



Health
Canada Santé
Canada

Your health and
safety... our priority.

Votre santé et votre
sécurité... notre priorité.

Proposed Re-evaluation Decision

PRVD2019-04

Acephate and Its Associated End-use Products

Updated Environmental Risk Assessment

Consultation Document

(publié aussi en français)

21 May 2019

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: canada.ca/pesticides
hc.pmra.publications-arla.sc@canada.ca
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
hc.pmra.info-arla.sc@canada.ca

Canada 

ISSN: 1925-0959 (print)
1925-0967 (online)

Catalogue number: H113-27/2019-4E (print)
H113-27/2019-4E-PDF (PDF version)

© Her Majesty the Queen in Right of Canada, represented by the Minister of Health Canada, 2019

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 Public Services and Procurement Canada, Ottawa, Ontario K1A 0S5.

Table of Contents

Proposed Re-evaluation Decision	1
Outcome of Environmental Evaluation	1
Proposed Regulatory Decision for Acephate.....	2
Next Steps.....	3
Additional Scientific Information.....	3
Environmental Evaluation	4
1.0 Introduction.....	4
2.0 Environmental Assessment.....	4
2.1 Fate and Behaviour in the Environment	4
2.2 Environmental Risk Characterization	4
2.3 Foliar Spray Uses.....	5
2.3.1 Pollinators	5
2.3.3 Aquatic Organisms.....	10
2.4 Tree Injection Uses	11
2.4.1 Pollinators	11
2.4.2 Birds and Mammals	13
2.5 Environmental Risk Assessment of Soil Treatment Uses.....	15
2.5.1 Pollinators	15
2.6 Environmental Incident Reports	16
3.0 Conclusion of Environmental Evaluation.....	16
List of Abbreviations	18
Appendix I Registered Acephate Products in Canada as of January 2019	20
Appendix II Label Amendments for Products Containing Acephate.....	21
Appendix III Environmental Assessment.....	25
Table 1 Half-lives of acephate and methamidophos in soil, water and food sources for animals used in the current risk assessment.....	25
Table 2 Use pattern and EECs	25
Table 3 Estimated acephate and methamidophos concentrations on bird and mammal food after acephate application to tobacco, vegetable crops, cranberries and ornamentals	27
Table 4 Summary of acephate and methamidophos residue concentrations in spruce and oak tree tissues and acephate and methamidophos residue concentrations normalized for the proposed application rate	30
Table 5 Summary of pollinator risk assessment endpoints for acephate and methamidophos	30
Table 6 Summary of bird and mammal risk assessment endpoints for acephate and methamidophos (corrected from those reported in PRVD2016-01).....	31
Table 7 Screening level risk assessment for birds and mammals associated with exposure to acephate following its use on tobacco	31
Table 8 Screening level risk assessment for birds and mammals associated with exposure to methamidophos following the use of acephate on tobacco	32
Table 9 Most sensitive aquatic organism acephate and methamidophos endpoints, as reported in PRVD2016-01	33
Table 10 Risk assessment for the most sensitive aquatic organisms	33

Table 11	Acephate Pollinator Risk Quotients considering the empirical data available	34
Table 12	EECs in plant tissues and screening assessment pollinator risk quotients associated with acephate uses in soil ¹ (soil injection and drench).....	35
Table 13	Toxic Substances Management Policy Considerations-Comparison to TSMP Track 1 criteria (As reported in PRVD2016-01)	35
Figure 1	On-field risk quotients for birds exposed to acephate; using mean estimated residues	36
Figure 2	On-field risk quotients for birds exposed to methamidophos following the use of acephate on various crops; using mean estimated residues	37
Figure 3	On-field reproduction NOAEL risk quotients for small insectivorous birds associated with the acephate EECs. Crops treated with hydrolic sprayers (ground boom)	37
Figure 4	On-field reproduction NOAEL risk quotients for small insectivorous birds associated with the acephate EECs. Crops treated with mist blowers (airblast) ..	38
Figure 5	On-field reproduction NOAEL risk quotients for small insectivorous birds associated with the methamidophos EECs. Crops treated with hydrolic sprayers (ground boom)	38
Figure 6	On-field reproduction NOAEL risk quotients for small insectivorous birds associated with the methamidophos EECs. Crops treated with mist blowers (airblast)	39
Figure 7	Off-field risk quotients for birds exposed to acephate.....	39
Figure 8	Off-field risk quotients for birds exposed to methamidophos following the use of acephate on various crops	40
Figure 9	Off-field reproduction NOAEL risk quotients for small insectivorous birds associated with the acephate EECs. Crops treated with hydrolic sprayers (ground boom)	40
Figure 10	Off-field reproduction NOAEL risk quotients for small insectivorous birds associated with the acephate EECs. Crops treated with mist blowers (airblast) ..	41
Figure 11	Off-field reproduction NOAEL risk quotients for small insectivorous birds associated with the methamidophos EECs. Crops treated with hydrolic sprayers (ground boom)	41
Figure 12	Off-field reproduction NOAEL risk quotients for small insectivorous birds associated with the methamidophos EECs. Crops treated with mist blowers (airblast)	42
Figure 13	Estimated concentrations of acephate and methamidophos in soil. The vertical blue line represents the time of flooding. Concentrations in soil at that time were used as a water input to estimate flooding water EECs (Fig. 14).....	42
Figure 14	Estimated concentrations of acephate and methamidophos in flood water. The vertical red line represents the time the last field was harvested.....	43
Figure 15	Measured acephate concentrations in spruce foliage after treatment at a rate of 17 mg a.i./cm diameter tree.....	43
Figure 16	Measured acephate concentrations in oak foliage after treatment at a rate of 310 mg a.i./tree	44

Figure 17	Risk to birds associated with peak acephate residue concentrations measured in various tree tissues (spruce needles, spruce cones and oak leaves) as surrogate for bird and mammal food. Residue concentrations were not adjusted for differences between the study application rate and the Canadian acephate product application rates.	44
Figure 18	Risk to mammals associated with peak methamidophos residue concentrations measured in various tree tissues (spruce needles, spruce cones and oak leaves) as surrogate for bird and mammal food. Residue concentrations were not adjusted for differences between the study application rate and the Canadian acephate product application rates.	45
Figure 19	Dissipation of acephate concentrations in honey bee diet after soil application at a rate of 2.55 kg a.i./ha on July 15th (refined risk assessment).....	45
References	46

Proposed Re-evaluation Decision

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

Acephate is an insecticide registered to control a broad spectrum of insect pests on a wide variety of crops and use sites, including forest and woodlots, terrestrial food and feed crops, and outdoor ornamentals. Acephate is an important component of pest management programs to manage economically important pests and is used as a rotational insecticide for managing insect resistance. All acephate products currently registered in Canada are listed in Appendix I.

A Proposed Re-evaluation Decision for acephate was first published on 8 January 2016 (PRVD2016-01). A comment on PRVD2016-01 pointed to the absence of tree injections as an application method in the initial environmental risk assessment. While addressing this comment, required changes were made to environmental endpoints used in the assessment.

This document presents revisions to the proposed regulatory decision for the re-evaluation of acephate (PRVD2016-01) with risk mitigation measures to protect the environment along with updates to the environmental evaluation on which the proposed decision was based. The current consultation covers only revisions to the proposed re-evaluation decision presented in this document. Consideration of and responses to comments pertaining to the health assessment already received for PRVD2016-01 will be presented in the final re-evaluation decision for acephate. All products containing acephate registered in Canada are subject to this proposed re-evaluation decision.

This document is subject to a 90-day public consultation period, during which the public including the pesticide manufacturers and stakeholders may submit written comments and additional information to the [PMRA Publications Section](#). The final re-evaluation decision will be published taking into consideration the comments and information received.

Outcome of Environmental Evaluation

Acephate, and its major transformation product methamidophos, enter the environment when acephate is used to control insect pests on a wide variety of sites, including forests and woodlots, terrestrial food and feed crops, and outdoor ornamentals.

- Environmental risks to birds and small wild mammals were identified for all outdoor foliar uses applied by mist blowers or airblast application equipment and were not shown to be acceptable. These types of applications are currently registered for use on various trees and ornamentals, and in Christmas tree plantations, farm woodlots, nurseries, shelter belts, right of ways and municipal parks.

- Risks to birds and small wild mammals were also identified for broadcast foliar spraying in farm woodlots, shelterbelts, right of ways and municipal parks and were not shown to be acceptable.
- When acephate is used as a tree-injection, the risk to the environment is expected to be acceptable with implementation of proposed mitigation measures.
- With implementation of proposed mitigation measures, the risk to the environment is expected to be acceptable when acephate is applied as a foliar spray by ground boom to other sites listed on the label.

Proposed Regulatory Decision for Acephate

Under the authority of the *Pest Control Products Act* and based on the evaluation of currently available scientific information, the registration of certain uses of acephate in Canada are proposed for cancellation. Other labelled uses of acephate are proposed for continued registration with mitigation measures to protect human health and/or the environment.

Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures to protect human health and the environment that must be followed by law. As a result of the re-evaluation of acephate, further risk mitigation measures for product labels are being proposed.

The proposed regulatory decision pertaining to human health was presented in PRVD2016-01, which included, among other mitigation measures, a prohibition of foliar application in residential areas, the cancellation of uses on potatoes, and the replacement of the soluble powder formulation with a pellet formulation. The transfer of uses from the soluble powder product label to the pellet product label is currently in progress. Consideration of and responses to comments pertaining to the health assessment already received for PRVD 2016-01 will be presented in the final re-evaluation decision for acephate.

To protect the environment, the following measures are proposed:

- Cancellation of airblast and outdoor mistblower applications, which are currently registered for use on various trees and ornamentals, and in Christmas tree plantations, farm woodlots, nurseries, shelter belts, right of ways and municipal parks
- Cancellation of the highest foliar application rate (resulting from the cancellation of applications by airblast/mistblower, the only method for which the highest rate is registered)
- Uses in farm woodlots, shelter belts, rights of way and municipal parks are limited to spot treatments using hand-held equipment only
- Precautionary and hazard statements to inform users of the toxicity and potential risk of acephate to pollinators, beneficial arthropods, birds, mammals, and aquatic organisms

- Label statements directing users to avoid application during periods of bloom or during the 9-day period before crop bloom for crops that are attractive to pollinators (or for other crops when using managed bees for pollination services)
- Statements directing users that tree injection applications must be made after the blooming/pollen shedding period
- A label statement directing users not to discharge acephate-contaminated effluent from greenhouses into aquatic environments
- Precautionary label statements informing users of ways to reduce the potential for runoff

Proposed label amendments resulting from these environmental mitigation measures are presented in Appendix II.

Next Steps

The public, including the registrant and stakeholders are encouraged to submit additional information that could be used to refine the environmental risk assessment during the 90-day public consultation period¹ upon publication of this proposed re-evaluation decision.

It should be noted that only information related to the updated environmental risk assessment or its impact on the value of uses will be considered within the context of this consultation.

All comments received during the 90-day public consultation period will be taken into consideration in preparation of a re-evaluation decision document,² which could result in revised risk mitigation measures. The re-evaluation decision document will include the final re-evaluation decision, the reasons for it and a summary of comments received on the proposed re-evaluation decision with Health Canada's responses.

Additional Scientific Information

No additional information is required at this time.

For uses where changes to the use pattern are proposed as mitigation measures, Health Canada is asking stakeholders to comment on the agronomic feasibility of the proposed changes and the potential impact on the associated pest management practices. Specifically, stakeholders are asked to comment on the feasibility of changes to application timing. It should be noted that restricting tree injection applications to post-bloom periods is contrary to current label directions for certain pests. Stakeholder feedback is therefore critical in determining whether these pests are expected to be controlled under the proposed restrictions. If the pests cannot be adequately managed under the new application timing, these claims may be removed from the labels.

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*.

Environmental Evaluation

1.0 Introduction

Acephate is a broad spectrum, systemic organophosphate insecticide registered to control a wide range of insect pests on a large variety of crops and use sites. Acephate belongs to the Resistance Management Mode of Action Group 1B, as classified by the Insecticide Resistance Action Committee. Acephate is applied using conventional ground application equipment, soil injection, and in trees as trunk injections or implant cartridges.

2.0 Environmental Assessment

2.1 Fate and Behaviour in the Environment

Refer to PRVD2016-01 for details on the fate and behaviour of acephate and methamidophos in the environment. The half-lives used to estimate environmental concentrations for this assessment are summarized in Appendix III, Table 1.

2.2 Environmental Risk Characterization

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

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

mesocosm studies, and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

The concentrations of acephate and methamidophos were estimated for the aquatic environment and for food items consumed by birds and mammals (vegetation, seeds, insects). The recalculated EECs, based on the use pattern proposed in PRVD2016-01 are presented in Appendix III, Table 2, EECs of bird and mammal food are presented in Appendix III, Table 3, and empirical residue data used to evaluate the environmental risk associated with tree injected acephate are presented in Appendix III, Table 4.

The following revisions were made to the environmental risk assessment that was published in PRVD2016-01:

- The environmental assessment was updated to account for changes in use patterns proposed in PRVD2016-01.
- New Tier 1 acute and chronic oral endpoints were used in the risk assessment for pollinators.
- Corrections were also made to the bird and mammal endpoints (NOECs and LC50s were converted to NOAELs and LD50s as per the standard procedure for bird and mammal risk assessment).
- An environmental risk assessment was conducted for soil treatment and tree injections.
- Buffer zones for aquatic habitats were re-calculated based on acephate endpoints for aquatic organisms. Previously, endpoints for methamidophos had been used; however, it was determined, based on laboratory fate studies, that methamidophos is not formed from acephate in the aquatic environment.

2.3 Foliar Spray Uses

2.3.1 Pollinators

When considering the comments received for PRVD2016-01, Health Canada determined that one of the studies referenced in the PRVD2016-01 contained a valid endpoint for chronic exposure to pollinators (PMRA# 2867217) that had not been used quantitatively in the initial assessment. This endpoint was used in the revised risk assessment summarized in this document. Pollinator endpoints used in the revised assessment are presented in Appendix III, Table 5. The risk profile presented in PRVD2016-01 remains the same; please refer to Section 4.2.1 of PRVD2016-01 for details.

To reduce potential risk to pollinators from foliar applications of acephate, the following limitations are proposed:

- For crops or plants that are highly attractive to pollinators (cranberry and outdoor ornamentals, excluding coniferous trees) - elimination of application during the crop blooming period and during the 9-day period before the crop blooms.
- All other crops, excluding coniferous trees - avoid application during the crop blooming period. When using managed bees for pollination services, do not apply during the crop blooming period.

2.3.2 Avian and Mammalian

The previously published risk assessment (PRVD2016-01) did not incorporate a conversion of treatment doses in the reproductive studies from the NOAEC to the NOAEL according to the current risk assessment methodology. This step has now been completed and the risk assessment has been revised accordingly.

- In the acephate reproduction study with the mallard duck (PMRA# 1208137), the NOAEC and LOAEC, were, 5 and 20 mg/kg diet, respectively. The associated NOAEL and LOAEL calculated from the reported food consumption and bird body weights were 0.44 and 2.03 mg a.i./kg bw d, respectively.
- In the methamidophos reproduction study with the bobwhite quail, the NOAEC and LOAEC were, 3 and 5 mg a.i./kg diet, respectively. The associated NOAEL and LOAEL calculated from default food consumption and bird body weights were 0.32 and 0.53 mg a.i./kg bw d, respectively.
- For methamidophos, the PRVD2016-01 reports a reproduction NOAEL = 10 mg a.i./kg bw day for mice. This was based on the EPA RED reported NOAEL of 10 ppm [mg a.i./kg diet]. The PMRA has since determined that the NOEAC is 10 mg a.i./kg diet which corresponds to a NOAEL of 0.5 mg a.i./kg bw d. This NOAEL of 0.5 mg/kg bw d was used in the current risk assessment.

The risk assessment endpoints for birds and mammals are summarised in Appendix III, Table 6.

2.3.2.1 Maximum Nomogram Residues

For a screening level risk assessment, exposure estimates are based on maximum residue concentrations expected from the maximum (cumulative seasonal) rate that appears on the product label. The use of acephate on tobacco results in the highest on-field residue concentration. For birds, the LOC is exceeded for acute and reproductive effects (RQ = 15 and 364 for small insectivore, based on acute endpoint and reproduction NOAEL, respectively). For mammals, the LOC is also exceeded with RQs of 6 and 4, respectively, calculated for the acute and reproduction endpoints (Appendix III, Table 7).

The methamidophos EECs were adjusted to 40% of the acephate peak EEC. This corresponds to the 90th percentile confidence bound on the available mean methamidophos/acephate ratio (corrected for molecular weight) in various crops. With this conversion, the LOC for birds and mammals is exceeded for acute and reproductive effects. The RQs for small insectivorous birds

based on the acute and reproduction methamidophos endpoints were 81 and 201, respectively. For mammals, the LOC for acute and reproductive effects are also exceeded with RQ = 55 for acute and 144 for reproduction (Appendix III, Table 8). As the LOC was exceeded at the screening level assessment, the risk was characterized further.

Further Characterization of the Risk Assessment:

Compared to mammals, birds are more sensitive to acephate and methamidophos and only the risk assessment for birds is presented below.

Given that a risk was identified with the maximum nomogram residues and using the default 10-day half-life on leaf surfaces, the risk to birds was further characterized for on- and off-field exposure calculated from mean nomogram residues for all labeled use scenarios. Additionally more realistic half-lives of 3.3 and 3.5 days for acephate and methamidophos on plant foliage (PMRA# 1930629) were used to calculate cumulative EECs from repeated applications, and to estimate concentrations on bird and mammal food items as acephate and methamidophos dissipate over time.

2.3.2.2.1 On-field Risk

The LOC based on the acute endpoint, the reproduction NOAEL, and reproduction LOAEL are all still exceeded for most bird guilds (Appendix III, Figures 1 and 2).

According to the current risk assessment scheme, small insectivore birds receive the highest dose and RQs calculated for the most sensitive endpoint (reproduction NOAEL) are equal to 137, 75, 100 and 167 for the tobacco, vegetables and cranberries, ornamentals (ground boom rate), and ornamental (airblast rate) use patterns, respectively. RQs for the same use patterns are equal to 30, 16, 22, and 36, when based on the reproduction LOAEL, and 6, 3, 4 and 7, when based on the acute LD₅₀.

Overall, RQs are lower for methamidophos because of lower EECs. However, because this transformation product is more toxic to birds, calculated RQs based on the acute LD₅₀ are higher than the acephate acute RQs and are equal to 23, 13, 17 and 38 for the tobacco, vegetables and cranberries, ornamentals (ground boom rate), and ornamental (airblast rate) use patterns, respectively.

Acephate and Methamidophos Dissipation:

The potential exposure of birds and mammals is expected to change over time as residues of the active ingredient dissipate. In Appendix III, Figures 3 to 6, present the on-field risk quotients for small insectivorous birds exposed to acephate and methamidophos, accounting for the dissipation of the active ingredient and the formation and decline of the transformation product methamidophos. Figures 3 and 5 present RQs for crops treated using hydraulic sprayer (ground boom) equipment; Figures 4 and 6 present RQs for crops treated using mist blower (airblast).

When acephate containing products are sprayed with hydraulic sprayers on tobacco, vegetable crops and cranberries, and ornamentals, the on-field reproduction risk quotients for acephate exceed the level of concern for periods of 59, 35, and 29 days, respectively, for the most

sensitive bird feeding guild (Appendix III, Figure 3). In addition, when cranberries and ornamental crops/trees are treated with airblast equipment, the on-field acephate risk quotients respectively exceed the level of concern for 35 and 25 days for the most sensitive bird feeding guild (Appendix III, Figure 4).

The on-field risk quotients associated with exposure to methamidophos formed from the degradation of acephate applied with hydraulic sprayers on tobacco, vegetable crops and cranberries, and ornamentals exceed the level of concern for a periods of 68, 45, and 38 days for the most sensitive bird feeding guild (Appendix III, Figure 3); and when cranberries and ornamental crops/trees are treated with airblast equipment, the on-field methamidophos risk quotients exceed the level of concern for 44 and 35 days, respectively, for the most sensitive bird feeding guild (Appendix III, Figure 6).

2.3.2.2.2 Off-field Risk

The off-field risk quotients, for birds exposed to acephate and its transformation product methamidophos using acute, reproduction NOAEL and reproduction LOAEL endpoints are presented in Appendix III, Figures 7 and 8.

RQs calculated for off-field exposure are highest for use patterns involving airblast equipment. Off-field acephate reproduction RQs for small insectivore birds are equal to 15, 8, 11, 56 and 99; and methamidophos acute RQs equal to 3, 1, 2, 9 and 17, respectively, for the tobacco, vegetables and cranberries, ornamentals (ground boom rate), cranberry (airblast) and ornamental (airblast rate) use patterns.

Acephate and Methamidophos Dissipation:

When acephate is sprayed with hydraulic sprayers on tobacco, vegetable crops and cranberries, and ornamentals, the off-field risk quotients (based on the reproduction endpoint) for acephate exceed the level of concern for periods of 48, 21, and 19 days, respectively, for the most sensitive feeding guild (Appendix III, Figure 9). When cranberries and ornamental crops/trees are treated with airblast equipment, the off-field acephate risk quotients for the reproduction endpoint respectively exceed the level of concern for 34 and 23 days for the most sensitive feeding guild (Appendix III, Figure 10).

The off-field risk quotients, based on the reproduction endpoint, associated with exposure to methamidophos formed from the degradation of acephate applied with hydraulic sprayers on tobacco, vegetable crops and cranberries, and ornamentals exceed the level of concern for periods of 55, 31, and 25 days, respectively (Appendix III, Figure 11). When cranberries and ornamental crops/trees are treated with airblast equipment, the on-field methamidophos risk quotients respectively exceed the level of concern for 42 and 33 days (Appendix III, Figure 12).

2.3.2.3 Bird and Mammal Risk Assessment Conclusion

Considering all the information available, a potential risk to birds and mammals exposed to acephate or its transformation product, methamidophos, cannot be ruled out. Consequently, amendments to the labelled uses are required to reduce the probability of exposure to birds and mammals.

Risk quotients exceeded the LOC for all on-field and off-field scenarios for reproductive endpoints. In general, the use of airblast and other mist-blower equipment results in significant off-target drift onto sensitive habitats (adjacent to treated areas) which are used by birds and mammals. Based on the application parameters for products containing acephate, the predicted concentrations of acephate and methamidophos, both on-field and off-field, might pose a risk to birds and, to a lesser extent, mammals.

Furthermore, direct applications to farm woodlots, shelter belts, rights of way and municipal parks (whether by airblast or other ground boom sprayers) are also expected to expose birds and mammals to high levels of acephate and methamidophos. These areas are important habitats used by birds and mammals for shelter, nesting and foraging. Thus, wildlife may be spending more time in these areas which would result in an increased likelihood of exposure to pesticide residues.

Based on a scientific review of available information, the environmental risks associated with 1) ground boom (hydraulic) applications for farm woodlots, shelter belts, rights of way and municipal parks and 2) all outdoor airblast/mist blower applications (including but not limited to cranberries, woodlots, shelter belts and Christmas trees) have not been shown to be acceptable as per current label directions or with any possible mitigation measures. As a result, Health Canada is proposing to:

- Cancel all uses of outdoor airblast/mist blower applications (which would also result in the removal of the highest labelled rate that is registered for use only with these types of applications); and
- Restrict the use of acephate in farm woodlots, shelterbelts, right of ways and municipal parks to spot treatments using hand-held application equipment only.

Although on- and off-field risk quotients for applications of acephate by ground boom (hydraulic) sprayers on tobacco, ornamental crops, tree nurseries (including Christmas tree plantations), vegetable crops and cranberries exceeded the level of concern, the off-field RQs were low compared to airblast applications (all off-field ground boom RQs are ≤ 15). Conservative assumptions were made for the risk assessment, including application at the highest rates with the maximum number of applications and the minimum time interval, and the same off-field drift to the same area for each application. As well, it is assumed that 100% of the diet is made up of single type of food items, whereas food items are likely to be mixed and come from both treated and untreated areas. These conservative assumptions suggest that exposure under actual use conditions may be less than the exposures estimated.

The prohibition of all mist-blower/air blast equipment and ground boom applications to woodlots, rights of way, shelterbelts and parks will mitigate the exposure to birds and help protect bird populations. Removal of these uses and restriction to spot treatment with hand-held application equipment only will reduce spray drift to non-target habitats and will limit the broadcast use of acephate in important foraging and shelter bird habitats. A label statement warning users of the potential risk to birds and mammals will also be required on all acephate product labels.

2.3.3 Aquatic Organisms

The most sensitive aquatic organisms reported in PRVD2016-01 were used to characterize the risk associated with the revised use pattern summarized in Appendix III, Table 9.

A re-examination of the aquatic biotransformation studies showed that little methamidophos is formed from acephate in the aquatic environment. The risk to aquatic organisms was calculated for the highest cumulative application rate of acephate which is for tobacco (563 g a.i./ha + 626 g a.i./ha followed by four applications at 825 g a.i./ha, 7-day interval between applications), and assumed a representative half-life of 14.8 days for aquatic biotransformation. Methamidophos peak EECs were set at 1.5% of the acephate peak EEC after correction for the difference in molecular weight by multiplying by 0.77. The RQs calculated for the most sensitive freshwater and marine organisms, identified in PRVD2016-01, are presented in Appendix III, Table 10. The RQ calculated using the *Daphnia magna* chronic endpoint for acephate was above the LOC (RQ = 2), but the LOC was not exceeded for other organisms. The risk associated with drift did not exceed the LOC. Methamidophos RQs estimated for the most sensitive aquatic organisms were below the level of concern.

Aquatic organisms can also be exposed to acephate and methamidophos when acephate is used on cranberries. The risk to aquatic organisms from exposure to acephate and methamidophos in tailwater from flooding during crop harvest was evaluated with a conservative interim model.

The following assumptions were made to model acephate and methamidophos concentrations in cranberry fields:

- 10 fields, sequentially treated with acephate before and after bloom, at a rate of 560 g a.i./ha.
- As cranberry plants bloom in mid-June, pre-bloom application timing was set for June 1st. The post-bloom application was set 6 days before flood-harvest, as a worst case scenario, at the peak of methamidophos residues in soil.
- The fate of acephate and methamidophos in soil was estimated assuming half-lives of 3.5 and 4.6 days, respectively.
- The estimated water concentrations were based on bed flooding to a water depth of 50 cm, with flooding starting at the beginning of October. For the model, 10 fields were assumed to be sequentially flooded with a 2-day interval between fields.

- 100% of the acephate and methamidophos estimated to remain in soil at the time of flooding was assumed to transfer to the water and no correction was made to account for the uptake of these two systemic active substances by plants.
- EECs in water were estimated assuming acephate and methamidophos half-lives of 14.6 and 8 days, respectively, and a negligible 1.55 % conversion of acephate to methamidophos (from PMRA# 1162659).

Other factors, such as the effect of temperature or desorption coefficients and time to equilibrium were not integrated into the current model.

Because both acephate and methamidophos have short soil and aquatic half-lives, the interval between the last application and flooding has an important impact on the estimated concentration predicted by this model. The highest methamidophos concentrations are predicted 6 days after acephate application to soil; and the model was set to a reasonable worst case scenario, with all fields treated 14 days before being flooded. Finally, it was assumed that the receiving water body would dilute cranberry field tailwater by a factor of 10. The resulting acephate and methamidophos concentrations in soil and water are respectively presented in Appendix III, Figures 13 and 14. The calculated EECs in receiving water are below the levels of concern for both acephate and methamidophos. Given the conservative assumptions made by the model, the use of acephate in cranberry fields is not expected to pose a risk to aquatic organisms in receiving water.

2.4 Tree Injection Uses

2.4.1 Pollinators

An environmental risk assessment for the tree injection uses of acephate was conducted following comments received in response to the publication of PRVD2016-01.

2.4.1.1 Screening Assessment

Bees can be exposed via dietary consumption of pollen and nectar that contain systemic pesticides after tree injection or pellet implant. For these application types, it is assumed that honey bees will not be directly exposed through contact with the pesticide.

For the screening assessment, in absence of residue concentrations in pollen or nectar produced by treated trees, pollinator exposure was estimated by dividing the mass of applied active ingredient by the tree leaf biomass, calculated from an allometric equation. This simplistic approach is suitable to conduct the screening risk assessment as it relies on conservative assumptions. For example, it assumes that the estimated concentrations in leaves can be used as a surrogate for the concentration in pollen and nectar. In studies where systemic active ingredients are measured in various plant tissues and secretions, the peak concentration in leaves is generally higher than in pollen or nectar. Furthermore, the approach assumes that the applied pesticide is homogeneously and instantaneously distributed in the tree leaves and flowers and is not present in other parts of the tree (for example, tree trunk).

Using this method, the estimated acephate concentration in leaves treated at rates of 0.239 and 0.256 g a.i./cm would be 1.53 and 1.64 µg a.i./mg of leaves, respectively, for 15 cm diameter trees. The calculated risk quotients based on these resulting EECs are well above the level of concern.

2.4.1.2 Refined Assessment

To refine the risk assessment, measured acephate and methamidophos concentrations in foliage or cones of treated trees were used as a surrogate for residue concentrations in pollen and nectar (Appendix III, Table 4). Together, the studies show that acephate and methamidophos residues can reach biologically active concentrations in coniferous and deciduous foliage and in spruce cones. The study under PMRA# 2867227 also provides evidence that residue concentrations can remain high in spruce cones one year after treatment.

There are uncertainties with extrapolations of measured residues from spruce needles, spruce cones, or deciduous tree leaves to estimate exposure of pollinators.

- Residues detected in foliage are a conservative estimate of expected residues in pollen and nectar. Information available from residue studies of other systemic pesticides suggest that the amount of pesticide detected in pollen and nectar is lower than the measured concentration in leaves of plants. On average, the available residue concentrations were 50 times higher in leaves than in nectar or pollen. No studies were available to bridge the measured residue concentrations in cones with potential residue concentrations in nectar or pollen.
- The application rates in the cited studies differed from the current labelled acephate application rates in Canada. Two of the rates were similar or slightly higher (PMRA# 2867227 and PMRA# 2867228) and the other study (PMRA# 2867223) used an application rate much lower than the current registered rate.
- In Appendix III, Figures 15 and 16 present evidence that acephate is not persistent in foliage. While the levels detected in the foliage samples exceed the colony-level effects observed in the colony feeding studies, the estimated levels in pollen and nectar do not exceed these endpoints. There is a large amount of uncertainty surrounding the estimated levels in pollen and nectar as extrapolations are made from the concentration detected in foliage to estimate levels in bee food sources.

When the empirical data is considered the RQs exceeded the LOC when used as a direct substitute for pollen and nectar and when the concentration is adjusted to estimate the pollen and nectar levels (Appendix III, Table 11).

2.4.1.3 Pollinator Risk Assessment Conclusions

After analysis of the available data, a risk to pollinators could not be excluded for trees treated during or before bloom. If applied in late autumn, acephate dissipation is expected to slow down as temperatures fall and residues may carry over to the following blooming period. It is unknown whether these residues could be translocated to pollen or nectar and, subsequently, pose a risk to pollinators during bloom in the following spring.

Several assumptions were made to estimate the concentrations of acephate residues in pollen and nectar of treated trees and there remain uncertainties related to the degree of conservatism associated with these estimates. Furthermore, several variables may influence the risk associated with tree injections, including the timing of treatment in relation to bloom, the attractiveness of the tree to pollinators, whether the tree produces both pollen and nectar or only pollen, and the number and density of trees treated in a given area and the availability of other food sources for pollinators is another important consideration.

While the blooming period is short, the possibility that acephate could reach high concentrations in pollen and nectar could not be excluded if trees are treated before or during bloom. These residues could then be brought back to the hive leading to an indirect acute and chronic exposure of the colony. Higher tier studies, in which bees were exposed to acephate in sucrose solution outside the hive, provide evidence of toxic effects to the queen, the honey bee brood and to adults when acephate is brought back by workers. While the acephate residue levels detected in foliage are higher than those that lead to adverse effects in colony-feeding studies, there remains uncertainty associated with the use of foliage as surrogate for pollen and nectar, and the calculated risk quotients are expected to be conservative.

Compared to foliar applications, tree injections are expected to lead to lower exposure to non-target organisms, including pollinators; and the residual activity of the active ingredient inside the tree provides long-term protection.

Given the potential risk identified for pollinators following tree injection with acephate, restricting application until after the blooming/pollen shedding period is proposed for tree varieties that are attractive to pollinators.

2.4.2 Birds and Mammals

Exposure of birds and mammals to acephate residues injected in trees can occur when these organisms feed on sap, fruits and seeds produced by the tree or on insects in the tree.

The concentrations of acephate and methamidophos in foliage of trees injected with acephate or implanted with Acecap pellet were estimated using the same allometric equation used to determine EECs for the pollinator risk assessment. These concentrations were used for a screening assessment as a surrogate for seeds and fruits consumed by birds and mammals. Because of the way acephate and methamidophos move in the plant, these active ingredients are expected to concentrate in leaves at higher concentrations than in fruits or seeds. Consequently, the resulting risk assessment is expected to be conservative. No data, however, were available to estimate residue levels in insects feeding on treated trees or in the sap of treated trees.

The calculated acute and reproductive RQs for grain-, seed- and fruit- eating birds and mammals all exceeded the LOC. Assuming that the methamidophos peak concentration reached 40% of the acephate peak concentration, the acute and reproduction RQs for this transformation product exceeded the LOC for birds and mammals.

To refine the risk assessment, RQs were calculated using the peak residues detected in the various studies available for both acephate and methamidophos (Residue levels presented in Appendix III, Table 4; RQs are presented in Appendix III, Figures 17 and 18). Calculated RQs for grain-, seed- and fruit- eating birds were all at or above the LOC for reproductive risk and above the LOC for acute risk when considering the residues detected in oak leaves only. For mammals the acute and reproductive LOCs were only exceeded when detected methamidophos levels in oak leaves were considered.

Overall, the risk assessment suggests a potential risk to birds and mammals exposed to the active ingredient in fruits and seeds produced by treated trees. However, there are some uncertainties and conservatisms in the risk assessment that would suggest the risk will be lower than predicted:

- The diet of bird and mammals is assumed to consist of 100% treated food sources;
- The levels measured in the tree foliage likely overestimates the levels that would be present in food sources for birds and mammals;
- The residues detected in tree foliage decreases rapidly to levels that would be below the LOC (Appendix III, Figures 15 and 16); and
- Many of the tree species do not represent a large food source for many birds and mammals until well into the late summer, early fall when the seeds and fruits are fully formed; potentially allowing time for the pesticide to dissipate.

Taking into consideration all of the above information, Health Canada concludes that the application of acephate as a tree injection is not likely to cause acute risks of concern for birds and mammals. While a reproductive risk cannot be ruled out, it is expected that the probability of large scale exposure remains low because only high value trees are expected to be treated. A hazard statement on the label informing users of the potential risk to birds and mammals is proposed for trees producing fruits/seeds consumed by birds and mammals.

Two scenarios were not considered which include 1) birds that feed on target pests in the tree (for example, woodpeckers) and 2) birds that feed on sap (for example, yellow-bellied sapsuckers). Health Canada does not have sufficient information in order to estimate the potential exposure to these species of birds. However, it is likely that the exposure will be limited given the biology of these organisms, as discussed in the following paragraph.

The yellow-bellied sapsuckers tend to prefer young forests and edge habitat, especially areas regenerating from timber harvest. Their preferred tree species include paper birch, yellow birch, sugar maple, red maple and hickory. There remains a high level of uncertainty associated with the potential exposure of birds and mammals following tree injections. However, tree injections

are expected to lead to lower environmental off-target exposure and provide an alternative to foliar treatment. Other factors expected to mitigate the risk to birds include the following:

- As insects are killed by the active ingredient, they are expected to eventually decay and also become less attractive to woodpeckers and other insectivores.
- Our current understanding of sap-feeding bird behaviour is that they typically drill wells into tree xylem in the spring or phloem later in the summer/fall of trees to harvest sugary sap. Xylem wells carry more sugar in early spring when trees come out of dormancy, and phloem wells during summer when photosynthesis products are moved from the leaves to other tissues. In plants, acephate and its transformation product methamidophos move in xylem and tend to accumulate in leaves, but have limited mobility in plant phloem. Restricting tree-injections of acephate containing products to the post-bloom period is therefore expected to reduce exposure of sap-feeding birds.
- The concentration in sap, fruits or seeds of treated trees is expected to be lower than in leaves. In cases when a highly attractive tree would be treated during fruit/seed production, individual birds could potentially be exposed to toxic doses of the active ingredient. A hazard statement on the label informing users of the potential risk to birds and mammals is proposed for trees producing fruits/seeds consumed by birds and mammals.

Because the scale of use of tree-injected pesticide is limited, bird populations are not expected to be at risk and the environmental risk is considered acceptable. A hazard label statement is proposed to inform users that residues in treated trees can move to seeds and fruits consumed by birds.

2.5 Environmental Risk Assessment of Soil Treatment Uses

2.5.1 Pollinators

The exposure of pollinators to residues found in food sources following soil application was not considered in PRVD2016-01. For soil treatment, bees will be exposed via dietary consumption of pollen and nectar that contain residues of acephate as a result of systemic transport of pesticides from soil. For these application types, it is assumed that honey bees will not be directly exposed through contact. The method for estimating dietary exposures to bees resulting from soil treatments is based on an empirically based model developed by Briggs et al. 1982 and 1983, with modifications (referred to as “the Briggs’ Model”). This model relates the Log K_{ow} of a chemical to its concentration in plant shoots, which can be used as a surrogate for concentrations in nectar and in pollen. The derived risk quotients for the soil application methods are summarized in Appendix III, Table 12 with the LOC of concern exceeded for both acute and chronic exposure.

When acephate is applied in soil to treat pollinator attractive crops before or during bloom, acute and chronic RQs calculated from estimated active ingredient concentrations are above the level of concern in pollen and nectar at rates above 330 g a.i./ha and 20 g a.i./ha, respectively.

However, because tobacco plants are not attractive to pollinators, the use of acephate as a soil treatment on this crop does not raise concerns.

The risk associated with the post-harvest use of acephate on Saskatoon berries is expected to be low as acephate levels will decline before the next blooming season. The dissipation profile of post-harvest soil application of acephate in honey bee diet, to Saskatoon berries, estimated using Brigg's equation and assuming a 16.5-day half-life in plant is presented in Appendix III, Figure 19. The half-lives were adjusted to estimated environmental temperatures. Acephate concentration approximately 1 year after treatment are estimated to be 0.003 mg a.i./kg diet. The associated acute and chronic RQs are, respectively, <0.01 and 0.21.

The potential for acephate to pose a risk to pollinators when used in transplant water on tomatoes was considered. The associated screening acute and chronic RQs are, respectively, 1 and > 40 (Appendix III, Table 12). There are uncertainties associated with this risk assessment since tomato plants are typically transplanted before they bloom. Because of its short half-life in soil, it is likely that the levels of residues in the pollen and nectar at the time of tomato bloom will be significantly lower than estimated.

The application of acephate through soil application methods is therefore not expected to cause risk of concern to pollinators.

2.6 Environmental Incident Reports

Refer to Section 4.3 of PRVD2016-01 *Acephate* for a description of environmental incident reports for acephate.

3.0 Conclusion of Environmental Evaluation

Acephate, and its major transformation product methamidophos, enter the environment when acephate is used to control insect pests on a wide variety of sites, including forests and woodlots, terrestrial food and feed crops, and outdoor ornamentals.

- Environmental risks to birds and small wild mammals were identified for all foliar spray uses outdoors applied by mist blowers or airblast application equipment and were not shown to be acceptable. These uses are proposed for cancellation along with their associated high rate.
- Risks to birds and small wild mammals were also identified for broadcast foliar spraying in farm woodlots, shelterbelts, right of ways and municipal parks and were not shown to be acceptable. The use of acephate in these areas is being restricted to spot treatment only, using hand-held application equipment.
- With implementation of proposed mitigation measures (in other words, restriction to post-bloom applications), the risk to the environment is expected to be acceptable when acephate is used as a tree-injection.

- With implementation of further proposed mitigation measures, the risk to the environment is expected to be acceptable when acephate is applied as a foliar spray by ground boom to other sites listed on the label.

List of Abbreviations

a.i.	active ingredient
ACP	acephate
app.	applications
ASAE	American Society of Agricultural Engineers
BAF	bioaccumulation factor
BCF	bioconcentration factor
bw	body weight
CFS	colony feeding study
cm	centimeter
d	day(s)
DIR	Regulatory Directive
EDE	estimated daily
EEC	estimated environmental exposure concentration
EFED	(EPA) Environmental Fate and Effects Division
EPA RED	Environmental Protection Agency Reregistration Eligibility Decision document
fw	fresh weight
g	gram(s)
ha	hectare
hr(s)	hour(s)
int.	interval
IR	incident report
kg	kilogram(s)
K_{ow}	octanol-water partition coefficient
L	litre(s)
Lab	laboratory study
LC ₅₀	lethal concentration 50%
LD ₅₀	lethal dose 50%
LOAEL	lowest observed adverse effect level
LOC	level of concern
LOEC	lowest observed effect concentration
m	metre
Max	maximum
mg	milligram(s)
Min	minimum
MOM	methamidophos
N	number of samples
n/a	not applicable
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
PCPA	Pest Control Products Act
PHED	Pesticide Handlers Exposure Database
PMRA	Pest Management Regulatory Agency
ppm	parts per million
PRVD	proposed re-evaluation decision document
Reg.No.	(PCPA) Registration Number

RQ	risk quotient
TSMP	Toxic Substances Management Policy
µg	microgram

Appendix I Registered Acephate Products in Canada as of January 2019

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Active Ingredient
14225	Commercial	Arysta Lifescience North America, LLC	Orthene 75% Soluble Powder Systemic Insecticide	Soluble powder	Acephate 75%
21568	Commercial		Acecap 97 Systemic Insecticide Implants	Soluble powder	Acephate 0.773 g / cartridge
22109	Technical Grade Active Ingredient		Orthene Technical	Soluble powder	Acephate 99.78%
27917	Technical Grade Active Ingredient		Acephate Technical	Soluble powder	Acephate 98.0%
29499	Commercial		Orthene 97% Pellet	Pellet	Acephate 97%

Appendix II Label Amendments for Products Containing Acephate

Note: 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.

The label amendments identified below reflect the updated environmental risk assessment presented in this document. Please refer to PMRA2016-01 for additional label amendments pertaining to toxicological information, restricted-entry intervals, engineering controls and personal protective equipment. Final label amendments may be revised based on information received during consultation.

I) The following amendments are required for all products containing acephate

- *On the front panel,*
 - replace:* 'Guarantee'
 - with:* 'Active ingredient'

II) The following amendments are required for technical products containing acephate

- *Under the ENVIRONMENTAL PRECAUTIONS section, add the following:*

Toxic to aquatic organisms

DO NOT discharge effluent containing this product into sewer systems, lakes, streams, ponds, estuaries, oceans or other waters.

- *Under the DISPOSAL section, add the following:*

Canadian manufacturers should dispose of unwanted active ingredients and containers in accordance with municipal or provincial regulations. For additional details and clean-up of spills, contact the manufacturer or the provincial regulatory agency.

III) The following amendments are required for all commercial end use products containing acephate

- *Update the resistance management section of all acephate labels to include the resistance management statements as per Regulatory Directive DIR2013-04, Pesticide Resistance Management Labelling Based on Target Site/Mode of Action.*

- *Under the ENVIRONMENTAL PRECAUTIONS section, add the following:*

Toxic to aquatic organisms.

Toxic to birds.

Toxic to small wild mammals.

TOXIC to bees. Bees may be exposed through direct spray, spray drift, and residues on/in 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 ground cover 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.

- ***Under the DIRECTIONS FOR USE section, add the following:***

As this product is not registered for the control of pests in aquatic systems, DO NOT use to control aquatic pests.

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

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

Under DIRECTIONS FOR USE ON FIELD CROPS:

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

Under DIRECTIONS FOR USE ON TREES AND ORNAMENTALS:

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

Toxic to bees: When used on outdoor ornamentals excluding coniferous trees (pine, fir, juniper, spruce, arborvitae, cedar, hemlock, cypress, yew, live Christmas trees), DO NOT apply during the crop blooming period or during the 9-day period before the crop blooms.

Under the DIRECTIONS FOR USE ON ORNAMENTAL DECIDUOUS AND CONIFEROUS TREES; TREE-INJECTION section:

TOXIC to bees, birds and mammals. This product is systemic and is transported upwards through the tree. Bees, birds and mammals can be exposed to residues in floral pollen and/or nectar, fruits, seeds or sap resulting from tree injections. EXCEPT FOR CONIFEROUS TREES, APPLICATION MUST BE MADE POST-BLOOM. Applying post-bloom reduces risk to pollinators.

Under the STORAGE section:

To prevent contamination store this product away from food or feed.

Under the DISPORAL section, statements should conform to DIR99-04 Disposal Statements for Control Product Labels.

IV) The following amendments required for the pellet-formulated commercial end use product label (Registration No. 29499) are contingent on the transfer of uses from the soluble powder product label (Registration No. 14225), which is proposed for cancellation.

- Remove all directions for airblast/mist blower applications, including associated high rates
- Add a statement limiting uses in farm woodlots, shelter belts, rights of way and municipal parks to spot treatments using hand-held equipment only

- ***Under the ENVIRONMENTAL PRECAUTIONS section, add the following:***

Observe buffer zones specified under DIRECTIONS FOR USE.

For applications on crops that are highly attractive to pollinators (cranberry, and outdoor ornamentals excluding coniferous trees), or when using managed bees for pollination services:

DO NOT apply during the crop blooming period or during the 9-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.

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

Avoid application when heavy rain is forecast.

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

- ***Under the DIRECTIONS FOR USE section, add the following:***

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 S572.1) fine classification. Boom height must be 60 cm or less above the crop or ground.

For outdoor uses, **DO NOT** apply with airblast or other mist-blower equipment.

DO NOT apply by air.

DO NOT allow effluent or runoff from greenhouses or mushroom houses containing this product to enter lakes, streams, ponds or other waters.

Buffer zones:

Spot treatments using hand-held equipment and soil drench or soil incorporation **DO NOT** require a buffer zone

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

Method of application	Crop	Buffer Zones (metres) Required for the Protection of:	
		Freshwater Habitat of Depths:	
		Less than 1 m	Greater than 1 m
Field sprayer	Tobacco	1	0

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

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

Under DIRECTIONS FOR USE ON FIELD CROPS:

Toxic to bees: For cranberry: DO NOT apply during the crop blooming period or during the 9-day period before the crop blooms.

For 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. When using managed bees for pollination services, DO NOT apply during the crop blooming period.

Under the DIRECTIONS FOR USE ON CHRISTMAS TREE PLANTATIONS, FARM WOODLOTS, TREE NURSERIES, SHELTER BELTS, RIGHT OF WAYS, MUNICIPAL PARKS (excluding National and Provincial Parks) section:

Toxic to bees: When used on pollinator attractive trees DO NOT apply during the tree blooming/pollen shedding period, or the 9 days before the tree blooming/pollen shedding period. This restriction excludes coniferous trees: pine, fir, juniper, spruce, arborvitae, cedar, hemlock, cypress, yew, live Christmas trees.

Appendix III Environmental Assessment

Table 1 Half-lives of acephate and methamidophos in soil, water and food sources for animals used in the current risk assessment

Media	Acephate		Methamidophos	
	Days	Reference (PMRA#)	Days	Reference (PMRA#)
Soil	3.5	1181142, 1181146, 1181138, 1208120	4.6	1181142, 1181146, 1181138, 1208120
Water	14.8	1162659	8	1162659
Food Sources (birds and mammals)	3.3	1930629	3.5	1930629

Table 2 Use pattern and EECs

End-use Product (Reg. No.)	Crop	Application Equipment	New Proposed Rates	Terrestrial EEC		Aquatic	
				Soil Exposure ¹ mg a.i./kg [mg MOM/kg] ² {mg combined a.s./kg} ³	Foliar Maximum Cumulative Application Rate ⁴ g a.i./ha	15 cm Water ⁵ mg a.i./L	EEC 80 cm Water ⁵ mg a.i./L
Orthene 97% Pellet Systemic Insecticide (29499)	Brussels sprouts; Cabbage; Cauliflower; Lettuce; Celery; Corn (seed or sweet); Cranberries ⁶ ; Peppers ⁷	Conventional ground application equipment	560 g a.i./ha × 2, 14-day interval	0.25 [0.11] {0.27}	t½(10d): 772 t½(3.3d):590	0.57	0.11
	Saskatoon berries	Soil injection probe	1.275 g a.i./ plant, max. 2.55 kg a.i./ha	1.13 [0.44] {1.13}	N/A	N/A	N/A
	Tobacco	Conventional ground application equipment;	563 to 825 g a.i./ha as needed, 7=day interval or as needed; max annual: 4489 g a.i./ha = (562.6) + (626.4) + (four applications of 825) g a.i./ha.	0.49 [0.096] {0.50}	t½(10d): 1978 t½(3.3d): 1070	1.62	0.30
Tomatoes	Transplant water; on cover crop (rye or wheat)/ soil; post plant	Transplant water; on cover crop (rye or wheat)/ soil; post plant	Maximum single application rate: 1125 g a.i./ha	0.50 [0.19] {0.50}	N/A	N/A	N/A
	Ornamentals, outdoors ⁸ ;	Mist blower /	900 g a.i./ha × 1 1312 g a.i. per 1000 L water	0.40 [0.15] {0.40}	N/A	N/A	N/A
				0.58	t½(10d): 1312	0.87	0.16

End-use Product (Reg. No.)	Crop	Application Equipment	New Proposed Rates	Terrestrial EEC		Aquatic	
				Soil Exposure ¹ mg a.i./kg {mg MOM/kg} ² {mg combined a.s./kg} ³	Foliar Maximum Cumulative Application Rate ⁴ g a.i./ha	15 cm Water ⁵ mg a.i./L	EEC 80 cm Water ⁵ mg a.i./L
	Christmas tree plantations, farm woodlots, tree nurseries, shelter belts, right of ways, and municipal parks (excluding National and Provincial Parks)	airblast	(mist blower) max annual rate of 1310 g a.i./ha	[0.22] {0.58}	t/2(3.3d): 1312		
	Trees injection	Hydraulic sprayer (ground boom); Max annual rate of 1310 g a.i./ha	637 g a.i./ 1000 L water	0.35 [0.15] {0.36}	784	0.73	0.14
Acecap 97 systemic insecticide implants (21568)		Injection	0.256 g a.i./cm dbh Once every 24 months	N/A	N/A	N/A	N/A
	Trees Pellet Implant cartridge	Implant cartridge	0.239 g a.i./cm tree dbh Optimum control of 10–12 weeks; no restriction specified on subsequent treatment	N/A	N/A	N/A	N/A

a.i.= active ingredient; combined a.s. = combined active substance (acephate + methamidophos); MOM = methamidophos; N/A = Not Applicable. EECs used in screening risk assessment are highlighted.

¹ Soil EEC calculated using soil half-lives of 3.5, 4.6 and 3.74 days for acephate, methamidophos and combined acephate + methamidophos respectively, assuming a soil bulk density of 1.5 g/cm³, and a 15 cm soil depth.

² Calculated from molecular ratio methamidophos/acephate (0.77) with assumption that 100% acephate application rate is an equivalent of 50% methamidophos rate.

³ Combined: calculated as acephate equivalent from active substance (acephate + methamidophos) half-life

⁴ Foliar EEC calculated using a default foliar half-life of 10 days and refined 3.3, and 3.5-day half-lives calculated by taking the average of the acephate and methamidophos foliar half-lives reported by Willis and McDowell (1987). The methamidophos EECs were adjusted to 40% of the acephate peak EEC. This corresponds to the 90th percentile confidence bound on the available mean methamidophos/acephate ratio (corrected for molecular weight) in various crops.

⁵ Aquatic EEC calculated using half-life of 14.8 for acephate and a direct overspray application to water bodies of different depths.

⁶ Rate rounded from 563 g a.i./ha to 560 g a.i./ha; the 14-day interval between application is considered a worst case scenario; a more realistic 45-day interval was used for the aquatic risk assessment scenario.

⁷ Rate rounded from 563 g a.i./ha to 560 g a.i./ha. Note that acephate can be used to control European corn borer on peppers at a rate of 825 g a.i./ha with 2 applications per year and a 14-day interval. EEC/RQ for this single crop/pest combination are not presented in this document; however, these are lower than the EEC/RQ calculated for tobacco.

⁸ Proposed for removal by HED because of concerns for potential exposure for drinking water.

⁹ Includes outdoor flowers, ornamentals, shrubs, trees, roses.

Table 3 Estimated acephate and methamidophos concentrations on bird and mammal food after acephate application to tobacco, vegetable crops, cranberries and ornamentals

Environmental Compartment	Fresh/Dry Weight Ratios	Maximum residue concentration		Mean residue concentration	
		Concentration Fresh Weight (on-field/off-field) mg a.i./kg	Concentration Dry Weight (on-field/off-field) mg a.i./kg	Concentration Fresh Weight (on-field/off-field) mg a.i./kg	Concentration Dry Weight (on-field/off-field) mg a.i./kg
Acephate on Tobacco: 562+626+(825x4) g a.i./ha, 7-day interval. Ground Boom Sprayer Fine - assuming a foliar dissipation of 10 days (Screening, worst case)					
short range grass	3.3	423.3 / 46.6	1396.8 / 153.6	150.3 / 16.5	496 / 54.6
long grass	4.4	193.8 / 21.3	852.8 / 93.8	63.3 / 7	278.5 / 30.6
broadleaf plants	5.4	239.3 / 26.3	1292.3 / 142.2	79.1 / 8.7	427.2 / 47
insects	3.8	166.1 / 18.3	631.3 / 69.4	114.7 / 12.6	435.9 / 47.9
grain and seeds	3.8	25.7 / 2.8	97.7 / 10.7	12.3 / 1.3	46.6 / 5.1
fruit	7.6	25.7 / 2.8	195.4 / 21.5	12.3 / 1.3	93.2 / 10.3
Methamidophos on Tobacco: 173+193+(254x4) g a.i./ha, 7-day interval. Ground Boom Sprayer Fine - assuming a foliar dissipation of 10 days (Screening, worst case)					
short range grass	3.3	130.4 / 14.3	430.3 / 47.3	46.3 / 5.1	152.8 / 16.8
long grass	4.4	59.7 / 6.6	262.7 / 28.9	19.5 / 2.1	85.8 / 9.4
broadleaf plants	5.4	73.7 / 8.1	398.1 / 43.8	24.4 / 2.7	131.6 / 14.5
insects	3.8	51.2 / 5.6	194.5 / 21.4	35.3 / 3.9	134.3 / 14.8
grain and seeds	3.8	7.9 / 0.9	30.1 / 3.3	3.8 / 0.4	14.4 / 1.6
fruit	7.6	7.9 / 0.9	60.2 / 6.6	3.8 / 0.4	28.7 / 3.2
Acephate on Tobacco: 562+626+(825x4) g a.i./ha, 7-day interval. Ground Boom Sprayer Fine - assuming a foliar dissipation of 3.3 days					
short range grass	3.3	229.1 / 25.2	756 / 83.2	81.4 / 8.9	268.5 / 29.5
long grass	4.4	104.9 / 11.5	461.6 / 50.8	34.3 / 3.8	150.7 / 16.6
broadleaf plants	5.4	129.5 / 14.2	699.4 / 76.9	42.8 / 4.7	231.2 / 25.4
insects	3.8	89.9 / 9.9	341.7 / 37.6	62.1 / 6.8	235.9 / 26
grain and seeds	3.8	13.9 / 1.5	52.9 / 5.8	6.6 / 0.7	25.2 / 2.8
fruit	7.6	13.9 / 1.5	105.8 / 11.6	6.6 / 0.7	50.4 / 5.5
Methamidophos on Tobacco: 169+188+(248x4) g a.i./ha, 7-day interval. Ground Boom Sprayer Fine - assuming a foliar dissipation of 3.5 days					
short range grass	3.3	70.6 / 7.8	232.9 / 25.6	25.1 / 2.8	82.7 / 9.1
long grass	4.4	32.3 / 3.6	142.2 / 15.6	10.6 / 1.2	46.4 / 5.1
broadleaf plants	5.4	39.9 / 4.4	215.5 / 23.7	13.2 / 1.5	71.2 / 7.8
insects	3.8	27.7 / 3	105.3 / 11.6	19.1 / 2.1	72.7 / 8
grain and seeds	3.8	4.3 / 0.5	16.3 / 1.8	2 / 0.2	7.8 / 0.9
fruit	7.6	4.3 / 0.5	32.6 / 3.6	2 / 0.2	15.5 / 1.7

Environmental Compartment	Fresh/Dry Weight Ratios	Maximum residue concentration		Mean residue concentration	
		Concentration Fresh Weight (on-field/off-field) mg a.i./kg	Concentration Dry Weight (on-field/off-field) mg a.i./kg	Concentration Fresh Weight (on-field/off-field) mg a.i./kg	Concentration Dry Weight (on-field/off-field) mg a.i./kg
Acceptate on Vegetable crops: 2x560 g a.i./ha (14 d int. between app.). Ground Boom Sprayer Fine - assuming a foliar dissipation of 3.3 days					
short range grass	3.3	126.2 / 13.9	416.4 / 45.8	44.8 / 4.9	147.9 / 16.3
long grass	4.4	57.8 / 6.4	254.2 / 28	18.9 / 2.1	83 / 9.1
broadleaf plants	5.4	71.3 / 7.8	385.2 / 42.4	23.6 / 2.6	127.4 / 14
insects	3.8	49.5 / 5.4	188.2 / 20.7	34.2 / 3.8	129.9 / 14.3
grain and seeds	3.8	7.7 / 0.8	29.1 / 3.2	3.7 / 0.4	13.9 / 1.5
fruit	7.6	7.7 / 0.8	58.3 / 6.4	3.7 / 0.4	27.8 / 3.1
Methamidophos on Vegetables: 2x171 g a.i./ha (14 d int. between app.). Ground Boom Sprayer Fine - assuming a foliar dissipation of 3.5 days					
short range grass	3.3	38.9 / 4.3	128.3 / 14.1	13.8 / 1.5	45.6 / 5
long grass	4.4	17.8 / 2	78.3 / 8.6	5.8 / 0.6	25.6 / 2.8
broadleaf plants	5.4	22 / 2.4	118.7 / 13.1	7.3 / 0.8	39.2 / 4.3
insects	3.8	15.3 / 1.7	58 / 6.4	10.5 / 1.2	40 / 4.4
grain and seeds	3.8	2.4 / 0.3	9 / 1	1.1 / 0.1	4.3 / 0.5
fruit	7.6	2.4 / 0.3	17.9 / 2	1.1 / 0.1	8.6 / 0.9
Acceptate on Ornamentals: 1x 637 g a.i./ha. Airblast - Late Season Fine - assuming a foliar dissipation of 3.3 days					
short range grass	3.3	136.3 / 80.4	449.9 / 265.4	48.4 / 28.6	159.8 / 94.3
long grass	4.4	62.4 / 36.8	274.7 / 162.1	20.4 / 12	89.7 / 52.9
broadleaf plants	5.4	77.1 / 45.5	416.2 / 245.6	25.5 / 15	137.6 / 81.2
insects	3.8	53.5 / 31.6	203.3 / 120	36.9 / 21.8	140.4 / 82.8
grain and seeds	3.8	8.3 / 4.9	31.5 / 18.6	3.9 / 2.3	15 / 8.9
fruit	7.6	8.3 / 4.9	62.9 / 37.1	3.9 / 2.3	30 / 17.7
Methamidophos on Ornamentals: 1x 466 g a.i./ha. Airblast - Late Season Fine - assuming a foliar dissipation of 3.5 days					
short range grass	3.3	99.7 / 58.8	329.1 / 194.2	35.4 / 20.9	116.9 / 69
long grass	4.4	45.7 / 26.9	200.9 / 118.5	14.9 / 8.8	65.6 / 38.7
broadleaf plants	5.4	56.4 / 33.3	304.5 / 179.6	18.6 / 11	100.6 / 59.4
insects	3.8	39.1 / 23.1	148.7 / 87.8	27 / 15.9	102.7 / 60.6
grain and seeds	3.8	6.1 / 3.6	23 / 13.6	2.9 / 1.7	11 / 6.5
fruit	7.6	6.1 / 3.6	46 / 27.2	2.9 / 1.7	22 / 13
Acceptate on Cranberries: 2x563 g a.i./ha (14 d int. between app.). Airblast - Early Season Fine - assuming a foliar dissipation of 3.3 days					
short range grass	3.3	126.9 / 93.9	418.6 / 309.8	45.1 / 33.3	148.7 / 110
long grass	4.4	58.1 / 43	255.6 / 189.1	19 / 14	83.5 / 61.8
broadleaf plants	5.4	71.7 / 53.1	387.3 / 286.6	23.7 / 17.5	128 / 94.7
insects	3.8	49.8 / 36.8	189.2 / 140	34.4 / 25.4	130.6 / 96.7
grain and seeds	3.8	7.7 / 5.7	29.3 / 21.7	3.7 / 2.7	14 / 10.3

Environmental Compartment	Fresh/Dry Weight Ratios	Maximum residue concentration		Mean residue concentration	
		Concentration Fresh Weight (on-field/off-field) mg a.i./kg	Concentration Dry Weight (on-field/off-field) mg a.i./kg	Concentration Fresh Weight (on-field/off-field) mg a.i./kg	Concentration Dry Weight (on-field/off-field) mg a.i./kg
fruit	7.6	7.7 / 5.7	58.6 / 43.3	3.7 / 2.7	27.9 / 20.7
Methamidophos on Ornamentals: 2x172 g a.i./ha. Airblast - Early Season Fine - assuming a foliar dissipation of 3.5 days					
short range grass	3.3	39 / 28.9	128.9 / 95.3	13.9 / 10.3	45.8 / 33.9
long grass	4.4	17.9 / 13.2	78.7 / 58.2	5.8 / 4.3	25.7 / 19
broadleaf plants	5.4	22.1 / 16.3	119.2 / 88.2	7.3 / 5.4	39.4 / 29.2
insects	3.8	15.3 / 11.3	58.2 / 43.1	10.6 / 7.8	40.2 / 29.8
grain and seeds	3.8	2.4 / 1.8	9 / 6.7	1.1 / 0.8	4.3 / 3.2
fruit	7.6	2.4 / 1.8	18 / 13.3	1.1 / 0.8	8.6 / 6.4
Acephate on Ornamentals: 1 x 1310 g a.i./ha. Airblast - Late Season Fine - assuming a foliar dissipation of 3.3 days					
short range grass	3.3	280.3 / 165.4	925.1 / 545.8	99.6 / 58.7	328.6 / 193.8
long grass	4.4	128.4 / 75.7	564.9 / 333.3	41.9 / 24.7	184.4 / 108.8
broadleaf plants	5.4	158.5 / 93.5	856 / 505	52.4 / 30.9	283 / 166.9
insects	3.8	110 / 64.9	418.2 / 246.7	76 / 44.8	288.7 / 170.3
grain and seeds	3.8	17 / 10	64.7 / 38.2	8.1 / 4.8	30.9 / 18.2
fruit	7.6	17 / 10	129.4 / 76.4	8.1 / 4.8	61.7 / 36.4
Methamidophos on Ornamentals: 1 x 404 g a.i./ha. Airblast - Late Season Fine - assuming a foliar dissipation of 3.5 days					
short range grass	3.3	86.4 / 51	285 / 168.2	30.7 / 18.1	101.2 / 59.7
long grass	4.4	39.6 / 23.3	174 / 102.7	12.9 / 7.6	56.8 / 33.5
broadleaf plants	5.4	48.8 / 28.8	263.7 / 155.6	16.1 / 9.5	87.2 / 51.4
insects	3.8	33.9 / 20	128.8 / 76	23.4 / 13.8	88.9 / 52.5
grain and seeds	3.8	5.2 / 3.1	19.9 / 11.8	2.5 / 1.5	9.5 / 5.6
fruit	7.6	5.2 / 3.1	39.9 / 23.5	2.5 / 1.5	19 / 11.2

Table 4 Summary of acephate and methamidophos residue concentrations in spruce and oak tree tissues and acephate and methamidophos residue concentrations normalized for the proposed application rate

Tree species	Application Rate mg a.i./cm dbh	Maximum Acephate Residue Concentration mg a.i./kg	Maximum Methamidophos Residue Concentration mg a.i./kg (MOM/ACP) ¹	Estimated Acephate Residue Concentration in Nectar or Pollen ²	Estimated Methamidophos Residue Concentration in Nectar or Pollen ²	Reference
Spruce needles (fw)	17	3.22	0.4 (16%)	0.97	0.12	PMRA# 2867223
Oak leaves ³	310	13	8 (80%)	0.215	0.132	PMRA# 2867228
Black spruce cones (fw)	270	4.04	0.78 (25%)	3.98	0.74	PMRA# 2867227

¹ MOM/ACP %: Corrected for molecular weight (MOM / (ACP * 0.77))

² Peak residue levels were normalised to the application rate by multiplying the measured residue level by the fraction of the label/study application rate. The normalized concentration in foliage were then divided by 50 to account for the estimated foliage: pollen/nectar concentration ratio. The normalized concentrations of the active ingredient in spruce cones were used in for the risk assessment as further refinements were not possible because no data on the relative concentrations of residues in this matrix vs in pollen or nectar were available.

³ The authors do not specify whether the residues are reported on a wet or dry weight basis; however, as the reference for the residue assessment methods (Richmond *et al.* 1979) does not involve desiccation, results are assumed to be for fresh weight leaves.

Table 5 Summary of pollinator risk assessment endpoints for acephate and methamidophos

Tier 1 or Higher Tier	Exposure	Endpoint Value Used in Current Assessment	Reference / Endpoints /Comment
Acephate			
Tier 1	Acute contact	LD ₅₀ = 1.2 µg a.i./bee	No change from PRVD2016-01
	Acute oral	LD ₅₀ = 0.18 µg a.i./bee	New endpoint (unpublished, referenced in PMRA# 2867217)
	14-d Chronic LD50	NOAEL: <0.0048 µg a.i./bee	PMRA# 2867217; Value was used quantitatively in this assessment (caged bees with dosed sugar solution)
Higher Tier	Lab	LOEC = 10 ppm; NOEC = 1 ppm	PMRA# 1598965, 2131268; Queen loss
	Lab	LOEC = 0.1 ppm	PMRA# 1598965, 2131268; Reduction in surviving brood
	IR	LOEC = 2.63	PMRA# 1598965, 2131268; alkali and alfalfa leaf cutter bee mortality (residues in bees determined in incidents)
	CFS	LOEC = 0.25 ppm	PMRA# 2550598; affected eggs, larvae and pupae

Tier 1 or Higher Tier	Exposure	Endpoint Value Used in Current Assessment	Reference / Endpoints /Comment
	CFS	NOEC = 0.5 ppm	PMRA# 2550598; no effect to adult survival
	CFS	LOEC = 1 ppm	PMRA# 2550598; reduced adult survival
	CFS	LOEC = 500 ppm	PMRA#2550595; effects to colony
Methamidophos			
Tier 1	Acute contact	LD ₅₀ = 1.37 µg a.i./bee	No change from PRVD2016-01

Lab = laboratory study; IR = Incident report; CFS = colony feeding study (colonies fed acephate mixed in sugar solution)

Table 6 Summary of bird and mammal risk assessment endpoints for acephate and methamidophos (corrected from those reported in PRVD2016-01)

Active substance	Acute Oral (mg a.i./kg bw)	Acute Dietary (mg a.i./kg bw)	Reproduction (mg a.i./kg bw)
Birds			
Acephate	Bobwhite quail: LD ₅₀ / 10 = 10.9	Bobwhite quail: LD ₅₀ / 10 = 7.48	Mallard duck: NOAEL= 0.44 LOAEL= 2.03
Methamidophos	Bobwhite quail: LD ₅₀ / 10 = 0.8	Dose not determined	Bobwhite quail: NOAEL = 0.32 LOAEL = 0.53
Mammals			
Acephate	Mouse (Meadow vole): LD ₅₀ / 10 = 32.1	N/A	Rat: NOAEL= 50 LOAEL= 500
Methamidophos	Rat: LD ₅₀ / 10 = 1.3	N/A	Rat: NOAEL= 0.5 LOAEL= 1.65

Table 7 Screening level risk assessment for birds and mammals associated with exposure to acephate following its use on tobacco

	Toxicity (mg ai/kg bw/d)	Feeding Guild (food item)	On-field EDE ¹ (mg ai/kg bw)	On-field RQ	Off-field RQ (11% drift)
Acephate on tobacco: 562 + 626 + (825 × 4) g a.i./ha, 7-day interval. Ground boom sprayer fine - assuming a foliar dissipation of 10 days					
Birds					
Small Bird (0.02 kg)					
Acute	10.90	Insectivore	160.99	15	1.6
Reproduction	0.440	Insectivore	160.99	364	40
Medium Sized Bird (0.1 kg)					
Acute	10.90	Insectivore	125.63	12	1.3
Reproduction	0.440	Insectivore	125.63	286	31
Large Sized Bird (1 kg)					
Acute	10.90	Herbivore (short grass)	81.15	8	0.8
Reproduction	0.440	Herbivore (short	81.15	184	20

	Toxicity (mg ai/kg bw/d)	Feeding Guild (food item)	On-field EDE ¹ (mg ai/kg bw)	On-field RQ	Off-field RQ (11% drift)
		grass)			
Mammals					
Small Mammal (0.015 kg)					
Acute	32.10	Insectivore	92.59	3	0.3
Reproduction	50.00	Insectivore	92.59	2	0.2
Medium Sized Mammal (0.035 kg)					
Acute	32.10	Herbivore (short grass)	179.58	6	0.6
Reproduction	50.00	Herbivore (short grass)	179.58	4	0.4
Large Sized Mammal (1 kg)					
Acute	32.10	Herbivore (short grass)	95.96	3	0.3
Reproduction	50.00	Herbivore (short grass)	95.96	2	0.2
¹ Estimated from maximum nomogram residues					

Table 8 Screening level risk assessment for birds and mammals associated with exposure to methamidophos following the use of acephate on tobacco

	Toxicity (mg ai/kg bw/d)	Feeding Guild (food item)	On-field EDE (mg ai/kg bw)	On-field RQ	Off-field RQ (11% drift)
Methamidophos on tobacco: 225+230+330x4) g a.i./ha, 7-day interval. Ground boom sprayer fine - assuming a foliar dissipation of 10 days					
Birds					
Small Bird (0.02 kg)					
Acute	0.80	Insectivore	64.39	80.49	8.85
Reproduction	0.320	Insectivore	64.39	201.23	22.14
Medium Sized Bird (0.1 kg)					
Acute	0.80	Insectivore	50.25	62.82	6.91
Reproduction	0.320	Insectivore	50.25	157.04	17.27
Large Sized Bird (1 kg)					
Acute	0.80	Herbivore (short grass)	32.46	40.58	4.46
Reproduction	0.32	Herbivore (short grass)	32.46	101.44	11.16
Mammals					
Small Mammal (0.015 kg)					
Acute	1.30	Insectivore	37.04	28.49	3.13
Reproduction	0.5	Insectivore	37.04	74.07	8.15
Medium Sized Mammal (0.035 kg)					
Acute	1.30	Herbivore (short grass)	71.83	55.26	6.08
Reproduction	0.5	Herbivore (short grass)	71.83	143.67	15.80
Large Sized Mammal (1 kg)					
Acute	1.30	Herbivore (short grass)	38.38	29.53	3.25
Reproduction	0.5	Herbivore (short grass)	38.38	76.77	8.44

Table 9 Most sensitive aquatic organism acephate and methamidophos endpoints, as reported in PRVD2016-01

Species	Exposure	Endpoint Value
Acephate		
Amphibian surrogate: Rainbow trout	Acute	LC ₅₀ /10 = 11 mg a.i./L
Fresh water: <i>Daphnia magna</i>	Chronic	NOEC = 0.15 mg a.i./L
Marine: Mysid shrimp	Chronic	NOEC = 0.58 mg a.i./L
Methamidophos		
Amphibian surrogate: Rainbow trout	Acute	LC ₅₀ /10 = 2.5 mg a.i./L
Fresh water: <i>Daphnia magna</i>	Acute	LC ₅₀ /2 = 0.013 mg a.i./L
Marine: Mysid shrimp	Acute	LC ₅₀ /2 = 0.5 mg a.i./L

Table 10 Risk assessment for the most sensitive aquatic organisms

Species	Exposure	Endpoint Value	Direct Overspray EEC (mg/L)	Direct Overspray RQ	Direct Overspray LOC Exceeded?	Drift (11%) EEC	Drift RQ	Drift LOC Exceeded ?
Acephate								
Amphibian surrogate: Rainbow trout	Acute	LC ₅₀ /10 = 11 mg a.i./L	1.623	0.15	No	0.179	0.016	No
Fresh water: <i>Daphnia magna</i>	Chronic	NOEC = 0.15 mg a.i./L	0.304	2	Yes	0.033	0.22	No
Marine: Mysid shrimp	Chronic	NOEC = 0.58 mg a.i./L	0.304	0.5	No	0.033	0.058	No
Methamidophos								
Amphibian surrogate: Rainbow trout	Acute	LC ₅₀ /10 = 2.5 mg a.i./L	0.0186	0.01	No	0.003	0.001	No
Fresh water: <i>Daphnia magna</i>	Acute	LC ₅₀ /2 = 0.013 mg a.i./L	0.0035	0.27	No	0.001	0.039	No
Marine: Mysid shrimp	Acute	LC ₅₀ /2 = 0.5 mg a.i./L	0.0035	0.01	No	0.001	0.001	No

Table 11 Acephate Pollinator Risk Quotients considering the empirical data available

Test Compound	Measured Concentration / Tissue (mg a.i./kg fw)	Risk Assessment Concentration* (mg a.i./kg fw)	Adult max. oral daily exposure (µg/bee)	Worker larvae max oral daily exposure (µg/bee)	Acute Adult Oral RQ	Chronic Adult Oral RQ
Acephate	Screening: Empirical data					
	3.22 in spruce leaves	P:3.22; N:3.22; R:0.032	0.94	0.4	5	> 196
	13 in oak leaves	P:13; N: 13; R: 0.13	3.8	1.61	21	> 791
	4.2 in spruce cones	P: 4.2; N: 4.2; R: 0.042	1.23	0.52	7	> 256
	Screening: Normalized empirical data					
	3.22 in spruce leaves	P: 48.7; N: 48.7; R: 0.487	14.22	6.02	79	> 2963
	13 in oak leaves	P: 10.735; N: 10.735; R: 0.107	3.14	1.33	17	> 653
	4.2 in spruce cones	P: 3.98; N: 3.98; R: 0.04	1.16	0.49	7	> 242
	Refined: Normalized data, accounting for expected residue level differences between foliage and pollen/nectar (Normalized/50)					
	3.22 in spruce leaves	P: 0.974; N: 0.974; R: 0.01	0.28	0.12	1.6	> 59.3
13 in oak leaves	P: 0.215; N: 0.215; R: 0.002	0.06	0.03	0.3	> 13.1	
Methamidophos	Screening: Empirical data					
	0.4 in spruce leaves	P: 0.4; N: 0.4; R: 0.004	0.12	0.05	1	> 35
	8 in oak leaves	P: 8; N: 8; R: 0.08	2.34	0.99	12	> 708
	0.78 in spruce cones	P: 0.78; N: 0.78; R: 0.008	0.23	0.1	1	> 69
	Screening: Normalized empirical data					
	0.4 in spruce leaves	P: 6; N: 6; R: 0.06	1.75	0.74	9	> 531
	8 in oak leaves	P: 6.6; N: 6.6; R: 0.066	1.93	0.82	10	> 584
	0.78 in spruce cones	P: 0.8; N: 0.8; R: 0.008	0.23	0.1	1	> 71
	Refined: Normalized data, accounting for expected residue level differences between foliage and pollen/nectar (Normalized/50)					
	0.4 in spruce leaves	P: 0.12; N: 0.12; R: 0.001	0.04	0.01	0.2	> 10.6
8 in oak leaves	P: 0.132; N: 0.132; R: 0.001	0.04	0.02	0	> 11.7	

*P= pollen; N= nectar; R=royal jelly

Table 12 EECs in plant tissues and screening assessment pollinator risk quotients associated with acephate uses in soil¹ (soil injection and drench)

Crop	Use Rate (g a.i./ha)	EEC in Diet (µg a.i./mg)	Adult Max Oral Daily Exposure (µg/bee)	Larvae Max Daily Exposure (µg/bee)	Acute Adult Oral RQ	Chronic Adult Oral RQ
Saskatoon berries	2550	0.002	0.54	0.25	3	> 113
Tobacco	1125	0.001	0.24	0.11	1	> 50
Tomatoes	900	0.001	0.19	0.09	1	> 40

¹ Concentrations in pollinator food sources were estimated using the equation: $10^{(0.95 \times (K_{ow}) - 2.05) + 0.82} \times (-0.0648 \times (K_{ow})^2) + 0.2431 \times (K_{ow}) + 0.5822 \times (1.5 / (0.2 + 1.5 \times (K_{oc}) \times 0.01)) \times 0.45 \times \text{Application Rate}$; where: Application Rate is expressed as kg a.i./ha, $K_{ow} = 0.126$, $K_{oc} = 2.7$.

Table 13 Toxic Substances Management Policy Considerations-Comparison to TSMP Track 1 criteria (As reported in PRVD2016-01)

TSMP Track 1 Criteria	TSMP Track 1 Criterion Value		Active Ingredient Endpoints (Acephate)	Transformation Products Endpoints (Methamidophos)
Toxic or toxic equivalent as defined by the <i>Canadian Environmental Protection Act</i> ¹	Yes		-	Yes
Predominantly anthropogenic ²	Yes		-	Yes
Persistence ³ :	Soil	Half-life ≥ 182 days	Half-life = 2d	Half-life = 0.5-36 d
	Water	Half-life ≥ 182 days	Half-life = 7 d	Half-life = 5.8 d
	Sediment	Half-life ≥ 365 days	Not available	Half-life
	Air	Half-life ≥ 2 days or evidence of long range transport	Half-life or volatilisation is not an important route of dissipation and long-range atmospheric transport is unlikely to occur based on the vapour pressure (2.26×10^{-4} Pa) and Henry's law constant (4.9×10^{-13} atm·m ³ ·mole ⁻¹).	Half-life or volatilisation is not an important route of dissipation and long-range atmospheric transport is unlikely to occur based on the vapour pressure (2.29×10^{-8} Pa) and Henry's law constant (1.6×10^{-11} atm·m ³ ·mole ⁻¹).
Bioaccumulation ⁴	Log $K_{ow} \geq 5$		Log $K_{ow} = -0.9$	Log $K_{ow} = -0.796$
	BCF ≥ 5000		Not available	Not available
	BAF ≥ 5000		Not available	Not available
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?			No, does not meet TSMP Track 1 criteria.	No, does not meet TSMP Track 1 criteria.

¹ All pesticides will be considered toxic or toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the toxicity criterion may be refined if required (in other words, all other TSMP criteria are met).

² The policy considers a substance "predominantly anthropogenic" if, based on expert judgement, its concentration in the environment medium is largely due to human activity, rather than to natural sources or releases.

³ If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment or air) then the criterion for persistence is considered to be met.

⁴ Field data (for example, BAFs) are preferred over laboratory data (for example, BCFs) which, in turn, are preferred over chemical properties (for example, log K_{ow}).

Figure 1 On-field risk quotients for birds exposed to acephate; using mean estimated residues

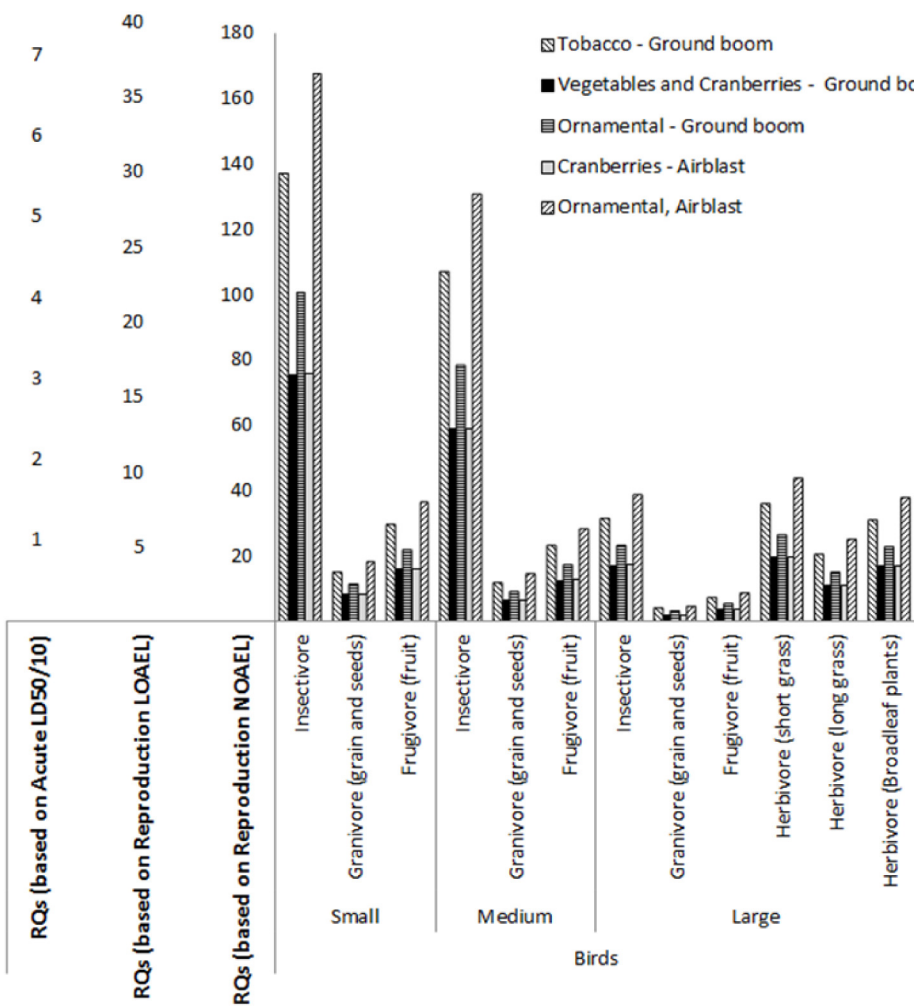


Figure 2 On-field risk quotients for birds exposed to methamidophos following the use of acephate on various crops; using mean estimated residues

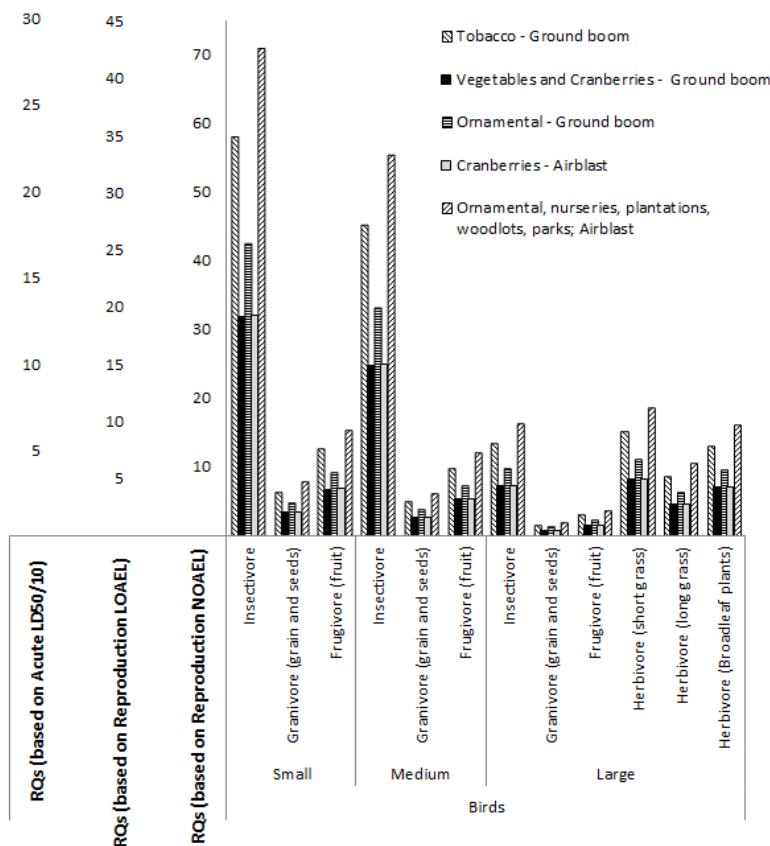


Figure 3 On-field reproduction NOAEL risk quotients for small insectivorous birds associated with the acephate EECs. Crops treated with hydrolic sprayers (ground boom)

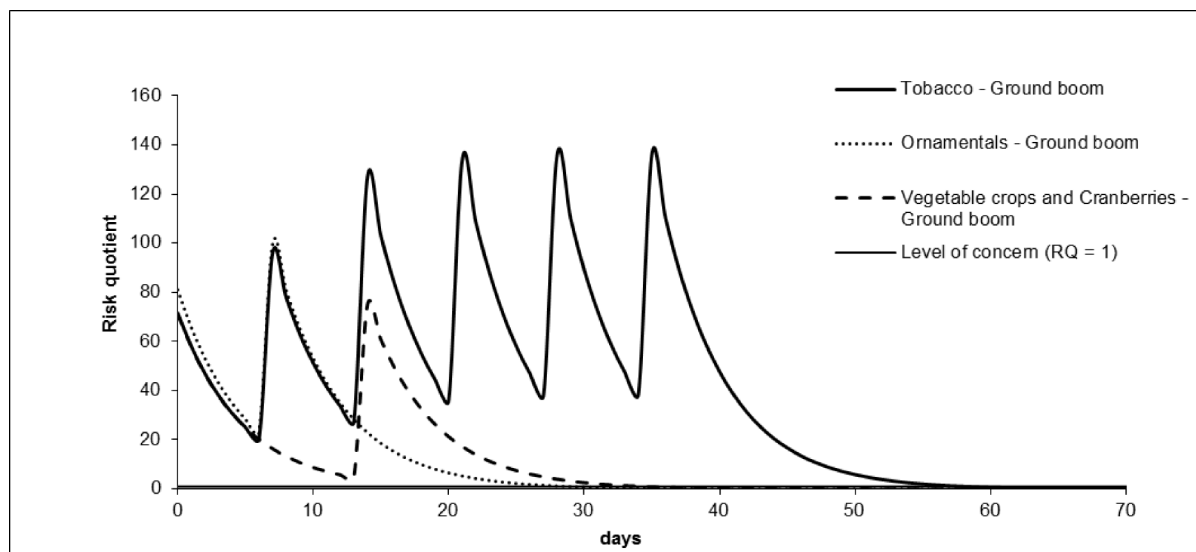


Figure 4 On-field reproduction NOAEL risk quotients for small insectivorous birds associated with the acephate EECs. Crops treated with mist blowers (airblast)

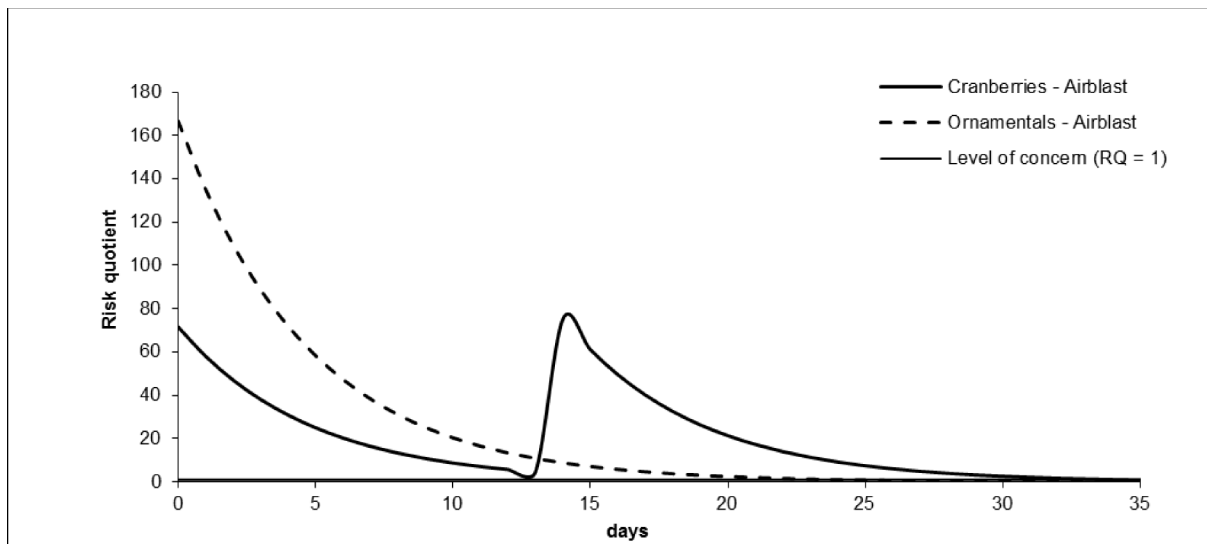


Figure 5 On-field reproduction NOAEL risk quotients for small insectivorous birds associated with the methamidophos EECs. Crops treated with hydrolic sprayers (ground boom)

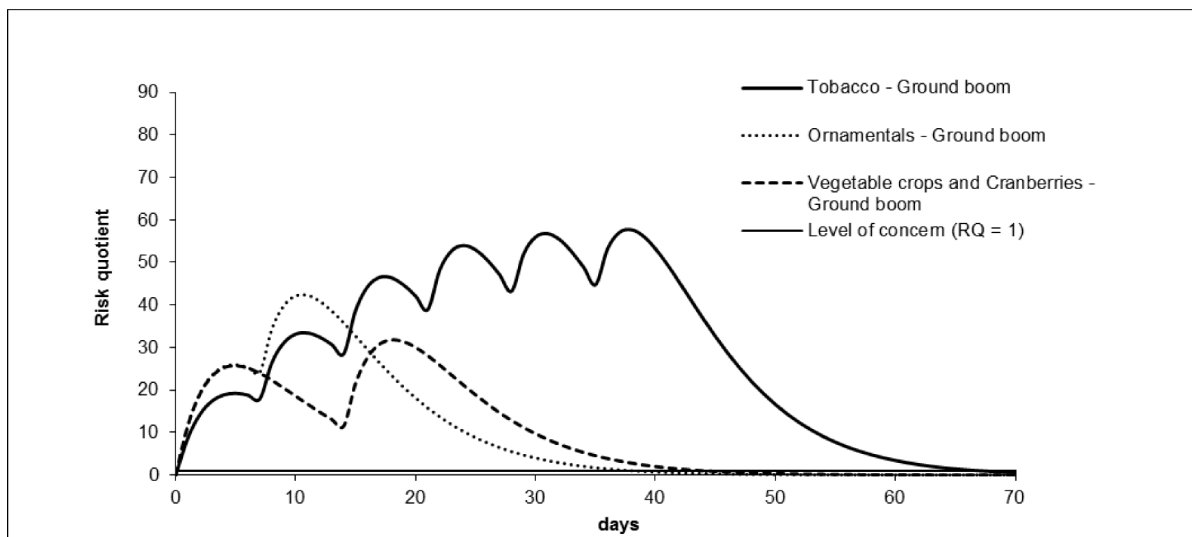


Figure 6 On-field reproduction NOAEL risk quotients for small insectivorous birds associated with the methamidophos EECs. Crops treated with mist blowers (airblast)

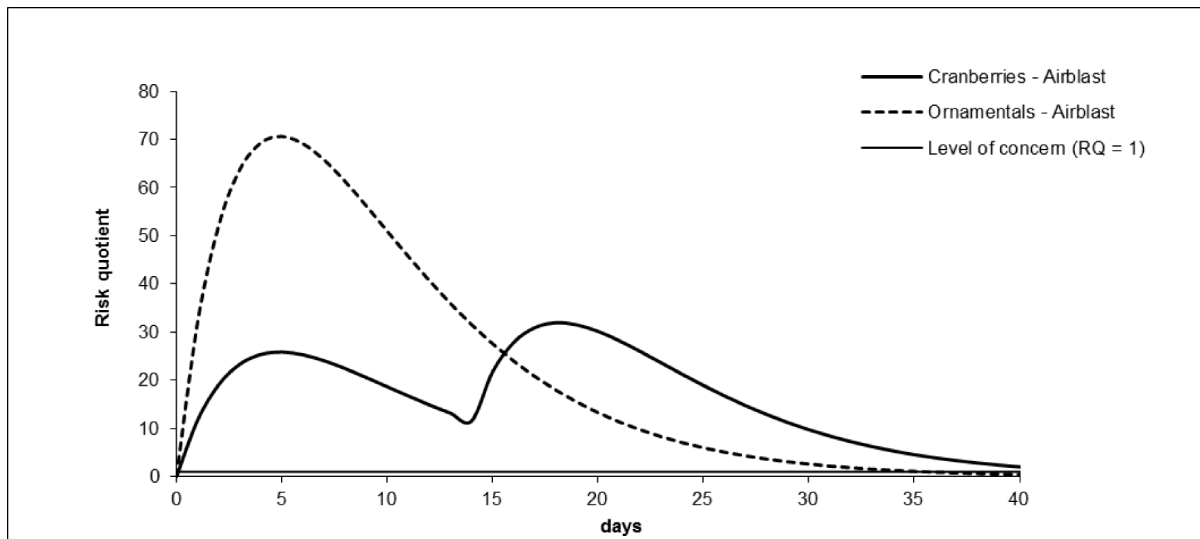


Figure 7 Off-field risk quotients for birds exposed to acephate

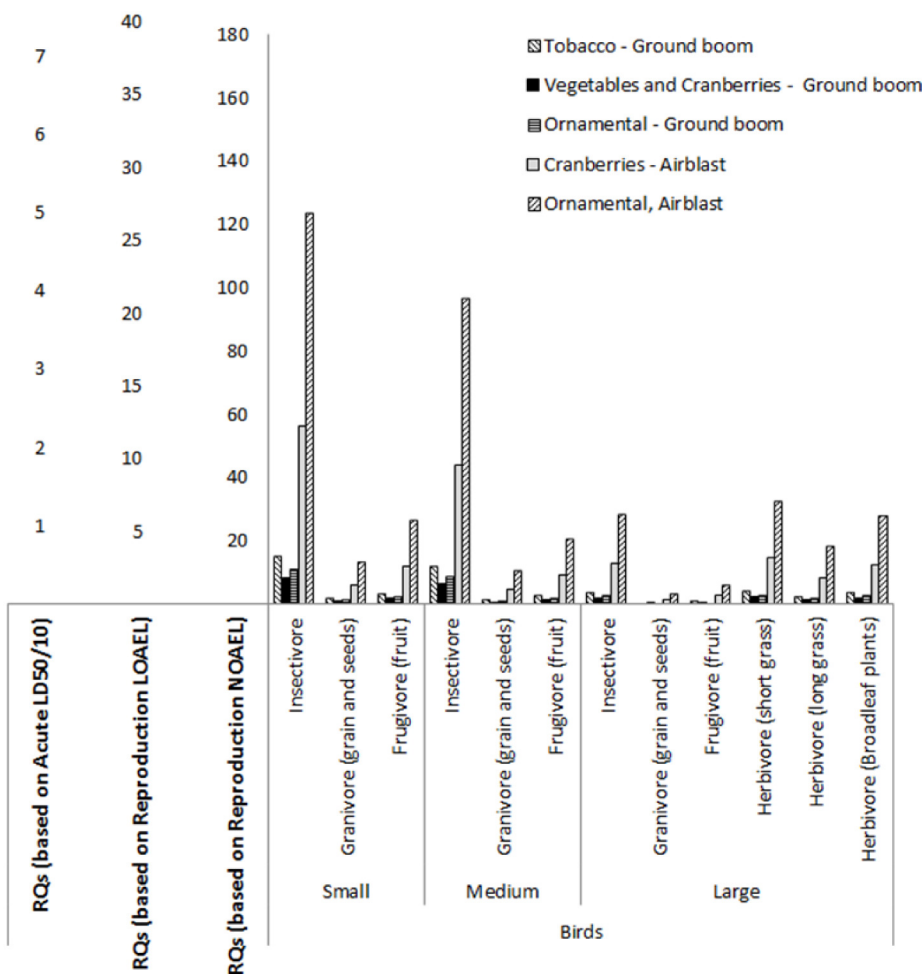


Figure 8 Off-field risk quotients for birds exposed to methamidophos following the use of acephate on various crops

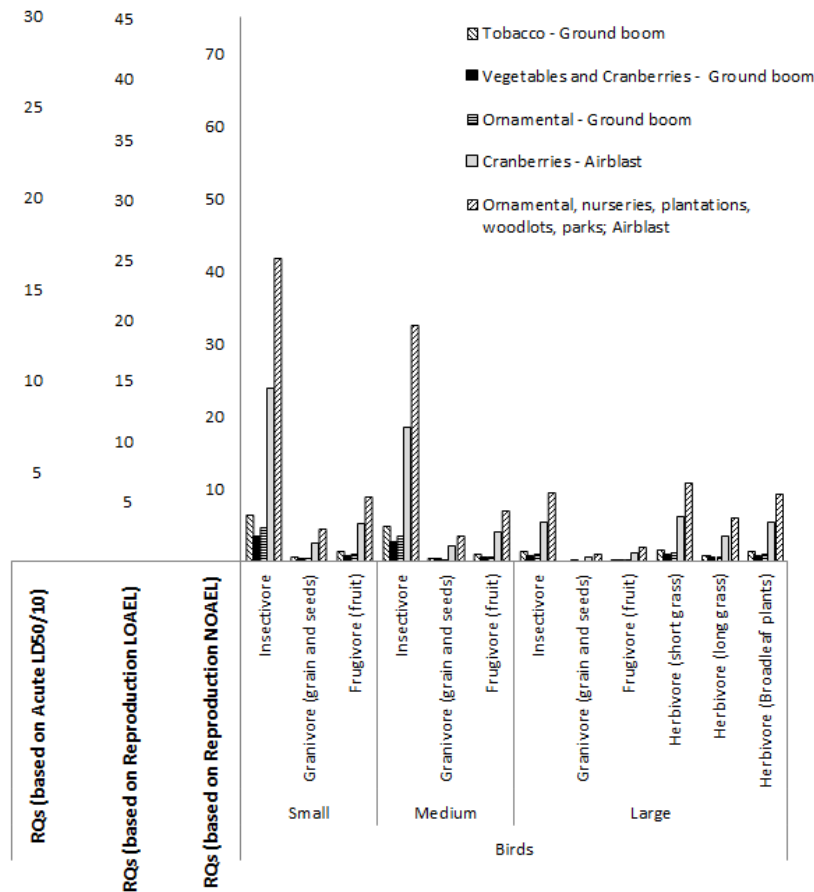


Figure 9 Off-field reproduction NOAEL risk quotients for small insectivorous birds associated with the acephate EECs. Crops treated with hydrolic sprayers (ground boom)

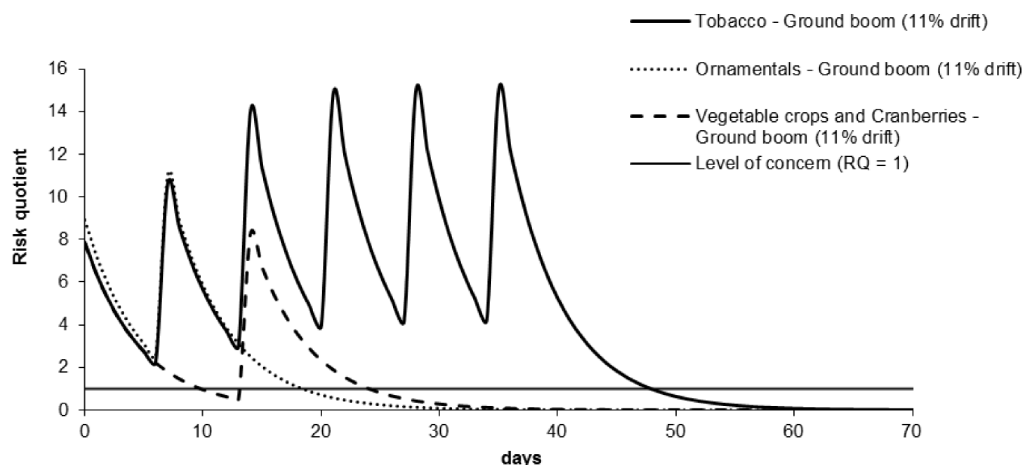


Figure 10 Off-field reproduction NOAEL risk quotients for small insectivorous birds associated with the acephate EECs. Crops treated with mist blowers (airblast)

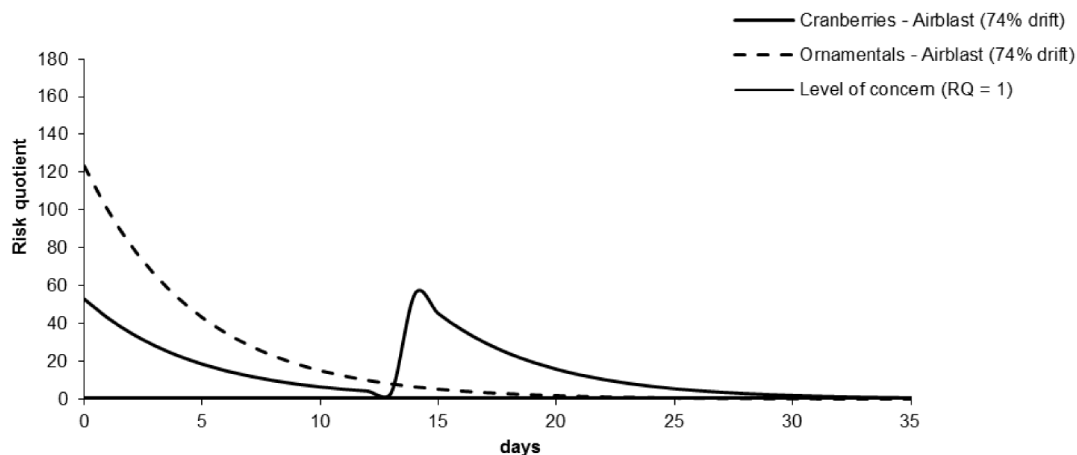


Figure 11 Off-field reproduction NOAEL risk quotients for small insectivorous birds associated with the methamidophos EECs. Crops treated with hydrolic sprayers (ground boom)

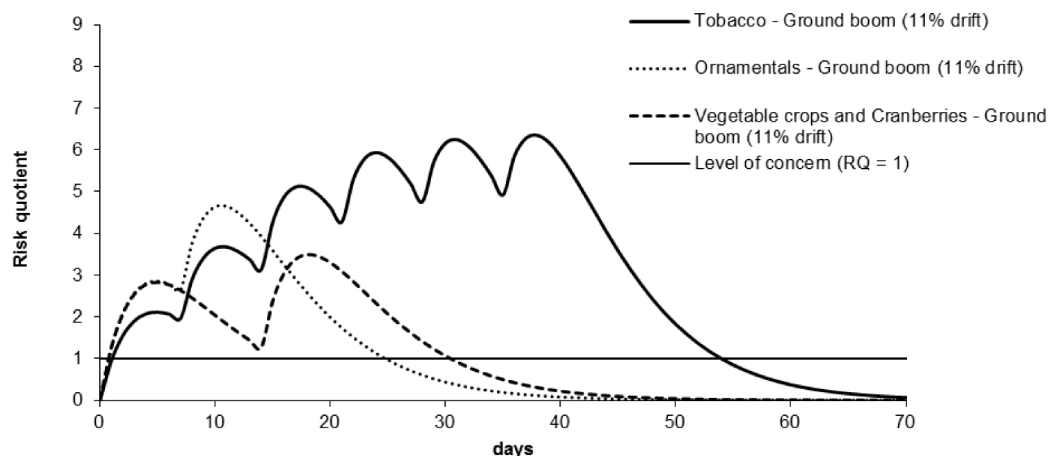


Figure 12 Off-field reproduction NOAEL risk quotients for small insectivorous birds associated with the methamidophos EECs. Crops treated with mist blowers (airblast)

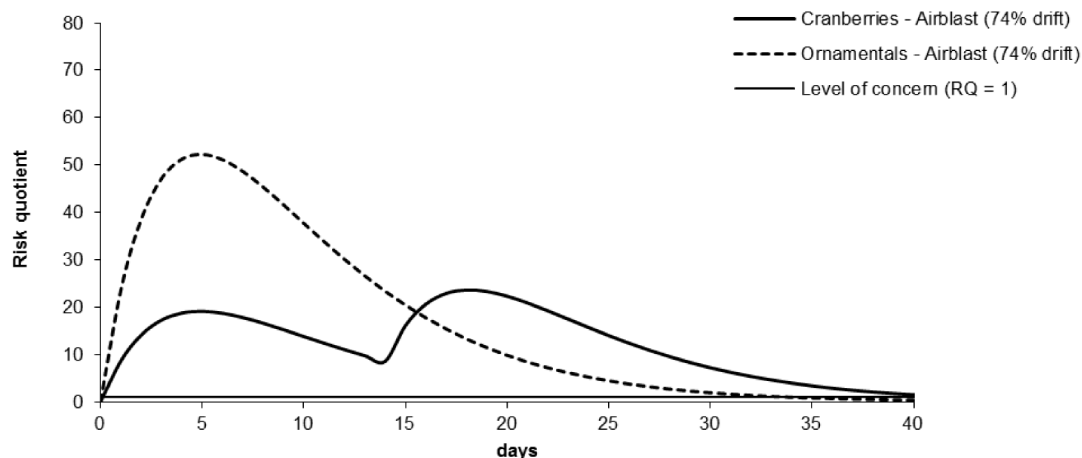


Figure 13 Estimated concentrations of acephate and methamidophos in soil. The vertical blue line represents the time of flooding. Concentrations in soil at that time were used as a water input to estimate flooding water EECs (Fig. 14)

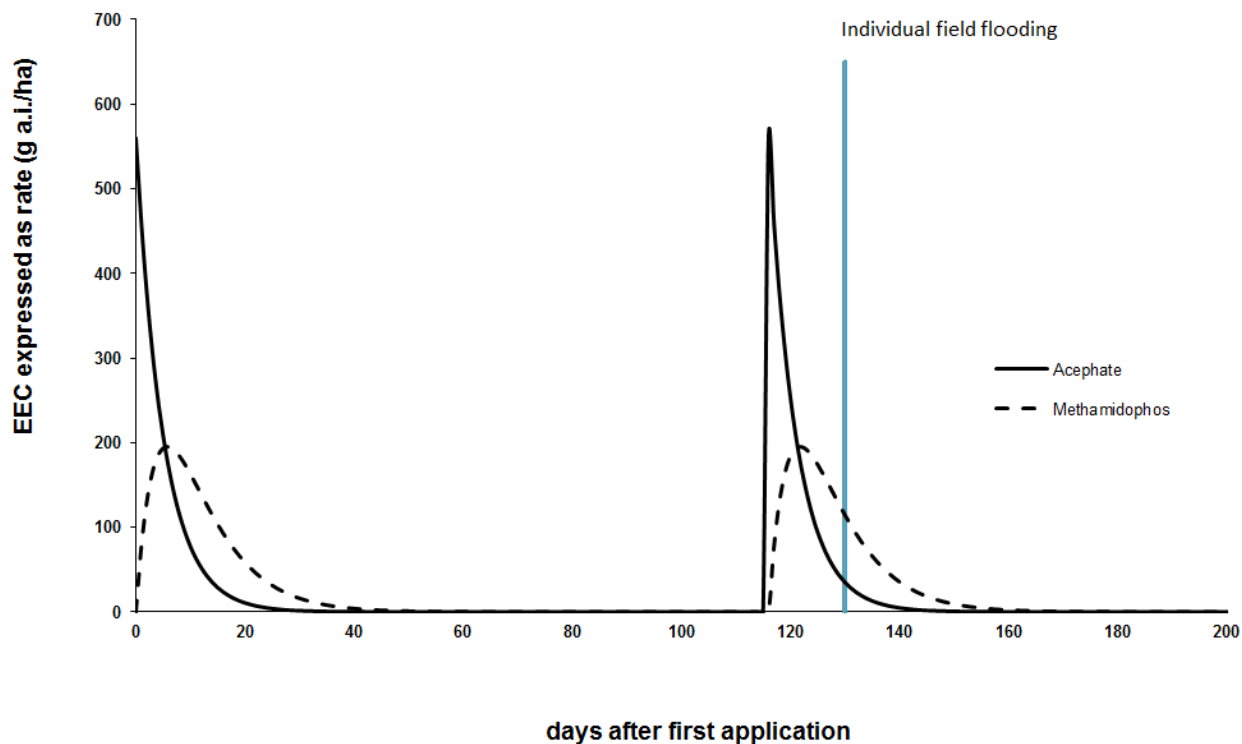


Figure 14 Estimated concentrations of acephate and methamidophos in flood water. The vertical red line represents the time the last field was harvested

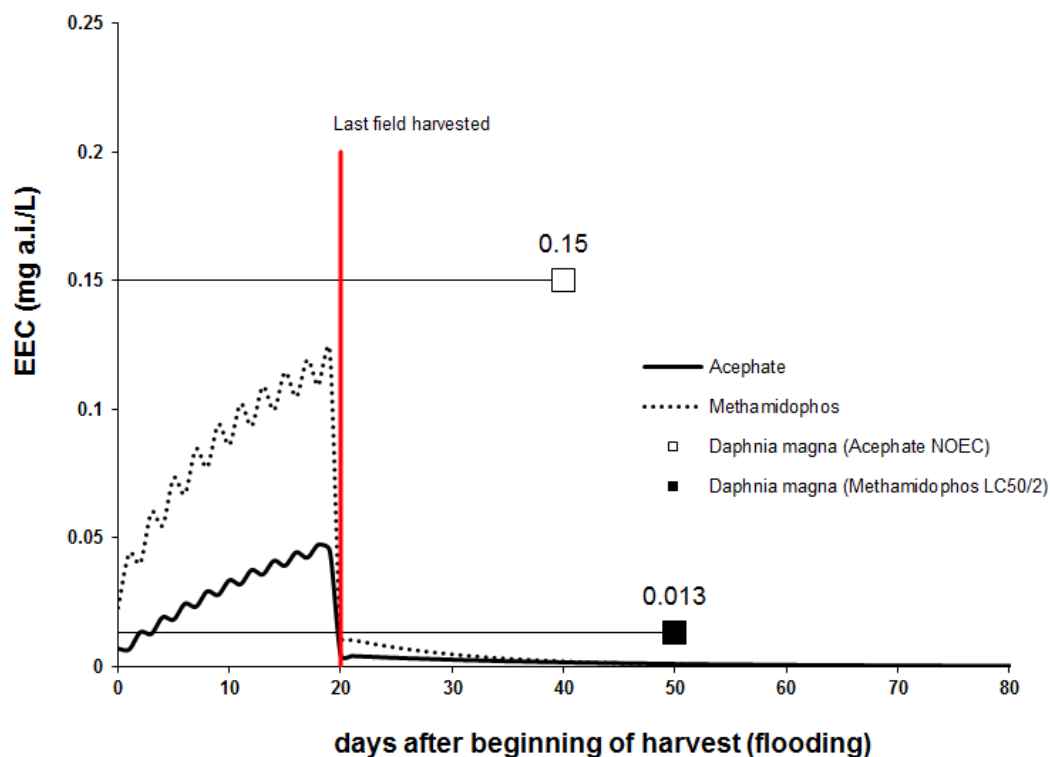


Figure 15 Measured acephate concentrations in spruce foliage after treatment at a rate of 17 mg a.i./cm diameter tree

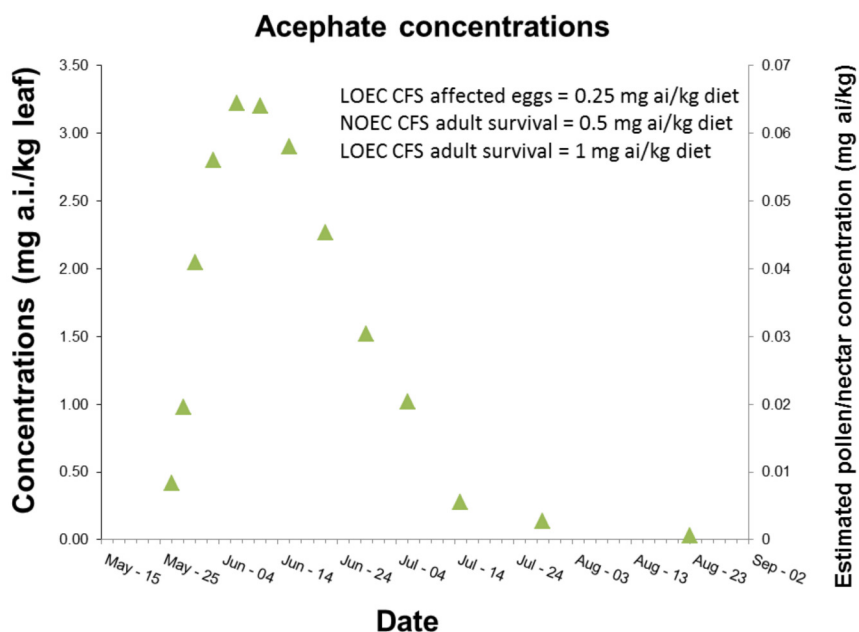


Figure 16 Measured acephate concentrations in oak foliage after treatment at a rate of 310 mg a.i./tree

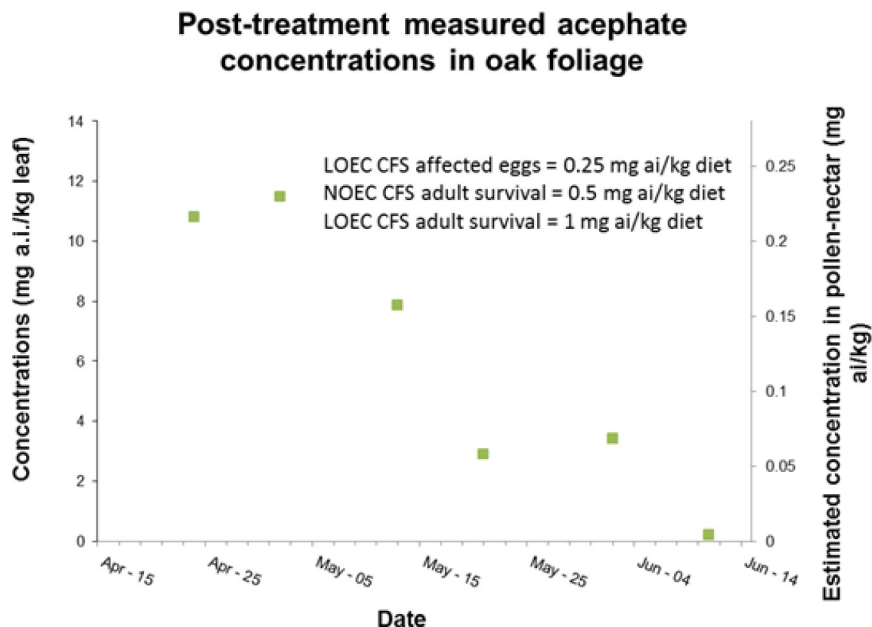


Figure 17 Risk to birds associated with peak acephate residue concentrations measured in various tree tissues (spruce needles, spruce cones and oak leaves) as surrogate for bird and mammal food. Residue concentrations were not adjusted for differences between the study application rate and the Canadian acephate product application rates.

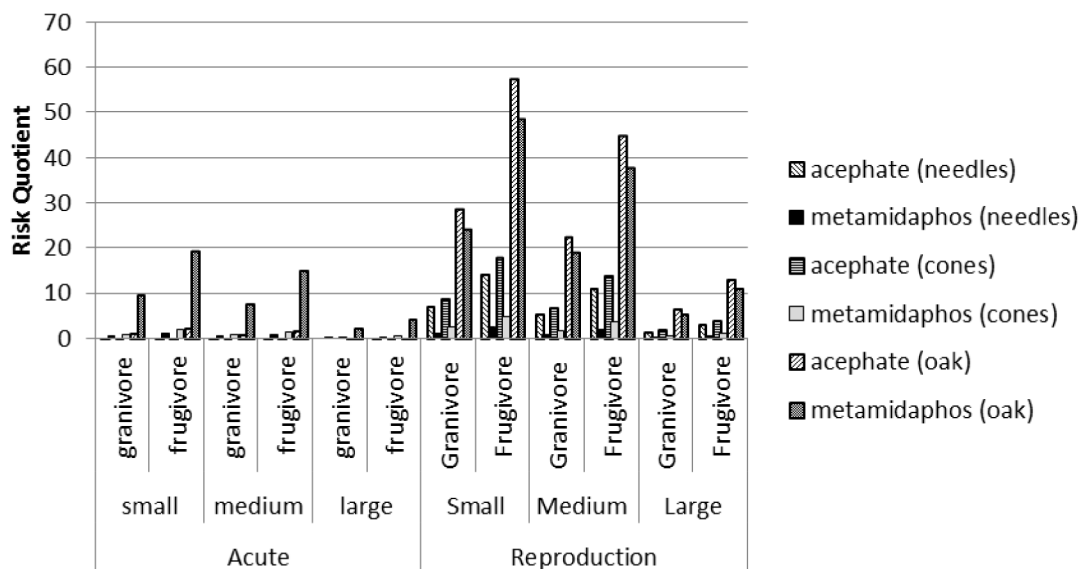


Figure 18 Risk to mammals associated with peak methamidophos residue concentrations measured in various tree tissues (spruce needles, spruce cones and oak leaves) as surrogate for bird and mammal food. Residue concentrations were not adjusted for differences between the study application rate and the Canadian acephate product application rates.

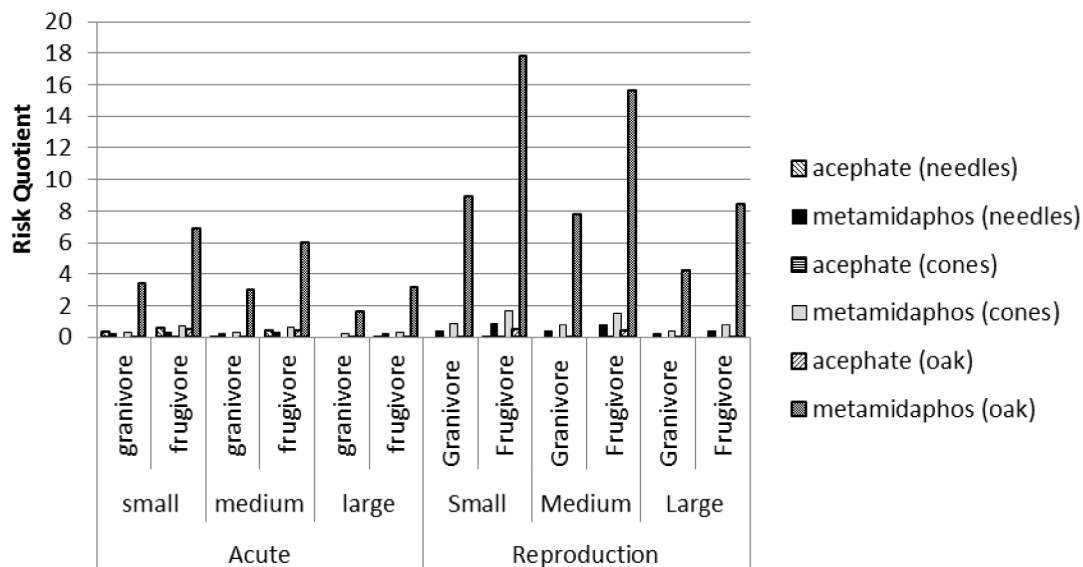
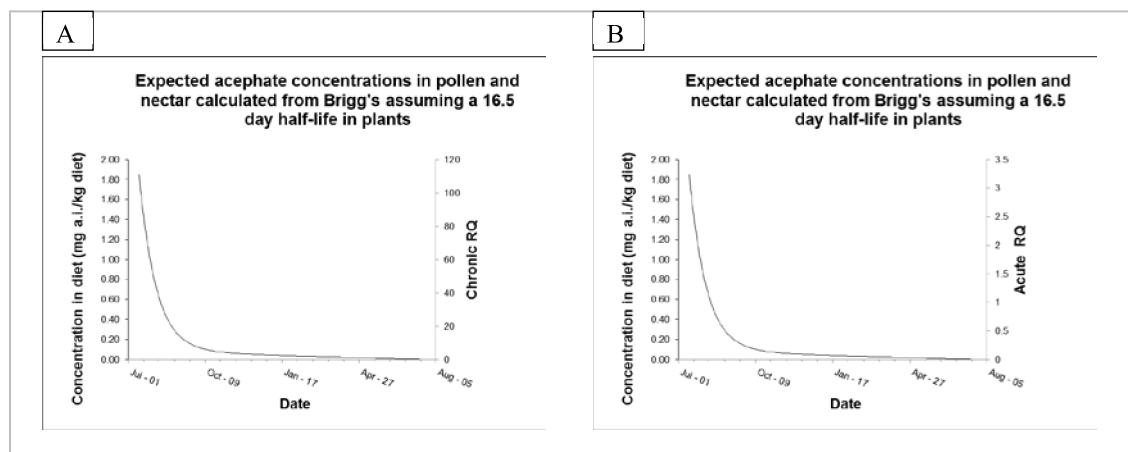


Figure 19 Dissipation of acephate concentrations in honey bee diet after soil application at a rate of 2.55 kg a.i./ha on July 15th (refined risk assessment)



References

Information Considered in the Environmental Assessment

Studies/Information Provided by the Registrant

PMRA Document Number	Reference
1162659	1995. Science Reviews: Basic Review: EED: Date Of Cover Letter 94.07.22/ Date Of Document 95.03.15/Orthene 75% WP: Rebuttal Of EED Review - Environmental Assessment Of Orthene: Response To Concerns Of Environment Canada, July 22 1994: Sub No. 89-1258 (*Handwritten Notations also*). DACO: 12.1
1181138	1993. Orthene 75/Acephate: Discussion Of Fate In Soil And Water And Potential For Leaching. [Orthene 75sp;Subn#89-1258;Regn#14225;Supplement: 10 September 1993]. DACO: 8.1
1181142	1996. Tomen Agro Inc., An Aerobic Soil Metabolism Study With [14c]Acephate. N.Lentz. Study Completed: October 2,1996. (6792-96-0070-Ef-001). [Orthene 75sp;Subn#89-1258;Regn#14225]. DACO: 8.2.3.4.2
1181146	1996. An Aerobic Soil Metabolism Study With [¹⁴ C]Acephate Preliminary Study Interim Report. Appendix 4. (6792-96-0070-Md;96-0070). [Orthene 75sp;Subn#89-1258;Regn#14225]. DACO: 8.2.3.4.2
1188712	1995. Environmental Assessment Of Orthene: Response To Concerns Of Environment Canada, July 22,1994. Cantox Inc. Consultants In Toxicology Health And Environmental Sciences. Prepared For: Tomen Pacific Agro Company, 444 Market Street, Suite 1060, San Fransico, Ca 94111. March 15,1995. (B-13) [Appendices A-E + Additional References Used In The Preparation Of The Response To The Concerns Of Environment Canada Regarding The Use Of Orthene On Agricultural Crops, Reference Sections A-Z] [Orthene]. DACO: 8.6, 9.9
1208120	1972. Orthene Soil Metabolism- Laboratory Studies - Supplement, J.B. Leary, December 27, 1972 (741.10). DACO: 8.2.3.1
1208137	1979. One-Generation Reproduction Study- Mallard Duck- Orthene Technical, Final Report, December 5, 1979 (SX-1032;162-107). DACO: 9.6.3.1

Additional Information Considered

PMRA Document Number	Reference
1598965	2006. Reregistration Eligibility Decision for Acephate, www.epa.gov/pesticides/cumulative . DACO: 12.5
1658043	US EPA, EFED Response to Comments submitted to the Methamidophos Docket during the 60-Day comment period on the EFED Methamidophos RED chapter. DACO: 12.5.8,12.5.9
1930629	1987. Pesticide persistence on foliage. Reviews of Environmental Contamination and Toxicology. DACO: 4.8
2131268	2006. Finalization of Interim Reregistration Eligibility Decisions (IREDs) and Interim Tolerance Reassessment and Risk Management Decisions (TREDs) for the Organophosphate Pesticides, and Completion of the Tolerance Reassessment and Reregistration Eligibility Process for the Organophosphate Pesticides. DACO: 12.5
2550595	1991. Doses and residues of acephate baits used to eradicate undesirable honey bees: A hazard assessment. - Bulletin of Environmental Contamination and Toxicology, Volume 47, Pages 422 to 427. DACO: 9.9
2550598	1987. Acephate Residues After Pre-Blossom Treatments: Effects on Small Colonies of Honey Bees - Bulletin of Environmental Contamination and Toxicology, Volume 38, Pages 594 to 601. DACO: 9.9
2867217	1987. Assessment of chronic toxicity of selected insecticides to honeybees. DACO: 9.2.4.2,9.2.4.4
2867223	1977. Uptake, translocation and metabolism of C-14 acephate in spruce trees. DACO: 8.2.4
2867227	1992. First- and second-year effects of acecap implants against cone insects of black spruce. DACO: 8.3.4
2867228	1988. Suppression of Gypsy Moth (Lepidoptera: Lymantriidae) Populations on Oak Using Implants or Injections of Acephate and Methamidophos. DACO: 8.3.4
2867230	1979. Brain Cholinesterase Activities of Passerine Birds in Forests Sprayed with Cholinesterase Inhibiting Insecticides. DACO: 9.6.5
2867231	1984. Brain cholinesterase activity and brain and liver residues in wild birds of a forest sprayed with acephate. DACO: 9.6.5