Proposed Registration Document PRD2014-05

Halosulfuron, present as methyl ester

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Overview

Proposed Registration Decision for Halosulfuron, present as methyl-ester

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Halosulfuron Technical Herbicide and the end-use products Sandea Herbicide, Permit Herbicide and SedgeHammer Turf Herbicide, containing the technical grade active ingredient halosulfuron, present as methyl ester (henceforth referred to as halosulfuron-methyl), for use in a broad range of field and horticultural crops for the control of yellow nutsedge and broadleaved weeds.

An evaluation of available scientific information found that, under the approved conditions of use, the products have value and do not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation section provides detailed technical information on the human health, environmental and value assessments of Halosulfuron Technical Herbicide and the end-use products Sandea Herbicide, Permit Herbicide and SedgeHammer Turf Herbicide.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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

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

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Before making a final registration decision on halosulfuron-methyl, the PMRA will consider all comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on halosulfuron-methyl, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

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

What Is Halosulfuron-methyl?

Halosulfuron-methyl is a Herbicide Resistance Action Committee (HRAC) Group B active ingredient commonly known as an inhibitor of acetolactate synthase, a key enzyme in plants. Halosulfuron-methyl is a selective herbicide for use in a broad range of field and horticultural crops for the control of yellow nutsedge and broadleaved weeds. Halosulfuron-methyl will be available as three commercial class end-use products: Sandea Herbicide (horticultural crop use); Permit Herbicide (field crop use); and SedgeHammer Turf Herbicide (turf and ornamental uses).

Health Considerations

Can Approved Uses of Halosulfuron-methyl Affect Human Health?

Products containing halosulfuron-methyl are unlikely to affect your health when used according to label directions.

Potential exposure to halosulfuron-methyl may occur through the diet (food and water) or when handling and applying the products. When assessing health risks, two key factors are considered: the levels where 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 the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

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

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

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

In laboratory animals, the technical grade active ingredient halosulfuron-methyl was of low acute oral, dermal and inhalation toxicity. It was minimally irritating to the eyes and non-irritating to the skin. Halosulfuron-methyl did not cause an allergic skin reaction.

The end-use products containing halosulfuron-methyl (Sandea, Permit and SedgeHammer Turf Herbicides) were slightly acutely toxic by the oral route and mildly irritating to the eyes; consequently, the hazard signal words "CAUTION – POISON" and "EYE IRRITANT" are required on the label. They were of low acute toxicity through both dermal and inhalation exposure, slightly irritating to the skin and did not cause an allergic skin reaction.

Halosulfuron-methyl did not cause cancer in animals and did not damage genetic material. Effects on the nervous system were seen in the rats and dogs at dose levels resulting in mortality. At doses toxic to the mothers, treatment with halosulfuron-methyl produced stillbirths and reduced pup survival and birth weights. Health effects in animals given repeated doses of halosulfuron-methyl included effects on body weight in all species, effects on the liver in rats and effects on the blood-forming system in dogs.

When halosulfuron-methyl was given to pregnant animals, increased embryofetal mortality and malformations of the tail and ribs in the developing fetus were observed at doses that were toxic to the mother. Because of these concerns, extra protective factors were applied in the risk assessment to further reduce the allowable level of human exposure to halosulfuron-methyl.

The risk assessment protects against the effects of halosulfuron-methyl by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Risks in Residential and Other Non-Occupational Environments

Residential and non-occupational risks are not of concern when SedgeHammer Turf Herbicide is used according to the proposed label directions.

Adults, youth and children may be exposed to halosulfuron-methyl while golfing on courses and conducting various activities on residential turf treated with SedgeHammer Turf Herbicide. Based on the expected short- to intermediate-term duration of this activity, risk to children, youth and adults is not a concern.

Occupational Risks From Handling Sandea Herbicide, Permit Herbicide, and SedgeHammer Turf Herbicide

Occupational risks are not of concern when Sandea Herbicide, Permit Herbicide, and SedgeHammer Turf Herbicide are used according to the proposed label directions, which include protective measures.

Farmers, custom applicators, and commercial applicators who mix, load or apply Sandea Herbicide, Permit Herbicide, or SedgeHammer Turf Herbicide as well as field workers re-entering freshly treated fields, orchards, commercial and residential turf, landscaped areas, nurseries, and industrial areas can come into direct contact with halosulfuron-methyl residues on the skin. Therefore, the label specifies that anyone mixing/loading and applying Sandea Herbicide, Permit Herbicide, or SedgeHammer Turf Herbicide must wear a long-sleeved shirt and long pants (or coveralls), chemical-resistant gloves, shoes and socks. Anyone who mixes/loads and applies SedgeHammer Turf Herbicide must wear coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, shoes and socks when treating roadsides and other industrial areas for horsetail with a mechanically-pressurized handgun. The Permit Herbicide label also requires that workers do not enter treated fields to detassel seed corn for 14 days after application. For other re-entry activities, the Sandea Herbicide and Permit Herbicide labels require that workers do not enter treated fields or orchards for 12 hours after application. The SedgeHammer Turf Herbicide label requires that workers do not enter treated areas until sprays have dried. Taking into consideration these label statements, the number of applications and the expectation of the exposure period for handlers and workers, the risk to these individuals are not a concern.

For bystanders, exposure is expected to be much less than that for workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

Residues in Water and Food

Dietary risks from food and drinking water are not of health concern.

Aggregate dietary intake estimates (food plus drinking water) revealed that the general population and children 1-2 years old, the subpopulation which would ingest the most halosulfuron-methyl relative to body weight, are expected to be exposed to less than 5% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from halosulfuron-methyl is not of health concern for all population subgroups.

Halosulfuron-methyl is not carcinogenic; therefore, a cancer dietary risk assessment is not required.

Acute dietary (food plus drinking water) intake estimates for the females 13-49 years of age were less than 1% of the acute reference dose, and are not of health concern.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted throughout the United States which included growing regions representative of Canada using halosulfuron-methyl on apples, highbush blueberries, raspberries, blackberries, rhubarb, asparagus, peppers (bell and non bell), tomatoes, cantaloupe, cucumber, summer squash, succulent snap beans, almonds, pecans, pistachios, dry beans, sweet corn, field corn, grain sorghum and proso millet are acceptable. The MRLs for this active ingredient can be found in the Science Evaluation section of this Consultation Document.

Environmental Considerations

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

Halosulfuron-methyl can pose a risk to freshwater algae and non-target terrestrial and aquatic vascular plants; therefore, statements on the product labels are required to inform users of the potential risks, and spray buffer zones are required during application.

Halosulfuron-methyl enters the environment when applied to control weeds on various field crops and non-crop areas. Halosulfuron-methyl can break down by reacting with water or in the presence of soil microbes and is unlikely to persist in terrestrial systems. Despite having properties that indicate a potential for leaching, field studies, monitoring and modelling data indicate that if halosulfuron-methyl reaches groundwater, levels are expected to be low. In aquatic environments, halosulfuron-methyl is rapidly broken down and is not expected to move into sediment or accumulate in aquatic organisms. Halosulfuron-methyl is also unlikely to enter the atmosphere. Although laboratory data indicate that breakdown products of halosulfuron-methyl are mobile and persistent, results from terrestrial field dissipation studies show little vertical movement and relatively quick dissipation.

When used according to the label directions, halosulfuron-methyl will pose a negligible risk to earthworms, bees, birds, small mammals, fish and aquatic invertebrates. Halosulfuron-methyl can pose a risk to freshwater algae and to non-target terrestrial and aquatic vascular plants. Risks to freshwater algae and non-target terrestrial and aquatic vascular plants can be mitigated with label statements and spray buffer zones to protect sensitive terrestrial and aquatic habitats. Runoff of halosulfuron-methyl into water bodies may pose a risk to freshwater algae and aquatic vascular plants. Label statements are required on the product labels to inform users of the potential risks.

Value Considerations

What Is the Value of Sandea Herbicide, Permit Herbicide and SedgeHammer Turf Herbicide?

Yellow nutsedge is a difficult-to-control perennial weed and chemical control options are lacking in almost all crops.

The registration of Sandea, Permit, and SedgeHammer Turf Herbicides will provide Canadian growers access to an active ingredient registered for many years in the United States, and will satisfy numerous weed control priorities found in the Canadian Grower Priority Database including: dry bean (high); apple (intermediate); highbush blueberry (high); asparagus (high); eggplant (high); tomatoes (high); pumpkin (high); squash (high), cucumber (high); snap bean (high); pecan (high); chestnut (intermediate).

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.

The key risk-reduction measures being proposed on the label of Sandea Herbicide, Permit Herbicide and SedgeHammer Turf Herbicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because there is a concern with users coming into direct contact with halosulfuron-methyl on the skin or through inhalation of spray mists, anyone mixing, loading and applying Sandea Herbicide, Permit Herbicide, or SedgeHammer Turf Herbicide must wear a long-sleeved shirt and long pants (or coveralls), chemical-resistant gloves, shoes and socks. Anyone who mixes/loads and applies SedgeHammer Turf Herbicide must wear coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, shoes and socks when treating roadsides and other industrial areas for horsetail with a mechanically-pressurized handgun.

The Permit Herbicide label also requires that workers do not enter treated fields to detassel seed corn for 14 days after application. For other re-entry activities, the Sandea Herbicide and Permit Herbicide labels require that workers do not enter treated fields or orchards for 12 hours after application. The SedgeHammer Turf Herbicide label requires that workers do not enter treated areas until sprays have dried. In addition, standard label statements to protect against drift during application were added to the label.

Environment

Halosulfuron-methyl can pose a risk to freshwater algae and to non-target terrestrial and aquatic vascular plants. Label statements and spray buffer zones to protect sensitive terrestrial and aquatic habitats are to be specified on the label.

To mitigate potential exposures via spray drift, spray buffer zones of 15 to 40 metres are required to protect sensitive terrestrial habitats, and spray buffer zones of 4 to 25 metres are required to protect sensitive aquatic habitats, depending on the crop. These spray buffer zones are to be specified on the product labels.

Next Steps

Before making a final registration decision on halosulfuron-methyl, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please note that, to comply with Canada's international trade obligations, consultation on the proposed MRLs will also be conducted internationally via a notification to the World Trade Organization. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency’s response to these comments.

Other Information

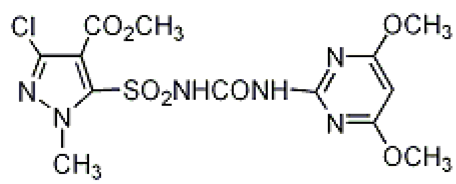
When the PMRA makes its registration decision, it will publish a Registration Decision on halosulfuron-methyl (based on the Science Evaluation section of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA’s Reading Room (located in Ottawa).

Science Evaluation

Halosulfuron-methyl

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Halosulfuron-methyl
Function	Herbicide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	methyl 3-chloro-5-(4,6-dimethoxypyrimidin-2-ylcarbamoylsulfamoyl)-1-methylpyrazole-4-carboxylate
2. Chemical Abstracts Service (CAS)	methyl 3-chloro-5-[[[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]amino]sulfonyl]-1-methyl-1*H*-pyrazole-4-carboxylate
CAS number	100784-20-1
Molecular formula	$C_{13}H_{15}ClN_6O_7S$
Molecular weight	434.82
Structural formula	
Purity of the active ingredient	96.2% as halosulfuron, 99.4% as halosulfuron-methyl

1.2 Physical and Chemical Properties of the Active Ingredients and End-Use Product

Technical Product—Halosulfuron-methyl Technical

Property	Result
Colour and physical state	White solid (powder)
Odour	Odourless
Melting range	175.5 – 177.2˚C
Boiling point or range	N/A as product is a solid at room temperature
Density	1.618 g/mL at 25°C
Vapour pressure at 25°C	<13 µPa
Henry's law constant at 20°C	3.4×10^{-11} atm·m³/mol
Ultraviolet (UV)-visible spectrum	In neutral and acidic methanol, λ_{max} is 203 nm; in basic methanol λ_{max} is 233 nm but sample appeared to decompose or dissociate.
Solubility in water at 20°C	<u>pH</u> — <u>Solubility (g/L)</u> 5 — 0.015 7 — 1.65 9 — 4.64 (sample not stable in basic water)
Solubility in organic solvents at 20°C (g/100 mL)	<u>Solvent</u> — <u>Solubility (g/L)</u> hexane — 0.01278 methanol — 1.616 toluene — 3.640 acetonitrile — 9.968 ethyl acetate — 15.26 acetone — 21.96 dichloromethane — 52.76
n-Octanol-water partition coefficient (K_{ow})	<u>pH</u> — <u>log K_{ow}</u> 5 — 1.67 7 — -0.02 9 — -0.54 (note – sample appeared to be unstable)
Dissociation constant (pK_a)	pK_a = 3.44
Stability (temperature, metal)	Stable upon exposure to zinc foil (reducing agent); degraded in aqueous solution upon exposure to elevated temperature or simulated sunlight.

End-Use Product—Sandea Herbicide, Permit Herbicide, SedgeHammer Turf Herbicide

Property	Result
Colour	Beige
Odour	Scorched vanilla
Physical state	Solid
Formulation type	Wettable granules
Guarantee	72.6% as halosulfuron
Container material and description	HDPE bottles Sandea 283.5 g, Permit 567 g, SedgeHammer 37.7 g
Density	0.541 g/mL
pH of 1% dispersion in water	6.6
Oxidizing or reducing action	Product is a reducing agent
Storage stability	Stable for 12 months in HDPE packaging under warehouse conditions
Corrosion characteristics	Not corrosive to commercial packaging
Explodability	Not explosive

1.3 Directions for Use

1.3.1 Sandea Herbicide

Sandea Herbicide is intended for selective weed control in the following horticultural crops: apple, caneberries (blackberry, loganberry, red and black raspberry), highbush blueberry, rhubarb, asparagus, peppers (chile, bell and banana), eggplant, tomatillo, pepino, groundcherry, cucumber, cantaloupe, honeydew, Crenshaw melon, watermelon, pumpkin, winter squash, summer squash for processing, succulent snap beans, tomatoes, okra and tree nuts. Apply 35-140 g/ha in a minimum of 140 L/ha of water, depending on the crop, to control labelled weeds. Sandea Herbicide may be applied pre-plant, pre-emergence or post-emergence. Sandea Herbicide may be applied via broadcast application or as a directed application at the base of the crop, or in between rows, depending on the crop and/or growth stage of the crop. Sandea Herbicide may be applied in tank mix with a labelled tank mix partner, where applicable. Sequential applications of Sandea Herbicide may be made where applicable, a minimum of 21 days apart.

1.3.2 Permit Herbicide

Permit Herbicide is intended for selective weed control in the following field crops: dry beans, sweetcorn, popcorn, field corn and corn grown for seed, grain sorghum and proso millet. Apply 35-93 g/ha in a minimum of 140 L/ha of water, depending on the crop, to control labelled weeds. Permit Herbicide may be applied pre-plant incorporated, pre-plant, pre-emergence, post-emergence or as a directed application at the base of the crop, or in between rows, depending on the crop and/or growth stage of the crop. Permit Herbicide may be applied in tank mix with a labelled tank mix partner, where applicable. Sequential applications of Permit Herbicide may be made where applicable, a minimum of 21 days apart.

1.3.3 SedgeHammer Turf Herbicide

Apply 35-93 g/ha for the control of labelled weeds in turfgrass, ornamentals or landscaped areas, and other specified non-crop areas. Apply 187 g/ha for the control of horsetail on specified non-crop areas only (such as roadsides, rights-of-way, tank farms, etc.). SedgeHammer Turf Herbicide may be applied in tank mix with a labelled tank mix partner, where applicable. Sequential applications of SedgeHammer Turf Herbicide may be made where applicable, a minimum of 21 days apart.

1.4 Mode of Action

Halosulfuron-methyl is classified as an Herbicide Resistance Action Committee Group B active ingredient commonly known as an acetolactate synthase (ALS) inhibitor. ALS is a key enzyme in the biosynthesis of certain branched chain amino acids and when it is blocked the biosynthesis of the branched-chained amino acids valine, leucine and isoleucine is inhibited. This inhibition leads to the rapid cessation of plant cell division and growth in plants. More specifically halosulfuron-methyl belongs to the sulfonylurea subgroup of ALS inhibitors.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

The methods provided for the analysis of the active ingredient and the impurities in Halosulfuron Technical Herbicide have been validated and assessed to be acceptable for the determinations.

2.2 Method for Formulation Analysis

The method provided for the analysis of the active ingredient in the formulations has been validated and assessed to be acceptable for use as an enforcement analytical method.

2.3 Methods for Residue Analysis

High-performance liquid chromatography methods with mass spectrometry or tandem mass spectrometry (HPLC-MS or MS/MS) were developed and proposed for data generation and enforcement purposes. These methods fulfilled the requirements with regards to selectivity, accuracy and precision at the respective method limit of quantitation. Acceptable recoveries (70–120%) were obtained in environmental media. Methods for residue analysis are summarized in Appendix I, Table 1.

Gas chromatography methods with nitrogen-phosphorous or electron capture detection were developed and proposed for data generation and enforcement purposes. These methods fulfilled the requirements with regards to specificity, accuracy and precision at the respective method limits of quantitation. Acceptable recoveries (70–120%) were obtained in plant and animal matrices. The proposed enforcement methods were successfully validated in plant and animal matrices by an independent laboratory. Adequate extraction efficiencies were demonstrated using radiolabelled samples of animal matrices analyzed with the enforcement method. Extraction solvents used in all plant methods were similar to those used in the metabolism studies; thus, further demonstration of extraction efficiency with radiolabelled crops was not required for the enforcement method.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

A detailed review of the toxicological database for halosulfuron-methyl was conducted. The database is complete, consisting of the full array of toxicity studies currently required for hazard assessment purposes. The studies were carried out in accordance with currently accepted international testing protocols and Good Laboratory Practices. The scientific quality of the data is high and the database is considered adequate to define the majority of the toxic effects that may result from exposure to halosulfuron-methyl.

In oral studies conducted with radiolabelled halosulfuron-methyl, absorption was rapid in rats, though incomplete, and distribution was extensive. According to a qualitative analysis of whole-body autoradiographs in treated pregnant females, there was limited to no placental transfer of the radiolabel. The highest levels of radioactivity in males, females and pregnant females were found in the plasma, whole blood, kidneys, liver and lungs. Elimination was rapid in nonpregnant animals given a single oral low dose, with all administered radioactivity excreted within 96 hours. While in pregnant animals given a single oral low dose, radioactivity was still detected up to 150 hours following a single high dose. Some radioactivity was still present at 7 days following a single high dose. The halosulfuron-methyl labelled on the pyrimidine moiety was retained in animals longer than the pyrazole-labelled compound. Bile was the major route of excretion in males and females. The major metabolites were 5-hydroxy desmethyl and desmethyl derivatives of halosulfuron-methyl.

In the rat, the acute toxicity of halosulfuron-methyl was low via the oral, dermal and inhalation routes of exposure. Halosulfuron-methyl was minimally irritating to the eyes and non-irritating to the skin of rabbits and was not a dermal sensitizer in guinea pigs.

The end-use-products, Sandea Herbicide, Permit Herbicide and SedgeHammer Turf Herbicide, were slightly acutely toxic via the oral route and low via the dermal and inhalation routes in rats. They were mildly irritating to the eyes and slightly irritating to the skin of rabbits and were not dermal sensitizers in guinea pigs.

In a 28-day dermal toxicity study, there were no adverse effects up to the limit dose in males or female rats.

In rats, decreased body weight and/or body weight gains were a common finding following repeat dosing. In a 28-day oral study, there was an increase in pancreatic acinar degeneration at the mid-high dose along with a decrease in food consumption and blood glucose at the highest dose. In the 13 week oral toxicity study, no effects on the pancreas were observed; effects consisted of decreased body weight, body weight gains and urinary volume, clinical chemistry parameters were affected and there was pathology of the liver and kidney.

In a 13-week oral dog study (capsule), there were effects on body weight gains, haematology parameters and liver weights in females with decreased protein and albumin at a higher dose. Males exhibited decreased protein and albumin at the same dose as females along with decreased body weight gains. In the one-year oral dog study (capsule), there was one mortality at the highest dose tested. Clinical signs, including those indicative of neurological changes, and decreased lymphocytes in males and decreased body weights and body weight gains, decreased food consumption, decreased haematological parameters and spleen weights and decreased cholesterol in females, were observed.

In a long-term dietary study in mice, there was an increase in microconcretions/mineralisation within the lumen of the epididymal and testicular tubules, with a concurrent decrease in testes and seminal vesicle weights at the highest dose tested. There were no effects on female mice and there was no evidence of carcinogenicity.

In the dietary chronic toxicity and carcinogenicity study in rats, body weights and body weight gains were decreased in males and females and an increase in clinical signs was noted in males at the high dose. There was no evidence of carcinogenicity.

Halosulfuron-methyl was considered non-genotoxic based on the results of a standard battery of in vitro and in vivo tests.

In the rat, effects of halosulfuron-methyl on reproductive performance occurred at doses higher than those causing maternal or offspring toxicity. In parental animals, there were decreases in body weight starting at the mid-dose in F_1 females at the beginning and ending of the second premating period. In offspring, body weights were decreased compared to controls at PND 7 – 21 in F_1 males and at PNDs 14 and 21 in F_1 females. At the high dose, reproductive toxicity was apparent with an increase in the number of stillborn pups in the F_{2a} litter and decreased birth weights in pups in both the F_{2a} and F_{2b} litters. At this dose, there were additional effects on the pups consisting of an increase in pup loss in both generations and reduced pup weights, and parental effects consisting of decreases in parental body weights and body weight gains in both sexes and both parental generations and decreased food consumption in adult F_1 females. These changes are indicative of serious effects in the presence of parental toxicity.

Developmental toxicity occurred at maternally toxic doses in rats and rabbits. In pregnant rats, clinical signs, decreased body weight, body weight gain, food consumption and food efficiency, increased total resorptions and postimplantation loss occurred with decreased fetal body weight, filamentous tail and increased soft tissue and skeletal variations in fetuses. In rabbits, decreased body weight and body weight gain, food consumption and food efficiency, increased early resorptions and decreased litter size in the dams occurred with fused-rib malformations in the fetuses.

In the oral neurotoxicity studies in rats, body weight effects were limited to males at the high-dose in the acute and subchronic studies. In the acute neurotoxicity study, at the high dose, there was one mortality and both males and females exhibited a decrease in rearing on Day 0 and incoordination in the righting reflex which was persistent in females. In a supplemental subchronic neurotoxicity study the potential for neurotoxicity could not be confidently characterized; however, body weight and body weight gain were decreased in males at the limit dose. Females were dosed without effect at lower dose levels. As previously discussed, there were suggestions of neurological effects at doses producing mortality in dogs.

A limited battery of tests was performed on 3-chlorosulfonamide acid, a plant and livestock metabolite of halosulfuron-methyl not identified in the rat metabolism study. It was found to be of low acute oral toxicity in rats and, following short-term oral dosing caused decreased body weights approaching the limit dose in females only. There were no effects in an oral gavage developmental toxicity study in rats. Of three genotoxicity studies, two were negative and one was equivocal at cytotoxic concentrations in the presence of metabolic activation. Overall, 3-chlorosulfonamide acid was not considered genotoxic.

Results of the toxicology studies conducted on laboratory animals with halosulfuron-methyl and its associated end-use products are summarized in Appendix I, Tables 2 and 3. The toxicology endpoints for use in the human health risk assessment are summarized in Appendix I, Table 4.

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. Information on the reporting of incidents can be found on the PMRA website. Incidents were searched and reviewed for active halosulfuron-methyl. As of 10 October 2013, there were three incident reports submitted to the PMRA for products containing halosulfuron-methyl. All three incidents involving accidental exposure occurred in the United States. The relationship to halosulfuron-methyl exposure was deemed definite in one case, possible in a second case and probable in a third case. In the definite and possible incidents, a chemical burn or rash developed on the skin. In the probable incident, nausea and eye irritation developed following exposure to the eyes. As the end-use product containing halosulfuron-methyl is a known skin and eye irritant, the PMRA concluded that the information from the incident reports was consistent with the toxicity database for Sandea, Permit and SedgeHammer Turf Herbicides.

3.1.1 *Pest Control Products Act* Hazard Characterization

For assessing risks from potential residues in food or from products used in or around homes or schools, the *Pest Control Products Act* requires the application of an additional 10-fold factor to threshold effects to take into account completeness of the data with respect to the exposure of, and toxicity to, infants and children, and potential prenatal and postnatal toxicity. A different factor may be determined to be appropriate on the basis of reliable scientific data.

With respect to the completeness of the toxicity database as it pertains to the toxicity to infants and children, extensive data were available for halosulfuron-methyl. The database contains the required studies including developmental toxicity studies in rats and rabbits and a reproductive toxicity study in rats.

With respect to potential prenatal and postnatal toxicity, effects of a serious nature were noted in the reproductive and developmental toxicity studies; however, these effects were observed in the presence of maternal toxicity. In the reproductive toxicity study, stillbirths and a decrease in pup viability were seen at the highest dose tested. The body weight of F_1 offspring and as both pups and adults was reduced at lower doses. Consequently, the parental and offspring NOAELs were approximately 8-fold less than the NOAEL for stillbirths/viability. In the rabbit developmental toxicity study, fused-rib malformations and early resorptions were observed at doses producing bodyweight effects in does. In a developmental toxicity study in rats, fetal malformations (filamentous tail), increased resorptions and post-implantation loss were observed in the presence of body weight effects and clinical signs in the dams. The NOAEL for these serious effects was 5-fold higher than the NOAEL for the serious effects noted in the rabbit developmental toxicity study.

Overall, the database is adequate for determining the sensitivity of the young. The effects on the young are well-characterized. The effects on the fetus and neonate were considered serious endpoints although the concern was tempered by the presence of maternal toxicity. Accordingly, where the selection of the rabbit developmental toxicity study was appropriate for risk assessment, the *Pest Control Products Act* factor was reduced to 3-fold. Where the selection of the reproductive toxicity study was appropriate for risk assessment, the *Pest Control Products Act* factor was reduced to 1-fold due to the intrinsic margin between the study NOAEL and the serious endpoints in that study.

3.2 Acute Reference Dose (ARfD)

Females 13-49 Years of Age

To estimate acute dietary risk (1 day) specific to females 13-49 years of age, the rabbit developmental toxicity study with a NOAEL of 50 mg/kg bw was selected for risk assessment. At the LOAEL of 150 mg/kg bw, fused-rib malformations and resorptions were observed in the presence of body weight effects in the dams. These effects could result from a single exposure and are therefore relevant to an acute risk assessment. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability have been applied. As discussed in the *Pest Control Products Act* Hazard Characterization section, the *Pest Control Products Act* factor was reduced to 3-fold. **The composite assessment factor (CAF) is 300.**

The ARfD is calculated according to the following formula:

$$\text{ARfD (♀ 13-49)} = \frac{\text{NOAEL}}{\text{CAF}} = \frac{\text{50 mg/kg bw}}{300} = \text{0.2 mg/kg bw of halosulfuron-methyl}$$

The ARfD provides a margin of 1250 to the NOAEL for developmental toxicity in the rat and is thus considered protective of pregnant women and their fetuses.

General Population (excluding females 13-49 years of age)

There were no effects in the toxicological database relevant to the establishment of an ARfD for the general population.

3.3 Acceptable Daily Intake (ADI)

To estimate risk following repeated dietary exposure, the reproductive toxicity study in rats with a NOAEL of 7.4 mg/kg bw/day was selected for risk assessment. At the LOAEL of 58.7 mg/kg bw/day, body weights were decreased in F_1 females and F_1 pups. This study provides the lowest NOAEL in the database. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability have been applied. As discussed in the *Pest Control Products Act* Hazard Characterization section, the *Pest Control Products Act* factor was reduced to 1-fold. **The composite assessment factor (CAF) is 100.**

The ADI is calculated according to the following formula:

$$\text{ADI} = \frac{\text{NOAEL}}{\text{CAF}} = \frac{\text{7.4 mg/kg bw/day}}{100} = \text{0.07 mg/kg bw/day of halosulfuron-methyl}$$

The ADI provides a margin of 839 to the NOAEL for stillbirths and decreased viability in the rat reproductive toxicity study and is thus considered protective of pregnant women and their fetuses and children.

Cancer Assessment

There was no evidence of carcinogenicity and therefore a cancer risk assessment is not necessary.

3.4 Occupational and Residential Risk Assessment

3.4.1 Toxicological Endpoints

Occupational exposure to halosulfuron-methyl is characterized as short- and intermediate-term and is predominantly by the dermal and inhalation route. Non-occupational exposure to halosulfuron-methyl is characterized as acute or short- to intermediate-term and is predominantly by the dermal and oral route.

Short- and Intermediate-term Dermal and Inhalation

For short- and intermediate-term exposures via the dermal and inhalation routes, the NOAEL of 7.4 mg/kg bw/day from the rat reproductive toxicity study was selected for risk assessment. At the LOAEL of 58.7 mg/kg bw/day, body weights were decreased in F_1 females and F_1 pups. Although a 28-day dermal study was available, the design of this study does not allow for the assessment of effects on the young following in utero exposure, and the effects defining the NOAEL for offspring toxicity in the reproductive toxicity study (body weight reductions) were observed in young animals that had been exposed to halosulfuron-methyl in utero. An oral endpoint was used to establish an inhalation endpoint for risk assessment, as a repeat-dose inhalation study was not available.

The target Margin of Exposure (MOE) for these scenarios is 100, which includes uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability. The selection of this study and MOE is considered protective of all populations including the unborn children of exposed female workers.

Non-Dietary Oral Ingestion (Children, Short-term)

Short-term non-dietary oral ingestion of halosulfuron-methyl was considered a potential route of exposure due to residential and turf use. The NOAEL of 7.4 mg/kg bw per day from the two-generation reproductive toxicity study was selected for risk assessment. At the LOAEL of 58.7 mg/kg bw/day, body weights were decreased in F_1 females and F_1 pups.

The target Margin of Exposure (MOE) for these scenarios is 100, which includes uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability. As outlined in the *Pest Control Products Act* Hazard Characterization section, the *Pest Control Products Act* factor was reduced to 1-fold. The selection of this study and MOE is considered protective of all populations including children.

Short-term Aggregate

Short-term aggregate exposure to halosulfuron-methyl may be comprised of food, drinking water, residential and turf exposure. The toxicological endpoint selected for aggregation for pregnant women, infants and children was reduced bodyweight. For the oral component, the NOAEL of 7.4 mg/kg bw/day from the reproductive toxicity study was selected with a target MOE of 100. For the dermal component, the NOAEL of 7.4 mg/kg bw/day from the reproductive toxicity study was selected with a target MOE of 100. While there was a dermal toxicity study, it did not address the effects in the F_1 generation seen in the reproductive toxicity study. For the inhalation component, the NOAEL of 7.4 mg/kg bw/day from the reproductive toxicity study was selected with a target MOE of 100 in the absence of a repeat-dose inhalation toxicity study. The *Pest Control Products Act* factor for all routes was 1-fold as set out in the *Pest Control Products Act* Hazard Characterization section.

3.4.1.1 Dermal Absorption

Dermal absorption data were not submitted for halosulfuron-methyl. As such, the default dermal absorption value of 100% was assumed for the risk assessment.

3.4.2 Occupational Exposure and Risk

3.4.2.1 Mixer/ Loader/ Applicator Exposure and Risk Assessment

Individuals have potential for exposure to halosulfuron-methyl during mixing, loading and application. Exposure to workers mixing, loading and applying Sandea Herbicide, Permit Herbicide, or SedgeHammer Turf Herbicide is expected to be short- to intermediate-term in duration and to occur primarily by the dermal and inhalation routes. Exposure estimates were derived for mixers/loaders/applicators applying Sandea Herbicide and Permit Herbicide to field crops and the ground of orchard crops using groundboom. Exposure estimates were derived for mixers/loaders/applicators applying SedgeHammer Turf Herbicide to commercial and residential turf, ornamentals and industrial areas using groundboom, manually-pressurized handwand, mechanically-pressurized handgun, backpack sprayer, right-of-way sprayer, and turf gun.

The exposure estimates are based on mixers/loaders/applicators with the following personal protective equipment:

- coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, shoes and socks when treating roadsides and other industrial areas for horsetail with a mechanically-pressurized handgun
- a long-sleeved shirt and long pants (or coveralls), chemical-resistant gloves, shoes and socks for all other mixing/loading/application scenarios

As chemical-specific data for assessing human exposures were not submitted, dermal and inhalation exposures were estimated using the Pesticide Handlers Exposure Database (PHED), version 1.1 for workers involved with application using groundboom, right-of-way sprayers, backpack sprayers, manually-pressurized handwand and mechanically-pressurized handgun. PHED is a compilation of generic mixer/loader and applicator passive dosimetry data with associated software which facilitates the generation of scenario-specific exposure estimates. Dermal and inhalation exposures for workers involved with low pressure handgun application were estimated using a study from the Outdoor Residential Exposure Task Force (ORETF).

Dermal exposure was estimated by coupling the unit exposure values with the amount of product handled per day and the dermal absorption value (100%). Inhalation exposure was estimated by coupling the unit exposure values with the amount of product handled per day with 100% inhalation absorption. Exposure was normalized to mg/kg bw/day by using 80 kg adult body weight.

Exposure estimates were compared to the toxicological endpoint (no observed adverse effects level [NOAEL] of 7.4 mg/kg bw/day) to obtain the margin of exposure (MOE); the target MOE is 100. Table 3.4.2.1.1 presents the PHED and ORETF unit exposure values used. Table 3.4.2.1.2 and Table 3.4.2.1.3 present the estimates of exposure and risk for Sandea Herbicide, Permit Herbicide and SedgeHammer Turf Herbicide. Calculated MOEs are above the target MOE of 100 for workers who wear the personal protective equipment stated on the product labels.

Table 3.4.2.1.1 PHED and ORETF Unit Exposure Estimates for Mixer/Loader/Applicators While Handling Sandea Herbicide, Permit Herbicide or SedgeHammer Turf Herbicide

Exposure scenario		PHED unit exposures (µg/kg a.i. handled)		
		Dermal	Inhalation	Combined*
Unit exposure values for single layer and CR gloves				
A	DF open mix/load	163.77	1.02	164.79
B	Open cab groundboom application (single layer only)	32.49	0.96	33.45
C	Right-of-way sprayer application	872.54	5.00	877.54
D	MLA Liquid backpack	5445.85	62.1	5507.95
E	MLA Liquid manually-pressurized handwand	943.37	45.2	988.57
F	MLA Liquid mechanically-pressurized handgun	5585.49	151	5736.49
G	MLA WDG with turf gun	1290	47.8	1337.8
A+B	MLA DF, open ML + groundboom A (no CR gloves during A)	196.26	1.98	198.24
A+C	MLA DF, open ML + right of way sprayer A	1036.31	6.02	1042.33
A+D	MLA DF, open ML + backpack A†	5609.62	63.12	5672.74
A+E	MLA DF open ML + manually-pressurized handwand A†	1107.14	46.22	1153.36
A+F	MLA DF, open ML + mechanically-pressurized handgun A†	5749.26	152.02	5901.28
Unit exposure values for coveralls over single layer and CR gloves				
H	DF open mix/load	91.94	1.02	92.96
I	MLA Liquid mechanically-pressurized handgun	2453.52	151	2604.52
H+I	MLA DF, open ML + mechanically-pressurized handgun A†	2545.46	152.02	2697.48

CR = chemical-resistant, ML = mix/load, A = application, MLA = mixer/loader/applicator, DF = dry flowable
WDG = water dispersible granules
NOTE: All unit exposure are from PHED, except for turf gun (which is from ORETF).
* Combined PHED or ORETF unit exposure =
(Dermal unit exposure × 100% dermal absorption) + (Inhalation unit exposure × 100% inhalation absorption)
† For backpack, low pressure handwand and high pressure handwand applications, only MLA unit exposure values for liquid formulations are available in PHED. As such, to calculate MLA unit exposure for soluble or wettable granules for these application equipment, the dry flowable open mix/load unit exposure is added to the liquid MLA unit exposure.

Table 3.4.2.1.2 Chemical handler Assessment for Sandea Herbicide and Permit Herbicide

Crop	Maximum rate (kg a.i./ha)	PHED total unit exposure (µg/kg a.i. handled)[1]	ATPD (ha/day)[2]	Exposure (mg/kg bw/day)[3]	Calculated MOE[4]
Sandea Herbicide					
Apples	0.105	198.73	26	0.0068	1090
Asparagus	0.079	198.73	26	0.0051	1460
Tree nuts	0.070	198.73	26	0.0045	1640
Highbush blueberry; Caneberries; Rhubarb; Chile, bell, banana peppers; Fruiting vegetables; Cucumbers, cantaloupes, honeydews, Crenshaw melons; Watermelon; Pumpkin and winter squash; Summer squash for processing; Succulent snap beans; Tomatoes	0.053	198.73	26	0.0034	2180
Okra	0.035	198.73	26	0.0023	3250
Permit Herbicide					
Field corn and field corn grown for seed	0.070	198.73	360	0.0624	119
Dry beans; Sweet corn, popcorn; Grain sorghum	0.053	198.73	360	0.0469	158
Proso millet	0.035	198.73	360	0.0315	235

[1] PHED total unit exposures from Table 3.4.2.1.1
[2] Default Area Treated per Day (ATPD) values
[3] Daily exposure = (PHED unit exposure × ATPD × Rate) / (80 kg bw × 1000 µg/mg)
[4] Based on NOAEL = 7.4 mg/kg bw/day; target MOE = 100
All MOEs were rounded to 3 significant figures.

Table 3.4.2.1.3 Chemical handler assessment for SedgeHammer Turf Herbicide

Exposure scenario		Combined PHED unit exposure (µg/kg a.i. handled)[1]	Rate[2]	ATPD[3]	Exposure (mg/kg bw/day)[4]	Calculated MOE[5]
PPE: Single layer and chemical-resistant gloves (gloves not required for groundboom application)						
A+B	MLA Open ML + groundboom A	198.73	0.140 kg a.i./ha	107 ha/day	0.0373	199
A+C	MLA Open ML + right-of-way sprayer A	1042.33	0.00035 kg a.i./L	3800 L/day	0.0174	426
A+D	MLA Open ML + backpack A	5672.74	0.00035 kg a.i./L	150 L/day	0.00373	1980
A+E	MLA Open ML+ manually-pressurized handwand A	1153.36	0.00035 kg a.i./L	150 L/day	0.000758	9760
A+F	MLA Open ML + mechanically-pressurized handgun A	5901.28	0.00035 kg a.i./L	3800 L/day	0.0983	*75*
		5901.28	0.00017 kg a.i./L (lower rate)	3800 L/day	0.0473	156
G	MLA with turf gun	1337.8	0.070 kg a.i./ha	2 ha/day	0.00233	3170
PPE: Coveralls over single layer and chemical-resistant gloves						
A+F	MLA Open ML + mechanically-pressurized handgun A	2697.48	0.00035 kg a.i./L	3800 L/day	0.0449	165

Italicized MOE indicates that it is below the target MOE; as such, additional PPE (personal protective equipment) is required.

MLA = mixing/loading and applying, ML = mixing/loading, A = applying

[1] PHED unit exposures from Table 3.4.2.1.1

[2] For the rate to be expressed as kg a.i./L for right-of-way sprayers and handheld equipment, the application rate was calculated as 1.40 g ai in 4 L of water = 0.00035 kg a.i./L, or 0.675 g ai in 4 L of water = 0.00017 kg a.i./L

[3] Default Area Treated per Day (ATPD) values

[4] Daily exposure = (PHED unit exposure × ATPD × Rate) / (80 kg bw × 1000 µg/mg)

[5] Based on NOAEL = 7.4 mg/kg bw/day, target MOE = 100

All MOEs were rounded to 3 significant figures.

3.4.2.2 Exposure and Risk Assessment for Workers Entering Treated Areas

There is potential for exposure to workers re-entering areas treated with Sandea Herbicide, Permit Herbicide and SedgeHammer Turf Herbicide when performing various activities. The duration of exposure is considered to be short- to intermediate-term for all re-entry activities. The primary route of exposure for workers re-entering treated areas would be through the dermal route. Inhalation exposure is not considered to be a significant route of exposure for people entering treated areas compared to the dermal route, since halosulfuron-methyl is relatively non-volatile ($<1.33\times10^{-5}$ Pa) and as such, an inhalation risk assessment was not required.

Sandea Herbicide and Permit Herbicide are for use on various crops at specific application timings. Applications made prior to crop emergence, on orchard ground between established trees, or as row middle/furrow applications are expected to result in minimal postapplication exposure. However, there is potential for postapplication exposure in crops that are sprayed over the top after crop emergence: rhubarb, asparagus, chile peppers, bell peppers, banana peppers, cucumbers, cantaloupes, honeydews, Crenshaw melons, pumpkins, winter squash, succulent snap beans, tomatoes, dry beans, sweet corn, popcorn, field corn, field corn grown for seed, grain sorghum, and proso millet. A quantitative risk assessment was conducted for these crops.

SedgeHammer Turf Herbicide is for use on turfgrass, ornamentals, landscaped areas and other specified non-crop areas. It can be sprayed around established woody ornamentals and as a post-directed spray in field or container grown ornamental production nurseries. SedgeHammer Turf Herbicide is not to be applied over the top of desirable plants. In addition, contact of this product with leaves of desirable plants is to be avoided. As such, residues on ornamental foliage are expected to be minimal, and a postapplication worker risk assessment for the use on ornamentals is not required. However, there is potential for postapplication exposure from the other uses. Golf course workers and sod farm workers may be exposed to halosulfuron-methyl when conducting postapplication activities in treated turf. In addition, workers re-entering industrial areas may also be exposed to halosulfuron-methyl.

Dermal exposure to workers entering treated areas is estimated by coupling dislodgeable foliar residue (DFR) or transferrable turf residue (TTR) values with activity-specific transfer coefficients (TCs). Activity TCs are based on data from the Agricultural Re-entry Task Force (ARTF) data. Chemical-specific DFR or TTR data were not submitted. As such, default DFR values (25% of the application rate on the day of application and 10% dissipation per day) were used in the exposure assessment. Default TTR values (1% of the application rate on the day of application and 10% dissipation per day) were used in the exposure assessment for turf uses.

Exposure estimates were compared to the toxicological endpoint (NOAEL = 7.4 mg/kg bw/day) to obtain the MOE; the target MOE is 100. Table 3.4.2.2.1 and Table 3.4.2.2.2 present the calculated MOEs on the PHI of 30 days for hand harvesting sweet corn, and the day of last application for other activities. All calculated MOEs are above the target MOE of 100 on the PHI for hand harvesting sweet corn and on the day of the last application for other re-entry activities, except for hand detasseling seed corn. At 14 days after the last application, the calculated MOE for hand detasseling seed corn is 107, which is above the target MOE. As such, the PHI of 30 days for hand harvesting sweet corn, a 14-day restricted entry interval (REI) for hand detasseling seed corn and REIs of 12 hours for other re-entry activities are adequate to protect postapplication workers who re-enter fields and orchards treated with Sandea Herbicide or Permit Herbicide. An REI of “until sprays have dried” is adequate to protect postapplication workers who re-enter areas treated with SedgeHammer Turf Herbicide.

Table 3.4.2.2.1 Worker Postapplication Exposure and Risk Estimates on the Day of Application for Fields and Orchards Treated with Sandea Herbicide or Permit Herbicide

Crops	Rate (kg a.i./ha)	# of apps (and min RTI)	Postapplication activity	DFR (µg/cm²)[1]	TC (cm²/hr)[2]	Exposure (mg/kg bw/day)[3]	Calculated MOE[4]
Sandea Herbicide							
Rhubarb	0.053	1	Hand set irrigation	0.1313	1750	0.0234	322
Asparagus	0.026 for 1st app, 0.079 for 2nd app	2 (21 days)	Hand set irrigation	0.2041	1750	0.0357	207
Chile, bell, banana peppers	0.053	2 (21 days)	Hand set irrigation	0.1470	1750	0.0257	288
Cucumbers, cantaloupes, honeydews, Crenshaw melons	0.053	2 (21 days)	Hand set irrigation	0.1470	1750	0.0257	288
Pumpkin and winter squash	0.053	1	Hand set irrigation	0.1313	1750	0.0230	322
Succulent snap beans	0.35 (for post-emergent)	1 at max rate	Hand set irrigation	0.0875	1750	0.0153	483
Tomatoes	0.053	2 (21 days)	Hand set irrigation	0.1470	1750	0.0257	288
Permit Herbicide							
Dry beans	0.053	1	Hand set irrigation	0.1313	1750	0.0230	322
Sweet corn, popcorn	0.053	2 (21 days)	Hand set irrigation	0.1470	1750	0.0257	288
Sweet corn	0.053	2 (21 days)	Hand harvesting **at 30-day PHI**	0.0062	16000	0.0100	742
Field corn, field corn grown for seed	0.070	2 (21 days)	Hand set irrigation	0.1941	1750	0.0340	218
Field corn grown for seed	0.070	2 (21 days)	Hand detasseling on **day of application**	0.1941	16000	0.3106	*24*
			Hand detasseling at **14 days after application**	0.0444	16000	0.0711	104
Grain sorghum	0.053	1	Scouting	0.1313	210	0.00276	2690
Proso millet	0.035	1	Scouting	0.0881	1100	0.00969	763

Italicized MOE indicates that it is below the target MOE; as such, a longer REI is required.

[1] Dislodgeable foliar residue (DFR) calculated based on the default values: 25% of the application rate dislodgeable on the day of application, 10% daily dissipation)

[2] Transfer coefficients (TCs) from the Agricultural Reentry Task Force (ARTF)

[3] Exposure = (Peak DFR × TC × 8 hr/day × 100% dermal absorption) / (80 kg bw × 1000 µg/mg)

[4] Based on NOAEL = 7.4 mg/kg bw/day, target MOE = 100

All MOEs were rounded to 3 significant figures.

Table 3.4.2.2.2 Worker Postapplication Exposure and Risk Estimates on the Day of Application for Areas Treated with SedgeHammer Turf Herbicide

Exposure scenario	Re-entry activity	Rate (kg a.i./ha)	# apps (and min RTI)	Peak DFR or TTR (µg/cm²)[1]	TC (cm²/hr)[2]	Exposure (mg/kg bw/day)[3]	MOE[4]
Golf course	Transplanting/ planting	0.070	2 (6 weeks)	0.0071	6700	0.00475	1560
Sod farm	Slab harvesting, transplanting/planting	0.070	2 (6 weeks)	0.0071	6700	0.00475	1560
Industrial areas	Scouting, mechanical weeding and mowing	0.140	1	0.3506	580	0.0203	364

[1] Peak dislodgeable foliar residue (DFR) for industrial areas and peak transferrable turf residue (TTR) for golf courses and sod farms, based on default values (25% DFR or 1% TTR, 10% dissipation per day)
[2] Transfer coefficients (TCs) from the Agricultural Reentry Task Force (ARTF)
[3] Exposure = (Peak TTR × TC × 8 hours/day)/(80 kg bw × 1000 µg/mg)
[4] Based on NOAEL= 7.4 mg/kg bw/day, target MOE = 100
All MOEs were rounded to 3 significant figures.

3.4.3 Residential Exposure and Risk Assessment

3.4.3.1 Handler Exposure and Risk

Sandea Herbicide, Permit Herbicide and SedgeHammer Turf Herbicide are not domestic products; therefore, a residential handler assessment was not required.

3.4.3.2 Postapplication Exposure and Risk

Sandea Herbicide can be applied on apples, highbush blueberries and caneberries, which can be harvested in pick-your-own farms. However, apples are treated with a broadcast spray to orchard floors on each side of tree rows, and contact of herbicides with the blueberry bushes and caneberry canes should be avoided. As such, minimal residue is expected on the foliage of these crops; thus, minimal dermal exposure is expected from the foliage. In addition, an acute incidental oral toxicological endpoint was not established. As such, an aggregate risk assessment is not required. In addition, no quantifiable residues in soil were observed in environmental field data; therefore, there is minimal potential for dermal exposure from the treated ground.

SedgeHammer Turf Herbicide can be used on turfgrass in residential properties, public recreation areas, golf courses, school grounds, tennis courts, campgrounds, etc. and around established woody ornamentals in landscaped areas. For the use on ornamentals, SedgeHammer Turf Herbicide is not to be applied over the top of desirable plants. In addition, contact of this product with leaves of desirable plants is to be avoided. As such, the postapplication residential exposure from spraying around ornamentals is not expected to exceed that from treated turfgrass.

There is potential for recreational and residential postapplication exposure from the use of SedgeHammer Turf Herbicide on turfgrass. Exposure was assessed according to equations and parameters stated in the 2012 United States Environmental Protection Agency (USEPA) Residential Standard Operating Procedures. Dermal exposure from golfing was assessed for adults (16 years plus), youth (11-<16 years), and children (6-<11 years). Dermal exposure from high contact lawn activities was assessed for adults (16 years plus), youth (11-<16 years) and children (1-<2 years). Dermal exposure was also assessed for adults (16 years plus) and youth (11-<16 years) when mowing. Incidental oral exposure from hand-to-mouth (HtM) and object-to-mouth (OtM) exposure was assessed for children (1-<2 years). Note that incidental oral exposure from soil ingestion was not assessed since no quantifiable residues in soil were observed in environmental field data. Default TTR values were used to assess postapplication exposure on the day of application (1% of the application rate).

Dermal postapplication risk was calculated using the dermal absorption value (100%) and toxicological endpoint for short- to intermediate-term dermal exposure (NOAEL = 7.4 mg/kg bw/day). Incidental oral postapplication risk was calculated using the toxicological endpoint for short- to intermediate-term incidental oral exposure (NOAEL = 7.4 mg/kg bw/day). Table 3.4.3.2.1 presents the calculated MOEs on the day of application for recreational and residential dermal exposure; which are above the target MOE of 100. Table 3.4.3.2.2 presents the calculated MOEs on the day of application for incidental oral exposure for toddlers; which are above the target MOE of 100.

Table 3.4.3.2.1 Dermal Recreational/Residential Postapplication Exposure and risk from the Use of SedgeHammer Turf Herbicide on the Day of Last Application

Re-entry activity	Rate (kg a.i./ha)	# apps (and min RTI)	Peak DFR or TTR[1] ($\mu g/cm^2$)	Age (yrs)	TC[2] (cm^2/hr)	ED[3] (hr/day)	kg bw	Exposure[4] (mg/kg bw/day)	MOE[5]
Golf courses									
Golfing	0.068	2 (6 weeks)	0.0069	16+	5300	4	80	0.00188	3940
				11-<16	4400	4	57	0.00219	3380
				6-<11	2900	4	32	0.00257	2880
Residential areas									
High contact lawn activities	0.068	2 (6 weeks)	0.0069	16+	180000	1.5	80	0.0239	310
				11-<16	148000	1.3	57	0.0239	309
				1-<2	49000	1.5	11	0.0473	156
Mowing	0.068	2 (6 weeks)	0.0069	16+	5500	1	80	0.000487	15200
				11-<16	4500	1	57	0.000559	13200

[1] Calculated based on default values (1% TTR, 10% dissipation per day)
[2] TC = Transfer coefficients from ARTF
[3] ED = exposure duration
[4] Exposure = (Peak TTR × TC × ED)/(kg bw × 1000 µg/mg)
[5] Based on NOAEL= 7.4 mg/kg bw/day, target MOE = 100
All MOEs were rounded to 3 significant figures.

Table 3.4.3.2.2 Incidental Oral Residential Postapplication Exposure and Risk from the Use of SedgeHammer Turf Herbicide on the Day of Last Application for Children 1-<2 years old

Re-entry activity	TDE[1] (mg/day)	Peak TTR[2] (µg/cm^2)	Area of mouthed surface (cm^2)	Hand residue loading[3] (mg/cm^2)	Frequency of mouthing events	Exposure (mg/day)[4]	Exposure[5] (mg/kg bw/day)	MOE[6]
Hand-to-mouth (HtM) exposure	0.521	-	150 (hand)	0.000104	13.9 (HtM)	0.0107	9.71×10^{-4}	7630
Object-to-mouth (OtM) exposure	-	0.0071	10 (turf)	-	8.8 (OtM)	0.000324	2.95×10^{-5}	251000

[1] TDE (total dermal exposure) = Dermal exposure of child 1-<2 yrs (mg/kg bw/day, from Table 3.4.3.2.1) × 11 kg bw

[2] Peak TTR from Table 3.4.3.2.1

[3] Hand residue loading = (6% of TDE on hands × TDE [mg/day]) / (surface area of hand [cm^2] × 2)

[4] **Hand-to-mouth (HtM) exposure (mg/day)** =
Hand residue loading (mg/cm^2) × 0.127 of hand surface mouthed/event × surface area of hand (cm^2) × 1.5 hr exposure time × 4 replenishment intervals/hr × [1 – (1- SEF) ^ (Freq. of HtM events/4 replenishment intervals/hr)]

Object-to-mouth (OtM) exposure (mg/day) =
Peak TTR (µg/cm^2) × 0.001 mg/µg × surface area of mouthed turf (cm^2/event) × 1.5 hr exposure time × 4 replenishment intervals/hr × [1 – (1- SEF) ^ (Freq. of OtM events/4 replenishment intervals/hr)]

SEF = saliva extraction factor = 0.48

[5] Exposure (mg/kg bw/day) = Exposure (mg/day) / 11 kg bw

[6] Based on NOAEL= 7.4 mg/kg bw/day, target MOE = 100
All MOEs were rounded to 3 significant figures.

3.4.3.3 Aggregate Exposure

Since adults and youth (11-16 years) can potentially conduct more than one turf re-entry activity in a day, the dermal exposures from all turf activities were combined. Children (1-<2 years) may be exposed through the dermal route and incidental oral route in the same day. Since the toxicological endpoints for short- to intermediate-term dermal and incidental oral exposure are the same, these exposures were also combined.

Halosulfuron-methyl is used on food crops as Sandea Herbicide and Permit Herbicide, and is used on residential areas and golf courses as SedgeHammer Turf Herbicide. Since toxicological endpoints for short- to intermediate term dermal exposure and chronic dietary exposure are the same, dermal exposure (and incidental oral exposure for toddlers) can be aggregated with chronic dietary + drinking water exposure.

Aggregate risk was calculated using the NOAEL of 7.4 mg/kg bw/day. Table 3.4.3.3.1 presents the aggregate MOEs on the day of application; which are above the target MOE of 100.

Table 3.4.3.3.1. Aggregate risk from the use of SedgeHammer Turf Herbicide

Age group	Exposure (mg/kg bw/day)						Aggregate MOE[4]
	Dermal[1]			Incidental oral[2]		Chronic Dietary + Drinking Water[3]	
	Golfing	High contact lawn activities	Mowing	Hand to mouth	Object to mouth		
Adults (16+)	0.00188	0.0239	0.000487	-	-	0.000613	275
Youth (11-16)	0.00219	0.0239	0.000559	-	-	0.001014	267
Children (1-2)	-	0.0473	-	9.71×10^{-4}	2.95×10^{-5}	0.003459	143

[1] Dermal exposure from Table 3.4.3.2.1
[2] Incidental oral exposure from Table 3.4.3.2.2
[3] Chronic dietary + drinking water exposure were derived from the DEEM-FCID software.
[4] Aggregate MOE = $\frac{\text{NOAEL}}{\text{(Dermal exposure + Incidental oral exposure + Chronic dietary + drinking water exposure)}}$

MOEs are based on NOAEL = 7.4 mg/kg bw/day, target MOE = 100 for both dermal and oral exposure

3.4.3.4 Bystander Exposure and Risk

For Sandea Herbicide and Permit Herbicide, bystander exposure should be negligible since the potential for drift is expected to be minimal. Application is limited to agricultural crops only when there is low risk of drift to areas of human habitation or activity such as houses, cottages, schools and recreational areas, taking into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings.

For SedgeHammer Turf Herbicide, risk to bystanders is considered negligible as exposure to spray drift is not expected to exceed the exposure for mixers/loaders and applicators.

3.5 Food Residues Exposure Assessment

3.5.1 Residues in Plant and Animal Foodstuffs

The residue definition for risk assessment and enforcement in plant products and animal commodities is halosulfuron-methyl. The data gathering/enforcement analytical method for the quantitation of halosulfuron-methyl residues as the rearrangement ester in crop and livestock matrices is valid for the determination of this analyte. Residues of halosulfuron-methyl are stable in representative high water (lettuce), high oil (soybean seed), high protein (soybean seed) and high starch (wheat grain) commodities for up to 34 months (1013 days), and are stable in a representative high acid commodity (tomato) for up to 131 days when stored in a freezer at <-18°C. Therefore, halosulfuron-methyl residues are considered stable in all frozen crop matrices and processed crop fractions for at least 131 days. The raw agricultural commodities, field corn grain, sorghum grain and tomatoes were processed. Quantifiable residues were not observed in tomatoes, paste and purée, and residues were not observed to concentrate in the field corn and sorghum grain fractions, with the exception of aspirated grain fractions (AGFs) (1.44x and 4.24x for field corn and sorghum, respectively) and sorghum grain bran (6.2x). Quantifiable residues were not observed in apples treated at exaggerated rates equivalent to 5x GAP; therefore, juice and wet pomace were not processed. Adequate feeding studies were carried out to assess the anticipated residues in livestock matrices resulting from the current uses. Crop field trials conducted throughout the United States including growing regions representative of Canada using end-use products containing halosulfuron-methyl at approved or exaggerated rates in or on all proposed crops are sufficient to support the proposed maximum residue limits.

3.5.2 Dietary Risk Assessment

Acute and chronic non-cancer dietary risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM–FCID™, Version 2.14), which uses updated food consumption data from the United States Department of Agriculture's Continuing Surveys of Food Intakes by Individuals, 1994–1996 and 1998.

3.5.2.1 Chronic Dietary Exposure Results and Characterization

The following criteria were applied to the basic chronic non-cancer analysis for halosulfuron-methyl: 100% crop treated, default processing factors (where available), residues based on the proposed MRLs for domestic crops and livestock commodities, and established tolerances for imported commodities. The basic chronic dietary exposure from all supported halosulfuron-methyl food uses (alone) for the total population, including infants and children, and all representative population subgroups is less than 5% of the acceptable daily intake (ADI). Aggregate exposure from food and drinking water is considered acceptable. The PMRA estimates that chronic dietary exposure to halosulfuron-methyl from food and drinking water is <1.3% (0.000921 mg/kg bw/day) of the ADI for the total population. The highest exposure and risk estimate is for children 1-2 years old at 4.9% (0.003456 mg/kg bw/day) of the ADI.

3.5.2.2 Acute Dietary Exposure Results and Characterization

The following assumptions were applied in the basic acute analysis for halosulfuron-methyl: 100% crop treated, default processing factors (where available), residues based on the proposed MRLs for domestic crops and livestock commodities, and established tolerances for imported commodities. The basic acute dietary exposure (food alone) for all supported halosulfuron-methyl registered commodities is estimated to be 0.72% (0.001439 mg/kg bw/day) of the ARfD for females 13–49 years old (95th percentile, deterministic). Aggregate exposure from food and drinking water is considered acceptable: 0.79% (0.001573 mg/kg bw/day) of the ARfD for females 13–49 years old.

3.5.3 Aggregate Exposure and Risk

The aggregate risk for halosulfuron-methyl consists of exposure from food and drinking water sources as well as residential uses. For the aggregate risk assessment for the residential uses, refer to section 3.4.3.3. Furthermore, there is no acute endpoint identified for the general population, including infants and children, thus a pick-your-own assessment was not required.

3.5.4 Maximum Residue Limits

Table 3.5.4.1 Proposed Maximum Residue Limits

Commodity	Recommended MRL (ppm)
Crop Subgroup 22A : Stalk and stem vegetables	1
Crop Subgroup 9B: Squash/Cucumber	0.5
Meat byproducts of cattle, goat, horse, sheep	0.2
Crop Subgroup 9A: Melon	0.1
Apples Crop Group 8-09: Fruiting Vegetables Crop Group 14: Tree nuts Grain lupin; dry kidney beans; dry lima beans; dry navy beans; dry pink beans; dry pinto beans; dry tepary beans; dry beans; dry adzuki beans; dry blackeyed peas; dry catjang seeds; dry cowpea seeds; dry moth beans; dry mung beans; dry rice beans; dry southern beans; dry urd beans; dry broad beans; dry chickpeas; dry guar seeds; dry lablab beans Edible-podded runner beans; edible-podded snap beans; edible-podded wax beans; edible-podded moth beans; edible-podded yardlong beans; edible-podded jackbeans; edible-podded sword beans Field Corn Popcorn grain Rhubarb Sorghum Subgroup 13-07A: Caneberry Subgroup 13-07B: Bushberry Sweet corn kernels plus cob with husks removed	0.05
Proso millet; Fat and meat of cattle, goat, horse, sheep; milk	0.01

MRLs are proposed for each commodity included in the listed crop groupings in accordance with the Residue Chemistry Crop Groups webpage in the Pesticides and Pest Management section of Health Canada's website.

For additional information on Maximum Residue Limits (MRLs) in terms of the international situation and trade implications, refer to Appendix II.

The nature of the residues in animal and plant matrices, analytical methodologies, field trial data, and acute and chronic dietary risk estimates are summarized in Appendix I, Tables 1, 5 and 6.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Halosulfuron-methyl is non-persistent to moderately persistent in terrestrial and aquatic systems based on laboratory and field dissipation studies. Hydrolysis is an important route of dissipation for halosulfuron-methyl in the environment, whereas phototransformation is not. Biotransformation is also an important route of dissipation for halosulfuron-methyl in both terrestrial and aquatic environments. Halosulfuron-methyl is not expected to volatilize from water or moist soils. Several major transformation products were detected in laboratory transformation studies in aerobic and anaerobic soil and water/sediment systems and in the field studies: halosulfuron-acid, aminopyrimidine, halosulfuron-methyl rearrangement ester, halosulfuron rearrangement acid, chlorosulfonamide ester, chlorosulfonamide acid and halosulfuron guanidine. Based on results of field dissipation studies, halosulfuron-methyl and its transformation products are not expected to carry over in significant amounts into the next growing season.

Based on the criteria of Cohen *et al.* (1984) and the groundwater ubiquity score (GUS; Gustafson, 1989), halosulfuron-methyl has the potential to leach under certain circumstances; however, terrestrial field dissipation studies, lysimeter/soil column studies and monitoring data, as well as water modelling results indicate that there is little movement of halosulfuron-methyl down the soil profile and that levels of halosulfuron-methyl in groundwater are expected to be low. Although laboratory biotransformation studies indicate that a number of major transformation products of halosulfuron-methyl are mobile and persistent in terrestrial and aquatic systems, results of terrestrial field dissipation studies show little vertical movement and relatively quick dissipation. In aquatic environments, halosulfuron-methyl is not expected to partition to sediment or bioaccumulate in aquatic organisms. Environmental fate data for halosulfuron-methyl are summarized in Appendix I, Table 7.

4.2 Environmental Risk Characterization

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. Estimated environmental concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are determined using standard models which take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications. Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants. Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species sensitivity as well as varying protection goals (i.e., protection at the community, population, or individual level).

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (for example, direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the risk quotient is then compared to the level of concern (LOC = 1 for most species, 0.4 for pollinators and 2 for beneficial arthropods (predatory mite and parasitic wasp)). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary. If the screening level risk quotient is equal to or greater than the level of concern, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

4.2.1 Risks to Terrestrial Organisms

A risk assessment for halosulfuron-methyl was conducted for terrestrial organisms. For acute toxicity studies, uncertainty factors of 1/2 and 1/10 the EC_{50} (LC_{50}) are typically used in modifying the toxicity values for terrestrial invertebrates, birds and mammals when calculating risk quotients (RQs). No uncertainty factors are applied to chronic NOEC endpoints. A summary of terrestrial toxicity data for halosulfuron-methyl is presented in Appendix I, Table 8 and the accompanying risk assessment is presented in Appendix I, Table 9 for terrestrial organisms other than birds and mammals, and Appendix I, Table 10 for birds and mammals.

Earthworms: Halosulfuron-methyl was not acutely toxic to earthworms. The risk quotient for earthworms resulting from acute exposure to halosulfuron-methyl did not exceed the level of concern at the screening level. The use of halosulfuron-methyl is not expected to pose an acute risk to earthworms.

Bees: Acute oral and contact exposure to halosulfuron-methyl did not result in treatment-related mortality in honey bees. The resulting risk quotients for both acute contact and oral exposure routes were all below the LOC, indicating halosulfuron-methyl is not expected to pose a risk to pollinators. Although studies on bee larval toxicity are not available at this time, none are required as larval bee toxicity is not expected from exposure to halosulfuron-methyl based on the mode of action, a lack of effects observed for adult bees, and a lack of effects for beneficial arthropods.

Beneficial arthropods: Acute exposure of the predacious mite, *Typhlodromus pyri*, and the parasitoid wasp, *Aphidius rhopalosiphi*, to a formulation of halosulfuron-methyl resulted in no statistically significant differences in reproduction or mortality. The risk quotients for predatory and parasitic arthropods resulting from exposure to halosulfuron-methyl did not exceed the level of concern at the screening level. The use of halosulfuron-methyl is not expected to pose a risk to predatory and parasitic arthropods.

Birds: Halosulfuron-methyl was not toxic to birds on an acute, dietary or reproductive basis, with no treatment-related mortality, sublethal or reproductive effects. The risk quotients for birds resulting from acute and reproductive exposure to halosulfuron-methyl did not exceed the level of concern at the screening level. The use of halosulfuron-methyl is not expected to pose a risk to birds.

Mammals: Mortality of rats and mice were observed at high doses in acute toxicity studies with halosulfuron-methyl and a 75% halosulfuron-methyl formulation. Effects on body weight, weight gain and food consumption were also observed in a reproductive study with halosulfuron-methyl. The risk quotients for mammals resulting from acute and reproductive exposure to halosulfuron-methyl did not exceed the level of concern at the screening level. The use of halosulfuron-methyl is not expected to pose a risk to mammals.

Vascular plants: Halosulfuron-methyl was toxic to non-target plants in vegetative vigour and seedling emergence studies using standard crop species. As multiple EC_{50} values were available for vascular plants, the program ETX 2.0 was used to generate species sensitivity distributions (SSDs) based on normally distributed toxicity data. The hazardous concentration to 5% of the species (HC_5) was then calculated for both vegetative vigour and seedling emergence from their respective SSDs. The HC_5 is the concentration which is theoretically protective for 95% of species. At the HC_5 exposure level, 5% of all species will be exposed to a concentration which exceeds their LC_{50} toxicity value. The HC_5 values were used to calculate the risk quotients for terrestrial vascular plants instead of the most sensitive species tested. This provides a more scientifically robust endpoint, which uses all of the data. No uncertainty factors are applied to the HC_5 when calculating risk quotients.

Using the HC_5 values from the SSDs for seedling emergence and vegetative vigour, the calculated risk quotients exceed the level of concern at the screening level. The risk to terrestrial vascular plants was further characterized by looking at off-field exposure from drift. Based on the risk quotients using the off-field EECs from drift, the level of concern for terrestrial vascular plants was still exceeded. Spray buffer zones will be required on halosulfuron-methyl product labels to protect non-target terrestrial vascular plants. The EECs for the screening level risk assessement were based on a conservative single application of halosulfuron-methyl at the maximum rate of 140 g a.i./ha; however, the spray buffer zones will be crop-specific for the product labels and will range from 15-40 metres.

4.2.2 Risks to Aquatic Organisms

A risk assessment for halosulfuron-methyl, and three of its transformation products, halosulfuron-methyl rearrangement, halosulfuron and aminopyrimidine, was conducted for freshwater and marine aquatic organisms based on available toxicity data. A summary of aquatic toxicity data for halosulfuron-methyl and its transformation products is presented in Appendix I, Table 11.

For acute toxicity studies, uncertainty factors of 1/2 and 1/10 the EC_{50} (LC_{50}) are typically used for aquatic plants and invertebrates, and fish species, respectively, when calculating risk quotients (RQs). No uncertainty factors are applied to chronic NOEC endpoints. For groups where the level of concern (LOC) is exceeded (i.e., RQ $\geq$1), a refined Tier 1 assessment is conducted to determine risk resulting from spray drift and runoff separately. Risk quotients for halosulfuron-methyl and its transformation products were calculated based on the highest maximum seasonal application rate for all uses. The calculated risk quotients for halosulfuron-methyl are summarized in Appendix I, Tables 12 (screening level), Table 13 (Tier 1 – spray drift only) and Table 14 (Tier 1 – runoff only). The screening level risk quotients for transformation products of halosulfuron-methyl are summarized in Appendix I, Table 15.

Invertebrates: Halosulfuron-methyl was not toxic to freshwater invertebrates on an acute or chronic exposure basis. Shell deposition in the marine oyster was reduced at high concentrations of halosulfuron-methyl on an acute exposure basis. The major transformation product, halosulfuron-methyl rearrangement, was not toxic to freshwater invertebrates on an acute exposure basis. The risk quotients for freshwater and marine invertebrates resulting from exposure to halosulfuron-methyl and its transformation product did not exceed the level of concern at the screening level. The use of halosulfuron-methyl is not expected to pose a risk to freshwater and marine aquatic invertebrates.

Fish and amphibians: Halosulfuron-methyl was not toxic to freshwater and marine fish on an acute exposure basis. The major transformation product, halosulfuron-methyl rearrangement, was also not toxic to freshwater fish on an acute exposure basis. At high concentrations of halosulfuron-methyl on a chronic exposure basis, reductions in length and weight in rainbow trout were observed. The risk quotients for freshwater and marine fish resulting from exposure to halosulfuron-methyl and its transformation product did not exceed the level of concern at the screening level. The use of halosulfuron-methyl is not expected to pose a risk to fish.

The risk for amphibians was characterized at the screening level by comparing EECs in 15 cm water depth with fish toxicity endpoints as surrogates for aquatic life-stages of amphibians. Acute risks were assessed for exposure to halosulfuron-methyl and the transformation product, halosulfuron-methyl rearrangement; chronic risk was assessed for halosulfuron-methyl. The risk quotients for amphibians resulting from exposure to halosulfuron-methyl and its transformation product did not exceed the level of concern at the screening level. The use of halosulfuron-methyl is not expected to pose a risk to amphibians.

Algae: Halosulfuron-methyl was toxic to algae at low levels of exposure. Transformation products, halosulfuron, halosulfuron-methyl rearrangement and aminopyrimidine, were much less toxic than the parent to algae. The risk quotient for marine algae resulting from exposure to halosulfuron-methyl did not exceed the level of concern at the screening level. The risk quotients for freshwater algae from exposure to the transformation products, halosulfuron-methyl rearrangement, halosulfuron and aminopyrimidine, also do not exceed the level of concern at the screening level.

The screening level risk quotient for freshwater algae resulting from acute exposure to halosulfuron-methyl slightly exceeded the level of concern. The risk to freshwater algae was further characterized by looking at exposure from spray drift and runoff. Refined risk quotients based on spray drift and runoff of halosulfuron-methyl did not exceed the level of concern for spray drift but did exceed the level of concern for runoff. There is a potential risk to freshwater algae from halosulfuron-methyl runoff. Standard label statements to mitigate runoff into aquatic habitats will be required on the label for all halosulfuron-methyl end-use products.

Aquatic vascular plants: Halosulfuron-methyl was toxic to aquatic vascular plants at low levels of exposure. The screening level risk quotient for aquatic vascular plants resulting from exposure to halosulfuron-methyl greatly exceeded the level of concern at the screening level. The risk to aquatic vascular plants was further characterized by looking at exposure from spray drift and runoff. Refined risk quotients based on spray drift and runoff of halosulfuron-methyl exceeded the level of concern. Spray buffer zones will be required on halosulfuron-methyl product labels to protect non-target aquatic vascular plants from the potential effects of spray drift. The EECs for the screening level risk assessement were based on a conservative single application of halosulfuron-methyl at the maximum rate of 140 g a.i./ha; however, the spray buffer zones will be crop-specific for the product labels and will range from 4-25 metres. Standard label statements to mitigate runoff into aquatic habitats will also be required on the label for all halosulfuron-methyl end-use products.

4.2.3 Incident Reports

Environmental incident reports are obtained from two main sources, the Canadian pesticide incident reporting system (including both mandatory reporting from the registrant and voluntary reporting from the public and other government departments) and the USEPA Ecological Incident Information System (EIIS). Specific information regarding the mandatory reporting system regulations that came into force 26 April 2007 under the *Pest Control Products Act* can be found at http://www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/incident/index-eng.php. As halosulfuron-methyl is only registered in the United States, a review of the EIIS was completed in May 2013. No environmental incident reports were found for halosulfuron-methyl.

5.0 Value

5.1 Effectiveness Against Pests

Although halosulfuron-methyl controls a broad range of broadleaved weeds, it is particularly effective at controlling yellow nutsedge, a problematic weed known to cause severe yield loss in many crops. The value information submitted in support of the effectiveness of halosulfuron-methyl was in the form of data from 137 field trials conducted primarily in the United States, use history information from users and experts in the United States, and scientific rationales. A considerable number of trials supported the effectiveness of halosulfuron-methyl on a group of 27 weed species, and the remaining weed species of agricultural or economic significance in Canada were supported through extrapolation and use history information.

5.2 Non-Safety Adverse Effects

The value information submitted included data from 137 field trials conducted primarily in the United States, use history information from users in the United States, and scientific rationales.

5.2.1 Permit Herbicide

Corn (field, seed, sweet and pop)

The safety of applications of halosulfuron-methyl applied to corn (field, seed, sweet and pop) was established through use history information from extension specialists/weed scientists at the University of Delaware, Iowa State University, North Dakota State University and Cornell University with 10+ years of experience with halosulfuron-methyl in research plots and with its commercial use. Comments suggest that halosulfuron-methyl is safe to the crop and very effective when used according to label directions and that the use of halosulfuron-methyl very rarely has a negative impact on yield. Data from 21 trials conducted in 12 different United States states and Ontario confirmed the tolerance of corn to applications of halosulfuron-methyl. The different trials included applications of halosulfuron-methyl both alone and in tank mix, applications made at different timings, and in direct seeded vs. conventional scenarios.

Dry bean

The safety of applications of halosulfuron-methyl applied to dry bean was established through use history information from North Dakota State University stating that halosulfuron-methyl is highly recommended for the control of certain broadleaved weeds in dry bean. The letter cites 10 years of experience with halosulfuron-methyl applied at a variety of timings with a non-inoic surfactant (NIS) or crop oil concentrate (COC), direct seeded, bare ground, split applications. Trial data from 25 trials conducted in six different states and Ontario including treatments of halosulfuron-methyl both alone and in tank mix, at different application timings confirmed the tolerance of dry bean to applications of halosulfuron-methyl.

Grain sorghum

Data from four trials conducted in the United States were submitted, confirming the tolerance of grain sorghum to applications of halosulfuron-methyl both alone and in tank mix, at different application timings.

Proso millet

Data from seven trials conducted in the United States were submitted, confirming the tolerance of proso millet to applications of halosulfuron-methyl both alone and in tank mix, at different application timings.

Pasture and rangeland grasses

Most sulfonylurea herbicides control only broadleaved weeds, with limited exceptions. The use of Permit Herbicide on pasture and rangeland grass can be supported based on the known selectivity of halosulfuron-methyl for broadleaved plants (i.e., it's mode of action as a sulfonylurea and its broad weed list which is limited to broadleaved weeds and sedges). Halosulfuron-methyl is not expected to have activity on perennial grasses.

5.2.2 Sandea Herbicide

Apple

The tolerance of apple to applications of halosulfuron-methyl was established through use history information from Columbia Ag Research stating Sandea Herbicide appears very safe to apple at recommended rates. The data from eight trials conducted in the United States confirmed the tolerance of apple (varieties tested included Fuji, Golden Delicious, Gala, Liberty, Empire, Ida Red, Rome and Stayman) to applications of halosulfuron-methyl.

Highbush blueberry

The tolerance of highbush blueberry to applications of halosulfuron-methyl was established through use history information from Washington State University stating Sandea Herbicide appears safe to highbush blueberry at recommended rates. The data from at least 10 trials conducted in the United States confirmed the tolerance of highbush blueberry to halosulfuron-methyl when applied as a directed spray at the base of the plants.

Caneberries (blackberry, loganberry, red and black raspberry)

Data from three trials in Canada on red raspberries and four trials in the United States on blackberry confirmed the tolerance of caneberries to directed applications of halosulfuron-methyl.

Rhubarb

Data from one trial conducted in the United States confirmed the tolerance of rhubarb to halosulfuron-methyl when applied to dormant rhubarb in spring prior to dormancy breaking.

Asparagus

The tolerance of asparagus to applications of halosulfuron-methyl was established through use history information from the Washington Asparagus Commission and the Michigan Asparagus Industry Research Farm stating that Sandea Herbicide appears very safe to asparagus when applied at recommended rates. The data from at least seven trials conducted in the United States confirmed the tolerance of asparagus to halosulfuron-methyl.

Peppers (chile, bell, banana)

The tolerance of peppers to applications of halosulfuron-methyl applied was confirmed through use history information from an extension specialist at the University of Delaware stating that halosulfuron-methyl appears very safe to many crops including peppers when applied at recommended rates and following the directions for use. The data from at least six trials conducted in the United States confirmed the tolerance of bell pepper to halosulfuron-methyl.

Other Fruiting Vegetables: Eggplant, Ground Cherry, Tomatillo, Pepino

Data from two trials conducted in the United States confirmed the tolerance of eggplant to directed applications of halosulfuron-methyl. Use history information from the applicant confirmed that halosulfuron-methyl has been used on eggplant, ground cherry, tomatillo and pepino in the United States since 2003 without incidence of crop injury when following the directions for use.

Tomato

The tolerance of tomato to applications of halosulfuron-methyl was established through use history information from extension specialists at Cornell University and the University of Delaware stating that halosulfuron-methyl has value to control yellow nutsedge in tomato when applied at recommended rates and following the directions for use. The data from at least 15 trials conducted in the United States and five in Canada, confirmed the tolerance of tomato to halosulfuron-methyl.

Cucurbits (cucumber, cantaloupe, honeydew, Crenshaw melon, watermelon, pumpkin, winter squash, and summer squash for processing)

The tolerance of cucurbits to applications of halosulfuron-methyl was established through use history information from extension specialists at the Washington Asparagus Commission, Oregon State University, University of Arizona, Washington State University, and the University of Delaware stating that halosulfuron-methyl has value to control yellow nutsedge in cucurbits when applied at recommended rates and following the directions for use. The data from at least 66 trials conducted in the United States, confirmed the tolerance of pumpkin, squash, cucumber, musk melon, cantaloupe and watermelon to halosulfuron-methyl.

Succulent Snap Bean

The tolerance of snap bean to applications of halosulfuron-methyl was established through use history information from extension specialists at Cornell University and the University of Delaware stating that halosulfuron-methyl has value to control yellow nutsedge in snap bean when applied at recommended rates and following the directions for use. Data from at least 13 trials conducted in the United States confirmed the tolerance of snap bean to halosulfuron-methyl, although a few trials indicated substantial crop injury, the weight of evidence suggests that the benefits, in terms of weed control, outweigh the risks of crop injury in most cases.

Okra

Data from at least four trials conducted in the United States confirmed the tolerance of okra to halosulfuron-methyl.

Tree Nuts (butternut, chestnut, filbert (hazelnut) hickory nut, pecan, walnut (black and English))

No information was provided in support of the use of halosulfuron-methyl in tree nuts. An internet search indicated that Sandea Herbicide is recommended for use in hazelnut, chestnut and walnut in the Pacific Northwest Weed Management Handbook 2013, in the Mississippi Weed Control Guidelines for 2013 for use in pecan, and by the University of Florida Extension Service for use in pecan (2013). Considering the data provided for review for all labeled crops combined, along with use histories for a variety of other crops, the weight of evidence suggests the proposed uses in tree nuts would not result in unacceptable crop injury when applied according to label directions, which are consistent with those on the American Sandea Herbicide label.

5.2.3 SedgeHammer Turf Herbicide

Turfgrass

The tolerance of cool season turf grasses including creeping bentgrass, fescue species including fine fescue and tall fescue, perennial ryegrass, and Kentucky bluegrass to applications of halosulfuron-methyl was established through use history information from Rutgers Cooperative Research and Extension. A number of research reports and factsheets from Rutgers, Iowa State University and University of Nebraska were also provided which further confirmed the tolerance of cool season turf grasses to applications of halosulfuron-methyl. It is also reasonable to assume that halosulfuron-methyl will control labeled weeds in turfgrass.

Ornamentals

The tolerance of labeled established woody ornamentals in landscaped areas and field grown production nurseries to applications of halosulfuron-methyl was confirmed through reports from IR-4 detailing the 373 trials conducted since 1995 in their Ornamental Horticulture Halosulfuron-methyl Crop Safety Program. The IR-4 report clearly classifies ornamental species based on observed injury following application of halosulfuron-methyl. It is also reasonable to assume that halosulfuron-methyl will control labeled weeds in and around ornamentals.

Industrial and domestic vegetation control

Halosulfuron-methyl exhibits activity on weeds through foliar application or soil uptake into the emerging shoots so it is reasonable to believe this active ingredient may be useful in some scenarios such as roadsides and rights-of-way. The use of SedgeHammer Turf Herbicide for the purposes of industrial and domestic vegetation control for the control of labeled weeds at labeled rates is acceptable, based on its use in agricultural settings including orchards and ornamentals, and historic use in the United States.

5.2.4 Rotational Cropping

Considerable information was provided by the applicant with regards to rotational cropping. The information included trial reports (dating back to the 1980s) and scientific rationale based on the behaviour of halosulfuron-methyl and its metabolites in the soil, and history of use. Much of the recropping studies were conducted in the southern United States where multiple crops might be grown in succession during a single year.

Also taken into consideration was the persistence of halosulfuron-methyl in terrestrial systems. As outlined in Section 4.0, Impact on the Environment, halosulfuron-methyl and its transformation products are not expected to carry over in significant amounts to the next growing season. This conclusion is consistent with the description of the persistence of halosulfuron-methyl in soils in the Weed Science Society of America Herbicide Handbook (9th edition, 2007).

The quantity of work presented however, is an indication as to how much recropping work has been done by the applicant, as well as by extension personnel and university researchers. According to the applicant the current recropping intervals on the Permit Herbicide and Sandea Herbicide labels are a reflection of years of work and constant refinement of the label over time. The recropping intervals can be accepted as proposed based on the information provided and in consideration that halosulfuron-methyl has been registered and used in the United States for over 15 years.

5.3 Consideration of Benefits

5.3.1 Social and Economic Impact

The potential social and economic impacts of the registration of halosulfuron-methyl in Canada include the availability to Canadian growers of a "tech-gap" herbicide used on a variety of minor use crops in the United States for many years. The use of halosulfuron-methyl is identified in the Canadian Grower Priority Database as having priorities in the following crops: dry bean (high); apple (intermediate); highbush blueberry (high); asparagus (high); eggplant (high); tomato (high); pumpkin (high); squash (high), cucumber (high); snap bean (high); pecan (high); chestnut (intermediate). Registration of halosulfuron-methyl could help to satisfy many of those priorities. Also, the availability of halosulfuron-methyl to control yellow nutsedge in a variety of crops is significant as yellow nutsedge is a difficult to control weed with few chemical control options presently in Canada.

5.3.2 Survey of Alternatives

The mode of action of halosulfuron-methyl is classified as an Herbicide Resistance Action Committee Group B inhibitor of ALS. The chemical family is called the sulfonylureas. There are presently 12 sulfonylurea active ingredients registered in Canada and these are found in a total of 75 end-use products. These are registered on various crops and for some non-crop uses, however the number of minor use crops proposed for halosulfuron-methyl is significantly greater than with any of these Canadian registered alternatives. In addition, halosulfuron-methyl should provide an important alternative to growers with yellow nutsedge, a problematic weed with few chemical control alternatives. Select alternatives are listed below:

Chlorimuron-ethyl is the only other Group 2 herbicide with activity on yellow nutsedge but it is only registered for use on soybean in eastern Canada.

Sinbar Herbicide (Group 5) provides suppression of yellow nutsedge in certain crops including apple, highbush blueberry, raspberry and asparagus.

EPTAM 8-E Herbicide (Group 8) provides some control of yellow nutsedge in dry bean and snap bean.

Basagran Forte Herbicide (Group 6) provides some control of yellow nutsedge in dry bean, corn, sorghum and millet.

Dual II Magnum and Frontier Herbicide (both Group 15) have activity on yellow nutsedge (depending on the application method and timing) in dry bean and corn (both end-use products) and snap bean, transplanted tomato, highbush blueberry, field peppers, cantaloupe, cucumber, asparagus, pearl millet and outdoor ornamentals (Dual II Magnum).

Glyphosate (Group 9) provides non-selective control of yellow nutsedge in glyphosate tolerant crops or as a directed application in certain crops.

5.3.3 Compatibility with Current Management Practices Including Integrated Pest Management

Halosulfuron-methyl offers broadleaved weed control, particularly for the control of yellow nutsedge, when used as a pre-seed, pre-emergence or post-emergence herbicide. It is compatible with integrated weed management practices because it controls a range of weeds with a single application and because it can control weeds that have already emerged as well as weeds before they emerge. It is compatible with both conservation tillage and conventional production systems. Halosulfuron-methyl offers considerable flexibility to users as it can be applied prior to planting via pre-plant incorporation or pre-plant surface applications, or as post-transplant or post-emergence applications, depending on the crop.

5.3.4 Information on the Occurrence or Possible Occurrence of the Development of Resistance

There is considerable resistance to Group 2 herbicides already, throughout Canada. For example in Ontario alone, the following weeds have developed resistance to ALS inhibitors: Powells amaranth, redroot pigweed, common waterhemp, common ragweed, lamb’s quarters, horseweed, giant foxtail, green foxtail and eastern black nightshade. At least three of these (Powells amaranth, common waterhemp and horseweed) have developed multiple resistance to different modes of action. Some resistance to halosulfuron-methyl has been reported in the United States including small flower umbrella sedge and rice flatsedge, in Arkansas; common waterhemp and common sunflower in Missouri; and common ragweed in Ohio.

Like any other herbicide, crop rotation and herbicide rotation play critical roles in delaying the development of resistance. Some of the proposed minor use crops have few registered herbicide alternatives so the registration of halosulfuron-methyl will benefit growers of these crops. There are also tank mixes proposed for use in corn and dry bean which should further help to mitigate resistance development.

5.4 Supported Uses

For supported uses, please refer to Appendix I, Table 17.

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), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*.

During the review process, halosulfuron-methyl and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

- Halosulfuron-methyl does not meet TSMP Track 1 criteria, and is not considered a TSMP Track 1 substance. See Appendix I, Table 16 for comparison with Track 1 criteria.

- The major transformation product, halosulfuron acid, does not meet TSMP Track 1 criteria as it is not persistent. The major transformation products, aminopyrimidine, halosulfuron-methyl rearrangement ester, halosulfuron rearrangement acid, chlorosulfonamide ester, chlorosulfonamide acid and halosulfuron guanidine, are not expected to meet TSMP Track 1 criteria; however, as they were found to be persistent in one or more of the laboratory biotransformation studies, log K_{OW} information will be required to confirm this, to show that the compounds do not meet the criterion for bioaccumulation.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*.[6] The list is used as described in the PMRA Notice of Intent NOI2005-01[7] and is based on existing policies

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5 DIR99-03, The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy.

6 *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) 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, SI/2008-67 (2008-06-25) 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.*

7 NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act.*

and regulations including DIR99-03 and DIR2006-02[8], 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 conclusions:

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

- The end-use products, Sandea Herbicide, Permit Herbicide and SedgeHammer Turf Herbicide, do not contain any formulants or 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[9].

7.0 Summary

7.1 Human Health and Safety

The toxicology database is adequate to define the majority of toxic effects that may result from exposure to halosulfuron-methyl. There was no evidence of carcinogenicity in rats or mice after longer-term dosing and no evidence that halosulfuron-methyl damaged genetic material. In short-term and long-term studies on laboratory animals, the primary target was body weight in rats and dogs and the haematopoietic system in dogs. When halosulfuron-methyl was given to pregnant animals, there were stillbirths, resorptions, malformations, reduced viability and reduced fetal weights; however, these effects occurred where there was clear toxicity in the dams. The risk assessment protects against the toxic effects noted above by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Mixers, loaders and applicators handling Sandea Herbicide, Permit Herbicide or SedgeHammer Turf Herbicide and workers re-entering treated orchards, fields, commercial or residential turf, landscaped areas, nurseries or industrial areas are not expected to be exposed to levels of halosulfuron-methyl that will result in risks of concern when Sandea Herbicide, Permit Herbicide and SedgeHammer Turf Herbicide are used according to label directions. The personal protective equipment on the product label is adequate to protect workers.

Additionally, exposure to the general public re-entering commercial or residential turf is not expected to result in risks of concern when SedgeHammer Turf Herbicide is used according to label directions.

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[8] DIR2006-02, *Formulants Policy and Implementation Guidance Document*.

[9] DIR2006-02, *Formulants Policy and Implementation Guidance Document.*

The nature of the residues in plants and animals is adequately understood. The residue definition for enforcement and dietary exposure assessment is halosulfuron-methyl in plant products and in animal matrices. The proposed use of halosulfuron-methyl on apples, asparagus, dry beans, caneberries (blackberry, loganberry, red and black raspberry), highbush blueberries, field corn and field corn grown for seed, sweet corn, popcorn, cucurbits (cantaloupes, honeydew melons, Crenshaw melons, cucumbers, summer squash for processing, watermelon, pumpkins, winter squash), tree nuts (beechnuts, butternuts, chestnuts, filberts [hazelnuts], hickory nuts, pecans, walnuts [black and English]), snap beans, proso millet, rhubarb, sorghum, and fruiting vegetables (chili, bell and banana peppers; eggplant, tomatillo, pepino, ground cherry, tomatoes and okra) does not constitute a risk of health concern for chronic or acute dietary exposure (food and drinking water) to any segment of the population, including infants, children, adults and seniors. Sufficient crop residue data have been reviewed to recommend MRLs. The PMRA recommends that the following MRLs be specified for residues of halosulfuron-methyl.

Commodity	Recommended MRL (ppm)
Crop Subgroup 22A : Stalk and stem vegetables	1
Crop Subgroup 9B: Squash/Cucumber	0.5
Meat byproducts of cattle, goat, horse, sheep	0.2
Crop Subgroup 9A: Melon	0.1
Apples Crop Group 8-09: Fruiting Vegetables Crop Group 14: Tree nuts Grain lupin; dry kidney beans; dry lima beans; dry navy beans; dry pink beans; dry pinto beans; dry tepary beans; dry beans; dry adzuki beans; dry blackeyed peas; dry catjang seeds; dry cowpea seeds; dry moth beans; dry mung beans; dry rice beans; dry southern beans; dry urd beans; dry broad beans; dry chickpeas; dry guar seeds; dry lablab beans Edible-podded runner beans; edible-podded snap beans; edible-podded wax beans; edible-podded moth beans; edible-podded yardlong beans; edible-podded jackbeans; edible-podded sword beans Field Corn Popcorn grain Rhubarb Sorghum Subgroup 13-07A: Caneberry Subgroup 13-07B: Bushberry Sweet corn kernels plus cob with husks removed	0.05
Proso millet; Fat and meat of cattle, goat, horse, sheep; milk	0.01

7.2 Environmental Risk

The use of Sandea Herbicide, Permit Herbicide and SedgeHammer Turf Herbicide, containing the active ingredient, halosulfuron-methyl, may pose a risk to freshwater algae and to non-target terrestrial and aquatic vascular plants, as a result, spray buffer zones to protect sensitive terrestrial and aquatic habitats from spray drift and label statements to inform users of potential risks to the environment are required.

7.3 Value

In summary, the weight of evidence provided through use history information, data and scientific rationales support the proposed uses from a value standpoint. The registration of halosulfuron-methyl will provide a new mode of action in a number of major and minor use crops and an effective tool to control broadleaved weeds and especially yellow nutsedge.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Halosulfuron Technical Herbicide and the end-use products Sandea Herbicide, Permit Herbicide and SedgeHammer Turf Herbicide, containing the technical grade active ingredient halosulfuron-methyl, for use in a broad range of field and horticultural crops for the control of yellow nutsedge and broadleaved weeds.

An evaluation of available scientific information found that, under the approved conditions of use, the products have value and do not present an unacceptable risk to human health or the environment.

List of Abbreviations

♂	male
♀	female
λ	wavelength
µg	microgram
µPa	micro pascal
3-CSA	3-chlorosulfonamide acid
3-CSE	3-chlorosulfonamide ester
1/n	exponent for the Freundlich isotherm
A	application
abs	absolute
a.i.	active ingredient
ADI	acceptable daily intake
AGF	aspirated grain fractions
ALS	acetolactate synthase
AP	aminopyrimidine
ARfD	acute reference dose
ARTF	Agricultural Re-entry Task Force
atm	atmosphere
ATPD	area treated per day
BBCH	Biologishe Bundesanstalt, Bundessortenamt and Chemical industry
bw	body weight
BW	generic body weight
bwg	body weight gain
CA	California
CAF	composite assessment factor
CAS	Chemical Abstracts Service
CEPA	Canadian Environmental Protection Act
chol	cholesterol
CI	Confidence Interval
COC	Crop oil concentrate
cm	centimetres
CR	chemical-resistant
d	day(s)
DACO	Data Code
DAT	days after treatment
DEEM-FCID	Dietary Exposure Evaluation Model - Food Commodity Intake Database
DER	data evaluation report
DF	dry flowable
DFR	dislodgeable foliar residue
DNA	deoxyribonucleic acid
DT_{50}	dissipation time 50% (the dose required to observe a 50% decline in concentration)
DT_{90}	dissipation time 90% (the dose required to observe a 75% decline in concentration)
dw	dry weight

E_bC_{50}	EC_{50} in terms of algal biomass
EC_{25}	effective concentration on 25% of the population
EC_{50}	effective concentration on 50% of the population
ED	exposure duration
EDE	estimated daily exposure
EEC	estimated environmental concentration
EIIS	USEPA Ecological Incident Information System
EPA	Environmental Protection Agency
EP	early postemergence
EPP	early preplant
E_rC_{50}	EC_{50} in terms of reduction of growth rate
ETOT	total erythrocyte cells
EU	European Union
F_0	parental generation
F_1	first generation
F_2	second generation
F_{2a}	second generation; first breeding
F_{2b}	second generation; second breeding
fc	food consumption
fe	food efficiency
FIR	food ingestion rate
g	gram
GAP	good agricultural practice
GC-ECD	gas chromatography with electron capture detection
GC-NPD	gas chromatography with nitrogen-specific thermionic detection
GI	gastrointestinal
GUS	groundwater ubiquity score
h	hours
ha	hectare(s)
HAFT	highest average field trial
HC	Historical control
HC_5	hazardous concentration to 5% of the species
HCT	haematocrit
HDPE	high-density polyethylene
HGB	haemogloblin
HPLC	high performance liquid chromatography
hr	hour(s)
HtM	hand-to-mouth
IA	Iowa
IORE	indeterminate order rate equation
IR-4	Inter-regional Research Project Number 4
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_{oc}	organic-carbon partition coefficient
K_{ow}	*n*–octanol-water partition coefficient
L	litre
LAFT	lowest average field trial

LC_{50}	lethal concentration 50%
LD	lactation day
LD_{50}	lethal dose 50%
LDH	lactate dehydrogenase
LLMV	lowest limit of method validation
LOAEL	lowest observed adverse effect level
LOC	level of concern
LOEC	low observed effect concentration
LOQ	limit of quantitation
LP	late postemergence
LR_{50}	lethal rate 50%
LSC	liquid scintillation counting
m	metre
mg	milligram
mL	millilitre
MAS	maximum average score
Max	maximum
MBD	maximum dietary burden
mC_i	millicurie
ME	Maine
MI	Michigan
Min	minimum
MIS	maximum irritation score
mL	millilitre
ML	mix/load
MLA	mixer/loader/applicator
mmole	millimole
MOE	margin of exposure
mol	mole
MON 12000	halosulfuron-methyl (ester)
MRID	Master Record Identification Number
MRL	maximum residue limit
MS	mass spectrometry
MS/MS	tandem mass spectrometry
MTD	maximum tolerated dose
MTOT	total granulopoietic cells
MW	molecular weight
n	number of field trials
N/A	not applicable
NA	not analyzed
NAFTA	North American Free Trade Agreement
NC	North Carolina
ND	not detected
NIS	Non-ionic Surfactant
NJ	New Jersey
nm	nanometre
NMR	nuclear magnetic resonance

NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NR	not required
NY	New York
NZW	New Zealand white
obs	observation
OC	organic carbon content
OM	organic matter content
OH	Ohio
ORETF	Outdoor Residential Exposure Task Force
OtM	object-to-mouth
P	parental generation
Pa	pascals
PBI	plantback interval
PD	pyridmidine radiolabel
PE	late postemergent
pH	potential of hydrogen
PHED	Pesticide Handlers Exposure Database
PHI	pre-harvest interval
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
PND	postnatal day
PO	Postemergence
PPE	personal protective equipment
PPI	preplant soil incorporated
ppm	parts per million
PZ	pyrazole radiolabel
PRE	pre-emergence
PCV	packed cell volume
RAC	raw agricultural commodity
RBC	red blood cell
RD	residue definition
REI	restricted entry interval
rel	relative
RQ	risk quotient
RRE	re-arrangement ester
RTI	retreatment interval
SAC	sacrificed
SEF	saliva extraction factor
SD	standard deviation
SFO	single first-order
SSD	species sensitivity distribution
tbili	total bilirubin
TC	transfer coefficient
TDE	total dermal exposure
TRR	total radioactive residue

TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
TRT1	untreated control
TTR	transferable turf residue
UV	ultraviolet
v/v	volume per volume dilution
wk	week(s)
WDG	water dispersible granule
WG	wettable granule
WP	wettable powder
wt	weight
yr	year(s)

Appendix I Tables and Figures

Table 1 Residue Analysis

Matrix	Method ID	Analyte	Method Type	LOQ		Reference (PMRA No.)
Soil	None	Active	HPLC-MS/MS	0.5 µg/kg		1995247
	None	Transformation products: HSMR, HSR, CSE, CSA	HPLC-MS	0.5 µg/kg		1995247
Sediment	Extended from soil					
Water – drinking, ground, surface	None	Active	HPLC-MS/MS	0.1 µg/L		1995248
Water – paddy	None	Transformation products: HSMR, HSR, CSE, CSA	HPLC-MS	5 µg/L		1995247
Plant	RES-109-97-4 (Enforcement method)	Halosulfuron-methyl	GC-NPD	0.05	Cotton, cotton processed fractions, corn, sugarcane, sorghum and tree nut matrices	1995250 and 2082280
	RES-026-92, Version 1	Halosulfuron-methyl and halosulfuron-methyl derived residues (in that, halosulfuron-methyl ester, acid; 3-chloro-sulfonamide acid and/or ester; determined as total halosulfuron-methyl equivalents	GC-ECD	Not determined per se; The lowest spiking levels that were adequately validated for halosulfuron-methyl and the CSA metabolite were: 0.1 ppm 0.2 ppm 0.3 ppm 0.05 ppm Halosulfuron-methyl: 0.05 ppm 3-CSA 0.09 ppm.	 Grain Fodder Forage, silage Starch and flour Corn flour Corn flour	2082276

Matrix	Method ID	Analyte	Method Type	LOQ		Reference (PMRA No.)
	RES-043-92, Version 2	Halosulfuron-methyl and 3-CSA	GC-ECD	0.0109 ppm	oil (crude and refined), meal, grits, flour and starch	2082277
				0.0181 ppm	grain and grain dust	
Animal	RES-046-93, Version 2	Halosulfuron-methyl and halosulfuron-methyl derived metabolites (halosulfuron acid, des-methyl MON 12000, chloro-sulfonamide ester)	GC-ECD	0.01 ppm	milk and edible cattle tissues	2082275 and 2082278
	ES-ME-0116-01 (Enforcement method)	Halosulfuron-methyl	GC-NPD	0.03 ppm	edible bovine tissues	1995249
				0.01 ppm	milk	

Table 2 Toxicity Profile of End-use Product(s) Containing Halosulfuron-methyl (Effects are known or assumed to occur in both sexes unless otherwise noted; in such cases, sex-specific effects are separated by semi-colons)

Study Type/Animal/PMRA #	Study Results
Acute oral toxicity CD@-Crl: CD@ (SD)BR rats PMRA #2082257	LD_{50} ♂ = 1129 mg/kg bw (95% CI 901-1414) LD_{50} ♀ = 1454 mg/kg bw (95% CI 1131-1869) LD_{50} ♂♀ = 1287 mg/kg bw (95% CI 1112-1489) **Slight toxicity**
Acute dermal toxicity CD@-Crl: CD@ (SD)BR rats PMRA #2082258	LD_{50} ♂ > 5000 mg/kg bw LD_{50} ♀ > 5000 mg/kg bw LD_{50} ♂♀ > 5000 mg/kg bw **Low toxicity**
Acute inhalation toxicity (nose-only) Sprague-Dawley rats PMRA #2082259	LC_{50} ♂ > 5.7 mg/L LC_{50} ♀ > 5.7 mg/L LC_{50} ♂♀ > 5.7 mg/L **Low toxicity**

Study Type/Animal/PMRA #	Study Results
Dermal irritation NZW Rabbits PMRA #2082261	MAS (24-72 hours) = 1/8 MIS (24 hours) = 1.3/8 **Slightly irritating**
Eye irritation NZW rabbits PMRA #2082260	MAS (24-72 hours) = 6.1/110 MIS (1 hour) = 14.1/110 With irritation persisting past 72 hours **Mildly irritating**
Dermal sensitization (Beuhler test) Dunkin-Hartley guinea pigs PMRA #2082262	Induction 1: 0/10 Induction 2: 0/10 Induction 3: 2/10 Challenge: 0/10 **Not a sensitizer**

Table 3 Toxicity Profile of Technical Halosulfuron-methyl

(Effects are known or assumed to occur in both sexes unless otherwise noted; in such cases, sex-specific effects are separated by semi-colons. Organ weight effects reflect both absolute organ weights and relative organ to bodyweights unless otherwise noted)

Study Type/Animal/PMRA #	Study Results
The metabolism of [^{14}C]-pyrimidine- and [^{14}C]-pyrazole halosulfuron-methyl were investigated in single oral doses of 5 and 250 mg/kg bw and repeat oral doses of 5 mg/kg bw × 14 days in male and female Sprague-Dawley rats and in single oral doses of 5 mg/kg bw in male, female and pregnant female Sprague-Dawley rats. Absorption was rapid, but incomplete, with no differences in sexes or doses noted. Distribution was extensive; however, according to a qualitative analysis of autoradiography in pregnant females, there was limited to no transfer across the placenta. The highest levels of radioactivity were found in the plasma, whole blood, kidneys, liver and lungs. Elimination was rapid in non-pregnant animals and essentially complete by 96 hours following a single dose of 5 mg/kg bw. However, in pregnant animals, radioactivity was still noted in the kidneys at 96 hours and in the intestines at 150 hours and, in non-pregnant animals dosed with 250 mg/kg bw, measurable radioactivity was noted in the whole blood samples at 7 days post-dosing, indicating a possible binding of test chemical and/or metabolites to blood component(s) or redistribution of radioactivity at the high dose. The pyrimidine label was retained in animals longer than the pyrazole-labelled compound. Bile was the major route of excretion and comprised 29 – 50% of the administered radioactivity. The majority of biliary excretion occurred in the first hour following dosing. There were no differences in excretion of labels in males given a single oral low dose (31-33%); however, females excreted 29% of the pyrimidine-labelled dose in the bile compared to 50% of the pyrazole-labelled dose. The major metabolites were the 5-hydroxy desmethyl and desmethyl derivatives of halosulfuron-methyl. There was a possible saturation of the 5-hydroxy desmethyl metabolic pathway between the low and high-doses as indicated by a relative reduction of this urinary metabolite in the high-dose group, while repeated low oral dosing resulted in an increased percentage of the desmethyl metabolite of halosulfuron-methyl.	
Acute Toxicity Studies	
Acute oral toxicity CD-1 mice PMRA 1995163; EU Doc: Vol 3 – B6.2.1.2	LD_{50} ♂ = 16156 mg/kg bw (CI 4363-48673 mg/kg bw) LD_{50} ♀ = 9295 mg/kg bw/day (CI 7052-12251 mg/kg bw) LD_{50} ♂♀ = 11173 mg/kg bw (CI 7978-15648 mg/kg bw) **Low toxicity**
Acute oral toxicity Sprague-Dawley (Crl:CD BR) albino rats PMRA 1995162; MRID 421394-13	LD_{50} ♂ = 10435.0 mg/kg bw (CI 6915.0 - 15746 .0 mg/kg bw) LD_{50} ♀ = 1758.3 mg/kg bw (CI 6243.7 - 9640.3 mg/kg bw) LD_{50} ♂♀= 8865.6 mg/kg bw (CI 7222.2 - 10883.0 mg/kg bw) **Low toxicity**
Acute dermal toxicity Sprague-Dawley albino rats (Crl:CD BR) PMRA 1995167; MRID 421394-15	LD_{50} ♂ > 2000 mg/kg bw LD_{50} ♀ > 2000 mg/kg bw LD_{50} ♂♀ > 2000 mg/kg bw **Low toxicity**

Acute inhalation toxicity Sprague-Dawley albino rats PMRA 1995169; MRID 421394-17	LC_{50} ♂ > 6.0 mg/L LC_{50} ♀ > 6.0 mg/L LC_{50} ♂♀ > 6.0 mg/L **Low toxicity**
Eye Irritation Study NZW rabbits PMRA 1995171; MRID 421394-19	MAS (24- 72 hours) 1.33/110 MIS (1 hour) 8.17/110 **Minimally irritating**
Dermal Irritation Study NZW rabbits PMRA 1995174; MRID 421394-21	MAS (24-72 hours) = 0/8 **Non-irritating**
Dermal Sensitization Study (Maximization) Guinea Pigs PMRA 1995175; MRID 421394-23	Induction = 0%, Challenge = 0% **Not a sensitizer**
Short-Term Toxicity Studies	
21d Dermal Toxicity Study Sprague-Dawley rats PMRA 1995188; MRID 426614-17	NOAEL 1000 mg/kg bw/d 1000 mg/kg bw/d: ↓ overall bwg ♂ - nonadverse
28d Oral Toxicity Study Sprague Dawley rats PMRA 1995187; EU Doc: Vol 3 – B6.3.1	NOAEL 1000 ppm (77.92/84.92 mg/kg bw/d) ≥ 3000 ppm: ↓ bwg (wk 0-2♂, wk 0-4♀), ↑ pancreatic acinar cell degeneration/necrosis 10 000 ppm: ↓ bw, ↓ blood glucose; ↓ fc wks 1, 2 and total ♂
13wk Oral Toxicity Study Sprague-Dawley rats PMRA 1995181; MRID 421715-01	NOAEL 1600 ppm (116/147 mg/kg bw/d) 6400 ppm: ↓ bw and bwg, ↓ urinary volume, ↓ thymus wts, ↓ chol, ↓ tbili, ↑ LDH, ↑ tubular pigmentation in kidneys; ↑ creatinine, ↑ liver vacuolation ♂
14d and MTD Oral Toxicity Study (Capsule) Beagle dog PMRA 1995184 Range-finding	MTD phase: 800 mg/kg bw/d: sac moribund, tremors, lack of sound response, ↓ fc and ↓ chol; lack of follow response, reddened lungs, enlarged spleen ♂; salivation, spasms, panting, hot-to-touch, vomiting, sluggishness, prostration, pupillary dilatation, pale spleen ♀ Repeat-dose phase: 200 mg/kg bw/d: vomiting, ↓ chol, reddened lungs ♀ 400 mg/kg bw/d: ↓ fc; sac moribund, unsteadiness, prostration, muscular spasms, increased salivation ♂, vomiting ♀

13 week Oral Toxicity Study (Capsule) Beagle dog PMRA 1995183; MRID 421715-02	NOAEL 40 mg/kg bw/d in ♂ and 10 mg/kg bw/d in ♀ ≥ 40 mg/kg bw/d: (↓ chol, ↑ liver weights – both adaptive); (↓ late erythroblasts and ETOT, ↑ MTOT and MTOT/ETOT ratios ♂ - adaptive); ↓ bw gains, ↓ HGB, RBC counts, PCV, ↑rel liver wts ♀ 160 mg/kg bw/d: ↓ protein and albumin; ↓ bw gains ♂; ↑ abs liver wts ♀
1-yr Oral Toxicity Study (Capsule) Beagle dog PMRA 1995186; MRID 423962-11	NOAEL: 10.0 mg/kg bw/d 40 mg/kg bw/d: **1 mortality ♂;** few and/or no feces, ataxia, sensitivity to touch (neck), swollen neck, exophthalmos (both eyes), lacrimation (both eyes), convulsions, rhinorrhea, sensitivity to touch, polypnea, languidness, prostration, ↓ lymphocytes, ♂; ↓ bwg wk 0-52, ↓ fc, ↓ RBC, HCT and HGB @ wks 26 and 52, ↓chol, ↓ spleen wts ♀
Chronic Toxicity/Oncogenicity Studies	
78 week Dietary Oncogenicity Study CD®-1 mice PMRA 1995189; EU Doc: Vol 3 – B6.5.2	NOAEL 3000 ppm (410.0 mg/kg bw/d) ♂ and 7000 ppm (1214.6 mg/kg bw/d) ♀ 7000 ppm: ↑ microconcretions/mineralisation within lumen of epididymal and testes tubules, ↓ testes and seminal vesicle weights ♂ **No evidence of carcinogenicity**
104 week Dietary Chronic and Carcinogenicity Study Sprague-Dawley CD rats PMRA 1995194; EU Doc: Vol 3 – B6.5.1	NOAEL 1000 ppm (46.3 mg/kg bw/d) ♀ and 2500 ppm (108.3 mg/kg bw/d) ♂ ≥ 2500 ppm: ↓ bw wks 52 – 104, ↓ bwg wks 13 – 76 and 0 – 104 ♀ 5000 ppm: ↓ bw wks 4 – 6, 10, 13 – 104, ↓ bwg wks 24 – 76 and 0 – 104, ↓ feces, languid behaviour, urine staining ♂ **No evidence of carcinogenicity**

Developmental/Reproductive Toxicity Studies	
Reproductive Toxicity Study Crl:CD®BR rats PMRA 1995208 Range-finding	Parental toxicity – 6400 ppm: ↓ bw ♂♀, gestation and lactation, ↓ fc 1st week of treatment Reproductive toxicity – ≥ 1600 ppm: ↓ viability 6400 ppm: ↓ implantations Offspring toxicity – ≥ 1600 ppm: ↓ pup weights, ↓ viability
Reproductive Toxicity Study Crl:CD®BR rats PMRA 1995205; MRID 421394-27	Parental NOAEL: 800 ppm (50.4 mg/kg bw/d) ♂ and 100 ppm (7.4 mg/kg bw/d) ♀ ≥ 800 ppm: ↓ bw at beginning and end of second premating period F_1 ♀(6-16%) 3600 ppm: ↓ bw/bwg in premating period F_1 (↓5-9; bwg ↓19%)/F_2 (↓12-7%; bwg ↓6%) and rest period (↓10; ↓16- 11%); ↓ bw/bwg lactation and gestation F_1(↓9-7%)/F_2 (↓12-9%), ↓ fc F_1 ♀ Reproductive NOAEL: 800 ppm (50.4/58.7 mg/kg bw/d) 3600 ppm: ↑ stillborns F_1/F_{2a}, ↓ bw day 0 F_1/F_{2ab} ♂♀ Offspring NOAEL: 100 ppm (7.4 mg/kg bw/d) ≥ 800 ppm: ↓ pup bw day 7 – 21 ♂ and days 14 & 21 ♀ P/F_1 3600 ppm: ↑ dying, killed, missing and/or cannibalized pups in days 0 – 4 P/F_1 [4 (3), 9 (3), 11 (9), 27 (15)], ↓bw day 0, 14, 21$F_{1/}F_{2a}$ ♂♀; ↓ bw day 0 ♂♀, day 14 and 21 ♀ F_1/F_{2b}
Rat Developmental Toxicity Study Crl:CD®BR rats PMRA 1995212 Range-finding	Maternal toxicity – None Developmental toxicity – 300 mg/kg bw/d: ↑ dilated ureters
Rat Developmental Toxicity Study Crl:CD®BR rats PMRA 1995211; MRID 421394-25	Maternal NOAEL 250 mg/kg bw/d 750 mg/kg bw/d: ↑ piloerection and urine staining, ↓ bw/bwg, fc & fe, ↑ total resorptions, ↑ postimplantation loss Developmental NOAEL 250 mg/kg bw/d 750 mg/kg bw/d: ↑ total resorptions, ↑ postimplantation loss, ↓ fetal bw, filamentous tail [0 (0), 0 (0), 0 (0), 3 (3), HC 0-1 (0-1)], ↑ soft tissue and skeletal variations

Rabbit Developmental Toxicity Study Hra: (NZW)SPF rabbits PMRA 1995214 Range-finding	Maternal Toxicity: ≥ 75 mg/kg bw/d: premature delivery, ↓ bw at end of observation period, ↓ overall bwg, net and carcass wts ≥ 250 mg/kg bw/d: ↑ signs of abortion, anorexia, thin, ↓ bw/bwg from day 1, ↑ abortions, ↓ litters with live fetuses, ↓ live fetuses/litter, ↓ % males, ↓ male fetal bw, ↓ fetal viability ≥ 750 mg/kg bw/d: ↑ sac moribund, red fluid in pan, ↓ bw/bwg throughout obs period, ↑ early resorptions/total # resorptions, 1000 mg/kg bw/d: one doe found dead, reduced motor activity, languid Developmental Toxicity: 75 mg/kg bw/d (highest dose with number of fetuses comparable to controls): skeletal malformations (misaligned cervical vertebrae, vertebral anomalies with/without assoc rib anomaly, forked- rib malformations) 250 mg/kg bw/d (highest dose with any surviving fetuses): ↑abortions, ↓ litters with live fetuses, ↓ live fetuses/litter, ↓ % males, ↓ male fetal bw, ↓ fetal viability ≥ 750 mg/kg bw/d: ↑ early resorptions/total resorptions, no live fetuses for comparison to controls
Rabbit Developmental Toxicity Study Hra: (NZW)SPF rabbits PMRA 1995215; MRID 421394-26	Maternal NOAEL 50 mg/kg bw/d 150 mg/kg bw/d: ↓ bw/bwg, fc &fe, ↑ early resorptions, ↓ litter size Developmental NOAEL 50 mg/kg bw/d 150 mg/kg bw/d: ↑ early resorptions, ↓ litter size, fused-rib malformations [1 (1), 0 (0), 0 (0), 4 (4), HC – 0-3 (0-2)]
Genotoxicity Studies	
Bacterial Reverse Mutation Assay S. typhimurium & E. coli PMRA 1995216; MRID 421394-28	**Negative**
In vitro gene mutation assay CHO cells PMRA 1995219; EU Doc: Vol 3 – B6.4.3	**Negative**
In vitro gene mutation assay CHO cells PMRA 1995221; MRID 421394-31	**Unacceptable**

Chromosomal aberration assay CHO cells PMRA 1995224; MRID 421394-29	**Negative**
In vivo mouse micronucleus assay Mouse PMRA 1995225; MRID 421394-30	**Negative**
Unscheduled DNA synthesis Rat hepatocyte cells PMRA 1995227; MRID 421394-32	**Negative**
Neurotoxicity Studies	
Acute Neurotoxicity Study Sprague-Dawley CD®-BR PMRA 1995209; MRID 45754701	NOAEL: 600 mg/kg bw 2000 mg/kg bw/d: ↓ rearing Day 0, ↑ slightly to moderate uncoordinated righting reflex (persistent in females); one mortality and ↓ bwg (↓21%) ♂
Subchronic Neurotoxicity Study Sprague-Dawley CD®-BR PMRA 1995210; MRID 45754702 **Supplemental**	**No NOAEL established** 10 000 ppm: ↓ bw and bwg ♂ Locomotor activity and organ weights were not investigated according to guidelines.
Metabolite Studies – 3-chlorosulfonamide – MON 5783	
Acute Oral Toxicity Study Crl:CD®BR rats PMRA	LD_{50} ♂♀ > 5000 mg/kg bw **Low toxicity**
90d Oral Toxicity Study Sprague-Dawley rats PMRA 1995178; MRID 43616301 Metabolite Study	NOAEL ≥ 20000 ppm (1400 mg/kg bw/d) ♂ and 1000 ppm (75.8 mg/kg bw/d) ♀ ≥ 10000 ppm : ↓ bw/bwg ♀
Rat Developmental Toxicity Crl:CD®BR rats PMRA 1995213; EU Doc: Vol 3 – B6.8.1.3	Maternal NOAEL 1000 mg/kg bw/d Offspring NOAEL 1000 mg/kg bw/d

Bacterial Reverse Mutation Assay *S. typhimurium* PMRA 1995217; EU Doc: Vol 3 – B6.8.1.4	**Negative**
In vitro gene mutation assay CHO cells PMRA 1995219; EU Doc: Vol 3 – B.6.8.1.5	**Equivocal at cytotoxic doses at 5% S9**
In vivo mouse micronucleus assay Mouse PMRA 1995226; EU Doc: Vol 3 – B.6.8.1.5	**Negative**

Table 4 Toxicology Endpoints for Use in Health Risk Assessment for Halosulfuron-methyl

Exposure Scenario	Study	Point of Departure and Endpoint	CAF[1] or Target MOE
Acute dietary general population	Not required for the general population		
	ARfD = NR		
Acute dietary females aged 13-49	Rabbit developmental toxicity study	NOAEL = 50 mg/kg bw Increased early resorptions, decreased litter size and fused-rib malformations	300
	ARfD = 0.2 mg/kg bw		
Repeated dietary	Reproductive toxicity study	NOAEL = 7.4 mg/kg bw/d Decreased body weights in F_1 ♀ and decreased body weights in F_0/F_1 pups from PND 7 – 21	100
	ADI = 0.07 mg/kg bw/d		
Short & Intermediate-term dermal and inhalation[2,3]	Reproductive toxicity study	NOAEL = 7.4 mg/kg bw/d Decreased body weights in F_1 ♀ and decreased body weights in F_0/F_1 pups from PND 7 – 21	100
Aggregate	Reproductive toxicity study	NOAEL = 7.4 mg/kg bw/d Decreased body weights in F_1 ♀ and decreased body weights in F_0/F_1 pups from PND 7 – 21	100

[1] CAF (composite assessment factor) refers to a total of uncertainty and *Pest Control Products Act* factors for dietary assessments; MOE refers to a target MOE for occupational and residential assessments
[2] Since an oral NOAEL was selected, a dermal absorption factor of 100% was used in a route-to-route extrapolation.
[3] Since an oral NOAEL was selected, an inhalation absorption factor of 100% (default value) was used in route-to-route extrapolation.

Table 5 Integrated Food Residue Chemistry Summary

NATURE OF THE RESIDUE IN CORN	PMRA # 1995241
Radiolabel Position	Pyrazole ring-labeled [^{13}C, ^{14}C]-halosulfuron methyl (PZ-label) and pyrimidine ring-labeled [^{15}N, ^{14}C]-halosulfuron methyl (PD-label)
Test Site	Individual pots in a climate controlled greenhouse
Treatment	Single pre-emergent application to soil containing 4 planted seeds; or, postemergent foliar treatment applied by pipette
Total Rate	560 g a.i./ha; the pre-emergent treatment included a herbicide safener (MON 13900) applied in a 1:1 ratio with the radio-labelled test compound
Formulation	Not reported
Preharvest interval	**Pre-emergent application [PRE]:** Forage - 41-45 days; Silage - 71-72 days; Fodder/Grain - 105-112 days **Postemergent application [POST]:** Forage - 21-24 days; Silage - 49 days; Fodder/Grain – 82-91 days

Matrices	**PHI (days)**		**[^{13}C, ^{14}C]-PZ label TRRs (ppm)**		**[^{15}N, ^{14}C]-PD label TRRs (ppm)**	
	PRE	**POST**	**PRE**	**POST**	**PRE**	**POST**
Forage	41-45	21-24	0.19	6.42	0.018	4.46
Silage	71-72	49	0.44	1.55	0.036	1.77
Fodder	105-112	82-91	1.52	7.56	0.080	12.72
Grain	105-112	82-91	0.40	0.034	0.014	0.0059

Metabolites Identified	**Major Metabolites (>10% of the TRRs)**		**Minor Metabolites (<10% of the TRRs)**	
Radiolabel Position	**[^{13}C, ^{14}C]-PZ label**	**[^{15}N, ^{14}C]-PD label**	**[^{13}C, ^{14}C]-PZ label**	**[^{15}N, ^{14}C]-PD label**
PRE Treatment				
Forage (41-45 day PHI)	Chlorosulfonamide acid (3-CSA) (64.1% of the TRRs; 0.12 ppm); *N*-conjugate chloro-sulfonamide ester (12.1% of the TRRs; 0.023 pm)	--	Halosulfuron-methyl; chloro-sulfonamide ester; hydroxymethyl chlorosulfonamide acid; *N*-demethyl chlorosulfonamide acid; *N*-Conjugate chlorosulfonamide acid; Metabolite Fraction 8*	Halosulfuron-methyl; Metabolite 11*
Silage (71-72 day PHI)	3-CSA (61.3% of the TRRs; 0.271 ppm)	--	Halosulfuron-methyl; chloro-sulfonamide ester; hydroxymethyl chlorosulfonamide acid; *N*-demethyl chlorosulfonamide acid; *N*-conjugate chlorosulfonamide acid; Metabolite Fraction 8*; *N*-conjugate chloro-sulfonamide ester	Halosulfuron-methyl; Metabolite 11*
Fodder (105-112 day PHI)	3-CSA (50.4% of the TRRs; 0.76 ppm)	--	Halosulfuron-methyl; chloro-sulfonamide ester; hydroxymethyl chlorosulfonamide acid; *N*-demethyl chlorosulfonamide acid; *N*-Conjugate chlorosulfonamide acid; Metabolite Fraction 8*; *N*-demethyl chloro-sulfonamide ester; *N*-	Halosulfuron-methyl; Metabolite 11*

			conjugate chloro-sulfonamide ester	
Grain (105-112 day PHI)	3-CSA (55.7% of the TRRs; 0.222 ppm); Metabolite fraction 8* (11.2% of the TRRs; 0.044 ppm)	--	Halosulfuron-methyl; chloro-sulfonamide ester; hydroxymethyl chlorosulfonamide acid	Halosulfuron-methyl
*While the identities of Metabolite Fraction 8 and Metabolite 11 could not be confirmed, some characterization was performed. The metabolites were present in roughly equal quantities. Organic/aqueous partitioning showed that these metabolites are polar and that Metabolite 11 is stable to acid.				
POST Treatment				
Forage (21-24 day PHI)	Halosulfuron-methyl (91.9% of the TRRs; 5.84 ppm)	Halosulfuron-methyl (97.3% of the TRRs; 4.34 ppm)	3-CSA; chloro-sulfonamide ester; halosulfuron-methyl acid	Halosulfuron-methyl acid
Silage (49-day PHI)	Halosulfuron-methyl (87.8% of the TRRs; 1.36 ppm)	Halosulfuron-methyl (97.2% of the TRRs; 1.72 ppm)	3-CSA; chloro-sulfonamide ester; halosulfuron-methyl acid	Halosulfuron-methyl acid
Fodder (82-91 day PHI)	Halosulfuron-methyl (92.3% of the TRRs; 6.98 ppm)	Halosulfuron-methyl (95.1% of the TRRs; 12.1 ppm)	3-CSA; chloro-sulfonamide ester; halosulfuron-methyl acid	Halosulfuron-methyl acid
Grain (82-91 day PHI)	3-CSA (35.3% of the TRRs; 0.012 ppm)	NA*	Halosulfuron-methyl; halo-sulfuron-methyl acid	NA*
*NA = not analysed: TRRs in grain were too low to warrant further residue characterization/identification.				

NATURE OF THE RESIDUE IN SUGARCANE	**PMRA # 1995242**
Radiolabel Position	Pyrazole ring-labeled [^{13}C, ^{14}C]-halosulfuron methyl (PZ-label) and pyrimidine ring-labeled [^{15}N, ^{14}C]-halosulfuron methyl (PD-label)
Test Site	In individual pots in a climate controlled greenhouse
Treatment	Single pre-emergent treatment applied one day after seeding of cut sugarcane pieces containing a growth rings and live buds, or postemergent foliar applied using a brush to the tops of leaves
Total Rate	560 g a.i./ha
Formulation	Not reported
Preharvest interval [PHI]	**Pre-emergent treatment [PRE]**: 217 days – forage; 295-300 days – cane and foliage (green leaves) **Postemergent treatment [POST]**: Forage - 165-days (without treated leaves); 186-days (with treated leaves); 243-248 days – cane and foliage (green leaves)

Matrices	**PHI (days)**		**[^{13}C, ^{14}C]-PZ label**		**[^{15}N, ^{14}C]-PD label**	
			TRRs (ppm)		**TRRs (ppm)**	
	PRE	**POST**	**PRE**	**POST**	**PRE**	**POST**
Forage without directly treated leaves	--	165	--	0.053	--	0.011
Forage with directly treated leaves	--	186	--	0.22	--	0.169
Forage	217	--	0.194	--	0.012	--
Cane	295-300	243-248	0.021	0.012	0.014	0.008
Foliage	295-300	243-248	0.709	0.541	0.071	0.121

Metabolites Identified	**Major Metabolites (>10% of the TRRs)**		**Minor Metabolites (<10% of the TRRs)**	
Radiolabel Position	**[^{13}C, ^{14}C]-PZ label**	**[^{15}N, ^{14}C]-PD label**	**[^{13}C, ^{14}C]-PZ label**	**[^{15}N, ^{14}C]-PD label**
PRE Treatment				
Forage (217-day PHI)	3-CSA (41.05% of the TRRs; 0.0796 ppm); N-hydroxy-methyl chloro-sulfonamide acid (14.36% of the TRRs; 0.0279 ppm); *N*-demethyl chloro-sulfonamide acid (10.40%	PD-Metabolite 1 (24.23% of the TRRs; 0.0029 ppm); PD-Metabolite 2 (25.53% of the TRRs; 0.0031 ppm)	Chlorosulfonamide ester; *N*-demethyl chlorosulfonamide ester-glycerate; chlorosulfonamide ester-glycerate	--

	of the TRRs; 0.0202 ppm)			
Cane (295-300 day PHI)	Halosulfuron-methyl (11.45 % of the TRRs; 0.0024 ppm); 3-CSA (20.09% of the TRRs; 0.0042 ppm); *N*-demethyl chlorosulfonamide acid (10.57% of the TRRs; 0.0022 ppm); chlorosulfonamide acid-glycerate (60.5% of the TRRs; 0.0013 ppm)	--	Chlorosulfonamide ester; N-hydroxy-methyl chloro-sulfonamide acid; N-demethyl chloro-sulfonamide ester-glycerate; chloro-sulfonamide ester-glycerate	--
Foliage (295-300 day PHI)	3-CSA (33.29% of the TRRs; 0.236 ppm); *N*-demethyl chlorosulfonamide acid (16.46% of the TRRs; 0.117 ppm);	PD-Metabolite 1 (20.92% of the TRRs; 0.0149 ppm); PD-Metabolite 2 (19.71% of the TRRs; 0.014 ppm)	Chlorosulfonamide ester; N-hydroxy-methyl chloro-sulfonamide acid; N-demethyl chloro-sulfonamide ester-glycerate; chloro-sulfonamide acid-glycerate; chloro-sulfonamide ester-glycerate	--
POST Treatment				
Forage without directly treated leaves (165-day PHI)	3-CSA (49.04% of the TRRs; 0.026 ppm); N-hydroxymethyl chloro-sulfonamide acid (10.82% of the TRRs; 0.0057 ppm); N-demethyl chloro-sulfonamide acid (10.57 % of the TRRs; 0.0056 ppm)	PD-Metabolite 1 (29.09% of the TRRs; 0.0032 ppm); PD-Metabolite 2 (23.64% of the TRRs; 0.0026 ppm)	Chlorosulfonamide ester; N-demethyl chlorosulfonamide ester-glycerate; chlorosulfonamide acid-glycerate; chlorosulfonamide ester-glycerate	--
Forage with directly treated leaves (186-day PHI)	Halosulfuron-methyl (47.41% of the TRRs; 0.1043 ppm); 3-CSA (16.74% of the TRRs; 0.0368 ppm)	Halosulfuron-methyl (70.57% of the TRRs; 0.119 ppm);	Chlorosulfonamide ester; N-hydroxy-methyl chloro-sulfonamide acid; N-demethyl chloro-sulfonamide acid; N-demethyl chloro-sulfonamide ester-glycerate; chloro-sulfonamide acid-glycerate; chloro-sulfonamide ester-glycerate	PD-Metabolite 1; PD-Metabolite 2
Cane (243-248 day PHI)	3-CSA (21.50% of the TRRs; 0.0026 ppm); N-hydroxy-methyl chlorosulfonamide acid (17.43% of the TRRs; 0.0021 ppm);	NA*	Chlorosulfonamide ester; N-demethyl chlorosulfonamide acid; N-demethyl chlorosulfonamide ester-glycerate; chlorosulfonamide acid-glycerate; chlorosulfonamide ester-glycerate	NA*
Foliage (295-300 day PHI)	Halosulfuron-methyl (23.74% of the TRRs; 0.128 ppm); 3-CSA (19.91% of the TRRs; 0.1078 ppm)	Halosulfuron-methyl (55.89% of the TRRs; 0.0676 ppm)	Chlorosulfonamide ester; N-hydroxy-methyl chlorosulfon-amide acid; N-demethyl chloro-sulfonamide acid;	PD-Metabolite 1; PD-Metabolite 2

			N-demethyl chloro-sulfonamide ester-glycerate; chloro-sulfonamide acid-glycerate; chloro-sulfonamide ester-glycerate	
*NA = not analyzed due to very low extracted radioactive residue level				

NATURE OF THE RESIDUE IN SOYBEAN				**PMRA # 1995239**	
Radiolabel Position	Pyrazole ring-labeled [^{13}C, ^{14}C]-halosulfuron methyl (PZ-label) and pyrimidine ring-labeled [^{15}N, ^{14}C]-halosulfuron methyl (PD-label)				
Test Site	Individual above ground containers (boxes) maintained in outdoor screenhouses in California				
Treatment	Single pre-emergent treatment applied to the soil surface immediately after seeding, or postemergent foliar applied using a brush to the tops of leaves at the second trifoliate leaf stage				
Total Rate	560 g a.i./ha				
Formulation	Not reported				
Preharvest interval [PHI]	**Pre-emergent treatment**: 54 days – forage; 130 days – straw and seed **Postemergent treatment**: 25 days – forage; 130 days – straw and seed				
Matrices	**PHI**	**[^{13}C, ^{14}C]-PZ label**		**[^{15}N, ^{14}C]-PD label**	
		TRRs (ppm)		**TRRs (ppm)**	
		PRE	**POST**	**PRE**	**POST**
Forage	54	2.713	14.982	0.458	11.884
Straw	130	3.563	1.848	0.469	1.799
Seed	130	0.272	0.055	0.138	0.091

Metabolites Identified	**Major Metabolites (>10% of the TRRs)**		**Minor Metabolites (<10% of the TRRs)**	
Radiolabel Position	**[^{13}C, ^{14}C]-PZ label**	**[^{15}N, ^{14}C]-PD label**	**[^{13}C, ^{14}C]-PZ label**	**[^{15}N, ^{14}C]-PD label**
PRE treatment				
Forage	3-CSA (58.88% of the TRRs; 1.597 ppm)	Pyrimidine urea (16.89% of the TRRs; 0.077 ppm)	Halosulfuron-methyl; chlorosulfonamide ester; chlorosulfonic acid; *N*-demethyl chlorosulfonamide acid; *N*-demethyl chlorosulfonamide ester-glycerate; chlorosulfonic ester; rearranged guanidine; guanidine acid; guanidine ester; hydrolyzed guanidine; guanidine-glycerate conjugate; guanidine-glycol conjugate; halosulfuron-methyl sugar conjugate; halosulfuron-methyl acid; rearrangement ester	Halosulfuron-methyl; halosulfuron-methyl acid; rearrangement ester; halosulfuron-methyl sugar conjugate; halosulfuron-methyl desmethyl; PD-Polar Metabolites; PD-Metabolite 1; PD-Metabolite 2; PD-Metabolite 3
Straw	3-CSA (42.04% of the TRRs; 1.498 ppm); *N*-demethyl chloro-sulfonamide acid (12.79% of the TRRs; 0.456	PD-Polar Metabolites (23.67% of the TRRs; 0.111 ppm)	Chlorosulfonamide ester; chlorosulfonic acid; *N*-demethyl chlorosulfonamide	Halosulfuron-methyl acid; halosulfuron-methyl sugar conjugate;

	ppm)		ester-glycerate; chlorosulfonic ester; rearranged guanidine; guanidine acid; guanidine ester; hydrolyzed guanidine; guanidine-glycerate conjugate; guanidine-glycol conjugate; halosulfuron-methyl sugar conjugate; halosulfuron-methyl acid	halosulfuron-methyl desmethyl; PD-Metabolite 1; PD-Metabolite 2; PD-Metabolite 3
Seed	3-CSA (54.10% of the TRRs; 0.147 ppm); *N*-demethyl chloro-sulfonamide acid (12.16% of the TRRs; 0.033 ppm)	PD-Polar Metabolites (24.16 % of the TRRs; 0.0333 ppm)	Halosulfuron-methyl; chlorosulfonic acid; *N*-demethyl chloro-sulfonamide ester-glycerate; chlorosulfonic ester; guanidine ester; hydrolyzed guanidine; guanidine-glycerate conjugate	Halosulfuron-methyl; halosulfuron-methyl acid; halosulfuron-methyl sugar conjugate; pyrimidine urea; MON 12000 desmethyl; PD-Metabolite 3
POST treatment				
Forage	Halosulfuron-methyl (86.55% of the TRRs; 12.98 ppm)	Halosulfuron-methyl (88.29% of the TRRs; 10.493 ppm)	3-CSA; chlorosulfonic ester; guanidine ester; Halosulfuron-methyl desmethyl; *N*-demethyl chloro-sulfonamide ester-glycerate; guanidine glycerate conjugate; guanidine glycol conjugate; MON 12000 sugar conjugate; chloro-sulfonamide ester; halosulfuron-methyl acid; rearrangement ester	Halosulfuron-methyl acid; rearrangement ester; halosulfuron-methyl sugar conjugate; pyrimidine urea; halosulfuron-methyl desmethyl; PD-polar metabolites
Straw	Halosulfuron-methyl ester (46.25% of the TRRs; 0.855 ppm); 3-CSA (11.34% of the TRRs; 0.210 ppm)	Halosulfuron-methyl (60.29% of the TRRs; 1.085 ppm)	*N*-Demethyl chlorosulfonamide acid; chlorosulfonic acid; chlorosulfonic ester; rearranged guanidine; guanidine acid; guanidine ester; halosulfuron-methyl desmethyl; N-demethyl-chlorosulfonamide ester-glycerate; guanidine glycerate conjugate; guanidine glycol conjugate; MON 12000 sugar	Halosulfuron-methyl acid; rearrangement ester; halosulfuron-methyl sugar conjugate; pyrimidine urea; halosulfuron-methyl desmethyl; PD-polar metabolites; PD-Metabolite 3

			conjugate; halo-sulfuron-methyl acid; rearrangement ester	
Seed	Halosulfuron-methyl (15.52% of the TRRs; 0.0085 ppm); 3-CSA (15.90% of the TRRs; 0.0087 ppm)	PD-Polar metabolites (17.00% of the TRRs; 0.0155 ppm)	*N*-Demethyl chlorosulfonamide acid; chlorosulfonic acid; chlorosulfonic ester; guanidine acid; guanidine ester; halosulfuron-methyl desmethyl; guanidine glycerate conjugate; halosulfuron-methyl sugar conjugate; chloro-sulfonamide ester; halosulfuron-methyl acid; re-arrangement ester	Halosulfuron-methyl; halosulfuron-methyl acid; halosulfuron-methyl sugar conjugate; pyrimidine urea; halosulfuron-methyl desmethyl; PD-polar metabolites; PD-Metabolite 3

Proposed Metabolic Scheme in Plants

Metabolism of halosulfuron-methyl in crops depends on the mode of application. Following **postemergence**, foliar application, little metabolism and translocation from the point of application occurs. The majority of residues are associated on tissue surfaces and were identified as unmetabolized halosulfuron-methyl. Where metabolism occurs, the predominant route appears to be conversion of halosulfuron-methyl to chlorosulfonamide acid (3-CSA), by either hydrolysis of the sulfonylurea linkage (chlorosulfonamide ester intermediate; 3-CSE), or initial ester cleavage of halosulfuron-methyl acid intermediate.

Following **pre-emergence** soil application, the metabolism of halosulfuron-methyl is much more extensive, and appears to begin in the soil, where the sulfonylurea linkage is split producing the chlorosulfonamide ester (3-CSE) and aminopyrimidine (AP) moieties. The chlorosulfonamide ester is preferentially taken up by the plant and further metabolized into various products, predominantly chlorosulfonamide acid (3-CSA) through cleavage of the methyl ester, with lesser quantities of N-conjugate chlorosulfonamide ester, hydroxymethyl chlorosulfonamide acid and N-demethyl chlorosulfonamide acid.

CONFINED ACCUMULATION IN ROTATIONAL CROPS – Lettuce, radish, winter wheat and soybeans	**PMRA #2082318**

Radiolabel Position	(^{14}C,^{13}C)-labeled in the pyrazole moiety (PZ-label) and (^{14}C)-labeled in the pyrimidine moiety (PD-label)
Test site	Bare sandy loam soil contained in above ground boxes maintained outdoors in screenhouses at a site located in Watsonville, CA
Formulation	Not reported
Application rate and timing	Bare soil was treated at 212 g a.i./ha, and aged for 30, 120 and 363 days.

Metabolites Identified			**Major Metabolites (>10% of the TRRs)**		**Minor Metabolites (<10% of the TRRs)**	
Crop	**Matrix**	**PBI (days)**	**PZ-label**	**PD-label**	**PZ-label**	**PD-label**
Soybean	Forage	30	3-chlorosulfon-amide (3-CSA) (66.69% of the TRRs; 0.021 ppm)	NA	N-conjugate 3-CSE	NA
		120	3-chlorosulfon-amide (3-CSA) (65.75% of the TRRs; 0.053 ppm)	NA	N-conjugate 3-CSE	NA

		363	3-chlorosulfon-amide (3-CSA) (77.55% of the TRRs; 0.1458 ppm)	NA	N-conjugate 3-CSE; N-conjugate 3-CSA; N-demethyl 3-CSA	NA
	Seed	30	3-chlorosulfon-amide (3-CSA) (43.56% of the TRRs; 0.0192 ppm)	NA	N-conjugate 3-CSE; N-conjugate 3-CSA; N-demethyl 3-CSA	NA
		120	3-chlorosulfon-amide (3-CSA) (26.33% of the TRRs; 0.0295 ppm)	NA	N-conjugate 3-CSE; N-conjugate 3-CSA; N-demethyl 3-CSA	NA
		363	3-chlorosulfon-amide (3-CSA) (53.27% of the TRRs; 0.0405 ppm)	NA	N-conjugate 3-CSE; N-conjugate 3-CSA; N-demethyl 3-CSA	NA
	Straw	30	3-chlorosulfon-amide (3-CSA) (51.97% of the TRRs; 0.6560 ppm); N-conjugate 3-CSA (10.54% of the TRRs; 0.07222 ppm); N-demethyl 3-CSA (15.81% of the TRRs; 0.1083 ppm)	Polar Fraction (30.47% of the TRRs; 0.0067 ppm)	N-conjugate 3-CSE	ND*
		120	3-chlorosulfon-amide (3-CSA) (50.91% of the TRRs; 0.8812 ppm); N-conjugate 3-CSA (15.61% of the TRRs; 0.2702 ppm); N-demethyl 3-CSA (13.48% of the TRRs; 0.2333 ppm)	NA	N-conjugate 3-CSE	NA
		363	3-chlorosulfon-amide (3-CSA) (58.611% of the TRRs; 0.3276 ppm); N-demethyl 3-CSA (14.77% of the TRRs; 0.0825 ppm)	NA	N-conjugate 3-CSE; N-conjugate 3-CSA;	NA
Wheat	Forage	30	3-chlorosulfon-amide (3-CSA) (64.88% of the TRRs; 0.0318 ppm)	Polar Fraction (31.78% of the TRRs; 0.0025 ppm); unknown metabolite 4 (13.08% of the TRRs; 0.001 ppm)	3-chlorosulfonic ester; 3-chloro-pyrazole acid; 3-chlorosulfonamide ester (3-CSE)	Unknown metabolites 2, 3 and 5
		120	3-chlorosulfon-amide (3-CSA) (51.82% of the TRRs; 0.0212 ppm)	NA	3-chlorosulfonic ester; N-demethyl 3-CSA; 3-chloro-pyrazole acid; 3-chlorosulfonamide ester (3-CSE)	NA

		363	3-chlorosulfon-amide (3-CSA) (75.20% of the TRRs; 0.0752 ppm)	NA	3-chlorosulfon-amide ester (3-CSE)	NA
	Grain	30	3-chlorosulfon-amide (3-CSA) (52.70% of the TRRs; 0.027 ppm)	Polar Fraction (31.78% of the TRRs; 0.0025 ppm); unknown metabolite 4 (13.08% of the TRRs; 0.001 ppm)	3-chlorosulfonic ester; N-demethyl 3-CSA; 3-chloro-pyrazole acid	ND
		120	3-chlorosulfon-amide (3-CSA) (25.85% of the TRRs; 0.0187 ppm)	NA	N-demethyl 3-CSA; 3-chloro-pyrazole acid; 3-chlorosulfonamide ester (3-CSE)	NA
		363	3-chlorosulfon-amide (3-CSA) (52.70% of the TRRs; 0.0348 ppm); N-demethyl 3-CSA (10.61% of the TRRs; 0.007 ppm)	NA	ND	NA
	Straw	30	3-chlorosulfon-amide (3-CSA) (34.15% of the TRRs; 0.2667 ppm); N-demethyl 3-CSA (10.61% of the TRRs; 0.007 ppm)	Polar Fraction (31.80% of the TRRs; 0.0318 ppm)	3-chlorosulfonic ester; N-demethyl 3-CSA; 3-chloro-pyrazole acid; 3-chlorosulfonic acid; 3-chloro-sulfonamide (3-CSE)	ND*
		120	3-chlorosulfon-amide (3-CSA) (35.66% of the TRRs; 0.2817 ppm)	NA	3-chlorosulfonic ester; N-demethyl 3-CSA; 3-chloro-pyrazole acid; 3-chlorosulfonic acid; 3-chloro-sulfonamide (3-CSE)	NA
		363	3-chlorosulfon-amide (3-CSA) (46.90% of the TRRs; 0.3194 ppm)	NA	3-chlorosulfonic ester; N-demethyl 3-CSA; 3-chloro-pyrazole acid; 3-chlorosulfon-amide (3-CSE)	NA
Radish	Tops	120	3-chlorosulfon-amide (3-CSA) (61.58% of the TRRs; 0.0092 ppm)	NA	ND	NA
		363	3-chlorosulfon-amide (3-CSA) (70.35% of the TRRs; 0.0331 ppm)	NA	ND	NA
	Roots	120	3-chlorosulfon-amide (3-CSA) (66.14% of the TRRs; 0.0106 ppm)	NA	N-demethyl 3-CSA	NA

		363	3-chlorosulfon-amide (3-CSA) (73.25% of the TRRs; 0.0164 ppm)	NA	N-demethyl 3-CSA	NA
Lettuce	Early	120	3-chlorosulfon-amide (3-CSA) (20.60% of the TRRs; 0.0008 ppm)	NA	N-demethyl 3-CSA; 3-chloro-sulfonamide ester (3-CSE)	NA
	Final	120	3-chlorosulfon-amide (3-CSA) (15.97% of the TRRs; 0.0008 ppm)	NA	3-chlorosulfon-amide ester (3-CSE)	NA
		363	3-chlorosulfon-amide (3-CSA) (42.38% of the TRRs; 0.0047 ppm)	NA	N-demethyl 3-CSA; 3-chloro-sulfonic acid; 3-chlorosulfon-amide ester (3-CSE)	NA

ND = not detected; NA – not analyzed; TRRs determined from combustion analysis were too low (<0.01 ppm) to warrant further analyses in these matrices.
*Two additional metabolites indicated as only “unknown” without any further designation were also identified in each of these matrices (soybean straw: 2.43% [0.0005 ppm] and 6.51% [0.0014 ppm] of the TRRs; wheat straw: 3.65% [0.0037 ppm] and 8.90% [0.0089 ppm] of the TRRs).

Proposed Metabolic Scheme in Rotational Crops following Planting in Treated Bare Soil:
Metabolism of halosulfuron-methyl in rotated crops planted in treated soil is similar to metabolism observed in pre-emergent (soil) treatments of primary crops. Prior to uptake in crops, halosulfuron-methyl first undergoes cleavage in the soil at the sulfonylurea linkage producing the 3-chlorosulfonamide ester (3-CSE) and aminopyrimidine (AP) moieties. Selective uptake of 3-CSE by the crop root system followed by ester hydrolysis leads to the formation of 3-chlorosulfonamide acid (3-CSA), which was the major metabolite detected in all rotational crop commodities at all PBIs. Further metabolic transformations of 3-CSA involving oxidative cleavage of the N-methyl group, hydrolysis of the sulfonamide group, and conjugation of the sulfonamide nitrogen, account for the formation of the remaining metabolites identified in this study.

NATURE OF THE RESIDUE IN LAYING HEN	PMRA #1995234 and 1995233

Fifteen laying hens were orally administered gelatin capsules containing ^{14}C-halosulfuron-methyl for four consecutive days, at a dose level equivalent to 9 ppm in the feed. Two different test materials were used; one containing pyrazole ring-labeled ^{14}C-halosulfuron-methyl (14.0 mCi/mmole), and the other containing equal portions of pyrazole ring-labeled ^{14}C-halosulfuron-methyl and pyrimidine ring-labeled ^{14}C- halosulfuron-methyl (resulting in 14.34 mCi/mmole). A total of twenty animals were used; five served as controls, five were fed the single-labeled test material, and ten were fed the double-labeled test material.

Eggs were collected twice each day and separated into yolks and whites; excreta was collected and weighed once a day. Eggs and excreta produced after the last dose were collected and labeled as day 4 collection. Eggs forming in the oviduct were included in the day 4 collection. Approximately 22 hours after the final dose, a sample of heparinized blood was taken from each animal; the test animals were then sacrificed, and the following samples were collected: muscle (breast and thigh), liver (entire), kidneys (both), fat (abdominal), skin with fat, GI tract, GI tract contents, shelled eggs in oviduct (if present), and yolks in ovary.

Matrices	[^{14}C-pyrazole + ^{14}C-pyrimidine]		[^{14}C-pyrazole]	
	TRRs (ppm)	% of Administered Dose	TRRs (ppm)	% of Administered Dose
Excreta (includes pan wash)	--	89.37, 88.26	--	102.43
GI tract contents	--	1.00, 0.35	--	0.81
Blood	0.032, 0.026	0.01, 0.01	0.011	<0.01

GI tract	0.080, 0.047	0.14, 0.08	0.094	0.18
Yolks from ovary	0.077, 0.058	0.09, 0.07	0.048	0.06
Liver	0.196, 0.125	0.19, 0.12	0.145	0.14
Kidneys	0.042, 0.035	<0.01, <0.01	0.027	<0.01
Fat (abdominal)	0.004, 0.002	<0.01, <0.01	0.002	<0.01
Skin with fat	0.006, 0.004	<0.01, <0.01	0.004	<0.01
Muscle (breast)	0.003, 0.002	<0.01, <0.01	<0.001	<0.01
Muscle (thigh)	0.004, 0.003	<0.01, <0.01	ND	ND
Egg yolk	0.008-0.057	0.03, 0.03	0.011-0.045	0.02
Egg white	0.006-0.034	0.05, 0.08	0.008-0.064	0.11

Metabolites identified	**Major Metabolites (>10% of the TRRs)**		**Minor Metabolites (<10% of the TRRs)**	
Radiolabel Position	**[^{14}C-pyrazole + ^{14}C-pyrimidine]**	**[^{14}C-pyrazole]**	**[^{14}C-pyrazole + ^{14}C-pyrimidine]**	**[^{14}C-pyrazole]**
Liver	--	--	Halosulfuron-methyl; aminopyrimidine or 4, 6-dihdroxy MON 12000	Halosulfuron-methyl; 4, 6-dihdroxy MON 12000
Kidney	--	--	MON 12000	MON 12000
Egg yolk	Halosulfuron-methyl (19.4%, 0.0111 ppm 3-chlorosulfonamide ester (15.7%, 0.00895 ppm)	Halosulfuron-methyl (18.7%, 0.00842 ppm); 3-chlorosulfonamide ester (23.6%, 0.0106 ppm)	Aminopyrimidine or 4, 6-dihdroxy MON 12000; rearrangement ester	3-chlorosulfonamide acid; 4, 6-dihdroxy MON 12000; MON 12000 acid; rearrangement ester
Egg white	Halosulfuron-methyl (52.5%, 0.0179 ppm)	Halosulfuron-methyl (47.2%, 0.0302 ppm); Desmethyl MON 12000 (13.6%, 0.0087 ppm	3-chlorosulfonamide ester; rearrangement ester	3-chlorosulfonamide acid; 3-chlorosulfonamide ester; rearrangement ester

NATURE OF THE RESIDUE IN LACTATING GOAT **PMRA #1995235**

Two lactating goats were orally administered gelatin capsules containing ^{14}C-halosulfuron-methyl for four consecutive days, at a dose level equivalent to 11 ppm in the feed. Two different test materials were used; one containing pyrazole ring-labeled ^{14}C-halosulfuron-methyl (14.0 mCi/mmole), and the other containing equal portions of pyrazole ring-labeled ^{14}C-halosulfuron-methyl and pyrimidine ring-labeled ^{14}C-halosulfuron-methyl (resulting in 14.34 mCi/mmole). A total of three animals were used; one served as a control, one was fed the single-labeled test material, and one was fed the double-labeled test material.

The animals were hand milked twice each day; excreta was collected and weighed twice a day. Approximately 22 hours after the final dose, a sample of heparinized blood was taken from each animal; the test animals were then sacrificed, and the following samples were collected: muscle (round), liver (entire), kidneys (both), fat (renal and omental), bile (from the gallbladder), urine (from the bladder) and GI tract and contents (treated animals only).

Matrices	**[^{14}C-pyrazole + ^{14}C-pyrimidine]**		**[^{14}C-pyrazole]**	
	TRRs (ppm)	**% of Administered Dose**	**TRRs (ppm)**	**% of Administered Dose**
Urine (includes cage wash)	--	83.24	--	86.08
Feces (includes GI tract contents)	--	11.40	--	12.98
Blood	0.009	<0.01	0.006	<0.01

GI tract	0.016	0.07	0.016	0.08
Bile (from gall bladder)	0.060	<0.01	0.075	<0.01
Liver	0.024	0.04	0.012	0.02
Kidneys	0.027	<0.01	0.017	<0.01
Fat (renal)	0.001	<0.01	0.001	<0.01
Fat (omental)	0.002	<0.01	0.001	<0.01
Muscle (round)	ND	ND	ND	ND
Milk	0.003-0.020	0.03	0.03-0.021	0.05

Metabolites identified	**Major Metabolites (>10% of the TRRs)**		**Minor Metabolites (<10% of the TRRs)**	
Radiolabel Position	**[^{14}C-pyrazole + ^{14}C-pyrimidine]**	**[^{14}C-pyrazole]**	**[^{14}C-pyrazole + ^{14}C-pyrimidine]**	**[^{14}C-pyrazole]**
Liver	Halosulfuron-methyl (14.2%, 0.0038 ppm)	Halosulfuron-methyl (24.3%, 0.0029 ppm)	Desmethyl MON 12000; MON 12000 acid	Desmethyl MON 12000; MON 12000 acid
Kidney	Halosulfuron-methyl (39.4%, 0.0106 ppm)	Halosulfuron-methyl (62.0%, 0.0105 ppm)	Desmethyl MON 12000	Desmethyl MON 12000; MON 12000 acid
Milk	Halosulfuron-methyl (60.4%, 0.0103 ppm); Desmethyl MON 12000 (11.7%, 0.0020 ppm)	Halosulfuron-methyl (45.7%, 0.0096 ppm)	3-chlorosulfonamide ester; 3-chlorosulfonamide acid; aminopyrimidine; rearrangement ester	Desmethyl MON 12000

Proposed Metabolic Scheme in Livestock

The metabolic pathway for halosulfuron-methyl in livestock was proposed based on the identified components. The majority of the radioactivity was excreted as unchanged halosulfuron-methyl and as its hydroxylated metabolite 5-hydroxy MON 12000. Small amounts of radioactivity were retained in eggs, milk and tissues; the major component was identified as unchanged halosulfuron-methyl. The presence of desmethyl halosulfuron and halosulfuron acid indicated that O-demethylation and ester hydrolysis occurred at the 4- or 6-methoxy group of the pyrimidine moiety and the 4-carbomethoxy group of the pyrazole moiety, respectively. Based on the results of the acid hydrolysis of selected samples, possible bound/conjugate residues of halosulfuron-methyl, aminopyrimidine, 3-chlorosulfonamide ester and 3-chlorosulfonamide acid in eggs, milk and tissues are also proposed.

FREEZER STORAGE STABILITY	**PMRA# 2082282, 2082283, 2082285, 2082286 (plant matrices); PMRA #2082236 (livestock matrices)**

Plant matrices: Almond nutmeat, field corn grain, silage, forage and fodder, lettuce, sugar beet root, wheat grain and forage, soybean grain and hay

The freezer storage stability data indicate that residues of halosulfuron-methyl and 3-CSA are stable in corn silage for up to 15 months (468 days), in corn fodder and forage (high water) for up to 25 months (755 and 762 days, respectively), in corn grain (high starch) for up to 27 months (827 days), in wheat grain (high starch), wheat forage (high water), soybean grain (high oil; high protein), soybean hay, lettuce (high water) and sugarbeet root (high starch) for up to 33-35 months (1021, 1057, 1058, 1069, 996 and 1013 days, respectively). Residues of halosulfuron-methyl are stable in almond nutmeat (high oil) for up to 295 days (10 months). Overall, residues of halosulfuron-methyl and 3-CSA are therefore considered to be stable under frozen storage conditions in high starch content matrices for up to 34 months, and in high water, high protein and high oil content matrices for up to 35 months.

Metabolites: Residues of aminopyrimidine are stable in corn forage, silage, grain and fodder for up to 27 months. Residues of N-demethyl CSA are stable in wheat forage, soybean hay, lettuce and sugarbeet root for up to 33-35 months. Residues of N-demethyl CSA showed stability in wheat grain for up to 31 months, and in soybean grain for up to 21 months but declined to levels below 70% at longer storage intervals of up to 35 months.

Animal matrices: Muscle, liver, fat, milk and eggs

The freezer storage stability data from the lactating dairy cattle feeding study indicate that residues of halosulfuron-methyl are stable in frozen storage in raw milk, liver, kidney, muscle and fat for intervals of up to 183, 223, 216, 209 and 230 days, respectively.

CROP FIELD TRIALS ON APPLE										
Thirteen field trials were conducted on apple in the United States during the 2006 growing season in Zones 1 (3 trials), 2 (2 trials), 5 (2 trials), 9 (1 trial), 10 (1 trial) and 11 (4 trials). At each trial site, two broadcast applications of halosulfuron-methyl (75% water dispersible granule [WDG]) were made at fruiting to the apple orchard floor on each side of the tree rows with a minimum swath of 0.9 m, at 49.3-59.4 g a.i./ha/application, with a 13-15 day retreatment interval (RTI), for total rates of 103-116 g a.i./ha/season. An adjuvant was not included in the spray mixtures. Whole fruit samples were harvested at 13-14 day PHIs.										
Commodity	**Total Application Rate (g a.i./ha)**	**PHI (days)**	**n**	**Halosulfuron-methyl* Levels (ppm)**						
				Min. [a]	**Max. [a]**	**LAFT[b]**	**HAFT[b]**	**Median[b]**	**Mean[b]**	**SD[b]**
Apple Fruit	103 –116	13-14	13	<0.05	<0.05	<0.05	<0.05	<0.05	0.05	N/A

PMRA #2082287

PHI = pre-harvest interval; LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial; SD = Standard Deviation; n = number of field trials. For computation of the LAFT, HAFT, median, mean and standard deviation, values < LOQ are assumed to be at the LOQ.
*Halosulfuron-methyl residues were determined as the re-arrangement ester [RRE] and converted to halosulfuron-methyl equivalents using a MW factor of 1.3.
[a] Values based on total number of samples.
[b] Values based on per-trial averages

CROP FIELD TRIALS & RESIDUE DECLINE ON CANTALOUPE										
Four and two field trials were conducted in the United States during the 1996-1997 and 1999 growing seasons, respectively, in Zones 2 (1 trial), 5 (1 trial), 6 (1 trial) and 10 (3 trials). At all trial sites, two applications of halosulfuron-methyl (75% WDG) were applied to treated plots at rates 53 g a.i./ha/application for a total rate of 105 g a.i./ha. The first application was made to the soil surface after planting, but prior to cracking. The second application was made postemergence to the crop, no later than the 5-leaf stage at intervals of 13 to 53 days. A NIS (0.5%) was included in both spray application mixtures at all test sites in the 1996-1997 trials except for the postemergent application at the MI trial (Zone 5) and both applications at the NJ trial (Zone 2). No adjuvants were included in the two 1999 trials. Samples were collected at earliest maturity, at 45- to 67-day PHIs.										
Commodity	**Total Application Rate (g a.i./ha)**	**PHI (days)**	**n**	**Halosulfuron-methyl* Residue Levels (ppm)**						
				Min.[a]	**Max. [a]**	**LAFT[b]**	**HAFT[b]**	**Median[b]**	**Mean[b]**	**SD[b]**
Cantaloupe	104-105	45-67	4	<0.10	<0.10	<0.10	<0.10	<0.10	0.10	0
		57	2	<0.05	<0.05	<0.05	<0.05	<0.05	0.05	--

PMRA #2082308 and 2082309

PHI = pre-harvest interval; LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial; SD = Standard Deviation; n = number of field trials. For computation of the LAFT, HAFT, median, mean and standard deviation, values < LOQ are assumed to be at the LOQ.
[a] Values based on total number of samples.
[b] Values based on per-trial averages
*Halosulfuron-methyl residues were determined as the re-arrangement ester [RRE] and converted to halosulfuron-methyl equivalents using a MW factor of 1.3.

CROP FIELD TRIALS ON CUCUMBER										
Six field trials were conducted in the during the 1996 growing season in which two halosulfuron-methyl (Sempra 75 WDG) treatments were applied to cucumbers at a nominal rate of 53 g a.i./ha/application for a total of 105 g a.i./ha. The first application was made to the soil surface after planting, but prior to cracking. The second application was made post emergence to the crop, no later than the 5-leaf stage. A NIS (0.5%) was included in the spray mixtures at all test sites except for the first application at the NC trial and both applications at the NJ trial. Samples were collected at 21-42 days after the final application.										
Commodity	**Total Application Rate (g a.i./ha)**	**PHI (days)**	**n**	**Halosulfuron-methyl* Residue Levels (ppm)**						
				Min. [a]	**Max. [a]**	**LAFT[b]**	**HAFT[b]**	**Median[b]**	**Mean[b]**	**SD[b]**
Cucumber	105**	21-42	6	< 0.10	< 0.10	< 0.10	< 0.10	<0.10	0.10	0

PMRA #2082299

PHI = pre-harvest interval; LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial; SD = Standard Deviation; n = number of field trials. For computation of the LAFT, HAFT, median, mean and standard deviation, values < LOQ are assumed to be at the LOQ.
[a] Values based on total number of samples per trial.
[b] Values based on per trial averages.
*Halosulfuron-methyl and 3-CSA-derived residues were determined as derivatized 3-CSA and converted to total halosulfuron-methyl equivalents using a MW factor of 1.8145.
**Includes trials conducted with and without adjuvants in the spray application mixtures.

CROP FIELD TRIALS ON SUMMER SQUASH										PMRA #2082305

Five field trials were conducted in the United States during the 1996-1997 growing seasons in Zones 1 (1 trial), 2 (1 trial), 3 (1 trial), 5 (1 trial) and 10 (1 trial). At each trial site, which consisted of one untreated and one treated plot, two halosulfuron-methyl (Sempra 75 WDG) treatments were made to summer squash varieties at rates of 53 g a.i./ha/application for a total of 105 g a.i./ha, with the exception of one trial (Zone 2) in which the individual application rates were 35-37 g a.i./ha for a total of 72 g a.i./ha. The first application was made to the soil surface after planting, prior to cracking. The second foliar application was made postemergence, between the 3- and 10-leaf stages. A NIS (0.5%) was included in the spray mixtures at all test sites except for the first application at the NY trial. Samples were collected at earliest maturity, at 14-37 day PHIs.

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	n	Halosulfuron-methyl** Residue Levels (ppm)						
				Min. [a]	Max. [a]	LAFT[b]	HAFT[b]	Median[b]	Mean[b]	SD[b]
Summer squash	72-105*	14-37	5	< 0.50	< 0.50	< 0.50	< 0.50	< 0.50	0.50	0

PHI = pre-harvest interval; LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial; SD = Standard Deviation; n = number of field trials. For computation of the LAFT, HAFT, median, mean and standard deviation, values < LOQ are assumed to be at the LOQ.
[a] Values based on total number of samples per trial.
[b] Values based on per trial averages.
*Includes trials conducted with and without adjuvants in the spray application mixtures.
**Halosulfuron-methyl and 3-CSA-derived residues were determined as derivatized 3-CSA and converted to total halosulfuron-methyl equivalents using a MW factor of 1.8145.

CROP FIELD TRIALS & RESIDUE DECLINE ON TOMATO										PMRA #2082317

Twelve field trials in standard and small tomato varieties were conducted in the United States during the 1999 growing season in Zones 1 (1 trial), 2 (1 trial), 3 (2 trials), 5 (1 trial), and 10 (7 trials). At each trial site, which consisted of one untreated and one treated plot, halosulfuron-methyl (75% WDG) was applied as two foliar spray applications to the treated plots at a rate of 52-55 g a.i./ha/application, at 28-35 day RTIs, for a total of 104-108 g a.i./ha. The first application occurred between early bloom and 2.54 cm fruit stage. Mature tomato fruit was harvested at 28-32 day PHIs. Samples at two sites were harvested at additional PHIs of 23, 33, 37 and 44 days to evaluate residue decline behaviour. A NIS (0.5%) was included in the spray mixtures at all test sites. No quantifiable halosulfuron-methyl residues were observed in any tomato fruit samples in this study. As such, residue decline behavior could not be evaluated.

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	n	Halosulfuron-methyl* Residue Levels (ppm)						
				Min. [a]	Max. [a]	LAFT[b]	HAFT[b]	Median[b]	Mean[b]	SD[b]
Tomatoes	104-108	28-32	12	<0.05	<0.05	<0.05	<0.05	<0.05	0.05	0

PHI = pre-harvest interval; LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial; SD = Standard Deviation; n = number of field trials. For computation of the LAFT, HAFT, median, mean and standard deviation, values < LOQ are assumed to be at the LOQ.
[a] Values based on individual residue measurements.
[b] Values based on per trial averages.
*Residues were determined as the RRE and are converted to and reported as halosulfuron-methyl equivalents using a MW factor of 1.3 ppm.

CROP FIELD TRIALS ON BELL AND NON BELL PEPPERS										PMRA #2082293

Nine field trials (6 bell and 3 chili) were conducted in the United States during the 1999 growing season in Zones 2 (1 bell pepper trial), 3 (1 bell pepper trial), 5 (1 bell pepper trial), 6 (1 bell pepper trial), 8 (1 chili pepper trial) and 10 (2 chili pepper trials). At each trial site, which consisted of one untreated and one treated plot, halosulfuron-methyl (75% WDG) was applied as two foliar spray applications to the treated plots at a rate of 52-54 g a.i./ha/application, at 30-36 day RTIs, for a total of 105-106 g a.i./ha. A NIS (0.5%, v/v) was included in all spray application mixtures. The first application occurred between early bloom and vegetative fruit stage. Mature pepper fruit was harvested at 28-32 day PHIs.

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	n	Halosulfuron-methyl* Residue Levels (ppm)						
				Min. [a]	Max. [a]	LAFT[b]	HAFT[b]	Median[b]	Mean[b]	SD[b]
Peppers – Bell	105-106	28-32	6	<0.05	<0.05	<0.05	<0.05	<0.05	0.05	0
Peppers – Non Bell		28-31	3	<0.05	<0.05	<0.05	<0.05	<0.05	0.05	0

PHI = pre-harvest interval; LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial; SD = Standard Deviation; n = number of field trials. For computation of the LAFT, HAFT, median, mean and standard deviation, values < LOQ are assumed to be at the LOQ.
[a] Values based on individual residue measurements.
[b] Values based on per trial averages.
*Residues were determined as the RRE and are converted to and reported as halosulfuron-methyl equivalents using a MW factor of 1.3 ppm.

CROP FIELD TRIALS ON HIGHBUSH BLUEBERRIES	PMRA #2082296

Six field trials were conducted in the United States during the 2006 growing season in Zones 1 (1 trial), 2 (2 trials), 5 (2 trials) and 12 (1 trial). At each trial site, consisting of one treated and one untreated plot, a single halosulfuron-methyl (Sandea 75% Herbicide; WG formulation) treatment was applied to either side of the highbush blueberry row (minimum swath of 1 m except for the ME site [Zone 2] where the swath was 0.5 m on each side of the row) at a total of 104-111 g a.i./ha. Mature blueberries were harvested at 13-14 day PHIs.

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	n	Halosulfuron-methyl* Residue Levels (ppm)						
				Min. [a]	Max. [a]	LAFT[b]	HAFT[b]	Median[b]	Mean[b]	SD[b]
Highbush blueberries	104-111	13-14	6	<0.05	<0.05	<0.05	<0.05	<0.05	0.05	0

PHI = pre-harvest interval; LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial; SD = Standard Deviation; n = number of field trials. For computation of the LAFT, HAFT, median, mean and standard deviation, values < LOQ are assumed to be at the LOQ.
[a] Values based on individual residue measurements.
[b] Values based on per trial averages.
*Residues were determined as the RRE and are converted to and reported as halosulfuron-methyl equivalents using a MW factor of 1.3 ppm.

CROP FIELD TRIALS ON CANEBERRIES (RASPBERRIES AND BLACKBERRIES)	PMRA #2108691

Eight field trials (4 each in raspberry and blackberry) were conducted in the United States and Canada during the 2008 growing season in Zones 1 (1 raspberry trial), 2 (1 blackberry trial), 5 (1 blackberry and 1 raspberry trial), 10 (1 blackberry trial) and 12 (2 raspberry trials and 1 blackberry trial). At each trial site, which consisted of one untreated and one treated plot, a single halosulfuron-methyl (Sandea 75% WDG Herbicide) treatment was made to either side of the caneberry row (minimum swath of ~1m) at a rate of 104-110 g a.i./ha. A NIS was used included in the spray application mixture at one trial site only. Mature caneberries were harvested at 13-15 day PHIs.

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	n	Halosulfuron-methyl* Residue Levels (ppm)						
				Min. [a]	Max. [a]	LAFT[b]	HAFT[b]	Median[b]	Mean[b]	SD[b]
Raspberry	104-110	13-15	4	<0.05	<0.05	<0.05	<0.05	<0.05	0.05	0
Blackberry			4	<0.05	<0.05	<0.05	<0.05	<0.05	0.05	0

PHI = pre-harvest interval; LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial; SD = Standard Deviation; n = number of field trials. For computation of the LAFT, HAFT, median, mean and standard deviation, values < LOQ are assumed to be at the LOQ.
[a] Values based on individual residue measurements.
[b] Values based on per trial averages.
*Residues were determined as the RRE and are converted to and reported as halosulfuron-methyl equivalents using a MW factor of 1.3 ppm.

CROP FIELD TRIALS & RESIDUE DECLINE ON TREE NUTS (ALMONDS, PECANS AND PISTACHIOS)	PMRA #2082307

Twelve field trials (5 in almonds, 4 in pecans and 3 in pistachios) were conducted in the United States during the 1996 growing season in Zones 2 (1 pecan trial), 4 (1 pecan trial), 6 (1 pecan trial), 8 (1 pecan trial) and 10 (5 almond trials and 3 pistachio trials). At each trial site, comprised of one treated and one untreated plot, halosulfuron-methyl (Sempra Herbicide; 75% WDG formulation) was applied as three sequential ground spray applications broadcast from trunk to trunk at rates of 68-72 g a.i./ha/application (first two applications) at 74-88 day RTIs, and at 138-141 g a.i./ha (third application) at 28-132 day RTIs for a total of 278-285 g a.i./ha. Samples were harvested at a 1-day PHI. Almond samples at the CA site were also harvested at additional 5-, 10-, and 15-day PHIs to evaluate residue decline behaviour. Residue decline behaviour could not be assessed in almond nutmeat samples as residues at all PHIs were non quantifiable. Residue decline data in almond hulls showed that residues were 0.063-0.086 ppm at the 1-day PHI and declined to non quantifiable levels at the longer PHIs of 5-15 days.

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	n	Halosulfuron-methyl* Residue Levels (ppm)						
				Min. [a]	Max. [a]	LAFT[b]	HAFT[b]	Median[b]	Mean[b]	SD[b]
Almonds Hulls	278-282	1	5	<0.05	<0.160	<0.05	0.154	0.077	0.088	0.039
Almond Nutmeats		1-15	5	<0.05	<0.05	<0.05	<0.05	<0.05	0.05	0
Pecan Nutmeats	279-282	1	4	<0.05	<0.05	<0.05	<0.05	<0.05	0.05	0
Pistachio Nutmeats	278-285	1	3	<0.05	<0.05	<0.05	<0.05	<0.05	0.05	0

PHI = pre-harvest interval; LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial; SD = Standard Deviation; n = number of field trials. For computation of the LAFT, HAFT, median, mean and standard deviation, values < LOQ are assumed to be at the LOQ.
[a] Values based on individual residue measurements.
[b] Values based on per trial averages.
*Residues were determined as the RRE and are converted to and reported as halosulfuron-methyl equivalents using a MW factor of 1.3 ppm.

CROP FIELD TRIALS & RESIDUE DECLINE ON ASPARAGUS | **PMRA #2082295**

Eight field trials were conducted in/on asparagus in the 1999-2000 growing season in the United States in NAFTA Growing Zones 2 (1 trial), 5 (2 trials), 10 (3 trials) and 11 (2 trials). Each trial site consisted of one untreated plot and one treated plot. At each trial location, the treated plot received two ground applications of halosulfuron-methyl (formulated as GWN-3060 [Permit Herbicide], 75% WG). All spears greater than 20 cm in height were removed from the plots prior to the first application, which was made broadcast over the top of the crop within 10 days prior to the final harvest of the 1999 season at a rate of 52-53 g a.i./ha. The second treatment was made broadcast over the crop (sites 1, 2, 3, 6 and 8) or with nozzle dropped below the top (ferns) of tall and ferning crops (sites 4, 5 and 7) approximately 30 days after the first application at a rate of 51-53 g a.i./ha. The total of the combined applications was 130-106 g a.i./ha and a non-ionic surfactant (NIS; 0.25-0.5% v/v) was used in the spray mixtures at all sites. Asparagus spear samples were collected 0, 2 and 4 days after the first application and 235-287 days after the second application.

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	n	Halosulfuron-methyl* Residue Levels (ppm)						
				Min. [a]	Max. [a]	LAFT[b]	HAFT[b]	Median[b]	Mean[b]	SD[b]
Asparagus spears	52-53	0	8	0.153	0.719	0.210	0.679	0.239	0.313	0.163
		2		<0.05	0.056	<0.05	0.053	0.05	0.05	--
		4		<0.05	<0.05	<0.05	<0.05	<0.05	0.05	0
	103-106	235-287	8	<0.05	<0.05	<0.05	<0.05	<0.05	0.05	0

PHI = pre-harvest interval; LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial; SD = Standard Deviation; n = number of field trials. For computation of the LAFT, HAFT, median, mean and standard deviation, values < LOQ are assumed to be at the LOQ.
[a] Values based on total number of samples.
[b] Values based on per trial averages.
* Residues determined as the RRE are reported as halosulfuron-methyl equivalents using a MW conversion factor of 1.3.

CROP FIELD TRIALS ON RHUBARB | **PMRA #2082303**

Four United States field trials were conducted in/on rhubarb in the 2006 growing season in Zones 5 (1 trial) and 12 (3 trials). At each trial site, comprised of one treated and one untreated plot, a single soil broadcast application of halosulfuron-methyl (Sandea 75% a.i.; WG formulation) was made at a rate of 104-113 g a.i./ha just prior to the breaking of dormancy. A NIS was used in all applications. Rhubarb petiole samples were harvested at PHIs of 61-78 days.

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	n	Halosulfuron-methyl* Residue Levels (ppm)						
				Min. [a]	Max. [a]	LAFT[b]	HAFT[b]	Median[b]	Mean[b]	SD[b]
Rhubarb petioles	104-113	61-78	4	<0.05	<0.05	<0.05	<0.05	<0.05	0.05	0

PHI = pre-harvest interval; LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial; SD = Standard Deviation; n = number of field trials. For computation of the LAFT, HAFT, median, mean and standard deviation, values < LOQ are assumed to be at the LOQ.
[a] Values based on individual residue measurements.
[b] Values based on per trial averages.
*Residues were determined as the RRE and are converted to and reported as halosulfuron-methyl equivalents using a MW factor of 1.3 ppm

CROP FIELD TRIALS ON SNAP BEANS											PMRA #2082292

Eight American field trials were conducted in/on snap beans in the 1998 growing season in Zones 2 (2 trials), 3 (1 trial), 5 (3 trials), 10 (1 trial) and 11 (1 trial). At each trial site, consisting of one treated and one untreated plot, a single broadcast foliar application of halosulfuron-methyl (Sempra 75WDG) was made postemergent at the 2-9 trifoliate leaf stage at rates of 53-57 g a.i./ha. A non-ionic surfactant was used in all applications. Samples (whole bean pods) were harvested at PHIs of 28-32 days.

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	n	Halosulfuron-methyl* Residue Levels (ppm)						
				Min. [a]	Max. [a]	LAFT[b]	HAFT[b]	Median[b]	Mean[b]	SD[b]
Snap beans	53-57	28-32	8	<0.05	<0.05	<0.05	<0.05	<0.05	0.05	0

PHI = pre-harvest interval; LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial; SD = Standard Deviation; n = number of field trials. For computation of the LAFT, HAFT, median, mean and standard deviation, values < LOQ are assumed to be at the LOQ.
[a] Values based on total number of samples.
[b] Values based on per trial averages.
* Residues determined as the RRE are reported as halosulfuron equivalents using a MW conversion factor of 1.3.

CROP FIELD TRIALS ON DRY BEANS – POSTEMERGENT FOLIAR APPLICATIONS	PMRA #2082300

Twelve field trials in the United States were conducted on several dry bean varieties in the 2005 growing season in Zones 1 (1 trial), 5 (5 trials), 7 (2 trials), 8/9 (2 trials), 10 (1 trial) and 11 (1 trial). Each trial consisted of one untreated plot and one treated plot. At each trial location, the treated plot received a single foliar broadcast application of a 75% WG formulation of halosulfuron-methyl (Sempra Herbicide) at a rate of 68.5-83.8 g a.i./ha. A non-ionic surfactant (NIS) was added to the spray mixture for all trials. Applications were made during blooming or fruiting growth stage using ground equipment in spray volumes of 168 to 327 L/ha. Samples of commercially mature dry bean seeds were collected at 27- to 31-day PHIs.

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	n	Halosulfuron-methyl* Residue Levels (ppm)						
				Min. [a]	Max. [a]	LAFT[b]	HAFT[b]	Median[b]	Mean[b]	SD[b]
Dry bean	68.5-83.8	27-31	12	<0.05	<0.05	<0.05	<0.05	<0.05	0.05	0

PHI = pre-harvest interval; LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial; SD = Standard Deviation; n = number of field trials. For computation of the LAFT, HAFT, median, mean and standard deviation, values < LOQ are assumed to be at the LOQ.
[a] Values based on individual residue measurements.
[b] Values based on per trial averages.
* Residues were determined as the RRE and are reported as halosulfuron-methyl equivalents based on a MW conversion factor of 1.3.

CROP FIELD TRIALS ON DRY BEANS – POST PLANT, PRE-EMERGENT APPLICATIONS	PMRA #2082291

Ten field trials in the United States were conducted in/on dry bean varieties in the 1999 growing season in Zones 1 (1 trial), 5 (3 trials), 7 (2 trials), 8/9 (1 trial), 10 (1 trial) and 11 (2 trials). At each trial site, consisting of one untreated and one treated plot, a single broadcast application of a 75% WDG formulation of halosulfuron-methyl was made pre-emergence, 0-6 days post seed planting, at rates of 34-36 g a.i./ha. No adjuvants were used in the spray mixtures. Dry bean seed samples were harvested at 86-113 day PHIs.

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	n	Halosulfuron-methyl* Residue Levels (ppm)						
				Min. [a]	Max. [a]	LAFT[b]	HAFT[b]	Median[b]	Mean[b]	SD[b]
Dry bean	34-36	86-113	10	<0.05	<0.05	<0.05	<0.05	<0.05	0.05	0

PHI = pre-harvest interval; LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial; SD = Standard Deviation; n = number of field trials. For computation of the LAFT, HAFT, median, mean and standard deviation, values < LOQ are assumed to be at the LOQ.
[a] Values based on individual residue measurements.
[b] Values based on per trial averages.
* Residues were determined as the RRE and are reported as halosulfuron-methyl equivalents based on a MW conversion factor of 1.3.

CROP FIELD TRIALS ON FIELD CORN	PMRA #2082297 and 2082289
Twenty field trials in the United States were conducted in/on field corn in the 1990 growing season in zones 1 (1 trial), 2 (3 trials), 4 (1 trial), 5 (12 trials), 8 (1 trial) and 10 (2 trials). At each site, the treated plots received a single pre-emergence (PRE), preplant soil incorporated (PPI), early postemergence (EP; up to the 5th true leaf stage or 20 cm plant height), postemergence (PO; 23-61 cm plant height) or late postemergence (LP; at layby or 64-91 cm plant height), or two sequential applications (PRE + PO; PPI + LP; PO + LP) of halosulfuron-methyl, formulated as a wettable powder (WP; MON 12007 with 25% a.i. by weight). For the single applications, halosulfuron-methyl was tank mixed with acetochlor (MON 8422; 1.68-3.36 kg a.i./ha) and a safener (MON 13900; 212-420 g a.i./ha). For the two sequential applications, the safener and acetochlor were included in the first application only. Nominal halosulfuron-methyl application rates were 140, 71 and 105 g a.i./ha for the single PRE/PPI/EP, EP, and PO/LP applications, respectively. Nominal halosulfuron-methyl rates for the sequential applications were 140 (PRE or PPI) plus 105 (PO or LP) g a.i./ha for a total of 246 g a.i./ha, and 105 (PO) plus 105 (LP) g a.i./ha for a total of 210 g a.i./ha. No adjuvant use was indicated at any of the trial sites. Samples of **forage** were harvested at PHIs of 7-91 days, with the exception of one sample which was harvested following the first of two sequential applications, 5 days prior to the second application. **Silage** samples were harvested at PHIs of 49-146 days, and samples of **fodder** and **grain** were harvested at PHIs of 54-191 days following the single PRE/PPI/EP/PO/LP applications, or after the final of the sequential PRE+PO/PPI+LP/PO+LP applications.	

Commodity	Method/ Total Application Rate (g a.i./ha)	PHI (days)	n	Halosulfuron-methyl* Residue Levels (ppm)						
				Min. a	Max. a	LAFTb	HAFTb	Medianb	Meanb	SDb
Grain	PO+LP/ 211	79-147	20	<0.018	0.069	<0.018	0.067	0.018	0.025	0.01
Forage		7-32		<0.018	0.284	<0.018	0.238	0.045	0.087	0.08
Silage		49-117		<0.018	0.211	<0.018	0.150	0.033	0.054	0.05
Fodder		79-147		<0.018	1.164	<0.018	1.053	0.033	0.097	0.23
Grain	PRE/140	124-189	14	<0.018	0.028	<0.018	0.027	0.018	0.019	0.003
Forage		47-91		<0.018	0.025	<0.018	<0.022	0.018	0.018	0.001
Silage		86-131		<0.018	0.042	<0.018	<0.03	0.018	0.02	0.004
Fodder		126-189		<0.018	0.164	<0.018	0.160	0.018	0.029	0.028
Grain	PPI/140	127-191	6	<0.018	0.033	<0.018	0.03	0.018	0.02	0.005
Forage		57-91		<0.018	0.026	<0.018	0.026	0.018	0.02	0.003
Silage		101-146		<0.018	0.021	<0.018	<0.02	0.018	0.018	0.0008
Fodder		127-191		<0.018	0.067	<0.018	<0.043	0.018	0.023	0.01
Grain	EP/71	54-136	20	<0.018	0.025	<0.018	0.024	0.018	0.019	0.003
	EP/140		20	<0.018	0.028	<0.018	0.027	0.018	0.019	0.003
Forage	EP/71	20-63	20	<0.018	0.026	<0.018	<0.022	0.018	0.020	0.003
	EP/140		20	<0.018	0.034	<0.018	0.03	0.018	0.019	0.003
Silage	EP/71	68-109	20	<0.018	0.022	<0.018	0.022	0.018	0.018	0.001
	EP/140		20	<0.018	0.052	<0.018	0.042	0.018	0.02	0.006
Fodder	EP/71	54-136	20	<0.018	0.063	<0.018	0.061	0.018	0.019	0.004
	EP/140		20	<0.018	0.238	<0.018	0.235	0.018	0.039	0.05

Grain	PO/105	93-140	20	<0.018	0.034	<0.018	0.034	0.018	0.020	0.004
Forage		16-49		<0.018	0.138	<0.018	<0.078	0.020	0.028	0.022
Silage		58-95		<0.018	0.127	<0.018	0.118	0.018	0.027	0.02
Fodder		93-140		<0.018	0.193	<0.018	0.185	0.018	0.041	0.047
Grain	LP/105	79-129	20	<0.018	0.036	<0.018	0.027	0.018	0.020	0.02
Forage		7-32		<0.018	0.214	<0.018	0.208	0.037	0.059	0.05
Silage		52-89		<0.018	0.127	<0.018	0.118	0.025	0.035	0.03
Fodder		79-129		<0.018	0.345	<0.018	0.318	0.020	0.056	0.073
Grain	PRE + PO/246	93-140	13	<0.018	0.069	<0.018	0.064	0.018	0.023	0.01
Forage		33-45		<0.018	0.047	<0.018	0.047	0.018	0.025	0.009
Silage		58-95		<0.018	0.04	<0.018	<0.03	0.019	0.027	0.02
Fodder		93-140		<0.018	0.120	<0.018	0.074	0.018	0.030	0.02
Grain	PPI + LP/246	80-129	7	<0.018	0.03	<0.018	0.03	0.018	0.020	0.005
Forage		(-5*) 30-32		<0.018	0.067	<0.018	0.059	0.021	0.028	0.014
Silage		57-84		<0.018	0.061	<0.018	0.058	0.02	0.029	0.02
Fodder		80-129		<0.018	0.131	<0.018	0.130	0.043	0.061	0.05

PHI = pre-harvest interval; n = no. of field trials; LAFT = lowest average field trial; HAFT = highest average field trial. For computation of the LAFT, HAFT, median, mean and standard deviation, values < LOQ are assumed to be at the LOQ.

[*] Residues (in ppm) were determined as the derivatized 3-CSA and expressed as halosulfuron-methyl equivalents using a molecular weight conversion factor of 1.8145.

[a] Values based on individual residue measurements.

[b] Values based on per trial averages.

*Samples at this site were harvested after the first application was made, 5 days prior to the second application

CROP FIELD TRIALS ON SWEET CORN	**PMRA #2082306**

Twelve field trials in the United States were conducted during the 1993 growing season on sweet corn in Zones 1 (2 trials), 2 (1 trial), 3 (1 trial), 5/5A/5B (3 trials), 6 (1 trial), 10 (2 trials), 11 (1 trial) and 12 (1 trial). Each trial site consisted of four plots with one untreated control (TRT1) and three treated plots. Among the treated plots, collected samples were analyzed from only one of the plots. At this plot, halosulfuron-methyl was applied by one of three soil treatment methods (pre-emergence [PRE], within 3 days of planting; preplant incorporated [PPI], up to one week before planting; or, early preplant [EPP], 2-4 weeks prior to planting) followed by sequential postemergent (PO) (23-51 cm high plants) and late postemergent (LP) (plants 61-91 cm high plants) applications. For the soil-directed applications, halosulfuron-methyl was applied as MON 12041 (a water dispersible granule [WDG] containing 15% halosulfuron-methyl and 45% MON 13900 [safener]); for the postemergence applications, halosulfuron-methyl was applied as MON 12037 (a WDG formulation containing 75% halosulfuron-methyl by weight). The soil applied treatment was applied at a nominal rate of 140 g a.i/ha followed by the PO and LP applications at a nominal rate of 72 g a.i/ha/application, for totals of 269-287 g a.i./ha. Adjuvant use was not reported. Forage samples were collected 7-52 days and sweet corn ear samples were harvested 21-59 days after the final LPO application. No stover samples were collected at any of the trial sites.

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	n	Halosulfuron-methyl[*] Residue Levels (ppm)						
				Min. [a]	Max. [a]	LAFT[b]	HAFT[b]	Median[b]	Mean[b]	SD[b]
Sweet corn kernels plus cob with husks	269-287	21-36	8**	<0.05	0.078	<0.05	0.076	0.05	0.053	0.009
		52-59	3	<0.05	<0.05	<0.05	<0.05	0.05	0.05	0
Forage		7-33	10	<0.05	0.533	<0.05	0.48	0.19	0.195	0.14
		52-57	2	<0.05	0.114	<0.05	0.105	--	--	--

PHI = pre-harvest interval; LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial; SD = Standard Deviation; n = number of field trials. For computation of the LAFT, HAFT, median, mean and standard deviation, values < LOQ are assumed to be at the LOQ.
[a] Values based on individual residue measurements.
[b] Values based on per trial averages.
* Halosulfuron-methyl and 3-CSA-derived residues were determined as derivatized 3-CSA and converted to total halosulfuron-methyl equivalents using a MW factor of 1.8145.
**Due to high temperatures at the site in Zone 6, no ear samples were collected.

CROP FIELD TRIALS ON SORGHUM	**PMRA #2082315**

Twelve field trials in the United States were conducted in/on grain sorghum (milo) in the 1992 growing season in which a single postemergent broadcast over the top application of halosulfuron-methyl (MON-12037; 75% a.i. formulated as a WDG) was made to actively growing crops 20-31 cm in height growing at two test plots per site, at rates of 61-75 g a.i./ha at one plot and 92-111 g a.i./ha at the second plot. No adjuvants were included in any spray applications. Forage and hay samples were collected at 17- 37 and 20-43 day PHIs, respectively, silage was collected at 29-73 day PHIs, and grain and stover samples were collected at 68-118 day PHIs.

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	n	Halosulfuron-methyl* Residue Levels (ppm)						
				Min. [a]	Max. [a]	LAFT[b]	HAFT[b]	Median[b]	Mean[b]	SD[b]
Grain	61-75	68-118	11	<0.036	0.081	<0.036	<0.059	0.036	0.038	0.007
Forage		17-37	12	<0.036	0.041	<0.036	<0.039	0.036	0.036	0.001
Hay		20-43	12	<0.036	0.176	<0.036	0.146	0.031	0.050	0.03
Silage		29-73	12	<0.036	0.069	<0.036	0.063	0.036	0.042	0.001
Stover		68-118	12	<0.036	0.084	<0.036	0.077	0.036	0.042	0.01
Grain	92-111	68-118	11	<0.036	0.041	<0.036	0.04	<0.036	0.036	0.001
Forage		17-37	12	<0.036	0.085	<0.036	0.076	<0.036	0.042	0.01
Hay		20-43	12	<0.036	0.293	<0.036	0.213	0.045	0.062	0.05
Silage		29-73	12	<0.036	0.135	<0.036	0.117	<0.036	0.052	0.03
Stover		68-118	12	<0.036	0.101	<0.036	0.082	0.047	0.051	0.02

PHI = pre-harvest interval; LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial; SD = Standard Deviation; n = number of field trials. For computation of the LAFT, HAFT, median, mean and standard deviation, values < LOQ are assumed to be at the LOQ.
[a] Values based on individual residue measurements.
[b] Values based on per trial averages.
* Halosulfuron-methyl and 3-CSA-derived residues were determined as derivatized 3-CSA and converted to total halosulfuron-methyl equivalents using a MW factor of 1.8145.

CROP FIELD TRIALS ON PROSO MILLET	**PMRA #2115745**

Five field trials in the United States were conducted on proso millet in the 2009 growing season in Zones 5 (1 trial), 7 (2 trials) and 8 (2 trials). At each trial site, consisting of one untreated and one treated plot, a single postemergent application of halosulfuron-methyl (Yukon 12.5% WDG; a combination of halosulfuron-methyl and the sodium salt of dicamba) was made at the 3-5 leaf stage at rates of 34.7-35.2 g a.i./ha. A NIS (0.25 %, v/v) and urea ammonium nitrate (~28% nitrogen; ~1% v/v) were used in all applications. Proso millet forage samples were harvested 0 and 7 days after treatment (DAT), when the crop was 13-15 cm tall to BBCH 22 (tillering). Hay samples were cut 36-37 DAT at BBCH 59-87 growth stage and allowed to dry 3 to 8 days to a typical moisture targeting 10-20%. Grain and straw samples were collected at maturity at 51-67 DAT. Additional samples were collected from one site at to evaluate residue decline behaviour; forage samples were collected 0, 3, 7, and 14 DAT, hay samples were cut 31, 36, 44, and 52 DAT, and grain and straw samples were collected 52, 59, 65, and 72 DAT.

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	n	Halosulfuron-methyl* Residue Levels (ppm)						
				Min. [a]	Max. [a]	LAFT[b]	HAFT[b]	Median[b]	Mean[b]	SD[b]
Forage	34.7 – 35.2	0	5	2.37	5.81	2.42	5.04	2.76	3.14	1.08
		7	5	0.0231	0.640	0.0261	0.634	0.0744	0.179	0.255
Hay		36-37	5	<0.01	<0.01	<0.01	<0.01	<0.01	0.01	0
Grain		51-67	5	<0.01	<0.01	<0.01	<0.01	<0.01	0.01	0
Straw		51-67	5	<0.01	<0.01	<0.01	<0.01	<0.01	0.01	0

LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial; SD = Standard Deviation; n = number of field trials. For computation of the LAFT, HAFT, median, mean and standard deviation, values < LOQ are assumed to be at the LOQ.
[a] Values based on individual residue measurements.
[b] Values based on per trial averages.
* Residues were determined as the RRE and are reported as halosulfuron-methyl equivalents based on a MW conversion factor of 1.3.

RESIDUE DATA IN ROTATIONAL CROPS – WINTER WHEAT, SPRING WHEAT, SUGARBEETS AND LETTUCE | **PMRA #20852322 and 2082326**

Three rotational crop field trials were conducted during the 1990 growing season in the United States in CA (Zone 10), IA (Zone 5) and OH (Zone 5). Halosulfuron-methyl, formulated as a wettable powder (25% a.i. by weight), was applied as an initial preplant incorporated treatment (PPI), just prior to planting seed of the primary crop, corn, at a rate of 0.14 kg a.i./ha, as a tank mixture with acetochlor (target rate: 3.36 kg a.i./ha) and a safener (MON 13900; target rate 0.42 kg/ha). This was followed by a late postemergent (PE) foliar application (1-2 months after planting the primary crop), consisting of halosulfuron-methyl alone, when the corn was 64-91 cm high, at a rate of 0.11 kg a.i./ha. The combined total application rate was 0.25 kg a.i./ha. Mature corn was harvested in the fall at which time winter wheat was planted at 109-167 day plant back intervals (PBIs) to the initial PPI application (66-122 days after the final PE treatment). The following spring, sugar beets, lettuce, soybeans and spring wheat were planted at PBIs ranging from 307-388 days after the PPI treatment (264-329 days after the final PE treatment). Samples of wheat forage (8 and 26 weeks after planting for spring and winter wheat, respectively), and grain/straw were harvested at PHIs (PPI/PE applications) of 314-338/273-295 days and 400-426/360-364 days, respectively, for winter wheat and at PHIs (PPI/PE applications) of 384-427/338-386 days and 420-458/377-423 days for spring wheat. Soybean forage, hay and seeds were harvested at PHIs (PPI/PE applications) of 406-441/363-386 days, 461-507/419-445 days and 492-528/449-476 days. Lettuce head samples (with and without wrapper leaves) were harvested from all sites, with the exception of the CA site, at PHIs (PPI/PE applications) of 406-426/363-364 days. Sugar beet samples (tops and roots) were harvested from all sites, with the exception of the CA site, at PHIs (PPI/PE applications) of 494-528/451-466 days. Lettuce and sugar beet samples from the CA site did not survive to maturity due to phytotoxicity.4

Commodity	Total Application Rate (g a.i./ha)	PBI* (days)	Residue Levels (ppm)							
			n	Min. [a]	Max. [a]	LAFT [b]	HAFT [b]	Median [b]	Mean [b]	SD [b]
Halosulfuron-methyl**										
Winter wheat forage	250 (140 [PPI] + 111 [PE])	109-167 [66-122]	3	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0
Winter wheat grain				<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0
Winter wheat straw				<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0
Lettuce with wrapper leaves		307-364 [264-329]	2	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0
Lettuce without wrapper leaves				<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0
Soybean forage		307-388 [264-329]	3	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0
Soybean seed				<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0
Soybean hay				<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0
Spring wheat forage		323-364	3	<0.01	0.077	<0.01	0.074	<0.01	0.028	0.03

Spring wheat grain		[280-329]		<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0
Spring wheat straw				<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0
Sugar beet tops		307-388	2	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0
Sugar beet roots				<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0
Triazole-derived metabolites* **										
Winter wheat forage	250 (140 [PPI] + 111 [PE])	109-167 [66-122]	3	<0.019	0.07	<0.019	0.069	0.060	0.046	0.02
Winter wheat grain				0.02	0.059	0.02	0.055	0.032	0.036	0.016
Winter wheat straw				0.059	0.141	0.060	0.123	0.09	0.087	0.03
Lettuce with wrapper leaves		307-364 [264-329]	2	<0.019	<0.019	<0.019	<0.019	<0.019	<0.019	0
Lettuce without wrapper leaves				<0.019	<0.019	<0.019	<0.019	<0.019	<0.019	0
Soybean Forage		307-388 [264-329]	3	<0.019	0.192	<0.019	0.188	0.041	0.083	0.11
Soybean seed				0.035	0.132	0.037	0.089	0.055	0.067	0.037
Soybean hay				0.07	0.368	0.071	0.367	0.105	0.181	0.145
Spring wheat forage		323-364 [280-329]	3	<0.019	0.08	<0.019	0.078	0.064	0.054	0.028
Spring wheat grain				<0.019	0.024	<0.019	0.023	<0.019	0.02	0.002
Spring wheat straw				<0.019	0.029	<0.019	0.028	0.019	0.022	0.005
Sugar beet tops		307-388	2	<0.019	<0.019	<0.019	<0.019	<0.019	<0.019	0
Sugar beet roots				<0.019	0.022	<0.019	0.022	<0.02	0.02	0.002

*Numbers not bracketed represent the plant-back interval (PBI) from the pre-emergent application; numbers in [ ] represent the PBI from the postemergent application.
**Residues were determined as the RRE and have been converted to and are reported as halosulfuron-methyl equivalents using a MW factor of 1.3.
***The method used does not distinguish between the possible triazole-dervied metabolites (in other words, 3-chlorosulfonamide ester, 3-chlorosulfonamide acid and N-demethyl chlorosulfonamide acid). All are determined as N,N-dimethyl 3-chlorosulfonamide ester (DMCSE). Residues of DMCSE are converted to and reported as halosulfuron-methyl equivalents using a MW factor of 1.544.

PROCESSED FOOD AND FEED – APPLES	**PMRA #2082287**
Test Site	One trial site in the United States
Treatment	Directed to the orchard floor at 0.267 and 0.275 kg a.i./ha/application at a 14-day RTI
Rate	542 g a.i./ha/season
End-use product/formulation	75% WDG
Preharvest interval	13-14
Processed Commodity	Apples were not processed into juice or wet pomace given that residues in the unprocessed commodity harvested from trees treated at exaggerated rates were non quantifiable.

PROCESSED FOOD AND FEED – CORN	**PMRA# 2082327**
Test Site	Three trials in the United States
Treatment	Pre-emergent (0.35 kg a.i./ha) + late postemergent (0.35-0.56 kg a.i./ha)
Rate	0.70-0.91 kg a.i./ha
End-use product/formulation	25% WP; MON 12007
Preharvest interval	87-129 days
Processed Commodity	**Average Processing Factor**
Corn grits	0.50x
Corn meal	0.75x
Corn flour	0.28x
Crude oil (dry-mill)	0.27x

Refined oil (dry mill)	0.27x
Corn starch	0.27x
Crude oil (wet-mill)	0.27x
Refined oil (wet mill)	0.27x
Corn grain dust (AGFs)	1.44x
PROCESSED FOOD AND FEED – SORGHUM	**PMRA# 2082315**
Test Site	Two trials in the United States
Treatment	Single postemergent
Rate	0.41-0.43 kg a.i./ha
End-use product/formulation	75% WDG; MON 12037
Preharvest interval	68-87 days
Processed Commodity	**Average Processing Factor**
Sorghum grits	0.82x
Sorghum flour	0.40x
Sorghum bran	6.20x
Sorghum grain dust (AGFs)	4.24x
PROCESSED FOOD AND FEED – TOMATO	**PMRA# 2082317**
Treatment	One trial in the United States
Rate	Two applications at RTI of 30 days
End-use product/formulation	0.21 kg a.i./ha
Preharvest interval	75% WDG; GWN-3060
Processed Commodity	30 days
Tomato puree Tomato paste	**Average Processing Factor** Residues were all <LOQ (<0.05 ppm) in tomato, paste & puree; processing factors could not be calculated for halosulfuron-methyl in tomato processed fractions.
LIVESTOCK FEEDING – Dairy cattle	**PMRA #2082236**

Lactating dairy cows were orally administered halosulfuron-methyl at dose levels of 0.5, 1.5 and 5 ppm using a balling gun for 28 consecutive days. The dose levels of 0.5, 1.5 and 5 ppm represent 1.4x, 4.3x, and 14.3x, respectively, the estimated dietary burden for beef cattle, and 0.12x, 0.35, and 1.2x, respectively, the estimated dietary burden for dairy cattle.

Commodity	Feeding Level (ppm)	Highest Residues (ppm)	MBD (ppm)	Anticipated Residues at MBD (ppm)
			Dairy	
Whole milk	5	<0.01	4.35	0.009
Cream		<0.01		0.009
Fat		<0.01		0.009
Liver		0.11		0.2
Kidney		0.24		0.096
Muscle		<0.01		0.009

LIVESTOCK FEEDING – Laying hens

A laying hen feeding study was not provided for review. The dietary burden determined from the more balanced diet was calculated using data from the hen metabolism study (PMRA #1995234 and 1995233).

Commodity	Feeding Level (ppm)	Highest Residues (ppm)	MBD (ppm)	Anticipated Residue at MBD (ppm)
Muscle	9	<0.007	0.19	0.00015
Fat		<0.007		0.00015
Liver		0.196		0.004
Eggs		0.064		0.0013

Table 6 Food Residue Chemistry Overview of Metabolism Studies and Risk Assessment

PLANT STUDIES			
RESIDUE DEFINITION FOR ENFORCEMENT **Primary and rotational crops**		Halosulfuron-methyl	
RESIDUE DEFINITION FOR RISK ASSESSMENT **Primary crops and rotational crops**		Halosulfuron-methyl	
METABOLIC PROFILE IN DIVERSE CROPS		Similar in soybean, sugarcane and field corn.	
ANIMAL STUDIES			
ANIMALS		**Ruminant and Poultry**	
RESIDUE DEFINITION FOR ENFORCEMENT		Halosulfuron-methyl	
RESIDUE DEFINITION FOR RISK ASSESSMENT		Halosulfuron-methyl	
METABOLIC PROFILE IN ANIMALS		Similar in goat, hen and rat.	
FAT SOLUBLE RESIDUE		No	
DIETARY RISK FROM FOOD AND WATER			
Basic chronic non-cancer dietary exposure analysis **ADI = 0.07 mg/kg bw/day** **Estimated chronic drinking water concentration = 0.20 μg a.i./L (Level 1)**	**POPULATION**	**ESTIMATED RISK % of ACCEPTABLE DAILY INTAKE (ADI)**	
		Food Alone	**Food and Water**
	All infants < 1 year	2.4	2.4
	Children 1–2 years	**4.9**	**4.9**
	Children 3 to 5 years	3.6	3.6
	Children 6–12 years	2.2	2.2
	Youth 13–19 years	1.2	1.2
	Adults 20–49 years	0.9	0.9
	Adults 50+ years	0.8	0.8
	Females 13-49 years	0.9	0.9
	Total population	1.3	1.3

Basic acute dietary exposure analysis, 95th percentile **ARfD = 0.2 mg/kg bw** **Estimated acute drinking water concentration = 5.6 µg a.i.//L (Level 1)**	**POPULATION**	**ESTIMATED RISK % of ACUTE REFERENCE DOSE (ARfD)**	
		Food Alone	**Food and Water**
	Females 13-49 years	0.72	0.79

Table 7 Fate and Behaviour of Halosulfuron-methyl in the Environment

Property	Test substance	Value[1]	Transformation products	Comments	Reference
Abiotic transformation					
Hydrolysis	Halosulfuron-methyl	pH 5: DT_{50} = 28.4 days DT_{90} = 94.4 days (SFO - combined labels) pH 7: DT_{50} = 15.4 days DT_{90} = 51.3 days (SFO - combined labels) pH 9: DT_{50} = 16.8 hours DT_{90} = 55.8 hours (SFO - combined labels)	Major: Aminopyrimidine Chlorosulfonamide ester Rearrangement ester Minor: Halosulfuron Desmethyl MON 12000 Chlorosulfonamide acid	Hydrolysis is an important route of dissipation for halosulfuron-methyl.	1995251
Phototransformation on soil	Halosulfuron-methyl	Stable to phototransformation. Transformation was attributed to hydrolysis, not photolysis.	Major: Aminopyrimidine Chlorosulfonamide ester Minor: CO_2	Not expected to be an important route of dissipation for halosulfuron-methyl.	1995252
Phototransformation in water	Halosulfuron-methyl	Stable to phototransformation. Transformation was attributed to hydrolysis, not photolysis.	Major: Aminopyrimidine Chlorosulfonamide ester Rearrangement ester Rearrangement acid Minor: Halosulfuron Chlorosulfonamide acid CO_2	Not expected to be an important route of dissipation for halosulfuron-methyl.	1995253
Phototransformation in air	Halosulfuron-methyl is not expected to be volatile under field conditions based on vapour pressure and Henry's law constant. A study is not required.				

Biotransformation					
Biotransformation in aerobic soil	Halosulfuron-methyl	Sable soil (pH 5.8): DT_{50} = 12.3 days DT_{90} = 113 days (IORE - combined labels; representative half-life for modelling purposes = 34.1 days) Sarpy soil (pH 8.0): DT_{50} = 9.9 days DT_{90} = 62.7 days (IORE - combined labels; representative half-life for modelling purposes = 18.9 days)	Major: Chlorosulfonamide ester: DT_{50} = 256 days DT_{90} = 849 days (SFO - pyrazole label) Halosulfuron: DT_{50} = 31.9 days DT_{90} = 106 days (SFO - combined labels) Rearrangement ester: DT_{50} = 27.1 days DT_{90} = 256 days (IORE - combined labels) CO_2 Half-lives could not be calculated for the major transformation products: chlorosulfonamide acid, aminopyrimidine and MON 12000 guanidine, as they continued to increase until study end. Minor: Desmethyl MON 12000 Rearrangement acid	Halosulfuron-methyl is non-persistent. Chlorosulfonamide ester is persistent. As chlorosulfonamide acid, aminopyrimidine and MON 12000 guanidine continued to increase until study end, they are therefore considered persistent. Halosulfuron and the rearrangement ester are slightly persistent. Biotransformation in aerobic soil is a route of dissipation for halosulfuron-methyl.	1995257
Biotransformation in anaerobic soil (Supplemental study – results not used in risk assessment)	Halosulfuron-methyl	Loamy sand (pH 6.2): DT_{50} = 37.2 days DT_{90} = 124 days (SFO - combined labels)	Major: Rearrangement ester Rearrangement acid Chlorosulfonamide ester Chlorosulfonamide acid Pd3 Minor: Aminopyrimidine Desmethyl MON	Halosulfuron-methyl is slightly persistent. Biotransformation in anaerobic soil is a route of dissipation for halosulfuron-methyl.	1995259

			12000 Halosulfuron CO_2		
Biotransfor-mation in aerobic water systems	Halosulfuron-methyl	Bury Pond clay loam (pH 8.1): DT_{50} = 5.94 days DT_{90} = 23.5 days (IORE – combined labels – total system; representative half-life for modelling purposes = 7.07 days) Chatsworth sandy loam (pH 6.7): DT_{50} = 10.3 days DT_{90} = 34.3 days (SFO – combined labels – total system)	Major: Rearangement ester: DT_{50} = 22.7-39 days DT_{90} = 75.6-130 days (SFO - combined labels) Halosulfuron: DT_{50} = 36.2 days DT_{90} = 120 days (SFO - combined labels) Half-lives were not calculated for the major transformation products, chlorosulfonamide acid and the rearrangement acid, as they continued to increase until study end, and are therefore considered persistent. Minor: Desmethyl MON 12000 Chlorosulfonamide ester Aminopyrimidine	Halosulfuron-methyl is non-persistent. Halosulfuron and the rearrangement ester are slightly persistent. As chlorosulfonamide acid and the rearrangement acid continued to increase until study end, they are therefore considered persistent. Biotransformation in aerobic water/sediment systems is a route of dissipation for halosulfuron-methyl.	1995260
Biotransfor-mation in anaerobic water systems	Halosulfuron-methyl	Clay loam (pH 7): DT_{50} = 25.3 days DT_{90} = 84.1 days (SFO – combined labels – total system)	Major: Chlorosulfonamide ester Aminopyrimidine Halosulfuron CO_2 Minor: Rearrangement ester	Halosulfuron-methyl is slightly persistent. As chlorosulfonamide ester and aminopyrimidine either continued to increase until study end, or too few data points were available for reasonable half-life estimation, they are therefore	1995262

				considered persistent. Halosulfuron is not considered persistent as it was detected sporadically in the samples. Biotransformation in anaerobic water/sediment systems is a route of dissipation for halosulfuron-methyl.	
Mobility					
Adsorption / desorption in soil	Halosulfuron-methyl and major transformation products	K_{OC}: 31.1 to 199.2	Chlorosulfonamide acid K_{OC} set to zero (very high potential for mobility in soil) Chlorosulfonamide ester K_{OC}: 65.1 to 342.7 (medium to high potential for mobility in soil) Aminopyrimidine K_{OC}: 260 to 8285 (medium potential for mobility in soil to being immobile)	Halosulfuron-methyl is classified as having a medium to very high potential for mobility in soil.	1995265
	Halosulfuron-methyl rearrangement (major transformation product)	K_{OC}: 81.4-145.5	Not applicable. Halosulfuron-methyl rearrangement is a major transformation product of halosulfuron-methyl.	Halosulfuron-methyl rearrangement is classified as having a high potential for mobility in soil.	1995263
Adsorption / desorption in sediment	Not required as an acceptable adsorption/desorption study in soil was submitted.				
Soil leaching	Not required as an acceptable adsorption/desorption study was submitted.				
Volatilization	Not required due to low vapour pressure (<13 µPa) and Henry's law constant (3.4×10^{-11} atm·m^3/mol)				
Field studies					
Field dissipation in ecoregions representative	Wettable powder formulations containing	DT_{50} = 6.7-85.5 days	Either the transformation product was not observed at	Halosulfuron-methyl is non-persistent to moderately	2082331 2082330 2082334 2082344

of Canadian conditions (Ecoregion 9.2 – Temperate Prairies)	halosulfuron-methyl applied alone or in tank mix with a safener		significant levels, or the residues formed reached maximum levels within the first six months in the top 15 cm soil layer and then dissipated relatively quickly.	persistent under a variety of terrestrial field conditions. Little evidence of vertical movement of the parent or transfomation products. No significant carryover of residues into the next growing season.	
Field dissipation in an ecoregions not representative of Canadian conditions (Supplemental studies done in the United States)	Wettable powder formulations containing halosulfuron-methyl applied alone or in tank mix with a safener	DT_{50} = 4.2-64.1 days	Either the transformation product was not observed at significant levels, or the residues formed reached maximum levels within the first month in the top 15 cm soil layer and then dissipated relatively quickly.	Halosulfuron-methyl is non-persistent to moderately persistent under a variety of terrestrial field conditions. Little evidence of vertical movement of the parent or transfomation products. No significant carryover of residues into the next growing season.	2082329 2082331 2082330 2082334 2082339 2082344 2082342
Aquatic field dissipation	No aquatic field dissipation study with halosulfuron-methyl was submitted, and data on the aquatic field disspiation of halosulfuron-methyl are not required.				
[1] Kinetics models: SFO = single first-order; IORE = indeterminate order rate equation.					

Table 8 Toxicity of Halosulfuron-methyl to Non-Target Terrestrial Species

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity[1]	Reference
Invertebrates					
Earthworm, *Eisenia foetida*	14d-Acute	Halosulfuron-methyl	LC_{50} >1000 mg a.i./kg dw soil	Not applicable	1995282
Bee, *Apis mellifera*	48h-Oral	Halosulfuron-methyl	LD_{50} >100 µg a.i./bee	Relatively non-toxic	1995286
	48h-Contact	Halosulfuron-methyl	LD_{50} >100 µg a.i./bee	Relatively non-toxic	1995284
Predatory arthropod, *Typhlodromus pyri*	7d-Contact, Glass plates	Halosulfuron-methyl 75WG (granular formulation containing 750 g a.i./kg)	LR_{50} >300 g a.i./ha	Not applicable	1995287

Parasitic arthropod, *Aphidius rhopalosiphi*	48h-Contact, Glass plates	Halosulfuron-methyl 75WG (granular formulation containing 750 g a.i./kg)	LR_{50} >300 g a.i./ha	Not applicable	1995290
Birds					
Bobwhite quail, *Colinus virginianus*	14d-Acute oral	Halosulfuron-methyl	LD_{50} >2250 mg a.i./kg bw	Practically non-toxic	1995311
	5d-Dietary	Halosulfuron-methyl	LC_{50} >5620 mg a.i./kg diet LD_{50} >2810 mg a.i./kg bw/day	Practically non-toxic	1995313
	20w-Reproduction	Halosulfuron-methyl	NOEC = 1010 mg a.i./kg diet (highest concentration tested) NOEL = 89.3 mg a.i./kg bw/day	Not applicable	1995317
Mallard duck, *Anas platyrhynchos*	5d-Dietary	Halosulfuron-methyl	LC_{50} >5620 mg a.i./kg diet LD_{50} >1936 mg a.i./kg bw/day	Practically non-toxic	1995316
	22w-Reproduction	Halosulfuron-methyl	NOEC = 1000 mg a.i./kg diet (highest concentration tested) NOEL = 119 mg a.i./kg bw/day	Not applicable	1995318
Mammals					
Rat	Acute oral	Halosulfuron-methyl	LD_{50} = 7758 mg a.i./kg bw/d (females) LD_{50} = 10435 mg a.i./kg bw/d (males) LD_{50} = 8866 mg a.i./kg bw/d (combined sexes)	Practically non-toxic	1995162
	Acute oral	Sandea Herbicide (75% halosulfuron-methyl)	LD_{50} = 1093 mg a.i./kg bw/d (females) LD_{50} = 849 mg a.i./kg bw/d (males) LD_{50} = 968 mg a.i./kg bw/d (combined sexes)	Slightly toxic	2082257
	Reproduction (2 generation)	Halosulfuron-methyl	NOAEL = 50/59 mg a.i./kg bw/d (males/females) LOAEL = 223/261 mg a.i./kg bw/d (males/females) (reduction in parental and pup body weight, body weight gains and food consumption)	Not applicable	1995205

Mouse	Acute oral	Halosulfuron-methyl	LD_{50} = 9295 mg a.i./kg bw/d (females) LD_{50} = 16156 mg a.i./kg bw/d (males) LD_{50} = 11173 mg a.i./kg bw/d (combined sexes)	Practically non-toxic	1995163
Vascular plants					
Vascular plant, 10 crop species (monocots: corn, oat, onion and ryegrass; dicots: cucumber, soybean, tomato, lettuce, radish and cabbage)	21d-Seedling emergence	Halosulfuron-methyl	NOEC = 0.013 g a.i./ha EC_{25} = 0.022 g a.i./ha EC_{50} = 0.12 g a.i./ha (for the most sensitive endpoint of lettuce dry weight) HC_5 of SSD = 0.081 g a.i./ha	Not applicable	1995330 and 1995334
	21d-Vegetative vigour	Halosulfuron-methyl	NOEC = 0.039 g a.i./ha EC_{25} = 0.064 g a.i./ha EC_{50} = 0.21 g a.i./ha (for the most sensitive endpoint: radish dry weight) HC_5 of SSD = 0.097 g a.i./ha	Not applicable	1995329 and 1995331

[1] Atkins *et al*. (1981) for bees and USEPA classification for others, where applicable

Table 9 Screening Level and Refined Risk Assessment of Halosulfuron-methyl for Non-Target Terrestrial Species, Other Than Birds and Mammals

Organism	Exposure	Endpoint Value	EEC[1]	RQ	Level of Concern
Invertebrates					
Earthworm	Acute	LC_{50}/2 >500 mg a.i./kg dw soil	0.062 mg a.i./kg soil	<0.01	Not exceeded
Bee	Oral	LD_{50} >100 µg a.i./bee	4.06 µg a.i./bee[2]	<0.04	Not exceeded
	Contact	LD_{50} >100 µg a.i./bee	0.336 µg a.i./bee[3]	<0.01	Not exceeded
Predatory arthropod	Contact	LR_{50} >300 g a.i./ha	140 g a.i./ha	<0.5	Not exceeded
Parasitic arthropod	Contact	LR_{50} >300 g a.i./ha	140 g a.i./ha	<0.5	Not exceeded
Vascular plants					
Vascular plant	Seedling emergence	HC_5 = 0.081 g a.i./ha	On-field: 140 g a.i./ha	1728	Exceeded
			Off-field (6% drift): 8.4 g a.i./ha	104	Exceeded
	Vegetative vigour	HC_5 = 0.097 g a.i./ha	On-field: 140 g a.i./ha	1443	Exceeded
			Off-field (6% drift): 8.4 g a.i./ha	86	Exceeded

[1] Risk was assessed based on expected environmental concentrations (EECs) for the highest maximum seasonal application rate of 140 g a.i./ha.
[2] Endpoint based on consumption rates primarily derived from Rortais *et al.* (2005) and Crailsheim *et al.* (1992 and

1993), whereby the oral exposure estimate for adult bees is calculated by multiplying the direct single rate by 29 µg a.i./bee per kg/ha: 0.140 kg a.i./ha × 29 µg a.i./bee per kg/ha = 4.06 µg a.i./bee. [3] Endpoint derived according to Koch and Weißer (1997), whereby the proposed upper-bound residue value for estimating exposure to bees is based on a maximum residue value: 0.140 kg a.i./ha × 2.4 µg a.i./bee per kg/ha = 0.336 µg a.i./bee.

Table 10 Screening Level Risk Assessment of Halosulfuron-methyl for Birds and Mammals

	Toxicity (mg a.i./kg bw/d)	Feeding Guild (food item)	EDE (mg a.i./kg bw)[1]	RQ	Level of Concern
Small Bird (0.02 kg)					
Acute	>225.0	Insectivore (small insects)	7.05	<0.03	Not exceeded
Reproduction	89.3	Insectivore (small insects)	7.05	0.08	Not exceeded
Medium Sized Bird (0.1 kg)					
Acute	>225.0	Insectivore (small insects)	5.51	<0.02	Not exceeded
Reproduction	89.3	Insectivore (small insects)	5.51	0.06	Not exceeded
Large Sized Bird (1 kg)					
Acute	>225.0	Herbivore (short grass)	5.74	<0.03	Not exceeded
Reproduction	89.3	Herbivore (short grass)	5.74	0.06	Not exceeded
Small Mammal (0.015 kg)					
Acute	84.9	Insectivore (small insects)	4.06	0.05	Not exceeded
Reproduction	50.0	Insectivore (small insects)	4.06	0.08	Not exceeded
Medium Sized Mammal (0.035 kg)					
Acute	84.9	Herbivore (short grass)	12.71	0.15	Not exceeded
Reproduction	50.0	Herbivore (short grass)	12.71	0.25	Not exceeded
Large Sized Mammal (1 kg)					
Acute	84.9	Herbivore (short grass)	6.79	0.08	Not exceeded
Reproduction	50.0	Herbivore (short grass)	6.79	0.14	Not exceeded

[1] EDE = Estimated dietary exposure; is calculated using the following formula: (FIR/BW) × EEC, where:
FIR: Food Ingestion Rate (Nagy, 1987). For generic birds with body weight less than or equal to 200 g, the "passerine" equation was used; for generic birds with body weight greater than 200 g, the "all birds" equation was used:
Passerine Equation (body weight < or =200 g): FIR (g dry weight/day) = 0.398 (BW in g) $^{0.850}$
All birds Equation (body weight > 200 g): FIR (g dry weight/day) = 0.648 (BW in g) $^{0.651}$
For mammals, the "all mammals" equation was used: FIR (g dry weight/day) = 0.235(BW in g) $^{0.822}$
BW: Generic Body Weight
EEC: Concentration of pesticide on food item based on Hoerger and Kenaga (1972) and Kenaga (1973) and modified according to Fletcher *et al*. (1994). At the screening level, relevant food items representing the most conservative EEC for each feeding guild are used.

Table 11 Toxicity of Halosulfuron-methyl and Major Transformation Products to Non-Target Aquatic Species

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity[1]	Reference
Freshwater species					
Daphnia magna	48h-Acute	Halosulfuron-methyl	EC_{50} >107 mg a.i./L	Practically non-toxic	1995294
	48h-Acute	Halosulfuron-methyl rearrangement (transformation product)	EC_{50} >19.2 mg a.i./L (limit of solubility)	Non-toxic up to the water solubility under the conditions of the test	1995295
	21d-Chronic	Halosulfuron-methyl	NOEC = 7.2 mg a.i./L (highest concentration tested)	No classification	1995299
Freshwater snail, *Lymnaea peregra*	96h-Acute	Halosulfuron-methyl	LC_{50} >89.9 mg a.i./L (mean measured); >100 mg a.i./L (nominal)	Practically non-toxic, based on the nominal concentration	2124815
Chironomid, *Chironomus riparius*	28d-Chronic, spiked water	Halosulfuron-methyl	NOEC = 7.8 mg a.i./L (mean measured overlying water concentration; highest concentration tested)	No classification	2124816
Rainbow trout, *Oncorhynchus mykiss*	96h-Acute	Halosulfuron-methyl	LC_{50} >131 mg a.i./L	Practically non-toxic	1995303
	96h-Acute	Halosulfuron-methyl rearrangement (transformation product)	LC_{50} >15.3 mg/L (maximum attainable exposure concentration)	Non-toxic up to the water solubility under the conditions of the test	1995305
	28d-Chronic	Halosulfuron-methyl	NOEC = 34 mg a.i./L (reduction in day-28 and day-60 post hatch length, and wet and dry weight)	No classification	1995310
Bluegill sunfish, *Lepomis macrochirus*	96h-Acute	Halosulfuron-methyl	LC_{50} >118 mg a.i./L	Practically non-toxic	1995307
Diatom, *Navicula pelliculosa*	5d-Acute	Halosulfuron-methyl	EC_{50} >350 µg a.i./L	No classification	1995320
Green algae, *Selenastrum capricornutum*	5d-Acute	Halosulfuron-methyl	EC_{50} = 5.3 µg a.i./L	No classification	1995321
	72h-Acute	Halosulfuron (transformation product)	E_bC_{50} = 84.7 mg/L E_rC_{50} >98 mg/L	No classification	1995323
	72h-Acute	Halosulfuron-methyl rearrangement (transformation product)	E_bC_{50} = 17.5 mg/L E_rC_{50} >20.3 mg/L	No classification	1995325
	72h-Acute	Aminopyrimidine	E_bC_{50} = 269 mg/L	No	2124818

		(transformation product)	E_rC_{50} = 521 mg/L	classification	
Blue-green algae, *Anabaena flos-aquae*	5d-Acute	Halosulfuron-methyl	EC_{50} = 158 µg a.i./L	No classification	1995322
Vascular plant, *Lemna gibba*	14d-Dissolved	Halosulfuron-methyl	EC_{50} = 0.038 µg a.i./L	No classification	1995336
	7d-Dissolved	Halosulfuron-methyl	E_bC_{50} = 0.217 µg a.i./L E_rC_{50} = 0.491µg a.i./L $E_{wt}C_{50}$ = 0.823 µg a.i./L	No classification	1995337
Marine species					
Crustacean, mysid shrimp, *Mysidopsis bahia*	96h-Acute	Halosulfuron-methyl	LC_{50} = 109 mg a.i./L	Practically non-toxic	1995300
Mollusk, Eastern oyster, *Crassostrea virginica*	96h-Acute	Halosulfuron-methyl	Shell deposition: EC_{50} = 94 mg a.i./L	Slightly toxic	1995301
Sheepshead minnow, *Cyprinodon variegatus*	96h-Acute	Halosulfuron-methyl	LC_{50} >125 mg a.i./L	Practically non-toxic	1995308
Marine diatom, *Skeletonema costatum*	5d-Acute	Halosulfuron-methyl	EC_{50} >400 µg a.i./L	No classification	1995328
[1] USEPA classification, where applicable					

Table 12 Screening Level Risk Assessment of Halosulfuron-methyl for Aquatic Organisms

Organism	Exposure	Endpoint Value	EEC[1]	RQ	Level of Concern
Freshwater species					
Invertebrates	Acute	LC_{50}/2 >53500 µg a.i./L	17.5 µg a.i./L	<0.001	Not exceeded
	Chronic	NOEC = 7200 µg a.i./L	17.5 µg a.i./L	0.002	Not exceeded
Fish	Acute	LC_{50}/10 >11800 µg a.i./L	17.5 µg a.i./L	<0.001	Not exceeded
	Chronic	NOEC = 34000 µg a.i./L	17.5 µg a.i./L	<0.001	Not exceeded
Amphibians	Acute	LC_{50}/10 >11800 µg a.i./L	93.3 µg a.i./L	<0.008	Not exceeded
	Chronic	NOEC = 34000 µg a.i./L	93.3 µg a.i./L	0.003	Not exceeded
Algae	Acute	EC_{50}/2 = 2.65 µg a.i./L	Direct overspray: 17.5 µg a.i./L	6.6	Exceeded
Vascular plant	Dissolved	EC_{50}/2 = 0.019 µg a.i./L	Direct overspray: 17.5 µg a.i./L	921	Exceeded
Marine species					
Crustacean	Acute	LC_{50}/2 = 54500 µg a.i./L	17.5 µg a.i./L	<0.001	Not exceeded
Mollusk	Acute	EC_{50}/2 = 47000 µg a.i./L	17.5 µg a.i./L	<0.001	Not exceeded
Fish	Acute	LC_{50}/10 >12500 µg a.i./L	17.5 µg a.i./L	<0.001	Not exceeded

Algae	Acute	EC_{50}/2 >200 µg a.i./L	17.5 µg a.i./L	<0.09	Not exceeded
[1] Risk was assessed based on expected environmental concentrations (EECs) for the highest maximum seasonal application rate of 140 g a.i./ha.					

Table 13 Risk Quotients for Aquatic Organisms Determined for Drift of Halosulfuron-methyl

Organism	Exposure	Endpoint value	Refined EEC	RQ	Level of Concern
Freshwater algae	Acute	EC_{50}/2 = 2.65 µg a.i./L	Ground appl. (6% drift): 1.05 µg a.i./L	0.4	Not exceeded
Vascular plant	Dissolved	EC_{50}/2 = 0.019 µg a.i./L	Ground appl. (6% drift): 1.05 µg a.i./L	55	Exceeded

Table 14 Risk Quotients for Aquatic Organisms Determined for Runoff of Halosulfuron-methyl in Water Bodies 80 or 15 cm deep

Organism (exposure)	Endpoint value	EEC 90th percentile concentrations[1] (time-frame and region)	RQ	Level of Concern
Algae (Acute, 5-d)	EC_{50}/2 = 2.65 µg a.i./L	Apple use (Peak – Ontario and Atlantic): 1.0 µg a.i./L	0.4	Not exceeded
		Apple use (Peak – Quebec): 0.75 µg a.i./L	0.3	Not exceeded
		Apple use (Peak – B.C.): 0.14 µg a.i./L	0.1	Not exceeded
		Corn use (Peak – Atlantic): 5.2 µg a.i./L	2.0	Exceeded
		Corn use (Peak – Prairie): 3.0 µg a.i./L	1.1	Exceeded
		Corn use (Peak – Ontario): 2.9 µg a.i./L	1.1	Exceeded
		Corn use (Peak – Quebec): 2.4 µg a.i./L	0.9	Not exceeded
		Corn use (Peak – B.C.): 0.25 µg a.i./L	0.1	Not exceeded
Vascular plant (Chronic, 14-d)	EC_{50}/2 = 0.019 µg a.i./L	Apple use (Peak – Ontario and Atlantic): 1.0 µg a.i./L	53	Exceeded
		Apple use (Peak – Quebec): 0.75 µg a.i./L	40	Exceeded
		Apple use (Peak – B.C.): 0.14 µg a.i./L	7.4	Exceeded
		Corn use (Peak – Atlantic): 5.2 µg a.i./L	274	Exceeded
		Corn use (Peak – Prairie): 3.0 µg a.i./L	158	Exceeded
		Corn use (Peak – Ontario): 2.9 µg a.i./L	153	Exceeded
		Corn use (Peak – Quebec): 2.4 µg a.i./L	126	Exceeded
		Corn use (Peak – B.C.):	13	Exceeded

Organism (exposure)	Endpoint value	EEC 90th percentile concentrations[1] (time-frame and region)	RQ	Level of Concern
		0.25 µg a.i./L		

[1] As per a request from the registrant, the minimum application interval for corn was changed from 14 days to 21 days; however, the 14-day application interval was retained in the EEC calculation for aquatic ecoscenario estimates, as it is considered to be more conservative. The increase in application interval would not impact the outcome of the risk assessment: runoff of halosulfuron-methyl into water bodies would still pose a potential risk to freshwater algae and aquatic vascular plants.

Table 15 Screening Level Risk Assessment of Transformation Products of Halosulfuron-methyl for Aquatic Organisms

Organism	Exposure	Endpoint Value	EEC	RQ	Level of Concern
Freshwater species					
Halosulfuron-methyl rearrangement					
Invertebrates	Acute	EC_{50}/2 >9600 µg a.i./L	13.2 µg a.i./L	<0.001	Not exceeded
Fish	Acute	LC_{50}/10 >1530 µg a.i./L	13.2 µg a.i./L	<0.009	Not exceeded
Amphibians	Acute	LC_{50}/10 >1530 µg a.i./L	70.3 µg a.i./L	<0.04	Not exceeded
Algae	Acute	EC_{50}/2 = 8750 µg a.i./L	13.2 µg a.i./L	0.002	Not exceeded
Halosulfuron					
Algae	Acute	EC_{50}/2 = 42400 µg a.i./L	16.9 µg a.i./L	<0.001	Not exceeded
Aminopyrimidine					
Algae	Acute	EC_{50}/2 = 134500 µg a.i./L	6.2 µg a.i./L	<0.001	Not exceeded

Table 16 Toxic Substances Management Policy Considerations-Comparison to TSMP Track 1 Criteria

TSMP Track 1 Criteria	TSMP Track 1 Criterion value		Active Ingredient Endpoints
CEPA toxic or CEPA toxic equivalent[1]	Yes		Yes
Predominantly anthropogenic[2]	Yes		Yes
Persistence[3]:	Soil	Half-life ≥ 182 days	DT_{50} of 9.9 to 37.2 days in aerobic and anaerobic soil systems.
	Water	Half-life ≥ 182 days	DT_{50} of 5.9 to 25.3 days in total system of aerobic and anaerobic water/sediment systems.
	Sediment	Half-life ≥ 365 days	DT_{50} of 5.9 to 25.3 days in total system of aerobic and anaerobic water/sediment systems.
	Air	Half-life ≥ 2 days or evidence of long range transport	Volatilisation is not an important route of dissipation and long-range atmospheric transport is unlikely to occur based on the vapour pressure (<13 µPa at 25°C) and Henry's Law Constant (3.4×10^{-11} atm·m^3/mol at 20°C). Supplemental information indicates the gas-phase and aerosol photochemical oxidative degradation half-life in air is 38 minutes.
Bioaccumulation[4]	Log $K_{OW} \geq 5$		-0.02 to 1.67
	Bioconcentration factor ≥ 5000		Not available
	Bioaccumulation Factor ≥ 5000		Not available
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?			No, does not meet TSMP Track 1 criteria.

[1] All pesticides will be considered CEPA-toxic or CEPA toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the CEPA toxicity criteria may be refined if required (in other words, all other TSMP criteria are met). CEPA = *Canadian Environmental Protection Act.*

[2] The policy considers a substance "predominantly anthropogenic" if, based on expert judgement, its concentration in the environment medium is largely due to human activity, rather than to natural sources or releases.

[3] If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment or air) than the criterion for persistence is considered to be met.

[4] Field data (for example, bioaccumulation factors) are preferred over laboratory data (for example, Bioconcentration factor s) which, in turn, are preferred over chemical properties (for example, log K_{OW}).

Table 17 List of Supported Uses

<u>Summary of the Value Assessment Results</u>

a) Use Claims That Are Supported for 2011-3148 (Sandea Herbicide):

Items	Use claims that are supported
Use sites/crops	• Apple, • Blueberry, highbush, • Caneberries (blackberry, loganberry, red and black raspberry), • Rhubarb, • Asparagus, • Peppers (chile, bell, banana), • Eggplant, • Ground cherry, • Tomatillo, • Pepino, • Tomato,

Items	Use claims that are supported
	• Cucumber, • Cantaloupe, • Honeydew, Crenshaw melon, • Watermelon, • Pumpkin, • Squash (winter and summer for processing), • Succulent snap bean, • Okra, • Tree nuts (butternut, chestnut, filbert (hazelnut) hickory nut, pecan, walnut (black and English).
Appl. rate	35 - 140 g of product/ha (26.25 - 105 g a.i./ha), (rate based on a combination of factors including crop, application timing, pest spectrum, soil type, etc.), as proposed.
No. of apps	Up to 2, depending on the crop, 14-21 days apart unless otherwise directed.
Use range	National.
Weed claims	Suppression or control of: spiny amaranth, hedge bindweed, burcucumber, California arrowhead, common chickweed, common cocklebur, corn spurry, purple deadnettle, devil's claw, false daisy, Philadelphia fleabane, hairy galinsoga, common groundsel, horseweed/marestail, horsetail, jimsonweed, kochia, lady's thumb, common lamb'squarters, prickly lettuce, common mallow, flower-of-an-hour, stinking chamomile, common milkweed, honeyvine milkweed, ivyleaf morningglory, common morningglory, wild mustard, yellow nutsedge, redroot pigweed, smooth pigweed, broadleaved plantain, common pokeweed, purslane, wild radish, common ragweed, giant ragweed, shepherd's purse, prickly sida, Pennsylvania smartweed, common sunflower, velvetleaf, fringed willowherb, creeping yellowcress
Appl. timing	Relative to crop: pre-emergence, post-transplant, post-emergence, directed application, application under plastic mulch, as proposed. Relative to weeds: pre-emergence, post-emergence, as proposed.
Appl. method	Apply in a minimum of 150 L of water per hectare by ground equipment, as proposed.
Tank mix partners	Tank mix partners are proposed for use on certain crops and the rates and directions for use are consistent with the tank mix partner labels.
Rotational crops (months after application)	Bean (dry, snap), field corn (0 months); field corn (1 month); spring cereals (wheat, barley, oats), winter cereals (barley, wheat, rye), seed corn, forage grasses, proso millet, sorghum (2 months); corn (sweet and pop) (3 months); peanut (6 months); tomato (8 months); cucumbers, melons, potatoes, soybean, forage legumes (alfalfa, clovers), peas (succulent, field), pumpkins, squash (9 months); peppers (10 months); eggplant, radish (12 months); cabbage, canola, carrot, mint (15 months); broccoli, cauliflower, collard, lettuce, onion, leeks, sunflower (18 months); spinach (24 months); strawberry, sugarbeet, table (garden) beet (36 months) as proposed.

b) Use Claims That Are Supported for 2011-3149 (Permit Herbicide):

Items	Use claims that are supported
Use sites/crops	• Corn (field, seed, sweet and pop), • Dry bean, • Grain sorghum, • Proso millet
Appl. rate	35 - 93 g of product/ha (26.25 - 70 g a.i./ha), (rate based on a combination of factors including crop, application timing, pest spectrum, soil type, etc.), as proposed.
No. of apps	Up to 2, depending on the crop, 14-21 days apart unless otherwise directed.
Use range	National.
Weed claims	Suppression or control of: spiny amaranth, hedge bindweed, burcucumber, California arrowhead, common chickweed, common cocklebur, corn spurry, purple deadnettle, devil's claw, false daisy, Philadelphia fleabane, hairy galinsoga, common groundsel, horseweed/marestail, horsetail, jimsonweed, kochia, lady's thumb, common lamb'squarters, prickly lettuce, common mallow, flower-of-an-hour, stinking chamomile, common milkweed, honeyvine milkweed, ivyleaf morningglory, common morningglory, wild

Items	Use claims that are supported
	mustard, yellow nutsedge, redroot pigweed, smooth pigweed, broadleaved plantain, common pokeweed, purslane, wild radish, common ragweed, giant ragweed, shepherd's purse, prickly sida, Pennsylvania smartweed, common sunflower, velvetleaf, fringed willowherb, creeping yellowcress
Appl. timing	Relative to crop: pre-emergence, pre-plant incorporated, post-transplant, post-emergence, directed application, as proposed. Relative to weeds: pre-emergence, post-emergence, as proposed.
Appl. method	Apply in a minimum of 150 L of water per hectare by ground equipment, as proposed.
Tank mix partners	Tank mix partners are proposed for use on certain crops and the rates and directions for use are consistent with the tank mix partner labels.
Rotational crops (months after application)	Bean (dry, snap), field corn (0 months); field corn (1 month); spring cereals (wheat, barley, oats), winter cereals (barley, wheat, rye), seed corn, forage grasses, proso millet, sorghum (2 months); corn (sweet and pop) (3 months); peanut (6 months); tomato (8 months); cucumber, melon, potato, soybean, forage legumes (alfalfa, clovers), peas (succulent, field), pumpkin, squash (9 months); peppers (10 months); eggplant, radish (12 months); cabbage, canola, carrot, mint (15 months); broccoli, cauliflower, collard, lettuce, onion, leek, sunflower (18 months); spinach (24 months); strawberry, sugarbeet, table (garden) beet (36 months) as proposed.

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c) Use Claims That Are Supported for turf, ornamental and non-crop use use:

Items	Use claims that are supported
Use sites/crops	• Turf • Landscaped areas • Outdoor ornamentals (established woody ornamentals, field grown ornamental nurseries, container grown ornamental nurseries) • USC 16 roadsides, rights-of-way, tank farms, lumberyards, fuel storage areas, fencerows
Appl. rate	35 - 187 g of product/ha (26.25 - 140 g a.i./ha) (rate based on a combination of factors including crop, application timing, pest spectrum, soil type, etc.), as proposed.
No. of apps.	Up to 2, 14-21 days apart unless otherwise directed.
Use range	National.
Weed claims	Suppression or control of: spiny amaranth, hedge bindweed, burcucumber, California arrowhead, common chickweed, common cocklebur, corn spurry, purple deadnettle, devil's claw, false daisy, Philadelphia fleabane, hairy galinsoga, common groundsel, horseweed/marestail, horsetail, jimsonweed, kochia, lady's thumb, common lamb'squarters, prickly lettuce, common mallow, flower-of-an-hour, stinking chamomile, common milkweed, honeyvine milkweed, ivyleaf morningglory, common morningglory, wild mustard, yellow nutsedge, redroot pigweed, smooth pigweed, broadleaved plantain, common pokeweed, purslane, wild radish, common ragweed, giant ragweed, shepherd's purse, prickly sida, Pennsylvania smartweed, common sunflower, velvetleaf, fringed willowherb, creeping yellowcress
Appl. timing	Relative to weeds: pre-emergence, post-emergence, directed application, as proposed.
Appl. method	Apply in a minimum of 150 L of water per hectare by ground equipment, as proposed.
Tank mix partners	Glyphosate is proposed as a tankmix partner for uses considered as USC 16 and the rates and directions for use are consistent with the tank mix partner labels.

Appendix II Supplemental Maximum Residue Limit Information—International Situation and Trade Implications

Halosulfuron-methyl is a new active ingredient which is being registered in Canada and is currently registered for use in the United States. The MRLs proposed for halosulfuron-methyl in Canada are the same as corresponding tolerances already established or to be promulgated in the United States, with the exception of the MRLs proposed for asparagus and certain livestock commodities, in accordance with Table 1.

The American tolerances for halosulfuron-methyl are listed in the Electronic Code of Federal Regulations, 40 CFR Part 180.

Currently, there are no Codex MRLs[10] listed for halosulfuron-methyl in or on any commodity on the Codex Alimentarius Pesticide Residues in Food website.

Table 1 Comparison of Canadian MRLs and American Tolerances (where different)

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)
Crop subgroup 22A: Stalk and Stem Vegetables	1.0	0.8 (Asparagus only)
Grain lupin; dry kidney beans; dry lima beans; dry navy beans; dry pink beans; dry pinto beans; dry tepary beans; dry beans; dry adzuki beans; dry blackeyed peas; dry catjang seeds; dry cowpea seeds; dry moth beans; dry mung beans; dry rice beans; dry southern beans; dry urd beans; dry broad beans; dry chickpeas; dry guar seeds; dry lablab beans	0.05	0.05 (Bean, dry, seed)
Edible-podded runner beans; edible-podded snap beans; edible-podded wax beans; edible-podded moth beans; edible-podded yardlong beans; edible-podded jackbeans; edible-podded sword beans	0.05	No MRL established
Fat and meat of cattle, goats, hogs, horse and sheep; milk	0.01	0.05
Meat byproducts of cattle, goats, horses, sheep	0.2	1.0
Hog, meat byproducts	Not established	0.1

10 The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)
Pea and bean, succulent shelled, subgroup 6	No MRL recommended	0.05
Pea and bean, succulent shelled, subgroup 6B	No MRL recommended	0.05

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the field crop trials used to generate residue chemistry data. For animal commodities, differences in MRLs can be due to different livestock feed items and practices.

Under the North American Free Trade Agreement (NAFTA), Canada, the United States and Mexico are committed to resolving MRL discrepancies to the broadest extent possible. Harmonization will standardize the protection of human health across North America and promote the free trade of safe food products. Until harmonization is achieved, the Canadian MRLs specified in this document are necessary. The differences in MRLs outlined above are not expected to impact businesses negatively or adversely affect international competitiveness of Canadian firms or to negatively affect any regions of Canada.

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B. Additional Information Considered

i) Published Information

1.0 Value

2012 Herbicide Guide for Iowa Corn and Soybean Production
http://www.weeds.iastate.edu/reference/wc9412.pdf

North Dakota Weed Control Guide
http://www.ag.ndsu.edu/weeds/weed-control-guides/nd-weed-control-guide-1

2013 Weed Control Guide for Ohio and Indiana
http://www.extension.purdue.edu/extmedia/WS/WS-16-W.pdf

2013 (MSU) Weed Control Guide
http://www.msuweeds.com/publications/weed-control-guide/
Weed Control for Corn, Soybean and Sorghum (U. of Illinois)

http://web.aces.uiuc.edu/vista/pdf_pubs/iapm2k/chap02.pdf

Penn State Extension Table2.3-1 Weed control recommendations for grain sorghum, forage sorghum, sorghum x sudan hybrids
http://extension.psu.edu/agronomy-guide/pm/tables/table-2-3-1

2010 Ohio Vegetable Production Guide
http://www.oardc.ohio-state.edu/weedworkshop/images/Asparagus.pdf

MSU Extension Bulletin E-433 2012 Weed Control Guide for Vegetable Crops
http://veginfo.msu.edu/bulletins/E433/index.cfm?crop=129

U. of Tennessee Extension Bulletin W245 Common Herbicides for Fruit and Vegetable Weed Control
https://utextension.tennessee.edu/publications/Documents/W245.pdf

U. of California Pest Management Guidelines, Eggplant Herbicide Treatment Table
http://www.ipm.ucdavis.edu/PMG/r211700411.html

U. of Florida Extension Publication #HS191 Weed Management in Eggplant
http://edis.ifas.ufl.edu/wg030

Pacific Northwest Weed Management Handbook, Tree and Fruit Nuts
http://pnwhandbooks.org/weed/horticultural/orchards-and-vineyards/tree-fruits-and-nuts

MSU Fruit and Nut Crops suggested herbicides
http://msucares.com/pubs/publications/p1532/fruit_nut.pdf

U. of Florida Extension Publication #HS95 Weed Management in Pecan
http://edis.ifas.ufl.edu/wg022

Clemson Cooperative Extension 2013 Pest Control Guidelines for Weed Control
http://media.clemson.edu/public/turfgrass/2013%20Pest%20Management/2013_weed_cont.pdf

Ohio State University Control of Yellow Nutsedge in Cool Season Turfgrass
http://c.ymcdn.com/sites/www.ohiolawncare.org/resource/resmgr/newsletter/olca_news_2007_special_part2.pdf

Pacific Northwest Weed Management Handbook- Turfgrasses
http://pnwhandbooks.org/weed/horticultural/turfgrasses

Clemson Cooperative Extension Nutsedge Control
http://www.clemson.edu/extension/hgic/pests/weeds/hgic2312.html

OSU Extension Service- Controlling crabgrass, Bermudagrass and nutsedge in your lawn
http://extension.oregonstate.edu/umatilla/sites/default/files/master_gardener/mg_lawns.pdf