Health Canada Santé Canada

Your health and safety… our priority. *Votre santé et votre sécurité… notre priorité.*

Re-evaluation Decision RVD2015-04

Dimethoate

(publié aussi en français)

30 December 2015

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607 D
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

ISSN: 1925-1017 (print)
1925-1025 (online)

Catalogue number: H113-28/2015-4E (print version)
H113-28/2015-4E-PDF (PDF version)

© Her Majesty the Queen in Right of Canada, represented by the Minister of Health Canada, 2015

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.

Table of Contents

Re-evaluation Decision ... 1
What Does Health Canada Consider When Making a Re-evaluation Decision? ... 2
What is Dimethoate? ... 2
Health Considerations ... 2
Environmental Considerations ... 5
Value Considerations ... 5
Incident Reports ... 6
Organisation for Economic Co-operation and Development Status ... 6
Measures to Minimize Risk ... 7
What Additional Scientific Information is Being Requested? ... 8
Other Information ... 8
List of Abbreviations ... 9
Appendix I Comments and Responses ... 11
1.0 Comments ... 11
1.1 Comment – Acute aggregate (food and drinking water) reference dose ... 11
1.2 Comment – Use of modeling versus monitoring data in the drinking water assessment 12
1.3 Comment – Aggregate occupational exposure considerations ... 12
1.4 Comment – Label statements regarding drift ... 14
1.5 Comment – Toxicity to terrestrial organisms ... 14
1.6 Comment – Toxicity to aquatic organisms ... 15
1.7 Comment – Cumulative risk assessment of organophosphates ... 17
1.8 Comment – Postapplication assessment ... 18
1.9 Comment – Discontinued uses ... 18
1.10 Comment – Label enforcement ... 19
1.11 Comment – Label language ... 20
1.12 Comment – Restricted-entry intervals ... 21
1.13 Comment – REI calculations ... 21
1.14 Comment – Postapplication forestry activities ... 22
1.15 Comment – Consultation ... 22
2.0 Comments Relating to Health ... 24
2.1 Comment - Cholinesterase inhibition ... 24
2.2 Comment - Historical control data ... 25
2.3 Comment - Additional studies ... 26
2.4 Comment - PMRA'S Assumption of 100% Dimethoate Conversion to Omethoate during Water Chlorination and Revised Dietary Risk Assessment ... 27
Table 1 Drinking Water Estimate Environmental Concentration Revisions ... 28
Table 2 Oil Seed Residue Estimate Revisions ... 29
Table 3 Acute Dietary and Aggregate Dietary and Drinking Water Exposure ... 29
Table 4 Chronic Dietary and Aggregate Dietary and Drinking Water Exposure ... 29
2.5 Comment - Residue Chemistry Data ... 30
Table 5 Summary of Field Trials Submitted ... 32

2.6 Comments - Occupational and Residential Exposure 34
2.6.1 Comment - Airblast Applications to Conifers 34
2.6.2 Comment - High Pressure Handwand Applications to Ornamentals and Structures 35
2.6.3 Comment - Paint-On Uses 36
2.6.4 Comment - Right-of-Way Sprayer 36
2.6.5 Comment - Drench Applications to Carnations 37
2.6.6 Comment - Re-Entry Exposures in Conifers 37
3.0 Comments Relating to Environment 39
3.1 General Comments 39
3.1.1 Comment - References 39
3.1.2 Comment – Good Laboratory Practices 39
3.1.3 Comment – K_{ow} value 40
3.1.4 Comment – Risk Quotient (RQ) 40
3.1.5 Comment – Insect exposure scenarios 40
3.1.6 Comment – Acute earthworm toxicity 41
3.1.7 Comment – Incorrect values 41
3.2 Comment - Direct overspray 41
3.2.1 Comment - Spray Drift 42
3.3 Physical and Chemical Properties, and Environmental Fate 42
3.3.1 Comment – Incorrect values 42
3.3.2 Comment – Dissipation half-life 43
3.3.3 Comment – Water modeling 43
3.4 Screening-Level Assessment 44
3.4.1 Comment - Bees and Wasps 44
3.4.2 Comment - Terrestrial Plants 44
3.4.4 Mammals 45
3.5 Refined Environmental Risk Assessment (ERA) 46
3.5.1 Comment - Terrestrial Invertebrates 46
3.5.2 Comment - Birds and Mammals 47
3.5.3 Comment – Droplet size 47
3.6 Aquatic Organisms 47
3.6.1 Reporting error 47
3.6.2 Water modeling 49
3.6.3 Comment - Water Monitoring 51
4.0 Comments Relating to Value 53
4.1 Comment - Douglas-fir seed cone use 53
4.2 Comment - Harmonization of use patterns for conifers 54
4.3 Comment - Spray volume 55
Appendix II Revised Occupational Risk Assessment for Douglas fir (Seed Tree), Sitka Spruce (Seed Tree), Spruce (Seed Tree and woodland), and Right-of-Way Sprayers 57
Table 1 M/L/A Exposure Estimates and MOEs 58
Table 2 Occupational Postapplication Exposure Estimates, MOEs and REIs 60
Table 3 Restricted-Entry Intervals 61

Appendix III Environmental Fate and Toxicity 63
Table 2 Environmental toxicity of Dimethoate 63
Table 3 Screening Level Risk Assessment for Terrestrial Organisms Other than Birds and Mammals 64
Table 5 Screening Level Risk Assessment of Dimethoate to Aquatic Organisms 64
Table 6 Refined Risk Assessment for Birds and Mammals (Off-field, spray drift) 66
Appendix IV Label Amendments for Products Containing Dimethoate 67
Table 1 Maximum Number of Applications per Year and Minimum Application Intervals 72
Table 2 Pre-harvest intervals (PHI), pre-grazing intervals (PGI), and changes to application rates 73
Table 3 Restricted-Entry Intervals 73
Table 4 Buffer zones 75
References 81

Re-evaluation Decision

After a thorough re-evaluation of the insecticide dimethoate, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, is granting continued registration for the sale and use of dimethoate products in Canada.

An evaluation of available scientific information found that, under the current conditions of use:

- Certain uses of dimethoate products have value in the food and crop industry, and do not pose unacceptable risks to human health or the environment. As a requirement of continued registration for these particular dimethoate uses, new risk-reduction measures must be included on the labels of certain dimethoate products.

- Some uses of dimethoate are, however, being phased out because the human health risks and/or risks to the environment do not meet current standards. These uses include the following: application to structural sites, paint-on treatments to birch, roses and lilac, as well as, soil drench application to carnations.

The regulatory approach regarding the re-evaluation of dimethoate was first proposed in the consultation document[1] Proposed Re-evaluation Decision PRVD2011-12, *Dimethoate*. This Re-evaluation Decision[2] describes the PMRA's regulatory process concerning the re-evaluation of dimethoate, as well, summarizes the Agency's decision, the reasons for it, and in Appendix I, a summary of comments received during the consultation process, and subsequently, the PMRA's response to these comments.

To comply with this decision, new and revised risk mitigation measures should be implemented as soon as possible but no later than 30 December 2017. Registrants of dimethoate products will be informed of the specific requirements affecting their product registration(s), as well as of the regulatory options available to them.

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

[2] "Decision statement" as required by subsection 28(5) 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 if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions, or proposed conditions of registration.[3] The Act also requires that products have value[4] when used according to the label directions. Conditions of registration may include 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, as well as 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 portion of the Health Canada website.

What is Dimethoate?

Dimethoate is a broad spectrum organophosphate insecticide and acaricide. It is used to control a broad range of insects and mites on a variety of agricultural sites and contributes to insecticide resistance management.

Health Considerations

Can Approved Uses of Dimethoate Affect Human Health?

Dimethoate is unlikely to affect your health when used according to the revised label directions.

Potential exposure to dimethoate may occur through the diet, when handling and applying the product, or when entering or contacting treated sites. When assessing health risks, two key factors are considered: the levels where no health effects occur in animal testing and the levels to which people may be exposed.

---

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

4 "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".

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

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical as well as identify the dose where no adverse effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when pesticide products are used according to label directions. Please see PRVD2011-12 for a detailed description of the dimethoate toxicology assessment.

Residues in Water and Food

Dietary risks from food and drinking water are not of concern.

Reference doses define levels to which an individual can be exposed over a single day (acute) or a lifetime (chronic) and expect no adverse health effects. Generally, dietary exposure from food and 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 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 dimethoate was estimated from residues in food and drinking water, including the most highly exposed subpopulation (for example, infants, and children 1-2 years old). Residue estimates in food were primarily based on monitoring data from the Canadian Food Inspection Agency, and the United States Department of Agriculture (USDA) Pesticide Data Program. Residues in drinking water were estimated using modeling data. The drinking water modeling estimates and residue estimates for some foods have been revised since PRVD2011-12 in consideration of new data submitted during the consultation period. Details on these changes can be found in Appendix I.

The revised aggregate acute and chronic exposure (for example, to dimethoate exposure from food and drinking water) accounted for no more than 71% of the acute reference dose and 16% of the chronic reference dose for all population groups. As a result, dietary exposure from food and drinking water were not of concern to the PMRA.

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 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.

MRLs for dimethoate are currently specified for a wide range of commodities. Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm.

Canadian MRLs for dimethoate on apples, cabbage, and spinach will be revoked as the use on these commodities has been discontinued by the registrant in both Canada and the United States. In addition, the MRL for lettuce will be changed to leaf lettuce as the use on head lettuce has also been discontinued.

Risks in Residential and Other Non-Occupational Environments

Aggregate risk from exposure incurred as a patron of a "Pick Your Own" orchard or berry facility is not of concern.

"Pick Your Own (PYO)" facilities are commercial farming operations that allow public access for harvesting in large-scale fields or orchards treated with commercially labelled dimethoate products. Estimates of exposure that aggregate the dermal exposure incurred during harvest and the dietary exposure from consuming fresh fruit reach the target Margin of Exposure (MOE) for orchard and berry crops, and are therefore, not of concern.

Occupational Risks from Handling Dimethoate

The majority of occupational risks are not of concern provided additional mitigation measures are followed.

Occupational risk assessments from handling dimethoate consider exposure to workers who mix, load and apply the pesticide. Most occupational risks are not of concern for commercial, and agricultural scenarios provided additional protective measures are followed.

Based on additional use pattern information submitted in response to PRVD2011-12 for dimethoate, the occupational risk assessments for forestry uses (Douglas fir (seed tree), Sitka spruce (seed tree) and spruce (seed tree and woodland)) and right-of-way sprayer application were reassessed. Following consideration of additional mitigation measures, including additional personal protective equipment and engineering controls, calculated margins of exposure (MOE) reach the target margin and are not of concern. Additional mitigation measures are required to minimize potential exposure and protect worker's health.

Use scenarios that remain of concern include paint-on-applications (ornamentals), soil drench applications (carnations), and applications to structural sites. Due to occupational risk concerns these uses will be cancelled.

Occupational postapplication risks are not of concern based on revised label directions.

Postapplication occupational risk assessments consider exposures to workers entering treated sites. When the proposed mitigation measures such as lengthened restricted-entry intervals (REIs) are considered, occupational postapplication risk estimates meet the target MOE, and are not of concern.

Based on additional use pattern information submitted in response to PRVD2011-12 for dimethoate, the REIs for forestry uses (Douglas fir (seed tree), Sitka spruce (seed tree) and spruce (seed tree and woodland)) were recalculated. Users have indicated that the calculated REIs for seed cone harvesting of 48 and 49 days are agronomically feasible.

Environmental Considerations

What Happens When Dimethoate Is Introduced into the Environment?

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

When dimethoate is released into the environment, it can enter soil and surface water, where it breaks down rapidly. Although laboratory studies indicate that dimethoate is mobile in soil, it is not detected in groundwater, most likely due to its rapid break down. Dimethoate is not expected to volatilize significantly.

In laboratory studies, dimethoate was found to be toxic to some terrestrial and aquatic organisms. Therefore, risk mitigation measures in the form of use restrictions and precautionary label statements are required in order to minimize exposure and mitigate risks. For pollinators, risks are mitigated by restricting applications to periods when bees are not actively foraging. The risk to aquatic organisms is mitigated with spray buffer zones and recommendations on the label to reduce runoff from fields. When dimethoate 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

In Canada, dimethoate is registered to control a wide range of insect pests such as: aphids, beetles, weevils, grasshoppers, flies, leafhoppers, scale insects, thrips, moths and spider mites.

Dimethoate is used on both agricultural and non-agricultural sites which include feed, food, industrial oil seed and fibre, forestry and ornamental crops. It is also effective as residual spray for fly control around farm buildings, animal quarters (empty), food processing plants (outdoor use), garbage cans (outdoor use), loading docks (outdoor use), warehouses (outdoor), outdoor refuse areas, pastures and wasteland.

Dimethoate contributes to insecticide resistance management. Dimethoate plays an important role in delaying resistance when used in rotation with insecticidal active ingredients from different Mode of Action (MoA) groups. Based on Canadian pesticide labels, dimethoate is the only insecticide currently registered in Canada to control insect pests of Douglas fir (seed tree), Sitka spruce (seed tree) and spruce (seed tree and woodland use).

Incident Reports

An incident involving adverse effects to cherry trees following application of a dimethoate product occurred in June 2011. It was reported that leaf necrosis and leaf drop were observed in a block of Lapin cherry trees in British Columbia. This variety of cherry trees has been documented to be sensitive to dimethoate. The label for this dimethoate product will be amended to better warn users of the sensitivity some plants may have to dimethoate (see Appendix IV). Details regarding this incident can be found under Incident Reports 2011-4810 and 2011-4464.

As of January 2015, eleven individual Canadian incident reports linked to dimethoate and bee mortality have been submitted to the PMRA. The classification of the reports ranged from probable to highly probable that application of dimethoate contributed to the mortality of the bees. The incidents occurred throughout Canada (Ontario, Manitoba, Saskatchewan and Nova Scotia) from June to August 2012 with the majority occurring in Saskatchewan. The reports indicated that dimethoate was being sprayed on strawberries (one report), soybeans (one report), alfalfa (one report) and canola (eight reports from two beekeepers). The reported magnitude of effects ranged from 2000 to 3000 dead bees in front of 95 colonies in Nova Scotia to a reported 50% loss of honey bees at sites in Saskatchewan. Many of the bees from the Nova Scotia and Saskatchewan sites contained dimethoate residues, as determined by laboratory analysis.

There were also twelve American incident reports involving dimethoate and bee mortality. Of the twelve incident reports, 10 were possible, one was probable and one was highly probable. Some (four) of the reports indicated that beans were the target crop. Other crops included corn, soybean and orchard. Of the known areas of the effects, three were a result of on-site application to agricultural areas, orchards or fields, and five were a result of application in the vicinity, indicating spray drift. The majority of the incidents indicated the route of exposure was ingestion or spray drift. The magnitude of effects ranged from 20 hives to 150 colonies, and up to 1256 dead bees.

The label for the dimethoate products will be amended to reduce exposure to pollinators (see Appendix IV).

Organisation for Economic Co-operation and Development Status

Canada is part of the Organisation for Economic Co-operation and Development (OECD), which assembles member countries as well as provides a forum for 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 country to prohibit all uses of an active ingredient for health or environmental reasons are considered for relevance to the Canadian situation.

Dimethoate is currently acceptable for use in other OECD countries, including the United States, New Zealand and the European Union. As of 18 March 2015, no decision by an OECD member country to prohibit all uses of dimethoate for health or environmental reasons has been identified.

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 must be followed by law.

Risk-reduction measures are being implemented to address potential risks identified in this assessment. These measures, in addition to those already identified on existing dimethoate product labels, are designed to further protect human health and the environment. Registrants will be required to amend their labels to reflect these additional measures. The following additional key risk-reduction measures are to be implemented:

Additional Key Risk-Reduction Measures

Human Health

After consideration of all other possible mitigation measures, the following use registrations are to be cancelled due to occupational risk concerns:

- application to structural sites,
- paint-on treatments to birch, roses and lilac, and
- soil drench application to carnations.

These uses must be removed from all dimethoate labels.

For all remaining uses, to protect mixer/loader/applicators using commercial products, additional personal protective equipment, engineering controls and restrictions on amount of product handled per day are required.

For all remaining uses, to protect workers entering treated sites: restrictions on the number of applications, increased application intervals and restricted-entry intervals are to be added to product labels.

Precautionary statements to avoid drift to areas of human habitation or areas of human activity are to be added to product labels.

Aggregate dietary and drinking water exposure including risk will be mitigated by increasing preharvest intervals (PHI) and reducing maximum application rates.

Environment

Changes to label statements, including precautionary statements; use restrictions, and spray buffer zones for non-target aquatic habitats are required as a result of the environmental risk assessment.

To reduce the potential for dimethoate to runoff to adjacent aquatic habitats, changes to label statements will include precautionary statements for sites with characteristics that may be conducive to runoff and when heavy rain is forecasted.

To protect pollinators, dimethoate cannot be applied to blooming crops when bees are foraging. This includes restricting applications during the blooming period of bee attractive crops.

What Additional Scientific Information is Being Requested?

Human Health

There are no outstanding data requirements with regard to human health.

Environment

There are no outstanding data requirements with regard to environment.

Other Information

Any person may file a notice of objection[5] based on scientific grounds regarding this decision on dimethoate within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting, please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the Pest Control Products Act

List of Abbreviations

µg	micrograms
ADI	acceptable daily intake
a.i.	active ingredient
ARfD	acute reference dose
bw	body weight
cm	centimetre(s)
d	day(s)
DACO	data code
DER	Data Evaluation Report
DFR	dislodgeable foliar residue
EEC	expected environmental concentration
EP	end-use product
EXAMS	Exposure Analysis Modeling System
g	gram(s)
GAP	good agricultural practice
ha	hectare(s)
K_d	adsorption coefficient
kg	kilogram(s)
K_{oc}	organic carbon partition coefficient
K_{ow}	octanol–water partition coefficient
L	litre(s)
LC_{50}	lethal concentration to 50% (a concentration causing 50% mortality in the test population
LD_{50}	lethal dose to 50% (a dose causing 50% mortality in the test population)
LOAEL	lowest observed adverse effect level
LOD	limit of detection
LOEC	lowest observed effect concentration
m	metre(s)
m^3	metre(s) cubed
mg	milligram(s)
min	minute(s)
mm	millimetre(s)
MOE	margin of exposure
MRL	maximum residue limit
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
PCPA	*Pest Control Products Act*
PGI	pre-grazing interval
PHI	preharvest interval
pH	-log10 hydrogen ion concentration
PHED	Pesticide Handlers Exposure Database
pKa	-log10 acid dissociation constant
PMRA	Pest Management Regulatory Agency

PPE	personal protective equipment
ppb	parts per billion
ppm	parts per million
PRVD	Proposed Re-evaluation Decision
PRZM	Pesticide Root Zone Model
RED	Reregistration Eligibility Decision
REI	restricted-entry interval
RQ	risk quotient
TAF	toxicological adjustment factor
TC	transfer coefficient
TGAI	technical grade active ingredient
TRR	total radioactive residue
US	United States
USEPA	United States Environmental Protection Agency

Appendix I Comments and Responses

In response to Proposed Re-evaluation Decision PRVD2011-12, *Dimethoate*, comments relating to the risk assessment were received from the registrant as well as a number of stakeholders. Comments have been grouped by content as there were multiple comments relating to the same topic.

1.0 Comments

The following comments were received from West Coast Environmental Law.

1.1 Comment – Acute aggregate (food and drinking water) reference dose

How did the PMRA reach the conclusion that there will be no "unacceptable effects" for a product whose acute aggregate reference dose significantly exceeds 100% at the 99.9th percentile? At what percentile does the water modeling data suggest that 100% aggregate reference dose is achieved for adults? For infants? And for infants based on the water monitoring data? How can dimethoate be approved in light of a greater than 100% aggregate exposure for infants?

PMRA Response

The PRVD is a consultation document that presents a risk assessment based on the available data, and current use pattern, and proposes possible mitigation measures to address potential risk. As stated in the PRVD, the acute aggregate (food and drinking water) risk for the general population and infants, respectively, was estimated to be 118% and 408% of the acute reference dose (ARfD) when using drinking water modeling data and 56% and 108% of the acute reference dose when using drinking water monitoring data.

The acute food and drinking water exposure and risk for dimethoate was determined by using probabilistic analysis. For the regulation of pesticides, the PMRA uses the exposure estimate at the 99.9th percentile for probabilistic acute aggregate (food and drinking water) exposure assessments. When the estimated intake from residues on food and in drinking water is less than the ARfD, exposure is not considered to be of concern. Since the acute aggregate risk at the 99.9th percentile exceeded 100% of the acute reference dose using modeling data and monitoring data, potential risk concerns were identified. However, the PMRA estimates for drinking water were based on several conservative assumptions, including 100% transformation of dimethoate to the more toxic metabolite omethoate. This assumption was the main risk driver in the exposure estimate for drinking water and likely overestimated actual risk.

Since potential risks were identified, mitigation measures were proposed to reduce risk, and data were requested to quantify the degree of transformation of dimethoate to omethoate in drinking water during chlorination. Refer to Appendix IV of the PRVD for details on the proposed mitigation measures. The proposed decision of continued registration was contingent upon the risk being mitigated through a reduced use pattern and potential refinements in drinking water exposure estimate.

A chlorinated drinking water transformation study was submitted by the registrant, which demonstrated the degree of omethoate formation is much less than 100%. The results of the study were incorporated into a revised aggregate risk assessment (please see Section 2.4 of this appendix for further details). The acute aggregate (food and drinking water) risk for the general population and infants, respectively, is now estimated to be 40% and 70% of the acute reference dose when using drinking water modeling data.

1.2 Comment – Use of modeling versus monitoring data in the drinking water assessment

How does PMRA reconcile the statements at pp. 25 and 4 of the PRVD, that dietary exposure of more than 100% of the acute reference dose is not acceptable with the water modeling and monitoring data? Is the aggregate dietary risk assessment based on modeling or monitoring data? Given the identified limitations of the monitoring data, we submit that the modeling data must be used, and the approval of dimethoate cannot be supported by that data. We would submit that the Registrants have not discharged the onus of demonstrating that the product is safe.

PMRA Response

In the PRVD, acute aggregate (food and drinking water) exposure assessments based on drinking water modeling and water monitoring data were both presented. The more conservative of the two (water modeling) has been used for the acute aggregate assessment.

Data was requested in the PRVD to confirm or refine assumptions used in the probabilistic acute aggregate (food and drinking water) exposure assessment regarding the degree of transformation of dimethoate to omethoate during the chlorination process in water treatment plants. The data requirement has been satisfied by the registrant and the aggregate assessment has been refined (revised numbers are presented in Section 2.4, Table 3 of this appendix). The acute aggregate (food and drinking water) risk for the general population and infants, respectively, is now estimated to be 40% and 70% of the acute reference dose when using drinking water modeling data.

1.3 Comment – Aggregate occupational exposure considerations

The PMRA has a responsibility to assess health risks of pesticides, which include the consideration of the aggregate risks of workplace and non-workplace exposure. The dimethoate PRVD was deficient in that it supports the view that aggregate workplace and occupational exposure may exceed appropriate aggregate acute reference doses, but entirely fails to assess the risk to a person who is exposed to this product at work, but also comes into contact with it through food and water and other routes of exposure that they share with the rest of the general population.

In relation to the need for an aggregate exposure assessment which includes occupational exposure, we would suggest that workers who live nearby, at their place of employment, or near farms where dimethoate is used are more likely to come into contact with the pesticide through non-workplace exposure than many segments of the public. For example, if they live in close proximity to areas where dimethoate is used, they are more likely to be exposed to drift, or to water which has been known to elevate dimethoate levels.

PMRA Response

The Pest Control Products Act requires that aggregate assessments be conducted in the context of potential risks from residential uses of pesticides, for bystanders, and potential exposure that may occur through diet or from drinking water. If the use of a pesticide poses unacceptable risks to human health or the environment, it is not registered for use in Canada.

It is acknowledged that workers who live near, or at, their place of employment, or near farms, where dimethoate is used, are more likely to come into contact with the pesticide through non-workplace exposure than in the case of many other segments of the public. Currently, the methodologies to combine aggregate assessments of potential occupational and non-occupational exposure are not sufficiently developed. Efforts continue to develop with a goal to refine the methodologies to a point where they can be incorporated into risk assessments and as well as support decision making. The factors and considerations that are built into the current risk assessment process account for exposures that may occur in occupational and non-occupational scenarios and are consistent with or exceed that of pesticide regulators of other Organization for Economic Co-operation and Development (OECD) countries.

Furthermore, due to the amount of dimethoate handled on a daily basis, as well as the direct exposure from occupational uses of pesticides, there are generally much greater chances of exposure than from dietary or residential uses. Typically, if the occupational risk is of no concern, the impact of other sources of exposure is minimal. When risks of concern are identified for occupational and/or residential uses, mitigation measures are implemented including changes to the use pattern; removal of certain uses or formulations; or denial/cancellation of registration of that active ingredient.

The PMRA has been working closely with the USEPA in identification and development of these data and methodologies. The USEPA also acknowledges that further research into available data, and identification of data needs must first be undertaken, as well as the development of science policy before aggregation of occupational and non-occupational can be implemented in risk assessments (USEPA, 2009).

In the interim, in order to promote best management practices, PMRA includes instructions on product labels to help limit the amount of exposure to residues both inside and outside the home. Label statements such as “keep and wash personal protective equipment separate from household laundry” give guidance on how to minimize potential contamination of living areas. In addition, in most provinces, farmers require a license to use pest control products. This requires training on the safe use of pesticides and general hygiene practices which reduce potential household contamination.

1.4 Comment – Label statements regarding drift

The PMRA's recommendation of precautionary statements related to drift in the PRVD implicitly recognizes drift as an aggregate source of exposure, but does not include that exposure in the aggregate exposure. The precautionary statement is vague and inherently unenforceable, consequently, cannot be relied upon to eliminate drift.

PMRA Response

Human health risk assessments for pesticides examine direct exposure to users (both professional applicators and residential users) as well as bystanders who may be nearby during application. The potential for exposure to pesticide residues deposited on the ground or foliage after application is also considered. In the majority of cases, the exposure to humans resulting from spray drift, or from spray residues resulting from drift to areas of human habitation, is expected to be much less than that of pesticide applicators (mixer/loader/applicator) wearing personal protective equipment, and agricultural workers or others who re-enter treated areas after application and who may be exposed to pesticide residues. Bystander exposure resulting from spray drift is, therefore, generally not expected to result in exposures of concern and spray buffer zones are not routinely required for areas of human habitation. In the event of possible high exposure scenarios associated with spray drift (for example, risk is only acceptable to mixer/loader/applicator with excessive engineering controls such as closed mixing and loading systems), mitigation measures may be considered and are assessed either qualitatively or quantitatively and on a case-by-case basis during the human health assessment.

1.5 Comment – Toxicity to terrestrial organisms

The Evaluation Report does not appear to provide for any mitigative measures or label requirements related to the toxicity of bees, birds and other terrestrial animals, with the exception of noting the toxicity to such organisms on the label – which carries with it no actual requirements. Having established the toxic impact on animal populations such as birds and bees, we do not believe that there is any basis on which the PMRA could find that there is no "possibility of harm to the environment, including its biological diversity, resulting from exposure to or use of the product."

PMRA Response

Under the *Pest Control Products Act* the PMRA is mandated "to prevent unacceptable risks to people and the environment from the use of pest control products". The *Pest Control Products* defines "acceptable risk" as "reasonable certainty that no harm to human health, future generations health, or the environment will result from exposure to or use of the product, taking into account its conditions or proposed conditions of registration". While considering environmental risk, as defined in the *Pest Control Products*, PMRA's scientific assessment considers both the inherent toxicity and the potential duration and magnitude of exposure to a pest control product to assess whether exposures could be high enough to cause unacceptable effects on non-target habitats or on their biological diversity.

The goal is to protect both habitats and populations of the most sensitive groups of organisms. This approach inherently protects other groups of organisms that are less sensitive and considers the inherent capacity for populations of organisms to recover, even if a few individual organisms are impacted.

With respect to required mitigation measures to protect terrestrial organisms such as birds and bees, the PMRA employs a variety of label statements to inform users of hazards, risks and the need for environmental protection. Hazard statements are used to inform the user of a product's inherent toxicity to certain biological entities. These hazard statements are triggered in two ways. First, a hazard statement is required if the active ingredient is highly toxic to a biological entity even if the risk assessment has determined that there is “negligible risk” of exposure sufficient to cause adverse effects when the product is used according to the label. Second, hazard statements are also triggered when a potential risk of adverse effects has been identified during the environmental assessment. Hazard statements are not meant to mitigate risks but to inform the user so that the product can be handled, stored and used with appropriate caution.

Where appropriate, the PMRA also requires that mitigation measures be specified on the label in order to reduce risks to acceptable levels. These measures can include restrictions on how and when the product can be used, such as restricting the application rate, and/or the number of times it can be applied. Mitigation measures can also include a requirement for the use of no-spray buffer zones to minimize pesticide drift into sensitive non-target habitats.

Finally the PMRA also makes use of “best practices” label statements. These statements are designed to inform users of beneficial practices that will help to further minimize the risk of any potential negative impacts resulting from pesticide.

Some standard label statements have been revised since the publication of PRVD2011-12. The revised label statements are presented in this re-evaluation decision document (Appendix IV). These label statements have been updated as required to reflect current standards and take into account any pertinent information submitted as part of the consultation process.

1.6 Comment – Toxicity to aquatic organisms

In terms of toxicity to aquatic organisms, how were these buffer zones arrived at, and what evidence is there that they are sufficient to prevent negative impacts on aquatic organisms and ecosystems? We submit that absent such data and analysis the evidence does not support the view that such buffers will adequately protect aquatic organisms.

PMRA Response

Pesticide spray buffer zone distances are designed to limit exposures of non-target organisms in sensitive aquatic and terrestrial habitats adjacent to the spray area to concentrations that do not have the potential to cause adverse effects.

Buffer zones are calculated using a science based approach that includes both generalized drift deposition models and toxicity data specific to the pesticide being assessed. It is generally accepted in the spray drift research community that the amount of drift is independent of the pesticide being applied, while potential effects are related to the toxicity of the specific pesticide being sprayed. Buffer zones are pesticide specific as they incorporate both generalized deposition data and pesticide specific toxicity data.

The PMRA uses empirical models for ground sprayers (for example, Wolf 2001 and 2011 data sets for field sprayers and Ganzelmeier 1995 data for airblast sprayers) and mechanistic models for aerial applications (for example, AgDISP v.8.21) to determine the distance from the edge of the spray swath needed to ensure concentrations in aquatic or terrestrial habitats will not cause any unacceptable effects. The calculations are based on application rate and other key factors which can affect drift, including the size of the spray drops and wind speed. For water bodies, the volume of water is also a factor and spray buffer zones are based on two water depths (< 1 m and > 1 m). Pesticide specific toxicity data for non-target organisms are used to determine the concentrations that will not cause unacceptable effects. Together, the two types of data determine the buffer zone size needed. In general the more toxic a pesticide is, the larger the buffer zones will be for a given exposure scenario.

For dimethoate, spray buffer zones were derived for three scenarios using the most sensitive toxicity endpoints available for shallow freshwater aquatic habitats, including seasonal water bodies (< 1 m depth: 1/10 LC_{50} for bluegill sunfish = 0.60 mg a.i./L), deeper freshwater habitat (> 1 m: 1/2 LC_{50} for stonefly = 0.0215 mg a.i./L) and marine habitats (> 1 m: - 1/2 LC_{50} for saltmarsh mosquito = 0.015 mg a.i./L). Additional aquatic toxicity data have been submitted and were considered as part of the final decision.

The PMRA is confident that calculated buffer zones are appropriate for mitigating the risk from spray drift due to a number of conservative assumptions built into their determinations:

- There are margins of safety on the effects endpoints used to determine buffer zones: Acute effects endpoints have uncertainty factors (ranging from 2 to 10) applied to account for interspecies variability. Chronic effects endpoints are based on the lowest no observed effect concentration (NOEC). For pesticides with sufficiently large datasets, species sensitivity distributions provide the level at which 95% of the species in a group (for example, freshwater invertebrates) are expected to be protected.
- The aquatic risk assessments are based on a range of water body depths (0.15 m deep for water dwelling life stages of amphibians and 0.80 m deep for other aquatic organisms) that are static closed systems (for example no inflow or outflow) and assume that pesticide deposits are instantaneously mixed homogeneously in the water body with exposure occurring at peak concentrations.
- The spray drift deposition models are based on conservative fits of the data distribution. For example, the ground boom sprayer model uses the 90% confidence interval for the data range, the airblast model is based on the 95th percentile of deposition data and the AgDISP aerial model uses the 50th percentile of an extensive data set encompassing a range of atmospheric conditions.

- For multiple applications it is assumed that spray drift into sensitive habitats is identical between applications (for example, the wind is always blowing towards the sensitive habitat each time the product is applied) with exposure concentrations being determined as the cumulative amount deposited, adjusted for major degradation processes between applications.
- It is assumed that there is no interception of spray drift by vegetation growing between the edge of the spray area and the sensitive habitats.

1.7 Comment – Cumulative risk assessment of organophosphates

As noted on page 10 of the PRVD:

> "Once all organophosphate pesticides have been re-evaluated, a cumulative risk assessment will be conducted, which will consider potential exposure to all chemicals causing toxicity in the same manner. The results of the cumulative risk assessment may affect any previous re-evaluation decision."

The PMRA is essentially conceding in this statement that dimethoate may have an unacceptable risk in concert with other organophosphate and other similar pesticides. We do not believe that the PMRA can credibly find that dimethoate will not have an unreasonable effect absent evidence, and an assessment, about how this pesticide works in concert with other similar pesticides. This is particularly true given that many exposure levels observed for dimethoate, and other organophosphates, are considered to pose a risk but for the label requirements. The onus is on the registrants to demonstrate that the substance will not cause an unacceptable risk, and cannot be satisfied unless the cumulative assessment is completed.

PMRA Response

Aggregate and cumulative assessments are two recent approaches that reflect the application of modern science in risk assessment at the PMRA. The PCPA requires the Minister to consider aggregate exposure when assessing the health risk of a pesticide as well as the cumulative effects of pesticides that share a common mechanism of toxicity. An aggregate assessment considers the risk from exposure to a single chemical via all routes (for example, oral, dermal and inhalation) and exposure pathways (for example, diet, drinking water and residential use). A cumulative assessment considers the risk from exposure via all routes and exposure pathways to all chemicals that share a common mechanism of toxicity, such as the organophosphates.

Although aggregate assessments have been fully implemented in the re-evaluation of pest control products and policies are in place (SPN2003-04, General Principles for Performing Aggregate Exposure and Risk Assessment), no cumulative assessments have been performed by the PMRA for a full group of pesticides sharing a common mechanism of toxicity (for example, organophosphates, carbamates) to date. Work is still underway on individual chemicals within the class, dimethoate being a case in point.

The PMRA has participated in various projects to develop the cumulative risk assessment methods, and has also provided input on associated USEPA science policies required to implement the new standards mandated by the Food Quality Protection Act. PMRA policies are in place for cumulative assessments (SPN2001-01: Guidance for Identifying Pesticides that have

a Common Mechanism of Toxicity). Canadian regulators, building on gains achieved through previous harmonization efforts, continue to review USEPA policies and procedures, and are adapting these to the Canadian regulatory framework.

The USEPA completed their organophosphate cumulative risk assessment in 2006, and concluded that, in part, due to the extensive risk mitigation and risk reduction efforts for many organophosphates through the single chemical risk assessment, the cumulative risks in general from food, water, and residential exposure to organophosphates generally do not exceed the USEPA's level of concern.

1.8 Comment – Postapplication assessment

Given the importance of no-entry periods to workers health, we find the "area of uncertainty in the postapplication assessment" to be unacceptable.

PMRA Response

Agricultural workers have the potential to be exposed to pesticides when they perform activities on crops that have previously been treated with pesticides. Typical activities that may lead to such exposure include hand harvesting crops (for example, for grapes and vegetables), thinning orchard crops, or scouting fields for pests. As part of the postapplication exposure assessment, restricted-entry intervals (REIs) are established to ensure that agricultural workers cannot enter previously treated areas to perform activities until pesticide residues have dissipated to acceptable levels. Since potential postapplication exposure to pesticides is dependent on the degree of contact with the treated foliage, REIs are established for individual activities. (See Appendix IV of this RVD for the required REIs).

When conducting postapplication risk assessments, there are uncertainties due to a lack of adequate tools and data to fully characterize exposure for all possible crop locations and scenarios. To address these uncertainties, conservative estimates (high-end assumptions) for exposure are routinely used. For example, dislodgeable foliar residue (DFR) data from the study site where the highest residues were observed was used in the assessment. It was assumed that the maximum application rate was used; the maximum number of applications with a minimum interval between applications was applied, and there was co-occurrence between peak residues, and the specific postapplication activity. Even with the residual uncertainties, given the number of conservative approaches in the postapplication exposure assessment, potential exposure is not expected to be underestimated, and the REI periods are expected to be protective of human health.

1.9 Comment – Discontinued uses

Why was the use of dimethoate on apples and lettuce discontinued by the registrants, and does that have any possible implications for the use of those plants for extrapolation?

PMRA Response

The technical registrant of dimethoate withdrew support of its use on apples and head lettuce; therefore, the PMRA did not conduct a risk assessment for these uses. This discontinuation is consistent with changes in the regulatory status of products containing dimethoate in the United States.

The discontinuation of dimethoate on apples and lettuce does not have any implications for the use of DFR data from these plants for extrapolation to DFRs in other crops. In the absence of crop-specific DFR data, the PMRA routinely extrapolates chemical-specific DFR data from surrogate crops to the crops of interest. The use of chemical-specific, surrogate DFR data is considered to be a superior predictor of exposure than default assumptions. A number of factors are considered when determining the applicability of surrogate chemical-specific DFR data such as crop, foliage type, formulation, application equipment, application rate, and study conditions.

1.10 Comment – Label enforcement

Certain terms used on labels appear to be ‘precautionary’ statements, but they are essentially unenforceable. We would refer you to the Commissioner on Environment and Sustainable Development’s comments in 2003 about the problems associated with vague and unenforceable pesticide labels. Clearly the Commissioner was under the impression, based on the information from the PMRA, that future label requirements would be written in precise and enforceable language. It is unacceptable to use unenforceable language such as ‘minimal’, ‘taking into consideration’, ‘consider’, ‘moderate to steep’ in relation to the harmful topics of drift, and runoff of dimethoate. We submit that this language provides no meaningful direction, and essentially delegates the PMRA’s mandate of determining what risks are acceptable to the pesticide user.

In our view, the PMRA is not entitled to assume that these types of precautionary statements have any on-the-ground impact on reducing environmental, or human health risk, absent actual data showing that such label requirements have an appreciable effect, and quantifying how much of a reduction in risk is occurring. The statements are unenforceable and may not be correctly understood by pesticide users.

Can you provide us with any additional information on how compliance with these provisions could be meaningfully assessed or enforced?

PMRA Response

PMRA has worked to improve clarity regarding label statements to ensure enforceability. However, it is also important to note that while labels include mandatory, enforceable mitigation statements (for example, not to be used around homes, do not apply directly to animals, etc.) that reduce any potential risks to acceptable levels, they also include advisory statements (for example, keep and wash personal protective equipment separate from household laundry, use only in well ventilated areas, etc.) on best application practices that may not be legally enforceable but have the potential to further reduce non-target exposures. Best management practices are encouraged and promoted through applicator training initiatives and label

statements. The PMRA and provincial authorities have developed national standards for pesticide education, training, and certification in Canada, which include factors affecting drift, as well as methods to reduce potential for drift to non-target areas during application. There is also compliance and enforcement programs in place that monitor the use of pesticides.

1.11 Comment – Label language

The label contains no actual conditions or directions related to the protection of bees, apart from the warning that dimethoate is toxic to bees. The PMRA appears to be assuming that the mere act of noting the toxicity to bees in some way reduces or eliminates the environmental risks to bees. As with precautionary statements, we submit that mere warning cannot be presumed to have any meaningful impact on environmental risk about evidence demonstrating, and quantifying, such reductions in risk. In addition to assuming that precautionary statements will affect the behavior of pesticide users and thus reduce or eliminate risks, does the PMRA also assume that bare warnings have such an effect?

PMRA Response

The PMRA employs a variety of label statements to achieve environmental protection. Hazard statements are used to inform the user of a product's inherent toxicity to certain biological entities. These hazard statements are triggered in two ways. First, a hazard statement is required if the active ingredient is highly toxic to a biological entity even if the risk assessment has determined that there is “negligible risk” of exposure sufficient to cause adverse effects when the product is used according to the label. Second, hazard statements are also triggered when a potential risk of adverse effects has been identified during the environmental assessment. Hazard statements are not meant to mitigate risks but to inform the user that the product can be handled and stored appropriately.

Where appropriate, the PMRA also requires that mitigation measures be specified on the label to bring the risks within the prescribed acceptable standard. These measures can include restrictions on how and when the product can be used, such as restricting the number of times a product can be applied in a growing season, or requiring no spray buffer zones to minimize pesticide drift into sensitive non-target habitats.

The PMRA also makes use of “best practices” label statements, to inform users of beneficial practices that will help to further reduce any potential non-target exposure.

Many dimethoate product labels already have pollinator label statements. The proposed label statements presented in PRVD2011-12 were intended to be added to labels, with more protective label statements remaining. The label statements presented in the PRVD have been revised to specify risk mitigation measures to reduce exposure to bees and other pollinators. The required label statements are presented in Appendix IV of the RVD.

1.12 Comment – Restricted-entry intervals

The Evaluation Report does not explain why the REIs for forestry-related activities are so much longer than for any agricultural activities. Is this due to differences in the formulation, or in the data which was used to calculate REIs, or some other factor(s)? In particular, please comment on how the REI periods for forestry can be so long as to be uneconomic, while the REI period for "Christmas Trees", which would appear to be a forestry activity, as reported on page 77 of the PRVD, is 18 days for thinning, 3 for hand-line irrigation, and a mere 12 hours for all other activities.

PMRA Response

Restricted-entry intervals establish a minimum period of time that must elapse before workers can re-enter treated areas. REIs require that agricultural workers do not enter previously treated areas to perform activities until pesticide residues have dissipated to acceptable levels. Postapplication exposure and REIs are calculated using generic transfer coefficient values, and chemical-specific dislodgeable foliar residue (DFR) values.

The DFR values used in the dimethoate postapplication exposure assessment were estimated using chemical-specific DFR data from the apple, lettuce, and tomato studies. In order to account for differences in the application rate used in the study and the maximum registered application rate, extrapolated DFR values were adjusted assuming a linear relationship. Thus, if the maximum application rate was higher than the rate used in the study, it was assumed that a greater amount of residue would be available for transfer from the surface of the treated plant resulting in greater postapplication exposure.

In the preliminary risk assessment, the REIs for forestry-related activities are primarily driven by the considerably greater application rate of dimethoate on forestry crops than other registered uses, including Christmas trees. The application rate for forestry crops (Douglas fir seed tree, Sitka spruce, and Spruce (woodland uses)) ranges from 9.98 to 24 kg a.i./ha, whereas the application rate for other agricultural crops ranges from 0.20 to 2.4 kg a.i./ha. This represents, depending on the crop, at least a 4-fold, and up to 100-fold difference in estimated DFR values and potential postapplication exposure, which results in longer REIs required to protect human health.

During the consultation period, further use information was gathered regarding forestry uses. As a result, the application rates and average area treated have been adjusted. Correspondingly, the REIs have been reduced.

1.13 Comment – REI calculations

As we understand it, the REIs were calculated based on the DFR studies which extrapolated the studies for apples, tomatoes and lettuce to a variety of crops. How were the REIs for forestry crops and Christmas Trees (which cannot easily be inferred from those crop studies) calculated?

PMRA Response

The postapplication assessments for forestry crops and Christmas trees are based on the same DFR data (apple DFR study) and transfer coefficients. The only difference in the two assessments is the maximum registered application rate, since forestry uses have a greater application rate. Although the extrapolation of chemical-specific surrogate DFR data to other crops in the dimethoate postapplication assessment represents an area of uncertainty, it is important to note that there are also a number of conservative approaches used.

1.14 Comment – Postapplication forestry activities

The term “all other activities” used in the postapplication exposure assessment for forestry uses appears to us to be a deliberately vague term, which could encompass activities which are on par, in terms of exposure levels, to thinning or harvesting. What activities were specifically assessed in relation to the “all other activities”? How did these activities translate into transfer coefficients, and into various REIs?

PMRA Response

When calculating REI values required to mitigate potential postapplication exposure, activities with similar exposure potential or that result in the same calculated REI value are commonly grouped together to simplify label recommendations. The specific activities that were assessed in relation to “all other activities” vary depending on the crop, and may include such activities as scouting and irrigation. Generally, the term is used for lower contact activities. PMRA has ensured that the REI for each crop captures the high contact activities known to occur for that crop. For example, for filberts, REIs have been specifically established for high contact activities that occur (for example, thinning, hand harvesting, and hand line irrigation). For filberts, no other activities are expected to result in such high contact. Other activities that are known to occur such as scouting and pruning are captured under “all other activities”. The specific activities assessed for each crop and calculated REI values for dimethoate are outlined in Appendix VI (Occupational Exposure Risk Estimates for Dimethoate), Table 4 (Postapplication Exposure Estimates, margin of exposures (MOEs) and REIs for Dimethoate) on pages 108 to 115 of PRVD2011-12.

1.15 Comment – Consultation

We would submit that any consultations with “user groups” must include consultation with farm and other workers likely to use and be exposed to Dimethoate. What consultations have taken place to date with farm workers? What consultations are planned? How have language, cultural and economic barriers to participation in consultations been addressed, and what plans are there to do so?

PMRA Response

During a re-evaluation, users may be consulted regarding a specific use pattern to determine how frequently certain commodity groups use the product; what kinds of activities typically follow an application (for example, pruning, hand harvesting etc.); how soon after application are workers likely to re-enter the field; and what kind of Personal Protective Equipment (PPE) is typically worn, among other information.

In the case of dimethoate, the public was recently consulted on the proposed re-evaluation decision. During this consultation, a wide range of members of the public including the dimethoate registrant, users, and a non-governmental organization provided comments and data.

While consultations in languages other than English and French are not planned, potential language and cultural barriers are considered in other ways. Pesticide labels in Canada are required by regulation to be available in both official languages, French and English. It is recognized that in some locations there may be a population of workers that speak other languages. Although the PMRA does not require labels to be generated based on the language needs of immigrant and migrant agricultural workers, the PMRA agrees that providing translated information could help reduce unintentional misuse of pesticides. For this reason the PMRA has made available a fact sheet on personal protective equipment on the Pesticides and Pest Management portion of Health Canada's website in several other languages including: Vietnamese, Punjabi, Spanish and Chinese. This fact sheet contains key information for workers regarding the proper use of protective equipment in reducing pesticide exposure.

The PMRA's 2011 Seasonal Worker Outreach Program has served to inform immigrant and migrant farmworkers of the Incident Reporting Program (IRP), as well as to improve incident reporting outreach tools. The program is designed for inspectors to meet with farm worker agencies, farm associations, and migrant workers in British Columbia, Ontario and Quebec to communicate safe pesticide use practices. Inspectors also provide the PMRA's incident reporting factsheet to respective parties to encourage voluntary reporting of any pesticide related incidents. Documentation was provided in various languages, and the association/agencies assisted the PMRA in getting translated messages to these workers.

The PMRA delivers a number of agricultural inspection programs annually that promote compliance with pesticide usage instructions and the importance of wearing the required personal protective equipment. Programs are increasingly focusing on informing the immigrant and migrant worker communities, for example, the "Pesticide Education with Punjabi Agricultural Community Program" in British Columbia in 2009, the "Agri-tourism and U-Pick Program" in 2009-10, and the "Seasonal Worker Outreach Program" in 2011.

Delivery of these programs includes components that address the communication barriers within these communities, such as: providing factsheets on worker safety and pesticide safety in the languages of workers (for example, Spanish or Punjabi); delivering presentations to recently arrived seasonal workers at employee centres; and offering employee orientations. This also includes organizing community-specific information sessions with translators present. Other tools that are common to all inspection programs to help promote compliance with regulatory requirements include discussions about requirements around pesticide product use and personal protective equipment, and an explanation of the PMRA's on-line label search tool.

2.0 Comments Relating to Health

2.1 Comment - Cholinesterase inhibition

A series of special studies have been submitted to the PMRA. The registrant stated that these studies clearly demonstrated dimethoate metabolites have a significantly lower potential to inhibit cholinesterase activity as compared to dimethoate, and as such these potential metabolites do not present a concern for dietary exposure. Therefore, the registrant feels that these metabolites should not be included in the dietary risk assessment.

PMRA Response

In PRVD2011-12, the PMRA stated that an acute comparative cholinesterase study (DACO 4.5.12) was required, investigating the ability of the metabolites of concern (O-desmethyl omethoate, O-desmethyl omethoate carboxylic acid, O-desmethyl isodimethoate, and dimethoate carboxylic acid) to inhibit brain cholinesterase activity following exposure. To address this data deficiency, the registrant submitted three acute cholinesterase inhibition studies (PMRA Nos. 1951288, 1951289 and 1951290), and one position paper (PMRA No. 1951287) discussing the results of these studies.

In the first acute cholinesterase inhibition study (PMRA No. 1951288), the erythrocyte cholinesterase inhibiting potential of dimethoate, omethoate and four potential metabolites of dimethoate (O-desmethyl omethoate K salt, O-desmethyl omethoate carboxylic acid K salt, O-desmethyl N-desmethyl omethoate K salt, and des-O-methyl-isodimethoate dicyclohexylammonium salt) were investigated in male Crl:CD®(SD)IGS BR rats exposed by a single gavage dose. The dosage levels used in this study were 30 mg/kg bw for all of the test substances, except omethoate which was administered at 5 mg/kg bw. The results of this study demonstrated that the four potential metabolites of dimethoate had a markedly lower potential to inhibit erythrocyte cholinesterase activity when compared to dimethoate and omethoate. However, conclusions concerning the ability of these potential metabolites to inhibit brain cholinesterase activity cannot be drawn from this study since brain cholinesterase activity was not investigated.

In the second acute cholinesterase inhibition study (PMRA No. 1951289), a single gavage dose of dimethoate, O-desmethyl-omethoate-carboxylic acid di-Na-salt, and des-O-methyl isodimethoate Na-salt was administered to Crl:CD®(SD) adult rats. The dosage levels used in this study were 0, 5 (for dimethoate only), 10, 20, 30 and 40 (for O-desmethyl-omethoate-carboxylic acid di-Na-salt and des-O-methyl isodimethoate Na-salt only) mg/kg bw. Male and

female rats exposed to dimethoate starting from 5 mg/kg bw experienced significant inhibition of brain and erythrocyte cholinesterase activity as compared to the corresponding control animals. In contrast, male and female animals exposed to O-desmethyl-omethoate-carboxylic acid di-Na-salt or des-O-methyl isodimethoate Na-salt did not experience any treatment-related inhibition in brain or erythrocyte cholinesterase activity up to 40 mg/kg bw.

In the third acute cholinesterase study (PMRA No. 1951290), the cholinesterase inhibiting potential and the time-to-peak effect of O-desmethyl-omethoate-carboxylic acid di-Na-salt, and des-O-methyl isodimethoate Na-salt was examined in male and female Crl:CD®(SD) rats exposed by a single gavage dose. Results indicated no treatment-related inhibition of brain or erythrocyte cholinesterase activity 2.5 hours post-dosing in males and females exposed to a single dose of 1,000 mg/kg bw O-desmethyl-omethoate-carboxylic acid di-Na-salt or des-O-methyl isodimethoate Na-salt.

The results from these three acute cholinesterase studies indicated that these metabolites of dimethoate displayed a markedly lower potential to inhibit erythrocyte and brain cholinesterase activity as compared to dimethoate and omethoate. However, it should be noted that conclusions concerning the ability of dimethoate carboxylic acid to inhibit erythrocyte and/or brain cholinesterase activity could not be drawn from these studies since this was not investigated. The registrant stated that the potential toxicity of dimethoate carboxylic acid has already been accounted for in the toxicological studies conducted with dimethoate. Dimethoate carboxylic acid is a major urinary metabolite of dimethoate, and as such, the effect levels and reference doses selected for dimethoate have already taken into account the toxicity, as well as cholinesterase inhibiting effects of this metabolite. The PMRA agrees with this argument based on the pharmacokinetic study on file and as such, a study investigating the cholinesterase inhibiting potential of dimethoate carboxylic acid is no longer required by the PMRA. Therefore, the PMRA has determined that the data requirement for an acute comparative cholinesterase study investigating the ability of metabolites of concern to inhibit cholinesterase activity following exposure has been satisfied. The metabolites of dimethoate have not been included in the dietary risk assessment.

2.2 Comment - Historical control data

The registrant submitted a document to address the data gap that was identified in the PRVD with respect to historical control data for vascular tumours in the rat (PMRA No. 2118847). The document contained the historical control incidence of vascular tumours in the spleens, and lymph nodes from 2 control groups in the BASF laboratory from 1987, varying from 16 to 22%. The registrant also supplied a re-evaluation of the slides of the spleen and lymph nodes undertaken by an independent pathologist.

PMRA Response

The incidence of combined hemangiomas/angiomas and hemangiosarcomas/angiosarcomas of the spleen and mesenteric lymph nodes was 2/50, 11/50, 10/50 and 10/50 at 0, 5, 25 and 100 ppm (~0, 0.25, 1.25 and 5 mg/kg bw/day) in male Wistar rats from the 1985 two-year dietary carcinogenicity study (PMRA No. 1216451). Statistical significance in this study was achieved at the low, mid and high dose levels. While the original tumour incidence suggested a

compound-related effect, the incidence of vascular tumours noted in the control male rats of this study may be unusually low (4%) compared to the limited historical control data of 16 and 22%. The reassessment of the spleen and lymph node slides by an independent pathologist resulted in an overall vascular tumour incidence of 0/50, 7/50, 4/50 and 6/50. These incidences cannot be compared to the historical control data as different diagnostic criteria were used. Collectively, the data shows an increase in vascular tumours in dimethoate-exposed animals; however, the lack of a dose response coupled with the historical incidence render the finding to be of an equivocal nature. In the PRVD, the PMRA had concluded that based on the scientific evidence, dimethoate is unlikely to pose a carcinogenic risk for humans. The PMRA has determined no changes to the cancer risk assessment are warranted and that the data requirement for historical controls for the incidence of vascular tumours in Wistar rats has been satisfied.

2.3 Comment - Additional studies

The registrant submitted two immunotoxicity studies (PMRA Nos. 2088650 and 2088651) to be considered in the risk assessment of dimethoate.

PMRA Response

The range-finding and main immunotoxicity studies conducted with Crl:CD1 (ICR) mice (PMRA Nos. 2088651 and 2088650, respectively) were reviewed by the PMRA after the publication of the PRVD.

In the range-finding study (PMRA No. 2088651), dimethoate was administered in the diet for 14 consecutive days to female Crl:CD1 (ICR) mice at dosage levels of 0, 4, 17, 35 or 57 mg/kg bw/day. This study was classified as acceptable as a range-finding study in the mouse. Since the purpose of this study was to determine the dosage levels to be used in the main immunotoxicity study, a NOAEL was not selected.

The immunotoxic potential of dimethoate was evaluated in a plaque-forming cell assay. In the main immunotoxicity study (PMRA No. 2088650), dimethoate was administered in the diet for 28 consecutive days to female Crl:CD1 (ICR) mice at dosage levels of 0, 1, 5, 14 and 36 mg/kg bw/day. Exposure of up to 36 mg/kg bw/day of dimethoate for 28 days did not result in any effects on the absolute or relative spleen and thymus weights, spleen cell number, or spleen IgM antibody response to the T-cell-dependent antigen, sheep erythrocytes. Based on the study results, a NOAEL for immunotoxicity was set at 36 mg/kg bw/day while a LOAEL for immunotoxicity was not established. An overall systemic LOAEL of 1 mg/kg bw/day was established based on inhibition of brain cholinesterase at this dosage level while an overall NOAEL was not established. This immunotoxicity study was classified as acceptable as an immunotoxicity study in the mouse.

These two studies were considered acceptable for risk assessment purposes and have been considered in the updated re-evaluation of dimethoate. The results of these two studies will not affect the previously established reference doses for dimethoate and as such the established reference doses are still considered protective of all populations, including infants and children. The reference list has also been updated to reflect the inclusion of these studies in the re-evaluation of dimethoate.

2.4 Comment - PMRA'S Assumption of 100% Dimethoate Conversion to Omethoate during Water Chlorination and Revised Dietary Risk Assessment

The PMRA assumed 100% transformation of dimethoate to omethoate in drinking water (see page 29 of the PRVD). PMRA recommended (on page 54 of the PRVD) that a non-guideline study be conducted to address these issues. The registrant submitted the following report to PMRA:

> Marin, J. (2010) Determination of the Effect of Chlorination of the Degradation of Dimethoate in Water. Project Number: 1970W. Unpublished study prepared by PTRL West, Inc. 170 p.

The study reports that the transformation of dimethoate to omethoate ranged from 11% to 23%, which is consistent with the results of the previous USEPA study mentioned by PMRA on page 162 of the PRVD.

PMRA Response

As noted in PRVD 2011-12, the modeled estimated environmental concentration (EEC) for drinking water was of concern in the acute aggregate food and drinking water risk assessment. This risk concern was primarily driven by the conservative assumption of 100% conversion of dimethoate to the more toxic metabolite omethoate in treated water, a worst-case estimate made in the absence of quality data to characterize the degree of omethoate transformation during water chlorination.

The submitted chlorination study (PMRA No. 1957106) has been reviewed by the PMRA and deemed adequate for use in the risk assessment. The data indicates that 23% of dimethoate is converted to omethoate during water chlorination. This value was incorporated into the revised risk assessment. In addition to this change, water modeling estimates were updated to align with the revised use pattern proposed in the PRVD. The previous model estimates were based on the use pattern for potatoes at 0.528 kg a.i/ha/application, and 3 applications per year, or a maximum cumulative application rate per year of 1.584 kg a.i/ha. The updated use pattern for potatoes is at 0.48 kg a.i/ha/application, and two applications per year, or a maximum cumulative application rate per year of 0.96 kg a.i/ha. Consistent with the previous assessment, the level two modeling surface water reservoir scenario was used to determine the EECs. For the acute estimate, the complete daily 50-year period distribution of model concentrations was incorporated into the assessment. For the chronic estimate, the 90th percentile of the yearly average water concentration was used. Refer to Table 1 for a summary of changes.

The residue estimates for safflower, canola, and flaxseed oil have also been revised in the risk assessment. The residue estimate for these commodities was previously based on half of the general MRL level of 0.1 ppm established under B.15.002 (1) of the Food and Drug Regulations for commodities where no specific residue limit has been established. Use of the general MRL as a residue estimate has a high degree of uncertainty, and is only used when more reliable estimates are not available. A processing study submitted during the consultation period for the PRVD indicates that dimethoate and omethoate residues in safflower oil were non detectable

(<0.01 ppm) when treated at rates higher than the maximum use rates in Canada. Thus, the residue estimate for safflower oil was changed to 0.01 ppm for dimethoate, and 0.01 ppm omethoate (to be adjusted with the toxicological adjustment factor (TAF)). A TAF of 12 was applied to omethoate residues for the acute assessment, and a TAF of 3 was applied to omethoate residues for the chronic assessment. These residue estimates were also applied to canola oil and flaxseed oil as they are in the same group as safflower and have lower use rates compared to the rates used in the safflower processing study. Refer to Table 2 for a summary of the changes. Residue estimates were not changed for other food commodities.

The revised food and drinking water exposure estimates are below the acute reference dose and the acceptable daily intake for all population groups and are not of concern. There was no need to further examine the risk using EECs based on water monitoring data as no risk concerns were identified using the more conservative model estimates. The data requirement to address the uncertainties around the formation of the oxygen analog (omethoate), resulting from chlorination, is satisfied. Refer to Table 3 and 4 for the exposure and risk estimates**.**

Table 1 Drinking Water Estimate Environmental Concentration Revisions

	Original Assessment	Revised Assessment
Monitoring Data Used	Yes	No
Modeling Data Used	Yes	Yes
Modeling Scenario Used	Level 2 Surface Water Reservoir Potato Use - 0.528 kg a.i/ha x 3 applications per year or 1.584 kg a.i/ha/season	Level 2 Surface Water Reservoir Potato Use - 0.48 kg a.i/ha x 2 applications per year or 0.96 kg a.i/ha/season
Model Daily EEC (µg/L)[1]	35	16.62
Model Yearly EEC (µg/L)[2]	2.5	1.22
Omethoate Transformation Adjustment	0% Dimethoate = 0	77% Dimethoate = 0.77 x EEC
	100% Omethoate = 1 x EEC x TAF[3]	23% Omethoate = 0.23 x EEC x TAF[3]
	Total Dimethoate Equivalent Concentration = 0% Dimethoate + 100% Omethoate	Total Dimethoate Equivalent Concentration = 77% Dimethoate + 23% Omethoate
Acute Risk Assessment Input	Entire 50 Year Distribution of Model Concentrations - Adjusted for Omethoate Transformation	Entire 50 Year Distribution of Model Concentrations - Adjusted for Omethoate Transformation
Chronic Risk Assessment Input	Model Yearly EEC – Adjusted for Omethoate Transformation 0 + 1 x 2.5 µg/L x 3= **7.5 µg/L**	Model Yearly EEC – Adjusted for Omethoate Transformation 0.77 x 1.22 µg/L + 0.23 x 1.22 µg/L x 3 = **1.78 µg/L**

EEC = Estimated Environmental Concentration, TAF = Toxicological Adjust Factor
[1] 90th percentile of yearly peak concentration
[2] 90th percentile of yearly average concentration
[3] TAF = Toxicological adjustment factor to convert omethoate residues into dimethoate equivalent residues. A TAF of 12 is applied to omethoate residues for the acute assessment and a TAF of 3 is applied to omethoate residues for the chronic assessment.

Table 2 Oil Seed Residue Estimate Revisions

Crop Matrix	Revised Assessment					Original Assessment				
	Dim (ppm)	Ome (ppm)	Total (ppm)[1]		Source	Dim (ppm)	Ome (ppm)	Total (ppm)[1]		Source
			Acute	Chronic				Acute	Chronic	
Safflower Oil	0.01	0.01	0.13	0.04	Safflower Processing Study	0.05	0.05	0.65	0.20	General MRL at 0.1 ppm[2]
Canola Oil	0.01	0.01	0.13	0.04		0.05	0.05	0.65	0.20	
Flax Oil	0.01	0.01	0.13	0.04		0.05	0.05	0.65	0.20	

Dim = dimethoate, Ome = omethoate

[1] Total = Dimethoate Residue + Omethoate Residue x TAF (where TAF = 12 for the acute assessment and 3 for the chronic assessment).

[2] Dimethoate and omethoate residues were assumed to be half the general MRL of 0.1 ppm specified by B.15.002(1) of the Food and Drug Regulations.

Table 3 Acute Dietary and Aggregate Dietary and Drinking Water Exposure

Population Group	Exposure from Food[1]		Exposure from Food and Water[1]	
	mg/kg bw/day	%ARfD[2]	mg/kg bw/day	% ARfD[2]
General Population	0.00475	37	0.00518	40
All Infants (<1 yrs)	0.00512	39	0.00911	70
Children 1-2 yrs	0.00869	67	0.00936	71
Children 3-5 yrs	0.00800	61	0.00843	65
Children 6-12 yrs	0.00728	56	0.00779	60
Male 13-19 yrs	0.00470	36	0.00516	40
Male 20-49 yrs	0.00342	26	0.00383	29
Adults 50+ yrs	0.00273	21	0.00329	25
Female 13-49 yrs	0.00389	29	0.00424	33

ARfD = Acute Reference Dose

Acute exposure reported at the 99.9th percentile

[1] Exposure accounts for both dimethoate and omethoate residues. 12x acute toxicological adjustment factor (TAF) was applied to omethoate residue estimates.

[2] Acute Reference Dose = 0.013 mg/kg bw/day

Table 4 Chronic Dietary and Aggregate Dietary and Drinking Water Exposure

Population Group	Exposure from Food[1]		Exposure from Food and Water[1]	
	mg/kg bw/day	%ADI[2]	mg/kg bw/day	% ADI[2]
General Population	0.00011	6	0.000147	7
All Infants (<1 yrs)	0.000107	5	0.000230	12
Children 1-2 yrs	0.000262	13	0.000318	16
Children 3-5 yrs	0.000244	12	0.000296	15
Children 6-12 yrs	0.000166	8	0.000202	10
Male 13-19 yrs	0.000105	5	0.000132	7
Male 20-49 yrs	0.000091	5	0.000126	6
Adults 50+ yrs	0.000078	4	0.000115	6
Female 13-49 yrs	0.000088	4	0.000122	6

ADI = Acceptable Daily Intake

[1] Exposure accounts for both dimethoate and omethoate residues. 12x acute toxicological adjustment factor (TAF) was applied to omethoate residue estimates.

[2] Acceptable Daily Intake = 0.002 mg/kg bw/day

2.5 Comment - Residue Chemistry Data

The technical registrant has submitted a number of residue chemistry studies in response to the residue chemistry data requirements (DACO 6 and 7) specified in the PRVD. The registrant has requested that the PMRA evaluate these studies and consider them into the re-evaluation decision.

PMRA Response

The PMRA has considered the newly submitted studies in the re-evaluation decision. A summary of the reviews is provided below. The following changes to the proposed re-evaluation decision were made in consideration of the data submitted:

- Plant back interval restrictions proposed in PRVD2011-12 are no longer required based on submitted crop rotational data.

- Residue estimates for safflower oil, flax oil, and canola oil have been revised based on submitted processing data.

Overall, the submitted residue chemistry studies improved the quality of the database available to the PMRA and confirmed a number of assumptions relied upon in PRVD2011-12. The data did not significantly impact the results of the dietary risk assessment and regulatory decision beyond removing the requirement for plant back intervals. In terms of the crop field trial data submitted by the registrant, in most cases the studies were conducted in regions, or at GAPs (good agricultural practices) that do not correspond to current Canadian labels. The registrant has indicated that new animal feeding studies, along with related storage stability and analytical methodology reports, are being conducted and/or prepared. They will be sent to the PMRA once completed. With the exception of new studies related to animal feeding, the PMRA does not require any additional residue chemistry data for the re-evaluation review.

The re-evaluation review will generally propose revisions or revocation of MRLs if risks of concern are identified, or if uses are no longer supported by the registrant. The PMRA was informed by the registrant during the re-evaluation that dimethoate uses on head lettuce, apples, cabbage, and spinach were no longer supported. Thus, the PMRA will revoke or modify the dimethoate MRLs on these crops. No other changes to MRLs will be made as the result of dimethoate re-evaluation. Registrants and other stakeholders may request additional or revised MRLs via data supported submissions to the PMRA.

Metabolism

The submitted metabolism studies confirm that the residue definition for risk assessment and enforcement in plant and animal commodities is: dimethoate and omethoate.

The data requirements for animal and plant metabolism are satisfied for the re-evaluation.

Plant metabolism studies for potatoes, wheat, and olives were submitted. The metabolic profile for dimethoate in the plant species tested was similar. Dimethoate is rapidly metabolized through oxidation, and demethylation processes, and to a minor degree through hydrolysis and rearrangement. Dimethoate related residues were found at higher concentration in the foliage or outer portions of plant samples as compared to the grain and root samples. This is consistent with its use profile as a foliar insecticide. The major compounds observed in the test species were: dimethoate, omethoate, O-desmethyl omethoate, O-desmethyl N-desmethyl omethoate, and des-O-methyl isodimethoate. Less significant compounds observed include: dimethoate carboxylic acid, dimethyl dithiophosphate, and O-desmethyl omethoate carboxylic acid. Of the major compounds identified, dimethoate and omethoate are of toxicological concern. Therefore, the residues of concern expected to occur in plants are dimethoate and omethoate.

Animal metabolism studies for goats and hens were submitted. The metabolic profile in the animal species tested was similar. Dimethoate related residues are rapidly metabolized and excreted. In tissues, residue concentrations were highest in the liver and kidneys. The next highest concentrations were found in eggs and milk, and lowest concentrations were observed in muscle and fat. Less than 1% of dose was found in any single tissue, milk, or egg matrices. The majority of the radiolabelled residues could not be identified in the residue characterization portion of the studies, although it can be concluded that dimethoate and omethoate are not likely to accumulate in animals. Dimethoate was not detected in any tissue, excreta, milk, or egg samples. The only metabolites identified were omethoate and dimethoate carboxylic acid in liver and egg matrices. Anionic components such as dimethyl thiophosphate and dimethyl phosphate were found at significant levels in excreta and to a lesser degree in tissues.

Analytical Methodology

Several methods have been developed for crop field trials to determine dimethoate and omethoate residues in plant matrices, although it should be noted that independent laboratory validation studies for the methods have not been conducted or submitted to the PMRA. For enforcement, monitoring programs in Canada and the US include multi-residue methods that analyze for dimethoate and omethoate in a variety of crop matrices. For the re-evaluation review, additional requirements for analytical methods in plant matrices are not required.

A number of analytical methodology studies for animal matrices were submitted during the consultation period. The PMRA is aware that the technical registrant has initiated new animal feeding (cow and hen) studies along with related storage stability and analytical methodology studies. The PMRA will consider this information when the studies are submitted to the Agency.

Storage Stability

For plant matrices, storage stability data was submitted for potato tuber, orange fruit, sorghum grain, sorghum forage, and cottonseed. Dimethoate and omethoate residues were shown to be stable in these matrices for a period of 6, 20, and 27 months. The data is sufficient to support storage stability requirements for oilseed (cottonseed), root (potato tuber), non-oil grain (sorghum grain), and fruiting vegetables (orange) crops. The PMRA disagrees with the registrant’s conclusion that sorghum forage data may be used to represent leafy vegetable crops. As indicated in the Residue Chemistry Guidelines DIR98-02 and the USEPA OPPTS 860.1500

test guidelines, the representative commodities for leafy vegetables (crop group 4) are lettuce, celery, and spinach. Sorghum forage is classified under crop group 16 (forage, fodder, and straw of cereal grains) and is not considered to be a representative commodity for leafy vegetables. Thus, concurrent storage stability data should be included in field trials for leafy vegetable crops.

For animal matrices, the registrant has indicated that they are in the process of conducting a frozen storage stability study of dimethoate and omethoate and will submit the study to the PMRA once it is complete. The PMRA will consider this information when the studies are submitted to the Agency.

Magnitude of Residue

Field trial data was submitted for domestically registered crop uses as well as registered crop uses in other countries. A summary list of field trials is reported in Table 5.

The majority of field trials submitted were conducted in Europe where climatic, soil conditions, and the use pattern may differ from those in Canada. Thus, the submitted trials are not considered adequate for the purposes of revising or establishing MRLs for registered domestic food crops. Should additional or revised MRLs be required for trade purposes, the registrant or other interested parties are encouraged to request MRLs be established via a submission to the PMRA. The studies that have been submitted during the consultation (for example, European field trials for olives) will also be considered accordingly in future MRL submissions.

For animal matrices, the registrant has indicated that they are currently conducting new cow and hen magnitude of residue studies on dimethoate as a result of a data call-in issued by the USEPA. The PMRA requests that these data be submitted when they become available.

Table 5 Summary of Field Trials Submitted

Crop	Registered in Canada	Canadian Trials Submitted	US Trials Submitted	European Trials Submitted
Apple	No	0	0	2
Artichoke	No	0	0	4
Alfalfa	Yes	1	4	0
Asparagus	Yes	0	4	6
Barley	Yes	0	0	24
Bean	Yes	0	5	0
Beets	Yes	0	0	31
Blueberry	Yes	0	0	6
Broccoli	Yes	0	0	4
Brussel Sprouts	Yes	0	0	13
Carrot	Yes	0	0	17
Celery	Yes	0	0	4
Cherry	Yes	0	0	15
Clementine	Yes	0	0	1
Corn	No	0	1	0
Cotton	Yes	0	3	0
Grass	No	0	3	0
Lemon	No	0	0	2
Lettuce	Yes	0	0	25

Crop	Registered in Canada	Canadian Trials Submitted	US Trials Submitted	European Trials Submitted
Mandarin	No	0	0	28
Melon	No	0	0	8
Onion	No	0	0	8
Orange	No	0	1	16
Olive	No	0	0	23
Pea	Yes	0	0	29
Potato	Yes	0	1	6
Sorghum	No	0	0	6
Tomato	Yes	0	1	8

Crop Rotation

A rotational crop study was submitted to the PMRA. The rotational crops used in the study were wheat (forage, hay, straw, and grain), lettuce, and turnips (foliage and root). The soil was treated with radiolabelled dimethoate with 1 application at a rate of 0.57 kg a.i./ha. The crops were planted back at either 30 days or 120 days after the application. Total radioactive residues (TRRs) in samples planted back at 30 days ranged from 0.008 ppm (turnip roots) to 0.045 ppm (wheat straw). Residues in samples planted back at 120 days ranged from 0.001 ppm (turnip roots) to 0.020 ppm (wheat straw). The crop matrices with TRRs > 0.01 ppm were further characterized. The majority of TRRs consisted of polar metabolites. Dimethoate and omethoate were not present at levels above 0.01 ppm or 10% of the TRR in the any test crops.

The PMRA had previously proposed a 30-day plant back interval for dimethoate uses based upon information obtained from foreign reviews; however, based upon review of the submitted data, it can be concluded that residues of dimethoate and omethoate are not expected to occur in significant amounts (<0.01 ppm or 10% TRR) in rotational crops planted back at 30 days or more. Therefore, plant-back intervals will not be required on labels.

Processing

A safflower processing study was submitted to the PMRA. Dimethoate was applied to safflower at nominal rates of either 0.56 kg a.i./ha or 2.80 kg a.i./ha. A portion of safflower samples from the control plot and the 2.80 kg a.i./ha treated plot were processed according to simulated commercial practices into meal and refined oil. The samples from the 0.56 kg a.i./ha treated plot was not processed or analyzed. Average dimethoate residues levels in the treated safflower samples were 0.67 ppm in seed, 0.63 ppm in meal and <0.01 ppm in refined oil. Average omethoate residue levels in the treated safflower samples were 0.01 ppm in seed, 0.01 ppm in meal, and <0.01 ppm in refined oil. There were no residues of dimethoate or omethoate detected (<0.01 ppm) in control samples.

The data indicates dimethoate residue concentrations remained relatively unchanged during the processing of safflower seed to meal. Dimethoate residue concentrations significantly decreased during processing of seed into oil and was not detectable in any of the treated oil samples (<0.01 ppm). Residues of omethoate were very low in seed and meal (0.01 ppm) and were not detectable in oil (<0.01 ppm). Overall, it can be concluded that dimethoate and omethoate residues are not expected to concentrate during the processing of safflower seed to meal or oil.

Furthermore, residues are not expected to exceed 0.01 ppm in safflower oil when treated according to label directions. Residue estimates in the dietary risk assessment for safflower, flax, and canola oil were updated in consideration of the data.

Processing studies were also submitted for corn, cottonseed, orange, potato, and tomato. The data from these studies confirm the processing factors used in the original dietary assessment, which were primarily based on information gathered from foreign reviews.

2.6 Comments - Occupational and Residential Exposure

2.6.1 Comment - Airblast Applications to Conifers

PMRA has concluded that airblast applications of dimethoate to Douglas fir seed trees, spruce (woodland) and Sitka spruce trees cannot be supported, with either open cab or closed cab equipment.

Open cab application

The registrant commented that dimethoate is efficacious against common insect pests to conifers at rates that are lower than those considered by the PMRA. For Douglas fir seed tree orchards, the registrant has indicated that a maximum application rate of 9.6 kg a.i./ha is currently used in British Columbia and that the daily area treated at one property is 2.8 ha/day. When these values are used, the resulting margin of exposure (MOE) is 222. Thus, based on application conditions obtained in British Columbia, the use of Douglas fir seed orchards can be supported at 9.6 kg a.i./ha.

The registrant asked the PMRA to consider the approach taken for these uses in the US. The current maximum application rates in the US are 4.15 lb a.i./acre (4.65 kg a.i./ha) for Douglas fir seed trees in Oregon and Washington and 1 lb a.i./acre (1.12 kg a.i./ha) for all other woody ornamentals, including conifer trees. The registrant is committed to achieving harmonized use patterns in the United States and Canada. When reduced harmonized application rates are incorporated into the exposure and risk assessment, MOEs greater than 100 result for open cab airblast applications. The registrant suggests that PMRA consider the USEPA's assumption of 20 acres (8 ha) treated daily in Douglas fir seed tree nurseries. The registrant feels that this value can be regarded as an absolute maximum value, since upon consultation with users it was found that the maximum daily treatment rate is 2.8 ha/day.

Closed cab applications

For closed cab applications (for example, the engineering control scenario), the PMRA conclusion is based on exposure estimates with PPE consisting of cotton coveralls over a single layer and gloves. Using the same revised input parameters for application rate and area treated discussed for open cab applications, the resulting MOEs are greater than 100.

Considering data obtained from users and assumptions made by the USEPA, the registrant feels that there are opportunities for the PMRA to re-evaluate these uses and conclude that they need not be cancelled.

PMRA Response

The conifer seed orchard risk assessment has been revised assuming a reduction in the application rate for Douglas fir and Sitka spruce, from 24 kg a.i./ha and 12 kg a.i./ha, respectively, to 9.6 kg a.i./ha and 10 kg a.i./ha, respectively, and an area treated per day value of 6 ha. The area treated per day value is based on information from a survey of stakeholders conducted by the PMRA. Using the maximum reported orchard sizes for Douglas fir, the average size of a Douglas fir orchard was determined to be 6 ha. As this value was similar to the median reported value of spruce orchards, and was higher than the maximum reported orchard size for Sitka spruce, a value of 6 ha was used for all conifer seed orchards.

Using these assumptions for airblast applications, calculated MOEs exceeded the target MOE of 100 with additional personal protective equipment and engineering controls (for example, chemical-resistant coveralls and respirators during mixing and loading, and closed cabs with coveralls over a single layer during airblast application). Therefore, registration of dimethoate on Douglas fir, Sitka spruce, and spruce can continue to be supported. The revised assessment is presented in Appendix II.

2.6.2 Comment - High Pressure Handwand Applications to Ornamentals and Structures

In the PRVD, PMRA concluded that high pressure handwand applications could not be supported for certain ornamentals and that a cap would be needed for other applications to other ornamentals and structures. PMRA concluded that high pressure handwand applications to Douglas fir seed trees, Sitka spruce and spruce (woodland) could not be supported due to very low MOEs. PMRA also concluded that a cap on the daily quantity handled of 2.8 kg ai was necessary to yield acceptable MOEs for high pressure handwand applications to several other ornamentals.

An outcome of the USEPA reregistration process is that the maximum dilute in-use concentration is now required to be no greater than 0.0025 lb a.i./gal (0.00030 kg a.i./L) when high pressure handwand equipment is used. This resulted in MOEs greater than 100. The registrant commented that PMRA’s proposed cap on the daily amount handled for high pressure handwand applications to ornamentals is unnecessary. The registrant will be decreasing the maximum dilute concentration for high pressure handwand applications to match the American rate. In doing so, exposures associated with all high pressure handwand applications will be associated with MOEs greater than 100;therefore, there is no reason to eliminate uses or restrict the quantity that can be applied per day with high pressure handwands.

PMRA Response

Although the alternative mitigation measure proposed by the registrant of restricting the maximum dilute in-use concentration to 0.00030 kg a.i./L would result in calculated MOEs that exceed the target, it is unknown whether a dilute in-use concentration of 0.00030 kg a.i./L would be efficacious for all uses. Restricting the amount of active ingredient handled per day allows the user to have a certain degree of flexibility when using the product. When using a lower dilute in-use concentration, a greater amount of product can be handled in one day; however, if a higher dilute in-use concentration is required, the user can then adjust the amount of product used allowing them to use a higher dilute in-use concentration when warranted.

Even with the change in application rate for Douglas fir, Sitka spruce, and spruce uses, calculated combined MOEs for mechanically-pressurized handgun (for example, high pressure handwand) range from 7 to 8, which is significantly lower than the target MOE of 100). Therefore, the use of mechanically-pressurized handguns in Douglas fir, Sitka spruce, and spruce will be prohibited. The revised assessment is presented in Appendix II.

2.6.3 Comment - Paint-On Uses

The registrant does not support paint-on uses in Canada, and these uses do not appear on its labels. Furthermore, the paint-on uses are not supported by the registrant in the United States. Therefore, the registrant requests that the evaluation of paint-on uses be removed from the PRVD.

PMRA Response

It is acknowledged that paint-on uses are not supported by the registrant in Canada. It should be noted that paint-on uses are still on registered dimethoate labels in Canada for roses, birch, and lilacs. These uses must be removed from all registered labels.

2.6.4 Comment - Right-of-Way Sprayer

The PMRA has concluded that applications to wastelands, pastures and forage grasses cannot be supported because occupational handler exposures are of concern. In estimating handler exposures, the PMRA assumed application to 75 hectares per day when using a right-of-way sprayer. In contrast, the USEPA assumption is that a right-of-way sprayer will treat 10 acres per day, which corresponds to approximately 4 hectares. An MOE greater than 100 is obtained when using the right-of-way parameters assumed by the USEPA for applications of dimethoate when the PPE consists of gloves, chemical-resistant coveralls. Therefore, right-of-way sprayer applications can be supported.

PMRA Response

The PMRA agrees with the registrant’s assertion that the 75 ha per day assumption for right-of-way sprayer is too high. The area treated per day value was refined to 5 ha per day based on the default values used by the USEPA for right-of-way sprayers in the dimethoate and fosamine reregistration eligibility decision documents (USEPA, 1995 and 2006). Using this area treated

per day value, calculated MOEs exceeded the target MOE provided that chemical resistant coveralls are worn over a single layer of clothing with chemical resistant gloves. Thus, no further restrictions are required on the dimethoate labels and this use is acceptable for continued registration.

2.6.5 Comment - Drench Applications to Carnations

PMRA has concluded that drench applications to carnations cannot be supported due to occupational handler exposures of concern. The registrant proposes to revise the label instructions for drench applications to carnations to specify a maximum in-use concentration. Although the value is yet to be determined, it could be on the order of that for camellias on the Canada label (0.00288 kg a.i./L) or that for camellias in the US (0.0075 kg a.i./L). Calculations performed by the registrant show that drench applications to carnations can be supported at dilute in-use concentrations up to 0.0276 kg a.i./L.

PMRA Response

In the absence of data to support an in-use concentration for carnations of 0.00288 kg a.i./L, the PMRA cannot support the maximum in-use concentration proposed by the registrant. Therefore, drench applications to carnations cannot be supported due to occupational handler exposures of concern and this use must be removed from all product labels.

2.6.6 Comment - Re-Entry Exposures in Conifers

PMRA estimated REIs to be 105 days for Douglas fir seed tress, 77 days for Sitka spruce and 70 days for spruce (woodland). PMRA concluded that these REIs were unfeasible.

In the PMRA assessment, the activity with the maximum transfer coefficient of 3000 cm^2/hr is for “thinning”. Thinning is not an activity associated with Douglas fir seed trees, Sitka spruce or spruce (woodland). Thinning is only associated with Christmas trees and similar heavily groomed trees.

The registrant believes that hand set irrigation activities should not be included for Douglas fir, Sitka spruce and spruce (woodland) because irrigation is rarely, if ever, used for these trees in Canada. In the rare instance where irrigation is used, the irrigation lines would be permanent. Regarding scouting activities, consultations with users indicate that scouting for cone moth larval attacks involves a no-touch protocol and that checking pheromone traps involves minimal contact (on the order of seconds) with foliage. Harvesting of the cones is done manually, but the harvest is performed from bucket trucks. The workers also wear gloves, which reduces potential exposures.

Based on registrant calculations, revised REIs for hand-harvest (the most contact-intensive relevant activity) are 32 days in Douglas fir at 9.6 kg a.i./ha and 20 days at 4.65 kg a.i./ha. For Douglas fir, the REI for hand pruning and scouting is 29 days at 9.6 kg a.i./ha and 17 days at 4.65 kg a.i./ha. REIs for all other activities are 12 hours. These REIs can be considered feasible, as there is at least a 35-day period between the last applications (early June) and cone harvesting (Aug-Oct) in Douglas fir seed trees.

PMRA Response

The conifer seed orchard postapplication risk assessment has been revised assuming a reduction in the application rate for Douglas fir and Sitka spruce, from 24 kg a.i./ha and 12 kg a.i./ha, respectively, to 9.6 kg a.i./ha and 10 kg a.i./ha, respectively. In addition, the transfer coefficients and activities assessed were revised based on information in the USEPA *Science Advisory Council for Exposure (ExpoSAC) Policy 3* (Revised March 2012), information obtained from a survey of stakeholders conducted by the PMRA, and updated Agricultural Re-entry Task Force (ARTF) (PMRA No. 2115788) activity specific transfer coefficients. Based on this information, thinning activities were removed as this is not a predominant activity in conifer seed orchards, and the transfer coefficient for hand harvesting was revised to be equivalent to the orchard hand harvesting transfer coefficient of 1500 cm^2/hr.

In the assessment presented in the PRVD, it was assumed that postapplication activities take place for 8 hours per day. However, according to a survey of dimethoate users for conifer seed orchards conducted by PMRA, scouting activities take place approximately once a week for a period of 5 minutes to 2 hours. Based on this information, the postapplication assessment was revised assuming that scouting takes place for a period of 2 hours per day.

Using the additional information in the above-noted documents, the following activities were assessed for Douglas fir, Sitka spruce, and spruce, and revised REIs were calculated:

- Douglas fir:
  - Seed Cone Harvesting: 48 days
  - Scouting: 5 days
  - Grading, animal control, baiting: 1 day
- Sitka spruce, spruce (seed tree):
  - Seed Cone Harvesting: 49 days
  - Scouting: 5 days
  - Hand pruning, staking, and tying: 27 days
  - Grading, animal control, baiting: 2 days

Users of dimethoate have indicated that REIs of 48 and 49 days are agronomically feasible; thus continued registration of dimethoate for conifer seed orchards can be supported. The revised assessment is presented in Appendix II of this document.

3.0 Comments Relating to Environment

3.1 General Comments

3.1.1 Comment - References

The registrant commented that the PRVD does not contain complete references for any cited documents. Original reference citations should be provided throughout the report and not be referred to as, for example, PMRA XXXXX, which can often represent a summary report such as the re-registration eligibility decision document (RED). Readers should not have to view a secondary document to find a primary reference, particularly when the PMRA authors should have reviewed the primary references before using the information to develop the ecological risk assessment for dimethoate.

PMRA Response

In keeping with our standard procedure, all references to data sources in the PRVD are provided in the appropriate tables. All information and data (studies) available in PMRA database have been assigned PMRA numbers. All PMRA numbers and related titles of studies or foreign reviews are identified in the section on References in the PRVD.

Following the announcement of the re-evaluation of dimethoate (June 29, 1999), the registrant had an opportunity to submit additional, more recent and/or appropriate data to PMRA for review and consideration. However, until recently (2011) the registrant did not provide any additional and/or more recent data that would be relevant to the ecological risk assessment of dimethoate. In lieu of original studies, for the purpose of re-evaluation, PMRA uses reliable published re-evaluation review documents from reliable international regulatory agencies such as the USEPA, the European Union agency EFSA, OECD (FAO) and those in the U.K. and Australia. International reviews, like the USEPA RED, are considered by the PMRA to be an appropriate source of data. The fate and toxicity endpoints used in the RED and IRED documents (from 1998 to 2006) are the same as those presented in the PRVD.

3.1.2 Comment – Good Laboratory Practices

When modeling was conducted, did PMRA conduct a quality screen of the information provided?

PMRA Response

It is PMRA’s standard practice to evaluate the scientific reliability of the studies before they are accepted as valid studies. Only those studies/publications that are deemed to be scientifically valid are considered as part of an environmental assessment.

3.1.3 Comment – K_{ow} value

The K_{ow} value for dimethoate is incorrect in several places in the PRVD. In Table 2.2 of the PRVD (Physical and Chemical Properties of the Technical Grade Active Ingredient), the log K_{ow} is presented as 0.704.

PMRA Response

PMRA agrees that the K_{ow} was incorrectly reported on pages 32 and 42 of the PRVD. The value of log K_{ow} (0.704) was reported correctly in Table 2.2 (page 12 of the PRVD).

3.1.4 Comment – Risk Quotient (RQ)

The registrant found that there was an inconsistency in the rules used for rounding (and use of significant digits) of RQ values.

PMRA Response

The RQs were generally rounded to one decimal point. No decimal point usually indicates that the value was rounded to the nearest point (for example, 2.7 rounded to 3). If the second decimal point was 5, then the number would be rounded up (for example, 3.15 rounded to 3.2). An RQ value of 5.123 would be rounded to 5.0.

3.1.5 Comment – Insect exposure scenarios

In Table 3 of Appendix XI of the PRVD, only the lowest of the exposure scenarios assessed (for example, 205, 1553.4 and 6000 g a.i./ha) was reported for the bee, whereas all three scenarios were shown for earthworms. Since all three application rates (screening level) show no risk to earthworms, only the highest one should be presented. For the parasitic wasp, no application rates or environmental exposure concentrations are given, even though an RQ of 30 was calculated.

PMRA Response

Assessment of the potential risk to bees from exposure at the lowest application rate showed that there was risk, indicating there would be a potential risk to bees at all application rates. Appropriate label statements are included to reduce risk to bees that may be foraging on bee attractive crops. Regarding earthworms, it is agreed that since all application rates at the screening level indicated no risk to earthworms, it would only be necessary to present information for the highest application rate. Table 3, Appendix XI of the PRVD did not display the application rate or the estimated environmental concentration (EEC) as a result of a formatting problem. In the column on Application Rate and EEC, a dividing line was inserted in error between the rows for the bee and the parasitic wasp. The application rate and EEC values for the bee also apply to the parasitic wasp.

3.1.6 Comment – Acute earthworm toxicity

The registrant noted that two acute endpoints were given (84.5 mg/kg and 24.3 mg/kg) for earthworms even though the study was chronic in nature (14 days).

PMRA Response

According to the OECD Guideline Test No. 207 "Earthworm, Acute Toxicity Tests", the test duration is 14 days. Mortality is assessed both at 7 and 14 days, and LC50 toxicity values calculated at both 7 and 14 days, are considered as acute endpoints. In Table 2, Appendix XI (page 132 of the PRVD), there were errors with regard to the earthworm toxicity endpoints. It should indicate that the 7-day LC50 is 533.8 mg a.i./kg soil and the 7-day NOEC is <62.5 mg a.i./kg soil. The risk to earthworms was assessed using the NOEC value of <62.5 mg a.i/kg soil. The corrected portion of the table can be found in Appendix III of this document.

3.1.7 Comment – Incorrect values

In Table 6, Appendix XI of the PRVD, the PMRA has provided incorrect refined RQ values for the following scenarios:

1) For birds (insectivore) of 100g acutely exposed to an application rate of 205 g a.i./ha, and
2) For mammals (insectivore) of 15g exposed to an application rate of 205 g a.i./ha.

PMRA Response

The RQ values provided in Table 6, Appendix IV (1.7 for 100 g birds and 1.25 for 15 g mammal) are from the screening level risk assessment conducted for an application rate of 205 g a.i./ha. A refined risk assessment had been carried out for both species, and the resulting RQ values were less than 1. However, they were omitted in error from Table 6. The corrected table can be found in Appendix III of this document.

3.2 Comment - Direct overspray

The registrant requested the removal of overspray portion of the first tier screening level assessment given that direct overspray of water is not permitted on the dimethoate end-use labels.

PMRA Response

The screening level assessment of the risk to terrestrial and aquatic non-target organisms is conducted as a standard procedure for all pesticides. The screening level assessment is based on exposure from 100% of the application rate. If a risk is not identified, no further assessment is required. If risk is identified at the screening level, it is required that the risk be refined with the use of available methods. When risks are still identified after the refined assessment, appropriate mitigative measures (for example, buffer zones) and advisory label statements are required.

3.2.1 Comment - Spray Drift

The spray drift assessment summarized in Table 6 and 7, Appendix XI of the PRVD assumed fine droplet sizes in estimating spray drift deposition from ground and aerial applications. However, many of the end-use labels for products used in Canada contain a statement to reduce spray drift. The registrant agrees that such language should be included on all labels. Therefore, the registrant requests that PMRA redo their spray drift assessment with the assumption that applicators will use medium spray nozzles when applying dimethoate.

PMRA Response

Unless a droplet size is specifically stated on the label, spray drift assessment is based on a fine droplet size as a standard procedure for all insecticides. If the registrant requires the use of medium droplet sizes for dimethoate products, then this should be specified on all product labels and the PMRA will address the buffer zones accordingly.

3.2.2 Comment - Bees

PMRA found that bees directly contacted with dimethoate spray would be at risk. However, there is language on most labels that would preclude bees coming in contact with dimethoate spray. The registrant agrees that such language should be included on all labels. To provide context on the risks of dimethoate to bees, the registrant requests that PMRA add the label statement regarding bees to the risk characterization and other relevant sections of the PRVD for bees.

PMRA Response

For pollinators, the mitigative measures and precautionary/warning statements resulting from the risk assessment are in Appendix IV of the RVD.

3.3 Physical and Chemical Properties, and Environmental Fate

3.3.1 Comment – Incorrect values

In many cases, the physical, chemical and environmental fate data for dimethoate cited by the PMRA are out of date, incomplete, inconsistent or based on poor studies. The registrant provided PMRA with their recommended values, which they stated have undergone rigorous quality assurance review.

PMRA Response

The physical and chemical properties of dimethoate as provided in a table in Section 2.2 of the PRVD are from a reliable source (The e-Pesticide Manual ver. 3.1; ed. British Crop Protection Council, 2004). The values were the same or close to those submitted by the registrant. The environmental fate data presented by the registrant are identical with the data provided in PMRA's PRVD (Table 1, Appendix XI). The references provided by PMRA (as listed in the Reference section of the PRVD) are also the same as those provided by the registrant.

3.3.2 Comment – Dissipation half-life

PMRA stated in the PRVD that: "For multiple applications the cumulative rates were calculated taking under consideration the dissipation half-life of dimethoate in the terrestrial environment (soil, foliage)." The PMRA does not indicate the rationale for the selection of the dissipation half-life used in the assessment, nor is the equation for calculating cumulative rates presented. No value for foliar half-life is presented in the PRVD. The results of numerous monitoring studies in Europe and the United States conducted on behalf of the registrant are available and are specific to dimethoate.

PMRA Response

As indicated in Sections 4.2.1 and 4.2.2 of the PRVD, for multiple applications, the cumulative rates were calculated taking into consideration the dissipation half-life of dimethoate in the terrestrial and aquatic environments. Information on foliar dissipation (4d) was provided along with a reference in the footnotes of Table 4. Cumulative rates were based on aerobic soil half-life value (see Table 1, Appendix XI) and average foliar half-life (see footnote Table 4, Appendix XI). As indicated in Table 1, soil half-life varied between 2 and 4 days, and a mean of the available four values was taken to calculate the cumulative rate.

3.3.3 Comment – Water modeling

When both aquatic metabolism and hydrolysis rate data are included in the calculation of aquatic half-life, the metabolism rate needs to be corrected for the hydrolysis rate at the pH of the aquatic metabolism study. This is based on the USEPA's latest guidance for the derivation of input parameter for PRZM/EXAMS (*Guidance for Selecting Input Parameters in Modeling the Environmental Fate and Transport of Pesticides*. Version 2.1; October 22, 2009. US Environmental Protection Agency, Office of Pesticide Programs, Environmental Fate and Effects Division. Washington, DC). The result is a biolysis half-life value of 27.9 days that should be used in PRZM/EXAMS. Note that this value is not the aerobic aquatic metabolism value, but is specific to biolysis only.

PMRA Response

While the modeling of dimethoate was done before the identified version of the EPA's guidance for the derivation of input parameters for PRZM/EXAMS was published, it must be noted that the EPA input guidance is not necessarily PMRA procedure. The PMRA typically calculates the water half-life without subtracting out hydrolysis since, for numerous chemicals, we have seen various anomalies between the different study data and, in some cases, we lack this data. Therefore, the PMRA identified an aerobic aquatic metabolism half-life of 17.2 days.

3.4 Screening-Level Assessment

3.4.1 Comment - Bees and Wasps

Toxicity in µg/bee and µg/wasp was converted to kg a.i./ha using a conversion factor of 1.12. This conversion factor is cited as originating in Atkins et al. (1981). This document is a leaflet produced by the University of California over 25 years ago. The document is not specific to dimethoate, and it is unclear whether the conversion factor is a generic one (for example, for all pesticides), or whether it is specific to carbamates.

PMRA Response

For the pollinator risk assessment, the PMRA uses the factor of 1.12 (Atkins et al 1981) to convert honey bee toxicity values from µg a.i./bee to g a.i./ha. This conversion allows comparison of bee toxicity values to estimated exposure values in the same units (g a.i./ha). The factor is used for all pesticides and is not chemical-specific.

3.4.2 Comment - Terrestrial Plants

PMRA did not conduct an assessment on terrestrial plants because these data were not available. The registrant provided PMRA with recent studies.

PMRA Response

The terrestrial plant studies (vegetative vigour and seedling emergence) that were recently submitted were reviewed. The results of the evaluation indicated that the risk to terrestrial plants are negligible (LOC <1). Terrestrial buffer zones are thus not required.

3.4.3 Birds

3.4.3.1 Comment – Acute Toxicity

In terms of the acute oral endpoint used to calculate a risk quotient (0.54 mg a.i./kg bw, which is the LD_{50}/10), it appears that the value was derived from an unreferenced study where an LD_{50} of 5.4 mg a.i./kg bw was established for red-winged blackbird. It is recommended that another study that is scientifically defensible be reviewed for this effect metric. The registrant recommends the GLP-derived LD_{50} (female) of 10.2 mg/kg bw for northern bobwhite quail (Zok, 2001a).

PMRA Response

The acute toxicity endpoint (LD_{50} 5.4 mg a.i./kg bw) for red-winged blackbird is cited in theUSEPA RED (2006), and the study was deemed acceptable. The recently submitted bobwhite quail acute study (PMRA No. 2034208) with an endpoint of LD_{50} of 10.2 mg a.i./kg bw, was not available at the time of the dimethoate review, therefore it was not used in the risk assessment.

3.4.3.2 Comment – Chronic toxicity

PMRA used a chronic reproductive effect endpoint of 0.22 mg a.i./kg bw/day for birds in the ERA. This value was calculated based on one of two chronic toxicity NOECs presented in Table 2, Appendix XI (PRVD) of 4.0 or 35.4 mg a.i./kg diet. PMRA cited reference 1415510, and 1415508 as the source of this information. These were previously identified as EPA Re-registration Eligibility Decision for Dimethoate (RED, EFED Chapter, January 1998, and revised February 1999, respectively). However, the NOAEL derived in Gallagher et al. (1996a) was 10.1 mg/kg diet, not 4.0 mg/kg diet.

PMRA Response

The NOAEC of 4.0 mg/kg diet and LOAEC of 10.1 mg/kg diet for bobwhite quail are reported in the USEPA RED of January 1998 and June 2006. PMRA reviewed the study by Gallagher et al. (PMRA No. 2034201) and noted that there were chronic effects recorded at 10.1 mg/kg diet. The author of the study disregarded the effects, but the rationale provided was not considered valid. The PMRA agreed with the USEPA NOAEC of 4.0 mg/kg in diet, and therefore, no revision of the risk assessment was required.

3.4.4 Mammals

3.4.4.1 Comment – Acute effects

The registrant recommends the use of Kynoch (1986) who derived a LD_{50} equal to 358 mg a.i./kg bw to derive the risk quotient for mammals.

PMRA Response

The PMRA has revised the assessment of the acute risk to mammals based on the LD_{50} value of 358 mg a.i. /kg bw as was used by the USEPA. The refined risk assessment, using current methodology, was conducted for multiple applications of 205 and 1320 g a.i./ha, and a single application of 6000 g a.i./ha. The results indicated that there is negligible acute risk from the cumulative rate of 289.5 g a.i./ha (four applications at 205 g a.i./ha with 7d interval). The risk assessment for the other applications is summarized in the table below.

Application Rate	Mammal size	RQ On-field	RQ Off-field
1553.43 (g a.i./ha) (Two applications of 1320 with 10 d intervals)	Small (0.015 kg)	0.15-0.70	< 0.01
	Medium (0.035 kg)	0.13-2.45	< 0.01
	Large (1 kg)	0.07-1.31	< 0.01
6000 (g a.i./ha)	Small (0.015 kg)	0.60-2.70	0.03-0.16
	Medium (0.035 kg)	0.51-9.48	0.03-0.57
	Large (1 kg)	0.27-2.88	0.91-9.67

3.4.4.2 Comment – Screening-level assessment

In guidance documents, the PMRA stated that for mammalian screening-level assessments, data from oral acute and long-term studies should be used, and dietary endpoints dropped entirely from assessments because they are less relevant than the former two study types. Furthermore, PMRA states that since, "most pesticides have a relatively short foliar half-life, it is thought that mammals will not be exposed for a sufficient period of time to elicit the effect observed in the mammalian dietary studies", which is generally a 28-day exposure period.

PMRA Response

The registrant is citing current risk assessment methodology which was not available at the time the dimethoate PRVD was originally drafted. The inclusion of dietary endpoints does not change the risk assessment outcome.

3.4.4.3 Comment – Chronic Reproductive Toxicity

The registrant agrees with the use of Brooker et al (1992) and endpoint value. However, in the case of the 6000 g a.i./ha application rate scenario, the chronic reproduction effects metrics is presented in the PRVD as 22.9 mg a.i./kg bw/day (Table 4, Appendix XI). PMRA cited secondary references (PMRA numbers1415510 and 1415508) and an internal review as the source of this effect metric. The actual scientific source of the effects metrics is not cited in the PRVD, nor could it be found in the supporting Environmental Assessment.

PMRA Response

The NOEL value of 22.9 mg a.i./kg bw/day is a typographical error and the correct value is actually 1.2 mg a.i./kg bw/day as was used in the other application rate scenarios.

3.5 Refined Environmental Risk Assessment (ERA)

The development of the PMRA ERA methodology/procedure is an ongoing process. The registrant makes reference to the current methodology that was updated in 2009. This was not available in 2008 when the ERA for dimethoate was finalized. At that time refinement of risk was based on exposure from spray drift. The current methodology is different as it includes additional considerations. Thus, comments based on current methodology may not be relevant since they do not reflect the methodology used at the time of the risk assessment.

3.5.1 Comment - Terrestrial Invertebrates

The PMRA states that a refined risk assessment will be carried out in cases where the RQ is greater than, or equal to 1 (the LOC) in the screening-level risk assessment. The RQs of 4 and 1.1 for honey bee acute oral and acute contact exposures, respectively, are presented in the PRVD. No data or calculations are provided in either PMRA document (PRVD or Environmental Assessment) to show that a refined assessment was carried out for bees and terrestrial invertebrates.

PMRA Response

A refined risk assessment for bees is conducted using higher tier studies such as semi-field and field effects studies using bee colonies, consideration of incident reports and any available public literature. Based on all available information for dimethoate, including incident report information, the risk assessment concluded that exposure to dimethoate has the potential to pose a risk to pollinators. Therefore, to mitigate this risk, additional application restrictions to minimize dimethoate exposure to pollinators have been implemented. The required label statements are presented in Appendix IV of the RVD.

3.5.2 Comment - Birds and Mammals

For the refined assessment for birds and mammals, the PMRA should make clear how they are refining the assessment of risk.

PMRA Response

Information provided in the PRVD table titled (Table 6, Appendix XI) explained that the refined risk was based on estimates of exposure to spray drift (off field) of 11 and 26% for ground and aerial application, respectively.

3.5.3 Comment – Droplet size

For the spray drift assessment, the assumption of fine droplet size is erroneous as labels indicate avoiding combinations of pressure and nozzle type that will result in fine particles. The registrant recommends the use of medium droplet sizes.

PMRA Response

Unless a droplet size is specifically stated on the label, spray drift assessment is based on a fine droplet size as a standard procedure for all insecticides. If the registrant requires the use of medium droplet sizes for the dimethoate products, then this may be done through the appropriate label amendment submission, and the PMRA will address the buffer zones accordingly.

3.6 Aquatic Organisms

3.6.1 Reporting error

3.6.1.1 Comment - Superscript

At the bottom of Table 5, Appendix XI (Screening Level Assessment of Dimethoate to Aquatic Organisms) of the PRVD, the superscript 3 indicating a cumulative rate (2 applications of 1320 g a.i./ha with the interval of 10 d) does not correspond to a superscript 3 in the table itself. It is not clear as to where this cumulative rate has been applied.

PMRA Response

The superscript 3 refers to the cumulative rate of 1553.4 g a.i. /ha. Due to a formatting error in Table 5, Appendix XI of the PRVD, the Use Rate for acute exposure of *Daphnia magna* was reported as 1553.43 g a.i./ha rather than 1553.4^3 g a.i./ha. Please see Appendix III of this document for the revised Table 5.

3.6.1.2 Comment – Missing data

The PMRA is missing toxicity data on freshwater vascular plants and algae.

PMRA Response

The freshwater vascular plants and algae toxicity studies that were submitted to PMRA have been reviewed. The results indicated that aquatic vascular plants and algae were not as sensitive as aquatic invertebrates and hence aquatic buffer zones do not need to be revised.

3.6.1.3 Comment – EC_{50} vs LC_{50}

Endpoints change between Table 2 and 5, Appendix XI of the PRVD. For example, in Table 2 the toxicity endpoint for *Daphnia magna* is a 48-h EC_{50} while in Table 5 it is given as an LC_{50}.

PMRA Response

For *Daphnia* magna, the LC_{50} should be an EC_{50}, please see Appendix III of this document for the corrected table.

3.6.1.4 Comment – Amphibian assessment

There is no explanation in the PRVD text as to which fish species was used as the surrogate for amphibians, nor why that particular surrogate was used.

Response

The LC_{50} value for bluegill sunfish was chosen as the surrogate for amphibian risk assessment. It was selected because it is standard practice to use fish species as surrogates for amphibians when amphibian data is not available. The bluegill sunfish was the most sensitive fish species.

3.6.2 Water modeling

3.6.2.1 Comment – Upper and lower bounds

The registrant believes that PRZM/EXAMS is highly conservative and results in unrealistic estimates of pesticide exposures for the aquatic risk assessment. In the models, the field is assumed to be directly adjacent to the farm pond. There is generally a buffer between the field and the farm pond that would reduce the concentration of pesticide in the runoff and reduce the amount of spray drift that would fall into the farm pond. The registrant provided an example of a dimethoate label statement recommending vegetative buffer strips.

Moreover, the USDA has provided a thorough summary of the impact of buffer strips on reducing runoff levels (USDA, 2000). Although results are variable across the different studies that were reviewed, the percent of pesticide trapped in buffer strips ranges from 10-100% for pesticides with relatively small K_{oc} values such as is the case with dimethoate (plot strips from 4.5 - 30m wide).

PMRA Response

While the PMRA acknowledges there is often vegetation between a pond and a cropped field, this is not always the case and the efficiency of trapping pesticides varies considerably and does not necessarily account for channeling that can occur during heavy rainfall events.

PMRA modeling attempts to simulate the required conditions of use as they appear on the pesticide label. Although the use of filter strips is recommended, and a statement (quoted below) does appear on Canadian labels, the use of filter strips is not a requirement. As such, PMRA currently does not use modeling to simulate a filter strip adjacent to the wetland. While there are models available, they have not been sufficiently validated for regulatory use.

The label statement quoted by the registrant does not appear on Canadian labels; however, the following best management practice statement appears on Canadian labels:

> *"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."*

3.6.2.2 Comment – Incorporation of water flow

The PRZM/EXAMS farm pond is assumed to be static, meaning there are no inflows or outflows of water that would remove or dilute pesticide concentrations. PMRA has suggested that: *"The PMRA models the ecological water body without an outflow because there are bodies of water such as prairie potholes which do not have an outflow"*. The PMRA farm pond does not accurately represent a prairie pothole scenario. Prairie potholes are known to be hydrologically dynamic and may recharge groundwater, receive water through groundwater discharge, or are flow-through systems (USGS, 2006).

Therefore, dilution or dissipation of pesticide concentrations in prairie potholes is likely to occur. Other aquatic systems near agricultural areas typically have inflows and outflows including streams, creeks, oceans, etc. that quickly dissipates pesticide concentrations.

Using the AgDrift Stream Assessment Tool, it has been found that pesticide concentrations quickly dissipate in a slow moving stream. Therefore, the registrant feels that it is inappropriate to use PRZM/EXAMS for water systems that have flow. Moreover, it is inappropriate to use PRZM/EXAMS to derive buffer zones for such flowable water systems. PMRA's buffer zones are overly conservative and should not be used nation-wide for all water bodies.

PMRA Response

Hydrological conditions typical of prairie potholes in the United States are not necessarily representative of Canadian scenarios, as hydrological conditions are distinct. Static systems are known to exist in dryer areas of the Canadian prairies. These potholes have the potential to have higher pesticide concentrations than systems that are dynamic, as the registrant has demonstrated. In the interest of protecting the most sensitive water bodies, PRZM/EXAMS modeling were done using a static system.

3.6.2.3 Comment – Representative bodies of water

Farm ponds or prairie potholes only represent one type of water body that supports aquatic life, and are likely to have a less diverse biota than other more common aquatic water bodies, such as natural ponds, lakes, and streams, due to little or no transfer of mass with other water bodies. Prairie potholes in particular are known to have aquatic invertebrate communities that consist of relatively few generalist taxa and that are well suited to the harsh and dynamic conditions experienced in the prairie pothole environment (USGS, 2011). PMRA has suggested that *"The PMRA models a small wetland such as a prairie pothole, not a farm pond. The drainage area was determined from prairie data on water body size, depth and drainage areas"*. We request that PMRA provide these data so a comprehensive review can be conducted.

PMRA Response

The PRZM/EXAMS models are used to simulate runoff to small permanent and seasonal water bodies following pesticide applications. Both the volume (depth and area) and the drainage basin area are critical factors in the outcome of the simulation. The PMRA uses a prairie wetland scenario for aquatic life risk assessment. The scenario is based on a 1 ha permanent wetland with a volume of 7665 m^3, with a catchment area of 4.63 ha (5.63 ha with the inclusion of the wetland). These values for wetland area and catchment size were chosen through analysis of available data from Ducks Unlimited and communication with experts from Environment Canada, other government departments and academic institutions.

3.6.2.4 Comment – 90th percentile of yearly peak EECs

The registrant believed that PMRA's description of 1-in-10 year EECs as "90th percentiles" was misleading. Before estimating a "90th percentile", PMRA determined the highest peak pesticide concentration (or longer-term concentrations for non-acute exposures) for each day of each year in a 50-year period. PMRA then calculated the 90th percentile of these 50 highest peak concentrations. On a daily basis, this estimate would actually be a 99.97th percentile – it is the concentration estimate that is essentially never exceeded over a 50-year period.

PMRA Response

The PMRA clearly identifies that the acute values are the 90th percentile of the yearly peak EECs generated by the model run. It is not intended to be a representation of the 90th percentile of the daily peaks over a 50-year period.

3.6.2.5 Comment – Model variables

Variables used in probabilistic exposures are generally conservative.

The co-existence in nature of the assumptions used for these variables is highly unlikely. The compounding effect of these multiple, conservative assumptions lead to unrealistic environmental conditions, and as a result implausible, high exposure estimates are derived.

Concentrations of dimethoate in water bodies near treated fields are likely to be substantially lower than those estimated by PMRA, as observed in the surface water monitoring studies.

PMRA Response

The PMRA, like many other regulatory agencies, uses a tiered approach from simple conservative screening through to a more refined assessment. Refinements could include less conservative model input parameters and more complex modeling, which may include probabilistic methods. For dimethoate, a refined exposure assessment was not required as the available monitoring data was of sufficient quality and used for the exposure assessment.

3.6.3 Comment - Water Monitoring

The registrant supports PMRA's use of surface water monitoring data in the risk characterization section. However, it appears that much of the decision making regarding proposed mitigation measures (for example, vegetative buffer strips of varying width) relied on modeling data, even though the monitoring data indicated minimal risk for aquatic biota.

Although monitoring data have shortcomings, they also have a number of strengths. We believe that PMRA overstated the shortcomings of monitoring data.

Peak exposures are considered to be critical because the mode of action of dimethoate, acetylcholinesterase inhibition, occurs rapidly after initial exposure. However, the toxicity data to which exposure concentrations were compared in PMRA's risk characterization were based

upon exposures of 48 hours (for most aquatic invertebrate species) to 96 hours (for most fish species). The effects metrics for dimethoate and other organophosphate pesticides are strongly inversely correlated with exposure duration (for example, as duration increases, LC50s and EC50s decrease) (Gupta, 1984; Johnson and Finley, 1980; Parra et al., 2005). In most flowing waters, concentrations of dimethoate will decline rapidly after the initial peaks arising from runoff and/or spray drift, often by orders of magnitude within a few hours. Temporally-averaged 48-hour and 96-hour concentrations in most surface waters will be far lower than peak instantaneous concentrations. Thus, it is scientifically invalid to compare peak instantaneous (for example, from PRZM-EXAMS) concentrations with 48-hour to 96-hour effects metrics.

- The above argues that the absence of peak instantaneous concentrations in the monitoring datasets is irrelevant. Even so, it is hard to accept the argument that peak exposure concentrations have been missed by all of the monitoring studies conducted to date in Canada and the United States. In this report, more than 7,000 Canadian water sample results were examined, with the vast majority of the data coming from monitoring or surveillance programs, or individual studies, that specifically target pesticide concentrations in surface waters during peak application times (for example, during the growing season). Similarly, data from Washington State, the USGS NAWQA program, and numerous California databases were reviewed, and more than 20,000 records were examined, also from programs specifically targeting pesticide use during growing seasons for multiple years. Many of the monitoring studies cited by PMRA in Appendix 1 of the Environmental Assessment document indicate that sampling was also conducted during times of peak pesticide application (for example, May to October) in areas of intense agriculture (for example, PEI potato-growing areas, Yamaska River in Quebec, lower Fraser River and Okanagan Basin in BC), in water bodies expected to have elevated pesticide concentrations (for example, ditches on the edge of treated fields), and during times when runoff would be highest (for example, following rainfall events) (for example, Savard et al.,1999; Wan et al., 1994). Similarly, the Washington State monitoring program (WSDE, 2011) was designed to characterize pesticide concentrations occurring during peak application times in areas of intense agricultural production. This program was intended to characterize exposures to sensitive populations of juvenile salmonids that could potentially frequent the monitored surface water (WSDE, 2011). Given the above, it is unlikely that all of the monitoring programs did not at some point detect peak concentrations of dimethoate in the monitored waterbodies.

PMRA Response

There is a distinction to be made between “vegetative strips” and “no-spray buffer zones”. Vegetative strips are not mandatory, but rather are indicated on Canadian pesticide labels as best management practices for mitigating potential effects from runoff. The PMRA does not use modeling or monitoring data to assess the need for vegetative strips. The standard label statement for vegetative strips reads as follows:

> “*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.”*

No-spray buffer zones are set to mitigate the risk from spray drift (not runoff) and are a legal requirement. No-spray buffer zones for ground applications are determined using models based on empirical data. For aerial applications, buffer zones are determined using the AGDISP model. From this, no-spray buffer zones of varying widths are set and listed on the product label. No-spray buffer zones are only required when the sensitive habitat is downwind from the spray and are not required if the wind is blowing away from sensitive habitat.

For dimethoate, a risk was identified for aquatic invertebrates, which triggered a requirement for no-spray buffer zones.

In addition to the potential risk from spray drift, the risk from run-off was assessed using the available monitoring data as it was deemed to be robust enough for that purpose. The resulting assessment using the monitoring data indicated negligible risk to aquatic organisms.

4.0 Comments Relating to Value

4.1 Comment - Douglas-fir seed cone use

Comments were received from stakeholders concerning the value of dimethoate to control cone and seed insects in Douglas-fir seed orchards. Presently, dimethoate is the only insecticide registered for use in Douglas-fir seed orchards. In the absence of this systemic insecticide, crop losses would be significant and the probability of a total loss of crop would be very high. Dimethoate controls many insect pests which directly damage the seeds. Comments on the application rates used in PRVD2011-12 noted that all calculations of the Margins of Exposure (MOE) were based on the maximum label rate of 24 kg a.i./ha for Douglas fir. Records indicate that the maximum rate applied operationally is 9.6 kg a.i. /ha, which is 40% of the rate used in the PRVD. Also, stakeholders asked why there was such a large difference between the assessed levels of risk to applicators and postapplication workers in seed cone orchards compared to other tree row crops. Stakeholders also stated that two of the four postapplication worker activities (pruning and thinning) assessed by the PMRA are never undertaken in Douglas-fir seed orchards during any portion of the season when cones are growing on the trees and when dimethoate treatments are applied. In addition, it was stated that workers come in direct contact with dimethoate-treated foliage or cones in Douglas-fir seed orchards only during cone harvesting.

PMRA Response

In the PRVD, PMRA acknowledged that based on Canadian pesticide labels, dimethoate is the only insecticide currently registered in Canada to control seed and cone pests of Douglas-fir, Sitka spruce and woodland spruce (for example, other spruce species). In response to why there was such a large difference between the levels of risk to applicators and postapplication workers in seed cone orchards compared to other tree row crops, this is largely attributable to differences in application rate. The MOE for Douglas fir was based on a rate of 24 kg a.i./ha compared with the much smaller maximum cumulative application rate for other tree row crops of 4.32 kg a.i./ha.

In the PRVD, the PMRA encouraged provision of feedback on the feasibility of proposed mitigation measures, the value of dimethoate for those uses where risk concerns were identified, and alternative control methods. Furthermore, the PMRA acknowledged that to refine the assumptions used in the occupational risk assessment, additional data and use information could be submitted. Additional information was submitted in response to PRVD2011-12; the PMRA has also subsequently consulted with stakeholders across Canada to better understand what worker activities are done, the feasibility of application rate reductions, and to obtain additional production information in Douglas fir, Sitka spruce and woodland spruce seed orchards. Responses were received from British Columbia (for Douglas fir and Sitka spruce) and from Quebec (for white spruce, larch and white pine, as Douglas fir and Sitka spruce are not native to Quebec). These responses were used to refine the occupational risk assessment; for example, it was based on new application rates of 9.6 kg a.i./ha for Douglas fir and 10.0 kg a.i./ha for Sitka spruce, but remained at 10.0 kg a.i./ha for woodland spruce species as only one response was received. This resulted in a reduction, compared with PRVD2011-12, in the duration of some REIs for seed cone harvesting and other activities.

The PMRA agrees that the worker activities, pruning and thinning, do not occur in Douglas fir orchards during the portion of the season that cones are growing and dimethoate could be applied. With respect to industry's view that workers come in direct contact with dimethoate-treated foliage only during cone harvesting, the PMRA is of the view that some contact would occur during scouting.

4.2 Comment - Harmonization of use patterns for conifers

The registrant has proposed a revision to the rates used on conifers so as to match those in the United States. For example, the registrant supports use rates of 4.15 lb a.i./acre (= 4.65 kg a.i./ha) for Douglas -fir seed trees, based on current application rates in Oregon and Washington state, and 1.0 lb a.i./acre (= 1.12 kg a.i./ha) for all other woody ornamentals, including conifer trees.

PMRA Response

The PMRA has reviewed the data submitted by the registrant for rates of 2.5, 5.0, and 10.0 kg a.i./1000 L water on Douglas fir and 10.0 kg a.i./1000 L water on Sitka spruce. No data were submitted to support the proposed rate of 1.12 kg a.i./ha for other woody ornamentals, including conifer trees. Efficacy on Douglas fir was not demonstrated at the low rate of 2.5 kg a.i/1000 L; the rates of 5.0, and 10.0 kg a.i./1000 L showed no statistically significant difference in efficacy but, in some cases, there was a reduction in control at the lower rate.

The PMRA consulted with the United States Environmental Protection Agency (USEPA) and determined that no efficacy data had been submitted to them in support of the reduced rates of 4.15 lb a.i./acre (= 4.65 kg a.i./ha) for Douglas fir seed trees, and 1.0 lb a.i./acre (= 1.12 kg a.i./ha) for all other woody ornamentals including conifer trees, in their *Revised Interim Reregistration Eligibility Decisions for Dimethoate* document from July 2006. Based on the review of data submitted by the registrant to the PMRA, and consultation with the Canadian seed cone industry, the PMRA decided to base the revised risk assessment on the industry-supported rates of 9.6 kg a.i./ha for Douglas fir and 10.0 kg a.i./ha for Sitka spruce, and to retain the rate of 10.0 kg a.i./ha for other spruce species. If the registrant still wishes to register lower rates of application to conifers, additional efficacy data or use history information can be provided in a new submission for the PMRA to review.

4.3 Comment - Spray volume

The registrant believes that the assumed maximum spray volumes of 3000 L/ha for fruit trees and 1000 L/ha for other crops are lower in practice.

PMRA Response

The PMRA uses the above maximum rates of water per hectare as standard assumptions since consideration needs to be given to application to larger orchard crops, and denser field and greenhouse crops, so as to ensure good coverage.

Appendix II Revised Occupational Risk Assessment for Douglas fir (Seed Tree), Sitka Spruce (Seed Tree), Spruce (Seed Tree and woodland), and Right-of-Way Sprayers

In response to the Proposed Re-evaluation Decision Document (PRVD 2011-12), a number of stakeholders have indicated a critical need for dimethoate in Douglas fir, Sitka spruce, and spruce. In order to refine the occupational and postapplication exposure assessment, the PMRA conducted a survey of stakeholders to gather additional use information. Based on the survey, the PMRA has reduced the application rate of dimethoate to Douglas fir, and Sitka spruce from 24 kg a.i./ha and 12 kg a.i./ha, respectively, to 9.6 kg a.i./ha, and 10 kg a.i./ha, respectively. The area treated per day value in the occupational risk assessment was also revised from 16 ha to 6 ha, based on this survey. The value of 6 ha is the average size of a Douglas fir orchard calculated from the maximum reported orchard sizes. As this value was similar to the median reported value of spruce orchards of 6.2 ha, and is higher than the maximum reported orchard size for Sitka spruce, a value of 6 ha was deemed representative of Douglas fir, Sitka spruce, and spruce orchards. Furthermore, the postapplication assessment was revised focusing on the main postapplication activities in these orchards of seed cone harvesting and scouting, and the scouting assessment was revised assuming that scouting activities take place for 2 hours per day.

The mixer/loader/applicator assessment for right-of-way sprayers was also revised in response to comments received from the registrant. The area treated per day value for right-of-way sprayers was reduced from 75 ha to 5 ha based on USEPA assessments for right-of-way sprayers (dimethoate and fosamine), which is believed to be representative of Canadian use.

Occupational Exposure Risk Estimates

The occupational exposure risk estimates are summarized in Table 1. The combined route MOEs are greater than 100 when using a combination of PPE and engineering controls, except for mixing, loading and applying liquids by mechanically-pressurized handguns (high-pressure handwands) to Douglas fir, Sitka spruce, and spruce. Since the MOEs ranged from 7-8 and were significantly below the target MOE, the application of dimethoate by mechanically-pressurized handguns to Douglas fir, Sitka spruce, and spruce will be prohibited. All risk mitigation measures are outlined below:

For Douglas fir, Sitka spruce and spruce:

- During mixing, loading, clean-up and repair, wear chemical resistant coveralls over long pants and a long-sleeved shirt, chemical resistant footwear plus socks, chemical resistant gloves, goggles or a face shield and suitable respiratory protection. “Suitable respiratory protection is defined as either a respirator with a NIOSH approved organic-vapour-removing cartridge with a prefilter approved for pesticides, or a NIOSH approved canister approved for pesticides.”

- During airblast application, use a closed cab that provides both a physical barrier, and respiratory protection (for example dust/mist filtering and/or vapour/gas purification system). The closed cab must have a chemical resistant barrier that totally surrounds the occupant, and prevents contact with pesticides outside the cab. Wear coveralls over long pants and a long-sleeved shirt, chemical resistant footwear, plus socks.
- During manually-pressurized handwand, or backpack application, wear chemical resistant coveralls over long pants, and a long-sleeved shirt, chemical resistant footwear, plus socks, chemical resistant gloves, and suitable respiratory protection. Suitable respiratory protection is defined as 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.
- DO NOT apply using mechanically-pressurized handgun equipment. Only for use with manually-pressurized handwands or backpack sprayers.

For Right-of-Way Sprayer Application to Forage Crops (Grasses, Hay, Clover), Grains, Pastures, Wastelands uses:

- During mixing, loading, application, clean-up and repair, wear chemical resistant coveralls over long pants and a long-sleeved shirt; chemical resistant footwear plus socks; chemical-resistant gloves; goggles or a face shield.

Table 1 M/L/A Exposure Estimates and MOEs

Crop	Method of Application	Rate[B] (kg a.i./ha) or (kg a.i./L)	Area Treated per Day[C]	Daily Exposure (µg/kg bw/day)		Margin of Exposure (MOE)		
				Dermal[D]	Inhalation[E]	Dermal[F]	Inhalation[G]	Combined[H]
Maximum PPE (open mixing and loading, chemical resistant coveralls over a single layer with chemical resistant gloves) and a Respirator (except during closed cab application)[A]								
Douglas fir (seed tree)	Airblast- Open Cab	9.6 kg a.i./ha	6 ha	413.01	6.09×10^{-1}	**46**	164	**36**
	Airblast – Closed Cab			55.76	6.09×10^{-1}	341	164	111
	Mechanically-Pressurized Handwand	9.6×10^{-3} kg a.i./L	3800 L	952.20	7.87	**20**	**13**	**8**
	Manually-Pressurized Handwand		150 L	14.27	9.30×10^{-2}	1332	1075	595
	Backpack sprayer			41.71	1.28×10^{-1}	456	783	288
Sitka spruce (seed tree), spruce (seed tree)	Airblast- Open Cab	10 kg a.i./ha	6 ha	430.22	6.34×10^{-1}	**44**	158	**34**
	Airblast – Closed Cab			58.08	6.34×10^{-1}	327	158	106
	Mechanically-Pressurized Handwand	1.0×10^{-2} kg a.i./L	3800 L	991.87	8.20	**19**	**12**	**7**
	Manually-Pressurized Handwand		150 L	14.86	9.69×10^{-2}	1278	1032	571
	Backpack sprayer			43.44	1.33×10^{-1}	437	751	276
Maximum PPE (open mixing and loading, chemical resistant coveralls over a single layer with chemical resistant gloves)								
Forage crops (grasses, hay, clover), grains, pastures and wastelands (also USC 16)	Right-of-Way Sprayer	0.48 kg a.i./ha	5 ha	16.57	2.26×10^{-1}	1146	442	319

[A] Mixer/Loader; all products are liquid formulations, includes solutions and emulsifiable concentrates.
[B] Maximum revised label rate in kilograms of active ingredient per hectare (kg a.i./ha) or kilograms of active ingredient per litre (kg a.i./L).
[C] Based mainly on information obtained from the PMRA stakeholder survey (PMRA, 2012) and standard defaults.
[D] Where dermal exposure µg/kg/day = (unit exposure x area treated x rate)/70 kg bw, includes protection factors for additional PPE.
[E] Where inhalation exposure µg/kg/day = (unit exposure x area treated x rate)/70 kg bw; includes protection factors for respirator.

[F] Based on a dermal $BMDL_{10}$ of 19 mg/kg bw/day. Target dermal MOE of 100.
[G] Based on an inhalation $BMDL_{10}$ of 0.1 mg/kg bw/day. Target inhalation MOE of 100.
[H] Calculated using the following equation: Combined MOE = 1/[1/dermal MOE + 1/inhalation MOE]. Shaded cells indicate calculated MOEs fail to meet the target MOE of 100.

Postapplication Worker Exposure and Risk Assessment

The postapplication exposure assessment for Douglas fir, Sitka spruce, and spruce crops was reassessed based on information obtained from the survey of stakeholders, activities reported in the USEPA *Science Advisory Council for Exposure (ExpoSAC) Policy 3* (revised March, 2012), and updated Agricultural Re-entry Task Force (PMRA No. 2115788) activity specific transfer coefficients. Postapplication exposure following right-of-way application to forage crops (grasses, hay, clover), grains, pastures, and wastelands is expected to be minimal.

According to the USEPA revised Policy 3, the key activities that take place in forestry are harvesting of seed cones, hand pruning, and scouting. This is consistent with the information obtained from the survey of stakeholders conducted by PMRA. In addition, the transfer coefficient for hand harvesting of seed cones is based on the orchard harvesting transfer coefficient. Therefore, the postapplication assessment was revised by removing thinning activities, and using the orchard harvesting transfer coefficient of 1500 cm^2/hr to represent harvesting seed cones (PMRA No. 2115788).

The information provided from stakeholders indicates that scouting activities take place approximately once a week for a period of 5 minutes to 2 hours. Thus, the postapplication assessment was revised assuming that scouting takes place for a period of 2 hours per day as opposed to 8 hours per day.

- Based on the information obtained from stakeholders, the following activities were assessed for Douglas fir, Sitka spruce, and spruce (seed tree and woodland): Douglas fir: Seed cone harvesting, scouting, grading, animal control, and baiting.
-
- Sitka spruce, spruce: Seed cone harvesting, scouting, pruning, staking, tying, grading, animal control, and baiting

Dislodgeable foliar residue values were based on data from a chemical specific DFR study conducted with apples (see Section 3.2.2.2 in PRVD 2011-12). When calculating risk, to account for the increased toxicity of omethoate, a toxicity adjustment factor (TAF) was used to convert exposures of omethoate into equivalent exposures of dimethoate. A TAF of 12 was applied to omethoate residues to calculate total dimethoate residue equivalents. The following equation was used to calculate total DFR:

Total Dislodgeable Foliar Residue (DFR) = Dimethoate DFR + 12x Omethoate DFR

Risk is mitigated by establishing an REI for specific tasks. An REI is the duration of time which must elapse before residues decline to a level, where entry into a treated area to perform a specific activity will result in a margin of exposure (MOE) above the target MOE. The postapplication exposure and risk assessments are summarized in Table 2. REIs were calculated based on the revised application rates from Douglas fir, Sitka spruce, and spruce, and 2 applications with the interval of 10 days used in the DFR study. The REIs range from 12 hrs to 27 days for most activities, except for seed cone harvesting for which the REI is 48 days for Douglas fir, and 49 days for Sitka spruce and spruce.

Even though a REI of 48 days for seed cone harvesting in Douglas fir is long, users of dimethoate have indicated that it is feasible. Thus, the recommended REIs are considered to be agronomically feasible.

Table 2 Occupational Postapplication Exposure Estimates, MOEs and REIs

Crop	Rate[A] (kg a.i./ha)	Applications		Activity	Transfer Coefficient[D] (cm^2/hr)	DFR[E] (µg/cm^2)	Dermal Exposure[F] (mg/kg bw/day)	MOE[G]	REI[H] (days)
		Number[B]	Interval[C] (days)						
Douglas fir (seed tree)	9.6	2	10	Seed cone harvesting	1500	17.8	3.05	6	48
				Scouting	500		0.254	75	5
				Hand weeding, grading, animal control, baiting	100		0.203	93	1
Sitka spruce (seed tree), spruce (seed tree)	10	2	10	Seed cone harvesting	1500	18.5	3.18	6	49
				Scouting	500		0.265	72	5
				Hand pruning, staking, tying	500		1.06	18	27
				Grading, animal control, baiting	100		0.212	90	2

[A] Revised application rates expressed in kilograms of active ingredient per hectare.
[B] Douglas fir, Sitka spruce, and spruce were assessed using a maximum of 2 applications per year as per the chemical-specific surrogate DFR data.
[C] A ten-day interval was applied to Douglas fir, Sitka spruce, and spruce based on the available DFR data.
[D] Transfer coefficients (TC) are from the USEPA *Science Advisory Council for Exposure (ExpoSAC) Policy 3 (*Revised March, 2012) and PMRA specific transfer coefficients (PMRA, 2008b).
[E] Dislodgeable foliar residue (DFR) is based on surrogate DFR data on day 0 scaled for Douglas fir, Sitka spruce and spruce application rates assuming a linear relationship.
[F] At Day 0, Dermal Exposure (mg/kg bw/day) = (DFR x TC x 8 hr (except for scouting where it is assumed that 2 hours are spent scouting per day))/(1000 µg/mg * Body Weight (70 kg))
[G] At Day 0, based on the short and intermediate term dermal $BMDL_{10}$ of 19 mg/kg bw/day.
[H] Day at which the dermal exposure results in a MOE ≥ 100.

Health Risk Mitigation

Number of Applications:

Due to the limited number of DFR studies available, Douglas fir and Sitka spruce were assessed according to the number of applications and application intervals described in the apple DFR study. It is therefore necessary to change the labels accordingly, using the following label statement for Douglas fir and Sitka spruce.

"Limit the number of applications to a maximum of 2 per year with a minimum 10-day interval between applications."

Engineering Controls and Personal Protective Equipment:

Statements must be added (or amended) to include the following directions to the appropriate labels in order to mitigate the risk of exposure to dimethoate.

For Douglas fir, Sitka spruce, and spruce:

- During mixing, loading, clean-up and repair, wear chemical resistant coveralls over long pants and a long-sleeved shirt, chemical resistant footwear plus socks, chemical resistant gloves, goggles or a face shield and suitable respiratory protection. Suitable respiratory protection is defined as 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 airblast application, use a closed cab that provides both a physical barrier and respiratory protection (for example, dust/mist filtering and/or vapour/gas purification system). The closed cab must have a chemical resistant barrier that totally surrounds the occupant and prevents contact with pesticides outside the cab. Wear coveralls over long pants and a long-sleeved shirt, chemical resistant footwear plus socks.
- During manually-pressurized handwand or backpack application, wear chemical resistant coveralls over long pants and a long-sleeved shirt, chemical resistant footwear plus socks, chemical resistant gloves and suitable respiratory protection.
- DO NOT apply using mechanically-pressurized handgun equipment. Only for use with manually-pressurized handwands or backpack sprayers.

For Right-of-Way Sprayer Application to Forage Crops (Grasses, Hay, Clover), Grains, Pastures, Wastelands uses:

- During mixing, loading, application, clean-up and repair, wear chemical resistant coveralls over long pants and a long-sleeved shirt; chemical resistant footwear plus socks; chemical-resistant gloves; goggles or a face shield.

Restricted-Entry Intervals

The REIs listed in Table 3 should be added to the appropriate labels.

Table 3 Restricted-Entry Intervals

Crop	Activity	REI (days)
Douglas fir (seed tree)	Seed cone harvesting	48
	Scouting	5
	Grading, animal control, baiting	1
Sitka spruce (seed tree), spruce (seed tree and woodland)	Seed cone harvesting	49
	Scouting	5
	Hand pruning, staking, tying	27
	Grading, animal control, baiting	2

Appendix III Environmental Fate and Toxicity

Below are corrected sections of some Environmental Fate and Toxicity assessment tables (Tables 2, 3 and 5) previously presented in the Proposed Re-evaluation Decision document (PRVD2011-12 *Dimethoate*). Items in **bold text** are the corrections.

Table 2 Environmental toxicity of Dimethoate

Organism	Study type	Species	Test material	Endpoint	Value	Reference
Terrestrial Species						
Invertebrate	Acute oral	Honeybee	Dimethoate Technical	48-h LD_{50}	0.05 µg a.i./bee	PMRA 1415508 PMRA 1415510
	Acute contact	Earthworm	Dimethoate Technical	**7**-d LC_{50} NOEC	**533.8** mg a.i./kg soil **<62.5** mg a.i./kg soil	PMRA 1191022
		Honeybee	Dimethoate Technical	48-h LD50	0.16 µg a.i./bee	PMRA 1415508 PMRA 1415510
		Parasitic wasp	Dimethoate (ECformulation)	LD_{50}	0.006 µg/animal	
		Ladybird beetle			1.6 µg/animal	

Text and numbers in **bold** have been corrected from the tables originally printed in the PRVD.

Table 3 Screening Level Risk Assessment for Terrestrial Organisms Other than Birds and Mammals

Organism	Exposure	Endpoint value	Applic. Rate	EEC [1]	RQ[3]	LOC[4] exceeded
Invertebrates						
Earthworm	Acute Oral	NOEC: 62.5 mg a.i./kg soil	205 g a.i./ha	0.09 mg a.i./kg soil	< 0.1	No
			1553.4 g a.i./ha	0.69 mg a.i./kg soil	<0.1	No
			6000 g a.i./ha	2.7 mg a.i./kg soil	0.1	No
Bee	Acute Oral	LD_{50} 0.05 µg a.i./bee (0.056 kg a.i./ha[2])	205 g a.i./ha	205 g a.i./ha	4	Yes
	Acute Contact	LD_{50} 0.16 µg a.i./bee (0.18 kg a.i./ha[2])			1.1	Yes
Parasitic wasp	Acute Contact	LD_{50} 0.006 µg a.i./animal (0.0067 kg a.i./ha[2])			30	Yes

1 Environmental Exposure Concentration (Soil: calculated based on a soil density of 1.5 g/cm^3, soil depth of 15 cm and the label rates taking into consideration dissipation between applications; Bee: maximum individual application rate; Parasitic wasp and vascular plants: maximum application rate not taking into consideration dissipation between applications)

2 Toxicity in µg/bee converted to the equivalent kg a.i./ha using a conversion factor of 1.12 (Atkins et al., 1981)

3 Risk Quotient (RQ) = exposure/toxicity

4 Level of Concern (LOC) = RQ = 1; a calculated RQ > 1 exceeds the LOC

Atkins EL; Kellum D; Atkins KW. 1981. Reducing pesticide hazards to honey bees: mortality prediction techniques and integrated management techniques. Univ Calif, Div Agric Sci, Leaflet 2883. 22 pp.

Table 5 Screening Level Risk Assessment of Dimethoate to Aquatic Organisms

Organism	Exposure	Endpoint value[1] (mg a.i./L)	Use Rate (g a.i./ha)	EEC[2] (mg a.i./L)	RQ	LOC exceeded
Freshwater Species						
D. magna	Acute	**EC_{50}** = 1.66	205	0.025	<0.1	No
			1553.4[3]	0.27	0.2	No
			6000	0.75	0.45	No
Stonefly		LC_{50} = 0.0215	205	0.025	1.2	Yes
			1553.4	0.27	12.5	Yes
			6000	0.75	35	Yes
Scud		LC_{50} = 0.1	205	0.025	0.25	No
			1553.4	0.27	2.7	Yes
			6000	0.75	7.5	Yes

Organism	Exposure	Endpoint value[1] (mg a.i./L)	Use Rate (g a.i./ha)	EEC[2] (mg a.i./L)	RQ	LOC exceeded
Yellow fever mosquito		LC_{50} = 2.5	205	0.025	<0.1	No
			1553.4	0.27	0.1	No
			6000	0.75	0.3	No
D. magna	Chronic	NOEC = 0.04	205	0.025	0.6	No
			1553.4	0.27	6.75	Yes
			6000	0.75	18.75	Yes
Rainbow trout	Acute	**LC_{50}/10** = 0.62	205	0.025	<0.1	No
			1553.4	0.27	0.4	No
			6000	0.75	1.2	Yes
Bluegill sunfish		**LC_{50}/10** = 0.6	205	0.025	<0.1	No
			1553.4	0.27	0.45	No
			6000	0.75	1.25	Yes
Rainbow trout (Early Life Cycle)	Chronic	NOEC = 0.43	205	0.025	<0.1	No
			1553.4	0.27	0.6	No
			6000	0.75	1.7	Yes
Amphibian[4]	Acute	**LC_{50}/10** = 0.6	205	0.14	0.2	No
			1553.4	1.43	2.4	Yes
			6000	4	6.7	Yes
	Chronic	NOEC = 0.43	205	0.14	0.3	No
			1553.4	1.43	3.3	Yes
			6000	4	9	Yes
Marine Species						
Saltmarsh mosquito	Acute	LC_{50} = 0.015	205	0.025	1.7	Yes
			1553.4	0.27	18	Yes
			6000	0.75	50	Yes
Longnose killifish		LC_{50} = 0.1	205	0.025	0.25	No
			1553.4	0.27	2.7	Yes
			6000	0.75	7.5	Yes

Text and numbers in **bold** have been corrected from the tables originally printed in the PRVD.

1 Endpoints were divided by an Uncertainty Factor to account for varying protection goals (for example, protection at the community, population, or individual level)

2 EEC based on a 15 cm water body depth for amphibians and a 80 cm water depth for all other aquatic organisms.

3 Cumulative rate (2 applications of 1320 g a.i./ha with the interval of 10 d)

4 Endpoints from fish as surrogate.

Table 6 Refined Risk Assessment for Birds and Mammals (Off-field, spray drift)

Organism	Exposure	Toxicity	Feeding Guild	EDE[1] (mg a.i./kg bw)		RQ		LOC exceeded	
				11%	26%	11%	26%	11%	26%
Application rate 205 g a.i./ha									
Bird 20 g	Acute	**LD_{50}/10** 0.54 mg a.i./kg bw	Insectivore	1.13	2.67	2.1	4.9	Yes	Yes
			Granivore	0.19	0.46	0.35	0.85	No	No
			Frugivore	0.58	1.38	1.1	2.5	Yes	Yes
	Dietary	**LD_{50}/10** 4.65 mg a.i./kg bw	Insectivore	1.13	2.67	0.2	0.6	No	No
			Fructivore	0.58	1.38	0.1	0.3	No	No
	Reproduction	NOEL = 0.22 mg a.i./kg bw/day	Insectivore	1.13	2.67	5	12	Yes	Yes
			Granivore	0.19	0.46	0.9	2.1	No	Yes
			Frugivore	0.58	1.38	2.6	6.3	Yes	Yes
Bird 100 g	Acute	**LD_{50}/10** 0.54 mg a.i./kg bw	Insectivore	0.9	2.1	**<1**	3.9	**No**	Yes
			Granivore	0.15	0.36	0.3	0.7	No	No
			Frugivore	0.45	1.1	0.8	2	No	Yes
	Reproduction	NOEL = 0.22 mg a.i./kg bw/day	Insectivore	0.9	2.1	4	9.5	Yes	Yes
			Granivore	0.15	0.36	0.7	1.6	No	Yes
			Frugivore	0.45	1.1	2	5	Yes	Yes
Bird 1000 g	Acute	**LD_{50}/10** 0.54 mg a.i./kg bw	Insectivore	0.9	2.1	1.7	3.9	Yes	Yes
			Herbivore	0.16	3.8	0.3	7	No	Yes
	Dietary	**LD_{50}/10** 4.65 mg a.i./kg bw	Herbivore	0.16	3.8	<0.1	0.8	No	No
	Reproduction	NOEL = 0.22 mg a.i./kg bw/day	Insectivore	0.9	2.1	4	9.5	Yes	Yes
			Granivore	0.15	0.36	0.7	1.6	No	Yes
			Frugivore	0.45	1.1	2	5	Yes	Yes
			Herbivore	0.16	3.8	0.7	17	No	Yes
Mammal 15 g	Reproduction	NOEL = 1.2 mg a.i./kg bw/day	Insectivore	0.65	1.5	0.5	**<1**	No	**No**
			Frugivore	0.33	0.8	0.3	0.7	No	No
Mammal 35 g	Dietary	NOEL = 4.7 mg a.i./kg bw/day	Insectivore	0.55	1.3	0.1	0.3	No	No
			Herbivore	3.5	8.2	0.7	1.7	No	Yes
	Reproduction	NOEL = 1.2 mg a.i./kg bw/day	Insectivore	0.55	1.3	0.45	1.1	No	Yes
			Frugivore	2.2	0.6	1.8	0.5	Yes	No
			Herbivore	3.5	8.2	2.9	6.8	Yes	Yes
Mammal 1000 g	Dietary	NOEL = 4.7 mg a.i./kg bw/day	Herbivore	1.9	4.5	0.4	0.95	No	No
	Reproduction	NOEL = 1.2 mg a.i./kg bw/day	Insectivore	0.3	0.7	0.25	0.6	No	No
			Frugivore	0.16	0.37	0.1	0.3	No	No
			Herbivore	1.9	4.5	1.6	3.75	Yes	Yes

Text and numbers in **bold** have been corrected from the tables originally printed in the PRVD.

[1] EDE calculated based on fine droplets for ground (11%) and aerial (26%) spray drift deposition.

Appendix IV Label Amendments for Products Containing Dimethoate

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. Additional information on labels of currently registered products should not be removed unless it contradicts the label statements below.

A submission to request label revisions will be required within 90 days of finalization of the re-evaluation decision.

The labels of end-use products in Canada must be amended to include the following statements to further protect workers and the environment.

All the label directions concerning the following uses and application equipment must be amended as follows:

- All label directions concerning application to structural sites and general outdoor use are to be removed;
- All label directions concerning paint-on treatments are to be removed;
- Label directions for soil drench application to carnations are to be removed.

TOXICOLOGICAL INFORMATION

The following hazard statement should appear on the label of the technical grade active ingredient:

> "POISON, DANGER. WARNING: EYE IRRITANT."

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 dimethoate-containing products must be expanded, and/or standardized, as follows:

Toxicological Information

> **"**Dimethoate is an organophosphate that is a cholinesterase inhibitor. Typical symptoms of overexposure to cholinesterase inhibitors include headache, nausea, dizziness, sweating, salivation, and runny nose and eyes. This may progress to muscle twitching, weakness, tremor, incoordination, vomiting, abdominal cramps and diarrhea in more serious poisonings. 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). Atropine, only by injection, is the preferable antidote.

Oximes, such as pralidoxime chloride, may be therapeutic if used early; however, use only in conjunction with atropine. 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."

PRECAUTION STATEMENTS

The following label statements are to be added to all labels:

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

"Not for use in greenhouses."

"This product is not to be used around homes or other residential areas such as parks, school grounds and/or playing fields. It is not for use by homeowners or other uncertified users."

"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."

Engineering Controls and Personal Protective Equipment:

Label statements must be amended (or added) to include the following directions where applicable:

A. <u>Mixing/loading liquids (for all uses except forestry)</u>:
Wear chemical resistant coveralls over long pants and a long-sleeved shirt, chemical resistant footwear plus socks, chemical resistant gloves, goggles or a face shield and suitable respiratory protection. Suitable respiratory protection is defined as 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.

B. <u>Mixing/loading liquids (forestry: hemlock, spruce and balsam fir):</u>
Use a closed system for aerial mixing/loading for forestry use (hemlock, spruce and balsam fir). Wear cotton coveralls over long pants and a long-sleeved shirt, chemical resistant footwear plus socks, chemical resistant gloves, goggles or a face shield.

C. Mixing/loading liquids (forestry: Douglas fir (seed tree), Sitka spruce (seed tree), spruce (seed tree and woodland)):

During mixing, loading, clean-up and repair, wear chemical resistant coveralls over long pants and a long-sleeved shirt, chemical resistant footwear plus socks, chemical resistant gloves, goggles or a face shield and suitable respiratory protection. Suitable respiratory protection is defined as 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.

D. Applying by air:

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

E. Applying by groundboom:

During groundboom application use a closed cab that provides both a physical barrier and respiratory protection (for example, dust/mist filtering and/or vapour/gas purification system). The closed cab must have a chemical resistant barrier that totally surrounds the occupant and prevents contact with pesticides outside the cab. Wear cotton coveralls over long pants and a long-sleeved shirt, chemical resistant footwear plus socks. Chemical resistant gloves are not required to be worn while driving closed cab equipment but are required for clean-up and repair activities.

F. Applying by airblast:

During airblast application use a closed cab that provides both a physical barrier and respiratory protection (for example, dust/mist filtering and/or vapour/gas purification system). The closed cab must have a chemical resistant barrier that totally surrounds the occupant and prevents contact with pesticides outside the cab. Wear cotton coveralls over long pants and a long-sleeved shirt, chemical resistant footwear plus socks. Chemical resistant gloves are not required to be worn while driving closed cab equipment but are required for clean-up and repair activities.

If a closed cab is not feasible, wear chemical resistant coveralls over long pants and a long-sleeved shirt, chemical resistant footwear plus socks, chemical resistant gloves and chemical-resistant headgear. Chemical resistant headgear includes so’westers, or large brimmed, water-proof hats, and hoods with sufficient neck protection. Avoid touching face or other unprotected parts of the body during application.

G. Applying by handheld equipment:

Wear chemical resistant coveralls over long pants and a long-sleeved shirt, chemical resistant footwear plus socks, chemical resistant gloves and suitable respiratory protection. Suitable respiratory protection is defined as 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. Limit the amount of active ingredient handled per day to 2.8 kg per person (for example, approximately 2950 L at a rate of 0.96 g a.i./L) when applying by handheld equipment.

H. Applying by manually-pressurized handwand or backpack (Douglas fir (seed tree), Sitka spruce (seed tree), spruce (seed tree and woodland)):

During manually-pressurized handwand, or backpack application, wear chemical resistant coveralls over long pants and a long-sleeved shirt, chemical resistant footwear plus socks, chemical resistant gloves and suitable respiratory protection. Suitable respiratory protection is defined as 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.

DO NOT apply using mechanically-pressurized handgun equipment. Only for use with manually-pressurized hand wands or backpack sprayers.

I. Applying by right-of-way sprayer:

During mixing, loading, application, clean-up and repair, wear chemical resistant coveralls over long pants and a long-sleeved shirt, chemical resistant footwear plus socks, chemical-resistant gloves, goggles or a face shield.

J. Applying by soil drench, soil injection or chemigation:

Wear chemical resistant coveralls over long pants and a long-sleeved shirt, chemical resistant footwear plus socks, chemical resistant gloves and suitable respiratory protection. Suitable respiratory protection is defined as 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.

Add to ENVIRONMENTAL PRECAUTIONS:

Note: *Label text should be expanded or standardized with the statements below, but should not replace existing label statements that are more protective.*

TOXIC to bees. Bees may be exposed through direct spray, spray drift, and residues on leaves, pollen and nectar in flowering crops and weeds. Minimize spray drift to reduce harmful effects on bees in habitats close to the application site. Avoid applications when bees are foraging in the treatment area in groundcover containing blooming weeds. To further minimize exposure to pollinators, refer to the complete guidance “Protecting Pollinators during Pesticide Spraying – Best Management Practices” on the Health Canada website (www.healthcanada.gc.ca/pollinators). Follow crop specific directions for application timing.

For applications on crops that are highly attractive to pollinators (alfalfa, clovers, canola, safflower, blueberries, cherries, peaches, pears, asparagus, and outdoor ornamentals excluding coniferous evergreens), or when using managed bees for pollination services:

DO NOT apply during the crop blooming period or during the 5-day period before the crop blooms.

For applications on all other crops:

Avoid application during the crop blooming period. If applications must be made during the crop blooming period, restrict applications to evening when most bees are not foraging.

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.

TOXIC to birds, mammals and aquatic organisms. Observe buffer zones specified under DIRECTIONS FOR USE.

To reduce runoff from treated areas into aquatic habitats, consider the characteristics and conditions of the site before treatment. Site characteristics and conditions that may lead to runoff include, but are not limited to: heavy rainfall, moderate to steep slope, bare soil, poorly draining soil (for example, soils that are compacted or fine textured such as clay).

Avoid application of this product 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.

Add to DIRECTIONS FOR USE:

Maximum Spray Volume:

For fruit trees (pears, peaches, cherries) where maximum spray volume is not specified, the following statement should be added to labels:

> "Apply at the recommended rate; do not exceed a maximum spray volume of 3000 L per hectare unless otherwise stated."

For other labels, the following statement should be added to the label:

> "Apply at the recommended rate; do not exceed a maximum spray volume of 1000 L per hectare unless otherwise stated."

Number of Applications:

Add the maximum number of applications and application intervals per crop as per Table 1 below:

NOTE: DO NOT increase the maximum number of applications if it is currently one application.
DO NOT decrease the minimum application interval if it is currently higher than the interval indicated in the Table 1.

Table 1 Maximum Number of Applications per Year and Minimum Application Intervals

Crop	Maximum Number of Applications per Year	Minimum Application Interval (Days)
Alfalfa, asparagus, beans, beets, beet greens, bok choi (pak choi), broccoli, Brussel sprouts, canola (rape) , cauliflower, celery, cereals (barley, oat, wheat and rye), chicory, Chinese broccoli, clover (sweet, red, alsike), eggplant, forage crops (grasses, alfalfa, hay, clover), grains (barley, oat, wheat and rye), leaf lettuce, peas, pastures, peppers, potatoes, safflower, soybeans, Swiss chard, tomatoes, turnip greens, wastelands	2	7
Camellias, lilac, peaches (non-bearing), pears, roses	2	10
Birch, blueberries (high and low bush), cherries, flax, hazelnuts (filberts), larch	No change required	
Arborvitae, azalea, beans, boxwood, cedar, euonymus, gardenias, holly (English, American), juniper, oak, pea	2	14
Ornamental and forestry use (ground application): hemlock, pine (mugho, red, Scots) Christmas trees (Balsam fir, spruce, hemlock, mugho pine, red pine, Scot pine)	2	14
Forestry use (restricted aerial): balsam fir, hemlock, spruce	1	Not applicable
Douglas fir (seed tree), Sitka spruce (seed tree), spruce (seed tree and woodland)	2	10
Day lilies, gerberas, gladioli, irises, poinsettias	1	Not applicable
canary grass	2	30
Kale	2	15
Strawberry	2	10
Taxus	2	14

Labels are to be revised to reflect the preharvest intervals (PHI), pre-grazing intervals (PGI), and application rates listed in Table 2.

Table 2 Pre-harvest intervals (PHI), pre-grazing intervals (PGI), and changes to application rates

Crop	Label Revisions for Commercial Products
Alfalfa	Minimum 10-day PHI/PGI
Asparagus	Dimethoate should be applied postharvest only, but if applied on immature asparagus do not harvest for feed or food
Blueberry	Minimum 21-day PHI
Broccoli, Cauliflower	Minimum 7-day PHI
Celery	Minimum 7-day PHI
Cereals (wheat, barley, rye, oats)	Minimum 14-day PGI and 35-day PHI
Kale, Leaf lettuce, Swiss Chard, Turnip (greens)	Minimum 14-day PHI
Peach (non-bearing)	Minimum 40-day PHI
Peas	Maximum rate reduced to 0.18 kg a.i./ha
Pear	Maximum rate reduced to 1.44 kg a.i./ha Minimum 28-day PHI
Potato, Tomato	Maximum rate reduced to 0.48 kg a.i./ha

Restricted-entry Interval:

Where applicable, the restricted-entry intervals listed in Table 3 below must be added to the label. Where deemed necessary, REIs are sub-divided according to re-entry activities.

Table 3 Restricted-Entry Intervals

Crops	Activity	**REI** (days)
Filberts (hazelnuts)	Thinning	34
	Hand harvesting, hand-line irrigation	21
	All other activities	5
Peaches	Thinning	32
	Hand harvesting, hand-line irrigation	20
	All other activities	3
Pears	Thinning	28
	Hand harvesting, hand-line irrigation	17
	All other activities	1
Cherries	Thinning	20
	Hand harvesting, hand-line irrigation	9
	All other activities	12 hrs
Blueberries	Hand harvesting (high bush)	12
	Hand harvesting (low bush) and all other activities	12 hrs
Boxwood	Thinning	7
	All other activities	12 hrs
Hemlock, spruce, Balsam fir	Thinning	13
	All other activities	12 hrs
Christmas trees (Balsam fir, spruce, hemlock, pine), pine, oak, cedar	Thinning	18
	Hand-line Irrigation	3
	All other activities	12 hrs
Douglas fir (seed tree)	Seed cone harvesting	48
	Scouting	5
	Grading, animal control, baiting	1

Crops	Activity	**REI** (days)
Sitka spruce (seed tree), spruce (seed tree and woodland)	Seed cone harvesting	49
	Scouting	5
	Hand pruning, staking, tying	27
	Grading, animal control, baiting	2
Lilac	All activities	15
Holly	All activities	12
Day lilies, irises	All activities	7
Broccoli, cauliflower	All activities	5
Bok choi (pak choi), chicory, Chinese broccoli	All activities	4
Leaf vegetables (beets and beet greens, turnip greens, kale, leaf lettuce, celery)	All activities	3
Azaleas, camellias, gerberas, gladioli, poinsettias, roses, brussel sprouts, strawberries	All activities	2
Larch	All activities	1
All other crops, soil drench or injection and chemigation application	All activities	12 hours

Application directions:

Where applicable, add the following statements:

Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) fine classification. Boom height must be 60 cm or less above the crop or ground.

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.

Aerial application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply when wind speed is greater than 16 km/h at the application site as measured from a height of two metres off the ground. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) fine classification. To reduce drift caused by turbulent wingtip vortices, the nozzle distribution along the spray boom length **MUST NOT** exceed 65% of the wing- or rotorspan.

Pollinator protection:

Appropriate restrictions should be repeated under the specific crop use directions, as follows:

To protect pollinators, follow the instructions regarding bees in the Environmental Precautions section.

For alfalfa, clovers, canola, safflower, blueberries, cherries, peaches, pears, asparagus, and outdoor ornamentals excluding coniferous evergreens, include:

> TOXIC to bees. DO NOT apply during the crop blooming period or during the 5-day period before the crop blooms.

For all other crops, excluding coniferous evergreens, barley, oats, wheat, and rye include:

> TOXIC to bees. Avoid application during the crop blooming period. If applications must be made during the crop blooming period, restrict applications to evening when most bees are not foraging. When using managed bees for pollination services, DO NOT apply during the crop blooming period.

No specific use directions are required for coniferous evergreens, barley, oats, wheat or rye.

Note: Coniferous evergreens include: arborvitae, juniper, Taxus (yew), hemlock, Christmas trees (Balsam fir, spruce, hemlock, mugho pine red pine, Scot pine), Douglas fir, Sitka spruce, spruce, spruce (woodland), and balsam fir.

Buffer zones:

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

The buffer zones specified in Table 4 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.

Table 4 Buffer zones

Method of application	Crop		Buffer Zones (metres) Required for the Protection of :			
			Freshwater habitat of Depth:		Estuarine/Marine habitats of Depth:	
			Less than 1m	Greater than 1m	Less than 1m	Greater than 1m
Field sprayer*	Cereals, wheat, forage crops, strawberries, vegetables, asparagus, potatoes, tomatoes, flax, clover		1	1	2	1
	Flowering plants		3	1	4	2
Airblast	Christmas trees, ornamentals	Early growth stage	10	4	15	5
		Late growth stage	5	2	5	3

Method of application	Crop		Buffer Zones (metres) Required for the Protection of :			
			Freshwater habitat of Depth:		Estuarine/Marine habitats of Depth:	
			Less than 1m	Greater than 1m	Less than 1m	Greater than 1m
	Fruit trees	Early growth stage	15	10	20	10
		Late growth stage	10	4	10	5
	Woodland	Early growth stage	30	20	30	25
		Late growth stage	20	10	25	15
	Sitka spruce	Early growth stage	35	25	40	30
		Late growth stage	25	20	30	20
Aerial	Flax	Fixed wing	1	0	1	0
		Rotary wing	1	0	1	0
	Cereals, forage crops, wheat	Fixed wing	5	1	10	1
		Rotary wing	4	1	10	1
	Clover	Fixed wing	10	1	15	1
		Rotary wing	5	1	10	1
	Shrubs and trees	Fixed wing	35	1	50	15
		Rotary wing	20	1	30	5
	Forestry hemlock, spruce, balsam fir)	Fixed wing	90	1	150	15
		Rotary wing	55	1	90	2

*For field sprayer application, buffer zones can be reduced with the use of drift reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy, the labelled buffer zone can be reduced by 30%.

When a tank mixture is used, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture.

Product specific label amendment:

The following statements are amended on the labels of Cygon 480 Systemic Insecticide (Registration Number 8277) and Lagon 480E INSECTICIDE (Registration Number 9382):

Remove from DIRECTIONS FOR USE:

> "Douglas fir Seed tree: Cone insects (cone or gall midge, cone moth, seed chalcid, scale midge). 2.5 L in 100 L of water (Apply as a wetting spray) or 5 L in 100 L of water (Applied with mist blower). COMMENTS: Ground application should be made when cones are at, or near the pendant stage. Complete coverage of the cones and foliage in the cone-bearing area of the tree is important for satisfactory results.
>
> Spruce Seed (woodland use): Seed and cone insects 10.4 - 20.8 L in 1000L of water or 104 - 208 mL in 10 L of water. COMMENTS: Thoroughly spray cone-bearing portions of tree to point of run-off using ground hydraulic spray equipment, when cones are closed and turning but before they reach the horizontal position. Contact your local forest pest control officer for more information on timing and spray application as well as spruce species that may be treated.
>
> Sitka-Spruce: Sitka-Spruce weevil. 25 L in 1000L of water or 250 ml in 10L of water. COMMENTS: Thoroughly spray the terminal growth to the point of runoff at the time of egg laying (usually during the first half of May)."

Add to DIRECTIONS FOR USE:

> "Douglas fir (seed tree): Cone insects (cone or gall midges, cone moths, seed chalcids, scale midges). 2 L per 100 litres of water. Maximum rate 20 L of product (= 9.6 kg a.i.) per hectare. Application should be made when cones are at or near the pendant stage. Complete coverage of the cones and foliage in the cone-bearing area of the tree is important for satisfactory results. Maximum of two applications per year.
>
> Spruce (seed tree and woodland use): Seed and cone insects. 10.4 - 20.8 L per 1000 L water. Maximum rate 20.8 L of product (10 kg a.i) per hectare. Thoroughly spray cone-bearing portions of tree to point of runoff when strobili cones are closed, and turning, but before they reach the horizontal position. Contact your local forest pest control office for more information on timing, and spray application, as well as spruce species that may be treated. Maximum of one application per year.
>
> Sitka spruce (seed tree): Sitka spruce weevils. 20.8 L per 1000 litres of water. Maximum rate 20.8 L of product (= 10 kg a.i.) per hectare. Thoroughly spray the terminal growth to the point of runoff at the time of egg laying (usually during the first half of May). Maximum two applications per year."

The following statement is to be added to the label of Lagon 480E INSECTICIDE (Registration Number 9382):

Add to DIRECTIONS FOR USE:

"Lagon 480E INSECTICIDE is a true systemic insecticide. A systemic insecticide is absorbed into the system of the plant upon application and, as with all systemic materials, may in specific plants cause reactions which are neither predictable nor common to all members of the species."

Appendix V Registered Products Containing Dimethoate (as of October 23, 2015)

Reg #	Product Name	Formulation	Marketing Class	Regt
8277	Cygon 480 Systemic Insecticide	Solution	Commercial + Restricted	FMC Corporation
9382	Lagon 480 E Insecticide	Emulsifiable concentrate or emulsion	Commercial + Restricted	Loveland Products Canada
9807	Cygon 480 EC Systemic Insecticide	Emulsifiable concentrate or emulsion	Commercial	Interprovincial Cooperative Limited
12864	Farm & Ranch Brand Dimethoate 480 EC Systemic Insecticide	Emulsifiable concentrate or emulsion	Commercial	Agrium Advanced Technologies
19067	Chemathoate Technical	Solid	Technical	FMC Corporation
19068	Chemathoate Manufacturing Concentrate	Solution	Manufacturing Concentrate	FMC Corporation
25650	Cygon 480-Orn Systemic Insecticide	Emulsifiable concentrate or emulsion	Commercial	FMC Corporation
25651	Cygon 480-Ag Systemic Insecticide	Emulsifiable concentrate or emulsion	Commercial	FMC Corporation

References

A. Studies/Information Provided by the Applicant/Registrant - Unpublished

Studies Considered in the Health Assessment – Toxicology

PMRA Document Number	Reference
1216451	The Toxicity Of Dimethoate In Rats After 24-month Administration in the Diet (Project #70CO326/8241) Vol. I. DACO: 4.4.1,4.4.2
1951287	Final Position Paper to EPA Comparative ChE of Dimethoate Metabolites. DACO: 4.5.12
1951288	2001, Dimethoate, Omethoate, 4 Methabolites. DACO: 4.5.12
1981289	2009, Oral (Gavage) Acute Dose Range-Finding Cholinesterase Depression Study. DACO: 4.5.12
1951290	2009, Oral (Gavage) Acute Dose Range-Finding Cholinesterase Depression Study. DACO: 4.5.12
2088650	Oral (Diet) Repeated Dose 28-Day Immunotoxicity Study of Dimethoate in Mice. DACO: 4.3.3
2088651	Oral (Diet) Repeated Dose 14-Day Dosage Range Study of Dimethoate in Mice. DACO: 4.2.1
2118847	Response to PRVD2011-12 - Historical Control data on rats. DACO: 0.8,4.4.4

Studies Considered in the Health Assessment – Occupational Exposure

PMRA Document Number	Reference
2115788	2008, Agricultural Re-entry Task Force (ARTF). Data Submitted by the ARTF to Support Revision of Agricultural Transfer Coefficients

Studies Considered in the Health Assessment – Dietary Exposure

PMRA Document Number	Reference
1957106	2010, Determination of the Effect of Chlorination on the Degradation of Dimethoate in Water. DACO: 8.2.3
2126413	Determination of Residues of Dimethoate and Omethoate after Three Applications of an EC Formulation Containing 400 g/L Dimethoate in Carrots at 4 Sites in Southern Europe 2008. DACO: 7.2.1,7.2.2,7.4.1
2126414	Final report on Project AF/8797/CN: Dimethoate and Omethoate Residues in Carrots in Northern Europe, 2005. DACO: 7.2.1,7.2.2,7.4.1
2126415	Residue Study (at Harvest) with an EC Formulation Containing 400 G/L Dimethoate Applied to Citrus in Spain and Italy in 2004.DACO: 7.2.1,7.2.2,7.4.1
2126417	2003, Decline of Dimethoate Residues in the Raw Agricultural Commodity Spring Wheat Resulting from a Single Application of an EC Formulation Containing 400 g/L Dimethoate in the UK and Germany During 2002. DACO: 7.4.2
2126418	Residue Study (at Harvest) with an EC Formulation Containing 400 G/L Dimethoate Applied to Globe Artichokes in Spain in 2001. DACO: 7.2.1,7.2.2,7.4.1
2126419	Dimethoate: Residue Study (at Harvest) with an EC Formulation containing 400 g/l Dimethoate applied to Celery in Spain in 2001. , DACO: 7.2.1,7.2.2,7.4.1
2126420	Residue Study (at Harvest) with an EC Formulation Containing 400 g/L Dimethoate Applied to Melons in Italy and Spain in 2001. , DACO: 7.2.1,7.2.2,7.4.1
2126422	Residue Study (at Harvest) with an EC Formulation Containing 400 g/L Dimethoate Applied to Sugar Beet in the United Kingdom and Germany in 2001. DACO: 7.2.1,7.2.2,7.4.1
2126424	Residue Study (at Harvest) with an EC Formulation Containing 400 G/L Dimethoate Applied to Wheat in Spain and Italy in 2001. DACO: 7.2.1,7.2.2,7.4.1
2126425	1998, Study to Determine the Magnitude of Residue of Dimethoate and Omethoate in Cabbage Following 6 Sequential Field Applications of Danadim Dimethoate 40 in the United Kingdom. DACO: 7.2.1,7.2.2,7.4.1

PMRA Document Number	Reference
2126427	Magnitude of the Residues of Dimethoate and Omethoate on Sugar Beet after Application of an EC Formulation (Perfekthion), containing 400 g/l of Dimethoate in Germany, the Netherlands, and the United Kingdom, 1995. DACO: 7.2.1,7.2.2,7.4.1
2126430	1995, Dimethoate and Omethoate: Determination of Residual Concentrations in Whole Plant, Leaves and Root of Sugarbeets. DACO: 7.2.1,7.2.2,7.4.1
2128187	Dimethoate: Magnitude of the Residue on Pea (edible podded). DACO: 7.2.1,7.2.2,7.4.1
2128188, 2128189	1996, Magnitude of the Residue: Dimethoate on Blueberry. DACO: 7.2.1,7.2.2,7.4.1
2128192	Freezer Storage Stability Study for Dimethoate and Its Oxygen Analog, Omethoate, in Raw Agricultural Commodities/Suppl 95/96. DACO: 7.3
2128193	Freezer Storage Stability Study for Dimethoate and Its Oxygen Analog, Omethoate, in Raw Agricultural Commodities. No. 2 Supplemental Information for MRID 43348801 , DACO: 7.3
2128194	Freezer Storage Stability Study for Dimethoate and Its Oxygen Analog, Omethoate, in Raw Agricultural Commodities. Supplemental Information for MRID 43348801. DACO: 7.3
2128196	Magnitude of the Residues of Dimethoate and Its Oxygen Analog, Omethoate, in or on Cottonseed and its Processed Commodities. DACO: 7.2.1,7.2.2,7.4.1
2128199	Petition Proposing a Tolerance for Dimethoate Use in Asparagus Production + Magnitude of Residue: Dimethoate on Asparagus. DACO: 7.4.1
2128201	Magnitude of the Residues of Dimethoate and Its Oxygen Analog, Omethoate, in or on Oranges and its Processed Commodities. DACO: 7.2.1,7.2.2,7.4.1
2128202	Magnitude of the Residues of Dimethoate and Its Oxygen Analog, Omethoate, in or on Corn Grain and Its Processed Commodities. DACO: 7.2.1,7.2.2,7.4.1
2128203	Magnitude of the Residues of Dimethoate and Its Oxygen Analog, Omethoate, in or on Raw Agricultural Commodities of Peas. DACO: 7.2.1,7.2.2,7.4.1
2128204, 2128205, 2128207, 2128208,	1992, Dimethoate: Summary on and Assessment of Plant Metabolsim and Residue Behaviour. DACO: 6.3

PMRA Document Number	Reference
2128209, 2128210	
2128211, 2128212, 2128213, 2128216, 2128217	1993, The Metabolism of Dimethoate in Plants. SCC Project No.: 104-013-04. DACO: 6.3
2128218	Determination of Residues of Dimethoate and Omethoate after To Applications of an EC Formulation Containing 400 g/L Dimethoate in Olives at 5 Sites in Southern Europe - 2009. DACO: 7.2.1,7.2.2,7.4.1
2128219	Determination of Residues of Dimethoate and Omethoate after One Application of an EC Formulation Containing 400 g/L Dimethoate (applied as bait spray treatment) in Olives at 2 Sites in Southern Europe - 2009. DACO: 7.2.1,7.2.2,7.4.1
2128224	2011, Method Validation of Analytical Methods for the Determination of Dimethoate and Omethoate in Animal Tissues. Method validation conducted according to OPPTS 860.1340, SANCO/825/00 rev.7, 17/3/2004. DACO: 7.2.3,7.2.4
2128227	2004, Dimethoate: Magnitude of the Residue on Pea (Succulent). EPA Series 860 Guidelines. DACO: 7.2.1,7.2.2,7.4.1
2128229	Determination of Residues of Dimethoate and Omethoate after Two applications of an EC Formulation Containing 400 g/L Dimethoate in Olives at 2 Sites in Southern Europe - 2010. DACO: 7.2.1,7.2.2,7.4.1
2128231	Determination of Dimethoate and Omethoate Residues in/on Pea (whole plant, whole and empty pod, seed, and straw) following treatment with Dimethoate 400 g/l EC (Danadim) from field trials in Denmark, 1994. DACO: 7.2.1,7.2.2,7.4.1
2128233	Report Amendment One: (Carbon-14)-Dimethoate Metabolism in Potatoes: DACO: 7.2.1,7.2.2,7.4.1
2128235	Residue Study (Decline Curve) with an EC Formulation containing 400 g/l Dimethoate applied to Tomatoes in Spain and Italy in 2000. DACO: 7.4.2
2128238	Dimethoate : Residue Decline Curve Study with an EC Formulation containing 400 g/l Dimethoate applied to Lettuce in Italy, Spain and Greece in 2000. DACO: 7.4.2
2128240	Dimethoate : Residue Decline Curve Study with an EC Formulation containing 400 g/l (Dimethoate) applied to Cherries in Spain and Italy, 1999. DACO: 7.4.2

PMRA Document Number	Reference
2128241	14C-Dimethoate Metabolism in Potatoes (amendment 1 included). DACO: 6.3
2128242	Analytical Residue Method for the Determination of Dimethoate and Omethoate in Goat and Hen Tissues, Milk and Eggs based upon Analytical Method Validation. DACO: 7.2.4,7.5
2128244	Validation and Radiovalidation of the Analytical Methods for the Determination of Dimethoate and Omethoate in Goat and Hen Tissues, Milk and Eggs. DACO: 7.2.3
2128245	Final report on Project AK/3376/CN: Study to Determine the Magnitude of Residue of Dimethoate and Omethoate in Outdoor Lettuce following 6 Sequential Field Applications of Danadim Dimethoate 40 in the United Kingdom. DACO: 7.2.1,7.2.2,7.4.1
2128246	Final report on Project AK/3379/CN: Study to Determine the Magnitude of Residue of Dimethoate and Omethoate in Brussels Sprouts following 6 sequential field applications of Danadim Dimethoate 40 in the United Kingdom. DACO: 7.2.1,7.2.2,7.4.1
2128247	Study to Determine the Magnitude of Residue of Dimethoate and Omethoate in Cauliflower following 6 Sequential Field Applications of Danadim Dimethoate 40 in the United Kingdom. DACO: 7.2.1,7.2.2,7.4.1
2128248	Magnitude of the Residues of Dimethoate and Its Oxygen Analog, Omethoate, in or on Raw Agricultural and Processed Commodities of Safflower (amendment 1 included), DACO: 7.4.5
2128249	Magnitude of the Residues of Dimethoate and Omethoate on Barley after Application of an EC Formulation (Perfekthion), containing 400 g/l of Dimethoate in Denmark, Germany, the Netherlands, and the United Kingdom, 1996.DACO: 7.2.1,7.2.2,7.4.1
2128250	Compilation of Dimethoate Residues Studies in Peas Conducted by RCC Umweltchemie GmbH & Co. KG in Denmark, United Kingdom and Germany in 1994. Individual Studies include RCC-D project 468303 (Denmark), RCC-D Project 468304 (United Kingdom), RCC-D Project 468305 (Germany), RCC-D Project 468306 (Method Validation). DACO: 7.8
2128251	Magnitude of the Residues of Dimethoate and Omethoate on Potato after Application of an EC Formulation (Perfekthion), containing 400 g/l of Dimethoate in Germany, the Netherlands, and the United Kingdom, 1995. DACO: 7.2.1,7.2.2,7.4.1

PMRA Document Number	Reference
2128252	Magnitude of the Residues of Dimethoate and Omethoate on peas after application of an EC formulation (Danadim) containing 400 g/l of Dimethoate in Germany, the Netherlands and in the United Kingdom, 1995. DACO: 7.2.1,7.2.2,7.4.1
2128256	Magnitude of the Residues of Dimethoate and Omethoate on peas after application of an EC formulation (Danadim) containing 400 g/l of Dimethoate in the Netherlands and in Denmark, 1995 and 1996. DACO: 7.2.1,7.2.2,7.4.1
2128257	Determination of Dimethoate and Omethoate Residues in/on Pea (whole plant, whole and empty pod, seed, and straw) following treatment with Dimethoate 400 g/l EC (Danadim) from field trials in Germany, 1994. DACO: 7.4.5
2128258	Determination of Dimethoate and Omethoate Residues in/on Pea (whole plant, whole and empty pod, seed, and straw) following treatment with Dimethoate 400 g/l EC (Danadim) from field trials in the United Kingdom, 1994. DACO: 7.4.5
2128260	Magnitude of the Residues of Dimethoate and Omethoate on Barley after Application of an EC Formulation (Perfekthion), containing 400 g/l of Dimethoate in Germany, the Netherlands, and the United Kingdom, 1995. DACO: 7.2.1,7.2.2,7.4.1
2128261	Dimethoate and Omethoate; Determination of Residual Concentrations in Whole Plant and tubers of Potatoes. DACO: 7.2.1,7.2.2,7.4.1
2128262	Dimethoate and Omethoate: Determination of Residual Concentrations in Whole Plant and Tubers of Potatoes. DACO: 7.2.1,7.2.2,7.4.1
2128263	1995, The Metabolism of Dimethoate in Plants. DACO: 6.3
2128265	The Metabolism of [14C] Dimethoate in the Lactating Goat Following Oral Administration for 3 Consecutive Days. DACO: 6.2
2128267	Further Characterization of [14C] Dimethoate Residues in the 48-60 Hour Milk Extract from the Study Entitled: The Metabolism of [14C]Dimethoate in the Lactating Goat Following Oral Administration for 3 Consecutive Days (MRID 43583301).DACO: 7.5
2128268	The Metabolism of [14C] Dimethoate in Laying Hens Following Oral Administration for 7 Consecutive Days. DACO: 6.2
2128270	Confined Rotational Crop Study with (Carbon-14)-Dimethoate Using Lettuce, Turnips and Wheat: DACO: 7.4.3
2128271	Determination of Residues of Dimethoate and Omethoate after One Application of an EC Formulation Containing 400 g/L Dimethoate in Sweet Cherries at 1 Site in Northern Europe 2009. DACO: 7.2.1,7.2.2,7.4.1

PMRA Document Number	Reference
2128272	Determination of Residues of Dimethoate and Omethoate after Two Applications of an EC Formulation Containing 400 g/L Dimethoate in Sweet Cherries at 4 Sites in Northern Europe 2008. DACO: 7.2.1,7.2.2,7.4.1
2128274	Determination of Residues of Dimethoate and Omethoate after One Application of an EC Formulation Containing 400g/L Dimethoate in Sweet Cherries at 3 Sites in Southern Europe 2008. DACO: 7.2.1,7.2.2,7.4.1
2128275	Determination of Residues of Dimethoate and Omethoate after One Application of an EC Formulation Containing 400 g/L Dimethoate in Sweet Cherries at 3 Sites in Northern Europe 2008. DACO: 7.2.1,7.2.2,7.4.1
2128277	Determination of Residues of Dimethoate and Omethoate after Two Applications of an EC Formulation Containing 400 g/L Dimethoate in Olives at 4 Sites in Southern Europe - 2008. DACO: 7.2.1,7.2.2,7.4.1
2128278	Final Analytical Report: Final field report: Magnitude of Residues in Pome Fruit Following One Application with Danadim Progress (Dimethoate 40% EC). DACO: 7.2.1,7.2.2,7.4.1
2128280	Magnitude of Residues in Pome Fruit Following One Application with Danadim Progress (Dimethoate 40% EC). DACO: 7.2.1,7.2.2,7.4.1
2128281	Final report on Project AF/11415/CN: Dimethoate and Omethoate Residues in Carrots in Northern Europe, 2007. DACO: 7.2.1,7.2.2,7.4.1
2128282	Final report (field and analytical phase): Magnitude of Residues in Pome Fruit Following One Application with Danadim Progress (Dimethoate 40% EC). DACO: 7.2.1,7.2.2,7.4.1
2128283	Final field report: Magnitude of Residues in Pome Fruit Following One Application with Danadim Progress (Dimethoate 40% EC). DACO: 7.2.1,7.2.2,7.4.1
2128284	Final Analytical Report: Magnitude of Residues in Pome Fruit following One Application with Danadim Progress (Dimethoate 40% EC).DACO: 7.2.1,7.2.2,7.4.1
2128285	Final Report: Residue Behaviour of Winter Barley after Application of Dimethoate 400 g/l EC - 4 sites in Northern Europe 2004. DACO: 7.2.1,7.2.2,7.4.1
2128286	Residue Behavior of Winter Barley after Application of Dimethoate 400 g/l EC - 4 Sites in Northern Europe 2005. DACO: 7.2.1,7.2.2,7.4.1
2128287	14C-Dimethoate Metabolism in Olives. DACO: 6.3

PMRA Document Number	Reference
2128288	Final report on Project AF/8163/CN: Dimethoate Residues in Carrots in Northern Europe, 2004. DACO: 7.2.1,7.2.2,7.4.1
2128290	Final Report amended on 15FEB2006 : Residue Behaviour of Winter Barley after Application of Dimethoate 400 g/l EC - 4 Sites in Northern Europe 2004. DACO: 7.2.1,7.2.2,7.4.1
2128292	Dimethoate: Magnitude of the Residue on Pea (Dry). DACO: 7.2.1,7.2.2,7.4.1
2128293	Residue Study (at Harvest) with an EC Formulation Containing 400 g/L Dimethoate Applied to Lettuce in Spain in 2002. DACO: 7.2.1,7.2.2,7.4.1
2128294	Dimethoate: Residue Study (Decline Curve) with an EC Formulation containing 400 g/l Dimethoate applied to Asparagus in Italy in 2002. DACO: 7.4.2
2128295	Residue Study (at Harvest) with an EC Formulation Containing 400 g/L Dimethoate Applied to Lettuce in Spain and Italy in 2001. DACO: 7.2.1,7.2.2,7.4.1
2128296	Dimethoate: Residue Study (at Harvest) with an EC Formulation containing 400 g/l (Dimethoate) applied to Cherries in Spain and Italy, 1999. DACO: 7.2.1,7.2.2,7.4.1
2128297	Dimethoate: Residue Study (Decline Curve) with an EC Formulation containing 400 g/l Dimethoate applied to Asparagus in Italy in 2000. DACO: 7.4.2
2128298	Dimethoate: Residue Study (at Harvest) with an EC Formulation Containing 400 g/l Dimethoate Applied to Tomatoes in Spain and Italy in 2001. DACO: 7.2.1,7.2.2,7.4.1
2128299	Dimethoate: Residue Study (Decline Curve) with an EC Formulation containing 400 g/l Dimethoate applied to Asparagus in Spain in 2001. DACO: 7.4.2
2128300	14C-Dimethoate Metabolism in Wheat. DACO: 6.3
2128301	14C-Dimethoate Metabolism in Potatoes: Investigation of Components A,G, and K. DACO: 6.3
2128307	Determination of Residues of Dimethoate and Omethoate after Two Applications of an EC Formulation Containing 400 g/L Dimethoate in Sugar Beet at 5 Sites in Northern Europe 2009. DACO: 7.2.1,7.2.2,7.4.1
2128311	Determination of Residues of Dimethoate and Omethoate after One Application of an EC Formulation Containing 400 g/L Dimethoate in Barley at 4 Sites in Northern Europe 2009. DACO: 7.2.1,7.2.2,7.4.1

PMRA Document Number	Reference
2128314	Determination of Residues of Dimethoate and Omethoate after One Application of an EC Formulation Containing 400 g/L Dimethoate in Wheat at 4 Sites in Southern Europe 2009. DACO: 7.2.1,7.2.2,7.4.1
2128317	Determination of Residues of Dimethoate and Omethoate after One Application of an EC Formulation Containing 400 g/L Dimethoate in Wheat at 4 Sites in Northern Europe 2009. DACO: 7.2.1,7.2.2,7.4.1
2128319	Determination of Residues of Dimethoate and Omethoate after Two Applications of an EC Formulation Containing 400 g/L Dimethoate in Head Cabbage at 4 Sites in Southern Europe 2008. DACO: 7.2.1,7.2.2,7.4.1
2128321	Determination of Residues of Dimethoate and Omethoate after Two Applications of an EC Formulation Containing 400 g/L Dimethoate in Head Cabbage at 4 Sites in Southern Europe 2008. DACO: 7.2.1,7.2.2,7.4.1
2128323	Determination of Residues of Dimethoate and Omethoate after Two Applications of an EC Formulation Containing 400 g/L Dimethoate in Cauliflower at 4 Sites in Northern Europe 2009. DACO: 7.2.1,7.2.2,7.4.1
2128326	Determination of Residues of Dimethoate and Omethoate after Two Applications of an EC Formulation Containing 400 g/L Dimethoate in Broccoli at 2 Sites in Northern Europe 2009. DACO: 7.2.1,7.2.2,7.4.1
2128327	Determination of Residues of Dimethoate and Omethoate after One Application of an EC Formulation Containing 400 g/L Dimethoate in Lettuce at 4 Sites in Northern Europe 2008. DACO: 7.2.1,7.2.2,7.4.1
2128328	Determination of Residues of Dimethoate and Omethoate after two applications of an EC formulation containing 400 g/L Dimethoate in Citrus fruits at 8 sites in Southern Europe 2008. DACO: 7.2.1,7.2.2,7.4.1
2128331	Determination of Residues of Dimethoate and Omethoate after Two Applications of an EC Formulation Containing 400 g/L Dimethoate in Sugar Beet at 4 Sites in Southern Europe 2008. DACO: 7.2.1,7.2.2,7.4.1
2128334	Determination of Residues of Dimethoate and Omethoate after One Application of an EC Formulation Containing 400 g/L Dimethoate in Barley at 4 Sites in Northern Europe 2008. DACO: 7.2.1,7.2.2,7.4.1
2128335	Determination of Residues of Dimethoate and Omethoate after Two Applications of an EC Formulation Containing 400 g/L Dimethoate in Broccoli at 2 Sites in Northern Europe 2008. DACO: 7.2.1,7.2.2,7.4.1

PMRA Document Number	Reference
2128337	Determination of Residues of Dimethoate and Omethoate after Two Applications of an EC Formulation Containing 400 g/L Dimethoate in Brussels Sprouts at 4 Sites in Northern Europe 2008. DACO: 7.2.1,7.2.2,7.4.1
2128338	Determination of Residues of Dimethoate and Omethoate after Two Applications of an EC Formulation Containing 400 g/L Dimethoate in Cauliflower at 4 Sites in Northern Europe 2008. DACO: 7.2.1,7.2.2,7.4.1
2128340	Determination of Residues of Dimethoate and Omethoate after Two Applications of an EC Formulation Containing 400 g/L Dimethoate in Head Cabbage at 4 Sites in Northern Europe 2008. DACO: 7.2.1,7.2.2,7.4.1
2128341	Determination of Residues of Dimethoate and Omethoate after One Application of an EC Formulation Containing 400 g/L Dimethoate in Head Cabbage at 4 Sites in Southern Europe 2008. DACO: 7.2.1,7.2.2,7.4.1
2128342	Determination of Residues of Dimethoate and Omethoate after Two Applications of an EC Formulation Containing 400 g/L Dimethoate in Lettuce at 4 Sites in Northern Europe 2008. DACO: 7.2.1,7.2.2,7.4.1
2128343	Determination of Residues of Dimethoate and Omethoate after Two Applications of an EC Formulation Containing 400 g/L Dimethoate in Onions at 4 Sites in Northern Europe 2008. DACO: 7.2.1,7.2.2,7.4.1
2128344	Determination of Residues of Dimethoate and Omethoate after Two Applications of an EC Formulation Containing 400 g/L Dimethoate in Onions at 3 Sites in Southern Europe 2008. DACO: 7.2.1,7.2.2,7.4.1
2128345	Determination of Residues of Dimethoate and Omethoate after Two Applications of an EC Formulation Containing 400 g/L Dimethoate in Sugar Beet at 4 Sites in Northern Europe 2008. DACO: 7.2.1,7.2.2,7.4.1
2128346	Determination of Residues of Dimethoate and Omethoate after One Application of an EC Formulation Containing 400 g/L Dimethoate in Wheat at 4 Sites in Northern Europe 2008. , DACO: 7.2.1,7.2.2,7.4.1
2128347	Determination of Residues of Dimethoate and Omethoate after One Application of an EC Formulation Containing 400 g/L Dimethoate in Wheat at 4 Sites in Southern Europe 2008. DACO: 7.2.1,7.2.2,7.4.1
2128389	Determination of Residues of Dimethoate and Omethoate after Two Applications of an EC Formulation Containing 400 g/L Dimethoate in Onions at 1 Site in Southern Europe 2010. DACO: 7.2.1,7.2.2,7.4.1
2128390	Determination of residues of Dimethoate and Omethoate after two applications of an EC formulation containing 400 g/l Dimethoate in Sugar Beet at 4 Sites in Southern Europe 2010. DACO: 7.2.1,7.2.2,7.4.1

PMRA Document Number	Reference
2128391	Determination of residues of Dimethoate and Omethoate after two applications of an EC formulation containing 400 g/l Dimethoate in Lettuce at 1 site in Northern Europe 2010 DACO: 7.2.1,7.2.2,7.4.1
2128392	Determination of residues of Dimethoate and Omethoate after two applications of an EC formulation containing 400 g/l Dimethoate in Brussels Sprouts at 1 Site in Northern Europe 2010 DACO: 7.2.1,7.2.2,7.4.1
2128393	Determination of Residues of Dimethoate and Omethoate after two Applications of an EC Formulation Containing 400 g/L Dimethoate in Sugar Beet at 1 Site in Northern Europe 2010. DACO: 7.2.1,7.2.2,7.4.1
2128394	Determination of Residues of Dimethoate and Omethoate after two Applications of an EC Formulation Containing 400 g/L Dimethoate in Cauliflower at 1 Site in Northern Europe 2010. DACO: 7.2.1,7.2.2,7.4.1
2128395	Magnitude of the Residues of Dimethoate and Omethoate in/on Alfalfa Seed Following Application of EC Formulation of Dimethoate to Alfalfa. DACO: 7.2.1,7.2.2,7.4.1
2128396	Magnitude of the Residues of Dimethoate and Omethoate in/on Cotton Gin By-Products Following Application of EC Formulation of Dimethoate to Cotton. DACO: 7.2.1,7.2.2,7.4.1
2128397	Dimethoate: Residue Study (at Harvest) with an EC Formulation containing 400 g/l Dimethoate applied to Citrus in Italy in 2002. DACO: 7.2.1,7.2.2,7.4.1
2128398	Dimethoate: Residue Study (Processed Commodity) with an EC Formulation containing 400 g/l Dimethoate applied to Wheat in the United Kingdom and Germany in 2001. DACO: 7.4.5
2128399	Dimethoate: Residue Study (Decline Curve and at Harvest) with an EC Formulation containing 400 g/l Dimethoate applied to Wheat in the United Kingdom and Germany in 2002. DACO: 7.4.2
2128400	Dimethoate: Residue Study (Decline Curve and at Harvest) with an EC Formulation containing 400 g/l Dimethoate applied to Citrus in Spain, Italy and Greece in 2001 DACO: 7.4.2
2128401	Residue Decline Curve Study with an EC Formulation containing 400 g/l Dimethoate applied to Sugar-beet in Italy and Spain in 2000 DACO: 7.4.2
2128402	Dimethoate: Residue Decline Curve Study with an EC Formulation containing 400 g/l Dimethoate applied to Olives in Spain, Italy and Greece, 1999 DACO: 7.4.2

PMRA Document Number	Reference
2128403	Dimethoate: Residue Study (Decline Curve and at Harvest) with an EC Formulation containing 400 g/l Dimethoate applied to Wheat in the United Kingdom and Germany in 2001. DACO: 7.4.2
2128404	Dimethoate: Residue Study (Decline Curve and at Harvest) with an EC Formulation containing 400 g/l Dimethoate applied to Sugar Beet in Spain and Italy 2001 (amendment 1 included). DACO: 7.4.2
2128405	Dimethoate: Residue Study (Decline Curve) with an EC Formulation containing 400 g/l (Dimethoate) applied to Globe Artichokes in Italy in 2000. DACO: 7.4.2
2128406	Dimethoate: Residue Study (Decline Curve and at Harvest) with an EC Formulation containing 400 g/l Dimethoate applied to Citrus in Spain, Italy and Greece in 2000. DACO: 7.4.2
2128407	Dimethoate: Residue Decline Curve Study with an EC Formulation containing 400 g/l Dimethoate applied to Citrus in Spain, Italy and Greece, 1999. DACO: 7.4.2
2128408	Dimethoate: Residue Study (Decline Curve and at Harvest) with an EC Formulation containing 400 g/l Dimethoate applied to Olives in Spain, Italy and Greece in 2000. DACO: 7.4.2
2128409	Dimethoate: Residue Decline Curve Study with an EC Formulation containing 400 g/l Dimethoate applied to Melons in Italy, Spain and Greece in 2000. DACO: 7.4.2
2128410	Dimethoate Residue Study (Decline Curve) with an EC Formulation containing 400 g/l Dimethoate applied to Wheat in Spain and Italy in 2000. DACO: 7.4.2
2128411	Dimethoate: Residue Study (Decline Curve) with an EC Formulation containing 400 g/l Dimethoate applied to Celery in Italy in 2000. DACO: 7.4.2
2128412	Magnitude of the Residue: Dimethoate on Grass (Grown for Seed). DACO: 7.2.1,7.2.2,7.4.1
2128415	Dimethoate: Supplementary Information on the Intervals and Conditions of Storage of Samples from the Following Residue Chemistry Studies: 43583301 Nature of the Residue in Laying Hens, 43583302 Nature of the Residue in the Lactating Goat, 00073444 Magnitude of the Residues in Ruminants, 00077543 Magnitude of the Residues in Ruminants, 00077495 Magnitude of the Residues in Poultry. DACO: 7.5
2128416	Magnitude of the Residues of Dimethoate and Its Oxygen Analog, Omethoate, in or on Raw Agricultural Commodities of Beans. DACO: 7.2.1,7.2.2,7.4.1

PMRA Document Number	Reference
2128419	Magnitude of the Residues of Dimethoate and Its Oxygen Analog, Omethoate, in or on Raw Agricultural Commodities of Grain Sorghum. DACO: 7.2.1,7.2.2,7.4.1
2128420	Organophosphates Market Basket Survey : Final Report. DACO: 7.8
2128421	Organophosphates Market Basket Survey : Interim Report. DACO: 7.8
2128438	Determination of selected Organophosphate and Carbamate Pesticides and their Major Metabolites in Commercially Processed Applejuice DACO: 7.4.5
2128439	Interim Report: Storage Stability of Residues of Dimethoate and Omethoate in Olives. DACO: 7.3
2128440	Final report Amendment 1 on Project AF/8163/CN: Dimethoate Residues in Carrots in Northern Europe, 2004. DACO: 7.2.1,7.2.2,7.4.1

Studies Considered in the Environmental Assessment

PMRA Document Number	Reference
2034208	Dimethoate: Acute Toxicity in the northern Bobwhite Quail (Colinus virginianus) after Single Oral Administration (LD50). DACO: 9.6.4
2034201	Dimethoate: A Reproduction Study with the Northern Bobwhite (Colinus virginianus). DACO: 9.6.4

B. Additional Information Considered – Published

Studies Considered in the Health Assessment – Occupational Exposure

Reference
USEPA, 1995. Reregistration Eligibility Decision: Fosamine ammonium. Washington, D.C. January 1995 http://www.epa.gov/oppsrrd1/REDs/2355.pdf
USEPA, 2006. Interim Reregistration Eligibility Decision: Dimethoate. Washington, D.C. July 2006 http://www.epa.gov/pesticides/reregistration/REDs/dimethoate_ired_revised.pdf
USEPA, 2012. Science Advisory Council for Exposure (ExpoSAC) Policy 3. Revised March 2012. http://www.epa.gov/opp00001/science/exposac_policy3.pdf

Studies Considered in the Environmental Assessment

Reference
Atkins EL; Kellum D; Atkins KW. 1981. Reducing pesticide hazards to honey bees: mortality prediction techniques and integrated management techniques. Univ Calif, Div Agric Sci, Leaflet 2883. 22 pp.
Hoerger, F., E. E. Kenaga (1972). Pesticide residues on plants: Correlation of representative data as a basis for estimation of their magnitude in the environment. *Environmental Quality and Safety.* 1: 9-28.
Kenaga, E. E. (1973). Factors to be considered in the evaluation of the toxicity of pesticides to birds in their environment. *Environmental Quality and Safety.* 2: 168-181.
Fletcher, J. S., J. E. Nellessen, and T. G. Pfleeger (1994). Literature review and evaluation of the EPA food-chain (Kenaga) nomogram, an instrument for estimating pesticide residues on plants. *Environmental Toxicology and Chemistry.* 13(9): 1383-1391.

C. Additional References

Reference
Ganzelmeier, H., D. Rautmann; R. Spangenberg, M. Streloke, M. Herrmann, H-J. Wenzelburger, H-F. Walter. 1995. Studies on the spray drift of plant protection products: Results of a test program carried Studies on the spray drift of plant protection protection products: Results of a test program carried out throughout the Federal Republic of Germany. Report Number 305 from the Biologischen Bundesanstalt fhr Land- und Forstwirtschaft, Berlin-Dahlem. Blackwell Wissenschafts-Verlag GmbH, Berlin/Vienna.
USEPA. 2009. 'Revised Risk Assessment Methods, for Workers, Children of Workers in Agricultural Fields, and Pesticides with No Food Uses' http://www.epa.gov/pesticides/health/revisedRAmethods.pdf
Wolf, T.M. and B.C. Caldwell. 2001. Development of a Canadian spray drift model for the determination of buffer zone distances**.** Page 60. In: Expert Committee on Weeds - Comité d'experts en malherbologie (ECW-CEM). Proceedings of the 2001 National Meeting, Québec City. Saint-Anne-de-Bellevue, Quebec: ECW-CEM. Eds. D. Bernier, D.R.A. Campbell and D. Cloutier.
Wolf, T.M. 2011. Personal communication. Unpublished data from spray drift trials using Tee-Jet XR8001 spray nozzles; 2004 Saskatoon, Saskatchewan. Dr. Tom Wolf, Research Scientist, Agriculture and Agri-Food Canada, Saskatoon, Saskatchewan.