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Proposed Special Review Decision

PSRD2022-01

Special Review of Chlorothalonil and Its Associated End-use Products: Proposed Decision for Consultation

Consultation Document

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1.0 Introduction

Health Canada's Pest Management Regulatory Agency (PMRA) initiated a special review of chlorothalonil in 2018 under subsection 17(1) of the *Pest Control Products Act* based on the information reported under section 13 of the *Pest Control Products Act*, and information from the 2016 European Food Safety Authority report, with respect to chlorothalonil.

Subsequent to the initiation of the special review, PMRA became aware of the the European Union (EU) decision to prohibit all uses of chlorothalonil as plant protection products due to human health and environmental concerns (European Commission, 2019). Certain aspects of concern identified by the EU have been included in this special review (refer to Section 3.0). The remaining aspects of concern were previously addressed as part of the re-evaluation of chlorothalonil that was completed in 2018 (Re-evaluation Decision RVD2018-11, *Chlorothalonil and Its Associated End-use Products for Agricultural and Turf Uses*).

Pursuant to subsection 18(4) of the *Pest Control Products Act*, Health Canada has evaluated the aspects of concern that prompted the special review of pest control products containing chlorothalonil. The aspects of concern for this special review are relevant to human health and the environment.

2.0 Uses of chlorothalonil in Canada

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 celery seedbeds, greenhouse ornamentals, outdoor ornamentals, mushroom houses, and turf (golf courses and sod farms). Chlorothalonil is applied by both aerial and ground application equipment. All registered pest control products containing chlorothalonil used in agriculture, horticulture and turf (Appendix I), are considered for the special review (summary of uses in Appendix II).

Chlorothalonil is also used as a dry-film material preservative agent against bacterial and fungi contamination or spoilage of paint and is currently under re-evaluation in Canada. Health Canada published the proposed re-evaluation decision for chlorothalonil in July 2020 (PRVD2020-06, *Chlorothalonil and Its Associated End-use Products, Used as a Preservative in Paints*), and the final decision will be published after considering the comments received during consultation. This use is not part of the scope of this special review.

3.0 Aspects of concern that prompted the special review

Based on the review of submitted information under section 13 of the *Pest Control Products Act*, as well as from the European Food Safety Authority report (2016) for chlorothalonil, Health Canada identified the following initial aspects of concern that prompted the special review:

- Environment
 - Potential changes to environmental fate and ecotoxicological endpoints.

Additionally, the European Union prohibited all uses of chlorothalonil based on human health and environmental concerns in 2020 based on the 2019 European Commission (EC) decision on the non-renewal of plant protection products containing chlorothalonil. The 2019 EC decision identified the following aspects of concern:

- Potential exposure to metabolites R417888, R419492, R471811, SYN507900, M3, M11, M2, M7 and M10 from groundwater.
- Potential genotoxicity of chlorothalonil metabolites.
- Potential carcinogenicity of chlorothalonil.
- Potential risk to amphibians and fish.

This special review added certain aspects of concern identified in the 2019 EC decision with the exception of the aspect of concern related to potential carcinogenicity of chlorothalonil (from occupational and residential exposure). The latter was previously assessed as part of the re-evaluation of chlorothalonil (RVD2018-11) and there was no additional information identified in the 2019 EC decision to indicate risks of concern relating to occupational and residential exposure.

Therefore, the aspects of concern considered in this special review of chlorothalonil are:

- Human Health
 - Potential exposure to metabolites R417888, R419492, R471811, SYN507900, M3, M11, M2, M7 and M10 from groundwater.
 - Potential carcinogenicity of chlorothalonil (related to dietary exposure).
 - Potential genotoxicity of chlorothalonil metabolites.
- Environment
 - Potential changes to environmental fate and ecotoxicological endpoints (expanded to include transformation products).
 - Potential risk to amphibians and fish.

4.0 Evaluation of the aspects of concern that prompted the special review

Following the initiation of the special review, Health Canada requested information related to the aspects of concern from provinces and other relevant federal government departments and agencies in accordance with the subsection 18(2) of the *Pest Control Products Act*.

In order to evaluate the aspects of concern for chlorothalonil, Health Canada considered currently available relevant scientific information, which includes information considered for the re-evaluation of chlorothalonil (Canada, 2018), water monitoring information, information submitted through the Canadian incident report database, information from the European Food Safety Authority, and the European Union decision.

4.1 Assessment of aspects of concern related to human health

4.1.1 Potential exposure to metabolites (R417888, R419492, R471811, SYN507900, M3, M11, M2, M7 and M10) from groundwater

As part of the special review, potential exposure from chlorothalonil and various transformation products in ground water was considered. Based on the additional environmental fate data that was not included in the 2018 re-evaluation (studies submitted through Incident Reporting program and EFSA review), the existing residue definition in drinking water was updated as part of this special review (Appendix III).

Based on the review of the available data, including new environmental fate and existing toxicological data, the residue definition in drinking water considered for this special review was determined to be the following: chlorothalonil and 15 of the transformation products – R182281 (also known as SDS-3701), R611965, R471811, SYN507900, SYN546671, R613636, R613801, R613841, PD1, PD2, PD3, PD4, PD5, Polar 1, and I. See Section 4.2.1 for details on transformation products of chlorothalonil.

Note that the transformation products identified as part of the aspects of concerns from the 2019 EC decision are: R417888, R419492, R471811, SYN507900, M3, M11, M2, M7 and M10 (from ground water). Due to the limited data available for identified major transformation products, as well as a large number of unidentified transformation products, not all transformation products are included in the residue definition. Potential dietary risk (acute and chronic) from exposure to relevant metabolites from groundwater is outlined in Section 4.1.4.

4.1.2 Potential carcinogenicity of chlorothalonil (related to dietary exposure)

See Section 4.1.4.

4.1.3 Potential genotoxicity of chlorothalonil metabolites (related to the health hazard)

Health Canada has considered all currently available relevant scientific information, which includes the available information from the European Union, the United States Environmental Protection Agency, and existing reviews of chlorothalonil (Canada, 2011; Canada, 2016; Canada, 2018) to assess the potential genotoxicity of chlorothalonil metabolites. The weight of evidence review suggests that chlorothalonil metabolites identified as residues of concern are not likely to be genotoxic. Note that since the chlorothalonil cancer assessment is already based on a linear, low dose extrapolation method and these metabolites of concern are included in the residue definition for risk assessment, the existing risk assessment is considered conservative and protective of any residual uncertainties regarding the potential risk from these metabolites. There are no further concerns regarding the potential genotoxicity of these metabolites identified at this time.

4.1.4 Dietary exposure and risk assessment

As part of the special review, Health Canada assessed the dietary risk from exposure to chlorothalonil and various metabolites (R182281, R611965, R471811, SYN507900, SYN546671, R613636, R613801, R613841, PD1, PD2, PD3, PD4, PD5, Polar 1 and I) from groundwater.

The residue definition for dietary risk assessment in plant commodities is chlorothalonil and the metabolite SDS-3701 (R182281). The residue definition for dietary risk assessment in animal commodities is the metabolite SDS-3701 (R182281).

The acute and chronic (non-cancer and cancer) dietary (food plus drinking water) exposure assessments were conducted using the Dietary Exposure Evaluation Model - Food Commodity Intake Database™ (DEEM-FCID™; Version 4.02) program which incorporates food consumption data from the National Health and Nutrition Examination Survey/“What We Eat in America” dietary survey for the years 2005- 2010 available through the Centers for Disease Control and Prevention’s National Center for Health Statistics.

The acute and chronic (non-cancer and cancer) dietary exposure estimates for chlorothalonil are considered to be highly refined as monitoring data, and domestic/import data were used to the extent possible. The dietary exposure assessment for chlorothalonil was conducted using the Canadian Food Inspection Agency’s (CFIA) and the United States Department of Agriculture’s (USDA) Pesticide Data Program (PDP) residue monitoring data for many of the commodities; for a few commodities with no monitoring data, anticipated residues from American and Canadian field trials or maximum residue limit (MRL)/American tolerance values were used. Policies from the PMRA and United States Environmental Protection Agency were used for crop translations when necessary. In addition, the following inputs were incorporated: 100% crop treated was assumed for all commodities; DEEM-FCID default processing factors were used. The residue definition in animal commodities only includes the metabolite, SDS-3701 (R182281). Residues of SDS-3701 (R182281) in animal commodities are covered under Part B, Division 15, subsection B.15.002(1) of the Food and Drug Regulations (in other words, ≤0.1 ppm). There is no indication SDS-3701 is carcinogenic (Canada, 2011; Canada, 2018) thus, contribution of SDS-3701 (R182281) residues from animal commodities to human dietary exposure is assumed negligible and was, therefore, not included in the cancer assessment.

Estimated environmental concentrations (EECs) of chlorothalonil and 15 of its transformation products (R182281, R611965, R471811, SYN507900, SYN546671, R613636, R613801, R613841, PD1, PD2, PD3, PD4, PD5, Polar 1, and I) were modelled using the Pesticide in Water Calculator (PWC, version 1.52). EECs in groundwater were calculated by selecting the highest EEC from a set of standard scenarios representing different regions of Canada. Simulations were run for 50 years. The use of a parent-daughter modelling approach was used to refine the groundwater EECs. This approach took into account the different sorption characteristics of the various compounds in the residue definition (where available). The final groundwater EEC (5380 µg/L [5.38 ppm]) was used as the input value to estimate dietary exposure to chlorothalonil and its 15 metabolites in drinking water. Details of estimated EECs are presented in Appendix III, Table 3.

The available ground water monitoring information was also considered (Appendix IV, Table 8); however, it was insufficient to characterize exposure due to limitations in the dataset including the fact that sampling was only for chlorothalonil and none of the transformation products of concern.

The acute reference dose (ARfD) for chlorothalonil is 0.58 mg/kg bw/day, based on the lowest observed adverse effect level (LOAEL) of 175 mg/kg bw/day determined in a 90-day feeding study in rats, and a composite assessment factor (CAF) of 300 (Canada, 2018). The refined acute dietary exposure from food uses alone for the general population and all representative population subgroups (at the 95th percentile) is less than 8% of the ARfD. The refined acute dietary exposures from food and drinking water (95th percentile), are in the range from 42% to 76% of the ARfD for all subpopulations except infants (<1 years old). The refined acute dietary exposure (food and drinking water) for infants (95th percentile) is 170 % of the ARfD, which is of health concern. The major contributor to the dietary exposure and risk estimate for infants is drinking water.

The chronic (non-cancer) reference dose for chlorothalonil is 0.015 mg/kg bw/day, based on a no observed adverse effect level (NOAEL) of 1.5 mg/kg bw/day determined in the 2-year study in rats, and a CAF of 100 (Canada, 2018). The refined chronic (non-cancer) dietary exposures from food uses alone are less than 42% of the acceptable daily intake (ADI) for the general population and all representative population subgroups. The refined chronic (non-cancer) dietary exposures (food and drinking water) for all population subgroups range from 519% to 2719% of the ADI, which are of health concern. The major contributor to the dietary exposure and risk is drinking water.

Based on a 2-year toxicity study in rats, a $q1^*$ of 7.66×10^{-3} (mg/kg bw/day)⁻¹ was established to assess cancer risk from chlorothalonil (Canada, 2011; Canada, 2016; Canada, 2018). Based on this information, the dietary risk was assessed. The refined chronic (cancer) exposure estimates from all supported food uses (alone) and food plus drinking water for the general population are 4.98×10^{-6} and 8.38×10^{-4} , respectively, which are of health concern. The major contributor to the dietary risk is exposure from drinking water.

The results of the acute, chronic (non-cancer) and chronic (cancer) dietary exposure and risk assessments for chlorothalonil are presented in Appendix III, Tables 1 and 2.

4.1.5 Dietary risk assessment conclusions

Based on the results of the dietary exposure assessments considering the currently available information, Health Canada has concluded that the acute dietary exposure risk from food alone for the general population and all subpopulations has been shown to be acceptable. Aggregate acute exposure risk from food and drinking water has not been shown to be acceptable for infants (<1 years old). The chronic (non-cancer) dietary exposure risk from food alone has been shown to be acceptable based on the currently registered use pattern. Aggregate chronic (non-cancer) exposure from food and drinking water has not been shown to be acceptable for all population subgroups. The lifetime cancer risks for the general population from exposure to food alone and food plus drinking water have not been shown to be acceptable.

Based on this, dietary health risks were not shown to be acceptable for all food uses of chlorothalonil. Therefore, all food uses of chlorothalonil are proposed for cancellation and all maximum residue limits (MRLs) are proposed for revocation.

4.2 Assessment of aspects of concern related to the environment

The aspects of concern were related to potential changes to environmental fate and ecotoxicological endpoints, including transformation products, as well as potential risks to amphibians and fish. Additional information indicating potential increased risk to bees (PMRA# 2781997) was provided, however, the risk to aquatic organisms was identified as eclipsing the risk to bees based on the 2016 EFSA draft review. Based on this, the aspects of concern were limited to aquatic organisms. If outdoor uses of chlorothalonil are maintained, further assessment of risk to bees and potential increased mitigation measures may be required.

The potential risks to non-target aquatic organisms resulting from application of chlorothalonil were assessed using information from registrant-submitted data, open literature, water monitoring data, incident reports and reviews from the European Food and Safety Authority (EFSA; 2016 and 2018; PMRA# 2778799, 2778800, 3169502, 3169504, 3169505, 3169506).

The review of two studies (aerobic aquatic biotransformation and amphibian metamorphosis assay) submitted through the Incident Reporting Program (IRP) show more conservative fate parameters and ecotoxicology endpoints than were considered in the existing assessments of chlorothalonil.

Furthermore, Health Canada considered the EFSA review (2016; PMRA# 2778799, 2778800, 3169502, 3169504, 3169505, 3169506), which included a large volume of data that was not previously available to Health Canada. This data set included newer fate studies conducted using new analytical methods that resulted in the detection of numerous new major transformation products.

Based on the above information, the special review focused on risk to aquatic organisms.

4.2.1 Potential changes to environmental fate and ecotoxicological endpoints

Fate and behaviour in the environment

Chlorothalonil

Chlorothalonil may reach soil when it is applied to foliage and through spray drift, with direct application being the primary route of exposure.

Hydrolysis and soil phototransformation are not a major route of transformation under most conditions. In water, photolysis results in the formation of a number of transformation products, including compounds with more complex chemical structures than the parent. Many of the major transformation products from this route of transformation were not identified.

In soil, chlorothalonil is classified as slightly persistent with a dissipation time of DT₅₀ of 47 days (90% confidence bound on the mean, n=23; range 0.33 to 246 days). The laboratory studies may not be indicative of the expected dissipation of chlorothalonil in Canadian soils. First, the extraction methods that were used were insufficient to remove all potential bioavailable residues of chlorothalonil. Thus, total residues of chlorothalonil could be higher resulting in longer dissipation times and more persistence. In addition, available scientific information shows that the rate of dissipation of chlorothalonil is affected by the application rate, with higher application rates resulting in longer dissipation times. The dissipation time (DT₅₀) of 47 days includes results from studies conducted with application rates below the lowest application rate in the Canadian use pattern. Thus, it is possible that including the laboratory studies that do not reflect the most relevant use rates for Canada could be underestimating the persistence of chlorothalonil in Canadian soils. Submitted soil studies included large numbers of unknown major transformation products which could not be assessed.

Chlorothalonil may enter the aquatic environment through spray drift or runoff, with runoff being the primary route of exposure.

In aquatic environments, chlorothalonil is classified as non-persistent with a DT₅₀ of 5.3 days (80th percentile, n=4; range 0.8 to 6.87 days). A study with only a water phase suggests that the application rate will also influence persistence in water, as is seen in the aerobic soil studies. Therefore, the water/sediment DT₅₀ value may be underestimating persistence in aquatic environments as the submitted studies were conducted at rates below the Canadian use pattern and dissipation rates are affected by application rates. Submitted studies reported numerous unknown major transformation products which could not be assessed.

Mobility of chlorothalonil ranges from being immobile to having medium mobility in soil with *K*_{oc} values ranging from 471.2 to 10 875. Chlorothalonil binds rapidly to soil (in 2-24 hours); therefore, binding to soil is expected to be the dominant route of dissipation in the environment compared to microbial transformation. The bound chlorothalonil can desorb (unbind) from soil under certain conditions. While the new desorption data did not follow the methods required by Health Canada, the data showed that under saturated conditions (for example, soil eroded from fields into water), chlorothalonil can desorb from soil and become bioavailable. Further, the data shows that the higher the concentration of chlorothalonil in the soil, the greater percentage that will desorb under these conditions. Given the high Canadian rates the higher rate of desorption is likely.

Transformation products of chlorothalonil

Data available for the previous re-evaluation of chlorothalonil (PRVD2011-14) identified a single major transformation product and three minor transformation products. In the new submitted studies, 38 transformation products were identified (16 major) and a further 61 unidentified transformation products were noted in the studies (19 major). See Appendix V, Table 2 for full details of the transformation products. In the lysimeter studies, a further 14 transformation products were not identified; however, due to poor mass balance in the studies, they cannot be characterized as minor or major. The reference standards used were inconsistent

across studies, with subsets used for different groups, in other words, aerobic soil, bringing into question if all major transformation products have been identified.

Of the 38 identified transformation products, 15 had available fate data and were determined to be as or more persistent in soil (DT₅₀ range from 15.5 to 582 days) and more mobile in the environment (leaching potential ranges from medium to very high) than the parent (refer to Appendix V, Table 2).

Environmental toxicity

Due to the rapid dissipation of chlorothalonil in aquatic environments, only those studies with confirmed concentrations of chlorothalonil were used in the risk assessment. A full list of acceptable studies and toxicity endpoints that were used in the risk assessment can be found in Appendix VI, Tables 1–3.

By limiting the studies to those that have confirmed concentrations, the number of species became too limited to conduct species sensitivity distributions (SSD). Vertebrates, fish and amphibians, were found to be the most sensitive organisms to chlorothalonil, for both acute and chronic exposure.

Mesocosm studies showed that some groups of organisms would recover from exposure to chlorothalonil. However, the duration of these studies was not long enough to determine that all groups would recover, nor were vertebrate organisms included in the study, the most sensitive group. Therefore, the utility of the mesocosm studies for the risk assessment was limited.

Overall, new environmental fate parameters and ecotoxicity end points were established; however, the movement of all possible transformation products to depth could not be assessed due to lack of data.

4.2.2 Potential risk to amphibians and fish

Risks to aquatic organisms

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

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

The rapid dissipation of chlorothalonil in aquatic habitats, combined with the large number of crops and up to nine applications per season, is expected to result in pulse exposures to aquatic environments. The pulsed nature of exposure will make detection of potentially lethal runoff events through water monitoring programs difficult unless a system of continuous sampling is in place, or sampling is tied to runoff events (precipitation).

All aquatic organism groups were assessed in the risk assessment (freshwater invertebrate, freshwater fish, freshwater aquatic plant, freshwater algae, amphibian, marine invertebrate, marine fish, and marine algae). The most sensitive endpoint from each group, acute and chronic (where available), were used (Appendix VI, Tables 1–3). The most sensitive endpoint overall is from a 21-d freshwater fish study. Effects on fecundity were observed at the lowest concentration tested ($NOEC < 0.000078 \text{ mg a.i./L}$), therefore a no-effect-level could not be determined. As this is the most sensitive endpoint, it was used in the risk assessment with risk quotients (RQs) reported as “greater than” values

For the initial screening level risk assessment, all RQs exceeded the LOC. Therefore, refined aquatic risk assessments for cranberry use, runoff and spray drift were conducted (see below).

Greenhouse and mushroom house uses

The aquatic risk assessment for greenhouses and mushroom houses is qualitative. Chlorothalonil is highly toxic to aquatic organisms. The highest single application rate is registered for mushroom houses (equivalent to 12.7 kg a.i./ha). Potential exposure of aquatic habitats through the release of effluent containing chlorothalonil must be avoided. A label statement prohibiting the release of effluent from greenhouses and mushroom houses is required to prevent entry into aquatic waterbodies which is already included on relevant labels. Therefore, potential risk to aquatic organisms from mushroom house and greenhouse uses are shown to be acceptable when current label use directions are followed.

Greenhouses using closed recirculation systems (for example, closed chemigation system) the following is proposed: a third-party audit that validates the facility's closed recirculation system and other measures are sufficient to prevent releases, effluent or runoff containing this product from entering lakes, streams, ponds, or other waters.

Cranberry use

Four scenarios were modelled and the risk from cranberry flood waters exceeded the LOC for all aquatic organisms with the exception of aquatic plants (*Lemna gibba*). The RQ for *Lemna gibba* ranged from 0.09 to 1.41. For all other aquatic organisms, the RQ ranged from 6.43 to 3978 (Appendix IV, Table 1–3). Based on the data explained above, including the behaviour of chlorothalonil in water and the high RQs for aquatic organisms, Health Canada has determined that the risks to aquatic organisms from use of chlorothalonil on cranberries are not shown to be acceptable. The risk to aquatic organisms may be mitigated through holding of flood water. However, the time-frame required to reduce concentrations in the water to acceptable levels to achieve mitigation may not be feasible where waters are released to the environment. Open stored water will still be accessible to amphibians.

Spray drift

The risk from spray drift was assessed initially using three different crops. The lowest cumulative application rate (wheat) for both ground boom and aerial application; a high rate for airblast application (stone fruit), and the highest ground boom rate (turf). The risk to aquatic organisms from spray drift 1 m downwind from the treated site was assessed taking into consideration the spray drift deposition for an ASAE medium spray quality for groundboom (6%), airblast early season (74%) and late season (59%), and medium spray quality for aerial (23%) application equipment. For marine habitats, only single applications at the maximum rate were assessed as chlorothalonil is expected to dissipate between applications due to twice daily tidal movement of water near shore. Only acute risk was assessed for spray drift based on the non-persistent nature of chlorothalonil in aquatic environments. For details, please refer to Appendix VII.

RQs exceeded the LOC for all methods of application (Appendix IV, Table 4):

- For ground boom application to wheat, the RQs ranged from 0.06 to 80.5. For aerial application to wheat, the RQs ranged from 0.22 to 309.
- For airblast application to stone fruit, application scenarios are separated into early and late season applications. For early season airblast the RQs ranged from 2.4-3415. For late season application they ranged from 1.9-2683.
- For ground boom applied to turf the RQs ranged from 0.41 to 585.
- As all scenarios exceeded the LOC, buffer zones were calculated for all outdoor crops.

Buffer zones are proposed for all crops ranging from 1–120 metres for ground applications and 15–800 metres for aerial applications. To summarize:

- Ground application buffer zones mitigate risks from spray drift to an acceptable level for all but turf applications.
- For turf, the RQ for amphibians with the maximum buffer zone of 120 metres in place is 334.6, and thus the risks have not been shown to be acceptable for this use.
- Aerial and airblast (early and late) buffer zones mitigate risks from spray drift for all crops.

Therefore, exposure from spray drift has been shown to be acceptable with the implementation of proposed buffer zones for all uses except turf.

Runoff

Chlorothalonil will be transported in runoff, both as a solute and bound to eroded soil, into adjacent water bodies following a rainfall event. Potential exposure of chlorothalonil to aquatic organisms through runoff was assessed using EECs from water modelling, surface water monitoring results and information from incident reports. Acute and chronic risk were assessed as the frequency of runoff events may be high at times.

EECs in water were calculated using the Pesticide in Water Calculator model (PWC, version 1.52) for a 10-ha field adjacent to a 1-ha water body with a depth of 80 cm to represent a permanent water body, or 15 cm to represent a seasonal water body used by amphibians. An aquatic DT₅₀ value of 6.87 days (80th percentile, n=6) was used in the water modelling for runoff. Subsequent to completing the water modelling, the data used to produce the aquatic DT₅₀ input parameter was further assessed which resulted in the removal of two data points, changing the 80th percentile to 5.3 days. Water modelling was not recalculated using the new endpoint as this would have had a minimal effect on the EEC value or any risk quotients derived from the EEC. While limited, water monitoring of surface water concentrations in two provinces overlap with the ecological surface water EEC values calculated by the model, supporting the decision to not update the modelling with the new aquatic DT₅₀. For acute risk the modelled 24-hour or 96-hour water concentrations were used while the 21-day water concentrations were used for chronic risk. Nine separate crops were modelled using crop specific application rates (highbush blueberries, lowbush blueberries, carrots, outdoor conifers, potatoes, stone fruit, processing tomatoes, turf, and wheat). The modelling inputs and resulting EECs are summarized in Appendix IV, Tables 1–3.

Using the EECs from the ecoscenario modelling and the most sensitive ecotoxicity endpoints, risks were determined for aquatic organisms. Amphibian RQs ranged across crops from 25.6 to 621 for acute risk and 7.5 to 226 for chronic risk. Freshwater fish RQs ranged across crops from 31.8 to 484 for acute risk and >46.2 to >1141 for chronic risk. Freshwater invertebrate RQs ranged from 28.9 to 439 for acute risk and 6 to 148 for chronic risk. Freshwater algae RQs ranged from 2.1 to 72 and freshwater plants RQs ranged from 0.04 to 0.79, both considered acute risk.

For marine organisms, using the 80 cm freshwater EEC as a surrogate, the invertebrate RQs ranged across crops from 3.9 to 69.2 for acute risk. Marine fish RQs ranged from 3.5 to 61.8 and for marine algae RQs range from 29.5 to 448 for acute risk.

The risk from transformation products could not be determined due to a lack of data. However, as the risk from parent chlorothalonil alone has not been shown to be acceptable, potential risk from transformation products and the parent is also considered not acceptable.

Incident reports in Canada have shown that chlorothalonil moves to waterbodies via runoff after rainfall causing fish mortality. Those incidents with reported eroded soil have brought to question if other factors, such as reduced dissolved oxygen (due to influx of soil-laden water) or physical damage to the fish from the eroded soils, are the main cause of death and not chlorothalonil. Laboratory studies conducted with sediment found no difference in the toxicity endpoints to fish when compared to studies with water only. However, these studies did not address physical damage to the fish from the sediment. It is expected that the levels of chlorothalonil in runoff are sufficiently toxic to result in death without any physical damage to fish. This is supported by the evidence that fish mortality occurred even when eroded soils were not reported. Laboratory fish toxicity studies conducted at different dissolved oxygen saturation levels found that fish were more sensitive to chlorothalonil when under low oxygen stress (low oxygen data were not used in the quantitative risk assessment). From the available data, while low oxygen levels and high sediment load in the water may increase sensitivity to chlorothalonil, chlorothalonil is still expected to be the source of toxicity.

Due to chlorothalonil's short dissipation time in water bodies, these runoff events result in short pulse inputs to the water body. Addressing the short pulse exposure scenarios for chlorothalonil is difficult and requires collection of robust water monitoring data. For water monitoring programs based on random sampling, the probability of capturing the peak exposure concentrations is extremely low. Only when autosamplers tied to precipitation /snow melt events are employed can there be confidence that the monitoring data captures the peak values.

Water monitoring data were collected across Canada and demonstrated that chlorothalonil can be detected in surface water in areas where this pesticide is used, particularly following rainfall events. A summary of chlorothalonil monitoring data in surface water bodies relevant to the aquatic risk assessment is presented in Appendix IV, Table 8. The available data is limited in scope and surveillance monitoring programs may not capture peak exposures. As an example, the water monitoring data in Prince Edward Island from 2010-2019 found no detections in water bodies. Over the same time period, there were four chlorothalonil related fish mortality events in PEI that had water detections of chlorothalonil at concentrations toxic to fish. All were associated with large rainfall events and water samples were taken within a day or two of the event, showing that sampling must be linked to rainfall events to capture peak concentrations. Even with the low frequency of detection in surface water, the available data shows that surface water concentrations can exceed the effects metrics for aquatic organisms. While there is limited information to make conclusions from the monitoring data, there is evidence to show that levels of chlorothalonil in surface water can reach levels high enough to result in fish mortality in highly intensive agricultural areas, especially following a significant rainfall.

The maximum detected values in monitoring data from two provinces exceeded modelled peak surface water values at 80 cm water depths which indicates that the modelled EECs are not overly conservative.

Vegetative filter strips (VFS) were assessed as a potential mitigative measure for runoff of chlorothalonil into aquatic systems. A VFS reduces the velocity of runoff water over a vegetated strip of land at the down-slope edge of the field. This allows any pesticide residues in water or on transported soil particles to settle out, thus reducing the amount that may enter an adjacent waterbody. In Prince Edward Island, where a minimum 15 m VFS has been required for over 10 years, fish mortalities related to runoff events where chlorothalonil has been detected have been reported. New toxicity data indicate that chlorothalonil is more toxic to fish than reported in PRVD2011-14.

Thus, lower levels of residues reaching water could be enough to cause effects. In addition, information regarding the desorption of chlorothalonil from soil and sediment suggests that chlorothalonil residues may be released from soil particles trapped in the VFS from subsequent contact with runoff water. Based on this information it is unlikely that a VFS will be an effective tool for protecting aquatic habitats from chlorothalonil.

Based on the lines of evidence explained above pertaining to parent chlorothalonil alone, including the available scientific information regarding the behaviour of chlorothalonil in water, the high RQs for aquatic organisms, the inability to mitigate these risks via use pattern restrictions or vegetative filter strips, repeated fish mortality events associated with measured levels of chlorothalonil that exceed acute fish effects metric, and modelled EECs supported by water monitoring data, Health Canada has determined that the risks to aquatic organisms, including amphibians and fish, from the outdoor use of chlorothalonil were not shown to be acceptable.

4.2.3 Environmental risk assessment conclusions

The environmental assessment shows that, in aquatic environments in Canada, chlorothalonil is expected to be present at concentrations that are toxic to aquatic organisms, with the greatest risks identified for fish and amphibians.

Based on the refined water modelling results, the risks to freshwater invertebrates, freshwater fish, freshwater plants, amphibians, marine invertebrates, marine fish, and marine plants following acute or chronic exposure to chlorothalonil were not shown to be acceptable. While the water monitoring data is insufficient to be used quantitatively for a risk assessment, the range of EECs in surface water predicted from modelling (0.0036–0.197 mg/L) overlaps with the range of concentrations measured in surface water bodies (0–1.851 mg/L). Therefore, the modelling EECs were used in the risk assessment. Based on the risk assessment, potential risk to aquatic organisms from all outdoor uses were not shown to be acceptable.

Indoor uses in mushroom houses and greenhouses were only assessed qualitatively. Waste water from both mushroom houses and greenhouses is expected to contain concentrations that would be toxic to aquatic organisms. Potential exposure of aquatic habitats through the release of

effluent containing chlorothalonil must be avoided. A label statement prohibiting the release of effluent from greenhouses and mushroom houses is required to prevent entry into aquatic waterbodies. Note that label statements relating to this are already included on relevant labels. Therefore, potential risk to aquatic organisms from mushroom house and greenhouse uses are shown to be acceptable when current label use directions are followed. Greenhouses using closed recirculation systems (for example, closed chemigation system) the following is proposed: a third-party audit that validates the facility's closed recirculation system and other measures are sufficient to prevent releases, effluent or runoff containing this product from entering lakes, streams, ponds, or other waters.

Overall, Health Canada has concluded that environmental risks relating to the aspects of concern were not shown to be acceptable for all outdoor uses. Therefore, all outdoor uses of chlorothalonil are proposed for cancellation.

5.0 Incident reports

5.1 Health incident reports

As of 22 November 2021, 16 human incidents involving chlorothalonil were submitted to the Health Canada through the Incident Reporting Program.

There were six serious human incidents. The incidents occurred in Canada (one major report) and the United States (4 major, 1 death). Several active ingredients (including chlorothalonil) were reported in these incidents. Overall, there was insufficient information to assess the role of chlorothalonil in the reported incidents. This was based on the lack of information on the circumstances surrounding the exposure of chlorothalonil. In addition, the reported effects in other words, myelodysplastic syndrome, Parkinson's disease or malignant neoplasm are considered multi-factorial in nature to the extent that the effect(s) are unclassifiable due to the role of other unknown confounding factors (for example, biological/environmental factors or causes).

The remaining human incidents were either minor or moderate in severity. None of these incidents were considered relevant to the outlined aspect of concerns based on either the reported symptom (for example, seizure, hair-loss, diarrhea) or the known route of exposure (for example, drift). Hence, no additional mitigation measures were recommended.

5.2 Environment incident reports

As of 22 November 2021, there have been six fish mortality events reported to Health Canada related to chlorothalonil through the Incident Reporting Program. Four of these incidents were previously described in RVD2018-11. As indicated in RVD2018-11, all were attributed to products used on potato on Prince Edward Island (PEI), however, one occurred at a golf course in Ontario. An additional event was reported in 2017 in PEI and was not assessed in time to include in the RVD. All resulted in fish mortalities listed as probable or highly probable with relation to chlorothalonil use. A fish mortality incident resulting from a fire in 2010 is not related to normal use and is outside the aspects of concern for the special review and not included.

Health Canada received information for eight other fish mortality incidents associated with chlorothalonil that occurred prior to 2007 (Since 26 April 2007, registrants are required by law to report pesticide incidents, including adverse effects to the environment, to the PMRA). Two were summarized, in part, in PRVD2011-14. Of those incidents occurring prior to 2007, three reported chlorothalonil concentrations in water which exceeded the acute fish effects metric used for this special review. A fourth reported a water concentration just below the acute fish effects metric; however, the report noted that there was a significant time lapse between the fish mortality incident and the water sampling, which would allow for dissipation of the chlorothalonil. In general, the fish mortality events related to chlorothalonil use (pre- and post-2007) consistently show that rain events and runoff can result in fish mortality. In addition, available water samples related to some incidents confirm the presence of chlorothalonil at levels that would be toxic to fish.

In the potato growing regions of Atlantic Canada where most of the incidents have occurred, the mortality events are associated with catastrophic rainfall leading to large erosion events with both soil and runoff water reaching water bodies. It was indicated in RVD2018-11 that the probability of these events occurring with the reduced use pattern (3 applications instead of 12 applications per year for potatoes) was assessed to be much lower and with the implementation of the VFS, that the risk to fish would be mitigated. However, the incident at the Ontario golf course occurred over a grassed area and did not involve either a catastrophic rainfall event or soil erosion.

As outlined in Section 4.2.2, the more sensitive endpoint for fish that is now available (acute fish effect metric is 0.00044 mg a.i./L) indicates that risks to aquatic organisms (fish) is higher (than previously reported in RVD2018-11; Acute fish SSD HC₅ 0.013 mg a.i./L) and that fewer chlorothalonil residues are needed to reach aquatic habitats to cause an effect. In addition, soil desorption data (Section 4.2.1) indicated that a VFS may not be as effective for retaining chlorothalonil residues as originally predicted in RVD2018-11. As all outdoor uses are proposed for cancellation, no additional risk mitigation measures are proposed.

A full list of the studies and environmental incidents reported to the PMRA can be found in Appendix IX.

6.0 Proposed special review decision for chlorothalonil

Under the authority of the *Pest Control Products Act* and based on an evaluation of available relevant scientific information related to the aspects of concern for human health and the environment, Health Canada is proposing continued registration of greenhouse ornamental uses of chlorothalonil and associated end-use products registered for sale and use in Canada. All other uses of chlorothalonil are proposed for cancellation since potential risks to human health and the environment were not shown to be acceptable when products are used according to the current conditions of registration.

With respect to human health, dietary risks (food alone and food plus water) were not shown to be acceptable for food uses when chlorothalonil is used according to current conditions of registration. Based on this, all food uses of chlorothalonil are proposed for cancellation and all maximum residue limits (MRLs) are proposed for revocation.

Environmental risks to aquatic organisms were not shown to be acceptable for all outdoor uses when chlorothalonil is used according to current conditions of registration. However, environmental risks to aquatic organisms from mushroom houses and greenhouse uses were shown to be acceptable with the following proposed risk mitigation: Greenhouses using closed recirculation systems (for example, closed chemigation system) the following requirement is proposed: a third-party audit that validates the facility's closed recirculation system and other measures are sufficient to prevent releases, effluent or runoff containing this product from entering lakes, streams, ponds, or other waters.

This proposed special review decision is a consultation document.¹ Health Canada will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information on the cover page of this document).

7.0 Additional information that may help refine risk assessments

The current health and environmental risk assessments for chlorothalonil is based on the data and information available at this time. No additional scientific data are being requested during the consultation period for this Proposed Special Review Decision. However, registrants and stakeholders are encouraged to provide available information that may address uncertainties in the available information database of chlorothalonil before the end of the consultation period for consideration in the final special review decision.

The evaluation of any additional data would be based on the scientific merit and relevance to the risk assessment. While additional data may reduce uncertainty in the risk assessment, continued registration of any uses would be based on the acceptability of risk assessed using a science-based approach.

Dietary

Although, no additional scientific data have been identified at this time that may help refine the dietary risk assessment, proposed changes to the use pattern, such as the removal of uses, could potentially be considered to address the identified risks.

Environment

No additional scientific data are required at this time.

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

8.0 Next steps

Before making a special review decision on the agricultural, horticultural and turf uses of chlorothalonil, Health Canada will consider all comments received from the public in response to this consultation document. A science-based approach will be applied in making a final decision on chlorothalonil. Health Canada will then publish a special review decision document, which will include the decision, the reasons for it, a summary of the comments received on the proposed decision, and Health Canada's response to these comments.

9.0 Other information

The relevant confidential test data on which the proposed decision is based (see References section of this document) are available for public inspection, upon application, in Health Canada's Reading Room. For more information, please contact Health Canada's [Pest Management Information Service](#).

List of abbreviations

µg	microgram(s)
AB	Alberta
ABN	Alberta north
ABS	Alberta south
ADI	acceptable daily intake
a.i.	active ingredient
ARfD	acute reference dose
BC	British Columbia
BCO	British Columbia Okanagan
BCV	British Columbia Vancouver
BCF	bioconcentration factor
bw	body weight
C	celcius
CAF	composite assessment factor
CAS	Chemical Abstracts Service
CFIA	Canadian Food Inspection Agency
cm	centimetres
d	day
DEEM-FCID	Dietary Exposure Evaluation Model - Food Commodity Intake Database
DFOP	double first order in parallel
DT ₅₀	dissipation time 50% (the dose required to observe a 50% decline in concentration)
EbC ₅₀	effective concentration for a 50% reduction in biomass
EC ₅₀	effective concentration on 50% of the population
EEC	Estimated environmental concentration
EFSA	European Food Safety Authority
ErC ₅₀	effective concentration for a 50% reduction in growth rate
EU	European Union
g	gram
ha	hectare(s)
HCB	hexachlorobenzene
IORE	indeterminate order rate equation model
IRP	Incident Reporting Program
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
K _d	soil-water partition coefficient
K _{oc}	organic-carbon partition coefficient
K _{ow}	n-octanoal-water partition coefficient
L	litre(s)
LC ₅₀	lethal concentration 50% of the population
LOAEL	lowest observed adverse effect level
LOC	level of concern
m	metre

MB	Manitoba
mg	milligram
MRL	Maximum Residue Limit
mg	milligram(s)
n	number
n/c	not calculated
NHANES	National Health and Nutrition Examination Survey
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
OC	organic carbon content
OM	organic matter content
ON	Ontario
ONE	Ontario east
ONW	Ontario west
PDP	Pesticide Data Program
pKa	dissociation constant
ppm	part per million
PRVD	proposed re-evaluation decision
q ₁ *	cancer potency factor
QC	Quebec
RQ	risk quotient
SFO	single first order
SK	Saskatchewan
SSD	species sensitivity distribution
TSMP	Toxic Substance Management Policy
USDA	United States Department of Agriculture's
USEPA	United States Environmental Protection Agency
VFS	vegetative filter strips

Appendix I Registered products containing chlorothalonil as of 19 November 2021

Registration Number	Marketing Class	Registrant	Product Name	Guarantee
25574	T	GB BioscienceS LLC.	Technical Chlorothalonil Fungicide	98.5%
27059	T	Sipcam Agro USA, Inc.	Chlorothalonil Technical Fungicide	98%
29354	T	Sipcam Agro USA, Inc.	Chlorothalonil Technical AG	99.3%
31763	T	Adama Agricultural Solutions Canada LTD.	Adama chlorothalonil technical	98.6%
24915	M	Bayer CropScience Inc.	Tattoo Manufacturing Use Product	375 g/L
15724	C	Syngenta Canada Inc.	Daconil 2787 Flowable Fungicide	500 g/L
28861	C	Syngenta Canada Inc.	Instrata Fungicide	362 g/L
28900	C	Syngenta Canada Inc.	Bravo ZN Agricultural Fungicide	500 g/L
29225	C	Syngenta Canada Inc.	Bravo 720 Agricultural Fungicide	720 g/L
29355	C	Sipcam Agro USA, Inc.	Echo 720 Agricultural Fungicide	720 g/L
30333	C	Production Agriscience Canada Company	Treoris Fungicide	250 g/L
31537	C	Syngenta Canada Inc.	Bravo Top Fungicide	500 g/L
32030	C	Adama Agricultural Solutions Canada LTD.	Chlorothalonil 720F	720 g/L
32363	C	Gowan Company, LLC	Zing Fungicide	500 g/L
33479	C	sipcam agro USA, Inc.	Echo NP Fungicide	720 g/L
33489	C	Syngenta Canada Inc.	Bravo Top 550 Fungicide	500 g/L
33515	C	Syngenta Canada Inc.	Bravo ZNC Agricultural Fungicide	500 g/L
33516	C	Syngenta Canada Inc.	Bravo Weatherstik Fungicide	720 g/L
33519	C	Sipcam Agro USA, Inc.	Echo 90WSP Agricultural Fungicide	90%
33565	C	UPL NA Inc.	Elixir WSB Fungicide	12.5%
33605	C	Adama Agricultural Solutions Canada LTD.	Equus 82.5 WSP	82.5%

C – Commercial, T – Technical, M – Manufacturing.

Appendix II Use pattern considered in the special review of chlorothalonil

Crop	Maximum Application Rate (kg a.i./ha)	Maximum Number of Applications per year for chlorothalonil	Retreatment Interval (days)
Asparagus	1.7 (SN) 1.2 (DF)	3	14
Highbush Blueberries	3.6	2	7
Lowbush Blueberries	3.6 (SN) 2.5 (DF)	2	42
Carrot	1.6	7	7
Celery, field	2.0	2	3
Celery seedbeds (greenhouse)	1.4	1	N/A
Cherry (sweet and sour)	4.5	2 (spring) + 1 (post-harvest)	10
Chickpeas	2.0 (1 st) 1.5 (2 nd)	2	10
Cole crops: Broccoli, Brussels sprouts, cauliflower	2.4	1	N/A
Cabbage	2.4	2	7
Conifers - outdoor (for example, cedar, Douglas- fir, cypresses, fir, junipers, pine, spruce); including Christmas trees	4.8	2	7
Conifer nursery beds (greenhouse)	1.2	1	N/A
Corn, sweet	1.6	2	10
Cranberry	5.8	1	N/A
Cucurbit vegetables (Cantaloupe, muskmelon, honeydew, squash, pumpkin, watermelon, cucumber)	2.4	2	7
Evening Primrose	1.2	2	14
Ginseng	2.4	2 + 1 (fall)	7
Hazelnut	3.4	3	20
Lentils	2.0	2	10
Mushroom houses	12.7	1	N/A
Onion (dry bulb)	2.4	2	7
Onion (green bunching)	2.4	2	7
Greenhouse ornamentals other than roses (not grown for cut flowers)	1.25	1	N/A
Greenhouse roses (not grown for cut flowers)	0.94	1	N/A
Outdoor ornamentals (not grown for cut flowers) except roses and <i>pachysandra</i>	2.5	2	7

Crop	Maximum Application Rate (kg a.i./ha)	Maximum Number of Applications per year for chlorothalonil	Retreatment Interval (days)
Outdoor ornamentals (cut flowers except roses)	2.5	1	N/A
Outdoor roses (not grown for cut flowers)	1.9	2	7
Outdoor pachysandra	5.0	1	N/A
Parsnip	1.4	7	7
Pea, dry	1.5	2	10
Peach and nectarine	4.5	2 (spring) + 1 (dormant)	10
Potato (seed)	1.2	3	7
Potato (table)	1.2	3	7
Strawberry	1.8	2 (spring) + 1 (post-harvest)	10
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)
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)
Turf (snow mould)	12.0	1	N/A
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)
Wheat	1.3	2	10

Appendix III Dietary exposure assessments

Table 1 Acute and chronic (non-cancer) dietary exposure assessments

Population Subgroup	Refined							
	Acute Dietary (95 th Percentile) ¹				Chronic (Non-Cancer) Dietary ²			
	Food Only		Food + Drinking Water		Food Only		Food + Drinking Water	
	Exposure (mg/kg/day)	% ARfD	Exposure (mg/kg/day)	% ARfD	Exposure (mg/kg/day)	% ADI	Exposure (mg/kg/day)	% ADI
General Population	0.019756	3.41	0.294681	50.81	0.001511	10.1	0.110210	734.7
All Infants <1 year old	0.022498	3.88	0.983359	169.54	0.001758	11.7	0.407797	2718.6
Children 1-2 years old	0.045642	7.87	0.439433	75.76	0.006229	41.5	0.155720	1,038.1
Children 3-5 years old	0.039672	6.84	0.343104	59.16	0.003764	25.1	0.125404	836.0
Children 6-12 years old	0.024972	4.31	0.264339	45.58	0.002257	15.0	0.092702	618.0
Youth 13-19 years old	0.016637	2.87	0.245723	42.37	0.001283	8.6	0.077912	519.4
Adults 20-49 years old	0.016596	2.86	0.287288	49.53	0.001192	7.9	0.109186	727.9
Adults 50+ years old	0.014570	2.51	0.250588	43.20	0.001044	7.0	0.106073	707.2
Females 13-49 years old	0.016255	2.80	0.288729	49.78	0.001166	7.8	0.107332	715.5

¹ Acute Reference Dose (ARfD) of 0.58 mg/kg bw/day applies to the general population and all population subgroups (Canada, 2018).

² Acceptable Daily Intake (ADI) of 0.015 mg/kg bw/day applies to the general population and all population subgroups (Canada, 2018).

Bolded cells indicated unacceptable risk.

Table 2 Chronic (cancer) dietary exposure assessments

Population Subgroup	Refined			
	Chronic (Cancer) Dietary ¹			
	Food Only		Food + Drinking Water	
	Exposure (mg/kg/day)	Lifetime Risk	Exposure (mg/kg/day)	Lifetime Risk
General Population	0.000651	4.98×10^{-6}	0.109350	8.38×10^{-4}

¹ q1* of 7.66×10^{-3} (mg/kg bw/day)⁻¹ applies to the general population (Canada, 2018).

Bolded cells indicate unacceptable risk.

Table 3 Refined level 1 estimated environmental concentrations (EECs) in potential sources of drinking water for the combined residues of chlorothalonil and 15 transformation products

Crop And Annual Application Rate	Active Ingredient (RD in water)	Groundwater ($\mu\text{g a.i./L}$)	
		Acute ¹	Chronic ²
2 applications of 9.5 kg a.i./ha + 1 application of 12 kg a.i./ha ³	chlorothalonil and 15 of its transformation products: R182281, R611965, R471811, SYN507900, SYN546671, R613636, R613801, R613841, PD1, PD2, PD3, PD4, PD5, Polar 1, I.	5380	5380

¹ 90th percentile of daily concentrations.

² 90th percentile of 365-day moving average concentrations.

³ Modelled using the turf use pattern, which covers the rates for all other assessed crops.

Table 4 Comparison of dietary exposure assessments (DEAs) (current vs previous)

		DEA (PRVD2011-14 and RVD2018-11)	DEA in 2021
Residue Definition	Plant	Chlorothalonil + SDS-3701	Chlorothalonil + SDS-3701
	Livestock	SDS-3701	SDS-3701
	Drinking water	Chlorothalonil	Chlorothalonil and 15 of its transformation products: R182281, R611965, R471811, SYN507900, SYN546671, R613636, R613801, R613841, PD1, PD2, PD3, PD4, PD5, Polar 1, I.
Reference values	ADI	0.015 mg/kg bw/day	
	ARfD	General population: 0.58 mg/kg bw/day	
	Cancer	$q_1^* = 7.66 \times 10^{-3} (\text{mg/kg bw/day})^{-1}$	
DEA (Chronic)	Food+Water	69.9% ADI, highest for Children 1-2 yrs	2719% ADI, highest for All infants
DEA (Acute)	Food+Water	27.3% ARfD, highest for Children 1-2 yrs	170% ARfD, highest for All infants
DEA (Cancer)	Food+Water	1.57×10^{-6}	8.38×10^{-4}

Appendix IV Water modelling and water monitoring reports

1.0 Water modelling

Table 1 Major fate inputs for the modelling

Fate Parameter	Drinking Water Value (chlorothalonil + 15 transformation products) ¹	Ecological Value (chlorothalonil)	Comment
K _d	-	15 L/kg	20 th percentile of 16 values
K _{oc}	1.2 L/kg	-	20 th percentile of 5 values
Water half-life	49.1 days at 20°C	6.87 days at 20°C	80 th percentile of 6 values, aerobic aquatic whole systems
Sediment half-life	61.7 days at 20°C	5.67 days at 20°C ³	Single study, anaerobic soil
Photolysis half-life	25.8 days at 35° latitude	18 days at 35° latitude	80 th percentile of 4 values
Hydrolysis	Stable	Stable	Stable to hydrolysis at ambient temperatures
Soil half-life	227 days at 20°C	37 days at 20°C ²	90% upper confidence bound on the mean of 18 values

¹ The residue definition for drinking water modelling included chlorothalonil and 15 transformation products: R182281 (also known as SDS-3701), R611965, R471811, SYN507900, SYN546671, R613636, R613801, R613841, PD1, PD2, PD3, PD4, PD5, Polar 1, and I.

² Post modelling errors were corrected in the soil fate data that resulted in a new 90% upper confidence bound on the mean of 18 values of 47 days. The change would not improve the risk assessment, therefore, water modelling was not updated.

³ Post modelling errors were corrected in the aquatic fate data that resulted in a removal of two endpoints from the data set.

Table 2 Groundwater model input parameters for parent-daughter refinement

Parameter	Chlorothalonil	Combined daughter
Molecular weight (g/mole)	265.9	265.9
Vapour pressure (mm Hg) at 20°C	7.65E-5	7.65E-5
Solubility (mg/L) in water at pH 7	0.81	0.81
Henry's law constant (unitless)	1.35E-3	1.35E-3
Hydrolysis at pH 7	Stable	Stable ¹
Aerobic soil half-life (day) at 20°C*	0.32-81.3 ²	46.4-2367 ³
Transformation fraction in soil*	NA	0.178-1.0 ⁴
K _{oc} (L/kg)	1290	1.2
Vapour phase diffusion coefficient (cm ² /day)	4520	4520
Heat of Henry (Joule/mole)	50000	50000

¹ assumed stable

² the range of half-lives for chlorothalonil for all 17 soils that curve fits could be achieved

³ the range of half-lives for the combined daughter for all 17 soils that curve fits could be achieved

⁴ the range of transformation fractions from chlorothalonil to the combined daughter for all 17 soils that curve fits could be achieved

* aerobic soil half-lives and fractions used are soil dependent

Table 3 Estimated environmental concentrations (EECs) ($\mu\text{g a.i./L}$) of chlorothalonil for the ecological risk assessment

Use	Region	Water Depth	Water column				Pore water	
			Peak	24-h	96-h	21-d	Peak	21-d
Blueberry, highbush	BC	80 cm	15	14	12	6.6	1.5	1.4
		15 cm	63	52	36	12	-	-
Blueberries, lowbush	Atlantic	80 cm	68	57	42	22	5.9	5.4
		15 cm	334	195	94	36	-	-
Carrots	Prairie	80 cm	44	39	29	11	2.6	1.9
		15 cm	221	147	63	15	-	-
Cherries	BC	80 cm	4.0	3.8	3.2	1.3	0.21	0.16
		15 cm	21	17	9.4	2.1	-	-
Peaches	ON	80 cm	39	36	28	17	5.0	4.8
		15 cm	200	137	79	42	-	-
	QC	80 cm	31	28	23	10	2.6	2.2
		15 cm	149	108	70	19	-	-
Conifers, nursery bed	Atlantic	80 cm	7.2	6.3	4.6	1.6	0.28	0.19
		15 cm	38	25	13	3.5	-	-
Conifers, outdoor	Atlantic	80 cm	63	57	41	20	4.4	4.3
		15 cm	335	240	108	35	-	-
Potatoes	Atlantic	80 cm	44	38	30	16	4.2	3.5
		15 cm	221	133	61	25	-	-
Tomatoes, fresh	ON	80 cm	45	40	31	12	2.8	1.8
		15 cm	211	142	83	19	-	-
	QC	80 cm	52	47	40	20	5.5	4.8
		15 cm	275	197	107	39	-	-
Tomatoes, processing	ON	80 cm	87	76	58	22	4.3	3.1
		15 cm	426	295	139	37	-	-
	QC	80 cm	108	101	78	34	9.1	8.4
		15 cm	480	393	197	66	-	-
Wheat	SK	80 cm	16	14	9.8	3.6	0.81	0.58
		15 cm	79	49	20	4.6	-	-
	MB	80 cm	14	13	9.0	3.6	0.73	0.50
		15 cm	76	51	21	4.4	-	-
Turf	BCO	80 cm	8.7	8.2	6.9	4.7	1.1	1.0
		15 cm	43	36	29	12	-	-
	BCV	80 cm	230	213	173	89	22	24
		15 cm	1170	896	509	138	-	-
	ABS	80 cm	145	131	102	38	7.0	5.2
		15 cm	644	454	231	51	-	-
	ABN	80 cm	62	57	46	20	3.4	2.7
		15 cm	330	251	130	29	-	-
	SK	80 cm	101	89	64	27	5.0	3.4
		15 cm	530	334	131	32	-	-

Use	Region	Water Depth	Water column				Pore water	
			Peak	24-h	96-h	21-d	Peak	21-d
	MB	80 cm	84	74	53	20	4.5	3.6
		15 cm	448	281	125	32	-	-
	ONE	80 cm	89	81	64	32	6.2	6.0
		15 cm	471	350	185	48	-	-
	ONW	80 cm	102	92	78	38	6.7	6.1
		15 cm	517	385	177	52	-	-
	QC	80 cm	139	135	121	59	16	16
		15 cm	719	581	307	134	-	-

2.0 Cranberry flood water modelling

Summary

Foliar use of chlorothalonil in cranberry fields was assessed by modelling estimated concentrations in receiving waters following the release of treated cranberry flood water. A range of chlorothalonil concentrations in cranberry tailwater were estimated with a simple risk assessment cranberry model internally developed by the PMRA, V.3.0. For this purpose, it was assumed that 5 or 10 fields can be flooded with the same water, and that 25% or 50% of chlorothalonil residues can transfer from soil to floodwater; yielding a total of 4 scenarios. The modelled RQs, based on a rainbow trout $LC_{50}/10$ of 0.00044 mg a.i./L ranged between 4.3 and 70 in receiving waters following immediate release of floodwaters from fields treated at the maximum allowable seasonal rate of 5800 g a.i./ha (Table 6). Based on the modelling results, chlorothalonil application on cranberries poses a risk to aquatic organisms and requires mitigation.

Mitigating measures could include a lower application rate, or the retention of water prior to release after the last application.

Table 4 Variable input parameters tested to estimate EECs of chlorothalonil in cranberry field floodwater.

Parameter	High value	Low value
Number of fields successively flooded	10 fields	5 fields
Estimate of residue transferred from soil to water	50%	25%

Table 5 Non-variable model input parameters

Parameter	Value
Rate (currently only one labeled rate) and number of applications	5800 g a.i./ha × 1
Soil half-life	46-d ¹
Aquatic half-life	5.3-d ²
Aquatic toxicity endpoint (chronic/acute)	Rainbow trout $LC_{50}/10 = 0.00044$ mg a.i./L
Q ₁₀	2

Parameter	Value
City	Vancouver
First treatment date (same date for all fields)	2 August
First harvest date	21 September
Flood water depth	0.6 m
Dilution factor by the water body receiving the tail water	10 ×

¹ Cranberry water modelling was completed with an updated soil half-life value that included a rounding error. This error is not expected to affect the resulting EECs. The error was corrected in Table 1

² Cranberry water modelling was completed with the updated aquatic half-life (see Table 1 for details)

The scenario results are summarised in Table 6. EECs and RQs are presented for water assuming two weeks retention time.

Table 6 Scenarios conducted with acute chlorothalonil endpoint ($LC_{50}/10=0.0044$ mg a.i./L)

No	Scenario short description	Rate (g/ha)	N app	interval (d)	N fields	soil to water (%)	Chlorothalonil DT ₅₀		Floodwater EEC (ug/L)	Floodwater RQ	Receiving water EEC (ug/L)	Receiving water RQ
							soil	water				
1	10 fields; 50% transfer from water to soil	5800	1	NA	10	50%	46	5.3	310.2756	705.2	31.0276	70.5
2	10 fields; 25% transfer from water to soil	5800	1	NA	10	25%	46	5.3	155.1378	352.6	15.5138	35.3
3	5 fields; 50% transfer from water to soil	5800	1	NA	5	50%	46	5.3	37.9481	86.2	3.7948	8.6
4	5 fields; 25% transfer from water to soil	5800	1	NA	5	25%	46	5.3	18.9740	43.1	1.8974	4.3

*The representative half-lives at 20°C were adjusted daily to Vancouver mean temperatures, ranging between 4.1°C and 18°C. The beginning of wet-harvest (flooding) was set to 21 September, with an interval of 5 days between fields. Treatment date was set 50 days prior to harvest, as per current label requirements. The floodwater depth was modelled at 0.6 m. The reported EECs and RQs are calculated two weeks after the beginning of the last harvest. Bolded cells are changes from the base (first) scenario listed.

3.0 Monitoring

Table 7 Summary of chlorothalonil detections in Canadian groundwater (2005-2019) available for consideration in the dietary risk assessment

Location/ Province	Year of Sampling	# Samples	# Detections	% Detection	Maximum Concentration (µg/L) ¹	Minimum Concentration (µg/L)	Limit of detection (µg/L)
Sampling between 2005-2019							
BC	2005-2010	33	14	42.42	0.000061	ND	0.00001-1
MB	2009	5	0	0	ND	ND	0.005
QC	2005-2019	792	2	0.27	0.19	ND	0.01 – 0.06
PEI	2005-2012	819	9	1.09	0.0008	ND	0.00002- 0.02
NS	2005-2011	174	1	0.57	0.09	ND	0.02-1
NB	2007	44	2	4.54	0.14	ND	0.025-0.05
Total	2005-2019	1933	28	1.44	0.19	ND	
Sampling between 2010-2018							
BC	2010	18	0	0	ND	ND	
QC	2010-2018	478	0	0	ND	ND	0.01-0.05
PEI	2010-2012	111	1	0.90	0.00003	ND	0.00002
NS	2011	5	0	0	ND	ND	1
AB	2010-2017	66	0	0	ND	ND	0.005
Total	2010-2018	686	1	0.14	0.00003	ND	

ND: No detection

¹ Only parent chlorothalonil is measured in monitoring, therefore, these values cannot be compared with the EECs determined through modelling

Table 8 Summary of chlorothalonil detections in Canadian surface water (2010-2019) available for consideration in the aquatic risk assessment

Location/ Province	Year of Sampling	# Samples	# Detections	% Detection	Maximum Concentration (µg/L)	Minimum Concentration (µg/L)	Limit of detection (µg/L)
BC	2010-2014	99	14	14.14	0.00132	0.000123	0.0000012-0.0001
AB	2010-2019	1566	2	0.13	0.018	0.009	0.005-0.025
MB	2010-2018	876	22	2.51	0.729	0.077	0.05-0.5
QC	2010-2018	2773	34	1.2	82	0.01	0.04-0.32
NB	2013-2015	43	3	6.9	0.81	0.23	0.05-0.06
PEI	2010-2018	298	0	0.56	ND	ND	0.02-0.05
	Incident reports 2011 - 2017	29	19	65.5	150.8	ND	0.01 – 0.06
NS	2013-2015	45	0	0	ND	ND	0.05-0.06
NFL	2013	1	0	0	ND	ND	0.05
Total	2010-2019	5701	75	1.31	82	ND	-

ND: No detection

Appendix V Environmental fate data

Table 1 Chlorothalonil fate studies used for the special review

Study	Details	DT50* (d)	Tr (d)	DT90 (d)	Kinetics	Study PMRA#
Hydrolysis	pH 9, 25°C	17.0	-	56.5	SFO	1340587
	pH 9, 20°C	9.53	-	31.6	SFO	2918264
	pH 9, 20°C	11.44	-	37.99	SFO	2918265
	pH 9, 20°C	50.62	-	168.1	SFO	1219851
Hydrolysis surrogate [Aquatic photolysis Natural water dark control]	pH 8.1, 25°C	229	-	762	SFO	2918269
Aquatic Photolysis	pH 7, corrected for dark control	0.5816	-	1.911	SFO	2918267
	pH 6.3, natural water	0.1892	0.3221	1.135	DFOP	2918268
	pH 8.1, natural water	0.1437	-	0.4773	SFO	2918269
Soil Photolysis	Corrected for dark control 28.8 d pH 7	8.74	14.4	47.7	IORE	2918266
Aerobic soil	Perry loamy sand pH 5.1 1 mg a.i./kg	2.5	16.9	56.1	IORE	1166165
	Perry loamy sand pH 5.1 10 mg a.i./kg	15.41	35.16	97.76	IORE	1166165
	Macomb silt clay loam pH 5.1 39 mg a.i./kg	45.9	127	335	DFOP	1180935
	Iowa peat pH 7 39 mg a.i./kg	12.3	23	76.5	IORE	1180935
	Tulia sandy loam pH 8 39 mg a.i./kg	10.3	21.4	71.1	IORE	1180935
	Painesville sandy loam pH 6 3.9 mg a.i./kg	7.15	16.4	54.5	IORE	1180935
	Marsillargues silty clay loam pH 7.8 1.29 mg a.i./kg	3.96	6.57	21.8	IORE	2548555
	18 Acres sandy clay loam pH 7.8 1.29 mg a.i./kg	4.67	-	15.5	SFO	2548555
	Gartenacker loam pH 7 1.29 mg a.i./kg	1.39	2.09	6.93	IORE	2548555
	White Swan loam/silt loam pH 5.9	3.4	9.9	32.9	IORE	2548555

Study	Details	DT50* (d)	Tr (d)	DT90 (d)	Kinetics	Study PMRA#
	1.29 mg a.i./kg					
	Speyer 2.2 pH 6.1 2.5 mg a.i./kg	9.59	20.2	67.3	IORE	2918270
	Evesham 3 clay loam pH 7.7 2.5 mg a.i./kg	1.98	4.31	14.3	IORE	2918271
	Malham silt loam pH 6.2 2.5 mg a.i./kg	3.15	-	10.5	SFO	2918271
	Wick sandy loam pH 5.1 2.5 mg a.i./kg	19.6	-	66.2	SFO	2918271
	Wick sandy loam (10°C) pH 5.1 2.5 mg a.i./kg	48.5	-	161	SFO	2918271
	18 Acres loam pH 6 0.1 mg a.i./kg	0.039	0.336	1.12	IORE	1500647 2918273
	18 Acres loam pH 6 1.0 mg a.i./kg	1.03	1.46	4.84	IORE	1500647 2918273
	18 Acres loam pH 6 10 mg a.i./kg	9.45	-	31.4	SFO	1500647 2918273
	18 Acres loam pH 6 25 mg a.i./kg	13.4	246	817	IORE	1500647 2918273
	18 Acres loam pH 6 1.0 mg a.i./kg	0.85	1.53	5.07	SFO	1500648 2918274
	Chamberlain's Farm loamy sand pH 7.5 1.0 mg a.i./kg	0.274	0.453	1.51	IORE	1500648 2918274
	ERTC sandy loam pH 6.7 1.0 mg a.i./kg	1.2	1.67	5.56	IORE	1500648 2918274
	Munster loamy sand pH 5.6 1.0 mg a.i./kg	1.63	2.36	7.84	IORE	1500648 2918274
Aerobic soil	90% upper confidence bound on the mean	47.0	-	-	-	-
Anaerobic soil	Anaerobic conditions were not confirmed in either of the studies submitted. Aquatic anaerobic studies will be used.					
Aerobic Aquatic	Emperor Lake Water pH 6.55 Sediment sandy loam pH 5.6 Whole system	2.47	-	8.22	SFO	1500651
	Water only	2.47	-	8.21	SFO	1500651
	Bury Pond Water pH 7.2 Sediment sandy clay	0.826	-	2.75	SFO	1500651

Study	Details	DT50* (d)	Tr (d)	DT90 (d)	Kinetics	Study PMRA#
	loam pH 7.9 Whole system					
	Water only	0.83	-	2.75	SFO	1500651
	Swiss Lake Water pH 7.0 Sediment sandy loam pH 5.3 Whole system	6.87	-	22.8	SFO	2737552
	Water only	7.55	-	25.1	SFO	
	Sediment only	0.9	-	3.0	SFO	
	Calwich Abbey Water pH 7.75 Sediment silt loam pH 7.4 Whole system	3.25	4.31	13.25	DFOP	2737552
	Water only	3.6	-	12	SFO	
Aerobic Aquatic	Whole system 80 th percentile	5.33	-	-	-	-
	Water only 80 th percentile	3.6	-	-	-	-
Anaerobic aquatic	Swiss lake Water pH 6.9 Sediment pH 5.3 Whole system	3.08	5.67	16.2	DFOP	2737552
-	Water only	4.59	-	15.3	SFO	2737552

Table 2 Transformation products of chlorothalonil found in acceptable fate studies and identification of ecotoxicity studies, if available

Compound ¹ (alternative names)	Study Type (hydrolysis, aerobic soil, etc) Reference standard (Y/N)	Geomean days from normalized data (n=number of studies)	Formation fraction in soil (transformed from) ²
IDENTIFIED (some incomplete)			
R182281 (SDS 3701)	Hydrolysis (Y)	Increasing with time	n/a
	Phototransformation (Y)	Increasing with time	n/a
	Aerobic soil (Y)	143.9 (n=13)*	0.186 (parent)
	Aerobic aquatic (Y)	265 (n=4)*	n/c
	Anaerobic aquatic (Y)	Could not calculate	n/c
R417888 (VIS01)	Hydrolysis (N)	-	-
	Phototransformation (Y)	None detected	n/a
	Aerobic soil (Y)	332 (n=14)*	0.106 (parent)
	Aerobic aquatic (Y)	Increasing with time	n/c
	Anaerobic aquatic (N)	-	-
R417888/Na	Hydrolysis (N)	-	-
	Phototransformation (N)	-	-
	Aerobic soil (Y)	None detected	n/a
	Aerobic aquatic (N)	-	-
	Anaerobic aquatic (N)	-	-

Compound ¹ (alternative names)	Study Type (hydrolysis, aerobic soil, etc) Reference standard (Y/N)	Geomean days from normalized data (n=number of studies)	Formation fraction in soil (transformed from) ²
R418503	Hydrolysis (N)	-	-
	Phototransformation (Y)	-	-
	Aerobic soil (Y)	30.8 (n=7)*	0.042 (parent)
	Aerobic aquatic (N)	-	-
	Anaerobic aquatic (N)	-	-
R419492	Hydrolysis (N)	-	-
	Phototransformation (N)	-	-
	Aerobic soil (Y)	377 (n=7)*	0.049 (parent) 1.0 (R418503) 0.451 (R417888)
	Aerobic aquatic (N)	-	-
	Anaerobic aquatic (N)	-	-
R471811	Hydrolysis (N)	-	-
	Phototransformation (N)	-	-
	Aerobic soil (Y)	582 (n=8)*	0.022 (parent) 0.755 (R417888)
	Aerobic aquatic (N)	-	-
	Anaerobic aquatic (N)	-	-
R611553	Hydrolysis (N)	-	-
	Phototransformation (N)	-	-
	Aerobic soil (Y)	None detected	n/c
	Aerobic aquatic (Y)	Could not calculate	-
	Anaerobic aquatic (N)	-	-
R611965 (SDS 46851)	Hydrolysis (N)	-	-
	Phototransformation (Y)	None detected	n/c
	Aerobic soil (Y)	381 (n=10)*	0.062 (parent) 0.946 (R611965)
	Aerobic aquatic (N)	-	-
	Anaerobic aquatic (N)	-	-
R611966 (SDS 47523)	Hydrolysis (N)	-	-
	Phototransformation (Y)	None detected	n/c
	Aerobic soil (Y)	75.2 (n=4)*	0.079 (parent)
	Aerobic aquatic (Y)	Could not calculate	n/c
	Anaerobic aquatic (N)	-	-
R611967 (SDS 47524)	Hydrolysis (N)	-	-
	Phototransformation (Y)	None detected	n/c
	Aerobic soil (Y)	26.5 (n=2)*	0.150 (parent)
	Aerobic aquatic (N)	-	-
	Anaerobic aquatic (N)	-	-
R611968 (SDS 47525)	Hydrolysis (N)	-	-
	Phototransformation (Y)	None detected	n/c
	Aerobic soil (Y)	55.1 (n=1)*	0.067 (parent)
	Aerobic aquatic (Y)	Could not calculate	n/c
	Anaerobic aquatic (N)	-	-
R613636 (SDS 19221)	Hydrolysis (Y)	220 (n=1)	n/c
	Phototransformation (Y)	Increasing with time	n/c
	Aerobic soil (Y)	33.0 (n=6)*	0.091 (parent)
	Aerobic aquatic (Y)	Could not calculate	n/c
	Anaerobic aquatic (Y)	Could not calculate	n/c

Compound ¹ (alternative names)	Study Type (hydrolysis, aerobic soil, etc) Reference standard (Y/N)	Geomean days from normalized data (n=number of studies)	Formation fraction in soil (transformed from) ²
R613801	Hydrolysis (N)	-	-
	Phototransformation (Y)	Could not calculate	n/c
	Aerobic soil (N)	-	-
	Aerobic aquatic (Y)	15.5 (n=3)*	0.223 (parent)
	Anaerobic aquatic (Y)	Could not calculate	n/c
R613841 (SDS 67042)	Hydrolysis (N)	-	-
	Phototransformation (N)	-	-
	Aerobic soil (Y)	None detected	n/c
	Aerobic aquatic (Y)	47.0 (n=3)*	0.245 (parent)
	Anaerobic aquatic (Y)	36.4 (n=1)	n/c
R613842	Hydrolysis (N)	-	-
	Phototransformation (N)	-	-
	Aerobic soil (N)	-	-
	Aerobic aquatic (Y)	34.7 (n=1)	n/c
	Anaerobic aquatic (Y)	Can not calculate	n/c
SYN507900 (SDS 66882) (monomide of chlorothalonil)	Hydrolysis (N)	-	-
	Phototransformation (N)	-	-
	Aerobic soil (Y)	Could not calculate	n/c
	Aerobic aquatic (Y)	180 (n=3)	n/c
	Anaerobic aquatic (N)	-	-
SYN546671 ¹ (R613803)	Hydrolysis (N)	-	-
	Phototransformation (N)	-	-
	Aerobic soil (N)	-	-
	Aerobic aquatic (N)	160 (n=2)	n/c
	Anaerobic aquatic (N)	-	-
SYN546934	Hydrolysis (N)	-	-
	Phototransformation (Y)	Could not calculate	n/c
	Aerobic soil (N)	-	-
	Aerobic aquatic (N)	-	-
	Anaerobic aquatic (N)	-	-
SYN564872	Hydrolysis (Y)	Increasing with time	n/c
	Phototransformation (N)	-	-
	Aerobic soil (Y)	Increasing with time	n/c
	Aerobic aquatic (Y)	Could not calculate	n/c
	Anaerobic aquatic (N)	-	-
SYN546677	Hydrolysis (N)	-	-
	Phototransformation (N)	-	-
	Aerobic soil (N)	-	-
	Anaerobic soil (Y)	None detected	n/a
	Aerobic aquatic (N)	-	-
SYN546673	Hydrolysis (N)	-	-
	Phototransformation (N)	-	-
	Aerobic soil (N)	-	-
	Anaerobic soil (Y)	None detected	n/a
	Aerobic aquatic (N)	-	-
PD1 (incomplete structure)	Hydrolysis (N)	-	-
	Phototransformation (Y)	Increasing with time	n/c
	Aerobic soil (N)	-	-
	Aerobic aquatic (N)	-	-
	Anaerobic aquatic (N)	-	-

Compound ¹ (alternative names)	Study Type (hydrolysis, aerobic soil, etc) Reference standard (Y/N)	Geomean days from normalized data (n=number of studies)	Formation fraction in soil (transformed from) ²
PD2 (incomplete structure)	Hydrolysis (N)	-	-
	Phototransformation (Y)	Could not calculate	n/c
	Aerobic soil (N)	-	-
	Aerobic aquatic (N)	-	-
PD3 (incomplete structure)	Hydrolysis (N)	-	-
	Phototransformation (Y)	Increasing with time	n/c
	Aerobic soil (N)	-	-
	Aerobic aquatic (N)	-	-
PD4 (incomplete structure)	Hydrolysis (N)	-	-
	Phototransformation (Y)	222.8 (n=1)	n/c
	Aerobic soil (N)	-	-
	Aerobic aquatic (N)	-	-
PD5 (incomplete structure)	Hydrolysis (N)	-	-
	Phototransformation (Y)	16.5 (n=1)	n/c
	Aerobic soil (N)	-	-
	Aerobic aquatic (N)	-	-
CTL-7	Hydrolysis (N)	-	-
	Phototransformation (Y)	None detected	-
	Aerobic soil (N)	-	-
	Aerobic aquatic (N)	-	-
CTL-8	Hydrolysis (N)	-	-
	Phototransformation (Y)	Could not calculate	n/c
	Aerobic soil (N)	-	-
	Aerobic aquatic (N)	-	-
CTL-9	Hydrolysis (N)	-	-
	Phototransformation (Y)	Could not calculate	n/c
	Aerobic soil (N)	-	-
	Aerobic aquatic (N)	-	-
CTL-10	Hydrolysis (N)	-	-
	Phototransformation (Y)	None detected	-
	Aerobic soil (N)	-	-
	Aerobic aquatic (N)	-	-
SDS 3113	Hydrolysis (Y)	Increasing with time	n/c
	Phototransformation (N)	-	-
	Aerobic soil (N)	-	-
	Aerobic aquatic (N)	-	-
SDS 66382	Hydrolysis (N)	-	-
	Phototransformation (N)	-	-
	Aerobic soil (Y)	None detected	n/c
	Aerobic aquatic (N)	-	-
	Anaerobic aquatic (N)	-	-

Compound ¹ (alternative names)	Study Type (hydrolysis, aerobic soil, etc) Reference standard (Y/N)	Geomean days from normalized data (n=number of studies)	Formation fraction in soil (transformed from) ²
SDS 66432	Hydrolysis (N)	-	-
	Phototransformation (N)	-	-
	Aerobic soil (Y)	None detected	n/c
	Aerobic aquatic (N)	-	-
	Anaerobic aquatic (N)	-	-
Pentachlorobenzonitrile	Hydrolysis (N)	-	-
	Phototransformation (Y)	None detected	n/c
	Aerobic soil (N)	-	-
	Aerobic aquatic (N)	-	-
	Anaerobic aquatic (N)	-	-
4-methoxy-2,5,6-trichlorisophthalonitrile	Hydrolysis (N)	-	-
	Phototransformation (N)	-	-
	Aerobic soil (Y)	None detected	n/c
	Aerobic aquatic (N)	-	-
	Anaerobic aquatic (N)	-	-
MM162	Hydrolysis (N)	-	-
	Phototransformation (Y)	Trace amounts, no data provided	n/c
	Aerobic soil (N)	-	-
	Aerobic aquatic (N)	-	-
	Anaerobic aquatic (N)	-	-
MM196	Hydrolysis (N)	-	-
	Phototransformation (Y)	None detected	n/c
	Aerobic soil (N)	-	-
	Aerobic aquatic (N)	-	-
	Anaerobic aquatic (N)	-	-
I (N-oxide of chlorothalonil)	Hydrolysis (N)	-	-
	Phototransformation (Y)	Could not calculate	n/c
	Aerobic soil (N)	-	-
	Aerobic aquatic (N)	-	-
	Anaerobic aquatic (N)	-	-
UNKNOWN			
PI	Hydrolysis	Increasing with time	-
PII	Hydrolysis	Increasing with time	-
A	Photolysis	Could not calculate	-
UN A	Aerobic aquatic	58.11 (n=1)	-
A (expected to be different compounds)	Photolysis	Could not calculate	-
	Aerobic aquatic	Could not calculate	-
B (expected to be different compounds)	Photolysis	Could not calculate	-
	Aerobic aquatic	Could not calculate	-
C (expected to be different compounds)	Photolysis	Could not calculate	-
	Aerobic aquatic	Could not calculate	-
D (expected to be different compounds)	Photolysis	Could not calculate	-
	Aerobic aquatic	Could not calculate	-
E (expected to be different compounds)	Photolysis	Could not calculate	-
	Aerobic aquatic	Could not calculate	-
F	Photolysis	Could not calculate	-
G (expected to be different compounds)	Photolysis	Could not calculate	-
	Aerobic aquatic	Could not calculate	-
H (expected to be different compounds)	Photolysis	Could not calculate	-
	Aerobic aquatic	Could not calculate	-
I (expected to be	Photolysis	Increasing with time	-

Compound¹ (alternative names)	Study Type (hydrolysis, aerobic soil, etc) Reference standard (Y/N)	Geomean days from normalized data (n=number of studies)	Formation fraction in soil (transformed from)²
different compounds)	Aerobic aquatic	Could not calculate	-
J	Photolysis	Could not calculate	-
K	Photolysis	Increasing with time	-
L	Photolysis	Increasing with time	-
Unk 3	Aerobic soil	Increasing with time	-
Unk 5	Aerobic soil	Increasing with time	-
Water soluble non- ether extraction	Aerobic soil	Increasing with time	-
UN1	Aerobic soil	Increasing with time	-
UN2	Aerobic soil	Increasing with time	-
UN5	Aerobic soil	Increasing with time	-
UN6	Aerobic soil	34.45 (n=2)	n/c
UK38	Aerobic aquatic	Could not calculate	-
	Anaerobic aquatic	Could not calculate	-
UK40	Aerobic aquatic	Increasing with time	-
	Anaerobic aquatic	Increasing with time	-
UK44	Aerobic aquatic	Could not calculate	-
	Anaerobic aquatic	Increasing with time	-
PI	Aerobic aquatic	Could not calculate	-
P2	Aerobic aquatic	Increasing with time	-
P3	Aerobic aquatic	Increasing with time	-
P4	Aerobic aquatic	Could not calculate	-
C1	Aerobic aquatic	Could not calculate	-
C2	Aerobic aquatic	Could not calculate	-
C3	Aerobic aquatic	Could not calculate	-
C4	Aerobic aquatic	Could not calculate	-
C5	Aerobic aquatic	Could not calculate	-
C6	Aerobic aquatic	Could not calculate	-
C7	Aerobic aquatic	Could not calculate	-
UK 21.1	Aerobic water	Could not calculate	-
UK 23.1	Aerobic water	Could not calculate	-
UK 25.6	Aerobic water	Could not calculate	-
UK 31.1	Aerobic water	Could not calculate	-
M2	Lysimeter	Could not calculate	-
M6	Lysimeter	Could not calculate	-
M7	Lysimeter	Could not calculate	-
M10	Lysimeter	Could not calculate	-
M15	Lysimeter	Could not calculate	-
M16	Lysimeter	Could not calculate	-
M17	Lysimeter	Could not calculate	-
M18	Lysimeter	Could not calculate	-
M19	Lysimeter	Could not calculate	-
M20	Lysimeter	Could not calculate	-
M21	Lysimeter	Could not calculate	-
M22	Lysimeter	Could not calculate	-
M23	Lysimeter	Could not calculate	-
M24	Lysimeter	Could not calculate	-
Polar (assumed not the same between studies but lumped together to make the table smaller)	Hydrolysis	Could not calculate	-
	Phototransformation	Could not calculate	-
	Aerobic soil	Could not calculate	-
	Aerobic aquatic	Could not calculate	-

Compound ¹ (alternative names)	Study Type (hydrolysis, aerobic soil, etc) Reference standard (Y/N)	Geomean days from normalized data (n=number of studies)	Formation fraction in soil (transformed from) ²
Others (assumed not the same between studies)	Hydrolysis	Could not calculate	-
	Phototransformation	Could not calculate	-
	Aerobic soil	Could not calculate	-
	Aerobic aquatic	Could not calculate	-
Unidentified (assumed not the same between studies)	Hydrolysis	Could not calculate	-
	Phototransformation	Could not calculate	-
	Aerobic soil	Could not calculate	-
	Aerobic aquatic	Could not calculate	-
Unknowns (assumed not the same between studies)	Hydrolysis	Could not calculate	-
	Phototransformation	Could not calculate	-
	Aerobic soil	Could not calculate	-
	Aerobic aquatic	Could not calculate	-
Minor unknowns (assumed not the same between studies)	Hydrolysis	Could not calculate	-
	Phototransformation	Could not calculate	-
	Aerobic soil	Could not calculate	-
	Aerobic aquatic	Could not calculate	-
Remainder (assumed not the same between studies)	Aerobic soil	Could not calculate	-
	Aerobic aquatic	Could not calculate	-
Baseline (assumed not the same between studies)	Aerobic soil	Could not calculate	-
	Aerobic aquatic	Could not calculate	-
Origin (thin layer chromatography)	Aerobic soil	Could not calculate	-
Zone 1	Aerobic soil	Could not calculate	-
Vessel wash	Aerobic aquatic	Could not calculate	-

*As reported in EFSA 2016 (PMRA# 2778799)

¹Transformation product naming and identification is inconsistent between studies. The lack of chemical structures for the identified transformation products does not allow for all cases to be correctly cross referenced. Example is SYN546671 which EFSA identified as a major transformation product in an aerobic aquatic study, but this could not be confirmed. Due to the inconsistencies, this transformation product is included and assumed a major transformation product.

²Arithmetic average of all relevant formation fractions in the report (taken directly from EFSA, 2016 (PMRA# 2778799)). Formation fraction is the maximum amount of a transformation product formed during a study as expressed as a percentage of applied radioactivity.

Appendix VI Ecotoxicity data

Table 1 Chlorothalonil ecotoxicity studies used in the special review

Species	Study PMRA#	Study Type/ Endpoint Type	Comments	Endpoint (mg a.i./L)
Freshwater				
<i>Daphnia magna</i>	1274228 (1500668)	48-h EC50	-	0.056
	1310980	48-h EC50	-	0.059
	1310981	21-d NOEC	-	0.0006
<i>Lampsilis siliquoidea</i> glochidia	3231061	48-h EC50	-	0.04
<i>Lampsilis siliquoidea</i> juvenile	3231061	96-h EC50	-	0.25
<i>Unio elongatulus</i> glochidia	3231062	48-h EC50	Not used by EFSA	0.047
<i>Dreissena polymorpha</i> embryos	3231062	48-h EC50	Not used by EFSA	0.00097
<i>Chironomus riparius</i>	Study not submitted	48-h EC50	Overlying water	0.015
		28-d NOEC	Overlying water	0.04
<i>Chironomus dilutus</i>	Study not submitted	10-d NOEC	Sediment (mg/kg) Pore water	10 0.0788
<i>Hyaella azteca</i>	Study not submitted	10-d NOEC	Sediment (mg/kg) Pore water	7.5 0.096
<i>Paratya australiensis</i>	3231076	7-d LC50	-	0.0109
<i>Astacopsis gouldi</i>	3231076	7-d LC50	-	0.0036
<i>Colubotelson chiltoni</i>	3231076	7-d LC50	-	>0.04
<i>Neoniphargus</i> sp	3231076	7-d LC50	-	>0.04
Rainbow trout <i>Oncorhynchus mykiss</i>	1274396 (1500664)	48-h LC50 96-h LC50	EFSA used the 48-h endpoint	0.0044 0.03
	1310982	96-h LC50		0.017
	3248240	96-h LC50	Analytically verified nominal	0.076
	-	96-h LC50	>9 mg O ₂ /L, static renewal	0.057
	Study not submitted	96-h LC50	-	0.033
	3231082	96-h LC50	Flow-through endpoint only. Same endpoint reported in Davies 1987	0.0171
	1310985	21-d NOEC	-	0.0069
		28-d LC50	Static renewal	0.054
Carp <i>Cyprinus carpio</i>	1310984	96-h LC50	-	0.060

Species	Study PMRA#	Study Type/ Endpoint Type	Comments	Endpoint (mg a.i./L)
<i>Galaxias maculatus</i>	3231082	96-h LC50	Flow-through	0.0163
<i>Galaxias truttaceus</i>	3231082	96-h LC50	Flow-through	0.0189
<i>Galaxias auratus</i>	3231082	96-h LC50	Flow-through	0.0292
Fathead minnow <i>Pimephales promelas</i>	1236946	45-w NOEC	Flow-through	0.003
Fathead minnow <i>Pimephales promelas</i> Fish Short Term Reproduction Assay (FSTRA)	2918311	21-d NOEC	Flow-through, repro endpoint	<0.000078
<i>Xenopus laevis</i> embryo	3231100	96-h LC50	-	0.0229
<i>Xenopus laevis</i> larvae	3231100	96-h LC50	-	0.0082
<i>Xenopus laevis</i> Amphibian Metamorphosis Assay (AMA)	2298718	21-d NOEC	-	0.00061
<i>Spea multiplicata</i> larvae	3231100	96-h LC50	-	0.0107
Marine				
<i>Scenedesmus subspicatus</i>	1310991	96-h EbC50	-	0.45
<i>Navicula pelliculosa</i>	1500676	120-h EbC50 72-h EbC50	-	0.0088 0.0051
	Study not submitted	120-h EbC50	sediment	0.069
	Study not submitted	72-h EbC50	-	0.0069
<i>Lemna gibba</i>	1500673	72-h EbC50	-	0.51
	Study not submitted	7-d EbC50	-	0.134
Marine				
<i>Amphiascus tenuiremis</i>	3231101	96-h LC50	male	0.02672
<i>Marsupenaeus japonicus</i>	3231172	96-h LC50	-	0.28
<i>Tigriopus japonicus</i>	3231172	24-h EC50	-	0.016
Oyster <i>Crassostrea virginica</i>	1237165	96-h EC50	-	0.005
Mysid <i>Mysidopsis bahia</i>	No study submitted	28-d NOEC	-	0.0004

Species	Study PMRA#	Study Type/ Endpoint Type	Comments	Endpoint (mg a.i./L)
Sheepshead minnow <i>Cyprinodon variegatus</i>	No study submitted	96-h LC50	-	0.028
Threespine stickleback <i>Gasterosteus aculeatus</i>	-	96-h LC50	Only three analytical measures used to verify nominal	0.035
<i>Fungulus heterolitus</i> embryo	3231172	8-w NOEC	-	0.011
<i>Skeletoma costatum</i>	3231172	72-h ErC50	-	0.00095

Table 2 End-use product ecotoxicity studies

Species	Study PMRA#	Study Type/Endpoint Type	Comments	Endpoint (mg a.i./L)
<i>Daphnia magna</i>	1181047	48-h EC50	Bravo 720	0.097
	1237159	22-d NOEC	Chlorothalonil 40.4%	<0.0023
	1838902	48-h EC50	Treoris	0.045
Rainbow Trout <i>Oncorhynchus mykiss</i>	1236945	21-d NOEC	Daconil 2787	0.00087
	1181045	96-h LC50	Bravo 720	0.061
	No study submitted	96-h LC50	Bravo 720	0.0332
	Geomean			0.045
1838901	96-h LC50	Treoris	0.0254	
Bluegill <i>Lepomis macrochirus</i>	1181046	96-h LC50	Bravo 720	0.064
<i>Pseudokirchneriella subcapitata</i>	1838903	72-h EC50 (cell density)	Treoris	0.17

Bolded cells refer to endpoints that are the data source for the geomean.

Table 3 Transformation product ecotoxicity studies

Chemical	Species	Study PMRA#	Study Type/Endpoint Type	Endpoint (mg a.i./L)
R182281	<i>Daphnia magna</i>	No data submitted	-	-
	Rainbow trout <i>Oncorhynchus mykiss</i>	Not submitted	96-h LC50	9.1
		-	28-d LC50	3.4
	Threespine stickleback <i>Gasterosteus aculeatus</i>	-	96-h LC50	21.2
	Freshwater algae	No data submitted	-	-
R417888	<i>Daphnia magna</i>	Not submitted	48-h EC50	>110
	Rainbow trout <i>Oncorhynchus mykiss</i>	Not submitted	96-h LC50	>100
	<i>Selenastrum capricornutum</i>	Not submitted	72-h EbC50	>100

Chemical	Species	Study PMRA#	Study Type/Endpoint Type	Endpoint (mg a.i./L)
	<i>Pseudokirchneriella subcapitata</i>	Not submitted	72-h EbC50	>100
R417888-Na	No data submitted	-		
R418503	No data submitted	-		
R419492	No data submitted	-		
R471811	No data submitted	-		
R611553	No data submitted	-		
R611965	<i>Daphnia magna</i>	Not submitted	48-h EC50	>123.6
	Rainbow trout <i>Oncorhynchus mykiss</i>	Not submitted	96-h LC50	>120
	<i>Selenastrum capricornutum</i>	Not submitted	72-h EbC50	0.045
	<i>Pseudokirchneriella subcapitata</i>	Not submitted	72-h EbC50	>45
R611966	No data submitted	-		
R611967	No data submitted	-		
R611968	No data submitted	-		
R613636	<i>Daphnia magna</i>	Not submitted	48-h EC50	12.4
	Rainbow trout <i>Oncorhynchus mykiss</i>	Not submitted	96-h LC50	18
	<i>Selenastrum capricornutum</i>	Not submitted	72-h EbC50	5
R613801	<i>Daphnia magna</i>	No data submitted		
	Rainbow trout <i>Oncorhynchus mykiss</i>	No data submitted		
	<i>Pseudokirchneriella subcapitata</i>	Not submitted	72-h EyC50	0.11
Not submitted		96-h EyC50	0.086	
R613841	<i>Daphnia magna</i>	Not submitted	48-h EC50	>0.94
	Rainbow trout <i>Oncorhynchus mykiss</i>	Not submitted	96-h LC50	>0.83
	<i>Selenastrum capricornutum</i>	Not submitted	72-h EbC50	0.00086
	<i>Pseudokirchneriella subcapitata</i>	Not submitted	72-h EbC50	0.12
	<i>Navicula pelliculosa</i>	Not submitted	72-h EbC50	0.06
R613842	<i>Daphnia magna</i>	No data submitted		
	Rainbow trout <i>Oncorhynchus mykiss</i>	Not submitted	96-h LC50	>0.99
	<i>Selenastrum capricornutum</i>	Not submitted	72-h EbC50	<0.88
SYN507900	No data submitted	-	-	-
SYN546671	No data submitted	-	-	-
SYN546934	No data submitted	-	-	-
SYN564872	No data submitted	-	-	-
SYN546677	No data submitted	-	-	-
SYN546673	No data submitted	-	-	-
PD1	No data submitted	-	-	-
PD2	No data submitted	-	-	-
PD3	No data submitted	-	-	-
PD4	No data submitted	-	-	-
PD5	No data submitted	-	-	-

Chemical	Species	Study PMRA#	Study Type/Endpoint Type	Endpoint (mg a.i./L)
CTL-7	No data submitted	-	-	-
CTL-8	No data submitted	-	-	-
CTL-9	No data submitted	-	-	-
CTL-10	No data submitted	-	-	-
MM162	No data submitted	-	-	-
MM196	No data submitted	-	-	-
SDS 3113	No data submitted	-	-	-
SDS 66382	No data submitted	-	-	-
SDS 66432	No data submitted	-	-	-
I (N-oxide of chlorothalonil)	No data submitted	-	-	-

Appendix VII Spray drift risk assessment

Table 1 Off-field refined risk assessment for aquatic organisms for wheat with spray drift deposition of 6% for ground boom and 23% for aerial applications

Organism	Exposure	Species	Endpoint for RA (mg a.i./L)	Application Method (% Spray Deposition)	EEC (mg a.i./L)	RQ	LOC Exceeded
Freshwater Invertebrates	Acute 48-h EC ₅₀	<i>Dreissena polymorpha</i> embryo	0.000485	Ground boom (6%)	0.0132	26.8	Yes
				Aerial (23%)	0.051	105.15	Yes
Freshwater Fish	Acute 48-h LC ₅₀	Rainbow trout <i>Oncorhynchus mykiss</i>	0.00044	Ground boom (6%)	0.0132	29.55	Yes
				Aerial (23%)	0.051	115.91	Yes
Amphibians	Acute 96-h LC ₅₀	<i>Xenopus laevis</i> embryo	0.00082	Ground boom (6%)	0.071	86.59	Yes
				Aerial (23%)	0.27	329.27	Yes
Aquatic Vascular Plants	Acute 7-d EbC ₅₀	<i>Lemna gibba</i>	0.22	Ground boom (6%)	0.0132	0.06	No
				Aerial (23%)	0.051	0.23	No
Algae	Acute Geomean 72-h EbC ₅₀	<i>Navicula pelliculosa</i>	0.00295	Ground boom (6%)	0.0132	4.4	Yes
				Aerial (23%)	0.051	17.3	Yes
Marine Invertebrates	Acute 96-h LC ₅₀	Oyster <i>Crassostrea virginica</i>	0.0025	Ground boom (6%)	0.012	4.8	Yes
				Aerial (23%)	0.046	18.4	Yes
Marine Fish	Acute 96-h LC ₅₀	Sheepshead minnow <i>Cyprinodon variegates</i>	0.0014	Ground boom (6%)	0.012	8.57	Yes
				Aerial (23%)	0.046	32.86	Yes
Marine Algae	Acute 72-h ErC ₅₀	<i>Skeletonema costatum</i>	0.00048	Ground boom (6%)	0.012	25.3	Yes
				Aerial (23%)	0.046	96.8	Yes

Table 2 Off-field refined risk assessment for aquatic organisms for stone fruit with spray drift deposition of 74% for early application and 59% for late application air blast

Organism	Exposure	Species	Endpoint for RA (mg a.i./L)	Application Method (% Spray Deposition)	EEC (mg a.i./L)	RQ	LOC Exceeded
Freshwater Invertebrates	Acute 48-h EC ₅₀	<i>Dreissenapolymorpha</i> embryo	0.000485	Early Airblast (74%)	0.57	1175.26	Yes
				Late Airblast (59%)	0.45	927.84	Yes
Freshwater Fish	Acute 48-h LC ₅₀	Rainbow trout <i>Oncorhynchus mykiss</i>	0.00044	Early Airblast (74%)	0.57	1295.45	Yes
				Late Airblast (59%)	0.45	1022.73	Yes
Amphibians	Acute 96-h LC ₅₀	<i>Xenopus laevis</i> embryo	0.00082	Early Airblast (74%)	3.03	3695.12	Yes
				Late Airblast (59%)	2.42	2951.22	Yes
Aquatic Vascular Plants	Acute 7-d EbC ₅₀	<i>Lemna gibba</i>	0.22	Early Airblast (74%)	0.57	2.59	Yes
				Late Airblast (59%)	0.45	2.05	Yes
Algae	Acute Geomean 72-h EbC ₅₀	<i>Navicula pelliculosa</i>	0.00295	Early Airblast (74%)	0.57	193.2	Yes
				Late Airblast (59%)	0.45	152.5	Yes
Marine Invertebrates	Acute 96-h LC ₅₀	Oyster <i>Crassostrea virginica</i>	0.0025	Early Airblast (74%)	0.44	177.6	Yes
				Late Airblast (59%)	0.35	141.6	Yes
Marine Fish	Acute 96-h LC ₅₀	Sheepshead minnow <i>Cyprinodon variegates</i>	0.0014	Early Airblast (74%)	0.44	317.14	Yes
				Late Airblast (59%)	0.35	252.86	Yes
Marine Algae	Acute 72-h ErC ₅₀	<i>Skeletoma costatum</i>	0.00048	Early Airblast (74%)	0.44	934.7	Yes
				Late Airblast (59%)	0.35	745.3	Yes

Table 3 Off-field refined risk assessment for aquatic organisms for turf with spray drift deposition of 6% for ground boom application

Organism	Exposure	Species	Endpoint for RA (mg a.i./L)	Application Method (% Spray Deposition)	EEC (mg a.i./L)	RQ	LOC Exceeded
Freshwater Invertebrates	Acute 48-h EC ₅₀	<i>Dreissena polymorpha</i> embryo	0.000485	Ground boom (6%)	0.09	185.57	Yes
Freshwater Fish	Acute 48-h LC ₅₀	Rainbow trout <i>Oncorhynchus mykiss</i>	0.00044	Ground boom (6%)	0.09	204.55	Yes
Amphibians	Acute 96-h LC ₅₀	<i>Xenopus laevis</i> embryo	0.00082	Ground boom (6%)	0.49	597.56	Yes
Aquatic Vascular Plants	Acute 7-d EbC ₅₀	<i>Lemna gibba</i>	0.22	Ground boom (6%)	0.09	0.41	No

Organism	Exposure	Species	Endpoint for RA (mg a.i./L)	Application Method (% Spray Deposition)	EEC (mg a.i./L)	RQ	LOC Exceeded
Algae	Acute Geomean 72-h EbC ₅₀	<i>Navicula pelliculosa</i>	0.00295	Ground boom (6%)	0.09	30.5	Yes
Marine Invertebrates	Acute 96-h LC ₅₀	Oyster <i>Crassostrea virginica</i>	0.0025	Ground boom (6%)	0.09	4.8	Yes
Marine Fish	Acute 96-h LC ₅₀	Sheepshead minnow <i>Cyprinodon variegates</i>	0.0014	Ground boom (6%)	0.09	8.57	Yes
Marine Algae	Acute 72-h ErC ₅₀	<i>Skeletonema costatum</i>	0.00048	Ground boom (6%)	0.09	25.3	Yes

Table 4 Comparison of environmental risk assessments (current vs previous) for chlorothalonil

Parent Chlorothalonil Only		Previous Risk Assessment (PRVD2011-14)	Current Risk Assessment
Fate endpoints	Hydrolysis	pH 5 stable pH 7 stable pH 9 38 days	pH 5 stable pH 7 stable pH 9 50.62 days
	Phototransformation – soil	Stable	14.4 days
	Phototransformation – water	65 days	18 days
	Aerobic soil	52 days (terrestrial field dissipation study used as it was longer than the laboratory studies)	47 days
	Anaerobic soil	5 – 15 days	n/a
	Mobility - adsorption	K _d 16.6 L/kg K _{oc} 1300-14000	K _d 1.2 L/kg K _{oc} 471.2-10875
	Mobility – desorption	n/a	Percent desorbed increases with increasing initial concentration, up to 30% desorption under saturated conditions
	Aerobic aquatic	0.5 days	5.33 days
	Anaerobic aquatic	n/a	3.08 days

Parent Chlorothalonil Only		Previous Risk Assessment (PRVD2011-14)	Current Risk Assessment
Water EECs (Turf use pattern)	Ecoscenario	Peak values (Prairie) 15 cm – 0.8 mg a.i./L 80 cm – 0.2 mg a.i./L Chronic 21-d (Atlantic) 15 cm – 0.07 mg a.i./L 80 cm – 0.07 mg a.i./L	96-h values (BC – Vancouver) 15 cm – 0.509 mg a.i./L 80 cm – 0.173 mg a.i./L Chronic values (BC – Vancouver) 15 cm – 0.138 mg a.i./L 80 cm – 0.089 mg a.i./L
Ecotoxicity effects metric	Acute freshwater fish	SSD HC ₅ 0.013 mg a.i./L	<i>Oncorhynchus mykiss</i> 48-h LC ₅₀ 0.00044 mg a.i./L
	Chronic freshwater fish	<i>Oncorhynchus mykiss</i> 21-d NOEC 0.003 mg a.i./L	<i>Pimephales promelas</i> 21-d NOEC <0.00007 mg a.i./ha
	Acute amphibians	<i>Bufo bufo japonicas</i> 48-h LC ₅₀ 0.016 mg a.i./L	<i>Xenopus laevis</i> 96-h LC ₅₀ 0.00082 mg a.i./L
	Chronic amphibians	<i>Oncorhynchus mykiss</i> surrogate 21-d NOEC 0.003 mg a.i./L	<i>Xenopus laevis</i> 21-d NOEC 0.00061 mg a.i./L
Runoff risk quotients (Turf use pattern ecoscenario EECs)	Freshwater fish	Acute RQ – 15.4 Chronic RQ – 6.7	Acute RQ – 484 Chronic RQ – >1141
	Amphibians	Acute RQ – 50 Chronic RQ – 23.3	Acute RQ – 621 Chronic RQ – 226

n/a – not available

Appendix VIII Runoff risk assessment

Table 1 Ecoscenario off-field refined risk assessment for freshwater aquatic organisms for 24 and 96-hours at 15 and 80 cm water depths

Organism	Effect matrix (mg a.i./L)	Risk Quotients								
		Highbush Blueberries	Lowbush blueberries	Carrots	Outdoor conifers	Potatoes	Peaches	Processing tomatoes	Turf	Wheat
Freshwater Acute										
24-hour 80 cm EEC (mg a.i./L)		0.014	0.057	0.039	0.0063	0.038	0.036	0.101	0.213	0.014
<i>D. polymorpha</i> embryo	Acute 48-h EC ₅₀ 0.000485 mg a.i./L	29	118	80	13	78	74	208	439	29
Rainbow trout <i>Oncorhynchus mykiss</i>	Acute 48-h LC ₅₀ 0.00044 mg a.i./L	32	130	89	14	86	82	230	484	32
<i>Navicula pelliculosa</i>	Acute Geomean 72-h EbC ₅₀ 0.00295 mg a.i./L	4.7	19	13.2	2.1	13	12	34.2	72.2	4.7
96-hour 80 cm EEC (mg a.i./L)		0.012	0.042	0.029	0.041	0.03	0.028	0.078	0.173	0.0098
<i>Lemna gibba</i>	Acute 7-d EbC ₅₀ 0.22 mg a.i./L	0.05	0.19	0.13	0.19	0.14	0.13	0.35	0.79	0.04
Amphibian Acute										
96-hour 15 cm EEC (mg a.i./L)		0.036	0.094	0.063	0.108	0.061	0.079	0.197	0.509	0.021
<i>Xenopus laevis</i> embryo	Acute 96-h LC ₅₀ 0.00082 mg a.i./L	44	115	77	132	74	96	240	621	26

Table 2 Ecoscenario off-field refined risk assessment for freshwater aquatic organisms for 21-day values at 15 and 80 cm water depths

Organism	Effect Matrix (mg a.i./L)	Risk Quotients								
		Highbush Blueberries	Lowbush blueberries	Carrots	Outdoor conifers	Potatoes	Peaches	Processing tomatoes	Turf	Wheat
Freshwater Chronic										
21-day 80 cm EEC (mg a.i./L)		0.0066	0.022	0.011	0.02	0.016	0.017	0.034	0.089	0.0036
<i>Daphnia magna</i>	Chronic 21-d NOEC 0.0006 mg a.i./L	11	37	18	33	27	28	57	148	6
Fathead minnow <i>Pimephales promelas</i> FSTRA	Chronic 21-d NOEC <0.000078 mg a.i./L (reproduction)	>85	>282	>141	>256	>205	>218	>436	>1141	>46
Amphibian Chronic										
21-day 15 cm EEC (mg a.i./L)		0.012	0.036	0.015	0.035	0.025	0.042	0.066	0.138	0.0046
<i>Xenopus laevis</i> AMA	Chronic 21-d NOEC 0.00061 mg a.i./L (development)	20	59	25	57	41	69	108	226	7.5

Table 3 Ecoscenario off-field refined risk assessment for marine aquatic organisms for 24 and 96-hour values at 80 cm water depths (based on freshwater 80 cm depth modelled values)

Organism	Effect Matrix (mg a.i./L)	Risk Quotients								
		Highbush Blueberries	Lowbush blueberries	Carrots	Outdoor conifers	Potatoes	Peaches	Processing tomatoes	Turf	Wheat
Marine Acute										
24-hour 80 cm EEC (mg a.i./L)		0.014	0.057	0.039	0.0063	0.038	0.036	0.101	0.213	0.014
<i>Skeletonema costatum</i>	Acute 72-h ErC ₅₀ 0.000475 mg a.i./L	29.5	120.0	82.1	13.3	80.0	75.8	212.6	448.4	29.5
96-hour 80 cm EEC (mg a.i./L)		0.012	0.042	0.029	0.041	0.03	0.028	0.078	0.173	0.0098
Oyster <i>Crassostrea virginica</i>	Acute 96-h LC ₅₀ 0.0025 mg a.i./L	4.8	16.8	11.6	16.4	12.0	11.2	31.2	69.2	3.9
Sheepshead minnow <i>Cyprinodon variegates</i>	Acute 96-h LC ₅₀ 0.0028 mg a.i./L	4.3	15.0	10.4	14.6	10.7	10.0	27.9	61.8	3.5

Appendix IX Environment incident report summary

Table 1 Incident reporting program submissions for chlorothalonil

Submission Number	Type	Details	Outcome
2011-4359	Study Acute daphnia	Study was conducted with a co-formulated (chlorothalonil and boscalid) end-use product	This study was found not relevant to the Canadian use pattern as there are no end-use products registered that co-formulate chlorothalonil and boscalid. No further action was required.
2013-2376	Study Amphibian metamorphosis assay (AMA)	At the time of the IR submission, the AMA was a newer study to the PMRA and was not a data requirement. The PMRA was in the process of determining how these studies would be used in the environmental risk assessment. Thus, the review was delayed until 2017.	The review of this study was completed in 2017 and the data provided a development endpoint for the new risk assessment. The results of this study indicated that the current risk assessment was under-predicting risk to amphibians. A Special Review was recommended.
2015-0257	Study Aerobic soil	This study was reviewed. This was the first fate study submitted that detailed the new analytical methods that allowed for the detection of a number of new, major transformation products. The DT ₅₀ values calculated were longer than previous laboratory studies but in-line with the Terrestrial Field Dissipation (TFD) endpoint used quantitatively in the re-evaluation risk assessment. While laboratory studies are typically used quantitatively to calculate EECs in the environmental risk assessment, the TFD study endpoints were used for the chlorothalonil re-evaluation, likely because they were longer than the laboratory aerobic soil endpoints.	A risk assessment conducted with the new endpoints did not result in higher risk to the environment. There was insufficient information on the new major transformation products to determine if a Special Review was required. No further action was required.
2016-7425	Study Chronic adult honeybee	The first of the new pollinator studies required by the PMRA. The EFSA risk assessment resulted in acceptable risk to bees (PMRA# 2778798, page 163).	The endpoint was found to result in higher risk to bees than the original risk assessment. There are no mitigation statements currently on chlorothalonil labels for bees. It was decided that the Special Review would focus on the aquatic risk as the area of concern was based on the EU decision of 2019.
2017-1175	Study Anaerobic soil	A second fate study using the new analytical methods. The endpoint calculated was not significantly different from previous endpoints.	The new study did not change the characterisation of risk to the environment and no further action was required.

Submission Number	Type	Details	Outcome
2017-1176	Study Aerobic water/sediment	A third fate study with the new analytical methods. This study resulted in much longer aquatic DT ₅₀ values which significantly altered the aquatic exposure estimates and the risk assessment.	The endpoint from the new study suggested an increased risk to aquatic organisms, increase in buffer zones required, and was expected to affect drinking water modelling. A Special Review was recommended.
2018-6413	Fish mortality 2017	Campbelton, PEI Sampling detections as high as 0.015 mg a.i./L	Draft – Highly Probable Chlorothalonil was the cause of the fish kill
2016-6334	Fish mortality 2011		Draft – Highly Probable Chlorothalonil was the cause of the fish kill
2016-5482	Fish mortality 2011	Barclay Brook and Trout River, PEI	Highly Probable Chlorothalonil was the cause of the fish kill
2016-5481	Fish mortality 2011		Highly Probable Chlorothalonil was the cause of the fish kill
2013-5390	Fish mortality 2013	Ontario	Draft - Highly Probable Chlorothalonil was the cause of the fish kill

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PMRA Number	Reference
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2423099	2013, Chlorothalonil: Magnitude of the Residue on Cranberry, DACO: 7.4.1

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PMRA Number	Reference
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1180935	Effect of microorganisms upon the soil metabolism of daconil and 4-hydroxy-2,5,6-trichloroisophthalonitrile. Date 2-5-1976. Document # 1000-3EF-76-2087-001, DACO: 8.2.3.4.2
1181045	Acute toxicity to rainbow trout (<i>Oncorhynchus mykiss</i>) under flow-through conditions with Bravo 720. Document # 5727-93-0120-TX-002. Date - 29 December 1994. DACO: 9.5.2.1
1181046	Bravo 720 - Acute toxicity to bluegill sunfish (<i>Lepomis macrochirus</i>) under flow-through conditions. Document # 5088-91-0428-TX-002. Date - 29 December 1994. DACO: 9.5.2.2
1181047	Bravo 720-acute toxicity to daphnids (<i>Daphnia magna</i>) under flow-through conditions. Document # 5087-91-0427-TX-002. Date 29 December 1994, DACO: 9.3.2
1219851	HYDROLYSIS OF DAPONIL & METABOLITE 4-HYDROXY-2,5,6-TRICHLOROISOPHTHALONITRILE IN ABSCENSE OF LIGHT AT PH LEVELS 5, 7 & 9, DACO: 8.2.1
1236945	Toxicity of daconil 2787 extra to rainbow trout by longer exposure (21-days). Date - 1989. Study # AF-705/3. DACO: 9.5.2.1
1236946	A chronic study in the fathead minnow with technical chlorothalonil. Document # 090-5TX-79-0049-003. 1980. DACO: 9.5.5
1237159	<i>Daphnia magna</i> , reproduction test with Daconil Extra. Date 1989. Project 025751. DACO 9.3.1
1237165	Flow-through, acute oyster shell deposition study with technical chlorothalonil. Report # 537-5TX-82-0133-003. 1983. DACO: 9.4.1
1274228	1998, CHLOROTHALONIL - ASSESSMENT OF ACUTE TOXICITY TO DAPHNIA MAGNA IN THE PRESENCE OF SEDIMENT, DACO: 9.3.2
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1310981	1992, An assessment of the effects of chlorothalonil on the reproduction of <i>Daphnia magna</i> , DACO: 9.3.3
1310982	1992, Chlorothalonil; the acute toxicity to rainbow trout (<i>Oncorhynchus mykiss</i>), DACO: 9.5.2.1

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1310985	1992, The prolonged toxicity of chlorothalonil to rainbow trout (<i>Oncorhynchus mykiss</i>), DACO: 9.5.3.1
1310991	1992, The algistatic activity of chlorothalonil, DACO: 9.8.2
1340587	1996, 14C-Chlorothalonil - Hydrolysis Under Laboratory Conditions, DACO: 8.2.3.2
1500647	2000, Chlorothalonil: Aerobic Soil Degradation at Four Treatment Rates, DACO: 8.2.3.4.2
1500648	2001, Degradation in Aerobic Soil, DACO: 8.2.3.4.2
1500651	2002, Chlorothalonil - Degradation of 14C-Labelled Compound in Natural Water Sediment Systems Under Laboratory Conditions, DACO: 8.2.3.5.4
1500664	1998, Chlorothalonil - Assessment of Acute Toxicity to Rainbow Trout in the Presence of Sediment, DACO: 9.5.2.1
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1838902	2009, Chlorothalonil/Penthiopyrad (DPX-QFA61) SC (250 g/L:100 g/L): A 48-hour static acute toxicity test with the cladoceran (<i>Daphnia magna</i>), DACO: 9.3.2,IIIA 10.2.2.2
1838903	2009, Chlorothalonil/Penthiopyrad (DPX-QFA61) SC (250 g/L:100 g/L): A 72-hour toxicity test with the freshwater alga (<i>Pseudokirchneriella subcapitata</i>), DACO: 9.8.2,9.8.3,IIIA 10.2.2.3
2548555	2015, Chlorothalonil - Rate and Route of Degradation of [14C]-Chlorothalonil Under Aerobic Laboratory Conditions in Four Soils at 20 degrees C - Final Report, DACO: 8.2.3.4.2
2737552	Chlorothalonil - Rate and route of degradation of [14C]-Chlorothalonil in two sediments at 20C. Report # 33213. DACO:2015
2918264	2006, CHLOROTHALONIL: HYDROLYSIS AT ONE pH VALUE, DACO: 8.2.3.2
2918265	2014, Chlorothalonil - Hydrolysis of [14C]- Chlorothalonil - Final Report, DACO: 8.2.3.2
2918266	2014, Chlorothalonil - Soil Photolysis of 14C-Chlorothalonil - Final Report Amendment 1, DACO: 8.2.3.3.1
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2918270	1996, CHLOROTHALONIL: AEROBIC SOIL METABOLISM AND ROUTE OF DEGRADATION, DACO: 8.2.3.4.2
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3169502	European Commission, Volume 3 ζ Annex B (A14111B) Chlorothalonil B.9 Ecotoxicology data, DACO: 12.5
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