Proposed Re-evaluation Decision PRVD2011-10

Diclofop-methyl

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Overview

What Is the Proposed Re-evaluation Decision?

After a re-evaluation of the herbicide diclofop-methyl, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and its Regulations, is proposing continued registration of products containing diclofop-methyl for sale and use in Canada.

An evaluation of available scientific information found that products containing diclofop-methyl do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of diclofop-methyl uses, new risk-reduction measures are proposed to be included on the labels of all products. No additional data are being requested at this time.

This proposal affects all end-use products containing diclofop-methyl registered in Canada. Once the final re-evaluation decision is made, the registrants will be instructed on how to address any new requirements.

This Proposed Re-evaluation Decision is a consultation document[1] that summarizes the science evaluation for diclofop-methyl and presents the reasons for the proposed re-evaluation decision. It also proposes additional risk-reduction measures to further protect human health and the environment.

The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the assessment of diclofop-methyl.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information indicated on the cover page of this document).

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

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

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03 *Pest Management Regulatory Agency Re-evaluation Program* presents the details of the re-evaluation activities and program structure.

Diclofop-methyl, one of the active ingredients in the current re-evaluation cycle, has been Re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- It covers the main science areas, such as human health and the environment, that are necessary for Canadian re-evaluation decisions;
- It addresses the active ingredient and the main formulation types registered in Canada; and
- It is relevant to registered Canadian uses.

Given the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA will propose a re-evaluation decision and appropriate risk-reduction measures for Canadian uses of an active ingredient. In this decision, the PMRA takes into account the Canadian use pattern and issues (for example, the federal Toxic Substances Management Policy [TSMP]).

Based on the health and environmental risk assessments published in the September 2000 RED Diclofop-methyl, the USEPA concluded that diclofop-methyl was eligible for re-registration provided risk-reduction measures were adopted. The PMRA compared the American and Canadian use patterns and found the USEPA assessments described in this RED were an adequate basis for the proposed Canadian re-evaluation decision.

For more details on the information presented in this overview, please refer to the Science Evaluation section of this consultation document.

What Is Diclofop-methyl?

Diclofop-methyl is a post-emergent herbicide used to control annual grasses in agricultural food/feed crops. Diclofop-methyl is applied by farm workers and professional applicators using ground-spray equipment and fixed-wing or rotary-wing aircrafts.

Health Considerations

Can Approved Uses of Diclofop-methyl Affect Human Health?

Diclofop-methyl is unlikely to affect your health when used according to the revised label directions.

People could be exposed to diclofop-methyl by consuming food and water, working as a mixer/loader/applicator or by entering treated sites. The PMRA considers two key factors when assessing health risks: 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 (for example, children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that diclofop-methyl was unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are proposed.

Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for the purposes of the *Food and Drugs Act* 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/on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Diclofop-methyl is currently registered in Canada for use on agricultural food/feed crops and could be used in other countries on crops that are imported into Canada. No specific MRLs have been established for diclofop-methyl in Canada. 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. However, changes to this general MRL will be implemented in the future, as indicated in the December 2009 Information Note, *Progress on Minimizing Reliance on the 0.1 Parts per Million as a General Maximum Residue Limit for Food Pesticide Residue*.

Environmental Considerations

What Happens When Diclofop-methyl Is Introduced Into the Environment?

Diclofop-methyl is unlikely to affect non-target organisms when used according to the revised label directions.

Non-target terrestrial and aquatic species could be exposed to diclofop-methyl in the environment. Environmental risk is assessed by the risk quotient method—the ratio of the estimated environmental concentration to the relevant effects endpoint of concern. In this screening level assessment, the resulting risk quotients are compared to corresponding levels of concern. A risk quotient less than the level of concern is considered a negligible risk to non-target organisms, whereas a risk quotient greater than the level of concern indicates some potential risks of concern.

The USEPA concluded that the re-registration of diclofop-methyl was acceptable provided risk-reduction measures to further protect the environment were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are proposed. Furthermore, the PMRA proposes both aquatic and terrestrial buffer zones for diclofop-methyl to protect aquatic organisms and terrestrial plants from spray drift.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of diclofop-methyl, the PMRA proposes further risk-reduction measures for product labels.

Human Health

- Revised toxicology hazard label statements
- Additional personal protective equipment for handlers
- Closed mixing/loading systems
- Enclosed-cab application equipment
- Maximum-permitted amount handled per day
- Restricted-entry interval

Environment

- Terrestrial and aquatic buffer zones
- Improvements to environmental label statements

A submission to implement label revisions will be required within 90 days of finalization of the re-evaluation decision.

Next Steps

Before making a final re-evaluation decision on diclofop-methyl, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a Re-evaluation Decision[2] that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments.

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

Science Evaluation

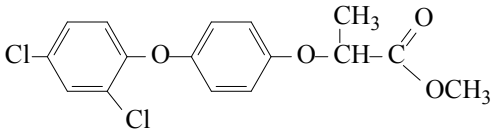
1.0 Introduction

Diclofop-methyl is a post-emergent herbicide, which acts by inhibiting plant cellular metabolism.Following the re-evaluation announcement for diclofop-methyl, the Canadian registrant of the technical grade active ingredient indicated they intended to support wheat and barley uses only. All other uses will be voluntarily phased out and removed from the product label.

The PMRA used recent assessments of diclofop-methyl from the United States Environmental Protection Agency (USEPA). The USEPA Reregistration Eligibility Decision (RED) document for diclofop-methyl, dated 29 September 2000, as well as other information on the regulatory status of diclofop-methyl in the United States can be found on the USEPA Pesticide Registration Status page at www.regulations.gov.

2.0 The Technical Grade Active Ingredient, Its Properties and Uses

2.1 Identity of the Technical Grade Active Ingredient

Common name		diclofop-methyl
Function		Herbicide
Chemical Family		aryloxyphenoxypropionate
Chemical name		
1	**International Union of Pure and Applied Chemistry (IUPAC)**	methyl (RS)-2-[4-(2,4-dichlorophenoxy)phenoxy]propionate
2	**Chemical Abstracts Service (CAS)**	methyl 2-[4-(2,4-dichlorophenoxy)phenoxy]propanoate
CAS Registry Number		51338-27-3 (for racemic isomers)
Molecular Formula		$C_{16}H_{14}Cl_2O_4$
Structural Formula		
Molecular Weight		341.2 amu
Purity of the Technical Grade Active Ingredient		93.7% NS
Registration Number		19514

Based on the manufacturing process used, contaminants of human health or environmental concern as identified in the Canada Gazette, Part II, Vol. 139, No. 24, SI/2005-114 (2005-11-30), including TSMP Track 1 substances, are not suspected to be present in the product.

2.2 Physical and Chemical Properties

Property	Result
Vapour pressure	0.25 mPa
Solubility in water	0.8 mg/L
n-Octanol/Water partition coefficient	log K_{ow} = 4.58
Dissociation constant	Not applicable

2.3 Comparison of Use Patterns in Canada and the United States

Diclofop-methyl is a post-emergent herbicide registered in Canada to control annual grasses in agricultural food/feed crops. Diclofop-methyl uses in wheat (spring, durum and winter) and barley (except Klages and Betzes) are being supported by the registrant and were, therefore, considered in the re-evaluation. All other uses have been voluntarily phased out and will be removed from the product label. Diclofop-methyl acts by inhibiting fatty acid synthesis by inhibition of acetyl CoA carboxylase.

Diclofop-methyl is applied to grass weeds at the1-4 leaf stage (wild oats can be up to 4-5 leaf stage) or when volunteer corn is 15-25 cm in height. The end-use product is formulated as an emulsifiable concentrate. In Eastern Canada and British Columbia, diclofop-methyl can be applied at a rate of 0.7-0.8 kg a.i./ha for barley and 0.7-1.0 kg a.i./ha for wheat using ground equipment. While, in the Prairie Provinces and Peace River region of British Columbia, diclofop-methyl can be applied at a rate of 0.7-0.8 kg a.i./ha for both barley and wheat using both ground or aerial equipment. A label revision is proposed to clarify application instructions for users in British Columbia. The proposed label amendments are listed in Appendix III.

The American and Canadian use patterns were compared. The Canadian formulation, guarantee, application methods, use sites and application rates are encompassed by the USEPA assessments. Based on this comparison of use patterns, it was concluded that the USEPA RED for diclofop-methyl is an adequate basis for the re-evaluation of uses of diclofop-methyl in Canada.

Appendix I lists all diclofop-methyl products that are registered as of 25 January 2011, under the authority of the *Pest Control Products Act*.

3.0 Impact on Human Health and the Environment

In their 2000 RED, the USEPA concluded that the end-use products formulated with diclofop-methyl met the safety standard under the *American Food Quality Protection Act* and would not pose unreasonable risks or adverse effects to humans and the environment if used according to the amended product labels.

3.1 Human Health

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels at which no effects are observed. Unless there is evidence to the contrary, it is assumed that effects observed in animals are relevant to humans and that humans are more sensitive to effects of a chemical than the most sensitive animal species.

Exposure to diclofop-methyl may occur through consumption of food and water, while working as a mixer/loader/applicator or by entering treated sites. When assessing health risks, the PMRA considers two key factors: 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 (for example, children and nursing mothers).

Diclofop-methyl is highly-to-moderately acutely toxic via the oral route; and of low acute toxicity via the dermal and inhalation routes. Diclofop-methyl is a slight ocular and dermal irritant; and a moderate-to-severe dermal sensitizer. Skin sensitization label amendments are proposed for the end-use product (Appendix III).

The USEPA's toxicological endpoints for assessing risk to human health are summarized in Appendix II.

3.1.1 Occupational Exposure and Risk Assessment

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

In the case where evidence of carcinogenicity is identified for the active ingredient, a cancer potency factor (Q_1*) is generated and used to estimate cancer risk. The product of the expected exposure and the cancer potency factor (Q_1*) estimates the lifetime cancer risk as a probability. A lifetime cancer risk in the range of 1 in 10^{-5} to 1 in 10^{-6} in worker populations is generally considered acceptable.

Workers can be exposed to diclofop-methyl when mixing, loading or applying the pesticide and when entering a treated site to conduct activities such as scouting and/or handling of treated crops.

3.1.1.1 Mixer/Loader/Applicator Exposure and Risk

The USEPA evaluated seven potential exposure scenarios for mixing/loading and applying diclofop-methyl by hand gun sprayer, groundboom and aerial application. To reduce occupational non-cancer and cancer risk, the USEPA required revised personal protective equipment and engineering controls, such as closed mixing/loading systems and enclosed application equipment.

The area treated per day assumed for the US assessment is significantly lower than standard values used by the PMRA for the occupational risk assessment. Therefore, the PMRA conducted a screening level occupation non-cancer and cancer assessment for workers mixing/loading and applying diclofop-methyl using groundboom or aerial equipment based on PMRA default values.

Short- and intermediate-term dermal and inhalation exposures of workers were assessed by the PMRA using exposure values from the Canadian Pesticide Handlers Exposure Database (PHED), Canadian application rates of 1.0 kg a.i./ha (ground application) and 0.8 kg a.i./ha (aerial application) and an area treated per day of 100 ha (farmers), 300 ha (custom workers) and 400 ha (aerial application). Additional assumptions included a dermal absorption factor of 100%, a default worker body weight of 70 kg, different levels of personal protective equipment (PPE), the use of a closed mixing/loading system and a closed cab during application.

To estimate the cancer risk for workers, the PMRA calculated the lifetime average daily dose (LADD) using the estimated daily exposure doses, the cancer potency factor of 0.23 (mg/kg bw/day)$^{-1}$ and assuming a dermal absorption factor of 15%, 10 and 20 days of exposure per year (farmers and custom applicators, respectively), a working lifetime of 40 years, and a lifespan of 75 years.

The PMRA determined that exposure of workers to diclofop-methyl results in acceptable non-cancer (MOE>100) and cancer risk (< 1x 10^{-5}) only when:

- The mixer/loader wears coveralls over single layer clothing and gloves, uses a closed mixing/loading system, and handles no more than 67 kg a.i./day;
- The applicator using a groundboom wears coveralls over single layer clothing, uses enclosed cab application equipment and applies no more than 144 kg a.i./day;
- The aerial applicator wears coveralls over single layer clothing and gloves and applies no more than 92 kg a.i./day.

Consequently, the PMRA proposes additional mitigation measures including additional PPE, closed mixing/loading systems, closed application equipment and a maximum permitted amount handled per day. Additional instructions concerning good hygiene practices are also required on labels. The proposed label amendments are listed in Appendix III.

3.1.1.2 Postapplication Exposure and Risk

The postapplication occupational risk assessment considered exposures to workers entering treated sites. Based on diclofop-methyl's supported use pattern, workers could be exposed to residues after the product is applied during scouting of wheat and barley fields.

Default dislodgeable foliar residue (DFR) values and activity-specific transfer coefficients (TC) were used to analyze postapplication exposure from contact with treated foliage at various times after treatment. DFR data includes the amount of residue that can be dislodged or transferred from a surface, such as the leaves of a plant. A TC is a factor that relates worker exposure to dislodgeable residues.

The postapplication MOE for scouting in wheat and barley is above the target MOE on the day of application and therefore is not of concern. The cancer risk value for postapplication exposure from scouting activities (cancer risk = 2.3×10^{-5}) on the day of application exceeded the USEPA's level of concern. However, the USEPA considered the cancer risk assessment to be conservative based on the 24-hour restricted entry interval (REI) and that the exposure is assumed to always occur on the day of application. The USEPA concluded that scouts are at little risk with the existing 24-hour restricted entry interval. No additional mitigation measures with respect to postapplication exposure were required by the USEPA.

The USEPA assessment is considered applicable to the Canadian situation. A 24-hour restricted entry interval for wheat and barley is proposed by the PMRA based on the carcinogenicity potential of diclofop-methyl. The proposed label amendments are listed in Appendix III.

3.1.2 Non-Occupational Exposure and Risk Assessment

3.1.2.1 Residential Exposure

There are no residential uses registered in Canada, therefore, residential handler exposure to diclofop-methyl is not expected. Based on the supported Canadian use-pattern, residential bystander exposure is also not expected.

3.1.2.2 Exposure from Food and Drinking Water

No maximum residue limits (MRL) have been established for diclofop-methyl in Canada.

Acute dietary risk is calculated considering the highest ingestion of diclofop-methyl that would be likely on any one day, and using food consumption and food residue values. A probabilistic statistical analysis allows all possible combinations of consumption and residue levels to be combined to estimate a distribution of the amount of diclofop-methyl residue that might be consumed in a day. A value representing the high end (99.9^{th} percentile) of this distribution is compared to the acute reference dose (ARfD), which is the dose at which an individual could be exposed on any given day and expect no adverse health effects. When the expected intake of residues is less than the ARfD, then acute dietary exposure is considered acceptable. The acute reference dose is referred to as the ARfD in Canada, and in the RED, it is expressed as the acute population adjusted dose (aPAD).

The aPAD of 0.1 mg/kg-bw/day was established by the USEPA based on the NOAEL of 10 mg/kg-bw/day from a developmental toxicity study in rats and the uncertainty factor of 100 (10× for interspecies extrapolation and 10× for intraspecies variation). The USEPA reported that acute dietary risk estimates for females 13-50 years of age were below 100% of the aPAD (<8% of the aPAD) and therefore not of concern. Acute dietary endpoints were not selected by the USEPA for general population.

Chronic dietary risk is estimated by determining how much of a pesticide residue may be ingested with the daily diet and comparing this potential exposure to an acceptable daily intake, which is the dose at which an individual could be exposed over the course of a lifetime and expect no adverse health effects. The acceptable daily intake is referred to as the ADI in Canada, and, in the RED, it is expressed as the chronic population adjusted dose (cPAD). The ADI/cPAD is based on a relevant endpoint from toxicology studies and on uncertainty factors protective of the most sensitive subpopulation (see Appendix II)

The cPAD of 0.1 mg/kg-bw/day was established by the USEPA based on the NOAEL of 0.23 mg/kg-bw/day from a chronic toxicity study in rats and the uncertainty factor of 100 (10× for interspecies extrapolation and 10× for intraspecies variation). Chronic dietary risk was less than 1% of cPAD for all population subgroups (children 1-6 highest exposed group)

Diclofop-methyl is classified as “likely to be carcinogenic to humans” based on laboratory studies in the rat and mouse. When evidence of carcinogenicity is identified for the active ingredient, a cancer potency factor (Q_1*) is generated and used to estimate cancer risk. The product of the expected exposure and the cancer potency factor (Q_1*) estimates the lifetime cancer risk as a probability. A lifetime cancer risk below 1 in 10^{-6} usually does not indicate an unacceptable risk for the general population when exposure occurs through pesticide residues in or on food and to otherwise unintentionally exposed persons.

The USEPA estimated cancer risk associated with diclofop-methyl dietary exposure to be 1.2×10^{-6} which exceeds the USEPA level of concern. The USEPA considered the cancer risk estimate to be conservative based on the decreasing use of the active ingredient and conservative estimates of dietary contribution from residues in milk and meat products (from animals feeding on treated wheat). On this basis, the USEPA concluded that cancer risk associated with diclofop-methyl was negligible.

The Canadian application methods and maximum application rates are encompassed by those assessed in the USEPA dietary exposure and risk assessment. Residue estimates in USEPA dietary assessment show that milk and meat products are the primary sources of dietary exposure. The Canadian registered label does not permit any grazing on treated crops; therefore, the dietary contributions from animal tissues, or milk, are not expected. The absence of dietary contribution from dairy and meat increases the conservatism of the USEPA assessment with respect to the Canadian situation. Residues of diclofop-methyl and it metabolites were non-detectable (LOQ = 0.10 ppm) in wheat and barley grain field trials (USEPA); therefore, exposure from grain is expected to be minimal. The USEPA assessment is considered to be relevant, and conservative, to the Canadian situation and the conclusions derived from the RED apply to the Canadian situation. The PMRA proposes a label amendment to limit application to once per season for barley and wheat (consistent with US labels).

The USEPA compared acute and chronic Drinking Water Levels of Comparison (DWLOCs) to estimated environmental concentrations (EECs) of diclofop-methyl in surface and ground water. The DWLOC is the highest concentration of a pesticide in drinking water that would be acceptable considering the estimated exposure to that pesticide from food. The acute and chronic DWLOCs (3000 ppb and >20 ppb, respectively) were greater than the ground and surface water EECs; and therefore, exposure to diclofop-methyl in drinking water was not of concern. The USEPA did not calculate a cancer DWLOC because the risk from food alone was estimated to be 1.2×10^{-6}. The USEPA concluded that based on fate properties, and the conservatism of the food and water assessments, there is not an aggregate cancer risk from diclofop-methyl. The USEPA did not require any mitigation measures with respect to drinking water.

The PMRA searched the current database of Canadian water monitoring data, and identified a number of studies which analyzed diclofop-methyl. The range of detectable concentrations reported to the PMRA is from 0.001 to 4.88 µg/L (0.001 to 4.88 ppb). The diclofop-methyl levels identified in the Canadian water monitoring database also do not exceed the acute and chronic DWLOC. Therefore, the USEPA assessment is considered applicable to the Canadian situation.

3.1.2.3 Aggregate Risk Assessment

Aggregate risk combines the different routes of exposure to diclofop-methyl. Acute and chronic aggregate risk assessments are comprised of contributions from food and drinking water exposures. Short- and intermediate-term aggregate risk assessments are comprised of contributions from food, drinking water and non-occupational exposure (dermal, inhalation).

The USEPA assessed acute and chronic aggregate exposure to diclofop-methyl. The acute/chronic aggregate exposure was not of concern since the DWLOCs were greater than the estimated concentrations of diclofop-methyl in surface and ground water. Diclofop-methyl is not expected to result in non-occupational exposures (dermal, inhalation). Therefore, short- and intermediate-term aggregate risk is encompassed by the acute/chronic aggregate risk assessment.

Overall, the Canadian aggregate exposure scenarios were adequately addressed by the USEPA aggregate risk assessment. Therefore, the USEPA aggregate exposure conclusions are considered applicable to the uses of diclofop-methyl in Canada.

3.1.3 Cumulative Effects

The USEPA has not determined whether diclofop-methyl has a common mechanism of toxicity with other substances or whether it shares a toxic metabolite produced by other substances. Therefore, it was assumed that diclofop-methyl does not share a common mechanism of toxicity with other substances and a cumulative risk assessment was not required.

3.2 Environment

3.2.1 Environmental Risk Assessment

Biodegradation and hydrolysis are the primary routes of dissipation of diclofop-methyl in the environment. Parent diclofop-methyl degraded to its acid metabolite, diclofop-acid, in less than 1 day in aerobic soil. In aerobically incubated soils, diclofop-methyl and diclofop-acid degraded with estimated half-lives of 21–51.3 days. Diclofop-methyl has very low persistence in anaerobic soil or water. No acceptable aerobic aquatic metabolism data were available. The USEPA assumed an aerobic aquatic metabolic half-life of 42 days based on the aerobic soil metabolism half-life of 21 days multiplied by 2 to account for change in media. In anaerobic soils, diclofop-acid is moderately persistent (half-life >60 days). Based on rapid degradation, and low solubility in water, diclofop-methyl is not expected to be mobile. Diclofop-acid has the potential to be mobile based on low tendency to bind to soil; therefore runoff may occur after heavy rainfall/irrigation.

On an acute basis, diclofop-methyl is practically non-toxic to avian species, moderately toxic to small mammals and highly toxic to freshwater fish and invertebrates.

Acute and chronic risk quotients (RQ) for birds and aquatic animals, as well as for mammals feeding on seeds are not of concern. Chronic RQs exceeded the level of concern (LOC) (RQs 3.7-8.0; LOC of 1.0) for mammals feeding on short grass, tall grass and broadleaf plants/insects. Acute RQs for non-target terrestrial plants exceeded the LOC (RQs 1.7-17; LOC of 1.0) for emergence. However, the EPA concluded that with refined foliar half-life data and revised labelling for spray drift, risks to small mammals and non-target terrestrial plants would not be of concern.

The USEPA risk assessment is considered relevant to the Canadian situation. The PMRA calculated terrestrial and aquatic buffer zones to minimize spray drift to non-target species during ground and aerial applications. Inputs to buffer zone models are summarized in Appendix IV. Buffer zones of up to 3 m are required for ground application and up to 100 m for aerial application. Buffer zone label statements are proposed to be included on product labels. Additional hazard labelling statements are proposed by the PMRA based on acute toxicity. Based on PMRA general practices, additional directions for use label amendments, and hazard labelling for runoff, are also proposed. The proposed label amendments are listed in Appendix III.

3.3 Pest Control Product Policy Considerations

3.3.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, i.e., persistent (in air, soil, water and/or sediment), bioaccumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the re-evaluation process, diclofop-methyl was assessed in accordance with the PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy,* and evaluated against the Track 1 criteria.

Diclofop-methyl does not meet Track 1 criterion for persistence, as its half-life values in soil (21 – 51.3 days), and water (42 days) are below cut-off values (half-life ≥ 182 days). Diclofop-methyl does not meet the Track 1 criterion for bioaccumulation, as its octanol-water partition coefficient (log K_{ow} = 4.58) is below the Track 1 criterion (log $K_{ow} \geq 5$). On this basis, it is concluded that the use of diclofop-methyl is not expected to result in the entry of Track 1 substances in the environment.

3.3.2 Contaminants and Formulants of Health or Environmental Concern

During the re-evaluation of diclofop-methyl, contaminants in the technical are compared against the *List of Pest control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*[3]. The list is used as described in the PMRA Notice of Intent NOI2005-01 and is based on existing policies and regulations including: DIR99-03; and DIR2006-02, and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusion:

Technical grade diclofop-methyl does not contain any contaminants of health or environmental concern identified in the *Canada Gazette.*

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

4.0 Incident reports

Starting 26 April 2007, registrants are required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame.

There were no incident reports submitted for diclofop-methyl as of January 25, 2011.

5.0 Organization for Economic Co-operation and Development Status of Diclofop-methyl

Canada is part of the Organisation for Economic Co-operation and Development (OECD), which groups 30 member countries and provides governments with a setting in which to discuss, develop and perfect economic and social policies. They compare experiences, share information and analyses, seek answers to common problems, and work to co-ordinate domestic and international policies to allow for consistency in practices across nations.

Diclofop is not included on the European Union list of active substances[4]; however, an application for inclusion has been submitted and is currently under evaluation. Diclofop holds authorization at a national level in: Greece, Spain, France, Italy, Portugal and the United Kingdom (OECD members).

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[3] *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette,* Part II, Volume 142, Number 13, pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

[4] Annex I to Directive 91/414/EEC

As described earlier in this document, the United States, also an OECD member, assessed the registration of all uses of diclofop-methyl in 2000 and concluded using diclofop-methyl as a pesticide does not result in unreasonable adverse effects to human health or the environment provided the risk-reduction measures recommended in the USEPA RED document were implemented.

The Canadian re-evaluation of diclofop-methyl is largely based on the 2000 USEPA RED assessments. Additional assessments were conducted by the PMRA where required. As described in Section 3.1 and 3.2 above, the PMRA has found additional mitigation measures are required to further protect workers and the environment.

6.0 Proposed Re-evaluation Decision

The PMRA is proposing continued registration of products containing diclofop-methyl for sale and use in Canada with the implementation of the proposed risk-reduction measures. These measures are required to further protect human health and the environment. The labels of Canadian end-use product must be amended to include the label statements listed in Appendix III. A submission to implement label revisions will be required within 90 days of finalization of the re-evaluation decision. No additional data are being requested at this time.

7.0 Supporting Documentation

PMRA documents, such as Regulatory Directive DIR2001-03, *Pest Management Regulatory Agency Re-evaluation Program,* and DACO tables can be found on the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra. PMRA documents are also available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra.infoserv@hc-sc.gc.ca.

The federal TSMP is available through Environment Canada's website at www.ec.gc.ca/toxics.

The USEPA RED document for diclofop-methyl is available at www.regulations.gov

The EFSA Draft Assessment Report for diclofop-methyl is available through EFSA's Pesticide Risk Assessment Peer Review website at http://www.efsa.europa.eu/en/panels/praper.htm

List of Abbreviations

ADI	acceptable daily intake
a.i.	active ingredient
aPAD	acute population adjusted dose
ARfD	acute reference dose
bw	body weight
CAS	Chemical Abstracts Service
cPAD	chronic population adjusted dose
DACO	data code
DFR	dislodgeable foliar residue
DWLOC	drinking water level of comparison
EEC	expected environmental concentration [also estimated environmental concentration]
EFSA	European Food Safety Authority
GLP	good laboratory practice
ha	hectare
kg	kilogram(s)
K_{ow}	*n*-octanol–water partition coefficient
L	litre(s)
LC_{50}	lethal concentration to 50%
LOC	level of concern
LOQ	level of quantification
mg	milligram(s)
MOE	margin of exposure
MRL	maximum residue limit
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
PCPA	*Pest Control Products Act*
PHED	Pesticide Handlers Exposure Database
PMRA	Pest Management Regulatory Agency
ppb	parts per billion
PPE	personal protective equipment
ppm	parts per million
PRVD	Proposed Re-evaluation Decision
Q_1*	cancer potency factor
RED	Reregistration Eligibility Decision
REI	restricted-entry interval
RfD	reference dose
RVD	Re-evaluation Decision
RQ	risk quotient
TC	transfer coefficient
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency

Appendix I Registered Products Containing Diclofop-methyl as of 25 January 2011

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
18042	Commercial	BAYER CROPSCIENCE INC.	HOE-GRASS 284 EMULSIFIABLE LIQUID HERBICIDE	Emulsifiable Concentrate	284 g a.i./L
19514	Technical	BAYER CROPSCIENCE INC.	HOEGRASS TECHNICAL HERBICIDE	Solid	93.7%
29398	Technical	BAYER CROPSCIENCE INC.	HOEGRASS TECHNICAL	Solid	99.4 %

Appendix II Toxicological Endpoints for Diclofop-methyl Health Risk Assessments

Exposure Scenario	NOAEL[a] (mg/kg bw/day)	Study	Endpoint	UF / MOE[b]
Acute Dietary (females 13-50 years of age)	10	Developmental toxicity (rat)	Decreased fetal body weights, extended ureters, skeletal abnormalities.	UF = 100
Chronic Dietary (non-cancer)	0.23	Chronic toxicity (rat)	Increased relative liver and kidney weights, liver histopathology.	UF = 100
Chronic Dietary (carcinogenic)		Carcinogenicity study (mouse)	$Q_1^* = 2.3 \times 10^{-1}$ (mg/kg/day)$^{-1}$ Based on liver adenomas and carcinomas with significant trend and pair-wise comparisons.	
Short- and Intermediate-Term Dermal	5.0	21-day dermal toxicity (rat)	Increased liver enzymes, proteins, and absolute and relative liver weights.	MOE = 100
Short- and Intermediate-Term Inhalation	1.6	Sub-chronic oral toxicity (rat)	Increased liver enzymes, proteins, and absolute and relative liver weights. 100% inhalation absorption assumed.	MOE = 100
Cancer (dermal and inhalation)		Carcinogenicity study (mouse)	$Q_1^* = 2.3 \times 10^{-1}$ (mg/kg/day)$^{-1}$ Based on liver adenomas and carcinomas with significant trend and pair-wise comparisons.	

[a] NOAEL = No Observed Adverse Effect Level.

[b] UF refers to total of uncertainty factor for dietary assessments, MOE refers to desired margin of exposure for occupational or residential assessments (10× interspecies variability, 10× intraspecies variability)

Appendix III Label Amendments for Products Containing Diclofop-methyl

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

A submission to request label revisions will be required within 90 days of finalization of the re-evaluation decision.

I) The following uses must be removed from the label:

Alfalfa
Bromegrass
Carrots
Clover (Red, Alsike and Sweet)
Creeping Red Fescue
Dry Common Beans (Black, White, Kidney, Pinto)
Faba beans
Flax (excluding low linolenic acid varieties)
Lentils
Lima Beans
Onions (Bulb only)
Peas (Field and Processing)

Potatoes
Rapeseed (Canola)
Rye (Spring and Fall)
Russian Wild Rye Grass
Sainfoin (Seed production only)
Snap Common Beans
Soybeans

Sugarbeets
Sunflowers (except Corona)
Tame Buckwheat
Tame Mustard
Triticale
Wheat Grass (Crested & Intermediate).

II) The following label amendment is required on the primary panel of the label as well as throughout the label text to address the overlap between label section for all ‘British Columbia’ and the ‘Peace River region of British Columbia’.

Replace: *“FOR SALE FOR USE IN EASTERN CANADA AND BRITISH COLUMBIA ONLY’*

With: *“FOR SALE FOR USE IN EASTERN CANADA AND THE PROVINCE OF BRITISH COLUMBIA EXCLUDING THE PEACE RIVER REGION”*

III) The following statements must be included on the primary display panel of the label:

POTENTIAL SKIN SENSITIZER

IV) The following statements must be included in a section entitled PRECAUTIONS.

Potential skin sensitizer.

Wear coveralls over long sleeved shirt and long pants, chemical-resistant gloves, socks, and chemical-resistant footwear during mixing, loading, application, clean up and repair. Wear goggles or face shield during mixing/loading.

Applicators using ground equipment must use an enclosed cab.

Applicators must use a respirator or an enclosed cab/cockpit that provides respirator equivalent protection.

Handlers performing tasks for which engineering controls are not feasible, such as spill cleanup, must wear coveralls over long-sleeved shirt and long pants, protective eyewear, chemical-resistant gloves, chemical-resistant footwear, chemical-resistant apron and a respirator.

When a respirator is required, handlers must wear either a respirator with a NIOSH/MSHA/BHSE approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH/MSHA/BHSE approved canister approved for pesticides.

DO NOT enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours.

V) The following statements must be included in a section entitled DIRECTIONS FORUSE.

Mixers/loaders must use a closed system that transfers liquid in a manner that prevents release of the liquid or any vapour.

Maximum of one application of diclofop-methyl per season.

Mixer/loaders must not handle more than 67 kg a.i. per day per worker. Applicators using ground equipment must not handle more than 144 kg a.i. per day per worker. Applicators using aerial equipment must not handle more than 92 kg a.i. per day per worker.

As this product is not registered for the control of pests in aquatic systems, DO NOT use to control aquatic pests.

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

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.

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 classification. To reduce drift caused by turbulent wingtip vortices, the nozzle distribution along the spray boom length MUST NOT exceed 65% of the wing- or rotorspan.

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, riparian areas and shrublands), sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of application	Crop		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*	Wheat, Barley		2	1	1	1	3
Aerial	Wheat, Barley	Fixed wing	45	1	5	1	100
		Rotary wing	30	1	5	1	85

* 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%.

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

VI) The following statements must be included in a section entitled ENVIRONMENTAL HAZARDS.

TOXIC to aquatic organisms, birds, small mammals and non-target terrestrial plants. Observe buffer zones specified under DIRECTIONS FOR USE.

To reduce runoff from treated areas into aquatic habitats avoid application to areas with a moderate to steep slope, compacted soil, or clay.

Avoid application when heavy rain is forecast.

Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.

Appendix IV Inputs to Buffer Zone Models

Table 1 Ground Use Data (from Canadian labels)

Crop	Formulation Type	Method of Application	Number of Applications	Maximum Application Rate (g a.i./ha)	Application Interval (days)
Wheat	Emulsifiable Concentrate	Field (medium)	1	994	n/a
Barley	Emulsifiable Concentrate	Field (medium)	1	795.2	n/a

Table 2 Model Input Data for Aquatic and Terrestrial Buffer Zones

Model Input Data for Aquatic Buffer Zones (from peer-reviewed product monograph)	
Half life for aquatic buffer zones	Stable
Most sensitive fish endpoint for amphibian risk assessment	*Lepomis macrochirus* $^{1}/_{10}$ LC_{50} = 0.013 mg/L
Most sensitive freshwater species	*Lepomis macrochirus* $^{1}/_{10}$ LC_{50} = 0.013 mg/L
Most sensitive estuarine/marine species	*Lepomis macrochirus* $^{1}/_{10}$ LC_{50} = 0.013 mg/L

Model Input Data for Terrestrial Buffer Zones	
Half life for terrestrial buffer zones	51 days
Most sensitive terrestrial plant species	Ryegrass (monocot) EC_{25} = 13.48 g/ha

Table 3 Aerial Use Data (from Canadian Labels)

Crop	Formulation Type	PCP Number*	Number of Applications	Maximum Application Rate (g a.i./ha)	Application Interval (days)
Wheat, Barley	Emulsifiable Concentrate	18042	1	795.2	n/a

Table 4 Product Information for Aerial Use

Parameter	Value
	PCP # 18042
Aircraft type (fixed and/or rotary wing)	Fixed, rotary
ASAE spray quality (e.g. fine, medium, coarse)	Medium
Carrier (water or oil)	Water
Product guarantee (g a.i./L for liquid formulations; % for dry formulations)	284 g a.i./L
Specific gravity of end-use product (g/mL for liquid formulations)	1.04 g/mL
Minimum spray volume (L/ha)	35
Water content of product (%)	0%
Wind speed (km/h) (default 16 km/h)	13 km/h
Temperature (°C) (default 25°C)	25°C
Relative humidity (%) (default 50%)	50%

References

Studies considered in the Chemistry Assessment

A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

PMRA Document Number	Reference
1642335	1982, Technical Chemistry DPP-BCQ-7. Diclofop-methyl technical Description of beginning materials and manufacturing process., DACO: 2.11.2, 2.11.3
1642336	1987, Technical Chemistry DPP-BCQ-7. Hoe 023408 Discussion of the formation of impurities in the technical grade substance., (B)120/87, DACO: 2.11.1, 2.11.4, 2.13.4
1642338	992, Technical Chemistry DPP-BCQ-7. Hoe 023408 Analysis of seven typical production batches., CP91/100, DACO: 2.12.1, 2.13.1, 2.13.2, 2.13.31992, Technical Chemistry DPP-BCQ-7. Hoe 023408 Analysis of seven typical production batches., CP91/100, DACO: 2.12.1, 2.13.1, 2.13.2, 2.13.3
1642156	Technical Chemistry DPP-BCQ-7. Basic Manufacturing Process of Diclofop-methyl technical, Purity Levels of Starting Points and Intermediates, Gas Chromatographic Analysis of the Secondary Products, Contents of 2,3,7,8-tetrachloro-dibenzo-1,4-dioxine., DACO 2.13.4

B. ADDITIONAL INFORMATION CONSIDERED

Published Information

e-Pesticide Manual, version 3.1 entry for Diclofop-methyl

Studies considered in the Canadian Water Monitoring Assessment

Published information

PMRA Document Number	Reference
130757	Currie, R.S., and D.A. Williamson (1995) An assessment of pesticide residues in surface waters of Manitoba, Canada. Water Quality Management Section. Manitoba Environment. Report #95-08. 155 pages
1398451,	Giroux, I., C. Robert, and N. Dassylva (2006) Présence de pesticides dans l'eau au 1398452, Québec: bilan dans des cours d'eau de zones en culture de maïs et de soya en 2002, 2003 1398453, et 2004, et dans les réseaux de distribution d'eau potable. Ministère du Développement durable, de l'Environnement et des Parcs, Direction du suivi de l'état de l'environnement, Direction des politiques de l'eau et Centre d'expertise en analyse environnementale du Québec. ISBN 2-550-46504-0, Envirodoq no ENV/2006/013, collection no QE/00173, 57 pages + 5 appendices.
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1311142	Byrtus, G., K. Pongar, C. Browning, R. Burland, E. McGuinness and D. Humphries (2004) A Summary of Pesticide Residue Data from the Alberta Treated Water Survey, 1995-2003, Alberta Environment, Alberta Research Council
1758182	Donald, D.B., A.J. Cessna, E.Sverko and N.E. Glozier (2007) Pesticides in Surface Drinking-Water Supplies of the Northern Great Plains. Environ. Health Perspect 115:1183-1191
1307577	Grover, R., D.T. Waite, A.J. Cessna, W. Nicholaichus, D.G. Irvin, L.A. Kerr and K. Best (1997) Magnitude and Persistence of Herbicide Residues in Farm Dugouts and Ponds in the Canadian Prairies. Environmental Toxicology and Chemistry 16(4):638-643

1307552 Donald, D.B., Narine P. Gurprasad, L. Quinnett-Abbott and K. Cash (2001) Diffuse Geographic Distribution of Herbicides in Northern Prairie Wetlands. Environmental Toxicology and Chemistry 20(2):273-279.

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1345581 Rawn, D.F.K., T.H.J. Halldorson, R.N Woychuk and D.C.G Muir (1999) Pesticides in the Red River and its Tributaries in Southern Manitoba:1993-95. Water Qual. Res. J. Canada 34(2): 183-219

Unpublished information

PMRA Document Number	Reference
1311110	(2004) Presence, Levels and Relative Risks of Priority Pesticides in Selected Canadian Aquatic Ecosystems. An Environment Canada Pesticide Science Fund Project. Year 1 (2003/04) Annual Report. Unpublished.
1311111	(2005) Unpublished Pesticide Science Fund Annual Report 2004-2005. (Water, Air, Plants, Mammals and Amphibians; and Fish and Birds.
1311112	(2004) Unpublished National Water Monitoring Data. Pesticide Science Fund
1403269	(2006) Pesticide Science Fund Annual Report 2005-2006. Prepared in fulfilment to Treasury Board Commitments by Environment Canada.
1311143	2004) Alberta Environment. Raw data for Byrtus, G., K. Pongar, C. Browning, R. Burland, E. McGuinness, D. Humphries (2004). A Summary of the Pesticide Residues from the Alberta Treated Water Survey, 1995-2003
1311128	(2000) Unpublished data on detections of Pesticides in Municipal Water Supplies (1981 - 1999)
1311107	(2004) Unpublished Water Monitoring Data Collected in Reservoirs of the Prairie Region (2003-2004). Pesticide Science Fund (PSF)

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