RVD2008-28

Re-evaluation Decision

Dicamba

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Table of Contents

Overview

Re-evaluation Decision for Dicamba

After a thorough re-evaluation of the herbicide dicamba (3,6-dichloro-2-methoxybenzoic acid), Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, has decided to allow continued registration for the sale and use in Canada of certain products containing dicamba.

- Products containing dicamba do not pose unacceptable risks to human health or the environment. They also have value for lawn, turf and agricultural and industrial uses when used according to the label directions proposed in previous consultation documents. As a condition of the continued registration of these dicamba products, new risk-reduction measures must be included on the labels. In addition, registrants must submit additional confirmatory scientific information identified in this document.

- Products containing the diethanolamine (DEA) form of dicamba are being phased out as there was a lack of adequate data for assessment.

The regulatory approach regarding the re-evaluation of dicamba was proposed in two consultation documents:[1]

- Proposed Acceptability for Continuing Registration PACR2007-02, *Re-evaluation of Dicamba for Lawn and Turf Uses*
- Proposed Re-evaluation Decision PRVD2007-05, *The Use of Dicamba in Agricultural and Industrial Sites*

This Re-evaluation Decision[2] describes this stage of the PMRA's re-evaluation of dicamba and summarizes the Agency's decision and reasons for it. Appendix I includes a summary of comments received during the consultation process and the PMRA's response to these comments. This decision is consistent with the proposed re-evaluation decisions stated in PACR2007-02 and PRVD2007-05. To comply with this decision, registrants of products containing dicamba will be informed of the specific requirements affecting their product registrations and of the regulatory options available to them.

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

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

What Does Health Canada Consider When Making a Re-evaluation Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions or proposed conditions of registration.[3] The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies hazard and risk assessment methods as well as policies that are rigorous and modern. These methods consider the unique characteristics of sensitive subpopulations in both humans (e.g. children) and organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the PMRA's website at www.pmra-arla.gc.ca.

What Is Dicamba?

Dicamba is a selective systemic herbicide. It belongs to the benzoic acid chemical family and is classified as a Group 4 herbicide. Dicamba mimics the natural plant hormone indole-3-acetic acid (also known as synthetic auxin). It produces an "auxin overload," thereby causing susceptible plants to be injured and controlled. Dicamba is registered for use on fine turf, terrestrial feed crops (canary seed, grasses for forage or seed production, and pastures/rangelands), terrestrial food crops (sweet corn and lowbush blueberries), terrestrial food and feed crops (field corn, spring, durum and winter wheat, barley, oats, spring rye, summer fallow and stubble fields), and industrial and non-food sites (non-crop areas). It may be used alone, in coformulation or tank mixed with other herbicides to control annual and perennial broadleaf weeds and brush. Dicamba is formulated as a solution, suspension or wettable granules and can be applied by ground equipment or by air.

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[3] "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

[4] "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact."

Health Considerations

Can Approved Uses of Dicamba Affect Human Health?

Dicamba is unlikely to affect your health when used according to the revised label directions. Additional risk-reduction measures are required on dicamba labels.

Exposure to dicamba may occur through diet (food and water), when handling treated plants, while working as a mixer/loader/applicator or by entering treated sites. When assessing health risks, two key factors are considered: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only those uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100 times higher (and often much higher) than levels to which humans are normally exposed when using dicamba products according to label directions.

An overexposure to dicamba may cause severe irritation to the eyes and irritation to the skin and mucous membranes. Additional symptoms 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 and loss of voice. Some neurological, developmental, liver and kidney effects occurred during laboratory testing at high doses only; therefore, they would not occur when dicamba is used according to label directions. Although there were no signs of cancer in the chronic mouse and rat studies, the rat study did not reach the maximum tolerated dose (MTD). However, based on the weight of evidence, a new study is not deemed necessary at this time.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Reference doses define levels to which an individual can be exposed over a single day (acute) or lifetime (chronic) and expect no adverse health effects. Generally, dietary exposure from food and water is acceptable if it is less than 100% of the acute reference dose on a daily basis, or less than 100% of the acceptable daily intake (ADI) over a lifetime. Exposure to dicamba was estimated from residues in treated crops and drinking water, including the most highly exposed subpopulations (e.g. infants, children, teenagers, adults and seniors).

Chronic exposure accounted for 3.1% of the ADI in children 1 to 2 years old and less for all other subgroups with 1.3% of the ADI for the general population. Acute dietary exposure as a percentage of the reference dose is 4.1% for the general population and 7.6% for the most affected population of children 1 to 2 years of age.

A drinking water level of comparison 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 maximum estimate of acute and chronic residues of dicamba in drinking water was 15 µg/L based on the available surveillance data . This value is well below the acute and chronic drinking water levels of comparison for the most sensitive populations, respectively established at 4157 and 163 µg/L, and therefore not a health concern.

Residue Definition and Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for the *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act.* Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods.

Currently, there are no specified MRLs for dicamba. Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm.

In order to accept residue data in support of lowering the postapplication grazing interval, a residue of concern (ROC) must be established with proper analytical methods for its enforcement. The ROC for enforcement is defined as dicamba *per se* (3,6-dichloro-2-methoxybenzoic acid), 5-OH-dicamba (3,6-dichloro-5-hydroxy-2-methoxybenzoic acid) and DCSA (3,6-dichloro-2-hydroxybenzoic acid). Confirmatory analytical methods for DCSA in plant and animal commodities, in order to establish these residues of concern, are required as part of this decision. The registrant is also required to show that the isomeric impurity (3,5-dichloro-2-methoxybenzoic acid) occurs at a concentration less than 1% w/w. This condition is necessary in order to exclude the impurity from the residue definition (RD).

Risks in Residential and Other Non-Occupational Environments

Non-occupational risks are not of concern.

The residential risk assessment for lawn and turf use of dicamba encompasses what adults may be exposed to while applying dicamba to their lawn, as well as what adults and children may be exposed to through contact with treated residential lawns and golf courses. Estimated risks are not of concern provided that products containing dicamba are used according to label directions and the required mitigation measures are followed.

Short-term aggregate exposure to dicamba was estimated based on contributions from food, drinking water and residential exposure (dermal, inhalation and oral components) and did not indicate any unacceptable risk.

Occupational Risks From Handling Dicamba

Occupational risks are not of concern.

Risk estimates associated with mixing, loading and applying activities for registered uses are acceptable, provided that products containing dicamba are used according to label directions and the required mitigation measures are followed. These measures are needed to minimize potential for exposure, thus protecting worker health and safety.

Postapplication risks to workers are not of concern.

Postapplication occupational risk assessments consider exposures to workers entering treated agricultural or industrial sites, golf courses and sod farms. Based on the precautions and directions for use on the original product labels reviewed for this re-evaluation, postapplication risks to workers performing various activities are not of concern, provided that products containing dicamba are used according to label directions.

Environmental Considerations

What Happens When Dicamba Is Introduced Into the Environment?

Dicamba poses a risk to certain terrestrial and aquatic organisms; therefore, additional risk-reduction measures need to be observed.

Dicamba released into the environment can be found in soil and surface water. It has been detected in many water bodies throughout Canada. There is some evidence indicating that the use of this herbicide may result in groundwater contamination. Dicamba residues will not bind to soil or sediment and can be moved by water. Most of the dicamba residues are rapidly transformed by microorganisms in soil with slower transformation in aquatic systems.

The use of dicamba poses a concern to terrestrial and aquatic plants. To reduce exposure of these organisms, it is important that additional risk-reduction measures (e.g. including buffer zones) be observed.

Value Considerations

What Is the Value of Dicamba?

Dicamba is a Group 4 herbicide that has been used for more than 40 years to efficiently control most broadleaf weeds. Dicamba is integral to the management of weed biotypes resistant to other herbicide groups.

Dicamba has long been recognized as a tank-mix partner with other herbicides for turf and lawn, agriculture, and industrial/non-crop use. These tank mixes control a broader range of weeds compared to products containing only a single active ingredient, resulting in fewer applications, less soil compaction and reduced costs for growers.

Measures to Minimize Risk

The labels of registered pesticide products include specific instructions for use. The directions include risk-reduction measures to protect human health and the environment. These directions must be followed by law.

Risk-reduction measures are being implemented to address potential risks identified in the assessment of all dicamba uses. In addition to the measures on existing dicamba product labels, these measures are designed to further protect human health and the environment. Registrants will be required to amend their labels to reflect these additional measures.

Additional Key Risk-Reduction Measures

- All products containing the DEA form of dicamba are being phased out.
- Label statements will more accurately describe the product and its allowed uses.

Human Health

- The TOXICOLOGICAL INFORMATION section will be updated to provide information about symptoms and treatment for overexposed individuals.
- A variety of mitigation measures are required to protect mixers, loaders and applicators with the highest potential for exposure. These include additional protective equipment, reductions in quantity and/or concentration of product applied, and use of approved application equipment.
- Workers entering treated sites must use personal protective equipment and observe restricted-entry intervals in some postapplication exposure scenarios.
- Restrictions on grazing and harvesting of forage must be observed to reduce dietary exposure.

Environment

- Product labels are being revised to reduce release of dicamba into the environment. Labels will have instructions for minimizing the contamination of aquatic sites resulting from surface runoff and for minimizing accidental spray drift to terrestrial and aquatic sites.

- Labels will also include statements to protect aquatic and terrestrial habitats that may contain sensitive species. Terrestrial and aquatic buffer zones must be observed. The specific distance depends on the type of spray equipment, the application rate and the water depth.

What Additional Scientific Information Is Being Requested?

The risks and value have been determined to be acceptable when all risk-reduction measures proposed in the consultation documents are followed while using the products accepted for continued registration. To refine the current risk assessment, confirmatory scientific information is being requested from registrants as a result of this re-evaluation. Registrants will be required to submit this information within specified time frames.

Chemistry

- Recent analytical data are required for all identifiable dioxins and furans[5] from at least five consecutive batches of technical grade product manufactured at each of the registered manufacturing sites of each of the registered technical products. The PMRA has data on file indicating low levels of dioxins and furans, at parts per trillion (ppt) levels, are sometimes found in dicamba products. The new data are required to confirm current levels of microcontaminants at those levels.

- An updated Statement Product Specification Form is required for all products to which dimethylamine (DMA) is added during the manufacturing or formulation process. The form must identify the levels of *N*-nitrosodimethylamine (NDMA) present in the DMA that is used. This requirement will ensure that registrants continue to purchase DMA with extremely low levels of microcontaminants.

Human Health

- The following analytical methodologies for monitoring and enforcement are required:
  - confirmatory analytical methods for DCSA in plant and animal commodities
  - confirmation that the isomeric dicamba impurity (3,5-dichloro-2-methoxybenzoic acid) is less than 1% w/w in all formulations.

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[5] This includes the 17 substances listed in Table 4 of the Priority Substances List 1 Polychlorinated dibenzodioxins and polychlorinated dibenzofurans.

Other Information

The relevant test data on which the decision is based are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[6] regarding this decision on dicamba within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Request a Reconsideration of Decision, www.pmra-arla.gc.ca/english/pubreg/reconsideration-e.html), or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

[6] As per subsection 35(1) of the *Pest Control Products Act*.

List of Abbreviations

ADI	acceptable daily intake
AGDISP	AGricultural DISPersal
a.i.	active ingredient
bw	body weight
cm	centimetre(s)
DEA	diethanolamine
DGA	diglycolamine
DMA	dimethylamine
DT_{50}	dissipation time to 50%
$D_{V0.5}$	droplet size spectrum volume median diameter
EC_{25}	effect concentration 25%
EEC	expected environmental concentration
g	gram(s)
kg	kilogram(s)
L	litre(s)
LC_{50}	lethal concentration to 50%
LOC	level of concern
m	metre(s)
MOE	margin of exposure
MRL	maximum residue limit
MTD	maximum tolerated dose
NOAEL	no observed adverse effect level
PACR	Proposed Acceptability for Continuing Registration
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
ppm	parts per million
PRVD	Proposed Re-evaluation Decision
ROC	residue of concern
RQ	risk quotient

Appendix I Comments and Responses

The PMRA received comments in response to PACR2007-02 and PRVD2007-05 from a variety of stakeholders, including registrants, non-governmental organizations with interests in human health or the environment, provincial governments, users of dicamba and the general public. Some included additional data or information for consideration by the PMRA. Some of the comments were requests for changes of an editorial nature, which have been incorporated into the reviews without further discussion and will not be reiterated in this section. The PMRA has consolidated and summarized the remaining comments received and provides responses below.

The comments have been grouped as indicated below:

1.0 Comments With Respect to Chemistry
2.0 Comments With Respect to Toxicology
3.0 Comments With Respect to Residues and Exposure
4.0 Comments With Respect to Environment
5.0 Comments With Respect to Value

1.0 Comments With Respect to Chemistry

1.1 Comment

The physical and chemical properties of other forms of dicamba should be presented along with the acid form.

Response

Other forms of dicamba (amine salts and mixed sodium and potassium salts) that were covered by PACR2007-02 are not registered as technical grade active ingredient products. Amine salts and mixed sodium and potassium salts of dicamba are formed during the formulation process of the end-use products. Consequently, the physical and chemical properties are only available for the formulations and as such are not presented.

1.2 Comment

The expression of the guarantee causes confusion. Why does the PMRA not adopt the American system, which is more detailed?

Response

The guarantee statement is expressed according to current PMRA practice for products in use in Canada.

- The ISO-approved common name is used on the label rather than the systematic name as on the label used in the United States.
- The guarantee is expressed in g/L for liquids.
- The label does not make reference to any other ingredients except for the active ingredient(s).

For dicamba, the guarantee statements must be expressed as follows:

Technical products example, solid: Dicamba ... 95% a.e.
End-use product example, liquid: Dicamba, present as the diglycolamine salt ... 500 g/L a.e.

2.0 Comments With Respect to Toxicology

2.1 Comment

The PMRA has stated in PACR2007-02 that no adequate acute inhalation study in rats is available and requests an additional acute inhalation study. A recent acute inhalation study has been submitted.

Response

The PMRA has examined the acute inhalation study and found it to be acceptable (4 hour nose-only LC_{50} = 4.46 mg/L in male rats, >5.19 mg/L in female rats).

2.2 Comment

The PMRA has stated in PACR2007-02 that the rat carcinogenicity study was deemed inadequate as an assessment of the carcinogenic potential and chronic toxicity of dicamba (the highest dose tested was 107 mg/kg bw) did not elicit any effects and was below the MTD. Therefore, conclusions that dicamba is non-carcinogenic cannot be considered definitive. The PMRA requested an additional chronic/carcinogenicity study, which includes an MTD. Additional studies are submitted along with an overview/justification for the adequacy of the dose selection.

Response

The registrant submitted three studies (subchronic toxicity, pharmacokinetic, plasmakinetic) and an overview/justification document in support of the adequacy of the dose selection. Text in italics was copied from the overview/justification document.

> *A new subchronic toxicity study was conducted using Wistar rats to help determine dose levels for a new chronic/oncogenicity study. The highest dose tested of approximately 1000 mg/kg bw/day produced toxicity in excess of an MTD. Body weight gain reductions of 28% in males and 40% in females were observed in conjunction with other evidence of toxicity, including serum liver enzyme changes, increased liver weight, centrilobular hypertrophy and urinary crystal formation. The next lower dose of approximately 500 mg/kg bw/day produced very little toxicity. Therefore, based solely on subchronic toxicity results, the predicted MTD would be between 500 and 1000 mg/kg bw/day.*

The PMRA has examined the subchronic toxicity study and is in agreement with this statement.

> *However, the pharmacokinetic results must also be taken into account... More recent studies (to be submitted now) with more dose levels and a treatment period for up to 90 days have confirmed the nonlinearity of blood levels and demonstrated that this occurs at doses of 200 mg/kg bw/day and above.*

The new pharmacokinetic study submitted showed some overproportional increase in the area under the curve (AUC), but a closer look at the results reveals considerable variability. Using the data presented in the study, clearance (i.e. the actual dose divided by the AUC) was calculated. The clearance values appeared to decrease with dose, with a consistent decrease observed at 400 and 800 mg/kg bw/day in both sexes, suggesting saturation of excretion between 200 and 400 mg/kg bw/day.

In addition to the AUC and clearance, half-life data was also examined. While the intermediate and terminal half-lives in plasma remained more or less unchanged, the initial half-life tended to increase at 400 and 800 mg/kg bw/day. Although this is a rather insensitive indicator for excretory saturation, the initial half-life data further support the conclusions drawn from the AUC data.

> *A study using probenecid demonstrated that the nonlinearity in blood levels is in fact due to a saturation of the active transport pathway in the kidney.*

This plasmakinetic study showed an increase in the AUC after probenicid treatment. This is an expected outcome of inhibiting the active transport system in the kidneys and is not necessarily indicative of the system becoming saturated. Furthermore, the study had only three animals per group and only analyzed one dose level of dicamba, overall weakening the study.

> *Evidence of liver and kidney toxicity has been observed in the original chronic/oncogenicity study and in the new subchronic toxicity study.*

The original chronic/oncogenicity study did indeed show some liver and kidney toxicity at the highest dose, consisting of an increase in liver necrosis in males (5/49, 4/49, 3/48 and 11/50) and in kidney hydronephrosis in males and females (1/49, 1/49, 0/48 and 4/50 in males at the respective doses of 0, 2, 11 and 107 mg/kg bw/day; 0/49, 0/49, 0/48 and 3/50 in females at the respective doses of 0, 3, 13 and 107 mg/kg bw/day). However, the extent of the toxicity was relatively minor and insufficient to accept the dose of 107 mg/kg bw/day as the MTD.

The newly submitted subchronic toxicity study showed evidence of both liver and kidney toxicity at the highest dose (1000/1065 mg/kg bw/day in males and females, respectively). Both sexes had increased relative liver weights and clinical chemistry showed markers for hepatic damage to be elevated. Evidence of kidney damage consisted of increased triple phosphate excretion in males administered 1000 mg/kg bw/day, and increased uric acid crystals in females administered 535 and 1065 mg/kg bw/day.

While this study provides convincing evidence for liver and kidney toxicity, it is important to note that all of the changes occur only in the highest dosed groups (except for uric acid crystals in females, which are seen at 535 mg/kg bw/day). These results indicate that an MTD for dicamba is between 500 and 1000 mg/kg bw/day, which is significantly higher than the 107 mg/kg bw/day that was used in the chronic/oncogenicity study.

Having carefully reviewed all of the evidence submitted, the PMRA maintains that the chronic/oncogenicity study did not reach the MTD. At the same time, it is acknowledged that there is little to be gained from a new carcinogenicity study, as the existing study database does not raise concerns over carcinogenicity and testing an MTD of 500 mg/kg bw/day may be above excretion saturation. In addition, the current acceptable daily intake (ADI) of 0.01 mg/kg bw/day results in a margin of approximately 10 000-fold less than the highest dose tested in the chronic/oncogenicity study (which was without effect) and is considered sufficient. Taking into account animal welfare considerations, a new chronic/carcinogenicity study will not be required at this time. However, in light of the residual uncertainty associated with the absence of a study achieving the MTD, the PMRA will maintain the current ADI.

2.3 Comment

The toxicological information required on product labels listed on page 24 of PACR2007-02 includes information that is typically provided on the Material Safety Data Sheet. Therefore, the standard statements currently found on product labels should be sufficient.

Response

The PMRA is of the opinion that including such information on the label is important to help users recognize the signs of overexposure.

2.4 Comment

PACR2007-02 states “the DGA form shows low toxicity.” This form is assessed using the dicamba acid database, which is considered a “surrogate.” Why permit continued registration to an untested pesticide? It would be more appropriate to cancel the product’s registration until the tests have been completed.

Response

Metabolism data indicate that the diglycolamine (DGA) form of dicamba rapidly dissociates to dicamba acid in the digestive tract. Based on the assessment, the PMRA considers the dicamba acid database to be a suitable surrogate for the DGA form.

2.5 Comment

The oral and dermal LD_{50} values and inhalation LC_{50} values for each chemical form of dicamba should have been indicated.

Response

As stated in PRVD2007-05, the isopropylamine (IPA), DGA and acid forms of dicamba had low acute dermal toxicity (i.e. $LD_{50} > 2000$ mg/kg bw). The IPA, DGA and acid forms also had low acute inhalation exposure (i.e. $LC_{50} > 2.0$ mg/L).

2.6 Comment

We did not find any toxicological studies on mixtures of 2,4-D, mecoprop-p and dicamba. Studies combining these different active ingredients are vital to know the effects of such mixtures on human health and to assess the overall risk.

Response

Acute studies are conducted on all mixtures as they appear in the end-use products. However, this data is not typically published in the PMRA's consultation documents.

2.7 Comment

No studies address the disruptive effects on the endocrine system and no such study is required in Section 9.2, Data Requirements Related to Toxicology. However, on page 6, the following sentence is very clear: "Findings from several different studies suggest effects on the endocrine system." Does this mean disruptive effects on the endocrine system are not considered relevant to human health and are therefore not assessed in Canada?

Response

PACR2007-02 and PRVD2007-05 both noted some potential effects on the endocrine system. However, these effects were not considered definitive. Furthermore, the doses selected for risk assessment were lower than the dose at which the endocrine effects were observed and hence were considered protective. Therefore, a request for an endocrine study is not warranted.

3.0 Comments With Respect to Residues and Exposure

3.1 Comment

The PMRA has proposed a maximum application rate for high-volume handwand applications in non-cropland of 0.01 kg a.e./L or use of a minimum spray volume of 500 L/hectare. For this use pattern, applicators must wear chemical-resistant coveralls over long pants and a long-sleeved shirt, chemical-resistant gloves and a respirator.

We would like the PMRA to consider a statement on the label allowing the application of dicamba in non-cropland with a high-pressure handwand without the requirement of a respirator or chemical-resistant coveralls for treatments using smaller volumes. In many scenarios, only spot application of an area is required or practical, particularly for brush control, which is very labour intensive. As such, smaller volumes than the standard default value for high-pressure handwand application of 3750 L/day may be used.

Response

The following appeared in Appendix V (PRVD2007-05) on the non-cropland uses with a high-pressure handwand.

Intermediate-Term Exposure Estimates and MOEs with Mid-Level[a] PPE

Crop	Method of Application	Formulation	Rate[b] (kg a/i./ha)	Area Treated (ha/day)	Daily Exposure (µg/kg/day)		Margins of Exposure	
					Dermal[c]	Inhalation[d]	Dermal [e]	Inhalation[f]
Non-cropland (brush control)	High-pressure handwand	Solution	0.0025[g]	3750[h]	328.596	20.223	3043	554
Non-cropland (Broadleaf control)	High-pressure handwand	Solution	0.0401[g]	3750[h]	5270.7	324.38	190	35
			0.01[g]	3750[h]	1314.4	80.89	761	138
		Wettable granules	0.0204[g]	3750[h]	2781.82	166.14	359	67
			0.01[g]	3750[h]	1364	81.439	733	138

[a] Mid-level PPE: Coveralls and gloves over single layer (long pants and a long-sleeved shirt) except aerial applicator and mixer/loader—only single layer and gloves.
[b] Rate for high-pressure handwand based on volume of 110 L/ha for broadleaf control and 220 L/ha for brush control; lower rate based on 440 L/ha for broadleaf control (solution), 220 L/ha for wettable granule and 250 L/ha for brush control (solution).
[c] Where dermal exposure µg/kg/day = (unit exposure × area treated × rate)/70 kg bw.
[d] Where inhalation exposure µg/kg/day = (unit exposure × area treated × rate)/70 kg bw.
[e] Based on a dermal NOAEL of 1000 mg/kg bw/day (target MOE of 1000).
[f] Based on an oral NOAEL of 11.2 mg/kg bw/day (target MOE of 300) (assuming an inhalation absorption factor of 100%).
[g] Application rate expressed as kg a.e./L.
[h] Area treated expressed as L/day.

Below are revised exposure estimates based on a reduced volume of solution handled (spot treatment) for broadleaf control for both solution (400 L) and wettable granule (750 L) formulations. Personal protective equipment (PPE) requirements would be limited to coveralls over long pants, a long-sleeved shirt and chemical-resistant gloves, as proposed.

Intermediate-Term Exposure Estimates and MOEs with Mid-Level[a] PPE

Crop	Method of Application[a]	Formulation	Rate[b] (kg ai/ha)	Area Treated (ha/day)	Daily Exposure (µg/kg/day)		Margins of Exposure	
					Dermal[c]	Inhalation[d]	Dermal[e]	Inhalation[f]
Non-cropland (brush control)	High-pressure handwand	Solution	0.0025[g]	3750[h]	328.596	20.223	3043	554
Non-cropland (broadleaf control)	High-pressure handwand	Solution	0.0401[g]	400[h]	562.21	34.6	1779	324
			0.01[g]	400[h]	140.2	8.63	7133	1298
		Wettable granules	0.0204[g]	750[h]	556.37	33.23	1797	337
			0.01[g]	750[h]	272.73	16.29	3667	688

[a] Mid-level PPE: Coveralls and gloves over single layer (long pants and a long-sleeved shirt) except aerial applicator and mixer/load—only single layer and gloves.
[b] Rate for high-pressure handwand based on volume of 110 L/ha for broadleaf control and 220 L/ha for brush control; lower rate based on 440 L/ha for broadleaf control (solution), 220 L/ha for wettable granule and 250 L/ha for brush control (solution).
[c] Where dermal exposure µg/kg/day = (unit exposure × area treated × rate)/70 kg bw.
[d] Where inhalation exposure µg/kg/day = (unit exposure × area treated × rate)/70 kg bw.
[e] Based on a dermal NOAEL of 1000 mg/kg bw/day (target MOE of 1000).
[f] Based on an oral NOAEL of 11.2 mg/kg bw/day (target MOE of 300) (assuming an inhalation absorption factor of 100%).
[g] Application rate expressed as kg a.e./L.
[h] Area treated expressed as L/day.

3.2 Comment

It was proposed that the PMRA should remove the metabolite DCSA from the residue definition for all commodities except soybean. An additional proposal included removing a manufacturing impurity from the residue definition because its toxicity is equivalent to the parent substance and because it occurs at low concentration in the end-use product.

Response

The PMRA has proposed that the residue definition include one parent, two metabolites and possibly an impurity from the manufacturing process:

- Parent dicamba (dicamba)
- 5-hydroxy-dicamba (5-OH dicamba)
- 3,6-dichloro-2-hydroxybenzoic acid (DCSA)
- 3,5-dichloro-2-methoxybenzoic acid (3-5 dicamba isomer)

No analytical data gaps were identified.

In the United States, the tolerance expression is defined as follows:

- For barley, corn, cotton, grasses, oat, proso millet, sorghum, sugarcane and wheat: dicamba and 5-OH dicamba
- For asparagus: dicamba and DCSA
- For aspirated grain fractions and soybeans: dicamba, 5-OH dicamba, and DCSA
- For ruminants: dicamba, DCSA
- For poultry: Not required

Analytical gaps were identified:

- Revision/improvement of the *Pesticide Analytical Manual*, Volume II (United States Food and Drug Administration) to include DCSA in animal matrices
- Multiresidue method and recovery data for 5-OH-dicamba and DCSA

The comment indicated agreement that the residue definition should include the first two substances, but proposed that DCSA be considered only for soybean.

The PMRA accepts that DCSA is significant in livestock but not in poultry and that DCSA also occurs at high concentrations in the aspirated grain fractions (barley, oats, rye, wheat). Further, the document consulted includes DCSA for soybean, aspirated grain fractions and asparagus.

Although not currently registered in Canada, asparagus and soybean are imported from the United States and should be included in the surveillance of imported commodities. Similarly, aspirated grain fractions are or can be part of feed, whether domestic or imported. In both cases DCSA must be defined.

In PRVD2007-05, the PMRA did not require additional analytical methods to discriminate between the three chemical species (dicamba *proper,* 5-OH dicamba and DCSA) because the residue definition included all of them and because variations of this basic method are reported, wherein the validation has been extended to other crop matrices and to include the DCSA metabolite. The comment included a request to harmonize with the United States and this would be acceptable provided that suitable monitoring and enforcement analytical methods to identify each species separately are shown. In the meanwhile, and to anticipate possible use expansion, the residue definition will remain inclusive of all three species. In any case, studies showing methods to include DCSA in animal matrices and a multiresidue method and recovery data for 5-OH-dicamba and DCSA will be required.

The PMRA concurs with the suggestion that, because the impurity was already present during toxicity testing, the request to remove the 3-5 dicamba isomer impurity from the residue definition is acceptable. Evidence will be required to show that the impurity in any formulation would occur at a concentration of less than 1%.

4.0 Comments With Respect to Environment

4.1 Comment

In PACR2007-02, Section 5.5, the PMRA has indicated that the environmental risk assessment was conducted using water monitoring data as well as an assumption based on a maximum deposit (100% overspray) when labelled rates are applied to a 1 ha pond that is 30 cm deep. We do not believe that the following sentence is appropriate: “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.” Our reason is that the risk assessment appears to be based on the assumption of 100% overspray, which represents the extreme worst-case scenario.

As the risk assessment using 100% overspray showed no risk to non-plant aquatic species, no further refinement is necessary. In the case of aquatic plant species, further refinement using surface water monitoring data is appropriate; however, there is some ambiguity as to what surface water monitoring data was used by the PMRA. We request that the PMRA consider using recently available water monitoring data (2003-2005 National Survey of Currently Used Pesticides by Environment Canada) for data which relate directly to actual exposure to aquatic life.

Response

The monitoring data available at the time the turf uses of dicamba were assessed was considered in the risk assessment, which is stated in PACR2007-02, Section 5.5. The sentence in question was included to stress the limitation of retrospective monitoring data. Given the sparseness of the available monitoring data and the uncertainty with regard to ancillary data for the monitoring data, it is appropriate to state that the “monitoring concentration may not reflect the maximum concentration of dicamba that may be present in the aquatic environment.”

The environmental risk assessment for turf uses of dicamba was completed prior to the assessment of the agricultural uses. At the time the assessment for the agricultural uses was conducted, advancements had been made in the aquatic risk assessment to include the ability to model runoff of dicamba into bodies of water following the application of dicamba in order to refine the risk assessment. Additional water monitoring data was available from various sources, including Environment Canada, at the time of the agricultural assessment and was used as a further refinement. A decision was made at that time not to update the turf assessment document given that the rates used in the agricultural assessment encompassed those assessed in the turf assessment.

4.2 Comment

The PMRA has indicated very low toxicity to aquatic macrophytes in PACR2007-02, Section 5.2 (Environmental Toxicology), but has not included this evaluation in the Aquatic Assessment in Section 5.5. We propose that the PMRA include the evaluation toxicity to aquatic macrophytes in Section 5.5 so that the overall aquatic toxicity conclusions are complete.

Response

The PMRA acknowledges the above statement. Typically, only those organisms for which a risk is identified are discussed in this section so as to simplify the text. In this case, the risk quotient (RQ) determined for the aquatic macrophytes was not above the level of concern (LOC); therefore, details regarding this were not included in Section 5.5.

4.3 Comment

Overall, in various sections of the Assessment of Environmental Effects (PACR2007-02), worst-case assumptions are made with respect to exposure. It is not always clear how these worst-case assumptions are refined for the overall risk assessment. We propose that the PMRA include an explanation of how these assumptions are used to approximate real exposure levels in cases where worst-case assumptions indicate a potential risk. We believe this would reduce the risk of misinterpretation of comments.

Response

In our recent updated methods for risk characterization, worst-case assumptions are made at the screening level assessment. If the screening level LOC exceeds one, a potential risk is identified and the risk is refined in a Tier 1 risk assessment. The Tier 1 assessment uses more realistic exposure scenarios.

4.4 Comment

Why are plants (soy and oats) used in the terrestrial plant toxicity assessment whereas dicamba is used in urban settings on turf? The plants affected would be trees, shrubs, grasses and ornamental plants.

Response
It must first be recognized that dicamba is also used in agricultural settings and not only in the urban environment. Therefore, there is a possibility that plant species growing in this type of environment will also be exposed. The standard plant toxicity studies submitted to the PMRA include 10 crop species. It is acknowledged that these crop species may not be those that could potentially be exposed in the urban environment. See Comment 4.12 for more information regarding the selection of toxicological endpoints used in the risk assessment on dicamba.

4.5 Comment
The environmental assessment section should include all dicamba transformation products and their fate.

Response
The PMRA only considers those transformation products that are regarded major (i.e. detected at greater than 10% of the applied in any environmental fate study) or considered a human health concern. As such, for dicamba, the only major transformation products were 3,6-dichlorosalcyclic acid and CO_2. At the time of the re-evaluation, information regarding the fate of 3,6-DCSA was limited. During the consultation period, the technical registrant for dicamba submitted a number of studies for 3,6-DCSA that included environmental fate and toxicity studies. As a result, it was determined that 3,6-DCSA is non-persistent in the environment, it has low mobility in soil and it poses negligible risk to aquatic organisms.

4.6 Comment
Landscaping companies apply dicamba four to five times a year instead of twice a year; therefore, the expected environmental concentration (EEC) is underestimated.

Response
One step in the re-evaluation process involves the registrant verifying the use pattern that the PMRA used during the re-evaluation. At that time, the registrant agreed to the number of applications per season to be set at two. The old labels do not specify the number of applications allowed per year. However, new labels must indicate that a maximum of two applications per year is permitted for turf uses.

4.7 Comment
2,4-D, mecoprop and dicamba were found in seven water treatment plants sampled in Quebec City at maximum concentrations of 5.7, 6.3 and 0.68 µg/L, respectively, because the application of these herbicides is often just before heavy rains or thunderstorms. These herbicides were detected at the six sampled storm drains (stream outlets) in Quebec City. They were also found in measurable concentrations These herbicides were detected at the six sampled storm drains (stream outlets) in Quebec City. They were also found in measurable concentrations in water source samples taken downstream from rainwater outlets (storm drains). All samples were taken during the summers of 2001–2002. The mentioned report confirmed the presence of urban pesticides in water treatment plant effluents in Montreal and Longueuil. These results should be considered when re-evaluating the risk of dicamba to aquatic organisms. No data regarding the assessment of these environments (effluents) were found in PACR2007-02.

Response
The assessment for lawn and turf uses was completed prior to the assessment for agricultural uses (PRVD2007-05) but they were released at the same time. The assessment described in PRVD2007-05 included a large amount of known dicamba detections for ambient surface water, which was taken into consideration in the environmental risk assessment. The levels of dicamba in ambient surface water assessed for agricultural uses (PRVD2007-05) were higher than those reported above. The drinking water assessment for all uses was conducted when the lawn and turf assessment was completed. Therefore, it was not amended when the agricultural assessment was completed. As a result, the new information regarding water monitoring in water treatment plants was not taken into consideration for the drinking water assessment. Upon review of the new monitoring data, it was determined that inclusion of these data will not result in increased drinking water estimates nor increased risk to the environment.

4.8 Comment
In response to missing data requirements (PACR2007-02) for the major transformation product, 3,6-DCSA, a number of studies or rationales were submitted to address the fate and toxicity of 3,6-DCSA.

Response
The PMRA has reviewed the submitted rationale and studies for the 3,6-DCSA and found them to be sufficient to assess the potential risk associated with its formation and decline as a result of the transformation of dicamba. Results from an aerobic water/soil biotransformation study indicated that 3,6-DCSA is non-persistent (DT_{50} = 8.5 days). The adsorption/desorption study submitted for 3,6-DCSA was previously considered by the PMRA and indicates that 3,6-DCSA has low to moderate mobility.

A screening level risk assessment using the aquatic toxicity study results submitted for *Daphnia magna*, rainbow trout, *Selenastrum capricornutum* and *Lemna gibba* and the aquatic EECs determined for dicamba indicate negligible risk for aquatic organisms from exposure to 3,6-DCSA, formed as a result of the entry of dicamba into the environment. The EECs used in this assessment assume 100% conversion of all the dicamba applied to 3,6-DCSA, which is an overly conservative assumption.

4.9 Comment
The deposition calculation module assumes 100% deposition efficiency (PRVD2007-05). This assumption fails for small droplets.

Response
It is important not to confuse field recovery data and the deposition efficiency assumed by the model. The field data indicates that the deposition rate is not far from the model assumption. The deposition rate in the model takes into account the field recovery rate.

4.10 Comment
The model is run with zero dispersion (night overcast option), which results in a significant underestimation of atmospheric turbulence (this is equivalent to a plume of smoke remaining at the diameter of the source as it moves downwind, instead of the gradual spread and dissipation that is normally seen as the smoke moves away from the source). This leads to a more

concentrated spray cloud and higher deposition concentrations at each downwind distance. However, the label prohibits application under conditions with no wind.

Atmospheric stability in AGricultural DISPersal (AGDISP) is one of the meteorological parameters that reflect the effect of weather on drift. In the AGDISP model, the default setting "night with 100% cloud cover (overcast)" is used. Given that spraying in dead calm conditions is not permitted on the product label, and little if any spraying is done at night, the category "day with solar insolation (strong)" is most common and appropriate.

Response
The PMRA uses the "night overcast" option in the model as this is the only selection that has been validated by the model developers. The atmospheric stability setting "day with solar insolation" is based on previous work that has not been validated in this context. The PMRA has looked at the impact of the various atmospheric stability settings and has found that although buffer zones may be reduced in some instances, the overall effect is minimal. When the "night overcast" option is changed to "day with solar insolation," the buffer zone calculation remains unchanged for the highest application rate (800 m).

4.11 Comment

There are several cases in which the buffer zones proposed in PACR2007-02 for ground application uses of dicamba products do not appear to be consistent. The terrestrial buffer zones range from "not required" (zero) to 35 m. Dicamba application on established forage grass requires a 5 m buffer zone, pasture requires a 20 m buffer zone and non-crop industrial land requires a 35 m buffer zone for protection of non-target terrestrial habitats. In the absence of a crop, the boundary between the protected habitat and the treated area on industrial property can be somewhat arbitrary and the distinction between right-of-way and industrial land could be hard to define under field conditions.

Response
The calculation of buffer zones for dicamba is based on risk (i.e. the greater the risk, the larger the buffer zones), application rate and toxicity endpoints. The variation in terrestrial buffer zone distances noted in PRVD2007-05 was a result of different application rates for the different uses.

The PMRA disagrees that the boundary between the protected habitat and the treated area on industrial property can be somewhat arbitrary as there is a clear distinction between industrial property on which the application is to occur and the habitat/property that would require a buffer zone.

Since the publication of PRVD2007-05, the methods used to calculate ground buffer zones have changed. Therefore, the ground buffer zones were recalculated and are provided in Appendix II, Tables 1, 2 and 3, and range from 1 to 40 m.

4.12 Comment

In calculating terrestrial buffer zones to protect non-target plants, the PMRA uses the most sensitive EC_{25} values from seedling emergence and vegetative vigour studies or the most sensitive species. For terrestrial habitats, soybeans were chosen as the indicator species. However, the ecological significance of this non-lethal endpoint for the ecological health of the terrestrial plant community may vary according to the species and circumstances in the habitat that needs to be protected. For aquatic habitats, the use of algae as an endpoint in the risk assessment must be done with particular caution. In non-agricultural uses, the reduction in algal growth that could occur from dicamba is temporary. Although only temporary, the reduction of algae in agricultural use scenarios would help to balance the effect of the increased nutrient levels that are associated with agricultural and pasture runoff and reduce the formation of algal blooms, which can be a benefit to the ecosystem. Therefore, an EC_{25} for a more highly evolved plant species such as *Lemna* would be a more appropriate endpoint.

Response

As with other areas of the environmental risk assessment, the use of surrogate species is necessary. For the aquatic risk assessment, the PMRA uses the most sensitive aquatic organism, in this case algae, as a surrogate species for aquatic plants. Algae are an important source of nutrients for many aquatic organisms and are therefore considered important in the aquatic ecosystem. The potential reduction in algae from dicamba entering a watercourse is not an acceptable solution to the effects of increased nutrient levels in agricultural areas. The PMRA will continue to use the most sensitive aquatic organism (e.g. algae) in the aquatic risk assessment and for the determination of mitigation measures unless there are sufficient toxicity endpoints to calculate a species sensitivity distribution. The risk assessment presented in PRVD2007-05 used the no observed effect concentration for algae. However, since the publication of this document, the PMRA has re-examined the endpoint selection process for aquatic plants. It now uses the EC_{50} for aquatic organisms multiplied by a species sensitivity factor of 0.5 to account for differences in species sensitivity as well as varying protection goals (e.g. community, population, individual). The RQs for aquatic organisms were recalculated along with the resulting buffer zones. The new aquatic buffer zones are presented in Appendix II, Tables 1, 2 and 3.

To assess the risk to terrestrial plants, the standard plant toxicity studies submitted to the PMRA include 10 crop species. When conducting an environmental risk assessment, it is impossible to have toxicity studies on all organisms that can potentially be exposed to the pesticide in question. As such, it is common practice to use surrogate species to represent all species within that organism group. With regard to plants, the PMRA is obliged to use the data available and to use a surrogate approach and will continue to use the EC_{25} of the most sensitive plant species at the screening level. If the LOC is exceeded at the screening level, a species sensitivity distribution may be employed at the EC_{50} level .

Since the publication of PRVD2007-05, the PMRA has become aware of additional terrestrial plant toxicity data, which includes non-crop terrestrial plant species. The risk assessment was redone to include these data and it incorporates a species sensitivity distribution approach. From the species sensitivity distribution (SSD), the 5th percentile of the SSD (HC_5) for the EC_{50} at 50% confidence intervals was calculated, using the SSD program ETx2 (version 2.0). The HC_5 results in a 5% protection level (i.e. for 95% of species, the chemical is expected to be less toxic than

the estimated 5th percentile toxicity value). Calculation of terrestrial buffer zones was based on the HC_5 of the species sensitivity distribution. The new terrestrial buffer zones are presented in Appendix II, Tables 1, 2 and 3.

4.13 Comment

Swath displacement or offset should be included in the model simulations conducted by the PMRA to determine the EEC. During normal application of pesticides, aerial applicators nearly always allow for some displacement by crosswind when determining their spray run positions.

Response

The amount of offset required for the spray width to reach the intended target depends on a number of site-specific variables, and the calculation is carried out by the pilot at the time of application. The PMRA does not include swath displacement or offset in the model simulations as it would result in the need for the swath displacement to be specified on the product labels.

4.14 Comment

The PMRA utilizes very conservative release height assumptions for aerial application buffers. It should be possible for skilled applicators to make applications at lower release heights, depending upon local conditions. Analysis of some AGDISP runs under various wind and spray quality configurations showed that reducing the release height from 10 to 5 metres reduced the terrestrial drift buffer by about 50% on average. Lowering to 3 metres gave an average 75% reduction. Employing the "buffer zone multiplier" concept as outlined in Regulatory Proposal PRO2005-06, *Agricultural Buffer Zone Strategy Proposal*, it is proposed that multipliers of 1, 0.5 and 0.25 could be applied for release heights of 10, 5 and 3 metres, respectively, for non-cropland applications.

Response

The release heights chosen by the PMRA are representative of what applicators are using as confirmed by the Canadian Aerial Applicators Association. The PMRA uses a release height of 3 m for agricultural uses, 10 m for non-crop uses and 15 m for forestry and right-of-way uses. Although skilled applicators may be able to apply the pesticides at lower release heights under specific situations, the PMRA needs to model drift for representative use scenarios across Canada.

4.15 Comment

The proposed label restrictions will specify application of dicamba products with no finer than medium spray nozzles. This should be used in the buffer zone calculations. Changing the nozzle type to the American Society of Agricultural Engineers (ASAE) classification "Very Coarse" (droplet size spectrum volume median diameter [$D_{V0.5}$)] = 477.9 µm) from ASAE "Coarse" gives a buffer multiplier of 0.8, while increasing to ASAE "Very Coarse to Extremely Coarse" ($D_{V0.5}$ = 512.4 µm) results in a multiplier of 0.65, based upon some representative AGDISP simulations. These multipliers should also be usable for aerial applications.

Response
As stated, the PMRA used the medium spray droplet size for modelling the dicamba buffer zones presented in PACR2007-02. If the coarse or very coarse spray droplet size is used for the buffer zone calculation, restrictions will have to be included on the labels stating that dicamba products must be applied with no finer than a coarse or very coarse spray quality.

The registrant wishes to maintain the option for the medium spray droplet size on the product label.

Based on comments received, the PMRA reassessed the dicamba buffer zones using both the medium and coarse droplet size, which will allow for increased flexibility for applicators. The resulting buffer zones for these uses are provided in Appendix II, Tables 1, 2 and 3.

There was consultation on a buffer zone strategy document that will allow an applicator to reduce the labelled buffer zone based on spray quality multipliers. This document is available on the PMRA website as Regulatory Proposal PRO2005-06, *Agricultural Buffer Zone Strategy Proposal*, but has not been finalized. Until this proposal is finalized, the proposed options will not be implemented.

4.16 Comment
The buffer zones should be reduced for use of newer drift reduction technologies, including drift reduction nozzles and air entrained nozzles, which work by reducing the proportion of fine drift-prone droplets in the spray. A buffer zone reduction factor is required for use of drift reduction nozzles (Ref. 11–13). These nozzles have an optimal pressure range that is higher than that of standard nozzles and this should also be included on the label.

Response
The PMRA will be looking at effects of drift reduction equipment; therefore, this issue will be addressed at a later date. If data exists to support certain spray reduction technologies, the registrant is encouraged to provide this information to the PMRA for review and the PMRA will consider additions to the buffer zone label statement.

4.17 Comment
Although not a big factor in directly reducing buffer zones, the water volume used will impact on the ability of the user to increase droplet size, thereby allowing larger droplets to be applied (very coarse to extremely coarse) in many situations. In some instances, the PMRA has chosen to use a 20–30 L/ha water volume across all use sites rather than the higher volumes recommended on some approved labels. The buffer zones should be determined with a representative water volume.

Response
The PMRA uses water volume that produces a conservative drift scenario if there is a range of volumes for a particular application rate/use pattern. For this parameter, there have to be some generalizations. Otherwise, the buffer zone table on the product label will be too complicated and cumbersome for the end user to understand. The PMRA has confirmed that the water volume for a conservative drift scenario was used, and it has recalculated the buffer zones. See Appendix II, Tables 1, 2 and 3 for new buffer zones.

4.18 Comment

The overutilization of compounded worst-case approximations for both the risk and the exposure values used in the calculation of the RQ leads to a compounded exaggeration of the risk and to unrealistic buffer zones. The buffer zones should represent more closely what a ground-based sprayer or aircraft can do under realistic worst-case field conditions.

Response

In the PMRA's recent updated methods for risk characterization, worst-case assumptions are made during the screening level assessment. If the screening LOC of one is exceeded, the risk is refined in a Tier 1 risk assessment using more realistic exposure scenarios. As part of the Tier 1 assessment, the risk from drift was considered by taking into consideration the drift expected 1 m downwind from the edge of the spray equipment for a given application rate. The drift percentage used in the assessment is dependent on the type of spray equipment along with the droplet size. The need for and calculation of buffer zones only occurs following the refined assessment. The calculation of buffer zones for dicamba are risk-based (i.e. the greater the risk the larger the buffer zones), and the calculations are based on the application rate and toxicity endpoints. Relevant effects endpoints are considered in the risk assessment and for the buffer zone calculation. For example, where possible, species sensitivity distributions are used to determine the effects endpoint on which the buffer zones will be set, rather than using the most sensitive species endpoint.

The mathematical deposition curves used in the PMRA's drift models were based on data generated either during field trials with representative spray equipment (ground applications) or on empirical models that have been validated in field trials (aerial applications).

5.0 Comments With Respect to Value

5.1 Comment

Pest Control Products Act Registration Number 28028 should have been included in Appendix I of PRVD2007-05.

Response

Appendix I of PRVD2007-05 listed the dicamba products currently registered (excluding discontinued products, products with a submission for discontinuation or products registered for use on fine turf only) as of 7 March 2005. Registration Number 28028 was first registered after that date. Thus, it was not included in Appendix I. Nonetheless, omission of this product would not have had any impact on the outcome of the decision as no new uses were included for this new product.

5.2 Comment

Pest Control Products Act Registration Number 25774 should have been included in Appendix I of PACR2007-02.

Response

Registration Number 25774 is a manufacturing concentrate that was listed in Appendix I of PRVD2007-05 as all manufacturing concentrate products were provided in that document.

Nonetheless, omission of this product from Appendix I of PACR2007-02 would not have impacted the outcome of the decision because this product is a manufacturing concentrate.

5.3 Comment
An issue was raised concerning the use of mechanical weed control as an alternative to dicamba with regards to environmental impact.

Response
The PMRA considers mechanical weed control to be a viable option for the control of broadleaf weeds and brush in non-crop areas only.

5.4 Comment
Studies on dicamba's effects on plants in the city are essential for understanding the risks of toxicity to plants located near residential or commercial lawns. Label recommendations could be more specific with respect to damage caused by the products.

Response
The types of non-target vegetation that have been found to be sensitive to dicamba are already listed on the labels of the products under "USE PRECAUTIONS."

5.5 Comment
The sales figures on page 25 are significantly underestimated. In Quebec alone, total sales of dicamba in 2001 for use on turf (including fertilizers-herbicides and amounts sold for home and commercial use) are at least four times greater than what was reported.

Response
The value that was indicated in PACR2007-02 was based on information from 1998 to 2001 in Canada. The use and sale of dicamba in Quebec alone could not be verified by the PMRA from currently published information because the data for individual products have been suppressed by combining those herbicides belonging to the same chemical family as dicamba.

Appendix II Label Changes Required for Increased Protection of Human Health and the Environment

The following must be added to the existing label statements.

1.0 Expression of Guarantee—All Products

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 PRVD2007-05, Table 2.3.1) and the proportion of dicamba acid equivalents. For example, for the DMA form, the guarantee should read as follows: "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.

2.0 Human Toxicology Statements

Labels of the Technical, Manufacturing 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 and loss of voice. Treat symptomatically.
>
> * *This statement concerning eye irritation may be modified by product-specific data.*

3.0 Personal Protective Equipment and Restricted-Entry Interval Relating to Occupational Exposure

For barley, lowbush blueberries, canary grass, corn (field and sweet), fallow, oats, pastures, red fescue, spring rye, seedling grasses, stubble fields, summer fallow and wheat (spring, durum), the following label statements are required:

> Applicators must wear a long-sleeved shirt, long pants and chemical-resistant gloves.
>
> DO NOT enter treated fields until 12 hours after application.

For non-cropland aerial application, the following label statements are required:

> Aerial applicators must wear long pants and a long-sleeved shirt.
>
> Aerial mixers/loaders must wear long pants and a long-sleeved shirt and chemical-resistant gloves.
>
> Must use closed cab aircraft.
>
> Mixer/loader and applicator must be different individuals.
>
> No human flaggers are permitted.

Solution Formulation
For non-crop areas (roadsides, hydro, pipeline and railway rights-of-way, airports, military bases, turf, wasteland), the following label statements are required:

> Applicators must wear coveralls over long pants, a long-sleeved shirt and chemical-resistant gloves.
>
> For high volume handwand applications, applicators must limit volume of solution used per day to 400 L (broadleaf control spot treatment only).

Wettable Granule Formulation
For non-crop areas (roadsides, hydro, pipeline and railway rights-of-way, airports, military bases, turf, wasteland), the following label statements are required:

> Applicators must wear coveralls over long pants, a long-sleeved shirt and chemical-resistant gloves.
>
> For high volume handwand applications, applicators must limit volume of solution used per day to 750 L (broadleaf control spot treatment only).

For All Formulations
For all products that do not include use on residential turf, the following statement must appear on the product label:

> DO NOT use in residential areas, which are defined as sites where bystanders may be present during or after spraying , including homes, schools, parks, playgrounds, playing fields and public buildings.

For all products relating to residential turf, the following must appear on the product label:

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 in the **DIRECTIONS FOR USE** section for commercial class products only:

> DO NOT apply by air.

The following statements must be included in the **DIRECTIONS FOR USE** section for all 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 must appear in the **DIRECTIONS FOR USE** section for products intended for broadcast application:

> DO NOT apply more than two broadcast applications per season. This does not include spot treatments.
>
> If weed populations do not warrant a broadcast application (e.g. entire lawn), consider spot treatments that target only weedy areas.

4.0 Statement Reducing Dietary Exposure

For barley, oats, spring rye, wheat, field corn, stubble land, pastures, rangelands, roadsides and uncropped land, the following statements are required:

> DO NOT permit lactating dairy animals to graze fields within 7 days after application.
>
> DO NOT harvest forage or cut hay within 30 days after application.
>
> Withdraw meat animals from treated fields at least 3 days before slaughter.

5.0 Statements Reducing Environmental Exposure

ALL PRODUCT LABELS

Add to **ENVIRONMENTAL HAZARDS:**

> TOXIC to aquatic organisms and non-target terrestrial plants. Observe buffer zones specified under **DIRECTIONS FOR USE**.

Add to **DIRECTIONS FOR USE:**

> DO NOT apply this product directly to freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands), estuarine or marine habitats.

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

Surface Runoff
To reduce runoff from treated areas into aquatic habitats, consider the characteristics and conditions of the site before treatment. Site characteristics and 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 such as clay).

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.

Avoid applying this product when heavy rain is forecast

Leaching
The use of this chemical may result in contamination of groundwater, particularly in areas where soils are permeable (e.g. sand, loamy sand and sandy loam soils) and/or the depth to the water table is shallow.

SPECIFIC TO COMMERCIAL PRODUCT LABELS FOR NON-TURF USES

Add to **ENVIRONMENTAL HAZARDS:**

Observe buffer zones specified under **DIRECTIONS FOR USE**.

Add to **DIRECTIONS FOR USE:**

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

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

For application to rights-of-way, buffer zones for protection of sensitive terrestrial habitats are not required; however, the best available application strategies to minimize off-site drift, including meteorological conditions (e.g. wind direction,

low wind speed) and spray equipment (e.g. coarse droplet sizes, minimizing height above canopy), should be used. Applicators must, however, observe the specified buffer zones for protection of sensitive aquatic habitats.

Buffer zones:

Use of the following spray methods or equipment DOES NOT require a buffer zone: hand-held or backpack sprayer, spot treatment, inter-row hooded sprayer, soil drench and soil incorporation.

For application to rights-of-way, buffer zones for protection of sensitive terrestrial habitats are not required; however, the best available application strategies to minimize off-site drift, including meteorological conditions (e.g. wind direction, low wind speed) and spray equipment (e.g. coarse droplet sizes, minimizing height above canopy), should be used. Applicators must, however, observe the specified buffer zones for protection of sensitive aquatic habitats.

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

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.

Table 1 Buffer Zones for Uses in Agriculture and Industrial Sites using ASAE Medium Applications

Method of Application	Crop	Buffer Zones (metres) Required for the Protection of:				
		Freshwater habitat of depths:		Estuarine/marine habitats of depths:		Terrestrial habitat
		Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m	
Field sprayer*	Barley, oats, rye, wheat, canary grass, forage grass (seedlings)	0	0	0	0	2
	Corn, forage grass (established), red fescue	1	0	0	0	5
	Stubble fields, fallow land	1	1	0	0	15
	Pasture and rangeland, non-cropland (2.2 kg a.i./ha)	1	1	0	0	20
	Blueberry (lowbush)	1	1	1	0	30

Method of Application	Crop		Buffer Zones (metres) Required for the Protection of:				
			Freshwater habitat of depths:		Estuarine/marine habitats of depths:		Terrestrial habitat
			Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m	
	Non-cropland (4.4 kg a.i./ha)		1	1	1	0	40
Aerial	Barley, oats, rye, wheat, canary grass	Fixed wing	0	0	0	0	75
		Rotary wing	0	0	0	0	65
	Stubble fields, fallow land	Fixed wing	0	0	0	0	85
		Rotary wing	0	0	0	0	65
	Non-cropland**	Fixed wing	70	35	1	0	800
		Rotary wing	35	20	1	0	775

*For field sprayer application, buffer zones can be reduced with the use of drift-reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy, the labelled buffer zone can be reduced by 30%.
**Buffer zones for the protection of terrestrial habitats are not required for use on rights-of-way, including railroad ballast, rail and hydro rights-of-way, utility easements, roads, and training grounds and firing ranges on military bases.

Table 2 Buffer Zones for Uses in Agriculture and Industrial Sites using ASAE Coarse Applications

Method of Application	Crop	Buffer Zones (metres) Required for the Protection of:				
		Freshwater habitat of depths:		Estuarine/marine habitats of depths:		Terrestrial habitat
		Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m	
Field sprayer*	Barley, oats, rye, wheat, canary grass, forage grass (seedlings), turf (up to 135 g a.i./ha)	0	0	0	0	1
	Corn, forage grass (established), red fescue, turf (550–600 g a.i./ha)	1	1	0	0	4
	Stubble fields, fallow land	1	1	0	0	5
	Pasture and rangeland, non-cropland (2.2 kg a.i./ha)	1	1	0	0	10
	Blueberry (lowbush)	1	1	1	0	15
	Non-cropland (4.4 kg a.i./ha)	1	1	1	0	20

Method of Application	Crop		Buffer Zones (metres) Required for the Protection of:				
			Freshwater habitat of depths:		Estuarine/marine habitats of depths:		Terrestrial habitat
			Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m	
Aerial	Barley, oats, rye, wheat, canary grass, stubble fields, fallow land	Fixed wing	0	0	0	0	50
		Rotary wing	0	0	0	0	45
	Non-cropland**	Fixed wing	45	30	0	0	800
		Rotary wing	30	20	0	0	525

*For field sprayer application, buffer zones can be reduced with the use of drift-reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy, the labelled buffer zone can be reduced by 30%.
**Buffer zones for the protection of terrestrial habitats are not required for use on rights-of-way, including railroad ballast, rail and hydro rights-of-way, utility easements, roads, and training grounds and firing ranges on military bases.

SPECIFIC TO COMMERCIAL PRODUCT LABELS FOR TURF USES

Add to **ENVIRONMENTAL HAZARDS**:

Observe buffer zones specified under **DIRECTIONS FOR USE**.

Add to **DIRECTIONS FOR USE**:

Avoid application of this product when winds are gusty.

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.

DO NOT apply to the exposed roots of trees and ornamentals.

To prevent runoff, DO NOT apply to driveways, sidewalks or any other hard surface.

DO NOT irrigate within 24 hours after application.

DO NOT apply by air.

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:

> Field sprayer application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) MEDIUM classification. Boom height must be 60 cm or less above the crop or ground.
>
> **Buffer zones:**
>
> Use of the following spray methods or equipment DOES NOT require a buffer zone: hand-held or backpack sprayer and spot treatment.
>
> The buffer zones specified in the tables below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands), sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.
>
> 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.

Table 3 Buffer Zones for Uses in Turf (for liquid commercial class products that may be applied by tractor-pulled field sprayers, e.g. to golf courses or sod farms)

Method of Application	Crop	Buffer Zones (metres) Required for the Protection of:		
		Aquatic habitat of depths:		Terrestrial habitat
		Less than 1 m	Greater than 1 m	
Field sprayer*	Turf (up to 135 g a.i./ha)	0	0	3
	Turf (550–600 g a.i./ha)	1	1	10

*For field sprayer application, buffer zones can be reduced with the use of drift-reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy, the labeled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy, the labeled buffer zone can be reduced by 30%.

SPECIFIC TO DOMESTIC CLASS PRODUCT LABELS FOR TURF PRODUCTS

Add to **DIRECTIONS FOR USE:**

DO NOT irrigate within 24 hours after application.

DO NOT apply to driveways, sidewalks or any other hard surface.

Avoid application of this product when winds are gusty.

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.

6.0 Description of Registered Use Sites

The designation “Canary Grass” or “Annual Canary Grass” must be revised on the label as “Canary Seed (*Phalaris canariensis*).”

If used on the label, the terms “non-cropland” and “industrial sites” must be defined specifically and indicated clearly on the label (e.g. for use on rights-of-way for transportation, rights-of-ways for utility lines, airports, wastelands, industrial parks, etc.).