



# Proposed Acceptability for Continuing Registration

PACR2007-02

## Re-evaluation of Dicamba for Lawn and Turf Uses

The purpose of this document is to inform registrants, pesticide regulatory officials and the Canadian public that Health Canada's Pest Management Regulatory Agency (PMRA) has re-evaluated the lawn and turf uses of the herbicide dicamba. The PMRA is proposing that dicamba is acceptable for continued registration for this use. Additional mitigation measures to further protect human health and the environment are identified in this document. Registrants will be required to submit additional specified data.

This Proposed Acceptability for Continuing Registration (PACR) document provides a rationale for the proposed regulatory decision for lawn and turf uses of dicamba. The PMRA will accept written comments on this proposal up to 60 days from the date of publication of this document. Please forward all comments to Publications at the address below.

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## Summary

Health Canada's Pest Management Regulatory Agency (PMRA) has re-evaluated the lawn and turf uses of the herbicide dicamba. This re-evaluation is part of the PMRA's commitment to review the most common lawn and turf chemicals used in Canada under the *Action Plan for Urban Use Pesticides*<sup>1</sup>.

The PMRA has assessed the available information and is proposing that the use of dicamba and its end-use products to treat lawns and turf is acceptable for continued registration with the implementation of additional mitigation measures to further protect human health and the environment.

The mitigation measures recommended include:

- phasing out the diethanolamine (DEA) form of dicamba; and
- requiring buffer zones for commercial products applied by tractor-pulled sprayers to protect surrounding broadleaf vegetation.

The PMRA will accept written comments on this proposal up to 60 days from the date of this document to allow interested parties an opportunity to provide input into the proposed re-evaluation decision for these products.

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<sup>1</sup> More information on this program can be obtained at [www.healthylawns.net](http://www.healthylawns.net).

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## 1.0 Purpose

This document describes the outcome of the PMRA's re-evaluation of the herbicide dicamba and its end-use products for use on lawns and turf in Canada. The assessment considered the potential impact of dicamba on the health and safety of users and others incidentally exposed when products are used on residential lawns as well as the potential environmental impact associated with the use of dicamba and its value as a herbicide in the maintenance of lawns and turf.

This re-evaluation was completed as part of the PMRA's commitment to review the most common lawn and turf chemicals used in Canada under the *Action Plan on Urban Use Pesticides*.

## 2.0 General Background on Re-evaluation

### 2.1 Regulatory History of Dicamba

Dicamba as a single active product was first registered in Canada in 1963 (Registration Number 8631, *Pest Control Products Act*); however, the first coformulation product containing 2,4-D/MCPP/dicamba was registered in 1947 (Registration Number 2278, *Pest Control Products Act*). A total of 40 products (14 commercial and 26 domestic class products) containing dicamba were registered for use on fine turf in Canada as of December 2005. These products are listed in Appendix I. They include 37 coformulations of 2,4-D, MCPP and dicamba; 1 coformulation of 2,4-D and dicamba; and 2 products that contain only dicamba. The two products that contain dicamba only are not registered as domestic class products. In addition to these products, fertilizer/herbicide products containing dicamba are registered by the Canadian Food Inspection Agency for use on fine turf in Canada. These products contain dicamba in the form of a 2,4-D/MCPP/dicamba coformulation with fertilizer.

In October 2000, the PMRA published the *Action Plan on Urban Use Pesticides*, which gave priority to re-evaluating the lawn and turf uses of a number of pesticides. On 27 September 2000, the PMRA also formally announced the re-evaluation of the most commonly used lawn and turf pesticides, including dicamba, in Re-evaluation Note [REV2000-04](#), *Re-evaluation of Lawn and Turf Uses of Pesticides*. In this document, the PMRA indicated that the review of the lawn and turf uses for dicamba would proceed in advance of the completion of the overall re-evaluation for dicamba, which will include agricultural and all other remaining uses. The re-evaluation of the remaining uses of dicamba is ongoing and will be the subject of a separate document in the future.

### 2.2 Definitions of Turf and Scope of this Review

The re-evaluation of the lawn and turf uses of dicamba has focussed on the assessment of risks resulting from the treatment of the following types of turf:

- sports and recreational turf such as turf in parks, playgrounds, golf courses<sup>2</sup>, zoos, botanical garden and athletic playing fields;
- lawn turf such as turf planted in or around residences, public and commercial buildings including schools, and cemeteries; and
- sod grown on sod farms that is harvested for transplanting<sup>2</sup>.

These types of turf are collectively known as fine turf, which may be maintained by homeowners or by professional applicators. Utility turf, also known as rough turf, is not included in this assessment. Utility turf is primarily intended for soil stabilization of industrial sites, requires less maintenance than fine turf and is usually maintained with commercial class products and equipment intended for large-scale application. Use of dicamba to maintain industrial sites (i.e., roadsides; rights-of-way for railways, hydro installations, pipelines and highways; highway interchanges; airports; wasteland; and industrial parks) will be considered when agricultural uses of dicamba are re-evaluated.

### **2.3 Forms of Dicamba**

Most products containing dicamba for use on turf are sold as amine salt forms based on dicamba acid. Although the primary route of dicamba entry into the plant is through the leaves, amine formulations greatly increase the water solubility of the herbicide, which can increase uptake by the plant via the roots.

The parent acid is the herbicidally active portion of the formulation. The parent acid is what binds to the herbicide target site within the plant and causes plant death; the amine portion of the formulated product allows greater absorption into the plant, but plays no direct role in herbicidal activity. Therefore, when assessing dicamba, the application rates were expressed in terms of the amount of acid equivalent per hectare (e.g., kg a.e./ha).

Other differences in the various forms of dicamba will be explained in the toxicology summary as well as the environmental toxicology and fate sections of this review. The various forms of dicamba for lawn and turf use are listed in Table 2.3.1.

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<sup>2</sup> Although excluded from the re-evaluation announcement concerning turf uses (REV2000-04), the use of dicamba on golf courses and sod farms is addressed in this re-evaluation.

**Table 2.3.1 Forms of Dicamba Included in this Assessment**

<b>Grouping</b>	<b>Form</b>
Parent compound	Dicamba acid
Salts	Diethanolamine salt (DEA)
	Dimethylamine salt (DMA)
	Diglycolamine salt (DGA)

### **3.0 Re-evaluation of the Turf Uses of Dicamba**

#### **3.1 Identity of the Active Substance and the End-Use Products Containing It**

Active substance: Dicamba

Function: Herbicide

Chemical names:

IUPAC: 3,6-dichloro-o-anisic acid

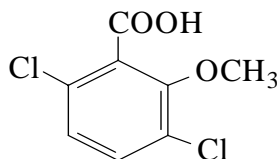
CAS: 3,6-dichloro-2-methoxybenzoic acid

CAS number: 1918-00-9

Molecular formula:  $C_8H_6Cl_2O_3$

Molecular weight: 221.0

Structural formula:



**Table 3.1.1 Registration Number, Purity and Registrant for the Technical Grade Active Ingredient**

Registration Number	Purity of Technical Grade Active Ingredient (%)	Registrant
19290	86.1 (limits: 82.0–91.0)	BASF Canada, Inc.
26613	86.1 (limits: 83.5–88.7)	Syngenta Crop Protection Canada, Inc.
26718	98.3 (limits: 95.4–99.9)	Gharda U.S.A., Inc.

**Table 3.1.2 Physicochemical Properties of Dicamba and Interpretation**

Property	Result	Interpretation
Vapour pressure	1.67 mPa (25°C, calculated) $1.25 \times 10^{-5}$ mm Hg	Slight potential for volatilization
Henry's law constant	$6.1 \times 10^{-5}$ Pa m <sup>3</sup> mol <sup>-1</sup> $6.02 \times 10^{-10}$ atm m <sup>3</sup> mol <sup>-1</sup>	Low potential to volatilize from water or moist sediment
Ultraviolet (UV)–visible spectrum	Not expected to show significant UV absorption at wave length > 350 nm	Not likely to be susceptible to direct phototransformation
Solubility in water at 25°C	6.1 g/L	Very soluble
<i>n</i> -Octanol–water partition coefficient	<b>pH</b> <b>log <i>K</i><sub>ow</sub></b> 5.0    -0.55 6.8    -1.88 8.9    -1.9	Unlikely to bioaccumulate
Dissociation constant	p <i>K</i> <sub>a</sub> = 1.97	Potentially mobile at environmental pH

## 4.0 Assessment of Human Health Effects

### 4.1 Toxicology Summary

Based on an assessment of the limited data available on the toxicological equivalencies of different forms of dicamba, it is considered that the acid and the diethanolamine salt (DMA) forms of dicamba are toxicologically equivalent. It is anticipated that the sodium salt of dicamba dissociates into dicamba acid and the relatively non-toxic sodium moiety and is toxicologically equivalent to dicamba free acid. Other forms of dicamba registered for turf uses include dicamba diglycolamine (DGA) and diethanolamine (DEA).

Limited toxicology data with the DGA form of dicamba were available at the time of this review. Metabolism data with the DGA form of dicamba show rapid dissociation to the acid form and respective moiety, with no significant differences from the acid form with respect to absorption, distribution, metabolism and excretion. Based on an assessment of the available data, the DGA form is considered to have comparable acute oral toxicity to the acid. With acute dermal exposure, the DGA form shows low toxicity similar to the acid form. With respect to acute inhalation exposure, the DGA form cannot be compared to the acid form due to the lack of an adequate acute inhalation study conducted with the free acid. However, the DGA and DMA forms both show low acute toxicity by this route. The DGA form is considered to be of less or comparable toxicity with respect to irritation and sensitization. With repeat-dose dermal studies in the rabbit, the DGA form shows low toxicity similar to the acid form. Although definitive comparisons of toxicological equivalency are hindered by dose limitations, the occurrence of dermal toxicity with dicamba acid at lower levels of acid equivalents (a.e.) than seen with the DGA form supports the use of the dicamba acid database as a suitable surrogate for the DGA. DGA is considered a List 3 formulant (see PMRA Regulatory Directive [DIR2004-01](#), *Formulants Program*) and has no identified health concerns at this time.

There was no toxicological information on the DEA form of dicamba. However, concerns arise from published literature showing repeated dermal application of DEA on its own is carcinogenic in mice. No tumours were evident in a similar study conducted in rats, although the doses were lower than those used in the mouse studies. Short-term oral and dermal studies also indicate that pure DEA causes brain and spinal cord demyelination in rats and is immunotoxic in rats and mice. DEA is also identified as a List 2 formulant (see Regulatory Directive [DIR2004-01](#)). DEA demonstrated greater systemic toxicity than dicamba. Based on the apparent difference in toxicological profile for DEA on its own relative to dicamba acid and other dicamba forms, further assessment for dicamba DEA was not possible. Therefore, regulatory actions are proposed for the DEA form of dicamba (see Section 8.1).

In laboratory animals, dicamba has low acute toxicity via oral and dermal routes. No adequate acute inhalation study is available. Dicamba is corrosive to the eyes, a dermal irritant and a potential skin sensitizer. Repeat-dose oral exposure resulted in liver effects, alterations in clinical chemistry as well as decreases in body-weight gain and food consumption. In repeat-dose oral studies, the dog appeared to be the most sensitive species. A comparison of data from dog studies of different durations (two months to one year) suggests that toxicity increases with length of exposure. As there is a lack of information from other species upon which to establish

species-specific relationships between duration of exposure and toxicity, it is assumed that the increased toxicity that accompanies increased length of exposure in the dog is not unique to this species. Despite the presence of behavioural neurotoxic indicators in several studies, a subchronic neurotoxicity study revealed few signs of neurotoxicity and only at very high dose levels.

Dicamba did not cause fetal malformations in rats or in rabbits, and the developmental studies did not demonstrate any sensitivity of the young relative to adult animals. In reproductive studies, offspring appeared to be more sensitive than parental animals to the toxic effects of dicamba. Decreased birth weight was observed in all litters from two generations in the absence of any prenatal indicator of parental toxicity. The sensitivity of the young to dicamba was thought to be associated with intermediate to long-term exposure of the maternal animal because no similar sensitivity of the young was observed under the short-term exposure scenario of the developmental studies. Furthermore, sensitivity of the young was considered to result from indirect (i.e., in utero) exposure because effects were noted at birth. Parental effects were almost exclusively limited to the first filial generation, suggesting that the first filial generation developed a higher sensitivity to dicamba, which may be due to in utero exposure.

Findings from several different studies suggest effects on the endocrine system. In the two-generation rat reproduction study, a dose-related decrease in sperm motility was seen. This is consistent with an absence of spermatozoa in the epididymides noted in the chronic mouse study. Additionally, inflammation of the prostate was seen in the one-year dog study, and a delay in preputial separation was seen among males of the first filial generation in the rat reproduction study. With the possible exception of delayed preputial separation, these findings cannot be considered definitive due to a variety of factors (e.g., lack of dose response, low animal numbers, age of animals, absence of incidence data, etc.), nor can they be discounted on the basis of any other existing data.

The weight of evidence from in vitro microbiological mutagenicity assays suggests that dicamba is not genotoxic, though several assays reported positive results for genotoxicity. These positive results indicate that dicamba may cause DNA damage in bacteria and yeast. Dicamba was found to be negative in an in vivo chromosomal aberration study in the rat. In the two-year dietary carcinogenicity studies in the mouse and the rat, there was no evidence of dicamba being carcinogenic. However, the rat study was deemed inadequate as an assessment of the carcinogenic potential and chronic toxicity of dicamba because the highest dose tested (107 mg/kg bw/day) did not elicit any effects and was below the maximum tolerated dose. In other studies, rats received approximately fourfold the high dose of rats in the carcinogenicity study, while exhibiting only minor effects. In light of the inadequacy of the repeat-dose carcinogenicity study and the presence of several positive in vitro genotoxicity results, conclusions that dicamba is non-carcinogenic cannot be considered definitive.

Route-specific reference doses have been set on the general toxicological parameters affected in the various studies. These reference doses incorporate various uncertainty factors to account for extrapolating between laboratory animals and humans, for variability within the human population and for data gaps. Additional safety factors have also been employed, where warranted, to protect pregnant females and their unborn children due to sensitivity concerns

arising from in utero exposure. The concerns regarding the sensitivity of the offspring were only considered relevant to risk assessments of an intermediate to chronic duration because effects indicative of sensitivity of the young were attributed to prolonged repeated dosing of the maternal animals. Reference doses for aggregate assessment were based on the no observed adverse effect levels (NOAELs) for common endpoints affected across the route-specific studies, which were not necessarily the study NOAELs.

## **4.2 Residential Risk Assessment**

Residential risk assessment for lawn and turf use of dicamba encompasses the exposures that adults may receive while applying dicamba to their lawn, and that adults and children may receive through contact with treated turf.

Residential risk is estimated by calculating a margin of exposure (MOE) based on comparing the potential exposure to the most relevant end points from toxicology studies. The calculated MOE is then compared to a target MOE, which incorporates safety factors protective of the most sensitive subpopulations. If the calculated MOE is less than this target MOE, it does not necessarily mean that exposure will result in adverse effects, rather that the absence of adverse effects is less certain. Mitigation measures are necessary to reduce exposure if MOEs are less than the target MOE.

### **4.2.1 Relevant Toxicological Endpoints and Target Margins of Exposure**

For short-term dermal risk assessments (1–7 days), all populations are considered equivalent with respect to sensitivity. The most relevant studies are three 3-week dermal studies in the rabbit. A NOAEL for systemic effects of 1000 mg/kg bw/day (highest dose tested) was selected from one study, while the two other studies had lowest observed adverse effect levels (LOAELs) of 2500 mg/kg bw/day (highest dose tested). Effects at this dose level consisted of increased blood glucose as well as decreased body weight, urine pH, hemoglobin and total protein. When considered together, these three dermal studies offer a consistent toxicological picture, which is corroborated by observed dermal absorption values (default of 25% was considered appropriate). For 1- to 7-day exposures, a target MOE of 100 from the systemic NOAEL of 1000 mg/kg bw/day is selected. This MOE is based on standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability. No additional safety factor for sensitivity of the young is required because sensitivity of the young was not evident with short-term exposure. This assessment is considered protective of all populations; it is also considered conservative for use in an acute (single day) risk assessment.

For the short-term inhalation risk assessments (1–7 days), all populations are considered equivalent with respect to sensitivity. In the absence of suitable inhalation studies, the assessments of short-term risk via inhalation are based on a maternal NOAEL of 30 mg/kg bw/day from the rabbit developmental study. For a 1- to 7-day exposure, a MOE of 100 from the NOAEL is selected based on standard uncertainty factors of 10-fold for intraspecies variability and 10-fold for interspecies extrapolation.

For toddlers and the non-dietary (incidental) oral ingestion risk assessment, a scenario of short-term exposure was considered. The most relevant endpoint was from a developmental rabbit study with a NOAEL of 30 mg/kg bw/day. The LOAEL in this study was 150 mg/kg bw/day, based on ataxia. The LOAEL from a corresponding range-finding study was 125 mg/kg bw/day based on hyper-reactivity, while more varied and severe clinical signs were observed at higher dose levels. A target MOE of 100 is selected based on standard uncertainty factors of 10-fold for intraspecies variability and 10-fold for interspecies extrapolation. This margin of exposure is adequate because no sensitivity of the young was evident under acute or short-term exposure scenarios and sensitivity of the young was associated with in utero exposure. This assessment is considered protective of orally exposed toddlers.

#### **4.2.2 Exposure and Risk Assessment**

Homeowners typically apply dicamba to their lawns twice a year, once in the spring and once in the fall, with occasional additional spot applications in the summer. Residential applicators, therefore, have the potential for short-term periods of exposure (less than 7 days).

Dermal and inhalation exposure estimates for homeowner's applying on residential turf are based on data from the PHED Version 1.1 and ORETF studies.

The PHED is a compilation of generic mixer/loader applicator passive dosimetry exposure data that can be used to generate scenario-specific exposure estimates. The Occupational and Residential Exposure Task Force (ORETF) studies monitored exposure to workers and homeowners mixing/loading and applying pest control products to turf. Monitoring was conducted using passive dosimetry, including hand washes, face/neck wipes and personal air samplers.

Exposure is calculated as the product of the unit exposure for a given scenario, the application rate and the area treated per day divided by body weight. For broadcast applications, it was assumed that homeowners treated an area of 2000 m<sup>2</sup> a day. This is considered an upper percentile estimate.

Exposure via the dermal and inhalation routes does not contribute to the same toxic effect; therefore, the route-specific MOEs are not combined.

Exposure and risk estimates and details on the calculations are presented in Appendix III. MOEs for all homeowners applying dicamba to turf are above the target MOE of 100.

#### **4.2.3 Exposure and Risk Assessment for Persons Entering a Treated Area**

Postapplication exposure and risk were estimated for children and adults contacting treated residential lawns and golf courses based on the assumptions outlined in the United States Environmental Protection Agency (USEPA) draft Standard Operating Procedures (SOPs) for Residential Exposure Assessments and the recommended revisions by the USEPA Science Advisory Council (USEPA 1997, 2001).

Postapplication dermal exposures were estimated using generic transfer coefficients and dicamba turf transferable residue (TTR) data. Transfer coefficients are defined in the USEPA draft SOP and measure the relationship between dermal exposure and TTR for individuals engaged in a specific activity on treated turf.

Acute and short-term risk assessments were conducted because there is potential for relatively higher exposures to children and adults on the day of application and for repeated lower exposures over a short-term period (1–7 days) as residues of dicamba dissipate. Based on the TTR data generated by the Broadleaf Turf Herbicide Transferable Foliar Residue Task Force, peak TTR levels were 2.6% of the applied rate and 7-day average TTR levels were 0.26% of the applied rate. The transferable turf residue study did not address residues from granular formulations; however, the same TTR value was used for granular and liquid formulations. As TTR values are expected to be lower following application of a granular formulation, this is a conservative assumption.

New postapplication exposure data relevant to estimating dermal exposure from contact with treated turf were received from the ORETF in February 2004. The PMRA, the USEPA and the California Department of Pesticide Regulation are currently evaluating these data. Preliminary calculations suggest that, while exposure estimates might increase slightly, target MOEs would still be met for all postapplication scenarios. If necessary, the PMRA will publish a revised risk assessment after a full review of the new data.

Non-dietary oral exposure was assessed for toddlers, as they could ingest residues through hand-to-mouth transfer from turf or other surfaces, by mouthing grass or by ingesting soil. As well, oral ingestion of granules was considered, although this is considered to be an acute, episodic exposure event rather than a typical exposure.

The contribution of inhalation exposure to overall exposure in postapplication scenarios is considered to be negligible due to the dilution effect of outdoor use.

Calculated acute and short-term MOEs for adults and toddlers exceeded the target MOEs. This indicates that the potential exposures are below levels that would be of concern. Further details are presented in the exposure calculation tables in Appendix III.

### **4.3 Dietary Assessment**

A dietary exposure assessment was conducted so that aggregate exposure and risk could be estimated. An aggregate risk assessment considers the risk resulting from combined exposures from all sources and routes, including food, drinking water and residential exposures.

#### **4.3.1 Dietary Exposure**

The dietary exposure assessment estimated how much dicamba residues, including residues in milk and meat, may be ingested with the daily diet. The assessment was age-specific and incorporated the different eating habits of the population at various stages of life. For example,

the assessment took into account the greater consumption of fruit, vegetables and juices by children, relative to their body weight, compared to adults.

The assessment is based on the residue of concern being defined as dicamba (parent compound only). The definition of the residue of concern will be considered when the overall re-evaluation of dicamba is performed.

All Canadian and American food commodities for which dicamba has a registered use were considered in the dietary risk assessment. Domestic uses for dicamba on foods and feeds include rye (winter and spring), barley (malting, winter and others), blueberry, cereal crops, corn, sweet corn, pasture and rangeland grasses, oats, wheat (spring, winter and durum) and strawberries. There are no registered aquatic uses of dicamba in Canada. Foreign uses include asparagus, sorghum, cotton (seed, meal), corn, oats, millet, proso, barley (grain, straw), grass (forage, hay), soybean (seeds, hull), wheat grain and sugarcane (forage and molasses).

The dietary risk assessments were conducted using data from processing studies as well as monitoring data from Canada and the United States. Where no data were available, potentially treated commodities were assessed using the maximum residue limit of 0.1 ppm under general regulation B.15.002(1) of the Food and Drug Regulations. The dietary exposure scenarios were assessed for the general population as well as for population subgroups. The dietary exposure and risk estimates were generated using the Dietary Exposure Evaluation Model (DEEM) and consumption data from the United States Department of Agriculture's Continuing Surveys of Food Intake of Individuals, 1994–1998.

#### **4.3.2 Dietary Risk**

An acute dietary exposure assessment considers the highest ingestion of dicamba likely on any one day. A probabilistic statistical analysis allows all possible combinations of food consumption and residue levels to be combined to generate a distribution of the amount of dicamba residue that might be eaten in a day. A value representing the high end (99.9<sup>th</sup> percentile) of this distribution, which is referred to as the potential daily intake (PDI), is compared to the acute reference dose (ARfD). The ARfD is the dose at which an individual could be exposed on any given day and expect no adverse health effects. When the expected intake (PDI) from residues is less than the ARfD, this intake is not considered to be of concern.

The acute (single day) dietary reference dose for all populations is 0.30 mg/kg bw, based on a NOAEL of 30 mg/kg bw/day derived from a developmental rabbit study. The LOAEL in this study was 150 mg/kg bw/day based on ataxia. The LOAEL from the corresponding range-finding study was 125 mg/kg bw/day based on hyper-reactivity, while more varied and severe clinical signs were observed at higher dose levels. Sensitivity of the young was not evident under acute exposure scenarios. A standard 100-fold uncertainty factor is applicable to account for interspecies extrapolation (10-fold) and intraspecies variability (10-fold). The ARfD is considered to be protective of all populations. The acute PDI accounted for < 8.5% of the ARfD for all population subgroups (Table 4.3.2.1).

Chronic dietary exposure is calculated using the average consumption of different foods and average residue values on those foods over a 70-year lifetime. This expected intake of residues is compared to the acceptable daily intake (ADI), which is the dose at which an individual could be exposed over the course of a lifetime and expect no adverse health effects. When the expected intake from residues is less than the ADI, this intake is not considered to be of concern.

The chronic (lifetime) dietary reference dose, or ADI value, for all populations is 0.0112 mg/kg bw/day, based on a NOAEL of 11.2 mg/kg bw/day derived from the 1-year dog study. The LOAEL of 58.5 mg/kg bw/day in this study resulted in alterations in clinical chemistry and inflammation of the prostate. Also considered is the 2-generation rat reproduction study, which demonstrated sensitivity in the young following indirect (in utero) exposure. An unacceptable rat carcinogenicity study, resulting from inadequate dose level selection, was also a factor in the risk assessment. Standard uncertainty factors of 10-fold for intraspecies extrapolation and 10-fold for interspecies variability are applied. An additional 10-fold is applied to account for potential sensitivity of the young and the lack of an acceptable carcinogenicity study in the rat, for an overall factor of 1000. This ADI is considered protective of the offspring and would also intrinsically address observations that are potentially related effects on the endocrine system. Although the rat chronic toxicity/carcinogenicity study was not performed at maximum tolerated doses, the ADI does provide a margin of safety more than 9500 to the NOAEL for chronic toxicity in this study. The chronic PDI accounted for < 15% of the ADI for all population subgroups.

These chronic and acute dietary risk assessments demonstrated that there were no health concerns for any population subgroup in Canada, including infants, children, teenagers, adults and seniors. The dietary exposure estimates are presented below in Table 4.3.2.1.

**Table 4.3.2.1 Chronic and Acute Dietary Exposure and Risk Summary for Dicamba**

Population Subgroup	Chronic Dietary Exposure		Acute Dietary Exposure	
	mg/kg bw/day	% ADI	mg/kg bw	% ARfD
General population	0.00073	7	0.0047	1.6
Non-nursing infants	0.0013	12	0.0254	8.5
Children 1–6 years	0.00168	15	0.0061	2
Children/Youth 7–12 years	0.0011	10	0.0042	1.4
Females 13–50 years	0.00063	6	0.0033	1.1

### 4.3.3 Drinking Water

As previously indicated, residues in drinking water can be a potential source of exposure to dicamba. To evaluate the contribution from this source to overall exposure, drinking water quality monitoring data from several sources, ranging from provincial reports to scientific studies, were considered. The combined Canadian data set incorporated monitoring results from ambient surface water and groundwater as well as treated municipal drinking water. These data were supplemented by relevant monitoring information from the United States. Based on these data, the locations of high dicamba concentrations are generally randomized and do not persist. When detected, residues of dicamba in ambient and treated drinking water were generally < 1 µg/L. The maximum estimates of acute and chronic residues of dicamba in drinking water were 15 and 5 µg/L, respectively.

Canadian drinking water levels of comparison (DWLOCs) were calculated to assess whether these concentrations posed any risk. The DWLOC is the maximum concentration in drinking water that, when considered together with all other sources of exposure, does not exceed a level of concern. The acute and chronic DWLOCs were > 2750 and 100 µg/L, respectively. As the acute and chronic anticipated residues of dicamba in drinking water do not exceed the respective DWLOCs indicated in Table 4.3.3.1, they are below the PMRA's level of concern.

**Table 4.3.3.1 Chronic and Acute Drinking Water Levels of Comparison for Dicamba**

Population Subgroup	Short-Term and Chronic Drinking Water Exposure	Acute Drinking Water Exposure
	DWLOC <sup>1</sup> µg/L	DWLOC <sup>1</sup> µg/L
General population	370	10340
Non-nursing infants	100	2750
Children 1–6 years	140	4410
Children/Youth 7–12 years	220	6510
Females 13–50 years	330	9220

<sup>1</sup> Where DWLOC = (reference dose - dietary exposure) × (body weight)/(water consumption). Body weight is considered to be 70, 62, 44, 15 and 10 kg for #adults, adult females, children/youth 7–12 years, children 1–6 years and infants, respectively. Water consumption is 2 L/day except for children and infants, where water consumption is 1 L/day.

## 4.4 Aggregate Risk Assessment

The purpose of aggregating exposure is to estimate the risk resulting from total exposure to dicamba from all sources and routes of exposure, including food, drinking water and residential exposures.

### 4.4.1 Acute Aggregate Risk Assessment

Acute aggregate risk is estimated as the risk that would result from the highest likely single day exposures to dicamba. Acute aggregate exposure to dicamba combines dietary and drinking water exposures only and is compared to the ARfD. The acute aggregate risk assessment did not incorporate residential exposure as it is improbable that an individual would be exposed to high-end dietary and residential exposures on the same day. Average (chronic) dietary exposure is a very small fraction of the highest one-day residential exposure and would not have an impact on the total risk.

The acute PDI for all subpopulations was < 8.5% of the ARfD (Table 4.3.2.1).

To aggregate the acute drinking water and dietary exposure, acute DWLOCs were calculated to be less than 2750 µg/L; these were assessed against the acute drinking water estimate of 15 µg/L. The acute exposure from drinking water sources is below the DWLOC. The acute aggregate exposure is not of concern because the dietary and drinking water exposures are acceptable.

### 4.4.2 Short-term Aggregate Risk Assessment

Short-term aggregate exposure to dicamba was estimated based on contributions from food, drinking water and residential exposure (dermal, inhalation and oral components).

Ideally, toxicity data reflecting the hazards associated with repeat exposure for one to seven days by the oral, dermal and inhalation routes would be relevant to the short-term aggregate risk assessment. As no one-week exposure data are available, the most relevant data for this risk assessment are from a two-week oral (capsule) developmental study in rabbits and from a three-week dermal study in rabbits. There are no short-term inhalation data. Decreased body weight is a common toxic effect among the oral and dermal studies (route-specific toxic effects are addressed in the non-aggregated risk assessments).

Decreased body weight were seen at 300 mg/kg bw/day in the developmental rabbit study and at 2500 mg/kg bw/day in the rabbit dermal study. The short-term aggregate risk assessment will be based on the following NOAELs for body-weight effects: 150 mg/kg bw/day in the rabbit oral developmental study and 1000 mg/kg bw/day in the 3-week rabbit dermal toxicity study. In lieu of suitable inhalation data, the oral NOAEL for body-weight effects of 150 mg/kg bw/day will also be used for the inhalation exposure component of the aggregate risk assessment. Sensitivity of the young observed in the 2-generation rat reproduction study is not deemed relevant to the 1- to 7-day exposure periods. For the 1- to 7-day aggregate assessment, standard uncertainty factors are applied (10-fold for interspecies extrapolation and 10-fold for intraspecies variability),

resulting in a target MOE of 100 to the aggregate risk assessment toxicity endpoints. This MOE is considered to be protective of all populations.

The chronic dietary exposure was considered representative of a typical exposure because it represents the average daily exposure over an individual's lifetime. Ingestion of granules is not aggregated in the short-term oral scenario as this is considered to be episodic rather than a typical exposure event.

Short-term aggregate exposure estimates from food, residential exposure (dermal, inhalation and incidental oral components) and drinking water did not indicate any unacceptable risk. The calculated DWLOCs ranged from 22 200 to 52 500  $\mu\text{g/L}$ . These were compared to the chronic estimate of dicamba residues in drinking water, which is 5  $\mu\text{g/L}$ . This is lower than the calculated DWLOCs for all populations; therefore, the short-term aggregate risk is below the PMRA's level of concern.

Further details of the exposure calculations and estimates of short-term aggregate exposure and risk are summarized in Appendix III.

#### **4.4.3 Chronic Aggregate Risk Assessment**

Chronic aggregate exposure to dicamba is considered to arise from dietary and drinking water exposures only and is compared to the ADI. Residential exposure is not included because all the relevant time frames and exposure routes are considered in the short-term aggregate risk assessment. The derivation of the dietary and drinking water exposure estimates is described in tables 4.3.2.1 and 4.3.3.1.

The chronic PDI accounted for < 15% of the ADI for all population subgroups, with children from 1 to 6 years of age being the most highly exposed subpopulation.

Chronic DWLOCs of > 100  $\mu\text{g/L}$  were calculated and assessed against the chronic drinking water estimate of 5  $\mu\text{g/L}$ . The chronic exposure from drinking water sources is below the DWLOC. The dietary and drinking water exposures are acceptable; therefore, the chronic aggregate exposure is not of concern.

#### **4.5 Occupational Risk Assessment**

Occupational risk is estimated by comparing the potential exposure of persons mixing, loading and applying pesticides or re-entering treated areas to the no-effect level for an endpoint from the most relevant toxicology study with respect to route and duration. This generates an MOE. The MOE is compared to a target MOE that incorporates the safety factors protective of the most sensitive population. If the MOE is less than this target MOE, it does not necessarily mean that exposure will result in adverse effects, rather that the absence of adverse effects is less certain. Mitigation measures will be necessary to reduce exposure if MOEs are less than the target MOEs.

#### **4.5.1 Relevant Toxicological Endpoints and Target Margins of Exposure**

The same acute and short-term dermal and inhalation endpoints and MOEs selected for the residential risk assessment (Section 4.2) are relevant for the occupational risk assessment; these are considered protective of all populations including pregnant females and their unborn children. For intermediate-term exposures (8–30 days), the same dermal and inhalation endpoints are selected, but the target MOE has been increased by 3-fold for both routes due to sensitivity of the young. Sensitivity of the young was demonstrated in the 2-generation reproduction study in rats following prolonged in utero exposure. In the absence of analogous data for the rabbits on which dermal and inhalation endpoints are based, sensitivity is also assumed, and pregnant females are considered to be the most sensitive population.

As stated in Section 4.1, there was no toxicological information on the DEA form of dicamba. The PMRA is proposing the phase-out of this form unless data are provided to address identified data gaps (see Section 8.1). Therefore, an occupational risk assessment for dicamba DEA has not been included at this time.

#### **4.5.2 Exposure and Risk Assessment**

Commercial lawn care operators treating residential lawns may handle dicamba for one month during the spring and fall. Applicators treating golf courses and sod farm turf are restricted to two applications per year and are likely to have less than a one-week exposure to dicamba in the spring and fall.

Exposure estimates for mixer/loader/applicators were based on data from the PHED and the ORETF studies. Refer to Section 4.2.2 for PHED and ORETF descriptions.

Exposure is calculated as the product of the unit exposure for a given scenario, the application rate and the area treated per day divided by the body weight. With applicators wearing long pants, long-sleeved shirt and gloves, all calculated MOEs are above the target MOE of 300 for commercial lawn care operators and for commercial mixer, loader and applicators treating golf courses and sod farms. Further details are presented in the exposure calculation tables in Appendix III.

#### **4.5.3 Postapplication Exposure and Risk Assessment**

Golf course and sod farm workers who enter treated sites to conduct turf maintenance activities may have acute and short-term (< 1 week) dermal exposure to dicamba. Potential exposure was estimated using the generic agricultural transfer coefficient (TC) for workers aerating, fertilizing, mowing, harvesting and transplanting treated turf, coupled with TTR data. A peak residue level of 2.6 % of the applied rate was used for the acute risk assessment and a 7-day average of 0.26% was calculated for the short-term risk assessment (1–7 days).

The MOEs for aerating, fertilizing, scouting and mowing golf course and sod farm turf are above the target MOEs for acute (1 day) and short-term (1–7 days) exposure. Details are presented in Appendix III.

## 5.0 Assessment of Environmental Effects

In assessing the environmental risk of dicamba, a deterministic approach was used. In this standard PMRA approach, risk was characterized by the quotient method, the ratio of the estimated environmental concentration to the effects endpoint of concern. Risk quotient (RQ) values less than one are considered indicative of a low risk of non-target effects occurring, whereas values greater than one are considered to indicate that some degree of risk exists for effects on non-target organisms.

Initial and cumulative expected environmental concentrations were calculated for soil and wildlife food sources for the spray formulations of dicamba used on turf by both commercial applicators and home owners. The expected environmental concentrations were calculated using minimum and maximum application rates along with the maximum number of applications and minimum intervals between applications. The cumulative expected environmental concentrations were estimated by adjusting the sum of the applications for dissipation between applications using the time for 50% dissipation ( $DT_{50}$ ) for the appropriate environmental media (soil and food sources). To assess the risk to aquatic organisms, surface water monitoring data resulting from turf uses were used. Effects endpoints included both acute and chronic points, chosen from the range of toxicity tests on the species available. Effects endpoints, chosen from the most sensitive species, were used as surrogates for the wide range of species that can be potentially exposed following treatment with dicamba.

Granular fertilizer/pesticide products containing dicamba were also assessed. These granular formulations provide a unique exposure scenario as birds use grits to aid in the digestion of food. In this assessment, the number of granules required to reach the  $LD_{50}$  for a particular size of bird and the number of granules available per square metre were compared to determine risk.

The risk assessment indicated high to very high risk for terrestrial plants from exposure to dicamba. Risks that exist for all other wildlife varied from none to low.

### 5.1 Environmental Fate

The available fate data indicate that dicamba and its major transformation product, 3,6-dichlorosalicylic acid (3,6-DCSA), will be slightly to moderately persistent in the environment. Dicamba was determined to be mobile, whereas there is evidence that 3,6-DCSA is not likely to be mobile. Dicamba is highly soluble in water (6069 mg a.i./L) and is unlikely to bioaccumulate ( $K_{ow} = 0.1$ ). Phototransformation is not an important route of dissipation of dicamba on soil ( $t_{1/2} = 201$  days), whereas aerobic soil biotransformation is the major transformation process for dicamba ( $DT_{50} = 2.9$  to 21 days). Under anaerobic conditions, biotransformation of dicamba occurs at a slower rate ( $DT_{50} = 84$  days) in soil; therefore, it will play a lesser role in the dissipation of dicamba from the environment. Calculated organic carbon partition coefficients ( $K_{oc}$ ) ranging from 3.5 to 21.2 indicate that dicamba is very mobile in soil; therefore, dicamba may significantly affect groundwater and surface water resources. Volatilization ( $vp = 1.25 \times 10^{-5}$  mmHg at 25°C) from soil and plant surfaces may contribute to the dissipation of dicamba in the environment and have an adverse effect on non-target plants in the vicinity of the treatment field.

The Henry's law constant ( $6.02 \times 10^{-10}$  atm m<sup>3</sup>/mol) suggests that volatilization from water should not be a significant process contributing to the dissipation of dicamba from the aquatic environment. Dissipation of dicamba from the aquatic environment is not expected to occur by hydrolysis as no transformation occurred in the laboratory studies. Phototransformation of dicamba in surface waters is not an important route of transformation ( $t_{1/2} > 30$  days). In water, aerobic biotransformation may be an important process for the removal of dicamba from aqueous environments ( $DT_{50} = 39.8$  to  $45.5$  days in sediment–water systems). These  $DT_{50}$  values indicated that dicamba is moderately persistent in water. Anaerobic biotransformation will not contribute substantially to the dissipation of dicamba from aquatic systems ( $DT_{50} = 141$  days). Given the high solubility, low  $K_{oc}$  and low  $K_{ow}$ , dicamba is likely to dissolve in water rather than adsorbed to organic particles in the water column.

The major transformation product resulting from biotransformation of dicamba was identified as 3,6-DCSA. 3,6-DCSA is very soluble (2122 mg a.i./L) and appears to be more persistent than the parent compound dicamba. It is also less mobile than dicamba ( $K_{oc} = 242$  to  $2930$ ) and is unlikely to reach groundwater sources. This transformation product has a low vapour pressure ( $10^{-7}$  mm Hg); therefore, it is not expected to volatilize. In addition, 3,6-DCSA is not expected to bioaccumulate as the  $K_{ow}$  was determined to be 0.29. Currently, there is not enough information available to fully assess the fate of 3,6-DCSA in the environment.

## 5.2 Environmental Toxicology

Dicamba is classified as practically non-toxic to honey bees ( $LD_{50} = 90.65$  µg a.e./bee) and mammals ( $LD_{50} = 1028$  mg a.e./kg bw) on an acute basis. The toxicity of dicamba to birds is classified as slightly to moderately toxic ( $LD_{50} = 1951$  to  $188$  mg a.e./kg bw) on an acute oral basis and practically non-toxic ( $LC_{50} = > 8680$  mg a.e./kg diet) on an acute dietary basis. Reproductive effects in birds are not expected at concentrations less than the NOEC of 800 mg a.e./kg diet determined in a reproductive study. Reproductive effects in small mammals are not expected to occur at exposure concentrations less than the NOEC of 500 mg a.e./kg diet determined in a 2-generation reproduction study in rats.

The toxicity of dicamba to plants varies depending on the species. Toxicity endpoints calculated for vegetative vigor varied from 14-day  $EC_{25}$  of 7.3 g a.e./ha (14-day NOEC < 4.5 g a.e./ha) for soybean to 14-day  $EC_{25}$  of 2465.9 g a.e./ha (14-day NOEC = 1120.9 g a.e./ha) for ryegrass. For seedling emergence, the toxicity endpoints range from 14-day  $EC_{25}$  of 3.0 g a.e./ha (14-day NOEC = 2.2 g a.e./ha) for soybean to 14-day  $EC_{25}$  of 638.9 g a.e./ha (14-day NOEC = 280.2 g a.e./ha) for oats.

Dicamba is practically non-toxic to freshwater invertebrates ( $LC_{50} = 110.7$  mg a.e./L) and fish ( $LC_{50} = 135.4$  mg a.e./L). Adverse effects to the freshwater diatom (*Navicula pelliculosa*) are not expected at a concentration equal to or less than 0.50 mg a.e./L. Adverse effects to the freshwater algae (*Anabaena flos-aquae*) and the freshwater vascular plant (*Lemna gibba*) are not expected at concentrations equal to or less than 0.0049 mg a.e./L and 0.25 mg a.e./L, respectively.

### 5.3 Concentrations in Drinking Water

The estimated concentrations of dicamba in potential drinking water sources were determined by examining the available water monitoring data. Dicamba is detected frequently in water sources at levels ranging from 10% in known municipal drinking water sources to 50% in ambient water sources that may serve as drinking water as well as in farm dugouts. The maximum or upper detection value estimated from the monitoring data ranged from 5 µg/L in municipal drinking water and ambient water sources to 15 µg/L in farm dugouts. A common detection value (one that is most often observed) was determined as 0.5 µg/L for municipal drinking water and ambient water sources, and 5 µg/L for farm dugouts.

### 5.4 Terrestrial Assessment

Toxicity data were available for the bobwhite quail and/or mallard duck for the acid, dimethylamine, potassium and diglycolamine salt forms. There is evidence that the toxicity of these forms do not differ therefore, these salt forms are considered toxicologically equivalent. No data were available to determine if the toxicity of the DEA salt form is equivalent to the acid.

Birds can be exposed to dicamba by consuming contaminated food (e.g., seeds, insects and vegetation). The toxicity endpoints were extrapolated to smaller bird species that are more likely to be present in an urban environment than the mallard duck and bobwhite quail. Using the standard PMRA scenarios, it was determined that birds would have to consume a 100% contaminated diet for 1 to 26 600 days, depending on body size, to reach a dose that resulted in 50% mortality in the laboratory population. To reach a dose equivalent to the no-effect level, birds are required to consume a 100% contaminated diet for 0.1 to 2660 days, depending on the body size of the bird. Values less than one day indicate a potential acute risk to wild birds, which was identified for the highest application rate assessed (600 g a.e./ha). This assessment assumes that the birds are consuming a 100% contaminated diet. The results of the dietary risk assessment that takes into consideration the percentage of food consumption per day indicate that a negligible risk exists for wild birds on an acute dietary basis and a reproductive basis.

Birds can also be exposed to dicamba by consuming fertilizer/pesticide granules either intentionally as grit or unintentionally while foraging. The assessment indicates that depending on the size of the bird, a bird would have to consume between 106 to 188 000 granules per day to reach a level where the population will be reduced by 50%. Although it is possible for some species of birds to consume 106 granules per day as grits, it is unlikely that this will occur with fertilizer/pesticide combination products as the average size of the granules in this product are larger than the grit size preferred by these birds. Therefore, the PMRA has concluded that the risk to birds exposed to granular forms of dicamba is low.

Mammals can be exposed to dicamba through consumption of contaminated food (e.g., vegetation, insects, seeds, etc.). Based on the acute toxicity values and using the standard PMRA scenarios, it was determined that small mammals would have to consume a contaminated diet for 1 to 23 days in order to reach a dose that is equivalent to the no-effect level determined in the laboratory. Therefore, the acute risk to mammals from exposure to dicamba is considered negligible. Taking into consideration the quantity of food consumed per day, it was concluded

that depending on application rates used, small mammals are at no to low risk of adverse effects from dietary exposure (RQ = 0.04 to 0.7) and no to low risk of reproductive effects (RQ = 0.05 to 0.9).

Toxicity data were available for a variety of plant species. The most sensitive species in the vegetative vigor and seedling emergence studies was soybean. Using the toxicity data for terrestrial plants as well as the minimum and maximum application rates for dicamba, the RQs ranged from 24 to 273 for seedling emergence and from 7.1 to 82 for vegetative vigor. These values indicate that the risk of non-target effects resulting from exposure of non-target plants to dicamba is moderate to high.

## **5.5 Aquatic Assessment**

For the aquatic risk assessment, the potential exposures were estimated for non residential areas (golf courses) where boom sprayers are used and for residential lawns where handheld sprayers are used. For areas where boom sprayers are used, the expected environmental concentrations were based on maximum deposit when label rates are applied to a 1 ha pond that is 30 cm deep. Currently, the PMRA does not have an acceptable model to estimate the potential environmental concentrations that may occur from the run-off of pesticides applied to turf. Thus, surface water monitoring data were used to assess the risk of aquatic organisms from exposure to dicamba. The risk calculated must be interpreted carefully as the monitoring concentration may not reflect the maximum concentration of dicamba that may be present in the aquatic environment. This may result in the underestimation of the actual hazard to aquatic organisms.

It was determined that no risk of acute effects exists for freshwater invertebrates (RQ = 0.002 to 0.03) and fish (RQ = 0.001 to 0.02) based on 100% spray drift into non-target aquatic areas. Using the monitoring data, it was determined that exposure to dicamba would cause no acute risk for aquatic invertebrates (RQ =  $1.4 \times 10^{-6}$  to  $3.5 \times 10^{-6}$ ) and fish (RQ =  $1.1 \times 10^{-4}$  to  $2.8 \times 10^{-4}$ ). In addition, no chronic risk was determined for freshwater fish based on 100% deposit of spray drift (RQ = 0.0001 to 0.0004) or monitoring data (RQ =  $1.0 \times 10^{-6}$  to  $2.5 \times 10^{-6}$ ).

A moderate risk of effects was determined for freshwater algae based on 100% spray drift (RQ = 3.5 to 66.7), whereas a low risk (RQ = 0.78) was determined for the exposure of aquatic algae to the concentrations of dicamba reported in monitoring data.

## **5.6 Environmental Assessment Conclusions**

The environmental assessment for turf uses of dicamba indicates that non-target effects are not expected to occur for most non-target organisms, except for terrestrial and aquatic plants.

## **5.7 Environmental Risk Mitigation**

Dicamba can enter into the terrestrial and aquatic ecosystems through spray drift. The observance of buffer zones, however, can effectively mitigate the risks to off-site non-target organisms. Pesticide spray drift from ground application to habitats of concern was predicted using the data of Wolf and Caldwell (2001). Based on the spray drift predictions and the most

sensitive toxicity endpoint, buffer zones are required to mitigate the entry of dicamba into terrestrial habitats. The most sensitive toxicity endpoint was the EC<sub>25</sub> of 7.3 kg a.i./ha (soybean) for terrestrial habitats.

From the predictions of the spray drift model for ground application, it was determined that a buffer zone of 5 m is required for terrestrial habitats and that a buffer zone is not required for aquatic habitats.

Many of the technologies used for treating turf (i.e., backpack sprayers, handheld sprayers) do not produce the same amount of spray drift as boom sprayers. The standard model to determine buffer zones is based on boom sprayer characteristics. Thus, exact buffer zones cannot be calculated for other types of sprayers. As non-target plants are highly susceptible to dicamba spray drift, it is important that the applicator take care not to directly spray, allow spray to drift onto or allow run-off to reach the roots of desirable non-target plants in gardens as well as ornamentals. When applying dicamba to larger areas that would require other technologies (i.e., tractor pulled boom sprayers), the applicator must adhere to the calculated buffer zones to protect non-target terrestrial plants (Table 8.2.4). If the spray booms are equipped with shrouds or cones, the buffer zones can be reduced by 70% when shrouds are used and by 30% when cones are used.

## 6.0 Value

As stated in Section 2.3, this re-evaluation has focussed on the use of dicamba in treating of lawns and turf (e.g., sports and recreational turf, lawn turf and sod). Sports and recreational turf, including parks, playgrounds, golf courses, zoos, botanical gardens and athletic playing fields provide enjoyment for users and spectators. Lawn turf is designed principally to serve a decorative function. Lawns include turf planted in or around residences, public and commercial buildings and cemeteries.

Hundreds of species of broadleaf weeds can infest turf in Canada. The type of weeds most likely to become problematic varies from region to region. Experience has shown that most of the broadleaf weed problems in Canadian turf can be attributed to a few weed species. These broadleaf weeds include dandelion, plantain, black medick, chickweed, prostrate knotweed, round-leaved mallow, henbit, ground-ivy (creeping Charlie), wild carrot and white clover.

As of May 2005, application rates for the commercial class products containing dicamba only range from 273 to 1106 g a.e./ha depending on the type of turf and weeds controlled. For the commercial class coformulations, the rate of application of dicamba is 550 g a.e./ha for the two-way coformulation (only one product used in very small amounts on fine turf) and ranges from 28 to 108 g a.e./ha for the three-way coformulations. Rates vary depending on the type of turf (e.g., low rates for bent grasses, high rates for established turf) and the weed species. The application rates of dicamba in domestic class products (all three-way products) range from 36 to 135 g a.e./ha. For most products, a maximum of two applications per year per treatment site are allowed.

All commercial class products containing dicamba are applied after weeds have emerged with groundboom, backpack and handheld sprayers; low-pressure lawn spray guns, or spreaders. Domestic class products are generally applied with backpack and handheld sprayers, hose sprays (container attached at end of hose to spray when watering turf) or ready-to-use applicators (e.g., bottle sprayers or wipe applicators). They are used as broadcast or spot treatments.

To illustrate the importance of dicamba for broadleaf weed control in turf, its weed-control spectrum was compared to other similar herbicides that are also registered for use on turf in Canada. The relative sensitivities of many broadleaf weeds to 2,4-D, MCPP, dicamba and MCPA alone as well as to products containing dicamba, 2,4-D and/or MCPP combinations are different. For example, dicamba has relatively good efficacy on many weeds, especially chickweeds, ground-ivy, knotweed, and round-leaved mallow; however, it is not as effective on plantains, which are known to be problematic turf weeds in Canada. Furthermore, dicamba has been shown to be phytotoxic to many ornamentals and shrubs. Therefore, in many domestic situations, it must be used with caution and at modest doses.

The spectra of weeds controlled with 2,4-D/MCPP, 2,4-D/dicamba and 2,4-D/MCPP/dicamba combinations is broader than the spectra of each of these herbicides when used alone. Combinations of 2,4-D, MCPP and dicamba, especially at a ratio of 2:1:0.1, have been shown to be synergistic. Thus, if 2,4-D, MCPP or dicamba were used alone, in sequence, the rate required to obtain a similar level of weed control would be much higher than the rate used in coformulations.

Dicamba is an auxinic benzoic acid herbicide. This type of herbicide mimics the natural plant hormone indole-3-acetic acid (IAA, also known as auxin). Despite decades of examination and research, the exact mechanism or mechanisms of most auxin- and auxinic-herbicide-mediated physiological responses in susceptible plants are not fully known. Their primary effects include altered gene expression and enhanced ethylene production. These two effects are likely the beginning of a cascade of events that lead to the biochemical and physiological responses observed. The action of dicamba in susceptible plants are likely severe and uncontrolled cell growth, leading to the disintegration of phloem, cortical cells and xylem tissues. When applied at appropriate doses, this herbicide produces an “auxin overload”, thereby causing susceptible plants to be injured/controlled. In general, dicot species are much more sensitive to auxinic herbicides than grasses; therefore, they have been widely used on turf to control many unwanted broadleaf weeds.

The actual sales of dicamba products used on turf in Canada ranged from 19 400 to 24 000 kg a.i. per year from 1998 to 2001. In 2001, the total sales of dicamba used on turf amounted to 2000 kg a.i., of which 8.5% were domestic class pesticide products, 89% commercial class pesticide products and 2.5% fertilizers containing dicamba. Lawn and turf products containing dicamba represent approximately 4.8% of the total estimated sales of dicamba in Canada.

Considering that weed control on fine turf is important, dicamba has unique efficacy to control certain of the most problematic broadleaf weeds on turf and that there are no registered alternative herbicides to phenoxyalkanoic and benzoic acid herbicides on turf, it is concluded that the use of dicamba on turf has value.

## 7.0 Other Assessment Considerations

### 7.1 Toxic Substances Management Policy

During the review of dicamba, the PMRA has taken into account the federal Toxic Substances Management Policy (TSMP)<sup>3</sup> and has followed its Regulatory Directive [DIR99-03](#)<sup>4</sup>. It has been determined that this active ingredient and one of its major transformation products do not meet the criteria TSMP Track 1 substances for the following reasons.

- Dicamba is not bioaccumulative. The log *n*-octanol–water partition coefficient (log  $K_{ow}$ ) is 0.1, which is below the TSMP Track 1 cut-off criterion of log  $K_{ow} \geq 5.0$ .
- Dicamba does not meet the criteria for persistence as its half-life values in water (up to 55.9 days) and soil (up to 31.3 days) are below the TSMP Track 1 cut-off criteria for water ( $\geq 182$  days) and soil ( $\geq 182$  days). No data were provided for persistence of dicamba in air.
- The toxicity of dicamba is described in sections 4.0 and 5.2.
- The major transformation product, 3,6 DCSA, does not meet the TSMP Track 1 cut-off criterion for bioaccumulation (log  $K_{ow} > 5.0$ ). The log  $K_{ow}$  of 3,6-DCSA is 0.24. No data were available on the persistence of 3,6-DCSA in soil, water and air or on its toxicity.

Technical grade products containing dicamba could contain polychlorinated -p-dibenzodioxins and polychlorinated dibenzofurans substituted in at least the 2,3,7,8 positions at levels of less than 1 part per billion (ppb). The end-use products containing the active ingredient would contain even lower levels, depending on the amount of the technical grade active ingredient used in the formulation. Subsequent use of formulated products could lead to environmental releases of these microcontaminants that would be close to environmental background levels. As noted in Health Canada's *It's Your Health* publication on dioxins and furans<sup>5</sup>, the greatest sources of dioxins in the environment include the incineration of medical and municipal waste, the burning of fuel and wood, electrical power generation and tobacco smoke.

As 2,3,7,8-TCDD and other dioxins of concern are Track 1 substances and subject to virtual elimination under the federal Toxic Substances Management Policy, the PMRA will require that

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<sup>3</sup> The federal Toxic Substances Management Policy is available through Environment Canada's website at [www.ec.gc.ca/toxics](http://www.ec.gc.ca/toxics)

<sup>4</sup> Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, is available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: [pmra\\_infoserv@hc-sc.gc.ca](mailto:pmra_infoserv@hc-sc.gc.ca); or through our website at [www.pmra-arla.gc.ca](http://www.pmra-arla.gc.ca).

<sup>5</sup> Health Canada. 2004. "Dioxins and Furans." *It's Your Health*. Available at [www.hc-sc.gc.ca/iyh-  
vsv/environ/dioxin\\_e.html](http://www.hc-sc.gc.ca/iyh-<br/>vsv/environ/dioxin_e.html)

registrants monitor levels of dioxins and related Track 1 substances using newer, more sensitive analytical methods.

## **7.2 Formulant Issues**

Products containing dicamba are subject to all the requirements of PMRA Regulatory Directive [DIR2004-01](#), *Formulants Program*, published on 9 January 2004.

Based on the considerations outlined in Section 4.1, Toxicology Summary, the PMRA is proposing that the DEA form of dicamba be phased out.

DMA formulations may contain trace levels of N-nitrosodimethylamine (NDMA). Typically, NDMA, if present as a microcontaminant, is at a concentration of less than 1 ppm. Toxicology studies done with these pesticide formulations do not exhibit any of the toxicological findings that are characteristic of NDMA. Also, sunlight rapidly decomposes NDMA; therefore, NDMA does not persist in the environment under use conditions. Thus, it is unlikely that trace levels of NDMA from pesticide sources would pose a health risk to humans. However, the PMRA will monitor the level of NDMA in certain formulations by requiring registrants to specify NDMA levels in the DMA used for manufacturing purposes (see Section 9.1.1).

## **8.0 Proposed Regulatory Action**

The use of dicamba on residential, recreational and commercial turf is acceptable for continuing registration provided that the mitigation measures described in Section 8.1 are implemented. Standard label precautionary statements and improvements are also recommended in Section 8.2 to further protect workers and the environment.

### **8.1 Mitigation Measures**

There was no toxicological information on the DEA form of dicamba. In light of published studies on the toxicological effects of DEA and in the absence of a toxicological and exposure database with which to conduct a quantitative risk assessment, the PMRA is proposing that dicamba formulations containing DEA be phased out. Registrants have voluntarily agreed to discontinue all products for use on turf that contained the DEA form of dicamba.

The buffer zones presented in Section 8.2.4 are required to protect terrestrial habitat.

### **8.2 Label Recommendations and Improvements**

#### **8.2.1 General**

The statement “Keep out of reach of children” must appear on the primary panel of all labels of products sold for use by homeowners.

The following statement must appear under the **DIRECTIONS FOR USE** section of the label of commercial class products only:

- Do not apply by air.

The following statement must appear under the **DIRECTIONS FOR USE** section of the label of products intended for broadcast application:

- Do not apply more than two broadcast applications per season. This does not include spot treatments.

### **8.2.2 Label Statements Relating to Chemistry**

The guarantee statement on the labels of all products should be revised, when necessary, to specify the form of dicamba contained (i.e., one of the forms indicated in Table 2.3.1. Section 2) and the proportion of dicamba acid equivalents. For example, for the DMA form, the guarantee should read: “Dicamba, present as the dimethylamine salt... y % a.e.” for solid products or “y g a.e./L” for liquid products, where “y” is the equivalent concentration of dicamba as the acid.

### **8.2.3 Label Statements Relating to Health**

The labels of technical, manufacturing concentrate and commercial class products containing dicamba must include the following text:

#### **Toxicological Information**

Dicamba may cause severe irritation to the eyes\*, and irritation to the skin and mucous membranes. Symptoms of overexposure to dicamba may include dizziness, muscle weakness, loss of appetite, weight loss, vomiting, decreased heart rate, shortness of breath, excitement, tenseness, depression, incontinence, cyanosis, muscle spasms, exhaustion, loss of voice. Treat symptomatically.

\* This statement may be modified by product-specific data.

### **8.2.4 Label Statements Relating to the Environment**

#### **Domestic Class Products**

The following statements must appear under the **DIRECTIONS FOR USE** section of the label of domestic class products only:

- DO NOT irrigate within 24 hours after application.
- Avoid application when heavy rain is forecast.

The following statements must appear under an **ENVIRONMENTAL HAZARDS** section of all domestic class products:

- Desirable broadleaf terrestrial plants can be harmed by contact with product spray. Do not directly spray or allow the spray to drift onto ornamental plants and trees, fruits, vegetables or exposed roots of trees and ornamentals.
- Avoid application of this product when winds are gusty.
- Do not contaminate irrigation/drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.
- Runoff into aquatic environments may be reduced by including an untreated vegetated strip between the treated area and the edge of the water body.
- Do not apply to driveways, sidewalks or any other hard surface.
- The use of this chemical may result in contamination of groundwater particularly in areas where soils are permeable (e.g., sandy soil) and/or the depth to the water table is shallow.

### **Commercial Class Products**

The following statements must appear under the **DIRECTIONS FOR USE** section of all commercial class products:

- Avoid application of this product when winds are gusty.
- Do not apply to the exposed roots of trees and ornamentals.
- Avoid application when heavy rain is forecast.
- Do not contaminate irrigation/drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.
- To reduce runoff from treated areas into aquatic habitats, consider the characteristics/conditions of the site before treatment. Site characteristics/conditions that may lead to runoff include, but are not limited to, heavy rainfall, moderate to steep slope, bare soil, poorly draining soil (e.g., soils that are compacted, fine textured or low in organic matter). Potential for contamination of aquatic areas as a result of runoff may be reduced by including an untreated vegetative strip between the treated area and the edge of the water body. To prevent runoff, do not apply to driveways, sidewalks or any other hard surface. Do not irrigate within 24 hours after application.
- The use of this chemical may result in contamination of groundwater particularly in areas where soils are permeable (e.g., sandy soil) and/or the depth to the water table is shallow.

In addition, the labels of liquid commercial class products that may be applied by tractor-pulled field sprayers (e.g., to golf courses or sod farms) must include the following statements:

## Buffer Zones

The 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 and shrublands).

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

<b>Application Method</b>	<b>Buffer Zone (metres) Required for the Protection of Terrestrial Habitat:</b>
Field sprayer	5
Field sprayer with shrouds	2
Field sprayer with cones	4

The following statements must appear under an **ENVIRONMENTAL HAZARDS** section of all commercial class products:

- Toxic to broadleaf terrestrial plants. This product may harm other broadleaf plants in the vicinity of the treatment area. If applying this product using a handheld sprayer, do not directly spray or allow the spray to drift onto ornamentals or gardens.

### 8.2.5 Label Statements Related to Value and Sustainability

The following statements are to be included in the **DIRECTIONS FOR USE** section of the label of all dicamba products applied to turf:

This product does not prevent weeds. Apply only when weeds are present. This product works best when applied to the leaves of actively growing weeds.

The following statement is to be included in the **DIRECTIONS FOR USE** section of all dicamba products applied to turf by broadcast application:

If weed populations do not warrant a broadcast application (e.g., entire lawn), consider spot treatments that target only weedy areas.

## 9.0 Additional Data Requirements

### 9.1 Data Requirements Relating to Chemistry

An updated Statement Product Specification Form is required for all products to which DMA is added during manufacturing/formulation process. The form must identify the levels of NDMA present in the DMA that is used. This requirement pertains only to products where DMA is

added as part of the manufacturing/ formulating process; this requirement does not apply to products that use the already manufactured DMA form of dicamba in the formulation process.

Data are required from the analysis of the last five batches of each technical product, using the most sensitive appropriate analytical methods for 2,3,7,8-TCDD, 2,3,7,8-TCDF and their respective higher substituted chlorinated congeners.

## 9.2 Data Requirements Relating to Toxicology

The following additional data are required to support the continued registration of technical dicamba and to support any expansion of dicamba use. Protocols for updated studies are to be finalized by the PMRA and the registrants.

- Acute inhalation (DACO 4.2.3); the available study is inadequate and does not give reliable accounts of achieved dosages.
- Combined chronic/carcinogenicity study in rats (DACO 4.4.4); the available rat study was conducted below the maximum tolerated dose with no effects elicited at the high dose.

Although not critical to the current dicamba re-evaluation, the following data may be required to support any expansion of dicamba use:

- Repeat-dose inhalation study (DACO 4.3.6 or 4.3.7); the available study is inadequate and does not give reliable accounts of achieved dosages.

## 9.3 Data Requirements Relating to the Environmental Risks

To assess the impact of 3,6-DCSA in the environment, the following studies with 3,6-DCSA are needed:

- aerobic water/sediment biotransformation (DACO 8.2.3.5.4);
- acute aquatic invertebrate toxicity (DACO 9.3.2); and
- additional data may be required depending on the results of these studies.

## 9.4 Additional Requirements Related to Regulatory Process

All registrants must have documented access to the data used in this evaluation, or provide equivalent data, including proprietary test data, the Broadleaf Turf Herbicide Transferable Foliar Residue Task Force and the ORETF. As noted in Science Policy Notice [SPN2002-01](#), *Children's Health Priorities within the Pest Management Regulatory Agency*, the ORETF has submitted new studies, which the PMRA is reviewing.

## **10.0 Proposed Re-evaluation Decision**

The PMRA has carried out an assessment of the available information on dicamba and is proposing that dicamba and associated end-use products for use on lawns and turf are acceptable for continued registration.

The PMRA will accept written comments on this proposal up to 60 days from the date of publication of this document to allow interested parties an opportunity to provide input into the proposed decision.

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## List of Abbreviations

2,4-D	(2,4-dichlorophenoxy)acetic acid
3,6-DCSA	3,6-dichlorosalicylic acid
ADI	acceptable daily intake
a.e.	acid equivalent
a.i.	active ingredient
ARfD	acute reference dose
bw	body weight
CAS	Chemical Abstracts Service
DEA	diethanolamine salt
DEEM	Dietary Exposure Evaluation Model
DFR	dislodgeable foliar residue
DMA	dimethylamine salt
DT <sub>50</sub>	time required for 50% dissipation
DWLOC	drinking water level of comparison
g	gram(s)
ha	hectare(s)
Hg	mercury
IPM	integrated pest management
IR	ingestion rate
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
$K_{oc}$	adsorption coefficient normalized for organic carbon
$K_{ow}$	<i>n</i> -octanol–water partition coefficient
L	litre(s)
LC <sub>50</sub>	median lethal concentration
LD <sub>50</sub>	median lethal dose
LOAEL	lowest observed adverse effect level
m	metre
MCCP	mecoprop-p [racemic mecoprop has been discontinued]
mg	milligram(s)
mm	millimetre(s)
MOE	margin of exposure
NDMA	N-nitrosodimethylamine
nm	nanometre(s)
NOAEL	no observed adverse effect level
ORETF	Occupational and Residential Exposure Task Force
Pa	Pascal(s)
PACR	Proposed Acceptability for Continuing Registration
PDI	potential daily intake
PHED	Pesticide Handlers' Exposure Database
PMRA	Pest Management Regulatory Agency
ppb	parts per billion
ppm	parts per million
RQ	risk quotient
SA	surface area

SEF	salivation extraction factor
$t_{1/2}$	half-life
TC	transfer coefficient
TTR	turf transferable residue
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
UV	ultraviolet
vp	vapour pressure
$\mu\text{g}$	microgram(s)

**Appendix I Dicamba Products Currently Registered for Use on Fine Turf as of 20 December 2005 (excluding discontinued products, products with a submission for discontinuation or products registered only for sites other than fine turf)**

Registration Number	Product Name	Form of Dicamba <sup>1</sup>	Registration Name	Marketing Class
11547	Dycleer 24 Liquid Herbicide	DMA	Syngenta Crop Protection Canada Inc.	Commercial
14593	Pro Turf K-O-G Granular Weed Control	Acid	Nu-Gro IP Inc.	Commercial
16971	Green Cross Killex 500 Turf Herbicide Liquid Concentrate	Amine	Scotts Canada Ltd.	Commercial
18963	Trillion Liquid Turf Herbicide	DMA	Plant Products Co. Ltd.	Commercial
24263	Wilson Lawn WeedOut Attach & Spray Concentrate	Amine	Nu-Gro IP Inc.	Domestic
24263.02	C-I-L Lawn WeedOut Attach & Spray Concentrate	Amine	Nu-Gro IP Inc.	Domestic
26708	Concentrated WeedEx Weed Control for Lawns	Amine	Virterra Products Corporation	Domestic
26711	Ready to Use WeedEx Weed Control for Lawn	Amine	Virterra Products Corporation	Domestic
26724	Home Gardener WeedEx Weed Control for Your Lawn	Amine	Home Hardware Stores Ltd.	Domestic
26980	Vanquish Herbicide	DGA	Syngenta Crop Protection Canada Inc.	Commercial
27010	WeedEx Ready to Spray	DMA	Virterra Products Corporation	Domestic
27799	Ortho Killex Ready-to-use Lawn Weed Control Herbicide	DMA	Scotts Canada Ltd.	Domestic
27800	Ortho Killex Ready-to-use Lawn Weed Control (Green Cross)	DMA	Scotts Canada Ltd.	Domestic
27801	Ortho Killex Lawn Weed Control Concentrate	DMA	Scotts Canada Ltd.	Domestic
27809	Ortho Killex Ready-to-spray Lawn Weed Control	DMA	Scotts Canada Ltd.	Domestic
27811	Killex with Pull N' Spray Applicator Ready-to-Use	DMA	Scotts Canada Ltd.	Domestic
27846	Ipco Premium 3-way XP Turf Herbicide	DMA	Interprovincial Cooperative Limited	Commercial
27848	Weedaway Premium 3-way XP Turf Herbicide	DMA	Interprovincial Cooperative Limited	Commercial
27884	Par III Turf Herbicide	DMA	United Agri Products Canada Inc.	Commercial
27914	Co-op Premium Spot Weed Killer Xp Herbicide	DMA	Interprovincial Cooperative Limited	Domestic

Registration Number	Product Name	Form of Dicamba <sup>1</sup>	Registration Name	Marketing Class
27915	Co-op Premium Lawn Weed Killer Xp Herbicide	DMA	Interprovincial Cooperative Limited	Domestic
27970	Wilson Tri-Kil Turf Herbicide	DMA	Spectrum Brands IP Inc.	Commercial
27972	Trillion-p Liquid Turf Herbicide	DMA	Plant Products Co. Ltd.	Commercial
27973	C-I-L Lawn WeedOut Ready to Use	DMA	Spectrum Brands IP Inc.	Domestic
27974	Wilson Lawn WeedOut Ready to Use	DMA	Spectrum Brands IP Inc.	Domestic
27975	Killex 500 Liquid Turf Herbicide Concentrate (Green Cross)	DMA	Scotts Canada Ltd.	Commercial
27976	Killex Turf Herbicide Liquid Concentrate (Green Cross)	DMA	Scotts Canada Ltd.	Commercial
27982	Home Gardener Ready-to-use WeedEx	DMA	Home Hardware Stores Ltd.	Domestic
27999	C-I-L Lawn WeedOut (2) Ready-to-Use	DMA	Spectrum Brands IP Inc.	Domestic
28000	Wilson Lawn WeedOut (2) Ready-to-Use	DMA	Spectrum Brands IP Inc.	Domestic
28045	Home Gardener Ready-to-spray WeedEx	DMA	Home Hardware Stores Ltd.	Domestic
28061	Home Gardener Concentrated WeedEx	DMA	Home Hardware Stores Ltd.	Domestic
28077	C-I-L Lawn WeedOut Attach & Spray Concentrate	DMA	Spectrum Brands IP Inc.	Domestic
28078	Wilson Lawn WeedOut Attach & Spray Concentrate	DMA	Spectrum Brands IP Inc.	Domestic
28081	Wilson Lawn WeedOut Concentrate	DMA	Spectrum Brands IP Inc.	Domestic
28082	C-I-L Lawn WeedOut Concentrate	DMA	Spectrum Brands IP Inc.	Domestic
19290	Banvel Dicamba Technical Herbicide	Acid	BASF Canada Inc.	Technical grade active ingredient
26613	Syngenta Dicamba Technical Herbicide	Acid	Syngenta Crop Protection Canada Inc.	Technical grade active ingredient
26718	Gharda Dicamba Technical Herbicide	Acid	Gharda USA, Inc.	Technical grade active ingredient

<sup>1</sup> Amine = DEA or DMA

## Appendix II Toxicology Endpoints for Risk Assessment for Dicamba

Exposure Scenario	Dose (mg/kg bw/day)	Endpoint	Study	UF/SF or MOE <sup>a</sup>
Acute Dietary	NOAEL = 30	Clinical signs (ataxia)	Developmental—rabbit	100
	ARfD = 0.30 mg/kg bw			
Chronic Dietary	NOAEL = 11.2	Alterations in clinical chemistry and inflammation of the prostate	1-year oral toxicity—dog	1000
	ADI = 0.0112 mg/kg bw/day			
Short-Term <sup>b</sup> Incidental Oral	Oral NOAEL = 30	Clinical signs (ataxia)	Developmental—rabbit	100
Acute and Short-Term <sup>b</sup> Dermal	Dermal NOAEL = 1000	Increased blood glucose; and decreased body weight, urine pH, hemoglobin and total protein	21-day dermal toxicity—rabbit	100
Intermediate-Term <sup>c</sup> Dermal	Dermal NOAEL = 1000	Increased blood glucose; and decreased body weight, urine pH, hemoglobin and total protein	21-day dermal toxicity—rabbit	300
Acute and Short-Term <sup>b</sup> Inhalation <sup>d</sup>	Oral NOAEL = 30	Clinical signs (ataxia)	Developmental—rabbit	100
Intermediate-Term <sup>c</sup> Inhalation <sup>d</sup>	Oral NOAEL = 30	Clinical signs (ataxia)	Developmental—rabbit	300
Short-Term <sup>b</sup> Aggregate <sup>f</sup>	Oral NOAEL = 150 <sup>d,e</sup>	Body weight	Developmental oral—rabbit	100
	Dermal NOAEL = 1000		21-day dermal—rabbit	

<sup>a</sup> UF/SF refers to total of uncertainty and/or safety factors for dietary assessments; MOE refers to desired margin of exposure for occupational or residential assessments.

<sup>b</sup> Duration of exposure is 1 to 7 days

<sup>c</sup> Duration of exposure is 8 to 30 days

<sup>d</sup> An inhalation absorption factor of 100% (default value) should be used in route-to-route extrapolation because an oral NOAEL was selected.

<sup>e</sup> An oral NOAEL is used for both the oral and inhalation components of the aggregate assessment because no acceptable short-term inhalation study is available.

<sup>f</sup> Based on NOAELs for common endpoint, which may or may not be the overall study NOAEL.

## Appendix III Exposure Calculation Tables

**Table 1 Homeowner Mixer/Loader/Applicator: Short-Term Exposure Estimates and Margins of Exposure for Turf**

Application Equipment	Data Source <sup>a</sup>	Formulation	Area Treated ha/day	Dermal Unit Exposure µg/kg handled	Dermal Exposure <sup>b</sup> µg/kg/day	Inhalation Unit Exposure µg/kg handled	Inhalation Exposure <sup>c</sup> µg/kg/day	Dermal MOE <sup>d</sup>	Inhalation MOE <sup>e</sup>	
<b>Residential lawns: Homeowner wearing short sleeves, short pants, no gloves</b>										
Low-pressure handwand/handpump	ORETF	Liquid (0.135 kg a.e./ha)	0.2	82 741	31.91	24	0.009	31 334	3 240 741	
			0.01		1.6		0.0005	626 677	64 814 815	
Ready-to-use hose-end sprayer	ORETF		0.2	6874	2.65	32.2	0.01	377 159	2 415 459	
			0.01		0.13		0.0006	7 543 185	48 309 179	
Dial-type hose-end sprayer	ORETF		0.2	21 525	8.3	35.6	0.01	120 446	2 184 769	
			0.01		0.42		0.0007	2 408 913	43 695 381	
Backpack <sup>f</sup>	PHED		0.2	10 149	3.91	62.1	0.02	255 453	1 252 460	
			0.01		0.2		0.001	5 109 060	25 049 204	
Push-type spreader	ORETF		Granular weed and feed <sup>g</sup> (0.12 kg a.e./ha)	0.2	1380	0.47	1.72	0.0006	2 113 527	50 872 093

<sup>a</sup> Median unit exposures are used from ORETF; best-fit unit exposures are used from the PHED.

<sup>b</sup> Where dermal exposure µg/kg/day = (unit exposure × area treated × use rate [expressed as acid equivalents])/70 kg bw.

<sup>c</sup> Where inhalation exposure µg/kg/day = (unit exposure × area treated × use rate [expressed as acid equivalents])/70 kg bw.

<sup>d</sup> Based on a dermal NOAEL of 1000 mg/kg bw/day. The target MOE is 100 for acid, sodium salt and DMA forms.

<sup>e</sup> Based on an oral NOAEL of 30 mg/kg bw/day. The target MOE is 100 for acid, sodium salt and DMA forms.

<sup>f</sup> The backpack application clothing scenario is short pants, a short-sleeved shirt and gloves (no non-gloved data). The USEPA's SOPs state that these PHED data are not completely applicable for lawns uses.

<sup>g</sup> Weed-and-feed products are not expected to be used as a spot treatment.

**Table 2 Postapplication Exposure Estimates and Margins of Exposure for Adults and Toddlers on Residential Lawns**

Scenario	Exposure	Dermal Exposure <sup>a</sup> µg/kg/d	Oral Exposure µg/kg/d				Dermal MOE <sup>f</sup>	Oral MOE <sup>g</sup>
			Hand-to-Mouth <sup>b</sup>	Turf Mouting <sup>c</sup>	Ingestion of Soil <sup>d</sup>	Ingestion of Granules <sup>e</sup>		
<b>Adult</b>								
Liquid/ soluble powder	Acute	14.49	N/A	N/A	N/A	N/A	69 035	N/A
	Short-term	1.43					698 436	
Granular (acid form)	Acute	118.7					8427	
	Short-term	11.73					85 252	
<b>Toddler</b>								
Liquid/ soluble powder	Acute	24.24	1.8	0.06	0.006	N/A	41 250	16 109
	Short-term	2.4	1.8	0.06	0.006	N/A	417 334	16 109
Granular <sup>h</sup> (acid form)	Acute	198.6	14.75	0.461	0.05	140	5035	193
	Short-term	19.63	14.75	0.461	0.05	N/A <sup>i</sup>	50 941	1966

The few commercial class products applied at higher rates have not been included in the quantitative postapplication risk assessment as relatively very small quantities are used on domestic turf. However, their use would not pose unacceptable risk, as their application rates are lower than for the granular formulations, for which calculated MOEs exceed target MOEs even after considering direct ingestion of granules by toddlers.

<sup>a</sup> Dermal exposure = % TTR × rate × TC × duration / bw (70 kg for adults, 15 kg for toddlers). TTR values are based on the TTR study and normalized for Canadian rates. TCs are 14 500 and 5 200 µg/hour for adults and children, respectively. Exposure duration is two hours. Rate expressed as acid equivalents = 0.135 kg a.i./ha for soluble powders/liquids and 1.106 kg a.i./ha for granular formulations.

<sup>b</sup> Based on 20 hand-to-mouth events/hour, a surface area of 20 cm<sup>2</sup>, saliva extraction factor (SEF) of 50%. Exposure = DFR × SA × hand-to-mouth events × SEF × duration/15 kg bw.

<sup>c</sup> Based on an ingestion of 25 cm<sup>2</sup> turf/day and a SEF of 50%. Exposure = application rate × DFR × 25 × SEF/15 kg bw.

<sup>d</sup> Based on an ingestion of 0.1 g soil/day, depth of 1cm, 100% available/cm soil, 0.67 cm<sup>3</sup>/g soil weight-to-volume conversion factor. Exposure = application rate × 0.1 × 0.67 × 1/15 kg bw.

<sup>e</sup> Based on an ingestion rate (IR) for dry pesticide formulations of 0.3 g/day. Granules contain 0.70 % active ingredient. Exposure = IR × a.i./15 kg bw.

<sup>f</sup> Based on a dermal NOAEL of 1000 mg/kg bw/day. The target MOE is 100 for the acid, sodium salt and DMA forms.

<sup>g</sup> Based on an oral NOAEL of 30 mg/kg bw/day. The target MOE is 100 for the acid, sodium salt and DMA forms.

<sup>h</sup> Calculations are based on TTR data for liquid formulation. Granular TTR would be much lower. The calculations is intended only to show that even with such highly conservative assumptions, aggregate MOEs incorporating potential ingestion of granules are greater than the target MOE.

<sup>i</sup> Considered an accidental or episodic event rather than a typical event; therefore, it was not included in the short-term scenario.

**Table 3 Postapplication Exposure Estimates and Margins of Exposure for Golfers**

Scenario	Acute Exposure		Short-Term Exposure	
	Dermal Exposure <sup>a</sup> µg/kg/d	Dermal MOE <sup>b</sup>	Dermal Exposure <sup>a</sup> µg/kg/d	Dermal MOE <sup>b</sup>
<b>Adults (70 kg)</b>				
Liquid	0.89	1 126 126	0.09	11393229
Granular <sup>c</sup>	8.18	122 184	0.81	1236155
<b>Adolescents (44 kg)</b>				
Liquid	1.41	707 851	0.14	7161458
Granular <sup>c</sup>	13.02	76 801	1.29	777 012

The few commercial class products applied at higher rates have not been included in the quantitative postapplication risk assessment as relatively very small quantities are used on domestic turf. However, their use would not pose unacceptable risk, as their application rates are lower than for the granular formulations, for which calculated MOEs exceed target MOEs.

<sup>a</sup> Dermal exposure = % TTR × rate as acid equivalents (1.2 µg/cm<sup>2</sup> for soluble powders/liquids and 11.06 µg/cm<sup>2</sup> for granular formulations) × TC × duration / bw (70 kg for adults, 44 kg for adolescents). TC is 500 cm<sup>2</sup>/hour based on generic transfer coefficients for turf. Duration is four hours. Acute TTR value (2.59 %) is based on the mean peak values and the short-term value (0.256 %) is based on a time-weighted average over seven days.

<sup>b</sup> Based on a dermal NOAEL of 1000 mg/kg bw/day. The target MOE is 100.

<sup>c</sup> Calculations are based on TTR data for liquid formulation. Granular TTR would be much lower. The calculations is intended only to show that, even with such highly conservative assumptions, aggregate MOEs incorporating potential ingestion of granules are greater than the target MOE.

**Table 4 Short-Term Aggregate Exposure Estimates and Margins of Exposure for Dicamba**

Age Group	Scenario	Food <sup>a</sup> µg/kg/day (MOE)	Application on Turf µg/kg/day (MOE)		Postapplication on Turf µg/kg/day (MOE)		Total MOE <sup>d</sup> Excluding Drinking Water	DWLOC <sup>e</sup> µg/L
			Dermal <sup>b</sup>	Inhalation <sup>c</sup>	Dermal <sup>b</sup>	Oral <sup>c</sup>		
Adults 70 kg	Low-pressure sprayer—broadcast turf	0.634 (236 593)	31.91 (31334)	0.009 (3 240 741)	1.43 (698 436)	N/A	26 398	52 301
	Low-pressure sprayer—spot turf	0.634 (236 593)	1.60 (626 677)	0.0005 (64 814 815)	N/A	N/A	171 297	52 469
	Ready-to-use sprayer—broadcast turf	0.634 (236 593)	2.65 (377 159)	0.01 (2 415 459)	1.43 (698 436)	N/A	137 135	52 462
	Ready-to-use sprayer—spot turf	0.634 (236 593)	0.13 (7 543 185)	0.0006 (48 309 179)	N/A	N/A	228 314	52 477
	Dial-type sprayer—broadcast turf	0.634 (236 593)	8.30 (120 446)	0.01 (2 184 769)	1.43 (698 436)	N/A	69 355	52 424
	Dial-type sprayer—spot turf	0.634 (236 593)	0.42 (2 408 913)	0.0007 (43 695 381)	N/A	N/A	214 377	52 476
	Backpack—broadcast turf	0.634 (236 593)	3.91 (255 453)	0.02 (1 252 460)	1.43 (698 436)	N/A	96 418	52 446
	Backpack—spot turf	0.634 (236 593)	0.20 (5 109 060)	0.001 (25 049 204)	N/A	N/A	224 099	52 477
	Weed-and-feed granular rotary spreader	0.634 (236 593)	0.47 (2 113 527)	0.0006 (50 872 093)	1.43 (698 436)	N/A	162 569	52 468
	Broadcast—granular commercial application	0.634 (236 593)	N/A	N/A	11.73 (85 252)	N/A	62 670	52 416
	Golfing (soluble powder/liquid)	0.634 (236 593)	N/A	N/A	0.09 (11 393 229)	N/A	231 780	52 477
	Golfing (granular)	0.634 (236 593)	N/A	N/A	0.81 (1 236 155)	N/A	198 585	52 474
	Child 44 kg	Golfing (soluble powder/liquid)	1.102 (136 116)	N/A	N/A	0.14 (7 161 458)	N/A	133 577
Golfing (granular)		1.102 (136 116)	N/A	N/A	1.29 (777 012)	N/A	115 826	32 972

Age Group	Scenario	Food <sup>a</sup> µg/kg/day (MOE)	Application on Turf µg/kg/day (MOE)		Postapplication on Turf µg/kg/day (MOE)		Total MOE <sup>d</sup> Excluding Drinking Water	DWLOC <sup>e</sup> µg/L
			Dermal <sup>b</sup>	Inhalation <sup>c</sup>	Dermal <sup>b</sup>	Oral <sup>c</sup>		
Toddler 15 kg	Broadcast turf (soluble powder / liquid)	1.685 (89 021)	N/A	N/A	2.40 (417 334)	1.87 (80 386)	38 359	22 441
	Broadcast turf (granular)	1.685 (89 021)	N/A	N/A	19.63 (50 941)	15.26 <sup>f</sup> (9830)	7542	22 202

The few commercial class products applied at higher rates have not been included in the quantitative postapplication risk assessment as relatively very small quantities are used on domestic turf. However, their use would not pose unacceptable risk, as their application rates are lower than for the granular formulations, for which calculated MOEs exceed target MOEs even after considering direct ingestion of granules by toddlers.

<sup>a</sup> Based on chronic dietary exposure estimates generated using DEEM. MOEs were calculated using an oral NOAEL of 150 mg/kg/day. The target MOE is 100.

<sup>b</sup> Based on a dermal NOAEL of 1000 mg/kg bw/day. The target MOE is 100 for the acid, sodium salt and DMA.

<sup>c</sup> Based on an oral NOAEL of 150 mg/kg bw/day. The target MOE is 100 for the acid, sodium salt and DMA.

<sup>d</sup> Total MOE =  $1 / (1/\text{MOE}_{\text{oral}} + 1/\text{MOE}_{\text{inhalation}} + 1/\text{MOE}_{\text{dermal}})$ .

<sup>e</sup> Where DWLOC is calculated as per the formula in section 7.0. Daily drinking water rate is 2 L/day for adults and 44 kg children and 1 L/day for toddlers (USEPA 2001).

<sup>f</sup> Does not include ingestion of granules because this is considered an accidental or episodic event rather than a typical event; therefore, it was not included in the short-term scenario.

**Table 5 Commercial Mixer/Loader/Applicator: Short-Term Exposure Estimates and Margins of Exposure for Turf**

Application Equipment	Data Source <sup>a</sup>	Formulation	Area Treated ha/day	Dermal Unit Exposure µg/kg handled	Dermal Exposure <sup>b</sup> µg/kg/day	Inhalation Unit Exposure µg/kg handled	Inhalation Exposure <sup>c</sup> µg/kg/day	Short-Term Exposure	
								Dermal MOE <sup>d</sup>	Inhalation MOE <sup>e</sup>
<b>Residential Lawns: Commercial Lawn Care Operator Wearing Long Pants, a Long-Sleeved Shirt and Gloves</b>									
Low-pressure turf gun	ORETF	Liquid (0.1 kg a.e./ha)	2	785	2.24	4	0.01	445 860	2 625 000
Backpack <sup>f</sup>	PHED		0.4 (spot)	5446	3.11	62.1	0.04	321 337	845 411
Low-pressure turf gun	ORETF	Wettable powder (water soluble powder) (0.12 kg a.i./ha)	2	1427	4.89	14.5	0.05	204 392	603 448
			2	1427	4.89	14.5	0.05	204 392	603 448
			0.4 (spot)	1427	0.98	14.5	0.01	1 021 957	3 017 241
Hand application	PHED	Granular (1.106 kg a.i./ha)	0.4 (spot)	157 418	24.87	605	0.1	40 206	313 840
Push rotary spreader	ORETF		2	474	7.49	16.5	0.26	133 526	115 075
			0.4 (spot)	474	3	16.5	0.1	333 814	287 687
<b>Golf Courses: Commercial Mixer/Loader/Applicator Wearing Long Pants, a Long-Sleeved Shirt and Gloves</b>									
Low-pressure turf gun	ORETF	Liquid (0.1 kg a.e./ha)	2	785	2.24	4	0.01	445 860	2 625 000
Backpack <sup>f</sup>	PHED	Liquid/wettable powder (0.12 kg a.e./ha)	0.4 (spot)	5446	3.73	62.1	0.04	267 781	704 509
Groundboom		Liquid (0.1 kg a.e./ha)	16	83.63	1.91	2.6	0.06	523 138	504 808

Application Equipment	Data Source <sup>a</sup>	Formulation	Area Treated ha/day	Dermal Unit Exposure µg/kg handled	Dermal Exposure <sup>b</sup> µg/kg/day	Inhalation Unit Exposure µg/kg handled	Inhalation Exposure <sup>c</sup> µg/kg/day	Short-Term Exposure	
								Dermal MOE <sup>d</sup>	Inhalation MOE <sup>e</sup>
Low-pressure turf gun	ORETF	Wettable powder (water soluble powder) (0.12 kg a.i./ha)	2	1427	4.89	14.5	0.05	204 392	603 448
			0.4 (spot)	1427	0.98	14.5	0.01	1 021 957	3 017 241
Groundboom	PHED		16	54	1.48	1.14	0.03	675 154	959 430
Push-type spreader	ORETF	Granular (1.106 kg a.i./ha)	2	474	14.98	16.5	0.52	66 763	57 537
			0.4	474	3	16.5	0.1	333 814	287 687
Tractor drawn spreader	PHED		16	28.9	7.31	3.8	0.96	136 875	31 229
<b>Sod Farms: Commercial Mixer/Loader/Applicator Wearing Long Pants, a Long-Sleeved Shirt and Gloves</b>									
Low-pressure turf gun	ORETF	Liquid (0.1 kg a.e./ha)	2	785	2.24	4	0.01	445 860	2 625 000
Groundboom	PHED		30	83.63	3.58	2.6	0.11	279 007	269 231
Low-pressure turf gun	ORETF	Wettable powder (water soluble powder) (0.12 kg a.i./ha)	2	1427	4.89	14.5	0.05	204 392	603 448
Groundboom	PHED		30	54	2.78	1.1	0.06	360 082	530 303
Tractor drawn spreader	PHED	Granular (1.106 kg a.i./ha)	30	28.9	13.7	3.8	1.8	73 000	16 656

The few commercial class products applied at higher rates have not been included in the quantitative risk assessment as relatively very small quantities are used. However, their use would not pose unacceptable risk, as evidenced by the magnitude of the calculated MOEs in the above table.

<sup>a</sup> Median unit exposures are used from ORETF; best-fit unit exposures are used from the PHED.

<sup>b</sup> Where dermal exposure µg/kg/day = (unit exposure × area treated × use rate [expressed as acid equivalents])/70 kg bw.

<sup>c</sup> Where inhalation exposure µg/kg/day = (unit exposure × area treated × use rate [expressed as acid equivalents])/70 kg bw.

<sup>d</sup> Based on a dermal NOAEL of 1000 mg/kg bw/day. The target MOE is 300 for a period of 8 to 30 days (residential lawns) and 100 for a period of 1 to 7 days (golf courses and sod farms).

<sup>e</sup> Based on an oral NOAEL of 30 mg/kg bw/day. The target MOE is 300 for a period of 8 to 30 days (residential lawns) and 100 for a period of 1 to 7 days (golf courses and sod farms).

<sup>f</sup> The USEPA's SOPs state that these PHED data are not completely applicable for lawns uses.

**Table 6 Postapplication Exposure Estimates and Margins of Exposure for Golf Course and Sod Farm Workers**

Scenario	Acute Exposure <sup>a</sup>			Short-Term Exposure <sup>a</sup>		
	% TTR <sup>b</sup>	Dermal Exposure <sup>c</sup> µg/kg/d	Dermal MOE	% TTR <sup>b</sup>	Dermal Exposure <sup>c</sup> µg/kg/d	Dermal MOE
<b>Golf Course/Sod Farm:</b> aerating, fertilizing, pruning, scouting, mowing (TC = 500 cm <sup>2</sup> /hour)						
Liquid	2.59	1.78	563 063	0.256	0.18	5 696 615
Granular		16.37	61 092		1.62	618 078
<b>Sod Farms:</b> harvesting, transplanting (TC = 16 500 cm <sup>2</sup> /hour)						
Liquid	2.59	58.61	17 063	0.256	5.79	172 625
Granular		540.2	1851		53.39	18 730

The few commercial class products applied at higher rates have not been included in the quantitative risk assessment as relatively very small quantities are used. However, their use would not pose unacceptable risk, as evidenced by the magnitude of the calculated MOEs in the above table.

<sup>a</sup> Based on a dermal NOAEL of 1000 mg/kg/day. The target MOE is 100.

<sup>b</sup> Chemical-specific data from turf transferable residue and dissipation studies. Acute TTR value is based on the mean peak values and the short-term value is based on a time-weighted average over seven days.

<sup>c</sup> Dermal exposure = % TTR × rate as acid equivalents (1.2 µg/cm<sup>2</sup> for soluble powders/liquids and 11.06 µg/cm<sup>2</sup> for granules) × TC × 8 hours/70 kg bw.

## References

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