Proposed Re-evaluation Decision PRVD2011-11

Fluazifop-P-butyl

(publié aussi en français)

20 June 2011

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

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ISSN: 1925-0959 (print)
1925-0967 (online)

Catalogue number: H113-27/2011-11E (print)
H113-27/2011-11E-PDF (PDF version)

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Overview

What Is the Proposed Re-evaluation Decision?

After a re-evaluation of the herbicide fluazifop-P-butyl, 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 fluazifop-P-butyl for sale and use in Canada.

An evaluation of available scientific information found that products containing fluazifop-P-butyl 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 fluazifop-P-butyl 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 fluazifop-P-butyl 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 fluazifop-P-butyl 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 fluazifop-P-butyl.

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, *Pest Management Regulatory Agency Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Fluazifop-P-butyl, 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

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

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, which 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 risk assessments published in the 2005 Tolerance Reassessment Eligibility Document (TRED) and the 2008 Human Health Risk Assessment, the USEPA concluded that fluazifop-P-butyl was eligible for continued registration provided risk-reduction measures were adopted. The PMRA compared the American and Canadian use patterns and found the USEPA assessments 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 Fluazifop-P-butyl?

Fluazifop-P-butyl is a post-emergent herbicide that is used to control grass weeds in broadleaf crops and ornamentals. It acts by inhibiting fatty acid synthesis in the plant. Fluazifop-P-butyl is applied using ground spray equipment or handheld sprayers by farm workers or professional applicators.

Health Considerations

Can Approved Uses of Fluazifop-P-butyl Affect Human Health?

Fluazifop-P-butyl is unlikely to affect your health when used according to the revised label directions.

People could be exposed to fluazifop-P-butyl 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 PMRA concluded that fluazifop-P-butyl is unlikely to affect human health provided that the proposed risk-reduction measures are implemented.

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.

Fluazifop-P-butyl is currently registered in Canada for use on canola, creeping red-fescue, flax, lentils, mustard, peas (field), soybeans, sugar beets, sunflowers, tobacco, ginseng, alfalfa, red clover and birdsfoot trefoil, asparagus, broccoli, Brussels sprouts, cabbage, cauliflower, carrots, cucumber, onions, potatoes, rutabagas, lupins (sweet white), tomatoes, apples, pears, peaches, cherry (sweet and sour), apricots, plums, blueberries, non-bearing cranberries, strawberries, raspberries, grapes, and plant shrub, tree, forest and ornamental nurseries. Fluazifop-P-butyl may be used on other crops in other countries which are imported into Canada.

In Canada, MRLs have been established for soybeans, strawberries, mustard, flax, solin, blueberries, grapes, milk, eggs, meat, meat-byproducts and animal fat. 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 Fluazifop-P-butyl Is Introduced Into the Environment?

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

Non-target aquatic organisms and terrestrial plants could be exposed to fluazifop-P-butyl in the environment. The PMRA concluded that the continued registration of fluazifop-P-butyl is acceptable provided that the proposed risk-reduction measures to further protect the environment are implemented. The PMRA proposes aquatic and terrestrial buffer zones for fluazifop-P-butyl 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 health and the environment. These directions must be followed by law. As a result of the re-evaluation of fluazifop-P-butyl, the PMRA is proposing further risk-reduction measures for product labels.

Human Health

- Improvements to the personal protective equipment label statements and additional instructions concerning good hygiene practices.
- Hazard label statement regarding the sensitization potential.
- Prohibition of fluazifop-P-butyl use in greenhouses.
- A 12-hour restricted-entry interval to protect workers re-entering treated sites.

Environment

- Additional hazard label statements for risks to aquatic species.
- Additional advisory label statements to reduce potential surface and groundwater contamination.
- Buffer zones to protect non-target 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 fluazifop-P-butyl, 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.

Science Evaluation

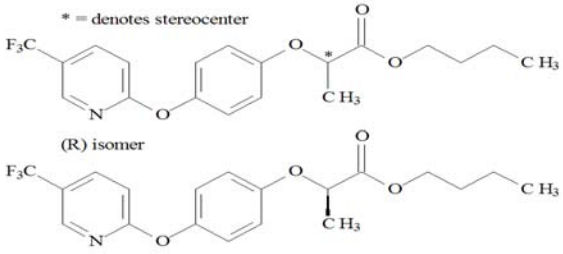
1.0 Introduction

Following the re-evaluation announcement for fluazifop-P-butyl, 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 fluazifop-P-butyl from the United States Environmental Protection Agency (USEPA). The USEPA Tolerance Reassessment Eligibility Document (TRED) for fluazifop-P-butyl, dated 13 September 2005, and the USEPA Human Health Risk Assessment (USEPA, 19 September 2008) as well as other information on the regulatory status of fluazifop-P-butyl in the United States can be found 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		Fluazifop-P-butyl
Function		Herbicide
Chemical Family		Aryloxyphenoxypropionate
Chemical name		
1	**International Union of Pure and Applied Chemistry (IUPAC)**	butyl (R)-2-[4-(5-(trifluoromethyl)-2-pyridyloxy)phenoxy]propionate
2	**Chemical Abstracts Service (CAS)**	butyl (+)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoate
CAS Registry Number		79241-46-6
Molecular Formula		$C_{19}H_{20}F_3NO_4$
Structural Formula		
Molecular Weight		383.4 amu

Based on the manufacturing process used, contaminants 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

Table 1 Physical and Chemical Properties of the Technical Grade Fluazifop-P-butyl

Property	Result
Vapour pressure	0.033 mPa
UV/Visible spectrum	No absorption above 300 nm
Solubility in water	1.1 mg/L
n-Octanol/Water partition coefficient	log K_{ow} = 4.5
Dissociation constant	< 1

2.3 Comparison of Use Patterns in Canada and the United States

Fluazifop-P-butyl is a post-emergent herbicide registered in Canada for control of grass weeds in:

- field crops: canola and triazine-tolerant canola, creeping red-fescue, flax, lentils, mustard, peas (field), soybeans, sugar beets, sunflowers, tobacco, ginseng;
- legume forages: alfalfa, red clover and birdsfoot trefoil;
- vegetables: asparagus, broccoli, Brussels sprouts, cabbage, cauliflower, carrots, cucumber, onions, potatoes, rutabagas, lupines (sweet white), tomatoes;
- fruit: apples, pears, peaches, cherry (sweet and sour), apricots, plums, blueberries, non-bearing cranberries, strawberries, raspberries, grapes; and
- ornamentals: plants, shrubs, trees, forest and ornamental nurseries.

Fluazifop-P-butyl is applied to actively growing grass weeds during 2-5 leaf stage. It is applied 1-3 times per year with an application rate of up to 250 g a.i./ha. Aerial application is not registered in Canada. The commercial end-use product is formulated as an emulsified concentrate and is applied using ground spray equipment or handheld sprayers.

The American and Canadian use patterns were compared. The Canadian formulation, guarantee and application equipment are encompassed by the USEPA assessments. The following Canadian uses are not encompassed by the USEPA assessments: cucumber, apple, pear, raspberry, blueberry, strawberry, cranberry, grape, alfalfa, birdsfood trefoil, red clover, mustard, canola, flax, and sunflower.

Based on this comparison of use patterns, it was concluded that the USEPA 2005 TRED, and the USEPA 2008 Human Health Risk Assessment, for fluazifop-P-butyl are an adequate basis for the re-evaluation of the Canadian uses of fluazifop-P-butyl. Additional occupational, post-application, dietary, pick-your-own and environmental assessments have been conducted by the PMRA.

All current uses are being supported by the registrant and were, therefore, considered in the re-evaluation of fluazifop-P-butyl. Appendix I lists all fluazifop-P-butyl products that are registered as of 15 December 2010, under the authority of the *Pest Control Products Act*.

3.0 Impact on Human Health and the Environment

In their 2005 TRED, the USEPA concluded that end-use products formulated with fluazifop-P-butyl met the safety standard under the *American Food Quality Protection Act* and would not pose unreasonable risks of adverse effects to humans.

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 fluazifop-P-butyl 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).

Fluazifop-P-butyl is of low acute toxicity via oral and dermal routes; and slight acute toxicity via the inhalation route. Fluazifop-P-butyl is a mild eye irritant, slight dermal irritant, and a skin sensitizer. Protective eyewear is required for mixers/loaders on the current label. Skin sensitization label amendments are proposed for the end-use product (Appendix III).

In 2005, the USEPA revised the fluazifop-P-butyl toxicology endpoints based on two-generation reproduction and developmental toxicity studies and determined that the degree of concern for pre-/post-natal toxicity is low. No exposures of concern were identified in the current PMRA human health risk assessments, based on the new USEPA toxicological endpoints, provided handlers follow the revised label directions. The 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.

Workers can be exposed to fluazifop-P-butyl 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 following occupational exposure scenarios were assessed by the PMRA:

- mixer/loader/applicator using ground boom equipment;
- mixer/loader/applicator using a low-pressure hand wand; and
- mixer/loader/ applicator using a backpack sprayer.

Short- and intermediate-term exposure for workers wearing coveralls and gloves, was assessed based on unit exposure values from the Canadian Pesticide Handlers Exposure Database (PHED), the maximum application rate of 250 g a.i./ha, a default area treated per day, a conservative dermal absorption factor of 9% and the USEPA toxicological endpoints.

Short- and intermediate-term combined (dermal plus inhalation) exposure for workers using groundboom, low-pressure hand wand and backpack sprayers was not of concern. The personal protective equipment (PPE) assumed for the risk assessment is already specified on the commercial end-use product label. The PMRA does not require additional mitigation measures; however, improvements to the PPE section of label and additional instructions concerning good hygiene practices are proposed.

Fluazifop-P-butyl is not registered for use in greenhouses; therefore, the PMRA did not assess the greenhouse application scenario. On this basis, the PMRA proposes a label statement prohibiting the use of fluazifop-P-butyl in greenhouses be added to the Direction For Use section of the end-use product label. The proposed label statement is listed in Appendix III.

3.1.1.2 Post-application Exposure and Risk

The post-application occupational risk assessment considered exposures to workers entering treated sites. Default dislodgeable foliar residue (DFR) and activity-specific transfer coefficients (TC) were used to analyze post-application exposure from contact with treated foliage at various times after treatment. DFR data include the amount of residue that can be dislodged or transferred from a surface, such as the leaves of a plant. A transfer coefficient is a factor that relates worker exposure to dislodgeable residues.

In Canada, workers could be exposed to fluazifop-P-butyl residues during scouting, irrigation, hand weeding and/or hand harvesting of field crops, vegetables, berries, vines and ornamental plants following the application. Based on default assumptions for residue deposition, and minimum foliage development, post-application exposure from scouting, irrigation and hand weeding activities is not of concern on the day of application. In addition, based on full foliage development, post-application exposure from hand-harvesting is also not of concern on the day of the pre-harvest interval (PHI).

A default 12-hour Restricted Entry Interval is proposed by the PMRA. Proposed label amendments are listed in Appendix III.

3.1.2 Non-Occupational Exposure and Risk Assessment

There is no domestic-class product containing fluazifop-P-butyl registered in Canada, therefore, residential handler exposure to fluazifop-P-butyl is not expected. The general public may be exposed to fluazifop-P-butyl through consumption of food and water and during pick-your-own (PYO) activities at berry or orchard operations.

3.1.2.1 Exposure from Food and Drinking Water

The PMRA conducted acute and chronic dietary exposure assessments for all registered commodities in Canada.

Acute dietary risk is calculated considering the highest ingestion of fluazifop-P-butyl that would be likely on any one day, and using food consumption and food residue values. A statistical analysis allows all possible combinations of consumption and residue levels to be combined to estimate a distribution of the amount of fluazifop-P-butyl residue that might be consumed in a day. A value representing the high end (95^{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.

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 (ADI), which is the dose at which an individual could be exposed over the course of a lifetime and expect no adverse health effects.

The ARfD and the ADI are based on relevant endpoints from toxicology studies and on uncertainty factors protective of the most sensitive subpopulation (see Appendix II). The PMRA adopted the ARfD for females age 13-49 from the 2005 USEPA TRED. No endpoint, which correlated to a single dose, was established by the PMRA, or the USEPA, for the general population including infants and children. Therefore, an acute dietary risk assessment was only conducted for females aged 13-49. The ADI of 0.005 mg/kg-bw/day for fluazifop-P-butyl used in the PMRA assessment is applicable to the general population and encompasses the USEPA chronic population adjusted dose (cPAD).

Acute and chronic dietary risk assessments were conducted by the PMRA using the Dietary Exposure Evaluation Model (DEEM–FCID™, Version 2.03), which incorporates food consumption data from the United States Department of Agriculture's Continuing Surveys of Food Intakes by Individuals (CSFII), 1994–1996 and 1998. The assessments also used Canadian MRLs, U.S. tolerances and default processing factors, as well as Canadian supervised trial mean/median residues (STMdRs), blended residues, experimental processing factors and/or field trials.

The PMRA acute dietary assessment included newly derived residue estimates in surface water from the 2008 USEPA assessment. For the chronic dietary risk assessment, as no chronic EEC value was available, 10% was added to the potential daily intake (PDI) to allocate for drinking water. Based on the recent review of Canadian water monitoring data, the maximum concentration of fluazifop-P-butyl detected in surface water is lower than residue estimates used in the PMRA risk assessments. On this basis, the PMRA dietary (food and drinking water) assessments are considered to be protective of detections of fluazifop-P-butyl in Canadian waters.

All dietary (food and drinking water) exposure scenarios were less than 100% of the ARfD and ADI, and therefore, not of concern. The acute exposure estimate from food and water, for females age 13-49, is 6.38% of the ARfD or 0.032 mg/kg bw/day, at the 95th percentile. The highest chronic dietary exposure estimate from food and water is 60.8% of the ADI for infants less than 1 year old. The PMRA does not require additional mitigation measures or label amendments relating to dietary risk.

3.1.2.2 Pick Your Own Exposure

"Pick Your Own (PYO)" farms are those that allow the public to harvest their own fruits and vegetables. As PYO fruit and vegetable operations become more and more prevalent, the PMRA recognizes the need for a means of assessing exposure to pesticides during hand-harvesting by members of the public. For the purpose of this risk assessment, PYO facilities are considered commercial farming operations that allow public access for harvesting in large-scale fields or orchards treated with commercially labelled fluazifop-P-butyl products.

A quantitative post-application assessment of the potential risk of exposure incurred by the public at PYO facilities was conducted for strawberries. Strawberries were considered representative of the registered orchard and berry crops.

Post-application inhalation exposure is not expected due to the air exchange in outdoor settings and the low vapour pressure of fluazifop-P-butyl. Consequently, only two exposure pathways were considered for the PYO exposure assessment: ingestion of fruit and dermal exposure through contact of the fruit or foliage. Although members of the public who harvest at PYO facilities may be of any age, an acute dietary endpoint for fluazifop-P-butyl was only identified for females 13-49. Therefore, the PMRA assessed acute dietary and dermal exposures and risks only for this population subgroup.

The acute dietary risk for females eating strawberries during PYO activities was assessed based on the 95th percentile of the exposure estimate for females 13-49 years old for the consumption of strawberries alone. The default DFR value on the day of the PHI, and the default hand-harvesting TC, were used to estimate dermal exposure during strawberry picking. The estimated acute dietary and dermal MOEs for females hand harvesting and consuming strawberries during PYO activities were above the target MOE, therefore, not of concern.

The PMRA does not require additional mitigation measures.

3.1.2.4 Aggregate Risk Assessment

Aggregate risk combines the different routes of exposure to fluazifop-P-butyl (food, water and residential exposures). In Canada, fluazifop-P-butyl is not registered for residential use; therefore, risk from aggregate exposure is expected from food and drinking water alone, and the exposure associated with PYO operations. No risks of concern were identified in the PMRA food and drinking water assessment. In addition, the aggregate PYO exposure (dermal and acute dietary) was not of concern on the day of the PHI for females age 13-49. Consequently, no mitigation measures are required.

3.1.3 Cumulative Effects

The USEPA determined that fluazifop-P-butyl does not have a common mechanism of toxicity with other substances. No cumulative risk assessment was conducted by the USEPA.

3.2 Environment

Environmental Risk Assessment

The USEPA (2005) determined that fluazifop-P-butyl is not mobile and not persistent. The aerobic soil half life of fluazifop-P-butyl is in the order of several hours. The predominant environmental fate process is microbial-assisted hydrolysis. The primary transformation products of fluazifop-P-butyl are fluazifop-acid and 5-trifluoromethyl-2-pyridone. The degradation products are more mobile and persistent than the parent compound; however based on their toxicity, are not expected to be of environmental concern.

To characterize the toxicity of fluazifop-P-butyl to non-target species, the PMRA used available environmental toxicity data including data from the European Food Safety Authority (EFSA) Draft Assessment Report (DAR) for fluazifop-P-butyl. Based on available data, the PMRA determined that fluazifop-P-butyl is toxic to aquatic organisms. The PMRA requires environmental hazard labelling for aquatic species and runoff; as well as additional directions for use label statements.

Aquatic and terrestrial buffer zones were calculated by the PMRA to minimize spray drift to non-target species during ground application. The PMRA will require terrestrial and aquatic buffer zones of 1 – 5 meters to protect aquatic organisms and terrestrial plants from spray drift. Proposed label amendments are listed in Appendix III. Inputs to buffer zone models are described in Appendix IV.

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, fluazifop-P-butyl 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. The PMRA has reached the following conclusions:

Fluazifop-P-butyl does not meet the Track 1 criterion for persistence in soil, as the half-life is less than the TSMP criterion of 182 days. In addition, fluazifop-P-butyl does not meet the Track 1 criteria for bioaccumulation, as the log K_{ow} is less than the TSMP criterion of 5. Therefore, fluazifop-P-butyl is not considered a Track 1 substance.

3.3.2 Contaminants and Formulants of Health or Environmental Concern

During the re-evaluation of fluazifop-P-butyl, 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*. 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 fluazifop-P-butyl does not contain any contaminants of health or environmental concern identified in the *Canada Gazette.*

The fluazifop-P-butyl end-use product contains an aromatic petroleum distillate. The presence of a petroleum distillate is noted in the toxicological information section and precautions section of the current label. The First Aid section of the label is consistent with DIR 2007-01 guidelines for products containing a petroleum distillate. The PMRA requires revised environmental hazard labelling for petroleum distillates. Proposed label amendments are listed in Appendix III.

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

3.3.3 Other Contaminants of Toxicological Concern

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[2].

4.0 Incidence 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.

As of 2 December, 2010, seven incident reports have been reported to the PMRA for products containing fluazifop-P-butyl. Two of the incidents occurred in Canada and lead to human exposure from being accidentally sprayed with the product. A third incident involving a fire at a warehouse facility in Canada where several pesticides, including products containing fluazifop-P-butyl, were being stored was reported to the PMRA. Water from fighting the fire entered a stream via the storm drain system, and a fish kill was reported. The causality of the other four incidents could not be established by the PMRA because the incidents occurred in the United States.

5.0 Organization for Economic Co-operation and Development Status of Fluazifop-P-butyl

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.

Based on the current available information on the status of fluazifop-P-butyl in other OECD member countries, the European Union review of fluazifop-P-butyl is ongoing (Draft Assessment Report was published in September 2007).

As described earlier in this document, the United States, also an OECD member assessed the dietary and residential risks of fluazifop-P-butyl in 2005 and concluded that using fluazifop-P-butyl as a pesticide does not result in unreasonable adverse effects to human health.

The Canadian re-evaluation of fluazifop-P-butyl is largely based on the 2005 and 2008 USEPA assessments. The PMRA has found the USEPA conclusions to be relevant to the use of fluazifop-P-butyl in Canada. Where necessary, PMRA assessments were also conducted. Concerns relating to teratogenic risk of the active ingredient were taken into consideration in the re-evaluation of fluazifop-P-butyl in Canada and have been addressed in the proposed Canadian re-evaluation decision.

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

6.0 Proposed Re-evaluation Decision

The PMRA has determined that fluazifop-P-butyl 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 as per 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 www.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/toxiques-toxics/.

The USEPA TRED document and Human Health Risk Assessment for fluazifop-P-butyl is available at www.regulations.gov.

The EFSA Draft Assessment Report for fluazifop-P-butyl 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
ARfD	acute reference dose
bw	body weight
CAS	Chemical Abstracts Service
cRfD	chronic reference dose
CSFII	Continuing Survey of Food Intakes by Individuals
DACO	data code
DAR	draft assessment report
DEEM	Dietary Exposure Evaluation Model
DFR	dislodgable foliar residue
EEC	expected environmental concentration [also estimated environmental concentration]
EFSA	European Food Safety Authority
K_{ow}	*n*-octanol–water partition coefficient
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*
PDI	potential daily intake
PHED	Pesticide Handlers Exposure Database
PIC	Prior Informed Concent
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
PRVD	Proposed Re-evaluation Decision
RED	Reregistration Eligibility Decision
REI	restricted-entry interval
TC	transfer coefficient
TGAI	technical grade active ingredient
TRED	Tolerance Reassessment Eligibility Document
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency

Appendix I

Registered Fluazifop-P-butyl Products as of 15 December 2010 (discontinued products excluded)

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
21208	Technical	SYNGENTA CROP PROTECTION CANADA INC.	FLUAZIFOP-P-BUTYL TECHNICAL	Solution	95.4 %
21209	Commercial	SYNGENTA CROP PROTECTION CANADA INC.	VENTURE L HERBICIDE	Emulsifiable Concentrate	125 g/L

Appendix II

Toxicological Endpoints Selected by the USEPA for Fluazifop-P-butyl Health Risk Assessments

Exposure Scenario	NOAEL (mg/kg bw/day)	Study	UF / target MOE[3]
Acute Dietary (females 13-49 years of age)	50 aPAD = 0.5	Developmental toxicity (rat)	UF = 100
Acute Dietary (General population)	An appropriate endpoint attributable to a single dose was not identified in the available studies including the developmental toxicity studies.		
Chronic Dietary (All populations)	0.74 cPAD = 0.0074	Two-generation reproduction (rat)	UF = 100
Short-Term Oral	100	Developmental toxicity (rat)	MOE = 100
Short-Term Inhalation, Dermal	2.0	Developmental toxicity (rat)	MOE = 100
Intermediate-Term Oral, Inhalation, Dermal	0.74	Two-generation reproduction (rat)	MOE = 100
Long-Term inhalation, Dermal	0.74	Two-generation reproduction (rat)	MOE = 100
Cancer	"Not likely to be carcinogenic to humans."		

Toxicological Endpoints Selected by the PMRA for Fluazifop-P-butyl Dietary Risk Assessment

Exposure Scenario	NOAEL (mg/kg bw/day)	Study	UF
Chronic Dietary (All populations)	0.5 ADI = 0.005	90 day rat feeding study	100

[3] UF refers to the total uncertainty factor for dietary assessments. MOE refers to the desired margin of exposure for occupational or residential assessments.

Appendix III

Label Amendments for Products Containing Fluazifop-P-butyl

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. Additional information on labels of currently registered products should not be removed unless it contradicts the label statements below.

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

The labels of end-use products in Canada must be amended as follows:

I) The following statement must be included on the primary display panel of the label:

POTENTIAL SKIN SENSITIZER

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

May be harmful if absorbed through skin. Avoid contact with skin and clothing. 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.

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 **DIRECTIONS FOR USE**.

DO NOT use in greenhouses.

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:

Use of the following spray methods or equipment DO NOT require a buffer zone: hand-held or backpack sprayer and spot treatment.

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:**		
		Aquatic Habitat of Depths:		**Terrestrial habitat**
		Less than 1 m	**Greater than 1 m**	
Field sprayer*	Ginseng	1	0	5
	All other crops	1	0	2

*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.

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

This product contains an active ingredient and aromatic petroleum distillates which are toxic to aquatic organisms. 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 Application	Maximum Application Rate (g ai/ha)
Ginseng	Emulsifiable concentrate	Field (medium)	3	250 g a.i./ha
All crops	Emulsifiable concentrate	Field (medium)	1	250 g a.i./ha

Table 2 Model Input Data for Aquatic and Terrestrial Buffer Zones

Model Input Data for Aquatic Buffer Zones[1]		
Half life for aquatic buffer zones	stable	
Most sensitive freshwater species	***Onchorynchus mykiss***	$^{1}/_{10}$ LC_{50} = 0.055 mg/L
Most sensitive estuarine/marine species	***Mysidopsis bahia***	$^{1}/_{10}$ LC_{50} = 0.27 mg/L
Model Input Data for Terrestrial Buffer Zones[2]		
Half life for terrestrial buffer zones	stable	
Most sensitive terrestrial plant species EC_{25} for vegetative vigour	*Zea mays*	½ ER50 = 4.55 g/ha

[1] Agriculture Canada Decision Document E88-01 for fluazifop-P-butyl. June 27, 1988. Based on Canadian end-use product formulation (Fusilade II 125EC, guarantee 125 g/L).

[2] European Food Safety Authority (EFSA) Draft Assessment Report (DAR). September 2007. Based active substance or the European end-use product formulation (Fusilade Max EC, guarantee 125 g/L).

References

A. Studies/Information Provided by the Applicant/Registrant-Unpublished

Studies Considered in the Chemistry Assessment

PMRA Document Number	Reference
1242274	2004, Chemical and Physical Properties Summary Ingredient, (TGAI) - Fluazifop-p-Butyl Technical Herbicide, DACO: 2.14.1,2.14.10,2.14.11,2.14.12,2.14.13,2.14.14,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6, 2.14.7,2.14.8,2.14.9 CBI
1242275	1999, Fluazifop-p-Butyl: Physical and Chemical Properties of Pure Material, DACO: 2.14.1,2.14.10,2.14.11,2.14.12,2.14.13,2.14.14,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6, 2.14.7,2.14.8,2.14.9 CBI
1242276	Fluazifop-p-Butyl (TGAI): Determination of Physical and Chemical Properties SPL Project Number: 1292/004, DACO: 2.14.1,2.14.10,2.14.12,2.14.13,2.14.14,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2. 14.8,2.14.9 CBI
1242277	2004, Discussion of Impurities of Toxicological Concern Ingredient (TGAI) - Fluazifop-p-Butyl Technical Herbicide, DACO: 2.13.4 CBI
1242278	Fluazifop-p-Butyl : Detailed Analysis of Technical Materials Representative of Large Scale Production, DACO: 2.13.3 CBI
1242279	2003, Fluazifop-p-Butyl : Mass Spectra Library of Fluazifop-p-Butyl and Associated Compunds, DACO: 2.13.2 CBI
1242280	The Determination of Enantiomer Ratio in Fluazifop-p-Butyl Technical Material by High Performance Liquid Chromatography, DACO: 2.13.2 CBI
1242281	The Determination of Fluazifop-Butyl and Associated Impurities in Fluazifop-p-Butyl Technical Material By Capillary Gas Chromatography, DACO: 2.13.2 CBI
1242282	The Determination of Polar Fluazifop-p-Butyl Associated Impurities in Technical Material by High Performance Liquid Chromatography, DACO: 2.13.2 CBI
1242283	Method Validation:AMP 10083-01B/VAL-01 the Determination of Fluazifop-p-Butyl Technical Material by Capillary Gas Chromatography, DACO: 2.13.1 CBI

1242284 Method Validation:AMP 10084-01A/VAL-01 the Determination of Enantiomer Ratio in Fluazifop-p-Butyl Technical Materials by High Preformance Liquid Chromatography, DACO: 2.13.1 CBI

1242285 Method Validation:AMP 10085-01B/VAL-01 the Determination of Polar Fluazifop-p-Butyl Associated Impurities in Technical Materials by High Preformance Liquid Chromatography, DACO: 2.13.1 CBI

1242286 Establishing Certified Limits Ingredient (TGAI) - Fluazifop-p-Butyl Technical Herbicide, DACO: 2.12.1 CBI

1242287 Discussion of Formation Impurities (Confidential Cross Reference 4), DACO: 2.11.4 CBI

1242288 Description of Product Process (Confidential Cross Reference 3), DACO: 2.11.3 CBI

1242289 Description of Materials Used to Produce the Product List of Starting Materials (Confidential Cross Reference 2), DACO: 2.11.2 CBI

1242290 Manufacturing Process PP 5 (ASF 615), Fluazifop-p-Butyl, DACO: 2.11.1 CBI

1242291 2004, Chemistry Requirements for the Registration of a Technical Grade Active Ingredient (TGAI) - Fluazifop-p-Butyl Technical Herbicide, DACO: 2.1,2.2,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9 CBI

B. Additional Information Considered - Published Information

Information Considered in the Canadian Water Monitoring Assessment

Published Information

PMRA Document Number	**Reference**
1311118	Anderson, A. 2005. Overview of pesticide data in Alberta surface waters since 1995. ISBN: 0-7785-3931-8 (Printed Edition), 0-7785-3933-4 (On-Line Edition). Alberta Environment, Environmental Monitoring and Evaluation Branch. Edmonton, Alberta.
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1311124. Byrtus, G., Anderson, A-M., and Saffran, K. 2002. Determination of New Pesticides in Alberta's Surface Waters (1999-2000). Prepared for The Water Research User Group, Alberta Environment.

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C. Additional Information Considered – Unpublished Information

Additional Unpublished Information Considered in the Health Assessment- Exposure

Unpublished Information PMRA Document Number	**Reference**
2028140	2005, Dietary (Food and Water) Exposure Assessment (DEA) Using DEEM FCID, DACO: FREAS_Dietary_Risk_Assessment