	N/M[3]	N/M[3]	N/M[3]	42	1.3	N/M[3]	N/M[3]	N/M[3]	N/M[3]	N/M[3]	N/M[3]
Apple, 1 x 1.89 kg a.i./ha	4.7	0.15	N/M[3]	N/M[3]	12	0.39	N/M[3]	N/M[3]	28	0.77	N/M[3]	N/M[3]	N/M[3]	N/M[3]
Sweet corn, 3 x 0.5625 kg a.i./ha, at 2-day intervals	2.1	0.095	17	0.47	55	1.6	N/M[3]	N/M[3]	N/M[3]	N/M[3]	N/M[3]	N/M[3]	N/M[3]	N/M[3]
Wheat, Barley, Oats, 2 x 0.486 kg a.i./ha, at 5-day intervals	N/M[3]	N/M[3]	N/M[3]	N/M[3]	N/M[3]	N/M[3]	N/M[3]	N/M[3]	N/M[3]	N/M[3]	18	0.72	22	0.94

Notes

1 Percentile of yearly peak concentrations.
2 90th percentile of yearly average concentrations.
3 Not modelled.

In addition to water modelling, available water monitoring data in Canada and the United States were assessed. Overall, the monitoring data available from Canada and the United States indicate that methomyl is detected very infrequently (< 1% detection frequency) in surface and groundwater (197 detections of methomyl out of a total of 52 170 samples in potential drinking water sources). In Canada, no detections of methomyl were recorded in 474 samples collected over five provinces. In the United States, it was not detected in finished drinking water, and rarely detected in ambient water samples collected from several states in a variety of land uses including agricultural, urban and mixed land use types. Methomyl would not be expected to persist in clear, shallow waters because of its susceptibility to phototransformation. Despite uncertainties associated with the monitoring data, taken as a whole, the data indicate that methomyl is rarely detected in water.

Given that methomyl is rarely detected in water, it is unlikely that humans would be chronically exposed to methomyl residues in surface water. Given the transient nature of methomyl, available monitoring data are unlikely to capture peak concentrations and, as such, the current monitoring data is not appropriate for estimating potential acute exposure (hours to days). Thus, only modelling estimates should be relied upon for short-term exposure estimates.

3.3.2 Drinking Water Exposure and Risk Assessment

To assess risks from drinking water exposure, the highest surface water daily peak EEC of 55 ppb (refined Level 2 value for sweet corn, Table 2) and the highest groundwater yearly average EEC of 16 ppb (Level 2 value for lettuce, Table 1) were used for the acute and chronic assessments, respectively.

To further refine the acute assessment, distribution files of estimates of possible concentrations were used to estimate risk. Approximately 18000 values were generated using the refined Level 2 surface water EECs based on sweet corn.

Acute exposure from drinking water alone exceeded 100% of the ARfD for the general population and all subpopulations for both the surface water and groundwater scenarios. The acute exposure from groundwater was 159% of the ARfD for the general population, and ranged from 119% to 567% for the population subgroups, with infants being the most exposed population subgroup. The acute exposure from surface water was 205% of the ARfD for the general population, and ranged from 157% to 750% for the population subgroups, with infants being the most exposed population subgroup. Therefore, acute exposure from drinking water is of concern.

Chronic exposure from drinking water alone was less than 100% of the ADI for the general population and all subpopulations, with the exception of one subpopulation. For infants, chronic exposure was 158% of the ADI using modelled drinking water concentrations from groundwater.

Aggregate risk due to exposure from both food and drinking water combined was not assessed, as risks were identified from the individual pathways of exposure.

3.4 Occupational and Non-Occupational Risk Assessment

Occupational and non-occupational risk is estimated by comparing potential exposures with the most relevant endpoint from toxicology studies to calculate a margin of exposure (MOE). This is compared to a target MOE incorporating uncertainty factors protective of the most sensitive subpopulation. If the calculated MOE is less than the target MOE, it does not necessarily mean that exposure will result in adverse effects, but mitigation measures to reduce risk would be required.

If a common toxic effect (for example, cholinesterase inhibition) occurs with multiple routes of exposure, risks from these routes are aggregated using an aggregate risk index (ARI). The ARI is a method of measuring combined risk when exposure occurs via multiple routes or pathways and different toxicological points of departure and uncertainty factors are defined for each route. ARIs greater than or equal to one do not require mitigation. The ARI is an extension of the MOE concept. As with the MOE, risk increases as the ARI decreases. If the calculated ARI is less than one, it does not necessarily mean that exposure will result in adverse effects, but mitigation measures to reduce risk would be required.

3.4.1 Toxicology Endpoint Selection for Occupational and Non-Occupational Risk Assessment

For **short-**, **intermediate-** and **long-term dermal risk assessment**, the results of two 21-day dermal toxicity studies in the rabbit were considered for risk assessment. A NOAEL of 90 mg/kg bw/day was established based on hyperactivity and inhibition of brain cholinesterase activity at 500 mg/kg bw/day. It should be noted that dermally, the effects were reversible following a recovery period. The comparative cholinesterase assay illustrated that direct exposure to oral doses of methomyl resulted in greater sensitivity to cholinesterase inhibition in the young compared to adult animals. Since the two 21-day dermal toxicity studies were conducted in adults, there was uncertainty whether or not the sensitivity observed with oral exposures to the young would also be manifested via the dermal route. Additional uncertainty arises as to whether sensitivity can occur in the fetus or nursing infant as a result of an indirect exposure via the mother. This was a concern because the population (including workers) could include pregnant or lactating women, who could potentially pass an indirect dose of methomyl to their offspring. Given the lack of appropriate dermal data (to confirm or refute the sensitivity) or data to assess the potential sensitivity of the fetus or nursing offspring, an additional threefold factor, in the form of a database deficiency, was considered appropriate to protect the young. The magnitude of this factor was supported by the observation that the young were approximately threefold more sensitive than adults to brain cholinesterase inhibition, after direct oral exposure to methomyl. The target MOE selected was 300, accounting for standard uncertainty factors of 10-fold for interspecies extrapolation, 10-fold for intraspecies variability and an extra threefold database deficiency factor for concerns relating to sensitivity of the young. For the residential risk assessment, the *Pest Control Products Act* factor was reduced to onefold. Residual uncertainty with respect to potential sensitivity of the young for cholinesterase effects by the dermal route was addressed through the use of a database deficiency factor.

For **short-**, **intermediate-** and **long-term inhalation risk assessment**, there were no repeat-dose inhalation toxicity studies available that assessed cholinesterase inhibition. Thus, the acute comparative cholinesterase study conducted via the oral route was selected for risk assessment with the assumption that absorption via inhalation is equivalent to oral absorption. In place of a NOAEL, a $BMDL_{10}$ of 0.07 mg/kg bw was determined in PND 11 pups based on inhibition of brain cholinesterase activity. A single dose study was considered appropriate for all durations since repeated daily exposures were considered as multiple acute exposures, each causing transient inhibition of cholinesterase with resulting potential toxicity. For occupational exposures, a MOE of 100 was selected, which includes uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability. For residential exposures, a MOE of 100 was selected, which includes a 10-fold uncertainty factor for interspecies extrapolation, 10-fold uncertainty factor for intraspecies variability and a *Pest Control Products Act* factor of onefold as discussed in the *Pest Control Products Act* Hazard Characterization section. These values were considered to be protective of all worker populations including women who may be pregnant or nursing.

Pick Your Own Apple Scenario

Since use of methomyl on apples is proposed for cancellation, exposure in PYO facilities is not expected to occur and was not included in this assessment.

Aggregate Risk Assessment

Aggregate risk due to exposure from food, drinking water and residential exposure was not assessed, as risks of concern were identified from food exposure alone and drinking water exposure alone.

Dermal Absorption

A dermal absorption value was not required for this assessment as dermal toxicity studies were selected for the dermal risk assessment.

3.4.2 Occupational Exposure and Risk Assessment

Workers may be exposed to methomyl through mixing, loading or applying the pesticide, and when entering a treated site to conduct activities such as scouting and/or handling treated crops or seeds.

The PMRA's initial occupational risk assessment for methomyl based on information available at the time was published in *Re-Evaluation Note: Preliminary Risk and Value Assessments of Methomyl (REV2009-02).* Additional use pattern information, dislodgeable foliar residue data and any other relevant data were requested for possible refinement of the occupational exposure assessment, particularly for greenhouse crops, structures treated with granular bait and to refine restricted-entry intervals for some crops.

The occupational assessment was updated to incorporate the comments and data received in response to REV2009-02. As well, the interim mitigation measures and any changes in the use pattern since the preliminary risk assessment were incorporated. Finally, the revised toxicological endpoint of departure for inhalation exposure and the revised target MOE for dermal exposure were used in the updated risk assessment.

Due to dietary risk concerns, the PMRA is proposing all food uses of methomyl, including tobacco, be cancelled. The current occupational assessment includes the food use applications in order to communicate to stakeholders that the PMRA did consider the comments and data received, and the impact of this information on the risk assessment. However, label statements and mitigation measures are presented only for uses proposed for continuing registration (in other words, application to balsam fir and spruce in Christmas tree plantations, farm woodlots and rights-of-way, and as granular baits in barns, poultry houses, feedlots and kennels).

For more information on occupational risk estimates, see Appendix VII. The PMRA response to comments on the preliminary occupational risk assessment and study review summaries are in Appendix VIII.

Mixer, Loader and Applicator Exposure and Risk Assessment

There are potential exposures to mixers, loaders and applicators. The following supported uses were assessed:

- Mixing/loading wettable powders in water soluble packages;
- Loading granules;
- Airblast application to apples;
- Groundboom application to broccoli, Brussels sprouts, cabbage, cauliflower, lettuce (field), tomatoes (field), canola, peas, snap beans, potato, sweet corn, tobacco, barley, wheat, flax, oats;
- Aerial application to canola, barley, wheat, flax, oats;
- Granular bait by hand application to barns, poultry houses, feedlots and kennels;
- Right-of-way application to balsam fir and spruce in Christmas tree plantations, farm woodlots, rights-of-way;
- Mixing/loading/applying by backpack to balsam fir and spruce in Christmas tree plantations, farm woodlots, rights-of-way;
- Mixing/loading/applying by manually-pressurized handwand to balsam fir and spruce in Christmas tree plantations, farm woodlots, rights-of-way;
- Mixing/loading/applying by mechanically-pressurized handgun to balsam fir and spruce in Christmas tree plantations, farm woodlots, rights-of-way.

Based on the number of applications and timing of application, workers applying methomyl would generally have a short- to intermediate-term (one day to six months) duration of exposure.

Custom applicators may also have intermediate-term exposure for those crops with multiple applications.

The PMRA estimated handler exposure based on different levels of personal protection and the personal protective equipment (PPE) currently required on the product labels:

- Mid-Level PPE: Cotton coveralls over long pants, long-sleeved shirt and chemical-resistant gloves.

- Maximum PPE: Chemical-resistant coveralls over long-sleeved shirt, long pants and chemical-resistant gloves

- Engineering Controls: Represents the use of appropriate engineering controls, such as closed cab tractor or closed loading systems. For airblast applicators, the engineering controls comprised closed cab and mid-level PPE. Engineering controls are limited for handheld application methods.

- Headgear: Open cab airblast, chemical resistant coveralls over long-sleeved shirt, long pants, chemical resistant headgear and chemical-resistant gloves.

- Respirator: a respirator with NIOSH approved organic-vapour removing cartridge with a prefilter approved for pesticides or a NIOSH-approved canister approved for pesticides.

One chemical-specific exposure study was available in the literature (PMRA #2251426 DeVreede, et al., 1998). This study monitored exposure to workers during mixing/loading and application of methomyl to chrysanthemums using a high-volume spray pistol. However, due to study limitations (for example, face/neck exposure was not monitored) and limitations with the study scenario that precluded possible refinements for the risk assessment, this study was not used quantitatively in the risk assessment. The study did support the results of the risk assessment using PHED data.

Dermal and inhalation exposures were calculated using data from the Pesticide Handlers Exposure Database Version 1.1 (PHED). The PHED is a compilation of generic mixer/loader applicator passive dosimetry data with associated software which facilitates the generation of scenario-specific exposure estimates based on formulation type, application equipment, mix/load systems and level of personal protective equipment (PPE). In most cases, PHED did not contain appropriate data sets to estimate exposure to workers wearing coveralls, chemical-resistant coveralls or a respirator. This was estimated by incorporating a 75% clothing protection factor for coveralls, a 90% clothing protection factor for chemical-resistant coveralls, and a 90% protection factor for a respirator into the units of exposures data. Similarly, a 90% protection factor was applied to head and neck dermal units of exposures values for chemical-resistant headgear. Chemical-resistant headgear includes sou'westers, or large brimmed, waterproof hats, and hoods with sufficient neck protection.

Inhalation exposures were based on light inhalation rates (17 Litres/minute) except for backpack applicator scenarios which were based on moderate inhalation rates (27 litres/minute).

Mixer/loader/applicator exposure estimates are based on the best available data at this time. The assessment might be refined with exposure data more representative of modern application equipment and engineering controls.

For all crops and application equipment, the calculated ARIs exceeded one and are not of concern for most application equipment. For handwand and airblast application, engineering controls, personal protective equipment, and limitations on amount handled per day, as summarized in Table VII.1 in Appendix VII, are required to reach an ARI of one. Section 8 summarizes mitigation required for uses proposed for continued registration.

Postapplication Worker Exposure and Risk Assessment

The postapplication occupational risk assessment considered exposures to workers who enter treated sites to conduct agronomic activities involving foliar contact (for example, pruning, thinning, harvesting or scouting). Based on the methomyl use pattern, there is potential for short-term (< 30 days) postapplication exposure to methomyl residues for workers.

Potential exposure of postapplication workers was determined using activity specific transfer coefficients (TC) (PMRA# 2115788) and dislodgeable foliar residue (DFR) values. The DFR refers to the amount of residue that can be dislodged or transferred from a surface, such as the leaves of a plant. A TC is a measure of the relationship between exposure and DFRs for individuals engaged in a specific activity, and is calculated from data generated in field exposure studies. The TCs are specific to a given crop and activity combination (for example, hand harvesting apples, scouting late season corn) and reflect standard agricultural work clothing worn by adult workers. Postapplication exposure activities include (but are not limited to) scouting, hand harvesting, pinching, pruning, and thinning for ornamental and agricultural crops.

Chemical-specific DFR studies submitted to the agency during the comment period for REV2009-02 were considered in the revised postapplication risk assessment.

For workers entering a treated site, restricted-entry intervals (REIs) are calculated to determine the minimum length of time required before workers can safely enter after application to perform tasks involving hand labour. An REI is the duration of time that must elapse before residues decline to a level where performance of a specific activity results in exposures above the target MOE (> 300) for dermal exposure.

Calculated MOEs exceeded the target MOE for most crops and activities on Day 0 (12-hour REI), with the exception of the following:

- Sweet corn (hand harvesting): MOE met the target MOE with a five-day REI
- Apple (thinning): MOE met the target MOE with a two-day REI

Table VII.2 in Appendix VII summarizes the postapplication exposure and risk assessment. All REIs determined from this risk assessment are less than the REIs required for the interim mitigation measures (REV2010-08). Section 8 summarizes REIs required for uses proposed for continued registration.

Postapplication exposure from activities following application of fly bait was considered to be minimal, with very low contact, especially when compared to exposure during application. Therefore, no REI is required for fly baits.

3.4.3 Non-Occupational and Residential Exposure and Risk Assessment

Non-occupational or residential risk assessment estimates risks to the general population, including children/youth, during or after pesticide application.

There are no registered domestic class products for methomyl. However, there is potential for short-term (1-30 days) exposure for adults and youth through contact with transferable residues following commercial application of methomyl to residential apple trees.

Non-Occupational Mixer, Loader and Applicator Exposure and Risk Assessment

As there are no domestic class products registered for methomyl, a mixer/loader/applicator assessment was not required.

Non-Occupational Postapplication Exposure and Risk Assessment

There is potential for exposure to adults and youth through contact with dislodgeable residues following commercial application to residential apple trees. Postapplication risk for residential uses is based on chemical-specific DFR studies. Calculated MOEs for methomyl exceed the target MOE for all activities and sub-populations, which was not of concern. See Table VII.3 of Appendix VII for more information.

As the use of methomyl on apple trees is proposed for cancellation due to dietary risk concerns, exposure in residential areas is not expected to occur.

3.5 Aggregate Risk Assessment

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential and other non-occupational sources, as well as via all known or plausible exposure routes (oral, dermal and inhalation). Aggregate risk estimates are performed for those scenarios where the exposures meet the targets and are not of concern. The likelihood of co-occurrence is also considered prior to aggregation of these scenarios.

Aggregate risk due to exposure from food, drinking water and residential exposure was not assessed, as potential risks of concern were identified from food exposure alone and from drinking water exposure alone.

3.6 Cumulative Risk

The *Pest Control Products Act* requires the Agency to consider the cumulative effects of pest control products that have a common mechanism of toxicity. Methomyl belongs to a group of pesticides classified as N-methyl carbamates. Once all N-methyl carbamate pesticides have been re-evaluated, it will be determined whether a cumulative effects assessment is necessary and if so, this will be performed with all relevant chemicals of the common mechanism group.

3.7 Incident Reports

Since 26 April 2007, registrants have been required by law to report incidents to the PMRA, including adverse effects to health and the environment. Information on the reporting of incidents can be found on the Pesticides and Pest Management portion of Health Canada's website. Incidents were searched and reviewed for the active ingredient methomyl. As of 11 March 2014, there were six human incidents and 67 domestic animal incidents involving methomyl. All domestic animal incidents as well as four of the human incidents involved fly baits containing methomyl and (Z)-9-tricosene. The remaining two human incidents involved products containing methomyl alone.

There was a high degree of association between the symptoms and reported exposure in two of the six human incidents and 63 of 67 domestic animal incidents (94%). Two human cases reported cholinergic symptoms and respiratory distress requiring intubation following one case of intentional ingestion and one case of ocular and dermal exposure. Sixty-three domestic animal incidents had a high degree of association with methomyl. Fifty-eight of these incidents occurred in the United States. The most commonly reported symptoms were drooling, convulsion/tremor, vomiting, weakness, and difficulty breathing. In all of these incidents the animal ate the product, exhibited signs highly consistent with carbamate poisoning within minutes to hours after exposure, and in cases of death, died the same day.

No significant risks were identified in the human incidents in the PMRA database. The Canadian labels currently carry warning statements regarding the oral, ocular and dermal exposure reported in the two incidents.

No significant health risks were identified in the domestic animal incidents. The results of the analysis indicated that improvements to the Canadian labels for scatterbaits containing methomyl could reduce the potential for accidental ingestion of these products. Label changes are described in Section XII.

These incident reports were considered in this evaluation of methomyl.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Summary: Available fate data (Table 1, Appendix X) indicate that methomyl is expected to be slightly or non-persistent in soil, depending on soil type, and non-persistent in water. Methomyl is very soluble in water (58 g a.i./L). It is mobile in soil and has the potential to leach to ground water. Methomyl is unlikely to bioaccumulate (log K_{ow} = 0.6). Phototransformation is not an important route of dissipation of methomyl on soil ($t_{½}$ = 34 d) whereas phototransformation in water is rapid ($t_{½}$ = 1 d), and can be an important route to transformation in clear shallow waters. Aerobic biotransformation in soil occurs relatively rapidly (DT_{50} = 5.2-45 d).

Hydrolysis: Hydrolysis is not expected to be a major transformation route for methomyl at pH evels below 9, as minimal transformation occurred in the 30-d laboratory studies at these pH levels. At pH 9, 50% hydrolysis required 30 days.

Phototransformation: Phototransformation of methomyl on soil is not an important route of transformation in the environment, with a half-life of 34 days. In clear and shallow surface waters, phototransformation is expected to be an important route of transformation ($t_{½}$ = 1d).

Volatilization: A low vapour pressure (vp = 5 x 10^{-5} mm Hg at 25°C) and a Henry's law constant of 1.84 x 10^{-10} atm m^3/mol, (1/H = 1.33 x 10^{-8}) suggests that volatilization from water is not likely to be a significant process contributing to the loss of methomyl from the aquatic environment. This can also be said for moist soil.

Soil biotransformation: Methomyl is transformed by microorganisms under both anaerobic and aerobic conditions. In aerobic soils, methomyl was found to have DT_{50}s ranging from 5.2-45 days, which would classify methomyl as non-persistent to slightly persistent, respectively. In anaerobic soils, methomyl is non-persistent having a first order half-life of 14 days.

Soil mobility: Calculated K_{oc}s ranging from 5-91 indicate that methomyl does not strongly adsorb to soil and, thus, can potentially be mobile. On the basis of soil Thin Layer Chromatography (TLC) studies, methomyl and its major transformation product, S-methyl-N-hydroxythioacetimidate, are classified as moderately mobile to mobile and moderately mobile to very mobile, respectively (McCall et. al. 1981). Methomyl meets all of the criteria for leaching according to Cohen et al. (1984). In addition, the calculated GUS score (Gustafson, 1989) is 3.96, which classifies methomyl as a leacher. Terrestrial field dissipation studies indicate some leaching although this can be variable depending on field conditions. Water modelling also predicts that methomyl has the potential to leach. Therefore, the PMRA concludes that methomyl has the potential to leach to groundwater. Methomyl's high solubility and mobility also indicate that it is likely to reach surface water sources via run-off.

Canadian field dissipation: No information is available on field dissipation of methomyl in relevant ecozones. Studies conducted in Mississippi and California, however, reported in field dissipation times (DT_{50}) of 6 days and 54 days, respectively, which concurs with the laboratory data. The majority of methomyl residues were detected in the top 30-cm soil layer.

Aquatic biotransformation: In water, aerobic biotransformation is the main route of transformation of methomyl ($t_{1/2}$ = 4-5 d in sediment:water systems). This classifies methomyl as non-persistent in water (McEwen and Stephenson, 1979). Due to the high solubility, low K_{oc}

(5-91) and low log K_{ow} (0.6), methomyl is likely to be in solution in aquatic environments rather than be adsorbed to dissolved or suspended organic matter in the water column and, therefore, likely susceptible to biotransformation in the water column.

Surface water monitoring: Overall, the monitoring data available from Canada and the United States indicate that methomyl is detected very infrequently in surface and groundwater (197 detections of methomyl out of a total of 52 170 samples (< 1% detection frequency) in potential drinking water sources). In Canada, no detections of methomyl were recorded in 474 samples collected over five provinces, although the detection limits were generally not highly sensitive, being in the range of 0.2-1 µg/L. In the United States, it was not detected in finished drinking water, and rarely detected in ambient water samples collected from several states in a variety of land uses including agricultural, urban and mixed land use types. Methomyl would not be expected to persist in clear, shallow waters because of its susceptibility to phototransform. Despite uncertainties associated with the monitoring data, taken as a whole, the data indicate that methomyl is rarely detected in water using standard (non-site specific) sampling methods. Monitoring data from the United States with directed studies (intensive on- and off-site monitoring of field trials) shows that methomyl can enter surface waters by drift or runoff, and that measured concentrations were generally of the same magnitude and in agreement with modelling results using PRZM/EXAMS.

Transformation products: Methomyl undergoes full mineralization in soil, producing no major transformation products other than CO_2. In aquatic systems, mineralization also occurs; three major transformation products were detected, S-methyl-N-hydroxythioacetimidate, acetonitrile (an organic solvent, in sediment and volatile phase) and acetamide in sediment.

4.2 Environmental Risk Characterization

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects to non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. EECs are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models, which take into consideration the application rate(s), chemical properties and environmental fate properties, including the transformation of the pesticide between applications. Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants. Toxicity endpoints used in risk assessments may be adjusted using uncertainty factors to account for potential differences in species sensitivity as well as varying protection goals (in other words, protection at the community, population or individual level).

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (for example, direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the risk quotient is then compared to the level of concern (LOC). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary. If the screening level risk quotient is equal to or greater than the level of concern, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

For methomyl, the worst case exposure scenario for non-target terrestrial and aquatic habitats results from application to apple orchards at a rate of 1890 g a.i./ha (one application). Other high use rates such as ground application to lettuce at 900 g a.i./ha (three applications) were also considered in the acute and chronic risk assessment to both aquatic and terrestrial organisms. The aquatic risk from drift deposition was determined for aerial application on cereals (486 g a.i./ha; two applications with fine droplet size as well as one application with medium droplet size)

4.2.1 Risk to Terrestrial Organisms

A risk assessment of methomyl to terrestrial organisms was based upon an evaluation of toxicity data on bees (acute contact), earthworm (acute), two standard test species of birds (acute oral, dietary, reproduction), three additional species of small birds (acute oral), rats (acute oral, dietary and reproduction) as well as four other species of mammals (mule deer, rabbit, dog, guinea pig; acute oral). A summary of terrestrial toxicity data for methomyl is presented in Table 2 of Appendix X. For the assessment of acute risk, toxicity endpoints based on the hazardous dose to five percent of species (HD_5) for birds and mammals (or the most sensitive species as appropriate) were used as surrogates for the wide range of species that can be potentially exposed following treatment with methomyl insecticide (Table 4A-4C of Appendix X).

Invertebrates

For acute contact toxicity of methomyl to bees, the LD_{50} is 0.1 μg a.i./bee which is equivalent to an application rate of 0.112 kg a.i./ha. In comparison, the application rates of methomyl range from 0.27-1.89 kg a.i./ha. Therefore, there is a risk of bee mortality resulting from the direct exposure of bees to methomyl given that all application rates of methomyl are higher than the application rate that would result in 50% mortality of honey bees (RQ = 2.4-16.9). Based on information available from the USEPA Ecological Effects Database, non-target beneficial invertebrates, such as wasps, damsel bugs, etc., are also at risk from exposure to the insecticide based on the use pattern in Canada.

Beneficial non-target invertebrate data is available for two species from the European (EFSA, 2008) review of methomyl. The contact LR_{50} from laboratory studies for the beneficial invertebrates *A. rhopalosiphi* and *T. pyri* was 0.25 g a.i./ha and 12.8 g a.i./ha, respectively. The risk quotients for these species at the high application rate used on apples (1890 g a.i./ha x 1) is 7560 and 148. The RQs for the lowest application rate as used on flax (248 g a.i./ha x 1) are 992 and 19, respectively. This indicates a potential risk of adverse effects to beneficial non-target invertebrates. Therefore, a precautionary label statement warning applicators to this effect is to be included on the product label as a risk mitigation measure.

Earthworms are at negligible risk of ecological effects following up to three applications of methomyl (RQ = 0.025); the risk assessment to invertebrates is presented in Table 4-A, Appendix X.

Birds and Small Wild Mammals

Soluble Powder Formulation

Standard exposure scenarios on vegetation and other food sources based on correlations in Hoerger and Kenaga (1972) and Kenaga (1973) and modified according to Fletcher et al. (1994) were used to determine the concentration of pesticide (EEC) on various food items (on a dry weight basis) in the diet of birds and small wild mammals, and are expressed as an estimated daily exposure (EDE). Exposure is dependent on the body weight of the organism and the amount and type of food consumed. In the screening level assessment, a set of generic body weights was used for birds (20, 100, 1000 g) and small wild mammals (15, 35, 1000 g) to represent a range of bird and small wild mammal species. For each body weight, the food ingestion rate (FIR) is equivalent to food consumption, and is based on equations from Nagy (1987). It is noted that diets of animals can be highly variable from season to season as well as day to day. Furthermore, animals are often opportunists and if they encounter an abundant and/or desirable food source they may consume large quantities of that food. For these reasons, the screening level assessment uses relevant food categories for each size group consisting of 100% of a particular dietary item. These items include the most conservative residue values for plants, grains/seeds, insects and fruits. It should be noted that a diet of 100% plant material for the smaller sizes of birds (20 and 100 g) is not included in the determination of the EDE as this is considered unrealistic. No small birds in North America are known to eat a diet primarily of leafy plant material or grass; a small bird would need to consume unrealistically high amounts of leafy plant material or grass to meet its energy requirements. Similarly, a 100% diet of plants for the smallest size of mammal (15 g) is not included in the assessment.

Birds

High Application Rate Crops

The risk to birds from exposure to methomyl was initially assessed using high application rate crops, including apple and lettuce. Risk summary tables are presented for apple use only (Table 4-B, Appendix X.)

Birds can be exposed to methomyl through the consumption of contaminated food (for example, seeds, insects or vegetation), as well as from drinking water and dermal contact. All small birds tested as well as mallard duck and bobwhite quail are acutely sensitive to methomyl. The red-winged blackbird is the most acutely sensitive species (LD_{50} = 10 mg a.i./kg bw/d), while the least sensitive species is the rock dove (LD_{50} = 168 mg a.i./kg bw/d). For acute oral toxicity and risk, the HD_5 was determined based on data for five species of birds, resulting in a value of 3.3 mg a.i./kg bw/d. This value is assumed to be protective of approximately 95% of bird species, which may be exposed to methomyl.

Dietary exposure to the test chemical showed somewhat lower sensitivity in the test species used, having LC_{50}s of 1100 mg a.i./kg diet or 11.7 mg a.i./kg bw/d (based on bobwhite quail food ingestion rate of 18.9 mg dw/day and body weight of 178 g). Upon chronic exposure via the diet, a small but biologically significant reduction in the numbers of eggs laid per hen and a subsequent reduction in the numbers of offspring were seen in bobwhite quail. A NOEC based on these reproduction effects of 150 mg a.i./kg diet was determined. Similarly in mallard duck, chronic effects such as reduction in number of viable embryos were observed, having an NOEC of 150 mg a.i./kg diet, equivalent to 8.48 mg a.i./kg bw/d (based on the food ingestion rate of 61.2 mg dw/day and body weight of 1082g for mallard duck). The risk quotients for birds are presented in Table 4-B, Appendix X.

Methomyl poses an acute and reproductive risk to birds. At the higher application rates of methomyl, it takes less than one day of continuous feeding of contaminated food to reach the oral dose that resulted in 50% mortality in the laboratory studies. The screening level assessment (assuming that the birds consume 100% of their diet after the final application within the treatment field) indicates that bird species of all size categories and most feeding guilds are at risk of acute, dietary and chronic (reproductive) risk.

For small-sized birds, the acute risk is highest to insectivores with an RQ of 28.8, while dietary exposure results in a RQ of 8.1. Reproductive endpoints are also exceeded as shown in Table 4-B. The LOC is also exceeded for reproductive effects in small birds, with RQ of 11.2. On other crops with multiple applications, reproductive risk was determined for small birds. Up to three applications of methomyl are permitted on lettuce, broccoli and corn; a reproductive risk was determined for use on lettuce for small insectivores with a RQ of 7.5-9.3 (for foliar dissipation half-life of 3-5 days).

For medium-sized birds a high acute RQ was determined for insectivores (RQ = 22.5) and a lower RQ of 5.6 for granivores. Dietary risk LOCs were exceeded for all feeding guilds with a high RQ value of 6.3 for insectivores. Reproductive risk from use on apples exceeds the LOC with RQ up to 8.7 while as determined for use on lettuce the RQs were up to 7.3.

Large birds were at acute risk from exposure to methomyl with RQs ranging from 6.5 (insectivores) to 23.5 (herbivores). Dietary risk was lower again in this class with not all feeding guilds exceeding the LOC, RQs ranged up to 6.6 for herbivores. Reproductive risk from use on apples exceeds the LOC with RQ up to 9.1 while the RQs were up to 7.6 from use on lettuce.

In summary, methomyl applied to high-use rate crops presents acute and reproductive risk to birds.

Medium- to Low-Application Rate Crops

Given the exceedence of the LOC (RQ > 1) at high application rates such as that on apples or lettuce, the risk to birds from the use of other crops with lower application rates were also evaluated. As these further assessments are for comparative purposes to high use rate results, only summary data are included and full RQ tables are not included. Two other crops having a medium and low application rate were chosen, canola (aerial application, 459 g a.i./ha x1) and flax (aerial application, 246 g a.i./ha x1).

For canola, some RQs exceed the LOC, having a high acute RQ of 7 and a reproductive RQ of 2.7 for small insectivores. All other feeding guilds have a lower risk, however, some of these guilds still exceed the level of concern for acute and or reproductive effects.

For flax (applied aerially), having the lowest application rate for methomyl there are only sporadic exceedance of the LOC for the various feeding guilds. The high acute RQ of 3.7 was determined for small insectivores, and the reproductive RQ is 1.4.

Based on the screening result with high application rates, there is the potential for acute, dietary and reproductive adverse effects in most feeding guilds based on the LOC being exceeded by up to 28.8 from acute exposure to methomyl contaminated food items and up to 9.3 for reproduction, based on the assumption that birds consume 100% treated diet. At medium- and low-use rates, risk to birds is lower but still present, indicating that some feeding guilds may experience adverse acute and/or reproductive effects.

Mammals

The risk to mammals from exposure to methomyl was initially assessed using high application rate crops, including apple and lettuce. Risk summary tables are presented for apple use only (Table 4-C, Appendix X.)

High-Application Rate Crops

The mammalian risk assessment results are summarized in Table 4-C. Mammals can be exposed to methomyl through the consumption of contaminated food (for example, vegetation, insects or seeds), as well as water and dermal uptake, however, only exposure through the diet is considered in this assessment. Generally mammals show very similar toxicity and risk profiles to birds from exposure to methomyl. The most sensitive mammal is the mule deer, having an acute LD_{50} of 11 mg a.i./kg bw/d. The acute HD_5 for mammals, based on the five test species available, is 9.1 mg a.i./kg bw/d. The reproductive NOEL for mammals is 75 mg a.i./kg bw/d, based on a rat study with the affected endpoint being body weight.

This screening level assessment indicates a risk to mammals following the application of methomyl in apple orchards as it would take less than one day of continuous feeding on a contaminated diet to reach the oral dose resulting in 50% mortality of the laboratory animals. Based on the acute HD_5 value and assuming consumption of 100% contaminated diet and maximum EEC (foliar residues), the level of concern was exceeded for acute and reproductive risk endpoints for most feeding guilds in all size classes. The LOCs for acute effects were exceeded up to 18.8 times, while for reproductive effects, they were exceeded up to 13.3 times for medium sized mammals (350 g).

The screening level risk assessment for lettuce, a representative high application rate field crop, indicates a higher risk to mammals due to the inclusion of the herbivore feeding guild consuming leafy foliage. This use/exposure combination results in acute LOCs being exceeded by up to 23.9-29.6 times and reproductive endpoint LOCs being exceeded by up to 16.8-20.8 times (range based on foliar half-life of 3-5 d) for medium-sized mammals.

Medium- to Low-Application Rate Crops

Given the exceedence of the LOC (RQ > 1) at high application rates such as that on apples or lettuce, the risk to mammals from the use of other crops with lower application rates were also evaluated. As these further assessments are for comparative purposes to high-use rate results, only summary data and descriptions are included and additional RQ tables are not included. Two other crops having a median and low application rate were chosen, these are canola (aerial application, 459 g a.i./ha x 1) and flax (aerial application, 246 g a.i./ha x1).

For canola, some RQs exceed the LOC, having a high acute RQ of 8.6 and a reproductive RQ of 6 for medium-sized herbivorous mammals feeding on leafy foliage.

For flax (applied aerially), which has the lowest application rate for methomyl, risk to mammals is clearly lower having only sporadic exceedance of the LOC for the various feeding guilds. The highest acute RQ of 4.5 was determined for medium-sized mammals, and the reproductive RQ is 3.2.

Refined Assessment

Given the conservative assumptions taken in the screening level assessment for birds and mammals, when the LOC is exceeded for terrestrial organisms the risk is further characterized by taking into consideration an off-field exposure resulting from pesticide drift during application (Appendix X, Table 4-B and 4-C). For this assessment, the deposition rate (or the rate at which the non-target plants and other food items will be exposed) was determined taking into consideration the percent drift at a point one metre downwind from the point of application that will result from a given application method. A spray droplet size of “fine” based on the American Society of Agricultural Engineers (ASAE) classification can be assumed for insecticides. For a “fine” droplet size, the maximum spray drift deposition for ground boom sprayer is 11% of the application rate. Similarly, for aerial application, off-site deposition rates for methomyl uses are assumed to be 26% for fine droplet size, while orchard airblast use produces 74% drift (early application). Using the maximum seasonal application rate on apples as a high (conservative) exposure scenario (1890 g a.i./ha x 1 application), the maximum off-field deposition on bird and mammal food items and non-target plants would therefore be 1398.6 g a.i./ha (1890 g a.i./ha x 0.74) for orchard airblast applications. Risk was also determined for methomyl use on lettuce, as it is the second highest use rate on a seasonal basis and is applied three times. Methomyl is applied to lettuce by ground boom at 900 g a.i./ha x 3, having a cumulative on-field application rate of 1575.1 g a.i./ha, and a cumulative off-field rate of 173.3 g a.i./ha (1575.1 x 0.11) Additionally, RQs for birds and mammals were recalculated based on mean daily exposure nomogram values (expressed as EDEs).

Birds:

High-Application Rate Crops

The risk to birds was further characterized by conducting an off-field assessment as outlined above. Off-field acute dietary and reproductive risk to birds from the use of methomyl insecticide was identified for most feeding guilds, showing a similar pattern to on-field risk, but with lower RQs. For airblast applications to apples, the RQs are 26% lower for all groups due to 74% drift deposit from the site of application. For example, small insectivore acute RQ is 21.3 and dietary RQ is 6. Medium-sized birds of all sizes show exceedance of the LOC for acute and dietary risk. Large herbivore birds have acute RQs of up to 17.4. Reproductive risk off-field exceeds the LOC with RQ of up to 8.3 in small birds.

Reproductive risk off-field is significantly reduced compared to on-field based on application to lettuce, and the LOC is exceeded in only one feeding guild among all size categories for birds. The reproductive RQs range from a low of < 0.1 to 1 for small insectivores exposed to methomyl off-field.

In order to provide an estimate of average exposure, EDEs based on mean residue values for various food sources were calculated in addition to maximum nomogram values used in the screening assessment. Based on the high application rates used on apples and lettuce, there is still risk on-field as the LOCs are exceeded for many guilds of all bird size classes for acute, and dietary effects. This pattern is also found in the off-field exposure scenario on apples with orchard airblast application, but not for use on lettuce. Acute risk to birds based on mean nomogram EDE values ranges up to 16 for small insectivores feeding on treated orchards, while the off-field RQs are all below 11.9. Reproductive risk LOCs are still exceeded for small birds both on and off-field from use on apples, having RQs of up to 6.2.

The equivalent RQs for birds feeding on fields growingttuce are 13.4 and 1.4 when feeding adjacent to treated fields. Reproductive risk still exists for small birds on field (RQ = 5.2) but it is considered negligible off-field using mean residue values and application to lettuce at 3 x 900 g a.i./ha (RQ = 0.5).

The above assessment on birds indicates potential acute and dietary risk to most feeding guilds exposed in apple orchards on and off field, based on maximum or mean foliar residue exposure concentrations (nomogram EECs). The most acutely sensitive group of birds are small insectivores, having RQs ranging from 11.9-28.6 (off-field with mean EECs to on field with maximum EECs). Similarly, acute risk is determined for most guilds feeding on fields of lettuce, with RQs ranging up to 24 on field for small birds. However, off field there is significantly lower risk to birds for this use pattern, with RQs being below 2.6 and the LOC not being exceeded for most feeding guilds.

Reproductive risk is indicated for both orchard and field crop applications of methomyl. Chronic exposure in orchards will not occur, as methomyl is applied only once per season. Reproductive effects may theoretically occur in birds if they are exposed to a single application at sensitive life stages. In this assessment, reproductive effect LOCs are exceeded for orchard applications at maximum and mean EECs for almost all feeding guilds. A potential reproductive risk in field crop application scenarios was also determined. The most sensitive groups are small and medium insectivores and large herbivorous birds feeding on leafy foliage. For this latter group, the reproductive RQ is 7 on-field, indicating an exceedance of the LOC. Based on mean nomogram EECs, the RQ for herbivores is 2.3, while off-field reproductive risk is expected to be negligible.

Medium- to Low-Application Rate Crops

For canola, based on refined exposure scenarios including medium residue values and off-field drift values, the high acute RQ for the small insectivore feeding group becomes 3.9 and 1 (on and off-field, respectively.) Reproductive risk is reduced, with an RQ of 1.5 on field and below the LOC off field. Overall, the medium application rate used on canola results in significantly lower exceedance of the LOQ compared to high rates used on other crops, and which is further reduced when considering mean residue values and deposit of the chemical off-field in non-target areas.

For flax, based on refined exposure scenarios including mean residue values and off-field drift values, the high RQ for the small insectivore feeding group becomes two and below one (on and off field, respectively.) Reproductive risk is reduced to below the LOC with mean residue values.

Based on the refined assessment result with high application rates, there is still a potential for acute, dietary and reproductive risks in several feeding. At medium use rates, the on-field risk to birds is lower but still present, indicating that some feeding guilds may experience acute and/or reproductive adverse effects. At low use rates, an acute risk to some birds is still expected on treated fields, however, reproductive risk is expected to be negligible. Off-field the exposure concentrations are reduced to a level at which risk is negligible to birds at medium to low application rates.

It should be noted that the bird risk assessment assumes that animals are feeding exclusively on contaminated food sources, which in some cases is a conservative assumption, particularly if a significant portion of the animals' daily food requirement must be consumed in order to exceed the LOC. It should also be noted that not all feeding guilds are likely to feed directly on treated fields because their preferred food source may not be present.

Mammals:

High-Application Rate Crops

The risk to mammals was further characterized by conducting an off-field assessment as outlined above. Off-field, with a drift rate of 74% from orchard airblast application, LOCs for acute toxicity and reproduction are still exceeded. The maximum off-field acute RQ is 13.9 or 9.8 for reproductive effects in medium-sized herbivores.

Using mean nomogram EECs, the general pattern or risk is similar to that seen with maximum EECs. Several of the same feeding guilds are still in exceedance of the LOC, although RQs are generally 50-65% lower. Using mean nomogram values, the majority of RQs are below 5. The off-field risk becomes lower still with mean nomogram values, having fewer exceedances with most RQs being below 4.

Using mean nomogram values for the second highest use rate of 900 g a.i./ha applied three times on lettuce, RQs are reduced by 50% to 70%. Similarly, reproductive risk is lower, with maximum RQs bracketing the range of 5.5-6.9 for medium sized mammals feeding on field. Off-field, there is negligible risk to mammals when mean EECs are used.

Medium- to Low-Application Rate Crops

For canola, based on refined exposure scenarios including mean residue values and off-field drift values, the highest RQs for medium-sized herbivorous mammals (leafy foliage feeding group) becomes 2.8 and below 1 (on- and off-field, respectively.) Reproductive risk is reduced, with an RQ of 2 on field and below the LOC off field. Overall, the medium application rate used on canola results in significantly lower exceedance of the LOQ for mammals compared to high rates used on other crops. This is further reduced when considering medium food exposure concentrations and deposit of the chemical off-field in non-target areas.

For flax, based on refined exposure scenarios including mean residue values and off-field drift values, the high acute RQ for medium sized mammals becomes 1.5 and below one off field. Reproductive risk is reduced to be equal to the LOC with medium exposures (RQ = 1). Overall, the lowest application rate, as used on flax, results in significantly lower exceedance of the LOQ to mammals compared to high rates used on other crops, and potential risk is further reduced when considering medium food exposure concentrations and deposit of the chemical off-field in non-target areas.

Both the medium and low application rate crops of canola and flax, using the refined assessment assumptions of medium food residues and off-field exposure, result in significantly reduced exposure and risk to mammals compared to high use rate crops. However, for medium use rate crops, some size groups can still be exposed to concentrations, specifically on treated fields, that would result in exceedance of the LOC and could result in adverse acute or reproductive effects. For low-use rate crops, acute LOCs may still be slightly exceeded in the most sensitive size groups on treated fields, but no other risk or adverse effects are likely to occur.

In summary, based on the mammalian risk assessment of low- and medium-use rate crops, methomyl may still pose acute and/or reproductive risk to some small wild mammals on treated fields. Adverse effects are not expected in non-target (off-field) areas.

It should be noted that the mammalian risk assessment assumes that animals are feeding exclusively on contaminated food sources, which in some cases is a conservative assumption, particularly if a significant portion of the animals' daily food requirement must be consumed in order to exceed the LOC. It should also be noted that not all feeding guilds are likely to feed directly on treated fields because their preferred food source may not be present.

Granular Formulation

Methomyl granular formulations are used as a fly bait and the product is scattered in areas where flies congregate at an application rate of 2.5 g a.i./100 m^2 or 87 500 granules/100 m^2. In the current assessment it was assumed that birds will not be attracted to the methomyl granules as a food source but may use it as a grit source. Therefore, the assessment compared the number of granules that would be required to reach the LD_{50} of five bird species (northern bobwhite quail, mallard duck, rock dove, house sparrow, red-winged blackbird). Based on the application rate, there would be enough granules available for consumption to reach the LD_{50} of all the bird species considered, although most species may not consume enough granules to reach this toxicity threshold in one day. However, mitigation of risk to birds is required and in order to prevent potential risk from the consumption of methomyl granules, a bait station must be used in areas where birds could otherwise access the granules.

Mammals can be exposed to granular pesticides through ingestion of food with granules attached (in other words, an earthworm or an insect that has granules attached to it), dermal contact, inhalation and inadvertent ingestion of granules as food (in other words, mistaking granules for seeds). The use of the granules requires bait stations outdoors and this also limits exposure of small mammals to indoor environments. In addition, the granular formulations contain a chemical that would deter the consumption of the granules, therefore it is unlikely that mammals will consume the number of granules required to reach the LD_{50}.

4.2.2 Effects on Aquatic Organisms

A summary of aquatic toxicity data for methomyl is presented in Table 3 of Appendix X. Risk to aquatic organisms (presented in Tables 5-7) is based on evaluation of toxicity data for methomyl on fourteen freshwater invertebrate species, nine freshwater fishes, six marine invertebrates and one marine fish species. With a robust aquatic toxicity data set, it was possible to determine acute species sensitivity distributions (SSD) and HC_5 concentrations for freshwater invertebrates, fish and marine invertebrates. For the assessment of risk, the hazardous concentration values protecting 95% of species or HC_5 were used where available. Otherwise, endpoints chosen from the most sensitive taxonomic groups were used as surrogates for the wide range of species that can be potentially exposed following treatment with methomyl.

For the screening level scenario, expected environmental concentrations were determined based on overspray of an 80-cm deep body of water for fish and invertebrate assessments and a 15-cm water depth is used to estimate risk to amphibians. These water depths are also used in the refined assessments, which characterize risk resulting from drift or runoff.

Fish, invertebrates and amphibians: The screening level assessment for aquatic organisms (see Table 5 of Appendix X) indicates that the acute levels of concern were exceeded for most freshwater invertebrates, fish and amphibians. Aquatic risk was determined as appropriate for high-use rate scenarios such as application of 1890 g a.i./ha x 1 to apple orchards. Runoff and drift deposition and resulting risk were also determined as detailed below.

Invertebrates (*Daphnia sp.*) are the most sensitive aquatic organisms to methomyl with an acute EC_{50} value of 16.5 µg/L and a RQ of up to 28.4. The HC_5 for this group of organisms is 15 µg/L, with an RQ of 15.7. Daphnia are also highly sensitive to chronic exposure and reproductive effects, having an NOEC value of 0.4 µg/L for the endpoint of number of offspring produced. This results in a chronic RQ of 590 for invertebrates (EEC = 236 µg/L).

As a comparison with lower use rate crops such as canola (459 g a.i./ha x 1), the EEC resulting in a water body due to overspray from aerial application would be 57 µg/L. The RQ for invertebrates based on aerial application to canola is 3.8; thus a buffer zone will be required as in the case of higher application crops.

Fish are less sensitive, with LC_{50} levels ranging from 370-6800 µg/L and the resulting RQs for individual species reaching 6.3 but generally being below 2. The fish "community" acute toxicity endpoint was determined to be 347 µg/L, as the hazardous concentration to five percent of species or HC_5. Using the SSD approach, an uncertainty correction factor is not used on the toxicity endpoint, as the SSD is assumed to represent the range of species that may be exposed in the environment. Thus, the acute LOC for fish as a community was not exceeded (HC_5 = 347 µg/L, EEC = 236 µg/L, RQ = 0.68). The chronic risk to freshwater fish did exceed the LOC for both early life stage and life-cycle endpoints. The early-life stage NOEC value of 57 µg/L was exceeded by the EEC value of 236 µg/L 4.14 times (EEC based on 1 application in apple orchards).

Marine invertebrates are also highly sensitive and are at risk of acute toxicity, having RQs of 90.7 as a community (based on the HC_5). Marine fish are less sensitive and there is no exceedance of the LOC for methomyl for this group of non-target organisms.

Amphibian toxicity data was not available, thus the fish acute HC_5 and reproductive NOEC values were used as a surrogate. At the high application rate used on apples, there is an exceedance of the LOC for both acute and chronic risk to amphibians (RQ = 3.6.-22.1 respectively), while a lower risk would result from other uses, the LOC is generally exceeded for amphibians living in shallow water bodies in or near the site of application of methomyl (see also refined assessment below).

Aquatic Plants
Aquatic plants were not considered in this risk assessment as methomyl is a neurotoxic insecticide and is not toxic to plants. The European Union risk assessment (EFSA, 2008) reported a low level of phytotoxicity and risk based on tests with six species of plants, both monocotyledon and dicotyledon. The maximum application rate of 450 g a.i./ha resulted in a 6.3% adverse effect on oats.

Refined Assessment

When the screening level RQ exceeds the LOC, the aquatic risk is further refined by considering a less conservative exposure scenario in which contamination of aquatic habitats occurs via spray drift or surface runoff. While these inputs can be additive, they are considered separately so that their relative importance can be determined and the need for mitigation assessed.

Runoff Refinement

For the refined aquatic eco-scenario assessment, EECs of methomyl from runoff into a receiving water body were simulated using the PRZM/EXAMS models. The PRZM/EXAMS models simulate pesticide runoff from a treated field into an adjacent water body and the fate of a pesticide within that water body. 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. 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. In this case the 80-cm water body was used to determine risk to invertebrates and fish from runoff and the 15-cm water body was used to determine risk to amphibians (based on acute toxicity data for fish). The values determined using the model include the 90th percentile of the yearly peak, yearly 96-h, 21-d, 60-d, 90-d and yearly average values. See Table 7 of Appendix X.

Three crop uses (apple, lettuce and corn) representing six standard regional scenarios were modelled to represent different regions of Canada. Several initial application dates between early April and late July were modelled. The EECs represent concentrations of pesticide resulting from runoff only; deposition from spray drift is not included. The models were run based on 50 years of weather data for all scenarios. The highest EECs in 0.8-m water bodies and in a 0.15-m water body of all selected runs of a given use pattern/regional scenario are reported in Table 2.2-1 and 2.2-2 of Appendix XI.

The highest runoff rates modelled resulted from the corn use scenario, which is used to derive risk from runoff of methomyl. Although highest single applications result from use on apples, runoff concentrations were the highest from multiple applications to corn. The peak value of 63 µg a.i./L (based on corn use in the prairie provinces) was used for the risk assessment in a 80-cm water body, while the peak value of 336 µg a.i./L was modelled for a 15 cm deep water body. For chronic endpoint comparisons, the 21-day mean concentrations of 26-93 µg/L were used.

The acute and chronic LOC was exceeded for freshwater invertebrates by 4.2 and 65 times, respectively. Freshwater fish, including early-life stages are not expected to be affected by even the peak runoff concentrations of methomyl, as the EEC is less than 50% of the NOEC value of 57 µg/L. The LOC was also exceeded for marine invertebrates (RQ = 31.5). Amphibians are at lower risk from runoff; the acute LOC is not exceeded, the chronic LOC is exceeded 1.6 times.

Standard runoff label statements are required on the end-use product label providing guidance on minimizing runoff into aquatic habitats.

Spray Drift Refinement

Similar to the terrestrial risk assessment, the risk to aquatic organisms from spray drift off the treated site was also assessed taking into consideration the spray drift deposition of spray quality of ASAE fine for ground boom (11%), aerial crop use fine to medium (26-23%) and orchard airblast (74% early use, 59% late use) into an adjacent water body 1 m downwind from the site of application. The water body used for the spray drift refinement is the same as is used for the runoff refinement.

Table 6 of Appendix X summarizes the refined drift risk assessment of methomyl for aquatic organisms. The acute and chronic LOC is exceeded for freshwater invertebrates for all three types of application methods, ground, airblast and aerial applications. The RQ is highest for airblast use due to the high drift potential (RQs 11.6-436.6, acute and chronic, respectively).

Aerial applications on cereals use a rate of two applications x 486 g a.i./ha. As a comparison, EECs and risk were also determined using a single application with medium spray droplet size. The EEC based on two application with a fine droplet size is 23.7 µg a.i./L, (26% off-field drift). The acute and chronic LOCs are exceeded for freshwater invertebrates (RQs of 1.6-59.2), as well as for chronic effects on amphibians (RQ = 2.2), and also acute and chronic effects on marine invertebrates (RQs 5.4-9.1). To determine risk to amphibians, two applications result in EECs of 126.4 µg a.i./L, while a single aerial application (with medium droplet size, with a deposition rate of 23%) results in an EEC of 74.5 µg/L in 15 cm of water. The LOCs resulting from aerial use on cereals are exceeded for freshwater invertebrates, amphibians and marine invertebrates with resulting RQs of up to 59, 2.2 and 9.1, respectively. Aerial use buffer zones will be required.

Freshwater fish are not at acute risk from drift deposition of methomyl. The LOC for fish is exceeded for the early-life stage chronic NOEC endpoint for the high use rate of 1890 ga a.i./ha for airblast application to apples (resulting in an RQ of 3).

Marine invertebrates are predicted to be adversely affected from drift from all three types of application methods, with the airblast use resulting in RQs of 67. Chronic endpoints for this group were not available.

Although amphibians are generally at lower risk than invertebrates from drift exposure, acute LOCs are exceeded for airblast use in orchards and chronic LOCs are exceeded for all three use patterns (ground, airblast and aerial applications), with RQs of 2.7 and up to16.3, respectively.

Overall, the screening level for aquatic risk assessment indicates that invertebrates, amphibians and early-life stages of fish are potentially at acute and reproductive risk from use of methomyl. The refined aquatic exposure scenarios of runoff and spray drift also indicate a possible risk to invertebrates, and in some cases to amphibians, and to fish (for drift). Risk mitigation measures in the form of precautionary label statements and spray buffer zones are required; these are presented in Appendix XII.

Incident Reports

Canadian Incident Reports
There are two reports of wildlife kills linked to methomyl in Canada.

In the first incident, the deaths of 24 crows, 2 starlings and 1 opossum in Chilliwack, British Columbia were reported. There were no visible signs of trauma that would indicate that the cause of death for the birds was due to attempted predation; observations regarding the condition of the opossum carcass were not reported. Exposure of the crows and starlings to methomyl was confirmed by multi-residue pesticides analysis of the stomach contents/lining; no other pesticide residues were detected. Measures of cholinesterase activity in crow and starling brain tissue were consistent with exposure to a carbamate pesticide. The source of methomyl to the birds is unknown. In the second incident, the deaths of 12 crows were reported, found along a creek bank in Sardis, British Columbia. Multi-residue pesticide analysis showed that methomyl was the only pesticide detected in bird stomach contents/lining, and measures of cholinesterase were consistent with exposure to a carbamate pesticide.

Based on these two incidents, methomyl was confirmed to be present in the birds killed. In these Canadian reports, the identity of the methomyl end-use product was not confirmed, and the specific use pattern (or possible misuse) resulting in the bird kills is not known.

United States and International Incident Reports from EIIS Database
According to the USEPA Ecological Incident Information System (EIIS) database, there are nine incidents reported for methomyl of which three are reported to be the result of registered labelled use, three as the result of intentional misuse, and three are reported as undetermined. Of the three incidents that resulted from registered use, two incidents involved bird kills and both incidents are classified as probable. The first incident occurred on an island off the coast of France in 1992 where 35 birds were found dead and another 31 intoxicated after reportedly drinking dew in a cabbage field the same morning as the application of Lannate 20L (methomyl) and Dithane M45 (mancozeb); the birds were green finches, gold finches and linnets. Methomyl was detected in a dead bird at 0.018 ppm. The second bird kill incident occurred in Val de Marne, France in 1989, the day after application of Lannate 20L Insecticide to cabbage; a total of 52 birds were reported killed (46 Bullfinch and 6 American goldfinch).

5.0 Pest Control Product Policy Considerations

5.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances (those that meet all four criteria outlined in the policy: in other words, persistent [in air, soil, water and/or sediment], bioaccumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*).

During the review process, methomyl and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03[6], *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, and evaluated against the Track 1 criteria.

The PMRA has reached the following conclusions:

- Methomyl does not meet Track 1 criteria, and is not considered a Track 1 substance. See Table 8, Appendix X for comparison with Track 1 criteria.
- Methomyl is not expected to form any transformation products that meet all Track 1 criteria.

The use of methomyl is not expected to result in the entry of TSMP Track-1 substances into the environment.

Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*.[7]

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6 DIR99-03*, The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*.

7 *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette,* Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

The list is used as described in the PMRA Notice of Intent NOI2005-01[8] and is based on existing policies and regulations including: DIR99-03; and DIR2006-02[9], and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

- Technical grade methomyl and associated end-use products do not contain any formulants of health or environmental concern identified in the *Canada Gazette*.
- The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.[10]

6.0 Organisation for Economic Co-operation and Development Status of Methomyl

Canada is part of the Organisation for Economic Co-operation and Development (OECD), which groups member countries and provides a forum in which governments can work together to share experiences and seek solutions to common problems.

As part of the re-evaluation of an active ingredient, the PMRA takes into consideration recent developments and new information on the status of an active ingredient in other jurisdictions, including OECD member countries. In particular, decisions by an OECD member to prohibit all uses of an active ingredient for health or environmental reasons are considered for relevance to the Canadian situation.

Methomyl is currently acceptable for use in other OECD member countries, including the United States, Australia and the European Union. As of 9 April 2015, no decision by an OECD member country to prohibit all uses of methomyl for health or environmental reasons has been identified.

7.0 Proposed Regulatory Decision

After a re-evaluation of methomyl, Health Canada's PMRA, under the authority of the *Pest Control Products Act*, is proposing continued registration of methomyl and associated end-use products for certain uses of methomyl in Canada, provided that the mitigation measures for the health and the environment described in this document are implemented.

An evaluation of available scientific information found that the non-food uses of methomyl have value and do not present an unacceptable risk to human health or the environment, when used according to revised label directions. Non-food uses include application to balsam fir and spruce in Christmas tree plantations, farm woodlots and rights-of-way, and as granular baits in barns, poultry houses, feedlots and kennels.

8 NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* under the New Pest Control Products Act.

9 DIR2006-02, *PMRA Formulants Policy*.

Based on the human health risk assessment,food and feed uses of methomyl, including use on tobacco, are being proposed for cancellation. Furthermore, all established maximum residue limits (MRLs) for methomyl are proposed for revocation.

7.1 Proposed Regulatory Actions

7.1.1 Proposed Regulatory Action Related to Human Health

All food and feed uses of methomyl, including use on tobacco, are proposed for cancellation and all established MRLs for methomyl are proposed for revocation.

7.1.1.1 Toxicology Information

Labels of pesticide products carry statements regarding symptoms of poisoning and treatment, which are especially important for those who may be overexposed when working with the product in a commercial or industrial setting, for example, mixers/loaders who handle more concentrated forms. Based on the toxicological assessments, the label text of the methomyl-containing products should be expanded and/or standardized, as indicated in Appendix XII.

7.1.1.2 Residue Definition for Risk Assessment and Enforcement

The current residue definition in plants and animals for both risk assessment and enforcement is methomyl. No revision to the residue definition is required.

7.1.1.3 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.
The PMRA recognizes, however, that interested parties may want to retain an MRL in the absence of a Canadian registration to allow legal importation of treated commodities into Canada. The PMRA requires similar chemistry and toxicology data for such import MRLs as those required to support Canadian food use registrations. In addition, the PMRA requires residue data that are representative of use conditions in exporting countries, in the same manner that representative residue data are required to support domestic use of the pesticide. These requirements are necessary so that the PMRA may determine whether the requested MRLs are needed and to ensure they would not result in unacceptable health risks.

MRLs for methomyl have been established on registered agricultural commodities and published in Health Canada's List of MRLs Regulated under the *Pest Control Products Act* on the Maximum Residue Limits for Pesticides web page. Currently, MRLs of methomyl resulting from its use in Canada and in other countries are established at: 0.1 parts per million (ppm) in sweet corn kernel plus cob with husk removed, 0.5 ppm in apples and celery, 1 ppm in citrus fruits and strawberries, 2 ppm in lettuce, 4 ppm in grapes, 5 ppm in cabbage and 6 ppm in blueberries.

By virtue of subsection B.15.002(1) of the Food and Drug Regulations, the MRL for other foods is 0.1 ppm when no specific MRL is established for a pest control. This requires that residues do not exceed 0.1 ppm, which is considered a general MRL for enforcement purposes. However, changes to this general MRL may be implemented in the future, as indicated in Discussion Document DIS2006-01, *Revocation of 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be set for specific commodities.

As a result of the current re-evaluation, the PMRA is proposing to revoke all established MRLs for methomyl.

For supplemental MRL information regarding the international situation and trade implications, refer to Appendix VI.

7.1.1.4 Proposed Mitigation for Mixer, Loader and Applicator Exposure, Postapplication Exposure and Residential Exposure

Label Clarification

For the commercial class granular bait products, the following label direction is proposed to ensure these products are not used in residential areas:

> "Not for use in residential areas."

Use Precautions

There may be potential for exposure to bystanders from drift following pesticide application to agricultural areas. In the interest of promoting best management practices and to minimize human exposure from spray drift or from spray residues resulting from drift, the following label statement is proposed:

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

Personal Protective Equipment

In order to mitigate the risk of exposure to methomyl, it is proposed that labels be amended to include the use directions outlined in Appendix XII. The personal protective equipment statements should be similar to what is already required on the current product labels. Additional measures are proposed for handheld application equipment for the restricted class product.

Restricted-Entry Intervals

It is proposed that the restricted-entry intervals (REIs) of 12 hours be added to the restricted class product. No REIs are required for the commercial class granular bait products.

7.1.1.5 Proposed Mitigation for Bait Products

For the commercial class granular bait products, the following label direction is proposed to reduce the potential for accidental ingestion of these products:

"This product is not to be used inside or around homes, or any other place where children or pets are likely to be present."

7.1.2 Regulatory Action Related to the Environment

The risk assessment identified a risk of adverse effects to non-target terrestrial and aquatic organisms. Precautionary statements are required and are identified in Appendix XII. In order to mitigate aquatic risk, buffer zones were determined for aquatic systems. The buffer zones for aquatic habitats ranged from 5-45 m for ground application. Environmental mitigation statements are listed in Appendix XII.

List of Abbreviations

ADI	Acceptable Daily Intake
a.i.	Active Ingredient
ARfD	Acute Reference Doseatm Atmosphere
ATPD	Area Treated Per Day
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
BE	Biomonitoring Equivalent
bw	Bodyweight
CAF	Composite Assessment Factor
CAS	Chemical Abstracts Service
CFIA	Canadian Food Inspection Agency
CHMS	Canadian Health Measures Survey
cm	Centimetre(s)
cm^2	Centimeter(s) Squared
CT	Crop Treated
DEEM	Dietary Exposure Evaluation Model
DFOP	Double First Order in Parallel
DFR	Dislodgeable Foliar Residue
DT_{50}	Dissipation Time 50% (the time required to observe a 50% decline in concentration)
DT_{90}	Dissipation Time 90% (the time required to observe a 90% decline in concentration)
dw	Dry Weight
EC_{25}	Effective Concentration on 25% of the population
EDE	Estimated Daily Exposure
EEC	Estimated Environmental Exposure Concentration
FC	Food Consumption
FHE	Food Handling Establishment
FIR	Food Ingestion Rate
g	Gram(s)
GB	Groundboom
GM	Geometric Mean
ha	Hectare
HPLC	High Performance Liquid Chromatography
HtM	Hand-to-Mouth
IUPAC	International Union of Pure and Applied Chemistry
kg	Kilogram
K_d	Soil-Water Partition Coefficient
K_F	Freundlich Adsorption Coefficient
K_{oc}	Organic-Carbon Partition Coefficient
Kow	n-Octanol/water partition coefficient at 25°C
L	Litre(s)

LC_{50}	Lethal Concentration 50%
LD_{50}	Lethal dose 50%
1/n	Exponent for the Freundlich Isotherm
LOAEL	Lowest Observed Adverse Effect Level
LOD	Limit of Detection
LOEC	Lowest observed effect Concentration
LOQ	Limit of Quantitation
mg	Milligram(s)
mL	Millilitre(s)
M/L/A	Mixer/Loader/Applicator
m^2	Meters Squared
Max	Maximum
mg	Milligram(s)
mmHg	Millimeter(s) of Mercury
MoA	Mode of Action
MOE	Margin of Exposure
mPa	Millipascal(s)
MPGH	Mechanically Pressurized Handgun
MPHG	Manually Pressurized Handwand
MRID	US EPA's Master Record Identifier Number
MRL	Maximum Residue Limit
MS	Mass Spectrometry
n/a	Not Available
nm	Nanometre(s)
NOAEL	No Observed Adverse Effect Level
NOEC	No Observed Effect Concentration
NOEL	No Observed Effect Level
N/R	Not Required
OC	Organic Carbon Content
OM	Organic matter Content
OtM	Object-to-Mouth
PF	Protection Factor
PHED	Pesticide Handlers Exposure Database
PHI	Pre-harvest Interval
p*K*a	Dissociation Constant
PMRA	Pest Management Regulatory Agency
PND	Post Natal Day
PPE	Personal Protection Equipment
ppm	Parts Per Million
REI	Restricted-entry Interval
RfD	Reference Dose
ROW	Right-of-Way
RSD	Relative Standard Deviation
SFO	Single First Order

SO	Solid
SOP	Standard Operating Procedure
SRt	Soil Residue (on Day ‘t’)
SU	Suspension
$t_{1/2}$	Half-life
TC	Transfer Coefficient(s)
TRR	Total Radioactive Residue
TSMP	Toxic Substances Management Policy
TTR	Turf Transferable Residue(s)
USEPA	United States Environmental Protection Agency
UV	Ultraviolet
v/v	Volume per Volume Dilution
µg	Microgram(s)
µL	Microlitre(s)

Appendix I Products Containing Methomyl That Are Registered in Canada Excluding Discontinued Products or Products With a Submission for Discontinuation as of 19 February 2015

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%
19139	Technical Grade Active Ingredient		Methomyl Technical Insecticide	Solid	Methomyl 98.7%
29457			DuPont Methomyl Technical		Methomyl 99.7%
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%

Appendix II Commercial and Restricted Class Uses of Methomyl Registered in Canada, Excluding Uses from Discontinued Products or Products with a Submission for Discontinuation as of 17 July 2014

Site (s)	Pest(s)	Formulation Type	Application Methods and Equipment	Guarantee	Rate			Maximum Number of Applications per Year[1]	Minimum Interval Between Applications (Days)	Is Use Supported by the Registrant?
					Product (g product/ha unless otherwise specified)	Active Ingredient (g a.i./ha unless otherwise specified)	Maximum Cumulative (g a.i./ha)			
Use-site Category 4: Forest and woodlots										
Balsam fir and spruce in Christmas tree plantations, farm woodlots, rights-of-way	Spruce budworm	Soluble powder in water soluble bag	Conventional ground equipment: hydraulic sprayers, mist blowers, airblast sprayers	Methomyl 90%	270-540	243-486	972	2	3	Yes
Use-site Category 7: Industrial oilseed crops and fibre crops Use-site Category 13: Terrestrial feed crops Use-site Category 14: Terrestrial food crops										
Canola	Alfalfa looper, bertha armyworm, beet webworm, clover cutworm	Soluble powder in water soluble bag	Conventional ground equipment: hydraulic sprayers Conventional aerial application equipment	Methomyl 90%	216-510	194-459	459	1	Not applicable	Yes
Flax	Bertha armyworm				220-270	198-243	243	1	Not applicable	Yes
Use-site Category 13: Terrestrial feed crops Use-site Category 14: Terrestrial food crops										
Barley, oats, wheat	Common armyworm	Soluble powder in water soluble bag	Conventional ground equipment: hydraulic sprayers Conventional aerial application equipment	Methomyl 90%	270-540	243-486	972	2	5	Yes
	Thrips				300	270	540			
	Brown marmorated stink bug				540	486	972			Yes
Use-site Category 13: Terrestrial feed crops Use-site Category 14: Terrestrial food crops										

Site (s)	Pest(s)	Formulation Type	Application Methods and Equipment	Guarantee	Rate			Maximum Number of Applications per Year[1]	Minimum Interval Between Applications (Days)	Is Use Supported by the Registrant?
					Product (g product/ha unless otherwise specified)	Active Ingredient (g a.i./ha unless otherwise specified)	Maximum Cumulative (g a.i./ha)			
Apple	Obliquebanded leafroller	Soluble powder in water soluble bag	Conventional ground equipment: air blast sprayer	Methomyl 90%	1600	1440	1440	1	Not applicable	Yes
	Mullein bug				1600	1440	1440			
	Apple aphids				1000-2100	900-1890	1890			Yes
	Codling moth				540-2100	486-1890	1890			
	Spotted tentiform leafminer (First generation)				1600-2100	1440-1890	1890			
	White apple leafhopper				1400	1260	1260			
	Winter moth				600	540	540			
	Brown marmorated stink bug				2100	1890	1890			Yes
Peas	Alfalfa looper, pea aphid		Conventional ground equipment: hydraulic sprayers		510	459	459	1	Not applicable	Yes
	Brown marmorated stink bug									Yes
Potatoes	Leafhoppers, fleabeetles, aphids				540	486	486	1	Not applicable	Yes
	Variegated cutworm				270-540	243-486				
Sweet corn	Aphids				430-620	387-558	1674	3	5	Yes
	Brown marmorated stink bug				625	563	1689	3	5	
	Corn earworm				430-625	387-563			2	Yes
	European corn borer				625	563			5	
Use-site Category 14: Terrestrial food crops										
Broccoli, Brussels sprouts, cabbage, cauliflower	Cabbage looper, imported cabbageworm, diamondback moth	Soluble powder in water soluble bag	Conventional ground equipment: hydraulic sprayers	Methomyl 90%	270-540	243-486	1458	3	5	Yes

Site (s)	Pest(s)	Formulation Type	Application Methods and Equipment	Guarantee	Rate			Maximum Number of Applications per Year[1]	Minimum Interval Between Applications (Days)	Is Use Supported by the Registrant?
					Product (g product/ha unless otherwise specified)	Active Ingredient (g a.i./ha unless otherwise specified)	Maximum Cumulative (g a.i./ha)			
Brussels sprouts	Slugs (larvae of grey garden slug)				775	698	698	1	Not applicable	Yes
Lettuce (field)	Cabbage looper, beet armyworm				510-1000	459-900	2700	3	5	Yes
Snap beans	European corn borer				550	495	495	1	Not applicable	Yes
	Brown marmorated stink bug				550	495	495	1	Not applicable	
Strawberry	Slugs (larvae of grey garden slug)				775	698	698	1	Not applicable	No
Tobacco	Tomato hornworm, aphids				540	486	486	1	Not applicable	Yes
Tomatoes	Tomato fruitworm, aphids, variegated cutworm				270-540	243-486	972	2	5	Yes
	Brown marmorated stink bug				540	486				Yes
Use-site Category 20: Structural										
Farm buildings (feedlots, dairies, stables, hog houses, livestock barns), kennels and poultry houses (broiler and caged layer houses)	Blow fly, eye gnat, flesh fly, house fly, little house fly, flies (general)	Granular	Shaker can/bait station	Methomyl 1%	250 g/100m^2	2.5 g /100m^2	Not applicable	Daily (365)	1	Yes

[1]Maximum number of applications per year as published in REV2010-08 Re-evaluation Note, *Methomyl* are included for apple, barley, broccoli, Brussels sprouts, cabbage, canola, cauliflower, flax, lettuce (field), oat, pea, potato, snap bean, sweet corn, tobacco, tomato and wheat.

Appendix III Toxicology Profile for Methomyl

Table 1 Toxicity Profile of Technical Grade Methomyl

(Effects are known or assumed to occur in both sexes unless otherwise noted; in such cases, sex-specific effects are separated by semicolons. Organ weight effects reflect both absolute organ weights and relative organ to bodyweights unless otherwise noted).

Study Type/ Animal/ PMRA #	Study Results
Toxicokinetic Studies	
Absorption, distribution, metabolism and excretion studies. Sprague Dawley rats and Cynomolgus ♂ monkeys. Oral administration. **Absorption**: Rapidly absorbed via G.I. tract. **Distribution**: Following a single dose, ~8%-9% in rat body and 4%-5% in monkey body at 7 days. Following repeat-dosing, ~10% retained in rat body after 24 hrs. Methomyl found in blood, liver, fat, and kidney but does not accumulate. **Metabolism**: The syn-isomer gives rise to an oxime that is metabolized primarily to CO_2 while the anti-isomer primarily produces acetonitrile. In the rat there is some conversion of the syn- to anti-isomer. **Metabolites**: In rats, the major urinary metabolite is mercapturic acid derivative of Methomyl (18% of AD), in air ~22-23% of AD is $^{14}CO_2$, ~12-13% of AD is ^{14}C-acetonitrile. In monkeys, in air ~31-38% of AD is $^{14}CO_2$ and ~4%-7% is ^{14}C-acetonitrile. > 10 additional minor urinary metabolites found in rats including acetonitrile, acetate, a sulfate conjugate of Methomyl oxime and acetamide. There are three metabolic pathways: • displacement of the S-methyl moiety with endogenous glutathione, which is subsequently further metabolized by enzymatic cleavage to the corresponding mercapturic derivative; • cleavage of the carbamate ester releasing Methomyloxime which then may be rapidly metabolized or conjugated; • in vivo isomerization of syn-Methomyl to the anti- isomer which upon hydrolysis produces anti-Methomyloxime; this metabolite may then undergo a Beckman rearrangement and elimination reaction to form acetonitrile. **Excretion**: Single dose in rats: ~50% urine, 35% expired air. Repeat dose in rats: ~30% urine, 50% expired air. Single dose in monkeys: ~24%-35% urine, 40% expired air. Very little in feces (2%-3%) in either species or dose regime. Near complete excretion within 24 hr. Elimination half-life in rats ~5 hrs.	
Acute Toxicity Studies	
Acute Oral Toxicity Rats	LD_{50} = 17-34/23.5-30 mg/kg bw (♂/♀) Clinical signs included tremors, low posture and salivation. High toxicity
Acute Oral Toxicity Rabbits	LD_{50} = 30 mg/kg bw (♂) High toxicity
Acute Oral Toxicity Dogs	LD_{50} = 20 mg/kg bw High toxicity
Acute Oral Toxicity	LD_{50} = 40 mg/kg bw

Study Type/ Animal/ PMRA #	Study Results
Monkeys	High toxicity
Acute Oral Toxicity Chickens	LD_{50} = 28 mg/kg bw (♀) High toxicity
Acute Dermal Toxicity Rats	LD_{50} > 1000 mg/kg bw (♂) Slight toxicity
Acute Dermal Toxicity Rabbits	LD_{50} > 2000 mg/kg bw Clinical signs included miosis, decreased motor activity, diarrhea, salivation and breathing difficulties. Low toxicity
Acute Inhalation Toxicity Rats	LD_{50} = 0.26 mg/L Clinical signs included exaggerated breathing, reduced respiration, tremors, hypersensitivity, exophthalmus, piloerection and staggering. Moderate toxicity
Acute Dermal Irritation Rabbits	Non-irritating
Acute Dermal Irritation NZW rabbits PMRA #1731555	Non-irritating
Acute Eye Irritation Rabbits	Non-irritating (cholinergic signs including miosis, incoordination, tremors, convulsions, salivation, lethargy and rales during first hour); death occurred in one ♀ rabbit 20 min post-dosing and following observations of cholinergic symptoms. High toxicity via ocular exposure.
Skin Sensitization Guinea pigs	No sensitization potential in Buehler assay.
Short-Term Toxicity Studies	
90-day Oral Toxicity Charles River rats	NOAEL = 6.25 mg/kg bw/day 12.5 mg/kg bw/day: Slight ↓ bw and ↓ food consumption; moderate erythroid hyperplasia in bone marrow (♂). No inhibition of ChE in any treated group.
90-day Oral Toxicity Fisher F344 rats	LOAEL = 16/18 mg/kg bw/day (♂/♀) ≥ 16/18 mg/kg bw/day: ↑number of thyroidal follicles lined by cuboidal to columnar cells, ↓glucose, ↓ BChE (slight); ↓bw, ↑spleen weight, ↓Hgb, ↓RBC (♂); ↑ urogenital staining, ↓hematocrit (♀) ≥ 58/57 mg/kg bw/day: ↓ BChE; ↑ urogenital staining, ↓water intake, ↓hematocrit (♂); ↑spleen weight, ↓Hgb, ↓RBC (♀) 243/187 mg/kg bw/day: ↑ EChE, congestion and capsular thickening of spleen; ↑food intake (♂); lacrimation, ↓bw, ↓water intake, ↓uterine wall thickness (♀)

Study Type/ Animal/ PMRA #	Study Results
21-day Dermal Toxicity NZW rabbits	NOAEL = 50 mg/kg bw/day ≥ 50 mg/kg bw/day: ↓ PChE (♂) 500 mg/kg bw/day: ↑hyperactivity, ↓BChE, ↓EChE (slight); ↓ PChE (♀) No effects observed on dermal irritation, hematology, clinical chemistry, organ weights or histopathology. All ChE returned to normal by end of recovery period.
21-day Dermal Toxicity NZW rabbits	NOAEL = 90 mg/kg bw/day No effects on ChE. Note: No assessment of hematology, clinical chemistry, organ weights or histopathology.
Chronic Toxicity/Oncogenicity Studies	
104-week Oncogenicity CD-1 mice	NOAEL = 8.7/10.6 mg/kg bw/day (♂/♀) ≥ 8.7/10.6 mg/kg bw/day: ↑food intake ≥ 15.3/19.1 mg/kg bw/day: ↓red cell mass (↓Hgb, ↓RBC, ↓hematocrit) at wk 13 and 26; ↑mortality by wk 26 (♀) 93.3/118.5 mg/kg bw/day: ↑mortality; ↑adrenal wt (♂) No evidence of carcinogenicity.
22-month Chronic Toxicity/Oncogenicity Charles River rats	Supplemental ≥ 10 mg/kg bw/day: ↓ Hgb after 18 months, ↑ extramedullary hematopoiesis of spleen (♀). 20 mg/kg bw/day: ↑renal tubular hypertrophy, vacuolation and inhibition of protein in cytoplasm in proximal tubule; ↓weight gain, ↑relative testes weight (♂); protein in lumen of kidney (♀) No evidence of carcinogenicity.
2-year Chronic Toxicity/Oncogenicity Sprague Dawley rats	NOAEL = 4.8/6.3 mg/kg bw/day (♂/♀) 19.9/26.2 mg/kg bw/day: ↓ bw gain; ↑bone marrow hyperplasia, ↑focal degeneration/angiectasis in adrenal cortex, ↑ focal hyperplasia in adrenal medulla (♂); ↓Hgb, ↓RBC, ↓hematocrit (♀) No evidence of carcinogenicity. Note: Study inadequate for ChE assessment.
2-year Chronic Toxicity Beagle dogs	NOAEL = 2.5 mg/kg bw/day ≥10.0 mg/kg bw/day: swollen/irregular epithelial cells of proximal convoluted tubules with ↑ pigment, ↑pigmentation of spleen (♂) 25.0 mg/kg bw/day: 2/4 ♂ exhibited cholinergic effects during wk 13, 1 ♀ died at wk 9, replacement ♀ died on day 18 exhibiting convulsive seizures, ↑ bile duct proliferation, ↑extramedullary hematopoiesis of spleen, ↑ hematopoiesis in bone marrow activity,

Study Type/ Animal/ PMRA #	Study Results
	↓HgB, ↓RBC, ↓hematocrit
Developmental/Reproductive Toxicity Studies	
Developmental Toxicity Charles River rats	**Maternal** NOAEL = 9.4 mg/kg bw/day 33.9 mg/kg bw/day: ↓ bw gain, ↓ food consumption **Developmental** NOAEL = 33.9 mg/kg bw/day No effects noted. No evidence of malformations.
Developmental Toxicity Sprague Dawley rats	**Maternal** NOAEL = 1.0 mg/kg bw/day ≥ 3.5 mg/kg bw/day: ↓ bw gain, ↓ food consumption 15 mg/kg bw/day: mortality, salivation, tremors **Developmental** NOAEL = 3.5 mg/kg bw/day 15 mg/kg bw/day; ↓fetal weight, ↓crown rump length, ↑malformations (*situs inversus*), ↑variations (14th rib, bilateral unossified metacarpals)
Developmental Toxicity NZW rabbits	**Maternal** NOAEL = 6.0 mg/kg bw/day 16 mg/kg bw/day: clinical signs (tremors, hyperactivity, body jerks, salivation, convulsions, ataxia), mortality (1-3 days after dosing). **Developmental** NOAEL = 16 mg/kg bw/day No effects noted. No evidence of malformations.
Developmental Toxicity NZW rabbits	**Maternal** NOAEL = 8.0 mg/kg bw/day 32 mg/kg bw/day; clinical signs (tremors, salivation, pupillary constriction), mortality, ↓weight gain, ↓uterine weight **Developmental** NOAEL = 8.0 mg/kg bw/day 32 mg/kg bw/day; ↑variations (13 thoracic verterbrae, bilateral lumbar ribs)
Reproductive Toxicity Sprague-Dawley rats (2-generation)	**Parental** NOAEL = 5.0 mg/kg bw/day ≥ 5-7 mg/kg bw/day: slight ↓ bw gain pre-mating and during gestation (F_1); ↑ body tics (F_0 ♂) ≥ 37-59 mg/kg bw/day:↓ bw gain pre-mating and during gestation (F_0), ↓ food intake

Study Type/ Animal/ PMRA #	Study Results
	(F_1/F_2); ↓Hgb, RBC and Hct, ↑ body tics (F_0 ♀) 74-128 mg/kg bw/day: clinical signs (F_0) including hyperactivity (♂/♀), abnormal gait, piloerection (♂), confusion, hyperexcitability, tremors (♀) **Reproductive** NOAEL = 5.0 mg/kg bw/day ≥ 37-59 mg/kg bw/day: ↓ birth weight (F_1/F_2) 74-128 mg/kg bw/day: ↑ stillborn (F_2) **Offspring** LOAEL = 5.0 mg/kg bw/day; ↓ bw at day 14 and 21 only (F_1) ≥ 37-59 mg/kg bw/day: ↓ bw gain (F_1/F_2) 74-128 mg/kg bw/day: ↓viability index (F_1/F_2), ↓lactation index (F_1)
Genotoxicity Studies	
Gene Mutation *S. typhimurium* TA 100, TA 1535, TA1537, TA 1538 *E. coli* WP2 uvrA	Negative
Gene Mutation *S. typhimurium* TA98, TA100, TA1535, TA1537, TA1538	Negative
Gene Mutation CHO cells, HGPRT	Negative
Gene Mutation CHO V79 cells	Negative
Sex-linked Recessive lethal *D. melanogaster*	Negative
In vitro Assays Human lymphocytes (whole blood cultures)	Negative for sister chromatid exchange, DNA single-strand breaks and DNA oxidative damage; positive for chromosome aberrations and micronuclei.
Micronucleus Test CHO cells	Positive
Micronucleus Test Mice	Positive
Micronucleus Test Mice	Negative
Micronucleus Test Mice	Negative

Study Type/ Animal/ PMRA #	Study Results
Micronucleus Test Rats	Negative
Unscheduled DNA Synthesis Rat hepatocytes	Negative
Unscheduled DNA Synthesis WI38 human fibroblasts	Negative
DNA Repair Assay *E. coli, B. subtilis*	Negative
In vivo DNA Damage Mice	Positive for single-strand breaks in liver and kidney measured by alkaline elution assay. Positive for oxidative damage in liver measured by 8-OH-guanosine formation. Negative for DNA adduct formation in liver measured by ^{32}P post-labelling assay.
Neurotoxicity Studies	
Acute Delayed Neurotoxicity Hens	Salivation, lacrimation and some convulsions in survivors but no paralysis or neuropathology observed. No evidence of delayed neurotoxicity
Acute Oral Neurotoxicity Rats	NOAEL = 0.25 mg/kg bw ≥ 0.5 mg/kg bw: ↓BChE; ↓EChE (♀) ≥ 0.75 mg/kg bw: ↓PChE, 2.0 mg/kg: tremors; ↓ weight gain between day 2-8 (♀) All ChE activity normal by 24 hours post-dosing
Cholinesterase Reversibility Rats	Supplemental (only one dose tested) 3 mg/kg bw: tremors and ↓BChE, ↓EChE at 30 minutes post-dosing Recovery by 2 hours post-dosing
Acute Cholinesterase study (gavage) Sprague Dawley Rats Non-guideline PMRA #1731530	**PND 11 pups** $BMD_{10}/BMDL_{10}$ for BChE = 0.08/0.07 mg/kg bw Time-to-peak inhibition of BChE (♂+ ♀) and EChE (♂) 30 min post-dosing. Peak EChE inhibition 60 min post-dosing (♀). ≥ 0.1 mg/kg bw: ↓BChE ≥ 0.2 mg/kg bw: ↓EChE No statistically significant sex differences in dose-response of PND 11 pups. **Young adults** LOAEL= 0.3 mg/kg bw; ↓BChE (♀), recovery by 4h post-dosing ≥ 0.5 mg/kg bw; ↓BChE (♂), EChE.

Study Type/ Animal/ PMRA #	Study Results
	PND 11 pups exhibit a higher sensitivity to BChE and EChE inhibition compared to young adults. BChE was the more sensitive parameter throughout this study. Sensitivity of the young
Acute Cholinesterase Study (gavage) Long-Evans rats Non-guideline PMRA #1721369	Supplemental Peak inhibition of BChE (53%) and EChE (67%) was observed 30 min post-dosing, with recovery observed by 4 hours post-dosing.
Acute Cholinesterase Study (gavage) Long-Evans rats Non-guideline PMRA #185793	**Time-course** Peak inhibition of BChE (60%) and EChE (80%) was observed 15 min post-dosing with recovery observed by 180 min post-dosing. **Dose-response** NOAEL = 0.25 mg/kg bw (♂) ≥ 0.75 mg/kg bw inhibition of BChE and EChE.
Acute Cholinesterase Study (gavage) Long-Evans rats Non-guideline PMRA #1721370	NOAEL = 0.25 mg/kg bw ≥ 0.6 mg/kg bw; ↓BChE,; ↓motor activity ≥ 1.25 mg/kg bw; ↓EChE
28-day oral toxicity Sprague Dawley rats	Supplemental NOAEL = 20 mg/kg bw/day 40 mg/kg bw/day: ↓BChE (♀)
Subchronic Oral Neurotoxicity Rats	NOAEL = 7.5 mg/kg bw/day 75 mg/kg bw/day**:** ↓weight gain, ↓food intake, tremors (particularly in first 4 weeks), FOB observations of ↑resistance to handling, ptosis and absent pupillary response, marginal inhibition of BChE

Table 2 Toxicology Endpoints for Use in the Health Risk Assessment for Methomyl

Exposure Scenario	Study	Point of Departure and Endpoint	CAF[1] or Target MOE
Acute dietary general population	Acute comparative cholinesterase	$BMDL_{10}$ = 0.07 mg/kg bw Decreased brain cholinesterase activity	100
	ARfD = 0.0007 mg/kg bw		
Repeated dietary	Acute comparative cholinesterase	$BMDL_{10}$ = 0.07 mg/kg bw Decreased brain cholinesterase activity	100
	ADI = 0.0007 mg/kg bw		
Short-, intermediate- and long-term dermal	21-Day Rabbit Dermal Study	NOAEL = 90 mg/kg bw Hyperactivity & decreased brain cholinesterase activity	300
Short-, intermediate- and long-term inhalation[2]	Acute comparative cholinesterase	$BMDL_{10}$ = 0.07 mg/kg bw Decreased brain cholinesterase activity	100
Cancer	Not required	Not required	Not required

[1] CAF (Composite Assessment Factor) refers to a total of uncertainty and *Pest Control Products Act* factors for dietary assessments; MOE refers to a target MOE for occupational assessments.
[2] Since an oral NOAEL was selected, an inhalation absorption factor of 100% (default value) was used in route-to-route extrapolation.

Appendix IV Dietary Exposure and Risk Estimates for Methomyl

Table 1 Acute Dietary Exposure and Risk for Methomyl

Population	Food Only		Surface Water Only	
	Exposure (mg/kg bw)	% of ARfD	Exposure (mg/kg bw)	% of ARfD
General population	0.000551	79	0.001439	206
All infants	0.001218	174	0.005249	750
Children 1-2 years	0.001476	211	0.002183	312
Children 3-5 years	0.001063	152	0.002045	292
Children 6-12 years	0.000572	81	0.001386	198
Youth 13-19 years	0.000399	57	0.001096	157
Adults 20-49 years	0.000329	47	0.001336	191
Adults 50+ years	0.000407	58	0.001289	184
Females 13-49 years	0.000344	49	0.001335	191

Shaded cells indicate exceedance of the acute reference dose (ARfD).

Table 2 Chronic Dietary Exposure and Risk for Methomyl

Population	Food Only		Groundwater Only	
	Exposure (mg/kg bw)	% of ADI	Exposure (mg/kg bw)	% of ADI
General population	0.000011	2	0.000337	48
All infants	0.000024	3	0.001106	158
Children 1-2 years	0.000055	8	0.000501	72
Children 3-5 years	0.000036	5	0.000469	67
Children 6-12 years	0.000015	2	0.000323	46
Youth 13-19 years	0.000007	1	0.000244	35
Adults 20-49 years	0.000007	1	0.0003115	45
Adults 50+ years	0.000007	1	0.000331	47
Females 13-49 years	0.000007	1	0.000314	45

Shaded cells indicate exceedance of the chronic reference dose (Acceptable Daily Intake).

Appendix V Update on Food Residue Chemistry

The food residue chemistry of methomyl was initially evaluated for Re-Evaluation Note REV2009-02 *Preliminary Risk and Value Assessments of Methomyl*. The review was based on foreign reviews, specifically the 2001 Joint Meeting on Pesticides Residues (JMPR) and the United States Environmental Protection Agency (USEPA). In order to support registration of methomyl and to confirm the JMPR review, the PMRA had requested the appropriate studies or the USEPA Data Evaluation Reports (DERs). Detailed data requirements were listed in Appendix VII of the REV2009-02 document. In response to REV2009-02, the registrant has submitted a number of studies. The PMRA's conclusions resulting from the review of the registrant's response to data deficiencies are as follows.

DACO 6.2-3 The PMRA noted that the requested metabolism studies in livestock and plants were not submitted; the PMRA continued to rely on USEPA and JMPR reviews as stated in REV2009-02, pending submission of original studies for confirmation. Based on USEPA and JMPR reviews, the PMRA concluded that the metabolism of methomyl in livestock and in plants is adequately understood. Methomyl is mainly degraded to acetonitrile, acetamide and CO_2, and these metabolites are ultimately incorporated into natural products. Methomyl oxime is a probable intermediate, but neither it nor methomyl showed any propensity to bioaccumulate over the duration of the studies. The PMRA concurred with the USEPA that residues of all methomyl degradates were not of concern and would not be regulated. The residue for estimation of dietary intake and for compliance with MRLs in plant and animal commodities was defined as methomyl per se. Since methomyl is also a degradation product (metabolite) of the structurally related insecticide thiodicarb in plants, methomyl residues resulting from application of both thiodicarb and methomyl were considered in the dietary risk assessment, as surveillance data included residues of methomyl and cannot distinguish the source of the residues.

DACO 7.2.1-3 The registrant has submitted analytical methods for the determination of residues of methomyl in various plant commodities. The methods have been reviewed by the PMRA and deemed adequate. No further data are required. Some methods involve solvent extraction followed by liquid/liquid partition and Florisil column cleanup. Quantitation is performed by HPLC with UV detection. The limit of quantitation (LOQ) is 0.02 ppm with a mean recovery of 98% at spike levels in the range 0.02-5.0 ppm. In other methods, extraction is carried out using a mixture of organic solvent and sample cleanup is achieved by solid phase extraction (SPE) using an aminopropyl cartridge. Quantitation uses high performance liquid chromatography (HPLC) with tandem mass spectroscopy detection (LC-MS/MS). Those methods have been validated on different crops at an LOQ of 0.01 ppm with acceptable recoveries at spike levels of 0.01 and 0.1 ppm. Further methods incorporate a post-column derivatization step; quantitation is then carried out by HPLC with fluorescence detection. Those methods have also been inter-laboratory validated on different edible crops, at spike levels of 0.02 ppm (LOQ) and 0.2 ppm with recoveries in the acceptable range (70-120%). Although no methods specific for the determination of methomyl in animal commodities were submitted, the PMRA endorses the USEPA's assessment stating that residues in animal commodities were measured using a modification of the above HPLC-Fluorescence detection method.

DACO 7.2.4 The PMRA has received and reviewed a multiresidue analytical method test, which shows that a multiresidue method is available for determining residues of methomyl among seven other carbamates with acceptable recoveries; and methomyl is listed as a compound that can be measured by the Canadian Food Inspection Agency (CFIA) multiresidue method. In addition, the USEPA reported that the United States Food and Drug Administration (USFDA) PESTDATA database indicated that methomyl is completely recovered using protocols A and D of the USFDA multiresidue protocols.

DACO 7.2.5 Not submitted. Storage stability of working solutions data deficiency still applies for any future submissions.

DACO 7.3 Based on the submitted freezer-storage stability studies in plant matrices, the PMRA has determined that the stability of residues in the studied crops is adequate to support the magnitude of residue (MOR) studies. The studies showed that residues in samples stored at -20ºC were stable for at least 1 year in all crops (except tobacco dried leaves: 6 months) and up to 33 months depending on the crop. In addition, the registrant referenced some other studies (not on file), which show that residues were stable for 30 months in green (snap) beans stored at -18ºC; for 1 year in beets and beet foliage stored at -10 ºC; for 6 months in mint hay stored at -10ºC and for 5 months in mint oil stored at -20 ºC. No data were submitted to the PMRA for the stability of residues in animal matrices. Thus, while the freezer-storage stability requirement for residues in plant matrices is considered fulfilled, the data deficiency for the stability of residues in animal commodities still holds and should be addressed for any future submissions.

DACO 7.4.1-2 To address the magnitude of the residue (MOR) data deficiency identified in REV2009-02, the registrant has submitted MOR studies of methomyl in apple, apricot, bean, broccoli, cabbage, cauliflower, celery, cherry, chicory, citrus, corn, cotton, cucumber, courgette, grape, lettuce, melon, nectarine, pea, peach, pear, pepper, plum, sorghum, soybean, sugar beet, tomato and turnip. The PMRA has reviewed the field trial studies (including residue decline studies) and noted that many of them were conducted according to the American or European use patterns at Good Agricultural Practices (GAPs), which differed from Canadian GAPs. Thus, the data deficiency still holds for some crops, in particular for those registered on Canadian labels.

DACO 7.4.3-4 Not submitted. Crop rotation data deficiency still applies for any future submissions.

DACO 7.4.5 The PMRA has reviewed the processing studies provided by the registrant in response to REV2009-02, and determined that the residues of methomyl did not concentrate in any processed commodities, with the exception of wheat bran (1.9 x). Additional experimental processing factors derived from the studies were used to refine residues in processed commodities for exposure estimation.

DACO 7.4.6 and 7.5 Residue data for crops used as livestock feed and livestock feeding studies were not submitted. These data deficiencies still apply for any future submissions.

Appendix VI Supplemental Maximum Residue Limit Information – International Situation and Trade Implications

Maximum Residue Limits (MRLs) may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the field crop trials used to generate residue chemistry data. For animal commodities, differences in MRLs can be due to different livestock feed items and practices.

Methomyl MRLs established under the Food and Drug Regulations were not reassessed during this re-evaluation process. A comparison of the Canadian MRLs and the corresponding American tolerances is presented in Table 1. The following conclusions can be made.

- MRLs are established only for the following Canadian registered uses: apple, cabbage, lettuce, strawberry and sweet corn kernel plus cob with husks removed. MRLs have been established to accommodate imports for blueberry, celery, citrus and grapes. All other commodities imported and consumed in Canada are covered by the 0.1 general MRL.
- Generally, the Canadian uses covered by the 0.1 ppm general MRL have higher corresponding American tolerances.

The Codex Alimentarius Commission has established MRLs for combined residues of methomyl and thiodicarb in/on plant and animal commodities. Canadian MRLs and Codex MRLs are not harmonized.

Table 1 Comparison Between MRLs in Canada and in Other Jurisdictions for Methomyl

Commodity	Methomyl		Methomyl + Thiodicarb Expressed as Methomyl	Thiodicarb
	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)	American Tolerance (ppm) = Thiodicarb + Methomyl Expressed as Thiodicarb
Alfalfa, fodder	–	–	20	–
Alfalfa, forage	–	10	–	–
Alfalfa, hay	–	10	–	–
Apple	0.5	1	0.3	–
Asparagus	*	2	2	–
Avocados	*	2	–	–
Barley, grain	*	1	2	–
Barley, hay	–	10	–	–
Barley, straw	–	10	–	–
Bean, common (pods and/or immature seeds)	–	–	1	–
Bean, dry, seed	*	0.1	0.05	–
Bean, fodder	–	–	10	
Bean, forage	–	10	–	–

Commodity	Methomyl		Methomyl + Thiodicarb Expressed as Methomyl	Thiodicarb
	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)	American Tolerance (ppm) = Thiodicarb + Methomyl Expressed as Thiodicarb
Bean, succulent	*	2	–	–
Beans, except broad bean and soya bean	–	–	1	–
Beet, garden, top	*	6	–	–
Bermudagrass, forage	–	10	–	–
Bermudagrass, hay	–	40	–	–
Blueberries	6	6	–	–
Broccoli	*	3	–	7
Brussels Sprouts	*	2	–	–
Cabbage	5	5	–	7
Cabbage, Chinese, bok choy	5	5	–	7
Cabbage, Chinese, napa	5	5	–	7
Canola	*	–	0.05 (rape seed)	–
Cauliflower	*	2	–	7
Celery	0.5	3	–	–
Citrus fruit	1	–	1	–
Citrus pulp, dry	–	–	3	–
Collards	*	6	–	–
Corn, field, forage	–	10	–	–
Corn, field, grain	*	0.1	–	–
Corn, field, stover	–	10	–	–
Corn, pop, grain	*	0.1	–	–
Corn, pop, stover	–	10	–	–
Corn, sweet, forage	–	10	–	
Corn, sweet, kernel plus cob with husks removed	0.1	0.1	–	2
Corn, sweet, stover	–	10	–	–
Cotton, seed	–	–	0.2	–
Cotton, seed, hulls	–	–	0.2	–
Cotton, seed, meal	–	–	0.05	–
Cotton, seed, oil, edible	*	–	0.04	–
Cotton, undelinted seed	–	0.1	–	0.4
Dandelion, leaves	*	6		–
Edible offal (mammalian)	–	–	0.02	–
Eggs	–	–	0.02	–
Endive	*	5	–	–
Grapes	4	5	0.3	–

Commodity	Methomyl		Methomyl + Thiodicarb Expressed as Methomyl	Thiodicarb
	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)	American Tolerance (ppm) = Thiodicarb + Methomyl Expressed as Thiodicarb
Grapefruit	1	2	See citrus fruit.	–
Hop, dried cones	*	12		–
Kale	*	6	–	–
Lemon	1	2	See citrus fruit.	–
Lentil, seed	*	0.1		–
Lettuce	2	5	0.2	See Vegetable, leafy
Maize	–	–	0.02	–
Maize oil, edible	–	–	0.02	–
Meat (from mammals other than marine mammals)	–	–	0.02	–
Milk	*	–	0.02	–
Mint hay	–	–	0.5	–
Mustard, Greens	*	6	–	–
Nectarine	*	5	0.2	–
Oat, forage	–	10		–
Oat, grain	*	1	0.02	–
Oat, hay	–	10	–	–
Oat, straw	–	10	–	–
Onion, bulb	*	–	0.2	–
Onion, green	*	3	–	–
Orange	1	2	See citrus fruit.	–
Parsley, leaves	*	6	–	–
Pea	*	5	See Peas (pods and succulent = immature seeds).	–
Pea, field, vines	–	10	–	–
Peach	*	5	0.2	–
Peanut	*	0.1	–	–
Pear	*	–	0.3	–
Peas (pods and succulent = immature seeds)	*	–	5	–
Pecan	*	0.1	–	–
Pepper, bell	*	2	–	–
Pepper, nonbell	*	2	–	–
Peppermint, tops	*	2	–	–
Peppers	*	–	0.7	–
Peppers, chili, dried	*	–	10	–
Plums (including prunes)	*	–	1	–
Pomegranate	*	0.2	–	–
Potato	*	–	0.02	–
Poultry meat	*	–	0.02	–
Poultry, edible offal			0.02	–

Commodity	Methomyl		Methomyl + Thiodicarb Expressed as Methomyl	Thiodicarb
	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)	American Tolerance (ppm) = Thiodicarb + Methomyl Expressed as Thiodicarb
of				
Rye, forage	–	10	–	–
Rye, grain	*	1	–	–
Rye, straw	–	10	–	–
Sorghum, grain, forage	–	1	–	–
Sorghum, Grain, grain	*	0.2	–	–
Soya bean (dry)	*	–	0.2	–
Soya bean fodder	–	–	0.2	–
Soya bean meal	–	–	20	–
Soya bean oil, crude	*	–	0.2	–
Soya bean oil, refined	*	–	0.2	–
Soybean, forage	–	10	–	–
Soybean, hulls	–	–	1	0.8
Soybean, seed	*	0.2	–	0.2
Spearmint, tops	*	2	–	–
Spices, fruits and berries	*	–	0.07	–
Spinach	*	6	–	–
Straw, fodder (dry) and hay of cereal grains and other grass-like plants	–	–	10	
Strawberry	1	–	–	–
Swiss chard	*	6	–	–
Tangerine	1	2	See citrus fruit.	–
Tomato	*	1	1	–
Turnips, Greens	*	6	–	–
Vegetable, brassica, leafy, group 5	*	6	–	–
Vegetable, cucurbit, group 9	*	0.2	0.1	–
Vegetable, fruiting, group 8	*	0.2	0.1	–
Vegetables, leafy	*	0.2	–	35
Vegetable, root and tuber, group 1	*	0.2	–	–
Wheat bran, unprocessed	*	–	3	–
Wheat, forage	–	10	–	–
Wheat, grain	*	1	2	–
Wheat, flour	*	–	0.03	–
Wheat, germ	*	–	2	–
Wheat, hay	–	10	See Straw, fodder (dry) and hay	–

Commodity	Methomyl		Methomyl + Thiodicarb Expressed as Methomyl	Thiodicarb
	Canadian MRL (ppm)	**American Tolerance (ppm)**	**Codex MRL (ppm)**	**American Tolerance (ppm) = Thiodicarb + Methomyl Expressed as Thiodicarb**
			of cereal grains and other grass-like plants.	
Wheat, straw	–	10	See Straw, fodder (dry) and hay of cereal grains and other grass-like plants.	–
Wheat, straw and fodder, dry	–	–	5	–

* Covered under Part B, Division 15, subsection B.15.002(1) of the FDR as 0.1 ppm (see DIS2006-1).

Appendix VII Occupational and Residential Exposure Risk Estimates for Methomyl

Table VII.1 Mixer/Loader/Applicator Exposure and Risk Assessment for Methomyl

Crop	Application Equipment	Application Rate	ATPD[a] (ha or L)	MOE			ARI[d] (Target =1)	
				Dermal[b] (Target = 300)	Inhalation[c] (Target = 100)			
					No Respirator	Respirator	No Respirator	Respirator
Mid-Level PPE: Closed M/L, Open Cab, Wearing Coverall Over Single Layer, CR Gloves								
Balsam fir and spruce in Christmas tree plantations, farm woodlots, rights-of-way	Airblast	0.486 kg a.i./ha	16 ha	1635	N/A[f]	1054	N/A[f]	3.59
	Right-of-Way Sprayer	0.486-4.86 kg ai /1000 L[e]	3750 L	650-6498		519-5190		1.53-15.28
	Backpack		150 L	3328-33 276		1082-10 824		5.48-54.78
	LPHW		150 L	11 754-117 543		1487-14 871		10.78-108
	HPHW		3750 L	141-1409		18-178		0.13-1.29
Apple	Airblast	1.89 kg a.i./ha	16 ha	420		271		0.92
Broccoli, cabbage, cauliflower	Groundboom (f)	0.486 kg a.i./ha	15 ha	29 841		5896		37.0
	Backpack	0.57-1.9 kg ai /1000 L[e]	150 L	8512-28 372		2768-9229		14.01-46.71
	LPHW		150 L	30 066-100 221		3804-12 679		27.57-91.91
Brussels sprouts	Groundboom (f)	0.698 kg a.i./ha	8 ha	38 958		7697		48.33
		0.486 kg a.i./ha		55 952		11 055		69.41
	Backpack	0.57-1.9 kg ai /1000 L[e]	150 L	8512-28 372		2769-9229		14.01-46.71
	LPHW		150 L	30 066-100 220		3804-12 679		27.57-91.91
Lettuce (field)	Groundboom (f)	0.900 kg a.i./ha	5 ha	48 343		9552		59.97
	Backpack	1.1-3.6 kg ai /1000 L[e]	150 L	4492-14 702		1461-4782		7.40-24.20
	LPHW		150 L	15 868-51 933		2008-6570		14.55-47.63
Tomatoes	Groundboom (f)	0.486 kg a.i./ha	15 ha	29 841		5896		37.02
	Backpack	0.57-1.9 kg ai /1000 L[e]	150 L	8512-28 372		2769-9229		14.01-46.71
	LPHW		150 L	30 066-100 221		3804-12 679		27.57-91.91
Canola	Groundboom (f)	0.459 kg a.i./ha	100 ha	4739		936		5.88
	Groundboom (c)		300 ha	1580		312		1.96

Crop	Application Equipment	Application Rate	ATPD[a] (ha or L)	MOE			ARI[d] (Target =1)	
				Dermal[b] (Target = 300)	Inhalation[c] (Target = 100)		No Respirator	Respirator
					No Respirator	Respirator		
	Aerial (M/L)		400 ha	4333		1483		7.32
	Aerial (A)			4840	381	N/A[g]	3.08	N/A[g]
Flax	Groundboom (f)	0.243 kg a.i./ha	100 ha	8952	N/A[f]	1769	N/A[f]	11.1
	Groundboom (c)		300 ha	2984		590		3.70
	Aerial (M/L)		250 ha	13 094		4481		22.11
	Aerial (A)		250 ha	14 627	1152	N/A[g]	9.32	N/A[g]
Barley, oats, wheat	Groundboom (f)	0.486 kg a.i./ha	100 ha	4476	N/A[f]	884	N/A[f]	5.55
	Groundboom (c)		300 ha	1492		295		1.85
	Aerial (M/L)		250 ha	6547		2241		11.06
Barley, oats, wheat	Aerial (A)	0.486 kg a.i./ha	250 ha	7313	576	N/A[g]	4.66	N/A[g]
Peas	Groundboom (f)	0.459 kg a.i./ha	100 ha	4739	N/A[f]	936	N/A[f]	5.88
	Groundboom (c)		300 ha	1580		312		1.96
	Backpack	1.3-4.6 kg ai /1000 L[e]	150 L	3516-12 440		1144-4046		5.79-20.48
	LPHW		150 L	12 419-43 943		1571-5559		11.39-40.30
Potatoes	Groundboom (f)	0.486 kg a.i./ha	70 ha	43 943		5559		40.30
	Groundboom (c)		300 ha	12 419		1571		11.39
Snap beans	Groundboom (f)	0.495 kg a.i./ha	100 ha	4395		868		5.45
	Groundboom (c)		300 ha	1465		289		1.82
	Backpack	1.3-4.6 kg ai /1000 L[e]	150 L	3516-12 440		1140-4035		5.78-20.45
	LPHW		150 L	12 419-43 943		1565-5537		11.36-40.18
Sweet corn	Groundboom (f)	0.563 kg a.i./ha	80 ha	4830		954		5.99
	Groundboom (c)		140 ha	2760		545		3.42
	Backpack	0.6-2.3 kg ai /1000 L[e]	150 L	7031-26 953		2287-8767		11.58-44.37
	LPHW		150 L	24 837-95 210		3142-12 045		22.78-87.31
Tobacco	Groundboom (f)	0.486 kg a.i./ha	45 ha	9947		1965		12.3
	Groundboom (c)		300 ha	1492		295		1.85
	Backpack	1.1-2.4 kg ai	150 L	6738-14 702		2192-4782		11.09-24.20

Crop	Application Equipment	Application Rate	ATPD[a] (ha or L)	MOE			ARI[d] (Target =1)	
				Dermal[b] (Target = 300)	Inhalation[c] (Target = 100)		No Respirator	Respirator
					No Respirator	Respirator		
	LPHW	/1000 L[e]	150 L	23 802-51 933		3011-6570		21.83-47.63
Farm buildings, kennels and poultry houses	Granules spread by hand (Open M/L)[i]	2.5 g/100 m^2 (0.25 kg/ha)	0.1 ha	4546	323	N/A[h]	2.66	N/A[h]
Max PPE: Closed M/L Wearing Coveralls Over Single Layer, CR Gloves; Open Cab Wearing CR Coveralls, CR Headgear, CR Gloves								
Apple	Airblast	1.89 kg a.i./ha	16 ha	3023	N/A[f]	271	N/A[f]	2.14
Engineering Controls: Closed M/L, Closed Cab Wearing Single Layer, CR Gloves								
Apple	Airblast	1.89 kg a.i./ha	16 ha	3288	213	N/A[g]	1.78	N/A[g]

Shaded cells indicate where MOEs do not reach the target MOE or the ARI is less than 1.
ATPD = area treated per day; Single layer = long sleeved shirt, long pants; M/L = mix/load, CR = chemical-resistant; (f) = farmer applicator; (c) = custom applicator, (M/L) = mix/load; (A) = application; LPHW = low pressure handwand (manually-pressurize handwand); HPHW = high pressure handwand (mechanically pressurized handgun)
[a] ATPD values were refined where possible.
[b] Dermal NOAEL of 90 mg/kg bw/day from a 21-day rat dermal study and target MOE of 300.
[c] Inhalation NOAEL of 0.07 mg/kg bw/day from a rat comparative cholinesterase study and target MOE of 100.
[d] Risk was aggregated using an aggregate risk index (ARI). ARI = 1/[(Target MOE_{dermal}/ MOE_{dermal}) + (Target $MOE_{inhalation}$/ $MOE_{inhalation}$)]. An ARI of 1 or greater does not require risk mitigation.
[e] Rate (kg a.i./L) was calculated using the crop-specific application volume.
[f] N/A = not applicable as respirators are required on the label for mixing/loading and application.
[g] N/A = not applicable as respirators are not required in closed cabs.
[h] N/A = not applicable as respirators were not required on the label for granular products and were not required to reach the target MOE or an ARI of 1.
[i] Granules are not packaged in WSP.

Table VII.2 Postapplication Exposure and Risk Assessment for Methomyl

Activity	TC[a] (cm^2/h)	Rate (kg a.i./ha)	MOE[b] (Target=300)	REI[c]
Balsam Fir and Spruce in Christmas Tree Plantations, Farm Woodlots and Rights of Way (2 Applications)[d]				
Handline irrigation	1100	0.486	1714	12 hours
Hand pruning, scouting, pinching, tying, training	500		3771	
Hand weeding, propping, animal control, baiting, grading/tagging	100		18 853	
Apple (1 Application)[e]				
Thinning	3000	1.89	233	2 days
Hand harvesting	1500		467	12 hours
Handline irrigation	1100		636	
Hand pruning, scouting, pinching	500		1400	
Broccoli, Cauliflower, Brussels Sprouts (3 Applications)[e]				
Hand weeding, thinning, topping[*]	4400	0.486	545	12 hours
Scouting, tying	4000		600	
Hand harvesting	5150		466	
Handline irrigation	1100		2181	

Activity	TC[a] (cm^2/h)	Rate (kg a.i./ha)	MOE[b] (Target=300)	REI[c]
Brussels Sprouts (1 Application)[f]				
Hand weeding, thinning, topping	4400	0.698	629	12 hours
Scouting, tying	4000		692	
Hand harvesting	5150		538	
Handline irrigation	1100		2518	
Cabbage (3 Applications)[e]				
Hand weeding, thinning, topping	4400	0.486	545	12 hours
Hand harvesting, scouting, thinning, topping	1300		1845	
Handline irrigation	1100		2181	
Lettuce (3 Applications)[e]				
Scouting in row conditions	200	0.900	6476	12 hours
Hand harvesting and similar contact activities	1000		1295	
Hand weeding and similar contact activities	100		12 953	
Canola (1 Application)[f]				
Scouting in solid stands	1100	0.459	3829	12 hours
Hand harvesting and similar contact activities	1000		4212	
Hand weeding and similar contact activities	100		42 119	
Flax (1 Application)[f]				
Scouting in solid stands	1100	0.243	7233	12 hours
Hand harvesting and similar contact activities	1000		7956	
Hand weeding and similar contact activities	100		79 558	
Barley, Oats, Wheat (2 applications)[f]				
Scouting in solid stands	1100	0.486	3616	12 hours
Hand harvesting and similar contact activities	1000		3978	
Hand weeding and similar contact activities	100		39 779	
Peas (1 Application)[f]				
Scouting in row conditions	200	0.459	21 059	12 hours
Hand harvesting and similar contact activities	1000		4212	
Hand weeding and similar contact activities	100		42 119	
Potatoes (1 Application)[f]				
Scouting in row conditions	200	0.486	19 890	12 hours
Hand harvesting and similar contact activities	1000		3978	
Hand weeding and similar contact activities	100		39 779	
Snap Beans (1 application)[f]				
Scouting in solid stands	1100	0.495	3551	12 hours
Hand harvesting and similar contact activities	1000		3906	
Hand weeding and similar contact activities	100		39 056	
Sweet Corn (3 Applications)[e]				
Hand harvesting	17 000	0.563	122	5 days
Scouting in solid stands	1100		1882	12 hours
Hand harvesting and similar contact activities	1000		2071	
Hand weeding and similar contact activities	100		20 706	
Tobacco (1 Application)[f]				
Tobacco hand harvesting	800	0.486	4972	12 hours
Scouting	100		39 779	
Tomatoes (2 Applications)[f]				
Scouting in row conditions	200	0.486	19 890	12 hours
Hand harvesting and similar contact activities	1000		3978	
Hand weeding and similar contact activities	100		39 779	
Farm Buildings, Kennels, Poultry Houses				
Considered to be minimal due to the lack of high-exposure postapplication activities for fly bait.				

Shaded cells indicate where the MOE is less than the target MOE.

[a] TC = transfer coefficient.

[b] Based on a dermal NOAEL of 90 mg/kg bw/day from a 21-day rat dermal study and target MOE of 300.
[c] REI = restricted-entry interval. Amount of time required for residues to decline to a level where the MOE reaches the target MOE.
[d] DFR residues determined using a peach DFR study based on 2 applications, 5-6 days apart.
[e] DFR residues determined by applying data from a lettuce DFR study twice to result in residues based on 4 applications, 2 days apart.
[f] DFR residues determined using a lettuce DFR study based on 2 applications, 2 days apart.

Table VII.3 Residential Postapplication Exposure and Risk Assessment

Sub-Population	Activity	TC[a] (cm^2/hr)	Dermal Exposure[b] (µg/kg bw/day)	Dermal MOE[c] (Target = 300)
Apples (1.89 kg a.i.—/ha)				
Adults (70 kg)	Thinning	3000	32.30	2787
	Hand harvesting	1500	16.15	5573
Youth (39 kg)	Thinning	2066	39.92	2254
	Hand harvesting	1033	19.96	4509

[a] TC = transfer coefficient. Based on ARTF TCs for apples and scaled for body weight and surface area for youths.
[b] Exposure = DFR (µg/cm^2) x TC x duration (0.67 hr)/BW. A DFR value of 1.125 µg/cm^2 from the peach DFR study was used. This value was based on two applications, five days apart using an airblast.
[c] Based on a dermal NOAEL of 90 mg/kg bw/day from a 21-day rat dermal study and target MOE of 300.

Appendix VIII

PMRA Responses to Comments Received for REV2009-02

Comments Pertaining to Value

Comment
Methomyl is important for pest management of house flies in livestock structures as there are no reported cases of resistance to methomyl.

PMRA Response
The PMRA acknowledges that methomyl is important as a pest management tool for control of house flies in livestock structures.

Flies can cause annoyance to livestock resulting in economic losses due to decreased weight gain or milk production and increased food safety risks. Also, flies may act as vectors for transmission of pathogens to, and between, livestock resulting in greater disease management costs.

Effective fly management programs involve monitoring populations and using multifaceted approaches including cultural control and chemical control when necessary to disrupt fly life cycles.

Resistance to a wide range of insecticides including methomyl has been documented for house flies around the world. However, there are no documented cases of resistance to methomyl for the other fly species identified on the registered methomyl labels.

Of the registered alternative active ingredients to methomyl, only thiamethoxam does not have a documented case of resistance for house flies. Effective resistance management strategies, including rotation between insecticides with differing modes of action, are required to delay the development of house fly resistance to neonicotinoids such as thiamethoxam. Methomyl, a resistance management MoA group 1A insecticide, provides a tool for this purpose as an alternative granular bait for use in rotation with thiamethoxam (MoA group 4A) and the biopesticide, *Beauveria bassiana*.

Methomyl is also important for resistance management purposes for the control of little house flies, as resistance to organophosphates (for example, malathion), synthetic pyrethroids (for example, permethrin) and pyrethrins has been documented for this pest.

Preliminary Dietary Risk Assessment

Comment
Removal of MRLs on strawberries, and their juice and removal of this crop from the dietary risk assessment. This is consistent with the approach taken in the United States.

PMRA Response
Since methomyl is no longer registered for use on strawberries in Canada and the United States, strawberries from these countries were assumed to have no methomyl residues. This had a major impact on the assessment, as most strawberries consumed in Canada are either grown domestically (26%) or are imported from the United States (97% of total imports). However, strawberries imported from other countries, such as Mexico, were considered in the assessment.

Comment
There is a lower MRL on grapes based on the proposal for new use pattern (longer pre-harvest interval) in the United States. In the submitted position paper, DuPont-25548, DuPont is now proposing Scenario 2 to the United States Environmental Protection Agency (USEPA), which allows a reduced rate and number of applications, only two pounds of product or less per season and preharvest interval of 21 days or more. The new proposed tolerance is 1.0 ppm.

PMRA Response
As surveillance data were used for residues of methomyl in grapes, any changes in the use pattern in the United States would be reflected in the surveillance data from the USDA PDP and the CFIA. As grapes consumed in Canada are also imported from countries such as Chile and Mexico, contribution from these countries were also taken into consideration in the dietary exposure assessment.

Comment
Regarding removal of sugarcane from the dietary risk assessment, there is no registration or tolerance in the United States and no need for inclusion of sugar cane in the dietary risk assessment.

PMRA Response
The PMRA has removed sugarcane in the revised dietary exposure assessment.

Comment
In DuPont's review of the acute dietary exposure assessment, it was found that the values determined by PMRA are anomalously high in comparison to USEPA values. The exposure values calculated for the United States and Canada should be similar. Hazard endpoints do not come into play when considering exposure.

PMRA Response
Compared to the United States, Canada's food supply relies to a greater extent on imported commodities, which could lead to different estimates of dietary exposure. When comparing the results of the 2007 USEPA acute dietary exposure assessment to the current PMRA assessment, the Canadian estimates are lower than the American estimates.

Preliminary Occupational and Residential Risk Assessment

Comment
The restricted-entry intervals (REIs) for sweet corn and apples can be refined using two more-recently conducted dislodgeable foliar residue (DFR) studies on peaches and grapes. When considering these new DFR data, the MOEs for apple thinning and corn detasseling reach the target MOE of 100 on Day 0.

PMRA Response
The PMRA has reviewed the five DFR studies submitted during the comment period, which were conducted on peaches, grapes, lettuce, greenhouse chrysanthemums and greenhouse roses. Summaries of the study reviews are included below. Based on a comparison of application equipment, foliage types, application rates, crop canopies, study conditions, and climatic zones, the peach and lettuce DFR studies were selected to estimate dislodgeable foliar residues for most Canadian agricultural crops. For field crops with hairy foliage (in other words tobacco), the default peak DFR of 20% and the dissipation rate of 10% per day was used, as lettuce (smooth foliage) may underestimate dislodgeable residues on hairy foliage. Data from these studies and default DFR data were used to refine the postapplication risk assessment. Revisions to the toxicological uncertainty factors and supported use pattern were also included in the revised risk assessment.

Based on the revised risk assessment, all crops and activities reached the target MOE on Day 0, with the exception of hand harvesting in sweet corn and thinning in apples. These required a 5-day and 2-day REI, respectively to reach the target MOE.

Comment
Information on postapplication activities requested in REV2009-02 is justified and can be readily obtained for commercial fly bait uses. These data are critical for the determination of potential adverse effects and is needed to improve the stewardship of fly bait products in Canada.

PMRA Response
To support the assumptions in the risk assessment, the PMRA requested from the registrant, information regarding postapplication worker activities following fly bait application. This information was received and considered in this revised assessment.

Comment
In REV2009-02, air monitoring data following application of granular bait was requested by the PMRA. Given the low vapour pressure of methomyl (5.6×10^{-6} mm Hg at $25^{o}C$), the need for air monitoring data are not required.

PMRA Response
Methomyl meets the North American Free Trade Agreement (NAFTA) criteria for an inhalation waiver based on low volatility due to a vapour pressure of $< 7.5 \times 10^{-4}$ mm Hg for outdoor scenarios and $< 7.5 \times 10^{-5}$ mm Hg for indoor scenarios. Therefore, air monitoring data are not required at this time.

Appendix IX DFR Study Review Summaries

Peach DFR Study (PMRA#1731402)

This study was designed to collect data to calculate dislodgeable foliar residue dissipation curves for methomyl on peaches at 2 test sites, California and Georgia, after application by airblast. The application rate and regime used in this study (2 applications at 1.0 kg a.i./ha with a 5-6 day interval) is not fully representative of the Canadian use pattern for apples (a maximum rate of 1.89 kg a.i./ha with a 5-7 day interval). Sites were monitored prior to application, immediately following application as soon as spray had dried, and at 1, 2, 4, 7, 14, 21, 28 and 35 days after the last application. The monitoring times were relevant to the currently registered use pattern. Triplicate samples were taken per sampling time per field site.

Peak residues were 1.026 µg/cm^2 (after spray had dried following the last application) and 1.129 µg/cm^2 (after spray had dried following the first application), for California and Georgia sites, respectively. Dissipation rates were modelled utilizing pseudo first order kinetics to estimate half-lives ($t_{1/2}$), which were 4.3 days at the California field site and 0.68 day at the Georgia field site. R-squared values of the dissipation curves of both the California and Georgia field sites were > 0.85 (0.96 and 0.91, respectively). The application rate and regime are not fully representative of the current Canadian use on apples; however, this study is applicable to the registered crops and the application equipment used. As such, this study is considered acceptable for risk assessment purposes. The California site was considered the more appropriate site for use in the risk assessment, based on the formulation (soluble powder), as well as climatic conditions (temperature and precipitation), which may affect residue dissipation.

Lettuce DFR Study (PMRA#1731404)

This study was designed to collect data to calculate dislodgeable foliar residue dissipation curves for methomyl on lettuce at 2 test sites, California and Florida, after application by broadcast sprayer. The application rate and regime used in this study (2 applications at 1.0 kg a.i./ha with a 2 day interval) is not fully representative of the Canadian use pattern for lettuce (3 applications at 0.90-0.97 kg a.i./ha with a 5-7 days interval). Sites were monitored prior to application, immediately following application as soon as spray had dried, and at 1, 2, 4, 7, 14, 21, 28 and 35 days after the last application. The monitoring times were relevant to the registered use pattern. Triplicate samples were taken per sampling time per field site.

Peak residues were 3.385 µg/cm^2 (immediately after the second application) and 1.825 µg/cm^2 (immediately after the first application), for Florida and California sites, respectively. Dissipation rates were modelled utilizing pseudo first order kinetics to estimate half-lives ($t_{1/2}$), which were 3.3 days at the California field site and 1.2 day at the Florida field site. The California field site had an R-squared value of the dissipation curve that was within 0.85 (0.845), while the Florida site had an R-squared value of 0.79. The application regime and growing regions are not fully representative of the current Canadian use on lettuce; however, this study is applicable to the registered crops and the registered application rate used. It should be noted that study data may underestimate dislodgeable residues from crops with hairy foliage, as hairy foliage is typically more efficient at accumulating pesticide residues than smooth foliage (for example, lettuce) following application. Based on the climatic conditions (temperature and precipitation), the California site was considered acceptable for risk assessment purposes.

Appendix X Environmental Fate and Toxicology

Table 1 Fate and Behaviour of Methomyl Insecticide in the Environment

Property (Study Length)	Test Substance	Value	Comments	Reference
Terrestrial				
Abiotic Transformation				
Hydrolysis (30 d)	Methomyl	pH 7: stable pH 5: stable pH 9: 30 d or pH 4.5: 392 d pH 6: 378 d pH 7: 266 d pH 8: 140 d	Not an important route of transformation.	USEPA Chapman and Cole
Phototransformation – Water	Methomyl	1 d	Important route of transformation.	USEPA
Phototransformation on soil	Methomyl	34 d	Not an important route of transformation.	USEPA
Biotransformation				
Biotransformation in aerobic soil (up to 365 d)	Methomyl	Silt loam DT_{50} = 30 - 45 d Loam soil DT_{50} = 5.2-10.5 d	Slightly persistent. Non-persistent.	USEPA
Biotransformation in anaerobic soil	Methomyl	Static conditions DT_{50} = 14 d Dynamic conditions DT_{50} = 2.1 d		USEPA
Mobility				
Adsorption or desorption in soil	Methomyl	K_d ads: 0.18-1.4 K_{oc}: 5-91	High to very high mobility.[3]	USEPA
Volatility	Methomyl	Vapour pressure: 5 x 10^{-5} mm Hg (EPA, 1998) Henry's law: 1.8 x 10^{-7} atm m^3/mole (EPA, 1998)	Not likely to volatilize from moist surfaces or water. (EPA, 1995)	USEPA
Soil TLC		Rf: 0.52-0.82	Moderately mobile to mobile.	USEPA
Field Studies				
Field dissipation	Methomyl	DT_{50}: NA DT_{90}: NA	No relevant field studies available.	USEPA
Aquatic				
Abiotic transformation				
Hydrolysis	Methomyl	pH 7: stable pH 5: stable pH 9: 3 or pH 4.5: 392 d pH 6: 378d pH 7: 266d pH 8: 140d	Not an important route of transformation.	USEPA Chapman and Cole
Phototransformation in water	Methomyl	1 d	Important route of transformation.	

Terrestrial				
Property (Study Length)	**Test Substance**	**Value**	**Comments**	**Reference**
Biotransformation				
Biotransformation in aerobic water systems	Methomyl	DT_{50} = 4-5 d	Non-persistent.[2]	USEPA
Biotransformation in anaerobic water systems	Methomyl	NA		

[1] Classified according to Goring et al. (1975).
[2] Classified according to McEwan and Stephenson (1979).
[3] McCall et al. (1981).

Table 2 Toxicity of Methomyl to Non-Target Terrestrial Species

Organism	Exposure	Test Substance	End Point Value	Degree of Toxicity[a]	Reference
Invertebrates					
Earthworm	Acute	Lannate 20 L	LC_{50}: 7 d-165 mg a.i./kg 14 d-102 mg a.i./kg	No classification	WHO 1996
Earthworm	Acute	Lannate 25 WP	LC_{50}: 7d-147 mg a.i./kg 14 d-87 mg a.i./kg	No classification	WHO 1996
Bee	Contact	methomyl	LC_{50}: 0.1 µg a.e./bee	Highly toxic according to Atkins (1981)	USEPA Ecological Effects Database
Birds					
Bobwhite quail	Acute	Methomyl	LD_{50}: 24.2 mg a.i./kg bw NOEL: 10 mg a.i./kg bw	Highly toxic	USEPA RED[b]
	Dietary	Methomyl	LC_{50}: 1100 mg a.i./kg diet	Slightly toxic	USEPA RED
Mallard duck	Acute	Methomyl	LD_{50}: 15.9 mg a.i./kg bw	Highly toxic	USEPA RED
	Dietary	Methomyl	LC_{50}:2883 mg a.i./kg diet	Slightly toxic	USEPA RED
	Reproduction	Methomyl	NOEC: 150 mg a.i./kg diet (hatchability)		USEPA RED
Red-wing blackbird (40 g)	Acute oral	Methomyl	LD_{50}: 10 mg a.i./kg bw	Highly toxic	USEPA RED
House Sparrow (13.9 g)	Acute oral	Methomyl	LD_{50}: 13.3 mg a.i./kg bw	Highly toxic	USEPA RED
Rock dove (340 g)	Acute oral	Methomyl	LD_{50}: 168 mg a.i./kg bw	Moderately toxic	WHO 1996
Avian Acute HD_5	$HD_{5\ (LD50)}$ = 3.3 mg ai./kg bw			Very highly toxic	PMRA
Avian dietary toxicity value	11.7 mg ai/kg bw/d (from EEC x FIR/BW; [110 x18.9/178])			–	PMRA
Avian chronic toxicity value	8.48 mg a.i./kg bw/d (from EEC x FIR/BW; [150 x 61.2/1082])			–	PMRA
Mammals					

Organism	Exposure	Test Substance	End Point Value	Degree of Toxicity[a]	Reference
Rat	Acute oral	Methomyl	LD_{50}: 17 mg/kg bw	Highly toxic	USEPA RED
	Dietary	Methomyl	LD_{50}: 99.4 mg a.i./kg diet	Highly toxic	USEPA RED
	Reproduction	Methomyl	NOEL: 75 mg a.i./kg diet	–	USEPA RED
Mule deer	Acute oral	Methomyl	LD_{50}: 11 mg/kg bw	Highly toxic	USEPA RED
Rabbit	Acute oral	Methomyl	LD_{50}: 30 mg/kg bw	Highly toxic	WHO 1996
Dog	Acute oral	Methomyl	LD_{50}: 20 mg a.i./kg bw	Highly toxic	WHO 1996
Guinea Pig	Acute oral	Methomyl	LD_{50}: 15 mg a.i./kg bw	Highly toxic	WHO 1996
Mammalian Acute HD_5	$HD_{5\ (LD50)}$ = 9.1 mg a.i./kg bw			Very highly toxic	PMRA
Mammalian Chronic Toxicity Value	12.9 mg a.i./kg bw/d (from EEC x FIR/BW; (75 x60/350))			–	PMRA
Vascular Plants					
No data are available, no effects are expected and no data are required for vascular plants.					

[a] According to USEPA classification.
[b] USEPA RED = United States Environmental Protection Agency re-registration eligibility document.

Table 3 Toxicity of Methomyl to Non-target Aquatic Species

Freshwater Species						
Invertebrate Acute Toxicity						
Water flea *(Daphnia magna*)	Acute 48 hr	Methomyl	EC_{50}	28.7	Very highly toxic	USEPA RED 1998
	Acute 48 hr	Methomyl	EC_{50}	31.7	Very highly toxic	USEPA RED 1998
	Acute 48 hr	Methomyl	EC_{50}	8.8	Very highly toxic	USEPA RED 1998
	Acute 48 hr	24% a.i.	EC_{50}	7.6	Very highly toxic	USEPA RED 1998
	Acute 48 hr	Methomyl	EC_{50}	17	Very highly toxic	EFSA 2008
	Acute 48 hr	Methomyl 20SL	EC_{50}	19.3	Very highly toxic	EFSA 2008
	Acute 48 hr	–	Mean EC_{50}	16.5	Very highly toxic	PMRA
Scuds (*Gammarus pseudolimnaeus*)	Static 96-h	Methomyl	LC_{50}	1050	Moderately toxic	EFSA 2008
Stonefly (*Isogenus* sp)	Static 96-h	Methomyl	LC_{50}	343	Highly toxic	EFSA 2008
Stonefly (*Skwala* sp)	Static 96-h	Methomyl	LC_{50}	29	Very highly toxic	EFSA 2008,
	Static 96-h	Methomyl	LC_{50}	34	Very highly toxic	Johnson and Finley 1980
	Static 96-h	Methomyl	Mean EC_{50}	31.4	Very highly toxic	PMRA

Stonefly (*Pteronarcella badia*)	Static 96-h	Methomyl	LC_{50}	60	Very highly toxic	EFSA 2008,
	Static 96-h	Methomyl	LC_{50}	69	Very highly toxic	Johnson and Finley 1980
	Static 96-h	Methomyl	Mean EC_{50}	64.3	Very highly toxic	PMRA
Midge (*Chironomus plumosus*)	Static 48-h	Methomyl	LC_{50}	88	Very highly toxic	EFSA 2008
Midge (*Chironomus sp)*	96 hr	Methomyl	LC_{50}	32	Very highly toxic	EFSA 2008
Scud (*Gammarus Italicus*)	96 hr	Methomyl	EC_{50}	47	Very highly toxic	EFSA 2008
Scud (*Echinogammarus tibaldii*)	96 hr	Methomyl	EC_{50}	250	Highly toxic	EFSA 2008
Water flea *(Daphnia longispina*)	96 hr	Methomyl	EC_{50}	220	Highly toxic	EFSA 2008
Cyclops strenuous	96 hr	Methomyl	EC_{50}	190	Highly toxic	EFSA 2008
Scud *(Gammarus pulex*)	96 hr	Methomyl	EC_{50}	760	Highly toxic	EFSA 2008
Bulinus truncatus	96 hr	Methomyl	EC_{50}	870	Highly toxic	EFSA 2008
Invertebrate acute HC_5	15 µg a.i. /L				Very highly toxic	PMRA
Invertebrate Chronic Toxicity						
Water flea *(Daphnia magna*)	Chronic 21d	Methomyl	NOEC (# of offspring produced)	0.4	No classification	USEPA RED 1998
			NOEC[1]	1.6	No classification	EFSA 2008
Fish Acute Toxicity						
Rainbow Trout	96 hr acute	Methomyl	LC_{50}	1600	Moderately toxic	USEPA RED
	96 hr acute	–	LC_{50}	1200	Moderately toxic	USEPA RED
	96 hr acute	–	LC_{50}	2400	Moderately toxic	USEPA Ecological Effects Database
	96 hr acute	–	Mean LC_{50}	1664	Moderately toxic	PMRA
Bluegill Sunfish	96 h acute	29%	LC_{50}	670	Highly toxic	USEPA RED
	96 h acute	24%	LC_{50}	700	Highly toxic	USEPA RED
	96 h acute	Methomyl 20SL	LC_{50}	1100	Moderately toxic	EFSA 2008

	96 h acute	Methomyl	LC_{50}	1050	Moderately toxic	USEPA RED
	96 hr acute	–	Mean LC_{50}	857.9	Highly toxic	PMRA
Brook Trout	96 hr acute	Methomyl	LC_{50}	1500	Moderately toxic	USEPA RED
	96 hr acute	24%	LC_{50}	2200	Moderately toxic	USEPA RED
	96 h acute	29%	LC_{50}	1220	Moderately toxic	Johnson and Finley 1980
	96 hr acute	–	Mean LC_{50}	1590.8	Moderately toxic	PMRA
Cutthroat trout	96 h acute	Methomyl	LC_{50}	6800	Moderately toxic	USEPA RED
Channel catfish	96 h acute	Methomyl	LC_{50}	530	Highly toxic	USEPA RED
	96 h acute	29%	LC_{50}	320	Highly toxic	USEPA RED
	96 h acute	24%	LC_{50}	300	Highly toxic	Johnson and Finley 1980
	96 hr acute	–	Mean LC_{50}	370.6	Highly toxic	PMRA
Largemouth bass	96 h acute	Methomyl	LC_{50}	1250	Moderately toxic	USEPA RED
	96 h acute	24%	LC_{50}	760	Highly toxic	Johnson and Finley 1980
Atlantic salmon	96 h acute	Methomyl	LC_{50}	560	Highly toxic	USEPA Ecological Effects Database
	96 h acute	Methomyl	LC_{50}	1120	Moderately toxic	USEPA RED
	96 h acute	24%	LC_{50}	1400	Moderately toxic	USEPA RED
	96 h acute	29%	LC_{50}	1200	Moderately toxic	Johnson and Finley 1980
	96 hr acute	–	Mean LC_{50}	1013.2	Moderately toxic	PMRA
Fathead minnow	96 h acute	Methomyl	LC_{50}	1120	Moderately toxic	USEPA RED

	96 h acute	Methomyl	LC_{50}	1400	Moderately toxic	USEPA RED
	96 h acute	Methomyl	LC_{50}	1200	Moderately toxic	Johnson and Finley 1980
	96 hr acute	–	Mean LC_{50}	1234.6	Moderately toxic	PMRA
Carp	48 h acute	Methomyl	LC_{50}	2800	Moderately toxic	USEPA Ecological Effects Database
Fish Acute HC_5	347 µg ai./L				Highly toxic	PMRA
Fish Chronic Toxicity						
Fathead minnow (*Pimephales promelas)*	Early life stage (28 d)	Methomyl	NOEC	57	–	USEPA RED
Fathead minnow (*Pimephales promelas)*	Life cycle (193 d)	Methomyl	NOEC	76	–	USEPA RED
Marine Species						
Marine Invertebrate Acute Toxicity						
Mysid (*Mysidopsis bahia*)	Static (96-h)	Methomyl	LC_{50}	230	Highly toxic	USEPA RED
Eastern oyster – shell deposition (*Crassostrea virginica*)	–	Methomyl	EC_{50}	140 000	Practically non-toxic	USEPA RED
Grass shrimp (*Palaemonetes vulgaris*)	–	Methomyl	TL_{50}	49	Very highly toxic	USEPA RED
	–	24%	TL_{50}	130	Highly toxic	USEPA RED
	–	–	Mean TL_{50}	79.8	Very highly toxic	PMRA
Pink shrimp (*Penaeus duorarum*)	Static (96-h)	Methomyl	TL_{50}	19	Very highly toxic	USEPA RED
Mud crab (*Neopanope texana*)	Static (96-h)	Methomyl	TL_{50}	410	Highly toxic	USEPA RED
Fiddler crab *(Uce pugilator)*	–	24%	TL_{50}	2380	Moderately toxic	USEPA RED
Marine Invertebrate Acute HC_5	2.6 µg a.i./L				Very highly toxic	PMRA
Marine Fish Acute Toxicity						
Sheepshead minnow	96 hr	Methomyl	LC_{50}	1160	Moderately toxic	USEPA RED

[1] Data from the same study based on EFSA review, 2009.
[a] Based on USEPA classification.
[b] Geometric mean.

Table 4-A Screening Level Risk Assessment for Methomyl Insecticide to Terrestrial Invertebrates

Organism	Exposure	Endpoint value	EEC[2]	RQ[3]
Earthworm	Acute	14-day LC_{50} ÷ 2 43.5 mg ai./kg soil	1.1 mg ai./kg soil (900 g ai./ha x 3)	0.025
Bee	Oral	NA	–	–
	Contact	0.112 kg ai./ha[1] (0.1 µg a.i../bee)	1.89 kg ai./ha x 1	16.9
A. rhopolosiphi	Contact	0.25 µg a.i./ha	248 mg a.i./ha-1890 mg a.i./ha	7560
T. pyri	Contact	12.8 µg a.i./ha	248 mg a.i./ha-1890 mg a.i./ha	148

[1]The LD_{50} in µg/bee is converted to the equivalent rate in kg/ha by multiplying by 1.12 according to Atkins et al. (1981).
[2] Estimated Environmental Concentration (EEC); Soil EEC determined from use on lettuce at the rate indicated and having a soil DT_{50} of 45 d; exposure to bees is based on application to apples with early airblast at the rate indicated.
[3] Risk Quotient (RQ) = exposure/toxicity.

Table 4-B Avian Risk Assessment for Methomyl Insecticide Use (Apples; 1890 g a.i./ha x 1)

Toxicity (mg a.i./kg bw/d)		Food Guild (Food Item)	Maximum Residues		Mean Residues	
			On-Field RQ	Off-Field RQ[1]	On-Field RQ	Off-Field RQ[1]
Small Bird (0.02 kg)						
Acute	3.3	Insectivore (small insects)	28.86	21.36	16.09	11.91
	3.3	Granivore (grain and seeds)	7.21	5.34	3.44	2.55
	3.3	Frugivore (fruit)	14.43	10.68	6.88	5.09
Dietary	11.70	Insectivore (small insects)	8.14	6.02	4.54	3.36
	11.70	Granivore (grain and seeds)	2.03	1.51	0.97	0.72
	11.70	Frugivore (fruit)	4.07	3.01	1.94	1.44
Reproduction	8.48	Insectivore (small insects)	11.23	8.31	6.26	4.63
	8.48	Granivore (grain and seeds)	2.81	2.08	1.34	0.99
	8.48	Frugivore (fruit)	5.62	4.16	2.68	1.98
Medium-Sized Bird (0.1 kg)						
Acute	3.30	Insectivore (small insects)	22.52	16.67	12.56	9.29
	3.30	Insectivore (large insects)	5.63	4.17	2.69	1.99
	3.30	Granivore (grain and seeds)	5.63	4.17	2.69	1.99
	3.30	Frugivore (fruit)	11.26	8.33	5.37	3.97
Dietary	11.70	Insectivore (small insects)	6.35	4.70	3.54	2.62
Reproduction	8.48	Insectivore (small insects)	8.76	6.49	4.89	3.62
	8.48	Insectivore (large insects)	2.19	1.62	1.04	0.77
	8.48	Granivore (grain and seeds)	2.19	1.62	1.04	0.77
	8.48	Frugivore (fruit)	4.38	3.24	2.09	1.55
Large-Sized Bird (1 kg)						
Acute	3.30	Insectivore (small insects)	6.58	4.87	3.67	2.71
	3.30	Insectivore (large insects)	1.64	1.22	0.78	0.58
	3.30	Granivore (grain and seeds)	1.64	1.22	0.78	0.58

Toxicity (mg a.i./kg bw/d)		Food Guild (Food Item)	Maximum Residues		Mean Residues	
			On-Field RQ	Off-Field RQ[1]	On-Field RQ	Off-Field RQ[1]
	3.30	Frugivore (fruit)	3.29	2.43	1.57	1.16
	3.30	Herbivore (short grass)	23.50	17.39	8.35	6.18
	3.30	Herbivore (long grass)	14.35	10.62	4.69	3.47
	3.30	Herbivore (forage crops)	21.74	16.09	7.19	5.32
Dietary	11.7	Insectivore (small insects)	1.85	1.37	1.03	0.77
	11.7	Insectivore (large insects)	0.46	0.34	0.22	0.16
	11.70	Granivore (grain and seeds)	0.46	0.34	0.22	0.16
	11.7	Frugivore (fruit)	0.93	0.69	0.44	0.33
	11.7	Herbivore (short grass)	6.63	4.90	2.35	1.74
	11.7	Herbivore (long grass)	4.05	2.99	1.32	0.98
	11.7	Herbivore (forage crops)	6.13	4.54	2.03	1.50
Reproduction	8.48	Insectivore (small insects)	2.56	1.89	1.43	1.06
	8.48	Insectivore (large insects)	0.64	0.47	0.31	0.23
	8.48	Granivore (grain and seeds)	0.64	0.47	0.31	0.23
	8.48	Frugivore (fruit)	1.28	0.95	0.61	0.45
	8.48	Herbivore (short grass)	9.14	6.77	3.25	2.4
	8.48	Herbivore (long grass)	5.58	4.13	1.82	1.35
	8.48	Herbivore (forage crops)	8.46	6.26	2.80	2.07

[1]Drift from early airblast applications to apples is 74% of applied rate.

Table 4-C Mammalian Risk Assessment for Methomyl Insecticide Use (Apples; 1890 g a.i./ha x1)

Small Mammal (0.015 kg)						
Toxicity (mg a.i./kg bw/d)		**Food Guild (Food Item)**	**Maximum Residues**		**Mean Residues**	
			On-Field RQ	**Off-Field RQ [1]**	**On-Field RQ**	**Off-Field RQ [1]**
Acute	9.1	Insectivore (small insects)	6.0192	4.4542	3.3569	2.4841
	9.1	Granivore (grain and seeds)	1.5048	1.1136	0.7177	0.5311
Reproduction	12.9	Insectivore (small insects)	4.2461	3.1421	2.3680	1.7523
	12.9	Granivore (grain and seeds)	1.0615	0.7855	0.5063	0.3746
	12.9	Frugivore (fruit)	2.1231	1.5711	1.0125	0.7493
Medium-Sized Mammal (0.035 kg)						
Acute	9.1	Insectivore (small insects)	5.2766	3.9047	2.9427	2.1776
	9.1	Insectivore (large insects)	1.3191	0.9762	0.6291	0.4656
	9.1	Granivore (grain and seeds)	1.3191	0.9762	0.6291	0.4656
	9.1	Frugivore (fruit)	2.6383	1.9523	1.2583	0.9311
	9.1	Herbivore (short grass)	18.8583	13.9551	6.6973	4.9560
	9.1	Herbivore (long grass)	11.5144	8.5207	3.7598	2.7823

	9.1	Herbivore (forage crops)	17.4479	12.9115	5.7679	4.2683
Reproduction	12.9	Insectivore (small insects)	3.7222	2.7544	2.0759	1.5361
	12.9	Insectivore (large insects)	0.9306	0.6886	0.4438	0.3284
	12.9	Granivore (grain and seeds)	0.9306	0.6886	0.4438	0.3284
	12.9	Frugivore (fruit)	1.8611	1.3772	0.8876	0.6568
	12.9	Herbivore (short grass)	13.3031	9.8443	4.7245	3.4961
	12.9	Herbivore (long grass)	8.1226	6.0107	2.6523	1.9627
	12.9	Herbivore (forage crops)	12.3082	9.1081	4.0688	3.0109
Large-Sized Mammal (1 kg)						
Acute	9.1	Insectivore (small insects)	2.8194	2.0864	1.5724	1.1636
	9.1	Insectivore (large insects)	0.7049	0.5216	0.3362	0.2488
	9.1	Granivore (grain and seeds)	0.7049	0.5216	0.3362	0.2488
	9.1	Frugivore (fruit)	1.4097	1.0432	0.6723	0.4975
	9.1	Herbivore (short grass)	10.0766	7.4567	3.5786	2.6482
	9.1	Herbivore (long grass)	6.1525	4.5529	2.0090	1.4867
	9.1	Herbivore (forage crops)	9.3230	6.8990	3.0820	2.2807
Reproduction	12.9	Insectivore (small insects)	1.9889	1.4718	1.1092	0.8208
	12.9	Insectivore (large insects)	0.4972	0.3680	0.2371	0.1755
	12.9	Granivore (grain and seeds)	0.4972	0.3680	0.2371	0.1755
	12.9	Frugivore (fruit)	0.9945	0.7359	0.4743	0.3510
	12.9	Herbivore (short grass)	7.1083	5.2601	2.5244	1.8681
	12.9	Herbivore (long grass)	4.3402	3.2117	1.4172	1.0487
	12.9	Herbivore (forage crops)	6.5767	4.8668	2.1741	1.6088

[1]Drift from early airblast applications to apples is 74% of applied rate.

Table 5 Screening Level Risk Assessment for Methomyl to Non-target Aquatic Species

Organism	Exposure	Test Substance	End Point[a]	Value (µg a.i./L)	Corrected Value[1] (ug/L)	EEC (µg/L)	RQ
Freshwater Species							
Invertebrate Acute Toxicity							
Water flea *(Daphnia magna)*	Acute 48 hr	–	Mean EC_{50}	16.5	8.3	236	28.4
Scuds (*Gammarus pseudolimnaeus*)	Static 96-h	Methomyl	LC_{50}	1050	525	236	0.45
Stonefly (*Isogenus* sp)	Static 96-hr	Methomyl	LC_{50}	343	171.5	236	1.38
Stonefly (*Skwala* sp)	Static 96-hr	Methomyl	Mean EC_{50}	31.4	15.7	236	15.03
Stonefly (*Pteronarcella badia*)	Static 96-hr	Methomyl	Mean EC_{50}	64.3	32.2	236	7.33

Midge (*Chironomus plumosus*)	Static 48-hr	Methomyl	LC_{50}	88	44	236	5.36
Midge (*Chironomus sp)*	96 hr	Methomyl	LC_{50}	32	16	236	14.75
Scud (*Gammarus Italicus*)	96 hr	Methomyl	EC_{50}	47	23.5	236	10.04
Scud (*Echinogammarus tibaldii*)	96 hr	Methomyl	EC_{50}	250	125	236	1.89
Water flea *(Daphnia longispina*)	96 hr	Methomyl	EC_{50}	220	110	236	2.15
Cyclops strenuous	96 hr	Methomyl	EC_{50}	190	95	236	2.48
Scud *(Gammarus pulex*)	96 hr	Methomyl	EC_{50}	760	380	236	0.62
Biomphalaria alexandrina	96 hr	Methomyl	EC_{50}	1100	550	236	0.43
Bulinus truncatus	96 hr	Methomyl	EC_{50}	870	435	236	0.54
Invertebrate Acute HC_5	15 µg/L				15	236	15.73
Invertebrate Chronic Toxicity							
Water flea *(Daphnia magna*)	chronic 21d	Methomyl	NOEC (# of offspring produced)	0.4	0.4	236	590
Fish Acute Toxicity							
Rainbow trout	96 hr acute	–	Mean LC_{50}	1664	166.4	236	1.42
Bluegill sunfish	96 hr acute	–	Mean LC_{50}	857.9	85.8	236	2.75
Brook Trout	96 hr acute	–	Mean LC_{50}	1590.8	159	236	1.48
Cutthroat trout	96 h acute	Methomyl	LC_{50}	6800	680	236	0.35
Channel catfish	96 hr acute	–	Mean LC_{50}	370.6	37	236	6.38
Largemouth bass	96 hr acute	–	Mean LC_{50}	974.6	97.5	236	2.42
Atlantic salmon	96 hr acute	–	Mean LC_{50}	1013.2	101.3	236	2.33
Fathead minnow	96 hr acute	–	Mean LC_{50}	1234.6	123.5	236	1.91
Carp	48 h acute	Methomyl	LC_{50}	2800	280	236	0.84
Fish Acute HC_5	347 μg a.i./L				347	236	0.68
Fish Chronic Toxicity							
Fathead minnow (*Pimephales promelas)*	Early life stage (28d)	Methomyl	NOEC	57	57	236	4.14
Fathead minnow (*Pimephales promelas)*	Life cycle (193 d)	Methomyl	NOEC	76	76	236	3.1
Amphibian Toxicity (based on fish data)							
Amphibians	96 hr	–	HC_5	347	347	1260	3.63
	chronic	–	NOEC	57	57	1260	22.1

Marine Species							
Invertebrate Acute Toxicity							
Mysid (*Mysidopsis bahia*)	Static (96-h)	Methomyl	LC_{50}	230	115	236	2.05
Eastern oyster – shell deposition (*Crassostrea virginica*)	–	Methomyl	EC_{50}	140 000	70000	236	0
Grass shrimp (*Palaemonetes vulgaris*)	–	–	Mean TL_{50}	79.8	39.9	236	5.91
Pink shrimp (*Penaeus duorarum*)	Static (96-h)	Methomyl	TL_{50}	19	9.5	236	24.8
Mud crab (*Neopanope texana*)	Static (96-h)	Methomyl	TL_{50}	410	205	236	1.15
Fiddler crab *(Uce pugilator)*	–	24%	TL_{50}	2380	1190	236	0.2
Marine Invertebrate Acute HC_5	2.6 µg a.i./L				2.6	236	90.77
Fish Acute Toxicity							
Sheepshead minnow	96 hr	Methomyl	LC_{50}	1160	580	236	0.41

[1] Correction factors of 1/10th the endpoint value are used for fish and amphibians, 1/2 are used for invertebrates and plants.
[a] Geometric mean endpoint from multiple studies with the same species.

Table 6 Risk Assessment on Non-Target Aquatic Species Considering Drift from Spray Area

Organism (Exposure)	Test Substance	Endpoint (µg a.i./L)	Application	EEC (µg ai./L)[1]	RQ	Factors
Freshwater invertebrates	Methomyl	Acute: HC_5 = 15	Ground	21.7	1.45	Freshwater invertebrates are expected to be exposed to off-field concentrations that exceed the threshold for acute and chronic toxicity from application of methomyl.
			Airblast	174.6	11.64	
			Aerial: 1 app 2 app	14 23.7	0.9 1.6	
		Chronic: NOEC: 0.4	Ground	21.7	54	
			Airblast	174.6	436.6	
			Aerial: 1app 2 app	14 23.7	35 59.2	
Freshwater fish	Methomyl	Acute: HC_5 = 347	Ground	21.7	< 1	Freshwater fish are not expected to be exposed off-field to acutely toxic concentrations of methomyl. Airblast application may result in reproductive effects in fish.
			Airblast	174.6	< 1	
			Aerial: 1 app 2 app	14 23.7	< 1 < 1	
		Chronic: NOEC: 57	Ground	21.7	< 1	
			Airblast	174.6	3	

			Aerial: 1 app 2 app	14 23.7	< 1 < 1	
Amphibians	Methomyl	Acute: HC_5 = 347	Ground	115.5	< 1	Amphibians are at potential acute and reproductive risk for some uses based on fish toxicity data.
			Airblast	932	2.69	
			Aerial: 1 app 2 app	74.6 126.4	< 1 < 1	
		Chronic: NOEC: 57	Ground	115.5	2	
			Airblast	932	16.3	
			Aerial: 1 app 2 app	74.6 126.4	1.3 2.2	
Marine invertebrates	Methomyl	Acute: HC_5: 2.6	Ground	21.7	8.35	Marine invertebrates are expected to be exposed to off-field concentrations that exceed the threshold for acute from both aerial and ground application of methomyl.
			Airblast	174.6	67.2	
			Aerial: 1 app 2 app	14 23.7	5.4 9.1	

[1] Maximum EEC in 80-cm water (15 cm for amphibians) for the following uses:

- Ground boom app. on lettuce at 900 g a.i./ha x 3; (% drift): 197 µg/L (11% = 21.7 µg/L, fine spray droplet size).
- Airblast on apples at 1890 g a.i./ha x 1 app: 236 µg/L (74% = 174.6 µg/L).
- Aerial use on cereals, at 486 g a.i./ha x 2 apps: 91.1 µg/L (26% = 23.7 µg/L; fine spray droplet size).
- Aerial use on cereals, at 486 g a.i./ha x 1 apps: 60.7 µg/L (23% = 14 µg/L; medium spray droplet size).
- Maximum corresponding EECs in 15 cm water: 115.5 µg/L, 932 µg/L and 74.6-126.4 gu/L (1 app. vs. 2 app).
- Drift data obtained from data set of Wolf and Caldwell (2001).

Table 7 Risk to Aquatic Organisms from Surface Runoff

Organism	Test Substance	Endpoint	EEC[1] (µg a.i./L)	RQ
Freshwater invertebrates	Methomyl	**Acute** HC_5: 15 µg a.i./L	63	4.2
		Chronic NOEC: 0.4 µg a.i./L	26	65
Freshwater fish	Methomyl	**Acute** HC_5: 347 µg a.i./L	63	< 1
		Chronic (Early life stage) 57 µg a.i./L	26	< 1
Marine invertebrates	Methomyl	**Acute** HC_5: 2.6 µg a.i./L	63	31.5
Amphibians	Methomyl	**Acute** HC_5: 347 µg a.i./L	336	< 1
		Chronic NOEC: 57 µg/L	93	1.63

Organism	Test Substance	Endpoint	EEC[1] (µg a.i./L)	RQ
[1] EEC 90th percentile concentration (time-frame and scenario) – acute EEC (peak); chronic daphnid EEC (21 d). Scenario based on application to sweet corn 3 x 562.5 g a.i./ha..				

Table 8 Toxic Substances Management Policy Considerations – Comparison to TSMP Track 1 Criteria

TSMP Track 1 Criteria	TSMP Track 1 Criterion Value		Methomyl Endpoints
CEPA toxic or CEPA toxic equivalent[1]	Yes		Yes
Predominantly anthropogenic[2]	Yes		Yes
Persistence[3]:	Soil	Half-life 182 days	45 days (aerobic soil)
	Water	Half-life 182 days	5 d (aerobic water/sediment)
	Sediment	Half-life 365 days	No
	Air	Half-life 2 days or evidence of long range transport	Half-life or volatilization is not an important route of dissipation and long-range atmospheric transport is unlikely to occur based on the vapor pressure [5 x 10^{-5} mm Hg (25ºC)] and Henry's law constant 1.84 x 10^{-10} atm m^3/mol), 1/H=1.33E-8
Bioaccumulation[4]	Log K_{OW} 5		0.6
	BCF 5000		NA
	BAF 5000		NA
Is the chemical a TSMP Track 1 substance? (All four criteria must be met.)	No, does not meet TSMP Track 1 criteria.		

[1]All pesticides will be considered CEPA-toxic or CEPA toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the CEPA toxicity criteria may be refined if required (in other words, all other TSMP criteria are met). [2]The policy considers a substance "predominantly anthropogenic" if, based on expert judgment, its concentration in the environment medium is largely due to human activity, rather than to natural sources or releases. [3] If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment or air) than the criterion for persistence is considered to be met.
[4]Field data (for example, BAFs) are preferred over laboratory data (for example, BCFs) which, in turn, are preferred over chemical properties (for example, log K_{OW}).

Appendix XI Methomyl Aquatic Ecoscenario and Drinking Water Assessment

1.0 Introduction

The following sections review the estimated environmental concentrations (EECs) of methomyl resulting from water modelling with respect to environmental exposure and drinking water. Methomyl was initially modelled in 2005 for drinking water assessment, and the current modelling was requested since new use patterns with new adsorption/desorption and soil aerobic fate studies were submitted and reviewed.

2.0 Modelling Estimates

2.1 Application Information and Model Inputs

Methomyl is an insecticide used on a number of trees, fruits and vegetables including balsam fir in Christmas tree plantations, farm woodlots, greenhouse cucumbers, canola, flax, oats, barley, wheat, apple, broccoli, brussels sprouts, cabbage, cauliflower, lettuce (field), peas, potatoes, snap beans, strawberries, sweet corn, tomatoes, tobacco, balsam fir in municipal parks and rights-of-way. The maximum annual application rate is for use on lettuce (field), three applications of 0.9 kg a.i./ha, at 5-day intervals. The second highest rate is used on apple, one application of 1.89 kg a.i./ha. Application information and the main environmental fate characteristics used in the models are summarized in Table 2.1-1.

Table 2.1-1 Major Groundwater and Surface Water Model Inputs for Assessment of Methomyl

Type of Input	Parameter	Value
Application Information	Crop(s) to be treated	Lettuce (field) Apple Sweet corn Wheat, Barley, Oats
	Maximum allowable application rate per year (g a.i./ha)	2700 1890 1687.5 972
	Maximum rate each application (g a.i./ha)	900 1890 562.5 486
	Maximum number of applications per year	3 1 3 2
	Minimum interval between applications (days)	5 – 2 5
	Method of application	Ground/airblast/aerial

Type of Input	Parameter	Value
Environmental Fate Characteristics	Hydrolysis half-life at pH 7 (days)	378
	Photolysis half-life in water (days)	1
	Adsorption K_{OC} (mL/g)	0.236 (20th percentile of nine K_d values for methomyl)
	Aerobic soil biotransformation half-life (days)	30 (80th percentile of six half-life values)
	Aerobic aquatic biotransformation half-life (days)	5 (longest of two half-lives)
	Anaerobic aquatic biotransformation half-life (days)	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 Root Zone Model/Exposure Analysis Modelling System (PRZM/EXAMS) models. The PRZM/EXAMS models simulate 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.

Six standard regional scenarios were modelled to represent different regions of Canada. Seven initial application dates between April and July were modelled. Table 2.1-1 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 for each run as follows. For each year of the simulation, PRZM/EXAMS 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 over each averaging period are reported as the EECs for that period. The largest EECs of all selected runs of a given use pattern/regional scenario are reported in Tables 2.2-1 and 2.2-2 for 15-cm and 80-cm deep water bodies, respectively.

Table 2.2-1 Level 1 Aquatic Ecoscenario Modelling EECs (g a.i./L) for Methomyl in a Water Body 0.15 m Deep, Excluding Spray Drift

Region	EEC (µg a.i./L)					
	Peak	96-hour	21-day	60-day	90-day	Yearly
Lettuce, 3 x 0.9 kg a.i./ha, at 5-day intervals						
B.C. – Raspberry	14	10	4.0	2.0	1.4	0.34
Que. – Corn	234	168	66	26	17	4.3
Apples, 1 x 1.89 kg a.i./ha						
B.C. – Apple	1.6	1.2	0.47	0.17	0.12	0.029
N.S. – Apple	48	36	15	5.6	3.7	0.92
Sweet Corn, 3 x 0.5625 kg a.i./ha, at 2-day intervals						
Man. – Potato	336	237	93	35	23	5.8
Ont. – Corn	152	110	41	15	10	2.5

Table 2.2-2 Level 1 Aquatic Ecoscenario Modelling EECs (µg a.i./L) for Methomyl in a Water Body 0.8 m Deep, Excluding Spray Drift

Region	EEC (ug a.i./L)					
	Peak	96-hour	21-day	60-day	90-day	Yearly
Lettuce, 3 x 0.9 kg a.i./ha, at 5-day intervals						
B.C. – Raspberry	2.6	2.2	1.2	0.67	0.45	0.11
Que. – Corn	44	37	18	7.6	5.1	1.3
Apples, 1 x 1.89 kg a.i./ha						
B.C. – Apple	0.30	0.25	0.14	0.060	0.040	0.010
N.S. – Apple	9.0	7.8	4.6	1.9	1.3	0.31
Sweet corn, 3 x 0.5625 kg a.i./ha, at 2-day intervals						
Man. – Potato	63	50	26	11	7.2	1.8
Ont. – Corn	29	24	12	4.7	3.2	0.78

2.3 Estimated Concentrations in Drinking Water Sources: Level 2 Modelling

Estimated environmental concentrations (EECs) of methomyl in potential drinking water sources (groundwater and surface water) were estimated using computer simulation models. An overview of how the EECs are estimated is provided in the PMRA's Science Policy Notice SPN2004-01, *Estimating the Water Component of a Dietary Exposure Assessment*. EECs of methomyl in groundwater were calculated using the Leaching Estimation and Chemistry Model (LEACHM) model to simulate leaching through a layered soil profile over a 50-year period. The concentrations calculated using LEACHM are based on the flux, or movement, of pesticide into shallow groundwater with time. EECs of methomyl in surface water were calculated using the Pesticide Root Zone Model/Exposure Analysis Modelling System (PRZM/EXAMS) models, which simulate pesticide runoff from a treated field into an adjacent water body and the fate of a pesticide within that water body. Pesticide concentrations in surface water were estimated in two types of vulnerable drinking water sources, a small reservoir and a prairie dugout.

Methomyl was assessed for risks to drinking water in 2005, both at Level 1 and Level 2. New use patterns and some new fate data were added in 2009, and the current Level 2 modelling is conducted to incorporate those changes. Table 2.1-1 lists the application information and main environmental fate characteristics used in the simulations. Eight (for surface water) and four (for groundwater) initial application dates between early May and late July were modelled. The model was run for 50 years for all scenarios. The largest EECs of all selected runs are reported in Table 2.3-1, which follows.

Table 2.3-1 Level 2 Estimated Environmental Concentrations of Methomyl in Potential Drinking Water Sources

Crop	Groundwater EEC (µg a.i./L)		Surface Water EEC (µg a.i./L)					
			Reservoir (P.E.I.)		Reservoir (Que.)		Dugout	
	Daily[1]	Yearly[2]	Daily[3]	Yearly[4]	Daily[3]	Yearly[4]	Daily[3]	Yearly[4]
Lettuce (field), 3 x 0.9 kg a.i./ha, at 5-day intervals	17	16	123	4.8	66	1.9	100	6.1
Sweet corn, 3 x 0.5625 kg a.i./ha, at 2-day intervals	N/M[5]	N/M[5]	83	3.3	N/M[5]	N/M[5]	67	4.0

Notes
1 90th percentile of daily average concentrations.
2 90th percentile of yearly average concentrations.
3 90th percentile of yearly peak concentrations.
4 90th percentile of yearly average concentrations.
5 Not modelled.

2.4 Estimated Concentrations in Drinking Water Sources: Refined Level 2 Modelling

The surface water modelling estimates were further refined for reservoirs and dugouts as the EECs reported above were of concern. Refinements to the modelling included using regional scenarios and weather information in consideration of specific information and use patterns for the following crops: lettuce, apples, small grains and corn. Results are tabulated in Tables 2.4-1, which follows.

Table 2.4-1 Refined Level 2 Estimated Environmental Concentrations of Methomyl in Potential Drinking Water Sources

Crop	Surface Water EEC (µg a.i./L)													
	Reservoir (B.C.)		Reservoir (Alta.)		Reservoir (Ont.)		Reservoir (Que.)		Reservoir (N.S.)		Reservoir (Sask.)		Dugout (Sask.)	
	Daily[1]	Yearly[2]	Daily[1]	Yearly[2]	Daily[1]	Yearly[2]	Daily[1]	Yearly[2]	Daily[1]	Yearly[2]	Daily[1]	Yearly[2]	Daily[1]	Yearly[2]
Lettuce (field), 3 x 0.9 kg a.i./ha, at 5-day intervals	N/M[3]	N/M[3]	N/M[3]	N/M[3]	N/M[3]	N/M[3]	42	1.3	N/M[3]	N/M[3]	N/M[3]	N/M[3]	N/M[3]	N/M[3]
Apple, 1 x 1.89 kg a.i./ha	4.7	0.15	N/M[3]	N/M[3]	12	0.39	N/M[3]	N/M[3]	28	0.77	N/M[3]	N/M[3]	N/M[3]	N/M[3]
Sweet corn, 3 x 0.5625 kg a.i./ha, at 2-day intervals	2.1	0.095	17	0.47	55	1.6	N/M[3]	N/M[3]	N/M[3]	N/M[3]	N/M[3]	N/M[3]	N/M[3]	N/M[3]
Wheat, Barley, Oats, 2 x 0.486 kg a.i./ha, at 5-day intervals	N/M[3]	N/M[3]	N/M[3]	N/M[3]	N/M[3]	N/M[3]	N/M[3]	N/M[3]	N/M[3]	N/M[3]	18	0.72	22	0.94

Notes

1 90th percentile of yearly peak concentrations.
2 90th percentile of yearly average concentrations.
3 Not modelled.

Note: Daily concentration values for some of the above scenarios were also provided for dietary assessment.

3.0 Water Monitoring Data

3.1 Sources of Data

In addition to water modeling, a search for methomyl water monitoring data in Canada was undertaken. When the original assessment was conducted in 2004-2005, the federal, provincial and territorial representatives from all of the provinces and territories in Canada were contacted, requesting water monitoring data for pesticides that were undergoing re-evaluation. Requests were also submitted to Environment Canada, the Department of Fisheries and Oceans and the drinking water subcommittee through Health Canada. A response was received from most provinces and territories and the available data were submitted. While methomyl is used across the country on commodities, which include fruits, vegetables, cereals and small grains, only a handful of Canadian monitoring studies were available that included methomyl. These were conducted in Prince Edward Island, New Brunswick, Ontario, Saskatchewan and British Columbia.

American databases were searched for detections of methomyl. Data on residues in water samples taken in the United States are important to consider in the Canadian water assessment given the extensive monitoring programs that exist in the United States. Runoff events, local use patterns, site specific hydrogeology as well as testing and reporting methods are probably more important influences on residue data rather than Northern versus Southern climate. As for the climate, if temperatures are cooler, residues may break down more slowly. On the other hand, if temperatures are warmer, growing seasons may be longer and applications may be more numerous and frequent.

Data were available from the United States Geological Survey's National Water Quality Assessment program (NAWQA), the United States Environmental Protection Agency (USEPA) STORET data warehouse, as well as the United States Department of Agriculture for both groundwater and surface water. A description of available monitoring data was also available from the United States Environmental Protection Agency re-registration eligibility document (USEPA RED) document for methomyl.

3.2 Approach to the Evaluation

Data from Canadian and American water monitoring studies in which methomyl was analyzed are summarized in Table 3.2-1.

For both the ecoscenario assessment and the drinking water assessment, information was extracted from the available sources, tabulated and sorted into categories as follows:

1. Residues in known drinking water sources (both surface and groundwater).
2. Residues in ambient water that may serve as a drinking water source (both surface and groundwater).
3. Residues in ambient water that are unlikely to serve as a drinking water source.

The majority of the data available for methomyl is from surveillance programs where the goal is to determine presence or absence of methomyl. An important limitation of this type of monitoring data set is that in many cases, the data were not accompanied with use information for methomyl. For instance, the application rate applied, when the application occurred and weather conditions prior to sampling were not known or reported. Without this information, it is difficult to conclude if non-detects are a result of non-transport or more simply a result of inappropriate timing or location of sampling. In addition, because the data are sparse and concentrations vary in time and space, the maximum concentration reported is unlikely to be the absolute maximum concentration that would be observed in Canada. Factors that may result in higher concentrations being detected include application at higher rates, precipitation and some areas/soils are simply more prone to leaching and/or run off. Sampling at intervals immediately following application would increase the likelihood that the maximum concentration would be detected.

Given the lack of ancillary data, it is possible that methomyl was not used in some of the areas monitored, and that higher concentrations of methomyl may occur in other areas not monitored. The methomyl monitoring data may underestimate the peak exposure because of the following limitations:

- In general, the data are sparse in both time and location. Methomyl use information from the areas surrounding where the samples were collected is often not available.

- The concentrations of pesticides 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 (in other words, once a month, once a week) and are unlikely to capture the absolute maximum concentration of methomyl.

The following statistics are used, where appropriate, to interpret the information available in each dataset and are summarized in Table 3.2-1.

- The detection frequency provides an indication of how often positive detections occur within the given data set. Detection frequency is primarily determined by the limits of detection and is influenced by pesticide use patterns and application rates. Consequently, a wide range of detection frequencies is likely to be expected.

- The 95th percentile concentration is calculated and reported. Maximum values should also be considered, especially when the 95th percentile is not available which occurs when there are insufficient detections to calculate a 95th percentile.

- The maximum concentration is reported and is used to determine the 95th percentile concentration to estimate an acute exposure value.

- The arithmetic mean with non-detects considered at ½ LOD is used to determine the 95th percentile concentration to estimate a chronic exposure value.

Table 3.2-1 Summary of the Monitoring Studies Available

Data Source	Detection Frequency					Concentration (µg/L)			
	Location	Minimum Detection or Detection Limit (µg/L)	Number of Systems Tested (or Absolute Number of Samples)	Number of Systems or Samples with Detections	% Detection Frequency	Mean Detection	95th percent-ile	Absolute Max.	Arithmetic Mean Including Non-detects at ½ LOD
Methomyl Residues in Municipal Drinking Water Sources and Ground Water									
PMRA 1307567	Groundwater in P.E.I. (1996)	0.5	10	0	0	–	–	–	0.25
PMRA 1303803	Wells, dugouts, raw water supply reservoirs, Saskatchewan (1986)	1	40	0	0	–	–	–	0.5
PMRA 1345591	Groundwater in the Lower Fraser Valley, British Columbia (1992-1993)	1	74	0	0	–	–	–	0.5
PMRA 1560632, 1640595	Drinking water supplies in New Brunswick municipalities (2003)	0.2-1	19	0	0	–	–	–	0.31
PMRA 2096281	United States – groundwater NAWQA (1992-2011)	0.0014-3.56	6342	4	0.06	0.19	0.36	0.38	0.0155
PMRA 2906281	Methomyl oxime United States – groundwater NAWQA (1999-2001)	0.0102-0.2	180	0	0	–	–	–	0.008
PMRA 1857399	United States finished drinking water (2001)	0.02	134	0	0	–	–	–	0.01
PMRA 1857396	United States finished drinking water (2002)	0.0018-0.023	495	0	0	–	–	–	0.0115
PMRA 1857388	United States finished drinking water (2003)	0.0018-0.023	542	0	0	–	–	–	0.0115
PMRA 1852616	United States finished drinking water (2004)	0.006	113	0	0	–	–	–	0.003

Data Source	Detection Frequency					Concentration (µg/L)			
	Location	Minimum Detection or Detection Limit (µg/L)	Number of Systems Tested (or Absolute Number of Samples)	Number of Systems or Samples with Detections	% Detection Frequency	Mean Detection	95th percent-ile	Absolute Max.	Arithmetic Mean Including Non-detects at ½ LOD
PMRA 1852618	United States finished drinking water (2005)	0.0036-0.025	230	0	0	–	–	–	0.0125
PMRA 1852619	United States finished drinking water (2006)	0.0036-0.075	365	0	0	–	–	–	0.0375
PMRA 1774484	United States finished drinking water (2007)	0.0036-0.075	368	0	0	–	–	–	0.0375
PMRA 1852614	United States finished drinking water (2008)	0.0018-0.0073	309	0	0	–	–	–	0.00365
Methomyl Residues in Ambient Water That May Serve as a Drinking Water Source									
PMRA 1307580	Grand, Saugeen and Thames River, Ontario (1981-1985)	< 1	314	0	0	–	–	–	0.5
PMRA 2096281	United States – surface water NAWQA (1992-2011)	0.0044-26.35	7948	65	0.8	0.15	0.61	1	0.03
PMRA 2096281	Methomyl oxime United States - surface water NAWQA (1999-2001)	0.0102-0.2	151	1	0.7	–	–	0.011	0.0096
PMRA 1469753	NCOD Database, US (1992-1997)	Not reported	32 156	33	0.1	1.343	–	3	–
PMRA 2096296	STORET Database, US (1986-2010)	Not reported	2711	14 (samples above LOQ) 95 (samples above LOD but below LOQ)	0.5 (samples above LOQ) 3.5 (samples above LOD but below LOQ)	6.2 (samples above LOD but below LOQ)	25.3 (samples above LOD but below LOQ)	50	–

Methomyl Residues in Water That Is Unlikely To Be Used as a Drinking Water Source									
PMRA 1345576	Elk Creek and Yorkson Creek; small urban and agricultural streams in the Lower Fraser Valley, British Columbia (spring and fall 2000)	0.01	8	0	0	–	–	–	0.005
PMRA 1763866	Wilmot and Dunn River Systems, Prince Edward Island (2008, dry periods)	0.15	9	0	0	–	–	–	0.075
PMRA 1307555	Eight urban streams, United States (1993-1994)	0.05	200	1	0.5	–	–	0.14	0.0256
PMRA 1852616	USDA – Untreated water at intake to treatment plants (2004)	0.006	114	0	0	–	–	–	0.003
PMRA 1852618	USDA – Untreated water at intake to treatment plants (2005)	0.0036-0.025	231	0	0	–	–	–	0.0125
PMRA 1852619	USDA – Untreated water at intake to treatment plants (2006)	0.0036-0.075	367	0	0	–	–	–	0.0375
PMRA 1774484	USDA – Untreated water at intake to treatment plants (2007)	0.0036-0.075	362	0	0	–	–	–	0.0375
PMRA 1852614	USDA – Untreated water at intake to treatment plants (2008)	0.0018-0.0073	308	0	0	–	–	–	0.00365
"–" indicates not applicable or cannot be calculated based on available data.									

4.0 Discussion and Conclusions

The Level 2 ecoscenario and drinking water exposure estimates determined using modelling are outlined in Section 2, above.

Overall, the monitoring data available from Canada and the United States indicate that methomyl is detected very infrequently in surface and groundwater (197 detections of methomyl out of a total of 52 170 samples (< 1% detection frequency) in potential drinking water sources). In Canada, no detections of methomyl were recorded in 474 samples collected over five provinces. In the United States, it was not detected in finished drinking water, and rarely detected in ambient water samples collected from several states in a variety of land uses including agricultural, urban and mixed land use types. Methomyl is not expected to persist in clear, shallow waters because of its susceptibility to phototransform.

The following monitoring information summary was available in the USEPA RED document for methomyl (PMRA 1299605). This information is not reflected in Table 3.2-1 above as details were lacking.

- A prospective ground water monitoring study reviewed by the USEPA was conducted in a vulnerable area in Georgia (1992-1994). Methomyl was detected in ground water at concentrations ranging from 0.110-0.428 µg/L. The monitoring study was conducted using a total application rate of 12 609 g a.i./ha, approximately 4.7 times the maximum label rate for methomyl in Canada (2700 g a.i./ha on lettuce). Although sampling continued for 27 months after application, no methomyl was detected after approximately 4 months. In addition, the Pesticides in Ground Water Database indicates that methomyl has been detected in three other states (Missouri, New York, and New Jersey) at concentrations up to 20 µg/L. The available information shows that methomyl has the potential to leach to ground water. However, the USEPA RED stated that as illustrated by the prospective study conducted in Georgia, this degradation of groundwater quality will probably be short-lived. It should be noted that methomyl was applied one year only in this study, whereas in reality, repeated applications of methomyl from year to year are likely, particularly in orchards, where there is no crop rotation.

- The South Florida Water Management District (SFWMD) collected samples every two to three months from 27 surface water sites within the SFWMD from November 1988 through November 1993 and analyzed them for multiple pesticides. Methomyl was detected (detection limits ranging from 1.9 to 20 µg/L) in one sample at a concentration of 1.9 µg/L. The detection limits reported for these samples are very high. In 1994, Washington State collected surface water samples in April, June and October from 8 sites (24 total samples) and analyzed them for multiple pesticides including methomyl. Methomyl was not detected in any of the samples above an approximate quantification limit of 0.04 µg/L. However, methomyl was detected at a concentration of 0.088 µg/L in a 1993 sample collected from a site (Salmon Creek) not resampled in 1994. Neither study indicated whether the samples were taken in major methomyl use areas and whether detections are related to actual methomyl usage.

- The USEPA STORET database contained 9 detections of methomyl in 3849 samples collected over 37 states. Detections were reported in California (5 detects ranging from 0.13 to 0.67 µg/L), Texas (3 detects ranging from 0.12 to 1 µg/L), Pennsylvania (0.19 µg/L), and Washington (0.9 µg/L). Most of the detection limits were below 1 µg/L.

Note that the summary of STORET data in the USEPA RED document does not reflect the data that were downloaded from the STORET data warehouse in August of 2011, and which are summarized in Table 3.2-1.

The USEPA RED document states that the reported monitoring data provide supplemental information on methomyl concentrations in surface water. However, these data were not used by the USEPA for determining ecological risks or drinking water concentrations because of uncertainties in sample collection and location (particularly the association with actual use areas), methods of analysis, limits of detection, and quality control. The USEPA RED document reviewed a number of directed field sampling studies where sampling was done over an extended period in and around fields or orchards treated with methomyl. These studies were done without a buffer zone, thus water concentrations are attributable to both runoff and drift. The PMRA reviewed a field study relevant to Canada, namely an apple orchard study in Michigan. In this study 5 applications were made with a 5 day interval; median pond water concentrations ranged from 0.16-13.3 µg/L during the study period, dropping below 0.2 µg/L in 9-30 days after the last application. It is noted that the Canadian apple use rate is only one application per season at 1890 g a.i./ha, thus concentrations are likely to be lower than in the American study, however, based on the aquatic dissipation profile of the active ingredient, the chronic NOEC of 0.4µg/L for invertebrates is predicted to be exceeded for more than 21 days.

Despite uncertainties associated with the monitoring data, taken as a whole, the data indicate that methomyl is rarely detected in water.

Given that methomyl is rarely detected in water, it is unlikely that humans or aquatic organisms would be chronically exposed to methomyl residues in surface water. Given the transient nature of methomyl, available monitoring data are unlikely to capture peak concentrations. As such, the current monitoring data is not appropriate for estimating potential acute exposure (hours to days) and thus modeling estimates should be relied upon for short term exposure estimates.

Appendix XII Label Amendments for 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 following label statements.

A) Label Amendments for Technical Products

I) The following statements must be included in the section entitled **TOXICOLOGICAL INFORMATION**:

"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."

II) The following statements must be included in the section entitled **PRECAUTIONS**: "May be fatal if swallowed, inhaled or absorbed through the skin or eyes."

B) Label Amendments for Both Commercial and Restricted Class Products

I) The following statements must be included in the section entitled **PRECAUTIONS** on all end-use product labels:

"Keep the following personal protective equipment immediately available for use in case of emergency (in other words, a broken package, spill or equipment breakdown): chemical-resistant coveralls, chemical-resistant gloves, chemical-resistant head gear and a respirator."

C) Label Amendments for the Commercial Class Granular Bait Products (add if not already present)

I) The following statements must be included in the section entitled **PRECAUTIONS** on all commercial end-use product labels > 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.”

II) The following statements must be included in a section entitled **DIRECTIONS FOR USE** on all end-use product labels:

“Not for use in residential areas.”

III) The following statements must be included in a section entitled **ENVIRONMENTAL HAZARDS:**

“TOXIC to birds and small wild mammals. Any spilled granules must be cleaned-up.”

C) Label Amendements for The Restricted Class Product (Wettable Powder in Water Soluble Package)

I) The following statements must be included in the section entitled **PRECAUTIONS**:

“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.”

“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.

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.”

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

II) The following statements must be included in a section entitled **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

<table>
<tr><th rowspan="3">Method of Application</th><th rowspan="3" colspan="2">Crop</th><th colspan="4">Buffer Zones (Metres) Required for the Protection of</th></tr>
<tr><th colspan="2">Freshwater Habitat of Depths</th><th colspan="2">Estuarine/Marine Habitats of Depths</th></tr>
<tr><th>Less than 1 m</th><th>Greater than 1 m</th><th>Less than 1 m</th><th>Greater than 1 m</th></tr>
<tr><td rowspan="2">Airblast</td><td rowspan="2">Balsam fir and spruce in Christmas tree plantations, farm woodlots, rights-of-way.</td><td>Early growth stage</td><td>45</td><td>35</td><td>25</td><td>15</td></tr>
<tr><td>Late growth stage</td><td>35</td><td>25</td><td>15</td><td>5</td></tr>
</table>

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.

III) The following statements must be included in a section entitled **ENVIRONMENTAL HAZARDS**:

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

"TOXIC to bees exposed to direct treatment, drift, or residues on flowering crops or weeds. 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."

"The use of this chemical may result in contamination of groundwater particularly in areas where soils are permeable (for example, sandy soil) and/or the depth to the water table is shallow."

"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."

References

A. List of Studies/Information Submitted by Registrant

Chemistry

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818713	1992, Technical Grade Methomyl: Analysis and Certification of Product Ingredients, DACO: 2.12.1,2.13.1,2.13.2,2.13.3,2.13.4 CBI
1503064	1984, Technical Chemistry file [privacy removed] Lannate methomyl. Analytical Procedure for the Determination of Methomyl and [CBI removed], Storage Stability, [CBI removed], DACO: 2.99
1503036	Technical Chemistry file [privacy removed] Methomyl, DACO: 2.99
1503053	Technical Chemistry file [privacy removed] Specifications, Product Identity, Manufacturing Process, Specifications for Technical Materials, Analytical Methods, Physical and Chemical Properties, DACO: 2.99
1700953	2008, Technical Grade Methomyl (Dpx-X1179) Manufacturing Description And Formation Of Impurities, Daco: 2.11.1,2.11.2,2.11.3,2.11.4 Cbi
1700955	2008, Batch Analysis Of Methomyl (Dpx-X1179) Technical, DACO: 2.13.3,2.13.4 CBI
2101189	2009, Batch Analysis Of Methomyl (Dpx-X1179) Technical, DACO: 2.13.3,2.13.4 CBI

Human Health

PMRA Document Number	Reference
Toxicology	
1225884 & 1229385	1981, Long term feeding study in rats - Methomyl, DACO: 4.4.1./4.4.2.
1229363	1981, 104 Week chronic tox and carcinogenicity study in mice - Methomyl, DACO: 4.4.1./4.4.2.
1146644	1983, Embryo-fetal toxicity and teratogenicity study of Methomyl in the rabbit, final report, DACO: 4.5.2.
1146645	1983, CHO/HGPRT assay for gene mutation - Methomyl, DACO: 4.5.4.
1146646	1985, Assessment of Methomyl in the *in vitro* unscheduled DNA synthesis assay in primary rat hepatocytes, DACO: 4.5.4.
1146647	1984, *in vivo* bone marrow chromosome study in rats, final report, Methomyl, DACO: 4.5.4.
1146648	1992, The metabolism of Methomyl in male Cynomolgus monkeys, DACO: 4.5.9.
1146649	1991, The metabolism of Methomyl in rats, DACO: 4.5.9.
1731530	2005, Report on Methomyl (DPX-X1179) Technical: Comparison of cholinesterase activity in adult and preweanling rats, DACO 4.5.12.

PMRA Document Number	Reference
1731555	1993, Primary dermal irritation study with DPX-X1179-394 in rabbits, DACO 4.2.5.
Occupational/Residential Exposure	
1731402	1998, Dissipation of dislodgeable foliar residues of Methomyl from peaches following application of Lannate LV or Lannate SP insecticide in the U.S.A. - season 1997, DACO: 5.9
1731404	1998, Dissipation of dislodgeable foliar residues of Methomyl from lettuce following application of Lannate LV insecticide or Lannate SP insecticide in the U.S.A. - season 1997, DACO: 5.9
2115788	Agricultural Reentry Task Force (ARTF). 2008. Data Submitted by the ARTF to Support Revision of Agricultural Transfer Coefficients. Submission #2006-0257
Dietary Exposure	
1184490	1986, Summary of residue data after methomyl treatments. E. I. DuPont de Nemours
1061035	1999, Combined decline and magnitude of residues of methomyl insecticide in/on pome fruits (apples and pears) grown in Europe following treatment with Lannate 20L and/or Lannate 25WP-Season 1996– Du Pont Report No AMR-3941-96
1061037	1999, Combined decline and magnitude of residues of methomyl insecticide in/on pome fruits (apples and pears) grown in Europe following treatment with Lannate 20L and/or Lannate 25WP-Season 1996– Du Pont Report No AMR-3941-96
1061038 1731292	1999, Magnitude of residues of methomyl insecticide in pears. 1996– Du Pont Report No AMR-1363-89
1731291	1990, Magnitude of residues of methomyl insecticide in apples. – Du Pont Report No AMR-1362-89
1731294	1990, Magnitude of residues of methomyl insecticide in grapes. – Du Pont Report No AMR-1364-89
1731298	1990, Magnitude of residues of methomyl insecticide in onion bulbs. – Du Pont Report No AMR-1365-89
1731299	1990, Magnitude of residues of methomyl insecticide in sugar beet foliage. – Du Pont Report No AMR-1366-89
1731301	1990, Magnitude of residues of methomyl insecticide in sorghum forage and hay. – Du Pont Report No AMR-1367-89
1731303	1991, Magnitude of residues of methomyl insecticide in beans. – Du Pont Report No AMR-1465-89
1731304	1991, Magnitude of residues of methomyl insecticide in broccoli and cauliflower. – Du Pont Report No AMR-1600-90
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1731306	1991, Magnitude of residues of methomyl insecticide in leaf and head lettuce. – Du Pont Report No AMR-1601-90
1731307	1991, Magnitude of residues of Lannate insecticide in dry beans. – Du Pont Report No AMR-1602-90
1731309	1991, Magnitude of residues of Lannate insecticide in dry English pea seed and straw. – Du Pont Report No AMR-1603-90
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1731312	1991, Magnitude of residues of methomyl insecticide in sweet corn and field corn. – Du Pont Report No AMR-1607-90
1731330	1992, Magnitude of residues of methomyl insecticide in sorghum grain. – Du Pont Report No AMR-1926-91
1731331	1993, Magnitude of residues of methomyl insecticide in citrus fruit when applied at the maximum proposed use pattern and sampled over time. – Du Pont Report No AMR-1967-91
1731332	1994, Magnitude of residues of methomyl insecticide in peach and nectarine when applied at the maximum proposed use pattern and sampled over time. – Du Pont Report No AMR-1968-91
1731333	1993, Magnitude of residues of methomyl insecticide in apple fruit when applied at the maximum proposed use pattern and sampled over time. – Du Pont Report No AMR-1969-91
1731334	1992, Magnitude of residues of methomyl insecticide in pear fruit when applied at the maximum proposed use pattern and sampled over time. – Du Pont Report No AMR-1970-91
1731337	1992, Magnitude of residues of methomyl insecticide in head lettuce as affected by normal trimming and washing. – Du Pont Report No AMR-2106-91
1731340	1993, Magnitude of residues of methomyl in apple fruit following application of Lannate L insecticide when applied at the maximum proposed use pattern and sampled over time. – Du Pont Report No AMR-2291-92
1731341	1993, Magnitude of residues of methomyl in sorghum forage and hay following multiple applications of Lannate L insecticide. – Du Pont Report No AMR-2343-92
1731342	1995, Magnitude of residues of methomyl in sorghum forage and hay following multiple applications of Lannate L insecticide. – Du Pont Report No AMR-2343-92 – supplement 1
1731343	1993, Magnitude of residues of methomyl in pears following multiple applications of Lannate L insecticide. – Du Pont Report No AMR-2344-92
1731355	1994, Magnitude of residues of methomyl in field peas following application of Lannate Insecticide at maximum label rates. – Du Pont Report No AMR-2566-93.
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1731371	1996, Magnitude of residues of methomyl in grain sorghum following application of Lannate Insecticide at maximum label rates. – Du Pont Report No AMR-3298-95
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1731399	1999, Magnitude of residues of methomyl in apples following application of either Lannate SP Insecticide or Lannate LV insecticide at maximum label rate. – Du Pont Report No AMR-4345-97
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1731453	2000, Magnitude of residues of methomyl in turnip tops following application of either Lannate insecticide at maximum label rate. – Du Pont Report No 2204
1731454	2007, Magnitude of residues of methomyl in grapes (berries and small fruits) following application of DPX-X1179 20 SL with standard and reduced-drift spray nozzles, season 2007. – Du Pont Report No 23088
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1731379	1998, Magnitude of residues of methomyl insecticide in/on stone fruits (plums) grown in Europe following treatment with Lannate 20L and/or Lannate 25WP – Season 1996 - Du Pont Report No 3894-96
1731380	1998, Combined decline and magnitude of residues of methomyl insecticide in/on stone fruits (plums) grown in Europe following treatment with Lannate 20L and/or Lannate 25WP – Season 1996 - Du Pont Report No 3895-96
1731382	1998, Combined decline and magnitude of residues of methomyl insecticide in/on pome fruits (apples and pears) grown in Europe following treatment with Lannate 20L and/or Lannate 25WP – Season 1996 - Du Pont Report No 3941-96
1731384	1998, Combined decline and magnitude of residues of methomyl insecticide in/on cucurbits (cucumbers and courgettes) grown in Europe following treatment with Lannate 20L and/or Lannate 25WP – Season 1996 - Du Pont Report No 3977-96
1731385	1998, Combined decline and magnitude of residues of methomyl insecticide in/on grapes (table and wine grapes) grown in Europe following treatment with Lannate 20L and/or Lannate 25WP – Season 1996 - Du Pont Report No 3995-96
1731388	1998, Combined decline and magnitude of residues of methomyl insecticide in/on cucurbits (melons) grown in Europe following treatment with Lannate 20L and/or Lannate 25WP – Season 1996 - Du Pont Report No 3998-96
1731389	1998, Combined decline and magnitude of residues of methomyl insecticide in/on solanacea vegetables (tomatoes and peppers) grown in Europe following treatment with Lannate 20L and/or Lannate 25WP – Season 1996 - Du Pont Report No 3999-96
1731390	1998, Combined decline and magnitude of residues of methomyl insecticide in/on cucurbits (cucumber and courgettes) grown in Europe following treatment with Lannate 20L and/or Lannate 25WP – Season 1996 - Du Pont Report No 4017-96
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1731395	1998, Combined decline and magnitude of residues of methomyl insecticide in/on oil seeds (cotton seeds) grown in Europe following treatment with Lannate 20L and/or Lannate 25WP – Season 1996 - Du Pont Report No 4039-96
1731396	1998, Combined decline and magnitude of residues of methomyl insecticide in/on citrus fruit (oranges and mandarins) grown in Europe following treatment with Lannate 20L and/or Lannate 25WP – Season 1996 - Du Pont Report No 4043-96
1731406	1999, Combined decline and magnitude of residues of methomyl insecticide in/on grapes (table and wine grapes) grown in Europe following treatment with Lannate 20L and/or Lannate 25WP – Season 1997 - Du Pont Report No 4498-97
1731408	1999, Combined decline and magnitude of residues of methomyl insecticide in/on stone fruits (peaches and apricots) grown in Europe following treatment with Lannate 20L and/or Lannate 25WP – Season 1997 - Du Pont Report No 4499-97
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1731320	1993, Freezer storage stability of methomyl in apples. Du Pont Report No 1768-90
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1731323	1994, Freezer storage stability of methomyl in sorghum forage. Du Pont Report No 1771-90
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1731325	1993, Freezer storage stability of methomyl in peanuts. Du Pont Report No 1773-90
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1731374	2000, Freezer storage stability of residues of methoyl in dry bulb onions following application to, weathering on, and storage of Lannate LV insecticide treated onions. Du Pont Report No 3746-96
1731398	2000, Storage stability of residues of methoyl in frozen grain sorghum forage and hay samples following application of Lannate LV insecticide at maximum label rates. Du Pont Report No 4344-97
1731436	2005, Storage stability of methomyl in peaches. Du Pont Report No 12710
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