PRVD2007-09

Proposed Re-evaluation Decision

Chlorsulfuron

(publié aussi en français)

3 October 2007

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

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ISBN: 978-0-662-46971-1 (978-0-662-46972-8)
Catalogue number: H113-27/2007-9E (H113-27/2007-9E-PDF)

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Overview

What Is the Proposed Re-evaluation Decision?

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

An evaluation of available scientific information found that products containing chlorsulfuron do not present unacceptable risks to human health or the environment. As a condition of the continued registration of chlorsulfuron uses, new risk-reduction measures must 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 chlorsulfuron 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 chlorsulfuron 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 chlorsulfuron.

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).

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, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

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

Chlorsulfuron, one of the active ingredients in the current re-evaluation cycle, has been re-evaluated under the 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 regulatory 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 regulatory 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 (e.g. the federal Toxic Substances Management Policy [TSMP]).

Based on the health and environmental risk assessments published in the 2005 RED, the USEPA concluded that chlorsulfuron was eligible for reregistration provided risk-reduction measures are 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 Chlorsulfuron?

Chlorsulfuron is a herbicide used to control weeds in wheat, barley and oat crops as well as on non-crop areas, i.e. rights-of way, industrial sites, lumber yards, railroads, airports, storage areas, pipelines and non-pastured rough turf. Chlorsulfuron is applied using a variety of ground equipment, such as groundboom, by farm workers and professional applicators.

Health Considerations

Can Approved Uses of Chlorsulfuron Affect Human Health?

Chlorsulfuron is unlikely to affect your health when used according to revised label directions.

People could be exposed to chlorsulfuron 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 (e.g. 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 chlorsulfuron 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 required.

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 *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/on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Chlorsulfuron is currently registered in Canada for use on wheat, barley and oats and could be used in other countries on crops that are imported into Canada. No specific MRLs have been established for chlorsulfuron 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 may be implemented in the future, as indicated in the Discussion Document DIS2006-01, *Revocation of the 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be set.

Environmental Considerations

What Happens When Chlorsulfuron Is Introduced Into the Environment?

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

The USEPA concluded that the reregistration of chlorsulfuron 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 required. Furthermore, the PMRA will require aquatic and terrestrial buffer zones for 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 chlorsulfuron, the PMRA is proposing further risk-reduction measures for product labels.

Human Health

- Additional protective equipment to protect mixer/loader/applicators
- A restricted-entry interval to protect workers re-entering treated sites

Environment

- Additional advisory label statements to reduce potential surface and groundwater contamination
- Buffer zones and a limit of one application per season to protect aquatic and terrestrial habitats

Next Steps

Before making a final re-evaluation decision on chlorsulfuron, 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] document 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

Chlorsulfuron is a herbicide that acts by inhibition of the activity of acetolactate synthase, an enzyme required for plant cell growth.

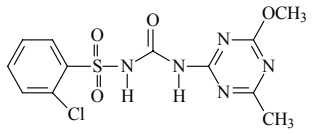
Following the re-evaluation announcement for chlorsulfuron, the registrant of the technical grade active ingredient in Canada indicated that they intended to provide continued support for all uses included on the labels of commercial and domestic class end-use products in Canada.

The PMRA used recent assessments of chlorsulfuron from the United States Environmental Protection Agency (USEPA). The USEPA Reregistration Eligibility Decision (RED) document for chlorsulfuron, dated 20 May 2005, as well as other information on the regulatory status of chlorsulfuron in the United States can be found on the USEPA Pesticide Registration Status page at www.epa.gov/pesticides/reregistration/status.htm.

2.0 The Technical Grade Active Ingredient, Its Properties and Uses

2.1 Identity of the Technical Grade Active Ingredient

Common name	Chlorsulfuron
Function	Herbicide
Chemical family	Sulfonylurea
Chemical name	
1 International Union of Pure and Applied Chemistry (IUPAC)	1-(2-Chlorophenylsulfonyl)-3-(4-methoxy-6-methyl-1,3,5-triazin-2-yl)urea
2 Chemical Abstracts Service (CAS)	2-Chloro-*N*-[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl] benzenesulfonamide
CAS Registry Number	64902-72-3
Molecular formula	$C_{12}H_{12}ClN_5O_4S$

Structural formula	
Molecular weight	357.8 amu
Purity of the Technical Grade Active Ingredient	98% nominal (lower limit: 95%; uppper limit: 100%)
Registration Number	19564

Nitrosamines were analysed in the technical grade active ingredient and were not detected at or above the limit of detection (LOD) of 1 ppm. Based on the manufacturing process, the product is not expected to contain impurities of human health or environmental concern as identified in Regulatory Directive DIR98-04, *Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product*, Section 2.13.4 or Toxic Substances Management Policy (TSMP) Track 1 substances as identified in Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, Appendix II.

2.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Result
Vapour pressure	3×10^{-6} mPa (at 25°C)
Henry's law constant	**pH** **Constant ($Pa \cdot m^3\ mol^{-1}$)** 5 5×10^{-10} 7 3.5×10^{-11} 9 3.2×10^{-12}
Ultraviolet (UV)–visible spectrum	Not expected to absorb UV at $\lambda > 300$ nm
Solubility in water at 25°C	pH 5: 590 mg/L pH 7: 31800 mg/L
n-Octanol–water partition coefficient	Log K_{ow} = -0.99 (at pH 7)
Dissociation constant (p*K*a)	p*K*a = 3.4

2.3 Comparison of Use Patterns in Canada and the United States

Chlorsulfuron is a herbicide registered in Canada to control a variety of weeds. It acts by inhibition of the activity of acetolactate synthase, an enzyme required for plant cell growth. Products containing chlorsulfuron are registered in Canada for use on food/feed crops (wheat, barley and oats) and on non-crop areas such as airports, industrial and roadside turf, utility and highway rights of ways, petroleum tank farms, lumber yards, industrial plant sites, fence lines and utility substations, railroads, storage areas and pipelines. It is applied at early postemergence

when weeds are actively growing. Chlorsulfuron is applied once per growing season with an application rate of up to 90 g a.i./ha on non-crop areas and 11.25g a.i./ha on food/feed crops. The end-use products are formulated as dry flowable and are applied using ground equipment.

The American and Canadian use patterns were compared. The Canadian formulation type of end-use products and use sites are among those registered in the United States. The maximum Canadian application rates include rates (11.25 g a.i./ha for food/feed crops and 90 g a.i./ha for non-food crops) lower than those registered in the United States (25.8 g a.i./ha for crop uses and 560 g a.i./ha for non-crop uses). Chlorsulfuron is applied only once per growing season in Canada, while it can be applied twice in the United States. The application methods Canadians can use are among those registered in the United States. Based on this comparison of use patterns, it was concluded that the USEPA RED for chlorsulfuron is an adequate basis for the re-evaluation of the Canadian uses of chlorsulfuron.

All current uses are being supported by the registrants and were, therefore, considered in the re-evaluation of chlorsulfuron. Appendix I lists all chlorsulfuron products that are registered under the authority of the *Pest Control Products Act*.

3.0 Impact on Human Health and the Environment

In their 2005 RED, the USEPA concluded that the end-use products formulated with chlorsulfuron 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 chlorsulfuron may occur through consumption of food and water, through residential exposure, when 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 (e.g. children and nursing mothers).

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 safety 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. The USEPA's toxicological endpoints for assessing of risk from occupational exposure are summarized in Appendix II.

3.1.1.1 Handlers

The USEPA did not anticipate intermediate (1–6 months) and chronic (> 6 months) exposures; therefore, no occupational risk assessments were calculated for these periods of exposure.

The PMRA identified a number of exposure scenarios for mixers, loaders, applicators and other handlers. Among the scenarios assessed in the RED, the following were considered relevant to the Canadian situation:

- Mixing/loading dry flowable for groundboom equipment
- Mixing/loading dry flowable for high-pressure handwand
- Applying sprays using a groundboom
- Applying sprays using high-pressure handwand

Handler exposure analyses were performed using the Pesticide Handlers Exposure Database (PHED), assuming baseling personal protective equipment (long pants, a long-sleeved shirt, shoes plus socks). Short-term dermal and inhalation risks were based on the maximum chlorsulfuron application rate of 156.8 g a.i./ha and a no observed adverse effect level (NOAEL) of 75 mg a.i./kg bw/day from a developmental study in the rabbit (target MOE of 100), assuming 100% absorption through dermal and inhalation routes.

The USEPA reported acceptable short-term MOEs ranging from 2000 to 56 000 for all combined (dermal + inhalation) occupational exposure scenarios. Based on these quantitative assessments, baseline personal protective equipment, without gloves as well as some additional basic hygiene label statements were required for all uses.

The RED adequately addressed potential exposure scenarios associated with the Canadian uses of chlorsulfuron, and conclusions derived from the RED apply to the Canadian situation. Therefore, the PMRA requires that workers wear long pants, a long-sleeved shirt and shoes plus socks during mixing, loading, application and other handling activities. 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 USEPA did not assess postapplication risks to agricultural workers because no postapplication exposure scenarios were identified.

The 1992 USEPA Worker Protection Standard is intended to decrease the number of injuries from handling pest control products. A restricted-entry interval (REI) is the amount of time following a pesticide application during which workers are not allowed to enter the treated area. According to the Standard, the length of the REI is determined by the toxicity of the active

ingredient. In lieu of a postapplication risk assessment, an REI of 12-hours for all products containing chlorsulfuron used in agriculture was required as per the Worker Protection Standard.

The American decision regarding REIs applies to the Canadian situation, and the PMRA requires a 12-hour REI to further protect workers from postapplication exposure. The proposed label amendments are listed in Appendix III.

3.1.2 Non-Occupational Exposure and Risk Assessment

3.1.2.1 Residential Exposure

Residential exposure is estimated using the MOE approach described in Section 3.1.1. The toxicological endpoints selected by the USEPA for assessment of risk from residential exposure are summarized in Appendix II.

Homeowners can be exposed to chlorsulfuron when through mixing, loading and applying the pesticide or when entering a treated site. Toddlers can be exposed via "hand-to-mouth" and "object-to-mouth" activities and through incidental soil ingestion.

In the United States, chlorsulfuron is registered for use on turf and lawns in residential areas (homes, parks, etc.). Risk to adults from handling exposure and risk to adults and toddlers from postapplication exposure (including incidental ingestion by toddlers) were assessed. These scenarios were not of concern because the MOEs ranged between 8800 and 190 000.

Based on the Canadian use pattern, no residential exposure is expected.

3.1.2.2 Exposure from Food and Drinking Water

No acute toxicological endpoint was identified, and chlorsulfuron was classified as having "no evidence of carcinogenicity". On this basis, acute and cancer dietary risk assessments were not conducted.

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 a chronic reference dose (cRfD), which is the dose at which an individual could be exposed over the course of a lifetime and expect no adverse health effects. This cRfD is based on a relevant endpoint from toxicology studies. The chronic population-adjusted dose (cPAD) is the cRfD adjusted for the *Food Quality Protection Act* safety factor to be protective of the most sensitive subpopulation (see Appendix II).When the expected intake of residues is less than the cPAD, then chronic dietary exposure is considered to be acceptable by the USEPA.

Exposure to pesticides through drinking water can occur as a result of groundwater or surface water contamination. The acute (one day) and chronic (multiple year) drinking water risks are considered, using either modelling or actual monitoring data, if available, to estimate those risks. Modelling is carried out in tiers of increasing refinement and is designed to provide high-end estimates of exposure. The risk assessment may be conducted by the drinking water level of comparison (DWLOC) approach or assessed probabilistically in Dietary Exposure Evaluation Model (DEEM) or Lifeline.

For chlorsulfuron, drinking water exposure was addressed by calculating DWLOCs. To establish the maximum allowable contribution from water in the diet, how much food and residential exposures contribute to the overall risk was evaluated. Following this, the DWLOC was determined.

A Tier I chronic dietary risk assessment due to risk from food was conducted using the DEEM that incorporates food consumption from the United States Department of Agriculture 1989–1992 Continuing Survey of Food Intake by Individuals, resulting in 6.6% of the cPAD for the American population and 19.3% of the cPAD for the most sensitive population subgroup, i.e. children 1–6 years old. This assessment was based on a cPAD value of 0.02 mg/kg bw/day (NOAEL of 5 mg/kg bw/day and a *Food Quality Protection Act* safety factor of 3-fold due to data deficiencies in the toxicology database). Assumptions included tolerance residue levels and 100% crop treated.

Chlorsulfuron was found to be persistent and highly mobile in the environment. It also has the potential to reach surface water via runoff and/or spray drift and to contaminate groundwater via leaching. Estimated drinking water concentrations (EDWCs) were generated in the RED using Tier I computer models, i.e. Screening Concentration in Ground Water (SCI-GROW) for ground water and *Food Quality Protection Act* Index Reservoir Screening Tool (FIRST) for surface water. Based on a worst case scenario of two applications of chlorsulfuron equaling 370 g a.i./ha per year, resulting EDWCs were 3.5 ppb (acute and chronic) for groundwater, and 59.7 ppb (acute) and 41.3 ppb (chronic) for surface water. These tier I, modelled EDWCs are considered applicable to, if not conservative for, the Canadian situation because chlorsulfuron is only applied once at a maximum rate of 90 g a.i./ha in Canada.

Uses on wheat, barley and oats assessed in the United States are also registered in Canada; however, the maximum application rate is lower in Canada. The assessment also included American residue tolerance levels (e.g. 0.1 ppm in wheat). Therefore, the USEPA assessment is considered applicable to the Canadian situation.

No MRLs have been established for chlorsulfuron residues in Canada. Thus, residues of chlorsulfuron in all commodities must not exceed the default MRL of 0.1 ppm[3].

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[3] Changes to this general MRL may be implemented in the future, as indicated in Discussion Document DIS2006-01, *Revocation of the 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be promulgated.

3.1.2.3 Aggregate Risk Assessment

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

EDWCs were compared to DWLOCs. The DWLOCs were calculated by combining risk estimates from food and residential exposures for short-term exposure with risk estimates from food for chronic exposure. For the most sensitive subpopulations outlined previously, the short-term DWLOC was determined to be 1461 ppb, and the chronic DWLOC was determined to be 161 ppb. Because the EDWCs were lower than the DWLOCs, short-term and chronic aggregate exposures were considered to be acceptable, and no mitigation with respect to aggregate risk was required.

Overall, the Canadian potential 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 chlorsulfuron in Canada.

3.1.3 Cumulative Effects

The USEPA has not determined whether chlorsulfuron 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 chlorsulfuron 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

Chlorsulfuron was found to be persistent and highly mobile in the environment. It also has the potential to reach surface water via runoff and/or spray drift and contaminate groundwater via leaching.

To assess the ecological risk of chlorsulfuron to non-target terrestrial and aquatic plants and animals, the USEPA calculated risk quotients (RQs) based on appropriate toxicity endpoints and expected environmental concentrations (EECs) and compared the resulting RQs to corresponding levels of concern (LOCs).

Chlorsulfuron was found to be practically non-toxic to birds, mammals and terrestrial insects; risk was not of concern for those species at rates relevant to the Canadian situation. It was found to be practically non-toxic to slightly toxic to freshwater and estuarine/marine fish and invertebrates; risk was not of concern for those species at rates relevant to the Canadian situation.

EECs for terrestrial plant were calculated based on application rates ranging up to 157 g a.i./ha for ground application using the AgDRIFT model. This model estimates exposure from off-target drift or runoff. In this refined assessment, RQs ranged from 3 to 83 for drift and runoff, and from 12 to 259 for drift and no runoff, thereby exceeding the LOC for non-target and endangered terrestrial plants (LOC = 1.0). Screening level RQs for semi-aquatic areas (wetlands) exceeded the LOC for ground application at 157 g a.i./ha (RQs ranged from 20 to 1552; LOC = 1.0), which suggested to the USEPA that non-target plants might be adversely affected through the use of contaminated irrigation waters. The USEPA concluded that sensitive crops in fields that are irrigated using surface water or groundwater contaminated with chlorsulfuron could possibly be adversely affected (RQs were 2 to 36 for ground water irrigation and 7 to 136 for surface water irrigation; LOC = 1.0). Therefore, the USEPA concluded that there is a risk to non-target terrestrial and semi-aquatic plants from chlorsulfuron.

Aquatic EECs were estimated using the the Pesticide Root Zone Model and the Exposure Analysis Modeling System (PRZM-EXAMS), surface water model. Modelling was based on two scenarios, aerial application on wheat at 26 g a.i./ha and aerial application on turf at 70 g a.i./ha. Screening-level RQs, ranging from 17 to 31 for non-target and endangered/threatened aquatic plants, exceeded the USEPA's LOC (LOC = 1.0).

Based on concerns regarding the risks to non-target terrestrial, semi-aquatic and aquatic plants, the USEPA required the maximum single application rate be limited to 120 g a.i./ha for non-crop uses, the number of applications be reduced to one application per year and statements to minimize water contamination and spray drift be added to the labels of end-use products containing chlorsulfuron.

The American use pattern for chlorsulfuron encompasses the Canadian use pattern, and the risk-reduction measures recommended by the USEPA must be applied to Canadian products containing chlorsulfuron. The USEPA mitigation measures will be adapted to the Canadian situation as follows.

- The rate reduction to 120 g a.i./ha required in the RED does not apply to Canada because the maximum Canadian label rate is 90 g a.i./ha.

- Although the Canadian registrants indicated to the PMRA that chlorsulfuron is applied only once per year for all uses, the directions for use on the Canadian end-use product labels are unclear. Therefore, a label statement is required to ensure that chlorsulfuron will only be used once per growing season.

- The PMRA requires additional label statements to minimize water contamination.

- The PMRA calculated terrestrial and aquatic buffer zones using the PMRA Field Sprayer Model v. 2.0 to minimize spray drift to non-target species during ground applications. Appendix IV shows the model inputs used for the buffer zone calculations. The resulting buffer zone distances are included in the label amendments listed in Appendix III.

The proposed label amendments are listed in Appendix III.

3.2.2 Toxic Substances Management Policy Considerations

The management of toxic substances is guided by the 1999 federal Toxic Substances Management Policy (TSMP), which puts forward a preventive and precautionary approach to deal with substances that enter the environment and which could harm the environment or human health. The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. One of the key management objectives is virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative. These substances are referred to in the policy as Track 1 substances.

The federal Toxic Substances Management Policy and PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, were taken into account during the re-evaluation of chlorsulfuron. The PMRA has reached the following conclusions.

- Chlorsulfuron is not bioaccumulative. The *n*-octanol–water partition coefficient (log K_{ow}) is −0.99 at pH 7, which is below the TSMP Track 1 cut-off criterion of ≥5.0. Chlorsulfuron does not meet all Track 1 criteria; thus, it is not a candidate for Track 1 classification.

- Nitrosamines were identified by the PMRA as a potential microcontaminant based on the manufacturing process. Batch analysis data of the technical grade active ingredient showed that nitrosamines were not detected at or above the LOD of 1 ppm. The technical grade active ingredient is not expected to contain other impurities of human health or environmental concern as identified in DIR98-04, Section 2.13.4, or TSMP Track 1 substances as identified in DIR99-03, Appendix II.

- Formulant issues are being addressed through the PMRA formulant initiatives and the Regulatory Directive DIR2006-02, *Formulants Policy and Implementation Guidance Document*, published on 31 May 2006.

4.0 Proposed Regulatory Decision

The PMRA has determined that chlorsulfuron is acceptable for continued registration 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 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.

5.0 Supporting Documentation

PMRA documents, such as Regulatory Directive DIR2001-03, and DACO tables can be found on our website at www.pmra-arla.gc.ca. 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 chlorsulfuron is available on the USEPA Pesticide Registration Status page at www.epa.gov/pesticides/reregistration/status.htm.

List of Abbreviations

a.i.	active ingredient
amu	atomic mass unit
bw	body weight
CAS	Chemical Abstracts Service
cPAD	chronic population adjusted dose
cRfD	chronic reference dose
DEEM	Dietary Exposure Evaluation Model
DWLOC	drinking water level of comparison
EDWC	estimated drinking water concentration
EEC	expected environmental concentration
EXAMS	Exposure Analysis Modeling System
FIRST	FQPA Index Reservoir Screening Tool
FQPA	*Food Quality Protection Act*
g	gram(s)
ha	hectare
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
K_{oc}	organic carbon partition coefficient
K_{ow}	*n*-octanol–water partition coefficient
L	litre(s)
LC_{50}	lethal concentration to 50%
LOC	level of concern
LOD	limit of detection
m^3	metre(s) cubed
mg	milligram(s)
mPa	milliPascal
MOE	margin of exposure
mol	mole
MRL	maximum residue limit
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
nm	nanometre
Pa	Pascal(s)
PCPA	*Pest Control Products Act*
pH	-log10 hydrogen ion concentration
PHED	Pesticide Handlers Exposure Database
p*K*a	-log10 acid dissociation constant
PMRA	Pest Management Regulatory Agency
ppb	parts per billion
ppm	parts per million
PRZM	Pesticide Root Zone Model
RED	Reregistration Eligibility Decision
REI	restricted-entry interval
RQ	risk quotient

SCI-GROW	Screening Concentration in Ground Water
SF	safety factor
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
UV	ultraviolet

Appendix I Registered Chlorsulfuron Products as of 13 June 2007

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee (%)
19564	Technical	E.I. Dupont Canada Company	Chlorsulfuron Technical Herbicide	Solid	98
25516	Manufacturing concentrate	E.I. Dupont Canada Company	Chlorsulfuron 75 DF MUP	Dry flowable	75
17245	Commercial	E.I. Dupont Canada Company	Glean Herbicide Dry Flowable	Dry flowable	75
21533	Commercial	E.I. Dupont Canada Company	Telar Herbicide Toss-N-Go Bags	Dry flowable	75

Appendix II Toxicological Endpoints for the Chlorsulfuron Health Risk Assessment

Exposure Scenario	Dose (mg/kg bw/day)	Study	Endpoint and UF/FQPA SF
Dietary Chronic All populations	NOAEL = 5.0	Chronic toxicity/ carcinogenicity in rat	UF = 300-fold Chronic RfD = 0.02 FQPA SF = 1-fold **cPAD = 0.02 mg/kg bw/day**
Incidental Oral Short-Term	NOAEL = 75	Developmental toxicity study in rabbit	UF = 300-fold FQPA SF = 1-fold **Target MOE = 300**
Incidental Oral Intermediate	NOAEL = 75	Developmental toxicity study in rabbit	UF = 300-fold FQPA SF = 1-fold **Target MOE = 300**
Dermal Short-term/ Intermediate	NOAEL = 75	Developmental toxicity study in rabbit	UF = 100-fold **Target Occupational MOE = 100** UF = 300-fold FQPA SF = 1-fold **Target Residential MOE = 300**
Dermal Long-Term	NOAEL = 5.0	Chronic toxicity/ carcinogenicity study in rats	UF = 300-fold FQPA SF = 1-fold **Target Residential MOE = 300**
Inhalation Short-Term/ Intermediate	Developmental NOAEL of 75	Developmental toxicity study in rabbit	UF = 100-fold **Target Occupational MOE = 100** UF = 300-fold FQPA SF = 1-fold **Target Residential MOE = 300**
Inhalation Long-Term	Systemic NOAEL of 5	Chronic toxicity/ carcinogenicity in rat	UF = 300-fold FQPA SF = 1-fold **Target Residential MOE = 300**

UF = uncertainty factor; FQPA SF = Food Quality Protection Act safety factor; target MOE = desired margin of exposure for occupational or residential assessments.

Appendix III Label Amendments for Products Containing Chlorsulfuron

The labels of Canadian end-use product must be amended to include the following statements to further protect workers and the environment.

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

Wear a long-sleeved shirt, long pants, shoes and socks during mixing, loading, application, clean-up and repair activities.

Do not apply this product in a way that will cause this product to contact workers or other persons, either directly or through drift. Only handlers (mixers, loaders and applicators) wearing personal protective equipment may be in the area being treated during application.

Do not enter or allow worker entry into treated areas for 12 hours following application and until sprays have dried.

II) The following statements must be included in the section entitled **DIRECTIONS FOR USE**.

DO NOT apply this product more than once per growing season.

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).

Avoid application of this product when heavy rain is forecast.

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) coarse classification.

DO NOT apply by air.

Buffer zones: The buffer zones specified in 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, rangelands, riparian areas and shrublands) and sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands).

Buffer Zone Requirements for Chlorsulfuron

Method of Application	Use	Buffer Zones (metres) Required for the Protection of:			
		Freshwater Habitat of Depths:			Terrestrial Habitat
		< 1 m	1 – 3 m	> 3 m	
Field sprayer*	Wheat, barley and oats	5	2	1	15
	Non-croplands	35	10	5	75**

* For field sprayer application, buffer zones can be reduced by 70% with the use of shroud spray shields, or 30% with the use of cone spray shields on booms.

** Terrestrial buffer zones are not required for rights-of-ways.

For application to rights-of-way, buffer zones for protection of sensitive terrestrial habitats are not required; however, the best available application strategies which 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.

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.

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

TOXIC to aquatic organisms and terrestrial plants. Observe buffer zones specified under DIRECTIONS FOR USE.

DO NOT apply this product directly to freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs, ditches and wetlands), estuaries or marine habitats. DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

The label amendments presented above do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements, and supplementary protective equipment. Additional 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.

Appendix IV Inputs to Buffer Zone Models for Chlorsulfuron

Ground Use Data (from Canadian labels)				
Crop	**Formulation Type**	**Method of Application**	**Number of Application**	**Maximum Application Rate (g a.i./ha)**
Wheat, barley and oats	Dry flowable	Field sprayer	1	11.25
Lumber yards, petroleum tank farms, plant sites, railroads, storage area	Dry flowable	Field sprayer	1	90
Rough turf areas such as roadsides, airports, industrial sites and utility and highway, right-of-ways, utility substations	Dry flowable	Field sprayer	1	90

Model Input Data for Aquatic Buffer Zones (from 2005 RED)		
Half life for aquatic buffer zones	N/A	Assumed stable
Most sensitive freshwater species	*Pseudokirchnerilla subcapita*	NOAEC = 9.5×10^{-6} mg a.i./L
Most sensitive estuarine/marine species	*Mysidopsis bahia*	1/10 LC_{50} = 8.9 mg a.i./L

Model Input Data for Terrestrial Buffer Zones (from 2005 RED)		
Half life for terrestrial buffer zones	Soil degradation half-life	320 days
Most sensitive terrestrial plant species EC_{25} for vegetative vigour	Sugar beet—vegetative vigour	8.9 g a.i./ha