Evaluation Report ERC2010-08

Sulfentrazone

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Overview

Registration Decision for Sulfentrazone

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, has granted conditional registration for the sale and use of Sulfentrazone Technical Herbicide and Authority 480 Herbicide containing the technical grade active ingredient sulfentrazone for use on chickpeas in Saskatchewan to control a variety of weeds.

An evaluation of available scientific information found that, under the approved conditions of use , the product has value and does not present an unacceptable risk to human health or the environment. The use pattern of chickpeas in Saskatchewan is based on results of the environmental risk assessment.

Although the risks and value have been found acceptable when all risk reduction measures are followed, the applicant must submit additional scientific information as a condition of registration.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Sulfentrazone Technical Herbicide and Authority 480 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.

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 (e.g. children) as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects

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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".

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 PMRA's website at healthcanada.gc.ca/pmra

What Is Sulfentrazone?

Sulfentrazone is a selective soil applied herbicide which is applied to bare land as a pre-plant or pre-emergence application (spring only) to control weeds. It belongs to the triazolinone chemical class and is an inhibitor of the protoporphyrinogen oxidase enzyme. This means that sulfentrazone controls plants by disrupting cell membranes through initiating the inhibition of protoporphyrinogen oxidase in the chlorophyll biosynthetic pathway which leads to the subsequent build-up of phytotoxic intermediates.

Authority 480 Herbicide contains the active ingredient sulfentrazone at 480 grams per Litre of product and is conditionally registered for use on chickpeas in Saskatchewan to control a variety of weeds.

Health Considerations

Can Approved Uses of Sulfentrazone Affect Human Health?

Sulfentrazone is unlikely to affect your health when used according to the label directions.

Exposure to Sulfentrazone may occur through diet (food and water), or when handling or applying the product. 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. 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 300-times higher (and often much higher) than levels to which humans are normally exposed when products containing sulfentrazone are used according to label directions.

Although the skin sensitization study did not show any effects, the dose selection for that study was not considered to be adequate according to the guideline used. As such, the technical grade active ingredient, sulfentrazone, was considered to be a potential skin sensitizer. Therefore, the label statement "Potential Skin Sensitizer" is required. Also, sulfentrazone was considered to be moderately toxic through the oral route, but of low toxicity through the dermal and inhalation routes. Although sulfentrazone was found to be minimally irritating to the eyes, it was not found to be irritating to the skin. As for the end use product, Authority 480 Herbicide, it was of low toxicity through the oral, inhalation and dermal routes. It was not irritating to the skin or to the eyes and was not considered to be a potential skin sensitizer.

Sulfentrazone was not considered to be genotoxic or cause cancer in animals. However, there were some indications that sulfentrazone caused damage to the developing fetus and the reproductive system. Although sulfentrazone did not cause irreversible nervous system damage,

it was considered to cause some neurotoxicity at doses causing other serious effects such as mortality. Health effects in animals given sulfentrazone on a daily basis for prolonged periods of time included clinical anaemia, liver and kidney effects. There were also effects on body weight and body weight gain.

The risk assessment is conducted to ensure that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests. The dose levels used to assess risks are established to protect the most sensitive human population (e.g., children, nursing mothers and women of child bearing age). Only those uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Residues in Water and Food

Dietary risks from food and water are not of concern

Aggregate dietary intake estimates (food plus water) revealed that the general population and infants, the subpopulation which would ingest the most sulfentrazone relative to body weight, are expected to be exposed to less than 53.7% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from sulfentrazone is not of concern for all population sub-groups.

A single dose of sulfentrazone is not likely to cause acute health effects in the general population (including infants and children) or in women aged 13-49 years. An aggregate (food and water) dietary intake estimate for women aged 13-49 years was 21.13% of the acute reference dose and for the general population was 0.77% of the acute reference dose, which are not a health concern.

The *Food and Drugs Act* (FDA) 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 FDA purposes through the evaluation of scientific data under the *Pest Control Products Act* (PCPA). 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 on asparagus, cabbage, horseradish, dry shelled beans, dry shelled peas, mint, soybean and sunflower and Canada on chickpeas using sulfentrazone were acceptable. The MRLs, both domestic and import, for this active ingredient can be found in the Science Evaluation section of this Evaluation Report.

Occupational Risks From Handling Authority 480 Herbicide

Occupational risks are not of concern when Authority 480 Herbicide is used according to the proposed label directions, which include protective measures.

Farmers and custom applicators who mix, load or apply, as well as field workers who re-enter freshly treated fields, can come in direct contact with Authority 480 Herbicide residues on the skin. The label will specify that anyone mixing or loading Authority 480 Herbicide, and doing

clean-up and repairs, must wear a long-sleeved shirt, long pants, chemical-resistant gloves and shoes plus socks. Anyone applying Authority 480 Herbicide must wear a long-sleeved shirt, pants and shoes plus socks. The label also specifies that workers do not enter treated fields for twelve hours. Taking into consideration these label requirements, risks to agriculture workers are not of concern.

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

Environmental Considerations

What Happens When Sulfentrazone Is Introduced Into the Environment?

Sulfentrazone is persistent in soil and water. Soil residues are expected to carryover to the following growing season and have a high potential to leach to groundwater. Without risk-reduction measures, sulfentrazone may impact non-target terrestrial plants adjacent to the treatment area. Additional information is needed to further characterize the risk to bees and the long term risk to fish.

Sulfentrazone enters the environment when used as a herbicide on chickpeas in Saskatchewan. Sulfentrazone is persistent in the environment with the only route of transformation being slow aerobic biotransformation in the soil with a half-life of up to 856 days. Sulfentrazone and the degradate, 3-carboxylic acid sulfentrazone, have a high potential to reach groundwater. Soil pH and texture may influence mobility in soil. Field studies demonstrated that sulfentrazone is persistent, will carryover to the following growing season and will leach to groundwater.

Sulfentrazone can enter the aquatic environment through spray drift and runoff from treated fields. In aquatic systems, sulfentrazone is expected to be persistent and remain primarily in the water column. Phototransformation in the photic zone of the water column is expected to be the only route of dissipation. Sulfentrazone is stable to hydrolysis and undergoes very slow anaerobic biotransformation with an estimated half-life value of up to nine years. Sulfentrazone does not bioconcentrate and is therefore unlikely to bioaccumulate.

The risk to the environment was assessed for the end-use product, Authority 480 Herbicide. Risks to terrestrial plants, algae, aquatic plants and small mammals on a chronic basis have been identified at the screening level. These risks may be mitigated by applying spray buffer zones and label statements. Further characterization of the risk indicated that sulfentrazone may pose a risk to terrestrial plants, but not to small mammals, algae and aquatic plants. Since sulfentrazone is persistent and likely to accumulate in aquatic systems, there may be risk from long term exposure to fish; additional information has been requested to address this concern. A honey bee oral toxicity study has been requested since there is the potential for bees to be exposed to residues on and within plants. There are no concerns with sulfentrazone affecting bees on a contact basis and birds, mammals, aquatic invertebrates and fish on an acute basis. To advise the user of the potential for carryover, leaching and run-off, advisory statements are included on the label.

Value Considerations

What Is the Value of Authority 480 Herbicide

Authority 480 Herbicide is a selective soil applied herbicide, i.e. an herbicide applied before the crop and weeds have emerged from the ground. It is applied to bare land as a pre-plant or pre-emergence application (spring only) on the soil surface to provide control in chickpea of common lamb's quarters, redroot pigweed and wild buckwheat, and for the suppression of kochia. Authority 480 Herbicide is the only selective herbicide that will provide a level of control of kochia in chickpea.

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 Authority 480 Herbicide to address the potential risks identified in this assessment are as follows:

Key Risk-Reduction Measures

Human Health

Anyone mixing or loading Authority 480 Herbicide and doing clean-up and repairs must wear a long-sleeved shirt, pants, chemical-resistant gloves and shoes plus socks, and that anyone applying the product must wear a long-sleeved shirt and pants and shoes plus socks. The label also specifies that workers do not enter treated fields for twelve hours, and apply only when the potential for drift to areas of human habitation or areas of human activity such as houses, cottages, schools and recreational areas is minimal, taking into consideration wind speed, wind direction, temperature inversion, application equipment and sprayer settings.

Environment

Precautionary label statements and buffer zones are required as a result of the environmental risk assessment.

To mitigate risks from the use of Authority 480 Herbicide to non-target terrestrial plants, a spray buffer zone of 10 metres is required for terrestrial habitats adjacent to the treatment area;

- To mitigate risks from the use of Authority 480 Herbicide to aquatic plants, a spray buffer zone of 1 metre is required for aquatic habitats adjacent to the treatement area;
- Precautionary label statements are required as a result of the environmental risk assessment;
- Advisory label statements are required for carryover, leaching and runoff.

Value

To minimize the carryover of sulfentrazone, due to the persistence of the active ingredient in soils of certain textures, Authority 480 Herbicide is to be applied only once every 36 months.

What Additional Scientific Information is Being Requested?

Although the risks and value have been found acceptable when all risk reduction measures are followed, the applicant must submit additional scientific information as a condition of registration. More details are presented in the Science Evaluation of this Evaluation Report or in the Section 12 Notice associated with these conditional registrations. The applicant must submit the following information within the time frames indicated.

Human Health

Information on the toxicity of the 3-carboxylic acid-sulfentrazone is required to characterize the potential risk to individuals exposed to 3-carboxylic acid sulfentrazone through the drinking of groundwater. A valid rationale comparing the toxicity of 3-carboxylic acid-sulfentrazone to the parent, including any available toxicology data on 3-carboxylic acid-sulfentrazone must be provided.

Environment

A validated analytical method for the active and its major metabolites in fish;

Depending on the outcome of the review of the new Canadian soil study, a new analytical method for the active and its major transformation products in soil;

Physico-chemical properties and environmental fate information for the major transformation products;

An aquatic field dissipation study conducted in a Canadian relevant ecoregion;

The final report on the ‘Small-Scale Prospective Groundwater Monitory study for Sulfentrazone in a Setting Classified as 95th Percentile Based on Vulnerability to Groundwater Contamination’;

‘Small-Scale Prospective Groundwater Monitory study for Sulfentrazone in a Setting Classified as 85th and 75th Percentile Based on Vulnerability to Groundwater Contamination’;

Acute oral toxicity study on honeybees.

Value

Due to the high leaching potential of sulfentrazone, the applicant must submit a stewardship plan/risk mitigation plan that will elaborate on the economic and social impact that the presence of sulfentrazone in groundwater will have and its possible effect on crops when groundwater, dugout water or well water, contaminated with sulfentrazone, is used for irrigation.

The applicant has amended the rates of application of Authority 480 Herbicide to a range of 105 to 140 grams of active ingredient per hectare. Additional data to confirm that the rates of 105 to 140 grams of active ingredient per hectare will control the four weeds for which control is required at these rates: kochia, common lamb's quarters, redroot pigweed and wild buckwheat.

The value assessment of Authority 480 Herbicide has identified potential concerns relating to the sustainability of the product due to the persistence of sulfentrazone under normal climatic conditions and that sulfentrazone may persist for even greater periods of time under atypical environmental conditions (i.e. drought), as well as its effect on rotational crops several years after the initial application of sulfentrazone. The applicant must submit additional data for all the rotational crops listed on the label plus a number of other crops as detailed in the Section 12 Notice associated with this conditional registration. It is suggested that one trial be conducted in Scott, Saskatchewan and another trial in Ontario along with three more trials distributed across the Prairie Provinces.

Other Information

As these conditional registrations relate to a decision on which the public must be consulted[3], the PMRA will publish a consultation document when there is a proposed decision on applications to convert the conditional registrations to full registrations or on applications to renew the conditional registrations, whichever occurs first.

The test data cited in this Evaluation Report (i.e. the test data relevant in supporting the registration decision) will be made available for public inspection when the decision is made to convert the conditional registrations to full registrations or to renew the conditional registrations (following public consultation). If more information is required, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

[3] As per subsection 28(1) of the *Pest Control Products Act.*

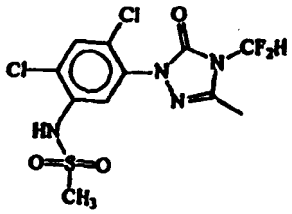
Science Evaluation

Sulfentrazone

Although the conditional registration of sulfentrazone is limited to use on chickpeas in Saskatchewan, the Science Evaluation section of this document also includes the PMRA review of the proposed uses on flax, soybeans, sunflower, asparagus, cabbage, shelled beans and peas, horseradish, strawberry and mint at application rates up to 210 g a.i./ha.

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance		Sulfentrazone
Function		Herbicide
Chemical name		
1.	**International Union of Pure and Applied Chemistry (IUPAC)**	2',4'-dichloro-5'-(4-difluoromethyl-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl)methanesulfonanilide
2.	**Chemical Abstracts Service (CAS)**	methanesulfonamide, N-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-1-yl]phenyl]-
CAS number		122836-35-5
Molecular formula		$C_{11}H_{10}Cl_2F_2N_4O_3S$
Molecular weight		387.19 g/mol
Structural formula		
Purity of the active ingredient		92.55% nominal

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

Technical Product—Sulfentrazone Technical Herbicide

Property	Result
Colour and physical state	Tan solid
Odour	Faint sulfur-like
Melting range	120-122°C
Boiling point or range	N/A
Density	1.66 g/cm^3
Vapour pressure at 25°C	0.107 µPa
Henry's law constant at 25°C	1.02 x 10^{-12} atm.m^3/mole
Ultraviolet (UV)-visible spectrum	λ_{max} = 110 nm
Solubility in water at 25°C	Medium — Solubility (mg/g) water — 0.40 pH 6 buffer — 0.49 pH 7 buffer — 1.8 pH 7.5 buffer — 2.0
Solubility in organic solvents at 25°C (g/100 mL)	Solvent — Solubility (% w/w) acetone — 64 acetonitrile — 18.6 toluene — 0.66 hexane — 0.011
n-Octanol-water partition coefficient (K_{ow})	pH — K_{ow} 5 — 31.1 7 — 9.8 9 — 0.27
Dissociation constant (pK_a)	6.56
Stability (temperature, metal)	Stable to metals and metal salts at room temperature; stable to sunlight in dry form but readily photolyses in water.

End-Use Product—Authority 480 Herbicide

Property	Result
Colour	Light brown
Odour	Faint alcohol
Physical state	Liquid
Formulation type	Solution
Guarantee	480 g/L nominal
Container material and description	Plastic 0.5-100 L
Density	1.206 g/mL
pH	5.3-6.0
Oxidizing or reducing action	Not expected to be an oxidizing or reducing agent
Storage stability	Stable for two years at room temperature
Explodability	Not expected to be explosive

1.3 Directions for Use

Authority 480 Herbicide is a selective herbicide for use as a pre-plant or pre-emergence treatment (pre-emerge to weeds and crop) on chickpea for the control of wild buckwheat, common lamb's quarters, redroot pigweed, and for the suppression of kochia. The product is applied once per growing season, in the spring, at rates between 105 and 140 g a.i./ha (Table 1.3.1.) as a broadcast treatment with ground application equipment only.

Table 1.3.1. Rates of Application for Authority 480 Herbicide on Chickpea

Percent (%) Organic Matter	Application Rates by Soil Types (g a.i./ha)	
	Medium	Fine
< 1.5%	105 - 140	--
1.5 - 3.0	140 - 140	140 - 140
> 3.0%	140 - 140	140 - 140

*Use the higher rates within the rate range for soils with pH less than 7.0

The following restrictions are to be applied:

- Do not apply to soils classified as coarse-textured soils.
- Do not apply in fine textured soils with less than 1.5% organic matter.
- Do not apply in any type of soils with an organic matter content greater than 6%.
- Do not use on soils with a pH of 7.8 or greater.

The rotational crops and plant interval are listed in Table 1.3.2.

Table 1.3.2. Rotational Crops for Authority 480 Herbicide on Chickpea

Rotational Crop	Replant Interval (Months)
Alfalfa	12
Canola	24
Corn, field	10
Corn, sweet	24
Sorghum	24
Soybeans	Anytime
Sunflowers	Anytime
Spring Wheat	12
Winter wheat	16

1.4 Mode of Action

Authority 480 Herbicide is classified as a Group 14 Herbicide (refer to Regulatory Directive DIR-99, Voluntary *Pesticide Resistance-Management Labelling Based on Target Site/Mode of Action*). The primary mode of action of sulfentrazone is the inhibition of the enzyme protoporphyrinogen oxidase in the chlorophyll biosynthetic pathway and leads to the subsequent buildup of phytotoxic intermediates and disruption of cell membranes. Sulfentrazone is taken up by the roots and foliage of treated plants; however, it is absorbed primarily by the roots of treated plants following soil applications. Plants treated with sulfentrazone become necrotic and die shortly after exposure to light.

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 Sulfentrazone 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 formulation has been validated and assessed to be acceptable for use as an enforcement analytical method.

2.3 Methods for Residue Analysis

For environmental residues, high-performance liquid chromatography methods with mass spectrometry (HPLC-MS) and gas chromatography methods with electron capture detection (GC-ECD) were developed and proposed for data generation and enforcement purposes. With some exceptions, these methods fulfilled the requirements with regards to selectivity, accuracy and precision at the respective method limit of quantitation. However, for soil, the original validation data demonstrated high variability; a newer Canadian-specific soil study was recently submitted which will be reviewed under a future application and, depending on the outcome of that review, new data may be required. A fish matrix has not been addressed.

Several data gathering methods were developed for the determination of sulfentrazone and its metabolites in plant (primary and secondary crop) matrices. The enforcement method includes a more stringent hydrolysis step to release the conjugated 3-hydroxymethyl sulfentrazone residues and to completely decarboxylate sulfentrazone 3-carboxylic acid (analyzed as 3-desmethyl sulfentrazone) and includes the use of halogen specific detectors allowing for the discrimination between residues of sulfentrazone and its metabolites. The enforcement method fulfilled the requirements with regards to specificity, accuracy and precision at the limit of quantitation. Acceptable recoveries were obtained in the primary and secondary (rotational) crops. Adequate extraction efficiency was demonstrated using radiolabled barley forage sample. Sulfentrazone, 3-hydroxymethyl sulfentrazone, 3-desmethyl sulfentrazone and 3-desmethyl-4-desdifluoromethyl sulfentrazone were analyzed according to the US Food and Drug Administration's (FDA) Multiresidue Method Testing guidelines in Pesticide Analytical Methods (PAM) Volume I, Appendix II (January 1994). The multiresidue method testing data indicated that sulfentrazone and the metabolites 3-hydroxymethyl sulfentrazone, 3-desmethyl sulfentrazone and 3-desmethyl-4-desdifluoromethyl sulfentrazone are not recovered through PAM, Vol I. Analytical methodologies are not required at this time for livestock matrices since finite residues of sulfentrazone and the metabolites 3-hydroxymethyl sulfentrazone and 3-desmethyl sulfentrazone are not anticipated in animal matrices.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

The PMRA conducted a detailed review of the toxicological database for sulfentrazone. The toxicological database is complete, consisting of the full array of laboratory animal (*in vivo*) and cell culture (*in vitro*) toxicity studies currently required for health 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 characterize the toxicity of this pest control product. However additional data/information is required for one metabolite (see below).

Sulfentrazone was rapidly absorbed, distributed, and excreted following oral administration in the rat at the low and high doses. Absorption was nearly complete and virtually all radioactivity was recovered in the urine. Pooled faecal radioactivity was less than 6% and expired air contained less than 0.01% of the administered dose. The metabolism profile was the same for males and females at all doses tested. The potential for bioaccumulation is considered low since only the carcass, liver (target organ) and bone (females, repeat dose only) showed a noticeable amount (less than 0.5% of the dose) of radioactivity. Sulfentrazone was extensively metabolized with less than 2% of unchanged compound recovered in the urine at any dose. Eighty four to 100% of the compound was metabolized into 3-hydroxy-methyl-sulfentrazone, a small amount of which can be further metabolized into 3-carboxylic acid-sulfentrazone. The elimination half-lives were ~12h and ~48h at the low and high dose respectively.

The 3-carboxylic acid-sulfentrazone is a major accumulating environmental transformation product identified in the environmental fate studies and in the prospective groundwater monitoring studies. Based on the results of these studies, this transformation product is expected to reach groundwater when used in accordance with the proposed label instructions. 3-Hydroxymethyl-sulfentrazone is a major metabolite in the rat and therefore the toxicity of this compound was assessed within the database for the parent compound. On the other hand, 3-carboxylic acid-sulfentrazone is a minor metabolite in the rat and therefore the toxicology profile has not been adequately addressed by the database for the parent compound and additional data is required.

Sulfentrazone (90.7-95.5% purity) was of moderate acute toxicity in mice and of low acute toxicity in rats following oral exposure. Sulfentrazone was of low acute toxicity by the dermal and inhalation routes in rabbits and rats respectively. It was not irritating to the skin and minimally irritating the eye of rabbits. Skin sensitization testing with guinea pigs, using the Buehler method, showed that sulfentrazone was not a dermal sensitizer, but the applicant failed to demonstrate the appropriateness of the dose used to induce the dermal sensitization. Instead of the highest non-irritating dose, the highest dose causing mild-to-moderate skin irritation should have been used. In absence of irritation, the induction dose should have been 100% w/v. In light of this fact, the signal words "Potential Skin Sensitizer" are required on the label.

Authority 480 Herbicide (43.66% a.i.) was of low acute toxicity by the oral, dermal and inhalation routes of exposure in male and female rats. This end-use product was not an eye irritant or skin irritant in rabbits. The formulation was not a dermal sensitizer when tested in guinea pigs based on the Buehler method.

The subchronic and chronic toxicity of sulfentrazone was investigated in mice, rats, rabbits and dogs. A series of range-finding 28-day studies were conducted initially. These studies were used to establish appropriate dose levels to be used in longer term studies. A 21-day dermal study was also carried out in rabbits.

In short-term testing in mice, rats and dogs, the observed effects were predominately related to sulfentrazone's mode of action as a protoporphyrinogen oxidase inhibitor. Because of its action in inhibiting heme formation, virtually all blood parameters were negatively affected by high doses of sulfentrazone as reflected by the clinical anaemia observed in these animals. For some

of the animals, recovery was possible. Since the inhibited enzyme participates in the last stage of heme formation, it was not unusual to observe an increase in extramedullary hematopoiesis and red blood cell precursors. Rabbits tested up to 1000 mg/kg/day in a 21-day dermal study showed no treatment related effects.

Body weights and body weight gains were also negatively affected in mice and dogs, while there was an increase in the relative spleen weight in rats. In addition to effects on haematology and clinical chemistry findings in the dogs, rats, and mice, the liver was clearly a target organ in the dogs with decreased activated partial thromboplastin time, increased serum ALPK and decreased total protein and albumin. Microscopic changes could also be observed as hepatocytic swelling and brown pigments (also observed in the spleen) were present. As with the rodent studies, the effects found in the dog are clearly related to the mode of action of the product.

The effects observed in the long-term studies with mice and rats were similar to those observed in the subchronic studies, such as decreased body weight and body weight gain, clinical anaemia, and extramedullary hematopoiesis, but also included preputial gland inflamation in the rat. An increase incidence of cataracts in rats at the highest dose tested (only dose for which ophtalmoscopic examination was performed) compared to control animals at termination of the study was also noted. Methaemoglobin was not measured and the mechanisms implicated in the formation of the cataracts remain unknown. In light of this data, the rat is the most sensitive species tested. The increase in exposure time to sulfentrazone did not correlate with greater toxicity when the LOAELs in short- and long-term studies were comparable. Again the effects are clearly related to the mode of action of the test product.

The genotoxic potential of sulfentrazone was assessed in *in vitro* and *in vivo* systems. It was not mutagenic when tested in Ames microbial cell system, but there was evidence of induced mutant colonies over background at precipitating concentrations, in the absence of S9 activation in mammalian cell systems. Sulfentrazone did not cause chromosomal aberrations in a dominant lethal test in rats or in vivo mouse bone marrow cells. Overall, sulfentrazone was not considered to be genotoxic.

In the multi-generation reproduction study, some females of the parental generation (F0) were affected by decreased body weight, prolonged gestation and abnormal parturition. In the F1 generation (adults), the effects noted included decrease in litter size, increase in abortion, decreased pregnancy rate and body weight and body weight gain in dams and degeneration or atrophy of testicular germinal epithelium, and thus a decrease in male fertility. It is worth mentioning that these adverse effects were only observed in adulthood after in utero exposure to sulfentrazone. Effects were also seen during the perinatal period in the offspring of the F0 and F1 generations at the same dose levels. These effects included decreased pup and litter survival (pre- and post-natally) and pup weight throughout lactation. Of all endpoints noted, sulfentrazone had its most profound effects on the reproduction capability of the rat.

Developmental toxicity was also observed in the rat at the mid-dose based on decreased fetal weight and increased incidences of fetal variations (reduced number of thoracic vertebral and rib ossification sites). At the highest dose, toxic effects were observed in fetuses (malformations: massive edema, short ribs, bent radius and ulna, bent left fibula, displacement of aortic arch) as

well as in the dams. The maternal toxicity consisted of an increase in spleen weights and severity of splenic extramedullary hematopoiesis. In the rabbit, the observed effects included an increased number of early resorptions, decreased faeces, hematuria, decreased body weight, fetal weight and litter viability, increased abortions, decreased gravid uterine weights and skeletal variations (unossified pubes) and malformations (incompletely or not ossified frontals, parietals, interparietals, supproccipital bones and exencephaly or fused caudal vertebrae) occurring at the highest tested dose.

Neurotoxicity was observed in the acute neurotoxicity study in rats at the highest dose tested. These findings included functional observational battery (FOB) data such as staggered gait, abnormal posture, impaired righting reflex, decreased mean landing foot splay and decreased mean hindlimbs grip strength. Systemic effects included decreased motor activity and reddish brown staining of pan litter. Although neurotoxicity was observed, systemic toxicity appeared at a lower dose.

A 90-day neurotoxicity study was also conducted in the rats. In this study, neurotoxicity (based on FOB findings) and mortality was observed at the highest dose tested. These findings included reduced hindlimb grip strength, increased tail flick latency, abnormal posture and gait, lack of auditory response, and an uncoordinated landing during righting reflex evaluation. The only effect noted in the females at the LOAEL was increased motor activity at week 13. Clinical findings at the LOAEL included decreased body weight and body weight gain and clinical signs. Mortality and gross pathological findings were observed at the highest dose tested. No neuropathology findings were noted.

PCPA Hazard Consideration

For assessing risks from potential residues in food or from products used in or around residential areas or schools, the Pest Control Products Act (PCPA) requires the application of an additional 10-fold factor to threshold effects. This factor should take into account completeness of the data with respect to the exposure of, and toxicity to, infants and children and potential pre- and post-natal 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 for the assessment of risk to infants and children, the database contains the full complement of required studies including developmental toxicity studies in rats and rabbits and a reproductive toxicity study in rats.

With respect to identified concerns relevant to the assessment of risk to infants and children, sensitivity of the young was identified in the reproduction study, in which effects noted in the offspring (i.e., decrease in litter size, decreased pup and litter survival [pre-, post-natal and during lactation], decreased pup weight throughout lactation in both generations of offspring and degeneration or atrophy of testicular germinal epithelium) were considered more severe than those that were observed in parental animals (i.e., increase in abortion, decreased pregnancy rate and body weight and body weight gain in F1 dams) at the same dose level. Toxic effects (decreased mean fetal body weights and decreased ossification sites) were also observed in fetuses during developmental study at a dose level that was not maternally toxic. Also, at the highest dose tested, serious effects were observed in the fetuses (malformations in 7 fetuses), in

the presence of maternal toxicity . This information was taken into account in determining the appropriate factors in the risk assessment.

3.2 Determination of Acceptable Daily Intake

The acceptable daily intake (ADI) for sulfentrazone was established at 0.046 mg/kg bw/day. The multi-generation reproduction study was considered to be most appropriate for the setting of the ADI with a NOAEL that was set at 13.7 mg/kg/day based on decreased litter size with a LOAEL of 33.3 mg/kg/day.

The standard uncertainty factors of 100 (10 fold for intraspecies variation and 10 fold for interspecies extrapolation) were applied in the setting of the ADI. With respect to the PCPA factor, all of the required studies relevant to assessing risk to infants and children were available and a NOAEL for reproductive endpoints was identified in the multi-generation reproduction study. A degree of concern analysis was conducted as part of the consideration on the magnitude of the PCPA factor. Qualitative sensitivity of the young was observed in the reproduction study based on severe endpoints, such as mortality and decreased fertility at doses that were also toxic to parental animals. However, these endpoints were addressed in a well-conducted study and a definitive NOAEL was established, resulting in a lower overall degree of concern. In light of this, the PCPA factor was reduced to 3 fold. As a consequence, the composite assessment factor (CAF) is 300.

The ADI is calculated according to the following formula:

$$\text{ADI} = \frac{\text{NOAEL}}{\text{CAF}} = \frac{13.7 \text{ mg/kg bw/day}}{300} = 0.046 \text{ mg/kg/day}$$

3.3 Determination of Acute Reference Dose

Women 13-49

An $ARfD_{(13\text{-}49)}$ for women of child bearing age was set at 0.083 mg/kg/day based on developmental toxicity in rats (oral) with a NOAEL of 25 mg/kg/day for malformations (massive edema, short ribs, bent radius and ulna, bent left fibula, displacement of aortic arch) observed in fetuses at the maternal LOAEL of 50 mg/kg/day.

The standard uncertainty factors of 100 (10 fold for intraspecies variation and 10 fold for interspecies extrapolation) was applied in the setting of the ARfD. With respect to the PCPA factor, all of the required studies relevant to assessing risk to infants and children were available and a NOAEL for fetal endpoints was identified in the rat developmental toxicity study. A degree of concern analysis was conducted as part of the consideration on the magnitude of the PCPA factor. Qualitative sensitivity of the offspring was observed in the developmental study based on severe endpoints, such as malformations at doses that were also toxic to dams. However, these endpoints were addressed in a well-conducted study and a definitive NOAEL

was established, resulting in a lower overall degree of concern. In light of this, the PCPA factor was reduced to 3 fold. Hence, the composite assessment factor (CAF) is 300. This will provide a margin of safety of 400 to the reproductive and offspring LOAEL for reduced litter size and survival, which occurred in the presence of maternal toxicity in the multi-generation study in the rat.

The $ARfD_{(13\text{-}49)}$ is calculated according to the following formula:

$$ARfD = \frac{NOAEL}{CAF} = \frac{25 \text{ mg/kg bw/day}}{300} = 0.083 \text{ mg/kg/day}$$

General population
An $ARfD_{(gen)}$ for the general population was set at 2.5 mg/kg bw based on the acute neurotoxicity study with a systemic NOAEL of 250 mg/kg and a systemic LOAEL of 750 mg/kg bw (clinical signs with the standard uncertainty factors of 100 (10 fold for intraspecies variation and 10 fold for interspecies extrapolation). With respect to the PCPA factor, all of the required studies relevant to assessing risk to the general population were available, and no residual uncertainty remains for the population of interest. On the strength of this information, the PCPA factor was reduced to 1 fold.

The $ARfD_{(gen)}$ is calculated according to the following formula:

$$ARfD = \frac{NOAEL}{UF} = \frac{25 \text{ mg/kg bw/day}}{100} = 2.5 \text{ mg/kg/day}$$

3.4 Occupational and Residential Risk Assessment

3.4.1 Toxicological Endpoints

Short (1-30 days) to intermediate-term dermal/inhalation (≤6 months)
The multi-generation reproduction study in rat was considered appropriate for the short (1-30 days) to intermediate-term dermal/inhalation (≤6 months) scenarios with an offspring NOAEL of 13.7 mg/kg bw/day and a LOAEL of 33.3 mg/kg bw/day (reduced litter survival) and a target margin of exposure (MOE) of 300. To attain this, the standard uncertainty factor of 100 (10 fold for intraspecies variation and 10 fold for interspecies extrapolation) as well as an additional 3 fold factor were applied. While the PCPA only requires the application of the additional 10 fold factor (PCPAf) to dietary and residential scenarios, it is important to provide an appropriate level of protection to the young. The worker population could include pregnant and lactating women and therefore it is appropriate to ensure adequate protection to the fetus or the nursing infant who may be exposed via their mother. In light of concerns regarding pre- and post-natal toxicity (as outlined in section 3.2), an additional uncertainty factor of 3 fold was applied to these endpoints.

3.4.1.2 Dermal Absorption

For sulfentrazone, no chemical specific dermal absorption data were submitted. Based on the physical and chemical properties of the sulfentrazone molecule and difference in oral and dermal NOAELs in animal toxicological studies, dermal absorption is expected to be less than 100%. On the weight of evidence, a dermal absorption value of 50% was used in the risk assessment.

3.4.2 Occupational Exposure and Risk

3.4.2.1 Mixer/loader/applicator Exposure and Risk Assessment

The mixer/loader/applicator (M/L/A) exposure and risk estimates were generated based on the efficacy and dietary supported use pattern and originally proposed rates of Authority 480 Herbicide (105 - 210 g ai/ha) for chickpeas, sunflowers and soybeans. Farmers and custom applicators have potential for dermal and inhalation exposures to sulfentrazone during mixing, loading and application of Authority 480 Herbicide to these crops. These exposures are expected to be of short- to intermediate-term in duration and to occur primarily by the dermal route. Chemical-specific data for assessing human exposure during pesticide handling activities were not submitted.

Exposure estimates for mixers, loaders and applicators are based on data from the Pesticide Handlers Exposure Database (PHED) Version 1.1. The PHED is a compilation of generic mixer/loader/applicator passive dosimetry data with associated software that helps generate scenario-specific exposure estimates. Appropriate subsets of A and B grade data (high confidence) were created from the database files of PHED for liquid open mixing/loading, and for groundboom application. All data were normalized for the kilogram of active ingredient handled. Exposure estimates are presented on the basis of the best-fit measure of central tendency, i.e. summing the measure of central tendency for each body part that is most appropriate to the distribution of data for that body part.

The exposure estimates are based on mixer/loaders wearing a single layer of clothing (long pants and long sleeved shirt) plus gloves and applicators wearing a single layer and no gloves.

The dermal exposures were estimated by coupling the unit exposure values with the amount of active handled per day and 50% dermal absorption. Inhalation exposure was estimated by coupling the unit exposure value with the amount of active handled per day with 100% inhalation absorption. The daily exposure estimates were normalized to mg/kg bw/day using an adult body weight of 70 kg.

Margins of Exposure (MOE) were determined by comparing the toxicological endpoints (NOAEL) with the exposure estimates; the target MOE is 300. The exposure and risk estimates are presented in Table 4 in Appendix I. The estimated MOEs for farmers and custom handlers mixing, loading and applying Authority 480 Herbicide at the maximum application rate exceed the target of 300 and are not of concern.

3.4.2.2 Exposure and Risk Assessment for Workers Entering Treated Areas

Based on the uses and application timing of Authority 480 Herbicide, early in spring to the soil surface prior to emergence of crops, postapplication exposure to field workers entering treated fields early in the crop cycle to conduct hand weeding, scouting and irrigation is expected to be low. In the absence of soil residue data and transfer coefficients for soil contact, the postapplication exposure estimates for these activities cannot be estimated, but are not expected to be of concern. However, an REI of 12 hrs is included to allow for residues to dry before reentering a treated field.

3.4.3 Residential Exposure and Risk Assessment

Application is limited to agricultural crops and bystander exposure is expected to be negligible; a residential exposure and risk assessment was not conducted.

3.4.4.3 Bystander Exposure and Risk

The product will be handled mainly by workers and application is limited to agricultural crops under conditions to minimize the spray drift to areas of human habitation. Therefore, bystander exposure and risk can be expected to be much less than that of field workers and, therefore, are not of concern.

3.5 Food Residues Exposure Assessment

3.5.1 Residues in Plant and Animal Foodstuffs

The residue definition for risk assessment and enforcement is sulfentrazone, 3-hydroxymethyl sulfentrazone and 3-desmethyl sulfentrazone in primary and rotational crops, except soybean, and is sulfentrazone and 3-hydroxymethyl sulfentrazone in soybean. In animals, the residue definition for risk assessment and enforcement is sulfentrazone, 3-hydroxymethyl sulfentrazone and 3-desmethyl sulfentrazone. The data gathering/enforcement analytical methodology, gas chromatography with electrolytic conductivity detection (GC-ELCD) or with halogen specific detection (GC-XSD), is valid for the quantification of sulfentrazone residues in crop commodities. The total sulfentrazone residues are stable in various plant commodities when stored in a freezer at -18˚C for up to 24 months. Raw agricultural commodities were processed, and residues were found to concentrate in soybean hulls, soybean meal, soybean dust and sunflower meal. Supervised residue trials conducted throughout the United States (on asparagus, cabbage, horseradish, dry shelled beans, dry shelled peas, mint, soybean and sunflower) and Canada (on chickpeas) using end-use products containing sulfentrazone at either the approved application rates or exaggerated rates are sufficient to support the proposed maximum residue limits.

Uses on strawberry and flax cannot be supported at this time. It is recommended that the applicant submit the final IR-4 strawberry and flax field trial study reports.

3.5.2 Dietary Risk Assessment

Acute and chronic dietary risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM–FCID™, Version 2.03), 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 assumptions were made in a refined chronic analysis: default and experimental processing factors, median values for certain commodities and U.S. tolerances for all other commodities. The refined chronic dietary exposure from all supported sulfentrazone food uses (alone) for the total population and all representative population subgroups is $\leq$4.2% of the acceptable daily intake (ADI). The PMRA estimates that chronic dietary exposure to sulfentrazone from food and water is 17.6% (0.008091 mg/kg bw/day) of the ADI for the total population. The highest exposure and risk estimate is for all infants (< 1 year) at 53.7% (0.024706 mg/kg bw/day) of the ADI. Aggregate exposure from food and water is considered acceptable.

3.5.2.2 Acute Dietary Exposure Results and Characterization

The following assumptions were made in a refined acute analysis: default and experimental processing factors, maximum residues for certain commodities and U.S. tolerances for all other commodities. The refined acute dietary exposure (food alone) for all supported sulfentrazone commodities (registered and imported) is estimated to be 1.79% (0.001486 mg/kg bw/day) of the ARfD for females 13–49 years old (95th percentile, deterministic) and 0.09% (0.002180 mg/kg bw/day) of the ARfD for the general population (95th percentile, deterministic). Aggregate exposure from food and water is considered acceptable at 21.13% of the ARfD (0.017535 mg/kg bw/day) for females 13–49 years old (95th percentile, deterministic) and 0.77% (0.019274 mg/kg bw/day) of the ARfD for the general population (95th percentile, deterministic).

3.5.3 Aggregate Exposure and Risk

The aggregate risk for sulfentrazone consists of exposure from food and drinking water sources only. Aggregate risks were calculated based on acute (females 13–49 years old and the general population) and chronic endpoints.

3.5.4 Proposed Maximum Residue Limits

Table 3.5.1 Proposed Maximum Residue Limits

MRLs (ppm)	Foods
0.15	Asparagus
0.2	Cabbages
0.2	Horseradish roots
0.15	Crop subgroup 6C- dried shelled pea and bean, except soybean
0.3	Peppermint tops/Spearmint tops
0.05	Dry soybeans
0.2	Sunflower seeds

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

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

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Soil
Sulfentrazone enters the environment when used as a herbicide on chickpeas in Saskatchewan. Sulfentrazone is persistent and highly to very highly mobile in soil. The transformation product, 3-carboxylic acid sulfentrazone, is also persistent and mobile in soil.

As sulfentrazone was stable to hydrolysis at environmentally relevant pHs and phototransformation in soil, these processes are not expected to be important routes of transformation in the terrestrial environment. The low vapour pressure (8×10^{-10} mm Hg at 25˚C) and Henry's law constant (1.02×10^{-12} atm.m^3/mole at 25˚C) indicate that sulfentrazone is non-volatile under field conditions and from water surfaces and moist soil. Sulfentrazone is a weak acid with a pKa of 6.56, which means that both the neutral and anionic form are present between pH 6 and 7 and it is expected that pH will affect the mobility of sulfentrazone in soil.

Laboratory studies indicate that slow aerobic biotransformation is the only route of sulfentrazone biotransformation in soil with half-life values of up to 856 days. Biotransformation results in the formation of a major degradate, 3-carboxylic acid sulfentrazone and several minor transformation products that did not exceed 10% of the total residues in any of the aerobic soil studies submitted.

The adsorptive characteristics of sulfentrazone indicate that sulfentrazone is expected to exhibit high to very high mobility in a variety of soil types. This was supported by the results in the column leaching study where aged sulfentrazone residues and two transformation products (3-hydroxymethyl and 3-carboxylic acid sulfentrazone) were measured in the leachate of the 30 cm soil column. Sulfentrazone and its transformation products have a combination of properties that favour leaching (persistence, high solubility, low binding potential, low volatility) which indicates they have a high potential to reach groundwater and aquatic systems.

Data from the only field dissipation study conducted in an ecoregion relevant to Canada, confirmed that sulfentrazone is persistent in soil (DT_{50}: >531 days, $t_{1/2}$: 710 days, extrapolated beyond the length of the study) and will carryover to following growing seasons, as 70% of applied sulfentrazone was measured 365 days after application. In this study, sulfentrazone remained primarily in the top layer of the soil. In field studies conducted in the U.S., including field dissipation and prospective groundwater monitoring studies, sulfentrazone leached readily and was measured in groundwater at concentrations up to 37.4 ppb (sulfentrazone) and 4.8 ppb (3-carboxylic acid sulfentrazone) four to five months after application in North Carolina and 0.86 ppb (sulfentrazone) and 2.50 ppb (3-carboxylic acid sulfentrazone) 455-577 days after application in Indiana. At one site, sulfentrazone was still detected in two out of eight shallow wells, whereas sulfentrazone 3-carboxylic acid was detected in all eight shallow wells, 800 days after application.

Laboratory studies, field studies, leaching indicators, groundwater modeling outputs and prospective groundwater monitoring studies indicated that sulfentrazone and 3-carboxylic acid sulfentrazone are expected to leach through the soil profile beyond 30 cm and are expected to leach to groundwater when used in accordance with the proposed label instructions.

Water

Although the use pattern of sulfentrazone does not include direct application to water, the possibility that aquatic systems will be exposed to sulfentrazone and its major transformation product, directly or indirectly, cannot be ruled out. Sulfentrazone may enter the aquatic environment through spray drift, run-off or groundwater recharge.

Sulfentrazone is expected to persist in the aquatic environment as it is very water soluble (400 mg/L), stable to hydrolysis, and persistent in anaerobic aquatic systems (estimated $t_{1/2}$ = 9 years). The only route of transformation is expected to be phototransformation in the photic zone of the water column. Sulfentrazone photolyses to many short-lived transformation products that are further transformed to methyl triazole, 1,3-dihydroxybenzene and methyl triazole oxidation products.

The laboratory data on mobility indicate that sulfentrazone will remain primarily in the aqueous phase of aquatic systems. Under anaerobic conditions, less than 15% of sulfentrazone residues partitioned to the aquatic sediment and only a minimal amount was bound (≤4%). The fate of sulfentrazone and its transformation products in surface waters could not be completely described as no aerobic water/sediment biotransformation study was provided. It was therefore assumed that sulfentrazone is stable to aerobic aquatic biotransformation based on the stability demonstrated in the anaerobic sediment and the aerobic soil biotransformation studies. An

aquatic field dissipation study has been requested to further characterise the fate of sulfentrazone in surface waters. The octanol-water partition coefficient of sulfentrazone indicates that it has a limited potential for bioconcentration in biological organisms.

Air
Sulfentrazone is non-volatile and is not expected to be transported long distances in the air.

4.2 Effects on Non-Target Species

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 are concentrations of pesticide in various environmental media, such as food, water, soil and air. The environmental concentrations are estimated 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 (e.g. 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). 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 Effects on Terrestrial Organisms

Risk of sulfentrazone and its related end-use product to terrestrial organisms was based upon the use pattern for the end-use product and the evaluation of toxicity data for the following (Appendix 1, Table 10):

- One bee species representing invertebrates;
- Two bird and three mammal species representing vertebrates (acute, short-term dietary, reproduction, developmental and neurotoxicity); and
- Ten crop species representing non-target vascular plants.

The screening level risk quotients for Authority 480 Herbicide were assessed based on the maximum application rate (one application of 140 g a.i./ha) for honeybees, birds, small mammals and terrestrial plants as these organisms may be exposed through direct application, contact with treated material or from ingestion of contaminated food. The assessment is addressed in this Section, 4.2.1, and in Section 4.2.2.

Terrestrial Invertebrates
An earthworm toxicity study for sulfentrazone was not submitted. The potential risk to earthworms has not been assessed.

Sulfentrazone was relatively non-toxic to honey bees when exposed by contact. At the proposed application rate, the screening level risk quotient values were less than the level of concern (Appendix I, Table 12). The use of sulfentrazone is not expected to pose an acute risk on a contact basis. The potential acute oral risk to honeybees was not assessed since an acute oral toxicity study for honeybees was not submitted.

Terrestrial Vertebrates
The acute bobwhite quail toxicity studies (oral and dietary) showed no treatment-related mortalities occurring at the highest dose tested in both study types. The mallard duck acute dietary toxicity study showed one mortality and a reduction in body weight gain at the highest concentration tested. In the reproductive studies, no significant reproductive effects were noted at the highest concentration tested.

Female mice were the most sensitive small mammals tested for acute oral toxicity and it was, therefore, the endpoint from this study that was used in the acute risk assessment. The most sensitive chronic endpoint was the no observed effect level (NOEL) from the rat prenatal development study which showed decrease in fetal bodyweight. Since the reproductive endpoint was more sensitive than the short-term dietary endpoint, it was chosen for the chronic mammalian risk assessment.

These toxicity endpoints were converted into daily doses with food ingestion rates and body weights taken directly from the studies for the bird assessment and using default values for the mammalian assessment (Appendix I, Table 13). These values were then compared to the daily exposure estimates to calculate the risk quotients. The exposure estimates for birds are calculated based on the body weight of the organisms and the amount and type of food consumed.

Since Authority 480 Herbicide is to be applied only once a year, the estimated environmental concentrations are based on the maximum application rate at the time of application. Since exposure is dependent on the body weight of the organisms and the amount and type of food consumed, the screening level risk assessment for birds and mammals considers a set of generic body weights (20, 100, 1000 g for birds and 15, 35, 1000 g for mammals) and food preferences (100% small insects for insectivores, 100% fruits for frugivores, 100% grain and seeds for granivores and 100% leaves and leafy crop for herbivores; food items considered at the screening level provide the most conservative estimated environmental concentrations for each food guild). Additionally, the acute toxicity endpoint is divided by an uncertainty factor of 10 to account for potential differences in species sensitivity as well as varying protection levels (e.g. community, population, individual).

The calculated screening level risk quotients for birds and mammals (Appendix I, Table 14 and 15) indicate that the level of concern was not exceeded for birds on an acute and chronic basis and for mammals on an acute basis. For mammals of all weight categories, the level of concern for the chronic screening level assessment was exceeded for various food guilds, and as a result, a refined assessment was conducted.

In the refined assessment (Appendix I, Table 16), how the product is expected to be used in the field, application method, application timing, dissipation half-life and foraging behaviour of the non-target animals are discussed to further refine and identify the potential reproductive risk to mammals.

Sulfentrazone is to be applied to bare soil as a preplant incorporated treatment or as a pre-emergence (to weed and crop) surface application. For small herbivorous, granivorous and frugivorous mammals, the on-field level of concern is not expected to be exceeded, since these food items are not expected to contain sulfentrazone residues or be available for consumption on the field. It is expected that small insectivorous mammals will avoid feeding on open bare ground soil where they would be susceptible to predation when similar food items are available off-field under the cover of vegetation. It is therefore unlikely that the level of concern for reproductive effects for wild mammals will be exceeded in the field under typical use conditions.

The off-field scenario assesses the risk to mammals that may be exposed to spray drift in habitats adjacent to the treated field. The off-field environmental concentration was calculated based on the percent deposition at one metre downwind according to the ground application model used by PMRA. This model predicts the percent deposition at one metre to be 6 % for applications using a ground boom sprayer and a medium spray quality.

The off-field assessment was conducted taking into consideration the spray drift deposition for medium sized spray droplets for ground application (6 %). The level of concern for reproductive effects was below the level of concern for all food guilds and weight size categories except for medium-sized herbivorous mammals with a diet of 100% leafy foliage. The off-field assessment assumes maximum exposure concentration on food items immediately after application, that the concentration remains at these high levels and that mammals would feed exclusively on treated food within 1 m of the treated field. Given that the risk only slightly exceeds the level of concern (1.6), that this is representative of a conservative scenario assuming that a wild mammal would

eat exclusively leafy foliage within 1 m of the treated field, this risk is not likely to manifest itself in the field.

The risk quotient values indicate that there is no risk to wild mammals on-field and that the small risk identified for mammals off-field is not likely to manifest itself in the field.

Terrestrial Plants

Non-target terrestrial vascular plants could be exposed to residues of sulfentrazone as a result of spray drift from the application of Authority 480 Herbicide. Seedling emergence and vegetative vigour studies on ten crop species were submitted. Using the endpoints from both study types and the maximum seasonal application rate, the screening level risk assessment indicated that level of concern was exceeded for terrestrial plants (Appendix I, Table 17).

Given the conservative assumptions taken in the screening level assessment, a refined assessment was conducted to further characterize the risk by taking into consideration an off-field exposure resulting from pesticide drift during application (Appendix I, Table 18). For this assessment, the application rate (or the rate at which the non-target plants will be exposed) was determined taking into consideration the percent drift that will result depending on the application method. A spray droplet size of 'medium' based on the ASAE[4] classification can be assumed for herbicides applied by field sprayer. For a 'medium' droplet size, the maximum spray drift deposition for ground boom sprayer to agricultural crops at one metre downwind from the point of application is 6% of the application rate. The maximum percent off-field deposition on non-target plants would therefore be 8.4 g a.i./ha (140 g a.i./ha x 0.06). Based on the revised risk quotients using the off-field estimated environmental concentrations from drift, the level of concern for terrestrial vascular plants was still exceeded.

The use of Authority 480 Herbicide may pose risks to non-target terrestrial plants. These risks may be mitigated by applying spray buffer zones and label statements.

3.1.2 Effects on Aquatic Organisms

Risk of sulfentrazone and its related end-use product to freshwater aquatic organisms was based upon the evaluation of toxicity data for the following:

- One invertebrate species (daphnid-acute and long-term exposure);
- Two fish species (acute and stage specific exposure);
- One green alage, one blue-green algae, one diatom and one vascular plant; and
- Amphibian species using fish toxicity studies as surrogate.

[4] ASAE: American Society of Agricultural Engineers

Risk of sulfentrazone to marine aquatic organisms was based upon evaluation of toxicity data for the following:

- Two invertebrates (mysid and eastern oyster-acute exposure);
- One fish species (acute exposure); and
- One diatom.

Aquatic organisms can be exposed to sulfentrazone as a result of drift and runoff from the application of Authority 480 Herbicide. To assess the potential effects from exposure to sulfentrazone, the screening level estimated environmental concentrations in the aquatic environment based on direct application to water were used as exposure estimates. The calculated estimated environmental concentrations were those determined in 15 cm body of water for amphibians and 80 cm body of water for all other aquatic organisms. For the screening level risk assessment for aquatic organisms the laboratory endpoints were adjusted using uncertainty factors to account for differences in species sensitivity and protection goals (e.g. community, population and individual) (Appendix I, Table 19).

In those cases where the screening level assessments resulted in the level of concern being exceeded, a refined assessment was conducted to further characterize the risk. Given the conservative assumptions in the screening level assessment which assumes a direct overspray to a water body, a refined assessment was conducted to further characterize the identified risk from drift and runoff to freshwater and marine organisms (Appendix I, Table 20 and Table 21).

For drift, a refined estimated environmental concentration for a ground broadcast application was calculated using a maximum percent drift deposition at one metre downwind of the site of application. A spray droplet size of ‘medium’ based on the ASAE classification can be assumed for herbicides applied by field sprayer. For a ‘medium’ droplet size, the maximum spray drift deposition for ground boom sprayer to agricultural crops at one metre downwind from the point of application is 6% of the application rate.

For runoff, a refined estimated environmental concentration using the maximum application rate for sulfentrazone in a 1-ha and 15-cm (amphibians) or 80-cm (all other aquatic organisms) deep body of water was estimated by PRZM-EXAMS. The estimated environmental concentrations used for the risk quotient calculations were the most conservative estimates for a particular time interval representative of the exposure period of the toxicity test.

Aquatic Invertebrates – Freshwater and Marine

Acute exposures to sulfentrazone were highly toxic to mysid shrimp (immobilization) and slightly toxic to daphnids (immobilization) and eastern oysters (shell deposition). In long-term studies, sulfentrazone had adverse effects on the reproduction of daphnids (decrease in reproduction, body weight and body length of the parent). Calculated risk quotients for both freshwater and marine invertebrates demonstrate that the level of concern for acute and chronic effects was not exceeded (Appendix I, Table 19).

Fish – Freshwater and Marine
In acute tests with freshwater and marine fish, mortality was observed in the warm water fish (bluegill sunfish) and the marine fish (silverside) following exposures to sulfentrazone. No mortality occurred at the highest concentration tested in the rainbow trout limit test. In an early life stage toxicity test with the rainbow trout, sulfentrazone had an adverse effect on survivability and growth. Risk quotients calculated at the screening level for fish indicated that the level of concern for acute and chronic effects was not exceeded (Appendix I, Table 19).

Amphibians
No studies assessing the toxicity of sulfentrazone to amphibians were submitted. In order to assess the risk to amphibians resulting from an acute and a chronic exposure to sulfentrazone, the endpoint values for the most sensitive fish species were used as surrogate data, along with the estimated environmental concentration in a 15-cm deep body of water. The risk quotients calculated at the screening level did not exceed the level of concern for amphibians (Appendix I, Table 19).

Algae and Aquatic Plants
Algal cell density and frond count in the vascular plant were adversely affected by sulfentrazone. The risk quotients calculated at the screening level were slightly exceeded for green algae and Lemna gibba (Appendix I, Table 19). These risks may be mitigated by applying spray buffer zones and label statements.

Given the conservative assumptions in the screening level assessment which assumes a direct overspray to a water body, a refined assessment was conducted to further characterize the acute risk from drift and runoff to algae and vascular plants (Appendix I, Table 20 and Table 21). Based on the revised risk quotients using the off-field estimated environmental concentrations from drift and runoff concentrations estimated from PRZM/EXAMS modeling and the acute aquatic plant toxicity information, the risk quotients were below the level of concern.

5.0 Value

5.1 Effectiveness Against Pests

5.1.1 Authority 480 Herbicide

Efficacy data were submitted from 328 replicated field trials conducted over a 21-year period (1986-2006) at several locations in 3 provinces (Alberta, Saskatchewan and Ontario) and 14 States (Colorado, Iowa, Illinois, Indiana, Kansas, Michigan, Minnesota, Montana, North Dakota, Nebraska, Ohio, South Dakota, Washington and Wyoming). Treatments included various rates of sulfentrazone to determine the lowest effective rate. The herbicide treatments were applied using small plot application equipment.

The efficacy of Authority 480 Herbicide was visually assessed as percent weed control and compared to an untreated weedy check. Observations were made up to three times throughout the growing season. Further to the review of efficacy data, the applicant has amended the rates of application of Authority 480 Herbicide to a range of 105 to 140 g a.i./ha. As conditions of the registration, additional trials have been requested to confirm the amended rates.

5.1.2 Acceptable Efficacy Claims

The submitted efficacy data established the lowest effective rate for Authority 480 Herbicide applied alone, either as a pre-plant application or as a pre-emergence application and support the claims of control for wild buckwheat, common lamb's quarters, Eastern black nightshade, redroot pigweed, common waterhemp and tall waterhemp and support the claims of suppression for kochia, yellow nutsedge and smooth pigweed at the rates of application summarized in Table 5.1.2.1.

Table 5.1.2.1 Rates of Application for Authority 480 Herbicide to control wild buckwheat, common lamb's quarters, Eastern black nightshade, redroot pigweed, common and tall waterhemp and to suppress kochia, yellow nutsedge and smooth pigweed.

Percent (%) Organic Matter	Application Rates by Soil Types (g a.i./ha)		
	Coarse	Medium	Fine
< 1.5%	105 - 140*	105 - 140	--
1.5 - 3.0	105 - 140	140 - 210	140 - 210
> 3.0%	140 - 210	140 - 210	140 - 210

*Use the higher rates within the rate range for soils with pH less than 7.0

5.1.3 Herbicide Tank Mix Combinations

No tank mixtures with Authority 480 Herbicide were proposed.

5.2 Phytotoxicity to Host Plants

Data from a total of 439 trials (28 trials on chickpea, 24 trials on flax, 298 trials on soybean, 61 trials on sunflower, 13 trials on strawberry and 15 trials on asparagus) conducted at multiple locations in the United States (Colorado, Iowa, Illinois, Indiana, Kansas, Minnesota, Montana, Nebraska, Ohio, North Dakota, South Dakota, Washington State and Wyoming) and in Canada (Alberta, British Columbia, Manitoba, Nova Scotia, Ontario and Saskatchewan) over a 13-year period (1992 to 2005) were submitted in support of the host crop tolerance claims.

Crop injury (%) was visually assessed up to three times during the growing season. Yield, expressed as a percentage of a weed-free or weedy check, was reported in a number of trials.

5.2.1 Acceptable Claims for Host Plants for Authority 480 Herbicide

Crop injury to chickpea, soybean, sunflower, flax and strawberry treated with Authority 480 Herbicide applied alone was acceptable in most soil textures and with most soil organic matter contents. However, due to an unacceptable level of injury, Authority 480 Herbicide cannot be applied to coarse-textured soils in chickpea. Authority 480 Herbicide cannot be applied to coarse-textured soil in flax and warnings for possible injury in medium-textured soils should appear on the label. A warning for early injury in sunflower should also appear on the label. Authority 480 Herbicide cannot be applied on medium and fine-textured soils in strawberry and should not be applied to newly established spring plantings until dormancy occurs in the fall. The acceptable use claims noted above will be required in the event that the label for Authority 480 Herbicide is amended to include soybean, sunflower, flax and strawberry.

5.3 Impact on Rotational Crops

Rotational crop tolerance data were submitted from 5 trials that were initiated within one to 2 years following an application of sulfentrazone. The number of trials, in which tolerance was evaluated, varied by rotational crop. Some trials included multiple crops. Trials were conducted in Colorado, Minnesota, Nebraska, Ohio and Virginia.

The review of sulfentrazone has identified potential concerns relating to the sustainability of the product due to the persistence of sulfentrazone under normal climatic conditions and that sulfentrazone may persist for even greater periods of time under atypical environmental conditions (i.e. drought), as well as its effect on rotational crops several years after the initial application of sulfentrazone. The applicant must submit additional data for all the rotational crops listed on the label plus a number of other crops as detailed in the Section 12 Notice associated with this conditional registration. It is suggested that one trial be conducted in Scott, Saskatchewan and another trial in Ontario along with three more trials anywhere in the Prairie Provinces.

5.3.1 Acceptable Claims for Rotational Crops for Sulfentrazone

The crop injury and yield data support a rotational crop tolerance claim for the following crops planted anytime after an application of sulfentrazone: soybean and sunflower. The data support alfalfa and spring wheat as rotational crops as of 12 months, winter wheat as of 16 months, and field corn as of 10 months after an application of sulfentrazone. The data also support canola, sweet corn and sorghum as rotational crops 24 months after an application of sulfentrazone. These rotational intervals are conditionally accepted, pending the review of additional trials.

5.4 Economics

No market analysis was assessed for this product review

5.5 Sustainability

5.5.1 Survey of Alternatives

No survey of alternatives was conducted for Authority 480 Herbicide.

5.5.2 Compatibility with Current Management Practices Including Integrated Pest Management

Sulfentrazone offers broad-spectrum weed control, particularly for the control of kochia and wild buckwheat, when used as a pre-plant or pre-emergence herbicide in chickpea, flax, soybean, sunflower and strawberry. It is compatible with integrated weed management practice because it controls a range of weeds with a single application and because it can control weeds before they emerge and cause damage to the crops. It is compatible with both conservation tillage and conventional production systems.

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

Repeated use of herbicides having the same mode of action in a weed control program increases the probability of selecting naturally resistant biotypes. Therefore, Authority 480 Herbicide should be used in rotation with herbicides having different modes of action.

The Authority 480 Herbicide label includes the resistance management statements, as per Regulatory Directive DIR99-06, *Voluntary Pesticide Resistance-Management Labelling Based on Target Site/Mode of Action*.

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, i.e. CEPA-toxic or equivalent, predominantly anthropogenic, persistent and bio-accumulative).

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

- Sulfentrazone does not meet Track 1 criteria, and is not considered a Track 1 substance. See Appendix 1, Table 22 for comparison with Track 1 criteria.
- Sulfentrazone is not expected to form any transformation products that meet all Track 1 criteria.

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*. The list is used as described in the PMRA Notice of Intent NOI2005-01 and is based on existing policies and regulations including: DIR99-03; and DIR2006-02, and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

Technical grade sulfentrazone and the end-use product Authority 480 Herbicide do not contain any formulants of health or environmental concern identified in the *Canada Gazette*. However, the TGAI does contain an aromatic petroleum distillate. Therefore, the label for both the technical and the end-use product Authority 480 Herbicide will include the statement: "This product contains aromatic petroleum distillates that are toxic to aquatic organisms."

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

7.0 Summary

7.1 Human Health and Safety

The toxicology database submitted for sulfentrazone is adequate to characterize the toxicity of sulfentrazone. The effects noted in subchronic and chronic studies with laboratory animals were clinical anaemia, decreases in body weight and body weight gain, histopathological findings in the spleen and the liver and increased liver weight. There were no evidence of carcinogenicity or genotoxicity. Reproductive and developmental effects were also observed. These effects included decreased pregnancy rates and male fertility, increased testicular degeneration or atrophy, degeneration of germinal epithelium and seminal product, decreased pre- and postnatal pup and litter survival, an increased incidence of skeletal variations and malformations and an increased incidence of resorptions. There was some evidence of neurotoxicity but no neuropathology. The risk assessment ensures that the level of human exposure is well below the lowest dose that these effects occurred in animals.

The residue definition for risk assessment and enforcement is sulfentrazone, 3-hydroxymethyl sulfentrazone and 3-desmethyl sulfentrazone in primary and rotational crops, except soybean, and is sulfentrazone and 3-hydroxymethyl sulfentrazone in soybean. In animals, the residue definition for risk assessment and enforcement is sulfentrazone, 3-hydroxymethyl sulfentrazone and 3-desmethyl sulfentrazone. The proposed use of sulfentrazone on chickpeas, including the importation of asparagus, cabbages, commodities in crop subgroup 6C- dried shelled pea and bean (except soybean), horseradish, soybean, sunflowers and mint, do not constitute an unacceptable chronic or acute dietary risk (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 maximum residue limits, both domestic and import, to protect human health. The PMRA recommends that the following maximum residue limits be specified under the authority of the *Pest Control Products Act* for:

Residues of sulfentrazone in and on asparagus (0.15 ppm); cabbages (0.20 ppm); horseradish roots (0.20 ppm); crop subgroup 6C- dried shelled pea and bean, except soybean (0.15 ppm); peppermint tops (0.30 ppm); dry soybeans (0.05 ppm); spearmint tops (0.30 ppm); and sunflower seeds (0.20 ppm).

Mixers, loaders, applicators and workers entering treated areas are not expected to be exposed to levels of Authority 480 Herbicide that may result in unacceptable risk when Authority 480 Herbicide is used according to label directions. The personal protective equipment stated on the product label is adequate to protect workers.

7.2 Environmental Risk

Sulfentrazone is persistent in the terrestrial and aquatic environment. Soil residues are expected to carryover to the following growing season and have a high potential to leach to groundwater and enter aquatic systems.

The risk to the environment was assessed for the end-use product, Authority 480 Herbicide. Risks to terrestrial plants, algae, aquatic plants and small mammals on a chronic basis have been identified at the screening level. These risks may be mitigated by applying spray buffer zones and label statements. Further characterization of the risk indicated that sulfentrazone may pose a risk to terrestrial plants, but not to small mammals, algae and aquatic plants. Since sulfentrazone is persistent and likely to accumulate in aquatic systems, there may be risk from long term exposure to fish; additional information has been requested to address this concern. A honey bee oral toxicity study has been requested since there is the potential for bees to be exposed to residues on and within plants. There are no concerns with sulfentrazone affecting bees on a contact basis, birds, mammals, aquatic invertebrates and fish on an acute basis. To advise the user of the potential for carryover, leaching and run-off, advisory statements are included on the label.

7.3 Value

The data submitted to register Authority 480 Herbicide are adequate to describe its efficacy for use as a pre-plant or pre-emergence application in chickpea, flax, soybean, sunflower and strawberry. A single application of Authority 480 Herbicide provides control of wild buckwheat, common lamb’s quarters, Eastern black nightshade, redroot pigweed, common waterhemp and tall waterhemp and will provide suppression of kochia, yellow nutsedge and smooth pigweed. The submitted phytotoxicity and yield data demonstrate an adequate margin of safety of labelled host crops to Authority 480 Herbicide with the exception of the labelled restrictions in some soil textures in chickpea, flax, sunflower and strawberry. Authority 480 Herbicide (Group 14) provides an alternative mode of action to commonly used herbicides for the labelled crops.

Since the applicant has amended the rates of application of Authority 480 Herbicide, supplementary data are requested to support the new rates of 105 to 140 g a.i./ha to control kochia, common lamb's quarters, wild buckwheat and redroot pigweed. Concerns were identified regarding the persistence of the product in various soils especially under atypical environmental conditions (i.e. drought), therefore, supplementary data are also requested to support the safety of sulfentrazone on rotational crops under normal and drought climatic conditions.

7.4 Unsupported Uses

Certain uses originally proposed by the applicant were not supported by the PMRA because the value was not adequately demonstrated. These uses include: 1) a variety of weed pests; 2) crops: asparagus, cabbage, shelled bean and pea, horseradish and mint; and 3) application methods: chemigation and aerial application. For more details see Appendix I, Table 23.

Uses on strawberry and flax cannot be supported at this time due to outstanding dietary data requirements. It is recommended that the applicant submit the final IR-4 strawberry and flax field trial study reports.

Due to questions and concerns remaining after the completion of the environmental risk assessment, Authority 480 Herbicide is conditionally supported for a limited use on chickpea in Saskatchewan.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, has granted conditional registration for the sale and use of Sulfentrazone Technical Herbicide and Authority 480 Herbicide containing the technical grade active ingredient sulfentrazone for use on chickpeas in Saskatchewan to control a variety of weeds.

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

Although the risks and value have been determined to be acceptable when all risk reduction measures are followed, as a condition of these registrations, additional scientific information is being requested from the applicant as a result of this evaluation to confirm the fate of sulfentrazone in the environment and ensure it's safety and value. (For more details, refer to the Section 12 Notice associated with these conditional registrations.) The applicant will be required to submit this information within the conditional registration time frame of three years.

NOTE: The PMRA will publish a consultation document at the time when there is a proposed decision on applications to convert these conditional registrations to full registrations or on applications to renew the conditional registrations, whichever occurs first.

Human Health
Information on the toxicity of the 3-carboxylic acid-sulfentrazone is required to characterize the potential risk to individuals exposed to 3-carboxylic acid sulfentrazone through the drinking of groundwater. A valid rationale comparing the toxicity of 3-carboxylic acid-sulfentrazone to the parent, including any available toxicology data on 3-carboxylic acid-sulfentrazone must be provided.

Environment
A validated analytical method for the active and its major metabolites in fish;

Depending on the outcome of the review of the new Canadian soil study, a new analytical method for the active and its major transformation products in soil;

Physico-chemical properties and environmental fate information for the major transformation products;

An aquatic field dissipation study conducted in a Canadian relevant ecoregion;

The final report on the 'Small-Scale Prospective Groundwater Monitory study for Sulfentrazone in a Setting Classified as 95th Percentile Based on Vulnerability to Groundwater Contamination';

'Small-Scale Prospective Groundwater Monitory study for Sulfentrazone in a Setting Classified as 85th and 75th Percentile Based on Vulnerability to Groundwater Contamination';

Acute oral toxicity study on honeybees.

Value
Due to the high leaching potential of sulfentrazone, the applicant must submit a stewardship plan/risk mitigation plan that will elaborate on the economic and social impact that the presence of sulfentrazone in groundwater will have and its possible effect on crops when groundwater, dugout water or well water, contaminated with sulfentrazone, is used for irrigation.

The applicant has amended the rates of application of Authority 480 Herbicide to a range of 105 to 140 grams of active ingredient per hectare. Additional data to confirm that the rates of 105 to 140 grams of active ingredient per hectare will control the four weeds for which control is required at these rates: kochia, common lamb's quarters, redroot pigweed and wild buckwheat.

The value assessment of Authority 480 Herbicide has identified potential concerns relating to the sustainability of the product due to the persistence of sulfentrazone under normal climatic conditions and that sulfentrazone may persist for even greater periods of time under atypical environmental conditions (i.e. drought), as well as its effect on rotational crops several years after the initial application of sulfentrazone. The applicant must submit additional data for all the rotational crops listed on the label plus a number of other crops as detailed in the Section 12 Notice associated with this conditional registration. It is suggested that one trial be conducted in Scott, Saskatchewan and another trial in Ontario along with three more trials distributed across the Prairie Provinces.

List of Abbreviations

µg	micrograms
µm	micrometer
1/n	exponent for the Freundlich isotherm
a.i.	active ingredient
ADI	acceptable daily intake
ALS	acetolactate synthase
ARfD	acute reference dose
ASAE	American Society of Agricultural Engineers
atm	atmosphere
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
bw	body weight
CAS	chemical abstracts service
cm	centimetres
DF	dry flowable
DFR	dislodgeable foliar residue
DNA	deoxyribonucleic acid
DT_{50}	dissipation time 50% (the dose required to observe a 50% decline in the concentration)
DT_{75}	dissipation time 75% (the dose required to observe a 75% decline in the concentration)
DT_{90}	dissipation time 90% (the dose required to observe a 90% decline in the concentration)
dw	dry weight
EC_{05}	effective concentration on 5% of the population
EC_{10}	effective concentration on 10% of the population
EC_{25}	effective concentration on 25% of the population
EDE	estimated daily exposure
EEC	estimated environmental concentration
ER_{25}	effective rate for 25% of the population
ER_{50}	effective rate for 50% of the population
FC	food consumption
FIR	food ingestion rate
F	flowable
FOB	functional observational battery
g	gram
GC-ECD	gas chromatography with electron caption detection
GC-ELCD	gas chromatography with electrolytic conductivity detection
GC-MSD	gas chromatography with mass selective detection
GC-XSD	gas chromatography with halogen specific detection
ha	hectare(s)
HDT	highest dose tested
Hg	mercury
HPLC	high performance liquid chromatography

IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_d	soil-water partition coefficient
K_F	Freundlich adsorption coefficient
km	kilometre
K_{oc}	organic-carbon partition coefficient
K_{ow}	*n*–octanol-water partition coefficient
L	litre
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LOAEL	lowest observed adverse effect level
LOD	level of detection
LOEC	low observed effect concentration
LOQ	limit of quantitation
LR_{50}	lethal rate 50%
mg	milligram
mL	millilitre
MAS	maximum average score
M/L/A	mixing/loading and application
MOE	margin of exposure
MRL	maximum residue limit
MS	mass spectrometry
N/A	not applicable
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NOER	no observed effect rate
N/R	not required
NZW	New Zealand white
OC	organic carbon content
OECD	Organisation for Economic Co–operation and Development
OM	organic matter content
PBI	plantback interval
PCPA	*Pest Control Products Act*
PHED	Pesticide Handlers Exposure Database
PHI	preharvest interval
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
ppm	parts per million
REI	restricted entry interval
RSD	relative standard deviation
SC	soluble concentrate
$t_{1/2}$	half-life
T3	tri-iodothyronine
T4	thyroxine
TC	transfer coefficient

TRR	total radioactive residue
TSMP	Toxic Substances Management Policy
UAN	urea ammonium nitrate
UF	uncertainty factor
USEPA	United States Environmental Protection Agency
UV	ultraviolet
v/v	volume per volume dilution

Appendix I Tables and Figures

Table 1 Residue Analysis

Matrix	Method ID	Analyte(s)	Method Type	LOQ		Reference
Plant	P-2689M	sulfentrazone	Data Gathering: GC-ECD (confirmatory GC-MSD)	0.025 ppm	soybean seed	1308971; 1275922
Plant	P-2718M	sulfentrazone	Data Gathering: GC-ECD (confirmatory GC-MSD)	0.025 ppm	soybean seed, meal, hulls, oil and soapstock	1275916
Plant	P-2811M	sulfentrazone and 3-hydroxymethyl sulfentrazone (HMS)	Data Gathering: GC-ECD (confirmatory GC-MSD)	0.025 ppm (sulfentrazone and HMS)	soybean seed	1275919; 1275921; 1275930
Plant	P-2982M	sulfentrazone, 3-desmethyl sulfentrazone (DMS), 3-hydroxymethyl sulfentrazone (HMS) and 3-desmethyl-4-desdifluoromethyl sulfentrazone (DDS)	Data Gathering: GC-ECD (confirmatory GC-MSD)	0.025 ppm (sulfentrazone, HMS and DMS)	winter wheat grain, forage and straw	1275918; 1275923; 1275924; 1275925; 1275929
				0.05 ppm (DDS)	winter wheat forage	
Plant	P-3063M	sulfentrazone, 3-desmethyl sulfentrazone (DMS) and 3-hydroxymethyl sulfentrazone (HMS)	Data Gathering: GC-ECD and GC-ELCD (confirmatory GC-MSD)	0.025 ppm (sulfentrazone, DMS and HMS)	winter wheat grain and forage	1275917; 1275926
				0.05 ppm (sulfentrazone, DMS and HMS)	winter wheat hay and straw	
Plant	P-3173	sulfentrazone, 3-desmethyl sulfentrazone (DMS)/ sulfentrazone 3-carboxylic acid (SCA) and 3-hydroxymethyl sulfentrazone (HMS)	Dat Gathering/ Enforcement: GC-ELCD or GC-XSD (confirmatory GC-MSD)	0.025 ppm (sulfentrazone, DMS and HMS)	soybean seed; grain of corn, rice, sorghum and wheat; forage of corn, sorghum and wheat; fodder of corn and sorghum	1275927; 1275928
				0.05 ppm (sulfentrazone, DMS and HMS)	straw of rice and wheat; wheat hay	
Soil	None	sulfentrazone	HPLC-MS	5 ppb		1279724, 1275987
		sulfentrazone 3-carboxylic acid (SCA)				

Matrix	Method ID	Analyte(s)	Method Type	LOQ	Reference
Sediment	Extended from soil				
Water	None	sulfentrazone	GC-ECD	0.5 ppb in fresh water	1279739
		sulfentrazone 3-carboxylic acid (SCA)			

Table 2 Acute Toxicity of Sulfentrazone Technical Herbicide and Its Associated End-use Product (Authority 480 Herbicide)

Study Type	Species	Result	Comment	Reference
Acute Toxicity of Sulfentrazone Technical Herbicide				
Oral	Rat	LD50 = 2855 mg/kg bw	Low Toxicity	1279669
Oral	Mouse	LD50 = 711 mg/kg bw	Moderate toxicity	1279668
Dermal	Rat	LD50 > 2000 mg/kg bw	Low Toxicity	1279670
Inhalation	Rat	LC50 > 4.13 mg/L	Low Toxicity	1279671
Skin irritation	Rabbit	MAS = 0	Non-irritating	1279673
Eye irritation	Rabbit	MAS = 4.39	Minimally irritating	1279672
Skin sensitization (Buehler)	Guinea pig	Negative (Dose selection not appropriate)	Potential dermal sensitizer	1279674
Acute Toxicity of End-Use Product—Authority 480 Herbicide				
Oral	Rat	LD50 = 2084 mg/kg bw	Low Toxicity	1275898
Dermal	Rat	LD50 > 2000 mg/kg bw	Low Toxicity	1275899
Inhalation	Rat	LC50 > 2.72 mg/L	Low Toxicity	1275900
Skin irritation	Rabbit	MAS = 0	Non-irritating	1275902
Eye irritation	Rabbit	MAS = 0	Non-irritating	1275901
Skin sensitization (Buehler)	Guinea pig	Negative	Not a dermal sensitizer	1275903

Table 3 Toxicity Profile of Sulfentrazone Technical Herbicide

Study Type	Species	Results (mg/kg bw/day)	Reference
90-d dietary	Mouse	NOAEL: 60.0 mg/kg bw/day LOAEL: 108.4 mg/kg bw/day	1279675
90-d dietary	Rat	NOAEL: 19.9 mg/kg bw/day LOAEL: 65.8 mg/kg bw/day	1279677
90-day dietary	Dog	NOAEL: 28 mg/kg bw/day LOAEL: 57 mg/kg bw/day	1279681
12-month dietary	Dog	NOAEL: 24.9 mg/kg bw/day LOAEL: 61.2 mg/kg bw/day	1279678
21-d dermal	Rabbit	NOAEL: * 1000 mg/kg bw/day LOAEL not established as no adverse effects were noted.	1279682
78-week dietary oncogenecity	Mouse	NOAEL: 93.9 mg/kg bw/day LOAEL: 160.5 mg/kg bw/day	1279685
2-year dietary	Rat	NOAEL: 36.4 mg/kg bw/day LOAEL: 67.0 mg/kg bw/day	1279686
Multi-generation	Rat	**Parental** NOAEL: 13.7 mg/kg bw/day LOAEL: 33.3 mg/kg bw/day **Reproductive** NOAEL: 13.7 mg/kg bw/day LOAEL: 33.3 mg/kg bw/day **Offspring** NOAEL: 13.7 mg/kg bw/day LOAEL: 33.3 mg/kg bw/day	1279688, 1279689, 1279690, 1279691, 1279692, 1279693
Multi-generation **Supplemental study**	Rat	**Parental** NOAEL: 18.2 mg/kg bw/day LOAEL: 45.4 mg/kg bw/day **Reproductive** NOAEL: 15.5 mg/kg bw/day LOAEL: 39.8 mg/kg bw/day **Offspring** NOAEL: 15.5 mg/kg bw/day LOAEL: 39.8 mg/kg bw/day	1279694
Developmental	Rat	A NOAEL and LOAEL were not established	1279698

Study Type	Species	Results (mg/kg bw/day)	Reference
Developmental toxicity (dermal)	Rat	**Maternal** NOAEL: 50 mg/kg bw/day LOAEL: 100 mg/kg bw/day **Developmental** NOAEL: 100 mg/kg bw/day LOAEL: 250 mg/kg bw/day	1279700
Developmental toxicity (oral)	Rat	**Maternal** NOAEL: 25 mg/kg bw/day LOAEL: 50 mg/kg bw/day **Developmental** NOAEL: 10 mg/kg bw/day LOAEL: 25 mg/kg bw/day	1279696
Developmental toxicity (oral) - Cardiac	Rat	Conducted to confirm findings in study 1279696	1279701
Developmental toxicity (oral)	Rabbit	**Maternal** NOAEL: 100 mg/kg bw/day LOAEL: 250 mg/kg bw/day **Developmental** NOAEL: 100 mg/kg bw/day LOAEL: 250 mg/kg bw/day	1279702
Acute neurotoxicity		**Neurotoxicity** NOAEL: 750 mg/kg bw/day LOAEL: 2000 mg/kg bw/day **Systemic** NOAEL: 250 mg/kg bw/day LOAEL: 750 mg/kg bw/day	1279708, 1279709
28-day neurotoxicity **Range finding study**	Rat	Conducted to set dose levels for 1279710-1279712 Effects noted at 95 mg/kg bw/day	1279713

Study Type	Species	Results (mg/kg bw/day)	Reference
90-day neurotoxicity	Rat	Neurotoxicity NOAEL: 37 mg/kg bw/day LOAEL: 180 mg/kg bw/day Systemic NOAEL: 30 mg/kg bw/day LOAEL: 150 mg/kg bw/day	1279710, 1279711, 1279712
Ames Test	*Salmonella typhimurium*	Negative	1279703
Mammalian cell gene mutation assay (*in vitro*)	Mouse lymphoma cells	Negative (+S9) Positive (-S9)	1279704
Micronucleus Assay (*in vivo*)	Mouse	Negative	1279705
Dominant Lethal Test	Rat	Negative	1279706

Table 4 M/L/A Exposure and Risk

Crop	Exposure Scenario	PHED Unit Exposures (dermal + inhalation) *g ai/kg handled[1]	Amount handled per day (kg)[2]	Systemic[3] Exposure (mg/kg bw/day)	MOE[4] Target 300
Sunflowers soybeans chickpeas	Farmers	44.38	31.65	0.0201	680
	Custom applicators	44.38	63.3	0.0401	340

1 Based on the PHED subsets corrected for dermal absorption for liquid open mix/load (51.14 x 50% dermal +1.6 light rate inhalation) and groundboom open cab application (32.49 x 50% dermal + 0.96 light rate inhalation) wearing a single layer of clothing plus gloves for mixer/loaders and a single layer of clothing for applicators.

2 Amount handled per day = maximum application rate of 210 g ai/ha x area treated per day (150 ha for farmers and 300 ha for custom applicators).

3 Systemic Exposure (mg/kg bw/day) = [unit exposure (mg ai/kg ai handled) x amount handled per day (kg) x 50% dermal absorption] / [body weight of 70 kg x 1000 (mg/mg)].

4 MOE = Oral NOAEL of 13.7 mg/kg bw/day ÷ Exposure (mg/kg bw/day); target MOE 300.

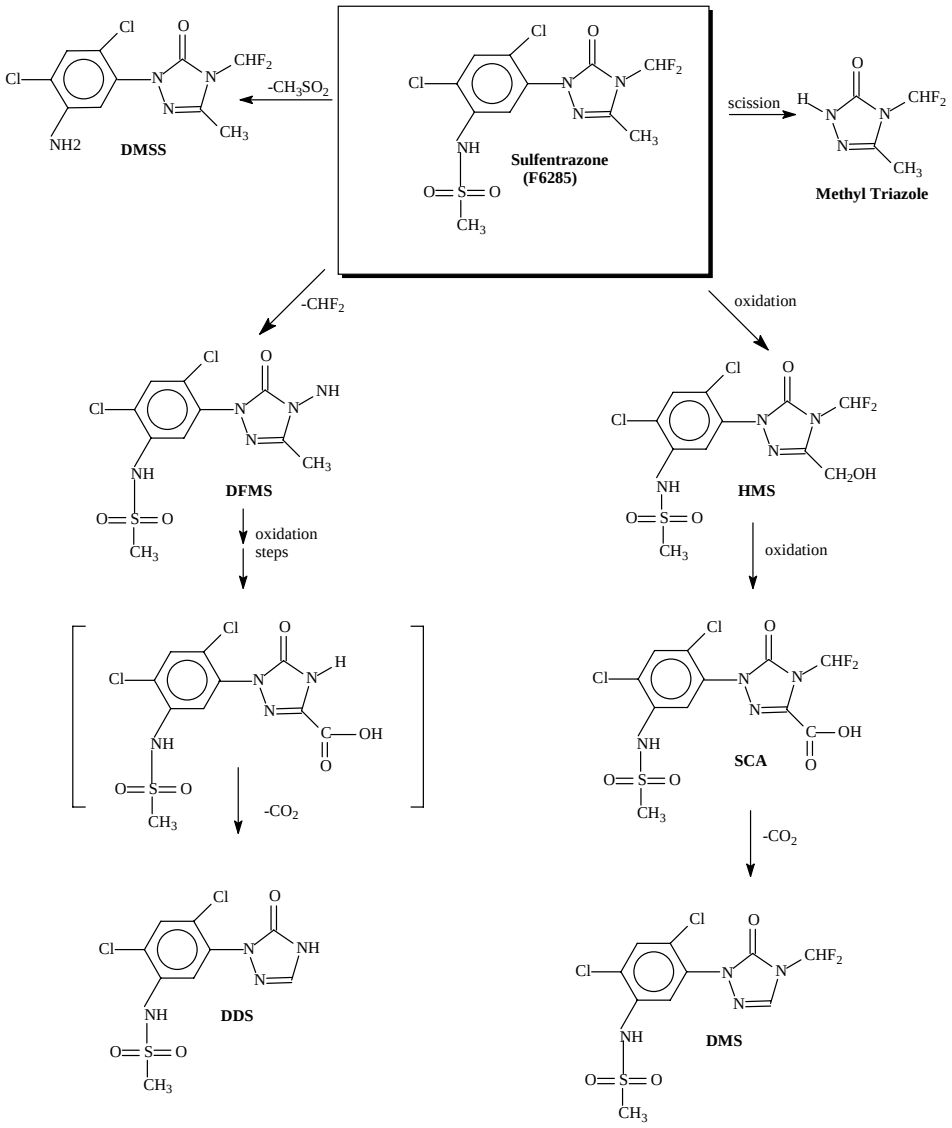
Table 5 Integrated Food Residue Chemistry Summary

NATURE OF THE RESIDUE IN PLANTS IN SOYBEAN		PMRA # 1279720
Radiolabel Position	**[^{14}C-U-Phenyl]**	**[^{14}C-Triazole]**
Test site	Outdoor test plots	
Treatment	Single broadcast preemergence application	
Rate	560.0 g a.i./ha/season	560.0 g a.i./ha/season
End-use product	Sulfentrazone- flowable formulation	
Preharvest interval	Immature forage (green): 63 or 98 days Mature hay (composed of dried foliage and empty pods) and seed: 114 or 145 days	

Total radioactive residues (TRRs) were determined in samples from two different plantings. Samples from the first (seed) and second (immature forage and hay) plantings were analyzed in the original study and the TRRs from the second planting were used in the supplemental work. Sulfentrazone is metabolized in soybean by four different pathways: i) oxidation of the 3-methyl group to form 3-hydroxymethyl sulfentrazone (HMS), followed by further oxidation to form sulfentrazone-3-carboxylic acid (SCA) which is decarboxylated to 3-desmethyl sulfentrazone (DMS), ii) hydrolysis of the difluoromethyl group to form 4-des(difluoromethyl) sulfentrazone (DFMS) which is oxidized and decarboxylated to form 4-des(difluoromethyl)-3-desmethyl sulfentrazone (DDS), iii) hydrolysis of the sulfonamide group to form 5-des(methylsulfonyl) sulfentrazone (DMSS) and iv) scission of the phenyl and triazole rings to produce methyl triazole.

Metabolites Identified	**Major Metabolites (> 10% TRRs)**		**Minor Metabolites (< 10% TRRs)**	
Radiolabel Position	**[^{14}C-U-Phenyl]**	**[^{14}C-Triazole]**	**[^{14}C-Phenyl]**	**[^{14}C-Triazole]**
Forage	HMS, DMS	HMS, DMS, methyl triazole	sulfentrazone, SCA, DMSS, DDS, DFMS	sulfentrazone, SCA, DMSS, DDS, DFMS
Hay	HMS, DMS	DMS, DFMS	sulfentrazone, DMSS, DDS, DFMS	sulfentrazone, HMS, SCA, DMSS, DDS, methyl triazole
Seed	sulfentrazone, HMS	HMS, methyl triazole	SCA, DMS, DMSS, DDS, DFMS	sulfentrazone, SCA, DMS, DMSS, DDS, DFMS

Proposed Metabolic Scheme in Soybean



DMSS: 5-des(methylsulfonyl) sulfentrazone
DFMS: 4-des(difluoromethyl) sulfentrazone
DDS: 4-des(difluoromethyl)-3-desmethyl sulfentrazone
HMS: 3-hydroxymethyl sulfentrazone
SCA: sulfentrazone-3-carboxylic acid
DMS: 3-desmethyl sulfentrazone

CONFINED ROTATIONAL CROP STUDY USING RADISH, LETTUCE, BARLEY		PMRA # 1275960
Radiolabel Position	**[^{14}C-U-Phenyl]**	**[^{14}C-Triazole]**
Test site	Greenhouse: stock tanks (61 cm x 183 cm x 25.4 cm deep) modified with drainage holes were filled with sandy loam soil.	
Formulation used for trial	Not reported	
Application rate and timing	soil was surface treated with 1 spray application at 560.0 g a.i./ha	soil was surface treated with 1 spray application at 560.0 g a.i./ha
The primary metabolic pathway involved initial oxidation of sulfentrazone at the exocyclic, allylic 3-methyl group to form 3-hydroxymethyl-sulfentrazone (free and conjugated). The hydroxymethyl group was further oxidized to the corresponding sulfentrazone-carboxylic acid (free and conjugated). The conjugated acid metabolites were released by acid workup with concomitant decarboxylation to form 3-desmethyl-sulfentrazone. The metabolite 5′-des(methylsulfonyl)-sulfentrazone was formed by hydrolysis of the sulfonamide group.		

Matrix	**Plantback Interval (Days)**	**TRRs (ppm)**	
		[^{14}C-U-Phenyl]	**[^{14}C-Triazole]**
Radish Root	30122245364	0.312 0.066 0.044 0.058	0.343 0.063 0.047 0.139
Lettuce Leaf	30122245364	0.651 0.194 0.044 0.115	0.440 0.110 0.034 0.030
Barley Forage	30122245364	1.406 0.350 0.475 0.219	2.067 0.595 0.329 0.494
Barley Straw	30122245364	2.984 2.725 1.060 0.673	3.362 4.264 1.705 1.831
Barley Grain	30122245364	0.052 0.035 0.014 0.012	0.041 0.054 0.035 0.031

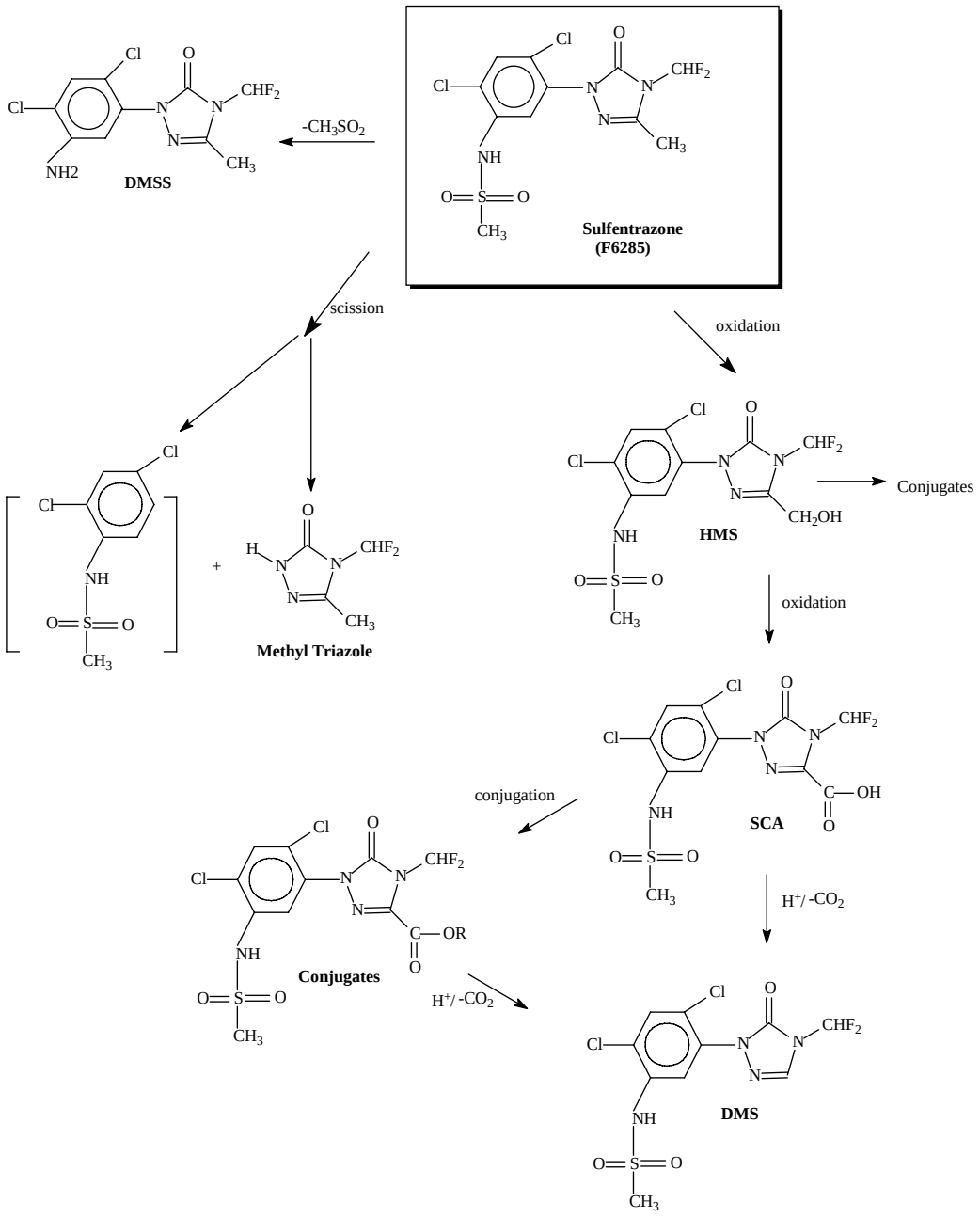
Metabolites Identified	Major Metabolites (> 10% TRRs)		Minor Metabolites (< 10% TRRs)	
Matrix	**[^{14}C-U-Phenyl]**	**[^{14}C-Triazole]**	**[^{14}C-U-Phenyl]**	**[^{14}C-Triazole]**
30 day PBI				
Radish Tops	HMS	HMS, methyl triazole	DDS, SCA/DMS, sulfentrazone, DMSS	DDS, SCA/DMS, sulfentrazone, DMSS
Radish Root	HMS, sulfentrazone	HMS, sulfentrazone	DDS, SCA/DMS, DMSS	DDS, SCA/DMS, DMSS, methyl triazole
Lettuce Leaf	HMS	HMS, methyl triazole	DDS, SCA/DMS, sulfentrazone, DMSS	DDS, SCA/DMS, sulfentrazone, DMSS
Barley Forage	HMS, SCA/DMS	HMS, SCA/DMS, methyl triazole	DDS, sulfentrazone, DMSS	DDS, sulfentrazone, DMSS
Barley Straw	HMS, SCA/DMS	HMS, SCA/DMS, methyl triazole	DDS, sulfentrazone, DMSS	DDS, sulfentrazone, DMSS
Barley Grain	HMS, SCA/DMS	-	sulfentrazone, DMSS	HMS, SCA/DMS, sulfentrazone, DMSS, methyl triazole
122 Day PBI				
Radish Tops	HMS	HMS, methyl triazole	DDS, SCA/DMS, sulfentrazone, DMSS	DDS, SCA/DMS, sulfentrazone, DMSS
Radish Root	HMS, sulfentrazone	HMS, sulfentazone	DDS, SCA/DMS, DMSS	SCA/DMS, DMSS, methyl triazole
Lettuce Leaf	HMS	HMS	DDS, SCA/DMS, sulfentrazone, DMSS	DDS, SCA/DMS, sulfentrazone, DMSS, methyl triazole

Metabolites Identified	Major Metabolites (> 10% TRRs)		Minor Metabolites (< 10% TRRs)	
Matrix	**[^{14}C-U-Phenyl]**	**[^{14}C-Triazole]**	**[^{14}C-U-Phenyl]**	**[^{14}C-Triazole]**
Barley Forage	HMS, SCA/DMS	HMS, SCA/DMS, methyl triazole	DDS, sulfentrazone, DMSS	DDS, DMSS
Barley Straw	HMS, SCA/DMS	HMS, SCA/DMS, methyl triazole	sulfentrazone, DMSS	DDS, sulfentrazone, DMSS
Barley Grain	HMS, SCA/DMS	HMS, SCA/DMS, methyl triazole	sulfentrazone, DMSS	sulfentrazone, DMSS
245 day PBI				
Radish Tops	HMS	HMS, methyl triazole	DDS, SCA/DMS, sulfentrazone	DDS, SCA/DMS, sulfentrazone, DMSS
Radish Root	HMS, sulfentrazone	HMS, SCA/DMS	DDS, SCA/DMS, DMSS	DDS, sulfentrazone, DMSS, methyl triazole
Lettuce Leaf	HMS	HMS	DDS, SCA/DMS, sulfentrazone, DMSS	DDS, SCA/DMS, sulfentrazone, DMSS
Barley Forage	HMS, SCA/DMS	HMS, methyl triazole	DDS, sulfentrazone, DMSS	DDS, SCA/DMS, sulfentrazone, DMSS
Barley Straw	HMS, SCA/DMS	-	DDS, sulfentrazone, DMSS	HMS,DDS, SCA/DMS, sulfentrazone, DMSS, methyl triazole
Barley Grain	HMS, SCA/DMS	methyl triazole	sulfentrazone, DMSS	HMS, SCA/DMS, sulfentrazone, DMSS
364 day PBI				
Radish Tops	HMS, SCA/DMS	HMS, methyl triazole	DDS, suflentrazone, DMSS	DDS, SCA/DMS, sulfentrazone, DMSS

Metabolites Identified	Major Metabolites (> 10% TRRs)		Minor Metabolites (< 10% TRRs)	
Matrix	**[^{14}C-U-Phenyl]**	**[^{14}C-Triazole]**	**[^{14}C-U-Phenyl]**	**[^{14}C-Triazole]**
Radish Root	-	-	HMS, SCA/DMS, sulfentrazone, DMSS	HMS, DDS, SCA/DMS, sulfentrazone, DMSS, methyl triazole
Lettuce Leaf	HMS	HMS	DDS, SCA/DMS, sulfentrazone, DMSS	DDS, SCA/DMS, sulfentrazone, DMSS, methyl triazole
Barley Forage	HMS, SCA/DMS	HMS, SCA/DMS, methyl triazole	DDS, sulfentrazone, DMSS	DDS, sulfentrazone, DMSS
Barley Straw	HMS, SCA/DMS	HMS, SCA/DMS	DDS, sulfentrazone, DMSS	DDS, sulfentrazone, DMSS, methyl triazole
Barley Grain	not analyzed	not analyzed	not analyzed	not analyzed
Sulfentrazone and the major metabolites HMS and SCA/DMS were observed in all food/feed commodities at the 1-year plant-back interval. The findings from the confined crop rotation study triggered the requirement for field accumulation studies.				

Metabolites Identified	Major Metabolites (> 10% TRRs)		Minor Metabolites (< 10% TRRs)	
Matrix	[^{14}C-U-Phenyl]	[^{14}C-Triazole]	[^{14}C-U-Phenyl]	[^{14}C-Triazole]

Proposed Metabolic Scheme in Rotational Radish, Lettuce and Barley



DMSS: 5-des(methylsulfonyl) sulfentrazone
HMS: 3-hydroxymethyl sulfentrazone

NATURE OF THE RESIDUE IN LAYING HEN	**PMRA # 1279722**

White leghorn laying hens (n = 15 per treament group) were dosed for 12 consecutive days at levels (based on feed consumption) of 4.70 ppm (^{14}C-phenyl) and 4.73 ppm (^{14}C-triazole). Hens were sacrifized ~21-24 hours after the final dose was admistered. The majority of the administered dose was excreted. Less than 0.1% of the administered radioactivity was recovered in eggs, kidney and liver. Although samples of kidney were not subjected to further analysis for metabolite characterization/identification, the nature of the radioactivity in egg and liver samples were further elucidated. The metabolism of sulfentrazone in the hen proceeds by oxidation of the 3-methyl group to form 3-hydroxymethyl sulfentrazone, followed by further oxidation to form sulfentrazone carboxylic acid which is decarboxylated to 3-desmethyl sulfentrazone.

Matrices	**% of the Administered Dose**	
	[^{14}C-U-Phenyl]	**[^{14}C-Triazole]**
Excreta (cumulative)	94-109	96-109

Metabolites Identified	**Major Metabolites (> 10% TRRs)**		**Minor Metabolites (< 10% TRRs)**	
Radiolabel Position	**[^{14}C-U-Phenyl]**	**[^{14}C-Triazole]**	**[^{14}C-U-Phenyl]**	**[^{14}C-Triazole]**
Excreta (Day 1)	HMS	HMS	-	-
Excreta (Day 12)	HMS	HMS	-	-
Egg White (Day 12)	sulfentrazone; HMS	sulfentrazone; HMS	-	-
Egg Yolk (Day 12)	sulfentrazone; HMS	not analyzed	-	not analyzed
Liver	sulfentrazone; HMS; DMS	not analyzed	-	not analyzed

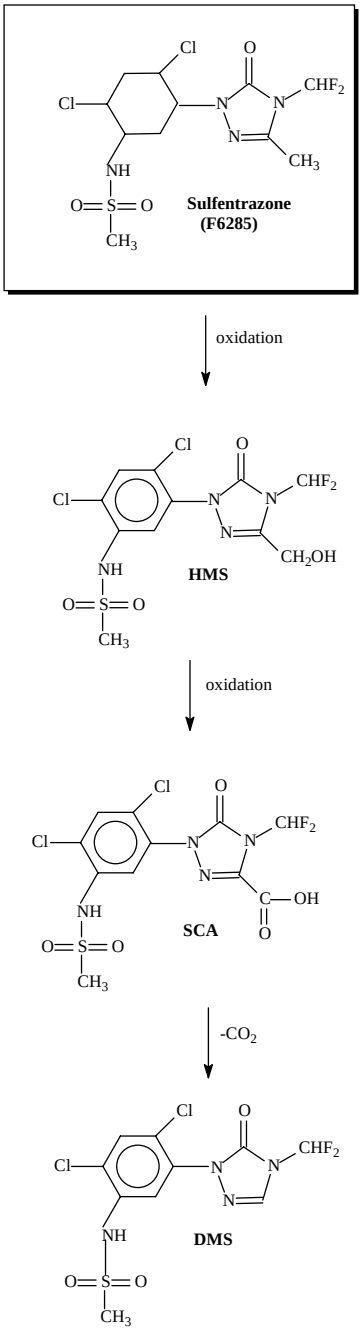
NATURE OF THE RESIDUE IN LACTATING GOAT	**PMRA # 1279718**

Two lactating goats (Capra hirus) were dosed for 10 consecutive days at levels (based on feed consumption) of 4.9 ppm (^{14}C-phenyl) and 6.0 ppm (^{14}C-triazole). Goats were sacrificed 22 hours after the final dose was administered.The primary metabolic pathway in the goat was hydroxylation of sulfentrazone on the exocyclic allylic methyl group at the 3 position of the triazolinone ring to generate the allylic alcohol, 3-hydroxymethyl sulfentrazone. The alcohol was further oxidized to 3-carboxylic acid-sulfentrazone.

Matrices	% of Administered Dose	
	[^{14}C-U-Phenyl]	[^{14}C-Triazole]
Urine (cumulative)	86.8	81.5
Feces (cumulative)	8.3	4
Liver	0.008	0.0005
Kidney	0.002	0.0002
Perirenal Fat	0.0001	<0.0001
Omental Fat	0.0004	<0.0001
Longissimus dorsi muscle	0.0003	<0.0001
Semimembranous muscle	0.0004	0.0002
Tricep Muscle	0.0002	<0.0001
Milk (cumulative)	0.02	0.01
Heart	0.0003	<0.0001
Blood	0.001	0.0001

Metabolites Identified	Major Metabolites (> 10% TRRs)		Minor Metabolites (< 10% TRRs)	
Radiolabel Position	^{14}C-U-Phenyl	^{14}C-Triazole	^{14}C-U-Phenyl	^{14}C-Triazole
Kidney	sulfentrazone	not analyzed	HMS	not analyzed
Urine	HMS	HMS	SCA	SCA
Feces	HMS	not analyzed	SCA	not analyzed

Proposed Metabolic Scheme in Livestock



Summary- Metabolism of Sulfentrazone in Plants and Livestock

The metabolism of sulfentrazone in livestock differs from that in plants as the metabolism in livestock proceeds only by oxidation of the 3-methyl group to form 3-hydroxymethyl sulfentrazone, followed by further oxidation to form sulfentrazone carboxylic acid which is decarboxylated to 3-desmethyl sulfentrazone.

STORAGE STABILITY	**PMRA # 1275938, 1275937, 1275936, 1275935, 1275939, 1308989 and 1308990.**

Residues of sulfentrazone are stable for 24 months in soybean seeds; 3 months in soybean processed fractions (soapstock, hulls, meal and oil); 14 months in wheat forage, grain and straw;11 months in corn silage, grain and fodder; and 6 months in corn processed fractions (meal, flour, starch and oil) under frozen storage conditions.

Residues of HMS are stable for11 months in soybean seeds,14 months in wheat forage and straw; 14 months in rice grain; 11 months in corn silage, grain and fodder; and 6 months in corn processed fractions (meal, flour, starch and oil) under frozen storage conditions.

Residues of DMS are stable for14 months in wheat forage, grain and straw; 11 months in corn silage, grain and fodder; and 6 months in corn processed fractions (meal, flour, starch and oil) under frozen storage conditions.

Residues of DDS are stable for14 months in wheat forage under frozen storage conditions.

STORAGE STABILITY- CONCURRENT	**PMRA # 1275940, 1275941, 1275943, 1275944, 1275945, 1275946, 1308983, 1275963**

Freezer storage stability studies were conducted concurrently with selected field trials (soybean, asparagus, cabbage, mint,and horseradish) and selected crop rotational trials (wheat and corn) to support the maximum storage interval of samples from the respective trials.

The freezer storage stability of sulfentrazone residues was demonstrated for 28 months in soybean seeds; 23-24 months in corn matrices (grain, forage and fodder); 14 months in cabbage; 19 months in horseradish roots; ~19 months in asparagus; ~2 months in mint tops and oil; and~22 months in wheat forage.

The freezer storage stability of HMS residues was demonstrated for 38 months in soybean seeds; 23-24 months in corn matrices (grain, forage and fodder); 14 months in cabbage; 19 months in horseradish roots; ~19 months in asparagus; ~2 months in mint tops and oil; and~22 months in wheat forage.

The freezer storage stability of SCA (determined as DMS) residues was demonstrated for 23-24 months in corn matrices (grain, forage and fodder); 14 months in cabbage; 19 months in horseradish roots; ~2 months in mint oil; and~22 months in wheat forage. Residues of SCA were not stable in asparagus or mint tops as a decline of ~40% was observed after 582 days and 54 days of freezer storage, respectively.

CROP FIELD TRIALS ON ASPARAGUS	**PMRA #1275943**

During the 1999 and 2000 growing seasons a sufficient number of trials were conducted in representative NAFTA growing regions to evaluate the magnitude of the residue of sulfentrazone in/on asparagus. A single broadcast application to the soil surface of the end-use product Authority 75DF (75% sulfentrazone) either pre-emergent to apsaragus was made; or at the vegetative or spear stages (spears removed before application). Mature spears were harvested at PHIs of 13-15 days. Data from the residue decline trial were inconclusive as residues of each analyte were <0.05 ppm (the lowest level for each analyte at which Method P-3173 was concurrently validated) in samples harvested at PHIs of 8, 14, 21 and 28 days. Residues of SCA were determined as DMS. The total DMS residues were calculated as SCA equivalents using a molecular weight conversion factor [[417 (MW of SCA) ÷ 373 (MW of DMS) = 1.12].

Commodity	Total Applic. Rate (kg a.i./ha)	Preharvest Interval (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Sulfentrazone									
Asparagus Spears	0.271 to 0.284	8	2	<0.05	<0.05	N/A	N/A	<0.05	0
		13 to 15	12	<0.05	<0.05	<0.05	<0.05	<0.05	0
		21	2	<0.05	<0.05	<0.05	<0.05	<0.05	0
		28	2	<0.05	<0.05	N/A	N/A	<0.05	0
DMS/SCA (Determined as DMS and Expressed as SCA Equivalents)									
Asparagus Spears	0.271 to 0.284	8	2	<0.05	<0.05	N/A	N/A	<0.05	0
		13 to 15	12	<0.05	<0.05	<0.05	<0.05	<0.05	0
		21	2	<0.05	<0.05	N/A	N/A	<0.05	0
		28	2	<0.05	<0.05	N/A	N/A	<0.05	0
HMS									
Asparagus Spears	0.271 to 0.284	8	2	<0.05	<0.05	N/A	N/A	<0.05	0
		13 to 15	12	<0.05	<0.05	<0.05	<0.05	<0.05	0
		21	2	<0.05	<0.05	N/A	N/A	<0.05	0
		28	2	<0.05	<0.05	N/A	N/A	<0.05	0
Total Residues (Sulfentrazone + DMS + HMS)									
Asparagus Spears	0.271 to 0.290	8	2	<0.15	<0.15	N/A	N/A	<0.15	0
		13 to 15	12	<0.15	<0.15	<0.15	<0.15	<0.15	0
		21	2	<0.15	<0.15	N/A	N/A	<0.15	0
		28	2	<0.15	<0.15	N/A	N/A	<0.15	0

CROP FIELD TRIALS ON CABBAGE	**PMRA# 1275944**

During the 1998 growing season a sufficient number of trials were conducted in representative NAFTA growing regions to evaluate the magnitude of the residue of sulfentrazone in/on cabbage. A single broadcast application of the end-use product Authoirty 75 DF (75% sulfentrazone) to the plots 1-3 days before transplanting or at the 2- to 4-leaf stage (Texas trial). Mature cabbage heads were harvested 68-104 days following application. Residues of SCA were determined as DMS. The total DMS residues were calculated as SCA equivalents using a molecular weight conversion factor [[417 (MW of SCA) ÷ 373 (MW of DMS) = 1.12].The lowest level for each analyte at which Method P-3173 was concurrently validated was 0.05 ppm.

Commodity	Total Applic. Rate (kg a.i./ha)	Preharvest Interval (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Sulfentrazone									
Cabbage Head (with wrapper leaves)	0.413 to 0.432	68 to 104	6	<0.05	<0.05	<0.05	<0.05	<0.05	0
Cabbage Head (without wrapper leaves)			6	<0.05	<0.05	<0.05	<0.05	<0.05	0
DMS/SCA (Determined as DMS and Expressed as SCA Equivalents)									
Cabbage Head (with wrapper leaves)	0.413 to 0.432	68 to 104	6	<0.05	<0.05	<0.05	<0.05	<0.05	0
Cabbage Head (without wrapper leaves)			6	<0.05	<0.05	<0.05	<0.05	<0.05	0
HMS									
Cabbage Head (with wrapper leaves)	0.413 to 0.432	68 to 104	6	<0.05	0.08	0.06	0.05	0.055	0
Cabbage Head (without wrapper leaves)			6	<0.05	0.07	0.06	0.05	0.053	0
Total Residues (Sulfentrazone + DMS + HMS)									
Cabbage Head (with wrapper leaves)	0.413 to 0.432	68 to 104	6	<0.15	0.179	0.164	0.15	0.155	0
Cabbage Head (without wrapper leaves)			6	<0.15	0.167	0.159	0.15	0.153	0

CROP FIELD TRIALS ON CHICKPEAS	PMRA# 1325968

During the 2004 growing season, seven field trials (5 trials in Saskatchewan- 4 trials in zone 7 and 1 trial in zone 14 and 2 trials in Alberta- zone 7A) were conducted at 3 locations in Canada to evaluate the magnitude of the residue of sulfentrazone in/on chickpeas following a single pre-emergent broadcast spray application of the end-use product Spartan 75 DF (750 g/kg sulfentrazone). Dir98-02 recommends for dry field beans a total of 5 trials with 4 trials in zone 5 and 1 trial in zone 7A. Although the total trial number was met for dry field beans as per DIR98-02, no trials were conducted in zone 5. However, given that residues of each analyte were <LOQ (0.025 ppm) in treated chickpea seed samples from a total of 7 trials conducted in 3 different geographical zones, each with different climatic and soil conditions, there is reasonable expectation that the residues in treated samples of chickpea seed from trials conducted in zone 5 would be similar. Samples of mature chickpeas were harvested at PHIs of 124-155 days. The residue decline trial conducted at one site (PHIs of 128, 138, 148 and 155 days) was inconclusive as residues of each analyte were <0.025 ppm (<LOQ) at all the PHIs. Residues of SCA were determined as DMS. The total DMS residues were calculated as SCA equivalents using a molecular weight conversion factor [[417 (MW of SCA) ÷ 373 (MW of DMS) = 1.12].

Commodity	Total Applic. Rate (kg a.i./ha)	Preharvest Interval (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Sulfentrazone									
Chickpea Seed	0.270 to 0.284	124 to 155	20	<0.025	<0.025	<0.025	<0.025	<0.025	0
DMS/SCA (Determined as DMS and Expressed as SCA Equivalents)									
Chickpea Seed	0.270 to 0.284	124 to 155	20	<0.025	<0.025	<0.025	<0.025	<0.025	0
HMS									
Chickpea Seed	0.270 to 0.284	124 to 155	20	<0.025	<0.025	<0.025	<0.025	<0.025	0
Total Residues (Sulfentrazone + DMS + HMS)									
Chickpea Seed	0.270 to 0.284	124 to 155	20	<0.075	<0.075	<0.075	<0.075	<0.075	0

CROP FIELD TRIALS ON DRIED SHELLED BEANS	PMRA# 1275947

During the 2001 growing season a sufficient number of trials were conducted in the representative NAFTA growing regions to evaluate the magnitude of the residue of sulfentrazone in/on dried shelled beans following a single pre-emergent spray application or a pre-plant incorporated spray application of the end-use product Authority 75 DF (75% sulfentrazone). Mature beans harvested at PHIs of 80-115 days were dried and shelled. Data from the residue decline trial conducted at one site (PHIs of 92, 97, 102 and 110 days) was inconclusive as residues of each analyte were <0.025 ppm (<LOQ) at all the PHIs. Residues of SCA were determined as DMS. The total DMS residues were calculated as SCA equivalents using a molecular weight conversion factor [[417 (MW of SCA) ÷ 373 (MW of DMS) = 1.12].

Commodity	Total Applic. Rate (kg a.i./ha)	Preharvest Interval (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Sulfentrazone									
Dry Shelled Bean	0.28	80 to 115	24	<0.025	<0.025	<0.025	<0.025	<0.025	0
DMS/SCA (Determined as DMS and Expressed as SCA Equivalents)									
Dry Shelled Bean	0.28	80 to 115	24	<0.025	<0.025	<0.025	<0.025	<0.025	0
HMS									
Dry Shelled Bean	0.28	80 to 115	24	<0.025	<0.025	<0.025	<0.025	<0.025	0
Total (Sulfentrazone + DMS + HMS)									
Dry Shelled Bean	0.28	80 to 115	24	<0.075	<0.075	<0.075	<0.075	<0.075	0

CROP FIELD TRIALS ON DRIED SHELLED PEAS — **PMRA# 1275947**

During the 2001 growing season a sufficient number of trials were conducted in representative NAFTA growing regions to evaluate the magnitude of the residue of sulfentrazone in/on dry shelled peas following a single pre-emergent spray application or a pre-plant incorporated spray application of the end-use product Authority 75 DF (75% sulfentrazone). Mature peas were harvested at PHIs of 89-112 days. The residue decline data collected at one site (PHIs of 91, 94, 99 and 106 days) did not indicate any noticeable decrease in residues as the PHI increased. Residues of SCA were determined as DMS. The total DMS residues were calculated as SCA equivalents using a molecular weight conversion factor [[417 (MW of SCA) ÷ 373 (MW of DMS) = 1.12].The LOQ for each analyte was reported as 0.025 ppm.

Commodity	Total Applic. Rate (kg a.i./ha)	Preharvest Interval (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Sulfentrazone									
Dried Shelled Peas	0.28	89 to 112	18	<0.025	0.03	0.03	0.025	0.025	0
DMS/SCA (Determined as DMS and Expressed as SCA Equivalents)									
Dried Shelled Peas	0.28	89 to 112	18	<0.025	<0.025	<0.025	<0.025	<0.025	0
HMS									
Dried Shelled Peas	0.28	89 to 112	18	<0.025	0.06	0.06	0.039	0.039	0
Total (Sulfentrazone + DMS + HMS)									
Dried Shelled Peas	0.28	89 to 112	18	<0.075	0.107	0.106	0.089	0.089	0

CROP FIELD TRIALS ON HORSERADISH	PMRA# 1275945

During the 1998 growing season a sufficient number of trials were conduced in the representative NAFTA growing regions to evaluate the magnitude of the residue of sulfentrazone in/on horseradish following a single pre-emergent (following the planting of horseradish) broadcast spray application of the end-use product Authority 75DF (75% sulfentrazone). Mature roots were harvested 116-133 days following application. Residues of SCA were determined as DMS. The total DMS residues were calculated as SCA equivalents using a molecular weight conversion factor [[417 (MW of SCA) ÷ 373 (MW of DMS) = 1.12].The lowest level for each analyte at which Method P-3173 was concurrently validated was 0.05 ppm.

Commodity	Total Applic. Rate (kg a.i./ha)	Preharvest Interval (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Sulfentrazone									
Horseradish Roots	0.413 to 0.429	116-133	6	<0.05	<0.05	<0.05	<0.05	<0.05	0
DMS/SCA (Determined as DMS and Expressed as SCA Equivalents)									
Horseradish Roots	0.413 to 0.429	116-133	6	<0.05	<0.05	<0.05	<0.05	<0.05	0
HMS									
Horseradish Roots	0.413 to 0.429	116-133	6	<0.05	0.05	0.05	0.05	0.05	0
Total Residues (Sulfentrazone + DMS + HMS)									
Horseradish Roots	0.413 to 0.429	116-133	6	<0.15	0.151	0.151	0.15	0.15	0

CROP FIELD TRIALS ON MINT	PMRA# 1275946

During the 2000 growing season a sufficient number of trials were conducted in representative NAFTA growing regions to evaluate the magnitude of the residue of sulfentrazone in/on mint following a single broadcast application of the end-use product Authority 75DF (75% sulfentrazone) at domancy and up to the rosette growth stage (breaking out of dormancy). Mature tops (stems and leaves) were harvested 92-130 days following application. Residues of SCA were determined as DMS. The total DMS residues were calculated as SCA equivalents using a molecular weight conversion factor [[417 (MW of SCA) ÷ 373 (MW of DMS) = 1.12]. Residues of HMS, when quantifiable, were corrected for the low concurent recoveries using the mean recovery at 0.05 ppm.The lowest level for sulfentrazone and HMS at which Method P-3173 was concurrently validated was was 0.05 ppm/analyte. LOQ.The lowest level for SCA at which Method P-3173 was concurrently validated was was 0.06 ppm.

Commodity	Total Applic. Rate (kg a.i./ha)	Preharvest Interval (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Sulfentrazone									
Mint Tops	0.420 to 0.437	92-130	10	<0.05	<0.05	<0.05	<0.05	<0.05	0
DMS/SCA (Determined as DMS and Expressed as SCA Equivalents)									

Mint Tops	0.420 to 0.437	92-130	10	<0.06	<0.06	<0.06	<0.06	<0.06	0
HMS									
Mint Ttops	0.420 to 0.437	92-130	10	<0.05	0.12	0.12	0.05	0.076	0
Total Residues (Sulfentrazone + DMS + HMS)									
Mint Tops	0.420 to 0.437	92-130	10	<0.16	0.23	0.23	0.16	0.186	0

CROP FIELD TRIALS ON SOYBEAN	**PMRA # 1275942, 1275951, 1275948, 1275941, 1275920**

During the 1992 and 1993 growing seasons trials were conducted in the representative NAFTA growing regions to determine the magnitude of the residue of sulfentrazone in/on soybean following a single preplant incorporated or pre-emergence application of the end-use products Authority 4F (480 g/L sulfentrazone), Authority 75DF (75% sulfentrazone) and F6285 4F (480 g/L sulfentrazone). Samples of mature soybean seed were harvested 101 to 167 days after treatment. Samples of immature soybean forage (green) were harvested at 30-33 days, 60-63 days and 90-93 days after treatment. Samples of mature soybean hay (dried stems, petioles and empty pods) were harvested at 119-150 days after treatment.

Samples of soybean seed from those trials yielding the highest residues [in these samples sulfentrazone residues were <LOD (<0.005 ppm) and HMS residues ranged from <LOD (<0.005 ppm) to >LOD but all were <LOQ (<0.025 ppm)] were re-analyzed with revised methodology that included a more stringent hydrolysis step to free all conjugated HMS residues and a more specific detector (ELCD).

Commodity	**Total Applic. Rate (kg a.i./ha)**	**Preharvest Interval (days)**	**Residue Levels (ppm)**						
			n	**Min.**	**Max.**	**HAFT**	**Median (STMdR)**	**Mean (STMR)**	**Std. Dev.**
Sulfentrazone									
Soybean Seed	0.42	115-167	30	<0.025	<0.025	<0.025	<0.025	<0.025	0
	0.56	101-160	21	<0.025	<0.025	<0.025	<0.025	<0.025	0
	1.68	137-143	10	<0.025	<0.025	<0.025	<0.025	<0.025	0
Soybean Forage	0.56	30-33	4	<0.025	<0.025	<0.025	<0.025	<0.025	0
		60-63	4	<0.025	<0.025	<0.025	<0.025	<0.025	0
		90-93	4	<0.025	<0.025	<0.025	<0.025	<0.025	0
	1.68	30	4	<0.025	0.04	0.03	0.028	0.029	0
		60	4	<0.025	<0.025	<0.025	<0.025	<0.025	0
		90	4	<0.025	<0.025	<0.025	<0.025	<0.025	0

Soybean Hay	0.56	139-150	4	<0.025	<0.025	<0.025	<0.025	<0.025	0
	1.68	119-150	4	<0.025	<0.025	<0.025	<0.025	<0.025	0
HMS									
Soybean Seed	0.42	115-167	30	<0.025	<0.025	<0.025	<0.025	<0.025	0
	0.56	101-160	21	<0.025	<0.025	<0.025	<0.025	<0.025	0
	1.68	137-143	10	<0.025	<0.025	<0.025	<0.025	<0.025	0
Soybean Forage	0.56	30-33	4	<0.025	0.06	0.06	0.04	0.042	0
		60-63	4	<0.025	<0.025	<0.025	<0.025	<0.025	0
		90-93	4	<0.025	<0.025	<0.025	<0.025	<0.025	0
	1.68	30	4	<0.025	0.07	0.06	0.044	0.045	0
		60	4	<0.025	0.109	0.107	0.065	0.066	0
		90	4	<0.025	0.07	0.06	0.042	0.045	0
Soybean Hay	0.56	139-150	4	<0.025	0.03	0.03	0.025	0.025	0
	1.68	119-150	4	<0.025	0.139	0.108	0.051	0.067	0
Total (Sulfentrazone + HMS)									
Soybean Seed	0.42	115-167	30	<0.05	<0.05	<0.05	<0.05	<0.05	0
	0.56	101-160	21	<0.05	<0.05	<0.05	<0.05	<0.05	0
	1.68	137-143	10	<0.05	<0.05	<0.05	<0.05	<0.05	0
Soybean Forage	0.56	30-33	4	<0.05	0.09	0.08	0.065	0.067	0
		60-63	4	<0.05	<0.05	<0.05	<0.05	<0.05	0
		90-93	4	<0.05	<0.05	<0.05	<0.05	<0.05	0
	1.68	30	4	<0.05	0.1	0.09	0.075	0.074	0
		60	4	<0.05	0.134	0.132	0.09	0.091	0
		90	4	<0.05	0.1	0.09	0.067	0.07	0
Soybean Hay	0.56	139-150	4	<0.05	0.05	0.05	0.05	0.05	0
	1.68	119-150	4	<0.05	0.164	0.133	0.076	0.092	0
Re-Analysis of Soybean Seed Samples									
Sulfentrazone									

Soybean Seed	0.42	133	4	<0.025	<0.025	<0.025	<0.025	<0.025	0
	0.56	132-144	6	<0.025	<0.025	<0.025	<0.025	<0.025	0
	1.68	137	2	<0.025	<0.025	<0.025	<0.025	<0.025	0
HMS									
Soybean Seed	0.42	133	4	<0.025	0.04	0.04	0.029	0.03	0
	0.56	132-144	6	<0.025	<0.025	<0.025	<0.025	<0.025	0
	1.68	137	2	<0.025	0.03	0.03	0.027	0.027	-
Total (Sulfentrazone + HMS)									
Soybean Seed	0.42	133	4	<0.05	0.06	0.06	0.054	0.055	0
	0.56	132-144	6	<0.05	<0.05	<0.05	<0.05	<0.05	0
	1.68	137	2	<0.05	0.05	0.05	0.052	0.052	-

CROP FIELD TRIALS ON SUNFLOWER **PMRA# 1275955**

During the 1998 growing season a sufficient number of trials were conducted in representative NAFTA growing regions to evaluate the magnitude of the residue of sulfentrazone in/on sunflower following a single pre-emergent (after planting of sunflower) broadcast application of the end-use product Authority 75DF (75% sulfentrazone). At one of the sites (Noth Dakota), two consecutive applications of sulfentrazone were made within hours of one another in order to acheive the target application rate of 420.0 g a.i./ha. Mature sunflower seeds were harvested 85-155 days following application. Residues of SCA were determined as DMS. The total DMS residues were calculated as SCA equivalents using a molecular weight conversion factor [[417 (MW of SCA) ÷ 373 (MW of DMS) = 1.12]. The lowest level for each analyte at which Method P-3173 was concurrently validated was 0.05 ppm.

Commodity	**Total Applic. Rate (kg a.i./ha)**	**Preharvest Interval (days)**	**Residue Levels (ppm)**						
			n	**Min.**	**Max.**	**HAFT**	**Median (STMdR)**	**Mean (STMR)**	**Std. Dev.**
Sulfentrazone									
Sunflower Seed	0.407 to 0.423	85 to 155	16	<0.05	<0.05	<0.05	<0.05	<0.05	0
DMS/SCA (Determined as DMS and Expressed as SCA Equivalents)									
Sunflower Seed	0.407 to 0.423	85 to 155	16	<0.05	<0.05	<0.05	<0.05	<0.05	0
HMS									
Sunflower Seed	0.407 to 0.423	85 to 155	16	<0.05	0.07	0.07	0.05	0.054	0
Total Residues (Sulfentrazone + DMS + HMS)									
Sunflower Seed	0.407 to 0.423	85 to 155	16	<0.15	0.171	0.168	0.15	0.116	0

FIELD ACCUMULATION IN ROTATIONAL CROPS- FIELD CORN	PMRA # 1275963, 1275964, 1275965, 1275967, 1308976

During the 1993, 1994 and 1995 growing seasons twenty soybean trials were conducted in the U.S. Soybean plots were treated with a single preplant incorporated or pre-emergent application of sulfentrazone (F6285 4F, F6285/Command WDG Premix, Authority 75DF or Authority 4F) at 420 g a.i./ha or 560 g a.i./ha. The soybean samples were harvested at maturity. Field corn was planted on the same plots 274-370 days after application of sulfentrazone. Samples of field corn were harvested at maturity. Residues of sulfentrazone, HMS and DMS were each <LOQ (<0.025 ppm) in corn grain, corn silage, corn fodder and corn stover. In corn forage, residues of sulfentrazone and HMS were each <LOQ (<0.025 ppm), and residues of DMS ranged from <LOQ (<0.025 ppm) to 0.054 ppm. Those trials yielding the highest residues were re-analyzed in duplicate. The previous methodology used was modified to include a more stringent hydrolysis step to ensure the release of conjugated HMS and the conversion of SCA to DMS; and by the use of a more specific detector- ELCD (electrolytic conductivity detector) instead of ECD (electron capture detector). In the re-analyzed samples, residues of sulfentrazone, HMS and DMS were each <LOQ (<0.025 ppm) in corn grain. In corn forage, residues of sulfentrazone and HMS were each <LOQ (<0.025 ppm) and residues of DMS ranged from <LOQ (<0.025 ppm) to 0.034 ppm. In corn fodder, residues of sulfentrazone and HMS were each <LOQ (<0.025 ppm) and residues of DMS ranged from <LOQ to 0.055 ppm. In summary, residues of sulfentrazone, HMS and DMS were each <LOQ in samples of grain; and residues of sulfentrazone and HMS were each <LOQ in forage and fodder samples both pre and post re-analysis. The maximum residue of DMS decreased from 0.054 ppm to 0.034 ppm in forage and increased from <LOQ to 0.055 ppm in fodder pre and post re-analysis.

Commodity	Total Applic. Rate (kg a.i./ha)	Plantback Interval (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMDR)	Std. Dev.
Re-Analyzed Field Corn Samples									
Sulfentrazone									
Field Corn Grain	0.420 or 0.560	291 to 339	12	<0.025	<0.025	<0.025	<0.025	<0.025	0
Field Corn Forage		291 to 339	12	<0.025	<0.025	<0.025	<0.025	<0.025	0
Field Corn Fodder		291 to 339	12	<0.025	<0.025	<0.025	<0.025	<0.025	0
DMS/SCA (Determined as DMS)									
Field Corn Grain	0.420 or 0.560	291 to 339	12	<0.025	<0.025	<0.025	<0.025	<0.025	0
Field Corn Forage		291 to 339	12	<0.025	0.03	0.03	0.025	0.027	0
Field Corn Fodder		291 to 339	12	<0.025	0.06	0.06	0.025	0.03	0
HMS									
Field Corn Grain	0.420 or 0.560	291 to 339	12	<0.025	<0.025	<0.025	<0.025	<0.025	0
Field Corn Forage		291 to 339	12	<0.025	<0.025	<0.025	<0.025	<0.025	0

Field Corn Fodder		291 to 339	12	<0.025	<0.025	<0.025	<0.025	<0.025	0
Total (Sulfentrazone + DMS + HMS)									
Field Corn Grain	0.420 or 0.560	291 to 339	12	<0.075	<0.075	<0.075	<0.075	<0.075	0
Field Corn Forage		291 to 339	12	<0.075	0.08	0.08	0.075	0.077	0
Field Corn Fodder		291 to 339	12	<0.075	0.105	0.105	0.075	0.08	0

FIELD ACCUMULATION IN ROTATIONAL CROPS- FIELD CORN INCLUDING PROCESSING	**PMRA # 1275969 and 1308969**

During the 1994 growing season, soybean plots were treated with sulfentrazone (Authority 75DF) at 420 g a.i./ha in 7 trials. Soybeans were grown and harvested. Field corn was planted onto the same plots 291-332 days after application. Mature field corn grain (13.6-22.7 kg/trial) from 5 of the 7 trials were combined to produce one control and one treated homogeneous bulk sample.Residues of sulfentrazone, HMS and DMS were not detected (<0.005 ppm) in/on corn grain or any of its processed fractions (grits, meal, flour, starch, wet milled crude oil, wet milled refined oil, dry milled crude oil and dry milled refined oil). Samples of field corn grain and flour were re-analyzed. The previous methodology used was modified to include a more stringent hydrolysis step to ensure the release of conjugated HMS and the conversion of SCA to DMS; and by the use of a more specific detector-ELCD (electrolytic conductivity detector) instead of ECD (electron capture detector). The processed commodity flour was selected for re-analysis because of the potential for concentration of residues. In the re-analyzed samples residues of sulfentrazone, DMS and HMS were not detected (<0.005 ppm) in the field corn grain or flour.

FIELD ACCUMULATION IN ROTATIONAL CROPS- SUCCULENT PEA	**PMRA # 1275968**

During the 1997 growing season 13 soybean trials were conducted in the U.S. during which sulfentrazone (Authority 75 DF; 75% sulfentrazone) was applied to the soil as a single pre-plant incorporated application at 414.4-440.2 g a.i./ha. Edible podded peas and succulent shelled peas were planted 263-307 days after treatment. Samples of edible podded peas were harvested 60-74 days after planting and samples of succulent shelled peas were harvested 55-95 days after planting.

Commodity	**Total Applic. Rate (kg a.i./ha)**	**Plantback Interval (days)**	**Residue Levels (ppm)**						
			n	**Min.**	**Max.**	**HAFT**	**Median (STMdR)**	**Mean (STMR)**	**Std. Dev.**
Sulfentrazone									
Edible Podded Peas	0.414 to 0.440	263 to 307	8	<0.025	<0.025	<0.025	<0.025	<0.025	0
Succulent Shelled Peas			18	<0.025	<0.025	<0.025	<0.025	<0.025	0

DMS/SCA (Determined as DMS)									
Edible Podded Peas	0.414 to 0.440	263 to 307	8	<0.025	<0.025	<0.025	<0.025	<0.025	0
Succulent Shelled Peas			18	<0.025	<0.025	<0.025	<0.025	<0.025	0
HMS									
Edible Podded Peas	0.414 to 0.440	263 to 307	8	<0.025	<0.025	<0.025	<0.025	<0.025	0
Succulent Shelled Peas			18	<0.025	<0.025	<0.025	<0.025	<0.025	0
Total (Sulfentrazone + DMS + HMS)									
Edible Podded Peas	0.414 to 0.440	263 to 307	8	<0.075	<0.075	<0.075	<0.075	<0.075	0
Succulent Shelled Peas			18	<0.075	<0.075	<0.075	<0.075	<0.075	0

FIELD ACCUMULATION IN ROTATIONAL CROPS- WINTER WHEAT	**PMRA # 1275966, 1308973, 1308972, 1308974 1308978, 1308979, 1308983**

During the 1992, 1993 and 1994 growing seasons twenty-three soybean field trials were conducted during which sulfentrazone (F6285 WDG, Treflan WDG, Authority 75DF, Authority 4F or 80WP) was applied as a single application at 420 or 560 g a.i./ha, either as a pre-plant incorporation application or as a pre-emergent application. The soybean samples were harvested at maturity and wheat was planted on the same plots 83-181 days after application of sulfentrazone to the soybean plots. Samples of wheat (forage, grain, straw and hay) were harvested at normal maturity. Residues of sulfentrazone, HMS and DMS were each <LOQ (<0.025 ppm) in wheat grain samples. In wheat forage samples, resides of sulfentrazone were <LOQ (<0.025 ppm), residues of HMS ranged from <LOQ (<0.025 ppm) to 0.052 ppm and residues of DMS ranged from <LOQ (<0.025 ppm) to 0.046 ppm. In wheat hay samples, residues of sulfentrazone, HMS and DMS were each <LOQ (<0.05 ppm). In wheat straw samples residues of sulfentrazone ranged from <LOQ (<0.025 ppm or <0.05 ppm depending on the analytical methodology used) to 0.068 ppm, residues of HMS ranged from <LOQ (<0.025 ppm or <0.05 ppm depending on the analytical methodology used) to 0.029 ppm and residues of DMS ranged from <LOQ (<0.025 ppm or <0.05 ppm depending on the analytical methodology used) to 0.081 ppm. Those trials (n = 6) with the highest residues were re-analyzed in duplicate. The previous methodology used was modified to include a more stringent hydrolysis step to ensure the release of conjugated HMS and the conversion of SCA to DMS; and by the use of a more specific detector- ELCD (electrolytic conductivity detector) instead of ECD (electron capture detector). In the re-analyzed wheat grain samples residues of sulfentrazone, DMS and HMS were each <LOQ (<0.025 ppm). In the re-analyzed wheat forage samples residues of sulfentrazone were <LOQ (0.025 ppm), residues of DMS ranged from <LOQ (<0.025 ppm) to 0.079 ppm and residues of HMS ranged from <LOQ (<0.025 ppm) to 0.054 ppm. In the re-analyzed hay samples, residues of sulfentrazone were <LOQ (<0.05 ppm), residues of DMS ranged from 0.058 ppm to 0.120 ppm and residues of HMS ranged from <LOQ (<0.05 ppm) to 0.073 ppm. In the re-analyzed straw samples, residues of sulfentrazone were <LOQ (<0.05 ppm), residues of DMS ranged from <LOQ (<0.05 ppm) to 0.494 ppm and residues of HMS ranged from <LOQ (<0.05 ppm) to 0.105 ppm.

Commodity	Total Applic. Rate (kg a.i./ha)	Plantback Interval (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Re-Analyzed Wheat Samples									
Sulfentrazone									
Wheat Grain	0.42	97 to133	12	<0.025	<0.025	<0.025	<0.025	<0.025	0
Wheat Forage	0.42		12	<0.025	<0.025	<0.025	<0.025	<0.025	0
Wheat Hay	0.42		8	<0.05	<0.05	<0.05	<0.05	<0.05	0
Wheat Straw	0.42		12	<0.05	<0.05	<0.05	<0.05	<0.05	0
DMS/SCA (Determined as DMS)									
Wheat Grain	0.42	97 to 133	12	<0.025	<0.025	<0.025	<0.025	<0.025	0
Wheat Forage	0.42		12	<0.025	0.08	0.08	0.033	0.042	0
Wheat Hay	0.42		8	0.1	0.12	0.111	0.079	0.083	0
Wheat Straw	0.42		12	<0.05	0.494	0.443	0.174	0.181	0
HMS									
Wheat Grain	0.42	97 to 133	12	<0.025	<0.025	<0.025	<0.025	<0.025	0
Wheat Forage	0.42		12	<0.025	0.05	0.05	0.033	0.036	0
Wheat Hay	0.42		8	<0.05	0.07	0.07	0.05	0.054	0
Wheat Straw	0.42		12	<0.05	0.105	0.1	0.05	0.065	0
Total (Sulfentrazone + DMS + HMS)									
Wheat Grain	0.42	97 to 133	12	<0.075	<0.075	<0.075	<0.075	<0.075	0
Wheat Forage	0.42		12	0.1	0.157	0.152	0.092	0.103	0
Wheat Hay	0.42		8	0.16	0.224	0.213	0.183	0.188	0
Wheat Straw	0.42		12	<0.15	0.649	0.592	0.282	0.296	0.2

FIELD ACCUMULATION IN ROTATIONAL CROPS- WINTER WHEAT INCLUDING PROCESSING	**PMRA # 1275970**
Sulfentrazone (Authority 75DF; 75% sulfentrazone) was applied as a single pre-plant incorporated application to soil at 420.0 g a.i./ha. Soybeans were harvested at maturity and wheat was planted on the same plots 116-124 days after the application of sulfentrazone. Wheat grain was harvested at maturity and analyzed. No detectable residues (<0.005-<0.01 ppm) of sulfentrazone, HMS or DMS were found. Wheat grain was processed into bran, flour, germ, middlings, shorts and aspirated grain fractions by simulated commercial practices. Residues of sulfentrazone and HMS were not detected (<0.01 ppm) in any of the treated wheat grain, bran, flour, germ, middlings, shorts or aspirated grain fractions. Residues of DMS were detected (0.007-0.010 ppm) only in the composite aspirated grain fractions.	

PROCESSED FOOD AND FEED- FIELD CORN	**PMRA # 1308965**
Test Site	Zone 5 (Illinois)
Treatment	Single post-emergent broadcast application at the V8 growth stage
Rate	0.420 kg a.i./ha
End-Use Product	Authority 75DF (75% sulfentrazone)
Preharvest Interval	104 days
Processed Commodity	Residues of sulfentrazone, HMS and DMS/SCA were each <LOQ (<0.025 ppm) in corn grain RAC and in the processed fractions starch, refined oil, grits, meal, flour and aspirated grain fraction. Therefore, processing factors could not be determined.

PROCESSED FOOD AND FEED- MINT	**PMRA # 1275946**	
Test Site	Zone 5A (Wisconsin)	Zone 11 (Washington)
Treatment	Single broadcast application at the rosette stage (vegetative)	Single broadcast application to dormant mint plants
Rate	0.421-0.427-0 kg a.i./ha	0.874 kg a.i./ha or 0.420 kg a.i./ha
End-Use Product	Sulfentrazone 75DF (75% sulfentrazone)	
Preharvest Interval	92 days	123 days
Processed Commodity	**Processing Factor**	
Mint Oil	<1	

PROCESSED FOOD AND FEED- SOYBEAN	**PMRA # 1275950 and 1275969**
Test Site	Zone 5 (Illinois)
Treatment	Single pre-emergent broadcast ground spray
Rate	1.68 kg a.i./ha
End-Use Product	Sulfentrazone 75DF

Preharvest Interval	139 days
Processed Commodity	**Procesing Factor**
Soybean Hulls	0.9 to1.5
Soybean Meal	1.1 to 1.2
Soybean Crude Oil	<1
Soybean Refined Oil	<1
Soybean Soap Stock	<1
Soybean Dust (>2450 µm)	8.8
Soybean Dust (<425 µm)	5.9
PROCESSED FOOD AND FEED-SUNFLOWER	**PMRA # 1275955**
Test Site	Zone 7 (North Dakota)
Treatment	Single pre-emergent broadcast spray
Rate	0.413 kg a.i./ha
End-Use Product	Authority 75 DF
Preharvest Interval	133 days
Processed Commodity	**Processing Factor**
Sunflower Meal	1.3
Sunflower Oil	<1
LIVESTOCK FEEDING	
Based on the results of the lactating goat and laying hen metabolism studies which were conducted at >10x the calculated maximum theoretical dietary burden (MTDB) each for cattle (dairy and beef) and poultry, finite residues of sulfentrazone and the metabolites DMS and HMS are not anticipated in the milk, meat and eggs from livestock fed crops treated with sulfentrazone according to the label directions. Therefore, livestock feeding studies were not required for the purpose of this registration.	

Table 5 Food Residue Chemistry Overview of Metabolism Studies and Risk Assessment

PLANT STUDIES	
RESIDUE DEFINITION FOR ENFORCEMENT **Primary crops (soybean)**	sulfentrazone and 3-hydroxymethyl sulfentrazone
Rotational crops (barley, lettuce and radish)	sulfentrazone, 3-desmethyl sulfentrazone and 3-hydroxymethyl sulfentrazone

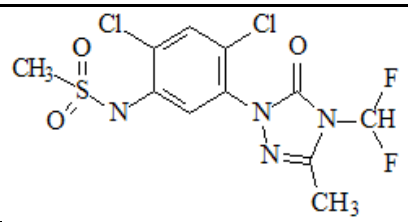
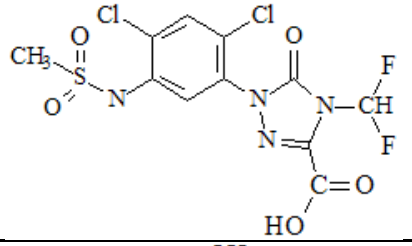
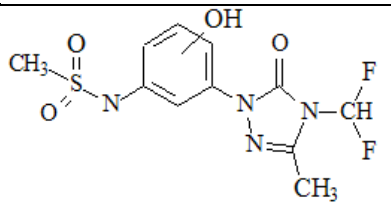
RESIDUE DEFINITION FOR RISK ASSESSMENT **Primary crops (soybean)** **Rotational crops (barley, lettuce and radish)**	sulfentrazone and 3-hydroxymethyl sulfentrazone sulfentrazone, 3-desmethyl sulfentrazone and 3-hydroxymethyl sulfentrazone
METABOLIC PROFILE IN DIVERSE CROPS	The profile in diverse crops was similar.
ANIMAL STUDIES	
RESIDUE DEFINITION FOR ENFORCEMENT (ruminant and poultry)	sulfentrazone, 3-desmethyl sulfentrazone and 3-hydroxymethyl sulfentrazone
RESIDUE DEFINITION FOR RISK ASSESSMENT (ruminant and poultry)	sulfentrazone, 3-desmethyl sulfentrazone and 3-hydroxymethyl sulfentrazone
METABOLIC PROFILE IN ANIMALS	Similar metabolic profile in the hen and goat.
FAT SOLUBLE RESIDUE	Depends on pH (K_{OW} = 31.1 at pH 5, 9.8 at pH 7 and 0.27 at pH 9)

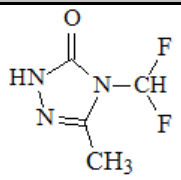
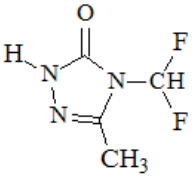
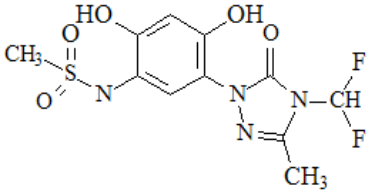
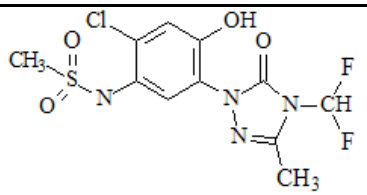
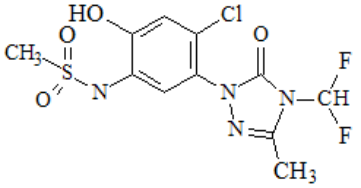
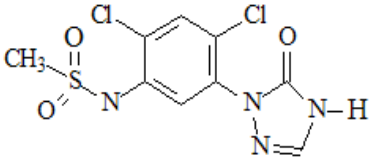
DIETARY RISK FROM FOOD AND WATER

	POPULATION	**ESTIMATED RISK % of ACCEPTABLE DAILY INTAKE (ADI)**	
		Food Only	**Food and Water**
Refined chronic non-cancer dietary risk **ADI = 0.046 mg/kg bw/day** **Interim estimated chronic drinking water concentration for sulfentrazone and the transformation product sulfentrazone-carboxylic acid = 345 µg a.i./L**	**All infants < 1 year**	1.9	53.7
	Children 1–2 years	4.1	27.5
	Children 3 to 5 years	4.2	26.2
	Children 6–12 years	3	18.1
	Youth 13–19 years	2	13.4
	Adults 20–49 years	1.4	16.2
	Adults 50+ years	1.1	16.6
	Females 13-49 years	1.4	16.1
	Total population	1.8	17.6

Refined acute dietary exposure analysis, 95th percentile **Interim estimated acute drinking water concentration for sulfentrazone and the transformation product sulfentrazone-carboxylic acid =** **346 µg a.i./L** **ARfD (general population) = 2.5 mg/kg bw** **ARfD (females 13+) = 0.083 mg/kg bw**	**POPULATION**	**ESTIMATED RISK % of ACUTE REFERENCE DOSE (ARfD)**	
		Food Only	**Food and Water**
	Total population	0.09	0.77
	Females 13-49 years	1.8	21.13

Table 6 Transformation Products in Environmental Fate Studies

Transformation Product	Chemical Structure	Maximum Occurrence- %AR (day)
Parent		
Sulfentrazone (F6285)		
Major (>10%) Transformation Products		
3-carboxylic acid sulfentrazone (SCA)		Aerobic soil: 23.9 (90), 10.9 (368)
desdichloromonohydroxy sulfentrazone		Aqueous photolysis -pH 5: 4.5 (1), 4.9 (8h) -pH 7: 12.8 (4h),17.9(6h) -pH 9 (carbonyl): 8.3 (4h), 12.1(8h)

Transformation Product	Chemical Structure	Maximum Occurrence-%AR (day)
Methyl triazole		Aqueous photolysis -pH 5: 42.4 (10) -pH 7: 25.7 (10) -pH 9 (carbonyl): 49.0 (10) -pH 9 (phenyl): ND
Methyl triazole oxidation product	Not provided	Aqueous photolysis -pH 5: 11.2 (10) -pH 7: ND -pH 9 (carbonyl): 17.1 (10)
Triazolinone cleavage product		Aqueous photolysis -pH 5: 8.3(8h) -pH 7: 12.6 (6h) -pH 9: 31.3 (8h)
2,4-dihydroxy sulfentrazone		Aqueous photolysis -pH 5:5.8 (10) -pH 7: 11.7 (4h) -pH 9 (carbonyl): 11.2 (4h) -pH 9 (phenyl): 17.8 (6h)
2-hydroxy-4-chloro sulfentrazone		Aqueous photolysis -pH 5: 10.0 (6h) -pH 7: 7.9 (8h) -pH 9: detected (6h)
2-chloro-4-hydroxy sulfentrazone		Aqueous photolysis -pH 5: identified -pH 7: identified -pH 9: identified
3-desmethyl-4-desdifluoromethyl sulfentrazone		Aqueous photolysis -pH 5: ND -pH 7: 21.3 (6 h) -pH 9: 21.3 (6 h)
1,3-dihydroxybenzene sulfentrazone	Not provided	Aqueous photolysis -pH 5: ND -pH 7: ND -pH 9: 21.5 (10 h)

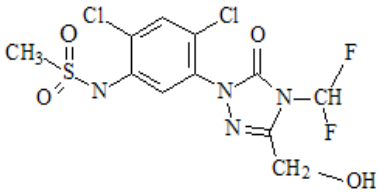
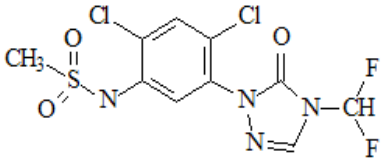
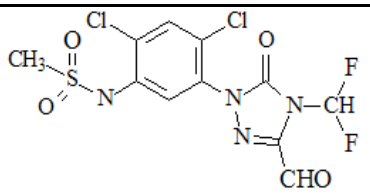
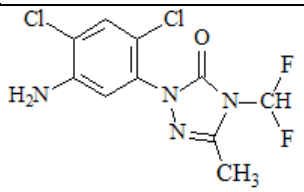
Transformation Product	Chemical Structure	Maximum Occurrence-%AR (day)
Minor (<10%) Transformation Products		
3-hydroxymethyl sulfentrazone (HMS)		Aerobic soil: 6.3 (33), 4.0 (29) Soil Photolysis: 3.9 (14)
3-desmethyl sulfentrazone (DMS)		Aerobic soil: 2.7 (7)
Free amine sulfentrazone	Not provided	Aerobic soil: 4.8 (195)
3-aldehyde sulfentrazone		Aerobic soil: 3.2 (195)
5-desmethylsulfonyl sulfentrazone (DMSS)		Aerobic soil: 5.9 (90), 5.7 (365) Anearobic aquatic: 2.9 (14)
Compound 3	Unknown	Anearobic aquatic: 7.1 (365)

Table 7 Fate and Behaviour of Sulfentrazone in the Terrestrial Environment

Property	Value	Classification[1]	References
Abiotic transformation			
Hydrolysis ($t_{1/2}$) pH 5 pH 7 pH 9	 Stable Stable Stable	Not expected to be an important route of transformation.	1279728
Phototransformation on soil ($t_{1/2}$)	Stable	Not expected to be an important route of transformation	1279729
Phototransformation in air	No data is requires as sulfentrazone is not expected to be volatile under field conditions.		

Biotransformation			
Biotransformation in aerobic soil (DT_{50})	Sandy loam $t_{1/2}$:835 days (DT_{50}>365 days) Silty clay loam $t_{1/2}$: 865 days (DT_{50}>365 days)	Persistent	1279732
	Preliminary study (non-GLP, soil was amended with lime to increase pH) Sandy loam $t_{1/2}$: 114-122	Moderately persistent	1279731
Biotransformation in anaerobic soil (DT_{50})	The anaerobic soil biotransformation study is required as per the PMRA Regulatory Directive DIR2003-03. The registrant submitted an anaerobic aquatic biotransformation study (PMRA#1279735) to support the anaerobic soil biotransformation data requirement. Since sulfentrazone was stable to transformation in the anaerobic aquatic study, it is assumed that sulfentrazone will also be stable to transformation in the anaerobic soil environment. Therefore an additional study to address this data requirement is not needed at this time.		
Mobility			
Adsorption/desorption in soil (K_{OC}) Sulfentrazone Sandy loam (pH 6.9): Silt loam (pH 7.1): Silty clay loam (pH 7.0) Sand (pH 6.0)	 29 mL/g 26 mL/g 40 mL/g 77 mL/g	 Very high mobility Very high mobility Very high mobility High mobility	1279736
Column leaching Sulfentrazone (30-day aged soil)	25.0-31.3% of parent residues remained in the top layer of aged soil. 37-6-44.4% of parent residues were in the leachate. Approximately 72% of the applied 3-hydroxymethyl sulfentrazone were detected in the leachate whereas 35% of the applied 3-carboxylic acid were found in the leachate at the end of the study.	Sulfentrazone has the potential to leach. Both transformation products (3-hydroxymethyl sulfentrazone and 3-carboxylic acid sulfentrazone) are very mobile.	1279737
Volatilization	Not required as sulfentrazone is not expected to be volatile under field conditions.		

Field studies			
Field dissipation (Ecozone 9.2-Iowa)	DT_{50} > 531 days $T_{1/2}$: 710 days (extrapolated beyond the length of the study) Sulfentrazone residues were detected down to the 90-cm soil depth. 70% of applied sulfentrazone carried over to the following use season.	Persistent.	1275985
Field Leaching North Carolina Field Dissipation and Small-Scale Prospective Groundwater Monitoring Study (Ecozone 8.3)	Maximum levels of 37.4 ppb (sulfentrazone) and 4.8 ppb (3-carboxylic acid sulfentrazone) in the groundwater were measured 4-5 months after application.	The study was not situated in an ecozone relevant to Canada, however, demonstrated evidence of leaching to groundwater.	1275988
Prospective Groundwater Studies (US 95th Percentile site)	Maximum levels of 0.86 ppb (sulfentrazone) and 2.50 ppb (3-carboxylic acid sulfentrazone) were measured in the groundwater 455-577 days after application.	Evidence of leaching to groundwater.	1485405

[1] Goring et al., 1975 classification for persistence in soil and McCall et al., 1981 classification for mobility in soil

Table 8 Fate and Behaviour of Sulfentrazone in the Aquatic Environment

Property	Value	Classification	Reference
Abiotic transformation			
Hydrolysis ($t_{1/2}$) pH 5 pH 7 pH 9	 Stable Stable Stable	Not expected to be an important route of transformation.	1279728
Phototransformation in water ($t_{1/2}$) pH 5 pH 7 pH 9	 12 hours 1 hour 1 hour	Important route of transformation in the photic zone of aquatic systems.	1279742

Phototransformation in air	No data is requires as sulfentrazone is not expected to be volatile under field conditions.		
Biotransformation			
Biotransformation in aerobic water systems	An aerobic water/sediment study is required as per the PMRA Regulatory Directive DIR2003-03. Since a study has not been submitted, the fate of sulfentrazone and its transformation products have not been characterised in aerobic aquatic environments.		
Biotransformation in anaerobic water systems (loamy sand) (DT_{50})	DT_{50}: stable ($t_{1/2}$: 9 years, extrapolated beyond the length of the study)	Persistent. Not expected to be an important route of transformation.	1279735
Partitioning			
Adsorption or desorption in sediment (K_{OC}) Sandy loam (pH 6.9) Silt loam (pH 7.1) Silty clay loam (pH 7.0) Sand (pH 6.0)	 29 mL/g 26 mL/g 40 mL/g 77 mL/g	Not expected to adsorb to sediment based on the batch equilibrium study.	1279736
Field studies			
Aquatic Field Dissipation Study	An aquatic field dissipation study is required to further characterize the fate of sulfentrazone in the aquatic environment.		

Table 9 Effects on Terrestrial Organisms

Organism	Exposure	Endpoint Value	Degree of toxicity[1]	Reference
Invertebrates				
Earthworm	Acute	Study not provided and is not required.		
Bee	Oral	Study was not provided, but is required. Given that sulfentrazone is a persistent systemic herbicide, an acute oral toxicity study on honeybees is required.		
	Contact	25.1 µg/bee	Relatively non-toxic	1279745
	Brood/Hive	Study was not provided and is not required since sulfentrazone was relatively non-toxic on a contact basis and the mode of action is not expected to affect the growth of juvenile bees.		
Predatory arthropod	Contact	Study was not provided and is not required since the proposed use pattern does not include crops where beneficial insects are typically used as part of an IPM program.		
Parasitic arthropod	Contact	Study was not provided and is not required since the proposed use pattern does not include crops where beneficial insects are typically used as part of an IPM program.		

Organism	Exposure	Endpoint Value	Degree of toxicity[1]	Reference
Birds				
Bobwhite quail	Acute (LD_{50})	>2250 mg a.i./kg	Practically non-toxic	1279758
	Dietary (LC^{50})	> 5620 mg a.i./kg	Practically non-toxic	1279759
	Reproduction (NOEC)	100 mg a.i./kg dw diet (female body weight gain)	N/A	1279762
Mallard duck	Acute (LD_{50})	Study not provided and is not required since the acute oral toxicity study provided for the bobwhite quail will satisfy this data requirement.		
	Dietary (LC_{50})	> 5620 mg a.i./kg	Practically non-toxic	1279760
	Reproduction (NOEC)	100 mg a.i./kg dw diet	N/A	1279764
Mammals				
Rat	Acute Oral (LD_{50}) TGAI	2855 mg/kg bw	Practically non-toxic	1279669
	Acute Oral (LD_{50}) EP	2084 mg/kg bw Equivalent to 828 mg a.i./kg bw	Slightly toxic	1275898
	Dietary (90 day) NOEL	65.8 mg/kg bw/day[2]	No classification	1279677
	Developmental Toxicity Oral (NOEL)	10 mg/kg bw/day	No classification	1279696
Mouse	Acute Oral(LD_{50})	701.8 mg/kg bw	Slightly toxic	1279668
Vascular plants				
Vascular plant	Seedling Emergence (EC_{25})	0.012 kg a.i./ha (tomato, dry weight reduction)	No classification	12797691279770
	Vegetative Vigour (EC_{25})	0.0009 kg a.i./ha (tomato, dry weight reduction)	No classification	12797711279772

[1] Atkins et al. (1981) for bees and the U.S. EPA classification for others, where applicable.

[2] The endpoint identified in the original study was not relevant to the environmental risk assessment (altered hematology). The effects observed at the next concentration level, 199.3 mg/kg bw/day, included death, decreased body weight and decreased body weight gain; were determined to be environmentally relevant. The environmental NOEL of 65.8 mg/kg bw/day was therefore based on these effects.

Table 10 Effects on Aquatic Organisms

Organism	Exposure	Endpoint Value	Degree of toxicity[1]	Reference
Freshwater species				
Invertebrate (*Daphnia magna*)	Acute	EC_{50}: 60.4 mg a.i./L	Slightly toxic	1279745
	Chronic	NOEC: 0.51 mg a.i./L (mortality and reproduction)	No classification	1279747
Rainbow Trout (*Oncorhynchus mykiss*)	Acute	LC_{50}: > 130 mg a.i./L	Practically non-toxic	1279752
	Chronic (ELS; 99 days)	NOEC: 2.95 mg a.i./L (survival and fish length)	No classification	1279755
Bluegill Sunfish (*Lepomis macrohirus*)	Acute	LC_{50}: 93.8 mg a.i./L	Slightly toxic	1279753
	Chronic	Study was not provided and is not required as the chronic rainbow trout ELS study has satisfied this data requirement.		
Green Algae (*Selenastrum capricornutum*)	Acute	IC_{50}: 0.031 mg a.i./L	Very highly toxic	1279765
Vascular Plant (*Lemna gibba*)	Acute (dissolved)	IC_{50}:0.029 mg a.i./L (frond count)	Very highly toxic	1279773
Marine species				
Mysid Shrimp (*Mysidopsis bahia*)	Acute	LC_{50}: 1.0 mg a.i./L	Highly toxic	1279748
	Chronic	No study was provided. This study is not required based on a small potential for marine exposure resulting from the proposed use pattern (chickpeas on Saskatchewan). If expansion of use results in the potential for marine habitat exposure, this study may be required.		
Eastern Oyster (*Crassostrea virginica*)	Acute	EC_{50}: >10.5 mg a.i./L	Slightly toxic	12797501279751
Silverside (*Menidia beryllina)*	Acute	LC_{50} > 114 mg ai/L	Practically non-toxic	1279754
	Salinity challenge	No study provided. This study is not required based on a small potential for marine exposure resulting from the proposed use pattern (chickpeas om Saskatchewan). If expansion of use results in the potential for marine habitat exposure, this study may be required.		
Diatom (*Skeletonema costatum*)	Acute	IC_{50}: 1.8 mg a.i./L	Highly toxic	1279768

[1] U.S. EPA classification, where applicable

Table 11 Screening Level Risk Assessment for Authority 480 Herbicide to Terrestrial Invertebrates

Organisms	Exposure	Endpoint value[1]	EEC[2]	RQ[3]	LOC[4]
Earthworm	Acute	Study was not provided.			**Exceeded**
Bee	Oral	Study was not provided, but is required. Given that sulfentrazone is a persistent systemic herbicide, an acute oral toxicity study on honeybees is required.			
	Contact	LD_{50}: >25.1 µg/bee >28.1 kg a.i./ha	0.14 g a.i./ha	<0.01	Not Exceeded
	Brood/hive	Study was not provided and is not required since sulfentrazone was relatively non-toxic on a contact basis and the mode of action is not expected to affect the growth of juvenile bees.			
Predatory arthropod	Contact	Study was not provided and is not required since the proposed use pattern does not include crops where beneficial insects are typically used as part of an IPM program.			
Parasitic arthropod	Contact	Study was not provided and is not required since the proposed use pattern does not include crops where beneficial insects are typically used as part of an IPM program.			

1 The LD_{50} in µg/bee is converted to the equivalent rate in kg/ha by multiplying 1.12 according to Atkins et al. (1981)

2 Estimated Environmental Concentration (EEC)

3 Risk Quotient (RQ) = exposure/toxicity

4 Level of Concern (LOC)

Table 12 Summary of the Avian and Mammalian Toxicity Data for Sulfentrazone with Appropriate Conversions

Exposure	Species	Toxicity (mg a.i./kg feed)	FIR[1] (g diet/day)	BW[2] (g)	Daily Dose (mg a.i./kg bw/day)
Acute Oral	Bobwhite Quail	LD50: >2250 mg a.i./kg bw; no conversion necessary.			
Short-term dietary	Bobwhite Quail	LC50: >5620.00	7.8	28.3	>1548.98
	Mallard Duck	LC50: >5620.00	61.2	277.3	>1240.78
Reproduction	Bobwhite Quail	NOEC: 100.00	24.3	225.5	10.78
	Mallard Duck	NOEC:100.00	1258	3563.2	35.31
Acute Oral	Rat	LD50:2688.9 mg a.i./kg bw; no conversion necessary			
Acute Oral	Mouse	LD50: 701.8 mg a.i./kg bw; no conversion necessary			
90-day dietary	Rat	NOEL[3]: 65.80	29	350	5.45
Developmental toxicity gavage	Rat	NOEL:10.00	29	350	0..83

1 Food Ingestion Rate (FIR) was calculated using the food consumption and bodyweight per individual values based on the average obtained from all individuals in the control group over the study period.

2 Bodyweight (BW) were calculated from the submitted studies

3 Environmentally relevant endpoint chosen

Table 13 Screening Level Risk Assessment on Non-Target Birds and Mammals for Authority 480 Herbicide Assuming an Application Rate of 1 x 140 g ai/ha

Weight (kg)	Endpoint value (mg a.i./kg bw/day)	Food Guild	EDE[1]	RQ[2]	Exceeds LOC[3]
Small Bird (0.02 kg)					
Acute	LD_{50}/10: 225	Insectivore (small insects)	7.05	0.03	No
		Granivore	1.21	0.01	No
		Frugivore	3.64	0.02	No
Dietary	LD_{50}/10: 124.1	Insectivore (small insects)	7.05	0.06	No
		Granivore	1.21	0.01	No
		Frugivore	3.64	0.03	No
Reproduction	NOEL: 10.78	Insectivore (small insects)	7.05	0.65	No
		Granivore	1.21	0.11	No
		Frugivore	3.64	0.34	No
Medium Sized Bird (0.1 kg)					
Acute	LD_{50}/10: 225	Insectivore (small insects)	5.51	0.02	No
		Granivore	0.94	0	No
		Frugivore	2.84	0.01	No
Dietary	LD_{50}/10: 124.1	Insectivore (small insects)	5.51	0.04	No
		Granivore	0.94	0.01	No
		Frugivore	2.84	0.02	No
Reproduction	NOEL: 10.78	Insectivore (small insects)	5.51	0.51	No
		Granivore	0.94	0.09	No
		Frugivore	2.84	0.26	No
Large Sized Bird (1 kg)					
Acute	LD_{50}/10: 225	Insectivore (large insects)	0.28	0	No
		Granivore	0.28	0	No
		Frugivore	0.83	0	No
		Herbivore (short grass)	5.74	0.03	No
		Herbivore (long grass)	3.51	0.02	No
		Herbivore (forage crops)	5.27	0.02	No
		Herbivore (leafy foliage)	10.02	0.04	No

Dietary	LD_{50}/10: 124.1	Insectivore (large insects)	0.28	0	No
		Granivore	0.28	0	No
		Frugivore	0.83	0.01	No
		Herbivore (short grass)	5.74	0.05	No
		Herbivore (long grass)	3.51	0.03	No
		Herbivore (forage crops)	5.27	0.04	No
		Herbivore (leafy foliage)	10.02	0.08	No
Reproduction	NOEL: 10.78	Insectivore (large insects)	0.28	0.03	No
		Granivore	0.28	0.03	No
		Frugivore	0.83	0.08	No
		Herbivore (short grass)	5.74	0.53	No
		Herbivore (long grass)	3.51	0.33	No
		Herbivore (forage crops)	5.27	0.49	No
		Herbivore (leafy foliage)	10.02	0.93	No

[1]Estimated Daily Exposure (EDE) = FIRww/BW*EEC
Estimated Environmental Concentration (EEC) in fresh diet (mg a.i./kg fresh weight diet)
Food Ingestion Rate of indicator species in wet weight (FIR)
Bodyweight (BW) (kg);
[2]Risk Quotient (RQ) = exposure/toxicity
[3]Level of Concern (LOC)

Table 14 Screening Level On-Field and Off-Field Risk Assessment on Mammals for Authority 480 Herbicide Assuming an Application Rate of 1 x 140 g a.i./ha

Weight (Kg)	Exposure	Endpoint value (mg a.i./kg bw/day)	Food Guild	On Field			Off Field		
				EDE	RQ	LOC exceeded	EDE - 6% Drift	RQ	LOC exceeded
Small Mammals									
15 g	Acute	LD_{50}/10: 70.18	Insectivore	4.06	0.06	No	0.24	<0.01	No
			Granivore	0.69	<0.01	No	0.04	<0.01	No
			Frugivore	2.09	0.03	No	0.13	<0.01	No
	Chronic	NOEL: 0.829	Insectivore	4.06	4.89	Yes	0.24	0.29	No
			Granivore	0.69	0.84	No	0.04	0.05	No
			Frugivore	2.09	2.52	Yes	0.13	0.15	No
Medium-Sized Mammal									
35 g	Acute	LD_{50}/10: 70.18	Insectivore small insects	3.56	0.05	No	0.21	<0.01	No
			Granivore	0.61	<0.01	No	0.04	<0.01	No
			Frugivore	1.83	0.03	No	0.11	<0.01	No
			Herbivore short grass	12.71	0.18	No	0.76	<0.01	No
			Herbivore long grass	7.76	0.11	No	0.47	<0.01	No
			Herbivore forage crops	11.66	0.17	No	0.7	<0.01	No
			Herbivore leafy foliage	22.18	0.32	No	1.33	<0.01	No
	Chronic	NOEL: 0.829	Insectivore small insects	3.56	4.29	Yes	0.21	0.26	No
			Granivore	0.61	0.73	No	0.04	0.04	No
			Frugivore	1.83	2.21	Yes	0.11	0.13	No
			Herbivore short grass	12.71	15.33	Yes	0.76	0.92	No
			Herbivore long grass	7.76	9.36	Yes	0.47	0.56	No
			Herbivore forage crops	11.66	14.07	Yes	0.7	0.84	No
			Herbivore leafy foliage	22.18	26.75	Yes	1.33	1.61	Yes

Large-Sized Mammal									
1 Kg	Acute	LD_{50}/10: 70.18	Insectivore large insects	0.33	<0.01	No	0.02	0	No
			Granivore	0.33	<0.01	No	0.02	0	No
			Frugivore	0.98	0.01	No	0.06	0	No
			Herbivore short grass	6.79	0.1	No	0.41	0.01	No
			Herbivore long grass	4.15	0.06	No	0.25	0	No
			Herbivore forage crops	6.23	0.09	No	0.37	0.01	No
			Herbivore leafy foliage	11.85	0.17	No	0.71	0.01	No
	Chronic	NOEL: 0.829	Insectivore large insects	0	<0.01	No	0	<0.01	No
			Granivore	0.33	0.39	No	0.02	0	No
			Frugivore	0.98	1.18	Yes	0.06	0	No
			Herbivore short grass	6.79	8.19	Yes	0.41	0.01	No
			Herbivore long grass	4.15	5	Yes	0.25	0	No
			Herbivore forage crops	6.23	7.52	Yes	0.37	0.01	No
			Herbivore leafy foliage	11.85	14.29	Yes	0.71	0.01	No

[1] Estimated Daily Exposure (EDE) = FIRww/BW*EEC
Estimated Environmental Concentration (EEC) in fresh diet (mg a.i./kg fresh weight diet)
Food Ingestion Rate of indicator species in wet weight (FIR)
Bodyweight (BW) (kg);

[2] Risk Quotient (RQ) = exposure/toxicity

[3] Level of Concern (LOC)

Shaded cells indicate that the RQ exceeds the LOC, triggering a refined risk assessment and further characterizationwhere possible.

Table 15 Refined On-Field and Off-Field Risk Assessment on Mammals for Authority 480 Herbicide Assuming an Application Rate of 1 x 140 g a.i./ha

Weight (Kg)	Exposure	Endpoint value (mg a.i./kg bw/day)	Food Guild	On Field	Off Field		
					EDE - 6% Drift	RQ	LOC exceeded
Small Mammals							
15 g	Chronic	NOEL: 0.829	Insectivore	Exposure is not expected [4]	0.24	0.29	No
			Granivore	Exposure is not expected [4]	0.04	0.05	No
			Frugivore	Exposure is not expected [4]	0.13	0.15	No
Medium-Sized Mammal							
35 g	Chronic	NOEL: 0.829	Insectivore small insects	Exposure is not expected [4]	0.21	0.26	No
			Granivore	Exposure is not expected [4]	0.04	0.04	No
			Frugivore	Exposure is not expected [4]	0.11	0.13	No
			Herbivore short grass	Exposure is not expected [4]	0.76	0.92	No
			Herbivore long grass	Exposure is not expected [4]	0.47	0.56	No
			Herbivore forage crops	Exposure is not expected [4]	0.7	0.84	No
			Herbivore leafy foliage	Exposure is not expected [4]	1.33	1.61	Yes
Large-Sized Mammal							
1 Kg	Chronic	NOEL: 0.829	Frugivore	Exposure is not expected [4]	0.06	0.07	No
			Herbivore short grass	Exposure is not expected [4]	0.41	0.49	No
			Herbivore long grass	Exposure is not expected [4]	0.25	0.3	No
			Herbivore forage crops	Exposure is not expected [4]	0.37	0.45	No
			Herbivore leafy foliage	Exposure is not expected [4]	0.71	0.86	**No**

[1] Estimated Daily Exposure (EDE) = FIRww/BW*EEC
Estimated Environmental Concentration (EEC) in fresh diet (mg a.i./kg fresh weight diet)
Food Ingestion Rate of indicator species in wet weight (FIR)
Bodyweight (BW) (kg);

[2] Risk Quotient (RQ) = exposure/toxicity

[3] Level of Concern (LOC)

[4] Exposure is not expected. Exposure is not expected based on the application method and/or the feeding behaviour of small mammals.
Shaded cells indicate that the RQ exceeds the LOC, triggering a refined risk assessment and further characterization where possible.

Table 16 Screening Level Risk Assessment on Non-Target Terrestrial Vascular Plants for Authority 480 Herbicide Assuming an Application Rate of 1 x 140 g a.i./ha

Organism	Exposure	Test Substance	Endpoint Value (g a.i./ha)	EEC (g ai/ha)	RQ	LOC exceeded
Vascular plant	Seedling emergence	Sulfentrazone TGAI (92%)	EC_{25}: 12	140	11.67	Yes
	Vegetative vigour	Sulfentrazone TGAI (92%)	EC_{25}: 0.9	140	155.56	Yes

Risk Quotient (RQ) = exposure/toxicity
Estimated Environmental Concentration (EEC) on foliage (vegetative vigour) and soil (seedling emergence) resulting from 1 applications of 140 g ai/ha.
Level of Concern (LOC)
Shaded cells indicate that the RQ exceeds the LOC, triggering a refined risk assessment and further characterization where possible.

Table 17 On Field and Off Field Refined Risk Assessment on Non-Target Terrestrial Vascular Plants for Authority 480 Herbicide Assuming an Application Rate of 1 x 140 g a.i./ha

Organism	Exposure	Test Substance	Endpoint Value (g a.i./ha)	On Field			Off Field		
				EEC (g ai/ha)	RQ	LOC exceeded	EEC (g ai/ha)	RQ	LOC exceeded
Vascular plant	Seedling emergence	Sulfentrazone TGAI (92%)	EC_{25}: 12	140	11.67	Yes	8.4	0.7	No
	Vegetative vigour	Sulfentrazone TGAI (92%)	EC_{25}: 0.9	140	155.56	Yes	8.4	9.33	Yes

Risk Quotient (RQ) = exposure/toxicity
Estimated Environmental Concentration (EEC) on foliage (vegetative vigour) and soil (seedling emergence) resulting from 1 application of 140 g ai/ha.
Level of Concern (LOC)
Shaded cells indicate that the RQ exceeds the LOC, triggering a further risk characterization and/or mitigative measures are required.

Table 18 Screening Level Risk Assessment on Non-Target Aquatic Organisms for Authority 480 Herbicide Assuming an Application Rate of 1 x 140 g a.i./ha

Organism	Exposure	Study Duration	Endpoint Value (mg a.i./L)	EEC[1] Value	RQ[2]	LOC[3] exceeded
Freshwater Species						
Daphnid (*Daphnia magna*)	Acute	48 hours	LC_{50}/2: 30.2	0.03	<0.01	No
	Chronic	21 days	NOEC: 0.05	0.03	0.53	No
Rainbow Trout (*Onchorhynchus mykiss*)	Acute	96 hours	LC_{50}/10: 13	0.03	<0.01	No
	Chronic - ELS	99 days	NOEC: 2.95	0.03	<0.01	No
Bluegill Sunfish (*Lepomis macrochirus*)	Acute	96 hours	LC_{50}/10: 9.38	0.03	<0.01	No
Green Algae (*Selenastrum capricornutum*)	Acute	120 hours	LC_{50}/2: 0.0155	0.03	1.69	Yes
Aquatic Vascular Plant (*Lemna gibba*)	Acute	14 days	LC_{50}/2: 0.0145	0.03	1.81	Yes
Amphibians (15 cm depth)						
Amphibians[4]	Acute	96 hours	LC_{50}/10: 9.38	0.14	0.01	No
	Chronic	99 days	NOEC: 2.95	0.14	0.05	No
Marine Species						
Mysid Shrimp (*Mysidopsis bahia*)	Acute	96 hours	LC_{50}/2: 0.5	0.03	0.05	No
Eastern Oyster (*Crassostrea virginica*)	Acute	96 hours	LC_{50}/2: 5.25	0.03	<0.01	No
Silverside (*Menidia beryllina*)	Acute	96 hours	LC_{50}/10: 11.4	0.03	<0.01	No
Diatom (*Skeletonema costatum*)	Acute	120 hours	LC_{50}/2: 0.9	0.03	0.03	No

1 Estimated Environmental Concentration (EEC) on in water.

2 Risk Quotient (RQ) = exposure/toxicity. For fish, RQ = EEC in an 80 cm deep water body / (EC50 ÷ 10 or LC50 ÷ 10); for a chronic exposure: RQ = EEC in an 80 cm deep water body / NOEC; for amphibians, the EEC in a 15 cm deep water body is used. For aquatic invertebrates and plants, RQ = EEC in a 80 cm deep water body / (EC50 ÷ 2 or LC50 ÷ 2); for a chronic exposure: RQ = EEC in a 80 cm deep water body / NOEC

3 Level of Concern (LOC)

4 the endpoint values for the most sensitive fish species at the appropriate exposure scenario were used as surrogate data for the amphibian risk assessment.

Shaded cells indicate that the RQ exceeds the LOC, triggering a refined risk assessment and further characterization where possible.

Table 19 Refined Risk Assessment on Non-Target Aquatic Organisms Using Level 1 Run-Off Values for Authority 480 Herbicide Assuming an Application Rate of 1 x 140 g a.i./ha[4]

Organism	Exposure	Study Duration	Endpoint Value (mg a.i./L)	EEC[1] Value	RQ[2]	LOC[3] exceeded
Freshwater Species						
Green Algae (*Selenastrum capricornutum*)	Acute	120 hours	LC_{50}/2: 0.0155	0.013	0.85	No
Aquatic Vascular Plant (*Lemna gibba*)	Acute	14 days	LC_{50}/2: 0.0145	0.013	0.9	No

1 Estimated Environmental Concentration (EEC) on in water.

2 Risk Quotient (RQ) = exposure/toxicity. For fish, RQ = EEC in an 80 cm deep water body / (EC50 ÷ 10 or LC50 ÷ 10); for a chronic exposure: RQ = EEC in an 80 cm deep water body / NOEC; for amphibians, the EEC in a 15 cm deep water body is used. For aquatic invertebrates and plants, RQ = EEC in a 80 cm deep water body / (EC50 ÷ 2 or LC50 ÷ 2); for a chronic exposure: RQ = EEC in a 80 cm deep water body / NOEC

3 Level of Concern (LOC)

4 It should be noted that the water model was run at 210 g a.i./ha which is higher than the proposed application rate.

Table 20 Refined Risk Assessment on Non-Target Aquatic Organisms Using Level 1 Drift Values for Authority 480 Herbicide Assuming an Application Rate of 1 x 140 g a.i./ha[4]

Organism	Exposure	Study Duration	Endpoint Value (mg a.i./L)	EEC[1] Value	RQ[2]	LOC[3] exceeded
Freshwater Species						
Green Algae (*Selenastrum capricornutum*)	Acute	120 hours	LC_{50}/2: 0.0155	0.002	0.1	No
Aquatic Vascular Plant (*Lemna gibba*)	Acute	14 days	LC_{50}/2: 0.0145	0.002	0.11	No

1 Estimated Environmental Concentration (EEC) on in water.

2 Risk Quotient (RQ) = exposure/toxicity. For fish, RQ = EEC in an 80 cm deep water body / (EC50 ÷ 10 or LC50 ÷ 10); for a chronic exposure: RQ = EEC in an 80 cm deep water body / NOEC; for amphibians, the EEC in a 15 cm deep water body is used. For aquatic invertebrates and plants, RQ = EEC in a 80 cm deep water body / (EC50 ÷ 2 or LC50 ÷ 2); for a chronic exposure: RQ = EEC in a 80 cm deep water body / NOEC

3 Level of Concern (LOC)

4 It should be noted that the water model was run at 210 g a.i./ha which is higher than the proposed application rate.

Table 21 Toxic Substances Management Policy Considerations-Comparison to TSMP Track 1 Criteria

TSMP Track 1 Criteria	TSMP Track 1 Criterion Value		Sulfentrazone Endpoints	Major Transformation Endpoints
CEPA toxic pr CEPA toxic equivalent[1]	Yes		Yes	Yes
Predominantly anthropogenic[2]	Yes		Yes	Yes
Persistence[3]	Soil	Half-life ≥ 182 days	856 days (aerobic soil)	Not available
	Water	Half-life ≥ 182 days	Stable (hydrolysis; aerobic water[5])	Not available
	Sediment	Half-life ≥ 365 days	Stable (anaerobic sediment)	Not available
	Air	Half-life ≥ 2 days or evidence of long range transport	Half-life or volatilisation is not an important route of dissipation and long-range atmospheric transport is unlikely to occur based on the vapour pressure [8×10^{-10} mm Hg (25°C)] and Henry's Law Constant ($K = 1.02 \times 10^{-12}$ $atm.m^3/mole$; $1/H = 2.4 \times 10^{10}$)	Not available
Bioaccumulation[4]	Log $K_{ow} \geq 5$		1.5	Not available
	BCF ≥ 5000		31.1	Not available
	BAF ≥ 5000		Not available	Not available

TSMP Track 1 Criteria	TSMP Track 1 Criterion Value	Sulfentrazone Endpoints	Major Transformation Endpoints
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?		No, does not meet TSMP Track 1 criteria	The log K_{ow} is required for the major transformation products expected to be present in the aquatic environment to confirm these do not meet 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 (i.e., all other TSMP criteria are met).

[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 (e.g., BAFs) are preferred over laboratory data (e.g., BCFs) which, in turn, are preferred over chemical properties (e.g., log K_{OW}).

[5] It assumed that sulfentrazone is stable in aerobic water based on the stability demonstrated in the anaerobic sediment and that an aerobic soil biotransformation study was not provided. A No information was provided on the fate of sulfentrazone in aerobic water.

Table 22 Use (label) Claims Proposed by Applicant and Whether Acceptable or Unsupported

Applicant proposed label claims	Accepted label claims	Unsupported label claims
Control of Palmer amaranth, Powell amaranth, barnyardgrass, catchweed bedstraw, field bindweed, bittercress, annual bluegrass, wild buckwheat, lawn burweed, smallflower buttercup, broadleaf buttonweed, white campion, carpetweed, common cocklebur, common chickweed, mouseear chickweed, cinquefoil, large	Control of: common lamb's quarters, Eastern black nightshade, redroot pigweed, common waterhemp, tall waterhemp and wild buckwheat. Suppression of: kochia, yellow nutsedge and smooth pigweed.	Control of Palmer amaranth, Powell amaranth, barnyardgrass, catchweed bedstraw, field bindweed, bittercress, annual bluegrass, lawn burweed, smallflower buttercup, broadleaf buttonweed, white campion, carpetweed, common cocklebur, common chickweed, mouseear chickweed, cinquefoil, large hop clover, large crabgrass,

Applicant proposed label claims	Accepted label claims	Unsupported label claims
hop clover, large crabgrass, smooth crabgrass, cudweed, dandelion, American daisy, devil's claw, curly dock, evening primrose, dog fennel, fiddleneck, redstem filaree, flixweed, giant foxtail, green foxtail, yellow foxtail, hairy galinsoga, wild garlic, Carolina geranium, goldenrod, goosegrass, clammy groundcherry, cutleaf groundcherry, common groundsel, henbit, ground ivy, jimsonweed, kochia, green kyllinga, green false kyllinga, prostrate knotweed, lady's thumb, common lamb's quarters, miners lettuce, wild lettuce, prickly lettuce, common Lespedeza, common mallow, Venice mallow, chamomile mayweed, black medic, honeyvine milkweed, blue morningglory, ivyleaf morningglory, pitted morningglory, tall morningglory, wild mustard, black nightshade, Eastern black nightshade, American black nightshade, hairy nightshade, purple nutsedge, yellow nutsedge, wild onion, parsley-piert, fall panicum, field pansy, green pigweed, redroot pigweed, tumble pigweed, smooth pigweed, pineapple weed, blackseed plantain, buckhorn plantain, narrow-leaved plantain, wild poinsettia, common puncturevine, common purslane, Florida pusley,		smooth crabgrass, cudweed, dandelion, American daisy, devil's claw, curly dock, evening primrose, dog fennel, fiddleneck, redstem filaree, flixweed, giant foxtail, green foxtail, yellow foxtail, hairy galinsoga, wild garlic, Carolina geranium, goldenrod, goosegrass, clammy groundcherry, cutleaf groundcherry, common groundsel, henbit, ground ivy, jimsonweed, green kyllinga, green false kyllinga, prostrate knotweed, lady's thumb, miners lettuce, wild lettuce, prickly lettuce, common Lespedeza, common mallow, Venice mallow, chamomile mayweed, black medic, honeyvine milkweed, blue morningglory, ivyleaf morningglory, pitted morningglory, tall morningglory, wild mustard, black nightshade, American black nightshade, hairy nightshade, purple nutsedge, wild onion, parsley-piert, fall panicum, field pansy, green pigweed, tumble pigweed, pineapple weed, blackseed plantain, buckhorn plantain, narrow-leaved plantain, wild poinsettia, common puncturevine, common purslane, Florida pusley, wild radish, redweed, London rocket, annual ryegrass, cylindrical sedge, Surinam sedge, globe sedge, Texas sedge, shepherd's

Applicant proposed label claims	Accepted label claims	Unsupported label claims
wild radish, redweed, London rocket, annual ryegrass, cylindrical sedge, Surinam sedge, globe sedge, Texas sedge, shepherd's purse, Pennsylvania smartweed, pale smartweed, American speedwell, corn speedwell, red sorrel, annual sowthistle, annual spurge, cypress spurge, prostrate spurge, spotted spurge, star of Bethlehem, bristly starbur, stinkweed, tansy mustard, Russian thistle, yellow toadflax, velvetleaf, wild violet, creeping wood sorrel, common waterhemp, tall waterhemp, yellow wood sorrel and biennial wormwood		purse, Pennsylvania smartweed, pale smartweed, American speedwell, corn speedwell, red sorrel, annual sowthistle, annual spurge, cypress spurge, prostrate spurge, spotted spurge, star of Bethlehem, bristly starbur, stinkweed, tansy mustard, Russian thistle, yellow toadflax, velvetleaf, wild violet, creeping wood sorrel, yellow wood sorrel and biennial wormwood
Agricultural uses on flax, soybeans, sunflower, asparagus, cabbage, shelled beans and peas, horseradish, strawberry and mint	Agricultural uses on flax, soybeans, sunflower, chickpeas and strawberry.	Agricultural use on asparagus, cabbage, shelled beans and peas, horseradish and mint.

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

The eight Canadian MRLs on asparagus, cabbage, horseradish roots, crop subgroup 6C- dried shelled pea and bean (except soybean), peppermint tops, spearmint tops, dry soybeans and sunflower seeds are the same as those in the U.S (www.access.gpo.gov/nara/cfr/waisidx_04/40cfr180_04.html:). Currently there are no Codex MRLs established for sulfentrazone on any commodity (www.mrldatabase.com).

Appendix III - Crop Groups: Numbers and Definitions

Crop Group Number	Name of the Crop Group	Commodity
6C	Dried Shelled Pea and Bean (except soybean) subgroup	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 seed dry moth beans dry mung beans dry rice beans dry southern peas dry urd beans dry broad beans dry chickpeas dry guar seed dry lablab beans dry lentils dry field peas dry pigeon peas

References

A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

1.0 Chemistry

Sulfentrazone

PMRA Document Number	Reference
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1279653	2006, Manufacturing Summary, DACO: 2.11.1 CBI
1279654	1996, Sulfentrazone (F6285) Product Identity and Disclosure of Ingredients, Description of Starting Materials and Manufacturing Process, Discussion on the Formation of Impurities, 162D61P94-1, MRID: 43926801, DACO: 2.11.2, 2.11.3, 2.11.4 CBI
1279655	1996, Confidential Attachment: Sulfentrazone (F6285) Product Identity and Disclosure of Ingredients, Description of Starting Materials and Manufacturing Process, Discussion on the Formation of Impurities, 162D61P94-1, DACO: 2.11.2, 2.11.3, 2.11.4 CBI
1279656	1991, Product Identity and Disclosure of Ingredients, Description of Starting Materials and Manufacturing Process, Discussion on the Formation of Impurities, 162D61P91-1, MRID: 41911603, DACO: 2.11.2, 2.11.3, 2.11.4 CBI
1279657	2006, Establishing Certified Limits, DACO: 2.12.1 CBI
1279658	1996, Sulfentrazone (F6285) Technical Analysis and Certification of Product Ingredients, 162D62P93-1, MRID: 43926802, DACO: 2.13.1, 2.13.3, 2.13.4 CBI
1279659	1994, Confidential Attachment: Sulfentrazone (F6285) Technical Analysis and Certification of Product Ingredients, 162D62P93-1, DACO: 2.13.1, 2.13.3, 2.13.4 CBI
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1279663	1991, FMC 97285 - Determination of Dissociation Constant, 4166-91-0075-AS, DACO: 2.14.10, 2.14.12, 8.2.1
1279664	1993, Sulfentrazone Spectra, DACO: 2.14.12, 8.2.1
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1279666	1995, F6285 TGAI (Technical Grade Active Ingredient) Stability to Sunlight, 162AF95311, MRID: 43761701, DACO: 2.16
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1596845 2008, CBI REMOVED Sulfentrazone Specification for Starting Materials, DACO: 2.11

Authority 480 Herbicide

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Environmental Fate

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