Proposed Re-evaluation Decision PRVD2014-06

Triflusulfuron-methyl

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Overview

What Is the Proposed Re-evaluation Decision?

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

An evaluation of available scientific information found that products containing triflusulfuron-methyl do not present unacceptable risks to human health or the environment when used according to the proposed label directions. As a condition of the continued registration of triflusulfuron-methyl uses, new risk reduction measures are proposed for the end-use product registered in Canada. No additional data are being requested at this time.

This proposal affects the end-use product containing triflusulfuron-methyl registered in Canada. Once the final re-evaluation decision is made, the registrant will be instructed how to address any new requirements.

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

The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the assessment of triflusulfuron-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).

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 DIR2012-02, *Re-evaluation Program Cyclical Re-evaluation*, presents the details of the cyclical re-evaluation approach.

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

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

What Is Triflusulfuron-methyl?

Triflusulfuron-methyl is a postemergence herbicide that belongs to the sulfonylurea class of crop protection chemicals, which inhibit the plant enzyme, acetolactate synthase. In Canada, this active ingredient is registered for control of certain broadleaved weeds and grasses in sugar beets and garden beets, as well as in root chicory (Ontario only). Triflusulfuron-methyl can be applied by applicators using groundboom equipment.

Health Considerations

Can Approved Uses of Triflusulfuron-Methyl Affect Human Health?

Triflusulfuron-methyl is unlikely to affect your health when used according to the proposed label directions.

Potential exposure to triflusulfuron-methyl may occur when applying the product, by entering treated sites, or through food and drinking water. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the level 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 effect in animal testing are considered acceptable for continued registration.

Toxicity endpoints established for technical triflusulfuron-methyl during the initial registration of products containing this active ingredient continue to meet current PMRA standards and policy.

Quantitative occupational mixer/loader/applicator and postapplication exposure and risk assessments were conducted. Risks are not of concern under current conditions of use. However, a standard 12-hour restricted-entry interval (REI) is proposed based on current PMRA practices. Residential postapplication dermal exposure is not expected. Based on the dietary exposure assessment, acute and chronic dietary exposure from food and drinking water are not of concern. No mitigation measures are proposed with regards to dietary exposure to triflusulfuron-methyl.

Environmental Considerations

What Happens When Triflusulfuron-Methyl Is Introduced Into the Environment?

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

Non-target terrestrial and aquatic organisms could be exposed to triflusulfuron-methyl in the environment. Based on exposure and risk assessments previously conducted by the PMRA at the time of the initial registration, the use of triflusulfuron-methyl was not expected to present a hazard to birds, mammals, aquatic invertebrates and fish. Identified risks to non-target aquatic and terrestrial plants were mitigated with the required buffer zone.

Terrestrial and aquatic buffer zones have been re-assessed by the PMRA during the re-evaluation using current models. Freshwater and terrestrial buffer zones of 1 and 3 m, respectively, are proposed to protect sensitive species. Standard advisory label statements are also required to further protect the environment.

Measures to Minimize Risk

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

Human Health
- Standard 12-hour REI.

Environment
- Standard advisory label statements to protect the environment.
- Revised buffer zones to protect non-target, sensitive aquatic and terrestrial habitats.

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 triflusulfuron-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

Triflusulfuron-methyl is a selective systemic herbicide. It belongs to the sulfonylurea chemical family and is classified as a Group 2 herbicide. The herbicidal activity of triflusulfuron-methyl is due to the inhibition of the plant enzyme acetolactate synthase (ALS), also called acetohydroxyacid synthase (AHAS).

Following the re-evaluation announcement for triflusulfuron-methyl, the registrant of the technical grade active ingredient in Canada indicated its intention to provide continued support for all uses included on the label of the commercial class end-use product currently registered in Canada.

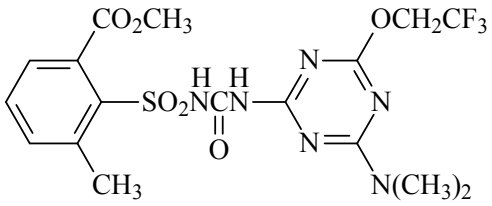
Currently registered products containing triflusulfuron-methyl are listed in Appendix I. All existing uses are being supported by the registrant and were, therefore, considered in the re-evaluation of triflusulfuron-methyl.

The purpose of this re-evaluation is to review existing information on the active ingredient, triflusulfuron-methyl, and the currently registered commercial class end-use product, to ensure that PMRA risk assessments meet the standards of modern science and current policy.

2.0 The Technical Grade Active Ingredient, Its Properties and Uses

2.1 Identity of the Technical Grade Active Ingredient

Common name			Triflusulfuron-methyl
Function			Herbicide
Chemical Family			Sulfonylurea
Chemical name	1	**International Union of Pure and Applied Chemistry (IUPAC)**	Methyl 2-[4-dimethylamino-6-(2,2,2-trifluoroethoxy)-1,3,5-triazin-2-ylcarbamoylsulfamoyl]-*m*-toluate
	2	**Chemical Abstracts Service (CAS)**	Methyl 2-[[[[[4-(dimethylamino)-6-(2,2,2-trifluoroethoxy)-1,3,5-triazin-2-yl]amino]carbonyl]amino]sulfonyl]-3-methylbenzoate
CAS Registry Number			126535-15-7
Molecular Formula			$C_{17}H_{19}F_3N_6O_6S$

Structural Formula	
Molecular Weight	492.4
Purity of the Technical Grade Active Ingredient	98%

Based on the manufacturing process used, impurities of human health or environmental concern as identified in the *Canada Gazette*, Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25), including TSMP Track 1 substances, are not expected to be present in the product.

2.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Result
Vapour pressure at 25°C	6×10^{-7} mPa
Ultraviolet (UV) / visible spectrum	λ_{max} = 230 nm Not expected to absorb at $\lambda > 300$ nm
Solubility in water at 25°C	pH — Solubility (mg/L) 3 — 1 5 — 3.8 7 — 260 9 — 11000
n-Octanol/water partition coefficient	pH — K_{ow} 5 — 220 7 — 9.2 9 — 0.86
Dissociation constant	4.4

2.3 Description of Registered Triflusulfuron-methyl Uses

Triflusulfuron-methyl is used as postemergence treatment on sugar beets, garden beets and root chicory (Ontario only). The commercial end-use product formulated as a 50% wettable granules can be applied alone (an adjuvant must be included) or in combination with BETAMIX (desmedipham and phenmedipham) using groundboom equipment.

Triflusulfuron-methyl can be applied as a broadcast application on:

- sugar beets - up to two applications at 17.5-35 g a.i./ha with a 5-10 days interval to a maximum of 50 g a.i./ha per season;
- garden beets - up to three applications at 18 g a.i./ha, when garden beets are in the 2-4 leaf, 4-6 leaf and 6-8 leaf stages, to a maximum of 54 g a.i./ha per season;
- root chicory (Ontario only) either as a single application at 35 g a.i./ha or two broadcast applications at 17.5 g a.i./ha with a re-treatment interval of 2-3 weeks to a maximum of 35 g a.i./ha per season prior to 4-leaf stage of velvetleaf.

For the band treatment, the recommended broadcast application rate is proportionally reduced based on the treated bandwidth.

3.0 Value

Triflusulfuron-methyl is one of the few active ingredients registered for the postemergent control of broadleaf weeds in sugar beets and garden beets in Canada. It can be tank-mixed with desmedipham plus phenmedipham (other herbicides used on sugar beets) to broaden the spectrum of weed control. It is the only alternative herbicide to carfentrazone-ethyl registered for use on root chicory in Ontario.

4.0 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.

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).

4.1 Toxicological Summary

In the toxicokinetic study in rats, triflusulfuron-methyl was shown to be well-absorbed when administered orally, extensively metabolized, and rapidly excreted in the urine and feces.

Triflusulfuron-methyl was found to be of low acute toxicity by the oral, dermal and inhalation routes of exposure, and minimally irritating to the skin and eyes. It was not a dermal sensitizer.

General effects found in short- and long-term oral administration of technical grade triflusulfuron-methyl to rodents and dogs included regenerative hemolytic anemia (rats), liver effects, and lower body weights. In the 2-generation rat reproductive study in rats, systemic effects in parental animals were observed at much lower doses than reproductive effects. No evidence of teratogenic effects in rats or rabbits was observed.

In chronic studies, an increased incidence of Leydig Cell tumors (adenomas) was reported in male rats but not in mice. Possible mechanisms of triflusulfuron-methyl-induced Leydig cell tumours in rats were studied in both in vivo and in vitro studies. The results indicated that triflusulfuron-methyl appears to inhibit the conversion of testosterone to estradiol by aromatase in vitro (in vivo results inconclusive). This aromatase inhibition is an established mechanism of disruption of the hypothalamic-pituitary-testis (HPT) axis. Disruption of the HPT axis is a well-recognized mechanism of Leydig cell adenoma formation in rats exposed to non-genotoxic compounds. A threshold for this effect exists; doses that do not disrupt the HPT axis should not cause tumours.

In a rabbit developmental toxicity study, abortions occurred during the last week of gestation in 8/16 dams at the lowest observed effect level (LOEL) and 12/20 dams at the next highest dose level. The same dose levels causing abortions also caused significant maternal toxicity (clinical signs, reduced food consumption and weight gain) and maternal deaths (2/20 at LOEL, 9/20 at next higher dose).

The prenatal developmental toxicity studies in rats and rabbits did not indicate increased susceptibility of fetuses following in utero exposure relative to the dams. No malformations occurred at any dose level in either study. In the rat developmental toxicity study, delayed ossification in the fetuses occurred at the LOEL, a dose resulting in maternal toxicity (reduced body weight gain, food consumption and efficiency). In the rat reproduction study, decreased maternal body weights/weight gain and F1 pup body weights during lactation were observed in the mid- and high-dose groups. There was no indication of sensitivity of the young.

Appendix II provides an overview of triflusulfuron-methyl toxicological endpoints used by the PMRA in human health risk assessments.

4.2 *Pest Control Products Act* Hazard Considerations

The *Pest Control Products Act* factor was not established as part of this assessment and is therefore not incorporated into the quantitative risk assessment.

The database contains the full complement of required studies including developmental toxicity studies in rats and rabbits and a multi-generation reproductive study in rats.

The prenatal developmental toxicity studies in rats and rabbits did not indicate increased susceptibility of fetuses following in utero exposure relative to the dams. No malformations occurred at any dose level in either study. In the rat developmental toxicity study, delayed ossification in the fetuses occurred at the LOEL, a dose resulting in maternal toxicity (reduced body weight gain, food consumption and efficiency). In the rat reproduction study, decreased maternal body weights/weight gain and F1 pup body weights during lactation were observed in the mid and high dose groups. There was no indication of sensitivity of the young.

Abortions occurred in the rabbit developmental toxicity study during the last week of gestation in 8/16 dams at the LOEL and 12/20 dams at the next highest dose level. The same dose levels causing abortions also caused significant maternal toxicity (clinical signs, reduced food consumption and weight gain) and maternal deaths (2/20 at LOEL, 9/20 at next higher dose).

Based on the information above, a qualitative assessment of the toxicity database suggests that the potential risks to sensitive subpopulations and the reliability of the scientific data are accounted for by the current assessment.

4.3 Dermal Absorption

A dermal absorption estimate of 100% was used in the dermal exposure assessment.

4.4 Occupational Exposure

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.

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

4.4.1 Mixer/Loader/Applicator Exposure and Risk

Workers can be exposed to triflusulfuron-methyl while mixing and loading the commercial end-use product and when applying using groundboom equipment. Based on the current triflusulfuron-methyl use pattern, there is a potential for short- to intermediate-term exposure of commercial mixer/loader/applicators.

A quantitative occupational mixer/loader/applicator exposure and risk assessment was recently conducted by the PMRA. The exposure dose for a mixer/loader/applicator wearing single layer clothing during all activities plus gloves during mixing/loading was estimated using unit exposure values from the Pesticide Handlers Exposure Database (PHED). A default area treated per day of 300 ha was assumed along with an application rate of 18 g a.i./ha, a dermal absorption factor of 100% and an average worker body weight of 70 kg. Using the no observed effect level (NOEL) of 4.06 mg/kg bw/day from the rat chronic/carcinogenicity study, the short- to intermediate-term total (dermal plus inhalation) MOE was 265 and not of concern (target MOE of 100).

Although the currently registered maximum application rate on sugar beets and root chicory (35 g a.i./ha) is 1.9 times higher than the assessed application rate (18 g a.i./ha), the estimated MOE provides a sufficient margin of protection to account for the difference in application rates. Further, the exposure and risk assessment is considered to be highly conservative, given the assumptions (for example, area treated per day and 100% dermal absorption) used.

The current end-use product label requires the worker to wear a long-sleeved shirt, long pants, shoes and socks while mixing/loading or applying the product. Chemical resistant gloves and a face shield or safety goggles are also required for mixing and loading.

Based on the above, the PMRA concluded that there are no occupational concerns with respect to triflusulfuron-methyl products under current conditions of use. No further risk mitigation measures are proposed.

4.4.2 Postapplication Exposure and Risk

Postapplication occupational risk assessments consider dermal exposure of workers entering treated agricultural sites to conduct agronomic activities involving foliar contact (for example, scouting). Based on the triflusulfuron-methyl use pattern, there is potential for short to intermediate-term (1-6 months) postapplication exposure for workers.

The postapplication exposure and risk assessment was updated during the re-evaluation using the default peak dislodgeable foliar residue (DFR) value of 25% retained on foliage on day zero (plus 10% dissipation per day) and updated re-entry activity specific transfer coefficients (TCs). Additional assumptions included the maximum application rates for sugar beets and garden beets, a retreatment interval (RTI) of five (sugar beets) or seven (garden beets) days, a dermal absorption factor of 100%, and an average worker body weight of 70 kg. The resulting MOEs (greater than 228) for workers conducting agronomic activities involving foliar contact following applications of triflusulfuron-methyl were above the target MOE of 100. On this basis, the PMRA concluded that there are no concerns with respect to postapplication workers re-entering treated fields.

A standard 12-hour restricted entry interval (REI) is proposed based on current PMRA practices. The proposed label amendments are listed in Appendix IV.

4.5 Non-occupational Exposure

4.5.1 Residential Exposure and Risk

Domestic-class products containing triflusulfuron-methyl are not registered in Canada. Based on the registered use pattern for the commercial class end-use product, postapplication residential exposure is not anticipated.

4.5.2 Residue Limits in Food Commodities

Canadian maximum residue limits (MRLs) for triflusulfuron-methyl were established at 0.05 ppm on sugar beet, sugar, molasses and on root chicory, and at 0.01 ppm on garden beet roots and garden beet tops. There are currently no Codex MRLs established for residues of triflusulfuron-methyl in or on food commodities. The USEPA's tolerances for triflusulfuron-methyl were established at 0.01 ppm on garden beet roots and 0.02 ppm on garden beet tops, as well as 0.05 ppm on sugar beet roots, sugar beet tops and root chicory.

4.5.3 Dietary Exposure and Risk

Acute and chronic dietary exposure assessments were recently conducted using Dietary Exposure Evaluation Model - Food Commodity Intake Database (DEEM-FCID) Software, Version 2.03. The basic chronic and acute dietary risk exposures were conducted using proposed and established Canadian MRLs and American tolerances for imported commodities. A value of 10% was added to the acceptable daily intake (ADI) and the acute reference dose (ARfD) to account for exposure from drinking water.

Acute dietary risk was calculated considering the highest ingestion of triflusulfuron-methyl that would likely occur on a single day, and using food consumption and food residue values. A statistical analysis allows all possible combinations of consumption and residue levels to estimate a distribution of the amount of triflusulfuron-methyl residue. A value representing the high end (95^{th} percentile) of this distribution is compared to the ARfD and expect no adverse health effects. When the expected intake of residues is less than the acute reference dose, then acute dietary exposure is considered acceptable. The acute dietary exposure from food and drinking water was estimated to be 10.3% of the ARfD established for the general population.

A 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 ADI, which is the amount an individual could be exposed to over the course of a lifetime and expect no adverse health effects. When the expected intake of residues is less than the acceptable daily intake, then chronic dietary exposure is considered acceptable. The basic chronic dietary (food and water) exposure risk estimates were below 100% of the ADI for the general population and all subgroups. The highest estimated risk, from food and drinking water, was for children 1-2 years of age (19.7 % of the ADI).

There was adequate evidence to support a threshold-based mode of action to the Leydig cell tumours in male rats. The established ADI provides an adequate margin to the dose at which Leydig cell tumours were observed. Therefore, a separate dietary cancer risk assessment was not required.

Based on the results of the dietary assessment, dietary exposure to triflusulfuron-methyl is not expected to result in a risk of concern. No further mitigation measures are proposed.

4.5.4 Aggregate Exposure and Risk

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

Triflusulfuron-methyl is not registered for residential uses, therefore, only food and drinking water residues are expected to contribute to aggregate exposure for this active ingredient. Dietary exposure to triflusulfuron-methyl residues in food and drinking water was below the level of concern (for more details see Section 4.5.3).

4.6 Cumulative Exposure and Risk

A common mechanism of toxicity has not been found for triflusulfuron-methyl and other pesticide products, nor is this active ingredient considered to produce a metabolite common to other pesticide active ingredients. Therefore, a cumulative risk assessment was not conducted.

5.0 Environment

5.1 Fate and Behaviour in the Environment

An environmental evaluation of triflusulfuron-methyl was conducted by the PMRA for the original registration. Triflusulfuron-methyl was found to be soluble to very soluble in water at an environmental-relevant pH. Triflusulfuron-methyl was not persistent in water. Hydrolysis was found to be a major route of transformation with triazine amine and methyl saccharin as transformation products. Phototransformation was not expected to be a major route of transformation of triflusulfuron-methyl. The active was expected to be of low volatility.

Triflusulfuron-methyl was not persistent in soil in aerobic and anaerobic biotransformation studies, respectively. The major biotransformation products were triazine amine and methyl saccharin. Under aerobic condition, these transformation products underwent further microbial transformation with the estimated half-lives of 40 days and 50 days, respectively. No further transformation of these products occurred under anaerobic conditions.

Triflusulfuron-methyl was expected to be highly to very highly mobile in sandy loam soils, and very highly mobile in silty clay, silt loam, and loamy sand soils, however, a short half-life of 6 -7 days in soil suggested that triflusulfuron-methyl was unlikely to leach into groundwater. The active ingredient was found to transform rapidly during the adsorption phase. Methyl saccharin was found to be the most mobile of the transformation products.

Triflusulfuron-methyl was unlikely to have a bioaccumulation potential based on the low octanol-water partition coefficient.

5.2 Environmental Exposure and Risk

To assess the ecological risk of triflusulfuron-methyl to both terrestrial and aquatic non-target plants and animals, the PMRA calculated risk quotients (RQs) based on appropriate toxicity endpoints and expected environmental concentrations (EEC's) and compared the resulting RQs to corresponding levels of concern (LOCs).

Triflusulfuron-methyl was classified as non-toxic to honey bees. In acute studies, technical triflusulfuron-methyl was found to be non-toxic to birds, aquatic invertebrates and fish, and to be of low toxicity to mammals. Triflusulfuron-methyl was classified as phytotoxic.

In a chronic reproductive study in birds, an increase in the percentage of cracked eggs and a decrease in eggshell thickness compared with the control group were observed in the bobwhite quail. Mallard ducks demonstrated a reduction in body weight of hens during the first eight weeks of the study and a reduction in the number of laying hens during the first three weeks of egg production.

Using the EECs, triflusulfuron-methyl was not expected to present a hazard to earthworms or pollinators, and was not expected to pose a risk to birds or mammals exposed to a contaminated diet. Triflusulfuron-methyl was not expected to pose a direct risk to aquatic invertebrates or to freshwater fish and algae. The calculated RQs indicated a significant risk to non-target terrestrial plant species and to aquatic vascular plants.

To protect sensitive terrestrial and aquatic habitats, buffer zones were calculated at the time of the initial assessment to minimize spray drift to non-target species during ground application. Terrestrial and aquatic buffer zones have been recalculated by the PMRA using current models. Freshwater and terrestrial buffer zones of 1 and 3 m, respectively, are proposed to protect sensitive species. Appendix III shows inputs to buffer zone calculations. Further, standard environmental label statements are proposed for the end-use product based on the current PMRA practices. The proposed label statements are listed in Appendix IV.

6.0 Pest Control Product Policy Considerations

6.1. 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, in other words, 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, triflusulfuron-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. In order for triflusulfuron-methyl to meet Track 1 criteria, the criteria for both bioaccumulation and persistence (in one medium) must be met. The PMRA has reached the following conclusions:

- Persistence. Triflusulfuron-methyl was found unlikely to persist in soil (half-life in aerobic soils of up to 50 days). Given that TSMP Track 1 criterion is a half-life in soil or water ≥182 days or in sediment >365 days it is concluded that triflusulfuron-methyl does not meet the criteria for persistence.
- Bioaccumulation. The log K_{ow} of 0.96 (pH 7) [K_{ow} of 9.2] for triflusulfuron-methyl is below the TSMP Track 1 criterion (log $K_{ow} \geq 5$). On this basis, it is concluded that triflusulfuron-methyl does not meet the criteria for bioaccumulation.
- Triflusulfuron-methyl does not meet any Track 1 criteria and therefore is not considered a Track 1 substance.

6.2 Contaminants and Formulants of Health or Environmental Concern

During the re-evaluation of triflusulfuron-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 triflusulfuron-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.

During the review process, the potential presence of impurities known to have, or suspected to have, health and/or environmental implications are assessed in accordance with DIR98-04.[4]

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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] DIR98-04, *Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product.*

7.0 Incident Reports

Since 26 April 2007, registrants have been 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 triflusulfuron-methyl as of 22 November 2013.

8.0 Organisation for Economic Co-operation and Development Status of Triflusulfuron-methyl

Canada is part of the Organisation for Economic Co-operation and Development (OECD), which groups 34 member countries and provides governments with a setting in which to discuss, develop and perfect economic and social policies.

As part of the re-evaluation of an active ingredient, the PMRA takes into consideration recent developments and new information on the status of an active ingredient in other jurisdictions, including OECD member countries. In particular, decisions by an OECD member to prohibit all uses of an active ingredient for health or environmental reasons are considered for relevance to the Canadian situation.

Triflusulfuron-methyl is currently registered for use in other OECD countries, including the United States. No decision by an OECD member country to prohibit all uses of triflusulfuron-methyl for health or environmental reasons has been identified.

9.0 Proposed Re-evaluation Decision

The PMRA is proposing that products containing triflusulfuron-methyl for sale and use in Canada are 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 the label statements listed in Appendix IV. No additional data are being requested at this time.

10.0 Supporting Documentation

PMRA documents, such as Regulatory Directive DIR2012-02, *Re-evaluation Program Cyclical Re-evaluation*, 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.

List of Abbreviations

ADI	Acceptable Daily Intake
a.i.	active ingredient
ARfD	Acute Reference Dose
bw	body weight
CAS	Chemical Abstracts Service
cm	centimetre(s)
DACO	Data Code
EEC	Expected Environmental Concentration [also Estimated Environmental Concentration]
f	first generation
g	gram(s)
ha	hectare
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
K_{ow}	*n*-octanol–water partition coefficient
LC_{50}	Lethal Concentration to 50%
LOEL	Low Observed Effect Level
mg	milligram(s)
MOE	Margin of Exposure
MRL	Maximum Residue Limit
nm	nanometre
m	metres
mPa	milipascal
NOEL	No Observed Effect Level
pH	-log10 hydrogen ion concentration
PHED	Pesticide Handlers Exposure Database
PMRA	Pest Management Regulatory Agency
ppm	parts per million
PRVD	Proposed Re-evaluation Decision
REI	Restricted Entry Interval
TC	Transfer Coefficient
TGAI	Technical Grade Active Ingredient
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
UV	ultraviolet

Appendix I Registered Products Containing Triflusulfuron-methyl as of 22 November 2013

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee (%w/w)
25812	Technical	E.I. du Pont Canada Co.	Triflusulfuron Methyl Technical Herbicide	Solid	98%
25813	Commercial	E.I. du Pont Canada Co.	UpBeet Herbicide	Wettable granules	50%
26482	Manufacturing concentrate	E.I. du Pont Canada Co.	Triflusulfuron Methyl 50 DF Herbicide	Wettable granules	50%

Appendix II Toxicological Endpoints for Triflusulfuron-methyl Health Risk Assessments

Exposure Scenario	Dose (mg/kg bw/day)	Study	UF or target MOE[1]
Acute Dietary General Population	NOEL = 90	Rabbit gavage developmental study, Reduced maternal body weight gains during initial days following initiation of dosing, LOEL ≥270 mg/kg	100
	ARfD = 0.9 mg/kg bw/day		
Chronic Dietary	NOEL = 4.06	Rat chronic/oncogenicity study; Reduced body weights/body weight gains and erythrocyte counts; increased Leydig cell hyperplasia, LOEL of 30.6 mg/kg bw/day	100
	ADI = 0.04 mg/kg bw/day		
Intermediate-term Dermal and Inhalation[2]	NOEL = 4.06	Rat chronic/oncogenicity study; Reduced body weights/body weight gains, and erythrocyte counts; increased Leydig cell hyperplasia, LOEL of 30.6 mg/kg bw/day	100
Dermal absorption factor	100% (no dermal in vivo absorption study available)		
Cancer	Evidence of carcinogenicity [increased incidence of Leydig cell adenomas]; MOE approach for risk assessment.		

ARfD = Acute Reference Dose; ADI = Acceptable Daily Intake; NOEL = No Observed Effect Level; LOEL = Lowest Observed Effect Level.

[1] UF refers to a total of uncertainty factors for dietary assessments; Target MOE refers to a target MOE for occupational assessments.

[2] Since an oral NOEL was selected, an inhalation factor of 100% was used in route-to-route extrapolation.

Appendix III Inputs to the Buffer Zone Models

Ground Use Data (from product labels)					
Crop	**Formulation Type**	**Method of Application**	**Number of Applications**	**Maximum Application Rate (g a.i./ha)**	**Application Interval (days)**
sugar beet	WG	Field (medium)	1-2	35	5
garden beet	WG	Field (medium)	3	18	7
root chicory	WG	Field (medium)	1	35	NA

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	Rainbow trout 1/10 LC50 > 21 mg a.i./L
Most sensitive freshwater species	*Lemna gibba* (duckweed) IC_{25} =2.03 µg a.i./L
Most sensitive estuarine/marine species	*Skeletonema costatum* (greville) ½ IC_{50}>33.75 µg a.i./L

Model Input Data for Terrestrial Buffer Zones	
Half-life for terrestrial buffer zones	10 days
Most sensitive terrestrial plant species	Sorghum IC_{25} of 0.5792 g a.i./ha

Appendix IV Label Amendments for End-Use Products Containing Triflusulfuron-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 following label statements. A submission to request label revisions will be required within 90 days of finalization of the re-evaluation decision.

I) The following statements must be included in a section entitled **DIRECTIONS FOR USE**:

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.

DO NOT apply by air.

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, wood lots, 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 (meters) Required for the Protection of:		
		Freshwater Habitat of Depths:		Terrestrial habitat
		Less than 1 m	Greater than 1 m	
Field sprayer	sugar beet garden beet root chicory	1	1	3

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.

II) The following statements must be included in a section entitled **PRECAUTIONS**:

DO NOT enter or allow worker entry into treated areas during the Restricted Entry Interval (REI) of 12 hours.

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

Toxic to aquatic organisms 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.

IV) The statements included in a section entitled **STORAGE** must be replaced with the following statement:

To prevent contamination store this product away from food or feed.

References

A. Studies/Information Considered in the Chemistry Assessment

Studies/Information Submitted by Applicant/Registrant (Unpublished)

PMRA Document Number	Reference
1544573	2003, Technical Grade Triflusulfuron Methyl (DPX-66037): Manufacturing Description and Formation of Impurities, DACO: 2.11
1544574	2003, Triflusulfuron Methyl (DPX-66037): Analysis and Certification of Product Ingredients for Technical Grade Material Produced at the [CBI Removed], DACO: 2.12.1, 2.13, 2.13.2, 2.13.3
1527787	1997, Triflusulfuron Methyl Technical Active Ingredient (Upbeet Herbicide - End Use Product), DACO: 2.0
1178811	1992, The Photodegradation of 14C-DPX-66037 in Buffer Solutions of pH 5, 7 and 9, DACO: 8.2.3.3.2

Additional Information Considered (Published)

The e-Pesticide Manual, CDS Tomlin, 13th edition, British Crop Protection Council, 2004-05, entry 837.

B. Studies/Information Considered in the Toxicological Assessment

Additional Information Considered (Published)

REG99-03, Regulatory Note, Triflusulfuron-Methyl

C. Studies/Information Considered in the Occupational Exposure Assessment

PMRA Document Number	Reference
2115788	2008, Agricultural Re-entry Task Force (ARTF). Data Submitted by the ARTF to Support Revision of Agricultural Transfer Coefficients

D. Studies/Information Considered in the Dietary Exposure Assessment

Studies/Information Submitted by Applicant/Registrant (Unpublished)

PMRA Document Number	Reference
1196314	2004, Triflusulfuron-methyl: Magnitude of the Residue on Chicory, DACO: 7.2.1, 7.2.5
1196513	2002, Independent Laboratory Validation of "Analytical method for the Determination of Triflusulfuron-Methyl in Sugar Beets and Red Beets by HPLC/MS/MS and Column Switching HLC-UV."DACO: 7.2.3
1196316	2005, Triflusulfuron-methyl: Magnitude of the Residue on Chicory, DACO 7.3, 7.4.1
1708274	2001, Analytical Method for the determination of Triflusulfuron-methyl in Sugar Beets and Red Beets by HPLC/MS/MS and Column-Switching HPLC-UV, DACO: 7.2.1
1708275	2008, Triflusulfuron-methyl: Magnitude of the Residue on Beet (Garden), DACO: 7.3, 7.4.1

Additional Information Considered (Published)

REG99-03, Regulatory Note, Triflusulfuron-Methyl

E. Studies/Information Considered in the Environmental Assessment

Additional Information Considered (Published)

REG99-03. Regulatory Note, Triflusulfuron-Methyl.