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Re-evaluation Decision

RVD2018-11

# Chlorothalonil and Its Associated End-use Products for Agricultural and Turf Uses

*Final Decision*

*(publié aussi en français)*

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## Re-evaluation Decision

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

Chlorothalonil is a contact and protectant fungicide with a multi-site mode of action. It controls a broad range of fungal diseases on a large number of field and orchard crops, conifers, greenhouse vegetables, greenhouse and outdoor ornamentals and turf. In agriculture, chlorothalonil is applied by both aerial and ground application equipment. This document will focus on agricultural and turf uses. Currently registered products containing chlorothalonil are listed in Appendix I.

Chlorothalonil is also used as a material preservative in paint; however, the PMRA plans to publish a separate document in the future examining the material preservative use of chlorothalonil. Further details may be found in the published document: (REV2018-02 *Approach for the Re Evaluation of Pesticides Used as Preservatives in Paints, Coatings and Related Uses*).

The regulatory approach for the re-evaluation of chlorothalonil was first presented in Proposed Re-evaluation Decision PRVD2011-14, *Chlorothalonil*. The amended proposed re-evaluation decision was presented in Re-evaluation Note, REV2016-06, *Chlorothalonil Amendment to the Proposed Re-evaluation Decision*.<sup>1</sup>

Comments received during the consultation process were taken into consideration. These comments and new data/information resulted in revisions to some parts of the risk assessments (see the Science Evaluation Update) and subsequently in some changes to the proposed regulatory decision as described in PRVD2011-14 and REV2016-06. Appendix II of this document summarizes comments received during consultation periods and provides the PMRA's response.

This document presents the re-evaluation decision<sup>2</sup> describing this stage of the PMRA's regulatory process for the re-evaluation of chlorothalonil and summarizes the Agency's decision and the reasons for it. A reference list for all data used as the basis for the re-evaluation decision is included in this document, as well as in PRVD2011-14 and REV2016-06.

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<sup>1</sup> "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

<sup>2</sup> "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

## **Regulatory Decision for Chlorothalonil**

The PMRA has completed the re-evaluation of chlorothalonil. Under the authority of the *Pest Control Products Act*, the PMRA has determined that continued registration of products containing chlorothalonil is acceptable. An evaluation of available scientific information found that most uses of chlorothalonil products meet current standards for protection of human health or the environment when used according to the conditions of registration, which include required amendments to label directions. Certain uses of chlorothalonil will be cancelled to address potential risks of concern for human health. Risk mitigation measures, as summarized below as well as outlined in Appendix III, are required for all end-use products.

### **Risk Mitigation Measures**

Registered pesticide product labels include specific instructions for use. Directions include risk reduction measures to protect human health and the environment. These directions must be followed by law. The key risk-reduction measures required are summarized below. Refer to Appendix III for details.

#### **Human Health**

- Cancellation of uses on greenhouse cut flowers, greenhouse pachysandra, and field grown roses (for cut flowers)
- All chlorothalonil products currently registered as dry flowable or water dispersible granules must be packaged in water soluble packaging.
- Additional measures to mitigate exposure of mixers/loaders/applicators, including personal protection equipment and/or engineering controls.
- Additional measures to mitigate exposure of postapplication workers, including reduced number of applications and restricted-entry intervals
- Additional label statements to clarify use directions.
- Standard precautionary label statement to mitigate a potential drift into residential areas

#### **Environment**

- Revised buffer zones
- Requirement for a vegetative filter strip

### **International Context**

Chlorothalonil is currently acceptable for use in member countries from the Organisation for Economic Co-operation and Development (OECD), including the United States, Australia and member states of the European Union. No decision by an OECD member country to prohibit all uses of chlorothalonil for health or environmental reasons has been identified at this time. Chlorothalonil is under registration review at the United States Environmental Protection Agency (USEPA).

## Next Steps

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

Please note that water soluble packaging is required for all chlorothalonil products registered as dry flowable or water dispersible granules. Should registrants of these specific products wish to keep their chlorothalonil registration, an application to register a new product in water soluble packaging is required as soon as possible so that the new formulation will be approved and available for sale no later than 24 months after the publication date of this decision document. Additional label requirements are outlined in Appendix III.

## Other Information

Any person may file a notice of objection<sup>3</sup> regarding this decision on chlorothalonil within 60 days from the date of publication of this re-evaluation decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Canada.ca website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

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<sup>3</sup> As per subsection 35(1) of the *Pest Control Products Act*





# Science Evaluation Update

## 1.0 Revised Health Risk Assessment

### 1.1 Toxicology Assessment for Chlorothalonil

Based on the comments received for PRVD2011-14, *Chlorothalonil* and REV2016-06, *Chlorothalonil: Amendment to the Proposed Re-evaluation Decision*, further refinements to the Toxicology Reference Values for dermal risk assessment were made and are reflected in Appendix IV.

The 21-day dermal study in rats, with a NOAEL (no observed adverse effect level) of 600 mg/kg bw/day, was determined to be appropriate for the short-term dermal risk assessment, with a target margin of exposure (MOE) of 100. Occupational dermal risk assessments of intermediate- and long-term durations continue to be based on the rat 90-day and 2-year studies, with a NOAEL (no observed adverse effect level) of 1.5 mg/kg bw/day and a target MOE of 100.

The cancer risk assessment approach has not changed from that presented in PRVD2011-14.

### 1.2 Risks in Residential and Other Non-Occupational Environments

Residential handler exposure is not expected as there are no domestic-class products containing chlorothalonil registered in Canada. There is, however, a potential for exposure to chlorothalonil residues on commercially treated turf (golfers) and plants, and to spray drift from agricultural applications (bystanders).

As indicated in REV2016-06, potential risks to individuals from pick-your-own activities and to bystanders are not of concern. Potential risks for golfers and individuals handling retail plants are not of concern under the revised conditions of use (Appendix V, Table 1 and 2).

For bystanders, potential aggregate non-cancer and cancer risks, where exposure from food and drinking water was combined with possible inhalation exposure from drift, are not of concern (Appendix V, Table 3).

For golfers and individuals handling retail plants (Appendix V, Table 3), non-cancer aggregate risk assessments were not required, as a common endpoint of concern was not identified for the relevant routes of exposure. The potential aggregate cancer risk is not of concern for individuals handling retail plants when combined with dietary exposure. For golfers, the aggregate cancer risk estimates ( $2 \times 10^{-6}$ ) slightly exceed the PMRA's Level of Concern ( $1 \times 10^{-6}$ ) when combined with dietary exposure, however, this is considered acceptable given the conservatism in the input values used in both the dietary and golfer assessments, including:

- Monitoring data used in the dietary exposure assessment are based on the current registered use pattern. As a result of the re-evaluation whereby the maximum number of applications is reduced, these levels are expected to be lower.

- For the golfer assessment, peak chlorothalonil residues are assumed. Chlorothalonil residues dissipate over time and golfers will not be exposed to the peak residues every time they play golf. Furthermore, conservative default values for exposure duration are used (e.g., 63 years for adults and 5 years for children and youth).

### **1.3 Occupational risk from handling chlorothalonil**

#### **1.3.1 Mixer/Loader/Applicator**

Occupational risk assessments from handling chlorothalonil consider exposure to workers who mix, load, and apply the pesticide in agricultural settings. The risk assessments for workers mixing, loading, and applying chlorothalonil were revised based on new exposure data and information provided during the comment period for REV2016-06. Resulting potential non-cancer and cancer risk estimates are not of concern provided that additional mitigation measures are followed, which includes reduced number of applications, the use of personal protective equipment and/or engineering controls (Appendix VI, Tables 1a – 5b).

#### **1.3.2 Postapplication Workers**

Postapplication risk assessments consider exposure to workers entering treated areas. The postapplication risk assessment for chlorothalonil was revised based on new data and updated use information provided by the registrants and stakeholders during the comment periods for PRVD2011-14 and REV2016-06. Mitigation measures proposed by registrants and stakeholders were also considered. These data and the revised risk assessment are presented in Appendix VII.

Target MOEs for certain uses of chlorothalonil are achieved when revised conditions of use and risk reduction measures, such as restricted-entry intervals (REIs), are considered. The revised conditions of use are presented in Appendix III, Table 1. The uses acceptable for continued registration are:

Asparagus, highbush blueberry, lowbush blueberry, carrot, celery (field and seedbed), cherry (sweet and sour), peach, nectarine, chickpea, broccoli, Brussels sprouts, cabbage, cauliflower, conifers (outdoor and nursery bed), sweet corn, cranberry, cucurbits, evening primrose, ginseng, hazelnut, lentil, mushroom, dry bulb onion, green onion, greenhouse ornamentals (except cut flowers), outdoor ornamentals (except cut flowers), outdoor ornamentals (cut flowers other than roses), outdoor roses (not grown for cut flowers), outdoor pachysandra, parsnip, dry pea, potato, strawberry, tomato, wheat, turf

Risks are not of concern to postapplication workers for the crops acceptable for continued registration.

For other uses, while additional information resulted in an exposure assessment that may more accurately reflect typical use conditions, the overall risk conclusions did not change significantly from those presented in REV2016-06. As postapplication risks of concern (cancer and/or non-cancer) could not be addressed through agronomically feasible REIs, the following uses must be cancelled:

Greenhouse cut flowers, greenhouse pachysandra, outdoor roses (grown for cut flowers)

#### **1.4 Residues in Food and Water**

As indicated in PRVD2011-14, acute and chronic aggregate dietary (from food and drinking water) risks, as well as the lifetime cancer risk for the general population are not of concern. There were no changes to the dietary risk assessment.

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

#### **1.5 Health Incident Reports**

No new incident reports related to human health have been submitted since the publication of PRVD2011-14.

### **2.0 Environmental Risk Assessment**

The environmental assessment in PRVD2011-14 considered the following application rates currently registered on the following crops:

- turf (golf course fairways):  $1 \times 12\,660$  g a.i./ha +  $4 \times 9\,500$  g a.i./ha, 14-day application interval;
- stone fruits:  $4 \times 4\,500$  g a.i./ha, 7-day application interval;
- highbush blueberries:  $3 \times 3\,600$  g a.i./ha, 7-day application interval;
- potatoes:  $12 \times 1\,200$  g a.i./ha, 7-day application interval.

Aquatic risk was assessed based on the above use patterns. Following consultation for PRVD2011-14 and REV2016-06, the use pattern has been revised (Appendix VIII) based on new data and information provided during the comment period and the updated human health assessment.

Environmental risk mitigation has been updated based on the revised use pattern. The number of applications allowed per year has been reduced significantly and consequently will result in significantly reduced exposure to aquatic habitats.

## **2.1 Environmental Incident Reports**

There were two major (fish mortality from runoff), one moderate (fish mortality from runoff) and eight minor environment incidents (two fish mortality from runoff, five honey bee mortality from spray drift and one tree damage from spray drift). One of the two major fish mortality incidents (reported in PRVD2011-14) was related to fire douse water containing many pesticides that overflowed into a creek; this incident does not relate to normal product use and was not assessed further. The other major or moderate incident reports involving fish mortality were submitted to the PMRA after the publication of PRVD2011-14. These occurred in Prince Edward Island and were related to runoff from potato fields treated according to label directions. Based on the review of these incidents, it was concluded that it was highly probable that chlorothalonil caused the fish mortality.

A significant rain event (greater than 20 mm in 4–5 hours) occurred within a day of application resulting in high levels of erosion that reached the nearby water bodies. Vegetative filter strips were in place based on provincial requirements and buffer zones were observed.

These findings are consistent with the incident report information reviewed as part of PRVD2011-14, which showed that when rain is very heavy, significant runoff may occur resulting in fish mortality.

To reduce potential risk to aquatic organisms from runoff of chlorothalonil, mandatory vegetative filter strips will be included as a requirement in the re-evaluation decision. While vegetative filter strips are expected to adequately mitigate the risk from runoff in most circumstances, it is recognized that vegetative filter strips may not be adequate to completely mitigate the risk of runoff from potato fields in Prince Edward Island in cases of heavy rainfall, given the unique soil properties in this area. The reduction in the number of applications for potatoes from the previous 12 applications per year to three applications per year under the new use pattern will minimize the likelihood of these rain events co-occurring with chlorothalonil applications.

## **3.0 Value Assessment**

Chlorothalonil is widely used in Canada for control of several economically important diseases on agricultural crops and turf. Its value is found in the consistency of the product performance under various environmental conditions, as well as its use as a rotational chemistry for resistance management purposes, especially on vegetable crops.

Currently, there are alternatives registered for all retained chlorothalonil uses, however chlorothalonil is especially important for managing peach, nectarine leaf curl and eastern filbert (hazelnut) diseases. Of the few alternatives remaining to manage these diseases, limitations were noted since the remaining alternatives have known adverse effects in terms of phytotoxicity to host crops or beneficial organisms or have a higher risk for resistance development in susceptible pathogens. In addition, access to chlorothalonil is of notable value to the ornamental industry since keeping flowers disease-free is necessary to maintain their retail value.

Rate reductions for chlorothalonil will also affect the application rates of other active ingredients in co-formulated fungicide products. Rate amendments for chlorothalonil will not reduce the rates of other active ingredients in co-formulations below the currently registered rates for food crops, however, it will for one turf disease (yellow patch). Chlorothalonil itself is not registered to control this particular disease and the efficacy of the product relies on the other active ingredient. As such, since current efficacy information does not support the use to control yellow patch on turf at the reduced rate of the other active ingredient in the co-formulation, the use will be removed from the product label.



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## List of Abbreviations

A	applicator
a.i.	active ingredient
ADI	Acceptable Daily Intake
AHETF	Agricultural Handlers Exposure Task Force
AR	application rate
ARfD	acute reference dose
ATPD	area treated per day
BAT	Best Available Technology
BCF	bioconcentration factor
bw	body weight
CAF	composite assessment factor
CEPA	Canadian Environmental Protection Act
cm	centimetre(s)
cm <sup>2</sup>	centimetres squared
CR	chemical-resistant
DA	dermal absorption
DACO	data code
DAF	Dermal Absorption Factor
DCB	decachlorobiphenyl
DF	dry formulation
DFR	dislodgeable foliar residue
EEC	estimated environmental concentration
EU	European Union
EUP	end-use product
FAO	Food and Agriculture Organisation of the United Nations
FIHOQ	Fédération interdisciplinaire de l'horticulture
ha	hectare
HCB	hexachlorobenzene
IPM	Integrated Pest Management
JMPR	Joint Meeting on Pesticide Residues
kg	kilogram
L	litre(s)
LADD	lifetime average daily dose
LC <sub>50</sub>	lethal concentration to 50% (a concentration causing 50% mortality in the test population)
LOAEL	lowest observed adverse effect level
LOC	level of concern
LOQ	Level of quantification
ML	mixer/loader
M/L/A	mixer/loader/applicator
mg	milligram(s)
MOA	mode of action
MOE	margin of exposure
MRL	maximum residue limit



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n/a	not applicable
NAFTA	North American Free Trade Agreement
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
ORETF	Outdoor Residential Exposure Task Force
PCDD	polychlorinated dibenzodioxins
PCDF	polychlorinated dibenzofurans
PeCB	pentachlorobenzene
PHED	Pesticide Handler Exposure Database
PMRA	Pest Management Regulatory Agency
POP	Persistent Organic Pollutant
PPE	personal protective equipment
ppm	parts per million
PRVD	proposed re-evaluation decision
q <sub>1</sub> *	cancer potency factor
RED	Reregistration Eligibility Decision
REI	restricted-entry interval
RED	Reregistration Eligibility Decision
REV	Re-evaluation Note
RQ	risk quotient
RTI	re-treatment interval
SBR	skin bound residues
SN	solution (liquid formulation)
SOP	Standard Operating Procedures
ST	short-term
TC	transfer coefficient
TCB	tetrachlorobenzene
TSMP	Toxic Substances Management Policy
TTR	turf transferable residues
TWA	time weighted average
UE	unit exposure
USDA	United States Department of Agriculture
USDL	United States Department of Labor
USEPA	United States Environmental Protection Agency
USEPA SAP	USEPA Scientific Advisory Panel
µg	microgram
WDG	water dispersible granules
WSP	water soluble packages

## Appendix I Registered Chlorothalonil Products for Use in Agriculture and Turf as of January 2018

### Registered Chlorothalonil Products for Use in Agriculture and Turf as of January 2018\*

Registration Number	Registrant Name	Product Name	Formulation Type	Active Guarantee (% unless otherwise stated)
<b>Technical Active</b>				
25574	GB BIOSCIENCES CORP.	Technical Chlorothalonil Fungicide	Solid	Chlorothalonil - 98%
27059	Sipcam Agro USA, Inc.	Chlorothalonil Technical Fungicide	Dust or Powder	Chlorothalonil - 98%
29354	Sipcam Agro USA, Inc.	Chlorothalonil Technical AG	Powder	Chlorothalonil - 99.3%
31763	ADAMA Agriculture Solutions Canada Ltd.	ADAMA chlorothalonil Technical	Solid	Chlorothalonil - 98.6%
<b>Manufacturing Concentrate</b>				
24915	BAYER CROPSCIENCE INC.	Tattoo Manufacturing Use Product	Suspension	Chlorothalonil - 375 g/L; Propamocarb Hydrochloride - 375 g/L
<b>End-use Products with Agricultural and Turf Uses</b>				
15723	Syngenta Canada, Inc.	Bravo 500 Agricultural Fungicide	Suspension	Chlorothalonil - 500 g/L
15724	Syngenta Canada, Inc.	Daconil 2787 Flowable Fungicide	Dry flowable	Chlorothalonil - 500 g/L
24544	BAYER CROPSCIENCE INC.	Tattoo C Suspension Concentrate Fungicide	Suspension	Chlorothalonil - 375 g/L; Propamocarb Hydrochloride - 375 g/L
26443	SYNGENTA CROP PROTECTION CANADA INC.	Ridomil Gold Bravo Fungicide	Suspension	Chlorothalonil - 500 g/L; Metalaxyl-M (Mefenoxam) - 480 g/L
28354	Syngenta Canada, Inc.	Daconil Ultrex Fungicide	Water dispersible granules	Chlorothalonil - 82.5%
28861	Syngenta Canada, Inc.	Instrata Fungicide	Suspension	Chlorothalonil - 362 g/L; Propiconazole - 57 g/L; Fludioxonil - 14.5 g/L
28900	Syngenta Canada, Inc.	Bravo ZN Agricultural Fungicide	Suspension	Chlorothalonil - 500 g/L
29225	Syngenta Canada, Inc.	Bravo 720 Agricultural Fungicide	Suspension	Chlorothalonil - 720 g/L

Registration Number	Registrant Name	Product Name	Formulation Type	Active Guarantee (% unless otherwise stated)
29237	Syngenta Canada, Inc.	Ridomil Gold SL/Bravo 720 Twin-Pack	Suspension	Chlorothalonil - 720 g/L; Metalaxyl-M and S-isomer - 480 g/L
29238	Syngenta Canada, Inc.	Ridomil Gold/Bravo 720 Twin-Pak	Emulsifiable concentrate	Chlorothalonil - 720 g/L; Metalaxyl-M and S-isomer - 480 g/L
29239	Syngenta Canada, Inc.	Ridomil Gold SL/ Bravo Twin-Pak	Suspension	Chlorothalonil - 500 g/L; Metalaxyl-M and S-isomer - 480 g/L
29306	Syngenta Canada, Inc.	Bravo Ultrex	Water dispersible granules	Chlorothalonil - 82.5%
29355	Sipcam Agro USA, Inc.	Echo 720 Agricultural Fungicide	Suspension	Chlorothalonil - 720 g/L
29356	Sipcam Agro USA, Inc.	Echo 90DF Agricultural Fungicide	Dry flowable	Chlorothalonil - 90%
29642	Syngenta Canada Inc.	Concert Fungicide	Suspension	Chlorothalonil - 473 g/L; propiconazole - 35.7 g/L
30165	Syngenta Canada Inc.	Daconil 720 Fungicide	Suspension	Chlorothalonil - 720 g/L
30333	E.I. Du Pont Canada Company	Treoris Fungicide	Suspension	Chlorothalonil - 250 g/L; Penthiopyrad -100 g/L
31537	Syngenta Canada Inc.	Bravo Top Fungicide	Suspension concentrate	Chlorothalonil - 500 g/L; Difenoxonazole - 50 g/L
31552	Syngenta Canada Inc.	Ridomil Gold SL/Bravo ZN Twin-Pak	Suspension	Chlorothalonil - 500 g/L; Metalaxyl-M and S-isomer - 480 g/L
32029	ADAMA Agricultural Solutions Canada Ltd.	Equus 82.5	Dry flowable	Chlorothalonil - 82.5%
32030	ADAMA Agricultural Solutions Canada Ltd.	Chlorothalonil 720F	Suspension	Chlorothalonil - 720 g/L
32271	United Phosphorus, Inc.	Elixir Fungicide	Water dispersible granule	Chlorothalonil - 12.5%; Mancozeb - 62.5%
32363	Gowan Canada	Zing! Fungicide	Suspension	Chlorothalonil - 500 g/L; Zoxamide - 85 g/L
32765	ADAMA Agricultural Solutions Canada Ltd.	Quali-Pro Intaglio Fungicide	Suspension	Chlorothalonil - 360 g/L Iprodione - 55 g/L Fludioxonil - 17.4 g/L

\*excluding discontinued products or products with a submission for discontinuation

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## Appendix II Comments and Responses

The PMRA received written comments relating to the Proposed Re-evaluation Decision PRVD2011-14, Chlorothalonil and REV2016-06. Comments received are summarized below, in conjunction with the PMRA responses to each science theme.

### 1.0 Comments Related to Human Health

#### 1.1 Comments and Responses Related to Toxicology

In response to the consultation for both PRVD2011-14 and REV2016-06, comments related to the toxicology assessment were received from the registrant and a non-government organization.

##### 1.1.1 Comment related to dermal risk assessment

The 21-day dermal toxicology study with a NOAEL of 600 mg/kg bw/day was the toxicology reference value used in PRVD2011-14 for dermal risk assessments of short- and intermediate-term durations. This reference value was revised in REV2016-06; the 21-day dermal toxicity study was replaced with 90-day oral toxicity study with a NOAEL of 1.5 mg/kg bw/day. A request to reconsider use of the 21-day dermal study for risk assessment of short- and intermediate-term durations, as per PRVD2011-14, was submitted in conjunction with a scientific rationale and additional scientific studies. Submitted scientific studies included general toxicity studies, additional kidney histopathology data, and dermal metabolism data, in addition to the 2009 JMPR report on chlorothalonil.

#### PMRA Response

The submitted scientific studies and other information were assessed and the results considered in the context of the available toxicology database described in PRVD2011-14. The following are the key findings:

- The kidney was confirmed as the primary relevant target organ of toxicity following oral exposure at levels as low as 3 mg/kg bw/day.
- The oral and dermal bioavailability of chlorothalonil is relatively low. Oral bioavailability ranges from 13 to 30% depending on dose, and saturation of absorption appears to occur between 5 and 50 mg/kg bw/day. Estimates of dermal bioavailability range from 3% (European Union (EU), Joint Meeting on Pesticide Residues (JMPR), United States Environmental Protection Agency (USEPA) to 19% (PMRA). The metabolism of chlorothalonil in the rat differs quantitatively between the oral and dermal routes of exposure. Following oral dosing, more of the presumed nephrotoxic metabolites (thiols) are produced, relative to the dermal route of exposure, by about 20-fold.

- There were limitations in comparing the results of the 21-day dermal study and the dermal metabolism study. The key finding of the dermal metabolism study was the demonstration of systemic exposure, with detection of urinary metabolites at doses of 5 mg/kg bw/day. However, in this study chlorothalonil was dissolved in acetone, whereas the 21-day dermal toxicity study was conducted with chlorothalonil as a moistened solid. The bioavailabilities in these two studies were expected to differ as a result. Thus, it is only possible to conclude that dermal absorption, and hence systemic exposure, is possible as a result of dermal exposure. It cannot be determined whether or not the form of chlorothalonil used in the 21-day dermal studies was systemically available since, although no effects were observed, neither blood nor urinary levels of chlorothalonil or its metabolites were measured.
- Humans have lower enzyme capacity than rats for metabolism of chlorothalonil to thiol metabolites, however, there is insufficient information available to quantify this difference. Data from monkey and dog oral dosing studies show these species have very low levels of the presumed nephrotoxic metabolites (thiols) relative to the rat. These data suggest that humans may be less sensitive to kidney toxicity than rats. Thus, using a rat study to derive a toxicology reference value is considered health protective.
- Given sufficient systemic exposure (bioavailable dose) to chlorothalonil or its metabolites, damage to the S2 segment of the proximal tubule of the kidney can occur following a single exposure.
- In rats, the toxic effect on the kidney occurs after short-term exposure to chlorothalonil and progresses with continued exposure, eventually resulting in kidney tumours following long-term exposure at a dose of 13 mg/kg bw/day. There was no apparent progression of kidney lesions (renal tubule hyperplasia and hypertrophy) in the 90-day dietary rat toxicity study at doses up to 10 mg/kg bw/day. However, kidney lesions did not regress after a 13-week recovery period following 90-days of treatment with chlorothalonil at 3 mg/kg bw/day.

Taking into account bioavailabilities via oral and dermal routes of exposure and the quantitative difference between these routes of exposure for the generation of the presumed nephrotoxic thiol metabolites; the 21-dermal toxicity study is considered appropriate for short-term (1–30 day) dermal risk assessment. However, for intermediate-term exposures (1–6 months), the 90-day oral toxicity study with a NOAEL of 1.5 mg/kg bw/day has been retained for dermal risk assessment.

Based on use pattern considerations and levels of postapplication activity within a 30-day period and the uncertainty in degradation kinetics, the short-term dermal endpoint can be supported for use in postapplication risk assessment for up to two applications, 7 days apart. This can be supported if applied at an early stage (for example, pre-bloom) with few postapplication exposure activities; or 2 applications, 14 days apart, with frequent post application exposure activity.

### 1.1.2 Comment related to cancer risk assessments

One comment stated that, based on mode of action (MOA) data evaluated by the USEPA, the MOE, or threshold approach, could be supported for chlorothalonil cancer risk assessments, would be protective of human health for all uses of chlorothalonil, and therefore, the linear approach using a cancer potency factor ( $q_1^*$ ) selected by the PMRA to assess cancer risks is not required.

#### PMRA Response

The PMRA is aware that the USEPA considers the threshold approach appropriate for characterization of forestomach and kidney cancer risks for chlorothalonil (USEPA 1999,<sup>4</sup> USEPA 2008,<sup>5</sup> USEPA 2012<sup>6</sup>), and is in agreement with the USEPA (EPA-HQ-OPP-2007-1106-0005[1].pdf) that this approach can be supported for the observed forestomach tumours in mice, based on the MOA of sustained cytotoxicity and regenerative cell proliferation.

Regarding the MOA for renal tumour formation, a 1998 USEPA Scientific Advisory Panel (SAP) concluded that the proposed MOA for chlorothalonil is plausible and likely to be valid, but noted data gaps that prevented a definitive conclusion. Following the Panel report, the USEPA published a Reregistration Eligibility Decision (RED) (April 1999) in which the USEPA presented both the linear ( $q_1^*$  approach) and non-linear models (MOE, or threshold approach). The Panel report is available in Appendix F of the RED. Due to the uncertainties identified by the Panel, the USEPA noted that it will regulate chlorothalonil based on the results of the  $q_1^*$  approach until the resolution of the uncertainties. Chlorothalonil is currently undergoing registration review in the U.S.

The PMRA is unaware of any additional data produced to address the concerns of the 1998 USEPA SAP. Therefore, the PMRA is of the opinion that the MOA for the renal carcinogenesis of chlorothalonil has not been adequately delineated and several aspects related to chlorothalonil activity in rodent kidney remain of concern. Consequently, in the absence of a fully delineated MOA, the assessment of carcinogenic risk for chlorothalonil was conducted using a more conservative quantitative risk assessment methodology utilizing linear extrapolation, as described in PRVD2011-14. A carcinogenic potency factor ( $q_1^*$ ) of  $7.66 \times 10^{-3}$  (mg/kg/day)<sup>-1</sup> calculated based on female rat renal (adenoma and/or carcinoma) tumour rates was used to assess cancer risks for the Canadian population.

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<sup>4</sup> USEPA 1999, Registration Eligibility Decision (RED) Chlorothalonil; EPA 738-R-99-004, April 1999

<sup>5</sup> Chlorothalonil. Petition For Tolerances on Brassica Head and Stem Subgroup 5A, Cucurbit Vegetable Group 9, Fruiting Vegetable Group 8, Ginseng, Horseradish, Lentil, Lupin, Okra, Persimmon, Rhubarb, Yam, Lychee, and Starfruit. Human-Health Risk Assessment (2008). Document ID: EPA-HQ-OPP-2007-1106-0007.

<sup>6</sup> USEPA 2012, Chlorothalonil. Human Health Assessment Scoping Document in Support of Registration Review. 13 March 2012

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### 1.1.3 Comment related to the assessment of cumulative effects, including carcinogenic effects

One comment stated that the cumulative effects of chlorothalonil and other pest control products that have a common mechanism of toxicity were not adequately assessed, as required by the *Pest Control Products Act*. In addition, with respect to the assessment of carcinogenic potential, the comment stated cumulative effects of chlorothalonil should be considered in combination with all other pest control products that directly contribute to carcinogenicity by other MOA.

#### **PMRA Response**

The concerns noted in the above comment were originally submitted to the PMRA in response to public consultations related to PRVD2011-14, as well as in a broader context in a submission to the Commissioner of the Environment and Sustainable Development, Office of the Auditor General of Canada as Environmental Health Petition 364: Regarding the Cancer Risks Posed by the Combined Effects of Disruptive Pesticides.

The petition, and Health Canada's detailed response, can be found at: [http://www.oag-bvg.gc.ca/internet/English/pet\\_364\\_e\\_39690.html](http://www.oag-bvg.gc.ca/internet/English/pet_364_e_39690.html). Section 1 of the response addresses Health Canada's cancer risk assessment approach and Section 2 of the response addresses the assessment of cumulative effects, in this case carcinogenic effects, via a common mechanism(s) of toxicity.

As noted in Section 3.4 of PRVD2011-14, it has not been determined whether chlorothalonil has a common mechanism of toxicity with other substances or whether it shares a toxic metabolite produced by other substances. In the 2008 USEPA Human-Health Risk Assessment, it was assumed that chlorothalonil does not share a common mechanism of toxicity with other substances, and a cumulative risk assessment was not required. No new information was submitted to the PMRA during the re-evaluation process to alter this conclusion.

### 1.1.4 Comment related to the protection of sensitive groups

It was requested that the PMRA re-examine the MOE in the assessment of chlorothalonil to ensure the protection of identifiable sensitive subgroups of Canadians, such as patients living with cancer, the overweight, pregnant women, those exposed in utero (as fetuses), nursing infants, and people who smoke, for carcinogenic and non-carcinogenic effects.

#### **PMRA Response**

The concerns noted in the above comment were originally submitted to the PMRA in response to public consultations related to PRVD2011-14, as well as in a broader context in a submission to the Commissioner of the Environment and Sustainable Development, Office of the Auditor General of Canada as Environmental Health Petition 364: Regarding the Cancer Risks Posed by the Combined Effects of Disruptive Pesticides.

The petition, and Health Canada's detailed response, can be found at: [http://www.oag-bvg.gc.ca/internet/English/pet\\_364\\_e\\_39690.html](http://www.oag-bvg.gc.ca/internet/English/pet_364_e_39690.html). Section 3 of the response describes how Health Canada addresses uncertainty and variability with respect to mammalian toxicity in the human health risk assessment of pesticides for non-cancer and cancer effects.

In the chlorothalonil risk assessment outlined in PRVD2011-14, the uncertainty factors applied take into account sensitive subpopulations including people living with cancer, obesity, pregnant or nursing mothers and people who smoke. Only those chlorothalonil uses that do not pose a risk of concern are acceptable for continued registration in Canada.

### **1.1.5 Comment related to the application of precautionary principle**

One commenter was of the opinion that there was evidence of immediate health concern from the ongoing use of chlorothalonil and recommended application of the precautionary principle to support the immediate discontinuation of chlorothalonil.

#### **PMRA Response**

Questions relating to how various regulatory groups within the Government of Canada apply the precautionary principle have been raised previously in relation to a variety of issues affecting the environment and human health, including pesticides. These concerns were submitted to the Commissioner of the Environment and Sustainable Development, Office of the Auditor General of Canada as Environmental Petition 349: Non-Compliance with International Obligations and Commitments: The precautionary principle. The petition, containing Health Canada's detailed response, is available at: [http://www.oag-bvg.gc.ca/internet/English/pet\\_349\\_e\\_38460.html](http://www.oag-bvg.gc.ca/internet/English/pet_349_e_38460.html). Several Government of Canada Departments provided responses to relevant portions of this petition, including Agriculture and Agri-Food, Environment, Natural Resources, Fisheries and Oceans, and Health Canada. The application of the precautionary principle to the regulation of several pesticides was addressed in the response from Health Canada, in Section A of the petition (questions 1 and 3). Although the petition does not refer to chlorothalonil specifically, it does describe Health Canada's application of the precautionary principle to the regulation of pesticides.

For the re-evaluation of chlorothalonil, the PMRA has adhered to the precautionary principle as per the *Pest Control Products Act*. Based on an evaluation of available scientific information, Health Canada's PMRA has found that certain uses of chlorothalonil do not present unacceptable risks to human health or the environment when used according to the revised label directions. As a condition of the continued registration of chlorothalonil uses, new risk-reduction measures will be included on the labels of all products. Risks of concern with certain uses have also been identified that cannot be adequately mitigated; therefore, these uses are required for phase-out. No additional data are being requested at this time.

There are no reasonable grounds to suggest any threat to human health or the environment that would warrant immediate cancellation.

### **1.1.6 Comment related to the selection of an Acute Reference Dose (ARfD)**

An explanation of the toxicological basis for the acute reference dose (ARfD) established by the PMRA was requested.



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**PMRA Response**

As noted in PRVD2011-14 and REV2016-06, an ARfD for chlorothalonil of 0.58 mg/kg bw for the general population was established based on squamous hyperplasia and hyperkeratosis in the forestomach and degenerative kidney changes that were observed as early as day 4 of treatment at a LOAEL (lowest observed adverse effect level) of 175 mg/kg bw/day from a 90-day rat feeding study. These effects were considered acute due to their rapid onset following initiation of dosing. A Composite Assessment Factor (CAF) of 300 was applied (10-fold uncertainty factor for interspecies extrapolation, 10-fold uncertainty factor for intraspecies variation, threefold uncertainty factor for extrapolation from a LOAEL to a NOAEL, and a *Pest Control Products Act* factor of onefold).

**1.2 Comments and Responses Related to Residential and Occupational Exposure**

In response to the consultation for REV2016-06, comments related to the residential and occupational exposure assessments were received from the registrant, individual growers, grower groups and associations, industries related to agriculture, such as packing plants, agronomy services, consultants, suppliers, distributors, and wholesalers, golf course superintendents, superintendent associations, turfgrass associations, researchers (university and research institute), Provincial ministries related to agriculture, and one municipality.

Comments recommended that the occupational and residential mixer, loader, applicator and postapplication risk assessments be revised based on a revised dermal endpoint, updated use information, revised postapplication activities and revised application frequencies.

The PMRA revised the occupational handler and postapplication risk assessments taking into consideration the comments received. These risk assessments were revised for most crops using the short-term dermal endpoint as well as the use description information received during the consultation period. The results of the revised risk assessments are presented in Appendix VII.

Specific comments are addressed below.

**1.2.1 Comment**

A request was made for the refinement of the dermal absorption factor based on in vitro human and rat and in vivo rat studies. Specifically, it was stated that the absorption of chlorothalonil in the in vitro human and rat and in vivo rat studies was low (< 1%) at all dilutions. The flux rate of chlorothalonil from human in vitro studies was also compared to address residues of chlorothalonil retained in the stratum corneum following dermal exposure. It was stated that based on the flux data, residues of chlorothalonil in the stratum corneum will not become systemically available over time and would be lost to desquamation. The flux data was also used quantitatively to estimate the dermal absorption of chlorothalonil as < 3%.

**PMRA Response:**

Since the non-cancer occupational and residential assessment was based on the short-term dermal toxicity study in rats for most scenarios, a dermal absorption value for chlorothalonil was not required. A dermal absorption factor was used in the assessments based on toxicological endpoints from non-dermal studies as well as the cancer assessments.

In the comment above, the registrant proposed adjusting the dermal absorption factor using human in vitro data and previously reviewed triple pack data (human in vitro, rat in vitro, rat in vivo). The dermal absorption values cited by the registrant in their comments do not include skin bound residues. Since the studies were terminated at 10 or 24 hours (immediately or 14 hours after exposure), characterization of the fate of the skin bound residues is not possible and, thus, skin bound residues were included in the PMRA estimate of dermal absorption, as per the USEPA Health Effects Test Guidelines USEPA, 1998.

The triple pack of dermal absorption studies were assessed based on the NAFTA Dermal Absorption Group position paper on the *Use of In Vitro Dermal Absorption Data in Risk Assessment*. This position paper states that when the in vitro animal technique is shown to be a good predictor of animal in vivo data (in other words, a ratio close to 1), the human in vitro data are likely to be a good predictor of human dermal absorption when conducted under the same conditions. This is also referred to as the ‘triple pack approach.’ This paper also discusses a number of ‘minimal standards’ which should be considered when applying the triple pack approach. These include: same dose/duration regimen, guideline studies (in other words, no major limitations), reproducibility of in vitro results, and consideration of regional variability in human skin.

The in vitro and in vivo studies cited by the registrant were previously reviewed and did not meet the criteria as per the NAFTA position paper. As shown in Table 1 (below), the studies do not result in a ratio close to 1 when dermal absorption values are compared, nor did they meet the minimal standards outlined in the position paper, as there were limitations identified with the in vitro studies. Therefore, the dermal absorption factor for chlorothalonil established under REV2016-06 was based on the rat in vivo study alone.

Furthermore, the submitted human in vitro and rat in vitro data alone are not sufficient to refine the established dermal absorption factor. These studies were not conducted with the same formulation, doses and/or exposure time as the studies on file. Therefore, the minimal standards outlined in the NAFTA position paper were not met. As such, the use of flux as a means of comparison between in vitro studies cannot be supported.

**Table 1 Comparison of Dermal Absorption (DA) Values for In Vivo and In Vitro Studies**

Rat In Vivo DA (Jones, 2000)		Rat In Vitro (Davies, 2000)		
Dose ( $\mu\text{g}/\text{cm}^2$ )	DA w/SBR <sup>1</sup> 24 hrs (10-hr skin wash)	Dose ( $\mu\text{g}/\text{cm}^2$ )	DA w/SBR <sup>1</sup>	
			10hrs <sup>2</sup>	24 hrs <sup>2</sup>
4.2	18.8	4.6	52.3	41.6
36	8.1	37.2	38.5	19.4
3400	2.0	6650	2.1	2.1

<sup>1</sup> w/SBR – with skin bound residues.

<sup>2</sup> Skin wash at time indicated

### 1.2.2 Comment

It was requested that the 8-hour workday assumed in the postapplication risk assessment be refined to reflect field conditions and specific tasks.

#### PMRA Response

The information available to the PMRA indicates that 8 hours is an appropriate estimate of work day duration for agricultural workers. This value may, in fact, underestimate actual work day duration; however, it is considered to be a suitable estimate for use in regulatory risk assessments. The question of workday duration was addressed by a 2008 USEPA Federal Insecticide, Fungicide, and Rodenticide Act Science Advisory Panel, which endorsed the use of 8 hours.

The 8-hour duration is based on a grower survey (Thompson, 1998) and a United States Department of Labor report (USDL, 2005) from the National Agricultural Worker Survey. These were considered to be the best available data. The Science Advisory Panel concurred with the USEPA's scientific analysis that these datasets were adequate to establish a workday duration of 8 hours for generic dermal exposure assessment.

### 1.2.3 Comment

It was stated that gloves are typically worn by postapplication workers and can result in a 90% exposure reduction.

#### PMRA Response

The PMRA acknowledges that gloves may be worn during certain postapplication activities for some crops, as protection (e.g., thorns) or to prevent the transmission of microorganisms from the worker to the plant commodity. However, the type of glove worn may not be chemical-resistant, so the level of chemical protection afforded by the gloves worn by postapplication workers is unknown (90% is a factor used for handlers who have only brief contact with concentrated products during mixing and loading, rather than for postapplication workers who have much longer contact with residues over an 8-hour workday, which can result in greater exposure). While the use of chemical-resistant gloves may be a "best practices" measure, the consideration of PPE as mitigation for postapplication workers in the risk assessment is not appropriate for regulatory purposes since there are no reliable data to indicate the degree of protection gloves may provide to postapplication workers, or conversely, the extent that gloves may enhance exposure under certain conditions. Moreover, gloves may not be worn consistently in hot weather, and delicate tasks such as hand thinning often cannot be adequately performed while wearing gloves.

### 1.2.4 Comment

Comments suggested that dislodgeable foliar residues would dissipate and rapid growth of the plant would decrease the contact potential to treated surfaces. Furthermore, due to the sticky nature of the end-use product, transfer of residues would be minimal after application.

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**PMRA Response**

A chemical specific DFR study was not available to the PMRA to determine the dissipation of chlorothalonil on treated plant foliage. In lieu of this data, the default peak DFR value of 25% of the application rate being dislodgeable after application and the default daily dissipation rate of 10% was used in the updated risk assessment.

**1.2.5 Comment**

For greenhouse ornamentals (other than cut flowers), the maximum spray volume can be reduced to 1000 L/ha in order to refine the risk assessment.

**PMRA Response**

The reduction of the maximum spray volume was used to refine the postapplication risk assessment and to determine agronomically feasible REIs. The maximum spray volume of 1000 L/ha was determined to be acceptable for use on greenhouse ornamentals, other than cut flowers.

**1.2.6 Comment**

Chlorothalonil is a critical active ingredient for processing tomatoes and stakeholders would like to retain as many applications as possible. Processing tomatoes are not hand harvested; therefore, restricted entry intervals for hand-harvesting tomatoes are not applicable to tomatoes grown for processing. Separate use directions should be supported for tomatoes grown for processing and tomatoes not grown for processing.

**PMRA Response**

The information received from stakeholders regarding hand-harvesting processing tomatoes was used to refine the postapplication risk assessment and determine agronomically feasible REIs. Separate directions for use were supported for processing tomatoes and tomatoes not grown for processing.

**1.2.7 Mitigation measures for golf course workers**

A REI of 22 days is not feasible for many golf courses, as winter protection activities (such as topdressing, tarping, and fencing) take place following the application. Without further winter protection, golf courses would sustain substantial damage to the turf that would result in financial hardships. The proposed REI is likely to reduce, if not even prevent, the use of chlorothalonil on golf courses. In addition, the requirement of enclosed cab groundboom equipment for applications to turf would add unreasonable costs to many golf courses, and may have a negative economic impact on the smaller clubs across Canada.

**PMRA response**

The PMRA considered all comments received during consultation and revised the risk assessment using the best available information. Based on the revised risk assessment, the PMRA supports a continued registration of all turf uses with mitigation measures. Enclosed cab application equipment is no longer required for groundboom applications to turf.

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## 2.0 Comments Related to the Environmental Assessment

In response to the consultation for PRVD2011-14, comments related to the environmental assessment were received from the registrant and one non-governmental organization related to cancer research and education.

### 2.1 Comments and Responses Related to Monitoring Data

#### 2.1.1 Comment

In PRVD2011-14 on Page 31 (published document is page 27), the order of the aquatic risk assessment that used the water monitoring data seems out of order and the risk assessment approach seems to be a bit inconsistent with the Agency's tiered approach for environmental risk assessment. The first approach (summarized in Table 11) used the 95<sup>th</sup> percentile of all maximum water values (and included non-detect levels) and compared them against the relevant toxicity endpoints for marine and freshwater species, including the SSD value (HC<sub>5</sub>) for fish. This was followed by an extremely conservative risk estimate that only used the maximum values at all locations (Table 12). This appears to be a step-back in the tiered approach as it only considered worst-case exposure, which is opposite of what was stated on page 31 that the data used in Table 12 including "Sampling occurred at these sites during runoff/precipitation events, capturing peak concentrations of chlorothalonil at those locations."

#### PMRA Response

The risk assessment for aquatic organisms summarized in Table 11 is routinely used in the re-evaluation risk assessments and uses surface water concentrations from Canadian monitoring data reported in Table 4 of Appendix IX. Acute risk is determined using the 95<sup>th</sup> percentile of the maximum detected concentrations from all the monitoring sites. Chronic risk is determined using the 95<sup>th</sup> percentile of the mean concentration for each study site including half of the level of concern (LOD) for instances of non-detection.

Table 12 in Appendix VIII is an additional risk assessment that summarizes the sites in Canada where the LOC for potential acute risk (HC<sub>5</sub> from SSD) for freshwater fish is exceeded. The exceedances all occurred in the Atlantic Provinces from 2006 to 2008 and the sampling that occurred at these sites during runoff/precipitation events captured peak concentrations of chlorothalonil at those locations.

As indicated in the third paragraph on page 31 (page 28 of PRVD2011-14), "there is some uncertainty regarding this analysis. The duration of exposure to these concentrations is unknown, whereas, the fish species used to generate the toxicity endpoint used in the analysis (HC<sub>5</sub> from a SSD) were exposed for a 96-hour period. If the actual exposure period at the monitoring sites was less than 96 hours, which is quite possible, then the calculated risk may be overestimated. This analysis supports the previous spray drift and runoff refined risk assessments for freshwater fish by showing that these actual concentrations observed in Canadian surface waters from monitoring data could present a risk to freshwater fish in some regions." The acute LOC for freshwater fish using the 95<sup>th</sup> percentile of the maximum detected concentrations from all the monitoring sites (Appendix VIII, Table 11) is also exceeded (RQ = 2.9).

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Our risk assessment concludes that in the aquatic environment chlorothalonil may pose a risk to some non-target aquatic organisms (particularly fish) as a result of spray-drift and runoff.

Our risk assessment concludes that in the aquatic environment chlorothalonil may pose a risk to some non-target aquatic organisms (particularly fish) as a result of spray-drift and runoff. This is supported by lower tiered environmental modelling, environmental monitoring data as well as incidents reports which all point to a potential risk to freshwater fish.

### **2.1.2 Comment**

In PRVD2011-14 on Page 68 (page 67 of published document), footnote 2, the PMRA stated that this table (Appendix VIII, Table 11) represents the results of the acute and chronic risk assessments using the 95<sup>th</sup> percentile of the maximum detected concentrations from surface water monitoring studies. However, footnote 2 suggests that these were modelled values based on either an 80 cm or 15 cm pond. Since these are worst-case field data, and not modelled exposure values, this footnote could be removed as no adjustment for water body depth is required.

#### **PMRA Response**

The PMRA agrees with this comment.

### **2.1.3 Comment**

In PRVD2011-14 on Page 69 (page 68 of the published document), it is unclear why maximum levels from other surface water sites were not used in this table to give some context to the occurrence of when the RQ is exceeded. For instance, surface water from agricultural sites in British Columbia and streams in apple growing regions in Quebec. Perhaps all sites should be added or text that the RQ was not exceeded at other surface water sites across Canada (including those from Nova Scotia).

#### **PMRA Response**

In PRVD2011-14, Table 4 in Appendix IX provides a summary of all monitoring studies considered and includes information on the number of samples and the detection frequency for each study. Section 4.2 in Appendix IX explains that chlorothalonil is generally detected infrequently and at low levels in most monitoring studies in Canada. However data from 2003 to 2008 from the Atlantic Provinces that was collected during runoff/precipitation events captured peak concentrations. In PRVD2011-14, the text in paragraph 2 on page 31 (page 28 of the published document) states “Table 12 summarizes the sites in Canada where the acute LOC for freshwater fish is exceeded.” The purpose of Table 12 in Appendix VIII is to provide additional information on the acute risks to freshwater fish from maximum concentrations of chlorothalonil in surface water.

### **2.1.4 Comment**

In PRVD2011-14 on Page 90 (page 89 of the published document), it is unclear what surface water monitoring data was used to calculate the values in Table 5. Perhaps a footnote could be added to the data in Table 4 to assist the reader?

**PMRA Response**

For reference, the data included in Table 4 “Summary of the Monitoring Studies Available” in Appendix IX PRVD2011-14 were used to calculate this data.

**2.1.5 Comment**

In PRVD2011-14 on Page 77, Table 4 - Summary of the Monitoring Studies Available, would it be possible to present the Time Weighted Average in these tables? The use of these values vs. absolute maximum levels could be a better measure of actual exposure to aquatic biota.

**PMRA Response**

In PRVD2011-14, the data provided in Table 4 are from retrospective water monitoring programs. The sampling programs were not designed to allow for the calculation of time-weighted averages.

**2.2 Comments and Responses Related to Incident Reports****2.2.1 Comment**

In PRVD2011-14 on Page 31 (page 28-29), “Incident reports from New Brunswick and P.E.I. (section 4.2.3) of fish mortality which may have resulted from the runoff of chlorothalonil residues also support this risk assessment.” we’re unclear as to how these incidents can be used as supportive evidence of the exceedance found in the Tier 1 risk assessment. For example, the cause of the 1994 incident was considered "undeterminable" but "not likely due solely to pesticide runoff.” With the 1996 incident, it is stated “Although for technical reasons Canadian authorities did not establish a definitive, formal attribution for the cause of the kill, the event does clearly show that chlorothalonil is susceptible to runoff and may cause adverse effects.” Based on qualitative nature of these observations and chlorothalonil, we would recommend that the statement on page 31 regarding the supportive nature of incident reports to the risk assessment be reconsidered.

**PMRA Response**

The incident reported in 1996 on Prince Edward Island involving salmon parr did implicate chlorothalonil as a possible cause although Canadian authorities did not establish a formal attribution for the cause of the kill. The other incidents reported also implicated chlorothalonil. More recent fish mortality incidents have been found to be highly probable to have been caused by chlorothalonil, as shown by supporting sample data (PMRA# 2683099; PMRA# 2727509).

**2.2.2 Comment**

In PRVD2011-14 on Page 68 and Page 90 – The Black Brook Watershed in New Brunswick is well-known as an example of highly sloped geography, relatively high precipitation, and high farm intensity, the combination of which suggests (and observational data supports) that the watershed is very highly prone to movement of matter from field to water. Ongoing AAFC research is focused on establishing beneficial management practices such as runoff buffers to significantly reduce the amount of nutrients, pesticides and other organic matter that enter the watershed.

As a result, it may be worth noting that the use of maximum chlorothalonil concentrations from this site represent an extremely conservative estimate of exposure to aquatic wildlife.

### **PMRA Response**

Monitoring data (PMRA# 2683099; PMRA# 2727509) collected as part of the recent fish mortality in Prince Edward Island show that the high concentrations observed in the Black Brook Watershed (New Brunswick) are not unique in Canada and may exceed threshold levels for effects to be observed in aquatic organisms.

## **2.3 Comments and Responses Related to Effects on Terrestrial Organisms (Invertebrates)**

### **2.3.1 Comment**

In PRVD2011-14 on Page 54 (page 53 of the published document), the acute honey bee (*Apis mellifera*) 48-h LD<sub>50</sub> identified in table 3 was not consistent with the most current data identified by the United States Environmental Protection Agency (> 181 µg/bee; Atkins et al. 1973). Please see Atkins, E. L., Greywood, E. A., and Macdonald, R. L. 1973. Toxicity of Pesticides and Other Agricultural Chemicals to Honey Bees: Laboratory Studies. Department of Entomology, University of California, Riverside. September 1973-SM, Rev.

### **PMRA Response**

The acute honey bee (*Apis mellifera*) 48-h LD<sub>50</sub> of > 40 µg/bee used in the risk assessment was obtained from the European Commission Health and Consumer Protection Directorate-General review for chlorothalonil. Although this value is more conservative than the value reported by the EPA (> 181 µg/bee; Atkins et al. 1973), the level of concern was still not exceeded in the screening level risk assessment for honey bees indicating negligible risk (PRVD2011-14, Appendix VIII, Table 4).

## **2.4 Comments and Responses Related to Effects on Aquatic Organisms**

### **2.4.1 Comment**

In PRVD2011-14 on Page 31 (page 28 of the published document), it is stated that “no toxicity data were available for amphibians”. However, acute data was submitted and listed in the appendix. Should this be amended to state that no chronic toxicity data for amphibians were submitted?

### **PMRA Response**

Agreed. No chronic toxicity data were available but acute toxicity data were available for amphibians. The 48-h LC<sub>50</sub> for Japanese common toad tadpoles (*Bufo bufo japonicus*) was reported as 160.0 µg a.i./L. In the absence of chronic toxicity data for amphibians, endpoints from fish were used as a surrogate. The most sensitive fish chronic toxicity value for chlorothalonil technical was the 21-day NOEC of 3.0 µg a.i./L.



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## 2.4.2 Comment

In PRVD2011-14 on Page 58, Footnote 1 for amphibians should be reworded to state that the use of fish data as a surrogate for this taxon is limited to chronic exposure, not acute (for which acute amphibian data exists).

### PMRA Response

The PMRA agrees with this comment.

## 2.4.3 Comment

In PRVD2011-14 on Page 68, Footnote 3 for acute amphibian risk estimate should be removed as actual amphibian data was used in the PMRA's assessment.

- Acute amphibian endpoint (0.016 mg/L; as per Table 10 for example) could have been used in this calculation instead of the acute fish value (0.002 mg/L) to be consistent with other risk estimates presented in the report.
- Resulting RQ would be 2.3 vs. 18.5, still exceeds the LOC but consistent with other aquatic species.

### PMRA Response

The PMRA agrees with this comment.

## 2.5 Comments Related to the Environmental Risk Assessment

### 2.5.1 Comment

We would like to suggest adding a table with the uncertainty factors used in the ecological risk assessment.

### PMRA Response

The uncertainty factors used in the risk assessment are contained in Tables 4 – 11 of Appendix VIII, so a separate table listing these factors is not necessary.

## 2.6 Comments and Responses Related to Pest Control Product Policy Considerations

### 2.6.1 Toxic Substances Management Policy Considerations

#### 2.6.1.1 Comment

In PRVD2011-14 on Page 70 (page 68 of the published document), TSMP table states the BCF (rainbow trout) = 4,500. However, only BCF studies with bluegill sunfish and oysters were discussed (page 23) and chlorothalonil was found not to bioconcentrate appreciably in either study.

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**PMRA Response**

The text on page 20 of PRVD2011-14 should read as “For fish, bioconcentration factors (BCFs) are 75-fold in edible portions and 264-fold in whole fish for bluegill, 9.4-fold in edible and 16-fold in whole fish for catfish and 310-fold in edible portions for rainbow trout.” The current BCF values are:

4500 rainbow trout (edible portion)  
264 bluegill (whole fish)  
16 catfish (whole fish)

**2.6.2 Formulants and Contaminants of Health or Environmental Concern****2.6.2.1 Comment**

The PMRA is not meeting Canada’s international obligations under the Stockholm Convention to eliminate these substances.

**PMRA Response**

Canada is a party to the Stockholm Convention on Persistent Organic Pollutants (POPs), which is a global treaty. The objective of this convention is to protect human health and the environment from POPs. By ratifying the Convention, Parties agreed to the management and control of POPs. The Stockholm Convention lays down measures to reduce or eliminate release of intentional production and use of POPs (Article 3, Annex A and B) and to reduce or eliminate, if feasible, unintentional production of POPs (Article 5, Annex C). Under Article 3, each Party shall eliminate the intentional production and use of the chemicals listed in Annex A (Elimination) and restrict the intentional production and use of the chemicals listed in Annex B (Restriction), however, these measures do not apply to POPs when formed and released unintentionally from anthropogenic sources (Annex C chemicals). Under Article 5, Parties shall take measures to reduce total releases of unintentional POPs, with the goal of ultimate elimination, where feasible.

HCB, dioxins and furans are unintentionally formed as contaminants; therefore, they are listed under Annex C of the Stockholm Convention. Parties are to develop and endeavour to implement an action plan taking into account the obligations set out under Article 5 of the Convention — namely, measures to reduce their release, with the goal of virtual elimination, if feasible.

The PMRA reduction strategy outlined in DIR99-03 for contaminants such as HCB in chlorothalonil is consistent with the Article 5 of the Stockholm Convention - reduce unintentional release through implementation of Best Available Technology and Best Environmental Practices (BAT/BEP).

**2.6.2.2 Comment**

It was stated that the PMRA has failed to achieve the department’s stated objective of virtual elimination, with respect to the contaminants of concern that are expected to be present in the chlorothalonil technical grade active ingredients.

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### **PMRA Response**

In June 1995, the federal government released the Toxic Substances Management Policy (TSMP) - a policy developed to provide direction to the federal government on the management of toxic substances and other substances of concern that are released into the environment. The policy applies to all substances that are subject to federal regulation. Although the impetus for the TSMP was to provide a means for managing substances that are not well regulated, the principles of the TSMP are relevant to chemicals that are used as pest control products.

The PMRA has the responsibility to implement TSMP for pesticides under the *Pest Control Products Act*. The TSMP and the *Pest Control Products Act* have the same fundamental purpose: to protect human health and the environment. The protection of human health and the environment is of primary importance in the regulation of pest control products in Canada.

In 1999, the PMRA published its strategy for implementation of the federal government's TSMP, for technical grade active ingredients, formulants and contaminants regulated under the *Pest Control Products Act* (Regulatory Directive, DIR99-03 "The PMRA's Strategy for Implementing the Toxic Substances Management Policy").

In the case of chlorothalonil, the PMRA followed the approach outlined in Directive 99-03 for addressing Track 1 substances that are found as unintentional contaminants in registered active ingredients due to manufacturing process. In working towards the goal of virtual elimination, the PMRA must track and review levels of Track 1 contaminants in registered pest control products for their continued acceptability, and work with registrants to reduce/eliminate contaminants of concern in line with the best available technology. This approach to reduce levels of contaminants in pesticides is in compliance with the recommended measures of the Stockholm Convention. For those products where it is not feasible to further reduce the level of the contaminants, the PMRA continues to work with registrants and other stakeholders to develop alternative products and/or pest control strategies to prevent formation or minimize their release to the environment, with the ultimate goal of virtual elimination. This is also in compliance with Article 5 of the Stockholm Convention.

While socio-economic factors and technical considerations have no bearing on setting the ultimate objective for a Track 1 substance, such factors are to be taken into account when determining and implementing risk management measures under the policy – for example, setting interim targets and time-lines. Virtual elimination of Track 1 substances is a long-term goal to be implemented through a common sense approach.

#### **2.6.2.3 Comment**

The PMRA should establish much stricter contamination limits for Track 1 substances that are expected to be found in chlorothalonil. These limits should reflect the Department's stated goal of virtual elimination as per the TSMP (1995) (i.e., measurable release limits are to be set at the lowest concentration of a substance that can be accurately detected and quantified using sensitive but routine analytical methods).

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**PMRA Response**

Environment Canada and Health Canada apply the TSMP for substances regulated under authority of the *Canadian Environmental Protection Act* (CEPA).

Under CEPA 1999, virtual elimination is the reduction of the quantity or concentration of a toxic substance in the release into the environment to below concentrations that can be accurately measured or a "level of quantification". The level of quantification (LOQ) is the lowest concentration of a toxic substance that can be accurately measured using sensitive but routine sampling and analytical methods.

The PMRA's TSMP approach for reduction of Track 1 contaminants in pesticides, aligned with international treaties, targets contaminant levels in the technical grade active ingredient since contaminants arise from the manufacturing process as an impurity and can be easily analyzed at this stage. The levels of contaminants released into the environment are much lower than those reported in the technical grade active ingredients and result in environmental concentrations (soil, water) below background levels. Although not released directly to the environment, pesticide technical grade active ingredients are much easier to analyze for low levels of dioxins, regulate and ensure compliance.

It is important to note that the PMRA's limit for HCB in chlorothalonil is already more conservative than the 40 ppm limit set by Food and Agriculture Organization of the United Nations (FAO).

**2.6.2.4 Comment**

The proposed decision document notes that hexachlorobenzene (HCB), decachlorobiphenyl (DCB), pentachlorobenzene (PeCB), tetrachlorobenzene (TCB), chlorinated dioxins (PCDD) and furans (PCDF) are expected to be present as contaminants in the chlorothalonil technical grade active ingredient, all of which are classified as TSMP Track 1 contaminants. The PMRA has not commented on the levels of these contaminants in chlorothalonil.

**PMRA Response**

The PMRA has management strategies in place for all Track-1 contaminants and is actively managing contaminants in pesticides as per DIR99-03 by ensuring these meet best available technology (BAT). Published documents generally focus on HCB because historically pesticides have been considered to be a significant source of HCB to the environment. HCB is an expected contaminant in pest control products where the manufacturing process includes the presence of an aromatic carbon source (for example, benzene) and a chlorinating agent at elevated temperature. Although few pesticides contain HCB, these are targeted by the PMRA for reduction. For this reason, the PMRA reported all of the Track 1 contaminants in chlorothalonil, but only the reduction strategy for HCB was described.

Pesticides containing polychlorinated biphenyls (including DCB), dioxins and furans are managed by the PMRA by requiring that registrants submit batch data on current levels of contaminants to ensure that levels remain low according to best available technology (BAT).

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The Food and Agriculture Organization of the United Nations (FAO) set an international standard limit of 30 ppm for DCB in chlorothalonil agricultural technical grade active ingredients. All Canadian registered technical grade active ingredients are at, or below this level.

Pentachlorobenzene and tetrachlorobenzenes are expected to be found in the same products containing HCB, however, observed levels tend to be lower than HCB. Changes to the manufacturing process that result in a reduction in HCB are also likely to result in a reduction of these contaminants. Thus, a reduction strategy for HCB is also expected to be relevant to these contaminants.

#### **2.6.2.5 Comment**

The Prohibition of Certain Toxic Substances Regulations, 2003 (which was updated in 2005) prohibits the use, sale and import of a number of prohibited toxic substances, including hexachlorobenzene. While all uses of hexachlorobenzene were originally scheduled for elimination as part of this broad prohibition, the PMRA is noted to have expressed its concerns over regulatory redundancy, so an exemption was added to exclude them from the CEPA Regulations.

#### **PMRA Response**

The *Pest Control Products Act* is scheduled under Sections 2 and 4 of CEPA, which means that pest control products are exempted from additional notification and assessment for toxicity under CEPA 1999 thus avoiding regulatory duplication. The regulatory authority for pesticides, including contaminants of concern, was confirmed in 2006 when the new *Pest Control Products Act* was brought into force. This authority is also reflected in the Prohibition of Certain Toxic Substances Regulations (2003, 2005-SOR/2005-41): “these regulations do not apply to any toxic substance that is contained in a pest control product as defined in subsection 2(1) of the *Pest Control Products Act*”. There was no legal authority for CEPA to regulate HCB or any contaminant, formulant, or active ingredient in pesticides– for this reason the *Pest Control Products Act* was excluded from the prohibition regulations.

As mentioned previously, the PMRA’s approach to managing contaminants is appropriate for pesticide regulation. The reduction plan targets those products considered to have the highest environmental loading and those that require reduction. This approach also allows regulatory flexibility to ensure that acceptable levels are continually lowering over time as analysis methods improve.

#### **2.6.2.7 Comment**

The *Prohibition of Certain Toxic Substances Regulations* provided an exception for products containing HCB as a by-product at concentrations below 20 ppb. However, the level of HCB in chlorothalonil (6–30 ppm) is significantly higher than this threshold.

#### **PMRA Response**

The level of HCB in technical grade active ingredient chlorothalonil for agricultural uses is 6–10 ppm. A limit of 30 ppm is only allowed in the technical grade active ingredient chlorothalonil registered for material preservative uses in paint products which have a limited potential for

environmental exposure. Similar to the agricultural example discussed previously, the paint technical grade active ingredient is used to formulate the end-use product which is further diluted when mixed with paint. Targeting the HCB level in the technical grade active ingredient makes it possible to regulate contaminants and ensure compliance, but it is not representative of the amount of HCB in the final product, nor is it representative of the amount of HCB released into the environment at the site of application. The manufacture of chlorinated substances includes a chlorination-process at high temperatures, where HCB is a known by-product. The level of contaminants can be reduced to lowest practical levels by adjusting various steps in the manufacturing process (e.g., temperature, pressure).

Pesticide companies are required to submit detailed descriptions of manufacturing processes along with batch data to the PMRA on a regular basis. The goal is to ensure that contaminant levels are being reduced, and that the manufacturer continues to pursue best available technology and practices to attain lowest practical levels of contaminants.

#### **2.6.2.8 Comment**

Comments argue that the proposed decision to approve the ongoing use of chlorothalonil, which contains HCB and a number of other persistent, bio-accumulative and toxic chemicals, is in violation of the *Pest Control Products Act*, which states that the Minister's primary objective is to prevent unacceptable risks.

#### **PMRA Response**

The PMRA's re-evaluation determined that at current levels of HCB and other contaminants, chlorothalonil does not pose unacceptable risks to health or the environment. Following the PMRA's TSMP strategy to reduce contaminants of concern in registered pesticides, the level of HCB concentration in technical grade chlorothalonil for agricultural uses are 4-fold lower than the previously reported levels in 2002. HCB levels in the chlorothalonil (for use in paint preservatives) are 8-fold lower than the previously reported levels in 1998 and 2000. As mentioned previously, the level of HCB in Canadian registered chlorothalonil are significantly below the Food and Agriculture Organization of the United Nations (FAO) limit of 40 ppm which is the international standard for chlorothalonil agricultural technical grade active ingredients.

Consistent with the TSMP goal of virtual elimination and in line with Canada's obligations under Stockholm Convention, levels of HCB in chlorothalonil active ingredient have been reduced significantly, which has subsequently reduced the amount of HCB released into the environment. The PMRA affirms that the reduction of HCB in chlorothalonil is consistent with the TSMP goal of virtual elimination. The PMRA will continue to work with registrants and stakeholders to reduce the amount of HCB released into the environment by monitoring levels of contaminants in active ingredients, and continue to meet international obligations under the Stockholm Convention.

The PMRA has implemented its TSMP policy to reduce levels of contaminants of concern in chlorothalonil. There is reasonable certainty that no harm to human health, future generations or the environment will result from exposure to or use of the product, taking into account its conditions of registration.

The petition, and Health Canada's detailed response to it, can be found at: [http://www.oag-bvg.gc.ca/internet/English/pet\\_364\\_e\\_39690.html](http://www.oag-bvg.gc.ca/internet/English/pet_364_e_39690.html). Sections 1 and 4 of the response address Health Canada's management approach for contaminants of toxicological concern; Sections 1b and c, describe Health Canada's approach to monitoring pesticides for impurities/contaminants and the application of the TSMP in federal government programs, and Sections 4a and b specifically address the contaminant hexachlorobenzene.

### **3.0 Comments Related to the Value Assessment**

In response to the consultation for REV2016-06, comments related to the value assessment were received from individual growers, grower groups and associations, industries related to agriculture, such as packing plants, agronomy services, consultants, suppliers, distributors, and wholesalers, golf course superintendents, superintendent associations, turfgrass associations, researchers (university and research institute), and Provincial ministries related to agriculture.

#### **3.1 Comment**

**Chlorothalonil is important for resistance management. The proposed restriction on the use of chlorothalonil put Canadian growers at a competitive disadvantage.**

Chlorothalonil is an effective, broad spectrum fungicide that has a very low risk of resistance due to its multi-site mode of action. It is an invaluable tool for resistance management and economical broad spectrum disease control. It is used as tank mix partner, in pre-mixes, and as rotational product for newer fungicides that are at high risk of resistance.

The proposed additional restrictions on the use of chlorothalonil, prior to similar action by the United States Department of Agriculture (USDA), would further handicap our producers and overall industry from effectively competing with North American growers particularly processed tomato sector.

#### **PMRA Response**

The PMRA acknowledges the importance of chlorothalonil to agriculture for disease control, resistance management for higher quality and yield. During consultation with stakeholders, the PMRA received additional information related to crop production practices and the use of chlorothalonil. This information was used to refine the assessment of exposure risks for chlorothalonil and as a result, the PMRA will retain most of the uses for chlorothalonil but with a reduced number of applications to mitigate risk concerns. Growers will have the option to rotate or tank mix chlorothalonil with other fungicides for disease control and resistance management.

#### **3.2 Comments: Chlorothalonil is important to the production of numerous Canadian agricultural and horticultural crops**

Many comments were received from various grower groups, as well as agricultural and horticulture organizations, expressing the important contribution of chlorothalonil to agricultural production practices. The associations representing the growers of the following crops provided information to the PMRA:

- field and processing tomato (late blight)
- ginseng (alternaria blight, botrytis blight)
- cranberry (fruit rot)
- highbush and lowbush blueberry (phomopsis canker, anthracnose fruit rot)
- peach, nectarine (peach curl disease)
- cole (Brassica) crops (alternaria leaf spot, downy mildew)
- cucurbit crops (foliar disease, downy mildew)
- potato (late blight)
- onion (foliar diseases, botrytis leaf blight)
- wheat (foliar diseases)
- pulse (legume) crops
- hazelnut (Eastern Filbert (hazelnut) blight)
- cherry (brown rot, blossom blight)
- asparagus (stemphylium (purple spot) disease)
- greenhouse and nursery conifers, including Christmas trees (needlecast, botrytis blight, sirococcus blight, phomopsis (phoma) tip blight)
- ornamental crops (several disease-causing fungi)

Justification for the importance of chlorothalonil in the production of the above agricultural and horticultural crops includes:

- high level of efficacy (that is, fewer applications required to control pathogens)
- broad spectrum control of multiple diseases using the same application timing
- lack of alternative fungicides
- lack of rotational fungicide products for resistance management
- limitations associated with alternative fungicide products (appropriate application timing, phytotoxicity)
- cost effectiveness
- improved crop quality and yield

### **PMRA Response**

The PMRA acknowledges the importance of chlorothalonil for disease management in many important Canadian agricultural and horticultural crops. As a result of additional information received from stakeholders during the consultation period used to refine the risk assessments for chlorothalonil exposure, many of the registered crops will be maintained on product labels by amending the use pattern. Risk mitigation measures are presented in Appendix III, Table 1 *Summary of Accepted Uses*. Appendix VIII, Table 1 *Comparison of PRVD2011-14 Application Rates versus Revised Application Rates* shows currently registered use patterns compared to the revised use patterns for the crops to be maintained on the chlorothalonil product labels. Growers will have the option of using chlorothalonil in rotation with other currently registered alternative fungicides for disease control and resistance management.

### **3.3 Comment: Chlorothalonil is the key active ingredient as part of an integrated pest management program on golf course turf.**

Chlorothalonil plays a key role in Integrated Pest Management Programs (IPM) on golf course turf as it is the only fungicide with multi-site control. Without the availability of chlorothalonil,



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turf managers would be forced to abandon IPM principles and begin focusing specifically on bi-weekly preventative applications of less effective fungicides, ultimately requiring a significant increase in chemical applications and pesticide load in the environment. It is the key tool required to maintain the high quality playing surfaces that will continue to attract golfers. This is an extremely important active ingredient used for the prevention and control of snow mould, anthracnose, *Helminthosporium* leaf spot, brown patch, *Microdochium* patch, and dollar spot. It is also important for resistance management in an IPM program.

### **PMRA Response**

The PMRA acknowledges the importance of chlorothalonil for the management of turf diseases in golf courses. During the consultation period for REV2016-06, the PMRA received information related to golf course turf grass management practices and the use of chlorothalonil from different stakeholders. This information was used to refine the assessed exposure risks associated with chlorothalonil. As a result, two applications of chlorothalonil per year for turf grass foliar disease management plus one application in the fall for snow mould control are acceptable.

A number of active ingredients other than chlorothalonil belong to different mode of action groups are currently registered for the control of several important golf course turfgrass diseases: dollar spot, foliar and basal rot anthracnose, leaf spot and brown patch. Growers have the option to rotate these fungicides with chlorothalonil in a golf course turf grass disease control and resistance management program. Growers also have the option for one application of a pre-mix product containing chlorothalonil, propiconazole and fludioxonil in the fall for season long control of pink and gray snow moulds in addition to other products from different mode of action groups.

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## Appendix III Revised Label Amendments for Agricultural and Turf End-use Products Containing Chlorothalonil

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

### STATEMENTS TO PROTECT HUMAN HEALTH

#### USE PRECAUTIONS

#### I THE FOLLOWING STATEMENTS MUST BE ADDED TO ALL END-USE PRODUCT LABELS

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

**The following statements must be added to the applicable labels of end-use products:**

For products with ornamental uses:

- Not for use on greenhouse ornamental cut flowers
- Not for use on roses grown for cut flowers

For products with golf course uses:

- Do not allow the public to enter into treated golf courses following late fall application for snow mould

For products with agricultural uses:

- Do not hand harvest processing tomatoes

**The following statement must be removed from the end-use product label Reg. No. 15723:**

For application to filbert (hazelnut) trees, applicators must wear pants, a long-sleeved shirt and chemical resistant gloves and use closed cab airblast application equipment only.

#### II END-USE PRODUCTS FORMULATION AS LIQUIDS:

- 1) The following minimum mitigation measure requirements based on the risk assessment for workers mixing, loading and applying end-use products formulated as liquids will be applied to applicable product labels.

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## **GROUNDBOOM**

### **Groundboom - Except Applications to Potatoes**

If handling more than [340 kg a.i.] in one day, mixers and loaders must use a closed system.

Wear coveralls over a long-sleeved shirt and long pants, chemical resistant gloves, socks and shoes during mixing, loading, clean-up, and repair activities. Wear a long sleeved-shirt, long pants, chemical resistant gloves, socks and shoes during application. Gloves are not required during application within a closed cab.

### **Groundboom Application to Potatoes**

Mixers and loaders must use a closed system.

Wear coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up, and repair.

Applicators treating potato fields must use groundboom equipment with an enclosed cab. Gloves are not required for an applicator in an enclosed cab. Wear chemical-resistant gloves when leaving the cab for clean-up and repair.

## **AIRBLAST**

Wear coveralls over a long-sleeved shirt and long pants, chemical resistant gloves, socks and shoes during mixing, loading, clean-up, and repair activities. Wear a long sleeved-shirt, long pants, chemical resistant gloves, socks and shoes during application. Gloves are not required during application within a closed cab. Wear chemical-resistant gloves when leaving the cab for clean-up and repair.

In addition, wear chemical-resistant headgear during open cab airblast application. Chemical-resistant headgear includes Sou'Wester hat, chemical-resistant rain hat or large brimmed waterproof hat and hood with sufficient neck protection.

If handling more than [122 kg a.i./day], an applicator must wear a respirator with a NIOSH-approved organic vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH-approved canister approved for pesticides or use airblast equipment with an enclosed cab.

## **AERIAL**

Mixers and loaders must use a closed system.

The field crew and the mixer/loaders: Wear coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, socks and shoes during mixing, loading, clean-up, and repair.

Aerial applicators: Wear a long-sleeved shirt, long pants, socks and shoes during application. Gloves are not required during application within a closed cockpit.

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**IRRIGATION SYSTEM**

Wear coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, socks and shoes during mixing, loading, clean-up, and repair.

**HAND-HELD SPRAY EQUIPMENT**

Wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up, and repair.

Mixers/loaders/applicators in greenhouses and mushroom houses must wear a respirator with a NIOSH-approved organic vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH-approved canister approved for pesticides.

**III END-USE PRODUCTS FORMULATED AS DRY FLOWABLE AND WATER DISPERSIBLE GRANULES:**

- 1) End-use products formulated as dry flowable (DF) and water dispersible granules (WDG) must be discontinued and reformulated in water-soluble packaging (WSP).

For DF and/or WDG products that will be re-formulated as WSP, label language will need to be clarified to indicate directions for the use of water-soluble packaging. Registrants will need to ensure that the sizes of the water-soluble packets are reconciled with the registered/required use-specific application rates.

- 2) The following minimum mitigation measure requirements based on the risk assessment for workers mixing, loading, and applying end-use products formulated in water-soluble packaging will be applied to applicable product labels.

**GROUNDBOOM****Groundboom - Except Applications to Potatoes**

Wear coveralls over a long-sleeved shirt and long pants, chemical resistant gloves, socks and shoes during mixing, loading, clean-up, and repair activities. Wear a long sleeved-shirt, long pants, chemical resistant gloves, socks and shoes during application. Gloves are not required during application within a closed cab.

**Groundboom Application to Potatoes**

Wear coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up, and repair. Gloves are not required during application within a closed cab.

Applicators treating potato fields must use groundboom equipment with an enclosed cab. Gloves are not required for an applicator in an enclosed cab. Wear chemical-resistant gloves when leaving the cab for clean-up and repair.

**AIRBLAST**

Wear coveralls over a long-sleeved shirt and long pants, chemical resistant gloves, socks and shoes during mixing, loading, clean-up, and repair activities. Wear a long sleeved-shirt, long pants, chemical resistant gloves, socks and shoes during application. Gloves are not required during application within a closed cab.

In addition, wear chemical-resistant headgear during open cab airblast application. Chemical-resistant headgear includes Sou'Wester hat, chemical-resistant rain hat or large brimmed waterproof hat and hood with sufficient neck protection.

**AERIAL**

The field crew and the mixer/loaders: Wear coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, socks and shoes during mixing, loading, clean-up, and repair.

Aerial applicators: Wear a long-sleeved shirt, long pants, socks and shoes during application. Gloves are not required during application within a closed cockpit.

**IRRIGATION SYSTEM**

Wear coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, socks and shoes during mixing, loading, clean-up, and repair.

**HAND-HELD SPRAY EQUIPMENT**

Wear coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up, and repair.

Applicators in greenhouses and mushroom houses must wear a respirator with a NIOSH-approved organic vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH-approved canister approved for pesticides.

**DIRECTION FOR USE**

The following uses must be removed from all current labels:

- greenhouse cut flowers,
- greenhouse pachysandra,
- outdoor roses (grown for cut flowers)
- control of yellow patch on turf

Ensure that only registered crops from Table 1 (Summary of Accepted Uses) below are included on the appropriate chlorothalonil product labels. The rates in Table 1 are the maximum rates of chlorothalonil that can be applied as a single application. Product application rates must be amended to reflect these rates of chlorothalonil as the maximum rate.

Application intervals indicated in Table 1 refer to the duration between applications of any product containing chlorothalonil. The statement\* appearing at the top of the Summary of Accepted Uses table should appear as the first row of each application table in the product label.

**Table 1 Summary of Accepted Uses**

\*Application of any product containing chlorothalonil cannot be made more frequently than the Retreatments Intervals stated below

Crop	Maximum Application Rate (kg a.i./ha)	Maximum Number of Applications per year for chlorothalonil	Retreatments Interval (days)	Activity	REI (days)	Additional Instructions
Asparagus	1.7 (SN) 1.2 (DF)	3	14	Scouting	4	All other directions for use remain unchanged.
				All other activities	0.5	
Highbush Blueberries	3.6	2	7	Handset irrigation	3	
				All other activities	0.5	
Lowbush Blueberries	3.6 (SN) 2.5 (DF)	2	42	All activities	0.5	All other directions for use remain unchanged.
Carrot	1.6	7	7	Hand harvesting	22	All other directions for use remain unchanged.
				Scouting	7	
				All other activities	0.5	
Celery, field	2.0	2	3	All activities	0.5	All other directions for use remain unchanged.
Celery seedbeds (greenhouse)	1.4	1	N/A	All activities	0.5	All other directions for use remain unchanged.
Cherry (sweet and sour)	4.5	2 (spring) + 1 (post-harvest)	10	Thinning	8	<b>(Pre-harvest)</b> <b>Target Disease</b> Blossom blight/Brown rot, cherry leaf spot, black knot <b>Use Rate</b> 2.5 – 4.5 kg a.i./ha <b>Application Instructions</b> - Apply 1-2 applications from pink through shuck split at 10 days apart. DO NOT apply after shuck split to avoid fruit injury. DO NOT make more than

Crop	Maximum Application Rate (kg a.i./ha)	Maximum Number of Applications per year for chlorothalonil	Retreatment Interval (days)	Activity	REI (days)	Additional Instructions
				All other activities	0.5	2 pre-harvest applications per season. DO NOT apply within 40 days of harvest.  <b>(Post-harvest)</b> <b>Target Disease</b> Cherry leaf spot and black knot <b>Use Rate</b> 3.6 kg a.i./ ha <b>Application Instructions</b> - Apply once to foliage 1-7 days after fruit is removed. <b>DO NOT</b> make more than 1 post-harvest application per season.
Chickpeas	2.0 (1 <sup>st</sup> )	2	10	Scouting	2	All other directions for use remain unchanged.
	1.5 (2 <sup>nd</sup> )			All other activities	0.5	
Cole crops: Broccoli, Brussels sprouts, cauliflower	2.4	1	N/A	Topping (Brussels sprouts)	5	All other directions for use remain unchanged.
				Scouting	5	
				All other activities	0.5	
Cabbage	2.4	2	7	Scouting, thinning	2	All other directions for use remain unchanged.
				Hand weeding	1	
				All other activities	0.5	
Conifers - outdoor (e.g., cedar, Douglas-fir, cypresses, fir, junipers, pine, spruce); including Christmas trees	4.8	2	7	Harvesting (seedling production)	15	All other directions for use remain unchanged.
				Handset irrigation	11	
				Harvest (seed cone), Christmas trees	7	
				Scouting, shaping	1	
				All other activities	0.5	
Conifer nursery beds (greenhouse)	1.2	1	N/A	All activities	0.5	All other directions for use remain unchanged.
Corn, sweet	1.6	2	10	Hand harvesting	18	All other directions for use remain unchanged.
				Mechanical harvesting	14	
				Scouting	1	

Crop	Maximum Application Rate (kg a.i./ha)	Maximum Number of Applications per year for chlorothalonil	Retreatment Interval (days)	Activity	REI (days)	Additional Instructions
				All other activities	0.5	
Cranberry	5.8	1	N/A	Scouting	5	<b>Target Disease</b> Fruit rots <b>Use Rate</b> 5.8 kg a.i./ ha <b>Application instructions</b> – Apply once per year as needed. <b>DO NOT</b> make more than one application per year. <b>DO NOT</b> apply within 50 days of harvest.
				All other activities	0.5	
Cucurbit vegetables (Cantaloupe, muskmelon, honeydew, squash, pumpkin, watermelon, cucumber)	2.4	2	7	All activities	0.5	All other directions for use remain unchanged.
Evening Primrose	1.2	2	14	All activities	0.5	All other directions for use remain unchanged.
Ginseng	2.4	2 + 1 (fall)	7	All activities	0.5	<b>Target Disease</b> Alternaria leaf blight; Grey mould <b>Use Rate</b> 1.2 – 2.4 kg a.i./ ha <b>Application Interval</b> <b>Days</b> 10 <b>Application instructions</b> - Start applications when disease threatens and make second application 10 days later. A third application may be made in the fall. <b>DO NOT</b> make more than three applications per year. <b>DO NOT</b> apply within 14 days of harvest.
Hazelnut	3.4	3	20	Scouting	18	All other directions for use



Crop	Maximum Application Rate (kg a.i./ha)	Maximum Number of Applications per year for chlorothalonil	Retreatment Interval (days)	Activity	REI (days)	Additional Instructions
				Transplanting	10	remain unchanged.
				Orchard maintenance	2	
				All other activities	0.5	
Lentils	2.0	2	10	Scouting	3	All other directions for use remain unchanged.
				All other activities	0.5	
Mushrooms	12.7	1	N/A	All activities	0.5	All other directions for use remain unchanged.
Onion (dry bulb)	2.4	2	7	Hand weeding	6	All other directions for use remain unchanged.
				Scouting	1	
				All other activities	0.5	
Onion (green bunching)	2.4	2	7	Hand weeding	6	All other directions for use remain unchanged.
				Scouting	1	
				All other activities	0.5	
Greenhouse ornamentals other than roses (not grown for cut flowers)	1.25	1	N/A	All activities	0.5	All other directions for use remain unchanged.
Greenhouse roses (not grown for cut flowers)	0.94	1	N/A	All activities	0.5	All other directions for use remain unchanged.
Outdoor ornamentals (not grown for cut flowers) except roses and <i>pachysandra</i>	2.5	2	7	Handset irrigation	3	All other directions for use remain unchanged.
				All other activities	0.5	All other directions for use remain unchanged.
Outdoor ornamentals (cut flowers except roses)	2.5	1	N/A	Hand harvesting, disbudding, hand pruning	10	All other directions for use remain unchanged.
				All other activities	0.5	
Outdoor roses (not grown for cut flowers)	1.9	2	7	Handset irrigation	1	All other directions for use remain unchanged.
				All other activities	0.5	
Outdoor pachysandra	5.0	1	N/A	Handset irrigation	2	All other directions for use remain unchanged.
				All other activities	0.5	
Parsnip	1.4	7	7	Hand harvesting	21	All other directions for use remain unchanged.
				Scouting	5	
				All other activities	0.5	
Pea, dry	1.5	2	10	Scouting	1	All other directions for use remain unchanged.
				All other activities	0.5	

Crop	Maximum Application Rate (kg a.i./ha)	Maximum Number of Applications per year for chlorothalonil	Retreatment Interval (days)	Activity	REI (days)	Additional Instructions
Peach and nectarine	4.5	2 (spring) + 1 (dormant)	10	Thinning	11	<p><b>Target Disease</b> Blossom blight/Brown rot  <b>Use Rate</b> 2.5 – 4.5 kg a.i./ha  <b>Application Instructions</b>  - Apply 1-2 applications from pink through shuck period.  <b>DO NOT</b> apply within 60 days of harvest.</p>
				All other activities	0.5	<p><b>Target Disease</b> Peach leaf curl  <b>Use Rate</b> 2.5 – 4.5 kg a.i./ha  <b>Application Instructions</b>  - Apply one application per year as a fall dormant spray at 75-100% leaf drop.  <b>DO NOT</b> make more than 3 applications per year including a dormant spray.</p>
Potato (seed)	1.2	3	7	Handset irrigation	23	All other directions for use remain unchanged.
				Roguing	19	
				Scouting	3	
				All other activities	0.5	
Potato (table)	1.2	3	7	Handset irrigation	23	All other directions for use remain unchanged.
				Scouting	3	
				All other activities	0.5	
Strawberry	1.8	2 (spring) + 1 (post-harvest)	10	All activities	0.5	<p><b>Target Disease</b> Botrytis Fruit Rot  <b>Application Instructions</b>  - Apply once in the fall.  Apply two pre-bloom</p>

Crop	Maximum Application Rate (kg a.i./ha)	Maximum Number of Applications per year for chlorothalonil	Retreatment Interval (days)	Activity	REI (days)	Additional Instructions
						sprays the following spring, one when new growth appears and again 10 days later. <b>DO NOT</b> make more than three applications per year. <b>DO NOT</b> apply within 30 days of harvest. <b>DO NOT APPLY BY AIR.</b>
Tomato (not for processing)	2.4 and 1.2	2 (total)	14 (2.4 kg a.i./ha); 8 (1.2 kg a.i./ha)	All activities	0.5	All other directions for use remain unchanged.
Tomato (for processing)	2.4 and 1.2	2 at 2.4 and 7 at 1.2	14 (2.4 kg a.i./ha); 8 (1.2 kg a.i./ha)	Scouting	7	All other directions for use remain unchanged.
				All other activities	0.5	
Turf (snow mould)	12.0	1	N/A	All activities	until sprays have dried	All other directions for use remain unchanged.
Turf – golf courses and sod farms	9.5 and 4.8	2 (total)	14 (9.5 kg a.i./ha) 7 (4.8 kg a.i./ha)	All activities	until sprays have dried	All other directions for use remain unchanged.
Wheat	1.3	2	10	All activities	0.5	All other directions for use remain unchanged.

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## DIRECTIONS FOR USE

- Remove all references to making subsequent applications “as needed” or “as necessary” or any other wording that implies that the user may make more applications than indicated in the use patterns noted in Table 1 above.
- The Principal display panels and Resistance Management sections of all labels must be updated to reflect the revised Fungicide Resistance Action Committee (FRAC) code for chlorothalonil, “GROUP M5 FUNGICIDE”.
- Resistance Management sections must be updated per the PMRA Directive DIR2013-04, *Pesticide Resistance Management Labelling Based on Target Site / Mode of Action*.
- Remove all references to application of chlorothalonil at shorter re-application intervals than indicated in Table 1, such as “Under severe conditions, shorten spray interval”.
- Reference to tank mix partners that contain active ingredients that have been discontinued or phased out must be removed from product labels.
- Where tank mix partners are not named on the chlorothalonil product label, all tank mixing instructions must be removed.
- All disease claims must have the associated Latin name (genus and species) of the causative pathogen added to the product label.
- For clarity, end-use product labels (Reg. No. 29225, 29306, 29355, and 29356), that specify only “Blueberry”, must be revised to specify “Blueberry (highbush)”.
- The following statement must be included for end-use product labels that include strawberry and cucurbit uses:

*DO NOT apply via sprinkler irrigation system.*
- A label statement prohibiting the use of products containing chlorothalonil on greenhouse-grown food crops, unless clearly specified on the label (e.g., celery seedbeds) must be included on the end-use product labels.

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**STATEMENTS TO PROTECT THE ENVIRONMENT (ALL END-USE PRODUCT LABELS)****Add to ENVIRONMENTAL PRECAUTIONS:**

TOXIC to aquatic organisms. Observe buffer zones specified under DIRECTIONS FOR USE. To reduce runoff from treated areas into aquatic habitats avoid applications to areas with a moderate to steep slope, compacted soil, or clay.

Avoid application when heavy rain is forecast.

**Add to DIRECTIONS FOR USE:**

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.

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

**Vegetative Filter Strips**

A Vegetative Filter Strip (VFS) of at least 10 metres wide must be constructed and maintained. The VFS is required between the field edge and adjacent, downhill aquatic habitats to reduce risk to aquatic organisms from run-off. Aquatic habitats include, but are not limited to, lakes, reservoirs, rivers, permanent streams, marshes or natural ponds, and estuaries.

The VFS is to be composed of grasses and may also include shrubs, trees, or other vegetation. Additional guidance can be found on the PMRA Environmental Risk Mitigation webpages.

Both VFS and spray drift buffer zones must be observed.

**Spray Drift Buffer Zones**

Spray drift buffer zones are to protect terrestrial and aquatic habitats from spray drift. Spray drift buffer zones are a separate requirement from VFS which are required to mitigate risks from runoff.

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) medium classification. Boom height must be 60 cm or less above the crop or ground.

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

For those labels that have no aerial application uses:

DO NOT apply by air.

For those labels that have aerial application uses:

Aerial application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply when wind speed is greater than 16 km/h at flying height at the site of application. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572.1) medium classification. To reduce drift caused by turbulent wingtip vortices, the nozzle distribution along the spray boom length **MUST NOT** exceed 65% of the wing- or rotorspan.

### Spray Drift Buffer Zones:

Spot treatments using hand-held equipment **DO NOT** require a buffer zone.

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

**Buffer Zone Table**

	Crop	Buffer Zones (metres) Required for the Protection of:				
		Freshwater Habitat of Depths:		Estuarine/Marine Habitats of Depths:		
		Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m	
Field sprayer	wheat, evening primrose, potato	2	1	2	1	
	asparagus, carrots, sweet corn, parsnip, dry pea	3	1	3	1	
	celery, chickpeas, lentils, strawberry	3	1	3	2	
	cole crops, cucurbit vegetables, ginseng, onion, cabbage, tomato, outdoor ornamentals (excluding <i>Pachysandra</i> )	4	1	4	2	
	blueberries (lowbush, highbush), outdoor <i>Pachysandra</i> , conifers - outdoor	5	1	5	3	
	cranberry	10	1	10	4	
	turf	15	2	15	5	
Airblast	outdoor ornamentals	Early growth stage	35	10	35	25

	Crop		Buffer Zones (metres) Required for the Protection of:			
			Freshwater Habitat of Depths:		Estuarine/Marine Habitats of Depths:	
			Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m
	(excluding <i>Pachysandra</i> )	Late growth stage	25	5	25	15
	filberts (hazelnuts), blueberry (lowbush, high bush)	Early growth stage	40	15	40	30
		Late growth stage	30	5	30	20
	cherries, peaches, nectarines, conifers - outdoors	Early growth stage	40	15	40	30
		Late growth stage	30	10	30	20
Aerial	potato, evening primrose	Fixed wing	65	4	65	20
		Rotary wing	50	1	50	15
	wheat	Fixed wing	75	5	75	20
		Rotary wing	55	2	55	15
	parsnip	Fixed wing	90	5	90	20
		Rotary wing	60	3	60	20
	dry pea	Fixed wing	95	5	95	25
		Rotary wing	70	4	70	20
	carrot	Fixed wing	100	5	100	30
		Rotary wing	75	5	75	20
	lentils, celery	Fixed wing	175	10	175	40
		Rotary wing	100	5	100	30
	cole crops, cucurbit, onion, tomato	Fixed wing	200	10	200	55
		Rotary wing	125	10	125	40

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.

The spray-drift buffer zones for this product can be modified based on weather conditions and spray equipment configuration by accessing the Buffer Zone Calculator on the Pest Management Regulatory Agency web site. This tool cannot be used to reduce the vegetative filter strips.

## Appendix IV Revised Human Health Toxicology Reference Values for Chlorothalonil

**Table 1 Revised Human Health Toxicology Reference Values for Chlorothalonil**

Exposure Scenario	Dose (mg/kg bw/day)	Study	CAF or Target MOE or LOC <sup>1</sup>
Acute dietary	LOAEL = 175	90-day special feeding study in rats; squamous hyperplasia and hyperkeratosis in the forestomach and degenerative kidney changes characterized by vacuolation in the proximal convoluted tubules observed beginning on Day 4 at 175 mg/kg bw/day	300
ARfD <sup>2</sup> = 0.58 mg/kg bw/day			
Chronic dietary (all populations)	NOAEL = 1.5	2-year study in rats; kidney (focal epithelial hyperplasia, karyomegaly, clear cell hyperplasia, interstitial fibrosis, cortical cysts and chronic progressive nephropathy) and stomach (squamous epithelial hyperplasia and hyperkeratosis of the fore stomach and erosion and ulceration of the glandular and nonglandular stomach) effects at $\geq 3.3$ mg/kg bw/day (males)	100
ADI = 0.015 mg/kg bw/day			
Short-term dermal	NOAEL = 600	21-day dermal study in rats; no adverse effects observed up to, and including, the highest dose tested.	100
Intermediate, long-term dermal and short-, intermediate- and long-term inhalation	NOAEL = 1.5	90-day dietary study in rats; increased relative kidney weights (to body weight) and kidney pathology (an increased incidence of irregular intracytoplasmic inclusion bodies in the proximal convoluted tubules cells in kidneys of males) observed at $\geq 3$ mg/kg/bw/day and dose-related increase in hyperplasia hyperkeratosis of the gastric epithelium in both sexes at $\geq 10$ mg/kg bw/day; 2-year rat dietary study: kidney (focal epithelial hyperplasia, karyomegaly, clear cell hyperplasia, interstitial fibrosis, cortical cysts and chronic progressive nephropathy) and stomach (squamous epithelial hyperplasia and hyperkeratosis of the fore stomach and erosion and ulceration of the glandular and nonglandular stomach) effects at $\geq 3.3$ mg/kg bw/day (males)	100
Non-dietary oral (children)			
Aggregate Short-term	Oral and inhalation: NOAEL = 1.5 Dermal: No common toxicological endpoint (21-day dermal toxicity study)		
Cancer Risk	$q1^* = 7.66 \times 10^{-3}$ (mg/kg bw/day) <sup>-1</sup>	2-year study in rats; based on incidences of renal tumours (adenoma and carcinoma) in female rats	Residential $1 \times 10^{-6}$ Occupational $1 \times 10^{-5}$

NOAEL – No Observed Adverse Effect Level; LOAEL – Lowest Observed Adverse Effect Level  
Dermal absorption is considered to be 19% of the oral dose based on dermal absorption studies and inhalation absorption is considered to be 100% (default) of the oral dose.

<sup>1</sup> CAF (composite assessment factor) for dietary assessments or MOE (Margin of Exposure) for occupational/residential assessments or LOC (Level of Concern) for cancer assessments; 100 (uncertainty factors of a 10-fold for interspecies extrapolation and 10-fold for intraspecies variations) and 300 (uncertainty factors of a 10-fold for interspecies extrapolation and 10-fold for intraspecies variations; 3 fold for LOAEL to NOAEL extrapolation).



2 Reference Dose (ARfD) previously used for the PMRA acute dietary risk assessment in PRVD2011-14.

## Appendix V Revised Residential Risk Assessments

**Table 1 Exposure and risk assessment for golfers**

Scenario		Peak TTR <sup>a</sup> ( $\mu\text{g a.i./cm}^2$ )	TC <sup>b</sup> (Arithmetic mean) ( $\text{cm}^2/\text{hr}$ )	BW <sup>c</sup> (kg)	Daily dermal exposure dose <sup>d</sup> ( $\text{mg/kg bw/day}$ )	Dermal MOE <sup>e</sup>	TC <sup>b</sup> (50th %-ile) ( $\text{cm}^2/\text{hr}$ )	LADD <sup>f</sup> ( $\text{mg/kg}$ $\text{bw/day}$ )	Cancer Risk <sup>g</sup>
4.8 kg a.i./ha 2x RTI 7 days	adult golfer (16+)	0.710	5300	80	0.1880	3191	2800	$8.4 \times 10^{-5}$	$8.0 \times 10^{-7}$
	youth golfer (11 < 16)	0.710	4400	57	0.2191	2738	2300	$7.6 \times 10^{-6}$	
	children (6 < 11)	0.710	2900	32	0.2572	2333	1500	$8.9 \times 10^{-6}$	
9.5 kg a.i./ha 2x RTI 14 days	adult golfer (16 +)	1.167	5300	80	0.3093	1940	2800	$1.4 \times 10^{-4}$	$1.0 \times 10^{-6}$
	youth golfer (11 < 16)	1.167	4400	57	0.3604	1665	2300	$1.3 \times 10^{-5}$	
	children (6 < 11)	1.167	2900	32	0.4232	1418	1500	$1.5 \times 10^{-5}$	

<sup>a</sup> Peak TTR –Turf Transferable Residue, 1% residue deposition following two applications at the maximum rate of 4.8 kg a.i./ha (RTI 7 days) or 9.5 kg a.i./ha (RTI 14 days)

<sup>b</sup> TC- Transfer Coefficient (2012 USEPA Residential SOPs)

<sup>c</sup> BW - Body weights (2012 USEPA Residential SOPs)

<sup>d</sup> Daily dermal exposure dose ( $\text{mg/kg bw/day}$ ) = (TTR ( $\mu\text{g a.i./cm}^2$ )  $\times$  0.001 ( $\mu\text{g/mg}$ )  $\times$  TC ( $\text{cm}^2/\text{hr}$ )  $\times$  4 hrs/day  $\times$  DAF of 100%) / BW (kg)

<sup>e</sup> Dermal MOE (Margin of Exposure) = Short-term NOAEL of 600/ $\text{mg/kg bw/day}$  from a 21-day dermal study in rats / daily dermal exposure dose ( $\text{mg/kg bw/day}$ ); target MOE=100

<sup>f</sup> LADD - lifetime average daily dose ( $\text{mg/kg bw/day}$ ) = (TTR ( $\mu\text{g a.i./cm}^2$ )  $\times$  0.001 ( $\mu\text{g/mg}$ )  $\times$  TC ( $\text{cm}^2/\text{hr}$ )  $\times$  4 hrs/day  $\times$  DAF of 19%) / BW (kg)  $\times$  2/year (365 days)  $\times$  yrs./lifetime); frequency of exposure in a lifetime (78 yrs.) of 63 years for adults and 5 years for youth and children

<sup>g</sup> Cancer risk = LADD  $\times$  q1\* of  $7.66 \times 10^{-3}$  ( $\text{mg/kg/bw/day}$ )<sup>-1</sup>, the PMRA's LOC for residential scenarios  $1 \times 10^{-6}$

**Table 2 Exposure and risk assessment for individuals handling retail plants.**

Scenario		DFR <sup>a</sup> ( $\mu\text{g}/\text{cm}^2$ )	TC <sup>b</sup> ( $\text{cm}^2/\text{hr}$ )	BW <sup>c</sup> (kg)	Daily Dermal Dose <sup>d</sup> ( $\text{mg}/\text{kg}$ bw/day)	Dermal MOE <sup>e</sup>	TWA DFR <sup>f</sup> ( $\mu\text{g}/\text{cm}^2$ )	Exposure Frequency (days/year)	LADD <sup>g</sup> ( $\text{mg}/\text{kg}$ bw/day)	Cancer Risk <sup>h</sup>
5 kg a.i./ha 1 application	Adult	12.500	1700	80	0.2656	2259	3.990	1	$4.0 \times 10^{-5}$	$3.0 \times 10^{-7}$
	Children 6 < 11 yrs	12.500	930	32	0.1816	3303	3.990	1	$2.0 \times 10^{-6}$	
2.5 kg a.i./ha 2 applications	Adult	9.239	1700	80	0.1963	3056	3.036	2	$5.0 \times 10^{-5}$	$4.0 \times 10^{-7}$
	Children 6 < 11 yrs	9.239	930	32	0.1343	4469	3.036	2	$3.0 \times 10^{-6}$	

<sup>a</sup> Peak DFR –Dislodgeable Foliar Residue, 25% residue deposition following one or two applications to ornamentals

<sup>b</sup> TC - Transfer Coefficient (2012 USEPA Residential SOPs)

<sup>c</sup> BW - Body weights (2012 USEPA Residential SOPs)

<sup>d</sup> Daily dermal exposure dose ( $\text{mg}/\text{kg}$  bw/day) = (DFR ( $\mu\text{g}$  a.i./ $\text{cm}^2$ )  $\times$  0.001 ( $\mu\text{g}/\text{mg}$ )  $\times$  TC ( $\text{cm}^2/\text{hr}$ )  $\times$  (adult 1 hr/day, child 0.5 hr/day)  $\times$  DAF of 100%) / BW (kg)

<sup>e</sup> Dermal MOE = Short-term NOAEL of 600/ $\text{mg}/\text{kg}$  bw/day from a 21-day dermal study in rats / daily dermal exposure dose ( $\text{mg}/\text{kg}$  bw/day); target MOE=100

<sup>f</sup> TWA DFR – Time-weighted Average DFR ( $\mu\text{g}/\text{cm}^2$ ) – DFR averaged over 30 days

<sup>g</sup> LADD - lifetime average daily dose ( $\text{mg}/\text{kg}$  bw/day) = (DFR ( $\mu\text{g}$  a.i./ $\text{cm}^2$ )  $\times$  0.001 ( $\mu\text{g}/\text{mg}$ )  $\times$  TC ( $\text{cm}^2/\text{hr}$ )  $\times$  (adult 1 hr/day, child 0.5 hr/day)  $\times$  DAF of 19%) / BW (kg)  $\times$  exposure frequency (days/year)  $\times$  yrs/lifetime); frequency of exposure in a lifetime (78 yrs) of 63 years for adults and 5 years for youth and children

<sup>h</sup> Cancer risk = LADD  $\times$  q1\* of  $7.66 \times 10^{-3}$  ( $\text{mg}/\text{kg}/\text{bw}/\text{day}$ )<sup>-1</sup>, the PMRA's LOC for residential scenarios  $1 \times 10^{-6}$

**Table 3 Aggregate exposure and risk assessment**

Scenario		Aggregate non-cancer exposure and risk	Residential lifetime cancer risk	Dietary lifetime cancer risk	Aggregate cancer risk <sup>c</sup>
Individual handling retail plants + dietary exposure		Aggregate non-cancer exposure and risk assessment not required (no common toxic effect for dermal and oral routes of exposure)	$4.0 \times 10^{-7}$	$8.0 \times 10^{-7}$	$1.0 \times 10^{-6}$
Golfer + dietary exposure	4.8 kg a.i./ha		$8.0 \times 10^{-7}$	$8.0 \times 10^{-7}$	$2.0 \times 10^{-6}$
	9.5 kg a.i./ha		$1.0 \times 10^{-6}$	$8.0 \times 10^{-7}$	$2.0 \times 10^{-6}$

<sup>a</sup> Lifetime cancer risk for individuals handling retail plants and golfers

<sup>b</sup> Dietary cancer risk for the general population (PRVD2011-14)

Aggregate cancer risk = Residential cancer risk + dietary cancer risk, the PMRA LOC  $1 \times 10^{-6}$ . For golfers, the aggregate cancer risk is not expected to be of concern given conservative assumptions used in dietary (for example monitoring data based on the current use pattern) and golfer (for example peak residue levels and 68 years of golfing) exposure assessments.

## Appendix VI Revised Mixer/Loader/Applicator Assessments

**Table 1a Short-term risk non-cancer and cancer risk assessment for mixers/loaders/applicators using groundboom equipment.**

Crop <sup>a</sup>	EUP type	Minimum mitigation measures <sup>b</sup>		Combined Non-cancer Unit Exposure <sup>c</sup> (mg/kg a.i.)		Combined Cancer Unit Exposure <sup>d</sup> (mg/kg a.i.)	AR <sup>e</sup> (kg a.i./ha)	ATPD <sup>f</sup> (ha)		Short-term MOE <sup>g</sup>		Exposure Frequency <sup>h</sup> (days/year)	Cancer risk <sup>i</sup>
		Minimum PPE	Closed ML	dermal	inhalation			non-cancer	cancer	dermal	inhalation		
Large field crops (lentils)	DF	ML: coveralls over a long-sleeved shirt and long pants, CR gloves	WSP	0.0333	0.00186	0.0082	2.0	240	240	3001	134	25	$1.0 \times 10^{-5}$
	SN	A: long sleeved shirt and long pants, CR gloves	YES*	0.0350	0.00179	0.0084				2856	140		$1.0 \times 10^{-5}$
Small field crops (cucurbits)	DF	ML: coveralls over a long-sleeved shirt and long pants, CR gloves A: long sleeved shirt and long pants, CR gloves	WSP	0.0333	0.00186	0.0082	2.4	26	12	> 10 000	1034	30	$1.0 \times 10^{-6}$
	SN	MLA: long sleeved shirt and long pants, CR gloves	-	0.0839	0.00231	0.0183				9168	833		$2.0 \times 10^{-6}$
Cranberry	DF	ML: coveralls over a long-sleeved shirt and long pants, CR gloves	WSP	0.0333	0.00186	0.0082	5.8	91	91	2729	122	15	$9.0 \times 10^{-6}$
	SN	A: long sleeved shirt and long pants, CR gloves	-	0.0567	0.00231	0.0131				1603	<b>98**</b>		$1.0 \times 10^{-5}$
Berries (blueberry lowbush)	DF	ML: coveralls over a long-sleeved shirt and long pants, CR gloves	WSP	0.0333	0.00186	0.0082	2.5	61	61	9446	423	30	$5.0 \times 10^{-6}$
	SN	A: long sleeved shirt and long pants, CR gloves	-	0.0567	0.00231	0.0131				3854	237		$1.0 \times 10^{-5}$
Conifers, outdoor	DF	ML: coveralls over a long-sleeved shirt and long pants, CR gloves A long sleeved shirt and long pants and CR gloves	WSP	0.0333	0.00186	0.0082	4.8	27.5	27.5	> 10 000	489	2	$3.0 \times 10^{-7}$
	SN	MLA: long sleeved shirt and long pants, CR gloves	-	0.0839	0.00231	0.0183				4334	394		$6.0 \times 10^{-7}$
Turf (sod farm)	DF	ML: coveralls over a long-sleeved shirt and long pants, CR gloves A: long sleeved shirt and long pants, CR gloves	WSP	0.0333	0.00186	0.0082	12.0	30	30	4002	179	1	$4.0 \times 10^{-7}$
	SN	MLA: long sleeved shirt and long pants, CR gloves	-	0.0839	0.00231	0.0183				1589	144		$9.0 \times 10^{-7}$

Crop <sup>a</sup>	EUP type	Minimum mitigation measures <sup>b</sup>			Combined Non-cancer Unit Exposure <sup>c</sup> (mg/kg a.i.)		Combined Cancer Unit Exposure <sup>d</sup> (mg/kg a.i.)	AR <sup>e</sup> (kg a.i./ha)	ATPD <sup>f</sup> (ha)		Short-term MOE <sup>g</sup>		Exposure Frequency <sup>h</sup> (days/year)	Cancer risk <sup>i</sup>
		Minimum PPE	Closed ML		dermal	inhalation			non-cancer	cancer	dermal	inhalation		
	DF	ML: coveralls over a long-sleeved shirt and long pants, CR gloves A: long sleeved shirt and long pants, CR gloves	WSP		0.0333	0.00186	0.0082	9.5	30	30	5055	226	2	$6.0 \times 10^{-7}$
	SN	MLA: long sleeved shirt and long pants, CR gloves	-		0.0839	0.00231	0.0183				2007	182		$1.0 \times 10^{-6}$

ML – mixer/loader; A – applicator; EUP – end-use product; DF – dry formulation; SN- solution (liquid formulation); CR – chemical-resistant; MOE - Margin of Exposure; WSP – water soluble packaging; LADD - lifetime average daily dose

\*Closed mixing/loading systems required if handling more than 340 kg a.i./day

\*\*Considered to meet the target MOE

<sup>a</sup> Crop (most conservative representative crop scenario)

<sup>b</sup> Minimum mitigation measures required for mixers/loaders/applicators

<sup>c</sup> Combined non-cancer unit exposure (UE) (mg/kg a.i.) - dermal and inhalation unit exposure for mixer/loader/applicator from the Pesticide Handler Exposure Database (PHED) or Agricultural Handlers Exposure Task Force (AHETF); 100% dermal absorption assumed for short-term scenarios

<sup>d</sup> Combined cancer unit exposure (UE) (mg/kg a.i.) - dermal plus inhalation unit exposure for mixer/loader/applicator from the Pesticide Handler Exposure Database (PHED) or Agricultural Handlers Exposure Task Force (AHETF); 19% dermal absorption assumed for cancer assessment

<sup>e</sup> AR - Application rate (kg a.i./ha) – based on the supported use pattern

<sup>f</sup> ATPD (ha) – area treated per day

<sup>g</sup> Short-term MOE = NOAEL (mg/kg bw/day) / daily dermal or inhalation exposure dose (mg/kg bw/day)

Dermal MOE estimated using a dermal NOAEL of 600 mg/kg bw/day with a target MOE of 100

Inhalation MOE estimated using an oral NOAEL of 1.5 mg/kg bw/day with a target MOE of 100

Daily dermal exposure dose (mg/kg bw/day) = [Combined non-cancer dermal or inhalation UE (mg/kg a.i.) × AR (kg a.i./ha) × non-cancer ATPD (ha)] / BW (80 kg)

<sup>h</sup> Exposure frequency (days/year) – default or use-specific information

<sup>i</sup> Cancer risk = LADD (mg/kg bw/day) × q1\* of 7.66 (mg/kg bw/day)<sup>-1</sup>, occupational LOC > 1 × 10<sup>-5</sup>

LADD = [Combined cancer UE (mg/kg a.i.) × AR (kg a.i./ha) × cancer ATPD (ha) × exposure frequency (days/year) × career duration (40 years/78 years)]/ BW (80 kg)

**Table 1b Intermediate-term risk non-cancer and cancer risk assessment for mixers/loaders/applicators using groundboom equipment.**

Crop <sup>a</sup>	EUP type	Minimum mitigation measures <sup>b</sup>			Combined Non-cancer Unit Exposure <sup>c</sup> (mg/kg a.i.)		Combined Cancer Unit Exposure <sup>d</sup> (mg/kg a.i.)	AR <sup>e</sup> (kg a.i./ha)	ATPD <sup>f</sup> (ha)		Intermediate-term MOE <sup>g</sup>			Exposure Frequency <sup>h</sup> (days/year)	Cancer risk <sup>i</sup>
		PPE	Closed ML	Closed cab*	dermal	inhalation			non-cancer	cancer	dermal	inhalation	combined		
Vegetables (tomato grown for processing)	DF	ML: coveralls over a long-sleeved shirt and long pants, CR gloves A long sleeved shirt and long pants, CR gloves	WSP	-	0.0063	0.00186	0.0082	2.4	26	12	304	1034	235	30	$1.0 \times 10^{-6}$
	SN	MLA: long sleeved	-	-	0.0159	0.00231	0.0183				121	833	105		$2.0 \times$

Crop <sup>a</sup>	EUP type	Minimum mitigation measures <sup>b</sup>			Combined Non-cancer Unit Exposure <sup>c</sup> (mg/kg a.i.)		Combined Cancer Unit Exposure <sup>d</sup> (mg/kg a.i.)	AR <sup>e</sup> (kg a.i./ha)	ATPD <sup>f</sup> (ha)		Intermediate-term MOE <sup>g</sup>			Exposure Frequency <sup>h</sup> (days/year)	Cancer risk <sup>i</sup>
		PPE	Closed ML	Closed cab*	dermal	inhalation			non-cancer	cancer	dermal	inhalation	combined		
		shirt and long pants, CR gloves												10 <sup>-6</sup>	
Potato	DF	MLA: coveralls over a long-sleeved shirt and long pants, CR gloves	WSP	YES	0.0023	0.00024	0.0026	1.2	360	240	118	1157	107	25	3.0 × 10 <sup>-6</sup>
	SN		YES	YES	0.0027	0.00017	0.0028				104	1634	98**		3.0 × 10 <sup>-6</sup>

ML – mixer/loader; A – applicator; EUP – end-use product; DF – dry formulation; SN- solution (liquid formulation); CR – chemical-resistant; MOE - Margin of Exposure; WSP – water soluble packaging; LADD - lifetime average daily dose

\*Gloves are not assumed for applicators using enclosed cab equipment

\*\*Considered to meet the target MOE

<sup>a</sup> Crop (most conservative representative crop scenario)

<sup>b</sup> Minimum mitigation measures required for mixers/loaders/applicators

<sup>c</sup> Combined non-cancer unit exposure (UE) (mg/kg a.i.) - dermal and inhalation unit exposure for mixer/loader/applicator from the Pesticide Handler Exposure Database (PHED) or Agricultural Handlers Exposure Task Force (AHETF); 19% dermal absorption assumed for intermediate-term scenarios

<sup>d</sup> Combined cancer unit exposure (UE) (mg/kg a.i.) - dermal plus inhalation unit exposure for mixer/loader/applicator from the Pesticide Handler Exposure Database (PHED) or Agricultural Handlers Exposure Task Force (AHETF); 19% dermal absorption assumed for cancer assessment

<sup>e</sup> AR - Application rate (kg a.i./ha) – based on the supported use pattern

<sup>f</sup> ATPD (ha) – area treated per day

<sup>g</sup> Intermediate-term MOE = NOAEL (mg/kg bw/day) / daily dermal plus inhalation exposure dose (mg/kg bw/day)

Dermal and inhalation MOEs estimated using an oral NOAEL of 1.5 mg/kg bw/day with a target MOE of 100

Daily dermal exposure dose (mg/kg bw/day) = [Combined non-cancer dermal or inhalation UE (mg/kg a.i.) × AR (kg a.i./ha) × non-cancer ATPD (ha)] / BW (80 kg)

<sup>h</sup> Exposure frequency (days/year) – default (30 days) or use-specific values

<sup>i</sup> Cancer risk = LADD (mg/kg bw/day) × q1\* of 7.66 (mg/kg bw/day)<sup>-1</sup>, occupational LOC > 1 × 10<sup>-5</sup>

LADD = [Combined cancer UE (mg/kg a.i.) × AR (kg a.i./ha) × cancer ATPD (ha) × exposure frequency (days/year) × career duration (40 years/78 years)]/ BW (80 kg)

**Table 2 Short-term risk non-cancer and cancer risk assessment for mixers/loaders/applicators using airblast equipment.**

Crop <sup>a</sup>	EUP type	Minimum mitigation measures <sup>b</sup>		Combined Non-cancer Unit Exposure <sup>c</sup> (mg/kg a.i.)		Combined Cancer Unit Exposure <sup>d</sup> (mg/kg a.i.)	AR <sup>e</sup> (kg a.i./ha)	ATPD <sup>f</sup> (ha)		Short-term MOE <sup>g</sup>		Exposure Frequency <sup>h</sup> (days/year)	Cancer risk <sup>i</sup>
		PPE	Closed ML	dermal	inhalation			non-cancer	cancer	dermal	inhalation		
Berries (blueberry highbush)	DF	ML: coveralls over a long-sleeved shirt and long pants, CR gloves	WSP	0.4229	0.00926	0.0896	3.6	31	31	1017	116	2	3.0 × 10 <sup>-6</sup>
	SN	A long sleeved shirt and long pants plus CR gloves plus CR headgear	-	0.4463	0.00971	0.0945				964	111		3.0 × 10 <sup>-6</sup>

Crop <sup>a</sup>	EUP type	Minimum mitigation measures <sup>b</sup>		Combined Non-cancer Unit Exposure <sup>c</sup> (mg/kg a.i.)		Combined Cancer Unit Exposure <sup>d</sup> (mg/kg a.i.)	AR <sup>e</sup> (kg a.i./ha)	ATPD <sup>f</sup> (ha)		Short-term MOE <sup>g</sup>		Exposure Frequency <sup>h</sup> (days/year)	Cancer risk <sup>i</sup>
		PPE	Closed ML	dermal	inhalation			non-cancer	cancer	dermal	inhalation		
Berries (blueberry lowbush)	DF	ML: coveralls over a long-sleeved shirt and long pants, CR gloves A long sleeved shirt and long pants, CR gloves, CR headgear	WSP	0.4229	0.00926	0.0896	2.5	40	40	1135	130	26	2.0 × 10 <sup>-6</sup>
	SN	ML: coveralls over a long-sleeved shirt and long pants, CR gloves A long sleeved shirt and long pants, CR gloves, CR headgear, <b>respirator</b> **	-	0.4463	0.00154	0.0863	3.6			747	542		3.0 × 10 <sup>-6</sup>
Fruit trees*	DF	ML: coveralls over a long-sleeved shirt and long pants, CR gloves A long sleeved shirt and long pants, CR gloves, CR headgear,	WSP	0.4229	0.00926	0.0896	4.5	10	10	2523	288	26	1.0 × 10 <sup>-5</sup>
	SN	A long sleeved shirt and long pants, CR gloves, CR headgear,	-	0.4463	0.00971	0.0945				2390	275		1.0 × 10 <sup>-5</sup>
Hazelnuts	SN	ML: coveralls over a long-sleeved shirt and long pants, CR gloves A: long-sleeved shirt and long pants, CR gloves, CR headgear	-	0.4463	0.00971	0.0945	3.4	20	7	1582	182	30	9.0 × 10 <sup>-6</sup>
Ornamentals, outdoor	DF	ML: coveralls over a long-sleeved shirt and long pants, CR gloves A long sleeved shirt and long pants, CR gloves, CR headgear	WSP	0.4229	0.00926	0.0896	2.5	20	7	2270	259	30	6.0 × 10 <sup>-6</sup>
	SN	A long sleeved shirt and long pants, CR gloves, CR headgear	-	0.4463	0.00971	0.0945				2151	247		7.0 × 10 <sup>-6</sup>
Conifers	DF	ML: coveralls over a long-sleeved shirt and long pants, CR gloves A long sleeved shirt and long pants, CR gloves, CR headgear	WSP	0.4229	0.00926	0.0896	4.8	20	7	1182	135	2	8.0 × 10 <sup>-7</sup>
	SN	MLA: long sleeved shirt and long pants, CR gloves A CR headgear	-	0.4734	0.00971	0.0997				1056	129		9.0 × 10 <sup>-7</sup>

ML – mixer/loader; A – applicator; EUP – end-use product; DF – dry formulation; SN- solution (liquid formulation); CR – chemical-resistant; MOE - Margin of Exposure; WSP – water soluble packaging; LADD - lifetime average daily dose

\*2 applications with a RTI of 10 days plus one post-harvest (cherry) or dormant (peach and nectarine) application. Since the interval between the second and 3<sup>rd</sup> applications is more than 30 days, applications considered as 2 separate short-term scenarios.

\*\*A respirator for applicators required if handling more than 122 kg a.i./day

<sup>a</sup> Crop (most conservative representative crop scenario)

<sup>b</sup> Minimum mitigation measures required for mixers/loaders/applicators

<sup>c</sup> Combined non-cancer unit exposure (UE) (mg/kg a.i.) - dermal and inhalation unit exposure for mixer/loader/applicator from the Pesticide Handler Exposure Database (PHED) or Agricultural Handlers Exposure Task Force (AHETF); 100% dermal absorption assumed for short-term scenarios

- <sup>d</sup> Combined cancer unit exposure (UE) (mg/kg a.i.) - dermal plus inhalation unit exposure for mixer/loader/applicator from the Pesticide Handler Exposure Database (PHED) or Agricultural Handlers Exposure Task Force (AHETF); 19% dermal absorption assumed for cancer assessment
- <sup>e</sup> AR - Application rate (kg a.i./ha) – based on the supported use pattern
- <sup>f</sup> ATPD (ha) – area treated per day
- <sup>g</sup> Short-term MOE = NOAEL (mg/kg bw/day) / daily dermal or inhalation exposure dose (mg/kg bw/day)  
 Dermal MOE estimated using a dermal NOAEL of 600 mg/kg bw/day with a target MOE of 100  
 Inhalation MOE estimated using an oral NOAEL of 1.5 mg/kg bw/day with a target MOE of 100  
 Daily dermal exposure dose (mg/kg bw/day) = [Combined non-cancer dermal or inhalation UE (mg/kg a.i.) × AR (kg a.i./ha) × non-cancer ATPD (ha)] / BW (80 kg)
- <sup>h</sup> Exposure frequency (days/year) – default or use-specific information
- <sup>i</sup> Cancer risk = LADD (mg/kg bw/day) × q1\* of 7.66 (mg/kg bw/day)<sup>-1</sup>, occupational LOC > 1 × 10<sup>-5</sup>  
 LADD = [Combined cancer UE (mg/kg a.i.) × AR (kg a.i./ha) × cancer ATPD (ha) × exposure frequency (days/year) × career duration (40 years/78 years)] / BW (80 kg)

**Table 3a Short-term risk non-cancer and cancer risk assessment for mixers/loaders for aerial applications and for pilots using a closed cab airplane.**

Crop <sup>a</sup>	EUP type	Minimum mitigation measures <sup>b</sup>		Combined Non-cancer Unit Exposure <sup>c</sup> (mg/kg a.i.)		Combined Cancer Unit Exposure <sup>d</sup> (mg/kg a.i.)	AR <sup>e</sup> (kg a.i./ha)	ATPD <sup>f</sup> (ha)		Short-term MOE <sup>g</sup>		Exposure Frequency <sup>h</sup> (days/year)	Cancer risk <sup>i</sup>
		PPE	Closed ML	dermal	inhalation			non-cancer	cancer	dermal	inhalation		
Large field crops (lentils)	DF	ML: coveralls over a long-sleeved shirt and long pants, CR gloves	WSP	0.0079	0.00018	0.0017	2.0	400	318	7576	833	30	4.0 × 10 <sup>-6</sup>
	YES		0.0096	0.00011	0.0019	6243				1364	5.0 × 10 <sup>-6</sup>		
	n/a	Pilot long sleeved shirt and long pants, closed cockpit	n/a	0.0027	0.00001	0.0005				> 10 000	> 10 000		1.0 × 10 <sup>-6</sup>
Small field crops (tomato not grown for processing)	DF	ML: coveralls over a long-sleeved shirt and long pants, CR gloves	WSP	0.0079	0.00018	0.0017	2.4	400	318	6313	694	30	5.0 × 10 <sup>-6</sup>
	YES		0.0190	0.00011	0.0037	2639				1136	1.0 × 10 <sup>-5</sup>		
	n/a	Pilot long sleeved shirt and long pants, closed cockpit	n/a	0.0027	0.00001	0.0005				> 10 000	> 10 000		2.0 × 10 <sup>-6</sup>
Berries (blueberry highbush)	DF	ML: coveralls over a long-sleeved shirt and long pants, CR gloves	WSP	0.0079	0.00018	0.0017	3.6	400	318	4209	463	30	8.0 × 10 <sup>-6</sup>
	YES		0.0096	0.00011	0.0019	3469				758	9.0 × 10 <sup>-6</sup>		
	n/a	Pilot long sleeved shirt and long pants, closed cockpit	n/a	0.0027	0.00001	0.0005				> 10 000	8600		2.0 × 10 <sup>-6</sup>

ML – mixer/loader; A – applicator; EUP – end-use product; DF – dry formulation; SN- solution (liquid formulation); CR – chemical-resistant; MOE - Margin of Exposure; WSP – water soluble packaging; LADD - lifetime average daily dose

<sup>a</sup> Crop (most conservative representative crop scenario)

<sup>b</sup> Minimum mitigation measures required for mixers/loaders/applicators

<sup>c</sup> Combined non-cancer unit exposure (UE) (mg/kg a.i.) - dermal and inhalation unit exposure for mixer/loader/applicator from the Pesticide Handler Exposure Database (PHED) or Agricultural Handlers Exposure Task Force (AHETF); 100% dermal absorption assumed for short-term scenarios

<sup>d</sup> Combined cancer unit exposure (UE) (mg/kg a.i.) - dermal plus inhalation unit exposure for mixer/loader/applicator from the Pesticide Handler Exposure Database (PHED) or Agricultural Handlers Exposure Task Force (AHETF); 19% dermal absorption assumed for cancer assessment

<sup>e</sup> AR - Application rate (kg a.i./ha) – based on the supported use pattern



- <sup>f</sup> ATPD (ha) – area treated per day  
<sup>g</sup> Short-term MOE = NOAEL (mg/kg bw/day) / daily dermal or inhalation exposure dose (mg/kg bw/day)  
 Dermal MOE estimated using a dermal NOAEL of 600 mg/kg bw/day with a target MOE of 100  
 Inhalation MOE estimated using an oral NOAEL of 1.5 mg/kg bw/day with a target MOE of 100  
 Daily dermal exposure dose (mg/kg bw/day) = [Combined non-cancer dermal or inhalation UE (mg/kg a.i.) × AR (kg a.i./ha) × non-cancer ATPD (ha)] / BW (80 kg)  
<sup>h</sup> Exposure frequency (days/year) – default or use-specific information  
<sup>i</sup> Cancer risk = LADD (mg/kg bw/day) × q1\* of 7.66 (mg/kg bw/day)<sup>-1</sup>, occupational LOC > 1 × 10<sup>-5</sup>  
 LADD = [Combined cancer UE (mg/kg a.i.) × AR (kg a.i./ha) × cancer ATPD (ha) × exposure frequency (days/year) × career duration (40 years/78 years)] / BW (80 kg)

**Table 3b Intermediate-term risk non-cancer and cancer risk assessment for mixers/loaders for aerial applications and for pilots using a closed cab airplane.**

Crop <sup>a</sup>	EUP type	Minimum mitigation measures <sup>b</sup>		Combined Non-cancer Unit Exposure <sup>c</sup> (mg/kg a.i.)		Combined Cancer Unit Exposure <sup>d</sup> (mg/kg a.i.)	AR <sup>e</sup> (kg a.i./ha)	ATPD <sup>f</sup> (ha)		Intermediate-term MOE <sup>g</sup>			Exposure Frequency <sup>h</sup> (days/year)	Cancer risk <sup>i</sup>
		PPE	Closed ML	dermal	inhalation			non-cancer	cancer	dermal	inhalation	combined		
Tomato (processing)	DF	ML: coveralls over a long-sleeved shirt and long pants, CR gloves	WSP	0.0015	0.00018	0.0017	2.4	257	257	129	1081	115	30	4.0 × 10 <sup>-6</sup>
	SN		YES	0.0018	0.00011	0.0019				107	1769	100		5.0 × 10 <sup>-6</sup>
	n/a	Pilot long sleeved shirt and long pants	n/a	0.0005	0.00001	0.0005				384	> 10 000	376		1.0 × 10 <sup>-6</sup>
Potato	DF	ML: coveralls over a long-sleeved shirt and long pants, CR gloves	WSP	0.0015	0.00018	0.0017	1.2	400	318	166	1389	148	30	3.0 × 10 <sup>-6</sup>
	SN		YES	0.0018	0.00011	0.0019				137	2273	129		3.0 × 10 <sup>-6</sup>
	n/a	Pilot long sleeved shirt and long pants	n/a	0.0005	0.00001	0.0005				493	> 10 000	484		8.0 × 10 <sup>-7</sup>

ML – mixer/loader; A – applicator; EUP – end-use product; AR – application rate; DF – dry formulation; SN- solution (liquid formulation); CR – chemical-resistant; MOE - Margin of Exposure; WSP – water soluble packaging; LADD - lifetime average daily dose

<sup>a</sup> Crop (most conservative representative crop scenario)

<sup>b</sup> Minimum mitigation measures required for mixers/loaders/applicators

<sup>c</sup> Combined non-cancer unit exposure (UE) (mg/kg a.i.) - dermal and inhalation unit exposure for mixer/loader/applicator from the Pesticide Handler Exposure Database (PHED) or Agricultural Handlers Exposure Task Force (AHETF); 19% dermal absorption assumed for intermediate-term scenarios

<sup>d</sup> Combined cancer unit exposure (UE) (mg/kg a.i.) - dermal plus inhalation unit exposure for mixer/loader/applicator from the Pesticide Handler Exposure Database (PHED) or Agricultural Handlers Exposure Task Force (AHETF); 19% dermal absorption assumed for cancer assessment

<sup>e</sup> AR - Application rate (kg a.i./ha) – based on the supported use pattern

<sup>f</sup> ATPD (ha) – area treated per day

<sup>g</sup> Intermediate-term MOE = NOAEL (mg/kg bw/day) / daily dermal plus inhalation exposure dose (mg/kg bw/day)

Dermal and inhalation MOEs estimated using an oral NOAEL of 1.5 mg/kg bw/day with a target MOE of 100

Daily dermal exposure dose (mg/kg bw/day) = [Combined non-cancer dermal or inhalation UE (mg/kg a.i.) × AR (kg a.i./ha) × non-cancer ATPD (ha)] / BW (80 kg)

<sup>h</sup> Exposure frequency (days/year) – default (30 days) values

<sup>i</sup> Cancer risk = LADD (mg/kg bw/day) × q1\* of 7.66 (mg/kg bw/day)<sup>-1</sup>, occupational LOC > 1 × 10<sup>-5</sup>

LADD = [Combined cancer UE (mg/kg a.i.) × AR (kg a.i./ha) × cancer ATPD (ha) × exposure frequency (days/year) × career duration (40 years/78 years)] / BW (80 kg)

**Table 4 Short-term risk non-cancer and cancer risk assessment for mixers/loaders for applications via irrigation systems.**

Crop <sup>a</sup>	EUP type	Minimum mitigation measures <sup>b</sup>		Combined Non-cancer Unit Exposure <sup>c</sup> (mg/kg a.i.)		Combined Cancer Unit Exposure <sup>d</sup> (mg/kg a.i.)	AR <sup>e</sup> (kg a.i./ha)	ATPD <sup>f</sup> (ha)		Short-term MOE <sup>g</sup>		Exposure Frequency <sup>h</sup> (days/year)	Cancer risk <sup>i</sup>
		PPE	Closed ML	dermal	inhalation			non-cancer	cancer	dermal	inhalation		
Berries (cranberry)	DF	ML: coveralls over a long-sleeved shirt and long pants, CR gloves	WSP	0.0079	0.00018	0.0017	5.8	91	91	>	1263	15	$2.0 \times 10^{-6}$
	SN		-	0.0313	0.00063	0.0066				2904	361		$7.0 \times 10^{-6}$
Celery seedbeds (greenhouse)	DF	ML: coveralls over a long-sleeved shirt and long pants, CR gloves	WSP	0.0079	0.00018	0.0017	1.4	0.081	0.081	> 10 000	> 10 000	1	$3.0 \times 10^{-11}$
	SN		-	0.0313	0.00063	0.0066				> 10 000	> 10 000		$1.0 \times 10^{-10}$
Conifers (greenhouse)	DF	ML: coveralls over a long-sleeved shirt and long pants, CR gloves	WSP	0.0079	0.00018	0.0017	1.2	0.6	0.6	> 10 000	> 10 000	1	$2.0 \times 10^{-10}$
	SN		-	0.0313	0.0006	0.0066				> 10 000	> 10 000		$6.0 \times 10^{-10}$
Conifers, outdoor	DF	ML: coveralls over a long-sleeved shirt and long pants, CR gloves	WSP	0.0079	0.00018	0.0017	4.8	41	41	> 10 000	3388	2	$9.0 \times 10^{-8}$
	SN		-	0.0313	0.00063	0.0066				7787	968		$3.0 \times 10^{-7}$

ML – mixer/loader; A – applicator; EUP – end-use product; DF – dry formulation; SN- solution (liquid formulation); CR – chemical-resistant; MOE - Margin of Exposure; WSP – water soluble packaging; LADD - lifetime average daily dose

<sup>a</sup> Crop (most conservative representative crop scenario)

<sup>b</sup> Minimum mitigation measures required for mixers/loaders/applicators

<sup>c</sup> Combined non-cancer unit exposure (UE) (mg/kg a.i.) - dermal and inhalation unit exposure for mixer/loader/applicator from the Pesticide Handler Exposure Database (PHED) or Agricultural Handlers Exposure Task Force (AHETF); 100% dermal absorption assumed for short-term scenarios

<sup>d</sup> Combined cancer unit exposure (UE) (mg/kg a.i.) - dermal plus inhalation unit exposure for mixer/loader/applicator from the Pesticide Handler Exposure Database (PHED) or Agricultural Handlers Exposure Task Force (AHETF); 19% dermal absorption assumed for cancer assessment

<sup>e</sup> AR - Application rate (kg a.i./ha) – based on the supported use pattern

<sup>f</sup> ATPD (ha) – area treated per day

<sup>g</sup> Short-term MOE = NOAEL (mg/kg bw/day) / daily dermal or inhalation exposure dose (mg/kg bw/day)

Dermal MOE estimated using a dermal NOAEL of 600 mg/kg bw/day with a target MOE of 100

Inhalation MOE estimated using an oral NOAEL of 1.5 mg/kg bw/day with a target MOE of 100

Daily dermal exposure dose (mg/kg bw/day) = [Combined non-cancer dermal or inhalation UE (mg/kg a.i.) × AR (kg a.i./ha) × non-cancer ATPD (ha)] / BW (80 kg)

<sup>h</sup> Exposure frequency (days/year) – default (15 days for a single application) or refined (maximum number of applications) values

<sup>i</sup> Cancer risk = LADD (mg/kg bw/day) × q1\* of 7.66 (mg/kg bw/day)<sup>-1</sup>, occupational LOC > 1 × 10<sup>-5</sup>

LADD = [Combined cancer UE (mg/kg a.i.) × AR (kg a.i./ha) × cancer ATPD (ha) × exposure frequency (days/year) × career duration (40 years/78 years)]/ BW (80 kg)

**Table 5a Short-term risk non-cancer and cancer risk assessment for mixers/loaders/applicators using hand-held equipment for outdoor and greenhouse applications.**

Crop <sup>a</sup>	EUP type	Minimum mitigation measures <sup>b</sup>		Combined Non-cancer Unit Exposure <sup>c</sup> (mg/kg a.i.)		Combined Cancer Unit Exposure <sup>d</sup> (mg/kg a.i.)	AR <sup>e</sup> (kg a.i./ha)	ATPD <sup>f</sup> (ha)		Short-term MOE <sup>g</sup>		Exposure Frequency <sup>h</sup> (days/year)	Cancer risk <sup>i</sup>
		PPE	Closed ML	dermal	inhalation			non-cancer	cancer	dermal	inhalation		
<b>BACKPACK SPRAYER</b>													
Turf (golf course, sod farm)	DF	MLA: coveralls over a long-sleeved shirt and long pants, CR gloves	WSP	2.6050	0.0623	0.5572	12.0	0.375 (150 L)	0.375 (150 L)	4095	428	1	$3.0 \times 10^{-7}$
	SN	MLA: long sleeved shirt and long pants, CR gloves	-	5.4459	0.0621	1.0968				1959	429		$7.0 \times 10^{-7}$
	DF	MLA: coveralls over a long-sleeved shirt and long pants, CR gloves	WSP	2.6050	0.0623	0.5572	9.5	0.375 (150 L)	0.375 (150 L)	5172	541	28	$7.0 \times 10^{-6}$
	SN	MLA: long sleeved shirt and long pants, CR gloves	-	5.4459	0.0621	1.0968				2474	542		$1.0 \times 10^{-5}$
Ornamentals, outdoor	DF	ML: coveralls over a long-sleeved shirt and long pants, CR gloves A long sleeved shirt and long pants, CR gloves	WSP	5.4538	0.0623	1.0985	5.0	0.075 (150 L)	0.075 (150 L)	> 10 000	5138	30	$2.0 \times 10^{-6}$
	SN	MLA: long sleeved shirt and long pants, CR gloves	-	5.4459	0.0621	1.0968				> 10 000	5153		$2.0 \times 10^{-6}$
Conifers, outdoor	DF	ML: coveralls over a long-sleeved shirt and long pants, CR gloves A long sleeved shirt and long pants, CR gloves	WSP	5.4538	0.0623	1.0985	4.8	1.5 (150 L)	1.5 (150 L)	1222	268	2	$2.0 \times 10^{-6}$
	SN	MLA: long sleeved shirt and long pants, CR gloves	-	5.4459	0.0621	1.0968				1224	268		$1.0 \times 10^{-6}$
Celery seedbeds (greenhouse)	DF	ML: coveralls over a long-sleeved shirt and long pants, CR gloves A long sleeved shirt and long pants, CR gloves, respirator*	WSP	5.4538	0.0064	1.0426	1.4	0.081	0.081	> 10 000	> 10 000	1	$2.0 \times 10^{-8}$
	SN	MLA: long sleeved shirt and long pants, CR gloves, respirator*	-	5.4459	0.0062	1.0409				> 10 000	> 10 000		$2.0 \times 10^{-8}$
Conifers (greenhouse)	DF	ML: coveralls over a long-sleeved shirt and long pants, CR gloves A long sleeved shirt and long pants, CR gloves, respirator*	WSP	5.4538	0.0064	1.0426	1.2	1.5 (150 L)	1.5 (150 L)	4890	> 10 000	1	$3.0 \times 10^{-7}$

Crop <sup>a</sup>	EUP type	Minimum mitigation measures <sup>b</sup>		Combined Non-cancer Unit Exposure <sup>c</sup> (mg/kg a.i.)		Combined Cancer Unit Exposure <sup>d</sup> (mg/kg a.i.)	AR <sup>e</sup> (kg a.i./ha)	ATPD <sup>f</sup> (ha)		Short-term MOE <sup>g</sup>		Exposure Frequency <sup>h</sup> (days/year)	Cancer risk <sup>i</sup>
		PPE	Closed ML	dermal	inhalation			non-cancer	cancer	dermal	inhalation		
	SN	MLA: long sleeved shirt and long pants, CR gloves, respirator*	-	5.4459	0.0062	1.0409				4897	> 10 000		$3.0 \times 10^{-7}$
<b>MANUALLY-PRESSURIZED HANDWAND</b>													
Ornamentals, outdoor	DF	ML: coveralls over a long-sleeved shirt and long pants, CR gloves A long sleeved shirt and long pants, CR gloves	WSP	0.9513	0.0454	0.2261	5.0	0.075 (150 L)	0.075 (150 L)	> 10 000	7052	30	$3.0 \times 10^{-7}$
	SN	MLA: long sleeved shirt and long pants, CR gloves	-	0.9434	0.0452	0.2244				> 10 000	7080		$3.0 \times 10^{-7}$
Conifer, outdoor	DF	ML: coveralls over a long-sleeved shirt and long pants, CR gloves A long sleeved shirt and long pants, CR gloves	WSP	0.9513	0.0454	0.2261	4.8	1.5 (150 L)	1.5 (150 L)	7008	367	2	$4.0 \times 10^{-7}$
	SN	MLA: long sleeved shirt and long pants, CR gloves	-	0.9434	0.0452	0.2244				7067	369		$4.0 \times 10^{-7}$
Celery seedbeds (greenhouse)	DF	ML: coveralls over a long-sleeved shirt and long pants, CR gloves A long sleeved shirt and long pants, CR gloves, respirator*	WSP	0.9513	0.0047	0.1854	1.4	0.081	0.081	> 10 000	> 10 000	1	$3.0 \times 10^{-9}$
	SN	MLA: long sleeved shirt and long pants, CR gloves, respirator*	-	0.9434	0.0045	0.1838				> 10 000	> 10 000		$3.0 \times 10^{-9}$
Conifer, greenhouse	DF	ML: coveralls over a long-sleeved shirt and long pants, CR gloves A long sleeved shirt and long pants, CR gloves, respirator*	WSP	0.9513	0.0047	0.1854	1.2	1.5 (150 L)	1.5 (150 L)	> 10 000	> 10 000	1	$4.0 \times 10^{-8}$
	SN	MLA: long sleeved shirt and long pants, CR gloves, respirator*	-	0.9434	0.0062	0.1855				> 10 000	> 10 000		$4.0 \times 10^{-8}$
<b>LOW-PRESSURE TURF GUN</b>													
Turf (golf course, sod farm)	DF	MLA: coveralls over a long-sleeved shirt and long pants, CR gloves	-	0.4330	0.048	0.2893	12.0	0.375 (150 L)	0.375 (150 L)	> 10 000	558	1	$2.0 \times 10^{-7}$
	SN	MLA: long sleeved shirt and long pants, CR gloves	-	0.7850	0.004	0.4027				> 10 000	6667		$2.0 \times 10^{-7}$
	DF	MLA: coveralls over a long-sleeved shirt and long pants, CR gloves	-	0.4330	0.048	0.2893	9.5	0.375 (150 L)	0.375 (150 L)	> 10 000	705	30	$4.0 \times 10^{-6}$
	SN	MLA: long sleeved shirt and long pants, CR gloves	-	0.7850	0.004	0.4027				> 10 000	8421		$2.0 \times 10^{-6}$

ML – mixer/loader; A – applicator; EUP – end-use product; DF – dry formulation; SN- solution (liquid formulation); CR – chemical-resistant; MOE - Margin of Exposure; WSP – water soluble packaging; LADD - lifetime average daily dose

\*A respirator is required for applicators (DF) and mixers/loaders/applicators (SN) using hand-held spray equipment in enclosed spaces (e.g., greenhouses) based on acute inhalation toxicity of end-use products.

- <sup>a</sup> Crop (most conservative representative crop scenario)
- <sup>b</sup> Minimum mitigation measures required for mixers/loaders/applicators
- <sup>c</sup> Combined non-cancer unit exposure (UE) (mg/kg a.i.) - dermal and inhalation unit exposure for mixer/loader/applicator from the Pesticide Handler Exposure Database (PHED) or Agricultural Handlers Exposure Task Force (AHETF); 100% dermal absorption assumed for short-term scenarios
- <sup>d</sup> Combined cancer unit exposure (UE) (mg/kg a.i.) - dermal plus inhalation unit exposure for mixer/loader/applicator from the Pesticide Handler Exposure Database (PHED) or Agricultural Handlers Exposure Task Force (AHETF) or Outdoor Residential Exposure Task Force (ORETF); 19% dermal absorption assumed for cancer assessment
- <sup>e</sup> AR - Application rate (kg a.i./ha) – based on the supported use pattern
- <sup>f</sup> ATPD (ha) – area treated per day
- <sup>g</sup> Short-term MOE = NOAEL (mg/kg bw/day) / daily dermal or inhalation exposure dose (mg/kg bw/day)  
Dermal MOE estimated using a dermal NOAEL of 600 mg/kg bw/day with a target MOE of 100; inhalation MOE estimated using an oral NOAEL of 1.5 mg/kg bw/day with a target MOE of 100  
Daily dermal exposure dose (mg/kg bw/day) = [Combined non-cancer dermal or inhalation UE (mg/kg a.i.) × AR (kg a.i./ha) × non-cancer ATPD (ha)] / BW (80 kg)
- <sup>h</sup> Exposure frequency (days/year) – default or use-specific information
- <sup>i</sup> Cancer risk = LADD (mg/kg bw/day) × q1\* of 7.66 (mg/kg bw/day)<sup>-1</sup>, occupational LOC > 1 × 10<sup>-5</sup>  
LADD = [Combined cancer UE (mg/kg a.i.) × AR (kg a.i./ha) × cancer ATPD (ha) × exposure frequency (days/year) × career duration (40 years/78 years)]/ BW (80 kg)

**Table 5b Long-term risk non-cancer and cancer risk assessment for mixers/loaders/applicators using hand-held equipment for greenhouse applications.**

Crop <sup>a</sup>	EUP type	Minimum mitigation measures <sup>b</sup>		Combined Non-cancer Unit Exposure <sup>c</sup> (mg/kg a.i.)		Combined Cancer Unit Exposure <sup>d</sup> (mg/kg a.i.)	AR <sup>e</sup> (kg a.i./ha)	ATPD <sup>f</sup> (ha)		Long-term MOE <sup>g</sup>			Exposure Frequency <sup>h</sup> (days/year)	Cancer risk <sup>i</sup>
		PPE	Closed ML	dermal	inhalation			non-cancer	cancer	dermal	inhalation	combined		
<b>BACKPACK SPRAYER</b>														
Mushrooms (mushroom house)	DF	ML: coveralls over a long-sleeved shirt and long pants, CR gloves A long sleeved shirt and long pants, CR gloves, respirator*	WSP	1.0362	0.0064	1.0426	12.7	0.015 (150 L)	0.015 (150 L)	608	> 10 000	604	50	1.0 × 10 <sup>-6</sup>
	SN	MLA: long sleeved shirt and long pants, CR gloves, respirator*	-	1.0347	0.0062	1.0409				609	> 10 000	605		1.0 × 10 <sup>-6</sup>
Ornamentals (greenhouse)	DF	ML: coveralls over a long-sleeved shirt and long pants, CR gloves A long sleeved shirt and long pants, CR gloves, respirator*	WSP	1.0362	0.0064	1.0426	1.25	0.15 (150 L)	0.15 (150 L)	618	> 10 000	614	30	8.0 × 10 <sup>-7</sup>
	SN	MLA: long sleeved shirt and long pants, CR gloves, respirator*	-	1.0347	0.0062	1.0968				619	> 10 000	583		8.0 × 10 <sup>-7</sup>

Crop <sup>a</sup>	EUP type	Minimum mitigation measures <sup>b</sup>		Combined Non-cancer Unit Exposure <sup>c</sup> (mg/kg a.i.)		Combined Cancer Unit Exposure <sup>d</sup> (mg/kg a.i.)	AR <sup>e</sup> (kg a.i./ha)	ATPD <sup>f</sup> (ha)		Long-term MOE <sup>g</sup>			Exposure Frequency <sup>h</sup> (days/year)	Cancer risk <sup>i</sup>
		PPE	Closed ML	dermal	inhalation			non-cancer	cancer	dermal	inhalation	combined		
<b>MANUALLY-PRESSURIZED HANDWAND</b>														
Mushrooms (mushroom house)	DF	ML: coveralls over a long-sleeved shirt and long pants, CR gloves A long sleeved shirt and long pants, CR gloves, respirator*	WSP	0.1807	0.0047	0.1854	12.7	0.015 (150 L)	0.015 (150 L)	3485	> 10 000	3397	50	$2.0 \times 10^{-7}$
	SN	MLA: long sleeved shirt and long pants, CR gloves, respirator*	-	0.1792	0.0045	0.1838				3514	> 10 000	3428		$2.0 \times 10^{-7}$
Ornamentals (greenhouse)	DF	ML: coveralls over a long-sleeved shirt and long pants, CR gloves A long sleeved shirt and long pants, CR gloves, respirator*	WSP	0.1807	0.0047	0.1854	1.25	0.15 (150 L)	0.15 (150 L)	3541	> 10 000	3443	30	$1.0 \times 10^{-7}$
	SN	MLA: long sleeved shirt and long pants, CR gloves, respirator*	-	0.1792	0.0045	0.1838				3571	> 10 000	3480		$1.0 \times 10^{-7}$

ML – mixer/loader; A – applicator; EUP – end-use product; DF – dry formulation; SN – solution (liquid formulation); CR – chemical-resistant; MOE – Margin of Exposure; WSP – water soluble packaging; LADD – lifetime average daily dose

\*A respirator is required for mixers/loaders/applicators (SN) and applicators (DF) using hand-held spray equipment in enclosed spaces (e.g., mushroom houses and greenhouses) based on acute inhalation toxicity of end-use products.

<sup>a</sup> Crop (most conservative representative crop scenario)

<sup>b</sup> Minimum mitigation measures required for mixers/loaders/applicators

<sup>c</sup> Combined non-cancer unit exposure (UE) (mg/kg a.i.) - dermal and inhalation unit exposure for mixer/loader/applicator from the Pesticide Handler Exposure Database (PHED) or Agricultural Handlers Exposure Task Force (AHETF); 19% dermal absorption assumed for long-term scenarios

<sup>d</sup> Combined cancer unit exposure (UE) (mg/kg a.i.) - dermal plus inhalation unit exposure for mixer/loader/applicator from the Pesticide Handler Exposure Database (PHED) or Agricultural Handlers Exposure Task Force (AHETF); 19% dermal absorption for cancer assessment

<sup>e</sup> AR - Application rate (kg a.i./ha) – based on the supported use pattern

<sup>f</sup> ATPD (ha) – area treated per day

<sup>g</sup> Long-term MOE = NOAEL (mg/kg bw/day) / daily dermal plus inhalation exposure dose (mg/kg bw/day)

Dermal and inhalation MOEs estimated using an oral NOAEL of 1.5 mg/kg bw/day with a target MOE of 100

Daily dermal exposure dose (mg/kg bw/day) = [Combined non-cancer dermal or inhalation UE (mg/kg a.i.) × AR (kg a.i./ha) × non-cancer ATPD (ha)] / BW (80 kg)

<sup>h</sup> Exposure frequency (days/year) – default (30 days) or refined (maximum number of applications per operation per year)

<sup>i</sup> Cancer risk = LADD (mg/kg bw/day) × q1\* of 7.66 (mg/kg bw/day)<sup>-1</sup>, occupational LOC > 1 × 10<sup>-5</sup>

LADD = [Combined cancer UE (mg/kg a.i.) × AR (kg a.i./ha) × cancer ATPD (ha) × exposure frequency (days/year) × career duration (40 years/78 years)] / BW (80 kg)



## Appendix VII Revised Occupational Postapplication Risk Assessments

**Table 1 Revised Non-Cancer and Cancer Postapplication Exposure Estimates, MOEs and REIs based on Updated Use Information**

Crop	Re-entry activity	Application rate <sup>1</sup> (kg a.i./ha)	Applications per Year <sup>2</sup>		Default DFR <sup>3</sup> ( $\mu\text{g}$ a.i./ $\text{cm}^2$ )	TC <sup>4</sup> ( $\text{cm}^2/\text{hr}$ )	Daily exposure dose <sup>5</sup> (mg/kg bw/day)	MOE <sup>6</sup> (day 0)	Non-cancer REI <sup>7</sup>	TWA DFR or TTR <sup>8</sup> ( $\mu\text{g}$ a.i./ $\text{cm}^2$ )	LADD <sup>9</sup> (mg/kg bw/day)	Cancer risk <sup>10</sup>	Cancer REI <sup>11</sup>	
			Number	Interval (days)										
Asparagus*	Scouting	1.7 (SN)	3	14	5.44	210	0.0218	69	4	2.83	$4.8 \times 10^{-4}$	$4 \times 10^{-6}$	0.5	
	Scouting	1.2 (DF)			3.84	210	0.0154	97	0.5	2.00	$3.4 \times 10^{-4}$	$3 \times 10^{-6}$	0.5	
Blueberry, highbush	Bird control, scouting, hand pruning, frost control, hand weeding	3.6	2	7	13.30	640	0.8512	705	0.5	3.64	$1.9 \times 10^{-3}$	$1 \times 10^{-5}$	0.5	
	Hand harvesting					1400	1.8620	322	0.5	2.75	$3.1 \times 10^{-3}$	$2 \times 10^{-5}$	5 <sup>13</sup>	
	Irrigation (hand set)					1750	2.3275	258	0.5	3.64	$2.6 \times 10^{-3}$	$2 \times 10^{-5}$	3	
Blueberry, lowbush	Hand weeding	3.6 (SN)	2	42	9.11	70	0.0638	9404	0.5	2.04	$1.2 \times 10^{-4}$	$9 \times 10^{-7}$	0.5	
	Scouting					1100	1.0021	599	0.5		$1.8 \times 10^{-3}$	$1 \times 10^{-5}$	0.5	
	Hand weeding	2.5 (DF)			6.32	70	0.0443	13544	0.5	1.96	$1.1 \times 10^{-4}$	$8 \times 10^{-7}$	0.5	
	Scouting				1100	0.6952	863	0.5	$1.7 \times 10^{-3}$		$1 \times 10^{-5}$	0.5		
Carrot*	Hand weeding	1.6	7	7	7.62	70	0.0102	147	0.5	4.92	$2.8 \times 10^{-4}$	$2 \times 10^{-6}$	0.5	
	Hand harvesting					1100	0.1593	9	22	2.37	$2.1 \times 10^{-3}$	$2 \times 10^{-5}$	1	
	Scouting					210	0.0305	49	7	4.92	$8.3 \times 10^{-4}$	$6 \times 10^{-6}$	0.5	
Celery	Field	2.0	2	3	8.65	70	0.0606	9901	0.5	1.69	$9.5 \times 10^{-5}$	$7 \times 10^{-7}$	0.5	
						Scouting	210	0.1817	3302	0.5	1.69	$2.9 \times 10^{-4}$	$2 \times 10^{-6}$	0.5
						Hand harvesting	1100	0.9515	631	0.5	1.48	$1.3 \times 10^{-3}$	$1 \times 10^{-5}$	0.5



Crop	Re-entry activity	Application rate <sup>1</sup> (kg a.i./ha)	Applications per Year <sup>2</sup>		Default DFR <sup>3</sup> (µg a.i./cm <sup>2</sup> )	TC <sup>4</sup> (cm <sup>2</sup> /hr)	Daily exposure dose <sup>5</sup> (mg/kg bw/day)	MOE <sup>6</sup> (day 0)	Non-cancer REI <sup>7</sup>	TWA DFR or TTR <sup>8</sup> (µg a.i./cm <sup>2</sup> )	LADD <sup>9</sup> (mg/kg bw/day)	Cancer risk <sup>10</sup>	Cancer REI <sup>11</sup>								
			Number	Interval (days)																	
	Irrigation (hand set)					1750	1.5138	396	0.5	1.69	$1.2 \times 10^{-3}$	$9 \times 10^{-6}$	0.5								
	Seedbed (greenhouse)*	All activities	1.4	1	N/A	3.50	230	0.0153	98	N/A	3.50	$1.1 \times 10^{-3}$	$8 \times 10^{-6}$	N/A							
Cherry (sweet and sour)	Orchard maintenance, hand weeding, bird control, propping	4.5	2 (spring) + 1 (post-harvest)	10	15.17	100	0.1517	3955	0.5	5.23	$4.2 \times 10^{-4}$	$3 \times 10^{-6}$	0.5								
	Scouting					580	0.8799	682	0.5	5.23	$1.2 \times 10^{-3}$	$9 \times 10^{-6}$	0.5								
	Hand harvesting					1400	2.1238	283	0.5	3.66	$4.1 \times 10^{-3}$	$3 \times 10^{-5}$	8 <sup>13</sup>								
	Fruit thinning					3000	4.5510	132	0.5	3.66	$4.4 \times 10^{-3}$	$3 \times 10^{-5}$	8								
Chickpea	Scouting	2.0 (1 <sup>st</sup> )	2	10	5.49	1100	0.6039	994	0.5	2.63	$2.3 \times 10^{-3}$	$2 \times 10^{-5}$	2								
		1.5 (2 <sup>nd</sup> )																			
Cole crops	All Cole crops	Irrigation (hand set)	2.4	1	N/A	6.00	1750	1.0500	571	0.5	1.91	$1.3 \times 10^{-3}$	$1 \times 10^{-5}$	0.5							
	Broccoli, Brussels sprouts, cauliflower	Scouting													4000	2.4000	250	0.5	$3.1 \times 10^{-3}$	$2 \times 10^{-5}$	5
	Brussels sprouts	Topping													4000	2.4000	250	0.5	$3.1 \times 10^{-3}$	$2 \times 10^{-5}$	5
	Cauliflower	Tying, training													4000	2.4000	250	0.5	$1.6 \times 10^{-3}$	$1 \times 10^{-5}$	0.5
	Broccoli, cauliflower, Brussels sprouts	Hand weeding													4400	2.6400	227	0.5	$1.8 \times 10^{-3}$	$1 \times 10^{-5}$	0.5
	Broccoli, Brussels sprouts, cauliflower	Hand harvesting													5150	3.0900	194	0.5	$3.9 \times 10^{-3}$	$3 \times 10^{-5}$	7
	Cabbage	Scouting, hand harvesting, mechanically assisted harvesting, thinning plants													2.4	2	7	8.87	1300	1.1531	520
Irrigation (hand set)		1750	1.5523	387	0.5	$1.6 \times 10^{-3}$	$1 \times 10^{-5}$	0.5													

Crop	Re-entry activity	Application rate <sup>1</sup> (kg a.i./ha)	Applications per Year <sup>2</sup>		Default DFR <sup>3</sup> (µg a.i./cm <sup>2</sup> )	TC <sup>4</sup> (cm <sup>2</sup> /hr)	Daily exposure dose <sup>5</sup> (mg/kg bw/day)	MOE <sup>6</sup> (day 0)	Non-cancer REI <sup>7</sup>	TWA DFR or TTR <sup>8</sup> (µg a.i./cm <sup>2</sup> )	LADD <sup>9</sup> (mg/kg bw/day)	Cancer risk <sup>10</sup>	Cancer REI <sup>11</sup>	
			Number	Interval (days)										
	Hand weeding					4400	3.9028	154	0.5		$2.1 \times 10^{-3}$	$2 \times 10^{-5}$	1	
Conifers	Outdoor (including Christmas trees)	Hand weeding, grading/tagging	4.8	2	7	17.74	100	0.1774	3382	0.5	4.40	$3.5 \times 10^{-4}$	$3 \times 10^{-6}$	0.5
		Scouting, shaping					580	1.0290	583	0.5	4.40	$2.0 \times 10^{-3}$	$2 \times 10^{-5}$	1
		Harvest, seed cone, harvest Christmas trees					1400	2.4836	242	0.5	3.33	$3.7 \times 10^{-3}$	$3 \times 10^{-5}$	7
		Irrigation (hand set)					1750	3.1045	193	0.5	4.40	$6.2 \times 10^{-3}$	$5 \times 10^{-5}$	11
		Harvest, seedling production					6700	11.8858	50	6	3.33	$8.9 \times 10^{-3}$	$7 \times 10^{-5}$	15
	Conifer nursery beds (greenhouse)*	All other activities except for irrigation (hand set)	4.8	1	N/A	12.00	230	0.0525	29	54	4.05	$3.0 \times 10^{-3}$	$2 \times 10^{-5}$	19
			2.4	1	N/A	6.00	230	0.0263	57	24	6.00	$4.4 \times 10^{-3}$	$3 \times 10^{-5}$	8
			1.2	1	N/A	3.00	230	0.0132	114	0.5	1.01	$7.5 \times 10^{-4}$	$6 \times 10^{-6}$	0.5
Corn, sweet	Scouting	1.6	2	10	5.39	1100	0.5929	1012	0.5	2.39	$2.1 \times 10^{-3}$	$2 \times 10^{-5}$	1	
	Hand harvesting					8800	4.7432	126	0.5	1.67	$1.2 \times 10^{-2}$	$9 \times 10^{-5}$	18	
Cranberry	Scouting, hand harvesting (raking)	5.8	1	N/A	14.50	1100	1.5950	376	0.5	7.38	$3.3 \times 10^{-3}$	$2 \times 10^{-5}$	5 <sup>13</sup>	
Cucurbits	Scouting, hand weeding, hand pruning, thinning fruit	2.4	2	7	8.87	90	0.0799	7509	0.5	1.97	$1.4 \times 10^{-4}$	$1 \times 10^{-6}$	0.5	
	Harvesting (hand, mechanically-assisted)					550	0.4879	1230	0.5	1.49	$6.6 \times 10^{-4}$	$5 \times 10^{-6}$	0.5	
Evening primrose	Scouting	1.2	2	14	3.69	1100	0.4059	1478	0.5	1.74	$1.5 \times 10^{-3}$	$1 \times 10^{-5}$	0.5	
Ginseng	Hand weeding	2.4	2 + 1 (fall)	7	8.87	70	0.0621	9662	0.5	3.64	$2.1 \times 10^{-4}$	$2 \times 10^{-6}$	0.5	
	Scouting					210	0.1863	3221	0.5	3.64	$6.1 \times 10^{-4}$	$5 \times 10^{-6}$	0.5	
	Hand harvesting					1100	0.9757	615	0.5	2.75	$2.4 \times 10^{-3}$	$2 \times 10^{-5}$	3	
Hazelnuts*	Orchard maintenance	3.4	3	20	9.55	100	0.0182	82	2	4.47	$3.6 \times 10^{-4}$	$3 \times 10^{-6}$	0.5	

Crop	Re-entry activity	Application rate <sup>1</sup> (kg a.i./ha)	Applications per Year <sup>2</sup>		Default DFR <sup>3</sup> ( $\mu\text{g}$ a.i./cm <sup>2</sup> )	TC <sup>4</sup> (cm <sup>2</sup> /hr)	Daily exposure dose <sup>5</sup> (mg/kg bw/day)	MOE <sup>6</sup> (day 0)	Non-cancer REI <sup>7</sup>	TWA DFR or TTR <sup>8</sup> ( $\mu\text{g}$ a.i./cm <sup>2</sup> )	LADD <sup>9</sup> (mg/kg bw/day)	Cancer risk <sup>10</sup>	Cancer REI <sup>11</sup>	
			Number	Interval (days)										
	Mechanical harvesting				9.55	190	0.0345	43	8 <sup>12</sup>	2.96	$4.5 \times 10^{-4}$	$3 \times 10^{-6}$	0.5	
	Transplanting				9.55	230	0.0418	36	10	4.47	$8.2 \times 10^{-4}$	$6 \times 10^{-6}$	0.5	
	Scouting				9.55	580	0.1052	14	18	4.47	$1.4 \times 10^{-3}$	$1 \times 10^{-5}$	0.5	
Lentil	Scouting	2.0	2	10	6.74	1100	0.7414	809	0.5	2.99	$2.6 \times 10^{-3}$	$2 \times 10^{-5}$	3	
Mushroom (mushroom house)*	Cutting, harvesting, sorting, packing	12.7	1	N/A	0.31	2500	0.0148	101	N/A	0.31	$1.0 \times 10^{-3}$	$8 \times 10^{-6}$	N/A	
Onion	Dry bulb	Scouting	2.4		8.87	1300	1.1531	520	0.5	1.97	$2.1 \times 10^{-3}$	$2 \times 10^{-5}$	1	
		Hand weeding									$3.5 \times 10^{-3}$	$3 \times 10^{-5}$	6	
	Green	Scouting,	2.4	2	7	8.87	1300	1.1531	520	0.5	1.97	$2.1 \times 10^{-3}$	$2 \times 10^{-5}$	1
		Hand harvesting										$1.6 \times 10^{-3}$	$1 \times 10^{-5}$	0.5
		Hand weeding										$3.5 \times 10^{-3}$	$3 \times 10^{-5}$	6
	Greenhouse ornamentals	Cut flowers - roses*	Hand harvesting, disbudding, hand pruning	1.9	1	N/A	4.75	4000	0.3610	4	137	1.60	$2.1 \times 10^{-2}$	$2 \times 10^{-4}$
All other activities except for irrigation (hand set)			230										0.0208	72
Cut flowers - other than roses*		Hand harvesting, disbudding, hand pruning	2.5	1	N/A	6.25	4000	0.4750	3	148	2.11	$2.7 \times 10^{-2}$	$2 \times 10^{-4}$	113
		All other activities except for irrigation (hand set)										230	0.0274	55
Ornamentals other than roses (not grown for cut flowers)*		All other activities except for irrigation (hand set)	1.25	1	N/A	3.13	230	0.0137	109	0.5	1.06	$7.8 \times 10^{-4}$	$6 \times 10^{-6}$	0.5
Roses (not grown for cut flowers)*		All other activities except for irrigation (hand set)	0.94	1	N/A	2.35	230	0.0103	146	0.5	0.79	$5.8 \times 10^{-4}$	$4 \times 10^{-6}$	0.5
Pachysandra*		All other activities except for irrigation (hand set)	5.0	1	N/A	12.50	230	0.0547	27	56	4.22	$3.1 \times 10^{-3}$	$2 \times 10^{-5}$	20

Crop	Re-entry activity	Application rate <sup>1</sup> (kg a.i./ha)	Applications per Year <sup>2</sup>		Default DFR <sup>3</sup> (µg a.i./cm <sup>2</sup> )	TC <sup>4</sup> (cm <sup>2</sup> /hr)	Daily exposure dose <sup>5</sup> (mg/kg bw/day)	MOE <sup>6</sup> (day 0)	Non-cancer REI <sup>7</sup>	TWA DFR or TTR <sup>8</sup> (µg a.i./cm <sup>2</sup> )	LADD <sup>9</sup> (mg/kg bw/day)	Cancer risk <sup>10</sup>	Cancer REI <sup>11</sup>	
			Number	Interval (days)										
Ornamentals outdoor (except cut flowers)	All activities except irrigation (hand set)	2.5	2	7	9.24	230	0.2126	2822	0.5	3.79	$7.0 \times 10^{-4}$	$5 \times 10^{-6}$	0.5	
	Irrigation (hand set)					1750	1.6170	371	0.5		$2.7 \times 10^{-3}$	$2 \times 10^{-5}$	3	
Outdoor roses (not for cut flowers)	All activities except irrigation (hand set)	1.9	2	7	7.02	230	0.1615	3715	0.5	2.88	$5.3 \times 10^{-4}$	$4 \times 10^{-6}$	0.5	
	Irrigation (hand set)					1750	1.2285	488	0.5		$2.0 \times 10^{-3}$	$2 \times 10^{-5}$	1	
Outdoor cut flowers	Roses	1.9	1	N/A	4.75	4000	1.900	316	0.5	2.42	$3.9 \times 10^{-3}$	$3 \times 10^{-5}$	7	
						Disbudding, hand pruning	4000	1.900	316		0.5	$3.9 \times 10^{-3}$	$3 \times 10^{-5}$	7
						Irrigation (hand set)	1750	0.8313	722		0.5	$1.7 \times 10^{-3}$	$1 \times 10^{-5}$	0.5
						All other activities except for irrigation (hand set)	230	0.1093	5489		0.5	$2.2 \times 10^{-4}$	$2 \times 10^{-6}$	0.5
	Cut flowers other than roses	2.5	1	N/A	6.25	4000	2.500	240	0.5	3.18	$5.1 \times 10^{-3}$	$4 \times 10^{-5}$	10	
						Disbudding, hand pruning	4000	2.500	240		0.5	$5.1 \times 10^{-3}$	$4 \times 10^{-5}$	10
						Irrigation (hand set)	1750	1.0938	549		0.5	$1.2 \times 10^{-3}$	$9 \times 10^{-6}$	0.5
						All other activities except for irrigation (hand set)	230	0.1438	4172		0.5	$2.9 \times 10^{-4}$	$2 \times 10^{-6}$	0.5
Outdoor pachysandra	Irrigation (hand set)	5.0	1	N/A	12.5	1750	2.1875	274	0.5	6.36	$2.4 \times 10^{-3}$	$2 \times 10^{-5}$	2	
	All other activities except for irrigation (hand set)					230	0.2875	2087	0.5		$5.9 \times 10^{-4}$	$4 \times 10^{-6}$	0.5	
Parsnip*	Hand weeding, thinning	1.4	7	7	6.67	70	0.0089	169	0.5	4.30	$2.4 \times 10^{-4}$	$2 \times 10^{-6}$	0.5	
	Hand harvesting					1100	0.1395	11	21	2.07	$1.8 \times 10^{-3}$	$1 \times 10^{-5}$	0.5	
	Scouting					210	0.0267	56	5	4.30	$7.2 \times 10^{-4}$	$6 \times 10^{-6}$	0.5	
Pea, dry	Scouting	1.5	2	10	5.06	1100	0.5566	1078	0.5	2.24	$2.0 \times 10^{-3}$	$2 \times 10^{-5}$	1	

Crop	Re-entry activity	Application rate <sup>1</sup> (kg a.i./ha)	Applications per Year <sup>2</sup>		Default DFR <sup>3</sup> (µg a.i./cm <sup>2</sup> )	TC <sup>4</sup> (cm <sup>2</sup> /hr)	Daily exposure dose <sup>5</sup> (mg/kg bw/day)	MOE <sup>6</sup> (day 0)	Non-cancer REI <sup>7</sup>	TWA DFR or TTR <sup>8</sup> (µg a.i./cm <sup>2</sup> )	LADD <sup>9</sup> (mg/kg bw/day)	Cancer risk <sup>10</sup>	Cancer REI <sup>11</sup>
			Number	Interval (days)									
Peach / Nectarine	Orchard maintenance, hand weeding, bird control, propping	4.5	2 (spring) + 1 (fall)	10	15.17	100	0.1517	3955	0.5	6.72	5.4 × 10 <sup>-4</sup>	4 × 10 <sup>-6</sup>	0.5
	Scouting, hand pruning, training					580	0.8799	682	0.5	6.72	1.6 × 10 <sup>-3</sup>	1 × 10 <sup>-5</sup>	0.5
	Hand harvesting					1400	2.1238	283	0.5	4.71	5.3 × 10 <sup>-3</sup>	4 × 10 <sup>-5</sup>	10 <sup>13</sup>
	Fruit thinning					3000	4.5510	132	0.5	4.71	5.7 × 10 <sup>-3</sup>	4 × 10 <sup>-5</sup>	11
Potato (seed)*	Scouting	1.2	3	7	5.12	210	0.0205	73	3	2.63	4.4 × 10 <sup>-4</sup>	3 × 10 <sup>-6</sup>	0.5
	Hand weeding					70	0.0069	217	0.5		1.5 × 10 <sup>-4</sup>	1 × 10 <sup>-6</sup>	0.5
	Irrigation (hand set)					1750	0.1703	9	23		3.7 × 10 <sup>-3</sup>	3 × 10 <sup>-5</sup>	7
	Roguing					1100	0.1071	14	19		2.3 × 10 <sup>-3</sup>	2 × 10 <sup>-5</sup>	2
Potato (table)*	Scouting	1.2	3	7	5.12	210	0.0205	73	3	2.63	4.4 × 10 <sup>-4</sup>	3 × 10 <sup>-6</sup>	0.5
	Hand weeding					70	0.0069	217	0.5		1.5 × 10 <sup>-4</sup>	1 × 10 <sup>-6</sup>	0.5
	Irrigation (hand set)					1750	0.1703	9	23		3.7 × 10 <sup>-3</sup>	3 × 10 <sup>-5</sup>	7
Strawberry	Hand weeding, canopy management	1.8	2 (spring) + 1 (post-harvest)	10	6.07	70	0.0425	14118	0.5	2.69	1.5 × 10 <sup>-4</sup>	1 × 10 <sup>-6</sup>	0.5
	Scouting					210	0.1275	4706	0.5	2.69	4.5 × 10 <sup>-4</sup>	3 × 10 <sup>-6</sup>	0.5
	Hand harvesting					1100	0.6677	899	0.5	1.88	1.7 × 10 <sup>-3</sup>	1 × 10 <sup>-5</sup>	0.5
Tomato (other than processing tomatoes)	Hand pruning, hand weeding	2.4	2	14	7.37	70	0.0516	11628	0.5	2.90	1.6 × 10 <sup>-4</sup>	1 × 10 <sup>-6</sup>	0.5
	Scouting					210	0.1548	3876	0.5	2.90	4.9 × 10 <sup>-4</sup>	4 × 10 <sup>-6</sup>	0.5
	Hand harvesting					1100	0.8107	740	0.5	1.91	1.7 × 10 <sup>-3</sup>	1 × 10 <sup>-5</sup>	0.5
	Hand pruning, hand weeding	1.2	2	8	4.29	70	0.0301	19934	0.5	1.81	1.0 × 10 <sup>-4</sup>	8 × 10 <sup>-7</sup>	0.5
	Scouting					210	0.0901	6659	0.5	1.81	3.1 × 10 <sup>-4</sup>	2 × 10 <sup>-6</sup>	0.5

Crop	Re-entry activity	Application rate <sup>1</sup> (kg a.i./ha)	Applications per Year <sup>2</sup>		Default DFR <sup>3</sup> ( $\mu\text{g}$ a.i./cm <sup>2</sup> )	TC <sup>4</sup> (cm <sup>2</sup> /hr)	Daily exposure dose <sup>5</sup> (mg/kg bw/day)	MOE <sup>6</sup> (day 0)	Non-cancer REI <sup>7</sup>	TWA DFR or TTR <sup>8</sup> ( $\mu\text{g}$ a.i./cm <sup>2</sup> )	LADD <sup>9</sup> (mg/kg bw/day)	Cancer risk <sup>10</sup>	Cancer REI <sup>11</sup>					
			Number	Interval (days)														
	Hand harvesting					1100	0.4719	1271	0.5	1.33	$1.2 \times 10^{-3}$	$9 \times 10^{-6}$	0.5					
Tomato (for processing)*	Hand pruning, hand weeding	2.4 and 1.2	2 at 2.4 and 7 at 1.2	14 (2.4 kg a.i./ha);	8.26	70	0.0110	136	0.5	4.18	$2.4 \times 10^{-4}$	$2 \times 10^{-6}$	0.5					
	Scouting			8 (1.2 kg a.i./ha)		210	0.0330	45	7		$7.0 \times 10^{-4}$	$5 \times 10^{-6}$	0.5					
Turf	Golf course (greens, tees)	Maintenance	12.0	1	N/A	1.2	2500	0.3000	2000	0.61	$6.1 \times 10^{-4}$	$5 \times 10^{-6}$	0.5					
	Golf course (greens, tees, and fairways), Sod farm	Transplanting/ planting (and slab harvesting for sod farm workers)					6700	0.8040	746		$1.6 \times 10^{-3}$	$1 \times 10^{-5}$	0.5					
		Mowing, watering, cup changing, irrigation repair, miscellaneous grooming					3500	0.4200	1429		$8.6 \times 10^{-4}$	$7 \times 10^{-6}$	0.5					
		Aerating, fertilizing, hand pruning, mechanical weeding, scouting and seeding					1000	0.1200	5000		$2.5 \times 10^{-4}$	$2 \times 10^{-6}$	0.5					
		Maintenance					2500	0.2925	2051		$1.1 \times 10^{-3}$	$8 \times 10^{-6}$	0.5					
	Golf course (greens, tees, and fairways), Sod farm	Transplanting/ planting (and slab harvesting for sod farm workers)					9.5	2	14		0.95	6700	0.7839	765	0.55	$1.9 \times 10^{-3}$	$1 \times 10^{-5}$	0.5
		Mowing, watering, cup changing, irrigation repair, miscellaneous grooming										3500	0.4095	1465		$1.5 \times 10^{-3}$	$1 \times 10^{-5}$	0.5

Crop	Re-entry activity	Application rate <sup>1</sup> (kg a.i./ha)	Applications per Year <sup>2</sup>		Default DFR <sup>3</sup> ( $\mu\text{g}$ a.i./ $\text{cm}^2$ )	TC <sup>4</sup> ( $\text{cm}^2/\text{hr}$ )	Daily exposure dose <sup>5</sup> ( $\text{mg}/\text{kg}$ bw/day)	MOE <sup>6</sup> (day 0)	Non-cancer REI <sup>7</sup>	TWA DFR or TTR <sup>8</sup> ( $\mu\text{g}$ a.i./ $\text{cm}^2$ )	LADD <sup>9</sup> ( $\text{mg}/\text{kg}$ bw/day)	Cancer risk <sup>10</sup>	Cancer REI <sup>11</sup>
			Number	Interval (days)									
	Aerating, fertilizing, hand pruning, mechanical weeding, scouting and seeding					1000	0.1170	5128	until sprays have dried		$4.4 \times 10^{-4}$	$3 \times 10^{-6}$	0.5
Golf course (greens, tees)	Maintenance					2500	0.1775	3380	until sprays have dried		$5.8 \times 10^{-4}$	$4 \times 10^{-6}$	0.5
	Transplanting/ planting					6700	0.4757	1261	until sprays have dried		$1.2 \times 10^{-3}$	$9 \times 10^{-6}$	0.5
Golf course (greens, tees, and fairways)	Mowing, watering, cup changing, irrigation repair, miscellaneous grooming	4.8	2	7	0.71	3500	0.2485	2414	until sprays have dried	0.29	$8.1 \times 10^{-4}$	$6 \times 10^{-6}$	0.5
	Aerating, fertilizing, hand pruning, mechanical weeding, scouting and seeding					1000	0.0710	8451	until sprays have dried		$2.3 \times 10^{-4}$	$2 \times 10^{-6}$	0.5
Wheat	Scouting	1.3	2	10	4.38	1100	0.4818	1245	0.5	1.94	$1.7 \times 10^{-3}$	$1 \times 10^{-5}$	0.5

<sup>1</sup> Maximum listed label rates expressed in kilograms a.i./hectare. The application rate for greenhouse ornamentals other than roses (not grown for cut flowers) and roses (not grown for cut flowers) were reduced in accordance with comments received from stakeholders.

<sup>2</sup> Maximum number of applications resulting in Re-entry Intervals (REIs) that are agronomically feasible. For crops where there is one post-harvest or fall application, only the exposure from the pre-harvest applications were assessed as exposure after the post-harvest or fall application is expected to be minimal.

<sup>3</sup> DFR/TTR – Dislodgeable Foliar Residue/Turf Transferable Residue ( $\mu\text{g}$  a.i./ $\text{cm}^2$ ) calculated for agricultural uses assuming a default 25% dislodgeable residue with 10% (outdoor uses), 0% (greenhouse vegetables) or 2.3% (greenhouse ornamentals) residue dissipation per day; for turf uses assuming a default 1% dislodgeable residue with 10% dissipation per day.

<sup>4</sup> TC – Transfer Coefficient ( $\text{cm}^2/\text{hour}$ ); Transfer coefficients are from the Agricultural Reentry Task Force (2008). Transfer coefficient for mushrooms from USEPA Policy#003.

<sup>5</sup> Daily exposure dose ( $\text{mg}/\text{kg}$  bw/day) = DFR/TTR ( $\mu\text{g}$  a.i./ $\text{cm}^2$ )  $\times$  TC ( $\text{cm}^2/\text{hour}$ )  $\times$  Exposure duration (hours) / Average worker body weight (80 kg)  $\times$  conversion factor (1 mg/1000  $\mu\text{g}$ ); Exposure duration of 8 hours per day.

For crops denoted with (\*), daily exposure dose ( $\text{mg}/\text{kg}$  bw/day) = DFR ( $\mu\text{g}$  a.i./ $\text{cm}^2$ )  $\times$  TC ( $\text{cm}^2/\text{hour}$ )  $\times$  Exposure duration (hours)  $\times$  DA / Average worker body weight (80 kg)  $\times$  conversion factor (1 mg/1000  $\mu\text{g}$ ); DA of 19% non-cancer and cancer assessments. Exposure duration of 8 hours per day.

<sup>6</sup> MOE = NOAEL /Daily exposure dose ( $\text{mg}/\text{kg}$  bw/day); Based on short-term dermal endpoint of 600  $\text{mg}/\text{kg}$  bw/day; target MOE of 100;

For crops denoted with (\*), MOE = NOAEL /Daily exposure dose ( $\text{mg}/\text{kg}$  bw/day); Based on intermediate and long-term endpoint of 1.5  $\text{mg}/\text{kg}$  bw/day; target MOE of 100.

<sup>7</sup> Non-cancer REI – minimum REI required to mitigate non-cancer risks to postapplication re-entry workers. Shaded cells represent REIs that are not considered agronomically feasible.

- <sup>8</sup> TWA (Time-Weighted Average) DFR/TTR calculated over 30 days (2 applications) or 15 days (1 application). TWA calculated using typical rates provided by stakeholders where available. For postapplication activities that occur between applications, TWA calculated starting on day 0 after the first application. For postapplication activities that occur after the last application, TWA calculated starting on day 0 after the last application.  
For crops denoted with (\*), TWA DFR calculated over 30 days for all crops except carrot (42 days), parsnip (42 days), greenhouse conifers and greenhouse ornamentals (120 days).
- <sup>9</sup> LADD (mg/kg bw/day) = [TWA DFR/TTR ( $\mu\text{g a.i./cm}^2$ )  $\times$  TC ( $\text{cm}^2/\text{hour}$ )  $\times$  exposure duration (hours/day)  $\times$  DA (19%) / average worker body weight (80 kg)  $\times$  conversion factor (1 mg/1000  $\mu\text{g}$ )]  $\times$  Frequency (days/year = 365 days)  $\times$  Career duration (40 years/ lifetime = 78 years); Frequency - 30 days (for 2 applications) and 15 days (for 1 application) except: 15 days for handset irrigation (highbush blueberry, cabbage, field celery, outdoor ornamentals (not for cut flowers) and outdoor roses (not for cut flowers)), cherry (thinning, scouting), peach and nectarine (thinning, scouting, hand pruning, training), conifer (harvest seedlings), dry bulb onion (hand weeding) and green onion (hand weeding); 8 days for broccoli, Brussels sprouts, cauliflower, cabbage (hand weeding), cauliflower (tying, training), outdoor cut flowers (other than roses)(handset irrigation), and outdoor pachysandra (handset irrigation); 20 days for hazelnuts (scouting); 50 days for celery seedbeds, mushrooms; 120 days for conifers (nursery beds) and greenhouse ornamentals.
- <sup>10</sup> Cancer risk = LADD (mg/kg bw/day)  $\times$   $q_1^*$  of  $7.66 \times 10^{-3}$  (mg/kg bw/day) $^{-1}$ ; occupational LOC  $> 1 \times 10^{-5}$
- <sup>11</sup> Cancer REI – REI required to mitigate cancer risks to postapplication workers. Shaded cells represent REIs that are not considered agronomically feasible.  
The pre-harvest interval (PHI) for the indicated crop is longer than the REI for harvesting activities. Therefore an REI for harvesting is not required on the label.





## Appendix VIII Comparison of Application Rates Used for Risk Assessments in PRVD2011-14 versus Revised Application Rates

**Table 1 Comparison of PRVD2011-14 Application Rates versus Revised Application Rates**

Crop	Original Application Rate Used (as published in PRVD2011-14; Appendix XI)			Revised Application Rate		
	Application Rate (kg a.i./ha) PMRA# 2292993	Number of Applications	Retreatment Interval (days)	Application Rate (kg a.i./ha)	Number of Applications	Retreatment Interval (days)
Asparagus	1.7	3	14	1.2 (dry flowable) 1.7 (solution)	3	14
Blueberries, highbush*	3.6	3	Not stated	3.6	2	7
Blueberries, lowbush*	3.6	2		3.6 (solution) 2.5 (dry flowable)	2	42
Cabbage	2.4	Not stated	7	2.4	2	7
Carrot	1.6	7	7	1.6	7	7
Celery, field	2.0	9	3	2.0	2	3
Celery seedbeds (greenhouse)	2.0	9	3	1.4	1	N/A
Cherry (sweet and sour)*	4.5	3	10	4.5	3	10 (two applications with retreatment interval of 10 days; one post-harvest application)
Chickpea	2.0	3	10	2.0 and 1.5	2 (1 at 2.0 kg a.i./ha + 1 at 1.5 kg a.i./ha)	10
Cole crops: Broccoli, Brussels sprouts, cauliflower	2.4	5	7	2.4	1	N/A
Conifers - outdoor (e.g., cedar, Douglas-fir,	4.75	4	7	4.8	2	7

Crop	Original Application Rate Used (as published in PRVD2011-14; Appendix XI)			Revised Application Rate		
cypresses, fir, junipers, pine, spruce);						
Conifer nursery beds (greenhouse)	2.4 4.75	Not stated Not stated	7 21	1.2	1	N/A
Corn, sweet	1.6	2	10	1.6	2	10
Cucurbit vegetables (Cantaloupe, muskmelon, honeydew, squash, pumpkin, watermelon, cucumber)	2.4	7	7	2.4	2	7
Evening Primrose	1.2	2	14	1.2	2	14
Ginseng	2.4	6	7	2.4	3	7 (two applications with retreatment interval of 7 days; one fall application)
Hazelnut	Not stated	Not stated	Not stated	3.4	3	20
Lentils	2.0	2	10	2.0	2	10
Mushrooms	12.7	2	Not stated	12.7	1	N/A
Onion (dry bulb)	2.4	3	7	2.4	2	7
Onion (green bunching)	2.4	5	7	2.4	2	7
Ornamentals - outdoor(excluding cut flowers)	2.5	23	7	2.5	2	7
Ornamentals - outdoor roses (not for cut flowers)	1.8	23	7	1.9	2	7
Ornamentals - outdoor cut flowers (other than roses)	2.5	23	7	2.5	1	N/A
Ornamentals - outdoor pachysandra	5.0	23	7	5.0	1	N/A
Ornamentals - greenhouse other than roses (not grown for cut	2.5	4	7	1.25	1	N/A

Crop	Original Application Rate Used (as published in PRVD2011-14; Appendix XI)			Revised Application Rate		
flowers)						
Ornamentals - greenhouse roses (not grown for cut flowers)	1.8	4	7	0.94	1	N/A
Ornamentals - greenhouse rose (cut flowers)	1.8	4	7	Not acceptable		
Ornamentals - greenhouse other than roses (cut flowers)	2.5	4	7	Not acceptable		
Ornamentals - greenhouse pachysandra	5.0	4	7	Not acceptable		
Parsnip	1.4	7	7	1.4	7	7
Pea, dry	1.5	3	10	1.5	2	10
Peach and nectarine*	4.5	4	Not stated	4.5	3	10 (two applications with retreatment interval of 10 days; one fall dormant application)
Potato (seed)*	1.2	12	7	1.2	3	7
Potato (table)*				1.2	3	7
Strawberry	1.75	3	10	1.8	3	10 (two applications with retreatment interval of 10 days; one post-harvest application)
Tomato (not grown for processing)	2.4	9	8	2.4	2	14
				1.2	2	8
Tomato (grown for processing)				2.4 and 1.2	9 (2 applications at 2.4 kg a.i./ha and 7 applications at 1.2 kg	14 (for applications at 2.4 kg a.i./ha) 8 (for applications

Crop	Original Application Rate Used (as published in PRVD2011-14; Appendix XI)			Revised Application Rate		
					a.i./ha)	at 1.2 kg a.i./ha)
Turf (snow mould)	12.7	2	7	12	1	N/A
Turf – golf courses and sod farms*	9.5	Greens – max 81.76 kg a.i./ha/yr	7	9.5	2	14
		Sod farms – max 29.12 kg a.i./ha/yr	7	4.8	2	7
Wheat	1.25	3	10	1.3	2	10

\*Crops were used in the refined environmental risk assessment (PRVD2011-14).

## References

### A. Studies/Information Submitted by the Registrant

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2651058	2000, OECD Summary - Chlorothalonil: 4 Day Repeat Dose Study in Rats, DACO: 4.3.3
2651059	2000, Chlorothalonil: 4 Day Repeat Dose Study in Rats, DACO: 4.3.3
2651060	2013, Chlorothalonil - Biotransformation of [14C]-Chlorothalonil in the Rat Final Report, DACO: 4.5.9
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**B. Published Information**

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	USEPA. 1998. Science Advisory Council for Exposure. Policy 003. Agricultural Default Transfer Coefficients. May 7, 1998.