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Proposed Registration Decision

Saflufenacil

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6605C
Ottawa, Ontario
K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

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Overview

Proposed Registration Decision for Saflufenacil

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of saflufenacil technical (Kixor) and end-use products Heat WG, Eragon and Integrity, containing the technical grade active ingredient saflufenacil, to control broadleaf weeds in lentils, soybean, barley, canary seed, chickpea, field corn, sweet corn, oats, dried field peas, wheat (spring, durum and winter) and in chemfallow.

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.

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 saflufenacil and end-use products Heat WG, Eragon and Integrity.

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 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 (such as children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticide and Pest Management portion of the Health Canada website at healthcanada.gc.ca/pmra.

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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."

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

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

What Is Saflufenacil?

Saflufenacil is a herbicidal compound which inhibits the protoporphyrinogen-IV oxidase enzyme in sensitive plants. The result is build-up of phytotoxic intermediates, rapid development of chlorotic to necrotic symptoms and ultimately plant death. This compound is efficacious against broadleaf weeds.

Saflufenacil is regarded as a Weed Science Society of America Group 14 or Herbicide Resistance Action Committee Group E herbicide.

Heat WG and Eragon contain the active ingredient saflufenacil at 70%; Integrity contains saflufenacil at 68 grams per litre of product and dimethenamid-P at 600 grams per litre of product.

Health Considerations

Can Approved Uses of Saflufenacil Affect Human Health?

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

Exposure to saflufenacil may occur through diet (food and water) or when handling and 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. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

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

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

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

Saflufenacil end-use products Heat WG and Eragon cause dermal irritation in rabbits. Integrity is a dermal and eye irritant as well as a potential skin sensitizer. All end-use formulations are of low acute toxicity by the oral, dermal, and inhalation routes of exposure.

When tested in laboratory animals, technical saflufenacil was not genotoxic, oncogenic, neurotoxic, or toxic to the reproductive system. Repeat administration of saflufenacil resulted in microcytic hypochromic anemia affecting the red blood cell parameters.

In the rat developmental toxicity study, saflufenacil delayed the development of fetuses and resulted in an increased incidence of the skeletal malformation (bent scapula) at a dose that was not toxic to the dams. No adverse developmental effects were observed in the rabbit developmental toxicity study. The identified offspring toxicity in the absence of maternal toxicity and the occurrence of skeletal formation in the rat developmental toxicity study are taken into consideration in the assessment of risk to infants and children.

The risk assessment protects against these effects by ensuring levels of human exposure are well below the lowest dose at which these effects occur in animal studies.

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—including infants, the subpopulation which would ingest the most saflufenacil relative to body weight—are expected to be exposed to less than 24.4% of the acceptable daily intake (ADI). Based on these estimates, the chronic dietary risk from saflufenacil is not of concern for all population sub-groups.

A single dose of saflufenacil is not likely to cause acute health effects in the general population or in women aged 13–49 years. The ADI estimates were 44.37% of the reference dose for females 13–49 years old and $\leq$0.61% of the reference dose for all other population subgroups, which are not a health concern.

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

Results proved acceptable from residue trials conducted throughout Canada and the United States using saflufenacil on legume vegetables (Crop Group 6), citrus fruits (Revised Crop Group 10), pome fruits (Crop Group 11), stone fruits (Crop Group 12), tree nuts (Crop Group 14), cereal grains (Crop Group 15), grapes, sunflower seeds and cotton. The MRLs for this active ingredient can be found in the Science Evaluation of this consultation document.

Occupational Risks From Heat WG, Eragon and Integrity

Occupational risks are not of concern when Heat WG, Eragon and Integrity are used according to the proposed label directions, which include protective measures.

Farmers and pesticide applicators mixing, loading or applying Heat WG, Eragon and Integrity as well as field workers re-entering freshly treated fields can come in direct contact with Heat WG, Eragon and Integrity on the skin or through inhalation of spray mists.

Therefore, the labels will specify appropriate personal protective equipment such as long-sleeved shirt, long pants, chemical-resistant gloves, shoes plus socks, coveralls, chemical-resistant coveralls, goggles or face shield, or engineering control for anyone conducting specific specific tasks with one of the end-use products of saflufenacil. Full details are provided in the risk-reduction measures for human health.

Occupational exposure is expected to be short- to intermediate-term because this herbicide may be applied to any given crop only twice per year. Taking into consideration the label requirements, risk to farmers, applicators or workers is not a concern.

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

For postapplication, exposure is expected to be minimal since Heat WG, Eragon and Integrity are applied directly to the ground using a groundboom sprayer either before the crop has been planted or after it has been planted but before emergence. Therefore, health risks to workers entering treated fields are not of concern.

Environmental Considerations

What Happens When Saflufenacil Is Introduced Into the Environment?

Saflufenacil and its degradates have high potential to reach groundwater. Without risk-reduction measures, saflufenacil may impact non-target terrestrial plants adjacent to the treatment area.

Saflufenacil is degraded by both chemical reactions and microorganisms in soil and water. The rate of degradation is enhanced by sunlight. Saflufenacil is non-persistent to slightly persistent in soil and moderately persistent in aquatic systems. Saflufenacil and its degradates are mobile in soil and have high potential to reach groundwater. Saflufenacil does not bioconcentrate and is therefore unlikely to bioaccumulate.

Risks to non-target terrestrial plants as a result of spray drift have been identified in areas adjacent to the treatment area. There are no concerns about saflufenacil or its transformation products affecting any other non-target organisms.

Risks to aquatic plants and amphibians have been identified for the Integrity formulation, which is a co-formulation of saflufenacil and another herbicide, dimethenamid-P.

Value Considerations

What Is the Value of Heat WG, Eragon and Integrity?

Saflufenacil, a postemergence and a residual herbicide, controls a broad spectrum of broadleaf weeds in lentils, soybean, barley, canary seed, chickpea, field and sweet corn, oats, dried field peas, wheat (spring, durum and winter) and in chemfallow.

A single application of saflufenacil provides effective control of several broadleaf weeds including kochia, Canada fleabane, lamb's quarters, redroot pigweed, round-leaved mallow, stinkweed, volunteer Canola (all herbicide tolerant types including Roundup Ready), wild buckwheat, wild mustard, common ragweed and velvetleaf; it also suppresses dandelion.

Saflufenacil is compatible with integrated weed management practices, conservation tillage and conventional crop production systems. Since saflufenacil is applied after weed emergence, growers are able to assess whether the herbicide is suitable for the particular weed species present.

Measures to Minimize Risk

Labels of registered pesticide products include specific, legally enforced instructions for use. Directions include risk-reduction measures to protect human and environmental health. The key risk-reduction measures proposed for the labels of Heat WG, Eragon and Integrity to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because there is a concern with users coming into direct contact with Heat WG, Eragon and Integrity on the skin or through inhalation of spray mists, anyone mixing, loading and applying Heat WG, Eragon and Integrity must wear appropriate personal protective equipment.

Integrity:
Wear a long-sleeved shirt, long pants, chemical-resistant gloves and shoes plus socks during mixing, loading, clean-up and repair. In addition, wear goggles or face shield during mixing and loading. Applicators must wear long-sleeved shirt, long pants and shoes plus socks.

Custom applicators performing mixing, loading and application must wear chemical-resistant coveralls over long-sleeved shirt, long pants, chemical-resistant gloves, and goggle or face shield during mixing and loading.

Heat WG and Eragon:
Wear coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves and shoes plus socks during mixing, loading, clean-up and repair. In addition, wear goggles or face shield during mixing and loading. Applicators must wear a long-sleeved shirt, long pants, coveralls and shoes plus socks.

Custom handlers treating corn fields must wear chemical-resistant coveralls over long-sleeved shirt, long pants and chemical-resistant gloves during mixing, loading, application, clean-up and repair and, additionally, goggles or a face shield during mixing and loading. Custom applicators performing mixing, loading, and application must use a closed mixing and loading system.

In addition, standard label statements to protect against drift during application were added to the labels.

Environment

To mitigate risks from the use of saflufenacil to non-target terrestrial plants, spray buffer zones are required to protect terrestrial habitats adjacent to the treatment area. The sizes of the buffer zones range from 4 to 15 metres for application rates ranging 18 to 100 g saflufenacil/ha.

To mitigate risks to aquatic plants and amphibians from the use of Integrity, a spray buffer zone of one metre is required on the Integrity label to protect aquatic habitats adjacent to the treatment areas.

Next Steps

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

Other Information

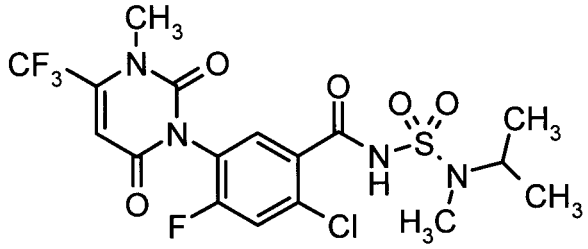
When the PMRA makes its registration decision, it will publish a Registration Decision on saflufenacil (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the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

Science Evaluation

Saflufenacil

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance		Saflufenacil
Function		Herbicide
Chemical name		
1.	**International Union of Pure and Applied Chemistry (IUPAC)**	*N*′-{2-chloro-4-fluoro-5-[1,2,3,6-tetrahydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)pyrimidin-1-yl]benzoyl}-*N*-isopropyl-*N*-methylsulfamide
2.	**Chemical Abstracts Service (CAS)**	2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2*H*)-pyrimidinyl]-4-fluoro-*N*-[[methyl-(1-methylethyl)amino]sulfonyl]benzamide
CAS number		372137-35-4
Molecular formula		$C_{17}H_{17}ClF_4N_4O_5S$
Molecular weight		500.86
Structural formula		
Purity of the active ingredient		97.4% nominal

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

Technical Product—Kixor

Property	Result
Colour and physical state	White powdery solid
Odour	Odourless
Melting range	189.9°C
Boiling point or range	N/A
Density	1.595 g/cm^3

Property	Result		
Vapour pressure at 20°C	$<10^{-10}$ Pa		
Henry's law constant at 25°C	4.01×10^{-20} atm m^3 mol^{-1}		
Ultraviolet (UV)-visible spectrum	pH	λ_{max} (nm)	ε (L/mol•cm)
	acidic	271.8	9539
	neutral	271.4	9708
	basic	309.4	2358
Solubility in water at 20°C	pH	Solubility (g/100 mL)	
	4	0.0014	
	5	0.0025	
	7	0.21	
Solubility in organic solvents at 20°C	Solvent	Solubility (g/100 mL)	
	N,N-dimethylformamide	55.4	
	tetrahydrofuran	36.2	
	butyrolactone	35.0	
	acetone	27.5	
	dichloromethane	24.4	
	acetonitrile	19.4	
	ethyl acetate	6.55	
	methanol	2.98	
	isopropanol	0.25	
	toluene	0.23	
	olive oil	0.01	
	1-octanol	<0.01	
	n-heptane	<0.005	
n-Octanol–water partition coefficient (K_{ow})	log K_{ow} = 2.6		
Dissociation constant (pK_a)	4.41		
Stability (temperature, metal)	Stable to heat and metals		

Note: atm = atmosphere, nm = nanometre, λ_{max} (nm) = wavelength, ε (L/mol•cm) = extinction coefficient

End-Use Products—Heat WG, Eragon and Integrity

Property	Result for Heat WG and Eragon	Result for Integrity
Colour	Light brown	Clear brown
Odour	Faint smoky	Not required
Physical state	Solid	Liquid
Formulation type	Wettable granules	Emulsifiable concentrate
Guarantee	70% nominal	Saflufenacil 68 g/L nominal Dimethenamid-P 600 g/L nominal

Property	Result for Heat WG and Eragon	Result for Integrity
Container material and description	Plastic jugs (0.25 to 100 kg) and bulk	High-density polyethylene containers lined with an inner barrier (for example, polyamide) and with a foil seal
Density	Bulk density: 0.574 g/cm^3 (free fall) and 0.628 g/cm^3 (packed)	Relative density: 1.092
pH of 1% dispersion in water	5.019	4.195
Oxidizing or reducing action	Mild reducing agent	Mild reducing agent
Storage stability	Stable in short-term studies; data from at least one year are required.	Stable in short-term studies; data from at least one year are required.
Corrosion characteristics	Not corrosive in short-term studies; data from a long-term ambient study are required.	Data from a long-term ambient study are required.
Explodability	Not explosive	Not explosive

1.3 Directions for Use

1.3.1 Heat WG

Heat WG, containing saflufenacil at 70%, is a selective herbicide for use as a preseed, preplant or pre-emergence treatment (pre-emergence to crops and postemergence to weeds) on lentils, soybean, barley, canary seed, chickpea, field corn, sweet corn, oats, dried peas, field peas, wheat (spring, durum and winter) and in chemfallow, for the control of many broadleaf weeds in the Prairie provinces and the Peace River region of British Columbia.

The product is applied once per growing season, in the spring or fall, at rates of 18 or 50 g active ingredient per hectare (a.i./h) as a broadcast treatment with ground application equipment only (Table 1.3.1.1).

Table 1.3.1.1 Rates of Application for Heat WG

Herbicide Rate	Weeds Controlled
18 g a.i./ha + 0.5 L/ha of Merge*	Kochia, Canada fleabane, lamb's quarters, redroot pigweed, round-leaved mallow, stinkweed, volunteer canola (all herbicide tolerant types including Roundup Ready), wild buckwheat and wild mustard.
50 g a.i./ha + 0.5 L/ha of Merge	Suppression of secondary flushes of redroot pigweed, stinkweed, wild buckwheat and wild mustard.

* Maximum application rate for lentils and soybeans (in the Prairie provinces and Western Canada).

1.3.2 Eragon

Eragon, containing saflufenacil at 70%, is a selective herbicide for use as a preplant or pre-emergence treatment (pre-emergence to crops and postemergence to weeds) on barley, field corn, sweet corn, wheat (spring, durum and winter) and soybeans for the control of many broadleaf weeds in Eastern Canada.

The product is applied once per growing season, in the spring or fall, at rates of 25 g a.i./ha in soybeans and 25 or 50 g a.i./ha in cereals and 50 to 100 g a.i./ha in corn (Table 1.3.2.1) as a broadcast treatment with ground application equipment only.

Table 1.3.2.1 Rates of Application for Eragon

Timing	Herbicide Rate	Weeds Controlled	Weeds Suppressed
Preplant burndown in cereals and soybeans	25 g a.i./ha + 1% v/v of Merge	Canada fleabane, common ragweed, lamb's quarters, redroot pigweed, and wild mustard	Dandelion
Preplant burndown and suppression of secondary weed flushes in cereals	50 g a.i./ha + 1% v/v of Merge	Lamb's quarters, redroot pigweed, stinkweed, wild buckwheat and wild mustard	Not Applicable
Preplant or pre-emergence burndown in corn	50 to 100 g a.i./ha + 1% v/v of Merge	Common ragweed, lamb's quarters, redroot pigweed, velvetleaf, wild buckwheat and wild mustard	Not Applicable

1.3.3 Integrity

Integrity, containing saflufenacil at 60 g/L and dimethenamid-P at 600 g/L, is a selective herbicide for use as a pre-emergence or preplant incorporated treatment on field and sweet corn for the control of many broadleaf and grassy weeds in Eastern Canada.

The product is applied once per growing season, in the spring, at rates between 488 to 735 g a.i./ha in corn (Table 1.3.3.1) as a broadcast treatment with ground application equipment only.

Table 1.3.3.1 Rates of Application for Integrity

Timing	Herbicide Rate	Weeds Controlled	Weeds Suppressed
Pre-emergence	488 g a.i./ha	Common ragweed, crabgrass (smooth and large, fall panicum, foxtail (green, yellow, giant), lamb's quarters, redroot pigweed, velvetleaf, wild buckwheat and wild mustard	Not applicable

Timing	Herbicide Rate	Weeds Controlled	Weeds Suppressed
Pre-emergence or preplant incorporated	735 g a.i./ha	Barnyard grass, common ragweed, crabgrass (smooth and large), Eastern black nightshade, fall panicum, foxtail (green, yellow, giant), lamb's quarters, redroot pigweed, yellow nutsedge, old witchgrass, velvetleaf, wild buckwheat and wild mustard	Not Applicable

1.4 Mode of Action

Saflufenacil belongs to the chemical family of pyrimidinediones and obtains its herbicidal activity through the inhibition of the enzyme protoporphyrinogen-IV oxidase in sensitive plants. The enzyme is necessary for chlorophyll and heme biosynthesis in plant organelles. Once it is inhibited, levels of protoporphyrinogen build in the cytosol and are converted to protoporphyrin. Upon exposure to light, protoporphyrin molecules interact with light energy to generate reactive oxygen molecules. These toxic oxygen molecules damage cell membranes, resulting in development of chlorotic to necrotic symptoms and ultimately plant death. Saflufenacil is regarded as a Group 14 or Group E herbicide (Weed Science Society of America and Herbicide Resistance Action Committee, respectively). Refer to Regulatory Directive DIR99-06, *Voluntary Pesticide Resistance Management Labelling Based on Target Site/Mode of Action*.

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 saflufenacil (Kixor) have been validated and assessed to be acceptable for the determinations.

2.2 Method for Formulation Analysis

The methods provided for the analysis of the active ingredients in the formulations have been validated and assessed to be acceptable for use as enforcement analytical methods.

2.3 Methods for Residue Analysis

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

BASF Method D0603/2 (LC-MS/MS) was developed and proposed for data generation and enforcement purposes in plant commodities. The method fulfilled the requirements with regards to specificity, accuracy and precision at the respective method limit of quantitation. Acceptable recoveries were obtained in plant matrices. Adequate extraction efficiencies were demonstrated using radiolabelled soybean samples (forage and straw, but not pod) analyzed with the enforcement method D0603/2. Additionally, Method D0603/2 was validated by an independent laboratory.

BASF Method L0073/01 (LC-MS/MS) was developed and proposed for data generation and enforcement purposes in livestock commodities. The method fulfilled the requirements with regards to specificity, accuracy and precision at the respective method limit of quantitation. Acceptable recoveries were obtained in livestock matrices. The extraction efficiencies were not demonstrated because Method L0073/01 uses the same extraction solvent as that used in the livestock metabolism studies. Method L0073/01 was validated by an independent laboratory.

Saflufenacil and the metabolites M800H11 and M800H35 were analyzed according to the United States' Food and Drug Administration's Multiresidue Method Testing guidelines in Pesticide Analytical Methods Volume I. The multiresidue testing data indicate that the multiresidue methods are not suitable for the determination of saflufenacil and the metabolites M800H11 and M800H35.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

The PMRA conducted a detailed review of the toxicological database for saflufenacil. The database consists of an 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 acceptable, and the database is considered adequate to characterize the toxicity of this pest control product.

Technical saflufenacil is of low acute toxicity by the oral, dermal, and inhalation routes in rats. It was not irritating to the rabbit eye, but was slightly irritating when applied to the skin of the rabbit. The skin sensitization testing in guinea pigs using the maximization method did not demonstrate a potential for sensitization.

All end-use formulations of saflufenacil—namely Heat WG, Eragon and Integrity herbicides—are of low acute toxicity by the oral, dermal and inhalation routes in rats. The WG formulations are minimally irritating to the rabbit eye but are mildly irritating to the rabbit skin. Neither Heat WG nor Eragon were dermal sensitizers when tested in guinea pigs. Integrity is an irritant when tested in the eye and skin of rabbits, and is a potential skin sensitizer based on the modified Buehler's assay in female guinea pigs.

The toxicokinetics data demonstrated that orally administered saflufenacil was rapidly absorbed, distributed and excreted. Regardless of the dose administered, the maximum concentration of saflufenacil in blood and plasma was reached within one hour of dosing and declined rapidly after 24 hours. The blood and plasma data demonstrated that the majority of saflufenacil residue occurred in the plasma and was not bound to cellular elements of the blood.

There was a sex dependent difference in the excretion of orally administered saflufenacil. Following single low- (5 mg/kg bodyweight [bw]) and high-dose (100 mg/kg bw) administration or a repeat high-dose administration (100 mg/kg bw/day for 15 days), the main route of elimination in male rats was via the feces. Meanwhile urinary excretion was the major route of elimination in females. The sex dependent excretion was more pronounced at the low dose level than at the high dose level. The sex dependent difference in excretion of orally dosed saflufenacil was also demonstrated by the biliary excretion data, which showed significantly higher biliary excretion of saflufenacil residues in males than in females. Excretion of orally dosed saflufenacil was essentially complete within 96 hours; the majority was eliminated within the first 24 to 48 hours. Exhalation was not a relevant excretion pathway of saflufenacil. At 168 hours after dosing, saflufenacil residues remaining in tissues were very low, and occurred mainly in the carcass, liver, skin and gut contents.

Studies of the metabolic pattern and identification on metabolites in rats indicated saflufenacil was metabolized by three major transformation steps: demethylation of the uracil ring system; degradation of the N-methyl-N-isopropyl group to NH_2; and cleavage of the uracil ring, forming a sulfonylamide group. The predominant metabolites were M800H01, M800H03, M800H07 and the parent compound. Other minor metabolites were M800H05, M800H16, M800H17, M800H18, M800M19 and M800M20. There were no significant gender differences in metabolic profiles.

A four-week dermal toxicity study in rats showed no skin reaction following daily application of saflufenacil at $\leq$1000 mg/kg bw/day. The only treatment-related finding was a decrease in hemoglobin level in the male at the high dose of 1000 mg/kg bw/day.

In short- and long-term dietary toxicity studies in mice, rats, and dogs, saflufenacil induced microcytic hypochromic anemia affecting red blood cell parameters. There were general decreases of erythrocyte, hemoglobin, hematocrit, mean cell volume, mean corpuscular haemoglobin or mean corpuscular haemoglobin concentration. The organs affected were generally the liver, spleen, and bone marrow. Pathology of the liver involved increased weight, fatty changes, iron storage, and occasionally extramedullary hemopoiesis. Extramedullary hematopoiesis was invariably observed in the spleen. The noted bone marrow finding was erythroid hyperplasia.

Long-term dietary toxicity studies in mice and rats demonstrated systemic toxicity similar to that seen in shorter term studies. Saflufenacil did not induce tumours in either rodent species tested.

No evidence of mutagenic potential of saflufenacil was observed in a battery of in vitro and in vivo genotoxicity assays assessing gene mutation and chromosome aberration.

When tested in the rat, saflufenacil did not affect reproductive performance or the reproductive system. In the rat developmental toxicity study, saflufenacil delayed the development of the fetuses. In addition, there were incidents of the skeletal malformation (bent scapula) at the mid- and high-dose groups at doses that showed minimal maternal toxicity. Bent scapula was not seen in the concurrent control fetuses, nor was it seen in historical control data from the performing laboratory. Available historical control data indicated the occurrence of this skeletal malformation in the high-dose group (5.1%) was outside the range (0–2.6%), but not at the mid-dose (1%), which is the established lowest observed adverse effect level (LOAEL). Thus, the overall conclusion regarding observed skeletal malformations is that they are considered relevant for risk assessment. No adverse developmental effects were observed in the rabbit teratology study.

Saflufenacil was not neurotoxic as demonstrated in acute and 90-day neurotoxicity studies in rats.

3.1.1 *Pest Control Products Act* Hazard Characterization

For assessing risks from potential residues in food or from products used in or around residential areas or schools, the *Pest Control Products Act* 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 prenatal and postnatal toxicity. A different factor may be determined to be appropriate on the basis of reliable scientific data.

With respect to the completeness of the toxicity database, no additional studies are required at this time. 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 as well as a reproductive toxicity study in rats.

With respect to concerns relevant to the assessment of risk to infants and children, sensitivity of the young was identified in the rat developmental toxicity study, in which effects noted in the offspring (delayed skeletal development and malformation in the form of bent scapula) occurred at a maternally non-toxic dose. This information was taken into account in determining the appropriate factors in the risk assessment.

Overall, the toxicological database for saflufenacil is adequate for determining the sensitivity of the young. In general, the 10-fold *Pest Control Products Act* factor is retained in situations for which malformations occur in the absence of maternal toxicity. In the case of saflufenacil, the significant skeletal malformation (bent scapula) in the rat developmental toxicity occurred at a relatively high dose when compared to the no observed adverse effect level (NOAEL) of 5 mg/kg bw/day used in risk assessment. Available historical control data indicated that this not an extremely rare malformation; it has been recorded in up to 2.6% of fetuses of this strain of rat. The occurrence in the high-dose group (5.1%) was outside the range (0–2.6%), but not at the mid-dose (1%), which is the established LOAEL. No adverse developmental effects were observed in the rabbit teratology study. Thus, overall, the level of concern for the malformation

is lessened. Consequently, the *Pest Control Products Act* factor is retained but a reduction of the factor to threefold is considered appropriate.

Results of the acute and chronic tests conducted on laboratory animals with saflufenacil technical and its associated end-use products, along with the toxicology endpoints for use in the human health risk assessment, are summarized in Appendix I, Table 2a, Table 2b and Table 3.

3.2 Determination of Acute Reference Dose

a. Acute reference dose determination for the general population

The NOAEL of 500 mg/kg bw established in the acute neurotoxicity is considered appropriate for the determination of the acute reference dose (ARfD) for the general population. At the LOAEL (2000 mg/kg bw), marginal decreased motor activity was observed in the male. A standard uncertainty factor of 100-fold is applied to account for the interspecies extrapolation and intraspecies variability. *The Pest Control Products Act* factor is reduced from 10-fold to 1-fold because the endpoint of concern with respect to the Act is applicable to developing fetuses in females of child-bearing ages only and does not apply to the general population. The composite assessment factor is 100.

The ARfD proposed is calculated according to the following formula:

$$ARfD = \frac{500\,mg/kg\,bw}{100} = 5\,mg/kg\,bw$$

b. Acute reference dose determination for females aged 13–49

For females aged 13–49, an ARfD of 0.017 mg/kg bw is determined based on the NOAEL of 5 mg/kg bw/day from the developmental toxicity study in the rat. At the LOAEL of 20 mg/kg bw/day, there was increased incidence of skeletal variation, delayed ossification and one incident of bent scapula, which is within the historical control values. The standard uncertainty of 100-fold to account for the interspecies extrapolation and intraspecies variability was applied in addition to the aforementioned reduced *Pest Control Products Act* factor of threefold. The composite assessment factor is 300.

The ARfD proposed is calculated according to the following formula:

$$ARfD = \frac{5\,mg/kg\,bw/d}{300} = 0.017\,mg/kg\,bw$$

3.3 Determination of Acceptable Daily Intake

a. Acceptable daily intake determination for the general population

The lowest NOAEL of 4.6 mg/kg bw/day was established in male mice in the 18-month dietary oncogenicity study. At the LOAEL of 13.8 mg/kg bw/day in male mice (female = 18.9 mg/kg bw/day), slight anemia was observed.

The ADI is determined based on the lowest NOAEL of 4.6 mg/kg bw/day and the standard uncertainty factor of 100 to account for the interspecies extrapolation and intraspecies variability. The *Pest Control Products Act* factor is reduced from 10-fold to 1-fold because the endpoint of concern with respect to the Act is applicable to developing fetuses in females of child-bearing ages only and does not apply to the general population. The composite assessment factor is 100.

The ADI proposed is calculated according to the following formula:

$$ADI = \frac{4.6\,mg/kg\,bw/d}{100} = 0.046\,mg/kg\,bw/d$$

b. Acceptable daily intake determination for females aged 13–49

The NOAEL of 5 mg/kg bw/day established in the rat developmental toxicity study is considered appropriate. At the LOAEL of 20 mg/kg bw/day, there was increased incidence of skeletal variation, delayed ossification and one incident of bent scapula, which is within the historical control values. The uncertainty factor applied included the standard 100-fold to account for the interspecies extrapolation and intraspecies variability, and the aforementioned reduced *Pest Control Products Act* factor of threefold. The composite assessment factor is 300.

The ADI proposed for females aged 13 to 49 is:

$$ADI = \frac{5\,mg/kg\,bw/d}{300} = 0.017\,mg/kg\,bw/d$$

3.4 Occupational and Residential Risk Assessment

3.4.1 Toxicological Endpoints

Short- and intermediate-term inhalation and dermal–to cover mixers, loaders, applicators (farmer and custom) and re-entry workers

The NOAEL of 5 mg/kg bw/day from the rat developmental toxicity study is considered the most appropriate endpoint for occupational risk assessment. The NOAEL is based on the observation of fetal effects including one incident of malformation (within historical control values) in the next higher dose level of 20 mg/kg bw/day (LOAEL). In addition, the value of

5 mg/kg bw/day is similar to the lowest NOAEL of 4.6 mg/kg bw/day from the mouse oncogenicity study. The worker population could include females of child-bearing age (13–49). For this reason, the residual uncertainty with respect to the possibility of effects in developing offspring is relevant, and an additional threefold factor is considered appropriate. The target Margin of Exposure (MOE) is 300, accounting for standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability, as well as the additional threefold factor. The selection of this study and MOE is considered to be protective of all populations including nursing infants and the unborn children of female workers who are exposed to products containing saflufenacil.

3.4.1.1 Dermal Absorption

In an in vivo rat study, the absorption, distribution and excretion (via urine and feces) of radioactivity was studied in male rats following a single dermal dose of a formulation containing ^{14}C-saflufenacil. Dose preparations resulted in nominal levels of 1.1723, 0.1172, and 0.0117 mg/cm^2. Three groups of 16 animals were dosed at one of each different dose levels, were exposed (duration between administration of dose and washing of the dose site) and sacrificed according to the following schedule:

Table 3.4.1.1.1 Schedule of Dermal Dose Exposure

Number of animals (16 animals total)	4	4	4	4
Duration of exposure (hours)	10	10	10	10
Sacrifice after (hours)	10	24	72	120

Mean recoveries of radioactivity from all dose groups were found to be acceptable in the range of 92 to 115.20% of the total radioactivity administered. The largest proportion of radioactivity was recovered from carcass and feces samples from the high-dose group. The mean relative amount of radioactivity absorbed (including urine, feces, cage wash, tissues/organs and carcass) showed a distinct time dependency in which skin-bound residues of ^{14}C-saflufenacil became systemically available over time and were not influenced by the dose level. A maximum apparent absorption (systemic absorption and skin-bound residues combined) of 82.55% was observed in the high-dose group after 10 hours of exposure and 120 hours sacrificed, based on the sum of skin at the application site, urine, feces, cage wash, blood cells, plasma, kidney, liver and carcass. All the high-dose groups showed signs of corrositivity due to the chosen formulation.

As a result, a value of 100% was considered appropriate for use in the dermal exposure assessment for Integrity since this formulation is nearly identical to the one tested. For both Heat WG and Eragon the default dermal absorption of 100% was reduced to 50%. This was based on these products not possessing the formulant that can cause skin corrositivity and the low apparent dermal absorption at the mid and low doses in the rat in vivo study.

3.4.2 Occupational Exposure and Risk

3.4.2.1 Exposure and Risk Assessment for mixing, loading and application

Farmers and custom pesticide applicators may be exposed to Heat WG, Eragon and Integrity when mixing, loading or applying these products to fields. Heat WG, Eragon and Integrity are applied at a range of 18 to 100 grams of active ingredient per hectare. A farmer can typically treat up to 150 hectares, while a custom applicator can typically treat up to 300 hectares per day, both using groundboom equipment. A farmer may be exposed for less than one week per year; a custom applicator may be exposed for up to a month over the course of a year.

Exposure estimates for mixers, loaders and applicators are based on data from the Pesticide Handlers Exposure Database (PHED) Version 1.1. PHED is a compilation of generic mixer/loader/applicator passive dosimetry data with associated software, which facilitates the generation of scenario-specific exposure estimates. Appropriate subsets of A and B grade data (high confidence) were created from the database files of PHED for either dry flowable liquid formulation types, open or closed mixing and loading, and open cab groundboom application. All data were normalized for kilograms of active ingredient handled. Exposure estimates are presented on the basis of the best-fit measure of central tendency (in other words, summing the measure of central tendency for each body part that is most appropriate to the distribution of data for that body part). Exposure estimates are based on unit exposure values from PHED, coupled with application rate and typical area treated per day inputs.

The exposure estimates are based on mixers and loaders wearing a single layer of clothing (long pants and long-sleeved shirt) and gloves or a single layer of clothing, coveralls and gloves. Applicator exposure estimates were based on a single layer of clothing (no gloves) or a single layer of clothing, gloves and chemical-resistant coveralls. Custom applicator exposure was also estimated using closed mixing and transferring equipment. The estimated worker exposure was based on a worker's body weight of 70 kg and dermal absorption of 100% or 50%, depending on the formulation.

For the short- to intermediate-term risk assessments, MOEs were generated based on the NOAEL of 5 mg/kg bw/day from the developmental toxicity study in rats. All MOEs are near or above the target MOE of 300; therefore, they are considered acceptable (Table 3.4.2.1.1).

Table 3.4.2.1.1 Exposure Summary for mixing, loading and application

Scenario	Maximum application rate (g a.i./ha)	ATPD (ha/day)	Amount of a.i. handled per day (kg a.i./day) [1]	Total dermal and inhalation exposure (µg a.i./kg bw/day) [2]	MOE [3]
Heat WG					
Farmer M/L/A	50	150	7.5	10.75	465
Custom M/L		300	15	10.07	497
Custom A			15	3.74	1337
Eragon					
Farmer M/L/A	100	150	15	13.81	362
Custom M/L		300	30	17.06	293
Custom A				7.48	669
Integrity					
Farmer M/L/A	75	150	11.25	13.93	359
Custom M/L		300	22.5	16.95	295
Custom A			22.5	10.91	458

[1] Amount of active ingredient (a.i.) handled per day is calculated by multiplying the application rate by the Area Treated Per Day (ATPD).

[2] Daily exposure was calculated using amount of a.i. handled per day multiplied by PHED unit exposure value divided by 70kg body weight; dermal absorption = 100% via inhalation and 50% or 100% (depending on the formulation) via dermal exposure.

[3] Exposure estimates for mixing, loading and application were compared to a NOAEL of 5 mg/kg bw/day established from the developmental toxicity study in rats, target MOE = 300.

3.4.2.2 Exposure and Risk Assessment for Workers Entering Treated Areas

Postapplication exposure to saflufenacil is expected to be minimal since Heat WG, Eragon and Integrity are applied directly to the ground using a groundboom sprayer either before the crop has been planted or after it has been planted but before emergence. Residues on the leaves are expected to be negligible. As a result, a postapplication risk assessment is not required.

3.4.3 Bystander Exposure and Risk

Bystander exposure is expected to be negligible when the label directions are followed. Label statements include directions to reduce potential drift to human habitation or to areas in which human activity occurs such as houses, cottages, schools or parks.

3.5 Food Residues Exposure Assessment

3.5.1 Residues in Plant and Animal Foodstuffs

The residue definition for risk assessment and enforcement in plant products is: saflufenacil and the metabolites M800H11 and M800H35, expressed as saflufenacil equivalents. The data gathering/enforcement analytical methodology D0603/02 (LC/MS-MS) is valid for the quantification of saflufenacil and the metabolites M800H11 and M800H35 residues in crop matrices. The residues of saflufenacil and the metabolites M800H11 and M800H35 are relatively stable when stored in a freezer at <-5°C for 548 to 553 days.

Raw agricultural commodities were processed, but were not further analyzed due to the lack of quantifiable residues in apples, wheat grain, field corn grain, rice grain, sweet sorghum stalks, grapes, oranges (oil analyzed but not juice and pulp), plums and soybean seed. The processing factors could not be determined for cotton and oranges (oil) as residues of saflufenacil and the metabolites M800H11 and M800H35 were each less than the limit of quantitation in the raw commodities and processed fractions.

Residues of saflufenacil and the metabolites M800H11 and M800H35 did not concentrate in sunflower meal or refined oil. Supervised residue trials conducted throughout the United States and Canada using end-use products containing saflufenacil at the label rates and at exaggerated rates in or on legume vegetables (Crop Group 6), citrus fruits (Revised Crop Group 10), pome fruits (Crop Group 11), stone fruits (Crop Group 12), tree nuts (Crop group 14), cereal grains (Crop group 15), cotton, grapes and sunflower seeds are sufficient to support the proposed maximum residue limits.

The residue definition for risk assessment and enforcement purposes is: saflufenacil in livestock commodities. The data gathering/enforcement analytical methodology L0073/01 (LC-MS/MS) is valid for the quantitation of saflufenacil residues in livestock commodities. Residues of saflufenacil were demonstrated to be stable in bovine matrices for 51 days (whole milk), 31 days (muscle), 32 days (liver and kidney) and 35 days (fat) when stored in a freezer at $\leq$-18^{o}C.The potential for secondary transfer of saflufenacil residues in meat, milk and eggs exist because there are feedstuffs associated with the proposed uses on apples, almonds, citrus, cereal grains, cotton, legumes and sunflowers. The data from the dairy cattle feeding study indicate that residues of saflufenacil are expected at below the limit of quantitation in fat, meat and milk, and above the limit in liver and meat byproducts (except liver) as a result of feeding livestock treated with saflufenacil. An acceptable science based rationale was submitted to waive the data requirements for a poultry feeding study. The results of the hen metabolism study indicate that there is no reasonable expectation of finite residues of saflufenacil in the meat, meat byproducts and eggs of poultry as a result of the proposed uses.

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 basic chronic dietary exposure (through food alone) from all supported saflufenacil food uses for the total population, including infants and children, and all representative population subgroups is 0.5–3.2% of the ADI. Aggregate exposure from food and water is considered acceptable. The PMRA estimates that chronic dietary exposure to saflufenacil from food and water is 7.6% (3.517 µg/kg bw/day) of the ADI for the total population. The highest exposure and risk estimate is for all infants <1 year at 24.4% (11.223 µg/kg bw/day) of the ADI.

3.5.2.2 Acute Dietary Exposure Results and Characterization

The basic acute dietary exposure from all supported saflufenacil food uses is estimated to be 3.86% (0.0657 µg/kg bw/day) of the ARfD for females 13–49 years old (95th percentile, deterministic) and ≤0.06% (≤3.097 µg/kg bw/day) of the ARfD for all other population subgroups (95th percentile, deterministic). Aggregate exposure from food and water is considered acceptable at 44.37% of the ARfD (7.542 µg/kg bw/day) for females 13–49 years old (95th percentile, deterministic) and ≤0.61% (≤30.696 µg/kg bw/day) of the ARfD for all other population subgroups (95th percentile, deterministic).

3.5.3 Aggregate Exposure and Risk

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

3.5.4 Maximum Residue Limits

Table 3.5.4.1 Proposed Maximum Residue Limits (for residues of saflufenacil and the metabolites M800H11 and M800H35)

Commodity	Recommended MRL (ppm)
Sunflower seeds	1.0
Legume vegetables (Crop Group 6), citrus fruits (Revised Crop Group 10), pome fruits (Crop Group 11), stone fruits (Crop Group 12), tree nuts (Crop Group 14), cereal grains (Crop Group 15), grapes, undelinted cotton seeds	0.03

Table 3.5.4.2 Proposed Maximum Residue Limits (for saflufenacil)

Commodity	Recommended MRL (ppm)
Liver of cattle, goats, hogs, horses and sheep	0.8
Meat byproducts (except liver) of cattle, goats, hogs, horses and sheep	0.02
Fat and meat of cattle, goats, hogs, horses and sheep; milk	0.01

The nature of the residues in animal and plant matrices, analytical methodology, field trial data, processing studies and the acute and chronic dietary risk estimates are summarized in Appendix I, Table 1, Table 4 and Table 5.

See Appendix II for a list of crop group commodities.

For additional information on MRLs in terms of the international situation and trade implications, refer to Appendix III.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

4.1.1 Soil

Saflufenacil enters the soil when used as a herbicide for various field and row crops. Saflufenacil is non-persistent to slightly persistent in soil with dissipation time to 50% (DT_{50}) values of 8.6–26 days under laboratory conditions and 1.4-36 days under field conditions. Biotransformation is the major route of transformation under aerobic conditions which can be divided into four main parallel reactions: demethylation at the sulfonylurea side chain; demethylation at the uracil ring; opening of the uracil ring followed by cleavage of low molecular weight fragments; or reduction of the uracil ring (Figure 1). The major transformation products formed by these reactions were M800H01, M800H02, M800H07, M800H08, M800H22, M800H26, and M800H31 (see Table 6 for structures and maxima). Of these products, M800H01, M800H02, M800H07, and M800H08 were detected under field conditions and remain structurally similar to saflufenacil.

The combined residues of saflufenacil with these four major transformation products are persistent in soil with half-life of 562-2180 days under laboratory conditions. By itself, M800H08 was persistent under laboratory conditions in aerobic soil with a half-life of 433 days and slightly to moderately persistent under field conditions with half-life of 34–149 days.

Under alkaline conditions, saflufenacil hydrolyses relatively quickly with a half-life of 4.93 days. Therefore, hydrolysis may be an important contributor to transformation of saflufenacil in alkaline soil, but it is not an important pathway under neutral (half-life of 248 days) or acidic conditions (stable). Additional transformation products that might be observed in alkaline soil as a result of hydrolysis include M800H04, M800H15 and M800H33 (trifluoroacetone). Soil

photolysis is not an important transformation pathway in the environment as indicated by a relatively long half-life of 66–87 days. Under anaerobic soil conditions, saflufenacil was persistent with a half-life of 217 days. The major transformation products under anaerobic soil conditions were M800H01, M800H02 and M800H08.

Saflufenacil and its transformation products do not strongly bind to soil particles and are potentially mobile in soil. The potential for binding to soil is not dependent on pH. In field studies, saflufenacil and M800H08 leached to soil depths greater than 60 cm, while M800H01, M800H02 and M800H07 were not detected below 15 cm. Saflufenacil and its transformation products have a combination of properties that favour leaching (persistence, high solubility, low binding potential and low volatility) which indicate they have high potential to reach groundwater and aquatic systems.

4.1.2 Water

Saflufenacil and its transformation products could reach surface water systems by spray drift or runoff. Saflufenacil is slightly to moderately persistent in aquatic systems with laboratory-derived half-lives of 29–71 days. The rate of dissipation in aquatic systems is less dependent on aerobic/anaerobic conditions of the system and more dependent on pH of the water (due to rapid hydrolysis at higher pH) and the water depth. The rate of dissipation in shallow water bodies (less than 9 cm) is expected to be significantly enhanced by sunlight (half-life of 3.6 days). Saflufenacil transforms in water by opening of the uracil ring to form M800H07 and subsequently small four-carbon fragments that remain in the water (Figure 2). Transformation continues by cleavage of the four-carbon fragment to form trifluoroacetone (M800H33), which decarboxylates to trifluoroacetic acid (M800H29). The majority of the residues remain in the water phase. Combined residues of saflufenacil and M800H07 are relatively stable in aquatic systems; however, they were not persistent in a shallow irradiated system (half-life of 15 days).

By themselves, M800H07 and the small cleavage product M800H29 (trifluoroacetic acid) are relatively stable in most aquatic systems; however, M800H07 was only slightly persistent in a shallow irradiated system (half-life of 18 days). M800H29 (trifluoroacetic acid) is a member of the haloacetic acid class of compounds and is known to be a persistent aquatic contaminant as a breakdown product of hydrochlorofluorocarbons and hydrofluorocarbons. The hydrolysis product M800H15 is expected to be a persistent product (half-life of 228 days) in alkaline aquatic environments (pH >8), but it is not expected to be important in neutral and acidic water. M800H33 (trifluoroacetone) is not persistent in aquatic systems (half-life of 1.6–11 days).

4.1.3 Sediment

Although the majority of saflufenacil remained in the water, 6-16% of applied radioactivity partitioned to the sediment in the aquatic systems where it was stable under aerobic conditions dissipated under anaerobic conditions (half-life of 24 days) and dissipated in a shallow irradiated system (half-life of 4.9 days). M800H07 is expected to be the only transformation product that could accumulate in the sediment. While it remained at low levels (<5% of applied radioactivity) in the sediment of the aerobic aquatic systems, it reached 13% of applied radioactivity in the sediment of the anaerobic system with a slow rate of dissipation (half-life of 320 days).

4.1.4 Air

Saflufenacil is non-volatile and is not expected to be transported long distances in the air. In the anaerobic aquatic systems, considerable amounts of M800H33 (trifluoroacetone) and 1,1,1-trifluoro-2-propanol volatilized. These products are known to be highly volatile (Betterton, 1991; Nelly and Blau, 1985; Rochester and Symonds, 1973). Based on their estimated atmospheric OH rate constants (Atkinson, 1989; Meylan and Howard, 1993), atmospheric half-lives were calculated to be 708-1063 days for M800H33 (trifluoroacetone) and 14–20 days for 1,1,1-trifluoro-2-propanol. Therefore, the transformation products M800H33 (trifluoroacetone) and 1,1,1-trifluoro-2-propanol that would primarily be formed in aquatic systems have potential for long-range transport.

4.1.5 Biota

Saflufenacil is unlikely to bioaccumulate, as indicated by relatively low log K_{ow} of 2.6 and a bioconcentration factor of 4.6 for total radioactive residues in whole fish. The transformation products M800H01, M800H02, M800H07 and M800H08 are also unlikely to bioaccumulate. This conclusion is based on the rat metabolism study, which indicated no tendency of saflufenacil or its metabolites (including M800H01, M800H02, M800H07 and M800H08) to bioaccumulate.

The estimated log K_{ow} values of the major transformation products M800H15 and M800H22 were 3.24 and 3.58 (United States Environmental Protection Agency, 2009), which indicate these substances have some potential for bioconcentration. M800H15 is expected to be a persistent product in alkaline aquatic environments (pH >8), but it is not expected to be present in other environments. Considering M800H22 was a major product in aerobic soil only and its precursor M800H08 is persistent, highly mobile and is expected to move quickly from the upper aerobic soil layer, M800H22 is not expected to be formed at detectable concentrations in the environment. In addition, M800H22 was not detected in the field studies. Therefore, there are no critical concerns with respect to bioaccumulation of M800H15 or M800H22.

The estimated log K_{ow} values of the major transformation products M800H29 (trifluoroacetic acid), M800H33 (trifluoroacetone), and 1,1,1-trifluoro-2-propanol were 0.50, 0.20 and 0.71, respectively (United States Environmental Protection Agency, 2009), which indicate these substances are unlikely to bioconcentrate or bioaccumulate.

In summary, identification of the major transformation products are summarized in Appendix I, Table 6. Data on the environmental fate and behaviour of saflufenacil and its transformation products are summarized in Appendix I, Table 7.

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 exposure concentrations (EECs) measure a pesticide in various environmental media such as food, water, soil and air. The EECs 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 are adjusted according to Appendix I, Table 11 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 or specific uses that do not pose a risk to non-target organisms and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (for example, direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value, 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 saflufenacil to terrestrial organisms was based upon the evaluation of toxicity data for the following (see Appendix I, Table 8 for toxicity data):

- one earthworm species (acute exposure) and one bee species (oral or contact exposure) representing invertebrates;
- two bird and one mammal species representing vertebrates (acute, short-term or long-term exposure); and
- 10 crop species representing non-target vascular plants.

Additional toxicity data are also available for the major soil transformation products M800H07 and M800H08 and for representative end-use products formulated as water dispersible granules or an emulsifiable concentrate (see Appendix I, Table 8 for toxicity data). The emulsifiable concentrate formulation contains saflufenacil and another herbicidal active ingredient, dimethenamid-P.

4.2.1.1 Invertebrates

There are no concerns about the use of saflufenacil affecting earthworms or bees. Saflufenacil and the major soil transformation product M800H08 are non-toxic to earthworms up to a concentration of 1000 mg/kg dry soil. Saflufenacil and its representative WG formulation are practically non-toxic to honey bees when exposed by contact or by ingestion. At an application rate of 100 g saflufenacil/ha, all screening level risk quotient values are less the level of concern (Appendix I, Table 13).

4.2.1.2 Birds and small wild mammals

There are no concerns about the use of saflufenacil affecting birds or small wild mammals. Saflufenacil is practically non-toxic to birds and mammals when exposed by acute or short-term ingestion. Reproductive effects observed in birds following chronic dietary exposure to saflufenacil were reduced hatchling body weight in the bobwhite quail study (NOEL of 7.3 mg a.i./kg bw/day) and reduced proportion of live three-week embryos to viable embryos in the mallard duck study (NOEL of 37 mg a.i./kg bw/day). The effect on hatchling body weight in the bobwhite quail was no longer apparent after 14 days. Reproductive effects observed in the rat following chronic dietary exposure to saflufenacil were increased stillborn pups, increased pup mortality during the early phase of lactation, reduced pup weight gains, and anemia (NOEL of 15 mg a.i./kg bw/day). Anemia is not a surprising effect considering saflufenacil inhibits the last common enzyme (protoporphyrinogen-oxidase) in the heme and biosynthetic pathways. The screening level risk assessment for birds and small wild mammals assessed dietary exposure to saflufenacil in potential food items within the treated field immediately after application of 100 g saflufenacil/ha (Appendix I, Table 12). All screening level risk quotient values for acute, short-term and long-term effects were less than the level of concern (Appendix I, Table 13).

4.2.1.3 Non-target plants

Saflufenacil may impact non-target terrestrial plants adjacent to the treatment area. Saflufenacil is selectively toxic to non-target terrestrial plants with plant biomass being the effect of most concern. Two wettable granule formulations of saflufenacil were tested on each of 10 crop species. Bean, corn, soybean and wheat are largely unaffected when saflufenacil is applied before emergence. Onion and ryegrass may show some sensitivity to saflufenacil following pre-emergent exposure. The most sensitive species following pre-emergent exposure, in order of most to least sensitive, were cabbage, oilseed rape, lettuce and tomato (average ER_{50} of 7.1–15 g a.i./ha). Saflufenacil is much more toxic to non-target plants when they have already emerged, and all test species were affected. In order of most to least sensitive, the most sensitive species were lettuce, tomato, bean, soybean, and cabbage (average ER_{50} of 0.41–5.5 g a.i./ha). Oilseed rape and onion had medium sensitivity relative to the other species (ER_{50} of 10–12 g a.i./ha),

while corn, wheat, and ryegrass were the least sensitive species following post-emergent exposure (average ER_{50} of 32–112 g a.i./ha).

A species sensitivity distribution of the post-emergent exposure data was used to assess the impact on off-field terrestrial habitats. For drift exposure to application rates ranging from 18 to 100 g saflufenacil/ha, all risk quotient values exceeded the level of concern (Appendix I, Table 15). Therefore, risk mitigation is necessary for the protection of non-target terrestrial plants adjacent to the treatment area. Based on the risks identified, spray buffer zones of 4 to 15 metres are required for application rates ranging 18 to 100 g saflufenacil/ha.

There are no concerns about major soil transformation products M800H07 and M800H08 affecting non-target terrestrial plants. Seedling emergence studies indicate that M800H07 does not have herbicidal activity, while M800H08 has limited herbicidal activity relative to the parent compound saflufenacil. Phytotoxic symptoms of M800H08 exposure, such as stunting, necrosis, and chlorosis, were most prevalent in the bean and tomato. The tomato was the only species that exhibited 50% inhibition of plant biomass below the highest test concentration (0.3846 mg/kg dry weight).

A soil incorporation depth of 5 cm was used for a screening level assessment because some infiltration of the transformation products in the soil is expected. At an application rate of 100 g saflufenacil/ha and assuming complete conversion from parent to either transformation product, both screening level risk quotient values were less than the level of concern (Table 13).

4.2.2 Effects on Aquatic Organisms

Risk of saflufenacil to aquatic organisms was based upon the evaluation of toxicity data for the following (see Appendix I, Table 9 and Table 10 for toxicity data):

- two freshwater and two estuarine/marine invertebrate species (acute or chronic exposure)
- three freshwater and one estuarine/marine fish species (acute or early life stage exposure)
- three freshwater and one estuarine/marine algal species
- one vascular plant species

Additional toxicity data are also available for the major soil transformation products M800H07 and M800H08 and for the representative end-use product that also contains another herbicidal active ingredient, dimethenamid-P (see Appendix I, Table 9 and Table 10 for toxicity data).

4.2.2.1 Freshwater Fish and Aquatic Invertebrates

There are no concerns about saflufenacil use affecting fish or aquatic invertebrates in freshwater habitats. Saflufenacil is practically non-toxic to freshwater species *Daphnia magna*, rainbow trout and bluegill sunfish. Following chronic exposure to saflufenacil, biologically significant mortality (30%) of adult *Daphnia magna* and reduced length of surviving adults were observed at 2.6 mg a.i./L (NOEC of 1.3 mg a.i./L); a slight (5%) but statistically significant reduction in embryo survival of fathead minnow was observed at 3.3 mg a.i./L (NOEC of 1.0 mg a.i./L).

Following chronic exposure to saflufenacil in sediment, a biologically significant reduction in emergence rate (17%) of the non-biting midge *Chironomus riparius* was observed at initial measured concentrations of 2.8 mg a.i./kg dry sediment, 18 mg a.i./L in pore water, and 1.2 mg a.i./L in overlying water (NOEC of 0.65 mg a.i./L in overlying water is used for screening level risk assessment). Assuming direct application of 100 g saflufenacil/ha to aquatic habitat, all screening level risk quotient values for acute or chronic exposure were less than the level of concern (Appendix I, Table 14).

There are no concerns about the use of the Integrity formulation affecting fish or aquatic invertebrates. Integrity is slightly toxic to *Daphnia magna* and rainbow trout. In the absence of chronic toxicity data on the whole formulation, the estimated early life stage toxicity of the active ingredient dimethenamid-P on rainbow trout causing reduced larval growth was used (NOEC of 0.3 mg dimethenamid-P/L). Assuming direct application of 1100 mL product/ha to aquatic habitat, all screening level risk quotient values were less than the level of concern (Appendix I, Table 14).

4.2.2.2 Freshwater Plants

There are no concerns about use of saflufenacil affecting algae or aquatic vascular plants in freshwater habitats. Dose-response relationships were observed between saflufenacil and aquatic plants. Green algae and duckweed were the most sensitive (EC_{50} of 0.042–0.087 mg a.i./L), freshwater diatoms also showed some sensitivity (EC_{50} of 1.8 mg a.i./L), while blue-green algae had only slight sensitivity (EC_{50} of 37 mg a.i./L). Aquatic plants were not sensitive to the major transformation product M800H07, and were only slightly sensitive to M800H08 (EC_{50} of 12–25 mg/L). However, the effect of M800H08 on algae was confounded by the presence of a fine white precipitate in the only treatment that showed adverse effects. Phytotoxicity (necrosis, chlorosis or root destruction) of both saflufenacil and M800H08 to duckweed was also observed. Assuming direct application of 100 g saflufenacil/ha to aquatic habitat, all screening level risk quotient values were less than the level of concern (Appendix I, Table 14).

The Integrity formulation may impact freshwater algae adjacent to the treatment area. Aquatic vascular plants are also sensitive to the formulation. Green algae and duckweed were very sensitive to the Integrity formulation (EC_{50} of 0.014–0.023 mg product/L). In the absence of toxicity data on the whole formulation to estuarine/marine algae, data on the active ingredient dimethenamid-P was used (EC_{50} of 0.12 mg dimethenamid-P/L). Assuming direct application of 1100 mL product/ha to aquatic habitat, all screening level risk quotient values exceeded the level of concern indicating aquatic plants are sensitive to the formulation (Appendix I, Table 14). For exposure to drift deposit on aquatic habitats adjacent to the treatment area, the off-field risk quotient values were less than the level of concern for estuarine/marine algae and aquatic vascular plants, but they still exceeded the level of concern for freshwater algae (Appendix I, Table 15). Therefore, risk mitigation is necessary for the protection of freshwater algae. Based on the risks identified and the sensitivity of the remaining aquatic plant species, a buffer zone of one metre is required for the protection of aquatic habitats adjacent to the treatment area.

4.2.2.3 Estuarine and marine organisms

There are no concerns about use of saflufenacil affecting fish, aquatic invertebrates, or algae in estuarine/marine habitats. In estuarine/marine habitats, the salinity of the water limits the solubility of saflufenacil. Saflufenacil is slightly toxic to the saltwater mysid *Americamysis bahia*, while the major transformation product M800H07 is practically non-toxic to this species. Saflufenacil is practically non-toxic to the Eastern oyster and fish at the limit of solubility. A dose-response relationship was observed between saflufenacil and the marine diatom with an EC_{50} of 0.18 mg a.i./L. Assuming direct application of 100 g saflufenacil/ha to aquatic habitat, all screening level risk quotient values were less than the level of concern (Appendix I, Table 14).

Estuarine/marine algae may be sensitive to the Integrity formulation. In the absence of toxicity data on the whole formulation to estuarine/marine algae, data on the active ingredient dimethenamid-P was used (EC_{50} of 0.12 mg dimethenamid-P/L). Assuming direct application of 1100 mL product/ha to aquatic habitat, the screening level risk quotient value exceeded the level of concern indicating estuarine/marine algae are sensitive to the formulation (Appendix I, Table 14). For exposure to drift deposit on aquatic habitats adjacent to the treatment area, the off-field risk quotient value was less than the level of concern (Appendix I, Table 15). To address the potential sensitivity of estuarine/marine algae to the Integrity formulation, a default buffer zone of one metre is required for estuarine/marine habitats.

4.2.2.4 Amphibians

There are no concerns about the use of saflufenacil affecting amphibians. The early life stage fish toxicity data were used as surrogate data for toxicity to amphibians. Assuming direct application of 100 g saflufenacil/ha to a shallow seasonal water body, the screening level risk quotient value was less than the level of concern (Appendix I, Table 14).

Amphibians may be sensitive to the Integrity formulation. The estimated early life stage fish toxicity data for dimethenamid-P were used as surrogate data for amphibians. Assuming direct application of 1100 mL product/ha to a shallow seasonal water body, the screening level risk quotient value exceeded the level of concern indicating amphibians may be sensitive to the formulation (Appendix I, Table 14). For exposure to drift deposit on shallow seasonal water bodies adjacent to the treatment area, the off-field risk quotient values were less than the level of concern, indicating no concern about the formulation impacting amphibians in habitats adjacent to the treatment area (Appendix I, Table 15). To address the potential sensitivity of amphibians to the Integrity formulation, a default buffer zone of one metre is required for seasonal water bodies.

5.0 Value

5.1 Effectiveness Against Pests

5.1.1 Acceptable Efficacy Claims for Heat WG

Efficacy data were submitted from 104 replicated field trials conducted from 2004 to 2007 at several locations in Alberta, Saskatchewan and Manitoba. Various rates of saflufenacil were assessed to determine the lowest effective rate. The herbicide treatments were applied using small plot application equipment.

The efficacy of Heat WG was visually assessed as percent weed control and compared to an untreated weedy check. Observations were made up to four times throughout the growing season. The data support the weed control claims summarized in Table 5.1.1.1 when Heat WG was applied as a preseed or pre-emergence treatment or in chemfallow.

Table 5.1.1.1 Weed Control Claims for Heat WG

Herbicide Rate	Weeds Controlled
18 g a.i./ha + 0.5 L/ha of Merge	kochia, Canada fleabane, lamb's quarters, redroot pigweed, round-leaved mallow, stinkweed, volunteer canola (all herbicide tolerant types including Roundup Ready), wild buckwheat, wild mustard
50 g a.i./ha + 0.5 L/ha of Merge	redroot pigweed, stinkweed, wild buckwheat, wild mustard

5.1.2 Acceptable Efficacy Claims for Eragon

Efficacy data were submitted from 90 trials conducted from 2004 to 2007 at multiple locations in Québec, Ontario and Manitoba. The herbicide treatments were applied using small plot application equipment.

The efficacy of Eragon was visually assessed as percent weed control and compared to an untreated weedy check. Observations were made up to four times throughout the growing season. The data support the weed control claims summarized in Table 5.1.2.1.

Table 5.1.2.1 Weed Control Claims for Eragon

Timing	Herbicide Rate	Weeds Controlled	Weeds Suppressed
Preplant burndown in cereals and soybeans	25 g a.i./ha + 1% v/v* of Merge	Canada fleabane, common ragweed, lamb's quarters, redroot pigweed, wild mustard	Dandelion
Preplant burndown and suppression of secondary weed flushes in cereals	50 g a.i./ha + 1% v/v of Merge	lamb's quarters, redroot pigweed, stinkweed, wild buckwheat wild mustard	Not Applicable
Preplant or pre-emergence burndown in corn	50 to 100 g a.i./ha + 1% v/v of Merge	common ragweed, lamb's quarters, redroot pigweed, velvetleaf, wild buckwheat, wild mustard	Not Applicable

* Volume per volume dilution

5.1.3 Acceptable Efficacy Claims for Integrity

Efficacy data were submitted from 58 trials conducted from 2004 to 2007 at multiple locations in Québec, Ontario and Manitoba. The herbicide treatments were applied using small plot application equipment.

The efficacy of Integrity was visually assessed as percent weed control and compared to an untreated weedy check. Observations were made up to four times throughout the growing season. The data support the weed control claims summarized in Table 5.1.3.1 with water or liquid nitrogen fertilizer as a carrier.

Table 5.1.3.1 Weed Control Claims for Integrity

Timing	Herbicide Rate	Weeds Controlled
Pre-emergence	488 g a.i./ha (50 g a.i./ha of saflufenacil + 438 g a.i./ha of dimethenamid-P)	Common ragweed, crabgrass (smooth and large, fall panicum, foxtail (green, yellow, giant), lamb's quarters, redroot pigweed, velvetleaf, wild buckwheat and wild mustard
Pre-emergence or preplant incorporated	735 g a.i./ha (75 g a.i./ha of saflufenacil + 660 g a.i./ha of dimethenamid-P)	Barnyard grass, common ragweed, crabgrass (smooth and large), Eastern black nightshade, fall panicum, foxtail (green, yellow, giant), lamb's quarters, redroot pigweed, yellow nutsedge, old witchgrass, velvetleaf, wild buckwheat and wild mustard

5.1.4 Herbicide Tank-mix Combinations

5.1.4.1 Heat WG

Data from 104 replicated field trials conducted from 2004 to 2007 at several locations in Alberta, Saskatchewan and Manitoba were submitted in support of the proposed tank-mix. Some trials included multiple varieties or hybrids, and many trials included treatments of Heat WG applied at two times the label rate.

The efficacy of Heat WG was visually assessed as percent weed control and compared to an untreated weedy check. Observations were made up to four times throughout the growing season. The data support the tank mixture with Heat WG for the uses in Table 5.1.4.1.1.

Table 5.1.4.1.1 Acceptable Tank Mixtures for Heat WG

Crop	Tank-mix
Lentils and Soybeans	Heat WG at 18 g a.i./ha + glyphosate* at 450 to 900 g a.i./ha + Merge or Amigo at 0.5 L/ha
Barley, Canary seed, Chickpeas, Oats, Dried Field Peas, Spring Wheat, Durum Wheat, Winter Wheat, Field Corn and Sweet Corn	Heat WG at 18 to 50 g a.i./ha + glyphosate* at 450 to 900 g a.i./ha + Merge or Amigo at 0.5 L/ha.

* Only products in which glyphosate is present as isopropylamine salt, di-ammonium salt or potassium salt are acceptable.

5.1.4.2 Eragon

Data from 90 trials conducted from 2004 to 2007 at multiple locations in Québec, Ontario, and Manitoba were submitted in support of the proposed tank-mixes. Some trials included multiple varieties or hybrids, and many trials included treatments of Eragon applied at two times the label rate.

The efficacy of Eragon was visually assessed as percent weed control and compared to an untreated weedy check. Observations were made up to four times throughout the growing season. The data support the tank mixtures with Eragon for the uses in Table 5.1.4.2.1.

Table 5.1.4.2.1 Acceptable Tank Mixtures for Eragon

Crop	Tank-mix
Barley, Spring Wheat, Durum Wheat and Winter Wheat	Eragon at 25 g a.i./ha + glyphosate* at 900 g a.i./ha + Merge at 1% v/v
Soybeans	Eragon at 25 g a.i./ha + glyphosate* at 900 g a.i./ha + Merge at 1% v/v
	Eragon at 25 g a.i./ha + glyphosate* at 900 g a.i./ha + Pursuit at 100 g a.i./ha + Merge at 1% v/v
Field Corn and Sweet Corn	Eragon at 50 to 100 g a.i./ha + glyphosate* at 900 g a.i./ha + Merge at 1% v/v
	Eragon at 50 or 75 g a.i./ha + Frontier Max Herbicide at 660 g a.i./ha applied as a pre-emergence or preplant incorporated application

* All glyphosate products in which glyphosate is present as isopropylamine salt, di-ammonium salt or potassium salt only.

5.1.4.3 Integrity

Data from 58 trials conducted from 2004 to 2007 at multiple locations in Québec, Ontario, and Manitoba were submitted in support of the proposed tank-mix. Some trials included multiple hybrids, and many trials included treatments of Integrity applied at two times the label rate.

The efficacy of Integrity was visually assessed as percent weed control and compared to an untreated weedy check. Observations were made up to four times throughout the growing season. The data support the tank mixture with Integrity for uses summarized in Table 5.1.4.3.1 with water or liquid nitrogen fertilizer as a carrier.

Table 5.1.4.3.1 Acceptable Tank Mixture for Integrity

Crop	Tank-mix
For Use in Field and Sweet Corn	Integrity at 735 g a.i./ha + Aatrex Liquid 480 at 750 g a.i./ha

5.1.5 Water Volumes

Heat WG data were generated in field trials in which it was applied in the proposed spray volume range of 50 to 100 L/ha. Eragon and Integrity data were generated in field trials in which they were applied in the proposed spray volume range of 100 to 200 L/ha.

The data support the application of Heat WG in a minimum water volume of 50 L/ha and a maximum of 100 L/ha for application with ground equipment.

The data support the application of Eragon and Integrity in a minimum water volume of 100 L/ha and a maximum of 200 L/ha for application with ground equipment.

5.2 Phytotoxicity to Host Plants

5.2.1 Heat WG

Data from 48 dedicated weed-free tolerance trials along with data from 52 efficacy trials conducted from 2004 to 2007 at multiple locations in Ontario, Alberta, Saskatchewan and Manitoba were submitted in support of the host crop tolerance claims. Some trials included multiple crops or varieties, and all dedicated tolerance trials included treatments of Heat WG applied at two times the maximum proposed rate.

Crop injury (by percentage) was visually assessed up to four times during the growing season, and crop yield—expressed as a percentage of a weed-free check—was reported in most dedicated tolerance trials.

Crop injury to lentils and soybeans was acceptable at the maximum application rate of 18 g a.i./ha. Crop injury to barley, canary seed, chickpeas (Kabuli type only), oats, dried field peas, spring wheat, winter wheat, durum wheat, field corn and sweet corn was acceptable at the maximum application rate of 50 g a.i./ha.

5.2.2 Eragon

Data from 23 dedicated weed-free tolerance trials along with data from 36 efficacy trials conducted from 2004 to 2007 at multiple locations in Ontario, Québec and Manitoba were submitted in support of the host crop tolerance claims of soybeans. Some trials included multiple cultivars, and all dedicated tolerance trials included treatments of Eragon applied at two times the maximum proposed rate.

Data from 16 dedicated weed-free tolerance trials along with data from 55 efficacy trials conducted from 2004 to 2007 at multiple locations in Ontario, Québec and Manitoba were submitted in support of the host crop tolerance claims of field corn. Some trials included multiple hybrids, and all dedicated tolerance trials included treatments of Eragon applied at two times the maximum proposed rate.

Data from eight dedicated weed-free tolerance trials conducted from 2005 to 2007 at multiple locations in Ontario were submitted in support of the host crop tolerance claims of sweet corn. Some trials included multiple hybrids, and all dedicated tolerance trials included treatments of Eragon applied at two times the maximum proposed rate.

Crop injury was visually assessed up to four times during the growing season, and crop yield—expressed as a percentage of a weed-free check—was reported in most dedicated tolerance trials.

Crop injury to soybeans was acceptable at the maximum application rate of 25 g a.i./ha. Crop injury to barley, spring wheat, winter wheat and durum wheat was acceptable at the maximum application rate of 50 g a.i./ha. Crop injury to field and sweet corn was acceptable at the maximum rate of application of 100 g a.i./ha.

5.2.3 Integrity

Data from 16 dedicated weed-free tolerance trials conducted from 2004 to 2007 at multiple locations in Ontario and Québec were submitted in support of the host crop tolerance claims of field corn. Some trials included multiple hybrids, and most dedicated tolerance trials included treatments of Integrity applied at two times the maximum proposed rate.

Data from 8 dedicated weed-free tolerance trials conducted from 2005 to 2007 at multiple locations in Ontario were submitted in support of the host crop tolerance claims of sweet corn. Some trials included multiple hybrids, and most dedicated tolerance trials included treatments of Integrity applied at two times the maximum proposed rate.

Crop injury was visually assessed up to four times during the growing season. Marketable yield of sweet corn—expressed as a percentage of a weed-free check—was reported in some sweet corn tolerance trials. Yield of field corn, expressed as a percentage of a weed-free check, was reported in most field corn dedicated tolerance trials.

Crop injury to field and sweet corn was acceptable at the maximum application rate of 100 g a.i./ha.

5.3 Impact on succeeding Crops

Rotational crop tolerance data were submitted from 25 trials initiated between six months and one year following an application of saflufenacil. The number of trials, in which tolerance was evaluated, varied by rotational crop. Some trials included multiple crops and multiple varieties or hybrids of one crop. Trials were conducted in Alberta, Saskatchewan and Manitoba.

5.3.1 Acceptable Claims for Rotational Crops for Saflufenacil

The crop injury and yield data support a plantback tolerance claim for the following crops planted in the same season within six months of an application of saflufenacil: barley, canary seed, chickpeas, field corn, sweet corn, lentils, oats, peas, soybean, and wheat (spring, durum and winter). The crop injury and yield data support a rotational crop tolerance claim for the following crops planted in the year following an application of saflufenacil: barley, canary seed, canola, chickpeas, field corn, sweet corn, dry beans, flax, lentils, mustard, oats, peas, soybean, and wheat (spring, durum and winter).

5.4 Economics

5.4.1 Heat WG

The registration of the Heat WG-plus-glyphosate tank-mix as a preseed or pre-emergence application timing provides value to western Canadian growers, as this would allow early season weed control on a broad-spectrum of grassy and broadleaf weeds with one application. Since growers prefer to control their annual grassy and broadleaf weeds early (to minimize weed competition with the crop), this preseed application timing fits with this common agronomic practice. In addition, when applied at proposed use rates, this tank-mix could be used when weed densities are high and overlapping or when weeds are under stress and not growing as actively due to moisture and/or temperature stress. In such cases, it is imperative to ensure early and rapid control of the annual grassy and broadleaf weeds in order to minimize the yield damage and economic loss already caused by the weed competition. Controlling the weeds at this time may also minimize the time and fuel costs, potentially avoiding applying an additional herbicide for weed escapes and when harvesting in the fall. Effective weed control also reduces weed seed rain and subsequent contribution to the weed seed bank, which could impact future crops grown in rotation. The dual mode of action of the Heat WG-plus-glyphosate tank-mix would also be an important tool to manage Roundup Ready volunteers (for example, Roundup Ready canola), current or future potentially glyphosate-resistant weed species, and weeds that have been confirmed to have resistance to other herbicide groups in commercial use. It could also limit associated economic losses that accompany this increasing threat to western Canadian agriculture.

5.4.2 Eragon and Integrity

According to data collected by Statistics Canada, soybean production in Canada totalled 1.18 million hectares in 2007. In no till situations and in conventional tillage system, it is important to provide early control of broadleaf and grassy weeds to minimize economic losses due to weed competition. Yield can be severely suppressed when weeds are not controlled. Saflufenacil plus glyphosate will provide rapid, early season burndown, and provide the necessary short-term residual to maintain yield. The dual mode of action of saflufenacil plus glyphosate is an important tool in managing or preventing the development of glyphosate resistant weeds and controlling weeds that already exhibit herbicide resistance.

According to data collected by Statistics Canada in 2006, field corn for grain and silage totalled 1 363 000 hectares. Field corn provides the greatest farm income of all the field crops in eastern Canada. In Ontario alone, the 2006 field corn crop was estimated by the Ontario Ministry of Agriculture and Food to be valued at $975 million (http://www.omafra.gov.on.ca/english/stats/crops/estimate_metric.htm).

Yield can be suppressed when weeds are not controlled. Without the use of safe and effective herbicides, the value of corn grown in Eastern Canada would be diminished.

5.5 Sustainability

5.5.1 Survey of Alternatives

No survey of alternatives was conducted for Heat WG and Eragon.

5.5.1.1 Integrity

Integrity is proposed to be applied at both the preplant incorporated (PPI) and pre-emergence (PRE) application timings.

The PPI timing is important for growers as it is the only effective application timing for the control of yellow nutsedge and also allows for the simultaneous incorporation of applied fertilizer. Currently, the only herbicides available to growers for the PPI segment are dimethenamid-P or s-metolachlor for the control of annual grasses, yellow nutsedge as well as pigweed and nightshade. For broad spectrum broadleaf weed control in the PPI segment, growers have to rely solely on atrazine. Triazine resistant weeds, such as lamb's quarters, pigweed and ragweed are very common in Eastern Canada and force growers to make a second application of an alternative broadleaf herbicide to control the triazine-resistant weed escapes. Integrity will give growers a herbicide program for the control of annual grass, yellow nutsedge and broadleaf weeds for the PPI application timing.

The PRE application timing includes many more alternative herbicides than the PPI segment does. However, there are few effective broadleaf herbicides that do not include atrazine. At present, the only non-atrazine based herbicide option for the PRE segment is dicamba. Although dicamba is a highly effective broadleaf herbicide, it has a short soil residual activity period and is often tank-mixed with atrazine for longer lasting control. Integrity will provide a unique mode of action herbicide for broadleaf weed control in the PRE application segment that does not necessarily rely on atrazine.

5.5.2 Compatibility with Current Management Practices Including Integrated Pest Management

Saflufenacil offers broadleaf weed control, particularly for kochia, volunteer canola and wild buckwheat, when used as a preseed or pre-emergence herbicide in lentils, chickpea, soybean, cereals (barley, oats and wheat), peas, canary seed, sweet corn and field corn. It is compatible with integrated weed management practices because it controls a range of weeds with a single application and because it can control weeds both before and after they have emerged. It is compatible with both conservation tillage and conventional production systems. Integrity can be applied by growers using the PPI and PRE application methods. Integrity offers the flexibility to be applied preplant, and allows the growers to make one pass across the field with light cultivation to incorporate their fertilizer and herbicide.

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, Heat WG, Eragon and Integrity should be used in rotation with herbicides having different modes of action.

The Heat WG, Eragon and Integrity labels include 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 is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The policy calls for the virtual elimination of Track 1 substances, which are those that meet all four criteria outlined in the policy: bioaccumulative, persistent (in soil and air), primarily a result of human activity, and toxic as defined in the *Canadian Environmental Protection Act*.

During the review process, saflufenacil and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria (see Table 16). The PMRA has reached the following conclusions:

- Saflufenacil does not meet all Track 1 criteria and is not considered a Track 1 substance. Saflufenacil is not expected to persist in the environment or bioaccumulate in living organisms.

- Saflufenacil is not expected to form any transformation products that are Track 1 substances.

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

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette.*[6] The list is used as described in the PMRA Notice of Intent NOI2005-01[7] and is based on existing policies and regulations including: DIR99-03; and DIR2006-02,[8] and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

- Technical grade saflufenacil and the end-use product Heat WG and BAS 800H EC do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette.*

- The end-use product Integrity does not contain any formulants of health or environmental concern identified in the *Canada Gazette*. However, the end-use product does contain an aromatic petroleum distillate that is known to be toxic to aquatic organisms. Aquatic toxicity data are available for the whole Integrity formulation, which account for any toxicity of the aromatic petroleum distillate. Therefore, an additional hazard statement on the label for the aromatic petroleum distillate component of the Integrity formulation is not necessary.

7.0 Summary

7.1 Human Health and Safety

The toxicology database submitted for saflufenacil is adequate to define the majority of toxic effects that may result from exposure to saflufenacil. In short- and long-term toxicity studies on laboratory animals, target organs included the blood, liver, spleen and bone marrow.

The nature of the residue in plants and animals is adequately understood. The residue definition for risk assessment and enforcement in plant products is saflufenacil and the metabolites M800H11 and M800H35. This residue definition applies only to preplant and pre-emergence uses in plants and to harvest-aid use in sunflowers. The residue definition for risk assessment and enforcement purposes is saflufenacil in livestock commodities.

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6 *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

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

8 DIR2006-02, PMRA Formulants Policy.

The use of saflufenacil on crops listed on the labels and the import of saflufenacil-treated commodities does not constitute an unacceptable chronic or acute dietary risk (food and drinking water) to any segment of the population, including infants, children, adults or seniors. Sufficient crop residue data have been reviewed to recommend maximum residue limits to protect human health. The PMRA recommends that the following MRLs be specified for:

- residues of saflufenacil and the metabolites M800H11 and M800H35, expressed as parent equivalents, in and on sunflower seeds (1.0 ppm); legume vegetables (Crop Group 6) (0.03 ppm); citrus Fruits (Revised Crop Group 10) (0.03 ppm); pome fruits (Crop Group 11) (0.03 ppm); stone fruits (Crop Group 12) (0.03 ppm); tree nuts (Crop Group 14) (0.03 ppm); cereal grains (Crop Group 15) (0.03 ppm); grapes (0.03 ppm); undelinted cotton seeds (0.03 ppm);

- residues of saflufenacil in and on liver of cattle, goats, hogs, horses and sheep (0.8 ppm); meat byproducts (except liver) of cattle, goats, hogs, horses and sheep (0.02 ppm); fat and meat of cattle, goats, hogs, horses and sheep (0.01 ppm); and milk (0.01 ppm).

A health assessment has been conducted, and mixers, loaders, and applicators handling Heat WG, Eragon or Integrity and workers re-entering treated fields are not expected to be exposed to levels of saflufenacil that will result in unacceptable risk when the products are used according to label directions .

7.2 Environmental Risk

There are no concerns about the use of saflufenacil affecting earthworms, bees, birds, wild mammals, fish, amphibians, aquatic invertebrates, algae, or aquatic vascular plants. Risks to non-target terrestrial plants as a result of spray drift have been identified in areas adjacent to the treatment area. To mitigate risks from the use of saflufenacil to non-target terrestrial plants, spray buffer zones are required for terrestrial habitats adjacent to the treatment area. The sizes of the buffer zones range from 4 to 15 metres for application rates ranging from 18 to 100 g saflufenacil/ha.

Risks to aquatic plants and amphibians could not be ruled out from an initial screening level assessment of the Integrity formulation, which is a co-formulation of saflufenacil and another herbicide, dimethenamid-P. An assessment of spray drift to aquatic systems adjacent to the treatment area indicates there is still concern about negative impacts on freshwater algae; while amphibians, aquatic vascular plants, and estuarine/marine algae are unlikely to be affected. To mitigate risks to aquatic plants and amphibians from the use of Integrity, a spray buffer zone of one metre is required (on the Integrity label) to protect aquatic habitats adjacent to the treatment areas.

7.3 Value

7.3.1 Heat WG

The value data submitted in support of Heat WG are adequate to describe its efficacy for use in barley, canary seed, chickpeas, lentils, oats, dried field peas, spring wheat, durum wheat, winter wheat, field corn, sweet corn and soybeans or in chemfallow. A single preseed or pre-emergence application of Heat WG at 18 g a.i./ha provides control of kochia, Canada fleabane, lamb's quarters, redroot pigweed, round-leaved mallow, stinkweed, volunteer canola (all herbicide tolerant types including Roundup Ready), wild buckwheat and wild mustard. A single preseed or pre-emergence application of Heat WG at 50 g a.i./ha suppresses secondary flushes of redroot pigweed, stinkweed, wild buckwheat and wild mustard (refer to Table 5.1.1.1 earlier in this document).

The submitted phytotoxicity and yield data demonstrate an adequate margin of safety of labelled crops to Heat WG. Heat WG also has a flexible re-cropping profile. Heat WG (Group 14) provides an alternative mode of action to commonly used herbicides for the labelled crops.

7.3.2 Eragon

The value data submitted in support of Eragon adequately describe its efficacy for use in barley, spring wheat, durum wheat, winter wheat, field corn, sweet corn and soybeans. A single preplant or pre-emergence application of Eragon controls of Canada fleabane, common ragweed, lamb's quarters, redroot pigweed, stinkweed, wild buckwheat and wild mustard and suppresses dandelion (refer to Table 5.1.2.1). The submitted phytotoxicity and yield data demonstrate an adequate margin of safety of labelled crops to Eragon. Eragon also has a flexible re-cropping profile. Eragon (Group 14) provides an alternative mode of action to commonly used herbicides for the labelled crops.

7.3.3 Integrity

The value data submitted in support of Integrity are adequate to describe its efficacy for use in field corn and sweet corn. A single pre-emergence or preplant incorporated application of Integrity controls numerous broadleaf and grassy weeds (refer to Table 5.1.3.1. earlier in this document).

The submitted phytotoxicity and yield data demonstrate an adequate margin of safety of labelled crops to Integrity. Integrity also has a flexible re-cropping profile. Integrity (Group 14 and 15) provides an alternative mode of action to commonly used herbicides for the labelled crops.

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 are listed as follows.

7.4.1 Heat WG

The use of the adjuvant Score in the tank-mix of Heat WG plus glyphosate plus adjuvant cannot be supported by the PMRA because the adjuvant Score (Registration Number 12200), registered only for use with Horizon, is only sold prepackaged with that herbicide. The amount of Score provided with Horizon is based on an application of 100 L/ha, which is the only labelled water volume. Score adjuvant is available only with Horizon Herbicide as a concept tank-mix and is not for sale on its own. If the use directions are followed as per the directions on the registered label, there should be no surplus of Score available for use with other herbicides.

7.4.2 Eragon

Eragon cannot be supported for PPI application on its own because an adequate level of control for the listed weeds was not achieved with this application timing.

7.4.3 Integrity

Rotational Crops:

- 100 days: canary seed
- 7–12 months after application: barley, canary seed, canola, chickpeas, dry beans, flax, mustard, peas, soybean.

The rotational crops restrictions were changed to reflect the most restrictive rotational recropping guidelines of the active ingredient dimethenamid-P.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of saflufenacil technical (Kixor) and its end-use products Heat WG, Eragon and Integrity, containing the technical grade active ingredient saflufenacil, to control broadleaf weeds in lentils, soybean, barley, canary seed, chickpea, field corn, sweet corn, oats, dried field peas, wheat (spring, durum and winter) and in chemfallow.

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.

List of Abbreviations

°C	degree(s) Celcius
µg	micrograms
µm	micrometer
1/n	exponent for the Freundlich isotherm
a.i.	active ingredient
AD	applied dose
ADI	acceptable daily intake
AR	applied radioactivity
ARfD	acute reference dose
atm	atmosphere
bw	body weight
CAS	Chemical Abstracts Service
cm	centimetres
d	day
DAP	days after planting
DFOP	double first order in parallel kinetics
DNA	deoxyribonucleic acid
DT_{50}	dissipation time 50% (the time required to observe a 50% decline in concentration)
DT_{75}	dissipation time 75% (the time required to observe a 75% decline in concentration)
DT_{90}	dissipation time 90% (the time required to observe a 90% decline in concentration)
dw	dry weight
EC	emulsifiable concentrate
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
ELS	early life stage
EP	end-use product
ER_{25}	effective rate on 25% of the population
ER_{50}	effective rate on 50% of the population
FC	food consumption
FIR	food ingestion rate
g	gram(s)
h	hour(s)
ha	hectare(s)
HAFT	highest average field trial
HGPRT	hypoxanthine-guanine phosphoribosyltransferase
HPLC	high performance liquid chromatography
HR5	5^{th} percentile hazard rate
HS	hockey stick dissipation kinetics
IUPAC	International Union of Pure and Applied Chemistry
K + CWHR	kernel plus cob with husks removed
K_d	soil-water partition coefficient
K_F	Freundlich adsorption coefficient
kg	kilogram(s)
K_{oc}	organic-carbon partition coefficient
K_{ow}	*n*-octanol–water partition coefficient
L	litre(s)

LC_{50}	lethal concentration to 50%
LC-MS/MS	Liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose to 50%
LOAEL	lowest observed adverse effect level
LOC	level of concern
LOD	limit of detection
LOEC	lowest observed effect concentration
LOEL	lowest observed effect level
LOQ	limit of quantitation
LR_{50}	lethal rate 50%
m^3	metre(s) cubed
MAS	mean average score
mg	milligram(s)
MIS	mean irritation score
mL	millilitre
mm	millimetre(s)
MOE	margin of exposure
MRL	maximum residue limit
MS	mass spectrometry
nm	nanometre
N/R	not required
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OC	organic carbon content
OM	organic matter content
PBI	plantback interval
PHI	preharvest interval
pKa	dissociation constant
PMRA	Pest Management Regulatory Agency
ppb	parts per billion
ppm	parts per million
Q_1*	cancer potency factor
RQ	risk quotient
RSD	relative standard deviation
SFO	simple first order kinetics
SSD	species sensitivity distribution
STMR	Standard Mean Residue
STMdR	Standard Median Residue
$t_{1/2}$	half-life according to simple first order kinetics
TGAI	technical grade active ingredient
TRR	total radioactive residue
TSMP	Toxic Substances Management Policy
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	Method Type	LOQ*		Reference (PMRA #)
Soil	BASF Analytical Method D0503	active M800H01 M800H02 M800H07 M800H08 M800H15 M800H22	LC-MS-MS	0.01 mg/kg for all analytes		1731026
Sediment	Extended from soil					
Water	BASF Analytical Method D0502	active M800H01 M800H02 M800H07 M800H08 M800H15 M800H22	LC-MS-MS	1 µg/kg for all analytes		1731027
Plant	BASF Method D0603/02	Saflufenacil (BAS 800H); M800H11; M800H35 Residues of each analyte are expressed as saflufenacil equivalents using a molecular conversion factor (1.0 for saflufenacil, 1.06 for M800H11 and 1.42 for M800H35)	Data Gathering and Enforcement (LC-MS/MS)	0.01 ppm for each analyte in food matrices	wheat grain; garbanzo bean; peach fruit; soybean seed; orange fruit; corn oil	1546790, 1546791, 1607919, 1669019, 1608333
				0.025 ppm for each analyte in feed matrices	wheat hay	
Animal	BASF Method L0073/01	Saflufenacil (BAS 800H)	Data Gathering and Enforcement (LC-MS/MS)	0.01 ppm	bovine liver, kidney, muscle, fat, whole milk, cream, skim milk; egg	1546800, 1546795, 1546793, 1607919

***** Limit of quantitation

Table 2a Acute Toxicity of Saflufenacil and Its Associated End-use Products (Heat WG, Eragon and Integrity)

Study	Species	Results	Comment	Reference (PMRA #)
Acute toxicity – Saflufenacil technical				
Oral	rat	LD_{50}, ♀ >2000 mg/kg bw	Low toxicity	1546961
Dermal	rat	LD_{50}, >2000 mg/kg bw	Low toxicity	1546963
Inhalation	rat	LC_{50}, >5.3 mg/L	Low toxicity	1546965
Eye irritation	rabbit	MIS[1] @ 1 h = 8.7/110 MAS[2] = 0.2/110	Minimally irritating	1546971
Skin irritation	rabbit	MIS[1] @ 1 h = 1/8 MAS[2] = 0/8	Slightly irritating	1546967
Dermal sensitization	guinea pig	Negative	Maximization assay	1546973
Acute toxicity – Heat WG and Eragon (containing saflufenacil)				
Oral	rat	LD_{50}, ♀ >2000 mg/kg bw	Low toxicity	1546803
Dermal	rat	LD_{50}, >2000 mg/kg bw	Low toxicity	1546806
Inhalation	rat	LC_{50}, >5 mg/L	Low toxicity	1546808
Eye irritation	rabbit	MIS[1] @ 1 h = 10/110 MAS[2] = 1.52/110	Minimally irritating	1546812
Skin irritation	rabbit	MIS[1] @ 1 h = 2/8 MAS[2] = 0.4/8	Mildly irritating **CAUTION – SKIN IRRITANT**	1546810
Dermal sensitization	guinea pig	Negative	Buehler assay (9 inductions)	1546814
Acute toxicity –Integrity (containing saflufenacil and dimethenamid)				
Oral	rat	LD_{50}, ♀ >2000 mg/kg bw	Low toxicity	1547322
Dermal	rat	LD_{50}, >5000 mg/kg bw	Low toxicity	1547323
Inhalation	rat	LC_{50}, >5.25 mg/L	Low toxicity	1547324
Eye irritation	rabbit	MIS[1] @ 1 h = 44/110 MAS[2] = 42/110	Moderately irritating **WARNING – EYE IRRITANT**	1547326
Skin irritation	rabbit	MIS[1] @ 1 h = 2/8 MAS[2] = 1.8/8	Mildly irritating **CAUTION – SKIN IRRITANT**	1547325
Dermal sensitization	guinea pig	Positive	Buehler assay (9 inductions) **POTENTIAL SKIN SENSITIZER**	1547327

[1] MIS = maximum irritation score;

[2] MAS = maximum average score (mean of 24, 48 and 72 h)

Table 2b Toxicity Profile of Saflufenacil Technical

Study	Species	Results	Reference (PMRA #)
4-week dermal	rat	Marginal haematological changes, not considered adverse NOAEL = 1000 mg/kg bw/day	1547055
28-day dietary/oral	mouse	Adverse effects: anemia and red blood cell parameters; liver and spleen pathology NOAEL : ♂ = 12.8, ♀ = 63.4 mg/kg bw/day LOAEL: ♂ = 36.6, ♀ = 153 mg/kg bw/day	1546975
	rat	Adverse effects: anemia and red blood cell parameters; liver and spleen pathology NOAEL : ♂ = 13.4, ♀ = 43.6 mg/kg bw/day LOAEL: ♂ = 39.2, ♀ = 130 mg/kg bw/day	1546987
	dog	Adverse effects: anemia and red blood cell parameters; liver and spleen pathology NOAEL : ♂♀ = 30 mg/kg bw/day LOAEL: ♂♀ = 100 mg/kg bw/day	1547034
90-day dietary/oral	mouse	Adverse effects: anemia and red blood cell parameters; liver pathology NOAEL : ♂ = 12.5, ♀ = 17.6 mg/kg bw/day LOAEL: ♂ = 36.7, ♀ = 51.8 mg/kg bw/day	1547010
	rat	Adverse effects: anemia and red blood cell parameters; liver and spleen pathology NOAEL : ♂ = 10.5, ♀ = 12.6 mg/kg bw/day LOAEL: ♂ = 32.3, ♀ = 110.5 mg/kg bw/day	1547000
	dog	Adverse effects: anemia and red blood cell parameters; spleen pathology NOAEL : ♂♀ = 10 mg/kg bw/day LOAEL: ♂♀ = 50 mg/kg bw/day	1547023
1-year oral	dog	Adverse effects: red blood cell parameters; liver pathology NOAEL : ♂♀ = 20 mg/kg bw/day LOAEL: ♂♀ = 80 mg/kg bw/day	1547044
18-month dietary oncogenicity	mouse	Adverse effects: slight anemia NOAEL : ♂ = 4.6, ♀ = 18.9 mg/kg bw/day LOAEL: ♂ = 13.8, ♀ = 38.1 mg/kg bw/day Not carcinogenic	1547081
2-year dietary/ oncogenicity	rat	Adverse effects: anemia and red blood cell parameters NOAEL : ♂ = 12.0, ♀ = 6.20 mg/kg bw/day LOAEL: ♂ = 24.2, ♀ = 31.4 mg/kg bw/day Not carcinogenic	1547069
2-generation dietary reproductive toxicity	rat	Adverse effects: Parental animals: anemia and red blood cell parameters Offspring: ↑ mortality; ↓ body weight NOAEL : parental systemic = 15 mg/kg bw/day Offspring and reproductive = 15 mg/kg bw/day LOAEL: parental systemic = 50 mg/kg bw/day Offspring and reproductive = 50 mg/kg bw/day Increased sensitivity of offspring based on severity of effects	1547104

Study	Species	Results	Reference (PMRA #)
Developmental toxicity	rat	Adverse effects: Parental animals: ↓ Hb, Hct, mean cell volume, mean corpuscular hemoglobin Offspring: ↑ skeletal variation, delayed development, malformation; ↓ fetal body weight NOAEL : maternal systemic = 20 mg/kg bw/day developmental = 5 mg/kg bw/day LOAEL: maternal systemic = 60 mg/kg bw/day developmental = 20 mg/kg bw/day Increased sensitivity of offspring	1547124
	rabbit	Adverse effects: Parental animals: decreased food intake Offspring: ↓ gravid uterine wt, corpora lutea, implantation, live fetuses NOAEL : maternal systemic = 200 mg/kg bw/day developmental = 200 mg/kg bw/day LOAEL: maternal systemic = 600 mg/kg bw/day developmental = 600 mg/kg bw/day Increased sensitivity of offspring	1547131
Gene mutations in bacteria	*Salmonella typhimurium, Escherichia coli*	Negative	1547057
		Negative	1547059
Gene mutations in mammalian cells in vitro	Chinese hamster ovary cells (HGPRT locus)	Negative	1547063
Chromosome aberrations in vitro	Chinese hamster lung V79 cells	Clastogenic with S9 metabolic activation; no dose relationship	1547061
in vivo/in vitro (oral) unscheduled DNA synthesis	Primary rat hepatocytes	Negative	1547067
Micronucleus assay (in vivo oral)	mouse	Negative	1547065
acute neurotoxicity	rat	Adverse effects: ♂ - ↓ motor activity NOAEL : ♂ = 500, ♀ = 2000 mg/kg bw LOAEL: ♂ = 2000 mg/kg bw Not neurotoxic	1547133
90-day dietary neurotoxicity	rat	Adverse effects: ↓ bw & bwg; anemia and red blood cell parameters; liver and spleen pathology NOAEL : ♂ = 16.6, ♀ = 19.4 mg/kg bw/day LOAEL: ♂ = 66.2, ♀ = 101 mg/kg bw/day Not neurotoxic	1547135

Study	Species	Results	Reference (PMRA #)
Metabolism	rat	Absorption: rapid; maximum concentration in blood reached within 1 h of dosing. Distribution: extensive, but at very low levels. Excretion: rapid; majority with 24 to 48 h; excretion almost complete within 96 h; route of excretion showed gender difference, urinary predominant in females while fecal predominant route in males. Metabolism: unchanged parent compound predominant in urine, other metabolites constituted up to 9% of the applied dose (AD). In feces (mainly in males), main metabolite was M800H01, the unchanged parent compound made up to 16.2% of AD in males. Major steps of transformation were: demethylation of uracil ring, degradation of N-methyl-N-isopropyl group to NH_2, and cleavage of uracil to form the sulfonylamide.	1546951 1546953
Mechanistic study – total porphyrin analysis	rat	Adverse effects: anemia and red blood cell parameters. Increased porphyrin in plasma, urine, feces and liver. No treatment-related findings after a two-week recovery period	1547101
	rat	Assessment: total porphyrin in feces NOEL for fecal porphyrin effect: ♂ = 0.1, ♀ = 0.5 mg/kg bw/day	1547099
Mechanistic study – comparative bioavailability / toxicity of H-hydrate and H-anhydrate form	rat	Similar effects induced by H-hydrate and H-anhydrate form of BAS 800 suggesting similarity in bioavailability after dietary exposure Adverse effects: ↓ food intake; anemia and red blood cell parameters ↑ porphyrin in liver and feces (an indicator of exposure)	1547097

Table 3 Toxicology Endpoints for Use in Health Risk Assessment for Saflufenacil

Exposure scenario	ARfD / ADI	NOAEL (mg/kg bw/day)	Study	Endpoint	UF / MOE
Acute dietary – general population	ARfD = 5 mg/kg bw	500	Acute neurotoxicity in rats	↓ motor activity in ♂	100
Acute dietary – females aged 13-49	ARfD = 0.017 mg/kg bw	5	Rat developmental	↑ skeletal variation, delayed development, malformation	300
Chronic dietary – general population	ARfD = 0.046 mg/kg bw	4.6	Mouse oncogenicity	♂ - slight anemia	100
Chronic dietary – females aged 13-49	ARfD = 0.017 mg/kg bw	5	Rat developmental	↑ skeletal variation, delayed development, malformation	300
Short-, intermediate- and long-term dermal and inhalation		5	Rat developmental	↑ skeletal variation, delayed development, malformation	300

Table 4 Integrated Food Residue Chemistry Summary

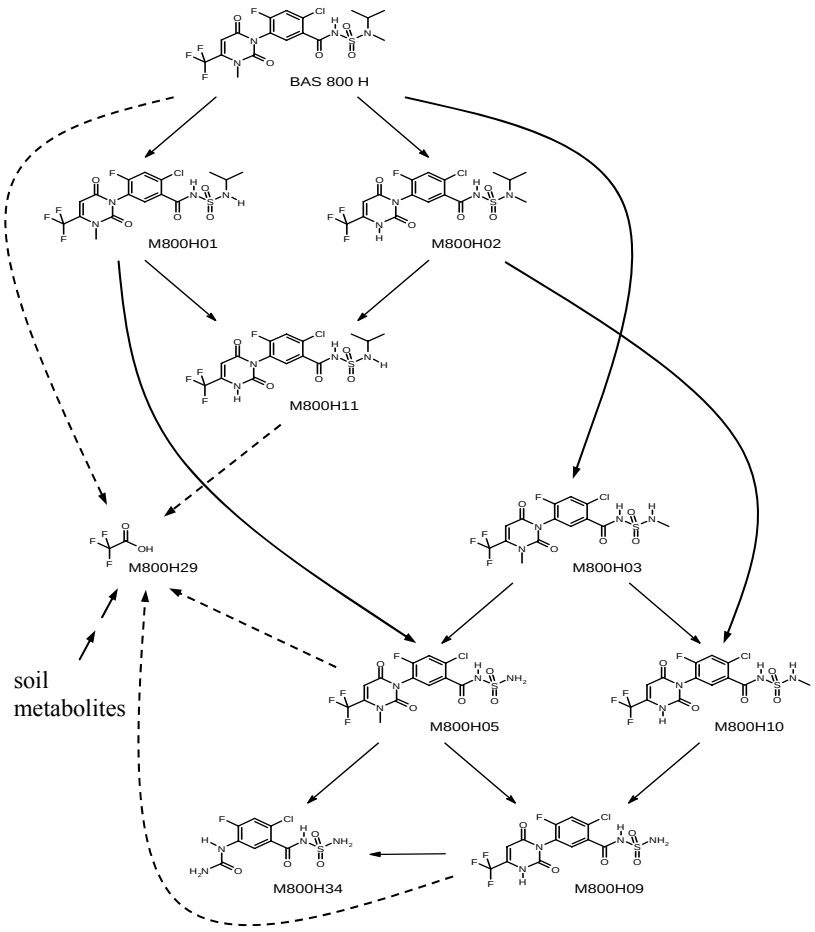
NATURE OF THE RESIDUE IN CORN			PMRA # 1547137	
Radiolabel Position	**[Phenyl-U-^{14}C]**		**[Uracil-4-^{14}C]**	
Test Site	The corn plants were cultivated in containers in climatic chambers (phytotrons).			
Treatment	Saflufenacil (BAS 800H) was applied as a single pre-emergent spray application to sandy loam soil after sowing of corn seed.			
Rate	The nominal target application rate was 200 g a.i./ha. The actual application rates were 189 g a.i./ha (phenyl label) and 220 g a.i./ha (uracil label).			
End-use product	BAS 800 UBH (EC)			
Preharvest interval	Samples of corn forage were harvested 42 and 101-102 days after treatment (DAT) of the soil. Samples of corn husks, cob, grain and stover were harvested 133 DAT of the soil. * TRR = total radioactive residue			
Matrix	**DAT (days)**	**[Phenyl-U-^{14}C] TRR (ppm)**	**[Uracil-4-^{14}C] TRR (ppm)**	
Direct Determination by Combustion				
Corn Forage	42	0.025	0.038	
Corn Forage	101-102	0.038	0.164	
Corn Husks	133	0.257	0.276	
Corn Cob	133	0.018	0.067	
Corn Grain	133	0.019	0.052	
Corn Stover	133	0.118	0.675	
Indirect Determination by Summation of the Extractable and Unextractable Radioactivity				
Corn Forage	42	0.018	0.039	
Corn Forage	101-102	0.029	0.149	
Corn Husks	133	0.215	0.226	
Corn Cob	133	0.016	0.065	
Corn Grain	133	0.020	0.049	
Corn Stover	133	0.096	0.553	
Metabolites Identified	**Major Metabolites (>10% TRR)**		**Minor Metabolites (<10% TRR)**	
Radiolabel Position	**[Phenyl-U-^{14}C]**	**[Uracil-4-^{14}C]**	**[Phenyl-U-^{14}C]**	**[Uracil-4-^{14}C]**
Corn Forage (42 DAT)	M800H01; M800H03; H800H05; H800H09; M800H10	M800H29	saflufenacil (BAS 800H); M800H02; M800H11; M800H34	saflufenacil (BAS 800H); M800H01; M800H02; M800H03; M800H05; M800H09; M800H10; M800H11
Corn Forage (101-102)	M800H09; M800H10; M800H34	M800H29	M800H01; M800H03; M800H11	H800H09; M800H10; M800H11
Corn Husks	none	M800H29	saflufenacil (BAS 800H); M800H05; M800H09; M800H10; M800H11; M800H34	M800H09; M800H10; M800H11

NATURE OF THE RESIDUE IN CORN			PMRA # 1547137	
Corn Cob	M800H34	M800H29	M800H09; M800H10; M800H11	M800H09
Corn Grain	none	M800H29	M800H09; M800H10; M800H11; M800H34	none
Corn Stover	M800H09; M800H10; M800H34	M800H29	saflufenacil (BAS 800H); M800H03; M800H11	H800H09; M800H10; M800H11

Saflufenacil (BAS 800H) is metabolized in corn by:

- *N*-demethylation at the uracil ring;
- Stepwise degradation (*N*-dealkylation) of the *N*-methyl-*N*-isopropyl group to NH_2, forming a sulfonamide group;
- Hydrolytic cleavage of the uracil ring generating a urea side chain.

Proposed Metabolic Scheme in Corn:



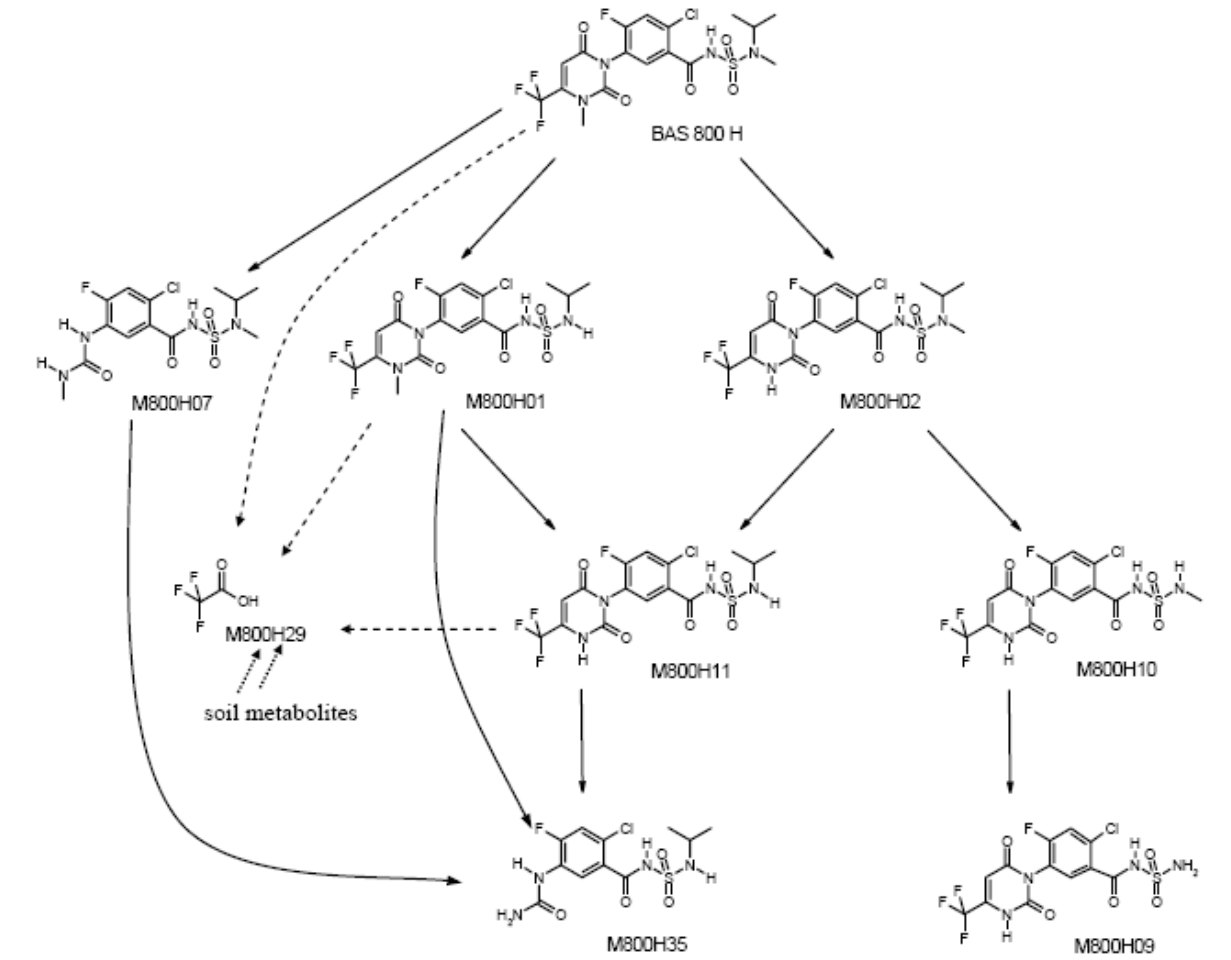
NATURE OF THE RESIDUE IN TOMATO			PMRA # 1547142	
Radiolabel Position	**[Phenyl-U-^{14}C]**		**[Uracil-4-^{14}C]**	
Test Site	Tomato plants were cultivated in containers in climatic chambers (phytotrons) initially and later in a greenhouse.			
Treatment	Saflufenacil (BAS 800H) was applied as a single preplant spray application directly to bare sandy loam soil. Following drying of the soil, tomato plants were planted.			
Rate	The nominal target application rate was 100 g a.i./ha.			
End-use product	BAS 800 UBH (EC, emulsifiable concentrate)			
Preharvest interval	Samples of immature tomato plants were sampled 68 DAT of the soil. Samples of mature tomato plants were harvested 113 DAT of the soil. The mature tomato plants were separated into tomato fruit and the residual tomato plant.			
Matrix	**DAT (days)**	**[Phenyl-U-^{14}C] TRR (ppm)**	**[Uracil-4-^{14}C] TRR (ppm)**	
Direct Determination by Combustion				
Immature Tomato Plant	68	0.089	0.131	
Mature Tomato Plant	113	0.113	0.138	
Mature Tomato Fruit	113	0.015	0.037	
Indirect Determination by Summation of the Extractable and Unextractable Radioactivity				
Immature Tomato Plant	68	0.103	0.143	
Mature Tomato Plant	113	0.108	0.140	
Mature Tomato Fruit	113	0.015	0.035	
Metabolites Identified	**Major Metabolites (>10% TRR)**		**Minor Metabolites (<10% TRR)**	
Radiolabel Position	**[Phenyl-U-^{14}C]**	**[Uracil-4-^{14}C]**	**[Phenyl-U-^{14}C]**	**[Uracil-4-^{14}C]**
Immature Tomato Plant	saflufenacil (BAS 800H); M800H07; M800H11	M800H29	M800H01; M800H02; M800H09/ M800H35 M800H10/unknown	saflufenacil (BAS 800H); M800H10; M800H11
Mature Tomato Plant	saflufenacil (BAS 800H); M800H10/ unknown	M800H29	M800H01; M800H02; M800H07; M800H09; M800H11; M800H35	saflufenacil (BAS 800H); M800H10; M800H11
Mature Tomato Fruit	sugar	M800H29; sugar	saflufenacil (BAS 800H)	none

Saflufenacil (BAS 800H) is metabolized in tomato by:

- *N*-dealkylation at either the sulfonamide nitrogen or the uracil nitrogen;
- Hydrolysis of the uracil ring;
- The sugar metabolite, most likely fructose, results from the uptake of the small carbon fragments generated by further degradation of the other identified metabolites.

NATURE OF THE RESIDUE IN TOMATO	PMRA # 1547142

Proposed Metabolic Scheme in Tomato:



NATURE OF THE RESIDUE IN SOYBEAN			PMRA # 1547140
Radiolabel Position	**[Phenyl-U-^{14}C]**		**[Uracil-4-^{14}C]**
Test Site	Soybean plants were cultivated in containers in climatic chambers (phytotrons) and in a greenhouse.		
Treatment	Saflufenacil (BAS 800H) was applied as a single pre-emergent spray application to loamy sand soil after sowing of soybean seed.		
Rate	The nominal target application rate was 150 g a.i./ha. The actual application rates were 149 g a.i./ha (phenyl label) and 180 g a.i./ha (uracil label).		
End-use product	BAS 800 UBH (EC, emulsifiable concentrate)		
Preharvest interval	Samples of soybean forage were harvested 39-40 DAT of the soil; samples of mature soybean plants were harvested 95 DAT of the soil. The harvested mature soybean plants were separated into seed, pod and straw.		
Matrix	**DAT (days)**	**[Phenyl-U-^{14}C]**	**[Uracil-4-^{14}C]**
		TRR (ppm)	**TRR (ppm)**
Direct Determination by Combustion			
Soybean Forage	39-40	0.086	0.404
Soybean Seed	95	0.041	0.238
Soybean Pod	95	0.182	2.123

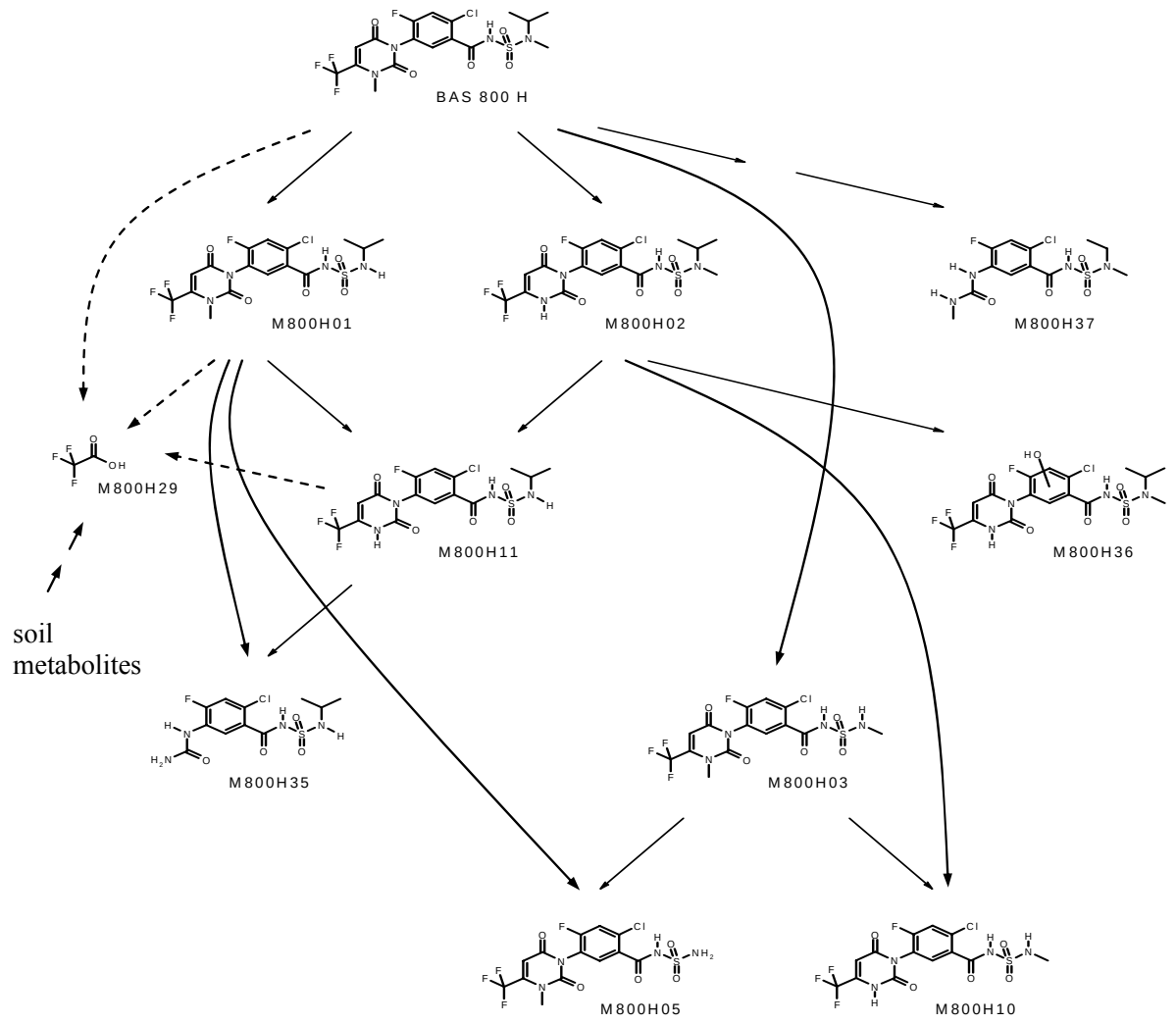
NATURE OF THE RESIDUE IN SOYBEAN			PMRA # 1547140	
Soybean Straw	95	0.382	1.466	
Indirect Determination by Summation of the Extractable and Unextractable Radioactivity				
Soybean Forage	39-40	0.081	0.383	
Soybean Seed	95	0.038	0.221	
Soybean Pod	95	0.179	2.031	
Soybean Straw	95	0.431	1.183	
Metabolites Identified	**Major Metabolites (>10% TRR)**		**Minor Metabolites (<10% TRR)**	
Radiolabel Position	**[Phenyl-U-^{14}C]**	**[Uracil-4-^{14}C]**	**[Phenyl-U-^{14}C]**	**[Uracil-4-^{14}C]**
Soybean Forage	saflufenacil (BAS 800H); M800H02	M800H29	M800H01; M800H03; M800H10 and/or M800H36; M800H11; M800H35; M800H37	saflufenacil (BAS 800H); M800H01; M800H02; M800H11
Soybean Seed	M800H10 and/or M800H36	M800H29	saflufenacil (BAS 800H); M800H01; M800H02; M800H05; M800H11; M800H35;	saflufenacil (BAS 800H); M800H01; M800H02
Soybean Pod	M800H10 and/or M800H36; M800H35	M800H29	saflufenacil (BAS 800H); M800H01; M800H02; M800H11	M800H02; M800H11
Soybean Straw	M800H10 and/or M800H36; M800H11; M800H35	M800H29; M800H11	saflufenacil (BAS 800H); M800H01; M800H02; M800H05	saflufenacil (BAS 800H); M800H01; M800H02

Saflufenacil (BAS 800H) is metabolized in soybean by:

- *N*-demethylation at the uracil ring;
- Stepwise degradation (*N*-dealkylation) of the *N*-methyl-*N*-isopropyl group to NH_2 forming a sulfonamide group;
- Hydrolytic cleavage of the uracil ring generating a urea side chain.
- Hydroxylation of the phenyl ring.

NATURE OF THE RESIDUE IN SOYBEAN	PMRA # 1547140

Proposed Metabolic Scheme in Soybean:



NATURE OF THE RESIDUE IN SUNFLOWER	PMRA # 1547145
BASF submitted an acceptable rationale to waive the data requirement for a plant metabolism study in support of the harvest-aid/desiccation use of saflufenacil on imported sunflower. Negligible metabolism of the parent compound saflufenacil is expected in the susceptible physiologically mature sunflower.	

CONFINED ACCUMULATION IN ROTATIONAL CROPS – LEAF LETTUCE, WHITE RADISH AND SPRING WHEAT		PMRA #1546860 and 1595375
Radiolabel Position	**[Phenyl-U-^{14}C]**	**[Uracil-4-^{14}C]**
Test site	Leaf lettuce, white radish and spring wheat plants were cultivated in plastic containers filled with loamy sand soil and placed under natural climatic conditions, without the influence of rain, in a glass-roofed vegetation hall or in a glass house depending on the climatic conditions outside.	
Formulation used for trial	BAS 800 UBH (EC, emulsifiable concentrate)	

NATURE OF THE RESIDUE IN SUNFLOWER				PMRA # 1547145	
Application rate and timing		Saflufenacil (BAS 800H) was applied as a single preplant spray application to bare loamy sand soil in plastic containers. The nominal target application rate was 150 g a.i./ha. The actual application rates were 160.5 g a.i./ha (phenyl label) and 136.5 g a.i./ha (uracil label). The treated soil was aged for 30, 58 (lettuce and radish only), 120 and 365 days before the white radish or spring wheat were sowed or leaf lettuce seedlings were planted. * PBI = plantback interval			
Metabolites Identified		**Major Metabolites (>10% TRR)**		**Minor Metabolites (<10% TRR)**	
Matrix	**PBI (days)**	**[Phenyl-U-^{14}C]**	**[Uracil-4-^{14}C]**	**[Phenyl-U-^{14}C]**	**[Uracil-4-^{14}C]**
Lettuce, head	30	saflufenacil (BAS 800H); M800H01	M800H29	M800H03; M800H11; M800H10/unknown; M800H35/M800H09	saflufenacil (BAS 800H); M800H01; M800H11
	120	Not analyzed	M800H29	Not analyzed	saflufenacil (BAS 800H)
	365	Not analyzed	Not analyzed	Not analyzed	Not analyzed
Radish, root	30	None	M800H29	None	None
	120	Not analyzed	M800H29	Not analyzed	saflufenacil (BAS 800H); M800H01
	365	Not analyzed	Not analyzed	Not analyzed	Not analyzed
Radish, top	30	saflufenacil (BAS 800H); M800H01; M800H11; M800H10/unknown	M800H29	M800H03; M800H35/M800H09	saflufenacil (BAS 800H); M800H01; M800H11
	120	M800H01; M800H10/unknown	M800H29	saflufenacil (BAS 800H); M800H03; M800H11; M800H35/M800H09	saflufenacil (BAS 800H); M800H01
	365	Not analyzed	M800H29	Not analyzed	saflufenacil (BAS 800H); M800H01
Wheat, forage	30	M800H05; M800H10/unknown; M800H35/M800H09	M800H29	saflufenacil (BAS 800H); M800H01; M800H03; M800H11	saflufenacil (BAS 800H); M800H01; M800H03; M800H05; M800H11; M800H10/unknown
	120	M800H10/unknown; M800H35/M800H09	M800H29	M800H01; M800H03; M800H05; M800H11	M800H01; M800H05
	365	M800H10/unknown; M800H35/M800H09	M800H29	M800H01; M800H03; M800H05	M800H01; M800H05

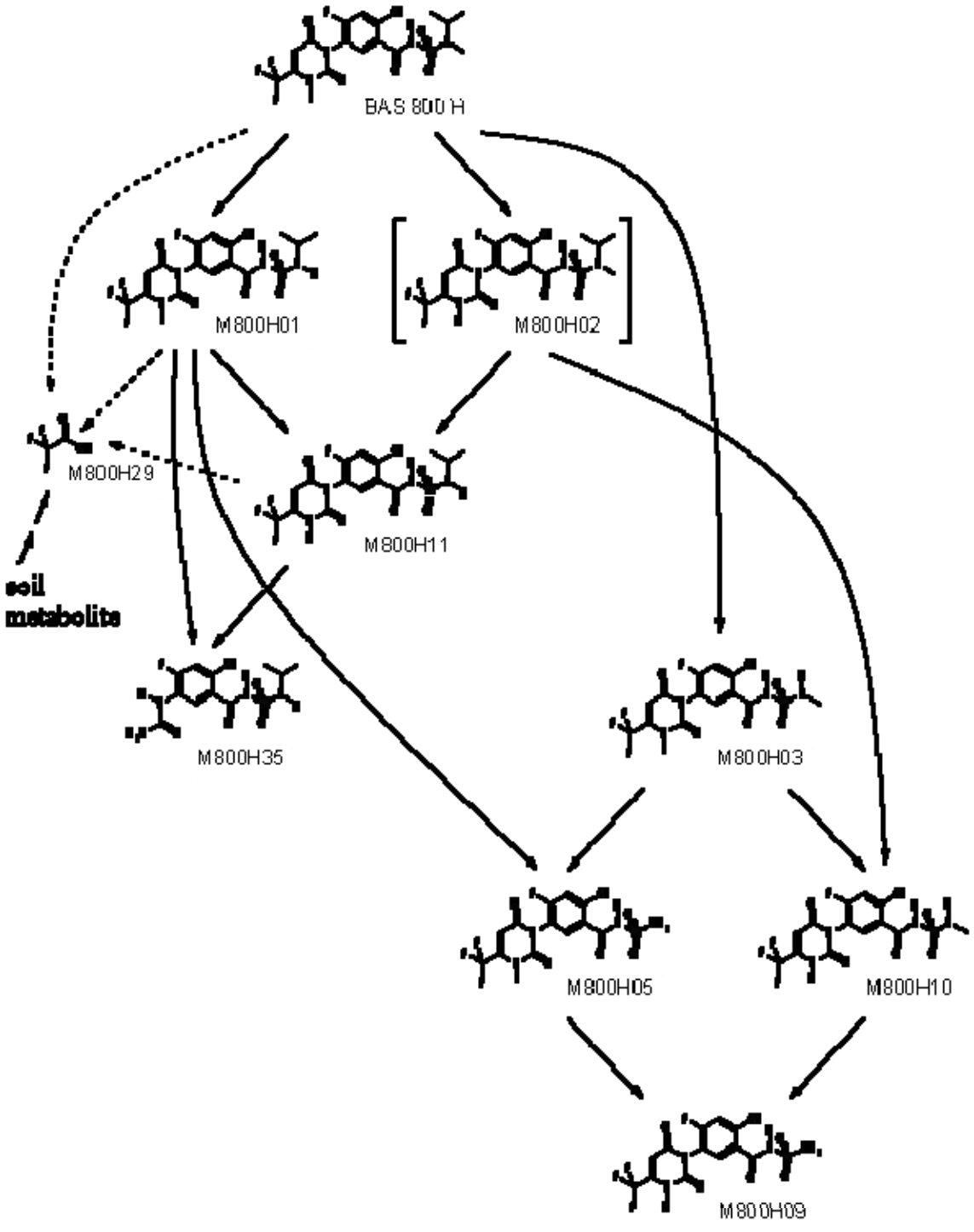
NATURE OF THE RESIDUE IN SUNFLOWER				PMRA # 1547145	
Wheat, straw	30	M800H05; M800H10/unknown; M800H35/M800H09	M800H29	M800H01; M800H03; M800H011	M800H01; M800H03; M800H05; M800H09; M800H11; M800H10/unknown
	120	M800H10/unknown M800H35/M800H09	M800H29	M800H01; M800H03; M800H05; M800H11	M800H01; M800H03; M800H05; M800H09; M800H11; M800H10/unknown
	365	M800H35/M800H09	M800H29	M800H05; M800H10/unknown	None
Wheat, chaff	30	M800H05; M800H10/unknown; M800H35/M800H09	M800H29	M800H01; M800H03/ M800H011	M800H01; M800H03/ M800H11 M800H05; M800H09; M800H10/unknown
	120	M800H35/M800H09	M800H29	M800H01; M800H03; M800H05; M800H10/unknown	None
	365	M800H35/M800H09	M800H29	M800H10/unknown	None
Wheat, grain	30	M800H35/M800H09	M800H29	M800H01; M800H03; M800H05; M800H11; M800H10/unknown	None
	120	Not analyzed	M800H29	Not analyzed	None
	365	None	M800H29	M800H05; M800H10/unknown; M800H35/M800H09	None

Saflufenacil (BAS 800H) is metabolized in rotational crops by:

- Stepwise degradation (*N*-dealkylation) of the *N*-methyl-*N*-isopropyl group to NH_2, forming a sulphonamide group;
- *N*-demethylation at the uracil ring;
- Hydrolytic cleavage of the uracil ring generating a urea side chain.

NATURE OF THE RESIDUE IN SUNFLOWER	PMRA # 1547145

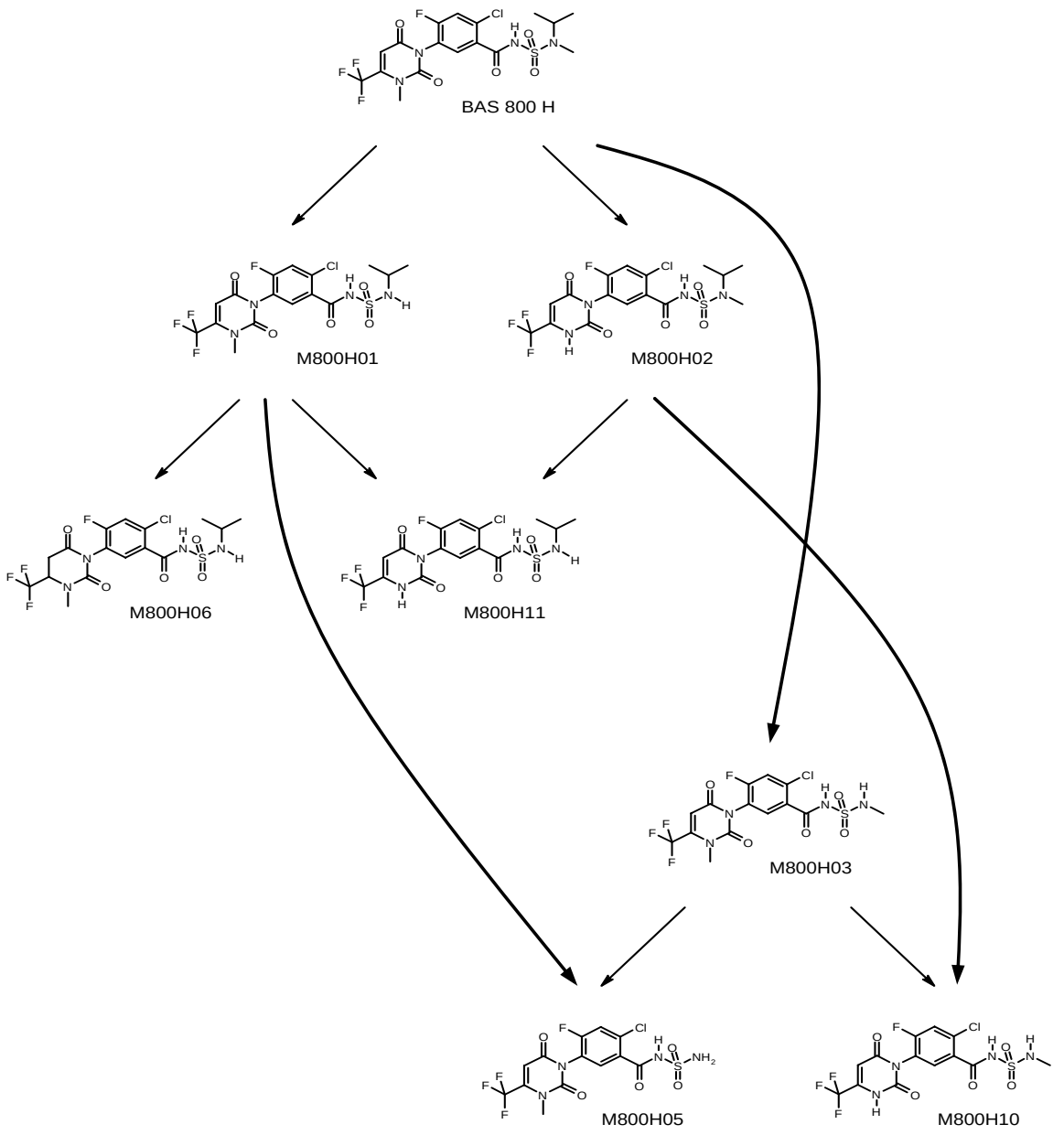
Proposed metabolic scheme in rotational crops (leaf lettuce, white radish, and spring wheat):



NATURE OF THE RESIDUE IN LAYING HEN			**PMRA #1547146 and 1547148**	
Laying hens (n = eight animals per treatment group) were dosed orally once daily in the morning with either [phenyl-U-^{14}C]-saflufenacil (BAS 800H) or [uracil-4-^{14}C]-saflufenacil (BAS 800H) at a rate equivalent to 12.6-12.7 ppm in the feed for 10 consecutive days. Samples of excreta were collected daily. Samples of eggs were collected in the morning before dosing and in the afternoon after dosing, except on weekends where only one collection per day was made. The treated hens were sacrificed approximately 23 hours after the final dosage and samples of blood, liver, muscle (leg and chest), fat and gastrointestinal tract (plus contents) were collected. All tissues were each processed as one pooled sample of eight animals per label, respectively.				
Matrices			**% of Administered Dose**	
			[Phenyl-U-^{14}C]	**[Uracil-4-^{14}C]**
Excreta			85.14	78.10
Cage Wash			2.93	4.86
Gastrointestinal Tract (skin and solvent)			0.43	0.54
Gastrointestinal Tract Contents			0.19	0.08
Muscle			0.03	0.02
Fat			0.00	0.00
Liver			0.02	0.02
Eggs (Cumulative)			0.029	0.046
Blood			0.01	0.01
Metabolites Identified	**Major Metabolites (>10% TRR)**		**Minor Metabolites (<10% TRR)**	
Radiolabel Position	**[Phenyl-U-^{14}C]**	**[Uracil-4-^{14}C]**	**[Phenyl-U-^{14}C]**	**[Uracil-4-^{14}C]**
Muscle	saflufenacil (BAS 800H); M800H10	saflufenacil (BAS 800H); M800H10	M800H01; H800H02; M800H03; M800H05; M800H11	M800H01; H800H02; M800H03
Fat	saflufenacil (BAS 800H); M800H10	saflufenacil (BAS 800H); M800H10	M800H01; M800H05	M800H01; H800H02; M800H05; M800H11
Liver	saflufenacil (BAS 800H); M800H01	saflufenacil (BAS 800H); M800H01	M800H02; M800H03; M800H05; M800H10; M800H11	M800H02; M800H03; M800H05; M800H10; M800H11
Eggs (Pooled sample; Day 2-10)	saflufenacil (BAS 800H); M800H10	M800H10	none	saflufenacil (BAS 800H); M800H01; M800H05; M800H11
• Saflufenacil (BAS 800H) is metabolized in the laying hen by different dealkylation steps, which occur at either the sulfamide side chain or the uracil ring.				

NATURE OF THE RESIDUE IN LAYING HEN	PMRA #1547146 and 1547148

Proposed Metabolic Scheme in the Laying Hen:



NATURE OF THE RESIDUE IN LACTATING GOAT	PMRA # 1547150 and 1547154

Lactating gloats (n = one animal per treatment group) were dosed orally once daily with either [phenyl-U-^{14}C]-saflufenacil (BAS 800H) or [uracil-4-^{14}C]-saflufenacil (BAS 800H) at a rate equivalent to 13.4-13.9 ppm in the feed for eight consecutive days. Samples of urine and feces were collected once a day. Samples of milk were collected in the morning before dosing and in the afternoon. The treated goats were sacrificed approximately 23 hours after the final dosage and samples of liver, kidney, blood, fat, muscle, gastrointestinal tract (plus contents) and bile were collected.

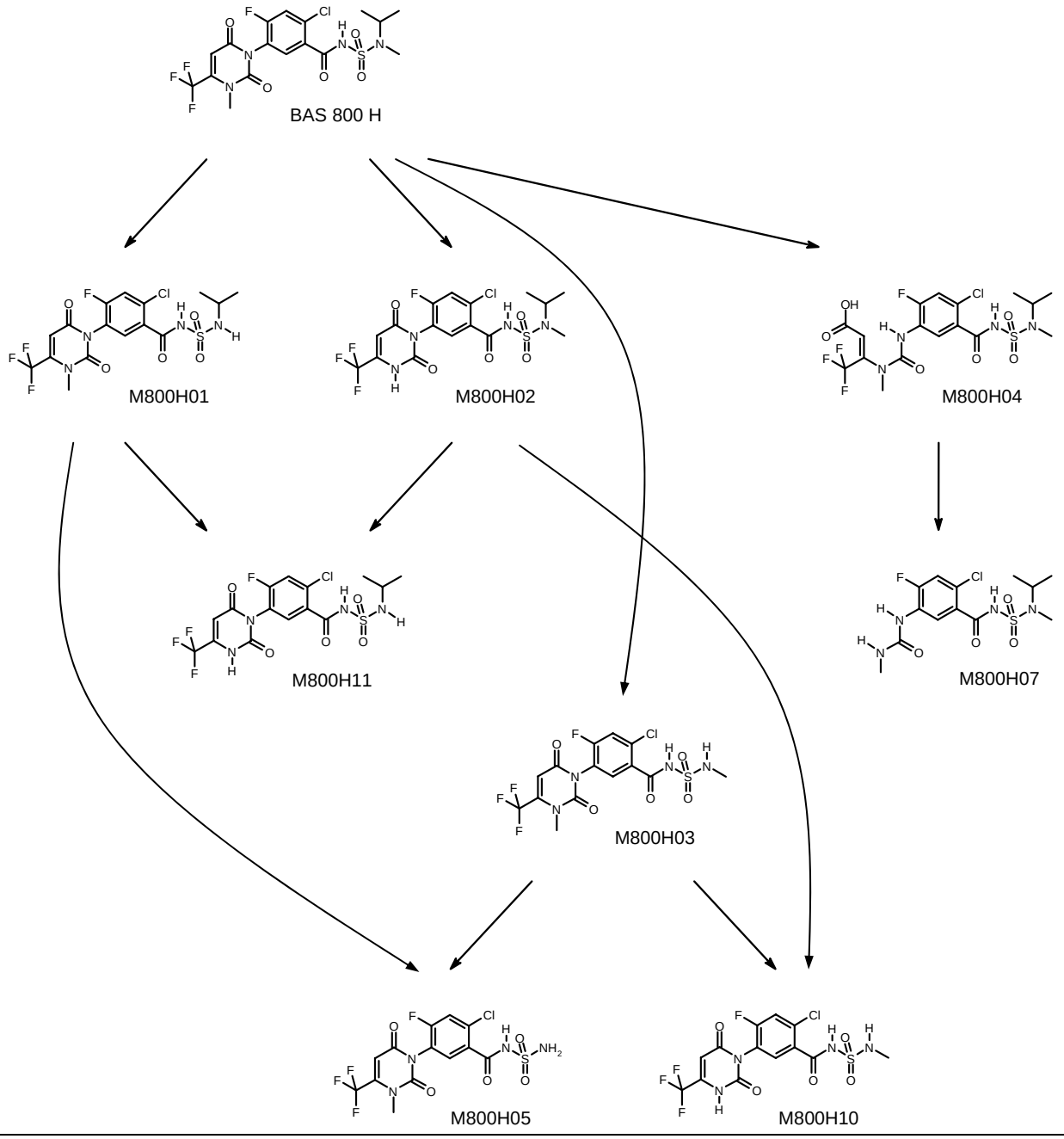
NATURE OF THE RESIDUE IN LACTATING GOAT			PMRA # 1547150 and 1547154	
Matrices			**% of Administered Dose**	
			[Phenyl-U-^{14}C]	**[Uracil-4-^{14}C]**
Urine			62.04	45.57
Feces			28.48	41.90
Cage Wash			2.46	1.81
Gut			0.064	0.149
Stomach			0.024	0.061
Stomach-Gut Contents			0.771	0.520
Muscle			0.020	0.024
Fat			0.001	0.001
Kidney			0.009	0.012
Liver			0.366	1.532
Bile			0.006	0.012
Milk (cumulative)			0.040	0.100
Blood			0.007	0.009
Metabolites identified	**Major Metabolites (>10% TRR)**		**Minor Metabolites (<10% TRR)**	
Radiolabel Position	**[Phenyl-U-^{14}C]**	**[Uracil-4-^{14}C]**	**[Phenyl-U-^{14}C]**	**[Uracil-4-^{14}C]**
Muscle	saflufenacil (BAS 800H); M800H10	saflufenacil (BAS 800H); M800H10	none	none
Fat	saflufenacil (BAS 800H); M800H10	saflufenacil (BAS 800H); M800H10	none	none
Kidney	saflufenacil (BAS 800H); M800H04	saflufenacil (BAS 800H)	M800H01; M800H10	M800H01; M800H03; M800H10; M800H04
Liver	saflufenacil (BAS 800H); M800H04	saflufenacil (BAS 800H); M800H04	M800H01	M800H01
Milk (Pooled sample; Day 1-8)	saflufenacil (BAS 800H); M800H10	saflufenacil (BAS 800H); M800H10	M800H01; M800H03	M800H01; M800H03

Saflufenacil (BAS 800H) is metabolized in the lactating goat by:

- A series of dealkylation steps at the *N*-isopropyl -*N*-methylsulfamide side chain and at the uracil ring;
- Hydrolytic opening of the uracil ring of BAS 800H.

NATURE OF THE RESIDUE IN LACTATING GOAT	PMRA # 1547150 and 1547154

Proposed Metabolic Scheme in the Lactating Goat



STORAGE STABILITY – PLANT MATRICES	PMRA # 1634459

Samples of corn (forage, grain and stover), garbanzo bean (chickpea), orange (fruit, juice, oil and pulp), radish (roots), grape (raisin) and soybean (forage, hay and seed) were spiked separately with saflufenacil (BAS 800H), M800H11 and M800H35 at a level of 1.0 ppm each and were stored at <-5 ºC for a duration of 0, 44, 130, 214, 410-422 and 548-553 days (approximately 0, 1.5, 4.3 and 7.1, 13.7-14.1 and 18.3-18.4 months). Overall, the data indicate that residues of saflufenacil and the metabolites M800H11 and M800H35 were relatively stable at <-5 ºC for approximately 18 months in corn (forage, grain and stover), garbanzo bean (chickpea), orange (fruit, juice, oil and pulp), radish (roots), grape (raisin) and soybean (forage, hay and seed).

STORAGE STABILITY – ANIMAL MATRICES	PMRA # 1546841

Storage stability was demonstrated concurrently during the dairy cattle feeding study by storing spiked (0.10 ppm saflufenacil) and untreated control samples of whole milk, muscle, liver, kidney and fat at $\leq$-18°C for 31-51 days. Based on acceptable recoveries, residues of saflufenacil were demonstrated to be stable in livestock matrices for 51 days (whole milk), 31 days (muscle), 32 days (liver and kidney) and 35 days (fat).

CROP FIELD TRIALS ON CEREAL GRAINS	PMRA # 1546835

The representative commodities for Crop Group 15 (cereal grains) are corn (fresh sweet corn and dried field corn), barley and wheat. During the 2006-2007 growing seasons, a sufficient number of trials were conducted in representative NAFTA growing regions to evaluate the magnitude of saflufenacil in/on cereal grains.

A single broadcast preplant incorporated or a pre-emergence application of the end-use product BAS 800 00 H (70% w:w saflufenacil; wettable granules, WG) was made to the soil surface at 0.139-0.158 kg a.i./ha. A crop oil concentrate adjuvant (1% v:v) was included in the spray mixture together with ammonium sulphate liquid fertilizer (2.04 kg/100 L). The applications were made in 95-346 L water/ha using ground equipment.

Samples of wheat were collected targeting the 6- to 8-inch stem-to-stem elongation (jointing) stage or early flowering stage for forage, early flower (boot) to soft dough stage for hay and at normal maturity for grain and straw. The harvested wheat hay was allowed to dry in the field for 2-20 days to a target moisture content of 10-20%. Samples of wheat were collected from two sites at additional sampling intervals to evaluate residue decline. Samples of sweet corn K + CWHR were harvested at commercial maturity. At four of the field corn trials, field corn was harvested at the milk stage to provide residue data translatable to sweet corn K + CWHR and forage. Samples of field corn were harvested targeting the late dough/early dent stage or the milk stage for forage and at maturity for grain and stover. Samples of grain sorghum were harvested targeting the soft dough to hard dough stage for forage and at maturity for grain and stover. Samples of barley and rice grain plus hulls were harvested at maturity. Samples of rice straw were collected from one site.

Residues of M800H11 and M800H35 were expressed as saflufenacil equivalents using molecular weight conversion factors of 1.06x and 1.42x, respectively. The LOQ each for saflufenacil and the metabolites M800H11 and M800H35 were reported as 0.01 ppm in/on grain and K + CWHR (combined LOQ of 0.03 ppm) and as 0.025 ppm in/on hay, forage, stover and straw (combined LOQ of 0.075 ppm).

Residues of each saflufenacil, M800H11 and M800H35 were all less than the LOQ in all cereal samples with one noted exception. Residues of M800H35 were quantifiable (0.03-0.04 ppm) in four grain sorghum stover samples, all collected from the same trial in Texas. Residues of each saflufenacil and M800H11 were each less than the LOQ in these four grain sorghum stover samples.

Residue decline could not be evaluated because residues of saflufenacil and the metabolites M800H11 and M800H35 were each less than the LOQ in/on all samples of wheat forage, hay, grain and straw from the decline trials.

Note: HAFT = highest average field trial, STMdR = standard median residue, STMR = standard mean residue

Commodity	Total Applic. Rate (kg a.i./ha)	DAT (days)	Total Saflufenacil Residue Levels (ppm) (Saflufenacil + M800H11+ M800H35)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Barley, Grain	0.139-0.158	81-99	12	<0.03	<0.03	<0.03	<0.03	<0.03	0
Corn, K + CWHR	0.141-0.157	81-114	18	<0.03	<0.03	<0.03	<0.03	<0.03	0
Corn, Forage		73-124	60	<0.075	<0.075	<0.075	<0.075	<0.075	0
Corn, Grain		118-158	30	<0.03	<0.03	<0.03	<0.03	<0.03	0
Corn, Stover		118-158	30	<0.075	<0.075	<0.075	<0.075	<0.075	0

CROP FIELD TRIALS ON CEREAL GRAINS							PMRA # 1546835		
Rice, Grain	0.148-0.152	121-146	12	<0.03	<0.03	<0.03	<0.03	<0.03	0
Rice, Straw			2	<0.075	<0.075	<0.075	<0.075	<0.075	0
Grain Sorghum, Forage	0.149-0.156	69-116	36	<0.075	<0.075	<0.075	<0.075	<0.075	0
Grain Sorghum, Grain		97-150	18	<0.03	<0.03	<0.03	<0.03	<0.03	0
Grain Sorghum, Stover		97-150	18	<0.075	0.09	0.09	0.075	0.08	0.005
Wheat, Forage	0.146-0.157	26-231	104	<0.075	<0.075	<0.075	<0.075	<0.075	0
Wheat, Hay		36-231	104	<0.075	<0.075	<0.075	<0.075	<0.075	0
Wheat, Grain		76-280	62	<0.03	<0.03	<0.03	<0.03	<0.03	0
Wheat, Straw		76-280	62	<0.075	<0.075	<0.075	<0.075	<0.075	0

CROP FIELD TRIALS ON CITRUS FRUITS — **PMRA # 1546824**

The representative commodities for Revised Crop Group 10 (citrus fruit) are orange or tangerine; lemon or lime; and grapefruit. During the 2006 and 2007 growing seasons a sufficient number of trials were conducted in representative NAFTA growing regions to evaluate the magnitude of saflufenacil in/on citrus fruits. Three broadcast applications of the end-use product BAS 800 00 H (70% saflufenacil; wettable granules, WG) were made to the orchard floor at fruiting, from the base of the tree to the drip-line, at 0.048-0.055 kg a.i./ha/application and a re-treatment interval of 20-22 days, for a seasonal rate of 0.149-0.159 kg a.i./ha. The applications, beginning at 41-43 days prior to harvest, were made in 183-339 L water/ha with ground equipment. A crop oil concentrate adjuvant (1% v:v) was included in the spray mixture together with ammonium sulphate liquid fertilizer (2.04 kg/100 L). Samples of mature citrus fruits were harvested on the day of the last application, a 0-day preharvest interval (PHI). Additional samples of oranges were harvested from two sites at 7, 14 and 21 days after the last application to evaluate residue decline. Residues of M800H11 and M800H35 were expressed as saflufenacil equivalents using molecular weight conversion factors of 1.06x and 1.42x, respectively. The LOQ was reported as 0.01 ppm each for saflufenacil and the metabolites M800H11 and M800H35 in/on citrus fruits (combined LOQ of 0.03 ppm).

In the decline trials, resides of saflufenacil and the metabolites M800H11 and M800H35 were each less than the LOQ in/on samples of orange fruit harvested 0, 7, 14 and 21 days after the last application. Therefore, residue decline could not be evaluated in citrus fruit.

Commodity	Total Applic. Rate (kg a.i./ha)	PHI (days)	Total Saflufenacil Residue Levels (ppm) (Saflufenacil + M800H11 + M800H35)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Grapefruit, Fruit	0.149-0.159	0	12	<0.03	<0.03	<0.03	<0.03	<0.03	0
Lemon, Fruit		0	10	<0.03	<0.03	<0.03	<0.03	<0.03	0
Orange, Fruit		0	24	<0.03	<0.03	<0.03	<0.03	<0.03	0
		7	4	<0.03	<0.03	<0.03	<0.03	<0.03	0
		14	4	<0.03	<0.03	<0.03	<0.03	<0.03	0
		21	4	<0.03	<0.03	<0.03	<0.03	<0.03	0

CROP FIELD TRIALS ON COTTON	PMRA # 1546837

During the 2007 growing season a sufficient number of trials were conducted in representative NAFTA growing regions to evaluate the magnitude of saflufenacil in/on cotton. A single pre-emergence broadcast spray of the end-use product BAS 800 00 H (70% saflufenacil; water dispersible granules, WG) was made to the soil surface at planting at 0.024-0.036 kg a.i./ha or at 0.049-0.072 kg a.i./ha. The applications were made to side-by-side plots with ground equipment using 187-265 L water/ha. A crop oil concentrate adjuvant (1% v:v) was included in the spray mixture together with ammonium sulphate liquid fertilizer (2.04 kg/100 L). Samples of mature cotton harvested by spindle-picker or stripper-picker, or by hand, at 130-186 days after treatment of the soil, were ginned into undelinted cotton seed and cotton gin byproducts. Residues of M800H11 and M800H35 were expressed as saflufenacil equivalents using molecular weight conversion factors of 1.06x and 1.42x, respectively. The LOQ each for saflufenacil and the metabolites M800H11 and M800H35 was reported as 0.01 ppm in/on cotton undelinted seed (combined LOQ of 0.03 ppm) and as 0.025 ppm in/on cotton gin byproducts (combined LOQ of 0.075 ppm). At one site (Hockley, Texas), following application of saflufenacil at the higher rate (0.050 kg a.i./ha) the crop was lost due to phytotoxicity.

Commodity	Total Applic. Rate (kg a.i./ha)	DAT (days)	Total Saflufenacil Residue Levels (ppm) (Saflufenacil + M800H11 + M800H35)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Cotton, Undelinted Seed	0.024-0.036	130-186	24	<0.03	<0.03	<0.03	<0.03	<0.03	0
Cotton, Gin Byproducts		147-186	12	<0.075	<0.075	<0.075	<0.075	<0.075	0
Cotton, Undelinted Seed	0.049-0.072	130-186	22	<0.03	<0.03	<0.03	<0.03	<0.03	0
Cotton, Gin By-Products		156-186	10	<0.075	<0.075	<0.075	<0.075	<0.075	0

CROP FIELD TRIALS ON GRAPES	PMRA # 1546833

During the 2006 growing season a sufficient number of trials were conducted in representative NAFTA growing regions to evaluate the magnitude of the residue of saflufenacil in/on grapes. Three broadcast applications of the end-use product BAS 800 00 H (70% saflufenacil; wettable granules) were made to the vineyard floor at 0.024-0.027 kg a.i./ha/application for a seasonal rate of 0.074-0.079 kg a.i./ha. The first application was made at dormancy, 115-159 days before harvest; the second application was made at 20-21 days before harvest and the third application was made at maturity. The applications were made with ground equipment using 186-340 L water/ha. A crop oil concentrate adjuvant (1% v:v) was included in the spray mixture together with ammonium sulphate liquid fertilizer (2.04 kg/100 L). Samples of mature grapes were harvested on the day of the last application (PHI = 0 days). For one trial, samples were harvested additionally at 14 days after the last application (PHI = 14 days). Residues of M800H11 and M800H35 were expressed as saflufenacil equivalents using molecular weight conversion factors of 1.06x and 1.42x, respectively. The LOQ was reported as 0.01 ppm each for saflufenacil and the metabolites M800H11 and M800H35 in/on grape fruit (combined LOQ of 0.03 ppm).

Commodity	Total Applic. Rate (kg a.i./ha)	PHI (days)	Total Saflufenacil Residue Levels (ppm) (Saflufenacil + M800H11 +M800H35)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Grape, Fruit	0.074-0.079	0	24	<0.03	<0.03	<0.03	<0.03	<0.03	0
		14	2	<0.03	<0.03	<0.03	<0.03	<0.03	N/A

CROP FIELD TRIALS ON LEGUMES	PMRA # 1546821

The representative commodities for Crop Group 6 (legume vegetables, succulent or dried) are bean (Phaseolus spp.; one succulent cultivar and one dried cultivar); pea (Pisum spp.; one succulent cultivar and one dried cultivar); and soybean. During the 2006-2007 growing seasons a sufficient number of trials were conducted in representative NAFTA growing regions to evaluate the magnitude of saflufenacil in/on legumes. Each trial consisted of one control plot and one or two treated plots. For sites with two treatment plots, one plot was designated to produce succulent peas and succulent beans, representing edible-podded seed and succulent shelled seed, and the second plot was designated to produce dried pea seeds and dried bean seeds. Because the representative crops succulent peas and succulent beans are not on any of the proposed Canadian labels, but are on the proposed American label, an MRL will be proposed for saflufenacil in/on imported legume crops, Crop Group 6.

A single broadcast preplant incorporated or a pre-emergence application of the end-use product BAS 800 00 H (70% saflufenacil; wettable granules) was made to the soil surface at 0.0926-0.1037 kg a.i./ha. A crop oil concentrate adjuvant (1% v:v) was included in the spray mixture together with ammonium sulphate liquid fertilizer (2.04 kg/100 L). The applications were made in 147-289 L water/ha using ground equipment.

Samples of pea and soybean immature pod with seed were harvested by hand 62-119 days after treatment to yield succulent seed with pod. A portion was shelled to generate samples of succulent seed without pod. Soybean forage and hay samples were harvested at the same time the succulent pods were collected. Hay samples were air-dried under ambient conditions. Samples of mature pea, garbanzo bean and soybean dry seed were harvested 82-117 days after treatment, 93-148 days after treatment, and 82-162 days after treatment, respectively. At four sites, additional samples of succulent pea, succulent soybean seed, soybean forage and soybean hay were collected at 2-3 additional sampling intervals to evaluate residue decline.

Residues of M800H11 and M800H35 were expressed as saflufenacil equivalents using molecular weight conversion factors of 1.06x and 1.42x, respectively. The LOQ each for saflufenacil and the metabolites M800H11 and M800H35 were reported as 0.01 ppm (combined LOQ of 0.03 ppm) in/on all legume samples except for soybean forage and soybean hay for which the LOQ was reported as 0.025 ppm in/on hay, forage and straw (combined LOQ of 0.075 ppm).

Because residues of saflufenacil and the metabolites M800H11 and M800H 35 were each less than the LOQ in/on all samples from the four decline trials, residue decline could not be evaluated.

Commodity	Total Applic. Rate (kg a.i./ha)	PHI (days)	Total Saflufenacil Residue Levels (ppm) (Saflufenacil + M800H11 +M800H35)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Pea, Succulent Seed with Pod	0.093-0.104	63-83	28	<0.03	<0.03	<0.03	<0.03	<0.03	0
Pea, Succulent Seed without Pod		63-83	28	<0.03	<0.03	<0.03	<0.03	<0.03	0
Pea, Dry Seed		82-117	18	<0.03	<0.03	<0.03	<0.03	<0.03	0
Garbanzo Bean, Dry Seed		93-148	22	<0.03	<0.03	<0.03	<0.03	<0.03	0
Soybean, Succulent Seed with Pod		62-119	42	<0.03	<0.03	<0.03	<0.03	<0.03	0
Soybean, Succulent Seed without Pod		62-119	42	<0.03	<0.03	<0.03	<0.03	<0.03	0
Soybean, Dry Seed		82-162	30	<0.03	<0.03	<0.03	<0.03	<0.03	0

Soybean, Forage		62-126	44	<0.075	<0.075	<0.075	<0.075	<0.075	0
Soybean, Hay		62-126	44	<0.075	<0.075	<0.075	<0.075	<0.075	0

CROP FIELD TRIALS ON POME FRUITS **PMRA # 1546826**

The representative commodities for Crop Group 11 (pome fruits) are apple and pear. During the 2006 growing season a sufficient number of trials were conducted in representative NAFTA growing regions to evaluate the magnitude of the residue of saflufenacil in/on pome fruits. Three broadcast applications of the end-use product BAS 800 00 H (70% saflufenacil; wettable granules) were made to the orchard floor at 0.048-0.053 kg a.i./ha/application for a seasonal rate of 0.145-0.157 kg a.i./ha. The first application was made at dormancy except at one site where the application was made during fruiting at 64 days prior to harvest due to frost damage to the original plot; the second application was made at 19-22 days before harvest, except 28 days at one site; and the third application was made on the day of harvest. The applications were made with ground equipment using 186-356 L water/ha. A crop oil concentrate adjuvant (1% v:v) was included in the spray mixture together with ammonium sulphate liquid fertilizer (2.04 kg/100 L). Samples of mature pome fruits were harvested on the day of the last application (0-day PHI). Additional samples of apples and pears were harvested from one site, respectively at 7, 14 and 21 days after the last application to evaluate residue decline. Residues of M800H11 and M800H35 were expressed as saflufenacil equivalents using molecular weight conversion factors of 1.06x and 1.42x, respectively. The limit of quantitation (LOQ) was reported as 0.01 ppm each for saflufenacil and the metabolites M800H11 and M800H35 in/on pome fruits (combined LOQ of 0.03 ppm).

In the apple and pear decline trials, residues of saflufenacil and the metabolites M800H11 and M800H35 were each less than the LOQ in/on fruit samples harvested 0, 7, 14 and 21-days after the last application. Therefore, residue decline could not be evaluated in pome fruits.

Commodity	**Total Applic. Rate (kg a.i./ha)**	**PHI (days)**	**Total Saflufenacil Residue Levels (ppm) (Saflufenacil + M800H11 +M800H35)**						
			n	**Min.**	**Max.**	**HAFT**	**Median (STMdR)**	**Mean (STMR)**	**Std. Dev.**
Apple, Fruit	0.147-0.157	0	30	<0.03	<0.03	<0.03	<0.03	<0.03	0
		7	2	<0.03	<0.03	<0.03	<0.03	<0.03	N/A
		14	2	<0.03	<0.03	<0.03	<0.03	<0.03	N/A
		21	2	<0.03	<0.03	<0.03	<0.03	<0.03	N/A
Pear, Fruit	0.145-0.153	0	20	<0.03	<0.03	<0.03	<0.03	<0.03	0
		7	2	<0.03	<0.03	<0.03	<0.03	<0.03	N/A
		14	2	<0.03	<0.03	<0.03	<0.03	<0.03	N/A
		21	2	<0.03	<0.03	<0.03	<0.03	<0.03	N/A

CROP FIELD TRIALS ON STONE FRUITS	PMRA # 1546828

The representative commodities for Crop Group12 (stone fruits) are sweet cherry or tart cherry; peach; and plum or fresh prune. During the 2006-2007 growing seasons a sufficient number of trials were conducted in representative NAFTA growing regions to evaluate the magnitude of the residue of saflufenacil in/on stone fruits. Three broadcast applications of the end-use product BAS 800 00 H (70% saflufenacil; wettable granules) were made to the orchard floor at 0.045-0.053 kg a.i./ha/application for a seasonal rate of 0.147-0.156 kg a.i./ha. The first application was made at dormancy, 76-196 prior to harvest; the second application was made at 20-24 days before harvest; and the third application was made on the day of harvest. The applications were made with ground equipment in 187-340 L water/ha. A crop oil concentrate adjuvant (1% v:v) was included in the spray mixture together with ammonium sulphate liquid fertilizer (2.04 kg/100 L). Samples of mature stone fruits were harvested on the day of the last application (0-day PHI). Additional samples of stone fruits were harvested at 6-8, 13-14 and 20-21 days after the last application to evaluate residue decline. Residues of M800H11 and M800H35 were expressed as saflufenacil equivalents using molecular weight conversion factors of 1.06x and 1.42x, respectively. The LOQ was reported as 0.01 ppm each for saflufenacil and the metabolites M800H11 and M800H35 in/on stone fruits (combined LOQ of 0.03 ppm).

Residues of saflufenacil and the metabolites M800H11 and M800H35 were each less than the LOQ in/on all stone fruit samples harvested on the day of the last application (0-day PHI) and in/on all stone fruit samples harvested 6-8, 13-14 and 20-21 days after the last application. Therefore, residue decline could not be evaluated in stone fruit.

Commodity	Total Applic. Rate (kg a.i./ha)	PHI (days)	Total Saflufenacil Residue Levels (ppm) (Saflufenacil + M800H11 +M800H35)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Peach, Fruit	0.0.147-0.156	0	26	<0.03	<0.03	<0.03	<0.03	<0.03	0
		6-8	25	<0.03	<0.03	<0.03	<0.03	<0.03	0
		13-14	19	<0.03	<0.03	<0.03	<0.03	<0.03	0
		21	19	<0.03	<0.03	<0.03	<0.03	<0.03	0
Plum, Fruit		0	20	<0.03	<0.03	<0.03	<0.03	<0.03	0
		6-7	20	<0.03	<0.03	<0.03	<0.03	<0.03	0
		14	20	<0.03	<0.03	<0.03	<0.03	<0.03	0
		21	18	<0.03	<0.03	<0.03	<0.03	<0.03	0
Sweet Cherry, Fruit		0	6	<0.03	<0.03	<0.03	<0.03	<0.03	0
		7	6	<0.03	<0.03	<0.03	<0.03	<0.03	0
		14	6	<0.03	<0.03	<0.03	<0.03	<0.03	0
		21	3	<0.03	<0.03	<0.03	<0.03	<0.03	0
Tart Cherry, Fruit		0	6	<0.03	<0.03	<0.03	<0.03	<0.03	0
		6-7	6	<0.03	<0.03	<0.03	<0.03	<0.03	0
		13-14	6	<0.03	<0.03	<0.03	<0.03	<0.03	0
		20-21	6	<0.03	<0.03	<0.03	<0.03	<0.03	0

CROP FIELD TRIALS ON SUNFLOWER	PMRA # 1546839

During the 2007 growing season a sufficient number of trials were conducted in representative NAFTA growing regions to evaluate the magnitude of the residue of saflufenacil in/on sunflower. Two late season over the top broadcast applications of the end-use product BAS 800 00 H (70% saflufenacil; wettable granules) were made to sunflowers with a re-treatment interval of seven days and at 0.049-0.052 kg a.i./ha/application for a seasonal rate of 0.099-0.102 kg a.i./ha. The applications were made with ground equipment using 182-193 L water/ha. A crop oil concentrate adjuvant (1% v:v) was included in the spray mixture together with ammonium sulphate liquid fertilizer (2.04 kg/100 L). Samples of mature sunflower seeds were harvested 6-8 and 13-15 days after the last application. During one trial, additional samples were harvested 3, 10 and 20 days after the last application to evaluate residue decline. The LOQ was reported as 0.01 ppm each for saflufenacil and the metabolites M800H11 and M800H35 in/on sunflower seed (combined LOQ of 0.03 ppm).

The residue decline data (n = two per sampling interval) indicated that the total residues of saflufenacil decreased gradually over the sampling period: 0.12 ppm at the 3-day PHI, 0.07-0.10 ppm at the 6-day PHI, 0.10 ppm at the 10-day PHI, 0.07-0.09 ppm at the 14-day PHI and 0.06 ppm at the 20-day PHI. Residues of M800H11 and M800H35 were expressed as saflufenacil equivalents using molecular weight conversion factors of 1.06x and 1.42x, respectively.

Commodity	Total Applic. Rate (kg a.i./ha)	PHI (days)	Total Saflufenacil Residue Levels (ppm) (Saflufenacil + M800H11 +M800H35)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Sunflower, Seeds	0.099-0.102	3	2	0.12	0.12	0.12	0.12	0.12	N/A
		6-8	16	0.05	0.58	0.50	0.17	0.20	0.14
		10	2	0.10	0.10	0.10	0.10	0.10	N/A
		13-15	16	0.04	0.56	0.48	0.12	0.20	0.17
		20	2	0.06	0.06	0.06	N/A	0.06	N/A

CROP FIELD TRIALS ON TREE NUTS	PMRA # 1546831

The representative commodities for Crop Group14 (tree nuts) are almond and pecan. During the 2006 growing season a sufficient number of trials were conducted in representative NAFTA growing regions to evaluate the magnitude of the residue of saflufenacil in/on tree nuts. Three broadcast applications of the end-use product BAS 800 00 H (70% saflufenacil; wettable granules) were made to the orchard floor at 0.049-0.052 kg a.i./ha/application for a seasonal rate of 0.148-0.154 kg a.i./ha. The first application was made at dormancy, 169-243 prior to harvest; the second application was made at 20-24 days before harvest; and the third application was made at maturity. The applications were made in 182-286 L water/ha with ground equipment. A crop oil concentrate adjuvant (1% v:v) was included in the spray mixture together with ammonium sulphate liquid fertilizer (2.04 kg/100 L). Samples of mature almond nutmeat, pecan nutmeat and almond hulls were harvested 7-8 days and 13-14 days after the last application. At one site, samples of almonds were harvested 0, 7, 14, 21 and 28 days after the last application to evaluate residue decline. Residues of M800H11 and M800H35 were expressed as saflufenacil equivalents using molecular weight conversion factors of 1.06x and 1.42x, respectively. The LOQ each for saflufenacil and the metabolites M800H11 and M800H35 was reported as 0.01 ppm in/on almond nutmeat and pecan nutmeat (combined LOQ of 0.03 ppm) and as 0.025 ppm in/on almond hulls (combined LOQ of 0.075 ppm).

Residues of saflufenacil and the metabolites M800H11 and M800H35 were each below the LOQ in/on all samples of almond nutmeat from the decline trial. Therefore, residue decline in almond nutmeat could not be evaluated. In almond hulls, residues of saflufenacil ranged from 0.139 to 0.181 ppm at the 0-day PHI and were below the LOQ in/on all samples harvested at later PHIs.

CROP FIELD TRIALS ON TREE NUTS									PMRA # 1546831
Commodity	**Total Applic. Rate (kg a.i./ha)**	**PHI (days)**	**Total Saflufenacil Residue Levels (ppm) (Saflufenacil + M800H11 +M800H35)**						
			n	**Min.**	**Max.**	**HAFT**	**Median (STMdR)**	**Mean (STMR)**	**Std. Dev.**
Almond, Nutmeat	0.148-0.154	0	2	<0.03	<0.03	<0.03	<0.03	<0.03	N/A
		7	10	<0.03	<0.03	<0.03	<0.03	<0.03	0
		14	10	<0.03	<0.03	<0.03	<0.03	<0.03	0
		21	2	<0.03	<0.03	<0.03	<0.03	<0.03	N/A
		28	2	<0.03	<0.03	<0.03	<0.03	<0.03	N/A
Almond, Hulls		0	2	0.1394	0.1808	0.1394	0.1601	0.1601	N/A
		7	10	<0.075	<0.075	<0.075	<0.075	<0.075	0
		14	10	<0.075	<0.075	<0.075	<0.075	<0.075	0
		21	2	<0.075	<0.075	<0.075	<0.075	<0.075	N/A
		28	2	<0.075	<0.075	<0.075	<0.075	<0.075	N/A
Pecan, Nutmeat		7-8	10	<0.03	<0.03	<0.03	<0.03	<0.03	0
		13-14	10	<0.03	<0.03	<0.03	<0.03	<0.03	0

FIELD ACCUMULATION IN ROTATIONAL CROPS – Radish, Lettuce and Wheat	PMRA # 1546866

The field rotational study was conducted in NAFTA Growing Regions 2 and 10 with three trials each in Georgia and California, respectively. The end-use product BAS 800 00 H (70% saflufenacil; wettable granules) was applied as a single pre-emergence application to the soil, after planting of the primary crop wheat, at 148-154 g a.i./ha. The representative rotational crops radish, lettuce, and wheat (spring and winter) were grown at PBIs of four months (119-125 days), six months (180-183 days) and nine months (270-274 days). All rotational crop samples were harvested at commercial maturity, 34-169 days after planting for radish, 39-187 days for lettuce, 59-147 days for forage and hay and 121-223 days for grain and straw. All collected samples were promptly frozen on the date of harvest. Residues of M800H11 and M800H35 were expressed as saflufenacil equivalents using molecular weight conversion factors of 1.06x and 1.42x, respectively. The LOQ was 0.01 ppm each for saflufenacil and the metabolites M800H11 and M800H35 in crop commodities, except for wheat forage, hay and straw, for which the LOQs were 0.025 ppm per analyte.

Summary of Residue Data in Rotational Crops Following Primary Treatment with Saflufenacil

Commodity	**Total Applic. Rate (kg a.i./ha)**	**PBI (days)**	**Total Saflufenacil Residue Levels (ppm) (Saflufenacil + M800H11 +M800H35)**						
			n	**Min.**	**Max.**	**HAFT**	**Median (STMdR)**	**Mean (STMR)**	**Std. Dev.**
Wheat, forage	148-154	120-125	4	<0.075	<0.075	<0.075	<0.075	<0.075	0
		180-183	4	<0.075	<0.075	<0.075	<0.075	<0.075	0
		270-273	4	<0.075	<0.075	<0.075	<0.075	<0.075	0
Wheat, hay	148-154	120-125	4	<0.075	<0.075	<0.075	<0.075	<0.075	0
		180-183	4	<0.075	<0.075	<0.075	<0.075	<0.075	0
		270-273	4	<0.075	<0.075	<0.075	<0.075	<0.075	0
Wheat, grain	148-154	120-125	4	<0.03	<0.03	<0.03	<0.03	<0.03	0
		180-183	4	<0.03	<0.03	<0.03	<0.03	<0.03	0
		270-273	4	<0.03	<0.03	<0.03	<0.03	<0.03	0
Wheat, straw	148-154	120-125	4	<0.075	<0.075	<0.075	<0.075	<0.075	0
		180-183	4	<0.075	<0.075	<0.075	<0.075	<0.075	0
		270-273	4	<0.075	<0.075	<0.075	<0.075	<0.075	0
Radish, tops	150-151	119-122	4	<0.03	<0.03	<0.03	<0.03	<0.03	0
		180-181	4	<0.03	<0.03	<0.03	<0.03	<0.03	0
		270-274	4	<0.03	<0.03	<0.03	<0.03	<0.03	0

FIELD ACCUMULATION IN ROTATIONAL CROPS – Radish, Lettuce and Wheat							PMRA # 1546866		
Radish, root	150-151	119-122	4	<0.03	<0.03	<0.03	<0.03	<0.03	0
		180-181	4	<0.03	<0.03	<0.03	<0.03	<0.03	0
		270-274	4	<0.03	<0.03	<0.03	<0.03	<0.03	0
Lettuce, leaves	150-151	119-122	4	<0.03	<0.03	<0.03	<0.03	<0.03	0
		180-181	4	<0.03	<0.03	<0.03	<0.03	<0.03	0
		270-274	4	<0.03	<0.03	<0.03	<0.03	<0.03	0

PROCESSED FOOD AND FEED	PMRA # 1546849, 1546851, 1546856, 1608334, 1546858, 1546847, 1546845 and 1546854

Processing studies were conducted on apple, cereal grains, oranges, cotton, grape, plum, soybean and sunflower. As quantifiable residues of each of saflufenacil and the metabolites M800H11 and M800H35 were not found in the raw agricultural commodities of apple, grape, plum, soybean seed, wheat grain, field corn grain, rice grain and sweet sorghum stalks, the respective processed commodities were not analyzed.

Raw Agricultural Commodity	Processed Commodity	Experimental Processing Factor
Undelinted Cotton Seed	Hulls	Could not be calculated as residues of saflufenacil and the metabolites M800H11 and M800H35 were each <LOQ in cotton seed and the processed fractions hulls, meal and refined oil.
	Meal	
	Refined Oil	
Orange Fruit	Orange Oil	Could not be calculated as residues of saflufenacil and the metabolites M800H11 and M800H35 were each <LOQ in orange fruit and orange oil. The processed commodities juice and pulp were accordingly not analyzed.
Sunflower Seed	Meal	0.8
	Refined Oil	<0.1

LIVESTOCK FEEDING – DAIRY CATTLE	PMRA # 1546841

Saflufenacil was administered orally in treated feed to 14 Friesian dairy cows for 28-29 consecutive days. The target doses were 0.1, 0.3 ppm and 1.0 ppm. The actual residue intakes in the diets were 0.118, 0.363, and 1.386 ppm. Samples of whole milk were collected twice daily during the dosing period. Samples of whole milk were separated into skim milk and cream, and each was analyzed. On study day 28 or day 29 animals were sacrificed and samples of liver, kidney, composite muscle and composite fat were collected for analysis. A depuration study was conducted for the 1.0 ppm dosing group in which selected animals were sacrificed two days and seven days after withdrawal of the dose(days 30 and 35, respectively). Half-lives of 2.5 and 4.0 days were calculated for saflufenacil residues in liver and kidney, respectively.

Summary of Residue Data from Ruminant Feeding Study with Saflufenacil

Matrix	Feeding Level (ppm)	Saflufenacil Residue Levels (ppm)					
		n	Minimum	Maximum	Median	Mean	Standard Deviation
Whole Milk/ Day 1-28-29	0	3	<0.01	<0.01	<0.01	<0.01	0
	0.1	3	<0.01	<0.01	<0.01	<0.01	0
	0.3	3	<0.01	<0.01	<0.01	<0.01	0
	1.0	5	<0.01	<0.01	<0.01	<0.01	0
	1.0 (2-day depuration)	1	<0.01	<0.01	N/A	<0.01	N/A
	1.0 (7-day depuration)	1	<0.01	<0.01	N/A	<0.01	N/A

Skim Milk/ Day 22	0	3	<0.01	<0.01	<0.01	<0.01	0
	0.1	3	<0.01	<0.01	<0.01	<0.01	0
	0.3	3	<0.01	<0.01	<0.01	<0.01	0
	1.0	5	<0.01	<0.01	<0.01	<0.01	0
	1.0 (2-day depuration)	1	<0.01	<0.01	N/A	<0.01	N/A
	1.0 (7-day depuration)	1	<0.01	<0.01	N/A	<0.01	N/A
Cream/Day 22	0	3	<0.01	<0.01	<0.01	<0.01	0
	0.1	3	<0.01	<0.01	<0.01	<0.01	0
	0.3	3	<0.01	<0.01	<0.01	<0.01	0
	1.0	5	<0.01	<0.01	<0.01	<0.01	0
	1.0 (2-day depuration)	1	<0.01	<0.01	N/A	<0.01	N/A
	1.0 (7-day depuration)	1	<0.01	<0.01	N/A	<0.01	N/A
Fat	0	3	<0.01	<0.01	<0.01	<0.01	0
	0.1	3	<0.01	<0.01	<0.01	<0.01	0
	0.3	3	<0.01	<0.01	<0.01	<0.01	0
	1.0	3	<0.01	<0.01	<0.01	<0.01	0
	1.0 (2-day depuration)	1	<0.01	<0.01	N/A	<0.01	N/A
	1.0 (7-day depuration)	1	<0.01	<0.01	N/A	<0.01	N/A
Muscle	0	3	<0.01	<0.01	<0.01	<0.01	0
	0.1	3	<0.01	<0.01	<0.01	<0.01	0
	0.3	3	<0.01	<0.01	<0.01	<0.01	0
	1.0	3	<0.01	<0.01	<0.01	<0.01	0
	1.0 (2-day depuration)	1	<0.01	<0.01	N/A	<0.01	N/A
	1.0 (7-day depuration)	1	<0.01	<0.01	N/A	<0.01	N/A
Liver	0	3	<0.01	<0.01	<0.01	<0.01	0
	0.1	3	0.17	0.26	0.19	0.21	0.047
	0.3	3	0.67	0.88	0.76	0.77	0.105
	1.0	3	2.09	3.49	2.25	2.61	0.77
	1.0 (2-day depuration)	1	1.66	1.66	N/A	1.66	N/A
	1.0 (7-day depuration)	1	0.34	0.34	N/A	0.34	N/A
Kidney	0	3	<0.01	<0.01	<0.01	<0.01	0
	0.1	3	<0.01	<0.01	<0.01	<0.01	0
	0.3	3	0.02	0.02	0.02	0.02	0
	1.0	3	0.03	0.04	0.004	0.037	0.006
	1.0 (2-day depuration)	1	0.03	0.03	N/A	0.03	N/A
	1.0 (7-day depuration)	1	<0.01	<0.01	N/A	<0.01	N/A

Matrix	Feeding level (ppm)	Maximum Residues (ppm)	Transfer Coeffecient[1]	Dietary Burden (ppm)		Anticipated Residues[2] (ppm)	
				Beef/Dairy Cattle	Swine	Beef/Dairy Cattle	Swine
Whole Milk	1.0	<0.01	<0.01	0.12/0.24	0.18	<0.0012/ <0.0024	<0.002
Skim Milk	1.0	<0.01	<0.01			<0.0012/ <0.0024	<0.002
Cream	1.0	<0.01	<0.01			<0.0012/ <0.0024	<0.002
Fat	1.0	<0.01	<0.01			<0.0012/ <0.0024	<0.002
Muscle	1.0	<0.01	<0.01			<0.0012/ <0.0024	<0.002
Kidney	0.3	0.02	0.067			0.006/0.013	0.010
	1.0	0.04	0.04				
			Mean = 0.054				
Liver	0.1	0.26	2.6			0.36/0.72	0.54
	0.3	0.88	2.9				
	1.0	3.49	3.49				
			Mean = 3.0				

[1]Calculated as residue level-to-feed ratios.
[2]Calculated as (mean transfer coefficient) × (dietary burden).
N/A = Not applicable.

LIVESTOCK FEEDING – POULTRY | **PMRA # 1546843**

BASF submitted an acceptable rationale to waive the data requirement for a poultry feeding study. The results of the hen metabolism study indicate that there is no reasonable expectation of finite residues of saflufenacil in the meat, meat byproducts and eggs of poultry as a result of the proposed uses.

FIELD ACCUMULATION IN ROTATIONAL CROPS – Radish, Lettuce and Wheat | **PMRA # 1546866**

The field rotational study was conducted in NAFTA Growing Regions 2 and 10 with three trials each in Georgia and California, respectively. The end-use product BAS 800 00 H (70% saflufenacil; wettable granules) was applied as a single pre-emergence application to the soil, after planting of the primary crop wheat, at 148-154 g a.i./ha. The representative rotational crops radish, lettuce, and wheat (spring and winter) were grown at PBIs of four months (119-125 days), six months (180-183 days) and nine months (270-274 days). All rotational crop samples were harvested at commercial maturity, 34-169 days after planting for radish, 39-187 days for lettuce, 59-147 days for forage and hay and 121-223 days for grain and straw. All collected samples were promptly frozen on the date of harvest. Residues of M800H11 and M800H35 were expressed as saflufenacil equivalents using molecular weight conversion factors of 1.06x and 1.42x, respectively. The LOQ was 0.01 ppm each for saflufenacil and the metabolites M800H11 and M800H35 in crop commodities, except for wheat forage, hay and straw, for which the LOQs were 0.025 ppm per analyte.

Summary of Residue Data in Rotational Crops Following Primary Treatment with Saflufenacil

Commodity	Total Applic. Rate (kg a.i./ha)	PBI (days)	Total Saflufenacil Residue Levels (ppm) (Saflufenacil + M800H11 +M800H35)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Wheat, forage	148-154	120-125	4	<0.075	<0.075	<0.075	<0.075	<0.075	0
		180-183	4	<0.075	<0.075	<0.075	<0.075	<0.075	0
		270-273	4	<0.075	<0.075	<0.075	<0.075	<0.075	0
Wheat, hay	148-154	120-125	4	<0.075	<0.075	<0.075	<0.075	<0.075	0
		180-183	4	<0.075	<0.075	<0.075	<0.075	<0.075	0
		270-273	4	<0.075	<0.075	<0.075	<0.075	<0.075	0

FIELD ACCUMULATION IN ROTATIONAL CROPS – Radish, Lettuce and Wheat							PMRA # 1546866		
Wheat, grain	148-154	120-125	4	<0.03	<0.03	<0.03	<0.03	<0.03	0
		180-183	4	<0.03	<0.03	<0.03	<0.03	<0.03	0
		270-273	4	<0.03	<0.03	<0.03	<0.03	<0.03	0
Wheat, straw	148-154	120-125	4	<0.075	<0.075	<0.075	<0.075	<0.075	0
		180-183	4	<0.075	<0.075	<0.075	<0.075	<0.075	0
		270-273	4	<0.075	<0.075	<0.075	<0.075	<0.075	0
Radish, tops	150-151	119-122	4	<0.03	<0.03	<0.03	<0.03	<0.03	0
		180-181	4	<0.03	<0.03	<0.03	<0.03	<0.03	0
		270-274	4	<0.03	<0.03	<0.03	<0.03	<0.03	0
Radish, root	150-151	119-122	4	<0.03	<0.03	<0.03	<0.03	<0.03	0
		180-181	4	<0.03	<0.03	<0.03	<0.03	<0.03	0
		270-274	4	<0.03	<0.03	<0.03	<0.03	<0.03	0
Lettuce, leaves	150-151	119-122	4	<0.03	<0.03	<0.03	<0.03	<0.03	0
		180-181	4	<0.03	<0.03	<0.03	<0.03	<0.03	0
		270-274	4	<0.03	<0.03	<0.03	<0.03	<0.03	0

PROCESSED FOOD AND FEED		PMRA # 1546849, 1546851, 1546856, 1608334, 1546858, 1546847, 1546845 and 1546854
Processing studies were conducted on apple, cereal grains, oranges, cotton, grape, plum, soybean and sunflower. As quantifiable residues of each of saflufenacil and the metabolites M800H11 and M800H35 were not found in the raw agricultural commodities of apple, grape, plum, soybean seed, wheat grain, field corn grain, rice grain and sweet sorghum stalks, the respective processed commodities were not analyzed.		
Raw Agricultural Commodity	**Processed Commodity**	**Experimental Processing Factor**
Undelinted Cotton Seed	Hulls	Could not be calculated as residues of saflufenacil and the metabolites M800H11 and M800H35 were each <LOQ in cotton seed and the processed fractions hulls, meal and refined oil.
	Meal	
	Refined Oil	
Orange Fruit	Orange Oil	Could not be calculated as residues of saflufenacil and the metabolites M800H11 and M800H35 were each <LOQ in orange fruit and orange oil. The processed commodities juice and pulp were accordingly not analyzed.
Sunflower Seed	Meal	0.8
	Refined Oil	<0.1

LIVESTOCK FEEDING – DAIRY CATTLE	PMRA # 1546841
Saflufenacil was administered orally in treated feed to 14 Friesian dairy cows for 28-29 consecutive days. The target doses were 0.1, 0.3 ppm and 1.0 ppm. The actual residue intakes in the diets were 0.118, 0.363, and 1.386 ppm. Samples of whole milk were collected twice daily during the dosing period. Samples of whole milk were separated into skim milk and cream, and each was analyzed. On study day 28 or day 29 animals were sacrificed and samples of liver, kidney, composite muscle and composite fat were collected for analysis. A depuration study was conducted for the 1.0 ppm dosing group in which selected animals were sacrificed two days and seven days after withdrawal of the dose(days 30 and 35, respectively). Half-lives of 2.5 and 4.0 days were calculated for saflufenacil residues in liver and kidney, respectively.	

LIVESTOCK FEEDING – DAIRY CATTLE		PMRA # 1546841					
Summary of Residue Data from Ruminant Feeding Study with Saflufenacil							
Matrix	**Feeding Level (ppm)**	**Saflufenacil Residue Levels (ppm)**					
		n	**Minimum**	**Maximum**	**Median**	**Mean**	**Standard Deviation**
Whole Milk/ Day 1-28-29	0	3	<0.01	<0.01	<0.01	<0.01	0
	0.1	3	<0.01	<0.01	<0.01	<0.01	0
	0.3	3	<0.01	<0.01	<0.01	<0.01	0
	1.0	5	<0.01	<0.01	<0.01	<0.01	0
	1.0 (2-day depuration)	1	<0.01	<0.01	N/A	<0.01	N/A
	1.0 (7-day depuration)	1	<0.01	<0.01	N/A	<0.01	N/A
Skim Milk/ Day 22	0	3	<0.01	<0.01	<0.01	<0.01	0
	0.1	3	<0.01	<0.01	<0.01	<0.01	0
	0.3	3	<0.01	<0.01	<0.01	<0.01	0
	1.0	5	<0.01	<0.01	<0.01	<0.01	0
	1.0 (2-day depuration)	1	<0.01	<0.01	N/A	<0.01	N/A
	1.0 (7-day depuration)	1	<0.01	<0.01	N/A	<0.01	N/A
Cream/Day 22	0	3	<0.01	<0.01	<0.01	<0.01	0
	0.1	3	<0.01	<0.01	<0.01	<0.01	0
	0.3	3	<0.01	<0.01	<0.01	<0.01	0
	1.0	5	<0.01	<0.01	<0.01	<0.01	0
	1.0 (2-day depuration)	1	<0.01	<0.01	N/A	<0.01	N/A
	1.0 (7-day depuration)	1	<0.01	<0.01	N/A	<0.01	N/A
Fat	0	3	<0.01	<0.01	<0.01	<0.01	0
	0.1	3	<0.01	<0.01	<0.01	<0.01	0
	0.3	3	<0.01	<0.01	<0.01	<0.01	0
	1.0	3	<0.01	<0.01	<0.01	<0.01	0
	1.0 (2-day depuration)	1	<0.01	<0.01	N/A	<0.01	N/A
	1.0 (7-day depuration)	1	<0.01	<0.01	N/A	<0.01	N/A
Muscle	0	3	<0.01	<0.01	<0.01	<0.01	0
	0.1	3	<0.01	<0.01	<0.01	<0.01	0
	0.3	3	<0.01	<0.01	<0.01	<0.01	0
	1.0	3	<0.01	<0.01	<0.01	<0.01	0
	1.0 (2-day depuration)	1	<0.01	<0.01	N/A	<0.01	N/A
	1.0 (7-day depuration)	1	<0.01	<0.01	N/A	<0.01	N/A

LIVESTOCK FEEDING – DAIRY CATTLE				PMRA # 1546841			
Liver	0	3	<0.01	<0.01	<0.01	<0.01	0
	0.1	3	0.17	0.26	0.19	0.21	0.047
	0.3	3	0.67	0.88	0.76	0.77	0.105
	1.0	3	2.09	3.49	2.25	2.61	0.77
	1.0 (2-day depuration)	1	1.66	1.66	N/A	1.66	N/A
	1.0 (7-day depuration)	1	0.34	0.34	N/A	0.34	N/A
Kidney	0	3	<0.01	<0.01	<0.01	<0.01	0
	0.1	3	<0.01	<0.01	<0.01	<0.01	0
	0.3	3	0.02	0.02	0.02	0.02	0
	1.0	3	0.03	0.04	0.004	0.037	0.006
	1.0 (2-day depuration)	1	0.03	0.03	N/A	0.03	N/A
	1.0 (7-day depuration)	1	<0.01	<0.01	N/A	<0.01	N/A

Matrix	Feeding level (ppm)	Maximum Residues (ppm)	Transfer Coeffecient[1]	Dietary Burden (ppm)		Anticipated Residues[2] (ppm)	
				Beef/Dairy Cattle	Swine	Beef/Dairy Cattle	Swine
Whole Milk	1.0	<0.01	<0.01	0.12/0.24	0.18	<0.0012/ <0.0024	<0.002
Skim Milk	1.0	<0.01	<0.01			<0.0012/ <0.0024	<0.002
Cream	1.0	<0.01	<0.01			<0.0012/ <0.0024	<0.002
Fat	1.0	<0.01	<0.01			<0.0012/ <0.0024	<0.002
Muscle	1.0	<0.01	<0.01			<0.0012/ <0.0024	<0.002
Kidney	0.3	0.02	0.067			0.006/0.013	0.010
	1.0	0.04	0.04				
			Mean = 0.054				
Liver	0.1	0.26	2.6			0.36/0.72	0.54
	0.3	0.88	2.9				
	1.0	3.49	3.49				
			Mean = 3.0				

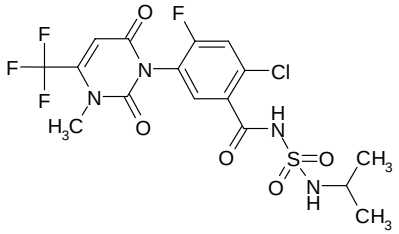
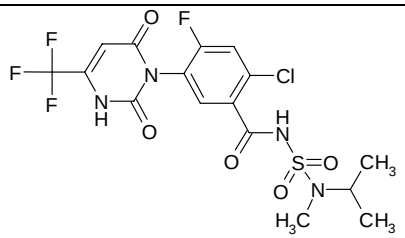
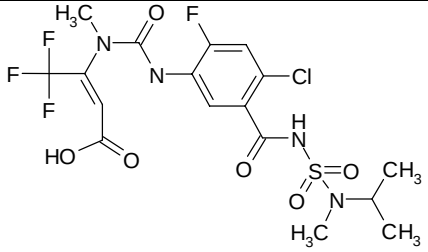
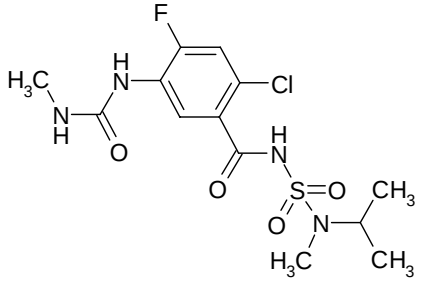
[1]Calculated as residue level-to-feed ratios.
[2]Calculated as (mean transfer coefficient) × (dietary burden).
N/A = Not applicable.

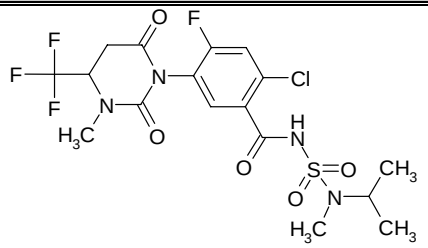
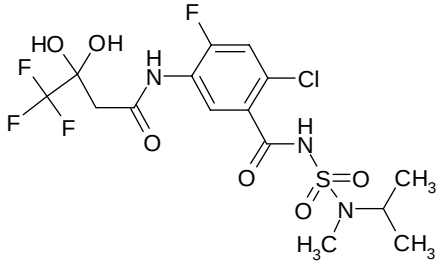
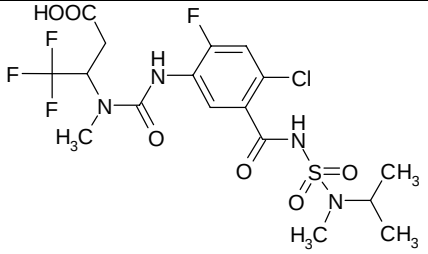
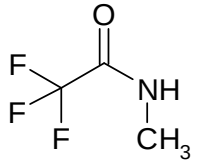
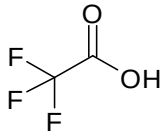
LIVESTOCK FEEDING – POULTRY	PMRA # 1546843
BASF submitted an acceptable rationale to waive the data requirement for a poultry feeding study. The results of the hen metabolism study indicate that there is no reasonable expectation of finite residues of saflufenacil in the meat, meat byproducts and eggs of poultry as a result of the proposed uses.	

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

PLANT STUDIES			
RESIDUE DEFINITION FOR ENFORCEMENT Primary crops (corn, soybean and tomato) Rotational crops (radish, lettuce and wheat)		Saflufenacil + M800H11 + M800H35 Saflufenacil + M800H11 + M800H35 All expressed as parent equivalents	
RESIDUE DEFINITION FOR RISK ASSESSMENT Primary crops (corn, soybean and tomato) Rotational crops (radish, lettuce and wheat)		Saflufenacil + M800H11 + M800H35 Saflufenacil + M800H11 + M800H35 All expressed as parent equivalents	
METABOLIC PROFILE IN DIVERSE CROPS		Similar in the crops evaluated.	
ANIMAL STUDIES			
ANIMALS		**Ruminant and Poultry**	
RESIDUE DEFINITION FOR ENFORCEMENT		Saflufenacil	
RESIDUE DEFINITION FOR RISK ASSESSMENT		Saflufenacil	
METABOLIC PROFILE IN ANIMALS (goat, hen, rat)		The metabolic profile was similar in all animals investigated.	
FAT SOLUBLE RESIDUE		No	
DIETARY RISK FROM FOOD AND WATER			
Basic chronic non-cancer dietary risk ADI = 0.046 mg/kg bw/day for the general population. ADI = 0.017 mg/kg bw/day for females 13-49 years. Estimated chronic drinking water concentration of saflufenacil combined residues (saflufenacil + M800H01, M800H02, M800H07 and M800H08) = 148 μg/L	**POPULATION**	**ESTIMATED RISK % of ACCEPTABLE DAILY INTAKE (ADI)**	
		Food Only	**Food and Water**
	All infants <1 year	2.2	24.4
	Children 1-2 years	3.2	13.3
	Children 3-5 years	2.4	11.8
	Children 6-12 years	1.4	7.9
	Youth 13-19 years	0.8	5.7
	Adults 20-49 years	0.6	6.9
	Adults 50+ years	0.5	7.2
	Females 13-49 years	1.6	18.6
	Total population	0.9	7.6
Basic acute dietary exposure analysis, 95th percentile ARfD = 0.017 mg/kg bw for females 13-49 years old and 5.0 mg/kg bw for all other population subgroups Estimated acute drinking water concentration of saflufenacil combined residues (saflufenacil + M800H01, M800H02, M800H07 and M800H08) = 148 μg/L	**POPULATION**	**ESTIMATED RISK % of ACUTE REFERENCE DOSE (ARfD)**	
		Food Only	**Food and Water**
	All infants <1 year	0.05	0.61
	Children 1-2 years	0.06	0.28
	Children 3-5 years	0.05	0.25
	Children 6-12 years	0.03	0.17
	Youth 13-19 years	0.02	0.14
	Adults 20-49 years	0.01	0.15
	Adults 50+ years	0.01	0.13
	Females 13-49 years	3.86	44.37
	Total population	0.02	0.17

Table 6 Major transformation products in environmental media

Codes	Structure Chemical name CAS number	Molecular formula Molar mass	Occurrence (max % AR)
M800H01	 N'-[2-Chloro-4-fluoro-5-(3-methyl-2,6-dioxo-4-(trifluoromethyl)-3,6-dihydro-1(2H)-pyrimidinyl)benzoyl]-N'-isopropylsulfamide	C16 H15 Cl F4 N4 O5 S 486.83 g/mol	Aerobic soil: 10 Anaerobic soil: 14
M800H02	 N'-[2-Chloro-5-(2,6-dioxo-4-(trifluoromethyl)-3,6-dihydro-1(2H)-pyrimidinyl)-4-fluorobenzoyl]-N-isopropyl-N-methylsulfamide	C16 H15 Cl F4 N4 O5 S 486.83 g/mol	Aerobic soil: 31 Anaerobic soil: 24
M800H04		518 g/mol	Hydrolysis pH 9: 13
M800H07	 N-{4-Chloro-2-fluoro-5-[({[isopropyl (methyl) amino] sulfonyl} amino) carbonyl] phenyl}-N'-methylurea	C13 H18 Cl F N4 O4 S 380.83 g/mol	Hydrolysis pH 7: 9.2 Hydrolysis pH 9: 76 Aerobic soil: 52 Aerobic water/sed: 23 Aerobic water: 20 Aerobic sediment: 3.7 Irradiated aerobic aquatic: water/sed: 43 water: 41 sediment: 4.6 Anaerobic water/sed: 71 Anaerobic water: 62 Anaerobic sediment: 13

Codes	Structure Chemical name CAS number	Molecular formula Molar mass	Occurrence (max % AR)
M800H08	 N'-[2-Chloro-4-fluoro-5-(3-methyl-2,6-dioxo-4-(trifluoromethyl) tetrahydro-1(2H)-pyrimidinyl) benzoyl]-N-isopropyl-N-methylsulfamide	C17 H19 Cl F4 N4 O5 S 502.87 g/mol	Aerobic soil: 66 Anaerobic soil: 25
M800H15	 -[({[isopropyl (methyl) amino] sulfonyl} amino) carbonyl] phenyl}-4-4-4-trifluoro-3,3-dihydroxybutanamide	C15 H18 Cl F4 N4 O5 S 479.84 g/mol	Hydrolysis pH 9: 22 Anaerobic water/sed: 17 Anaerobic water: 17 Anaerobic sediment: 1.4
M800H22	 3-[({4-Chloro-2-fluoro-5-[({[isopropyl(methyl)amino]sulfonyl}amino)carbonyl]anilino}carbonyl)(methyl)amino]-4,4,4-trifluorobutanoic acid	C17 H19 Cl F4 N4 O6 S 520.89 g/mol	Aerobic soil: 16
M800H26	 N-Methyl-2,2,2-trifluoroacetamide	C3 H4 F3 N O 127 g/mol	Aerobic soil: 18
M800H29 TFA	 Trifluoroacetic acid CAS 76-05-1	C2 H F3 O2 114 g/mol	Aqueous photolysis pH 7: continuous light: 29 dark control: 0 Irradiated aerobic aquatic: water/sed: 33 water: 24 sediment: 10 Anaerobic water/sed: 11 Anaerobic water: 9.2 Anaerobic sediment: 3.6

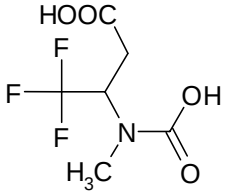
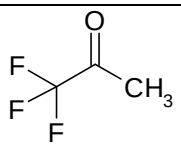
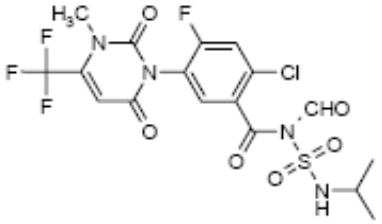
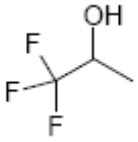
Codes	Structure Chemical name CAS number	Molecular formula Molar mass	Occurrence (max % AR)
M800H31	 3-[Carboxy(methyl)amino]-4,4,4-trifluorobutanoic acid	C6 H8 F3 N O4 215 g/mol	Aerobic soil: 18
M800H33	 1,1,1-trifluoroacetone CAS 421-50-1	C3 H3 F3 O 112.05 g/mol	Hydrolysis pH 9: 74 Aerobic water/sed: 23 Aerobic water: 23 Aerobic sed: 0 Irradiated aerobic aquatic: water/sed: 28 water: 28 sed: 0 Anaerobic water/sed: 16 Anaerobic water: 15 Anaerobic sediment: 0.9 Anaerobic volatilized: 13
Photoproduct 8		C17 H15 Cl F4 N4 O6 S 514 g/mol	Soil photolysis: continuous light: 17 12h light/ 12h dark: 6.6 dark control: 5.5
TFP	 1,1,1-trifluoro-2-propanol CAS 374-01-6	C3 H4 F3 O 114.07 g/mol	Anaerobic water/sed: 19 Anaerobic water: 16 Anaerobic sediment: 3.4 Anaerobic volatilized: 24
Unknown photoproduct (phenyl label, t_R 3.07-3.97min)			Irradiated aerobic aquatic: water/sed: 10 water: 9.4 sed: 0.99
Unknown photoproduct (phenyl label, t_R 4.22-5.03min)			Irradiated aerobic aquatic: water/sed: 13 water: 12 sed: 0.45
Unknown photoproduct (phenyl label, t_R 18.00-20.27min)			Irradiated aerobic aquatic: water/sed: 10 water: 10 sed: 0.45
Unknown photoproduct (uracil label, t_R 18.22min)			Irradiated aerobic aquatic: water/sed: 22 water: 22 sed: 0

Table 7 Fate and behaviour in the environment

Study	Compound	Value	Remarks	Reference (PMRA #)
Hydrolysis	Saflufenacil	pH 5: hydrolytically stable pH 7: t½ 248 d pH 9: t½ 4.93 d	Only slightly susceptible at neutral pH	1546926
	Combined[1]	pH 7: stable	M800H07 accumulated to end of study	
Soil photolysis	Saflufenacil	t½ 66-87 d (environmental, 40ºN latitude in spring)	Susceptible	1547168
Aqueous photolysis	Saflufenacil	pH 5, buffered pure water: t½ 56 d pH 7, natural water: t½ 22 d (environmental, 40ºN latitude in spring)	Susceptible	1608335
Aerobic soil	Saflufenacil	DT_{50} 8.6, DT_{90} 38 d, DFOP (silt loam) DT_{50} 20, DT_{90} 153 d, DFOP (sandy loam) DT_{50} 21, DT_{90} 108 d, DFOP (loamy sand) DT_{50} 26, DT_{90} 87 d, SFO (silty clay loam)	Non- to slightly persistent	1547163
	M800H01	rates of dissipation not calculable	1.8-10% AR at 7-57 DAT	
	M800H02	rates of dissipation not calculable	13-31% AR at 91-334 DAT	
	M800H07	rates of dissipation not calculable	6.8-52% AR at 14-246 DAT	
	M800H08	DT_{50} 433, DT_{90} 1440 d, SFO (silty clay loam)	Persistent, 36-66% AR	
	Combined[1]	rate of dissipation not calculable in silt loam DT_{50} 562, DT_{90} 2510 d, DFOP (sandy loam) DT_{50} 722, DT_{90} 2400 d, SFO (loamy sand) DT_{50} 2180, DT_{90} 10200 d, DFOP (silty clay loam)	Persistent	
Anaerobic soil	Saflufenacil	DT_{50} 217, DT_{90} 721 d, SFO (loamy sand)	Persistent	1686946
Aerobic water/ sediment (dark system)	Saflufenacil	water: DT_{50} 56, DT_{90} 187 d, SFO sediment: stable system: DT_{50} 71, DT_{90} 235 d, SFO	Moderately persistent, majority in water, stabilized at 6-10% AR in sediment after 7 DAT	1547180
	M800H07	rates of dissipation not calculable	20% AR in water, 3.7% AR in sediment	
	M800H33	system: DT_{50} 11, DT_{90} 37 d, SFO	Non-persistent, 23% AR in water, not in sediment	
	Combined[1]	system: DT_{50} 404, DT_{90} 1340 d, SFO	Persistent	
Aerobic water/ sediment (12h light/12h dark)	Saflufenacil	water: DT_{50} 2.8, DT_{90} 9.5 d, SFO sediment: DT_{50} 4.9, DT_{90} 16 d, SFO system: DT_{50} 3.6, DT_{90} 12 d, SFO	Non-persistent, majority in water, 6% AR in sediment	1547180
	M800H07	system: DT_{50} 18, DT_{90} 60 d, SFO	Slightly persistent, 41% AR in water, 1.0% in sediment	
	M800H29	system: stable	23% AR in water, 9.9% AR in sediment	
	M800H33	system: DT_{50} 1.6, DT_{90} 5.4 d, SFO	Non-persistent, 28% AR in water, not in sediment	
	Combined[1]	system: DT_{50} 15, DT_{90} 49 d, SFO	Non-persistent	

Study	Compound	Value	Remarks	Reference (PMRA #)
Anaerobic water/ sediment	Saflufenacil	water: DT_{50} 26, DT_{90} 87 d, SFO sediment: DT_{50} 24, DT_{90} 80 d, SFO system: DT_{50} 29, DT_{90} 95 d, SFO	Slightly persistent, majority in water, 16% AR in sediment	1547165
	M800H07	sediment: DT_{50} 230, DT_{90} 1064 d, SFO system: stable	Persistent, 62% AR in water, 13% AR in sediment	
	M800H15	system: DT_{50} 228, DT_{90} 757 d, SFO	Persistent, 17% AR in water, 1.0% AR in sediment	
	M800H29	rates of dissipation not calculable	9.2% AR in water, 3.6% AR in sediment	
	M800H33	rates of dissipation not calculable	15% AR in water, 0.9% AR in sediment, 13% volatilized	
	Combined[1]	system: DT_{50} 1900, HS	HS is defined as SFO of data from 62 days onward	
Adsorption/ desorption	Saflufenacil	K_{oc} 10-51, 20th centile 16 ml/L (n=6)	High to very high mobility	1547172
	M800H01	K_{oc} 4-26, 20th centile 7 ml/L (n=6)	Very high mobility	1547177
	M800H02	K_{oc} 6-39, 20th centile 8 ml/L (n=5)	Very high mobility	
	M800H07	K_{oc} 3-107, 20th centile 28 ml/L (n=6)	High to very high mobility	
	M800H08	K_{oc} 4-20, 20th centile 5 ml/L (n=6)	Very high mobility	
	M800H15	K_{oc} 9-57, 20th centile 11 ml/L (n=6)	High to very high mobility	
	M800H22	K_{oc} 4-22, 20th centile 6 ml/L (n=5)	Very high mobility	
	Combined[1]	K_{oc} 3-107, 20th centile 6.6 ml/L (n=29)	Very high mobility	
Field dissipation[2]	Saflufenacil	DT_{50} 1.4, DT_{90} 4.5 d, SFO (Ecoregion 10.1, WA) DT_{50} 6.2, DT_{90} 50 d, DFOP (Ecoregion 9.2, AR) DT_{50} 11, DT_{90} 36 d, SFO (Ecoregion 8.3, GA) DT_{50} 11, DT_{90} 37 d, SFO (Ecoregion 8.3, IL) DT_{50} 24, DT_{90} 79 d, SFO (Ecoregion 8.1, ON) DT_{50} 32, DT_{90} 107 d, SFO (Ecoregion 11.1, CA) DT_{50} 36, DT_{90} 118 d, SFO (Ecoregion 9.2, MB)	Non- to slightly persistent, DT_{50} values in regions relevant to Canada range 1.4 to 36 days	1546870 1546872 1546874
	M800H08	DT_{50} 34, DT_{90} 37 d, SFO (Ecoregion 8.3, IL) DT_{50} 149, DT_{90} 37 d, SFO (Ecoregion 9.2, AR)	Slightly to moderately persistent	

[1] Combined residues relevant to the environment are saflufenacil, M800H01, M800H02, M800H07, M800H08 (parent substance and major non-transient transformation products formed under aerobic conditions in the medium to which the parent substance is applied).

[2] Ecoregions relevant to Canada are 8.1 (mixed wood plains), 9.2 (temperate prairies), and 10.1 (cold deserts); Ecoregions not relevant to Canada are 8.3 (south-eastern USA plains), 8.5 (Mississippi alluvial and southeast USA plains), and 11.1 (Mediterranean California).

Table 8 Toxicity to Non-Target Species

Test organism	Study type	Substance	Endpoint value	Reference (PMRA #)
Eisenia fetida (earthworm)	acute	saflufenacil	14d LC_{50} >1000 mg a.i./kg dry soil 14d NOEC = 1000 mg a.i./kg dry soil (no effect at highest dose)	1547238
		M800H08	14d LC_{50} >1000 mg a.i./kg dry soil 14d NOEC = 1000 mg a.i./kg dry soil (no effect at highest dose)	1681997
Apis mellifera (honey bee)	oral	BAS 800 01H[1]	48h LD_{50} >121 µg a.i./bee 48h NOEL = 121 µg a.i./bee (no effect at highest dose)	1608338
	contact	saflufenacil	48h LD_{50} >100 µg a.i./bee 48h NOEL= 100 µg a.i./bee (no effect at highest dose)	1547236
		BAS 800 01H[1]	48h LD_{50} >100 µg a.i./bee 48h NOEL = 100 µg a.i./bee (no effect at highest dose)	1608338
Aphidius rhopalosiphi (parasitoid wasp)	glass plate	BAS 800 01H[1]	48h LR_{50} = 567 g a.i./ha	1636082
	glass plate	BAS 781 02H[2]	48h LR_{50} = 19 ml product/ha	1636089
Typhlodromus pyri (predatory mite)	glass plate	BAS 800 01H[1]	48h LR_{50} = 453 g a.i./ha	1604191
	glass plate	BAS 781 02H[2]	48h LR_{50} = 284 ml product/ha	1636087
Coturnix virginianus (bobwhite quail)	acute	saflufenacil	LD_{50} >2000 mg a.i./kg bw NOEL = 2000 mg a.i./kg bw (no effect at highest dose)	1547185
	short-term	saflufenacil	5d LD_{50} >884 mg a.i./kg bw/day 5d NOEL = 884 mg a.i./kg bw/day (no effect at highest dose)	1547188
	sub-chronic/ reproduction	saflufenacil	22wk NOEL = 7.3 mg a.i./kg bw/day (↓hatchling weight at 282 mg a.i./kg bw/day)	1731030
Anas platyrhynchos (mallard duck)	acute	saflufenacil	LD_{50} >2000 mg a.i./kg bw NOEL = 2000 mg a.i./kg bw (no effect at highest dose)	1547183
	short-term	saflufenacil	5d LD_{50} >1646 mg a.i./kg bw/day 5d NOEL = 674 mg a.i./kg bw/day (↓food consumption at 1646 mg a.i./kg bw/day)	1547190
	sub-chronic/ reproduction	saflufenacil	20wk NOEL = 37 mg a.i./kg bw/day (↓proportion of live 3-wk embryos to viable at 114 mg a.i./kg bw/day)	1547195
Rat	acute	saflufenacil	LD_{50} >2000 mg a.i./kg bw	1546961
	reproduction	saflufenacil	NOEL = 15 mg a.i./kg bw/day (↑pup mortality at 50 mg a.i./kg bw/day)	1547104

Test organism	Study type	Substance	Endpoint value	Reference (PMRA #)
Terrestrial plants, 10 crop species	seedling emergence	BAS 800 01H[1] BAS 800 02H[1]	ER_{25} = 1.1 to >357 g a.i./ha ER_{50} = 2.9 to >389 g a.i./ha	1547203 1547206
		M800H07	EC_{25} = 0.2500 to >0.3813 mg/kg dry soil EC_{50} >0.3813 mg/kg dry soil	1664715
		M800H08	EC_{25} = 0.1443 to >0.3846 mg/kg dry soil EC_{50} = 0.3840 to >0.3846 mg/kg dry soil	1681999
	vegetative vigour	BAS 800 01H[1] BAS 800 02H[1]	ER_{25} = 0.15 to 127 g a.i./ha ER_{50} = 0.26 to 170 g a.i./ha HR_5 of SSD of ER_{50} = 0.22 g a.i./ha	1547208 1547210
soil micro-organisms	nitrogen turnover	BAS 800 01H[1]	<25% deviation from the control up to 6.53 mg a.i./kg dry soil[3]	1604189
	carbon turnover	BAS 800 01H[1]	<25% deviation from the control up to 6.53 mg a.i./kg dry soil[3]	1604187

[1] BAS 800 01 H contains 70% saflufenacil (a.i.) and BAS 800 02H contains 12% saflufenacil (a.i.); both are formulated as water dispersible granules.

[2] BAS 781 02 H contains 68 g saflufenacil/L and 600 g dimethenamid-P/L (6.2% saflufenacil, 55% dimethenamid-P); formulated as an emulsifiable concentrate.

[3] At soil density of 1.5 g/cm3: 6.53 mg a.i./kg dw (dry weight) corresponds to 15000 g a.i./ha (5-cm soil depth) or 5000 g a.i./ha (15-cm soil depth).

Table 9 Toxicity to non-target freshwater species

Test organism	Study type	Substance	Endpoint value	Reference (PMRA #)
Oncorhynchus mykiss (rainbow trout)	static acute	saflufenacil	96h LC_{50} >112 mg a.i./L 96h NOEC = 112 mg a.i./L (no effect at highest dose)	1547213
		BAS 781 02H[1]	96h LC_{50} = 17.7 mg product/L 96h NOEC = 2.5 mg product/L (hyperventilation at 5.0 mg product/L)	1662895
	chronic; ELS	dimethenamid-P	NOEC = 0.3 mg a.i./L (see note[2]) (↓larval growth)	1044837
Lepomis macrochirus (bluegill sunfish)	static acute	saflufenacil	96h LC_{50} >108 mg a.i./L 96h NOEC = 108 mg a.i./L (no effect at highest dose)	1547215
Pimephales promelas (fathead minnow)	chronic; ELS	saflufenacil	35d NOEC = 1.0 mg a.i./L (↓survival at hatch at 3.3 mg/L)	1547217
Daphnia magna (water flea)	static acute	saflufenacil	48h EC_{50} >98 mg a.i./L 48h NOEC = 98 mg a.i./L (no effect at highest dose)	1547219
		BAS 781 02H[1]	96h EC_{50} = 13.6 mg product/L 96h NOEC = 6.5 mg product/L (↑immobilization at 11 mg product/L)	1662893
	static renew chronic	saflufenacil	21d NOEC = 1.3 mg a.i./L (↑mortality, ↓length at 2.6 mg a.i./L)	1547221
Chironomus riparius (non-biting midge)	static chronic	saflufenacil	28d NOEC = 0.65 mg a.i./L (↓emergence rate at 1.2 mg a.i./L)	1547232
Pseudokirchneriella subcapitata (green alga)	chronic	saflufenacil	96h E_yC_{50} = 0.042 mg a.i./L	1547225
		BAS 781 02H[1]	96h E_bC_{50} = 0.014 mg product/L	1662897
		M800H07	96h E_rC_{50} >29 mg/L	1664711
		M800H08	96h E_yC_{50} = 25 mg/L	1681998
Anabaena flos-aquae (blue-green alga)	chronic	saflufenacil	96h E_yC_{50} = 37 mg a.i./L	1547223

Test organism	Study type	Substance	Endpoint value	Reference (PMRA #)
Navicula pelliculosa (freshwater diatom)	chronic	saflufenacil	96h E_yC_{50} = 1.8 mg a.i./L	1547227
Lemna gibba (duck weed)	chronic	saflufenacil	7d E_vC_{50} = 0.087 mg a.i./L (frond number)	1547234
		BAS 781 02H[1]	7d E_vC_{50} = 0.023 mg product/L (biomass)	1662899
		M800H07	7d E_rC_{50} >30 mg/L (frond number, biomass)	1664720
		M800H08	7d E_yC_{50} = 12 mg/L (biomass)	1682000

[1] BAS 781 02 H contains 68 g saflufenacil/L and 600 g dimethenamid-P/L (6.2% saflufenacil, 55% dimethenamid-P); formulated as an EC.

[2] Calculated by United States Environmental Protection Agency on acute to chronic ratio of racemic dimethenamid for rainbow trout (×0.046) and acute toxicity of dimethenamid-P to rainbow trout (LC_{50} = 6.3 mg a.i./L).

Table 10 Toxicity to non-target estuarine/ marine species

Test organism	Study type	Substance	Endpoint value	Reference PMRA #)
Cyprinodon variegatus (sheepshead minnow)	static acute	saflufenacil	96h LC_{50} >98 mg a.i./L 96h NOEC = 98 mg a.i./L (no effect at highest dose)	1547201
Americamysis bahia (mysid shrimp)	flow through acute	saflufenacil	48h LC_{50} = 8.5 mg a.i./L 48h NOEC = 1.3 mg a.i./L (↑mortality at 2.2 mg a.i./L)	1547199
	static acute	M800H07	48h LC_{50} >98 mg/L 48h NOEC = 25 mg/L (↑lethargy at 50 mg/L)	1664709
Crassostrea virginica (eastern oyster)	flow through acute	saflufenacil	96h EC_{50} >6.1 mg a.i./L 96h NOEC = 6.1 mg a.i./L (no effects at highest dose)	1547197
Skeletonema costatum (marine diatom)	chronic	saflufenacil	96h E_yC_{50} = 0.18 mg a.i./L	1547230
		dimethenamid-P	120h E_yC_{50} = 0.12 mg a.i./L	1128718

Table 11 Endpoints used for risk assessment and the uncertainty factors applied

Taxonomic group	Exposure	Endpoint	Uncertainty Factor
Earthworm	Acute	LC_{50}	0.5
	Chronic	NOEC	1.0
Bees	Acute	LD_{50}	1.0
Birds	Acute oral	LD_{50}	0.1
	Dietary	LD_{50}	0.1
	Reproduction	NOEL	1.0
Mammals	Acute oral	LD_{50}	0.1
	Reproduction	NOEL	1.0
Non-target terrestrial plants	Acute	ER_{25} OR HR_5 of SSD of ER_{50}[1]	1.0 1.0
Aquatic invertebrates	Acute	EC_{50}	0.5
	Chronic	NOEC	1.0
Fish	Acute	LC_{50}	0.1
	Chronic	NOEC	1.0
Amphibians	Chronic	Fish NOEC	1.0

Taxonomic group	Exposure	Endpoint	Uncertainty Factor
Algae	Chronic	EC_{50}	0.5
Aquatic vascular plants	Chronic	EC_{50}	0.5

[1] A 5th percentile hazard rate of the species sensitivity distribution of ER_{50} values.

Table 12 Screening level estimated daily exposure (EDE) values for birds and mammals

Organism	FIR[1] (g dw/day)	Feeding guild	Matrix	EEC[2] (mg a.i./kg dw)	EDE[3] (mg a.i./kg bw/day)
1000 g bird	58.12	Herbivore	Leaves, leafy crops	123	7.2
35 g mammal	4.37	Herbivore	Leaves, leafy crops	123	15

[1] Food ingestion rate (FIR) based on Nagy (1987).

[2] Estimated environmental concentration (EEC) based on Hoerger and Kenaga nomogram immediately after application of 100 g saflufenacil/ha.

[3] Estimated daily exposure (EDE) = FIR/BW × EEC.

Table 13 Screening level risk assessment on non-target terrestrial species

Organism	Exposure	Substance	Endpoint[1]	EEC[2]	Units	RQ[3]
Earthworm	acute	saflufenacil	LC_{50}/2 >100	0.0444	mg/kg dw	<0.01
		M800H08	LC_{50}/2 >100	0.0444	mg/kg dw	<0.01
Bee	oral	BAS 800 01 H[4]	LC_{50}×1.12 >136	0.1	kg/ha	<0.01
	contact	saflufenacil	LC_{50}×1.12 >112	0.1	kg/ha	<0.01
		BAS 800 01 H[4]	LC_{50}×1.12 >112	0.1	kg/ha	<0.01
1000 g bird, herbivore	acute	saflufenacil	LD_{50}/10 >200	7.2	mg/kg bw	<0.04
	dietary	saflufenacil	LD_{50}/10 >88	7.2	mg/kg bw	<0.08
	reproduction	saflufenacil	NOEL 7.3	7.2	mg/kg bw	0.98
35 g mammal, herbivore	acute	saflufenacil	LD_{50}/10 >200	15	mg/kg bw	<0.08
	reproduction	saflufenacil	NOEL 15	15	mg/kg bw	1.0
Terrestrial plants, eleven spp.	acute	BAS 800 01 H[4] BAS 800 02 H[4]	HR_5 of SSD of ER_{50} 0.22	100	g/ha	455
		M800H07	ER25 0.2500	0.1333	mg/kg dw	0.53
		M800H08	ER25 0.1443	0.1333	mg/kg dw	0.92

[1] Endpoint values are modified according to uncertainty factors listed in Table 11. In the case of bees, 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] EECs based on application rate of 100 g saflufenacil/ha or 1100 mL BAS 781 02 H/ha (1200 g BAS 781 02 H/ha). Soil EEC based on soil density of 1.5 g/cm^3, soil depths of 15 cm for earthworms and 5 cm for plants. Dietary EEC for birds and small wild mammals based on EDE values derived in Table 12. EECs for transformation products M800H07 and M800H08 assume 100% conversion from parent.

[3] Risk Quotient (RQ) = exposure/toxicity; shaded cells indicate the screening level RQ exceeds the LOC (1.0).

[4] BAS 800 01 H contains 70% saflufenacil (a.i.) and BAS 800 02H contains 12% saflufenacil (ai); both are formulated as water dispersible granules.

[5] BAS 781 02 H contains 68 g saflufenacil/L and 600 g dimethenamid-P/L (6.2% saflufenacil, 55% dimethenamid-P); formulated as an EC.

Table 14 Screening level risk assessment on non-target aquatic species

Organism	Exposure	Substance	Endpoint[1]	EEC[2]	Units	RQ[3]
Freshwater organisms						
Aquatic invertebrate	acute	saflufenacil	EC_{50}/2 >49	0.0125	mg/L	<0.01
		BAS 781 02 H[4]	EC_{50}/2 6.8	0.1500	mg/L	0.02
	chronic	saflufenacil	NOEC 0.65	0.0125	mg/L	0.02
Fish	acute	saflufenacil	LC_{50}/10 >11	0.0125	mg/L	<0.01
		BAS 781 02 H[4]	LC_{50}/10 1.8	0.1500	mg/L	0.08
	ELS	saflufenacil	NOEC 1.0	0.0125	mg/L	0.01
		dimethenamid-P	NOEC 0.3	0.0825	mg/L	0.28
Amphibians[5]	ELS	saflufenacil	NOEC 1.0	0.0667	mg/L	0.07
		dimethenamid-P	NOEC 0.3	0.440	mg/L	1.5
Algae	chronic	saflufenacil	EC_{50}/2 0.021	0.0125	mg/L	0.60
		BAS 781 02 H[4]	EC_{50}/2 0.007	0.1500	mg/L	21
		M800H07	EC_{50}/2 >15	0.0125	mg/L	<0.01
		M800H08	EC_{50}/2 13	0.0125	mg/L	<0.01
Aquatic vascular plants	chronic	saflufenacil	EC_{50}/2 0.044	0.0125	mg/L	0.29
		BAS 781 02 H[4]	EC_{50}/2 0.012	0.1500	mg/L	13
		M800H07	EC_{50}/2 >15	0.0125	mg/L	<0.01
		M800H08	EC_{50}/2 6.0	0.0125	mg/L	<0.01
Estuarine/marine organisms						
Crustacean	acute	saflufenacil	EC_{50}/2 4.3	0.0125	mg/L	<0.01
		M800H07	EC_{50}/2 >49	0.0125	mg/L	<0.01
Mollusc	acute	saflufenacil	EC_{50}/2 >3.1	0.0125	mg/L	<0.01
Fish	acute	saflufenacil	LC_{50}/10 >10	0.0125	mg/L	<0.01
Algae	chronic	saflufenacil	EC_{50}/2 0.09	0.0125	mg/L	0.14
		dimethenamid-P	EC_{50}/2 0.06	0.0825	mg/L	1.4

[1] Endpoint values are modified according to uncertainty factors listed in Table 11.

[2] Estimated environmental exposure concentrations based on application rate of 100 g saflufenacil/ha or 1100 mL BAS 781 02 H/ha (1200 g BAS 781 02 H/ha). Water EEC is based on water depth of 15 cm to represent a seasonal water body for amphibians and 80 cm to represent a permanent water body for remaining aquatic organisms. EECs for transformation products M800H07 and M800H08 assume 100% conversion from parent.

[3] RQ = exposure/toxicity; shaded cells indicate that the screening level RQ exceeds the LOC (1.0).

[4] BAS 781 02 H contains 68 g saflufenacil/L and 600 g dimethenamid-P/L (6.2% saflufenacil, 55% dimethenamid-P); formulated as an EC.

[5] Amphibian assessment is based on fish toxicity data.

Table 15 Refined risk assessment on non-target species

Organism	Exposure	Substance	Endpoint[1]	EEC[2]	Units	RQ[3]
Non-target terrestrial plants and aquatic organisms: Off-field exposure to 6% drift deposition at 1 metre from the treatment area is determined.						
Terrestrial plants, eleven spp.	off-field	BAS 800 01 H[5] BAS 800 02 H[5]	HR_5 of SSD of ER_{50} 0.22	6.0	g/ha	27
				4.5	g/ha	21
				3.0	g/ha	14
				1.5	g/ha	6.8
				1.1	g/ha	4.9
Amphibians[6]	off-field	dimethenamid-P	NOEC 0.3	0.0264	mg/L	0.09
Freshwater algae	off-field	BAS 781 02 H[4]	EC_{50}/2 0.007	0.0090	mg/L	1.3
Aquatic vascular plants	off-field	BAS 781 02 H[4]	EC_{50}/2 0.012	0.0090	mg/L	0.78
Marine algae	off-field	dimethenamid-P	EC_{50}/2 0.06	0.0050	mg/L	0.08

1 Endpoint values are modified according to uncertainty factors listed in Table 11.

2 EECs based on application rates of 18, 25, 50, 75, or 100 g saflufenacil/for terrestrial plants and 1100 mL BAS 781 02 H/ha (1200 g BAS 781 02 H/ha) for remaining organisms. Water EEC is based on water depth of 15 cm to represent a seasonal water body for amphibians and 80 cm to represent a permanent water body for remaining aquatic organisms.

3 RQ = exposure/toxicity; shaded cells indicate that the screening level RQ exceeds the LOC (1.0).

4 BAS 781 02 H contains 68 g saflufenacil/L and 600 g dimethenamid-P/L (6.2% saflufenacil, 55% dimethenamid-P); formulated as an EC.

5 BAS 800 01 H contains 70% saflufenacil (a.i.) and BAS 800 02 H contains 12% saflufenacil (a.i.); both are formulated as water dispersible granules.

6 Amphibian assessment is based on fish toxicity data.

Table 16 Toxic Substances Management Policy considerations

TSMP Track 1 criteria	TSMP Track 1 criterion value		Active ingredient (saflufenacil) endpoints
Canadian Environmental Protection Act toxic or toxic equivalent[1]	Yes		Yes
Predominantly anthropogenic[2]	Yes		Yes
Persistence[3]:	Soil	Half-life ≥182 days	DT50 8.6-26 days
	Water	Half-life ≥182 days	DT50 2.8-56 days
	Sediment	Half-life ≥365 days	DT50 4.9 days to stable
	Air	Half-life ≥2 days or evidence of long range transport	Not relevant
Bioaccumulation[4]	log K_{OW} ≥5		log K_{OW} 2.6
	Bioconcentration factor ≥5000		Bioconcentration factors 4.6 for TRR (whole fish)
	Bioaccumulation factor ≥5000		No data
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?			No

1 All pesticides will be considered toxic or equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of *Canadian Environmental Protection Act* toxicity criteria may be refined if required (in other words, 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 (for example, bioaccumulation factors) are preferred over laboratory data (such as bioconcentration factors), which, in turn, are preferred over chemical properties (for example, log K_{OW}).

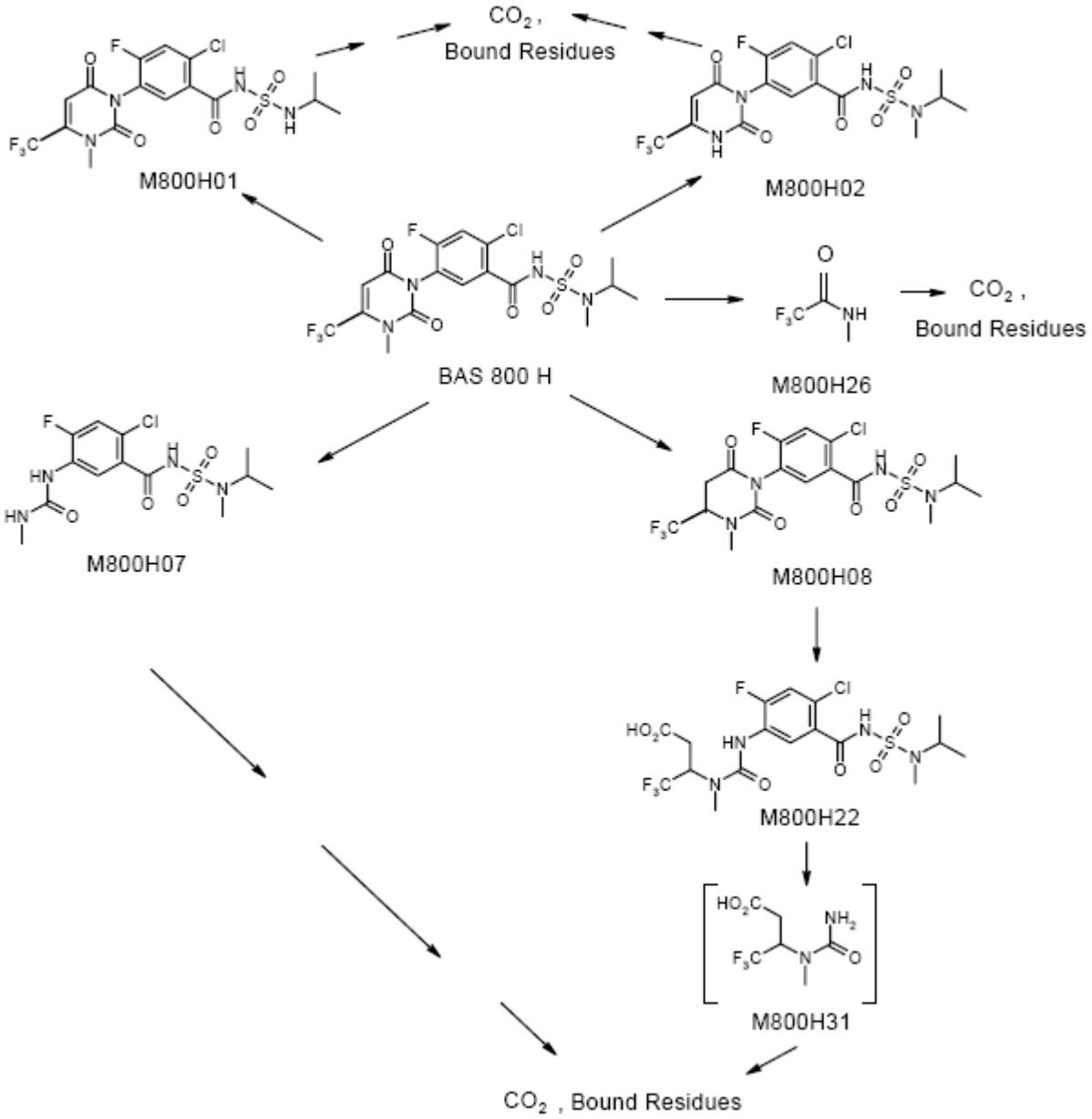


Figure 1: Proposed biotransformation pathway of saflufenacil in aerobic soil

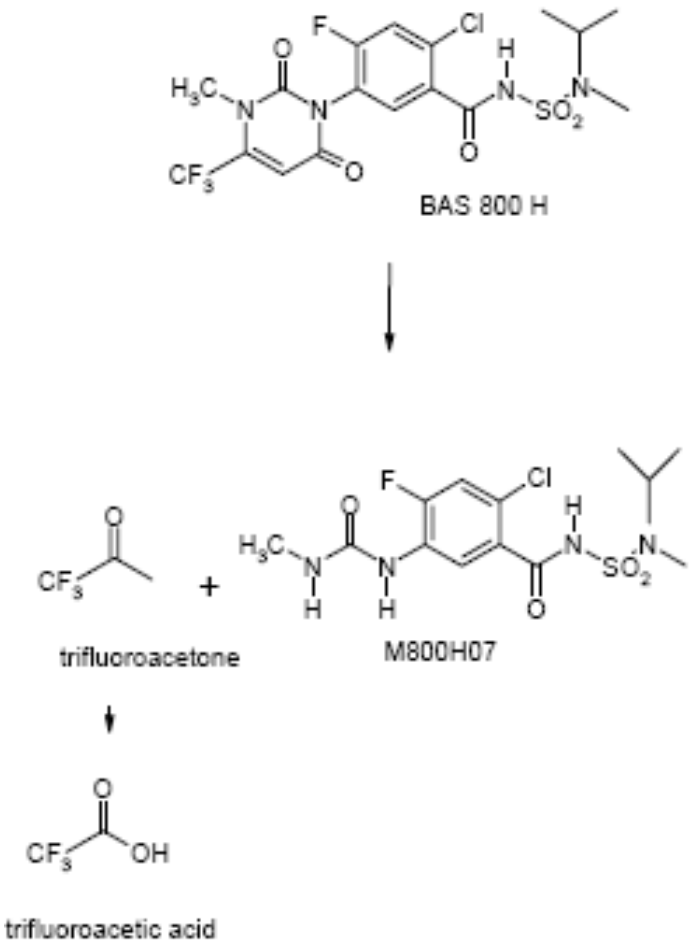


Figure 2: Proposed biotransformation pathway of saflufenacil in aerobic aquatic systems

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

The proposed Canadian MRLs are the same as corresponding tolerances recommended in the United States (tolerances listed in the Electronic Code of Federal Regulations by pesticide). Currently, Codex[9] MRLs have not been established for saflufenacil on any commodity. A listing of all established Codex MRLs is available on the Pesticide Residues in Food website.

[9] Codex is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Appendix III Crop Groups: Numbers and Definitions

Crop Group Number	Name of the Crop Group	Food Commodities Included in the Crop Group
6	Legume vegetables (succulent or dried)	Dry adzuki beans Dry beans Dry blackeyed peas Dry broad beans Dry catjang seeds Dry chickpeas Dry field peas Dry guar seed Dry kidney beans Dry lablab beans Dry lentils Dry lima beans Dry moth beans Dry mung beans Dry navy beans Dry pigeon peas Dry pink beans Dry pinto beans Dry rice beans Dry southern peas Dry soybeans Dry tepary beans Dry urd beans Edible-podded dwarf peas Edible-podded jackbeans Edible-podded moth beans Edible-podded peas Edible-podded pigeon peas Edible-podded runner beans Edible-podded snap beans Edible-podded snow peas Edible-podded soybeans Edible-podded sugar snap peas Edible-podded sword beans Edible-podded wax beans Edible-podded yardlong beans Grain lupin Succulent shelled blackeyed peas Succulent shelled broad beans Succulent shelled English peas Succulent shelled garden peas Succulent shelled green peas

Crop Group Number	Name of the Crop Group	Food Commodities Included in the Crop Group
		Succulent shelled lima beans Succulent shelled peas Succulent shelled pigeon peas Succulent shelled southern peas
10 (revised)	Citrus fruits	Australian desert limes Australian finger limes Australian round limes Brown River finger limes Calamondins Citrus citron Citrus hybrids Grapefruits Japanese summer grapefruits Kumquats Lemons Limes Mediterranean mandarins Mount White limes New Guinea wild limes Oranges Pummelos Russell River limes Satsuma mandarins Sweet limes Tachicana oranges Tahiti limes Tangelos Tangerines Tangors Trifoliate oranges Uniq fruits
11	Pome fruits	Apples Crabapples Loquats Mayhaws Oriental pears Pears Quinces

Crop Group Number	Name of the Crop Group	Food Commodities Included in the Crop Group
12	Stone fruits	Apricots Nectarines Peaches Plumcots Plums Prune plums Sweet cherries Tart Cherries
14	Tree nuts	Almonds Beechnuts Black walnuts Brazil nuts Butternuts Cashew nuts Chestnuts Chinquapins English walnuts Filberts Hickory nuts Macadamia nuts Pecans Pistachios
15	Cereal grains	Barley Buckwheat Field corn Oats Pearl millet Popcorn grain Proso millet Rice Rye Sorghum Sweet corn kernels plus cob with husks removed Teosinte Triticale Wheat Wild rice

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2.0 Human and Animal Health

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Reference: 2008, Aerobic aquatic metabolism of 14C BAS 800H under dark and light conditions, Lab Report # 133487, MRID # 47127827, Data Numbering Code 8.2.3.5.2, 8.2.3.5.4, IIA 7.8.1

PMRA Document Number: 1547183
Reference: 2006, BAS 800H - Acute toxicity in the mallard duck (Anas platyrhynchos) after single oral administration (LD50), Lab Report # 13W0414/015145, MRID # 47127912, Data Numbering Code 9.6.2.1, 9.6.2.2, 9.6.2.3, IIA 8.1.1

PMRA Document Number: 1547185
Reference: 2006, BAS 800H - Acute toxicity in the bobwhite quail (Colinus virginianus) after single oral administration (LD50), Lab Report # 11W0414/015141, MRID # 47127911, Data Numbering Code 9.6.2.1, 9.6.2.2, 9.6.2.3, IIA 8.1.1

PMRA Document Number: 1547188
Reference: 2006, BAS 800H - Avian dietary LC50 test in chicks of the bobwhite quail (Colinus virginianus), Lab Report # 31W0414/015139, MRID # 47127913, Data Numbering Code 9.6.2.4, 9.6.2.5, IIA 8.1.2

PMRA Document Number: 1547190
Reference: 2006, BAS 800H - Avian dietary LC50 test in chicks of the mallard duck (Anas plathyrhynchos), Lab Report # 32W0414/015140, MRID # 47127914, Data Numbering Code 9.6.2.4, 9.6.2.5, IIA 8.1.2

PMRA Document Number: 1547195
Reference: 2006, BAS 800H - 1-generation reproduction study on the mallard duck (Anas platyrhynchus) by administrtion in the diet, Lab Report # 72W0414/015149, MRID # 47127916, Data Numbering Code 9.6.3.1, 9.6.3.2, 9.6.3.3, IIA 8.1.4

PMRA Document Number: 1547197
Reference: 2007, A 96-hour shell deposition test with the eastern oyster (Crassostrea virginica), Lab Report # 147A-214; BASF 132884, MRID # 47127902, Data Numbering Code 9.4.2, 9.4.3, 9.4.4, IIA 8.11.1

PMRA Document Number: 1547199
Reference: 2007, BAS 800H: A 96-hour flow-through acute toxicity test with the saltwater mysid (Americamysis bahia), Lab Report # 147A-212C; BASF 132881, MRID # 47127903, Data Numbering Code 9.4.2, 9.4.3, 9.4.4, IIA 8.11.1

PMRA Document Number: 1547201
Reference: 2007, BAS 800H: A 96-hour static acute toxicity test with the sheepshead minnow (Cyprinodon variegatus), Lab Report # 147A-213; BASF 132878, MRID # 47127906, Data Numbering Code 9.4.2, 9.4.3, 9.4.4, IIA 8.11.1

PMRA Document Number: 1547203
Reference: 2007, BAS 800 02 H: A toxicity test to determine the effects of the test substance on seedling emergence of ten species of plants, Lab Report # 147-228; BASF 147485, MRID # 47127918, Data Numbering Code 9.8.4, IIA 8.12

PMRA Document Number: 1547206
Reference: 2007, BAS 800 01 H: A toxicity test to determine the effects of the test substance on seedling emergence of ten species of plants, Lab Report # 147-226; BASF 147488, MRID # 47127919, Data Numbering Code 9.8.4, IIA 8.12

PMRA Document Number: 1547208
Reference: 2007, BAS 800 01 H: A toxicity test to determine the effects of the test substance on vegetative vigor of ten species of plants, Lab Report # 147-227; BASF 147482, MRID # 47127921, Data Numbering Code 9.8.4, IIA 8.12

PMRA Document Number: 1547210
Reference: 2007, BAS 800 02 H: A toxicity test to determine the effects of the test substance on vegetative vigor of ten species of plants, Lab Report # 147-229; BASF 147479, MRID # 47127920, Data Numbering Code 9.8.4, IIA 8.12

PMRA Document Number: 1547213
Reference: 2005, BAS 800H - Acute toxicity study on the rainbow trout (Oncorhynchus mykiss) in a static system over 96 hours, Lab Report # 12F0414/015146, MRID # 47127904, Data Numbering Code 9.5.2.1, 9.5.2.3, IIA 8.2.1.1

PMRA Document Number: 1547215
Reference: 2005, BAS 800H - Acute toxicity study on the bluegill sunfish (Lepomis macrochirus) in a static system over 96 hours, Lab Report # 14F0414/015147, MRID # 47127905, Data Numbering Code 9.5.2.2, 9.5.2.3, IIA 8.2.1.2

PMRA Document Number: 1547217
Reference: 2007, BAS 800H - Early life-stage test on the fathead minnow (Pimephales promelas) in a flow through system (Including amendment no.1), Lab Report # 51F0414/015150, MRID # 47127908, Data Numbering Code 9.5.3.1, IIA 8.2.4

PMRA Document Number: 1547219
Reference: 2006, Acute toxicity of BAS 800H to Daphnia magna STRAUS in a 48 hour static test, Lab Report # 132860, MRID # 47127901, Data Numbering Code 9.3.2, 9.3.4, IIA 8.3.1

PMRA Document Number: 1547221
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PMRA Document Number: 1547223
Reference: 2006, Effect of BAS 800H (Reg.No. 405449) on the growth of the blue-green alga Anabaena flos-aquae (including amendment No. 1), Lab Report # 132851, MRID # 47127925, Data Numbering Code 9.8.2, 9.8.3, IIA 8.4

PMRA Document Number: 1547225
Reference: 2006, Effect of BAS 800H (Reg.No. 405449) on the growth of the green alga pseudokirchneriella subcapitata (including amendment No. 1), Lab Report # 132848, MRID # 47127923, Data Numbering Code 9.8.2, 9.8.3, IIA 8.4

PMRA Document Number: 1547227
Reference: 2007, BAS 800H: A 96-hour toxicity test with the freshwater diatom (Navicula pelliculosa), Lab Report # 147A-215; 132854, MRID # 47127924, Data Numbering Code 9.8.2, 9.8.3, IIA 8.4

PMRA Document Number: 1547230
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PMRA Document Number: 1547232
Reference: 2007, Chronic toxicity of BAS 800H (Reg. No. 4054449) to the non-biting midge Chironomus riparius exposed via spiked sediment, Lab Report # 132875, MRID # 47127910, Data Numbering Code 9.3.4, IIA 8.5.1

PMRA Document Number: 1547234
Reference: 2007, Effect of BAS 800H on the growth of Lemna gibba (including amendment No. 1), Lab Report # 134222, MRID # 47127922, Data Numbering Code 9.8.5, IIA 8.6

PMRA Document Number: 1547236
Reference: 2007, BAS 800H: An acute contact toxicity study with the honey bee, Lab Report # 147-231; BASF 132908, MRID # 47127927, Data Numbering Code 9.2.4.1, IIA 8.7.2

PMRA Document Number: 1547238
Reference: 2006, Acute toxicity of BAS 800H (Reg. No. 4054449) on earthworms (Eisenia fetida) in artificial soil with 5% peat, Lab Report # 06/230-125G, MRID # 47127903, Data Numbering Code 9.2.3.1, IIA 8.9.1

PMRA Document Number: 1604187
Reference: 2008, Effects of BAS 800 01 H on the activity of soil microflora (carbon transformation test), Lab Report # 08 10 48 014 C; MRID # 474308-01, Data Numbering Code 9.9

PMRA Document Number: 1604189
Reference: 2008, Effects of BAS 800 01 H on the activity of soil microflora (nitrogen transformation test), Lab Report # 08 10 48 014 N, MRID # 474308-02, Data Numbering Code 9.9

PMRA Document Number: 1604191
Reference: 2008, Effects of BAS 800 01 H on the predatory mite (Typhlodromus pyri), Lab Report # 08/640-335RA, MRID # 474308-03, Data Numbering Code: 9.2.5

PMRA Document Number: 1608335
Reference: 2008, Aerobic soil metabolism of 14C-BAS 800H on US soils, Lab Report # 132650, MRID # 0, Data Numbering Code 8.2.3.4.2

PMRA Document Number: 1608338
Reference: 2008, Assessment of side effects of BAS 800 01 H to the honey bee, Apis mellifera L. in the laboratory, Lab Report # 317342; 20071545/S1-BLEU, MRID # 0, Data Numbering Code 9.2.4.1

PMRA Document Number: 1636082
Reference: 2008, A rate-response laboratory test to determine the effects of BAS 800 01 H on the parasitic wasp, Aphidius rhopalosiphi (Hymenoptera, Braconidae), Lab Report # EU-BASF-08-24, EU-1275526, EU-355425, MRID # 47523804, Data Numbering Code 9.5.2.2, 9.5.2.3, IIA 8.2.1.2

PMRA Document Number: 1636087
Reference: 2008, A rate-response laboratory test to determine the effects of BAS 781 02 H on the predatory mite, Typhlodromus pyri (Acari: Phytoseiidae), Lab Report # EU-355540; MRID # 47523902, Data Numbering Code 9.2.5, IIA 8.8.1.2

PMRA Document Number: 1636089
Reference: 2008, A rate-response laboratory test to determine the effects of BAS 781 02 H on the parasitic wasp, Aphidius rhopalosiphi (Hymenoptera, Braconidae), Lab Report # EU-BASF-08-25, EU-1275523, EU-355543, MRID # 47523901, Data Numbering Code 9.2.6, IIA 8.8.1.1

PMRA Document Number: 1662893
Reference: 2008, BAS 781 02 H: A 48-hour static acute toxicity test with the cladoceran (Daphnia magna), Lab Report # SubNo-200809-03-01, US-WIL 147A-238, US-355545, MRID # 47560402, Data Numbering Code 9.3.5

PMRA Document Number: 1662895
Reference: 2008, BAS 781 02 H: A 96-hour static acute toxicity test with the rainbow trout (Oncorhynchus mykiss), Lab Report # SubNo-200809-02-01, US-WIL 147A-239, US-355546, MRID # 47560401, Data Numbering Code 9.5.4

PMRA Document Number: 1662897
Reference: 2008, BAS 781 02 H: A 96-hour toxicity test with the freshwater algae (Pseudokirchneriella subcapitata), Lab Report # SubNo-200809-05-01, US-WLI 147A-240A, US-355544, MRID # 47560403, Data Numbering Code 9.8.6

PMRA Document Number: 1662899
Reference: 2008, BAS 781 02 H: A 7-day toxicity test with duckweed (Lemna gibba G3), Lab Report # SubNo-200809-09-01, US-WLI 147A-241, US-355547, MRID # 47560404, Data Numbering Code 9.8.6

PMRA Document Number: 1662942
Reference: 2008, Freezer storage stability of BAS 800H and the relevant metabolites in soil samples, Lab Report # SubNo-200801-08-02, US-132671, MRID # 47560309, Data Numbering Code 8.3.2

PMRA Document Number: 1664709
Reference: 2008, BAS 800H metabolite M07: A 96-hour static acute toxicity test with the saltwater mysid (Americamysis bahia), Lab Report # SubNo-200810-18-01, US-WIL 147A-246, US-356246, MRID # 47560303, Data Numbering Code 9.4.2

PMRA Document Number: 1664711
Reference: 2008, BAS 800H Metabolite M07: A 96-hour toxicity test with the freshwater alga (Pseudokirchneriella subcapitata), Lab Report # SubNo-200809-06-01, US-WLI 147A-242, US-355548, MRID # 47560301, Data Numbering Code 9.8.2

PMRA Document Number: 1664715
Reference: 2008, Effect of Reg.No.: 4775453 (metabolite of BAS 800H, M800H07) with incorporation into soil on seedling emergence of ten species of terrestrial plants (Including amendment No. 1), Lab Report # EU-AC/BASF/08/11, EU-1275259, EU-314466, MRID # 47560304, Data Numbering Code 9.8.4

PMRA Document Number: 1664720
Reference: 2008, BAS 800H Metabolite M07: A 7-day toxicity test with duckweed (Lemna gibba G3), Lab Report # SubNo-200809-08-01, US-WLI 147A-243, US-355549, MRID # 47560302, Data Numbering Code 9.8.5

PMRA Document Number: 1681997
Reference: 2008, Acute toxicity (14 days) of Reg. No. 4773881 (metabolite of BAS 800H, M800H08) to the earthworm Eisenia fetida in artificial soil, Lab Report # EU-44431021, EU-355542, EU-1275916; MRID # 47560307, Data Numbering Code 9.2.3.1

PMRA Document Number: 1681998
Reference: 2008. BAS 800H metabolite M08: A 96-hour toxicity test with the freshwater alga (Pseudokirchneriella subcapitata).Lab Report # SubNo-200809-01-01, US-WIL 147A-244, US-355550, MRID # 47560305, Data Numbering Code 9.8.2

PMRA Document Number: 1681999
Reference: 2008, Effects of Reg.No.: 4773881 (metabolite of BAS 800H, M800H08) with incorporation into soil on seedling emergence and seedling growth of ten species of terrestrial plants, Lab Report # EU-AC/BASF/08/12, EU-1275262, EU-314469; MRID # 47560308, Data Numbering Code 9.8.4

PMRA Document Number: 1682000
Reference: 2008, BAS 800H metabolite M08: A 7-day toxicity test with duckweed (Lemna gibba G3). Lab Report # BASF-2008/7013851; MRID # 47560306, Data Numbering Code 9.8.5

PMRA Document Number: 1686946
Reference: 2008, Anaerobic Soil Metabolism of 14C-BAS 800H, Lab Report # 332554, MRID # 47611201, Data Numbering Code 8.2.3.4.4

PMRA Document Number: 1731028
Reference: 2009, Amended final report: Aqueous photolysis of 14C-BAS 800H, Lab Report # SubNo-200711-09-02, US-132683, MRID # 47699901, Data Numbering Code 8.2.3.3.2

PMRA Document Number: 1731030
Reference: 2009, BAS 800H - 1-generation reproduction study on the bobwhite quail (Colinus virginianus) by administration in the diet (including amendment No. 1), Lab Report # EU-71W0414/015148, MRID # 47699904, Data Numbering Code 9.6.3.1

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PMRA Document Number: 1546730
Reference: 2008, Application for BAS 800H Applied Preseed/ Pre-emerge and to Chemfallow, Preplant to Soybean, and Preplant or Preplant Incorporated to Corn-Field and Sweet Corn, Lab Report # 2008/7002707, MRID # 47128239, Data Numbering Code 1.1, 10.1 (OECD), 10.2.1, 10.2.2, 10.2.3.1, 10.2.3.2, 10.2.3.3, 10.3.1 (OECD), 10.3.2, 10.3.3, 10.4, 10.5.1, 10.5.2, 10.5.3, 10.5.4, 5.2, IIIA 1.6, IIIA 3.1, IIIA 3.2, IIIA 3.3.3, IIIA 3.8.1, IIIA 6.2.1, IIIA 6.2.8, IIIA 6.3, IIIA 6.4.1, IIIA 6.4.2, IIIA 6.4.3

PMRA Document Number: 1546731
Reference: 2008, Application for BAS 800H Applied Preseed/ Pre-emerge and to Chemfallow, Preplant to Soybean, and Preplant or Preplant Incorporated to Corn-Field and Sweet Corn, MRID # 47128239, Data Numbering Code 1.1, 10.1 (OECD), 10.2.1, 10.2.2, 10.2.3.1, 10.2.3.2, 10.2.3.3, 10.3.1 (OECD), 10.3.2, 10.3.3, 10.4, 10.5.1, 10.5.2, 10.5.3, 10.5.4, 5.2, IIIA 1.6, IIIA 3.1, IIIA 3.2, IIIA 3.3.3, IIIA 3.8.1, IIIA 6.2.1, IIIA 6.2.8, IIIA 6.3, IIIA 6.4.1, IIIA 6.4.2, IIIA 6.4.3

PMRA Document Number: 1546732
Reference: 2008, Application for BAS 800H Applied Preseed/ Pre-emerge and to Chemfallow, Preplant to Soybean, and Preplant or Preplant Incorporated to Corn-Field and Sweet Corn, MRID # 47128239, Data Numbering Code 1.1, 10.1 (OECD), 10.2.1, 10.2.2, 10.2.3.1, 10.2.3.2, 10.2.3.3, 10.3.1 (OECD), 10.3.2, 10.3.3, 10.4, 10.5.1, 10.5.2, 10.5.3, 10.5.4, 5.2, IIIA 1.6, IIIA 3.1, IIIA 3.2, IIIA 3.3.3, IIIA 3.8.1, IIIA 6.2.1, IIIA 6.2.8, IIIA 6.3, IIIA 6.4.1, IIIA 6.4.2, IIIA 6.4.3

PMRA Document Number: 1546733
Reference: 2008, Application for BAS 800H Applied Preseed/ Pre-emerge and to Chemfallow, Preplant to Soybean, and Preplant or Preplant Incorporated to Corn-Field and Sweet Corn, MRID # 47128239, Data Numbering Code 1.1, 10.1 (OECD), 10.2.1, 10.2.2, 10.2.3.1, 10.2.3.2, 10.2.3.3, 10.3.1 (OECD), 10.3.2, 10.3.3, 10.4, 10.5.1, 10.5.2, 10.5.3, 10.5.4, 5.2, IIIA 1.6, IIIA 3.1, IIIA 3.2, IIIA 3.3.3, IIIA 3.8.1, IIIA 6.2.1, IIIA 6.2.8, IIIA 6.3, IIIA 6.4.1, IIIA 6.4.2, IIIA 6.4.3

PMRA Document Number: 1546734
Reference: 2008, Application for BAS 800H Applied Preseed/ Pre-emerge and to Chemfallow, Preplant to Soybean, and Preplant or Preplant Incorporated to Corn-Field and Sweet Corn, MRID # 47128239, Data Numbering Code 1.1, 10.1 (OECD), 10.2.1, 10.2.2, 10.2.3.1, 10.2.3.2, 10.2.3.3, 10.3.1 (OECD), 10.3.2, 10.3.3, 10.4, 10.5.1, 10.5.2, 10.5.3, 10.5.4, 5.2, IIIA 1.6, IIIA 3.1, IIIA 3.2, IIIA 3.3.3, IIIA 3.8.1, IIIA 6.2.1, IIIA 6.2.8, IIIA 6.3, IIIA 6.4.1, IIIA 6.4.2, IIIA 6.4.3

PMRA Document Number: 1546735
Reference: 2008, Application for BAS 800H Applied Preseed/ Pre-emerge and to Chemfallow, Preplant to Soybean, and Preplant or Preplant Incorporated to Corn-Field and Sweet Corn, MRID # 47128239, Data Numbering Code 1.1, 10.1 (OECD), 10.2.1, 10.2.2, 10.2.3.1, 10.2.3.2, 10.2.3.3, 10.3.1 (OECD), 10.3.2, 10.3.3, 10.4, 10.5.1, 10.5.2, 10.5.3, 10.5.4, 5.2, IIIA 1.6, IIIA 3.1, IIIA 3.2, IIIA 3.3.3, IIIA 3.8.1, IIIA 6.2.1, IIIA 6.2.8, IIIA 6.3, IIIA 6.4.1, IIIA 6.4.2, IIIA 6.4.3

PMRA Document Number: 1546736
Reference: 2008, Application for BAS 800H Applied Preseed/ Pre-emerge and to Chemfallow, Preplant to Soybean, and Preplant or Preplant Incorporated to Corn-Field and Sweet Corn, MRID # 47128239, Data Numbering Code 1.1, 10.1 (OECD), 10.2.1, 10.2.2, 10.2.3.1, 10.2.3.2, 10.2.3.3, 10.3.1 (OECD), 10.3.2, 10.3.3, 10.4, 10.5.1, 10.5.2, 10.5.3, 10.5.4, 5.2, IIIA 1.6, IIIA 3.1, IIIA 3.2, IIIA 3.3.3, IIIA 3.8.1, IIIA 6.2.1, IIIA 6.2.8, IIIA 6.3, IIIA 6.4.1, IIIA 6.4.2, IIIA 6.4.3

PMRA Document Number: 1546738
Reference: 2008, Application for BAS 800H Applied Preseed/ Pre-emerge and to Chemfallow, Preplant to Soybean, and Preplant or Preplant Incorporated to Corn-Field and Sweet Corn, MRID # 47128239, Data Numbering Code 1.1, 10.1 (OECD), 10.2.1, 10.2.2, 10.2.3.1, 10.2.3.2, 10.2.3.3, 10.3.1 (OECD), 10.3.2, 10.3.3, 10.4, 10.5.1, 10.5.2, 10.5.3, 10.5.4, 5.2, IIIA 1.6, IIIA 3.1, IIIA 3.2, IIIA 3.3.3, IIIA 3.8.1, IIIA 6.2.1, IIIA 6.2.8, IIIA 6.3, IIIA 6.4.1, IIIA 6.4.2, IIIA 6.4.3

PMRA Document Number: 1546739
Reference: 2008, Application for BAS 800H Applied Preseed/ Pre-emerge and to Chemfallow, Preplant to Soybean, and Preplant or Preplant Incorporated to Corn-Field and Sweet Corn, MRID # 47128239, Data Numbering Code 1.1, 10.1 (OECD), 10.2.1, 10.2.2, 10.2.3.1, 10.2.3.2, 10.2.3.3, 10.3.1 (OECD), 10.3.2, 10.3.3, 10.4, 10.5.1, 10.5.2, 10.5.3, 10.5.4, 5.2, IIIA 1.6, IIIA 3.1, IIIA 3.2, IIIA 3.3.3, IIIA 3.8.1, IIIA 6.2.1, IIIA 6.2.8, IIIA 6.3, IIIA 6.4.1, IIIA 6.4.2, IIIA 6.4.3

PMRA Document Number: 1546740
Reference: 2008, Application for BAS 800H Applied Preseed/ Pre-emerge and to Chemfallow, Preplant to Soybean, and Preplant or Preplant Incorporated to Corn-Field and Sweet Corn, MRID # 47128239, Data Numbering Code 1.1, 10.1 (OECD), 10.2.1, 10.2.2, 10.2.3.1, 10.2.3.2, 10.2.3.3, 10.3.1 (OECD), 10.3.2, 10.3.3, 10.4, 10.5.1, 10.5.2, 10.5.3, 10.5.4, 5.2, IIIA 1.6, IIIA 3.1, IIIA 3.2, IIIA 3.3.3, IIIA 3.8.1, IIIA 6.2.1, IIIA 6.2.8, IIIA 6.3, IIIA 6.4.1, IIIA 6.4.2, IIIA 6.4.3

PMRA Document Number: 1546743
Reference: 2008, Application for BAS 800H Applied Preseed/ Pre-emerge and to Chemfallow, Preplant to Soybean, and Preplant or Preplant Incorporated to Corn-Field and Sweet Corn, MRID # 47128239, Data Numbering Code 1.1, 10.1 (OECD), 10.2.1, 10.2.2, 10.2.3.1, 10.2.3.2, 10.2.3.3, 10.3.1 (OECD), 10.3.2, 10.3.3, 10.4, 10.5.1, 10.5.2, 10.5.3, 10.5.4, 5.2, IIIA 1.6, IIIA 3.1, IIIA 3.2, IIIA 3.3.3, IIIA 3.8.1, IIIA 6.2.1, IIIA 6.2.8, IIIA 6.3, IIIA 6.4.1, IIIA 6.4.2, IIIA 6.4.3

PMRA Document Number: 1546746
Reference: 2008, Application for BAS 800H Applied Preseed/ Pre-emerge and to Chemfallow, Preplant to Soybean, and Preplant or Preplant Incorporated to Corn-Field and Sweet Corn, MRID # 47128239, Data Numbering Code 1.1, 10.1 (OECD), 10.2.1, 10.2.2, 10.2.3.1, 10.2.3.2, 10.2.3.3, 10.3.1 (OECD), 10.3.2, 10.3.3, 10.4, 10.5.1, 10.5.2, 10.5.3, 10.5.4, 5.2, IIIA 1.6, IIIA 3.1, IIIA 3.2, IIIA 3.3.3, IIIA 3.8.1, IIIA 6.2.1, IIIA 6.2.8, IIIA 6.3, IIIA 6.4.1, IIIA 6.4.2, IIIA 6.4.3

PMRA Document Number: 1546748
Reference: 2008, Application for BAS 800H Applied Preseed/ Pre-emerge and to Chemfallow, Preplant to Soybean, and Preplant or Preplant Incorporated to Corn-Field and Sweet Corn, MRID # 47128239, Data Numbering Code 1.1, 10.1 (OECD), 10.2.1, 10.2.2, 10.2.3.1, 10.2.3.2, 10.2.3.3, 10.3.1 (OECD), 10.3.2, 10.3.3, 10.4, 10.5.1, 10.5.2, 10.5.3, 10.5.4, 5.2, IIIA 1.6, IIIA 3.1, IIIA 3.2, IIIA 3.3.3, IIIA 3.8.1, IIIA 6.2.1, IIIA 6.2.8, IIIA 6.3, IIIA 6.4.1, IIIA 6.4.2, IIIA 6.4.3

PMRA Document Number: 1546771
Reference: 2007, BAS 800 00 H: Tank mix uniformity of a WG formulation in a simulated spray tank., Lab Report # F200713, MRID # 47128217, Data Numbering Code 10.6, 3.7, IIIA 1.7, IIIA 2.15

PMRA Document Number: 1546772
Reference: 2008, BAS 800 UC H: Tank mix uniformity of an EC formulation in a simulated spray tank, Lab Report # F200714, MRID # 47128238, Data Numbering Code 10.6, 3.7, IIIA 1.7, IIIA 2.15

PMRA Document Number: 1546784
Reference: 2008, Use Site Description for Heat WG and BAS 800H WG containing active ingredient Saflufenacil for use in Barley, Canary Seed, Chickpeas, Lentils, Oats, Peas, Wheat, Corn Field and Sweet, Soybeans and Chemfallow., Data Numbering Code 1.1, 10.2.2, 10.2.3.1, 10.2.3.2, 10.2.3.3, 5.2, IIIA 3.3.1, IIIA 3.3.2, IIIA 3.3.3

PMRA Document Number: 1546860
Reference: 2007, Rotational crop study with 14C-BAS 800H, Lab Report # 132587, MRID # 47128017, Data Numbering Code 7.4.3, 7.4.4, IIIA 8.6

PMRA Document Number: 1547297
Reference: 2008, Application for BAS 781 H Applied Pre-Emergence or Preplant Incorporated to Corn (Field and Sweet), Data Numbering Code 1.1, 10.1 (OECD), 10.2.3.1, 10.2.3.2, 10.2.3.3, 10.2.3.4, 10.3.1 (OECD), 10.3.2, 10.3.3, 10.4, 10.5.1, 10.5.2, 10.5.3, 10.5.4, 5.2, IIIA 3.3.3, IIIA 3.8.1, IIIA 6.1.3, IIIA 6.2.1, IIIA 6.2.8, IIIA 6.3, IIIA 6.4.1, IIIA 6.4.2, IIIA 6.4.3

PMRA Document Number: 1547299
Reference: 2008, Application for BAS 781 H Applied Pre-Emergence or Preplant Incorporated to Corn (Field and Sweet), Data Numbering Code 1.1, 10.1 (OECD), 10.2.3.1, 10.2.3.2, 10.2.3.3, 10.2.3.4, 10.3.1 (OECD), 10.3.2, 10.3.3, 10.4, 10.5.1, 10.5.2, 10.5.3, 10.5.4, 5.2, IIIA 3.3.3, IIIA 3.8.1, IIIA 6.1.3, IIIA 6.2.1, IIIA 6.2.8, IIIA 6.3, IIIA 6.4.1, IIIA 6.4.2, IIIA 6.4.3

PMRA Document Number: 1547302
Reference: 2008, Application for BAS 781 H Applied Pre-Emergence or Preplant Incorporated to Corn (Field and Sweet), Data Numbering Code 1.1, 10.1 (OECD), 10.2.3.1, 10.2.3.2, 10.2.3.3, 10.2.3.4, 10.3.1 (OECD), 10.3.2, 10.3.3, 10.4, 10.5.1, 10.5.2, 10.5.3, 10.5.4, 5.2, IIIA 3.3.3, IIIA 3.8.1, IIIA 6.1.3, IIIA 6.2.1, IIIA 6.2.8, IIIA 6.3, IIIA 6.4.1, IIIA 6.4.2, IIIA 6.4.3

PMRA Document Number: 1547303
Reference: 2008, Application for BAS 781 H Applied Pre-Emergence or Preplant Incorporated to Corn (Field and Sweet), Data Numbering Code 1.1, 10.1 (OECD), 10.2.3.1, 10.2.3.2, 10.2.3.3, 10.2.3.4, 10.3.1 (OECD), 10.3.2, 10.3.3, 10.4, 10.5.1, 10.5.2, 10.5.3, 10.5.4, 5.2, IIIA 3.3.3, IIIA 3.8.1, IIIA 6.1.3, IIIA 6.2.1, IIIA 6.2.8, IIIA 6.3, IIIA 6.4.1, IIIA 6.4.2, IIIA 6.4.3

PMRA Document Number: 1547304
Reference: 2008, Application for BAS 781 H Applied Pre-Emergence or Preplant Incorporated to Corn (Field and Sweet), Data Numbering Code 1.1, 10.1 (OECD), 10.2.3.1, 10.2.3.2, 10.2.3.3, 10.2.3.4, 10.3.1 (OECD), 10.3.2, 10.3.3, 10.4, 10.5.1, 10.5.2, 10.5.3, 10.5.4, 5.2, IIIA 3.3.3, IIIA 3.8.1, IIIA 6.1.3, IIIA 6.2.1, IIIA 6.2.8, IIIA 6.3, IIIA 6.4.1, IIIA 6.4.2, IIIA 6.4.3

PMRA Document Number: 1547305
Reference: 2008, Application for BAS 781 H Applied Pre-Emergence or Preplant Incorporated to Corn (Field and Sweet), Data Numbering Code 1.1, 10.1 (OECD), 10.2.3.1, 10.2.3.2, 10.2.3.3, 10.2.3.4, 10.3.1 (OECD), 10.3.2, 10.3.3, 10.4, 10.5.1, 10.5.2, 10.5.3, 10.5.4, 5.2, IIIA 3.3.3, IIIA 3.8.1, IIIA 6.1.3, IIIA 6.2.1, IIIA 6.2.8, IIIA 6.3, IIIA 6.4.1, IIIA 6.4.2, IIIA 6.4.3

PMRA Document Number: 1547307
Reference: 2008, Application for BAS 781 H Applied Pre-Emergence or Preplant Incorporated to Corn (Field and Sweet), Data Numbering Code 1.1, 10.1 (OECD), 10.2.3.1, 10.2.3.2, 10.2.3.3, 10.2.3.4, 10.3.1 (OECD), 10.3.2, 10.3.3, 10.4, 10.5.1, 10.5.2, 10.5.3, 10.5.4, 5.2, IIIA 3.3.3, IIIA 3.8.1, IIIA 6.1.3, IIIA 6.2.1, IIIA 6.2.8, IIIA 6.3, IIIA 6.4.1, IIIA 6.4.2, IIIA 6.4.3

B. Additional Information Considered

i) Published Information

1.0 Chemistry

none

2.0 Human and Animal Health

none

3.0 Environment

Reference: Atkinson R. 1989. Kinetics and mechanisms of the gas-phase reactions of the hydroxyl radical with organic compounds. Journal of Physical and Chemical Reference Data. Monograph No. 1.

Reference: Betterton EA. 1991. The partitioning of ketones between the gas and aqueous phases. Atmos Environ 25A: 1473-1477.

Reference: Meylan WM, Howard PH. 1993. Computer estimation of the atmospheric gas-phase reaction rate of organic compounds with hydroxyl radicals and ozone. Chemosphere 26: 2293-2299.

Reference: Neely WB, Blau GE. 1985. Environmental exposure from chemicals. Boca Raton, Florida: CRC Press.

Reference: Rochester CH, Symonds JR. 1973. Thermodynamic studies of fluoroalcohols. J Chem Soc Faraday Trans 1 69:1577-1585.

Reference: US EPA. 2009. Estimated Program Interface Suite™ for Microsoft® Windows, v 4.00. United States Environmental Protection Agency, Washington, DC, USA. As of 2009-May-25.

4.0 Value

none

ii) Unpublished Information

1.0 Chemistry

none

2.0 Human and Animal Health

none

3.0 Environment

PMRA Document Number: 1044837
Reference: 1998, US EPA, Data Evaluation Record - Request to Register Resolved Isomer of Dimethenamid, DACO: 12.5.8

PMRA Document Number: 1128718
Reference: 1997, SAN 1289 H Technical: Toxicity to the Freshwater Green Alga, *Selenastrum capricornutum*, DACO: 9.8.3

4.0 Value

none