Proposed Re-evaluation Decision PRVD2021-08

Tebuconazole and Its Associated End-use Products

Consultation Document

(publié aussi en français)

23 July 2021

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

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

Catalogue number: H113-27/2021-8E (print)
H113-27/2021-8E-PDF (PDF version)

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Proposed re-evaluation decision for tebuconazole and associated end-use products

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

Tebuconazole is a systemic fungicide registered for foliar uses (including large field crops, asparagus, and turf), seed treatment, and as a heavy-duty wood preservative. The joinery wood use was assessed separately (RVD2017-06; *Re-evaluation Decision for Joinery Use of Tebuconazole*) and is not included in the current re-evaluation. Currently registered products containing tebuconazole can be found in the Pesticide Label Search and in Appendix I.

This document presents the proposed re-evaluation decision for tebuconazole, including the proposed amendments (risk mitigation measures) to protect human health and the environment, as well as the science evaluation on which the proposed decision is based. All products containing tebuconazole that are registered in Canada are subject to this proposed re-evaluation decision. This document is subject to a 90-day public consultation period,[1] during which the public (including the pesticide manufacturers and stakeholders) may submit written comments and additional information to PMRA Publications. The final re-evaluation decision will be published after taking into consideration the comments and information received during the consultation period.

Proposed re-evaluation decision for tebuconazole

Under the authority of the *Pest Control Products Act* and based on an evaluation of available scientific information, Health Canada is proposing continued registration of tebuconazole and all associated end-use products registered for sale and use in Canada.

Tebuconazole is of value to agricultural producers and turfgrass managers, as it controls numerous economically important foliar, seed-borne, and soil-borne diseases, as well as several damaging turfgrass pathogens. In addition, tebuconazole is used as a non-metallic heavy-duty wood preservative to extend the service life of treated wood, and is also used in conjunction with other active ingredients that protect treated wood against termite damage.

Risks to human health and the environment were shown to be acceptable when tebuconazole is used according to the proposed conditions of registration, which include the mitigation measures identified below.

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

Risk mitigation measures

Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures to protect human health and the environment and must be followed by law. The proposed label amendments, including any revised/updated label statements and/or mitigation measures as a result of the re-evaluation of tebuconazole, are summarized below. Refer to Appendix IX for details.

Human health

As a result of the re-evaluation of tebuconazole, the PMRA is proposing further risk-reduction measures in addition to those already identified on tebuconazole product labels. Additional revisions to the tebuconazole labels are proposed to meet the current labelling standards and for consistency.

To protect the general population from dietary exposure including through drinking water:

- For turf uses, reduce the maximum cumulative rate from 3.10 kg a.i./ha/year to 1.44 kg a.i./ha/year.
- In addition, for consistency among product labels, a rotational plant back interval of 120 days is proposed for food and feed crops, unless the current label directions are more restrictive.

To protect workers using agricultural and turf end-use products:

- For mixer/loaders and applicators, additional or updated personal protective equipment.
- For postapplication workers harvesting (seedling production) short-rotation intensive culture crops (poplar and willow), a restricted-entry interval (REI) of 1 day.
- An REI of 12 hours is proposed for all other crop activities.
- For golf course turf, a re-entry interval of “until sprays have dried” is proposed.

To protect workers treating seed, workers conducting clean-up and repair activities at seed treatment facilities, and workers handling and planting treated seed:

- For corn seed, closed mix/load and transfer systems during treatment.
- For wheat, barley, oat, rye, and triticale seed, personal protective equipment during handling and planting treated seed, and when performing clean-up and repair activities.
- Closed cab tractor for planting of commercially-treated seed.

To protect workers treating wood and handling treated wood:

- Personal protective equipment, as per the "Recommendations for Design and Operation of Wood Preservation Facilities, 2013 Technical Recommendations Document", which is enforced by Environment and Climate Change Canada (PMRA# 3079324).

Environment

To protect the environment, the following risk mitigation measures are proposed:

- For products registered for use on turf, precautionary label statements to inform users of the potential toxic effects of tebuconazole to foliar-dwelling arthropods (certain beneficial insects) and birds.

- Precautionary label statements to inform users of the potential toxicity of tebuconazole to non-target terrestrial plants and aquatic organisms.

- Precautionary label statements on all outdoor uses of tebuconazole, except seed treatments, regarding potential for runoff to adjacent aquatic habitats for sites with characteristics that may be conducive to runoff and when heavy rain is forecast.

- Standard label statements to protect the environment from potential discharge or runoff of tebuconazole from wood preservation facilities.

- Spray buffer zones for the protection of non-target terrestrial and aquatic habitats (1–15 metres).

International context

Tebuconazole is acceptable for use in other Organisation for Economic Co-operation and Development (OECD) member countries, including the United States, European Union and Australia. No decision by an OECD member country to prohibit all uses of tebuconazole for health or environmental reasons has been identified.

Next steps

Upon publication of this proposed re-evaluation decision, the public, including the registrants and stakeholders, are encouraged to submit additional information that could be used to refine risk assessments during the 90-day public consultation period.

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

Refer to Appendix I for details on specific products impacted by this proposed decision.

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

Science evaluation

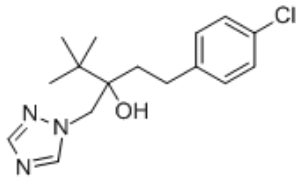
1.0 Introduction

Tebuconazole is a systemic fungicide registered for foliar uses (including large field crops, asparagus, and turf), seed treatment, and as a heavy-duty wood preservative. The joinery wood use was assessed separately (RVD2017-06 Re-evaluation Decision for Joinery Use of Tebuconazole) and is not included in the current re-evaluation.

Appendix I lists all tebuconazole products that are registered under the authority of the *Pest Control Products Act*. Appendix II lists all plant protection and heavy-duty wood preservative uses for which tebuconazole is presently registered.

2.0 Technical grade active ingredient

2.1 Identity

Common name		Tebuconazole
Function		Fungicide
Chemical Family		Triazole
Chemical name		
1	**International Union of Pure and Applied Chemistry (IUPAC)**	(*RS*)-1-*p*-chlorophenyl-4,4-dimethyl-3-(1*H*-1,2,4-triazol-1-ylmethyl)pentan-3-ol
2	**Chemical Abstracts Service (CAS)**	α-[2-(4-chlorophenyl)ethyl]-α-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol
CAS Registry Number		107534-96-3
Molecular formula		$C_{16}H_{22}ClN_3O$
Structural formula		
Molecular weight		307.81

2.2 Physical and chemical properties

Property	Result
Vapour pressure	1.3×10^{-3} mPa at 2°C; 3.1×10^{-3} mPa at 25°C
Ultraviolet (UV) / visible spectrum	Not expected to absorb at λ >300 nm
Solubility in water at 25°C	36 mg/L (pH 5-9)
n-Octanol/water partition coefficient	Log K_{ow} = 3.70
Dissociation constant	pKa = 5.0; uncharged at environmental pH

3.0 Human health assessment

3.1 Toxicology summary

Tebuconazole is a systemic fungicide which belongs to the demethylation inhibitor group of fungicides. A detailed review of the toxicological database for tebuconazole was conducted. The database is complete, consisting of the full array of toxicity studies currently required for hazard assessment purposes. The studies were carried out in accordance with accepted international testing protocols and Good Laboratory Practices. The toxicology assessment for tebuconazole also considered information found in the published scientific literature. The scientific quality of the data is acceptable and the database is considered adequate to characterize the potential health hazards associated with tebuconazole.

Radiolabelled [phenyl-UL-14C]-tebuconazole administered to rats as a single or repeated oral dose was rapidly absorbed from the gastrointestinal tract. It was excreted in the bile and eliminated via the feces. Excretion of tebuconazole via the urine was also significant, while excretion via respired air was negligible. Absorption, distribution and excretion of tebuconazole were independent of dose and dose level; however, sex-related differences in excretion were observed, with slightly higher urinary excretion noted in females. Tebuconazole was completely metabolized within 48–72 hours. The major metabolites included an alcohol and an acid derivative. The alcohol intermediate was further metabolized to give minor sulfate and glucuronide conjugates or triol metabolites, while the acid was changed to a “keto” acid. Tebuconazole was also cleaved to 1,2,4-triazole, which was excreted as a minor metabolite in the urine.

After 72 hours, the radioactivity remaining in the body, excluding the gastrointestinal tract, was low (<1%) with the highest residue concentration found in liver and kidney. Remaining radioactivity in most tissues and organs was generally 1.5–2.5 times higher in males of all dose groups than in the corresponding females.

Tebuconazole was of low to slight acute toxicity via the oral route to mice and rats respectively. Clinical signs following oral exposure were observed in rats and mice at high doses and included sedation and abnormal gait. Tebuconazole was of low acute toxicity to rabbits via the dermal route. The assessment of the acute inhalation toxicity of tebuconazole in rats was limited by the

highest achievable aerosol concentration of the test material. The LC_{50} obtained in the acute inhalation toxicity study would suggest that tebuconazole was moderately toxic via the inhalation route; however, the absence of any clinical signs indicated lower toxicity via this route of exposure and, therefore, tebuconazole was considered of slight acute inhalation toxicity. Tebuconazole was minimally irritating to rabbit eyes, non-irritating to rabbit skin and was not a dermal sensitizer to guinea-pigs following testing via the Buehler method.

In repeat-dose short-term dietary studies in mice and rats, the main target organ of toxicity was the liver. Changes in liver weight, increased enzyme activities (alkaline phosphatase, aminotransferases, O-demethylase and cytochrome P450), and histopathological effects (lipid accumulation) were observed in short-term studies. In rats, the adrenals were also affected as indicated by vacuole formation and enlarged cells.

Long-term dietary administration of tebuconazole also mainly affected the liver, with an increased incidence of pigment deposits in the Kupffer cells, centrilobular and periportal fine vacuolation and fatty degeneration observed in mice and liver enzyme induction noted in rats. Other notable systemic effects in long-term toxicity studies included decreased body weight in mice and rats, increased iron content in the spleen, and cortical degeneration of the adrenal glands in rats.

In repeat-dose dietary toxicity studies in dogs (90-day and one-year), tebuconazole exposure resulted in effects on the eyes (cataracts, lens degeneration) and red blood cells, as indicated by accumulation of iron pigment (hemosiderin) in the liver, spleen and adrenals, as well as vacuole formation in the adrenals.

In rats and dogs, increased duration of dosing resulted in more pronounced histological changes in the liver and adrenals. Additionally, accumulation of iron pigment in the spleen was noted at lower dose levels in both species following prolonged exposure.

In short-term dermal toxicity studies, no systemic toxicity was noted in rabbits up to the limit dose of testing. In a short-term head/nose only inhalation toxicity study in rats, increased N-demethylase activity and incidences of piloerection were noted; however, these signs were not considered adverse.

No evidence of oncogenicity was observed in rats in a long-term dietary toxicity study. In a long-term dietary study in mice, increased incidences of hepatocellular adenoma, carcinoma and combined adenoma/carcinoma were observed at the highest dose tested, in the presence of liver toxicity. Tebuconazole was not genotoxic in a battery of in vivo and in vitro studies. Mechanistic studies were provided to support both mitogenic and cytotoxic modes of action (MOAs) for tebuconazole-induced liver tumour formation in mice. Constitutive androstane receptor (CAR) and/or pregnane X receptor (PXR) activation, as well as tebuconazole-induced hepatotoxicity and subsequent regenerative proliferation appeared to play a role in the induction of the hepatocellular tumours in mice. The submitted data were largely consistent with the key events established for a CAR/PXR MOA. Activation of CAR/PXR, increased hepatic CYP450 enzyme activity, as well as hepatocyte hypertrophy and cell proliferation were noted in the available mechanistic studies, and each of these responses showed both dose and temporal concordance. Additionally, evidence of cytotoxicity and regenerative proliferation was noted in short- and

long-term toxicity studies in the database. Thus, the submitted data supported a threshold mode of action (MOA) for the liver tumours observed in the mouse. Although a recently published study provided some evidence of a CAR-dependant MOA for tebuconazole-induced liver tumours in mice, tebuconazole has also been shown to trigger liver hypertrophy independently of CAR activation (PMRA# 2873585).

In a dietary two-generation reproductive toxicity study in rats, reproductive effects consisted of decreased litter size and birth weight at the highest dose level. In parental animals, slight decreases in body weight and body weight gain were observed at the highest dose level. In pups, decreased viability and lactation indices, as well as decreased body weight were noted at the high-dose level. The effects in pups were noted in the presence of maternal toxicity.

In a gavage developmental toxicity study in rats, tebuconazole was not considered to be teratogenic. Developmental toxicity consisted of increased resorptions, decreased number of live foetuses, reduced fetal weight, as well as increased incidences of visceral (fluid in thoracic cavity) and skeletal (bipartite/dumbbell-shaped thoracic vertebral centra) findings, all at the high dose. These effects were noted in the presence of maternal toxicity characterized by reduced body weight gain and food consumption, as well as increased liver weight and resorptions. In a dermal developmental study in rats, there were no signs of maternal or developmental toxicity at the limit dose of testing.

In gavage developmental toxicity studies in rabbits and mice, fetal malformations were observed at dose levels where minimal maternal toxicity was observed. In rabbits, post-implantation loss, as well as multiple malformations including spina bifida, malpositioning of limbs, meningocele and omphalocele, were observed at doses where decreases in food consumption or body weight gain were observed in dams. In two separate mouse gavage developmental toxicity studies, (PMRA# 1227400 and PMRA# 1038120) increased incidences of cleft palate were consistently observed at the highest dose tested. In one study (PMRA# 1227400), although there was apparent evidence of fetal sensitivity, the livers of maternal animals were not examined histopathologically. In another study (PMRA# 1038120), in addition to cleft palate, there were also increased incidences of exencephaly, acrania, open eye, wart-like growths and protruding tongue at the highest dose level. In this study, evidence of maternal toxicity in the form of histopathological findings in the liver and post-implantation loss were observed at the same dose where increased incidences of malformations were noted. In a dermal developmental toxicity study in mice, malformations including palatoschisis and exencephaly, as well as skeletal variations, were noted at a dose that was maternally toxic, based on histopathological and biochemical liver changes.

In an acute gavage neurotoxicity study in rats, decreased motor and locomotor activity, as well as clinical signs of neurotoxicity (uncoordinated gait; diminished approach, touch and auditory responses), were observed on the day of dosing. Females were more affected than males. In a published study that specifically assessed motor activity, no evidence of hyperactivity was observed on the day of dosing, following acute gavage administration of tebuconazole (PMRA# 2873579). In a dietary subchronic neurotoxicity study in rats, no treatment-related effects in the functional observational battery, motor/locomotor activity assessment, or neuropathological examination were observed at any dose level tested.

In a rat dietary developmental neurotoxicity (DNT) study, reduced pre-weaning pup body weight, decreased auditory startle response at postnatal day (PND) 23 (both sexes combined), as well as equivocal evidence of decreased brain weight in males, were noted in offspring at the mid-dose level in the absence of any effects on maternal animals. At the high-dose level, there was an increased duration of gestation, a decreased total number of live-born pups, reduced gestation and viability indices, and an increased number of stillborn pups. Offspring-specific effects at this dose included decreased pre-weaning pup body weight, delayed eye opening, decreased motor activity (PND 22) and auditory startle response (PND 63), in addition to decreased brain weights and decreased cerebellum length (PND 12 and PND 83). These effects occurred in the presence of maternal toxicity characterized by decreases in body weight, body weight gain and food consumption (in addition to effects noted above). The decrease in auditory startle response, motor activity, and brain weight, as well as the noted brain morphometric changes, were considered evidence of developmental neurotoxicity.

A published study that examined the effect of tebuconazole on adult neurological function following perinatal gavage exposure in rats (PMRA# 2873583), reported reduced motor activity habituation and impaired acquisition of learning in a Morris water maze one month post-dosing. Additionally, increased handling reactivity in males was noted at the highest dose level. Treatment-related neuropathological changes were noted in this study; however, all reported neuropathological findings were subsequently retracted (PMRA# 2918348).

Despite some disparity between the types of neurological effects noted in the DNT study and the information available in the published scientific literature, taken together these studies indicate that tebuconazole can produce developmental neurotoxicity.

In a series of assays, the potential effect of tebuconazole on the endocrine system was examined. Tebuconazole was considered negative in both the in vitro estrogen receptor binding and estrogen receptor alpha transcriptional activation assays, and negative in the in vivo uterotrophic assay. In contrast, in a steroidogenesis assay using H295R cell cultures, tebuconazole inhibited the production of both estradiol and testosterone. It reduced the binding of androgens to androgen receptors in the androgen receptor assay and inhibited the enzyme aromatase responsible for androgen to estrogen conversion in an aromatase assay. In the in vivo pubertal assay, tebuconazole reduced testosterone levels in males, while a delay in vaginal opening (VO) was observed in females. Tebuconazole did not have androgenic/anti-androgenic effects on castrated rats in a Hershberger assay. Several studies were also available in the published scientific literature that described the effects of tebuconazole on testosterone and androgen receptor activation. However, due to the in vitro nature of these studies, the results could not be quantitatively factored into the hazard assessment. Overall, the in vivo and in vitro results demonstrate the potential of tebuconazole to alter the steroidogenesis pathway, which may result in effects on hormone sensitive tissues. However, in vivo, these effects occurred at much higher doses than the point of departure used for human health risk assessment. Thus, the risk assessment is protective of these effects.

The toxicology reference values used for human health risk assessment are summarized in Table 1 of Appendix III. The summary of major metabolites of tebuconazole is presented in Appendix III, Table 2.

3.1.1 *Pest Control Products Act* Hazard Characterization

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

With respect to the completeness of the toxicity database as it pertains to the toxicity to infants and children, the database contains the standard complement of required studies including developmental toxicity studies in rats and rabbits and a two-generation reproductive toxicity study in rats. Additionally, a DNT study in rats, two gavage developmental toxicity studies in mice, dermal developmental toxicity studies in rats and mice, published literature studies, as well as a battery of assays generated for the United States Environmental Protection Agency (USEPA) Endocrine Disruptor Screening Program were available.

With respect to potential prenatal and postnatal toxicity, sensitivity of the young was identified in the rat DNT study. In this study, decreases in pre-weaning pup body weight and auditory startle response at PND 23, in addition to an equivocal decrease in brain weight in males was noted at a dose-level that did not cause adverse effects in maternal animals. At the high-dose level, clear evidence of systemic toxicity (decreased viability index) and developmental neurotoxicity characterized by effects on motor activity, auditory startle response, and changes in brain morphometry (brain weight and cerebellum length) were observed in the offspring in the presence of maternal toxicity. Reproductive toxicity consisting of increased duration of gestation and increased stillbirth, as well as reduced gestation index, was also noted at this dose level. The neurological effects observed at the high dose in the DNT study were considered serious, although the level of concern was tempered by the presence of maternal toxicity. Effects on the offspring noted in the DNT study in the absence of maternal toxicity were not serious (decreased pup body weight), or were considered marginal/equivocal (decreased brain weight in males). Decreased auditory startle response at PND 23 was also observed in the absence of maternal toxicity; however, the seriousness of this endpoint was questionable given that there is evidence that the startle response may not be fully mature in the early post-weaning period and that the effect was not maintained at this dose level at the later assessment time point of PND 63.

A published study that examined adults following perinatal exposure to tebuconazole also showed evidence of impaired functional effects on the nervous system. In this study, reduced motor activity habituation, impaired acquisition of learning, and increased handling reactivity in males was observed at a dose level that produced minimal toxicity in maternal animals.

The offspring and reproductive findings in the DNT study were supported by the results from the two-generation reproductive toxicity study in rats where decreased pup viability and lactation indices, as well as decreased litter size and weight, were observed in the presence of slight toxicity in parental animals.

In the developmental and reproductive toxicity studies, there was no indication of increased sensitivity of the young relative to parental animals. In the rat oral and dermal developmental toxicity studies, there was no evidence of teratogenicity. Increased resorptions, decreased

number of live fetuses, reduced fetal weight, increased incidences of visceral (fluid in thoracic cavity) and skeletal (bipartite/dumbbell-shaped thoracic vertebral centra) variations, were observed in the presence of maternal toxicity (decreased body weight gain and food consumption) in the oral studies. In the dermal study, no signs of maternal toxicity or developmental effects were noted up to the limit dose of testing. In the mouse and rabbit oral developmental toxicity studies, craniofacial malformations were observed at doses that elicited decreased food consumption, liver toxicity or post-implantation loss in maternal animals. In a mouse dermal developmental toxicity study, evidence of malformations (palatoschisis and excencephaly) and increased skeletal variations including bipartite sternebrae, non-ossification of the forelimb distal phalanx, supernumerary ribs occurred in the presence of liver histopathological and biochemical changes in maternal animals.

Overall, the database is adequate for determining the sensitivity of the young. Certain fetal effects were considered serious although the level of concern was tempered by the presence of maternal toxicity in most instances. As previously noted, the morphometric and neurobehavioral effects noted in the DNT study in the absence of maternal toxicity were considered either marginal/equivocal or of questionable severity. Therefore, it was deemed overly conservative to retain the default 10-fold *Pest Control Products Act* factor (PCPA factor) when using these endpoints to establish a point of departure. As a result, the PCPA factor was reduced to threefold when endpoints from the DNT study, or malformations occurring in the presence of maternal toxicity in the developmental toxicity studies, are used to establish the point of departure.

3.2 Dietary exposure and risk assessment

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

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

Residue estimates used in the dietary risk assessment may be based conservatively (in other words, are high-end estimates) on the maximum residue limits (MRLs) or the field trial data representing the residues that may remain on food after treatment at the maximum label rate. Surveillance data representative of the national food supply may also be used to derive a more accurate estimate of residues that may remain on food when it is purchased.

These include the Canadian Food Inspection Agency's (CFIA) National Chemical Residue Monitoring Program and the United States Department of Agriculture Pesticide Data Program (USDA PDP). Specific and empirical processing factors as well as specific information regarding percent of crops treated may also be incorporated to the greatest extent possible.

Sufficient information was available to adequately assess the dietary exposure and risk from tebuconazole. Acute and chronic dietary exposure and risk assessments were conducted using the Dietary Exposure Evaluation Model - Food Commodity Intake Database™ (DEEM-FCID™, Version 4.02, 05-10-c) program which incorporates consumption data from the National Health and Nutrition Examination Survey/What We Eat in America (NHANES/WWEIA) for the years 2005–2010 available through the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics (NCHS). Further details on the consumption data are available in Health Canada's Science Policy Note SPN2014-01, General Exposure Factor Inputs for Dietary, Occupational and Residential Exposure Assessments. Information on the residue chemistry of tebuconazole is published in Regulatory Note REG2006-11: Tebuconazole, and in subsequent Evaluation Reports for the use expansions since then.

Canadian MRLs for tebuconazole and the residue definitions for enforcement are available on the Pesticides section of the Canada.ca website. The residue definition in animal commodities was determined previously to be tebuconazole (parent) and hydroxy-tebuconazole (metabolite). As a result of the re-evaluation, it is proposed to revise the residue definition in animal commodities to include parent and metabolite conjugates. While the residue definition in animal commodities will be updated, no MRL actions are required because, by using the current analytical methods, residues obtained from animal feeding studies already included conjugated forms. There are no changes to the residue definitions in plant commodities being proposed at this time.

Currently, the residue definition for drinking water (for risk assessment) is tebuconazole.

3.2.1 Determination of acute reference dose (ARfD)

To estimate acute dietary risk (1 day), the dietary DNT study in rats with a no observed adverse effect level (NOAEL) of 8.8 mg/kg bw/day was selected for risk assessment. At the Lowest Observed Adverse Effect Level (LOAEL) of 22 mg/kg bw/day, decreased auditory startle response at PND 23 in both sexes combined, decreased pre-weaning pup body weight and an equivocal decrease in brain weight in males was observed. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability were applied. As discussed in the *Pest Control Products Act* Hazard Characterization section, the PCPA factor was reduced to threefold. Thus, the composite assessment factor (CAF) is 300.

The ARfD is calculated according to the following formula:

$$\text{ARfD} = \frac{\text{NOAEL}}{\text{CAF}} = \frac{8.8 \text{ mg/kg bw}}{300} = 0.03 \text{ mg/kg bw of tebuconazole}$$

3.2.2 Acute dietary exposure and risk assessment

The acute dietary risk was calculated considering the highest ingestion of tebuconazole that would be likely on any one day, and using food and drinking water consumption and residue values. The expected intake of residues is compared to the ARfD, which is the dose at which an individual could be exposed on any given day and expect no adverse health effects. When the expected intake of residues is less than the ARfD, the acute dietary exposure has been shown to be acceptable.

Acute food residue estimates for tebuconazole were based on the maximum residues obtained from the available monitoring data from CFIA (2013−2017) and PDP (2014−2018). Where no monitoring data were available from CFIA and PDP or the sample size was small (that is, <100 samples), the highest average field trial residue values from crop field trials were used. Canadian MRLs, American tolerances or Codex MRLs were included when neither monitoring data nor crop field trial data were available. All commodities were assumed to be 100% treated. Residue refinements using acute percent crop treated information were not warranted at this time (because drinking water from groundwater sources was the risk driver). Default and experimental food processing factors were applied for relevant processed commodities. The assessment considered all foods that may potentially be treated with tebuconazole including imported foods that may be treated outside of Canada.

Residues in drinking water were estimated using environmental concentrations modelling discussed in Section 3.3.

The acute dietary risk assessment was conducted for the general population and all population subgroups. Acute risks for all populations were shown to be acceptable for exposure from food alone at less than 71% of the ARfD. However, when exposure from drinking water was considered, acute risks from drinking water exposure alone were not shown to be acceptable (that is greater than 100% of the ARfD). Infants represented the highest exposed subpopulation at 146% of the ARfD. Residues in drinking water were estimated based on the maximum cumulative rate on turf (3.10 kg a.i./ha/year). In order to mitigate potential risk from drinking water exposure, residues in drinking water at different yearly cumulative rates on turf were considered. Acute risks from drinking water alone were shown to be acceptable at a cumulative rate of 1.44 kg a.i./ha/year. Acute risks from combined food and drinking water exposure at the cumulative rate of 1.44 kg a.i./ha/year were also shown to be acceptable (<87% of the ARfD).

Therefore, for the purposes of risk mitigation from potential drinking water exposure and risks, it is proposed to reduce the cumulative application rate for turf from 3.10 kg a.i./ha/year to 1.44 kg a.i./ha/year (current label directions do not specify this lower cumulative rate).

The dietary risk estimates are presented in Appendix IV.

3.2.3 Determination of acceptable daily intake (ADI)

To estimate risk from repeated dietary exposure to tebuconazole, the results from the one-year dog studies were selected for risk assessment. Two 1-year dog studies were available for the assessment of chronic dietary exposure and the NOAEL from the study with a narrower dose

range was selected. The most relevant NOAEL was 3 mg/kg bw/day, based on hypertrophy in the adrenal zona fasciculata and the presence of fatty vacuoles in the adrenal zona glomerulosa cells (increase in sized and number) at the LOAEL of 4.4 mg/kg bw/day.

Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability were applied. As discussed in the *Pest Control Products Act* Hazard Characterization section, the PCPA factor was reduced to onefold when using the one-year dog study. Thus, the CAF is 100.

The acceptable daily intake (ADI) proposed is calculated according to the formula:

$$\text{ADI} = \frac{\text{NOAEL}}{\text{CAF}} = \frac{3 \text{ mg/kg bw/day}}{100}$$

$$= 0.03 \text{ mg/kg bw/day tebuconazole}$$

This ADI provides a margin of > 2800 to the NOAEL for liver tumours observed in male and female mice in a dietary oncogenicity study, a margin of 1000 to the NOAEL for malformations observed in the mouse gavage developmental study in the presence of maternal toxicity, and a margin of 300 to the NOAEL for effects on auditory startle observed in the rat DNT study in the absence of maternal toxicity.

3.2.4 Chronic dietary exposure and risk assessment

Generally, the chronic dietary risk (from food and drinking water) is calculated using average consumption of different foods and drinking water, and the average residue values on those foods and drinking water. The estimated exposure was then compared to the ADI, which is an estimate of the level of daily exposure to a pesticide residue that, over a lifetime, is believed to have no significant harmful effects. When the estimated exposure is less than the ADI, the chronic dietary exposure is shown to be acceptable.

Chronic food residue estimates for tebuconazole were based on the average residues obtained from the available monitoring data from CFIA (2013−2017) and PDP (2014−2018). Where no monitoring data were available from CFIA and PDP or the sample size was small (that is, < 100 samples), the median residue values from crop field trials were used. Canadian MRLs, American tolerances or Codex MRLs were included when neither monitoring data nor crop field trial data were available. Updated percent crop treated information (both Canadian and American) was used for the chronic risk assessment. Default and experimental food processing factors were applied for relevant processed commodities. The assessment considered all foods that may potentially be treated with tebuconazole including imported foods that may be treated outside of Canada.

Residues in drinking water were estimated using environmental concentrations modelling discussed in Section 3.3.

The chronic dietary risk assessment was conducted for the general population and all population subgroups. Chronic dietary risks were shown to be acceptable for all populations at less than 33% of the ADI. This risk estimate is based on exposure following the risk mitigation required in order to have acceptable acute dietary risks, that is, reduction of the cumulative application rate for turf from 3.10 kg a.i./ha/year to 1.44 kg a.i./ha/year. (See Section 3.2.2).

The dietary risk estimates are presented in Appendix IV.

3.2.5 Cancer assessment

An increase in liver tumours, was observed in mice following prolonged dosing; however, the proposed MOA was supported by the submitted studies and a threshold approach to risk assessment was considered appropriate for these tumours.

Therefore, the endpoints selected for non-cancer risk assessment are protective of carcinogenic potential.

3.3 Exposure from drinking water

3.3.1 Concentrations in drinking water

The estimated environmental concentrations (EECs) in potential sources of drinking water were modelled for tebuconazole only. The EECs were calculated for surface water and groundwater using the Pesticide Water Calculator model (PWC, version 1.52). The Level 1 modelling used standard scenarios and a conservative use pattern with regard to application rates and timing. All scenarios were run for 50 years. Level 1 EECs are presented in Table 1. Acute dietary risks were not shown to be acceptable when using Level 1 EECs from use on turf to determine exposure from drinking water. Refined Level 2 modelling was therefore conducted.

Table 1 Estimated Environmental Concentrations of tebuconazole in potential sources of drinking water

Use pattern	Groundwater (µg a.i./L)		Surface Water (µg a.i./L)	
	Daily[1]	Yearly[2]	Daily[3]	Yearly[4]
Level 1, for use on crops: four applications of 126 g a.i./ha, yearly total of 504 g a.i./ha	87	87	16	4.9
Level 2, for use on turf: 1536 + 782 + 782 g a.i./ha, at 14-day interval, yearly total of 3100 g a.i./ha	228	228	87	65

1 90th percentile of daily average concentrations
2 90th percentile of 365-day moving average concentrations
3 90th percentile of the peak concentrations from each year
4 90th percentile of yearly average concentrations

To refine EECs in groundwater from tebuconazole uses on turf, the modelling was expanded to separately consider the labelled diseases on turf in order to further inform the acute dietary risk assessment. This result is presented in Table 2.

Table 2 Level 2 Estimated Environmental Concentrations of tebuconazole in groundwater, from tebuconazole uses on turf

Use pattern	Groundwater (µg a.i./L)	
	Daily[1]	Yearly[2]
snow mould: 1 application of 1440 g a.i./ha	124	125
other labelled diseases: yearly total of 3100 g a.i./ha	228	228

[1] 90th percentile of daily average concentrations
[2] 90th percentile of 365-day moving average concentrations

3.3.2 Drinking water exposure and risk assessment

Exposure from drinking water and food sources were combined to determine the total dietary exposure and risk. Refer to Sections 3.2.2 and 3.2.4 for the results of the acute and chronic dietary exposure and risk assessments.

3.4 Occupational and non-occupational risk assessment

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

3.4.1 Toxicology reference values for occupational and non-occupational exposure

Short-, intermediate-, and long-term dermal and inhalation exposure:

The available 21-day dermal toxicity study and 21-day inhalation toxicity study were not considered appropriate for endpoint selection as they did not assess the relevant endpoints of concern (for example, offspring effects). For short-, intermediate- and long-term dermal and inhalation risk assessment in all populations, the rat developmental neurotoxicity study with a NOAEL of 8.8 mg/kg bw/day was selected. At the LOAEL of 22 mg/kg bw/day, observations included decreased auditory startle response at PND 23 in both sexes combined, decreased pre-weaning pup body weight and an equivocal decrease in brain weight in males. For occupational risk assessment, the target MOE is 300, which includes uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability, and a factor of threefold for the reasons outlined in the *Pest Control Products Act* Hazard Characterization section. The selection of this study and MOE is considered to be protective of all populations, including nursing infants and the unborn children of exposed female workers.

For residential risk assessment, the target MOE is 300, which includes uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability. The PCPA factor was reduced to threefold for the reasons outlined in the *Pest Control Products Act* Hazard Characterization section. The selection of this study and MOE is considered to be protective of all populations.

Combined inhalation and dermal:

To conduct a combined dermal and inhalation occupational exposure assessment, the NOAEL of 8.8 mg/kg bw/day from the rat dietary DNT study based on decreased auditory startle response at PND 23 in both sexes combined, decrease pre-weaning pup body weight and an equivocal decrease in brain weight in males, was selected.

The target MOE of 300 selected includes a 10-fold uncertainty factor for interspecies extrapolation, a 10-fold uncertainty factor for intraspecies variability, and a factor of threefold for the reasons outlined in the *Pest Control Products Act* Hazard Characterization section. The selection of this study and MOE is considered to be protective of all populations, including nursing infants and the unborn children of exposed female workers.

Short- and intermediate-term non-dietary incidental oral ingestion:

For assessment of short- and intermediate-term non-dietary (incidental) oral exposure to children, the NOAEL of 8.8 mg/kg bw/day from the rat dietary DNT study was selected for risk assessment. At the LOAEL of 22 mg/kg bw/day, effects included decreased auditory startle response at PND 23 in both sexes combined, decreased pre-weaning pup body weight and an equivocal decrease in brain weight in males.

The target MOE of 300 was selected which includes 10-fold for interspecies extrapolation, 10-fold for intraspecies variability, as well as a factor of threefold for the reasons outlined in the *Pest Control Products Act* Hazard Characterization section.

Dermal absorption:

Dermal absorption studies were on file (PMRA# 580258, 1865243, 2990781), and were re-examined to ensure current policies and standards were met. A dermal absorption value of 13% was used for tebuconazole risk assessments.

Cancer assessment:

See Section 3.2.5.

3.4.2 Non-occupational exposure and risk assessment

Non-occupational (residential) risk assessment involves estimating risks to the general population, including adults, youth, and children, during or after pesticide application.

The USEPA has generated standard default assumptions for developing residential exposure assessments for both applicator and postapplication exposures when chemical- and/or site-specific file data are limited. These procedures may be used in the absence of, or as a supplement to, chemical- and/or site-specific data and generally result in high-end estimates of exposure. These procedures relevant to the tebuconazole re-evaluation are outlined in the 2012 USEPA Standard Operating Procedures (SOP) for Residential Pesticide Exposure Assessments (PMRA# 2409268) under the following sections:

Section 3: Lawns and Turf

Section 10: Treated Paints and Preservatives

3.4.2.1 Residential applicator exposure and risk assessment

As there are no domestic-class tebuconazole end-use products registered in Canada, a residential applicator exposure risk assessment was not required.

3.4.2.2 Residential postapplication exposure and risk assessment

Residential postapplication exposure occurs when an individual is exposed through dermal, inhalation, and/or incidental oral (non-dietary ingestion) routes as a result of being in a residential environment that has been previously treated with a pesticide. For tebuconazole, this would include postapplication exposure from contact with treated golf course turf and from contact with treated wood.

Residential postapplication exposure to tebuconazole is expected to be intermittent short-term in duration (that is, less than 30 days of exposure). It was assumed that individuals would enter previously treated areas on the same day the pesticide is applied. For these scenarios, adults (> 16 years old), youth (11 < 16 years old), and children (6 < 11 years old, 1 < 2 years old) were chosen as the index lifestages to assess based on behavioral characteristics and the quality of the available data.

The following scenarios were assessed for short-term postapplication exposure following the commercial application of products containing tebuconazole in residential areas:

- Adults, youth (11 < 16 years old), and children (6 < 11 years old) dermal exposure resulting from exposure to treated golf course turf.
- Adult dermal exposure resulting from contact with treated wood.
- Children (1 < 2 years old) dermal and incidental oral exposure resulting from contact with treated wood.

Postapplication inhalation exposure and risk assessment

Inhalation is not considered to be a significant route of exposure for people entering or contacting treated areas following application to golf course turf or using treated wood due to the combination of the low vapour pressure of tebuconazole and the expected dilution in outdoor air. In addition, for golf courses, any spray droplets in the air would be expected to have settled when entry is permitted and residues have dried.

Postapplication dermal exposure and risk assessment

Exposure is expected to be predominately dermal. Postapplication dermal exposure to treated golf course turf was calculated using activity-specific transfer coefficients (TCs), estimated turf transferable residues (TTR) and exposure times from the USEPA Residential SOPs (2012) for golfing. A TC is a factor that relates dermal exposure to the TTR and is based on the amount of treated surface that a person contacts while performing activities in a given period (usually expressed in units of cm^2 per hour). It is specific to a particular population and activity/location (for example, adults golfing on turf). Chemical-specific TTR data were not available for tebuconazole. Therefore, a default peak of 1% of the application rate was used. For the postapplication assessment, the maximum rate of 1536 g a.i./ha was used to calculate exposure.

To determine postapplication exposure from activities conducted on treated wood, a residue study (PMRA# 2486047) was used to estimate dislodgable residues of tebuconazole from pressure treated lodgepole pine lumber. The day 0 average value of 0.858 $\mu g/cm^2$ was used to estimate the amount of tebuconazole that is dislodged from treated wood.

For the residential postapplication dermal risk assessments, target MOEs were achieved and risks were shown to be acceptable for all scenarios and lifestages. The results of the dermal risk assessments are presented in Appendix V Tables 1 and 2.

Incidental oral exposure and risk assessment

Incidental oral exposure occurs when pesticide residues are transferred to the hands of children playing on treated surfaces and are subsequently ingested as a result of hand-to-mouth (HtM) transfer. Residues can also be transferred to objects in treated areas (for example, a child's toy) and subsequently ingested as a result of object-to-mouth (OtM) transfer. Incidental oral exposure is expected to occur from hand-to-mouth activity by children (1 < 2 years old) following contact with treated wood.

Since very young children (1 < 2 years) are typically not expected to be golfing, an incidental oral exposure risk assessment is not required for golf course turf.

For incidental oral exposure, calculated MOEs exceeded the target MOE and risks were shown to be acceptable. Short-term incidental oral exposure estimates are presented in Appendix V, Table 3.

3.4.3 Occupational exposure and risk assessment

There is potential for exposure to tebuconazole in occupational scenarios as follows:

- Workers handling tebuconazole products during mixing/loading and application activities for agriculture, turf, seed treatment and wood treatment
- Workers entering treated agricultural areas and treated turf
- Workers handling and planting treated seeds
- Workers handling treated wood

3.4.3.1 Agriculture and turf applicator exposure and risk assessment

Workers applying tebuconazole products have the potential for short- to intermediate-term (< 30 days to < 6 months) durations of exposure. The following scenarios were assessed:

- Open mixing/loading of liquids
- Aerial application
- Airblast application
- Groundboom application
- Handheld airblast/mistblower (HH AB/MB) application
- Mixing/loading and application using backpack sprayer
- Mixing/loading and application using manually-pressurized handwand (MPHW)
- Mixing/loading and application using mechanically-pressurized handgun (MPHG)
- Turf gun sprayer application

The exposure estimates for mixer/loaders and applicators are based on different levels of personal protective equipment (PPE) and engineering controls:

- Baseline PPE: long-sleeved shirt, long pants, and chemical-resistant (CR) gloves
- Mid-level PPE: coveralls over long-pants and long-sleeved shirt, and CR gloves
- Maximum PPE: CR coveralls (with a CR hood) over long-sleeved shirt and long pants, CR gloves, socks, CR footwear, and a respirator

No appropriate chemical-specific handler exposure data were available for tebuconazole. Therefore, dermal and inhalation exposures for occupational applicators were estimated using data from the Pesticide Handlers Exposure Database (PHED), the Agricultural Handler Exposure Task Force (AHETF), and the Outdoor Residential Exposure Task Force (ORETF).

The PHED version 1.1 is a compilation of generic mixer/loader and applicator passive dosimetry data with associated software which facilitates the generation of scenario-specific exposure estimates based on formulation type, application equipment, mix/load systems and level of personal protective equipment. PHED data were used to assess exposure to MPHW, backpack, and MPHG.

The AHETF was formed in 2001 with the objective of providing more up-to-date generic exposure data to replace the data currently being used in PHED. AHETF data were used to assess exposure to mixing and loading, as well as groundboom, airblast and aerial applications. ORETF data was used to assess the turf-gun scenario.

In addition, two worker exposure studies were available to PMRA that monitored workers when applying pesticides using application equipment representative of HH AB/MB. One study (PMRA# 2873196) monitored only dermal exposure, while the other study (PMRA# 2905452) monitored only inhalation exposure. These studies were reviewed by the PMRA and the calculated dermal and inhalation unit exposures were determined to be acceptable for assessing applicator exposure when using this type of equipment.

Inhalation exposures were based on light inhalation rates (17 L/min) except for backpack and handheld airblast/mistblower applicator scenarios, which are based on moderate inhalation rates (27 L/min). Aerial application was based on sedentary inhalation rates (8.3 L/min).

While there are limitations in the use of generic data, these exposure data represent the most reliable information currently available.

The calculated dermal, inhalation, and combined MOEs are greater than the target MOE at baseline PPE for all scenarios except application using a MPHG and application using a handheld airblast/mistblower. Mid-level PPE (coveralls over long pants and long-sleeved shirt, and CR gloves) is proposed for mixing, loading, and application using a mechanically-pressurized handgun and maximum PPE is proposed for application using a HH AB/MB. With this proposed mitigation, risks were shown to be acceptable. The mixer, loader, and applicator exposure and risk estimates are summarized in Appendix V, Table 4.

3.4.3.2 Agricultural and turf postapplication exposure and risk assessment

The occupational postapplication risk assessment considered exposures to workers who enter treated sites to conduct agronomic activities involving foliar or turf contact (for example, scouting). Based on the registered use pattern, there is potential for short- to intermediate-term (< 30 days to < 6 months) postapplication exposure to tebuconazole residues for workers.

Exposure would be predominantly dermal for workers performing postapplication activities in crops, sod farms, and golf courses following spray application. Based on the vapour pressure of tebuconazole, inhalation exposure would be low, provided that the minimum restricted-entry interval is followed.

Potential dermal exposure to postapplication workers was estimated using activity-specific TCs and dislodgeable foliar residue (DFR) or TTR data. The DFR or TTR refers to the amount of residue that can be transferred from a surface, such as the leaves of a plant or turf. The TC is a measure of the relationship between exposure and DFR/TTR for individuals engaged in a specific activity and is calculated from data generated in field exposure studies. The TCs are specific to a given crop and activity combination (for example, harvesting asparagus, mowing treated turf) and reflect standard agricultural work clothing worn by adult workers.

Activity-specific TCs from the Agricultural Re-Entry Task Force (ARTF) were used. For more information about estimating worker postapplication exposure, refer to Health Canada's Regulatory Proposal PRO2014-02 *Updated Agricultural Transfer Coefficients for Assessing Occupational Exposure to Pesticides*.

There were no chemical-specific DFR or TTR studies submitted to the PMRA for the re-evaluation of tebuconazole; therefore, the following standards were used:

- A standard peak DFR value of 25% of the application rate with a dissipation rate of 10% per day
- A standard peak TTR value of 1% of the application rate with a daily dissipation rate of 10% per day

Health Canada's Science Policy Note SPN2014-02, Estimating Dislodgeable Foliar Residues and Turf Transferable Residues in Occupational and Residential Postapplication Assessments presents further details on the derivation and use of these standards for pesticide assessments.

For workers entering a treated site, restricted-entry intervals (REIs) are calculated to determine the minimum length of time required before workers can safely enter after application. An REI is the duration of time that must elapse before residues decline to a level at which risks are shown to be acceptable (that is, performance of a specific activity that results in exposures above the target MOE).

The calculated MOEs were above the target MOE, and risks were shown to be acceptable for all postapplication activities at the minimum REI except for harvesting (seedling production) in Short Rotation Intensive Culture (SRIC) (spruce and willow) crops. An REI of 1 day is proposed for harvesting (seedling production) in SRIC crops and an REI of 12 hours is proposed for all other crop activities. A re-entry interval of "until sprays have dried" is proposed for golf course turf. The results of the postapplication risk assessment are summarized in Appendix V, Table 5.

3.4.3.3 Commercial and on-farm seed treatment exposure and risk assessment

Exposure to workers treating seeds and/or handling and planting treated seed is expected to be short- to intermediate-term (< 30 days to < 6 months) in duration. The following seed treatment scenarios were assessed:

- Commercial liquid or wettable powder (in water soluble packaging) treatment of wheat, barley, oats, rye, triticale, and corn. Activities may include treating, bagging, sewing, stacking, tagging, and cleaning. Includes commercial facilities and mobile treaters.
- On-farm liquid or wettable powder (in water soluble packaging) treatment of wheat, barley, oats, rye, and triticale followed by planting treated seed.
- Planting of commercially treated or imported seed (activities may include loading) for wheat, barley, oat, rye, triticale, and corn.

Surrogate commercial and on-farm treatment exposure studies, as well as exposure studies for planting treated seeds, were used to estimate worker exposure (see Appendix V, Tables 6, 7 and 8). These are the best available data for the assessment of worker exposure during the treatment and handling of seeds.

For the commercial treatment of wheat, barley, oat, rye, and triticale seed, baseline PPE is proposed for treater (mixer/loader/applicator) activities (with open or closed M/L) as well as bagger/sewer/stacker activities. For clean-up and repair activities, CR coveralls over a long-sleeved shirt, long pants, and CR gloves are proposed. For the commercial treatment of corn seed, baseline PPE is proposed for all activities, with closed mix/load and closed transfer.

For planting of commercially treated or imported seeds, calculated MOEs exceeded the target MOE for all seed types with the following proposed PPE. For planting of treated corn, long-sleeved shirt, long pants, and CR gloves and a closed-cab tractor is proposed. For planting of wheat, barley, oat, rye, and triticale, coveralls over long-sleeved shirt and long pants, and CR gloves and a closed-cab tractor is proposed.

For the on-farm seed treatment and planting risk assessment, baseline PPE with an open mix/load system is proposed for all activities. Although a closed-cab planter was used in the study to estimate exposure during planting, the calculated MOEs well exceeded the target MOE providing a sufficient margin to address the protection that would be provided by a closed-cab. As such, closed-cab mitigation measures are not required for this scenario.

Using the proposed PPE and engineering controls, target MOEs were met and risks were shown to be acceptable for all seed treatment scenarios. The results of the seed treatment risk assessment are summarized in Appendix V, Tables, 6, 7 and 8.

3.4.3.4 Heavy duty wood preservatives

Exposure to tebuconazole from its use in industrial settings as a heavy duty wood preservative is expected to be intermittent (a few minutes daily or once a week) over an intermediate- to long-term duration (that is > 30 days to several months). The following scenarios were assessed:

- Exposure to Treatment Operators:
    - Operating and inspecting system controls and components; set-up and operation of bulk tank unloading systems; opening and closing treatment vessel doors; cleaning cylinder doors, gaskets, floors, and latches; and performing routine maintenance on cylinders, tanks, valves, and other system components
- Exposure to Wood Handlers:
    - Operating self-propelled vehicles or automated equipment to transfer wood products to and from trams and to move charges in/out of treatment cylinders and to drip, stacking, and storage areas; handling of leads and bands (where used); culling and end-marking of treated wood products; positioning of drip pad drawbridges (where used); cleaning and set-up of trams/transfer equipment; and waste removal from and cleaning of wood-handling equipment, drip trenches and pads, and tank “farms”

A chemical-specific passive dosimetry study (PMRA# 2444348) was used to estimate exposure to individuals treating wood with tebuconazole. Since most individuals in the study wore long sleeves, long pants, and gloves, these data are considered to be representative of an individual wearing baseline PPE.

The results of the wood treatment risk assessment are summarized in Appendix V Table 9. Target MOEs were exceeded and risks were shown to be acceptable at baseline PPE (long-sleeved shirt, long pants, and CR gloves).

There are no available data to quantify potential postapplication exposure to downstream industrial workers and secondary workers handling treated wood. Exposure is expected to be low given the occupational hygiene standards in these workplaces which require safe work conditions, including chemical exposures and that many of these downstream processes are highly automated, which would also help to minimize exposure.

For all personnel who work with preservatives for treatment or for downstream tasks, additional PPE beyond baseline PPE is required, as per the "Recommendations for Design and Operation of Wood Preservation Facilities, 2013 Technical Recommendations Document (TRD)" which is enforced by Environment and Climate Change Canada. The PPE requirements in the Technical Recommendations Document (TRD) are task-based and are dependent on whether workers are working under dry conditions, when there is risk of getting wet from the preservative, or in an enclosed environment with pesticides.

3.5 Aggregate risk assessment

Aggregate exposure is the total exposure to a single pesticide that may occur from dietary (food and drinking water), residential, and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal and inhalation).

3.5.1 Toxicology reference values for aggregate risk assessment

Short- and intermediate-term aggregate exposure to tebuconazole may be comprised of food, drinking water, residential postapplication dermal and incidental oral exposure. The available dermal toxicity studies were not considered appropriate for endpoint selection, as they did not assess the relevant endpoints of concern (decreased auditory startle response and brain weight in offspring). Therefore, an oral study was used as a surrogate. For oral and dermal aggregate risk assessment of the general population (including pregnant women, infants, and children), the selected endpoint was decreased auditory startle response at PND 23 in both sexes combined, decrease pre-weaning pup body weight and an equivocal decrease in brain weight observed in males at a dose level of 22 mg/kg bw/day in the rat dietary DNT study. The NOAEL in this study was 8.8 mg/kg bw/day. In the absence of an appropriate dermal study to assess this endpoint, this oral study is used for both the oral and dermal routes of exposure.

For the oral and dermal routes of exposure, the target MOE of 300 selected includes a 10-fold uncertainty factor for interspecies extrapolation, a 10-fold uncertainty factor for intraspecies variability and a PCPA factor of threefold for the reasons outlined in the *Pest Control Products Act* Hazard Characterization section.

3.5.2 Aggregate exposure and risk assessment

In an aggregate risk assessment, the combined potential risk associated with food, drinking water and various residential exposure pathways is assessed. A major consideration is the likelihood of co-occurrence of exposures and durations of exposures. Additionally, only exposures from routes that share common toxicological effects are aggregated.

For tebuconazole, the following scenarios were expected to co-occur:

- Postapplication dermal exposure (adults, youth (11 to < 16 years old) and children (6 to < 11 years old)) from postapplication activities in treated golf course turf + chronic dietary (food and drinking water).
- Postapplication dermal exposure (adults) from postapplication activities with and on treated wood + chronic dietary (food and drinking water).
- Postapplication dermal exposure (children (1 < 2 years old)) + incidental oral exposure from postapplication activities on treated wood + chronic dietary (food and drinking water).

The aggregate risk was based on the chronic dietary exposure from the cumulative rate of 1.44 kg a.i./ha per year on turf required to mitigate dietary exposure.

The calculated MOEs for aggregate risk were above the target MOE of 300 for all scenarios and populations, except for children on treated wood, which had an MOE of 260. Although the aggregate MOE for children did not meet the target MOE for this scenario, it was considered that due to the conservatisms of the risk assessment (that is, upper bound estimates of potential exposure and risk), the calculated aggregate MOE for children is acceptable. The aggregate risks in children were driven by dermal exposure, as opposed to incidental oral exposure. The conservatisms in the risk assessment include a) using transferable residue estimates from wood on the day of application before any dissipation or weathering has occurred and, b) a methodology for determining transferable residues that would result in high values in comparison to actual conditions, that is total extracts from a cloth wiped over a relatively large surface area of wood.

Therefore, aggregate risks are considered to be acceptable when the proposed mitigation measures from the dietary risk assessment for tebuconazole are considered. The results of the risk assessment are summarized in Appendix VI, Table 1.

3.6 Cumulative risk assessment

Tebuconazole is a triazole-based fungicide which belongs to a group of pesticides known as the conazole fungicides. These pesticides are structurally similar and contain a triazole moiety. As a result of these structural similarities, conazole fungicides share common metabolites including 1,2,4-triazole and triazole conjugates. Variable toxicological responses are found for conazoles including hepatotoxicity and hepatocarcinogenicity in mice, thyroid tumours in rats, as well as developmental, reproductive, and neurological effects in rodents.

No clear common mechanism of toxicity has been confirmed on which to base a cumulative risk assessment for any of these effects. However, a cumulative risk assessment for the common triazole metabolites will be addressed in a separate assessment.

3.7 Health incident reports

As of 13 November 2020, 39 human and 15 domestic animal incident reports were submitted to the PMRA.

In human incidents, eighteen were considered to be related to pesticide exposure. In these incidents, minor to moderate effects such as eye or skin irritation/burning, paresthesia and gastrointestinal effects (for example, nausea and diarrhea) were reported. Exposure was to products with multiple active ingredients and mostly occurred through the skin or eyes following accidental contact via splashes or sprays during the use of the product; other exposure scenarios reported in incidents included accidental ingestion, pesticide spills due to equipment failure and drift from an aerial application. The remaining incident reports, including the 2 serious American human incidents, did not contain sufficient information to determine an association to the pesticide exposure or were unrelated or unlikely to be related to the exposure. The labels of tebuconazole products already contain appropriate hazard signal words and precautionary labelling statements, and/or require personal protective equipment (PPE) to reduce the likelihood of exposures following use of the product. Given this and the relatively low severity of symptoms in the minor or moderate cases, as well as the accidental nature of the reported incidents, no additional mitigation is recommended as a result of these incidents.

Eight of the domestic animal incidents were considered to be related to pesticide exposure. Animals were exposed as a result of ingesting plants treated with a product containing multiple active ingredients including tebuconazole and they experienced minor or moderate effects such as lethargy, vomiting, ataxia, agitation, and anorexia. The remaining incident reports, including 3 animal deaths (2 United States, 1 Canada), were unrelated or unlikely to be related to the exposure. Given the relatively low severity of the reported symptoms and the accidental nature of the reported exposures, no additional mitigation is recommended as a result of these incidents.

3.8 Human health conclusion

Based on the current use pattern of tebuconazole, human health risks were shown to be acceptable for all uses with proposed risk mitigation measures. The risk mitigation proposed include: a reduction in the maximum yearly cumulative application rate on turf, rotational plant back intervals (for consistency across product labels), personal protective equipment, engineering controls and restricted-entry intervals.

4.0 Environmental assessment

4.1 Fate and behaviour in the environment

A summary of the environmental fate of tebuconazole is presented in Appendix VII, Table 1.

Tebuconazole is soluble in water. Based on a low vapour pressure and Henry's law constant, tebuconazole is relatively non-volatile from moist soil and water surfaces and entry into the atmosphere is not expected. If tebuconazole enters the air, it is not expected to accumulate or be transported medium- or long-range distances in the atmosphere.

Tebuconazole is stable to hydrolysis and direct photolysis. Indirect aqueous photolysis enhanced by photosensitizers in the environment may contribute to the dissipation of tebuconazole in the photic zone of water bodies.

Based on laboratory studies, tebuconazole is persistent in soil. Two minor transformation products, 1,2,4-triazole and HWG 1608-5 enol, were reported in aerobic soil and mineralization to carbon dioxide was negligible. In soil, tebuconazole has a strong propensity to associate with soil particles over time. In contrast to laboratory results, dissipation times in terrestrial field studies were significantly shorter suggesting that tebuconazole may be less persistent under actual field conditions. Longer-term field trials of three to six years indicated that carry-over of tebuconazole in soil to subsequent growing seasons was not significant.

In aerobic aquatic systems, dissipation of tebuconazole from the water phase occurred slowly through degradation and adsorption to the sediment. Tebuconazole is persistent in aerobic water/sediment systems with only minor transformation products produced. Similar to soil, tebuconazole was more persistent in aquatic laboratory studies than in an outdoor mesocosm study.

Tebuconazole has low to moderate potential for mobility in soil. The GUS score, criteria of Cohen et al., and modelled concentrations in groundwater suggest that tebuconazole could move downward in soil. However, other evidence from laboratory data (adsorption/desorption, soil thin-layer chromatography, and soil column leaching) and field dissipation studies (no detections below 30 cm) indicated tebuconazole has a propensity to bind to soil. Tebuconazole is moderately persistent under field conditions. Data, largely from the United States, indicates tebuconazole is rarely detected in groundwater (< 1% of 7146 groundwater samples). The potential for leaching of tebuconazole to groundwater is expected to be low.

Tebuconazole is not expected to bioaccumulate in organisms.

4.2 Environmental risk characterization

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse ecological effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. Estimated environmental concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using models, which take into consideration the application rate(s), chemical

properties and environmental fate properties, including the dissipation of the pesticide between applications (Appendix VII, Tables 2–9). 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 (that is, protection at the community, population, or individual level). Summaries of toxicity data for both terrestrial and aquatic non-target organisms are presented in Appendix VII, Tables 10–11. The endpoints for each taxa that were considered to be appropriate for use in the risk assessment are presented in Appendix VII, Table 12.

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (for example, direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the RQ is then compared to the level of concern (LOC = 1 for most species, 0.4 for acute risk to pollinators, and 2 for glass plate studies, using the standard beneficial arthropod test species (*Typhlodromus pyri*, and *Aphidius rhopalosiphi*)). If the screening level RQ is below the level of concern, the risk is considered negligible and no further risk characterization is necessary. If the screening level RQ is equal to or greater than the LOC, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats), and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

The representative use patterns for tebuconazole that were considered in the environmental risk assessment and selected to represent conservative scenarios are presented in Appendix VII, Table 13.

4.2.1 Risks to terrestrial organisms – Agricultural uses

A summary of EECs, toxicity endpoints and RQs for terrestrial organisms is presented in Appendix VII, Tables 14- 25.

4.2.1.1 Terrestrial invertebrates

The screening level risk assessment indicated acute and chronic risks to earthworms and soil-dwelling arthropods from the use of tebuconazole are acceptable.

Acute and chronic risks to honey bees from the use of tebuconazole on soybean, field corn (seed treatment), asparagus and SRIC poplar/willow are acceptable (Appendix VII, Table 15). This is supported by the results of a semi-field tunnel study with honeybees which demonstrated no adverse effects at the colony level when tebuconazole was applied at 250 g a.i./ha on a bee-attractive flowering crop. Potential risks were identified for bees at the application rate used on

turf (1536 g a.i./ha). However, available information indicates that turf is not attractive to bees, thus reducing the potential for exposure. Weed management on golf courses and sod farms is likely to significantly reduce the presence of flowering plants in turf. In addition, the screening level assessment indicated no risk to bumblebees (non-apis bee) on the basis of acute oral and acute contact exposure to 1536 g a.i./ha. The off-field acute and chronic risk to adult or larval bees resulting from exposure to spray drift of tebuconazole is considered to be negligible at the highest registered rate (Appendix VII, Tables 15 and 16). Based on the available information, risks to pollinators (Apis and non-apis bees) from all uses of tebuconazole are acceptable and no mitigation measures are required.

A refined assessment was conducted for adult beneficial arthropods (Appendix VII, Tables 17 and 18). A semi-field study using ladybird (*C. septempunctata*) and application of tebuconazole (Folicur EW 250) at a rate of 375 g a.i./ha supported that, with the exception of turf, current uses of tebuconazole on crops do not cause harm to beneficial arthropods in-field. For turf (uses on golf courses and sod farms), the LOC was exceeded on-field only. It is expected that turf is less attractive to beneficial arthropods due to a lack of different species of plants other than grass, thus reducing the potential for exposure. As a result, risks are considered acceptable. However, a label statement to inform users of the potential for toxicity to beneficial arthropods on the label of formulated products used on turf is proposed.

4.2.1.2 Birds and mammals

Tebuconazole does not pose risks of concern to birds on an acute basis (on- and off-field) or on a chronic basis off-field. The level of concern was exceeded for all sizes of birds on-field based on reproductive effects for application of tebuconazole at the currently registered rate on turf. Refinement of the risk assessment (using mean residues and the reproductive LOEL) indicated that for on-field exposure for birds the LOC was still exceeded, but RQs were <5 (Appendix VII, Tables 19–21). Exposure to large birds that may consume grass is the most likely scenario, but results in the lowest RQ (1.2). Risks are considered to be acceptable. However, a label statement to inform users of the potential for toxicity to birds is proposed on the label of formulated products used on turf.

For mammals, the screening level assessment indicated that the on-field risk quotients exceeded the LOC for all mammal size classes based on reproductive effects from application of tebuconazole on turf only (Appendix VII, Table 22). Refinement of the risk assessment indicated on-field reproductive RQs for mammals were lower than the LOC from the application on turf (Appendix VII, Table 23); therefore, risks to wild mammals are acceptable and no precautionary label statement is required.

4.2.1.3 Terrestrial plants

The LOC for terrestrial plants is exceeded for both seedling emergence and vegetative vigour when tebuconazole is applied at the rate used on turf (1969.55 g a.i./ha) (Appendix VII, Table 9, 24 and 25). The LOC for terrestrial plants is also exceeded for seedling emergence when tebuconazole is applied on soybean and SRIC poplar/willow. Potential risk to plants was further investigated by taking into consideration exposure from spray drift deposition 1 m downwind from the site of application. The LOC was exceeded for the seedling emergence of terrestrial

non-target plants from the spray drift of tebuconazole when applied as ground boom on turf and as airblast and aerial application on SRIC. To mitigate potential risks, terrestrial spray buffer zones and label statements are required on the formulated products used on turf and SRIC.

4.2.2 Risks to aquatic organisms – Agricultural uses

A summary of endpoints, EECs and risk quotients (screening level and refined assessments) for aquatic organisms is presented in Appendix VII, Table 3, 26–32.

Potential risks to aquatic organisms were identified at the screening level for turf uses and various other crop applications (rates and application methods). The risk assessment was refined to take into account risk to aquatic organisms resulting from exposure to tebuconazole through spray drift and surface runoff into waterbodies.

Spray drift data was used to determine the maximum spray deposit into an aquatic habitat located 1 meter downwind from a treated field. For spray drift, no aquatic risks were identified for ground boom applications to asparagus or soybeans, however potential risks were identified for other ground boom applications, as well as airblast and aerial applications. As a result, aquatic spray buffer zones and mitigative label statements informing users of the potential toxicity of tebuconazole to aquatic organisms will be required.

Modelled EEC values were used to assess risk due to runoff. EECs were calculated for two different water depths, 80 cm and 15 cm, using the Pesticide in Water Calculator (PWC) version 1.52. When compared to aquatic ecotoxicity values, RQs exceeded the LOC for certain aquatic organisms. To reduce the potential for runoff of tebuconazole to adjacent aquatic habitats, precautionary statements for sites with characteristics that may be conducive to runoff and when heavy rain is forecasted are proposed.

4.2.3 Risk characterisation – Wood treatment

The screening level assessment of tebuconazole wood preservative uses followed the 2013 Organisation for Economic Cooperation and Development (OECD) Emission Scenario Document (ESD) for Wood Preservatives methodology. Various exposure scenarios and parameters are described in the OECD ESD. Environmental exposure estimates for wood preservative treatment facilities, including application processes and storage of treated wood prior to shipment, were not considered in this assessment. The existing controls and best management practices in effect for wood treatment plants in Canada, as outlined in the 2013 Technical Recommendations Document - Recommendations for the Design and Operation of Wood Preservation Facilities are expected to mitigate the risks.

The screening level environmental assessment is based on the maximum relevant retention rates for wood treatment listed under the use pattern (see Appendix VII, Table 33); the retention rate is defined as kg of active ingredient retained per cubic meter of wood. Data derived from a treated wood leaching study was used to refine the risk assessment.

Although exposure to non-target organisms may occur in soil through leaching and runoff from wood surfaces treated with tebuconazole, exposure to terrestrial organisms was not considered. For in-service treated wood, the OECD Guidance suggests that the area of potential impact from

treated wood in soil is 10 cm from source. These values suggest that impacts on non-target terrestrial organisms from treated wood uses are limited in area, and population level effects are not expected. As the potential area of exposure is expected to be limited, any potential risks to non-target terrestrial organisms from the use of tebuconazole as a wood preservative are expected to be negligible.

4.2.3.1 Risk to aquatic organisms

In-service uses of tebuconazole-treated wood, where exposure to the aquatic environment is possible, are through above-ground and freshwater contact uses, such as docks, poles and posts. For the screening level assessment, the following exposure scenarios (from OECD guidance) were assessed to represent potential exposure routes for aquatic organisms from treated wood in-service for tebuconazole:

- Exposure of amphibians: Bridge/walkway/dock over shallow pond/lake
- Exposure to other aquatic organisms: Flowing freshwater environment (bridge, walkway or dock over a small waterway). This scenario represented the largest input to the aquatic environment as the ratio of wood to water volume (2.7 m^2m^{-3}) was the most conservative exposure parameter for freshwater exposure.

Default parameter values from the OECD ESD (type and volume of waterbody, wood surface area to water ratios) were used. The screening input values for this assessment are presented in Tables 34 and 35, Appendix VII. Fate and ecotoxicity input parameters were the same as those used for the other uses of tebuconazole.

The conservative screening level assessment assumed 100% of the applied tebuconazole would leach from treated wood surfaces into water and resulted in exceedances of risk. The aquatic risk assessment was refined by using leaching and degradation data to modify aquatic exposure estimates, as well as to account for the fact that only some fraction of leached active ingredient will find its way to adjacent water bodies (default = 50%; not used for bridge/dock scenarios).

Tier I refined risk assessment

A leaching study conducted using wood treated with an end-use product containing tebuconazole (waterborne and solvent-borne Preventol A20, no guarantee provided) was used. When the Tier 1 EECs for the retention rate of 0.268 kg a.i./m^3 (retention rate used in study) were used to assess potential risk, a different OECD scenario for treated sheet piling in a small body of freshwater resulted in the highest EECs and risk quotients. The Tier I assessment indicated potential risk to aquatic invertebrates on a chronic basis (RQ = 59), aquatic vascular plants (RQ = 8) and freshwater fish (acute; RQ = 3) as well as amphibians on both an acute and chronic basis with risk quotients of 2 and 17, respectively (see Appendix VII, Table 36 and 37 for details).

Further risk characterisation

Results of leaching studies (PMRA# 2761505) indicate that by 14 days after treatment, 28.7–37.6% of applied tebuconazole had leached, with leaching rate being rapid over the first 2 days, reaching a steady state by the end of the 14-day test period. Based on this information, the most

relevant endpoints for assessing aquatic risk are expected to be acute endpoints as the period of greatest leaching from treated wood, and subsequently highest exposure to the aquatic environment, occurs within the first two days of immersion. As such, the potential risk indicated at the screening level from chronic exposure is not expected to occur.

Regarding the potential for acute risk to certain aquatic organisms indicated by the Tier 1 assessment, it is expected that the overall impact of any potential exposure to tebuconazole in the aquatic environment will be limited in scope and magnitude. Based on OECD Guidance, the proposed area of potential impact for in-service treated wood uses is 10 m from the source in the waterbody. This suggests impacts on non-target organisms from uses of treated wood are limited in area. In addition, populations of freshwater aquatic organisms outside the affected area would act as a natural reservoir for immigration, emigration and reproduction of freshwater aquatic populations affected. Thus population level effects are not expected. Relevant hazard statements will be required on the product labels.

In summary, risks to aquatic organisms from use of tebuconazole-treated wood are acceptable and relevant hazard and mitigation statements will be proposed for the product labels. Label statements will be consistent as per the Recommendations for the Design and Operation of Wood Preservation Facilities, 2013 Technical Recommendations Document (PMRA# 3079324).

4.2.4 Environmental incident reports

As of 13 November 2020, the PMRA has not received any environmental incident reports associated with tebuconazole.

4.3 Conclusion

Based on the available scientific information, risk to the environment is acceptable when tebuconazole is used according to the revised label directions.

5.0 Value assessment

Tebuconazole is a systemic fungicide registered for use on cereal grains, soybeans, asparagus, short rotation intensive culture poplar and willow, and turfgrass. Due to its protective, curative, and eradicative properties, tebuconazole is of value to agricultural producers and turfgrass managers as it will control several fungal diseases of economic importance on crops, or that can have deleterious effects on turfgrass.

From a value perspective, a reduction of the yearly cumulative application rate for turfgrass for mitigation purposes is expected to have minimal impact on users, since this active ingredient would still be registered for use to manage all listed turfgrass diseases, albeit at a lower maximum rate or number of applications for some products. However, alternative fungicides are registered for all turfgrass pathogens.

Tebuconazole is used to preserve nearly half of the wood for the Canadian domestic market. It is also used in conjunction with other active ingredients that protect against termite damage. Tebuconazole can be used to protect wood installed above ground, and in contact with the ground.

6.0 Pest control product policy considerations

6.1 Assessment of the active ingredient tebuconazole under the Toxic Substances Management Policy (TSMP)

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

During the review process, tebuconazole was assessed in accordance with the PMRA Regulatory Directive DIR99-03[3] and evaluated against the Track 1 criteria. The PMRA has reached the conclusion that tebuconazole does not meet all of the TSMP Track 1 criteria. Please refer to Appendix VII, Table 38 for further information on the TSMP assessment.

Tebuconazole did not form any major transformation products, based on the available information.

6.2 Formulants and contaminants of health or environmental concern

During the review process, contaminants in the active ingredient as well as formulants and contaminants in the end-use products are compared against Parts 1 and 3 of the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern.*[4] The list is used as described in the PMRA Science Policy Note SPN2020-01[5] and is based on existing policies and regulations, including the Toxic Substances Management Policy and Formulants Policy, and taking into consideration the *Ozone-depleting Substances and Halocarbon Alternatives Regulations* under the *Canadian Environmental Protection Act*, 1999 (substances designated under the Montreal Protocol).

The PMRA has reached the conclusion that tebuconazole and its end-use products do not contain any formulants or contaminants identified in the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.[6]

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[3] DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*

[4] SI/2005-114, last amended on June 24, 2020. See Justice Laws website, Consolidated Regulations, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*

[5] PMRA's Science Policy Note SPN2020-01, *Policy on the List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* under paragraph 43(5)(b) of the *Pest Control Products Act*

[6] DIR2006-02, *Formulants Policy and Implementation Guidance Document*

List of abbreviations

°C	degree(s) Celsius
%	percent
↑	increased
↓	decreased
14C	carbon-14
µg	microgram
a.i.	active ingredient
abs	absolute
ADI	Acceptable Daily Intake
AHETF	Agricultural Handlers Exposure Task Force
ALP	alkaline phosphatase
ALT	alanine aminotransferase
AR	applied radioactivity
ARfD	Acute Reference Dose
ARTF	Agricultural Re-entry Task Force
ASAE	American Society of Agricultural Engineers
AST	aspartate aminotransferase
BAF	bioaccumulation factor
BCF	bioconcentration factor
bw	body weight
bwg	body weight gain
CAF	Composite Assessment Factor
CFIA	Canadian Food Inspection Agency
cm	centimeter
CR	Chemical Resistant
d	day
DA	Dermal Absorption
DAT	days after treatment
DDAC	didecyldimethylammonium chloride
DFR	Dislodgeable Foliar Residue
DNT	Developmental Neurotoxicity
DT_{50}	dissipation time 50% (time required to observe a 50% decline in concentration)
dw	dry weight
EC	emulsifiable concentrate
EC_{50}	effective concentration to 50% of the population
EDE	estimated daily exposure
EEC	estimated environmental concentration
F0	parent generation
F1	first generation
F2	second generation
fc	food consumption
g	gram
GD	gestation day
GUS	Groundwater Ubiquity Score
ha	hectare(s)
Hb	hemoglobin

HH AB/MB	Handheld Airblast/Mistblower
hr(s)	hour(s)
kg	kilogram
K_{oc}	organic carbon-water partition coefficient
$K_{oc\text{-}ads}$	adsorption organic carbon-water partition coefficient
K_{ow}	octanol-water partition coefficient
L	litre
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LOC	level of concern
LOAEL	Lowest Observed Adverse Effect Level
LOEC	Lowest Observed Effect Concentration
LOEL	Lowest Observed Effect Level
LR_{50}	lethal rate 50%
M/L/A	Mixer/Loader/Applicator
m	meter
max.	maximum
mg	milligram
MIS	maximum irritation score
mL	millilitre
mm Hg	millimeters of mercury
MOA	mode of action
MOE	Margin of exposure
MPHG	Mechanically pressurized handgun
MPHW	Manually pressurized handwand
MRL	maximum residue limits
N/A	not applicable
NOAEL	No Observed Adverse Effect Level
NOEC	No Observed Effect Concentration
NOEL	No Observed Effect Level
OECD	Organisation for Economic Co-operation and Development
ORETF	Outdoor Residential Exposure Task Force
PCPA	*Pest Control Product Act*
PDP	Pesticide Data Program
PHED	Pesticide Handlers Exposure Database
PMRA	Pest Management Regulatory Agency
PND	Postnatal Day
PPE	Personal Protective Equipment
PWC	Pesticide in Water Calculator
REI	Restricted-Entry Interval
RQ	risk quotient
S9	mammalian metabolic activation system
SOP	standard operating procedures
SRIC	Short rotation intensive culture
SU	Suspension
TC	Transfer coefficient
TEU	Tebuconazole
TSMP	Toxic Substances Management Policy

TTR	Turf transferable residue
UF	Uncertainty factor
USEPA	United States Environmental Protection Agency
WP	wettable powder
wt	weight

Appendix I Registered products containing tebuconazole in Canada[1]

Table 1 Products containing tebuconazole subject to proposed label amendments

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type[2]	Active Ingredient (%, g/L)[3]
25763	Technical grade active ingredient	Bayer CropScience Inc.	Folicur Technical Fungicide	SO	TEU: 97.0%
29409		LANXESS Corp.	Preventol A8 Technical Fungicide	SO	TEU: 95.0%
33447		ADAMA Agricultural Solutions Canada Ltd.	ADAMA Tebuconazole Technical	SO	TEU: 98.3%
33718		Rotam Ltd.	Tebuconazole TG	SO	TEU: 98.0%
33758		Farmer's Business Network Canada Inc.	FBN Tebuconazole Technical	SO	TEU: 98.9%
33894		Sharda CropChem Ltd.	Tebuconazole Technical Fungicide	SO	TEU: 98.6%
Plant Protection Products:					
25762	Commercial	Bayer CropScience Inc.	Raxil 312 FS Seed Treatment Fungicide	SU	TEU: 312 g/L
25940		Bayer CropScience Inc.	Folicur 432 F Foliar Fungicide	SU	TEU: 432 g/L
26137		Bayer CropScience Inc.	Raxil SP Soluble Pack	WP	TEU: 9.55%
26138		Bayer CropScience Inc.	Raxil 250 FL Flowable Fungicide	SU	TEU: 6.0 g/L
27692		Bayer CropScience Inc.	Raxil MD Fungicide	SU	TEU: 5.0 g/L; MTA: 6.6 g/L
29818		Bayer CropScience Inc.	USF 2010 Fungicide	SU	TEU: 261 g/L; TFY: 261 g/L
29819		Bayer CropScience Inc.	Prosaro 421 SC Foliar Fungicide	SU	TEU: 210.5 g/L; PRB: 210.5 g/L
29820		Bayer CropScience Inc.	Folicur 250 EW Fungicide	SU	TEU: 250 g/L
29821		Bayer CropScience Inc.	Prosaro 250 EC Fungicide	EC	TEU: 125 g/L; PRB: 125 g/L
30102		Bayer CropScience Inc.	Raxil Pro	SU	TEU: 3.0 g/L; PRB: 15.4 g/L; MTA: 6.2 g/L
30491		Bayer CropScience Inc.	Palliser Foliar Fungicide	SU	TEU: 432 g/L
30687		Bayer CropScience Inc.	Raxil Pro Concentrate Seed Treatment Fungicide	SU	TEU: 15.5 g/L; PRB: 77.0 g/L; MTA: 30.9 g/L
32073		Bayer CropScience Inc.	Deflect Fungicide	SU	TEU: 5.0 g/L; MTA: 6.6 g/L
32405		Bayer CropScience Inc.	Mirage Stressgard	SU	TEU: 240 g/L
32500		Nufarm Agriculture Inc.	Hornet 432 F Foliar Fungicide	SU	TEU: 432 g/L

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type[2]	Active Ingredient (%, g/L)[3]
32824		Bayer CropScience Inc.	Prosaro XTR fungicide	EC	TEU: 125 g/L; PRB: 125 g/L
33236		Bayer CropScience Inc.	Dedicate Stressgard	SU	TEU: 190 g/L; TFY: 48.0 g/L
33453		FMC of Canada Ltd.	F9651-2 Fungicide	SU	TEU: 340 g/L; BIX: 160 g/L
33672		ADAMA Agricultural Solutions Canada Ltd.	Custodia	SU	TEU: 200 g/L; AZY: 120 g/L
33673		ADAMA Agricultural Solutions Canada Ltd.	Orius 430 SC Foliar Fungicide	SU	TEU: 430 g/L
33719		Rotam Ltd.	Toledo 250 EW	EC	TEU: 250 g/L
33779		Farmer's Business Network Canada Inc.	FBN Tebuconazole 250 Fungicide	SU	TEU: 250 g/L
33825		Bayer CropScience Inc.	Tilmor 240 EC Fungicide	EC	TEU: 160 g/L; PRB: 80 g/L
33887		Advantage Crop Protection Inc.	Advantage Tebuconazole 250	SU	TEU: 250 g/L
33901		Sharda CropChem Ltd.	Tebbie	SU	TEU: 250 g/L
Heavy-Duty Wood Preservative Products:					
27132	Commercial	Arch Wood Protection Canada Corp.	Wolman NB	EC	TEU: 0.37%; CUR: 9.25%
30003		Arch Wood Protection Canada Corp.	Wolman AG	SN	TEU: 5.00%; QAV: 9.68%; PON: 2.43%
30379		Timber Specialties Ltd.	MTZ	SU	TEU: 33.95%
30570		Arch Wood Protection Canada Corp.	Wolman µNB	SU	TEU: 0.37%; CUV: 9.25%
31160		Viance LLC	Viance CA-B	EC	TEU: 0.37%; CUR: 9.25%
31545		Timber Specialties Ltd.	FIM-3	SN	TEU: 2.40%; QAV: 21.7%
32008		Timber Specialties Ltd.	MP200A-TS	SU	TEU: 1.12%; CUV: 28.0%
32361		Viance LLC	Ecolife - CDN	SN	TEU: 11.43%
33525		Timber Specialties Ltd.	NW-CA-B	SU	TEU: 0.37%; CUR: 9.25%

[1] As of 2020-11-12, excluding discontinued products, products with a submission for discontinuation, or joinery wood preservatives (re-evaluated separately).

[2] EC = emulsifiable concentrate; SN = solution; SO = solid; SU = suspension; WP = wettable powder.

[3] TEU = tebuconazole; AXY = azoxystrobin; BIX = bixafen; CUR = copper (present as copper monoethanolamine complexes); CUV = copper (present as basic copper carbonate); MTA = metalaxyl; PON = propiconazole; PRB = prothioconazole; QAV = didecyldimethyl ammonium (present as carbonate and bicarbonate salts); TFY = trifloxystrobin.

Appendix II Registered commercial uses of tebuconazole in Canada

Table 1 Registered commercial class plant protection uses of tebuconazole[1, 2, 3]

Site	Pest(s)	Formulation[4]	Application Method and Equipment	Application Rate (g TEU/ha)		Maximum Number of Applications per year	Minimum Interval Between Applications (Days)
				Maximum Single	Maximum per Year		
Use-site category 4 – Forests and Woodlots							
SRIC[5] poplar and willow	Leaf rust	SU	Ground: field sprayer; Aerial: fixed-wing or rotary wing aircraft	126	252	2	Not applicable
Use-site category 7, 13, 14 – Terrestrial Non-food and Non-feed Seed and Fibre Crops, Terrestrial Feed Crops, Terrestrial Food Crops							
Barley	Fusarium head blight; leaf, stem, and stripe rusts; powdery mildew; septoria leaf blotch; net blotch; spot blotch; scald	EC	Ground: field sprayer; Aerial: fixed-wing or rotary wing aircraft	100	100	1	Not applicable
		SU		126	130.5		
Barley (spring)	Leaf rust; powdery mildew; septoria leaf blotch; net blotch; spot blotch; scald	SU		65.25	130.5	2	14
Oats	Crown rust; stem rust; septoria leaf blotch and black stem	EC		100	100	1	Not applicable
	Crown rust; stem rust; powdery mildew; septoria leaf blotch and black stem	SU		125	130.5	2	14
Triticale (spring and winter)	Fusarium head blight; leaf, stem, and stripe rusts; powdery mildew; septoria leaf and glume blotch; spot blotch; tan spot	EC		100	100	1	Not applicable
		SN		125	125		
Wheat (winter, durum, spring)	Fusarium head blight; leaf, stem, and stripe rusts; powdery mildew; septoria leaf and glume blotch; tan spot	EC		100	100	1	Not applicable
		SU		126	130.5		
Wheat (winter, spring, hard red, durum, Canada prairie, soft white)	Leaf, stem, and stripe rusts; powdery mildew; septoria leaf blotch; tan spot	SU		65.25	130.5	2	14
Soybean	Asian soybean rust; frogeye leaf spot; powdery mildew; brown spot	SU		136	272	2	10
Use-site category 10 – Seed and Plant Propagation Materials Food and Feed							

Site	Pest(s)	Formulation[4]	Application Method and Equipment	Application Rate (g TEU/ha)		Maximum Number of Applications per year	Minimum Interval Between Applications (Days)
				Maximum Single	Maximum per Year		
Barley	Smut; barley leaf stripe; seed rot; damping-off; seedling blight; root and crown rot	SU	Seed treatment: Standard slurry or mist-type commercial equipment; Conventional on-farm and commercial equipment	3.6	3.6	1	Not applicable
	Smut; barley leaf stripe; seed rot; seedling blight	WP	Seed treatment: Conventional on-farm and commercial equipment	2.4	2.4		
Corn (sweet)	Soil- and seed-borne head smut; seed rot and pre-emergent damping-off	SU	Seed treatment: Standard slurry or mist-type commercial equipment	2.3	2.3	1	Not applicable
Corn (field corn and field corn grown for seed)				4.7	4.7		
Corn (popcorn)				2.2	2.2		
Oats	Smut; seed rot; damping-off; seedling blight; root and crown rot	SU	Seed treatment: Standard slurry or mist-type commercial equipment; Conventional on-farm and commercial equipment	3.4	3.4		
Rye	Smut; seed rot; damping-off; seedling blight; seed-borne septoria nodorum; root and crown rot	SU	Seed treatment: Conventional on-farm and commercial equipment	1.0	1.0		
Triticale				3.1	3.1		
Wheat	Smut; seed rot; damping-off; seedling blight; seed-borne septoria nodorum; root and crown rot	SU	Seed treatment: Standard slurry or mist-type commercial equipment; Conventional on-farm and commercial equipment	5.2	5.2		
	Smut; seed rot; seedling blight; common root rot	WP	Seed treatment: Conventional on-farm and commercial equipment	3.5	3.5		
Use-site category 14 – Terrestrial Food Crops							
Asparagus	Asparagus rust	SU	Ground: field sprayer	126	504	4	14

Site	Pest(s)	Formulation[4]	Application Method and Equipment	Application Rate (g TEU/ha)		Maximum Number of Applications per year	Minimum Interval Between Applications (Days)
				Maximum Single	Maximum per Year		
Use-site category 30 – Turf							
Turfgrass on golf courses and sod farms	Dollar spot; anthracnose (basal rot and foliar); summer patch; fairy ring; brown patch; pink snow mould; grey snow mould; fusarium patch (microdochium patch); leaf spot	SU	Ground: field sprayer	1536	3100	[2 applications at maximum single rate]	14

[1] As of 2020-11-12, excluding discontinued products or products with a submission for discontinuation. While all plant protection uses registered at the time of re-evaluation initiation and also those registered between the time of initiation and 2020-02-03 were considered in the health and environmental risk assessments, the following products were registered since then but fall within the currently registered use pattern: Reg. No's. 33672; 33673; 33779; 33825; 33887; 33901.

[2] The registration of Reg. No. 33719, which occurred after 2020-02-03, has lead to the following changes to the use pattern, which were not considered during the re-evaluation of tebuconazole:

- The maximum foliar application rate (single and per year) to barley, oats, triticale (spring and winter), and wheat (winter, durum, and spring) with a product formulated as an EC increased from 100 g TEU/ha to 125 g TEU/ha;
- Foliar treatment to soybeans with a product formulated as an EC at a maximum application rate (single and per year) of 125 g TEU/ha is now supported;
- Foliar treatment to rye (spring and fall) and canary seed at a maximum application rate (single and per year) of 125 g TEU/ha is now supported.

[3] All information is derived from registered product labels, except for information provided by the registrants, which is indicated by [ ].

[4] EC = emulsifiable concentrate; SN = solution; SU = suspension; WP = wettable powder.

[5] SRIC = Short-rotation intensive culture.

Table 2 Registered commercial class heavy-duty wood preservative uses of tebuconazole in Canada[1]

Registration Number	Registrant Name	Product Name	% Active Ingredient[2]	Site	Pest	Treatment Solution Concentration (% TEU)	Target Retention Rate (kg TEU/m3 wood)
27132	Arch Wood Protection Canada Corp	WOLMAN NB	9.25% (CUR), 0.37% (TEU)	Wood for Residential construction above ground ground contact fresh water contact subject to salt water splash	Termites, white rot, brown rot fungi.	0.01–0.12%	above ground - 0.065 ground contact - 0.127 ground contact (solid sawn lumber, severe decay hazard) - 0.154 ground contact (severe decay hazard) - 0.192
30003	Arch Wood Protection Canada Corp	WOLMAN(R) AG	5.00% (TEU), 9.68% (QAV), 2.43% (PON)	Non-Industrial Wood for above ground	Decay fungi	0.03–0.29%	above ground 0.15–0.20
30379	Timber Specialties Limited	MTZ	33.95% (TEU)	Above ground ground contact fresh water contact	Decay fungi	0.01–0.12%	above ground (non-structural) - 0.035 above ground (structural) - 0.065 ground contact - 0.127 ground contact (severe decay hazard) - 0.192
30570	Arch Wood Protection Canada Corp	WOLMAN UNB	0.37% (TEU), 9.25% (CUV)	Non-Industrial Wood for above ground	Decay fungi	0.01–0.12%	above ground - 0.065 ground contact - 0.127 ground contact (severe decay hazard) - 0.192

Registration Number	Registrant Name	Product Name	% Active Ingredient[2]	Site	Pest	Treatment Solution Concentration (% TEU)	Target Retention Rate (kg TEU/m3 wood)
31160	Viance LLC	VIANCE CA-B	0.37% (TEU), 9.25% (CUR)	Above ground ground contact fresh water contact subject to salt water splash	Termites, white rot, brown rot fungi.	0.01–0.12%	above ground - 0.065 ground contact - 0.127 ground contact (severe decay hazard) - 0.192
31545	Timber Specialties Limited	FIM-3	2.4% (TEU), 21.7% (QAV)	Above ground	Decay fungi	0.02–0.2%	above ground (non structural) - 0.09 above ground (structural) - 0.17
32008	Timber Specialties Limited	MP200A-TS	1.12% (TEU), 28% (CUV)	Above ground ground contact fresh water contact	Decay fungi	0.01–0.12%	above ground (non-structural) - 0.035 above ground (structural) - 0.065 ground contact - 0.127
32361	Viance LLC	ECOLIFE - CDN	11.43% (TEU)	Above ground ground contact	Decay fungi	0.1–1.0%	above ground - 0.3–0.6
33525	timber specialties limited	NW-CA-B	0.37% (TEU), 9.25% (CUR)	Above ground ground contact fresh water contact subject to salt water splash	Termites, white rot, brown rot fungi.	0.01–0.12%	above ground - 0.065 ground contact - 0.127 ground contact (severe decay hazard) - 0.192

[1] As of 2020-11-05, excluding discontinued products, products with a submission for discontinuation, or joinery wood preservatives (re-evaluated separately).

[2] TEU = tebuconazole; CUR = copper (present as copper monoethanolamine complexes); CUV = copper (present as basic copper carbonate); PON = propiconazole; QAV = didecyldimethyl ammonium (present as carbonate and bicarbonate salts).

Appendix III Toxicity endpoints for health risk assessment

Table 1 Tebuconazole toxicology reference values for use in health risk assessment

Exposure Scenario	Study	Point of Departure and Endpoint	CAF[1] or Target MOE
Acute Dietary (All Populations)	Rat dietary DNT study	NOAEL = 8.8 mg/kg bw/d (↓ pre-weaning pup bw, ↓auditory startle response at PND 23 and equivocal ↓ in brain weight in males)	300
	ARfD = 0.03 mg/kg bw		
Repeated Dietary (All populations)	One-year dietary toxicity study in dogs	NOAEL = 3 mg/kg bw/d (↑ hypertrophy in the adrenal zona fasciculata, presence of fatty vacuoles in the adrenal zona glomerulosa cells (↑ size and number))	100
	ADI = 0.03 mg/kg bw/day		
Incidental oral short-to intermediate-term	Rat dietary DNT study	NOAEL = 8.8 mg/kg bw/d (↓ pre-weaning pup bw, ↓ auditory startle response at PND 23 and equivocal ↓ in brain weight in males)	300
Dermal and Inhalation All durations[2, 3]	Rat dietary DNT study	NOAEL = 8.8 mg/kg bw/d (↓ pre-weaning pup bw, ↓ auditory startle response at PND 23 and equivocal ↓ in brain weight in males)	300
Oral and Dermal[3] Short- and Intermediate-term aggregate assessments	Rat dietary DNT study	NOAEL = 8.8 mg/kg bw/d (↓ pre-weaning pup bw, ↓ auditory startle response at PND 23 and equivocal ↓ in brain weight in males)	300
Cancer	Evidence of liver tumours in mice. MOA data supported a threshold risk assessment approach. The endpoints selected for non-cancer risk assessment are protective of this finding.		

[1] CAF (composite assessment factor) refers to a total of uncertainty and PCPA factors for dietary assessments; MOE refers to a target margin of exposure for occupational and residential assessments

[2] Since an oral NOAEL was selected, an inhalation absorption factor of 100% (default value) was used in route-to-route extrapolation.

[3] Since an oral NOAEL was selected, a dermal absorption factor of 13% was used in a route-to-route extrapolation

Table 2 Summary of the major metabolites of tebuconazole in rats

Coded Name	Chemical name
HWG 2443	5-(4-chlorophenyl)-3-hydroxy-2,2-dimethyl-3-(1H-1,2,4-triazol-1-ylmethyl)pentanoic acid
HWG 2061	5-(4-chlorophenyl)-2,2-dimethyl-3-(1H-1,2,4-triazol-1-ylmethyl)pentane-1,3-diol

Appendix IV Dietary exposure and risk estimates

Table 1 Summary of acute deterministic dietary exposure and risk analyses for tebuconazole

Subpopulation	Food only		Food and Drinking Water – Level 1 EEC (Agri. uses=all other uses except turf uses) [1]		Food and Drinking Water – Level 2 EEC (Turf uses with a cumulative rate of 1.44 kg a.i./ha) [2]		Food and Drinking Water – Level 2 EEC (Turf uses with a cumulative rate of 3.1 kg a.i./ha) [3]	
	Exposure (mg/kg bw)	%ARfD [4]	Exposure (mg/kg bw)	%ARfD	Exposure (mg/kg bw)	%ARfD	Exposure (mg/kg bw)	%ARfD
General Population	0.007828	26.1	0.010743	35.8	0.012412	41.4	0.017154	57.2
All Infants (<1 year old)	0.011600	38.7	0.020411	68.0	0.025813	86.0	0.043646	145.5
Children 1–2 years old	0.021186	70.6	0.024218	80.7	0.025933	86.4	0.031596	105.3
Children 3–5 years old	0.014274	47.6	0.016907	56.4	0.018318	61.1	0.022614	75.4
Children 6–12 years old	0.008171	27.2	0.010013	33.4	0.011446	38.2	0.015895	53.0
Youth 13–19 years old	0.003357	11.2	0.005748	19.2	0.007204	24.0	0.011734	39.1
Adults 20–49 years old	0.006485	21.6	0.009409	31.4	0.011193	37.3	0.015918	53.1
Adults 50+ years old	0.007762	25.8	0.009998	33.3	0.011152	37.2	0.015340	51.1
Females 13–49 years old	0.006839	22.8	0.009374	31.3	0.011208	37.4	0.016140	53.8

[1] The modelled daily groundwater estimated environmental concentrations (EECs) of tebuconazole of 87 µg/L, based on four applications of 126 g a.i./ha, yearly total of 504 g a.i./ha to agricultural crops, was used in the dietary risk assessment.

[2] The modelled daily groundwater EECs of tebuconazole of 124 µg/L, based on one application of 1440 g a.i./ha to turf, was used in the dietary risk assessment.

[3] The modelled daily groundwater EECs of tebuconazole of 228 µg/L, based on a yearly total rate of 3100 g a.i./ha to turf, was used in the dietary risk assessment.

[4] Acute Reference Dose (ARfD) of 0.03 mg/kg bw; A deterministic acute risk assessment is conducted (due to drinking water EEC is from ground water) and exposure is reported at 95th percentile.

Table 2. Summary of chronic non-cancer and cancer dietary exposure and risk analyses for tebuconazole

Subpopulation	Food only		Food and Drinking Water – Level 1 EEC (Agri. uses=all other uses except turf uses) [1]		Food and Drinking Water – Level 2 EEC (Turf uses with a cumulative rate of 1.44 kg a.i./ha) [2]		Food and Drinking Water – Level 2 EEC (Turf uses with a cumulative rate of 3.1 kg a.i./ha) [3]	
	Exposure (mg/kg bw)	%ADI [4]	Exposure (mg/kg bw)	%ADI [4]	Exposure (mg/kg bw)	%ADI [4]	Exposure (mg/kg bw)	%ADI [4]
General Population	0.000201	0.7	0.001959	6.5	0.002726	9.1	0.004807	16.0
All Infants (<1 year old)	0.000370	1.2	0.006937	23.1	0.009804	32.7	0.017578	58.6
Children 1–2 years old	0.000832	2.8	0.003249	10.8	0.004305	14.4	0.007167	23.9
Children 3–5 years old	0.000509	1.7	0.002476	8.3	0.003335	11.1	0.005664	18.9
Children 6–12 years old	0.000297	1.0	0.001760	5.9	0.002399	8.0	0.004130	13.8
Youth 13–19 years old	0.000155	0.5	0.001395	4.6	0.001936	6.5	0.003403	11.3
Adults 20–49 years old	0.000152	0.5	0.001898	6.3	0.002661	8.9	0.004728	15.8
Adults 50+ years old	0.000146	0.5	0.001844	6.1	0.002586	8.6	0.004597	15.3
Females 13–49 years old	0.000138	0.5	0.001855	6.2	0.002605	8.7	0.004637	15.5

[1] The modeled yearly groundwater estimated environmental concentrations (EECs) of tebuconazole of 87 µg/L, based on four applications of 126 g a.i./ha, yearly total of 504 g a.i./ha to agricultural crops, was used in the dietary risk assessment.

[2] The modeled yearly groundwater EECs of tebuconazole of 125 µg/L, based on one application of 1440 g a.i./ha to turf, was used in the dietary risk assessment.

[3] The modeled yearly groundwater EECs of tebuconazole of 228 µg/L, based on a yearly total rate of 3100 g a.i./ha to turf, was used in the dietary risk assessment.

[4] Acceptable daily intake (ADI) of 0.03 mg/kg bw/day.

Appendix V Non-occupational and occupational exposure and risk assessment

Table 1 Short-term postapplication dermal exposure and risk assessment to golf course turf

Scenario	TC [a] (cm^2/hr)	TTR [b] (µg.cm^2)	Dermal Exposure [c] (mg/kg bw/day)	Dermal MOE [d]
Postapplication Exposure to Golf Course Turf				
Adult	5300	0.19	0.0065	1400
Youth (11 < 16)	4400		0.0076	1200
Children (6 to <11)	2900		0.0089	990

TC = transfer co-efficient; TTR = turf transferable residue; MOE = margin of exposure; NOAEL = no observed adverse effect level

[a] Transfer coefficients standard values from the USEPA Residential SOPs (USEPA, 2012) were used.

[b] Turf transferable residue calculated based on a standard peak value of 1% of the maximum application rate (1536 g a.i./ha) and a daily dissipation rate of 10%. 2 applications with a 14 day interval were considered in the calculation as it addresses the lower rate scenario.

[c] Dermal exposure (mg/kg bw/day) = TTR (µg/cm^2) × TC (cm^2/hr) × Duration (4 hrs) × Dermal Absorption (13%)/Body Weight (80 kg for adults, 57 kg for youth (11<16 years old) and 32 kg for children (6< 11 years old)).

[d] MOE = NOAEL/Exposure. Adult, youth (11<16 years old), and children (6 < 11 years old) MOEs are based on an oral NOAEL of 8.8 mg/kg bw/day. Target MOE = 300.

Table 2 Short-term postapplication dermal exposure from treated wood

Lifestage	Transferable Residue (mg/cm^2) [a]	SA/BW (cm^2/kg)	F_{body}	Dermal Exposure (mg/kg bw/day) [b]	Dermal MOE [c]
Adult	0.000858	280	0.31	0.0097	910
Children (1<2 years old)		640		0.0221	400

SA/BW = surface area to body weight ratio; Fbody = fraction of body exposed; MOE = margin of exposure; DA = Dermal Absorption; NOAEL = no observed adverse effect level

[a] Transferable residue = 0.858 µg/cm^2 (Minchin and Morris, 2014) (Day 0 average).

[b] Dermal Exposure (mg/kg bw/day) = Transferable Residue (mg/cm^2) × SA/BW (cm^2/kg) × Fbody × DA (13%)

[c] MOE = NOAEL/Exposure. Based on an oral NOAEL of 8.8 mg/kg bw/day; Target MOE = 300.

Table 3 Short-term postapplication hand-to-mouth exposure and risk assessment for children (1<2 years) [a]

Exposure Scenario	Hand Residue (mg/cm^2) [a]	ET (hours)	Oral Dose (mg/kg bw/day) [b]	MOE [c]
Residues from treated wood	0.000858	1.5	0.0082	1100

ET = exposure time; MOE = margin of exposure; NOAEL = no observed adverse effect level

[a] Transferable residue = 0.858 µg/cm^2 (Minchin and Morris, 2014) (Day 0 average).

[b] Where Oral Dose (mg/kg bw/day) = [Hand Residue (mg/cm^2) × Fraction of hand mouthed/event (0.13) × Surface Area of one hand (150 cm^2)) × ET (hr) × Replenishment Intervals (4/hr) × (1 – (1 – Saliva Extraction Factor (0.48)) $^{\text{Number events per hour (14)/Replenishment Intervals (4/hr)}}$)]/ Body Weight (11 kg).

[c] MOE = NOAEL/Exposure. Based on an oral NOAEL of 8.8 mg/kg bw/day; Target MOE = 300

Table 4 Mixer/Loader/Applicator commercial agriculture exposure and risk assessment

Application Equipment	Scenario	Max Rate [a] (kg/ha)	ATPD	Dermal Exposure [b] (mg/kg bw/day)	Inhalation Exposure [c] (mg/kg bw/day)	Dermal MOE [d]	Inhalation MOE [d]	Combined MOE [e]
Baseline PPE								
Groundboom[f]	M/L/A	0.136	360 ha/day	0.0067	0.0014	1300	6200	1100
Groundboom (sod)	M/L/A	1.536	30 ha/day	0.0063	0.0013	1400	6600	1200
Turf gun sprayer	M/L/A	1.536	2 ha/day	0.0039	1.5E-04	2300	57 000	2200
Airblast	M/L/A	0.126	20 ha/day	0.0157	3.1E-04	560	29 000	550
Backpack	M/L/A	1.26E-03[g]	150 L/day	0.0017	1.5E-04	5300	60 000	4800
MPHW	M/L/A	1.26E-03[g]	150 L/day	2.9E-04	1.1E-04	30 000	82 000	22 000
MPHG	M/L/A	1.26E-03[g]	3800 L/day	0.0435	0.0090	200	970	170
Mid-level PPE								
MPHG	M/L/A	1.26E-03[g]	3800 L/day	0.0191	0.0090	460	970	310
M/L: Baseline PPE; A: Max PPE + CR hood + respirator								
HH AB/MB	M/L/A	1.26E-03[g]	150 L/day	0.0100	0.0093	880	950	460
M/L: Baseline PPE; A: Baseline PPE, Closed-cockpit application								
Aerial	M/L	0.136	400 ha/day	0.0052	4.3E-04	1700	21 000	1600

M/L/A = mix/load/apply; ATPD = area treated per day; MOE = margin of exposure; PPE = personal protective equipment; MPHG = mechanically pressurized handgun; MPHW = manually pressurized handwand; CR = chemical-resistant; HH AB/MB = handheld airblast/mistblower; Max = maximum; NOAEL = no observed adverse effect level

Baseline PPE = long-sleeved shirt, long pants, CR gloves

Mid-Level PPE = coveralls over long-sleeved shirt, long pants, CR gloves

Max PPE = CR coveralls over long-sleeved shirt, long pants, socks and shoes, CR gloves

Shaded cells indicate target MOE not met.

[a] Maximum rate in kg/ha unless otherwise indicated.

[b] Dermal exposure (mg/kg bw/day) = (dermal unit exposure × ATPD × maximum application rate × 13% dermal absorption)/80 kg body weight

[c] Inhalation exposure (mg/kg bw/day) = (inhalation unit exposure × ATPD × maximum application rate)/80 kg body weight

[d] MOE = NOAEL/Exposure. Based on an oral NOAEL of 8.8 mg/kg bw/day. Target MOE = 300.

[e] Combined MOE = 1/[1/dermal MOE + 1/inhalation MOE], Target MOE = 300.

[f] Groundboom application assessed as custom (360 ha/day) as a Tier 1 assessment.

[g] Maximum rate (kg/L) = Maximum Active Ingredient application rate (0.126 kg a.i./ha)/minimum spray volume (100 L/ha)

Table 5 Commercial agriculture postapplication exposure and risk assessment

Crop	Activity	TC (cm^2/hr)	Max Rate (kg a.i./ha)	Number of applications per year	Min intervals between applications	MOE[a] (Day 0)	REI[b] (hrs)
Use-site category 4: Forests and Woodlots							
SRIC	Harvest (seedling production)	6700	0.126	2	14	260	1 day
	Handset/hand line irrigation related activities involving foliar contact	1750				1000	12
	Hand Pruning, Scouting	580				3000	
	Transplanting, Hand Weeding	230				7600	
Use-site category 7, 13, 14							
Spring Barley	Scouting	1100	0.066	2	14	3000	12
Barley	Scouting	1100	0.126	1	-	2000	
Soybean	Scouting	1100	0.136	2	14	1500	
	Hand Weeding	70				23 000	
Wheat, Oats, Triticale	Scouting	1100	0.126	1	-	2000	
	Hand Weeding	70			-	31 000	
Use-site category14: Food Crops							
Asparagus	Handset/hand line irrigation related activities involving foliar contact	1750	0.126	4	14	950	12
	Harvesting	1100				1500	
	Transplanting	230				7200	
	Scouting	210				7900	
	Hand Weeding	70				24 000	
Use-site category 30: Turf grass [c]							
Turf - Golf Courses	Transplanting/ Planting	6700	1.536	2 [d]	14	540	[e]
	Mowing, Watering, Cup Changing, Irrigation Repair, Miscellaneous Grooming	3500				1000	
	Aerating, Fertilizing, Hand Pruning, Mechanical Weeding, Scouting, Seeding	1000				3600	
Turf - Sod Farms	Harvesting (Slab), Transplanting/Planting	6700				540	12
	Mowing, Watering, Handset/hand line irrigation related activities involving foliar contact	3500				1000	
	Aerating, Fertilizing, Hand Pruning, Mechanical Weeding, Scouting, Seeding	1000				3600	

MOE = margin of exposure; REI = restricted-entry interval; TC = transfer coefficient; Min = minimum; Max = maximum; SRIC = short rotation intensive culture; NOAEL = no observed adverse effect level

There were no chemical-specific DFR or TTR studies submitted. Therefore, a standard peak DFR value of 25%, with a 10% dissipation per day and a standard peak TTR value of 1% of the application rate with a 10% dissipation per day were used.
Shaded cells indicate target MOE not met.
[a] MOE = NOAEL/Exposure. Based on an oral NOAEL of 8.8 mg/kg bw/day; Target MOE of 300.
[b] Day at which dermal exposure results in an MOE greater than the target MOE.
[c] The maximum rate was used as this addresses the lower rate scenarios.
[d] Not stated on label (based on max product rate: 2 at high rate).
[e] Golf courses: re-entry statement of "DO NOT enter, or allow entry until spray has dried"

Table 6 Short- to intermediate-term commercial seed treatment exposure and risk assessment

Crop	Study Formulation [a]	Activity [b]	Application Rate (g a.i./kg seed) [c]	Throughput (kg seed/day) [d]	Dermal MOE [e]	Inhalation MOE [e]	Combined MOE [f]
PPE: Baseline; Open M/L (PMRA# 1335563)							
Wheat, Barley, Oats, Rye, Triticale	Liquid	Treater (M/L/A)	0.03	325 700	2100	29 000	1900
PPE: Baseline (PMRA# 1772278)							
Wheat, Barley, Oats, Rye, Triticale	Liquid	Bagger/Sewer/Stacker	0.03	325 700	31 000	81 000	23 000
PPE: Maximum (PMRA# 1772278)							
Wheat, Barley, Oats, Rye, Triticale	Liquid	Cleaner	0.03	-	98 000	370 000	77 000
PPE: Baseline; Closed M/L, Closed Transfer (PMRA#1885209)							
Corn	Liquid	Treater/Applicator	0.15	125 000	1100	10 000	1000
		Bagger/Sewer/Stacker			2500	690	540
		Cleaner		-	2800	1900	1200

MOE = margin of exposure; M/L/A = Mixer/Loader/Applicator; NOAEL = No observed adverse effects level; PPE = personal protection equipment; CR = chemical-resistant; DA = dermal absorption; BW = body weight; NOAEL = no observed adverse effect level
Baseline PPE = long-sleeved shirt, long pants, CR gloves
Maximum PPE = CR coveralls over long-sleeved shirt, long pants, CR gloves
[a] Liquid formulation addresses exposure to wettable powders in water soluble packaging.
[b] Activities are based on what was monitored in the surrogate exposure studies.
[c] Maximum application rates were used in the assessment. Cleaning activities were normalized to the application rate rather than the amount handled.
[d] Standard commercial throughput data were used for all crops.
[e] Where: MOE = NOAEL/Exposure, based on the short-, intermediate-, and long-term dermal/inhalation NOAEL of 8.8 mg/kg bw/day. Exposure (mg/kg bw/day) = (Unit exposure (µg/kg a.i.) × Application Rate (g a.i./kg seed) × Throughput (kg seed/day) × DA (13%) × 0.001 mg/µg/BW (80 kg). Target MOE = 300.
[f] Combined MOE = 1/[1/dermal MOE + 1/inhalation MOE], Target = 300.

Table 7 Short- to intermediate-term on-farm seed treatment and planting exposure and risk assessment

Crop	Formulation[a]	Activity	Application Rate (g a.i./kg seed)[b]	Throughput (kg seed/day)[c]	Dermal MOE[d]	Inhalation MOE[d]	Combined MOE[e]
PPE: Baseline; Open M/L; Closed Cab Planter (PMRA# 1335563)[f]							
Wheat, Barley, Oats, Rye, Triticale	Liquid	All Tasks (loading/treating/planting)	0.03	60000	21000	51000	15000

MOE = margin of exposure; PPE = personal protection equipment; NOAEL = no observed adverse effect level; CR = chemical-resistant; M/L/A = mixer/loader/applicator; DA = dermal absorption; BW = body weight; NOAEL = no observed adverse effect level
Baseline PPE = long pants, long-sleeved shirt, CR gloves
[a] Liquid formulation includes suspensions.
[b] Maximum application rates were used in the assessment.
[c] Farm throughput data are upper bound estimates for amount of seeds treated per day based on PMRA survey data.
[d] Where; MOE = NOAEL/Exposure, based on the short- to intermediate-term dermal/inhalation NOAEL of 8.8 mg/kg bw/day. Exposure (mg/kg bw/day) = (Unit exposure (µg/kg a.i.) × Application Rate (g a.i./kg seed) × Throughput (kg seed/day) × DA (13%) × 0.001 mg/µg/BW (80 kg). Target MOE = 300.
[e] Combined MOE = 1/[1/dermal MOE + 1/inhalation MOE], Target MOE = 300
[f] The Krolski (2006) study was used (PMRA# 1335563). Although this study was conducted using a closed cab planter, this mitigation has been waived since the calculated MOEs well exceeded the target MOE of 300 which is sufficient to address the protection that would be provided by using a closed cab.

Table 8 Planting exposure and risk assessment for commercially treated and bagged seed

Crop	Formulation	Application Rate (g a.i./kg seed)[a]	Seeding Rate (kg seed/ha)[b]	Farm Size Planted per Day (ha/day)[b]	MOE		
					Dermal[c]	Inhalation[c]	Combined[d]
PPE: Baseline; Open Loading, Closed Cab Planter (PMRA# 1571553)							
Corn	Liquid	0.150	31.5	100	7600	18000	5300
PPE: Mid-level; Open Loading, Closed Cab Planter (PMRA# 2313627)							
Wheat, Barley, Oats, Rye, Triticale	Liquid	0.03	209.88	162	5500	2300	1600

PPE = personal protective equipment; MOE = margin of exposure; CR = chemical-resistant; BW = body weight; NOAEL = no observed adverse effect level
Baseline PPE: long-sleeved shirt, long pants, CR gloves
Mid-level PPE: Coveralls over long-sleeved shirt, long pants, CR gloves
[a] Maximum application rates were used in the assessment.
[b] Maximum seeding rates and farm size data are upper bound estimates.
[c] MOE = NOAEL/Exposure, based on the short- to long-term NOAEL of 8.8 mg/kg bw/day, Target = 300
Exposure (mg/kg bw/day) = (Unit exposure (µg/kg a.i.) × Application Rate (g a.i./kg seed) × Seeding rate (kg seed/day) × Farm Size Planted per Day (ha/day) × 0.001 mg/µg)/BW (80 kg)
[d] Combined MOE = 1/[1/dermal MOE + 1/inhalation MOE], Target = 300

Table 9 Occupational exposure and risk assessment for heavy-duty wood preservatives

Application Method	Worker Category	Absorbed Dermal Exposure (mg/kg bw/day) [a]	Inhalation Exposure (mg/kg bw/day) [b]	Dermal MOE [c]	Inhalation MOE [c]	Combined MOE [d]
Pressure Retort	TO	2.08×10^{-3}	3.65×10^{-4}	4200	24000	3600
	WH	8.97×10^{-3}	1.73×10^{-3}	980	5100	820

TO = Treatment Operators; WH = Wood Handlers; MOE = margin of exposure; DA = dermal absorption; BW = body weight; NOAEL = no observed adverse effect level

[a] Calculated using unit exposure values from Bookbinder (2014). Dermal Exposure (mg/kg bw/day) = Unit Exposure (µg/% a.i.) × Concentration of treating solution (1% a.i.) × DA (13%)/BW (80kg).

[b] Calculated using unit exposure values from Bookbinder (2014). Inhalation Exposure (mg/kg bw/day) = Unit Exposure (µg/% a.i.) × Concentration of treating solution (1% a.i.)/BW (80 kg).

[c] MOE = NOAEL/Exposure. Based on a short- to long-term oral NOAEL of 8.8 mg/kg bw/day; Target MOE = 300.

[d] Combined MOE = 1/[1/dermal MOE + 1/inhalation MOE], Target = 300.

Appendix VI Aggregate exposure and risk assessment tables

Table 1 Short-term aggregate exposure and risk assessment

Population	Postapplication Scenario	Total Dermal Exposure[a] (mg/kg bw/day)	Incidental Oral Exposure[b] (mg/kg bw/day)	Dietary Exposure[c] (mg/kg bw/day)	Total Exposure[d] (mg/kg bw/day)	Aggregate MOE[e]
Lawns and Turf						
Adult	Golfing	0.007	-	0.0026	0.0091	970
Youth (11 <16 years)		0.008	-	0.0019	0.0095	930
Children (6<11 years)		0.009	-	0.0026	0.0115	760
Treated Wood						
Adult	Treated Wood	0.0097	-	0.0026	0.0123	720
Children (1<2 years)		0.0221	0.0082	0.0041	0.0344	260 [f]

MOE = margin of exposure; NOAEL = no observed adverse effect level

[a] Dermal Exposure (mg/kg bw/day) = Dermal Exposures from Postapplication Scenarios (See Appendix V Tables 1 and 2)

[b] Value taken from Appendix V, Table 3.

[c] The tebuconazole chronic dietary exposure estimates was based on exposure following the risk mitigation required in order to have acceptable acute dietary risks, that is, reduction of the cumulative application rate for turf from 3.10 kg a.i./ha/year to 1.44 kg a.i./ha/year.

[d] Total Exposure (mg/kg bw/day) = Total Dermal Exposure + Chronic Dietary Exposure + Incidental oral Exposure (if applicable)

[e] MOE = NOAEL/Exposure. Based on an oral NOAEL of 8.8 mg/kg bw/day and a target MOE of 300.

[f] Due to conservatisms in the risk assessment (standard values from USEPA Residential SOPs (USEPA, 2012), Day 0 residue average value), the calculated MOE for children (1<2 years old) is acceptable.

Appendix VII Environmental assessment

Table 1 Fate and behaviour of tebuconazole and 1,2,4-triazole in the environment

Property	Test Substance	Value	Comments	References (PMRA#)
Abiotic Transformation				
Hydrolysis (25°C)	Tebuconazole	Stable at pH 5, 7, 9	Not a route of dissipation in the environment	1229597
Phototransformation on soil	Tebuconazole	Stable	Not a route of dissipation in the terrestrial environment	1229598
Phototransformation in water	Tebuconazole	DT_{50} = 1144 days	Not a route of dissipation in the aquatic environment	1229598
Chemical half-life in air (estimated)	Tebuconazole	< 3.8 days	Atkinson model (V. 1.9)	3093535
Biotransformation				
Biotransformation in aerobic soil (23°C)	Tebuconazole	Stable Study conducted over 365 days. DT_{50} = 883 days	Persistent in soil No major transformation products were identified in this study.	1229603 (Note: this study has an aerobic phase and an anaerobic phase)
	Tebuconazole	Silt loam, (Nisse, treated with manure); 30–42% remained as tebuconazole at 433 days. Silt soil (Hofchen): 62–69% remained as tebuconazole at 433 days.	The study was considered to be supplementary as there were only 3 sampling points; the study provided information about minor transformation products, a DT_{50} value was not determined. 1,2,4-triazole (Max. 9% AR; levels were higher in Nisse soil); mixture of HWG 1608-5-keto (M09) (or its tautomer, HWG 1608-05-enol, M08) (max. 5%) and HWG 1608-4-hydroxy (M05) (max. 4.8% AR; levels were generally higher in Hofchen soil)	1148913, 3093536
Biotransformation in anaerobic soil	Tebuconazole	Stable	Persistent in soil > 1 year (based on the aerobic soil, aerobic water and anaerobic water results)	1229603 (Note: this study has an aerobic phase and an anaerobic phase)
Biotransformation in aerobic water/sediment	Tebuconazole	Stable DT_{50} = 1140 days[2] (whole system)	Persistent in aerobic water/sediment DT_{50} = 1140 days was	1238624, 1238625, 1238626 and 3093536
Biotransformation in anaerobic water	Tebuconazole	Stable DT_{50} = 866 days (whole system)	Persistent in anaerobic Water	1038343
Mobility				
Adsorption/ desorption in soil	Tebuconazole	$K_{oc\text{-}ads}$ = 803–1249 (based on 6 soils)	Low to moderate mobility	3093536
Leaching				
Soil leaching (thin layer chromatography)	Tebuconazole	Retention factor values of 0.09–0.22	Low to immobile in soil	1417830
Soil leaching (aged soil column)	Tebuconazole	Less than 1% of the radioactivity leached	Low potential for mobility in soil	1417830

Property	Test Substance	Value	Comments	References (PMRA#)
		through the column (44.5 cm in length).		
Soil leaching (Cohen criteria and GUS index)	Tebuconazole	- meets five out of eight leaching criteria of the Cohen et al. (1984). - a borderline leacher or leacher, depending to the soil type, based on GUS index (2.6–3.2)_		N/A
Dissipation and Accumulation under Field Conditions				
Canada – EcoRegion 9.2: Minto, Manitoba (bare soil)	Folicur 432 F Foliar fungicide	DT_{50} (SFO) = 157, 52.1 and 88.5 days for 1st, 2nd and 3rd application year. Minor transformation product = 1, 2, 4-Triazole Carryover = 44.28 % (1st year), 25.58% (2nd year), 20.81% (3rd year) and 15.3% (4th year).	Tebuconazole is moderately persistent 1,2,4-Triazole was detected at low concentrations at depths up to 45 cm.	1522419
EU- Italy and France (bare plot)	Folicur EW 250	DT_{50}: 34.5 days (Italy) DT_{50}: 19.9 days (France)	Tebuconazole is slightly persistent	3093536
Field Dissipation in UK, France and Germany (cropped plots – tebuconazole immediately applied after the sowing barley)	Folicur EW 250	DT_{50}: 77 days (UK), DT_{50}: 57 days (France), DT_{50}: 36 days (Burscheid, Germany) and DT_{50}: 58 days (Monheim, Germany)	Tebuconazole is slightly persistent to moderately persistent	
Long-term determination of residues in soil in England	Folicur EW 250	N/A	Concentrations in the 0–30 cm layers do not show a significant accumulation from the second year onwards	
Long-term determination of residues in soil in the England	Folicur EW 250	N/A	Over the course of the 5-year study, 0–30 cm layers do not show an increase in concentrations	
Long-term determination of residues in soil in England	Folicur EW 250	N/A	90% or more of the amount applied will dissipate before the next season	
Aquatic mesocosm	Folicur EW 250	DT_{50}s values, 43 days and 54 days for water phase and entire system, respectively	Supplementary. The study showed that light-induced, microbial degradation and binding to sediment may take part in the overall dissipation of tebuconazole in aquatic systems under natural conditions. Low recovery of test substance was attributed to adsorption to aquatic plants in mesocosm enclosures (not measured by study authors).	3093536
Bioconcentration/Bioaccumulation				
Bioconcentration in fish	[^{14}C-triazole] tebuconazole	Bioconcentration factor (BCF) values: edible 13; viscera: 150; whole fish: 78 DT_{50} for depuration = 1–3 d	Unlikely to bioaccumulate. `	1417830

Property	Test Substance	Value	Comments	References (PMRA#)
Bioaccumulation in earthworm	[^{14}C-triazole] tebuconazole	Bioaccumulation factor (BAF) value: 1.35 DT_{50} for depuration = 1–3 d	Unlikely to bioaccumulate.	1417830
1,2,4-Triazole (main transformation product of tebuconazole, formed at maximum concetration of 9% in aerobic soil)				
Hydrolysis	1, 2, 4-triazole	DT_{50}: > 30 days at pH 5–9	Stable	3093536
Photolysis		Not measured	Stable	
Biotransformation in aerobic soil		DT_{50}: 10 days	Non-persistent in aerobic soil	
Biotransformation in anaerobic soil		DT_{50}: 81 days	Moderately persistent in anaerobic soil	
Adsorption/desorption in soil		K_{oc}-ads = 21.1–126.7	Very high to high mobility	

NA = not applicable

Table 2 Soil EECs for representative crops*

Site	Tebuconazole (mg a.i./kg soil)
Use-site category 7, 13 and 14 – Terrestrial Non-Food and Non-Feed Seed and Fibre Crops, Terrestrial Food and Feed crops (highest rate for aerial application on crops)	
Soybean	0.12
Use-site category 10 – Seed Treatments Food and Feed (highest rate for treated seed)	
Corn and wheat	0.002
Use-site category 30 – Turf (highest rate for ground boom application)	
Turfgrass (golf courses, sod farms)	1.4
Use-site category 14 – Terrestrial Food Crops	
Asparagus	0.22
Use-site category 4 – Forests and Woodlots	
SRIC Poplar and Willow	0.11

* Soybean, 2 × 136 g a.i./ha, interval 14 days; Corn, 1 × 15 g a.i.100 kg seed (4.7 g a.i./ha); Wheat, 1 × 3 g a.i/100 kg seed (5.2 g a.i./ha); Turf, 2 × 1536 g a.i./ha, interval 14 days (see note); Asparagus, 4 × 126 g a.i./ha, interval 14 days; SRIC poplar/willow, 2 × 126 g a.i./ha, interval 28 days. The 28-day interval for SRIC is an estimation because application depends on climate and signs of disease.

Note: for turf, tebuconazole can be applied twice at a higher rate or 4 applications at a lower rate (PMRA# 3080400). The EEC for the environmental risk assessment was calculated with 2 applications at the higher rate (2 × 1536 g a.i./ha).

Table 3 Screening level aquatic EECs for representative crops*

Site	Tebuconazole	
	15 cm; mg a.i./L	80 cm; mg a.i./L
Use-site category 7, 13 and 14 – Terrestrial Non-Food and Non-Feed Seed and Fibre Crops, Terrestrial Food and Feed crops (highest rate for aerial application on crops)		
Soybean	0.18	0.03
Use-site category 14 – Terrestrial Food Crops		
Asparagus	0.11	0.02
Use-site category 30 – Turf		
Turfgrass (golf courses, sod farms)	2.04	0.39
Use-site category 10 – Seed Treatments Food and Feed (highest rate)		
Corn/wheat	0.11	0.02
Use-site category 4 - Forests and Woodlots		
SRIC Poplar and Willow	0.11	0.02

* Soybean, 2 × 136 g a.i./ha, interval 14 days; Asparagus, 4 × 126 g a.i./ha, interval 14 days; Corn, 1 × 15 g a.i./ha/100 kg seed (4.7 g a.i./ha); Wheat, 1 × 3 g a.i/100 kg seed (5.2 g a.i./ha); Turf, 2 × 1536 g a.i./ha, interval 14 days; Poplar/Willow 2 × 126 g

a.i./ha, interval 28 days.

Table 4 Maximum/mean on-field and off-field estimated daily exposure (EDE) for birds and mammals (turf: 2 × 1536 g a.i./ha, foliar half-life 7.67 days, field sprayer)

Generic Body weight (kg)	FIR[a] (kg dw diet/day)	Food Guild (food item)[b,c]	Maximum/mean nomogram residues			
			On-field		Off-field (6% deposition)	
			EEC	EDE[d]	EEC	EDE
			(mg a.i./kg diet)	(mg a.i./kg bw)	(mg a.i./kg diet)	(mg a.i./kg bw)
Birds						
0.02	0.0051	Insectivore (small insect)	628.7/434.1	160.3/110.7	37.7/26.0	9.6/6.6
0.02	0.0051	Granivore (grain and seeds)	97.3/46.4	24.8/11.8	5.8/2.8	1.5/0.7
0.02	0.0051	Frugivore (fruit)	194.6/92.8	49.6/23.7	11.7/5.6	3.0/1.4
0.1	0.0199	Insectivore (large insect)	628.7/434.1	125.1/86.4	37.7/26.0	7.5/5.2
0.1	0.0199	Granivore (grain and seeds)	97.3/46.4	19.4/9.2	5.8/2.8	1.2/0.6
0.1	0.0199	Frugivore (fruit)	194.6/92.8	38.7/18.5	11.7/5.6	2.3/1.1
1	0.0581	Insectivore (small insect)	628.7/434.1	36.5/25.2	37.7/26.0	2.2/1.5
1	0.0581	Granivore (grain and seeds)	97.3/46.4	5.7/2.7	5.8/2.8	0.3/0.2
1	0.0581	Frugivore (fruit)	194.6/92.8	11.3/5.4	11.7/5.6	0.7/0.3
1	0.0581	Herbivore (short grass)	1390.9/494.0	80.8/28.7	83.5/29.6	4.8/1.7
1	0.0581	Herbivore (long grass)	849.3/277.3	49.3/16.1	51.0/16.6	3.0/1.0
1	0.0581	Herbivore (Broadleaf plants)	1286.9/425.4	74.8/24.7	77.2/25.5	4.5/1.5
Mammals						
0.015	0.0022	Insectivore (small insect)	628.7/434.1	92.2/63.7	37.7/26.0	5.5/3.8
0.015	0.0022	Granivore (grain and seeds)	97.3/46.4	14.3/6.8	5.8/2.8	0.9/0.4
0.015	0.0022	Frugivore (fruit)	194.6/92.8	28.5/13.6	11.7/5.6	1.7/0.8
0.035	0.0045	Insectivore	628.7/434.1	80.8/55.8	37.7/26.0	4.9/3.3
0.035	0.0045	Granivore (grain and seeds)	97.3/46.4	12.5/6.0	5.8/2.8	0.8/0.4
0.035	0.0045	Frugivore (fruit)	194.6/92.8	25.0/12.0	11.7/5.6	1.5/0.7
0.035	0.0045	Herbivore (short grass)	1391.0/494.0	178.8/63.5	83.5/29.6	10.7/3.8
0.035	0.0045	Herbivore (long grass)	849.3/277.3	109.2/35.7	51.0/16.6	6.6/2.1
0.035	0.0045	Herbivore (forage crops)	1287.0/425.4	165.5/54.7	77.2/25.5	10.0/3.3
1	0.0687	Insectivore	628.7/434.1	43.2/29.8	37.7/26.0	2.6/1.8
1	0.0687	Granivore (grain and seeds)	97.3/46.4	6.7/3.2	5.8/2.8	0.4/0.2
1	0.0687	Frugivore (fruit)	194.6/92.8	13.4/6.4	11.7/5.6	0.8/0.4
1	0.0687	Herbivore (short grass)	1391.0/494.0	95.6/34.0	83.5/29.6	5.7/2.0
1	0.0687	Herbivore (long grass)	849.3/277.3	58.3/19.1	51.0/16.6	3.5/1.1
1	0.0687	Herbivore (Broadleaf plants)	1287.0/425.4	88.4/29.2	77.2/25.5	5.3/1.8

[a] Food Ingestion Rates (Nagy, 1987). For generic birds with body weight less than or equal to 200 g, the "passerine" equation was used; for generic birds with body weight greater than 200 g, the "all birds" equation was used:

Passerine Equation (body weight < or =200 g): FIR (g dry weight/day) = 0.398(BW in g) $^{0.850}$
All birds Equation (body weight > 200 g): FIR (g dry weight/day) = 0.648(BW in g) $^{0.651}$. For mammals, the "all birds" equation was used: FIR (g dry weight/day) = 0.235(BW in g) $^{0.822}$

[b] Large insects not considered to be a relevant food source for small birds and mammals.

[c] For granivorous species, only grains and seeds were considered as a relevant source of exposure (as opposed to seeds in pods, which were not considered).

[d] EDE = Estimated dietary exposure; is calculated using the following formula: (FIR/BW) × EEC. At the screening level, food items representing the most conservative EEC are used.

Table 5 Maximum/mean on-field and off-field estimated daily exposure for birds and mammals (asparagus: 4 × 126 g a.i./ha, foliar half-life 7.67 days, field sprayer)

Generic Body weight (kg)	FIR[a] (kg dwdiet/day)	Food Guild (food item)[b,c]	Maximum/mean nomogram residues			
			On-field		Off-field (6% deposition)	
			EEC	EDE[d]	EEC	EDE
			(mg a.i./kg diet)	(mg a.i./kg bw)	(mg a.i./kg diet)	(mg a.i./kg bw)
Birds						
0.02	0.0051	Insectivore (small insect)	55.7/38.4	14.2/9.8	3.3/2.3	0.9/0.6
0.02	0.0051	Granivore (grain and seeds)	8.6/4.1	2.2/1.0	0.5/0.2	0.1/0.1
0.02	0.0051	Frugivore (fruit)	17.2/8.2	4.4/2.1	1.0/0.5	0.3/0.1
0.1	0.0199	Insectivore (large insect)	55.7/38.4	11.1/7.7	3.3/2.3	0.7/0.5
0.1	0.0199	Granivore (grain and seeds)	8.6/4.1	1.7/0.8	0.5/0.2	0.1/0.05
0.1	0.0199	Frugivore (fruit)	17.2/8.2	3.4/1.6	1.0/0.5	0.2/0.1
1	0.0581	Insectivore (small insect)	55.7/38.4	3.2/2.2	3.3/2.3	0.2/0.1
1	0.0581	Granivore (grain and seeds)	8.6/4.1	0.5/0.2	0.5/0.2	0.03/0.01
1	0.0581	Frugivore (fruit)	17.2/8.2	1.0/0.5	1.0/0.5	0.1/0.03
1	0.0581	Herbivore (short grass)	123.2/43.7	7.2/2.5	7.4/2.6	0.4/0.2
1	0.0581	Herbivore (long grass)	75.2/24.6	4.4/1.4	4.5/1.5	0.3/0.1
1	0.0581	Herbivore (Broadleaf plants)	114.0/37.7	6.6/2.2	6.8/2.3	0.4/0.1
Mammals						
0.015	0.0022	Insectivore (small insect)	55.7/38.4	8.2/5.6	3.3/2.3	0.5/0.3
0.015	0.0022	Granivore (grain and seeds)	8.6/4.1	1.3/0.6	0.5/0.2	0.1/0.04
0.015	0.0022	Frugivore (fruit)	17.2/8.2	2.5/1.2	1.0/0.5	0.2/0.07
0.035	0.0045	Insectivore	55.7/38.4	7.2/5.0	3.3/2.3	0.4/0.3
0.035	0.0045	Granivore (grain and seeds)	8.6/4.1	1.1/0.5	0.5/0.2	0.1/0.03
0.035	0.0045	Frugivore (fruit)	17.2/8.2	2.2/1.1	1.0/0.5	0.1/0.06
0.035	0.0045	Herbivore (short grass)	123.2/43.7	15.8/5.6	7.4/2.6	1.0/0.3
0.035	0.0045	Herbivore (long grass)	75.2/24.6	9.7/3.2	4.5/1.5	0.6/0.2
0.035	0.0045	Herbivore (forage crops)	114.0/37.7	14.7/4.8	6.8/2.3	0.9/0.3
1	0.0687	Insectivore	55.7/38.4	3.8/2.6	3.3/2.3	0.2/0.2
1	0.0687	Granivore (grain and seeds)	8.6/4.1	0.6/0.3	0.5/0.2	0.04/0.02
1	0.0687	Frugivore (fruit)	17.2/8.2	1.2/0.6	1.0/0.5	0.07/0.03
1	0.0687	Herbivore (short grass)	123.2/43.7	8.5/3.0	7.4/2.6	0.5/0.2
1	0.0687	Herbivore (long grass)	75.2/24.6	5.2/1.7	4.5/1.5	0.3/0.1
1	0.0687	Herbivore (Broadleaf plants)	114.0/37.7	7.8/2.6	6.8/2.3	0.5/0.2

[a] Food Ingestion Rates (Nagy, 1987). For generic birds with body weight less than or equal to 200 g, the "passerine" equation was used; for generic birds with body weight greater than 200 g, the "all birds" equation was used:
Passerine Equation (body weight < or =200 g): FIR (g dry weight/day) = 0.398(BW in g) $^{0.850}$
All birds Equation (body weight > 200 g): FIR (g dry weight/day) = 0.648(BW in g) $^{0.651}$. For mammals, the "all birds" equation was used: FIR (g dry weight/day) = 0.235(BW in g) $^{0.822}$

[b] Large insects not considered to be a relevant food source for small birds and mammals.

[c] For granivorous species, only grains and seeds were considered as a relevant source of exposure (as opposed to seeds in pods, which were not considered).

[d] EDE = Estimated dietary exposure; is calculated using the following formula: (FIR/BW) × EEC. At the screening level, food items representing the most conservative EEC are used.

Table 6 Maximum/mean on-field and off-field estimated daily exposure for birds and mammals (soybean: 2 × 136 g a.i./ha, 14 d interval, foliar half-life 7.67 days; field sprayer and aerial application)

Generic Body weight (kg)	FIR[a] (kg dw diet/day)	Food Guild (food item)[b,c]	Maximum/mean nomogram residues			
			On-field		Off-field (field, 6% spray drift)	Off-field (aerial, 23% spray drift)
			EEC (mg a.i./kg diet)	EDE[d] (mg a.i./kg bw)	EDE (mg a.i./kg bw)	EDE (mg a.i./kg bw)
Birds						
0.02	0.0051	Insectivore (small insect)	55.7/38.4	14.2/9.8	0.9/0.6	3.3/2.3
0.02	0.0051	Granivore (grain and seeds)	8.6/4.1	2.2/1.0	0.1/0.1	0.5/0.2
0.02	0.0051	Frugivore (fruit)	17.2/8.2	4.4/2.1	0.3/0.1	1.0/0.5
0.1	0.0199	Insectivore (large insect)	55.7/38.4	11.1/7.6	0.7/0.5	2.5/1.8
0.1	0.0199	Granivore (grain and seeds)	8.6/4.1	1.7/0.8	0.1/0.05	0.4/0.2
0.1	0.0199	Frugivore (fruit)	17.2/8.2	3.4/1.6	0.2/0.1	0.8/0.4
1	0.0581	Insectivore (small insect)	55.7/38.4	3.2/2.2	0.2/0.1	0.7/0.5
1	0.0581	Granivore (grain and seeds)	8.6/4.1	0.5/0.2	0.03/0.01	0.1/0.1
1	0.0581	Frugivore (fruit)	17.2/8.2	1.0/0.5	0.1/0.03	0.2/0.1
1	0.0581	Herbivore (short grass)	123.2/43.7	7.2/2.5	0.4/0.2	1.7/0.6
1	0.0581	Herbivore (long grass)	75.2/24.6	4.4/1.4	0.3/0.09	1.0/0.3
1	0.0581	Herbivore (Broadleaf plants)	114.0/37.7	6.6/2.2	0.4/0.1	1.5/0.5
Mammals						
0.015	0.0022	Insectivore (small insect)	55.7/38.4	8.2/5.6	0.5/0.3	1.9/1.3
0.015	0.0022	Granivore (grain and seeds)	8.6/4.1	1.3/0.6	0.1/0.04	0.3/0.1
0.015	0.0022	Frugivore (fruit)	17.2/8.2	2.5/1.2	0.2/0.1	0.6/0.3
0.035	0.0045	Insectivore	55.7/38.4	7.2/5.0	0.4/0.3	1.7/1.1
0.035	0.0045	Granivore (grain and seeds)	8.6/4.1	1.1/0.5	0.1/0.03	0.3/0.1
0.035	0.0045	Frugivore (fruit)	17.2/8.2	2.2/1.1	0.1/0.1	0.5/0.2
0.035	0.0045	Herbivore (short grass)	123.2/43.7	15.8/5.6	1.0/0.3	3.6/1.3
0.035	0.0045	Herbivore (long grass)	75.2/24.6	9.7/3.2	0.6/0.2	2.2/0.7
0.035	0.0045	Herbivore (forage crops)	114.0/37.7	14.7/4.8	0.9/0.3	3.4/1.1
1	0.0687	Insectivore	55.7/38.4	3.8/2.6	0.2/0.2	0.9/0.6
1	0.0687	Granivore (grain and seeds)	8.6/4.1	0.6/0.3	0.04/0.02	0.1/0.1
1	0.0687	Frugivore (fruit)	17.2/8.2	1.2/0.6	0.1/0.03	0.3/0.1
1	0.0687	Herbivore (short grass)	123.2/43.7	8.5/3.0	0.5/0.2	2.0/0.7
1	0.0687	Herbivore (long grass)	75.2/24.6	5.2/1.7	0.3/0.1	1.2/0.4

Generic Body weight (kg)	FIR[a] (kg dw diet/day)	Food Guild (food item)[b,c]	Maximum/mean nomogram residues			
			On-field		Off-field (field, 6% spray drift)	Off-field (aerial, 23% spray drift)
			EEC	EDE[d]	EDE	EDE
			(mg a.i./kg diet)	(mg a.i./kg bw)	(mg a.i./kg bw)	(mg a.i./kg bw)
1	0.0687	Herbivore (Broadleaf plants)	114.0/37.7	7.8/2.6	0.5/0.2	1.8/0.6

[a] Food Ingestion Rates (Nagy, 1987). For generic birds with body weight less than or equal to 200 g, the "passerine" equation was used; for generic birds with body weight greater than 200 g, the "all birds" equation was used:
Passerine Equation (body weight < or =200 g): FIR (g dry weight/day) = 0.398(BW in g) $^{0.850}$
All birds Equation (body weight > 200 g): FIR (g dry weight/day) = 0.648(BW in g) $^{0.651}$. For mammals, the "all birds" equation was used: FIR (g dry weight/day) = 0.235(BW in g) $^{0.822}$

[b] Large insects not considered to be a relevant food source for small birds and mammals.

[c] For granivorous species, only grains and seeds were considered as a relevant source of exposure (as opposed to seeds in pods, which were not considered).

[d] EDE = Estimated dietary exposure; is calculated using the following formula: (FIR/BW) × EEC. At the screening level, food items representing the most conservative EEC are used.

Table 7 Maximum and minimum on-field and off-field estimated daily exposure for birds and mammals (SRIC poplar/willow: 2 × 126 g a.i./ha, interval 28 days, foliar half-life 7.67 days; field sprayer, early and late airblast, and non-crop-aerial)

			Maximum/mean nomogram residues					
Generic Body weight (kg)	FIR[a] (kg dw diet/day)	Food Guild (food item)[b,c]	on-field		off-field (6% spray drift for field sprayer)	off-field (74% spray drift for early airblast)	off-field (59% spray drift for late airblast)	off-field (60% spray drift for non-crop aerial)
			EEC (mg a.i./kg diet)	EDE[d] (mg a.i./kg bw)	EDE[d] (mg a.i./kg bw)	EDE[d] (mg a.i./kg bw)	EDE[d] (mg a.i./kg bw)	EDE[d] (mg a.i./kg bw)
Birds								
0.02	0.0051	Insectivore	43.4/30.0	11.1/7.6	0.7/0.5	8.2/5.7	6.5/4.5	6.6/4.6
0.02	0.0051	Granivore (grain and seeds)	6.7/3.2	1.7/0.8	0.1/0.05	1.3/0.6	1.0/0.5	1.0/0.5
0.02	0.0051	Frugivore (fruit)	13.4/6.4	3.4/1.6	0.2/0.1	2.5/1.2	2.0/1.0	2.0/1.0
0.1	0.0199	Insectivore	43.4/30.0	8.6/6.0	0.5/0.4	6.4/4.4	5.2/3.5	5.1/3.6
0.1	0.0199	Granivore (grain and seeds)	6.7/3.2	1.3/0.6	0.1/0.04	1.0/0.5	0.8/0.4	0.8/0.4
0.1	0.0199	Frugivore (fruit)	13.4/6.4	2.7/1.3	0.2/0.1	2.0/1.0	1.6/0.8	1.6/0.8
1	0.0581	Insectivore	43.4/30.0	2.5/1.7	0.2/0.1	1.9/1.3	1.5/1.0	1.5/1.0
1	0.0581	Granivore (grain and seeds)	6.7/3.2	0.4/0.2	0.02/0.01	0.3/0.1	0.2/0.1	0.2/0.1
1	0.0581	Frugivore (fruit)	13.4/6.4	0.8/0.4	0.05/0.02	0.6/0.3	0.5/0.2	0.5/0.2
1	0.0581	Herbivore (short grass)	96.1/34.1	5.6/2.0	0.3/0.1	4.1/1.5	3.4/1.2	3.4/1.2
1	0.0581	Herbivore (long grass)	58.7/19.2	3.4/1.1	0.2/0.07	2.5/0.8	2.0/0.7	2.0/0.7
1	0.0581	Herbivore (Broadleaf plants)	88.9/29.4	5.2/1.7	0.3/0.1	3.8/1.3	3.1/1.0	3.1/1.0
Mammals								
0.015	0.0022	Insectivore	43.4/30.0	6.3/4.4	0.4/0.3	4.7/3.2	3.8/2.6	3.8/2.6
0.015	0.0022	Granivore (grain and seeds)	6.7/3.2	1.0/0.5	0.1/0.03	0.7/0.3	0.6/0.3	0.6/0.3
0.015	0.0022	Frugivore (fruit)	13.4/6.4	2.0/1.0	0.1/0.06	1.5/0.7	1.2/0.6	1.2/0.6

Generic Body weight (kg)	FIR[a] (kg dw diet/day)	Food Guild (food item)[b,c]	Maximum/mean nomogram residues					
			on-field		off-field (6% spray drift for field sprayer)	off-field (74% spray drift for early airblast)	off-field (59% spray drift for late airblast)	off-field (60% spray drift for non-crop aerial)
			EEC (mg a.i./kg diet)	EDE[d] (mg a.i./kg bw)	EDE[d] (mg a.i./kg bw)	EDE[d] (mg a.i./kg bw)	EDE[d] (mg a.i./kg bw)	EDE[d] (mg a.i./kg bw)
0.035	0.0045	Insectivore	43.4/30.0	5.6/3.8	0.3/0.2	4.1/2.9	3.3/2.3	3.4/2.3
0.035	0.0045	Granivore (grain and seeds)	6.7/3.2	0.9/0.4	0.05/0.02	0.6/0.3	0.5/0.2	0.5/0.3
0.035	0.0045	Frugivore (fruit)	13.4/6.4	1.7/0.8	0.1/0.05	1.3/0.6	1.0/0.5	1.0/0.5
0.035	0.0045	Herbivore (short grass)	96.1/34.1	12.2/4.4	0.7/0.3	9.1/3.2	7.3/2.6	7.4/2.6
0.035	0.0045	Herbivore (long grass)	58.7/19.2	7.5/2.5	0.5/0.2	5.6/1.8	4.5/1.5	4.5/1.5
0.035	0.0045	Herbivore (forage crops)	88.9/29.4	11.4/3.8	0.7/0.2	8.5/2.8	6.7/2.2	6.9/2.3
1	0.0687	Insectivore	43.4/30.0	3.0/2.1	0.2/0.1	2.2/1.5	1.8/1.2	1.8/1.2
1	0.0687	Granivore (grain and seeds)	6.7/3.2	0.5/0.2	0.03/0.01	0.3/0.2	0.3/0.1	0.3/0.1
1	0.0687	Frugivore (fruit)	13.4/6.4	1.0./0.4	0.1/0.03	0.7/0.3	0.5/0.3	0.6/0.3
1	0.0687	Herbivore (short grass)	96.1/34.1	6.6/2.3	0.4/0.1	4.9/1.7	3.9/1.4	4.0/1.4
1	0.0687	Herbivore (long grass)	58.7/19.2	4.0/1.3	0.2/0.08	3.0/1.0	2.4/0.8	2.4/0.8
1	0.0687	Herbivore (Broadleaf plants)	88.9/29.4	6.1/2.0	0.4/1	4.5/1.5	3.6/1.2	3.7/1.2

[a] Food Ingestion Rates (Nagy, 1987). For generic birds with body weight less than or equal to 200 g, the "passerine" equation was used; for generic birds with body weight greater than 200 g, the "all birds" equation was used:
Passerine Equation (body weight < or =200 g): FIR (g dry weight/day) = 0.398(BW in g) $^{0.850}$
All birds Equation (body weight > 200 g): FIR (g dry weight/day) = 0.648(BW in g) $^{0.651}$. For mammals, the "all birds" equation was used: FIR (g dry weight/day) = 0.235(BW in g) $^{0.822}$

[b] Large insects not considered to be a relevant food source for small birds and mammals.

[c] For granivorous species, only grains and seeds were considered as a relevant source of exposure (as opposed to seeds in pods, which were not considered).

[d] EDE = Estimated dietary exposure; is calculated using the following formula: (FIR/BW) × EEC. At the screening level, food items representing the most conservative EEC are used.

Table 8 Estimated Dietary Exposure for treated seeds (corn and wheat)

EDE (mg a.i./kgbw/d)		
Organisms	**Field corn**	**Wheat**
Small bird (0.02 kg)	38.1	7.6
Medium bird (0.10 kg)	30.0	6.0
Large bird (1.00 kg)	8.7	1.7
Small mammals (0.015 kg)	21.8	4.4
Medium mammals (0.035 kg)	18.7	3.7
Large mammals (1.00 kg)	10.3	2.1

Table 9 On-field and off-field cumulative rates for application to turf, asparagus, soybean and SRIC poplar/willow for determining exposure on foliage of terrestrial plants

Crop	**Use rate (g a.i./ha)**	**On-field cumulative rate (g a.i./ha)[1]**	**Off-field cumulative rate/ EEC (g a.i./ha)[3]**	
			Drift[2]	**EEC (g a.i./ha)**
Turf	2 × 1536 (14 d interval)	1969.6	6% (field sprayer)	118.2
Asparagus	4 × 126 (14 d interval)	174.4	6% (field sprayer)	10.5
Soybean	2× 136 (14 d interval)	174.4	6% (field sprayer)	10.5
			23% (aerial-crop, medium droplets)	40.1
SRIC Poplar/ Willow	2 × 126 (28 d interval)	136.0	6% (ground application)	8.2
			74% (airblast-early season, fine droplets)	100.6
			59% (airblast-late season, fine droplets)	80.2
			60% (aerial-non-crops, medium droplets)	81.6

[1] Using a foliar dissipation half-life of 7.67 d (PMRA# 3133553)

[2] Drift is estimated at 1 metre from treated area. Application on turf (any time at the first of disease symptoms or as early as spring and as late as snow cover); Application on soybean (when first symptoms of disease can be found or the risk of infection is imminent; application on poplar/willow (timing depends on tree and climate zone. First application: can be as early as late April to late May (British Columbia Coast) and as late as mid June to early July (Prairie region). Second application as early as mid July and as late as mid August.

[3] Off-field EEC = (cumulative rate × drift factor)

Table 10 Summary of effects on terrestrial organisms

Organism	Exposure	Test substance	Endpoint	Value and Description	Comments	Reference (PMRA#)
Invertebrates						
Earthworms (*Eisenia fetida*)	14-d Acute	Tebuconazole	LC_{50} NOEC	1381 mg a.i./kg dw soil 178 mg a.i./kg dw soil (based on weight loss)	Relatively non-toxic	1417830
	14-d Acute	Folicur EW 250 (contained 254 g a.i./L)	LC_{50}	>1000 mg formulation/ kg dw soil Based on a.i. > 254 mg a.i./kg dw soil	No symptoms of significant weight changes observed in all test concentrations.	3131949
Earthworms *(Lumbricus terrestris)*	28-d Chronic	Folicur 250 EW	LR_{50}	>1875 g a.i./ha	No effects to adult *Lumbricus terrestris* after 1 month exposure.	
Earthworms *(Aporrectodea caliginosa)*	28-d and 56-d Chronic		LR_{50}	>1875 g a.i./ha	No effects to adult *Aporrectodea caliginosa* after 1 and 2 months exposure.	
Earthworms (*Eisenia fetida*)	14-d Acute	Raxil FS 040 (contained Tebuconazole (21.4g/L) and triazoxide (22.2 g/L)	LC_{50}	>1000 mg formulation/kg dw soil Based on a.i. >21.4 mg a.i./kg dw soil	No mortality was observed at any concentration.	
	56-d Chronic	Tebuconazole (97% purity)	NOEC (reproduction) LOEC	10 mg a.i./kg dw soil 32 mg a.i./kg dw soil	No significant mortality No impact on weight Significant reduction of number of offspring/adult at the two highest concentration	
	28-d Chronic	Tebuconazole 250 EW (also called Folicur EW 250, a.i.= 255 g/L)	NOER based on reproduction	< 375 g a.i./ha	No mortality or effects on biomass of adult earthworms. Significant reduction of number of juvenile at both tested rates. No significant reduction of juvenile biomass.	

Organism	Exposure	Test substance	Endpoint	Value and Description	Comments	Reference (PMRA#)
	56-d Chronic	Raxil FS 040 (tebuconazole 21.4 g/l and triazoxide 22.2 g/L)	NOER	> 950 kg barley seed/ha >1.9 mg formulation/kg dw soil	Application rates: 190, 380 and 950 kg barley/ha. No significant mortality or body weight reduction at the highest application rate.	
Earthworm populations, 7 species	Field study – 5 years	First year (1991): 2 × Matador EC 300 (225 g tebuconazole and 75 g triadimenol/L as active ingredients Other years: 2 × Folicur EW 250 (Tebuconazole 250 g/L)	No effect on populations at 2 applications/year of 225–375 g a.i./ha in an arable field under natural conditions over 5 years.			3131949
Earthworm populations, 5 species	Field study – 5 years	First year: 2 × Matador EC 300 (225 g tebuconazole and 75 g triadimenol/L as active ingredients Other years: 2 × Folicur EW 250 (Tebuconazole 250 g/L)	No effect on populations at 2 applications/year of 225–375 g a.i./ha in an arable field under natural conditions over 5 years.			
Earthworm populations, 4 species	Field study – 5 years	Folicur EC 250/EW 250	No effect on populations at 2 applications/year of 225–375 g a.i./ha in an arable field under natural conditions over 5 years.			
Pollinators (studies submitted to PMRA during data call in)						
Honeybee (*Apis Mellifera*)	48-h Oral	Tebuconazole (technical grade active ingredient)	LD_{50} (Limit test)	> 83.05 µg a.i./bee	**S**ingle dose (nominal) 200 µg a.i./bee, corresponded to intake of 83.05 µg a.i./bee. Practically non-toxic	2758964
		Tebuconazole EW 250 (253 g/L a.i.)	LD_{50}	78.8 µg a.i./bee (302 µg product/bee)	Registered formulated product in Canada. Practically non-toxic	2758961
		Tebuconazole 430 (HWG 1608) (433.95 g/L a.i.)	LD_{50}	42.16 µg a.i./bee (108.94 µg product/bee)	Mortality occurred in all treatment groups in a dose-related pattern with the lowest	2758962

Organism	Exposure	Test substance	Endpoint	Value and Description	Comments	Reference (PMRA#)
					mortality (8%) occurring at the lowest dose (32.3 µg product/bee) and the highest mortality (76%) at the highest dose (516.89 µg product/bee) of test item. Practically non-toxic	
		JAU 6476 and Tebuconazole EC 250	LD_{50}	> 484.31 µg product/bee	Practically non-toxic	2758963
	48-h Contact	Tebuconazole (technical grade active ingredient)	LD_{50} (Limit test)	> 200 µg a.i./bee	Practically non-toxic	2758964
		Folicur EW 250 (250 g/L a.i.)	LD_{50}	47.8 µg a.i./bee (183 µg product/bee)	Practically non-toxic	2758961
		Tebuconazole 430 (HWG 1608)	LD_{50}	> 200.0 µg a.i./bee (>516.80 µg product/bee)	Practically non-toxic	2758962
		JAU 6476 and Tebuconazole EC 250	LD_{50}	339.57 µg product/bee	Practically non-toxic	2758963
	10-d Chronic	Tebuconazole SC 430 (430 g/L a.i.)	Chronic feeding, LD_{50} NOEL	10.2 µg a.i./bee/day 4.86 µg a.i./bee/day	Bees were continuously exposed ad libitum for 10 days to 6.25, 12.5, 25, 50 and 100 µg a.i./bee/d). Actual mean daily intake was 2.87, 4.86, 8.80, 19.5 and 38.3 µg a.i./bee/d. Mortality ranged from 6.7% to 100% from the lowest to the highest dose on day 10. At dose level of 8.80 µg a.i./bee/day 50% mortality was observed on day 10.	2758967
	96-h Larval Toxicity Test (diet)	Tebuconazole (technical grade active ingredient)	LD_{50}	11.4 µg a.i./larva	First instar larvae (36) from three different honey bee colonies	2758966

Organism	Exposure	Test substance	Endpoint	Value and Description	Comments	Reference (PMRA#)
					were exposed to tebuconazole spiked in artificial diets at doses of 1.2 , 3.7, 11.1, 33.3 and 100 µg a.i./larva on day 4 of their developmental stage (single exposure). 96 hours following dosing, 100.0, 91.7, 47.2, 22.2 and 19.4% mortality was observed in the test item treated groups of 100.0, 33.3, 11.1, 3.7 and 1.2 µg a.i./larva. **Practically non-toxic**	
	Honey Bee Brood	Tebuconazole EW 250R (248.7 g/L a.i.)	N/A	Tebuconazole EW 250R has no adverse effects on the honey bee at colony level	Semi-field (4 tunnel).	2758968
Non-Apis Bee (*Bombus terrestris*)	Oral	Tebuconazole (technical grade active ingredient) – limit test	48-h LD_{50}	> 154.47 µg a.i./bee	Practically non-toxic	2758960
	Contact		48-h LD_{50}	> 200 µg a.i./bee	Practically non-toxic	
Beneficial Arthropods (studies submitted to the PMRA during data call in)						
Predatory mites						
Predaceous mite (*Hypoaspis aculeifer*) Soil dwelling	Contact (media: soil)	Tebuconazole EW 250 (also called Folicur EW 250)	LC_{50} NOEC	79.8 mg a.i./kg dry soil 56.2 mg a.i./kg dry soil (based on effect on reproduction)	More than 50% mortality at >100 mg a.i./kg soil.	2758977
Predaceous mite (*Typhlodromus pyri*) (standard species)	Contact (media: leaves)	Tebuconazole EW 250	LR_{50}	211 g a.i./ha	Effect on reproduction is 38% and 57% at 100 and 150 g a.i./ha, respectively.	2758979
		Prothioconazole and Tebuconazole EC 250	LR_{50}	144.4 mL product/ha	Negative effect on reproduction is significant from rate 213 mL/ha onward.	2758976

Organism	Exposure	Test substance	Endpoint	Value and Description	Comments	Reference (PMRA#)
			N/A - Only one rate used (1 L product/ha), which caused 100% mortality on the first day and significant mortality due to exposure to 7-day aged residue	Mortality occurred on mites exposed to foliage one week after the treatment (7-day aged residues); Mites exposed to foliage collected two weeks after the treatment (14-day aged residues) were not adversely affected.		2758978
		Tebuconazole SC 430	LR_{50}	>800 g a.i./ha	No significant effects on reproduction. Practically non-toxic.	2758975
	Contact (media: glass plate)	Folicur EW 250 (identified in the study as HWG 1608 EW 250)	LR_{50} NOER	58 g a.i./ha 17.5 g a.i./ha	Delay in development at 30 g a.i./ha and higher.	2758983
	Semi-field (maize leaves)	Prothioconazole and Tebuconazole EC 125 +125	N/A	Only 1% mortality in treated mites. Significant effects on reproduction (73.3%) on DAT 0 (exposure to fresh residues). No significant effects on reproduction on DA0T 14 (exposures to aged residues).		2758974
		Tebuconazole EW 250	N/A	Application of 2 × 375 g a.i./ha/14 days interval to potted maize plants. No significant mortality due to fresh and aged residues. No significant impact on reproductive success. Practically non-toxic.		2758971
Parasitoids (studies submitted to the PMRA during data call in)						
Parasitic wasp (*Aphidius rhopalosiphi*) (standard species)	Contact (media: barley leaves)	Folicur EW 250	LR_{50}	36.8 g a.i./ha	No sub-lethal treatment effects observed for the 1, 10 and 25 g a.i./ha treatment rates. No impact on the fecundity of surviving individuals.	2758990
		Prothioconazole and Tebuconazole EC 250 (124.97 g/L each a.i.)	N/A	LR_{50} not determined due to insufficient mortality in the first rate.	Two rates, 1000 and 2000 mL product/ha used; Mortality is significant for both rates	2758988

Organism	Exposure	Test substance	Endpoint	Value and Description	Comments	Reference (PMRA#)
					(28.6% and 92.6%); No significant effects on fecundity of surviving females at 1000 mL/ha group.	
		HWG 1608 430 SC	LR_{50}	> 800 g a.i./ha	No significant effects on fecundity at the highest rate. Practically non-toxic	2758987
	Contact (media: glass plate)	Tebuconazole EW 250 (also called Folicur EW 250)	LR_{50}	62.5 g a.i./ha		2758989
Foliage dwelling predators (studies submitted to the PMRA during data call in)						
Ladybird (*Coccinella septempunctata*)	Contact (media: leaves)	Tebuconazole SC 430	LR_{50}	> 650 g a.i./ha	No adverse effects on reproduction. Practically non-toxic	2758970
		Prothioconazole and Tebuconazole EC 125 +125	LR_{50}	1863 mL product/ha	No adverse effects on reproduction.	2758973
	Contact (media: glass; larval study	Tebuconazole EW 250 (Folicur EW 250)	Larvae LR_{50}	158 g a.i./ha	No abnormalities were recorded in the larvae.	2758981
	Semi-field, life cycle (media: plant)	Folicur EW 250	LR_{50}	Could not be calculated	Application of Folicur EW 250 at 1.5 L product/ha (375 g a.i./ha) will not cause adverse effects on ladybird at the population level.	2758985
Green lacewing (*Chrysoperla carnea*)	Contact (media: leaves)	Prothioconazole and Tebuconazole EC 125 + 125	LR_{50}	> 3600 mL product/ha	Fecundity not affected. Practically non-toxic	2758972
Ground dwelling predators (studies submitted to the PMRA during data call in)						
Rove beetle (*Aleochara bilineata*)	Contact (media: soil)	Tebuconazole SC 430	ER_{50} NOER	> 900 g a.i./ha 900 g a.i./ha	26.6% reduction in reproductive capacity at 900 g a.i./ha relative to control. Practically non-toxic.	2758969

Organism	Exposure	Test substance	Endpoint	Value and Description	Comments	Reference (PMRA#)
		Tebuconazole EW 250 (Folicur EW 250) – Life cycle	ER_{50}	> 500 g a.i./ha	No effects were found on the life-cycle of beetles at the highest rate tested. Practically non-toxic	2758980
Carabid beetle (*Poecilus cupreus*)	Contact (media: soil)	Tebuconazole EW 250 (Folicur EW 250)	LR_{50}	> 500 g a.i./ha	Tebuconazole EW 250 at an application rate of 500 g a.i./ha did not cause mortality or adverse effects on ground beetles. Practically non-toxic	2758982
		Folicur EW 250	LR_{50}	> 375 g a.i.//ha	Exposure to spray treatment with Folicur EW 250 at an application rate of 375 g a.i./ha did not cause adverse effects on: rate of development and metamorphosis of ground beetles larvae and body mass of emerging beetles. Practically non-toxic.	2758984
Birds						
Bobwhite quail (*Colinus virginianus*)	Acute oral	Tebuconazole	LD_{50} NOEL	1988 mg a.i./kg bw 432 mg a.i./kg bw (based on transient decreases of bw)	Slightly toxic	3131947
	Dietary	Tebuconazole	LC_{50} LD_{50} NOEC	>5000 mg a.i./kg diet > 703 mg a.i./kg bw/d <325 mg a.i./kg diet (based on reduced bw)	Practically non-toxic	

Organism	Exposure	Test substance	Endpoint	Value and Description	Comments	Reference (PMRA#)
	Reproduction (24 weeks)	Tebuconazole	NOEC NOEL	≥ 73.5 mg a.i./kg diet ≥ 5.8 mg a.i./kg bw/d (highest tested dose)	At the highest concentration tested, there were: No mortalities or overt abnormal clinical signs. No effects on feed consumption or body weight. No effect on reproductive parameters.	
			NOEC (21 weeks) NOEL (based on the reduction in body weights of hatchlings and 14-day survivors) LOEC LOEL	<156 mg a.i./kg diet <12.4 mg a.i./kg bw/d 290 mg a.i./kg diet 23.2 mg a.i..kg bw/d	Negative impact on number of eggs (reduction). Negative impact on % hatching (reduction). Reduced body weight of hatchlings and 14-d survivors. Treatment-related lesion of liver (females).	
Mallard duck (*Anas platyrhynchos*)	Dietary	Tebuconazole	LC_{50} LD_{50} NOEC	>4816 mg a.i./kg diet > 1394 mg a.i./kg bw/d <4816 mg a.i./kg diet (based on transient weight gain and reduced bw)	Slightly toxic	3131947
	Reproduction (20 weeks)	Tebuconazole	NOEC NOEL	≥75.8 mg a.i./kg diet, the highest concentration tested ≥8.76 mg a.i./kg bw (the highest dose tested)	At the highest concentration tested there was: no mortalities or overt abnormal clinical signs, no effects on feed consumption or body weight, no effect on reproductive parameters.	1417830

Organism	Exposure	Test substance	Endpoint	Value and Description	Comments	Reference (PMRA#)
Mammals						
Rat	Acute oral	Tebuconazole	LD_{50}	2850 mg a.i./kg bw (combined males and females)	Slight acute toxicity	1417830
		Folicur 432F	LD_{50}	3743 a.i./kg bw (combined males and females)	Low acute toxicity	1417830
	Reproduction (Multi-generation dietary)	Tebuconazole	NOEL NOEL LOEL	24.4 mg a.i./kg bw/d (females) 30.9 mg a.i./kg bw/d (males) based on decreased pup viability and lactation index (survival during lactation) and decreased pup body weight. 84.8 mg a.i./kg bw/d (females) 103.1 mg a.i./kg bw/d (males)	NA	1417830
Mouse	Acute oral	Tebuconazole	LD_{50}	4000 mg a.i./kg bw (combined males and females)	Low acute toxicity	1417830
Vascular Plants						
Vascular plant	Vegetative vigour	Folicur 432F (Foliar Fungicide)	ER_{25}	> 453 g a.i./ha	No adverse effects were observed in the vegetative vigour test for all crops at the highest application rate tested.	1417830
	Seedling emergence and seedling growth (21-d)	Folicur 432F (Foliar Fungicide)	ER_{25}	63.3 g a.i./ha (biomass of tomato seedlings)	Tested turnip, soybean, tomato. Minimal phytotoxicity symptoms.	1522420
Six monocotyledon and five dicotyledon species	Laboratory herbicidal screening (21 days, pre-emergence)	Tebuconazole	N/A	N/A	4 out of 11 species showed relevant phytotoxic effects at 250 g a.i./ha	3131949
	Laboratory herbicidal		N/A	N/A	No relevant phytotoxic	

Organism	Exposure	Test substance	Endpoint	Value and Description	Comments	Reference (PMRA#)
	screening (17 days, foliar applied)				effects at 250 g a.i./ha	
Five monocotyledon and seven dicotyledon species	Laboratory herbicidal screening (21 days, pre-emergence)	Folicur EW 250	N/A	N/A	2 out of 12 species showed relevant phytotoxic effects at 250 g a.i./ha	
	Laboratory herbicidal screening (21 days, foliar applied)		N/A	N/A	No relevant phytotoxic effects at 250 g a.i./ha	
Oat, turnip and cress	OECD 208 study (14 days, test substance incorporated in the soil)	Tebuconazole	LC_{50} (emergence (all species) Lowest EC_{50} (growth of cress) Lowest EC_{25} (growth of cress)	≥ 100 mg a.i./kg dry soil, corresponding to ≥7 5000 g a.i./ha[1] 14 mg/kg dry soil = 10 500 g a.i./ha 6 mg/kg dry soil = 4500 g a.i./ha		
Two monocotyledon and five dicotyledon species	OECD 208 study (21 days, pre-emergence spray application)	Folicur EW 250	ER_{50} and ER_{25} (emergence and growth of all tested species)	>500 g a.i./ha		

[1]Calculated by the PMRA reviewer based on the soil bulk density of 1.5 g/cm^3 and depth of 5 cm (concentration (mg/kg) × density × depth × 100 = g/ha) (standard conversion).

Table 11 Summary of effects on Aquatic Organisms

Organism	Exposure	Test substance	Endpoint	Value and Description	Comments	Reference (PMRA#)
Freshwater Invertebrate						
Water flea (*Daphnia magna*) - pelagic	48-h Acute	Tebuconazole	EC_{50}	2.79 mg a.i./L	Abnormal effects of mortality, quiescence and/or daphnids laying on the bottom of test vessels were observed in the 1.6, 2.6 and 6.2 mg a.i./L. Moderate toxicity	3131948
	48-h Acute	Folicur EC 250	EC_{50}	5.6 mg a.i./L	Moderate toxicity	

Organism	Exposure	Test substance	Endpoint	Value and Description	Comments	Reference (PMRA#)
		Folicur EW 250	EC_{50}	4.7 mg a.i./L	Moderate toxicity	
	48-h Acute on young daphnia1st instars 6-24 h old)	Folicur EW 250	**Formulation** EC_{50} **Converted to a.i.** EC_{50}	7.3 mg product/L 1.9 mg a.i./L	Moderate toxicity	
	21-d Chronic	Tebuconazole	**Immobility** EC_{50} **Reproduction** NOEC LOEC	0.33 mg a.i./L 0.12 mg a.i./L 0.23 mg a.i./L	All young produced at all levels during the study appeared normal.	1417830 and 3131948
			Reproduction EC_{50} NOEC LOEC	0.14 mg a.i./L 0.01 mg a.i./L 0.03 mg a.i./L	No significant mortality and immobilization of parental occurred Significant numbers of stillborn at highest test concentration (0.9 mg a.i./L) Living juveniles per parent was reduced significantly at 0.01 mg a.i./L	3131948
Midge (*Chironomus riparius*)-bentic (sediment-dwelling)	28-d Chronic	Tebuconazole	NOEC (Larval emergence) **NOEC** (Development rate)	1.52 mg a.i./L 0.833 mg a.i./L	No comments.	1487904
Freshwater Fish						
Rainbow Trout (*Oncorhynchus mykiss*)	96-h Acute	Tebuconazole	LC_{50}	4.4 mg a.i./L	Moderately toxic	1417830
	96-h Acute	Folicur EW 250	<u>Formulation</u> LC_{50} <u>Converted to a.i.</u> LC_{50}	17.5 mg formulation/L 4.4 mg a.i./L	Moderately toxic	3131948
			Formulation LC_{50} **Converted to a.i.** LC_{50}	9.28 mg formulation/L 2.3 mg a.i./L	Moderately toxic	
	21-d prolonged toxicity test –semi-static (young fish)	Tebuconazole	NOEC LOEC	0.01 mg a.i./L 0.032 mg a.i./L	Refusal of diet, started from 0.032 to 1.0 mg a.i./L after 12 days and continued to the end of the study statistically significant effects	

Organism	Exposure	Test substance	Endpoint	Value and Description	Comments	Reference (PMRA#)
					on body weight and body length from 0.1 to 1.0 mg a.i./L.	
Rainbow Trout (*Salmo gairdneri*)	60-d Early life stage	Tebuconazole	NOEC LOEC	0.012 mg a.i./L 0.025 mg a.i./L	No adverse effects on fertilization and hatching of eggs; Reduction of larval survival; Post-hatched larval abnormal appearance and behaviour at conc. ≥0.025 mg a.i./L.	
Bluegill Sunfish (*Lepomis macrochirus*)	96-h Acute	Tebuconazole	LC_{50}	5.7 mg a.i./L	Moderately toxic	1417830
Freshwater Algae						
Green alga (*Scenedesmus subspicatus* – now *Desmodesmus subspicatus*)	96-h Acute	Tebuconazole	**Biomass growth** EC_{50} **Growth rate** EC_{50}	1.64 mg a.i./L 4.01 mg a.i./L	No abnormalities were observed.	1417830 and 3131948
Green Alga (*Selenastrum capricornutum*)	96-h Acute		**Biomass growth** EC_{50}	2.83 mg a.i./L	No abnormalities were observed.	3131948
Green alga (*Scenedesmus subspicatus*)	72-h Acute	Folicur EW 250	**Biomass growth** EC_{50} **Growth rate** EC_{50}	mg formulation/L 13.8 23.3	mg a.i./L 3.45 5.83	No abnormalities were observed
Freshwater Macrophytes						
Duckweed *(Lemna gibba G3)*	14-d Acute	Tebuconazole	EC_{50} (frond number) EC_{50} (biomass)	0.14 mg a.i./L 0.18 mg a.i./L	No comments.	1417830
Amphibians						
Dog frog (*Physalaemus cuvieri*)	96-h Acute	Tebuconazole 200 EC	LC_{50}	0.98 mg a.i./L	Highly toxic	3133551
Rainbow Trout (*Salmo gairdneri*) (Fish value used as surrogate for amphibians)	60-d Early life stage	Tebuconazole	NOEC	0.012 mg a.i./L	No comments.	3131948
Marine Invertebrates						
Mysid shrimp (*Mysidopsis bahia*)	96-h Acute	Tebuconazole	LC_{50}	0.45 mg a.i./L	Behavioural effects were observed at all test concentrations higher than 0.30 mg a.i./L. Highly toxic.	1417830

Organism	Exposure	Test substance	Endpoint	Value and Description	Comments	Reference (PMRA#)
	28-d Chronic		**Mortality** NOEC **Reproduction** (offspring/female/reproductive day) NOEC	≥150 mg a.i./L 0.035 mg a.i./L	No comments.	3131948
Eastern oyster (*Crassostrea virginica*)	96-h Acute	Tebuconazole	LC_{50} (based on the impact on shell deposition)	3.0 mg a.i./L	Moderately toxic	1417830
Marine Fish						
Sheepshead minnow (*Cyprinodon variegatus*)	96-h Acute	Tebuconazole	LC_{50}	>7.82 mg a.i./L (measured; maximum concentration tested)	No mortality at all the test concentrations. Quiescence and loss of equilibrium was observed 4 hours after treatment at 7.82 mg a.i./L and throughout the study up until study completion. Moderate toxicity	1522442
	96-h Acute		LC_{50}	5.9 mg a.i./L	Moderate toxicity	3131948
	36-d toxicity to embryos		NOEC (based on fry growth)	0.0219 mg a.i./L	Statistically significant effects on fry growth (expressed as length and weight).	
	24 weeks-Full life cycle		NOEC (based on growth of F_0)	0.044 mg a.i./L	Of the 13 measured endpoints, growth of F_0 at day 33 was the most sensitive endpoint.	1417830 and 3131948
Marine Algae						
Saltwater Diatom (*Skeletonema costatum*)	96-h Acute (static)	Tebuconazole	EC_{50} (cell density) EC_{50} (biomass) EC_{50} (growth rate)	0.24 mg a.i./L 0.19 mg a.i./L 1.14 mg a.i./L	-Endpoint affected: cell density, cumulative biomass and growth rate.	1453965

Table 12 Selected endpoints used in the risk assessment

Organism	Exposure	Endpoint	Value
Earthworm	Acute	14-d LC_{50}	1381 mg a.i./kg dw soil
	Chronic	56-d NOEC	10 mg a.i./kg dw soil
Honeybee	Oral	48-h LD_{50}	42.16 µg a.i./bee
	Contact	48-h LD_{50}	47.8 µg a.i./bee
	Adult feeding	10-d NOEL	4.86 µg a.i./bee/d
	Larval toxicity	96-h LD_{50}	11.4 µg a.i./larva
Bumblebee	Oral	48-h LD_{50}	>154.47 µg a.i./bee
	Contact	48-h LD_{50}	> 200 µg a.i./bee
Beneficial Insects	*T. pyri* (glass plate)	Acute LR_{50}	58 g a.i./ha

Organism	Exposure	Endpoint	Value
(foliar-dwelling)	*A. rhopalosiphi* (glass plate)	Acute LR_{50}	62.5g a.i./ha
	Ladybird Larvae (*C. septempunctata*) (glass plate)	Acute LR_{50}	158 g a.i./ha
Beneficial insects (ground-dwelling)	*Hypoaspis aculeifer*	Acute LC_{50}	79.8 mg a.i./kg soil
Birds - Bobwhite quail	Acute	LD_{50}	1988 mg a.i./kg bw
	Dietary	LD_{50}	>703 mg a.i./kg bw/d
	Reproduction	21-week NOEL LOEC	<12.4 mg a.i./kg bw/d 23.20 mg a.i./kg bw/d
Mammals - Rat	Acute	LD_{50}	2850 mg a.i./kg bw
	Reproduction (multigeneration)	NOEL LOEL	24.4 mg a.i./kg bw/d 84.8 mg a.i./kg bw/day
Terrestrial vascular plants	Vegetative vigour	ER_{25}	>453 g a.i./ha
	Seedling emergence	ER_{25}	63.3 g a.i./ha
Freshwater invertebrates	Acute (*D. magna*)	48-h EC_{50}	2.79 mg a.i./L
	Acute (*D. magna,1st instars*)	48-h EC_{50}	1.9 mg a.i./L
	Chronic (*D. magna*)	21-d NOEC	0.01 mg a.i./L
	Chronic Sediment (*C. riparius*, larvae)	28-d NOEC	0.833 mg a.i./L
Freshwater fish (rainbow)	Acute (trout)	96-h LC_{50}	2.3 mg a.i./L
	Chronic / Early Life-Stage (trout, *S. gairdneri*)	60-d NOEC	0.012 mg a.i./L
Amphibians[1]	Acute (*Physalaemus cuvieri*)	96-h LC_{50}	0.98 mg a.i./L
	Chronic (Rainbow Trout (*Salmo gairdneri*))	60-d NOEC	0.012 mg a.i./L
Aquatic vascular plants	Acute (*Lemna gibba G3*)	14-d EC_{50}	0.14 mg a.i./L
Algae	Acute (*Scenedesmus subspicatus*)	96-h EC_{50}	1.64 mg a.i./L
Saltwater invertebrates	Acute (*M. bahia*)	96-h LC_{50}	0.45 mg a.i./L
	Chronic (*M. bahia*)	28-d NOEC	0.035 mg a.i./L
Eastern oyster	Acute	96-h LC_{50}	3.0 mg a.i./L
Saltwater fish	Acute (Sheepshead minnow)	96-h LC_{50}	5.9 mg a.i./L
	Chronic (toxicity to embryos)	36-d NOEC	0.022 mg a.i./L
	Full life cycle	24-weeks NOEC	0.044 mg a.i./L
Saltwater algae	Acute (*Skeletonema costatum*)	96-h EC_{50}	0.19 mg a.i./L

[1] PMRA# 3133551.

Table 13 Registered tebuconazole use pattern considered for risk assessment[1]

Use pattern	Application Method	Application rate	Retreatment Interval (d)[2]	Maximum cumulative application rate per year (g a.i./ha)
Turf	Field sprayer	2 × 1536 g a.i./ha	14	3100
Asparagus	Field sprayer	4 × 126 g a.i./ha	14	504
Soybean	Field sprayer and aerial	2 × 136 g a.i./ha	14	272

SRIC Poplar and Willow	Field sprayer, airblast and aerial	2 × 126 g a.i./ha	28	252
Field corn	Seed treatment	15 g a.i./100 kg seed	N/A	4.7
Wheat	Seed treatment	3 g a.i./100 kg seed	N/A	5.2

[1] Indicates the uses that were the main focus of the risk assessment: the most conservative application pattern for each of field sprayer, airblast, and aerial application methods.
[2] The shortest application interval was estimated based on application instructions (see Table 2), which includes climate and signs of disease.

Table 14 Screening-level risk for earthworms

Use Pattern[1]	EEC (mg a.i./kg soil)[2]	Endpoint/UF[3] (mg a.i./kg soil)	RQ	LOC exceeded?[4]
Acute				
Soybean[5]	0.12	1381 × 1/2	0.0002	No
Field corn	0.002		0.000003	No
Turf[e]	1.4		0.002	No
Chronic				
Soybean[5]	0.12	10	0.012	No
Field corn	0.002		0.0002	No
Turf[5]	1.4		0.14	No

[1] Selected use patterns
[2] Soil dissipation DT_{50} of 883 days
[3] UF = Uncertainty factor (½ for acute and zero for chronic)
[4] LOC = 1
[5]Soybean also represents poplar/willow and turf represents asparagus.

Table 15 Screening level risk for honeybees

Application method	Application rate (kg a.i./ha)	Bee stage	Exposure		Exposure to bee (µg a.i./bee/day)[1]	Toxicity endpoint (µg a.i./bee/day)[2]	RQ[3]	Exceeded LOC?[4]
Honey bees								
Turf								
Foliar	1.536	adult	Contact	acute	3.7	= 47.8	0.1	No
			Oral	acute	44.0	= 42.2	1.0	Yes
				chronic	44.0	= 4.9	9.0	Yes
		larvae	Oral	acute	18.7	= 11.4	1.6	Yes
Soybean[5]								
Foliar	0.136	adult	Contact	acute	0.3	= 47.8	0.006	No
			Oral	acute	3.9	= 42.2	0.1	No
				chronic	3.9	= 4.9	0.8	No
		larvae	Oral	acute	1.7	= 11.4	0.1	No
Corn								
Seed treatment	0.0047	adult	Oral	acute	0.29	= 42.2	0.007	No
				chronic	0.29	= 4.9	0.06	No
		larvae	Oral	acute	0.12	= 11.4	0.01	No
Bumblebees								
Turf								
Foliar	1.536	adult	Contact	acute	3.7	>200	<0.02	No
			Oral	acute	44.0	>155	<0.3	No

[1] Exposure estimate for bees (µg a.i./bee):
For contact exposure route: application rate (kg a.i./ha) × 2.4 µg a.i./bee per kg a.i./ha;
For oral exposure route: For foliar application, application rate (kg a.i./ha) × 98 µg a.i./g × consumption rate (0.292 g/day for adult bee, 0.124 g/day for larvae)
For seed treatment: (default residue level of 1 µg a.i./g) × consumption rate (0.292 g/day for adult bee, 0.124 g/day for larvae)
[2] Toxicity Endpoint (µg a.i./bee): LD_{50} for acute exposure; NOEL for chronic exposure.
[3] RQ=Exposure estimate for bees / Toxicity endpoint.
[4] LOC for bees is set at 0.4 for acute exposure, 1 for chronic exposure. "Yes" indicates RQ≥LOC, and risk is identified, "No" indicates RQ>LOC, and risk is not identified;
[5] Soybean represents asparagus and SRIC (single application rate: 0.126 kg a.i./ha).

Table 16 Foliar application: off-field exposure to bees from spray drift of application on turf

Chemical	Bee stage	Exposure	Conversion factor	Exposure estimate for bees[1]	Toxicity endpoint	RQ[2]	LOC[3] exceeded?
				µg a.i./bee/day	µg a.i./bee/day		
Ground Field Spray (6% drift): 0.092 kg a.i./ha (Turf maximum off-field spray drift)							
Tebuconazole	Adult	Acute contact	2.4	0.22	47.8	0.005	No
		Acute oral	29	2.7	42.2	0.06	No
		Chronic oral	29	2.7	4.9	0.6	No
	Larvae	Acute oral	12.2	1.12	11.4	0.1	No

[1] *Exposure estimate for bees = application rate (kg a.i./ha) × conversion factor (µg a.i./bee per kg a.i./ha)*
[2] *Exposure estimate for bees/toxicity endpoint*
[3] *LOC for bees is set at 0.4 for acute endpoints and 1.0 for chronic endpoints.*

Table 17 Screening level risk assessment for beneficial arthropods (on-field and off-field)

Organism	Crop	Exposure	Endpoint[1]	EEC[2]	Units	RQ[3]	LOC exceeded?[4]
Foliar-dwelling							
Typhlodromus pyri (predatory mite) (glass plate)[1]	Turf	on-field	LR_{50} = 58	1969.55	g a.i./ha	**34**	**Yes**
		off-field[5](6%)	LR_{50} = 58	118.2	g a.i./ha	**2**	**Yes**
	Asparagus	on-field	LR_{50} = 58	174.4	g a.i./ha	**3**	**Yes**
		off-field[5] (6%)	LR_{50} = 58	10.5	g a.i./ha	0.2	No
	Soybean[6]	on-field	LR_{50} = 58	174.4	g a.i./ha	**3**	**Yes**
		off-field[5](6%)	LR_{50} = 58	10.5	g a.i./ha	0.2	No
		off-field[5] (23%)	LR_{50} = 58	40.1	g a.i./ha	0.7	No
	SRIC Poplar/willow	on-field	LR_{50} = 58	136	g a.i./ha	**2.3**	**Yes**
		off-field[5] (6%)	LR_{50} = 58	8.2	g a.i./ha	0.1	No
		off-field[5] (74%)	LR_{50} = 58	100.6	g a.i./ha	1.7	No
		off-field[5] (59%)	LR_{50} = 58	80.2	g a.i./ha	1.4	No
		off-field[5] (60%)	LR_{50} = 58	81.6	g a.i./ha	1.4	No
Aphidius rhopalosiphi (aphid parasitoid) (glass plate)[1]	Turf	on-field	LR_{50} = 62.5	1969.6	g a.i./ha	**31.5**	**Yes**
		off-field[5] (6%)	LR_{50} = 62.5	118.2	g a.i./ha	1.9	No
	Asparagus	on-field	LR_{50} = 62.5	174.4	g a.i./ha	**2.8**	**Yes**
		off-field[5] (6%)	LR_{50} = 62.5	10.5	g a.i./ha	0.2	No
	Soybean[6]	on-field	LR_{50} = 62.5	174.4	g a.i./ha	**2.8**	**Yes**
		off-field[5] (6%)	LR_{50} = 62.5	10.5	g a.i./ha	0.2	No
		off-field[5] (23%)	LR_{50} = 62.5	40.1	g a.i./ha	0.6	No
	SRIC Poplar/willow	on-field	LR_{50} = 62.5	136.0	g a.i./ha	1.2	No
		off-field[5] (6%)	LR_{50} = 62.5	8.2	g a.i./ha	0.1	No
		off-field[5] (74%)	LR_{50} = 62.5	100.6	g a.i./ha	1.6	No
		off-field (59%)	LR_{50} = 62.5	80.2	g a.i./ha	1.3	No

Organism	Crop	Exposure	Endpoint[1]	EEC[2]	Units	RQ[3]	LOC exceeded?[4]
		off-field[5] (60%)	LR_{50} = 62.5	81.6	g a.i./ha	1.3	No
C. septempunctata Ladybird Larvae (glass plate)	Turf	on-field	LR_{50} = 158	1969.6	g a.i./ha	**12.5**	**Yes**
		off-field[5] (6%)	LR_{50} = 158	118.2	g a.i./ha	0.75	No
	Asparagus	on-field	LR_{50} = 158	174.4	g a.i./ha	**1.1**	**Yes**
		off-field[5] (6%)	LR_{50} = 158	10.5	g a.i./ha	0.07	No
	Soybean[6]	on-field	LR_{50} = 158	174.4	g a.i./ha	**1.1**	**Yes**
		off-field[5] (6%)	LR_{50} = 158	10.5	g a.i./ha	0.07	No
		off-field[5] (23%)	LR_{50} = 158	40.1	g a.i./ha	0.25	No
	SRIC Poplar/willow	on-field	LR_{50} = 158	136	g a.i./ha	**1.6**	**Yes**
		off-field[5] (6%)	LR_{50} = 158	8.2	g a.i./ha	0.05	No
		off-field[5] (74%)	LR_{50} = 158	100.6	g a.i./ha	0.6	No
		off-field (59%)	LR_{50} = 158	80.2	g a.i./ha	0.5	No
		off-field[5] (60%)	LR_{50} = 158	81.6	g a.i./ha	0.6	No
Soil-dwelling							
Hypoaspis aculeifer (soil)	Turf	In-field	LC_{50} = 79.8	1.4	mg a.i./kg soil	0.02	No
	Soybean[6]	In-field	LC_{50} = 79.8	0.12	mg a.i./kg soil	0.002	No
	Field corn	In-field	LC_{50} = 79.8	0.002	mg a.i./kg soil	0.00002	No
	SRIC Poplar/willow	In-field	LC_{50} = 79.8	0.11	mg a.i./kg soil	0.001	No

[1] Arthropod data are based on tier I (glass plate) tests;
[2] EEC from Table 13;
[3] Risk Quotient (RQ) = EEC / endpoint. Uncertainty factor: none;
[4] LOC of 2.0 for spray application on glass plate tests with *T. pyri* and *A. rhopalosiphi* only;
[5] Off-field applications of tebuconazole using field sprayer (6%), aerial-crop methods (23%), airblast early and late season (74% and 59%, respectively) and aerial-non-crop (60%);
[6] Soybean cover off both asparagus and SRIC.

Table 18 Refined on-field and off-field risk to predatory and parasitic arthropods

Crop	Cumulative rate (foliar DT_{50} 7.67)[1] (g a.i./ha)	In-field					Off-field			
		Crop interception (F_{Int})[2]	EEC[3] (g a.i./ha)	Endpoint (g a.i./ha)	RQ[5]	LOC exceeded?	Drift EEC × vegetation distribution[4]	EEC[3] (g a.i./ha)	RQ[5]	LOC exceeded?
Typhlodromus pyri										
Turf	1969.6	0.40	787.8	LR_{50} = 58	**13.58**	**Yes**	118.2× 0.10	11.8	0.2	No
Soybean	174.4	0.20	34.9		0.61	No	40.1× 0.10	4	0.07	No
Aphidius rhopalosiphi										
Turf	1969.6	0.40	787.8	62.5	**12.6**	**Yes**	118.2 × 0.10	11.8	0.19	No
Soybean	174.4	0.20	34.9		0.56	No	40.1 × 0.10	4	0.06	No
C. septempunctata larvae										
Turf	1969.6	0.40	787.8	LR_{50} = 158	**4.98**	**Yes**	118.2 × 0.10	11.8	0.75	No
Soybean	174.4	0.20	34.9		0.22	No	40.1 × 0.10	4	0.03	No

[1] Values from Table 13

[2] Foliar interception fraction, based on most suitable crop group; turf based on "grass I"; Soybean based on "soybean I" (EAD Guidance document, Characteristics of risk to predatory and parasitic arthropods, version 14, 2010-Jun-10).

[3] In-field EEC = (cumulative rate × crop interception factor); off-field EEC = (cumulative rate × drift factor × vegetation distribution factor 0.10). Drift is estimated 6% and 23% at 1 metre downwind for field sprayer (spray quality medium) for turf and aerial agricultural crop (spray quality medium) for soybean, respectively;

[4] The vegetation distribution factor is also applied as drift is overestimated to the lower or interior portions of a three-dimensional habitat structure. Most of the drift would be intercepted by the top or side portions of the habitat.

[5] For refinement (spray application on glass plates for *T. pyri* and *A. rhopalosiphi*), the LOC of 1 was used (EAD Guidance document, Characteristics of risk to predatory and parasitic arthropods, version 14, 2010-Jun-10).

Table 19 Screening level on-field risk to birds

Exposure	Toxicity (mg a.i./kg bw/d)[1]	Feeding Guild (food item)	Turf[2]		Soybean and asparagus[3]		Field corn[4]		SRIC[5]	
			EDE (max/mean) (mg a.i./kg bw)	RQ (max/mean)	EDE (max) (mg a.i./kg bw)	RQ	EDE (max) (mg a.i./kg bw)	RQ	EDE (max) (mg a.i./kg bw)	RQ
Small Bird (0.02 kg)										
Acute	198.8	Insectivore	160.31/110.69	0.7/0.5	14.19	0.07	38.091	0.2	10.94	0.06
Reproduction	12.4	Insectivore	160.31/110.69	**12.9/8.9**	14.19	1.1/(0.8 when mean residues is used)	38.091	**3.1**	10.94	0.88
Medium Sized Bird (0.1 kg)										
Acute	198.8	Insectivore	125.11/86.38	0.6/0.4	11.08	0.06	29.921	0.2	8.54	0.04
Reproduction	12.4	Insectivore	125.11/86.38	**10.1/7.0**	11.08	0.9	29.921	**2.4**	8.54	0.69

Exposure	Toxicity (mg a.i./kg bw/d)[1]	Feeding Guild (food item)	Turf[2]		Soybean and asparagus[3]		Field corn[4]		SRIC[5]	
			EDE (max/mean) (mg a.i./kg bw)	RQ (max/mean)	EDE (max) (mg a.i./kg bw)	RQ	EDE (max) (mg a.i./kg bw)	RQ	EDE (max) (mg a.i./kg bw)	RQ
Large Sized Bird (1 kg)										
Acute	198.8	Herbivore[6]	80.81/28.7	0.4/0.1	7.16	0.04	8.723	0.04	5.51	0.03
Reproduction	12.4	Herbivore[6]	80.81/28.7	**6.5/2.3**	7.16	0.6	8.723	0.7	5.51	0.44

[1] Acute effects based on an acute oral LC_{50} of 1988 mg a.i./kg for bobwhite quail, divided by the uncertainty factor of 10. Chronic effects based on a NOEL (reproduction) of 12.4 mg a.i./kg bw/d for bobwhite quail
[2] 1356 g a.i./ha, 2 applications per season, 14 day retreatment interval
[3] 136 g a.i./ha, 2 applications per season, 14 day retreatment interval (on-field risk of soybean would cover off asparagus)
[4] Single application of 15 g a.i./100 kg seed (4.7 g a.i./ha)
[5] 126 g a.i./ha, 2 applications per season, 30 day retreatment interval
[6] Herbivore assumed to eat 100% short grass
max/mean: maximum and mean nomogram residues
Bolded values indicate that the RQ exceeds the LOC of 1.

Table 20 Turf, refined risk quotients (on-field) for birds (using LOEL and mean nomogram residues)

Exposure	Toxicity (mg a.i./kg bw/d)[1]	Feeding Guild (food item)	EDE (mean) (mg a.i./kg bw)	On-field RQ	LOC exceeded?
Small Sized Bird (0.02 kg)					
Reproduction	23.20	Insectivore	110.69	**4.8**	**Yes**
Medium Sized Bird (0.1 kg)					
Reproduction	23.20	Insectivore	86.38	**3.7**	**Yes**
Large Sized Bird (1 kg)					
Reproduction	23.20	Herbivore (short grass)	28.70	**1.2**	**Yes**

Bolded values indicate that the RQ exceeds the LOC of 1.

Table 21 Risk assessment of tebuconazole-treated seed to birds

Number of corn seeds and area required to reach reproduction endpoint							
Study Endpoint (mg a.i./kg bw/day / UF)		**EDE (mg a.i./kg bw/day)**	**RQ**	**Number of seeds needed to reach endpoint**		**Area required (m^2)**	
						Standard drilling - spring	
				min	**max**	**min**	**max**
Small bird (0.02 kg)							
Reproduction	12.40	38.091	**3.1**	4.96	4.96	104.86	157.46
Medium bird (0.10 kg)							
Reproduction	12.40	29.921	**2.4**	24.80	24.80	524.31	787.30
Screening level risk assessment of tebuconazole to birds, using treated wheat seeds							
Small bird (0.02 kg)							
Reproduction	12.40	7.6	0.6	LOC of 1 not exceeded			
Medium bird (0.10 kg)							
Reproduction	12.40	6.0	0.5	LOC of 1 not exceeded			

Bolded values indicate that the RQ exceeds the LOC of 1.

Table 22 Screening level on-field risk to mammals

Exposure	**Toxicity (mg a.i./kg bw/d)[1]**	**Feeding Guild (food item)**	**Turf[2]**		**Soybean and asparagus[3]**		**Field corn[4]**		**SRIC[5]**	
			EDE (max/mean) (mg a.i./kg bw)	**RQ (max/mean)**	**EDE (mg a.i./kg bw)**	**RQ**	**EDE (mg a.i./kg bw)**	**RQ**	**EDE (mg a.i./kg bw)**	**RQ**
Small Mammal (0.015 kg)										
Acute	285	Insectivore	92.21/63.67	0.3/0.2	8.16	0.03	21.768	0.1	6.29	0.02
Reproduction	24.4	Insectivore	92.21/63.67	**3.8/2.6**	8.16	0.3	21.768	0.9	6.29	0.26
Medium Sized Mammal (0.035 kg)										
Acute	285	Insectivore	178.83/63.51	0.6/0.2	15.83	0.06	18.720	0.1	12.20	0.04
Reproduction	24.4	Insectivore	178.83/63.51	**7.3/2.6**	15.83	0.7	18.720	0.8	12.20	0.50
Large Sized mammal (1 kg)										
Acute	285	Herbivore[6]	95.56/33.94	0.3/0.1	8.46	0.03	10.308	0.04	6.52	0.02
Reproduction	24.4	Herbivore[6]	95.56/33.94	**3.9/1.4**	8.46	0.4	10.308	0.4	6.52	0.27

[1] Acute effects based on an acute oral LC_{50} of 2850 mg a.i./kg for rats, divided by the uncertainty factor of 10. Chronic effects based on a NOEL (reproduction) of 24.4 mg a.i./kg bw/d for rats;
[2] 1356 g a.i./ha, 2 applications per season, 14 day retreatment interval;
[3] 136 g a.i./ha, 2 applications per season, 14 day retreatment interval. (on-field risk of soybean would cover off asparagus);
[4] Single application of 15 g a.i./100 kg seed (4.7 g a.i./ha);
[5] 126 g a.i./ha, 2 applications per season, 30 day retreatment interval;
[6] Herbivore assumed to eat 100% short grass;
max/mean: maximum and mean nomogram residues;
Bolded values indicate that the RQ exceeds the LOC of 1.

Table 23 Turf, refined level RQ (on field) for mammals (using LOEL and mean nomogram residues)

Exposure	Toxicity (mg a.i./kg bw/d)[1]	Feeding Guild (food item)	EDE (mean) (mg a.i./kg bw)	On-field RQ	LOC exceeded?
Small mammals (0.015 kg)					
Reproduction	84.4	Insectivore	63.7	0.7	No
Medium mammals (0.0.035 kg)					
Reproduction	84.4	Herbivore (short grass)	63.5	0.7	No
Large mammals (1 kg)					
Reproduction	84.4	Herbivore (short grass)	33.9	0.4	No

[1] LOEL of rat was used.

Table 24 Screening level risk assessment (direct overspray) for non-target terrestrial plants

Ecotox endpoint descriptor:	Ecotox endpoint[1]	Converted ecotox endpoint value[2]	EEC	EEC unit	RQ	LOC exceeded?
Turf						
Vegetative vigour (EC_{25})	> 453 g a.i./ha	453 g a.i/ha	1969.55	g a.i/ha	**4.4**	**Yes**
Seedling emergence (ER_{25})	63.3 g a.i./ha	0.028 mg a.i/kg soil	1.4	mg a.i/kg soil	**50**	**Yes**
Soybean						
Vegetative vigour (EC_{25})	> 453 g a.i./ha	453 g a.i/ha	174.4	g a.i/ha	0.4	No
Seedling emergence (ER_{25})	63.3 g a.i/.ha	0.028 mg a.i/kg soil	0.12	mg a.i/kg soil	4.3	**Yes**
SRIC Poplar and Willow						
Vegetative vigour (EC_{25})	> 453 g a.i./ha	453 g a.i/ha	136.0	g a.i./ha	0.3	No
Seedling emergence (ER_{25})	63.3 g a.i/.ha	0.028 mg a.i/kg soil	0.11	mg a.i/kg soil	**3.9**	**Yes**

[1] Most sensitive endpoints from Table 12;

[2] The value for the seedling emergence was converted to a soil concentration with the following equation: 63.3 g a.i./ha÷100÷15 cm soil depth÷1.5 g/cm^3 bulk density = 0.028 mg a.i./kg soil;

Bolded values indicate that the RQ exceeds the LOC of 1.

Table 25 Refined risk assessment (off-field spray drift) for non-target terrestrial plants

Ecotox endpoint descriptor:	Ecotox endpoint[1]	Converted ecotox endpoint value[2]	EEC	EEC unit	RQ	LOC exceeded?
Turf -ground boom sprayer medium (6% drift)						
Vegetative vigour (EC_{25})	> 453 g a.i./ha	453 g a.i/ha	118.2	g a.i/ha	0.3	No
Seedling emergence (ER_{25})	63.3 g a.i./ha	0.028 mg a.i/kg soil	0.084	mg a.i/kg soil	**3**	**Yes**
Asparagus-ground boom sprayer medium (6% drift)						
Vegetative vigour (EC_{25})	> 453 g a.i./ha	453 g a.i/ha	10.5	g a.i/ha74%)	0.02	No
Seedling emergence (ER_{25})	63.3 g a.i./ha	0.028 mg a.i/kg soil	0.01	mg a.i/kg soil	0.4	No
Soybean- aerial-agr. medium (23% drift)						
Seedling emergence (ER_{25})	63.3 g a.i./ha	0.028 mg a.i/kg soil	0.0276	mg a.i/kg soil	0.98	No
SRIC – airblast-early (74%)						
Seedling emergence (ER_{25})	63.3 g a.i./ha	0.028 mg a.i/kg soil	0.08	mg a.i/kg soil	2.9	**Yes**
SRIC – airblast-late (59%)						
Seedling emergence (ER_{25})	63.3 g a.i./ha	0.028 mg a.i/kg soil	0.06	mg a.i/kg soil	2.3	**Yes**
SRIC – aerial-non-crop (60%)						
Seedling emergence (ER_{25})	63.3 g a.i./ha	0.028 mg a.i/kg soil	0.07	mg a.i/kg soil	2.4	**Yes**

[1] Most sensitive endpoints from Table 12;

[2] The value for the seedling emergence was converted to a soil concentration with the following equation: 63.3 g a.i./ha÷100÷15 cm soil depth÷1.5 g/cm^3 bulk density = 0.028 mg a.i./kg soil.

Bolded values indicate that the RQ exceeds the LOC of 1.

Table 26 Screening level risk assessment for aquatic organisms and multiple applications of tebuconazole to turf (1536 g a.i./ha × 2 apps, 14-day interval)

Organism	Exposure	Endpoint Value (mg a.i./L)	EEC (mg a.i./L)	RQ	LOC exceeded
Freshwater species					
Invertebrates (*Daphnia magna*)	Acute	$EC_{50}/2$ = 2.79	0.39	0.28	No
	Acute (1st instat 6-24 h old)	$EC_{50}/2$ = 1.9	0.39	0.4	No
	Chronic (reproduction)	NOEC = 0.01	0.39	**39**	**Yes**
Chironomus riparius	Chronic	NOEC = 0.833	0.39	0.47	No
Fish	Acute	$LC_{50}/10$ = 2.3	0.39	**1.7**	**Yes**
	Early-life stage	NOEC = 0.012	0.39	**32.5**	**Yes**
Amphibians	Acute	$LC_{50}/10$ = 0.98	2.04	**20.8**	**Yes**
	chronic	NOEC = 0.012	2.04	**170**	**Yes**
Lemna gibba	Acute	$EC_{50}/2$ = 0.14	0.39	**5.6**	**Yes**
Green algae	Acute	$EC_{50}/2$ = 1.64	0.39	0.48	No

Organism	Exposure	Endpoint Value (mg a.i./L)	EEC (mg a.i./L)	RQ	LOC exceeded
Marine species					
Mysid shrimp	Acute	$LC_{50}/2 = 0.45$	0.39	**1.7**	**Yes**
	Chronic	NOEC = 0.035	0.39	**11**	**Yes**
Eastern oyster	Acute	$LC_{50}/2 = 3.0$	0.39	0.3	No
Sheepshead minnow	Acute	$LC_{50}/10 = 5.9$	0.39	0.7	No
	Chronic (toxicity to embryos)	NOEC = 0.022	0.39	**17.7**	**Yes**
	Full life cycle	NOEC = 0.044	0.39	**8.9**	**Yes**
Diatom	Acute	$EC_{50}/2 = 0.19$	0.39	**4.1**	**Yes**

Bolded values are organism and exposure for which the level of concern (LOC) was exceeded at the screening level.

Table 27 Screening level and refined (based on aerial spray drift) risk assessment for aquatic organisms and multiple applications of tebuconazole to soybean (soybean, 136 g a.i./ha × 2 apps, 14-day interval)

Organism	Exposure	Endpoint Value (mg a.i./L)	Screening EEC/refined EEC (aerial 23% drift) (mg a.i./L)	Screening RQ/refined RQ[1]	LOC exceeded (screening/refined)?
Freshwater species					
Invertebrates (*Daphnia magna*)	Acute	$EC_{50}/2 = 2.79$	0.03	0.022	No
	Acute (1st instat 6-24 h old)	$EC_{50}/2 = 1.9$	0.03	0.03	No
	Chronic (reproduction)	NOEC = 0.01	0.03/0.007	**3**/0.7	**Yes**/No
Chironomus riparius	Chronic	NOEC = 0.833	0.03	0.04	No
Fish (rainbow)	Acute	$LC_{50}/10 = 2.3$	0.03	0.1	No
	Early-life stage	NOEC = 0.012	0.03/0.007	**2.5**/0.6	**Yes**/No
Amphibians	Acute	$LC_{50}/10 = 0.98$	0.18/0.04	**1.8**/0.4	**Yes**/No
	chronic	NOEC = 0.012	0.18/0.04	**15/3.3**	**Yes/Yes**
Lemna gibba	Acute	$EC_{50}/2 = 0.14$	0.03	0.4	No
Algae	Acute	$EC_{50}/2 = 1.64$	0.03	0.04	No
Marine species					
Mysid shrimp	Acute	$LC_{50}/2 = 0.45$	0.03	0.1	No
	Chronic	NOEC = 0.035	0.03	0.86	No
Eastern oyster	Acute	$LC_{50}/2 = 3.0$	0.03	0.02	No
Sheepshead minnow	Acute	$LC_{50}/10 = 5.9$	0.03	0.05	No
	Chronic (toxicity to embryos)	NOEC = 0.022	0.03/0.04	**1.4**/0.3	**Yes**/No
	Full life cycle	NOEC = 0.044	0.03	0.7	No
Diatom	Acute	$EC_{50}/2 = 0.19$	0.03	0.3	No

[1] Refined Risk Quotient = Modified (Drift) EEC value ÷ Ecotoxicity Endpoint of Concern.
Bolded values are organism and exposure for which the level of concern (LOC) was exceeded.

Table 28 Screening level risk assessment for aquatic organisms and multiple applications of tebuconazole to SRIC poplar (126 g a.i./ha × 2 apps, 28-day interval)

Organism	Exposure	Endpoint Value (mg a.i./L)	EEC (mg a.i./L)	RQ	LOC exceeded?
Freshwater species					
Invertebrates (*Daphnia magna*)	Acute	$EC_{50}/2 = 2.79$	0.02	0.007	No
	Acute (1st instar 6-24 h old)	$EC_{50}/2 = 1.9$	0.02	0.01	No
	Chronic (reproduction)	NOEC = 0.01	0.02	**2**	**Yes**
Chironomus riparius	Chronic	NOEC = 0.833	0.02	0.02	No
Fish (rainbow)	Acute	$LC_{50}/10 = 2.3$	0.02	0.01	No
	Early-life stage	NOEC = 0.012	0.02	0.2	No
Amphibians	Acute	$LC_{50}/10 = 0.98$	0.11	0.1	No
	chronic	NOEC = 0.012	0.11	**9.2**	**Yes**
Lemna gibba	Acute	$EC_{50}/2 = 0.14$	0.02	0.1	No
Algae	Acute	$EC_{50}/2 = 1.64$	0.02	0.01	No
Marine species					
Mysid shrimp	Acute	$LC_{50}/2 = 0.45$	0.02	0.04	No
	Chronic	NOEC = 0.035	0.02	0.6	No
Eastern oyster	Acute	$LC_{50}/2 = 3.0$	0.02	0.02	No
Sheepshead minnow	Acute	$LC_{50}/10 = 5.9$	0.02	0.07	No
	Chronic (toxicity to embryos)	NOEC = 0.022	0.02	0.9	No
	Full life cycle	NOEC = 0.044	0.02	0.5	No
Diatom	Acute	$EC_{50}/2 = 0.19$	0.02	0.1	No

Bolded values are for organism and exposure for which the level of concern (LOC) was exceeded at the screening level;

Table 29 Refined risk assessment for aquatic organisms and EECs resulting from drift of tebuconazole from application to turf and asparagus (field sprayer, 6%)

Organism[1]	Exposure	Endpoint value (mg a.i./L)	Refined EEC mg a.i./L	RQ[2]	LOC exceeded ?
Invertebrates (*Daphnia magna*)	Chronic (reproduction)	NOEC = 0.01	Turf: 0.02 Asparagus: 0.001	**Turf: 2** Asparagus: 0.1	**Yes** No
Freshwater fish (rainbow)	Acute	$LC_{50}/10 = 2.3$	0.02	0.09	No
	Early-life stage	NOEC = 0.012	Turf: 0.02 Asparagus: 0.001	**Turf: 1.7** Asparagus: 0.08	**Yes** No
Amphibians	Acute	$LC_{50}/10 = 0.98$	Turf: 0.12 Asparagus: 0.007	**Turf: 1.2** Asparagus: 0.007	**Yes** No
	chronic	NOEC = 0.012	Turf: 0.12 Asparagus: 0.007	**Turf: 10** Asparagus: 0.6	**Yes** No
Lemna gibba	Acute	$EC_{50}/2 = 0.14$	Turf: 0.02	0.3	No
Mysid shrimp	Acute	$LC_{50}/2 = 0.45$	Turf: 0.02	0.09	No
	Chronic	NOEC = 0.035	Turf: 0.02	0.6	No

Organism[1]	Exposure	Endpoint value (mg a.i./L)	Refined EEC mg a.i./L	RQ[2]	LOC exceeded ?
Sheepshead minnow	Chronic (toxicity to embryos)	NOEC = 0.022	Turf: 0.02	0.9	No
	Full life cycle	NOEC = 0.044	Turf: 0.02	0.5	No
Diatom	Acute	$EC_{50}/2$ = 0.19	Turf: 0.02	0.2	No

[1] Organism and Exposure for which the level of concern (LOC) was exceeded at the screening level;
[2] Refined Risk Quotient = Modified (Drift) EEC value ÷ Ecotoxicity Endpoint of Concern;
Bolded values indicated that the level of concern (LOC) exceeded at refined level.

Table 30 Refined risk assessment for aquatic organisms and EECs resulting from drift of tebuconazole from application to SRIC poplar (airblast, 59% and 74% and aerial- non-crop application, 60%)

Organism	Exposure	Endpoint value (mg a.i./L)	Refined EEC (airblast-E[1], 74%)	RQ	Refined EEC (airblast-L[2], 59%)	RQ	Refined EEC (aerial, 60%)	RQ	LOC exceeded?
Invertebrates (*Daphnia magna*)	Chronic (reproduction)	NOEC = 0.01	0.015	**1.5**	0.011	**1.1**	0.012	**1.2**	**Yes**
Amphibians	chronic	NOEC = 0.012	0.08	**6.7**	0.06	**5.0**	0.07	**6.0**	**Yes**

Bolded values indicated that the level of concern (LOC) exceeded at refined level.
[1] E = early;
[2] L = late

Table 31 Refined risk assessment for aquatic organisms and EECs determined for runoff of tebuconazole into water bodies (Turf)

Organism	Exposure	Endpoint value (mg/L)	Refined EEC (mg a.i./L)	RQ[1]	LOC exceeded?
Daphnia magna	21-d Chronic (reproduction)	NOEC = 0.01	21-d EEC = 0.17	**17**	**Yes**
Fish	96-h Acute	$LC_{50}/10$ = 2.3	4-d EEC = 0.17	0.7	No
	60-d Early-life stage	NOEC = 0.012	21-d EEC = 0.17	**14**	**Yes**
Amphibians	96-h Acute	$LC_{50}/10$ = 0.98	4-d EEC = 0.239	**2.4**	**Yes**
	60-d Chronic	NOEC = 0.012	21-d EEC = 0.206	**17**	**Yes**
Lemna gibba	14-d Acute	$EC_{50}/2$ = 0.14	4-d EEC = 0.17	**2.4**	**Yes**
Mysid shrimp	96-h Acute	$LC_{50}/2$ = 0.45	4-d EEC = 0.17	0.8	No
	28-d Chronic	NOEC = 0.035	21-d EEC = 0.17	**4.8**	**Yes**
Sheepshead minnow	36-d Chronic (toxicity to embryos)	NOEC = 0.022	21-d EEC = 0.17	**7.7**	**Yes**
	24-week Full life cycle	NOEC = 0.044	21-d EEC = 0.17	**3.9**	**Yes**
Diatom	96-h Acute	$EC_{50}/2$ = 0.19	4-d EEC = 0.17	0.9	No

[1] Refined Risk Quotient = Modelled (Runoff) EEC value ÷ Ecotoxicity Endpoint of Concern;
Bolded values indicated that the level of concern (LOC) exceeded at refined level.

Table 32 Refined risk assessment for aquatic organisms and EECs determined for runoff of tebuconazole into water bodies (Soybean)

Organism	Exposure	Endpoint value (mg/L)	Refined EEC (mg a.i./L)	RQ[a]	LOC exceeded?
Daphnia magna	21-d Chronic (reproduction)	NOEC = 0.01	21-d EEC = 0.0793	**8**	**Yes**
Fish	60-d Early-life stage	NOEC = 0.012	21-d EEC = 0.0793	**6.6**	**Yes**
Amphibians	96-h Acute	LC_{50}/10 = 0.98	4-d EEC = 0.0958	0.97	No
	60-d Chronic	NOEC = 0.012	21-d EEC = 0.0886	**7.4**	**Yes**
Sheepshead minnow	36-d Chronic (toxicity to embryos)	NOEC = 0.022	21-d EEC = 0.0793	**3.6**	**Yes**

[1] Refined Risk Quotient = Modelled (Runoff) EEC value ÷ Ecotoxicity Endpoint of Concern;
Bolded values indicated that the level of concern (LOC) exceeded at refined level.

Table 33 Tebuconazole registered commercial end-use products and technical grade active ingredients for wood preservatives

Reg. No.	Product Name	Percentage of Active Ingredient	Co-formulant	Uses	kg total a.i./m^3 wood	kg TEU/m^3 wood
Technical Grade						
29409	Preventol A8 Technical	95.0%	N/A	Manufacturing concentrate for formulating or re-pack	N/A	N/A
33447	Adama tebuconazole technical	98.3%	N/A	Manufacturing concentrate for formulating or re-pack	N/A	N/A
End-use Products						
30379	MTZ	33.95%	N/A	Above ground (structural)	1.7	0.065
				Ground and/or Freshwater contact	3.3	0.127
				Ground contact (severe decay hazard)	5.0	0.192
27132	Wolman NB	0.37%	Copper monoethanol-amine complexes	Above ground	1.7	0.065
				Ground contact	3.3	0.127
				Ground Contact (utility poles and posts, severe decay hazard)	5.0	0.192
30003[1]	**Wolman AG CN**	**5.00%**	**DDAC and propiconazole**	**Above ground (includes water contact – docks)**	**0.70**	**0.20**
30570	Wolman µNB	0.37%	Copper carbonate	Above ground	1.7	0.065
				Ground contact	3.3	0.127

Reg. No.	Product Name	Percentage of Active Ingredient	Co-formulant	Uses	kg total a.i./m^3 wood	kg TEU/m^3 wood
				Ground contact (severe decay hazard)	5.0	0.192
31160	Viance CA-B	0.37%	Copper monoethanol-amine complexes	Above ground	1.7	0.065
				Ground contact	3.3	0.127
				Ground contact (severe decay hazard)	5.0	0.192
31545	FIM-3	2.4%	DDAC	Above ground non-structural	0.9	0.09
				Above ground - structural	1.7	0.17
32008	MP200A-TS	1.12%	Copper carbonate	Above ground, non-structural	0.9	0.0346
				Above ground, structural	1.7	0.065
				Ground and/or Freshwater contact	3.3	0.127
32361[2]	Ecolife-CDN	11.43%	N/A	Above ground	0.6	0.069

[1] Registered product with the highest retention rate and freshwater contact uses
[2] Use Assessment under Sub 2014-5451 (PMRA# 2549523 and 2549522)

Table 34 Screening level EECS for treated wood in-service (flowing water body where treated wood is in service) wood treated at 0.2 kg tebuconazole/m^3 retention rate

OECD Scenario No.	Generic freshwater environment	EECs (mg a.i./L)
2a	Amphibians compartment: Bridge, walkway or dock; over a shallow pond or lake.	0.2
3a	Flowing freshwater environment: Bridge, walkway or dock over a small waterway	9.95

Table 35 Screening assessment for aquatic organisms, based on highest EEC (Scenario 3a, flowing water body where treated wood is in service) wood treated at 0.2 kg tebuconazole /m^3 retention rate

Organism	Endpoint[1]	EEC[2] (mg a.i./L)	RQ
Daphnia magna	1/2 48-hr EC50 = 1.4 mg a.i./L	9.95	**7**
Daphnia magna	21-d NOEC = 0.01 mg a.i./L	9.95	**995**
Green algae	1/2 96-h EC50 = 0.82 mg a.i./L	9.95	**12**
Lemna gibba	1/2 14-d EC50 = 0.07 mg a.i./L	9.95	**142**
Rainbow trout	1/10 96-h LC50 = 0.23 mg a.i./L	9.95	**43**

Organism	Endpoint[1]	EEC[2] (mg a.i./L)	RQ
Amphibian[2]	1/10 96 h LC50 = 0.098 mg a.i./L	0.2	**2**
Amphibian[2]	60d NOEC = 0.012 mg a.i./L	0.2	**17**

Bolded values indicate LOC was exceeded.

[1] Endpoints adjusted by dividing the EC_{50} or LC_{50} by a factor of two (2) for aquatic invertebrates and plants, and by a factor of ten (10) for fish and amphibians. Sub-lethal endpoints, like NOECS, are not adjusted.

[2] Amphibian EECs are based on a generic freshwater environment (OECD 2a).

Table 36 Tier 1 EECs and risk quotients for Scenario 3b, sheet piling in a small freshwater water way using leaching data from wood treated at 0.268 kg tebuconazole /m^3 retention rate

Organism	Endpoint	EEC ($mg_{a.i.}/l$)	RQ
Daphnia magna	48-hr EC_{50} = 1.4 mg a.i./L	0.59	0.42
Daphnia magna	21-d NOEC = 0.01 mg a.i./L	0.59	**59**
Green alga	1/2 96-h EC_{50} = 0.82 mg a.i./L	0.59	0.72
Lemna gibba	1/2 14-d EC_{50} = 0.07 mg a.i./L	0.59	**8**
Rainbow trout	1/10 96-h LC_{50} = 0.23 mg a.i./L	0.59	**3**

Bolded values indicate LOC was exceeded

Table 37 Tier 1 EECs and risk quotients amphibians based on Scenario 2a, amphibian compartment of a generic freshwater environment where treated wood is in service using leaching data from wood treated at 0.268 kg/m^3 retention rate

Organism	Endpoint	EEC_{max} (mg a.i./L)	RQ_{max}
Amphibian	1/10 96-h LC_{50} = 0.098 mg a.i./L	0.199	**2**
Rainbow trout	60-d NOEC = 0.012 mg a.i./L	0.199	**17**

Bolded values indicate LOC was exceeded

Table 38 Toxic substances management policy considerations comparison to TSMP Track 1 criteria for tebuconazole

TSMP Track 1 Criteria	TSMP Track 1 Criterion value		Tebuconazole Endpoints
Toxic or toxic equivalent according to the *Canadian Environmental Protection Act*[1]	Yes		Yes
Predominantly anthropogenic[2]	Yes		Yes
Persistence[3]	Soil	Half-life ≥ 182 days	883 days (aerobic soil)
	Water	Half-life ≥ 182 days	1140 days (whole water:sediment in aerobic system)
	Sediment	Half-life ≥ 365 days	Not measured or not available

TSMP Track 1 Criteria	TSMP Track 1 Criterion value		Tebuconazole Endpoints
	Air	Half-life ≥ 2 days or evidence of long range transport	With a low vapour pressure (1.7×10^{-6} Pa) and Henry's law constant of 1×10^{-5} Pa m^3/mole (at 20°C), tebuconazole can be regarded as non-volatile. Chemical half-life in air (estimated) < 3.8 days (PMRA# 3093535).
Bioaccumulation[4]	Log $K_{ow} \geq 5$		Log K_{ow} = 3.7
	BCF ≥ 5000		BCF = 78 (whole fish)
	BAF ≥ 5000		N/A
Is the chemical a TSMP Track 1 substance (all four criteria must be met)			No, does not meet all TSMP Track 1 criteria.

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

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

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

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

Appendix VIII Water Modelling and Monitoring Data

1.0 Introduction

To support the re-evaluation of tebuconazole, estimated environmental concentrations (EECs) in water were calculated for use in both the ecological and human health risk assessments. The modelling was conducted using the Pesticide in Water Calculator (PWC) version 1.52. A summary of the methodology and results is provided below and in Section 3.3.1.

In addition, an updated summary of available monitoring information for tebuconazole is provided below. Monitoring data and modelling estimates are complementary and are considered in conjunction with each other when estimating the potential exposure of aquatic organisms or humans.

2.0 Modelling estimates

2.1 Application information and model inputs

Modelling for the tebuconazole re-evaluation built on previous modelling conducted for recent use expansions. The fate inputs were, therefore, not significantly modified since the previous modelling. Model inputs are presented in Table 1. The ecological and drinking water modelling was conducted on parent alone.

To better inform the assessments, tebuconazole was modelled separately for uses on crops and on turf. Four spray applications of 126.1 g a.i./ha were modelled for the use on crops. The use on turf allows up to four spray applications ranging from 768 to 1536 g a.i./ha, without exceeding 3100 g a.i./ha. For modelling, this was applied as one application of 1536 g a.i./ha followed by two applications of 782 g a.i./ha. In addition, the use for snow mould was modelled separately for groundwater, based on a single application of 1440 g a.i./ha.

Table 1 Major fate inputs for the modelling

Fate parameter	Value
K_{oc}	543 L/kg
Water half-life	stable
Sediment half-life	1478 days, at 22°C
Photolysis half-life	1144 days
Hydrolysis	stable
Soil half-life	883 days at 23°C

2.2 Ecological water modelling

For the ecological risk assessment, EECs in water are calculated by modelling a 10 ha field adjacent to 1 ha water bodies of two different depths, 80 cm and 15 cm.

The PWC model calculates the amount of pesticide entering the water body and the subsequent degradation of the pesticide in the water and sediment. In ecological modelling, pesticide enters the water by runoff only; deposition of pesticide on the water body due to spray drift is not included, as it is assessed separately. The model is run for 50 years.

For each year of the simulation, PWC calculates peak (or daily maximum) and time-averaged concentrations. The time-averaged concentrations are calculated by averaging the peak concentrations over different time periods (24-hour, 96-hour, 21-day, 60-day, 90-day, and 1 year). The highest value of these averages for each calendar year is then calculated. The 90th percentiles of these yearly maxima are reported as the EECs for that period. In addition, the peak and 21-day average EECs in sediment pore water are generated by the model.

Several representative scenarios are selected for modelling different regions of Canada. The highest EECs from all modelled scenarios are reported in Table 2, for each use pattern and water depth. This table reports only the peak, 24-hour, 96-hour, and 21-day EECs, as these are generally found to be the most relevant for the environmental assessment. EECs for other time periods are found in the modelling notes, if needed.

Table 2 EECs for ecological risk assessment (in µg a.i./L) for tebuconazole

Water depth	Use	Water column				Pore water	
		Peak	24 h	96 h	21 d	Peak	21 d
15 cm	Crops: 4 × 126.1 g a.i./ha	104	101	95.8	88.6	84.2	84.1
	Turf: 3 apps totalling 3100 g a.i./ha	274	264	239	206	177	177
80 cm	Crops: 4 × 126.1 g a.i./ha	79.6	79.6	79.5	79.3	77.4	77.3
	Turf: 3 apps totalling 3100 g a.i./ha	172	172	171	170	161	161

2.3 Estimated concentrations in drinking water sources

For the human health assessment, EECs in potential drinking water sources are calculated for both groundwater and surface water.

For surface water, PWC calculates the amount of pesticide entering the water body by runoff and drift, and the subsequent degradation of the pesticide in the water system. EECs are calculated by modelling a total land area of 173 ha draining into a 5.3 ha reservoir with a depth of 2.7 m. Groundwater EECs are calculated by simulating leaching through a layered soil profile and reporting the average concentration in the top 1 m of a water table.

Drinking water modelling follows a tiered approach consisting of progressive levels of refinement. Level 1 EECs are conservative values intended to screen out pesticides that are not expected to pose any concern related to drinking water. These are calculated using conservative inputs with respect to application rate, application timing, and geographic scenario. Level 2 EECs are based on a narrower range of application timing, methods, and geographic scenarios, and are not considered conservative values that cover all regions of Canada.

Level 2 EECs were calculated for turf. Other crops were also modelled but turf presented the most conservative estimates. Refer to Tables 1 and 2 of Section 3.3.1 for EECs of tebuconazole.

3.0 Water monitoring data

3.1 Background and sources of data

Monitoring data collected from the year 2005 onward were considered relevant for this assessment; older data were deemed unlikely to represent current Canadian use conditions. Water monitoring information was available for tebuconazole from Ontario, Quebec, Nova Scotia, Manitoba, Alberta, British Columbia and the United States.

For the purposes of the water assessment, information extracted from the available sources was summarized by water type. Groundwater, finished/treated water and ambient surface water bodies such as rivers, lakes and reservoirs are considered potential sources of drinking water and thus relevant for use in the dietary risk assessment for human health. The ambient surface water sources mentioned above, in addition to water bodies that are not considered drinking water sources for humans like ponds, ditches and runoff, are considered relevant for aquatic risk assessment purposes.

3.2 Summary of water monitoring results

Samples were taken from a wide array of water types and at various times of year. It was not always evident if samples were drawn from waterbodies in areas in which tebuconazole was used.

Groundwater

(PMRA# 1774484, 1852614, 2312776, 2312778, 2312780, 2505827, 2505828, 2893272, 2988086, 3104172)

A total of 7146 groundwater samples were analyzed for tebuconazole in Canada and the United States, with the vast majority of the samples being from the United States. Tebuconazole was detected in only 15 of the samples and the maximum concentration detected was 0.0959 µg/L, from an American sample. Tebuconazole was only analyzed in a total of 15 groundwater samples from Canada, all in British Columbia. The maximum concentration detected in Canadian groundwater was 0.000178 µg/L.

Treated water sources and bottled water

(PMRA# 1774484, 1852614, 1852618, 1852619, 2312776, 2312778, 2312780, 2505827, 2505828)

A total of 3004 samples of treated water or bottled water were analyzed for tebuconazole, all of which were from the United States. There were no data for Canada. Tebuconazole was detected in 76 of the samples (< 3%), and the maximum concentration measured was 0.15 µg/L.

Ambient surface water

(PMRA# 1774484, 1852614, 1852618, 1852619, 2312776, 2312778, 2312780, 2505827, 2505828, 2526244, 2548876, 2548877, 2834287, 2839822, 2893272, 2893537, 2945668, 2988073, 2988086, 3072201, 3072202, 3104172, 3104173)

A total of 20 549 ambient surface water samples were analyzed for tebuconazole residues in Canada and the United States. Of these, tebuconazole was detected in 2380 of the samples analyzed (12%). The maximum concentration of tebuconazole residues detected was 3.28 µg/L from a sample taken in Minnesota. The second highest detection was similar, measuring 3.24 µg/L from a sample taken in California. Considering Canadian data only, tebuconazole was detected in ambient surface water in 304 out of the 2308 water samples analyzed (13%). In Canada, the highest concentration of tebuconazole residues detected in ambient surface water was 1.322 µg/L from a sample taken in Alberta.

A total of 18801 surface water samples from potential drinking water sources were analyzed for tebuconazole residues in Canada and the United States. Of these, tebuconazole was detected in 2164 of the samples analyzed (12%) with a maximum concentration of 3.28 µg/L from a sample taken in Minnesota. Considering Canadian data only, tebuconazole was detected in surface water from potential drinking water sources in 94 out of the 686 water samples analyzed (14%) with a maximum concentration of 0.0539 µg/L from a sample in Manitoba.

Passive sampling was conducted using Polar Organic Chemical Integrative Samplers deployed during two consecutive 14-day periods between May and June 2016 in a total of 18 watersheds in southwestern Ontario. The highest 14-day time-weighted average concentration for tebuconazole was 0.0151 µg/L in the Grand River. Approximately 24% of the Grand River watershed is pasture, 10% is urbanized, with 43% of the watershed being cropland with corn, soybeans and winter wheat being the major crops.

4.0 Discussion and conclusion

Potential drinking water sources for humans

Based on the available monitoring data, tebuconazole is seldom detected in groundwater across Canada and the United States but is detected in surface water more often. The relatively small number of samples in Canada preclude the use of an EEC based on Canadian monitoring data for acute and chronic drinking water exposure.

Water monitoring data, particularly for surface water, may miss peak concentrations, as sampling is typically sporadic and peak concentrations can be flushed through a system in a short amount of time after a runoff event. Therefore, particularly for surface water, EECs generated through modelling are typically better suited for use in an acute dietary risk assessment as opposed to surface water monitoring values. In addition, since there were few sites which were sampled repeatedly, an estimate for long-term exposure concentration was not able to be determined using these data. Therefore, the use of the daily and yearly groundwater modelling EECs (both 228 µg/L in Section 3.3.1, Table 1) are recommended as conservative estimates for the acute and chronic dietary risk assessments of tebuconazole in drinking water, respectively.

Surface water relevant for aquatic risk assessments

Tebuconazole was detected in 13% of Canadian samples with a maximum concentration of 1.322 µg/L. The maximum concentration detected in the United States was 3.28 µg/L. The relatively small number of samples from Canada (2308) preclude the use of an EEC based on Canadian monitoring data for acute and chronic risk assessments for aquatic organisms.

Water monitoring data, particularly for surface water, may miss peak concentrations, as sampling is typically sporadic and peak concentrations can be flushed through a system in a short amount of time after a runoff event. Therefore, particularly for surface water, EECs generated through modelling are typically better suited for use in an acute aquatic risk assessment as opposed to surface water monitoring values. In addition, since there were few sites which were sampled repeatedly, an estimate for long-term exposure concentration was not able to be determined using these data. Therefore, as a conservative estimate of tebuconazole concentrations in surface water relevant to the aquatic risk assessment, values generated from modelling (Section 3.3.1, Table 1) should be used in the acute and chronic risk assessments for aquatic organisms.

Appendix IX Label amendments for products containing tebuconazole

Information on approved labels of currently registered products should not be removed unless it contradicts the label statements provided below.

1.1 General directions for use

For labels with turf use, in the Disease/Use Rate table:

- To reduce potential drinking water exposure and risks, it is proposed to reduce the maximum cumulative rate from 3.10 kg a.i./ha/year to 1.44 kg a.i./ha/year. Registrants are required to provide label directions to clarify the maximum cumulative rate of 1.44 kg a.i./ha/year on labels of all commercial-class end-use products registered for turf uses.

The following statement is required on all end-use products with agricultural and turf uses, unless the current label directions are more restrictive.

- Under a “Crop Rotation” sub header, add: “A rotational plantback interval of 120 days must be observed for crops not listed on the label.”

1.2 Precautions

In the “Precautions” section of the secondary display panel of the label, the statements "Harmful if inhaled" should be added.

1.2.1 General label improvements

In order to promote best practices, and to minimize human exposure from spray drift or from spray residues resulting from drift due to the use of tebuconazole, the following label statements are proposed:

- End-use Products with agricultural crops, sod farms and golf courses.
  “Apply only to agricultural crops when the potential for drift to areas of human habitation and human activity (other than golf courses), such as houses, cottages, schools and recreational areas, is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment, and sprayer settings.”
- Seed Treatment End-use Products:
  “Apply only in a way that this product will not contact workers or other persons, either directly or through drift. Only workers wearing personal protective equipment may be in the area when seed is being treated or bagged.”

1.2.2 Personal protective equipment

The following statement is proposed to be added to all commercial-class end-use products that have uses for agricultural crops, sod farms and golf courses unless more protective statements are already present:

> "Wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up and repair (unless otherwise specified below)."
>
> "For mixing, loading, and application using a mechanically-pressurized handgun, wear coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up and repair."
>
> "For application using handheld airblast/mistblower equipment, wear chemical-resistant coveralls with a chemical-resistant hood over long-sleeved shirt, long pants, chemical-resistant gloves, socks, chemical-resistant footwear and a respirator with a NIOSH-approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH-approved canister approved for pesticides."
>
> "Gloves are not required during application within a closed cab or cockpit."

1.2.3 Restricted-entry interval

The following statement is proposed to be added to all commercial-class end-use products that have uses for agricultural crops and sod farms.

"**DO NOT** enter or allow worker entry into treated areas during the intervals specified in the following table:"

This table must be added to the label under PRECAUTIONS. Remove any crops from the table that are not registered on that specific product label from that product as a result of the re-evaluation.

Crop	Activity	REI and/or PHI
Short Rotation Intensive Culture (SRIC) (poplar and willow)	Harvest (seedling production)	1 day
	All Other Activities	12 hours
Barley, Spring Barley, Oat, Soybean, Triticale, Wheat	All Activities	12 hours
Asparagus	Harvesting	8 months
	All Other Activities	12 hours
Turf – sod farm	All Activities	12 hours

REI = restricted-entry interval; PHI = preharvest interval

The following statement is proposed to be added to all commercial-class end-use products that have uses for golf courses:

"**DO NOT** enter or allow entry into treated areas of the golf course until sprays have dried."

1.2.4 Occupational seed treatment label statements

On the principal panel:

The following statements are proposed to be added to all commercial-class seed treatment end-use products:

For Corn:

"For use in commercial seed treatment facilities (and mobile treaters) with closed transfer including closed mixing, loading, calibrating, and closed treatment equipment only. No open transfer is permitted."

For wheat, barley, rye, triticale, and oats:

"For use in commercial and on-farm seed treatment facilities (and mobile treaters) with open or closed transfer treatment equipment."

Under precautions:

Label statements must be amended (or added to) unless the current label mitigation is more restrictive.

Seed Types	Tasks	PPE/Engineering Controls
For Commercial Seed Treatment Facilities (and Mobile Treaters)		
Corn	Treaters, bagger/sewer/stacker, clean-up and repair activities (Closed M/L, Closed Transfer)	Wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, cleaning, repair activities and any other activities involving handling treated seeds.
Wheat, Barley, Oat, Rye, Triticale	Treaters (Open or Closed M/L), Bagger/Sewer/Stacker	Wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, and any other activities involving handling treated seeds.
	Clean-up and repair activities	Wear chemical-resistant coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during cleaning and repair activities.
For On-Farm Seed Treatment Facilities		
Wheat, Barley, Oat, Rye, Triticale	All Tasks (Open or Closed M/L)	Wear a long-sleeved shirt, long pants, shoes and chemical-resistant gloves during mixing, loading, application, clean-up, repair and any other activities involving handling treated seeds.
For Planting Treated Seeds (also include on seed tags)		
Corn	Planting	Wear a long-sleeved shirt, long pants, socks, shoes and chemical-resistant gloves during handling and planting treated seeds. Use a closed-cab tractor when planting. Gloves are

Seed Types	Tasks	PPE/Engineering Controls
		not required with a closed cab.
Wheat, Barley, Oat, Rye, Triticale		Wear coveralls over a long-sleeved shirt, long pants, socks, shoes and chemical-resistant gloves during handling and planting treated seeds. Use a closed-cab tractor when planting. Gloves are not required with a closed cab.

Under directions for use:

For all end-use products that are in water soluble packaging add the following label statements:

> Water-Soluble Packages (WSPs) are designed to dissolve in water. Agitation may be used, if necessary, to help dissolve the WSP. Failure to follow handling and mixing instructions can increase your exposure to the pesticide products in WSPs.
>
> **Handling instructions**
> Follow these steps when handling pesticide products in WSPs.
>
> 1. Mix in spray tank only.
> 2. Handle WSP(s) in a manner that protects package from breakage and/or unintended release of contents. If package is broken, put on a minimum of coveralls, chemical-resistant gloves, chemical-resistant footwear, and a NIOSH-approved N95 (minimum) filtering facepiece respirator (dust mask) that is properly fit tested and then continue with mixing instructions.
> 3. Keep the WSP(s) in outer packaging until just before use.
> 4. Keep the WSP dry prior to adding to the spray tank.
> 5. Handle with dry gloves and according to the label instructions for PPE.
> 6. Keep WSP intact. Do not cut or puncture WSP.
> 7. Reseal the WSP outer packaging to protect any unused WSP(s).
>
> **Mixing instructions**
> Follow the steps below when mixing this product, including if tank mixed with other pesticide products. If being tank mixed, the mixing directions 1 through 9 below take precedence over the mixing directions of the other tank mix products. All other directions for use of all tank mixed products should be followed provided they do not conflict. Do not tank mix this product with products that prohibit tank mixing or have conflicting mixing directions.
>
> 1. If a basket or strainer is present in the tank hatch, remove prior to adding the WSP to the tank.

2. Fill tank with water to approximately one-third to one-half of the desired final volume of spray.
3. Stop adding water and stop any agitation.
4. Place intact/unopened WSP(s) into the tank.
5. Do not spray water from a hose or fill pipe to break or dissolve the WSP(s).
6. Start mechanical and recirculation agitation from the bottom of tank without using any overhead recirculation, if possible. If overhead recirculation cannot be turned off, close the hatch before starting agitation.
7. Dissolving the WSP(s) may take up to 5 minutes or longer, depending on water temperature, water hardness and intensity of agitation.
8. Stop agitation before tank lid is opened.
9. Open the lid to the tank, exercising caution to avoid contact with dusts or spray mix, to verify that the WSPs have fully dissolved and the contents have been thoroughly mixed into the solution.
10. Do not add other allowed products or complete filling the tank until the bags have fully dissolved and pesticide is thoroughly mixed.
11. Once the WSP have fully dissolved and any other products have been added to the tank, resume filling the tank with water to the desired level, close the tank lid, and resume agitation.
12. Use the spray solution when mixing is complete.
13. Maintain agitation of the diluted pesticide mix during transport and application.

It is unlawful to use any registered pesticide, including WSPs, in a manner inconsistent with its label.

For seed tags:

It is proposed that the following statement be added to all seed tags containing direction for imported treated seed for sale or use in Canada:

“Keep treated seed out of reach of children and animals.”

For corn seed tags, the following is proposed:

“Wear a long-sleeved shirt, long pants, socks, shoes and chemical-resistant gloves during handling and planting treated seeds. Use a closed-cab tractor when planting. Gloves are not required with a closed cab.”

For wheat, barley, oat, soybean and triticale seed tags, the following is proposed:

"Wear coveralls over a long-sleeved shirt, long pants, socks, shoes and chemical-resistant gloves during handling and planting treated seeds. Use a closed-cab tractor when planting. Gloves are not required with a closed cab."

1.2.5 Occupational heavy-duty wood preservative label statements

Label statements, including personal protective equipment, consistent with the Recommendations for Design and Operation of Wood Preservation Facilities, 2013 Technical Recommendations Document" (Environment and Climate Change Canada, 2013) are proposed to be added to all commercial-class heavy-duty wood preservative end-use products.

1.2.6 Environmental precautions

Technical grade products

The following statement is proposed to be added under ENVIRONMENTAL PRECAUTIONS for all technical grade products:

"Toxic to aquatic organisms."

Commercial class products – Agricultural uses

The following statement is proposed to be added for products registered for use on turf only:

"Toxic to aquatic organisms, foliar-dwelling arthropods (certain beneficial insects), birds and non-target terrestrial plants. Observe spray buffer zones specified under DIRECTION FOR USE."

The following statements are proposed to be added under ENVIRONMENTAL PRECAUTIONS for all commercial class products with agricultural uses:

"Toxic to aquatic organisms and non-target terrestrial plants. Observe spray buffer zones specified under DIRECTION FOR USE.

To reduce runoff from treated areas into aquatic habitats avoid application to areas with a moderate to steep slope, compacted soil, or clay. Avoid application when heavy rain is forecast. Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative filter strip between the treated area and the edge of the water body.

Field sprayer application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572.1) medium classification. Boom height must be 60 cm or less above the crop or ground.

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

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

Apply only by fixed-wing or rotary aircraft equipment which has been functionally and operationally calibrated for the atmospheric conditions of the area and the application rates and conditions of this label.

Label rates, conditions and precautions are product specific. Read and understand the entire label before opening this product. Apply only at the rate recommended for aerial application on this label. Where no rate for aerial application appears for the specific use, this product cannot be applied by any type of aerial equipment.

Ensure uniform application. To avoid streaked, uneven or overlapped application, use appropriate marking devices."

Under BUFFER ZONES:

"Spot treatments using hand-held equipment do not require a spray buffer zone.

The spray buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands), sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of application	Crop		Spray Buffer Zones (metres) Required for the Protection of:				
			Freshwater Habitat of Depths:		Estuarine/Marine Habitat of Depths:		Terrestrial Habitat:
			Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m	
Field sprayer	SRIC poplar and willow, Soybean, Asparagus		1	1	0	0	1
	Wheat (spring, winter, durum), Barley, Oats		1	0	0	0	1
	Turf		5	1	1	0	2
Airblast	SRIC poplar	Early growth stage	15	1	0	0	4

	and willow	Late growth stage	5	1	0	0	2
Aerial	SRIC poplar and willow, Soybean	Fixed-wing	10	1	0	0	15
		Rotary-wing	10	1	0	0	15
	Wheat (spring, winter, durum), Barley, Oats	Fixed-wing	1-5	0	0	0	15
		Rotary-wing	1-3	0	0	0	10-15

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

The spray buffer zones for this product can be modified based on weather conditions and spray equipment configuration by accessing the Spray Buffer Zone Calculator on the Pest Management Regulatory Agency web site."

Commercial class products – Wood treatment uses

The following statements are proposed to be added under ENVIRONMENTAL PRECAUTIONS for all commercial class products with wood treatment uses:

"Toxic to aquatic organisms.

Drip aprons must be roofed, paved and drained to prevent dilution and loss of treatment solution.

Store treated lumber on a roofed drip pad until dripping has ceased. Slope lumber on the drip pad to expedite drainage and to ensure that no puddles remain on the surface of the wood. Manage drippage and other related wastes to prevent release in the environment.

DO NOT expose treated lumber to rains immediately after treatment.

For further information on storage, handling, and disposal of treated wood, contact the manufacturer of this product or the provincial regulatory agency.

This registration is granted under the *Pest Control Products Act* and does not exempt the user from any other legislative requirements.

Use of this product and management of any resulting discharge or release of any effluents or runoff containing this product must also be in accordance with the Fisheries Act and with any required provincial legislation.

Consult with provincial regulatory authorities on any authorizations or other requirements for use of this product and management of any resulting discharge or release of any effluents or runoff containing this product."

References

A. Information Considered in the Updated Chemistry Assessment

List of Studies/Information Submitted by Registrant

PMRA Document Number	Title
1534242	1988, Water Solubility (MG/L), DACO: 2.14.7 CBI
1534243	1988, Octanol/Water Partition Coefficient, DACO: 2.14.11 CBI
1534244	1988, Solvent Solubility (MG/L), DACO: 2.14.8 CBI
1534246	1988, Vapour Pressure, DACO: 2.14.9 CBI
1534247	1988, Stability (Temperature, Metals), DACO: 2.14.13,2.14.14 CBI
1534249	1988, Stability (Temperature, Metals), DACO: 2.14.13 CBI
1534286	1990, Supplement 1 - Part 2 - Product Chemistry of BAY HWG 1608 Technical, DACO: 2.1,2.11,2.12, 2.13,2.15,2.16,2.2,2.3,2.4,2.5,2.6,2.7,2.8
1534318	1993, Vapour Pressure, DACO: 2.14.9 CBI
2013251	2011, 29409-Preventol A8 TGAI-letter of intent-28jan2011-new source, DACO: 0.8
2013262	2010, Manufacturing Summary, DACO: 2.11.1,2.11.2,2.11.3,2.11.4,2.12.1,2.13.1,2.13.2 CBI
2013265	2009, Batch Data, DACO: 2.13.3 CBI
2013267	2009, Batch Data, DACO: 2.13.3 CBI
2013269	2009, Colour, DACO: 2.14.1,2.14.10,2.14.11,2.14.12,2.14.13,2.14.2,2.14.3,2.14.4,2.14.6,2.14.7 CBI
2013271	2009, EXP W 199-8 Vapour Pressure, DACO: 2.14.9
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2363561	2013, Bayer response to PMRA clarification request -Chemistry, DACO: 0.8
2363566	2013, Discussion of Formation of Impurities, DACO: 2.11.4 CBI
2764240	2017, Impurities of Toxicological Concern, DACO: 2.13.1,2.13.4 CBI
2878374	2011, Tebuconazole (HWG 1608) Description of the Manufacturing Process of the Technical Grade Active Substance, DACO: 2.11
2878375	2016, Material accountability of technical Tebuconazole (AE F069623), DACO: 2.13.3
1534240	1984, Physical and Chemical Properties of the Active Ingredient (AI): HWG 1608, DACO: 2.11.4,2.14.13,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9,2.16,2.5,2.7,2.8,2.9 CBI
1534241	1988, Density of FOLICUR Technical, DACO: 2.14.6 CBI
1534239	1988, Maximum and Minimum Certified Limits for Technical FOLICUR (BAY HWG 1608), DACO: 2.16 CBI
1532595	Chemistry Requirements for(TGAI) OR (ISP), DACO: 2.0
3174894	1989, Analytical Method TM C-10.17 Determination of Acidity or Basicity of Folicur Technical, DACO: 2.13.1
3166454	2016, Validation of GC Method AM046416FP1, DACO: 2.13.1
3166455	2016, Validation of GC Method AM007405FP2, DACO: 2.13.1
3166456	2016, Validation of GC Method AM045415FP1, DACO: 2.13.1

PMRA Document Number	Title
3166457	2016, Validation of GC Method AM022408FP2, DACO: 2.13.1
2264548	2012, Material accountability of technical tebuconazole (AE F069623), DACO: 2.13.2,2.13.3 CBI

B. Information Considered in the Updated Toxicological Assessment

List of Studies/Information Submitted by Registrant

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1038099	1991, HWG 1608 Technical Acute Oral Toxicity Study on Rats (Study No. 91A016). Report # 103290. 47 pages., DACO: 4.2.1
1038100	1989, HWG 1608 Study for Acute Toxicity. Report # 94395-1. 6 pages., DACO: 4.2.1
1038102	1990, Dermal Sensitization Study With Technical Grade Tebuconazole (FOLOCUR) in Guinea Pigs. Report # 99869. 21 pages., DACO: 4.2.6
1038103	1991, HWG 1608 Technical: Acute Oral Toxicity Study on Mice (Study No. 91A017). Report # 103951. 35 pages., DACO: 4.2.9
1038108	2001, Range-Finding Toxicological Study with NMRI Mice to Establish Dosage for a Chronic Study (Feeding for Four Weeks). Report # 110225. 75 pages., DACO: 4.3.3
1038109	1987, Subchronic Study of Toxicity to Dogs with Oral Administration (Thirteen-week Feeding Study). Report # 94984. Part 1 of 2. 282 pages., DACO: 4.3.8
1038110	1987, Subchronic Study of Toxicity to Dogs with Oral Administration (Thirteen-week Feeding Study). Report # 94984. Part 2 of 2. 282 pages., DACO: 4.3.8
1038113	1990, HWG 1608: (Proposed C.N.: Tebuconazole) Subacute Inhalation Toxicity to Cats - Study for Cataracts. Report # 100649. 223 pages., DACO: 4.3.8
1038116	1993, HWG 1608: Study for Carcinogenicity in NMRI Mice (Administration in Diet for up to 21 Months). Report # 96709-4. 31 pages., DACO: 4.4.3
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1038118	1993, Original Report: Folicular (HWG 1608): Chronic Toxicity and Carcinogenicity in Wistar Rate (Administration in Diet over a Period of 2 Years). Report # 96711-3. 70 pages., DACO: 4.4.4
1038119	1995, Limit Test of Embryo Toxicity (Including Teratogenicity) with HWG 1608 Technical (c.n. Tebuconazole) in the Rat (Dermal Application). Report # 106887. 258 pages., DACO: 4.5.2
1038120	1995, HWG 1608 Technical (c.n. Tebuconazole) Embryo Toxicity Study (Including Teratogenicity) and Supplementary Embryo Toxicity Study (Including Teratogenicity) in the Mouse. Report # 107009. 921 pages. Part 1 of 4, DACO: 4.5.2
1038121	1995, HWG 1608 Technical (c.n. Tebuconazole) Embryo Toxicity Study (Including Teratogenicity) and Supplementary Embryo Toxicity Study (Including Teratogenicity) in the Mouse. Report # 107009. 921 pages. Part 2 of 4, DACO: 4.5.2
1038122	1995, HWG 1608 Technical (c.n. Tebuconazole) Embryo Toxicity Study (Including Teratogenicity) and Supplementary Embryo Toxicity Study (Including Teratogenicity) in the Mouse. Report # 107009. 921 pages. Part 3 of 4, DACO: 4.5.2
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1038124	1991, HWG 1608: Study of Embryo Toxic Effects on Mice After Oral Administration. Report # 97411-4. 4 pages., DACO: 4.5.2
1038125	1991, HWG 1608: Study of Embryo Toxic Effects on Mice After Oral Administration. Report # 97411-5. 4 pages., DACO: 4.5.2

PMRA Document Number	Title
1038126	1995, HWG 1608 Technical (c.n. Tebuconazole): Embryo Toxicity Study (Including Teratogenicity) and Supplementary Investigation on the Maternal Toxicity in Pregnant Rabbits. Part 1 of 2. Report # 106899. Part 1 of 2. 503 pages., DACO: 4.5.3
1038127	1995, HWG 1608 Technical (c.n. Tebuconazole): Embryo Toxicity Study (Including Teratogenicity) and Supplementary Investigation on the Maternal Toxicity in Pregnant Rabbits. Part 1 of 2. Report # 106899. Part 2 of 2. 503 pages., DACO: 4.5.3
1038128	1991, HWG 1608: Reverse Mutation Assay (Salmonella Typhimurium and Escherichia Coli) Study No. 91A015. Report # 103275. 31 pages., DACO: 4.5.4
1038129	1986, HWG 1608: Dominant Lethal Test on the Male Mouse to Evaluate For Mutagenic Effect. Report # 94404. 46 pages., DACO: 4.5.8
1038130	1992, HWG 1608: REC-assay With Spores in the Bacterial System -Study No. 91A037. Report # 102685. 23 pages., DACO: 4.5.8
1038131	1998, A Subchronic Dietary Neurotoxicity Screening Study with Technical Grade Tebuconazole in Fischer 344 Rats. Report # 108029. Part 1 of 2. 410 pages., DACO: 4.5.11
1038132	1998, A Subchronic Dietary Neurotoxicity Screening Study with Technical Grade Tebuconazole in Fischer 344 Rats. Report # 108029. Part 2 of 2. 410 pages., DACO: 4.5.11
1038133	1997, An Acute Oral Neurotoxicity Screening Study with Technical Grade Tebuconazole (FOLICUR) in Fischer 344 Rats. Report # 107782. Part 1 of 2. 393 pages., DACO: 4.5.12
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1038136	2000, Developmental Neurotoxicity Study of Technical Grade Tebuconazole Administered Orally Via Diet to Crl:CDRBR VAF/Plus Presumed Pregnant Rats. Sponsor Study No. 98-C6-12-QU. Report # 109616. Part 1 of 6. 1405 pages., DACO: 4.5.12
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1145301	HWG 1608 Study Of Embryotoxic Effects On Mice After Oral Administration (97411-1;T5021859)(Folicur Tebuconazole), DACO: 4.5.2
1145664	1991, Supplemental Submission to EPA MRID 40700943: Embryotoxicity Study (Including Teratogenicity) With HWG 1608 Technical In the Rat (96756-1;83-3;074057)(Tebuconazole Folicur/Raxil), DACO: 4.5.2
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1145682	1989, Supplemental Submission to EPA MRID 4821501: HWG 1608 Study Of Embryotoxic Effects On Mice After Oral Administration (97411-3;83-3;T5021859) (Tebuconazole Folicur/Raxil), DACO: 4.5.2
1227392	1988, Study For Chronic Toxicity And Cancerogenicity in Wistar Rat (96711) (Con't From 760), DACO: 4.4.1,4.4.2
1227394	1988, Mutagenicity Test On HWG 1608 Technical in the Rat Primary Hepatocyte Unscheduled DNA Synthesis Assay (94988) (Con't on 762), DACO: 4.5.4
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1227397	1987, Two-Generation Study In Rats (91064), DACO: 4.5.1
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1227402	1988, Embryotoxicity Study (Including Teratogenicity) With HWG 1608 Technical In the Rat (96756), DACO: 4.5.2
1229425	1988, HWG 1608 Study For Acute Inhalation Toxicity to the Rat (96754), DACO: 4.2.3
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1229439	1988, Study For Chronic Toxicity And Cancerogenicity in Wistar Rat (96711) (Con't On 761), DACO: 4.4.1,4.4.2
1229474	1988, HWG 1608 : Salmonella/Microsome Test to Evaluate For Point Mutagenic Effects (91068), DACO: 4.5.4
1229493	1988, Mutagenicity Study For the Detection Of Induced Forward Mutations in the CHO-HGPRT Assay In Vitro (87318), DACO: 4.5.4
1229494	1985: Micronucleus Test on the Mouse to Evaluate For Mutagenic Effect (94529), DACO: 4.5.4
1229495	1987, Sister Chromatid Exchange Assay in Chinese Hamster Ovary (CHO) Cells (94858), DACO: 4.5.4
1229496	1988: In Vitro Cytogenetic Study With Human Lymphocytes For the Detection Of Induced Clastogenic Effects (95694), DACO: 4.5.4
1229497	1983: Pol Test On E Coli to Evaluate For Harmful Effects on DNA (94556), DACO: 4.5.4
1229498	1988 Study For Carcinogenicity in NMRI Mice (Administered In Diet For Up to Twenty-One Months) (96709), DACO: 4.4.2
1230727	1989, HWG 1608 Study Of Embryotoxic Effects on Mice After Oral Administration (974111-2), DACO: 4.5.2
2250370	2012, Tebuconazole - 28-day liver mechanistic study in the male and female mice by dietary administration (liver enzyme activity and gene transcript investigation), DACO: 4.8
2250374	2012, Tebuconazole - 28-day liver mechanistic study in male and female mice by dietary administration (liver histopathology and cell proliferation investigations), DACO: 4.8
2250377	2012, Assessment of pubertal development and thyroid function in juvenile/peripubertal male and female rats, DACO: 4.8
2250378	2012, Tebuconazole - Evaluation in the immature rat - Uterotrophic assay, DACO: 4.8
2250379	Tebuconazole: evaluation in the in vitro (hela-9903) estrogen receptor transcriptional activation assay
2758950	2012, Tebuconazole - Evaluation in the Hershberger bioassay, DACO: 4.8
2758951	2011, Evaluation of tebuconazole in the aromatase assay, DACO: 4.8
2758952	2011, Evaluation of tebuconazole in the androgen receptor binding assay, DACO: 4.8
2758953	2011, Evaluation of tebuconazole in the H295R steroidogenesis assay, DACO: 4.8
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2918348	Barone, S., Jr, & Moser, V. C. 2004. The effects of perinatal tebuconazole exposure on adult neurological, immunological, and reproductive function in rats. Toxicological Sciences, 77:183. https://doi.org/10.1093/toxsci/kfh036
2918351	Draft Assessment Report (DAR) - public version - Initial risk assessment provided by the rapporteur Member State Denmark for the existing active substance Tebuconazole, Volume 3, Annex B, Part 2/A, B.6
2918350	Tebuconazole, Joint FAO/WHO Meeting on Pesticide Residues
2918349	EDSP Weight of Evidence Conclusions on the Tier 1 Screening Assays for the List 1 Chemicals

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1417830	PMRA, 2006. REG2006-11: Tebuconazole
2717618	PMRA, 2016c. PRD2016-33: Tebuconazole
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1929697	PMRA, 2010a. Evaluation Report under Application Number 2007-8782
1890262	PMRA, 2010b. Evaluation Report under Application Number 2007-8783
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1865243	Sebesta, C. 2003a. An Exploratory Study To Determine the Rate and Route of Elimination of Folicur EW 250 When Administered Intravenously or Dermally to Male Rhesus Monkeys: Final Report. Project #VCBZ-0104-03-169. Unpublished study prepared by Charles River Laboratories. 119 p.
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1335563 1449840 2313625	Krolski, M.E. November 20, 2006, GAUCHO 480 SC – Worker Exposure During On-farm and Commercial Seed Treatment of Cereals, Bayer CropScience Environmental Research Bayer Research Park 17745 South Metcalf Avenue Stilwell, KS 66085-9104 & Grayson Research, LLC 1040 Grayson Farm Road Creedmoor, NC 27522. RANTY012. Unpublished. AHETF, AH803.
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1563670 1563673 1563654 1563636 1563641	Klonne, D. (1999). Integrated Report on Evaluation of Potential Exposure to Homeowners and Professional Lawn Care Operators Mixing, Loading, and Applying Granular and Liquid Pesticides to Residential Lawns. Sponsor/Submitter: Outdoor Residential Exposure Task Force. OMA005. EPA MRID # 44972201 Volumes 1-6
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1229597	Coffman, M. W. and W. K. Sietsema. 1984. Hydrolysis study of Bay HWG 1608 in sterile aqueous buffered solutions. Report number, 88726. DACO8.2.3.2.
1229598	Coody, P.N. 1987. Photodecomposition of Folicur in soil and water. Report number, 94901. DACOs 8.2.3.3.1 and 8.2.3.3.2.
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2758966	Ehmke, A. 2016. Tebuconazole tech.: Honey bee (*Apis mellifera* L.) larval toxicity test, single exposure. Report number M-568697-01-2. DACO 9.2.4.3
2758975	Feije, R. 2004. Tebuconazole SC 430: Extended laboratory study to evaluate the effects on the predaceous mite *Typhlodromus pyri* Scheuten (Acari: Phytoseiidae) on Zea Mais. Report number B126TPE. DACO 9.2.8
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2758967	Gossmann, A. 2002. Tebuconazole SC 430 (430 g/L): 10-day chronic feeding test on the honey bee (Apis mellifera L.) in the laboratory - 1st final report amendment. Report number M-542440-02-2. DACO 9.2.4.4
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2758971	Jans, D. 2009. Toxicity to the predatory mite *Typhlodromus pyri* Scheuten (Acari, Phytoseiidae) using an extended laboratory test (under semi-field conditions aged residues on Zea mays Tebuconazole EW 250 g/L). Report number CW09/027. DACO 9.2
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2758980	Stäbler, P. 2001. Tebuconazole EW 250: A laboratory study to evaluate the effects on the rove beetle, *Aleochara bilineata* Gyll. (Coleoptera, Staphylinidae). Report number 20001425/01-NLAb. DACO 9.2.8
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2758989	Vinall, S. 2001. A laboratory test to determine the effects of Tebuconazole EW 250 on the parasitic wasp, *Aphidius rhopalosiphi*. Report number BAY-01-8. DACO 9.2.8
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