Proposed Registration Document PRD2013-20

Flumioxazin

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Overview

Proposed Registration Decision for Flumioxazin

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 Flumioxazin Technical and Flumioxazin 51WDG Herbicide to control weeds in numerous crops, and Flumioxazin 0.25G Herbicide to control weeds in container grown ornamentals.

Flumioxazin Technical (Registration Number 29233), Flumioxazin 51WDG Herbicide (Registration Number 29235) and Flumioxazin 0.25G Herbicide (Registration Number 29234) are conditionally registered in Canada. The detailed review of these products can be found in Evaluation Report ERC2010-05, *Flumioxazin*. The current applications were submitted to convert Flumioxazin Technical, Flumioxazin 51WDG Herbicide and Flumioxazin 0.25G Herbicide from conditional registration to full registration.

Several other end-use products were conditionally registered based on the products outlined in ERC2010-05, *Flumioxazin*. Broadstar Herbicide (Registration Number 29229) was based on Flumioxazin 0.25G Herbicide. Chateau Herbicide WDG (Registration Number 29231), Payload Herbicide (Registration Number 29232), Sureguard Herbicide (Registration Number 29236) and Valtera Herbicide (29230) were based on Flumioxazin 51WDG Herbicide.

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

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Flumioxazin Technical, Flumioxazin 51WDG Herbicide and Flumioxazin 0.25G Herbicide.

What Does Health Canada Consider When Making a Registration Decision?

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

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

Before making a final registration decision on flumioxazin, 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 flumioxazin, 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.

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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."

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*.

What Is Flumioxazin?

Flumioxazin is an active ingredient in the end-use products Flumioxazin 51WDG Herbicide and Flumioxazin 0.25G Herbicide. Flumioxazin belongs to the N-phenylphthalimide chemical family and is a Weed Science Society of America (WSSA) Group 14 herbicide. The mode of action is the inhibition of the enzyme protoporphyrinogen oxidase (PPO). This enzyme is part of the chlorophyll biosynthesis pathway, and its inhibition leads to a loss of chlorophyll and carotenoids, and irreversible damage to cell membrane function and structure. Sensitive plants emerging from soils treated with the herbicide flumioxazin become necrotic and die shortly after exposure to sunlight.

Health Considerations

Can Approved Uses of Flumioxazin Affect Human Health?

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

Potential exposure to flumioxazin 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 those uses where exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

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

Flumioxazin technical grade active ingredient and the end-use products, Flumioxazin 0.25G Herbicide and Flumioxazin 51WDG Herbicide showed a potential for slight toxicity by the inhalation route in animals. Because of this, the label statement CAUTION - POISON is required. Flumioxazin did not cause cancer in animals and was not genotoxic. There was also no indication that flumioxazin caused damage to the nervous system. There were significant effects on fetal development. The first signs of toxicity in animals given daily doses of flumioxazin over longer periods of time were effects on the blood, and liver and bile systems. The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

When flumioxazin was given to pregnant animals, effects on the developing fetus were observed at doses that were not toxic to the mother, indicating that the fetus was more sensitive to flumioxazin than the adult animal. Because of this observation, extra protective measures were applied during the risk assessment to further reduce the allowable level of human exposure to flumioxazin.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Aggregate dietary intake estimates (food plus water) revealed that women 13-49 years old, the most sensitive population group to flumioxazin, are expected to be exposed to ≤5.5% of the acceptable daily intake, and children 1-2 years old, the population group that would ingest the most flumioxazin relative to body weight, are expected to be exposed to ≤3.7% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from flumioxazin is not of concern for all segments of the population. Flumioxazin is not carcinogenic; therefore, a chronic cancer dietary risk assessment is not required.

A single dose of flumioxazin is not likely to cause acute health effects in the general population (including infants and children). An aggregate (food and water) dietary intake estimate for females 13-49 years old used less than 15% of the acute reference dose, which is 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 a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted throughout the United States using flumioxazin on potatoes, dry bulb onions, soybeans, apples, pears, peaches, plums, cherries, blueberries, grapes, strawberries, and asparagus were acceptable. The MRLs for this active ingredient can be found in the Science Evaluation of Evaluation Report ERC2010-05, *Flumioxazin*.

Occupational Risks From Handling Flumioxazin 51WDG Herbicide or Flumioxazin 0.25G Herbicide

Occupational risks are not of concern when Flumioxazin 51WDG Herbicide or Flumioxazin 0.25G Herbicide are used according to the label directions, which include protective measures.

Farmers, custom applicators, or ornamental nursery operators who mix, load or apply Flumioxazin 51WDG Herbicide or Flumioxazin 0.25G Herbicide as well as field workers re-entering freshly treated fields, bare ground non-crop areas, and nurseries can come in direct contact with flumioxazin residues on the skin. Therefore, the labels specify that anyone mixing/loading and applying Flumioxazin 51WDG Herbicide or Flumioxazin 0.25G Herbicide

must wear the personal protective equipment (PPE). The label also requires that workers do not enter treated crop areas until 12 hours after application. Also, no entry is allowed into treated, non-crop bare ground use areas until the sprays have dried. Taking into consideration these label statements, the number of applications, and the expectation of the exposure period for handlers and workers, it was determined that exposures to these individuals are not a concern.

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

For people who enter treated fields for "pick-your-own" activities, exposure is expected to be short-term even though this activity may be performed once or several times per year. Taking into consideration the label requirements, the risk to people that enter treated fields to pick apples, pears, highbush blueberries, or strawberries is not of concern.

Environmental Considerations

What Happens When Flumioxazin Is Introduced Into the Environment?

Flumioxazin enters the environment when used on various crops and ornamentals for weed control. In soil, flumioxazin breaks down in the presence of bacteria and is not likely to persist for long periods. Flumioxazin is not expected to volatilise into the atmosphere and is not expected to move through soil and reach groundwater. When flumioxazin breaks down it does not form any other major residues in soil.

Although the use pattern for flumioxazin does not include direct application to water, the possibility that aquatic systems will be exposed to flumioxazin and its breakdown products, directly or indirectly, cannot be ruled out. Flumioxazin can enter the aquatic environment through spray drift and runoff from treated fields. In aquatic systems, flumioxazin breaks down rapidly in the presence of bacteria and sunlight. Any major breakdown products are not likely to persist in the aquatic environment. Flumioxazin and its breakdown products are unlikely to accumulate in fish.

The use of the granular formulation of flumioxazin (Flumioxazin 0.25 G) may pose a risk to terrestrial and aquatic organisms, including small mammals, algae and aquatic plants. Precautionary statements are required on the product labels to identify and mitigate the risks. Advisory runoff statements on the label may minimise the risk from runoff.

The use of the spray formulation of flumioxazin (Flumioxazin 51 WDG) may pose a risk to terrestrial and aquatic organisms, including arthropods, terrestrial plants, algae and aquatic plants. Precautionary statements are required on the product labels to identify and mitigate the risk from spray drift to beneficial arthropods and plants. Also, terrestrial spray buffer zones of five to twenty-five meters and aquatic buffer zones of up to five metres are required to protect sensitive non-target plant specides from spray drift. Advisory runoff statements on the label may minimise the risk from runoff.

Value Considerations

What Is the Value of Flumioxazin 51WDG Herbicide and Flumioxazin 0.25G Herbicide?

Flumioxazin 51WDG Herbicide provides pre-emergence control or suppression of common lamb's-quarters, redroot pigweed, common ragweed, green pigweed, eastern black nightshade, hairy nightshade, green foxtail, kochia, Canada fleabane, and dandelion in non-crop areas, field-grown coniferous and deciduous ornamental trees, mint, soybean, dry-bulb onion, field pea, pome fruit, grape, highbush and lowbush blueberries, stone fruit, nut tree, asparagus, potato, field pepper, celery, and strawberry and suppression of moss in lowbush blueberry.

With the exception of ornamentals, Flumioxazin 51WDG Herbicide represents a new mode of action for pre-emergence weed control for all uses listed on the label. Therefore, the registration of Flumioxazin 51WDG will provide a key tool in weed resistance management in the labelled crops.

Flumioxazin 0.25G Herbicide provides pre-emergence control or suppression of specific broadleaf weeds in container-grown ornamentals.

Weed management is critical in container-grown ornamental production. Containers that are over-run with weeds become less marketable, as consumers want clean, weed-free product. There are very few herbicides registered for use in container-grown ornamentals.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the labels of Flumioxazin 51WDG Herbicide and Flumioxazin 0.25G Herbicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Since there is a concern with users coming into direct contact with flumioxazin on the skin or through inhalation of spray mists, anyone mixing, loading, applying, and involved in clean-up or repair activities with Flumioxazin 51WDG Herbicide or Flumioxazin 0.25G Herbicide must wear the recommended personal protective equipment (PPE). Standard label statements to protect against spray drift during application are included on the label. A restricted entry interval (REI) was required for post-application handline irrigation after over-the-top application to field-grown coniferous trees and trees grown for reforestation.

Environment

Mitigative measures are required to protect sensitive terrestrial and aquatic habitats from the use of flumioxazin. These mitigative measures include precautionary statements on the label as well as appropriate buffer zones to protect sensitive habitats from spray drift.

Next Steps

Before making a final registration decision on flumioxazin, 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 forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

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

Science Evaluation

Flumioxazin

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Please refer to Evaluation Report ERC2010-05, *Flumioxazin* for the identity of the active ingredient.

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

Technical Product—Flumioxazin Technical

Please refer to Evaluation Report ERC2010-05, *Flumioxazin* for the physical and chemical properties of the active ingredient.

End-Use Products— Flumioxazin 51WDG Herbicide and Flumioxazin 0.25G Herbicide

The end-use products have been shown to be stable in the commercial container at ambient temperature for twelve months.

1.3 Directions for Use

Flumioxazin 51WDG Herbicide provides pre-emergence control or suppression of common lamb's-quarters, redroot pigweed, common ragweed, green pigweed, eastern black nightshade, hairy nightshade, green foxtail, and dandelion in field-grown coniferous and deciduous ornamental trees, mint, soybean, dry-bulb onion, field pea, pome fruit, grape, highbush and lowbush blueberries, stone fruit, nut tree, asparagus, potato, field pepper, celery, and strawberry and to maintain bare ground non-crop areas. The product is applied once or twice per growing season at a rate of 54, 71, 107, or 143 g a.i./ha (Table 1.3.1) on coarse-textured soil with < 5% organic matter (OM) content, or at a rate of 54, 107, or 214 g a.i./ha on medium-textured soil with < 5% OM content, or at a rate of 71 g a.i./ha on muck soil. The number of applications and application rates vary by soil and crop combinations. This product cannot be used in any other soil conditions. Flumioxazin 51WDG Herbicide may be applied as a broadcast treatment or as a directed hooded spray with ground application equipment only.

Table 1.3.1 Efficacy claims for Flumioxazin 51WDG Herbicide

Host and soil combinations	Herbicide rate	Efficacy claims
† Coarse-textured soil < 5% OM	71 or 143 g a.i./ha	Control or suppression of common lamb's-quarters, redroot pigweed, common ragweed, green pigweed, eastern black nightshade, hairy nightshade, dandelion, kochia, Canada fleabane, and green foxtail. Suppression of moss in lowbush blueberry with the higher rate only.
† Medium-textured soil < 5% OM	107 or 214 g a.i./ha	
Potato on coarse- and medium-textured soils < 5% OM	54 g a.i./ha	Suppression of common lamb's-quarters, common ragweed, green pigweed, redroot pigweed, eastern black nightshade, hairy nightshade, kochia, and Canada fleabane.
Strawberry on coarse- and medium-textured soils < 5% OM	107 g a.i./ha	Control of common lamb's-quarters, redroot pigweed, common ragweed, green pigweed, eastern black nightshade, hairy nightshade, kochia, Canada fleabane, and dandelion and suppression of green foxtail.
Muck soils	71 g a.i./ha	Suppression of common lamb's-quarters, redroot pigweed, common ragweed, green pigweed, eastern black nightshade, hairy nightshade, kochia, and Canada fleabane.
Do not apply on mineral soils with > 5% OM, or on fine-textured soils.		

† The lower rate is for use on soybean, field pea, dry bulb onion, lowbush blueberry, field pepper, and celery, while the higher rate is for use in bare ground non-crop areas, field grown ornamental deciduous and coniferous trees, pome fruit, grape, nut tree, mint, asparagus, highbush blueberry, and stone fruit.

1.4 Mode of Action

Flumioxazin belongs to the N-phenylphthalimide chemical family and is a WSSA Group 14 herbicide. The mode of action is the inhibition of the enzyme PPO. This enzyme is part of the chlorophyll biosynthesis pathway, and its inhibition leads to a loss of chlorophyll and carotenoids, and irreversible damage to cell membrane function and structure. Sensitive plants emerging from soils treated with the herbicide flumioxazin become necrotic and die shortly after exposure to sunlight.

2.0 Methods of Analysis

Please refer to Evaluation Report ERC2010-05, *Flumioxazin* for the methods of analysis.

3.0 Impact on Human and Animal Health

Please refer to Evaluation Report ERC2010-05, *Flumioxazin* for the toxicology and food residue assessments.

3.1 Occupational and Residential Risk Assessment

Occupational exposure to flumioxazin is characterized as short- to intermediate-term duration for mixer, loader, applicator and post-application worker, and is predominantly by the dermal and inhalation routes. There were no exposure data available for intense contact with treated bare ground of soil. However, worker exposure to treated soil was calculated using default transferable turf residue values.

3.1.1 Toxicological Endpoints

3.1.1.1 Dermal Absorption

An acceptable in vivo rat dermal absorption study, following EPA guidelines was reviewed. However, all dermal exposure estimates were compared to a dermal endpoint determined from a rat developmental study. Therefore, a dermal absorption value for the purposes of the present assessments was not required.

3.1.2 Occupational Exposure and Risk

3.1.2.1 Mixer/loader/applicator Exposure and Risk Assessment

Individuals have potential for exposure to flumioxazin during mixing, loading and application. Dermal and inhalation exposure estimates for workers were generated from the Pesticide Handlers Exposure Database (PHED) version 1.1. The PHED is a compilation of generic mixer/loader and applicator passive dosimetry data with associated software which facilitates the generation of scenario-specific exposure estimates. To estimate exposure for each use scenario, appropriate subsets of A and B grade data were created from the database files of PHED for dry flowable open mix/loading coupled, with application equipment of groundboom, low- and high-pressure handwand, backpack, and right-of-way sprayers. The PHED estimate for the granular formulation mixer/loader exposure was the open mix/load, granule scenario, coupled with the application equipment of push-type and hand-cranked rotary spreaders, broadcast granular spreader, and dispersal by hand. The maximum application rate is 214 grams active ingredient per hectare, depending on soil characteristics for Flumioxazin 51WDG Herbicide, and maximum application rate of 420 grams active ingredient per hectare for Flumioxazin 0.25G Herbicide.

Chemical-specific exposure data for assessing human exposures during pesticide handling activities were not submitted.

Exposure to workers mixing, loading and applying Flumioxazin 51WDG Herbicide is expected to be short-term duration (up to 30 days per season), or intermittent intermediate-term duration (up to 6 months) including potential post-emergence burndown uses, and to occur primarily by the dermal and inhalation routes. Exposure estimates were derived for mixer/loaders/applicators applying Flumioxazin 51WDG Herbicide for pre-emergence control of annual broadleaf and grassy weeds in field-grown ornamentals, deciduous trees, and coniferous trees including Christmas trees and trees produced for reforestation, soybean (post-emergence burndown also), dry bulb onion, pome fruit (apple and pear), grape, highbush blueberry (post-emergence

burndown also), stone fruit (peach, prune, sweet and sour cherry) (post-emergence burndown also), asparagus (post-emergence burndown also), and to maintain bare ground non-crop areas (including railroad beds, under guard rails, above-ground pipelines, parking and storage areas, plant sites, substations, pumping stations, oil yards/substations and tank farms, airports, brick yards, industrial plant sites, lumber yards and storage areas, around farm buildings, along fence rows, road surfaces and gravel shoulders, in and around ornamental nurseries and farms, and military installations) using ground application equipment.

Short-term exposure duration is expected for Flumioxazin 0.25G Herbicide use on container-grown ornamentals, by ground spreader equipment or by manual dispersal.

Dermal exposure was estimated by coupling the unit exposure values with the amount of product handled per day and the dermal absorption factor of 1, (the occupational NOAEL being based on an endpoint determined from a dermal study). Inhalation exposure was estimated by coupling the unit exposure values with the amount of product handled per day with 100% inhalation absorption. Exposure was normalized to mg/kg bw/day by using 70 kg adult body weight (Table 3.1.2.1.1.).

Exposure estimates were compared to a route-specific toxicological end point (no observed adverse effects level) to obtain the margin of exposure (MOE). The target MOE is 1000.

The initial exposure estimates were derived with mixers/loaders/applicators wearing a long-sleeved shirt, long pants, chemical-resistant gloves, goggles or a faceshield, socks and shoes. Mixer/loader/applicator exposure refinement was necessary when the target margin of exposure was not met for a specific equipment scenario. Where appropriate, further mitigation measures were based on a prescribed maximum amount of product handled per day. Additional PPE, engineering controls, or restricted amount of product handled per day, were considered in achieving the target MOE (Tables 3.1.2.1.1 and 3.1.2.1.2).

Table 3.1.2.1.1. Mixer, loader, and applicator summary exposure and risk assessment.

Crop Scenario	Application Equipment (Notes 1,2, and 3)	Maximum Application Rate (g a.i./ha)	ATPD[A] (ha/day) Or Amount of a.i. handled per day (kg a.i./day)	Dermal Unit Exposure[B] (µg/kg a.i.)	Inhalation Unit Exposure[B] (µg/kg a.i.)	Combined MOE [C,D]
Flumioxazin 51 water dispersible granule formulation						
Crop, and non-crop bare ground areas	Backpack	214	0.765 (kg a.i./day)	2689	63.12	1642
	Right-of-Way sprayer		3.542 (kg a.i./day)	532	6.02	1000
	Groundboom, closed cab		21.1 (kg a.i./day)	89	1.08	1000
	Groundboom, open cab		19.1 (kg a.i./day)	98.6	1.12	1000
	Low-pressure handwand		0.161 (kg a.i./day)	11568	142	1007
	High-pressure handwand		0.518 (kg a.i./day)	2545	152	1001
Flumioxazin 0.25 Granular formulation						
Container-grown ornamentals	Open-cab, Solid Broadcast (granular) spreader (M/L+A)	420	5 (ha/day)	28.93	3.8	14900
	Push-type rotary spreader (M/L/A)		2 (ha/day)	2034	3.68	1207
	Hand-crank (Belly grinder) spreader (M/L/A)		0.68 (ha/day)	5548.67	126.9	1079
	dispersed by hand (A)		0.08 (ha/day) (0.00336 kg a.i./day)	55422.5	605	1017

Note 1: Assumption that mixer, loader, and applicator are the same person

Note 2: Backpack scenario was based on extrapolation of Liquid, open pour, backpack scenario summed with dry flowable, open pour, mix/load, which was not expected to underestimate spraying of water dispersible granules, providing there is continuous agitation of mixture.
Note 3: High-pressure handwand scenario was based on extrapolation of Liquid, open pour, high-pressure scenario summed with dry flowable, open pour, mix/load, which was not expected to underestimate spraying of water dispersible granules, providing there is continuous agitation of mixture.

A. Area-treated-per-day default database, 2004
B. Scenario dermal and inhalation unit exposures were used from the Pesticide Handlers Exposure Database, version 1.1
Push-type spreader PHED scenario unit exposure of 6448.49 µg a.i./kg a.i., with **no head or neck data**, single layer and **no gloves**, A,B, and C grade data, which was corrected for head surface area of 1205 cm^2 (for head and neck) as a proportion of whole body area of 18440 cm^2: 6448.49+ ((6448.49x(1205/18440)) = 6870 µg a.i./kg a.i.. Coveralls over single layer **and gloves** exposure was calculated as a 75% protection factor of the total PHED value of 6448.49 µg a.i./kg a.i., which includes hands. This was not expected to overestimate protection, as chemical-resistant gloves, if able to be included, are rated as a 90% protection factor (Recommended Protection Factors, January 2000) and the calculated head exposure added: (6448.49 × 0.25)+ ((6449.49 × (1205/18440)) = 2034 µg a.i./kg a.i.

C. (Dermal or Inhalation) Exposure Estimates

$$= \frac{[\text{Application Rate} \times \text{Area treated per day}] \text{ or } [\text{Amount of a.i. handled per day}] \times \text{PHED Exposure (µg a.i./kg a.i. handled)} \times \text{Absorption Factor}}{\text{bw (70kg)}}$$

where,
body weight = 70 kg
Dermal absorption assumed to be 100%, since NOAEL based on a dermal study, therefore factor = 1;
Inhalation absorption assumed to be 100% systemically available, therefore factor =1;

Occupational endpoints: Short and Intermediate duration exposure: Dermal, based on the rat dermal developmental study NOAEL of 30 mg/kg bw/day; inhalation, based on the rat oral developmental study NOAEL of 3 mg/kg bw/day; a target MOE of 1000 for both routes.

$$\text{MOE} = \frac{\text{(Dermal or Inhalation) NOAEL (mg/kg bw/day)}}{\text{(Dermal or Inhalation) exposure estimates (mg/kg/day)}}$$

D. Combined MOE calculated according to SPN2003-04

Table 3.1.2.1.2. Personal Protective Equipment Instructions for Flumioxazin 51WDG Herbicide.

Follow mixer/loader and applicator scenario, as appropriate in the chart below. In addition, wear coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, socks and shoes, goggles or faceshield, during clean-up and repair activities.

Equipment	Personal Protective Equipment		Maximum amount of product handled per day (kg)
	Mixer/Loader	Applicator	
Groundboom	Chemical-resistant coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, socks and shoes, and goggles or faceshield	**Open cab**: Coveralls over long-sleeved shirt, long pants, socks and shoes, and chemical-resistant gloves, and respirator with a NIOSH/MSHA/BHSE approved organic-vapour-removing cartridge with a prefilter approved for pesticides, or a NIOSH/MSHA/BHSE approved canister approved for pesticides	37 kg
		Closed cab: Long-sleeved shirt, long pants, socks and shoes. (No gloves are required, but must be available for maintenance activities)	

Equipment	Personal Protective Equipment		Maximum amount of product handled per day (kg)
	Mixer/Loader	Applicator	
Right-of-Way sprayer	Chemical-resistant coveralls and chemical-resistant gloves, socks and shoes. Mixers and loaders must also wear goggles or faceshield.		7.0 kg
Backpack or High-pressure handwand equipment	Coveralls over long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes, and respirator with a NIOSH/MSHA/BHSE approved organic-vapour-removing cartridge with a prefilter approved for pesticides, or a NIOSH/MSHA/BHSE approved canister approved for pesticides. Mixers and loaders must also wear goggles or faceshield.		1.2 kg
Low-pressure Hand-held Equipment			0.315 kg
Airblast	Not for use with airblast equipment		

Do not enter or allow entry into treated areas until the sprays have dried in non-crop bare ground use areas.

Do not enter or allow worker entry into treated areas during the restricted entry interval of 12 hours for all crop uses.

For field-grown coniferous trees, including Christmas trees and trees produced for reforestation: Do not enter treated areas for handline irrigation for a period of 6 days after over-the-top application.

Personal protective equipment and use restrictions for Flumioxazin 0.25G Herbicide are:

Personal Protective Equipment
Loaders, applicators, and other handlers must wear coveralls over long-sleeved shirt and long pants, chemical-resistant gloves made of any waterproof material such as polyethylene or polyvinyl chloride, shoes and socks.

Restrictions
The maximum amount of product handled per day for hand dispersal must not exceed 13 kg product/day.

3.1.2.2 Exposure and Risk Assessment for Workers Entering Treated Areas

There is potential for exposure to workers re-entering crops or areas treated with flumioxazin from scouting, transplanting, grafting/propagating, trellising, staking, mowing, cultivation, spraying other pesticides, pruning, thinning, irrigating, harvesting, moving plants or container-grown plants. Given the nature of activities performed, dermal contact with treated surfaces are expected. Post-application inhalation exposure is not expected as the water dispersible granule formulation has low vapour pressure and unlikely to volatilize, and the active will be soil-bound once irrigation has occurred or sufficient moisture is present. The duration of exposure is

considered to be short- to intermediate-term, and the primary route of exposure for workers re-entering treated areas would be through the dermal route.

Dermal exposure to workers entering foliar treated areas is estimated by coupling dislodgeable foliar residue values with activity-specific transfer co-efficients. Activity transfer coefficients are based on Agricultural Re-entry Task Force data, of which Valent USA Corporation is a member. Chemical-specific dislodgeable foliar residue data were not submitted. As such, a default dislodgeable foliar residue value of 20% of the application rate on the day of application and 10% daily dissipation was used in the exposure assessment. Dermal surface area available for contact with treated bare ground was considered not to be underestimated by the post-application foliar transfer co-efficients for the activities conducted. Dermal surface area of contact in military installations was calculated based on coveralls over long-sleeved shirt and long pants.

Exposure estimates were compared to the relevant toxicological endpoint to obtain the margin of exposure (MOE). The target MOE was 1000. All post-application tasks assessed for field, nursery (field or container-grown) crops or bare ground non-crop areas were considered acceptable (Tables 3.1.2.2.1 and 3.1.2.2.2).

Table 3.1.2.2.1. Exposure and risk estimate for post-application re-entry to treated field and nursery crops, and non-crop bare ground areas by workers.

Application site scenario	Tasks	Maximum application rate (g a.i./ha)	Number of applications	Transfer Co-efficient (cm^2/hour)[A]	DFR value (µg/cm^2)	Dermal Adherence factor (µg/cm^2)	Days after last application	Exposure Duration[B] (hours)	Daily Dose [C,D] (mg/kg bw/day)	MOE[E]	Restricted entry interval [F] (days)
over-the-top application to hardened off Coniferous trees (based on foliar application)[F]	Soil-contact tasks: Transplanting or harvesting trees for market, hand weeding, (mowing not conducted on treated ground)	214	2 (56 day interval)	1500	0.4292	Not applicable	0	8	0.0734	**409**	9 days transplanting tasks not likely to be performed so soon after application;
	Handline irrigation			1100					0.0540	**556**	6 days
	Scouting, training (staking, tying)			500					0.0245	1227	none
	Hand weeding			100					0.0049	6116	none
Bare ground, crop and non-crop areas, and in and around ornamental nurseries	Occupational dermal contact with treated crop (30 day spray interval) and non-crop ground (60 day spray interval) are not quantified; expected to be mitigated by the use of clothing appropriate to crop-specific tasks (pre-emergence to crop and burndown (see scouting, above), be no more than military use, and therefore considered not to be of concern										none
Bare ground, non-crop area; ground-directed, on Military Installations	All activities	214	2 (60 day interval)	6200	Not applicable	1.0	0	12	1.9×10^{-3}	1.58×10^{4}	none

A. Transfer co-efficients were used from the Interim Revisions to Policy 003.1, and Transfer Coefficients for Orchard Tree Crops and Christmas Trees (2004)
B. Typical work day duration of 8 hours. Recommended revisions to the Standard Operating Procedures (SOPs) for Residential Exposure Assessments, revised February 22, 2001.
C. Daily Dose estimates from foliar application were calculated using the following formula. Draft Standard Operating Procedures (SOPs) for Residential Exposure Assessments, December 1997:

$$\frac{\text{DFR Value (µg/cm}^2\text{)} \times \text{Transfer Coefficient (cm}^2\text{/hr)} \times \text{Hours Worked per Day (hr)} \times \text{Conversion Factor (1mg/1000µg)} \times \text{DA}}{\text{Body Weight}} \quad \text{Equation 1}$$

Where,
DFR value for a single application = application rate g ai/ha × 10^6 µg/g × 10^{-8} ha/cm^2 × soil or foliar dislodgeable fraction on the day of application.
Dissipation is considered not to occur on the same day as application.
Based on a dermal absorption (DA) value of 100%, based on a NOAEL for a rat dermal study. Default of 20 % dislodgeable foliar residue on day of application and 10% daily dissipation rate following foliar application to Conifers. Body weight is considered to be 70kg for an adult;

D. Using an amended (accounting for multiple applications) equation from the Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual (Part A) ("RAGS", EPA, 1989) presents an equation used to estimate exposure from dermal contact with soil (as stated in Technical Guidance Manual, Mid Atlantic Risk Assessment, Office of Superfund Programs, Hazardous Waste Management Division, United States Environmental Protection Agency), the Part E, Supplemental Guidance for Dermal Risk Assessment) Interim, and Exposure Factors Handbook, 1997 edition:

$$AD = ((\sum_{n=1,2}^{N} (CS \times (1\text{-}DD)^{\wedge}(DALA)_n)) \times CF \times SA \times AF \times ABS \times EF \times ED)/(bw \times AT) \qquad \text{Equation 2}$$

Where,

AD = Absorbed dose (mg/kg bw/day)
$\sum$ = summation of residue from n number of applications
N = Total number of applications ; there are 2 in total
n = number of application
CS = Chemical concentration in soil (mg/kg)) = 2.14 µg a.i. /cm^2 × 1/cm (depth) = 2.14 µg a.i./cm^3 × 0.67 cm^3/g soil = 1.434 µg a.i./g soil (=mg a.i./kg soil)
DD = Daily dissipation rate = assumed to be 2.42% = 0.0242, based on the laboratory soil dissipation study half-life of 28.66 days
DALA = Days after last application = spray interval = minimum of 30 days for fruit crops (56 days for field-grown ornamentals; 60 days for non-crop areas, including military installations); entry of 0 days after last application
CF = Conversion factor (10^{-6} kg/mg)
SA = Skin surface area available for contact (cm^2/event) = 6200 cm^2/hour
AF = Soil-to-skin adherence factor (mg/cm^2) = 1 for military; 0.2 for workers
ABS = Absorption factor (unitless) = 100% = 1
EF = Exposure frequency (events/day) = 8 hours/day for crop work; 12 hours/day for military
ED = Exposure duration (one day)
bw = Body weight (kg)
AT = Averaging time (period over which exposure is averaged-days) = 1 day

E. MOE = NOAEL/ Daily dose, for dermal exposure, based on a dermal NOAEL of 30 mg/kg bw/day from the rat developmental study; with a target MOE of 1000
F. None = no REI time in addition to the product REI of 12 hours; otherwise the product REI is included with the task-specific REI

Table 3.1.2.2.2. Exposure and risk estimate for post-application re-entry after treating ornamental containers with Flumioxazin 0.25G Herbicide.

Sub-population	Tasks	Maximum application rate [A] (g a.i./ha)	Number of applications	Body Surface Area available for soil contact[B] (cm^2/hour)	Absorbed Dose[C] (mg/kg bw/day)	MOE [D]	Restricted entry interval (days)
Adult worker (including females 13-49, dermal)	Transplanting, digging plants, other high-contact soil-related tasks; moving and transporting contain-grown ornamentals	420	2	1500	1.11×10^{-4}	$2.70x10^5$	none

A) Maximum application rate = 420 g a.i./ha = 4.2 µg/cm^2 .
B). Body surface area of 1500 cm^2/h was used for minimum surface area of hands + lower forearms (904 cm^2 + (1173 cm^2/2)) from International Harmonisation Position Paper of Methodology Issues, 1999, Appendix II, and tree harvesting from Transfer Coefficients for Orchard Tree Crops and Christmas Trees (2004).
C). Using the equation from the Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual (Part A) ("RAGS", EPA, 1989) presents an equation used to estimate exposure from dermal contact with soil (as stated in Technical Guidance Manual, Mid Atlantic Risk Assessment, Office of Superfund Programs, Hazardous Waste Management Division, United States Environmental Protection Agency), the Part E, Supplemental Guidance for Dermal Risk Assessment) Interim, and Exposure Factors Handbook, 1997 edition.
Assumption 1: All active ingredient (a.i.) is sequestered in top 1 cm of soil at time of post-application entry;
Soil density = 0.67 cm^3/g soil (U.S. EPA Standard Operating Procedures for Residential Exposure Assessments)

Soil concentration = 4.2 µg a.i. /cm^2 × 1/cm (depth) = 4.2 µg a.i./cm^3 × 0.67 cm^3/g soil = 2.814 µg a.i./g soil (= mg a.i./kg soil)
Assumption 2: Post-application entry occurs the same day as the second application, therefore no degradation, dissipation, but adsorption to soil achieves saturation;
Assumption 3: That the treated soil is dry when entry occurs;
Assumption 4: That 100% of active residue contained in the soil-to-skin adherence (i.e. flux), is considered a monolayer, is available for skin contact and is rapid compared to dermal absorption (instantaneous), and not the rate-limiting step;
Assumption 5: An event is 1 hour, and each 1 hour interval represents a fresh soil loading.

$$AD = ((\sum_{n=1,2}^{N} (CS \times (1\text{-}DD)^{(DALA)_n})) \times CF \times SA \times AF \times ABS \times EF \times ED)/(bw \times AT) \qquad \text{Equation 2}$$

Where,

AD = Absorbed dose (mg/kg bw/day)
CS = Chemical concentration in soil (mg/kg) = 2.814 mg a.i./kg soil
N = Total number of Applications are 2
n = for 1 to N number of applications,
DD = Daily total dissipation and degradation rate = assumed to be 2.42% = 0.0242, based on the laboratory soil dissipation study half-life of 28.66 days
DALA = Days after last application = re-entry 77 days after first application; re-entry 0 days after second application
CF = Conversion factor (10^{-6} kg/mg)
SA = Skin surface area available for contact (cm^2/event) = Transfer co-efficient (cm^2/hour) = 1500
(based on Interim Golf Course and Sod Farm Transfer Coefficients**,** 2003)
AF = Soil-to-skin adherence factor (mg/cm^2) = 0.2
ABS = Absorption factor (unitless) = 100% = 1
EF = Exposure frequency (events/day) = 8 hour workday
ED = Exposure duration = 1 day
bw = Body weight (kg) = 70 kg
AT = Averaging time (period over which exposure is averaged-days) = 1

D. MOE = NOAEL/ Daily dose, for dermal exposure, based on a dermal NOAEL of 30 mg/kg bw/day from the rat developmental study; with a target MOE of 1000.

3.1.3 Residential Exposure and Risk Assessment

3.1.3.1 Handler Exposure and Risk

There are no domestic class products; therefore, a residential handler assessment was not required.

3.1.3.2 Post-application Exposure and Risk

There are no domestic class products, or commercial products for application in residential areas. Therefore, a residential post-application assessment was not required.

3.1.3.3 Bystander Exposure and Risk

Bystander exposure should not be of concern since the potential for drift is expected to be minimal. Application to agricultural and ornamental crops, and bare ground, non-crop areas, is limited to when there is low risk of drift to areas of human habitation or activity such as houses, cottages, schools and recreational areas, taking into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings.

Table 3.1.3.3.1. Post-application exposure and risk assessment for dermal contact with treated ground for treated non-crop bare ground areas, and pickers at pick-your-own (U-pick) operations after use of Flumioxazin 51WDG Herbicide.

Sub-population by crop	Tasks	Maximum application rate (g a.i./ha)	Number of applications[A]	Transfer Co-efficient (cm^2/hour)[B]	Body Weight (kg)	Daily Dose [C,D] (mg/kg bw/day)	MOE [E]	Restricted entry interval (days)
Adult non-worker (contact with treated ground)	Dermal contact with treated bare ground (hands only)	214	2	500	70	5.11×10^{-6}	5.87×10^6	none
Children (average of 3 years of age, dermal) from treated ground				213	15	1.02×10^{-5}	2.94×10^6	none
Child (1-3 years of age)(Incidental oral ingestion of soil)	Oral ingestion not quantified, as no acute reference dose required for this sub-population							

Note: Highbush Blueberry, application ground-directed at crop base; PHI = 7 days

A. Covers highbush blueberry and strawberry

B. Transfer coefficient value of 500 (low-contact, ground) was adjusted for average body surface area of Child (1-6 years-old) 7860 cm^2, compared to adults, 18440 cm^2. NAFTA, 1999

C. Expected exposure duration for bystanders entering pick-your-own operation of 2 hours. Recommended revisions to the Standard Operating Procedures (SOPs) for Residential Exposure Assessments. Revised 2001.

D. No dermal absorption value required due to a dermal NOAEL of 30 mg/kg bw/day from the rat developmental study. Modified use of Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual (Part A) ("RAGS", EPA, 1989) presents an equation used to estimate exposure from dermal contact with soil (as stated in Technical Guidance Manual, Mid Atlantic Risk Assessment, Office of Superfund Programs, Hazardous Waste Management Division, United States Environmental Protection Agency), the Part E, Supplemental Guidance for Dermal Risk Assessment) Interim, and Exposure Factors Handbook, 1997 edition, to account for the pre-harvest interval of 7 days.

$$AD = ((\sum_{n=1,2}^{N}(CS \times (1\text{-}DD)^{\wedge}(DALA)_n)) \times CF \times SA \times AF \times ABS \times EF \times ED)/(bw \times AT) \qquad \text{Equation 2}$$

Where,

AD = Absorbed dose (mg/kg bw/day)
CS = Chemical concentration in soil (mg/kg) = 2.14 µg a.i. /cm^2 × 1/cm (depth) = 2.14 µg a.i./cm^3 × 0.67 cm^3/g soil = 1.434 µg a.i./g soil (=mg a.i./kg soil)
DD = Daily dissipation rate = 2.42% = 0.0242, from the laboratory soil dissipation study half-life (DT_{50}) of 28.66 days
DALA = Days after last application = 30 days spray interval; and re-entry interval of 7 days after second application.
CF = conversion factor; 10^{-6} kg/mg soil
SA = Skin surface area available for contact (cm^2/event) = Transfer co-efficient (cm^2/hour) = 500 (from U.S. EPA Policy 003.1)
AF = Soil-to-skin adherence factor (mg soil/cm^2) = 0.2
ABS = Absorption factor (unitless) = 100% = 1
EF = Exposure frequency (events/day) = 2 hours/day for picking
ED = Exposure duration (one day)
BW = Body weight (kg); adult 70kg; Child 15kg
AT = Averaging time (period over which exposure is averaged-days)

E. MOE = NOAEL/ Daily dose, for dermal exposure, based on a dermal NOAEL of 30 mg/kg bw/day from the rat developmental study; with a target MOE of 1000

3.1.4 Food Residues Exposure Assessment

3.1.4.1 Aggregate Exposure and Risk

Pick-your-own scenarios were considered for highbush blueberry, strawberry, pear, peach, cherry, and apple crops. Exposure associated with post-application harvesting and picking includes dermal exposure from contact with treated ground, and oral exposure by dietary intake. There was no acute hazard identified for children, or the general population. An aggregate

assessment was not required for these sub-populations. The sub-population at risk was the female 13-49 age-group. Contact related to harvesting or fruit picking activity with crops having pesticide residues was not quantifiable; however, application is ground-directed, and shielded if necessary, to minimize spraying of foliage and edible fruit. Dermal contact with treated ground (represented by soil) was estimated for bare ground contact for non-workers. Exposure was considered minimal, not to be of concern, and aggregate assessments were not conducted.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Please refer to Evaluation Report ERC2010-05, *Flumioxazin* for a detailed evaluation of the fate and behaviour in the environment.

The additional information provided shows flumioxazin residues break down easily in the presence of microorganisms in aquatic systems. Under aerobic aquatic conditions, flumioxazin transforms to several major transformation products with representative half-lives (DT_{50}s) for the whole system of 17.2, 27.3, 41.5 and 82.9 days. The observed DT_{50} values were much shorter, ranging from 0.002 - 3.17 days. In aerobic aquatic systems, flumioxazin is expected to partition to the sediment before biotransforming and/or hydrolysing. It is possible that sorption to sediment may be slowing down the transformation process over time. Additional information provided indicates that the transformation products are transient and not expected to persist in the aquatic environment. The relevant endpoints are summarised in Appendix I, Table 1.

4.2 Environmental Risk Characterization

Please refer to ERC2010-05, *Flumioxazin* for a detailed evaluation of the environmental risk characterization.

4.2.1 Risks to Terrestrial Organisms

Please refer to ERC2010-05, *Flumioxazin* for a detailed evaluation of the risks to terrestrial organisms.

Additional information on the potential effects to bees, beneficial insects and birds was submitted and reviewed to support the European information reported in ERC2010-05. The information confirms the previously reported results. No changes to the endpoints or conclusions are required. The relevant endpoints are summarised in Appendix I, Table 2.

4.2.2 Risks to Aquatic Organisms

Please refer to ERC2010-05, *Flumioxazin* for a detailed evaluation of the risks to aquatic organisms.

Additional information on the potential toxicity to aquatic vascular plants indicate that flumioxazin is very highly toxic to aquatic plants when exposed via direct overspray (EC_{50}: 0.41 µg a.i./L). The endpoint was slightly higher (less toxic) than the endpoint reported previously (EC_{50}:0.33 µg a.i./L). The results are reported in Appendix I, Table 3.

The risk assessment for aquatic systems was revised to take into account the new aquatic biotransformation half-life estimates and the new aquatic plant endpoint. This information only resulted in changes to the estimated environmental concentrations (EECs) and the subsequent risk quotients (RQs) calculated for the screening level (Flumioxazin 51WDG and 0.25G) and the refined spray drift assessment (Flumioxazin 51WDG) for aquatic habitats. The new information did not require any changes to the EECs for the refined runoff assessments, but did require a revised RQ calculation for aquatic vascular plants.

Although the revised RQs are slightly lower than the previously reported RQs, there were no changes to the organisms identified as potentially being at risk (terrestrial and aquatic organisms including beneficial arthropods, terrestrial non-target vascular plants, algae and aquatic vascular plants). The appropriate precautionary label statements for aquatic organisms, beneficial arthropods and terrestrial plants are present on the label. The buffer zones have been amended slighlty to reflect the new information.

The revised risk assessment calculations are presented in Appendix I, Table 4, Table 5, Table 6, Table 7 and Table 8.

4.2.3 Incident Reports

There are currently no incident reports with flumioxazin.

5.0 Value

Please refer to Evaluation Report ERC2010-05, *Flumioxazin*, for a detailed evaluation of the value of Flumioxazin 51WDG Herbicide and Flumioxazin 0.25G Herbicide.

5.1 Effectiveness Against Pests

Outstanding value information was identified as a condition of registration for the following label claims.

- Control of redroot pigweed, common ragweed, green pigweed, eastern black nightshade, hairy nightshade, green foxtail, and dandelion at the rates of 71 and 143 g a.i./ha on coarse-textured soil with <5% OM content.

- Control of common lamb's quarters, redroot pigweed, common ragweed, green pigweed, eastern black nightshade, hairy nightshade, green foxtail, and dandelion at the rates of 107 and 214 g a.i./ha on medium-textured soil with <5% OM content.

- Suppression of redroot pigweed, common lamb's quarters, eastern black nightshade, and hairy nightshade at the rate of 54 g a.i./ha in potato grown on both coarse- and medium-textured soils with <5% OM content.

- Suppression of redroot pigweed, common lamb's quarters, common ragweed, green pigweed, eastern black nightshade, and hairy nightshade at the rate of 71 g a.i./ha on muck soil.

5.1.1. Acceptable Efficacy Claims

Data from 19 trials were submitted to address the deficiency in support of efficacy claims on coarse-textured soil with <5% OM content. The information available confirmed that application of Flumioxazin 51WDG Herbicide at 71 and 143 g a.i./ha provided control of common lamb's-quarters, green pigweed, common ragweed, dandelion, eastern black nightshade, hairy nightshade, and redroot pigweed and suppression of green foxtail in such soil conditions. The lower rate is for use on annual crops and lowbush blueberry, while the higher rate is for use in bare ground, perennial crops, field ornamentals, and trees.

Data from 31 trials were submitted to address the deficiency in support of efficacy claims on medium-textured soil with <5% OM content. The information available confirmed that application of Flumioxazin 51WDG Herbicide at 107 or 214 g a.i./ha provided control of common lamb's-quarters, green pigweed, common ragweed, dandelion, eastern black nightshade, hairy nightshade, and redroot pigweed and suppression of green foxtail in such soil conditions. The lower rate is for use on annual crops and lowbush blueberry, while the higher rate is for use in bare ground, perennial crops, field ornamentals, and trees.

Data from 22 trials were submitted to address the deficiency in support of efficacy claims in potato on coarse- and medium-textured soils with <5% OM content. The information available confirmed that application of Flumioxazin 51WDG Herbicide at 54 g a.i./ha provided suppression of redroot pigweed, common lamb's-quarters, hairy nightshade, common ragweed and eastern black nightshade in such soil conditions.

Data from 15 trials were submitted to address the deficiency in support of efficacy claims on muck soil. The information available confirmed that Flumioxazin 51WDG Herbicide at 71 g a.i./ha provided suppression of redroot pigweed, green pigweed, lamb's-quarters, hairy nightshade, and eastern black nightshade on muck soil.

The conditions of registration of Flumioxazin 51WDG Herbicide regarding effectiveness against pests have been satisfied.

5.2 Phytotoxicity to Host Plants

Outstanding value information was identified as a condition of registration for the following host crop and soil combinations.

- Soybean on medium-textured soil with 3-5% OM content.
- Established asparagus on coarse- and medium-textured soils with < 5% OM content.
- Apricot on coarse- and medium-textured soils with <5% OM content.
- Strawberry on coarse- and medium-textured soils with <5% OM content

5.2.1 Acceptable Claims for Host Plants

Data from eight trials were submitted to address the deficiency in support of soybean on medium-textured soil with 3-5% OM content. Minor crop injury to soybean was observed at early rating, but declined at mid and late ratings. Final grain yield further confirmed that soybean exhibits an adequate margin of crop safety to Flumioxazin 51WDG Herbicide at up to 107 g a.i./ha on medium-textured soil with <5% OM content.

Data from 11 trials were submitted to address the deficiency in support of asparagus on coarse- and medium-textured soils with <5% OM content. Crop injury to asparagus was observed over ratings, but the observed injury was comparable to that of the registered herbicide treatments. Yield data further confirmed that established asparagus exhibits a similar margin of crop safety to Flumioxazin 51WDG Herbicide at 143 g a.i./ha on coarse-textured soil and at 214 g a.i./ha on medium-textured soil with <5% OM content when compared to other registered herbicide treatments.

Crop tolerance data collected from peach, cherry, nectarine, and plum and use history information demonstrated that apricot exhibits an adequate margin of crop safety to Flumioxazin 51WDG Herbicide at 143 g a.i./ha on coarse-textured soil and 214 g a.i./ha on medium-textured soil with <5% OM content.

Data from six trials were submitted to address the deficiency in support of strawberry on coarse- and medium-textured soils with <5% OM content. Minor injury was observed at early rating, but disappeared at the mid and late ratings. Yield data further confirmed that strawberry exhibits an adequate margin of crop safety to Flumioxazin 51WDG Herbicide at up to 107 g a.i./ha on coarse- and medium-textured soils with <5% OM content.

The conditions of registration of Flumioxazin 51WDG Herbicide regarding phytotoxicity to host plants have been satisfied.

6.0 Pest Control Product Policy Considerations

Please refer to Evaluation Report ERC2010-05, *Flumioxazin*, for a detailed evaluation of the pest control product policy considerations.

6.1 Toxic Substances Management Policy Considerations

Additional information was received to characterise the bioaccumulation potential of major transformation products of flumioxazin. The transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria. The log K_{ow} values for the transformation products of flumioxazin are all ≤1 indicating that they are unlikely to bioaccumulate in aquatic organisms. None of the transformation products of flumioxazin are considered Track 1 substances.

7.0 Summary

7.1 Human Health and Safety

The toxicology database submitted for flumioxazin is adequate to define the majority of toxic effects that may result from exposure. In subchronic and chronic studies on laboratory animals, target organs included the blood system and the liver. There was no evidence of oncogenicity. Both qualitative and quantitative sensitivity of the young were observed in terms of fetal malformations at maternally non-toxic doses. Flumioxazin is not considered to be a neurotoxicant. The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

The nature of the residue in plants (soybean, peanut, grape and apple) and animals (hen and goat) is adequately understood. The residue definition for enforcement purposes in plant products is flumioxazin. The use of flumioxazin on crops listed on the labels and the import of flumioxazin-treated commodities does not constitute an unacceptable chronic dietary risk (food and drinking water) to any segment of the population, including infants, children, adults and seniors. Sufficient crop residue data have been reviewed to recommend maximum residue limits to protect human health. The PMRA recommends that the following maximum residue limits be specified for residues of flumioxazin.

MRLs (ppm)	Foods
0.02	Tuberous and Corm Vegetables (Crop Subgroup 1C); Bulb Onion Subgroup (Crop Subgroup 3-07A); Soybean, seed; Pome fruits (Crop Group 11), Stone fruits (Crop Group 12); Bushberries, except lowbush blueberries (Crop Subgroup 13-07B); Small fruit vine climbing, except fuzzy kiwifruit (Crop Subgroup 13-07F); asparagus
0.07	Low growing berries (Crop Subgroup 13-07G)

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

Mixer, loader applicators handling Flumioxazin 51WDG Herbicide or Flumioxazin 0.25G Herbicide and workers re-entering treated agricultural or ornamental crops, or bare ground non-crop areas are not expected to be exposed to levels of flumioxazin that will result in an unacceptable risk when Flumioxazin 51WDG Herbicide or Flumioxazin 0.25G Herbicide is used according to label directions. The personal protective equipment on the product label is adequate to protect workers.

Mixer, loader applicators handling Flumioxazin 51WDG Herbicide or Flumioxazin 0.25G Herbicide and workers re-entering treated agricultural or ornamental crops, or bare ground non-crop areas are not expected to be exposed to levels of Flumioxazin that will result in an unacceptable risk when Flumioxazin 51WDG Herbicide or Flumioxazin 0.25G Herbicide is used according to label directions. The personal protective equipment on the product label is adequate to protect workers.

Health risks to bystanders are considered not to be of concern.

Health risks for people who enter treated fields to pick apples, pears, highbush blueberries, or strawberries are not of concern.

7.2 Environmental Risk

The use of Flumioxazin 51WDG Herbicide may pose a risk to terrestrial and aquatic organisms, including beneficial arthropods, terrestrial non-target vascular plants, algae and aquatic vascular plants. Precautionary label statements appear on the product labels to identify and mitigate the risk from spray drift to beneficial athropods. Also, terrestrial spray buffer zones of five to twenty-five metres and aquatic buffer zones of zero to five metres are required to protect sensitive non-target plant species from spray drift. Advisory runoff statements on the label may minimise the risk from runoff.

The use of Flumioxazin 0.25G Herbicide is not expected to pose a risk to terrestrial organisms when used according to the label directions. In the aquatic environment, Flumioxazin 0.25G Herbicide at the proposed application rate is not expected to pose a risk to aquatic invertebrates, fish and amphibians on an acute or chronic basis. Flumioxazin 0.25G Herbicide may pose a risk to algae and vascular plants on an acute basis if runoff containing flumioxazin is discharged into water bodies. Advisory runoff statements on the label may minimise the risk from runoff to aquatic plants.

7.3 Value

The information submitted to register Flumioxazin 51WDG Herbicide is adequate to describe its value for use in field-grown coniferous and deciduous ornamental trees, mint, soybean, dry-bulb onion, field pea, pome fruit, grape, highbush and lowbush blueberries, stone fruit, nut tree, asparagus, potato, field pepper, celery, and strawberry and to maintain bare ground non-crop areas. A single pre-emergence application of Flumioxazin 51WDG Herbicide provides control or suppression of common lamb's-quarters, redroot pigweed, common ragweed, green pigweed, eastern black nightshade, hairy nightshade, green foxtail, and dandelion. With the exception of

ornamentals, Flumioxazin 51WDG Herbicide provides new mode of action (Group 14) for pre-emergence weed control for labelled crops. Therefore, the registration of Flumioxazin 51WDG will provide a key tool in weed resistance management in the labelled crops.

The original data submitted to register Flumioxazin 0.25G Herbicide were adequate to describe its efficacy for use in container-grown woody ornamentals. A single pre-emergence application of Flumioxazin 0.25G Herbicide provides control of hairy bittercress and liverwort and suppression of common groundsel and common chickweed. The submitted data demonstrated an adequate margin of safety of labelled woody ornamentals to Flumioxazin 0.25G Herbicide. Flumioxazin 0.25G Herbicide provides a relatively new mode of action (group 14) for herbicides in container-grown woody ornamentals.

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 Flumioxazin Technical and Flumioxazin 51WDG Herbicide to control weeds in numerous crops and Flumioxazin 0.25G Herbicide to control weeds in container grown ornamentals.

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

µg	microgram
a.i.	active ingredient
ATPD	area-treated-per-day
BHSE	British Health and Safety Executive
bw	body weight
cm	centimetre
d	day
DA	dermal absorption
DFOP	double first order parallel
DT_{50}	dissipation time 50% (the dose required to observe a 50% decline in concentration)
EC_{50}	effective concentration on 50% of the population
EEC	estimated environmental concentration
ELS	early life stage
EPA	Environmental Protection Agency
EU	European Union
FDA	*Food and Drugs Act*
g	gram
G	granular
h	hour
ha	hectare
IORE	indeterminate order rate equation
kg	kilogram
K_{ow}	*n*–octanol-water partition coefficient
L	litre
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LOC	level of concern
LR_{50}	lethal rate 50%
M/L/A	mixer/loader/applicator
mg	milligram
mL	millilitre
MSHA	Mine Safety and Health Admistration
MOE	margin of exposure
MRL	maximum residue limit
NAFTA	North American Free Trade Agreement
NIOSH	National Institute for Occupational Safety and Health
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
OM	organic matter content
PHED	Pesticide Handlers Exposure Database
PHI	preharvest interval
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment

ppm	parts per million
PPO	protoporphyrinogen oxidase
REI	re-entry interval
RQ	risk quotient
$t_{1/2}$	half life
TSMP	Toxic Substances Management Policy
WDG	water dispersible granular
WSSA	Weed Science Society of America
WP	wettable powder
US	United States

Appendix I Tables and Figures

Table 1 Fate and Behaviour of Flumioxazin in Aquatic Systems (Aerobic Water-Sediment Biotransformation)

Test system and label	Model	DT_{50} (days)	$t_{1/2}$ representative (days)	Major transformation products	Classification	PMRA No.
Biotransformation in aerobic water-sediment systems (whole system)						
Millstream-THP Millstream-PH	IORE DFOP	0.04 3.17	0.23 41.5	THPA, APF, Unk@23.9 (DT_{50}: 2.9-23.2 and $t_{1/2}$:8.4-23.2)	Flumioxazin: Non-persistent Transformation products: non- to slightly persistent	2230463
Emperor Lake-THP Emperor Lake-PH	IORE DFOP	0.002 0.96	17.2 82.9	THPA, APF, Unk@5.5 (DT_{50}: 0.04-21.1 and $t_{1/2}$:0.055-21.1)	Flumioxazin: non-persistent Transformation products: non- to slightly persistent	2230463

Table 2 Effects on Terrestrial Organisms (bees, beneficial insects and birds)

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity[a]	Reference
Invertebrates					
Bee	Oral	Pledge WP	LD_{50} >100 µg a.i./bee	Relatively non-toxic	2300966
Predatory arthropod *T. pyri*	Contact	Pledge WP	14-d LR_{50} >600 g a.i./ha	2%	2283867
P. cupreus		Pledge WP	14-d LR_{50} >600 g a.i./ha	0%	2283864
C. carnea		Pledge WP	14-d LR_{50} >600 g a.i./ha	0%	2283866
A.bilineata		Flumioxazin 50% WP	30-d LR_{50} >600 g a.i./ha	0%	2309046
P. amentata		Flumioxazin 50% WP	14-d LR_{50} >600 g a.i./ha	0%	2283865
Parasitic arthropod *A. rhopalosiphi*	Contact	Pledge WP	48-h LR_{50} <600 g a.i./ha	75%	2315356
Birds					

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity[a]	Reference
Mallard duck	Acute	S-53482 (flumioxazin)	LD_{50} >2250 mg a.i./kg	Practically non-toxic	2302559

Table 3 Effects on Aquatic Organisms (Vascular Plants)

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity[a]	PMRA No.
Freshwater species					
Lemna	7d-Over-spray	Chateau 51 WDG	EC_{50}: 0.416 µg a.i./L	Very highly toxic	2283862

a US EPA classification, where applicable

Table 4 Revised Screening level risk assessment on non-target aquatic organisms (Flumioxazin 0.25 G Herbicide) assuming an application rate of 2 × 420 g a.i./ha and an 11 week interval between applications

Organism	Exposure	Test Substance	Endpoint value (mg a.i./L)	EEC[1] (mg a.i./L)	RQ[2]	Exceeds LOC[3]
Freshwater species						
Daphnia	Acute (flow-through)	Flumioxazin	EC_{50}/2: 2.95	0.053	0.02	No
	Chronic (flow-through)	Flumioxazin	21-d NOEC: 0.05	0.053	1.06	Yes
Rainbow trout	Acute	Flumioxazin (flow-through)	LC_{50}/10: 0.23	0.053	0.23	No
	Chronic –ELS	Flumioxazin (flow-through)	87-d NOEC: 0.0077	0.053	6.88	Yes
	Chronic – juvenile growth	Flumioxazin (flow-through)	21-d NOEC: 0.37[4]	0.053	0.14	No
Bluegill sunfish	Acute	Flumioxazin	96-h LC_{50}/10: >2.1	0.053	0.03	No
Green algae (*Selenastrum capricornutum*)	Acute	^{14}C-Flumioxazin	96-h EC_{50}/2: 0.00051[4]	0.053	103.9	Yes
Blue-green algae (*Anabaena flos-aqua*)	Acute	^{14}C-Flumioxazin	96-h EC_{50}/2: 0.00042[4]	0.053	127.7	Yes
Diatom (*Navicula pelliculosa*)	Acute	^{14}C-Flumioxazin	96-h EC_{50}/2: 0.0007[4]	0.053	75.7	Yes
Vascular plant (*Lemna gibba*)	Dissolved	^{14}C-Flumioxazin	96-h EC_{50}/2: 0.00021	0.053	258.5	Yes
Amphibians (15 cm depth)						
Amphibians	Acute (based on acute fish studies)	Flumioxazin (flow-through)	96-h LC_{50}/10: 0.23[5]	0.28	1.2	Yes
	Chronic (based on early life stage fish study)	Flumioxazin (flow-through)	87-d NOEC: 0.0077[5]	0.28	36.4	Yes

Organism	Exposure	Test Substance	Endpoint value (mg a.i./L)	EEC[1] (mg a.i./L)	RQ[2]	Exceeds LOC[3]
Marine species						
Mysid shrimp	Acute	Flumioxazin (flow-through)	96-h LC_{50}/10: 0.023	0.053	0.46	No
	Chronic	Flumioxazin (flow-through)	NOEC: 0.0015 [4]	0.053	35.3	Yes
Eastern oyster	Acute	Flumioxazin	96-h LC_{50}/10: 0.28	0.053	0.04	No
Sheepshead minnow	Acute	Flumioxazin (flow-through)	96-h LC_{50}/10: >0.47	0.053	0.11	No
Diatom (*Skeletonema costatum*)	Acute	Flumioxazin (static)	96-h LC_{50}/10:0.0019[4]	0.053	5.58	Yes

[1]Estimated Environmental Concentration (EEC) in water.
[2]Risk Quotient (RQ) = exposure/toxicity. For fish, RQ = EEC in an 80-cm deep water body / (EC50 ÷ 10 or LC50 ÷ 10); for a chronic exposure: RQ = EEC in an 80-cm deep water body / NOEC; for amphibians, the EEC in a 15 cm-deep water body is used. For aquatic invertebrates and plants, RQ = EEC in a 80-cm deep water body / (EC50 ÷ 2 or LC50 ÷ 2); for a chronic exposure: RQ = EEC in a 80-cm deep water body / NOEC
[3]Level of Concern (LOC)
[4]EPA or EU endpoint – study was not reviewed by PMRA. Analytical methods in the algal studies reported total radioactivity only, therefore concentrations are reported as total radioactivity (µg ^{14}C/L) instead of on an a.i. basis.
[5]the endpoint values for the most sensitive fish species at the appropriate exposure scenario were used as surrogate data for the amphibian risk assessment.
Shadded cells indicate that the RQ exceeds the LOC, triggering a refined risk assessment and further characterization where possible.

Table 5 Revised refined risk assessment on non-target aquatic plants using Level 1 run-off values (Flumioxazin 0.25 G Herbicide) assuming an application rate of 2 × 420 g ai/ha and a 11 week interval between applications

Species	Exposure	Study Duration	Endpoint value (mg a.i./L)		EEC[1] value	RQ[2]	LOC[3] Exceeded
Freshwater Species							
Aquatic Vascular Plant (*Lemna gibba*)	Acute	14 days	LC_{50}/2:	0.00021	0.00501	24.4	yes

[1]Estimated Environmental Concentration (EEC) in water.
[2]Risk Quotient (RQ) = exposure/toxicity. For fish, RQ = EEC in an 80-cm deep water body / (EC_{50} ÷ 10 or LC_{50} ÷ 10); for a chronic exposure: RQ = EEC in an 80-cm deep water body / NOEC; for amphibians, the EEC in a 15 cm-deep water body is used. For aquatic invertebrates and plants, RQ = EEC in a 80-cm deep water body / (EC_{50} ÷ 2 or LC_{50} ÷ 2); for a chronic exposure: RQ = EEC in a 80-cm deep water body / NOEC
[3]Level of Concern (LOC)
Shadded cells indicate that the RQ exceeds the LOC, triggering a refined risk assessment and further characterization where possible.

Table 6 Revised Screening level risk assessment on non-target aquatic organisms (Flumioxazin 51WDG Herbicide) assuming an application rate of 2 × 214 g a.i./ha and a 30 day interval between applications.

Organism	Exposure	Study Duration	Endpoint Value (mg a.i./L)		EEC[1] value	RQ[2]	LOC[3] exceeded
Freshwater Species							
Daphnid (*Daphnia magna*)	Acute (flow-through)	48 hours	LC_{50}/2:	2.95	0.027	0.01	no

	Chronic (flow-through)	21 days	NOEC	0.05	0.027	0.54	no
Rainbow Trout (*Onchorhynchus mykiss*)	Acute (flow-through)	96 hours	LC_{50}/10:	0.23	0.027	0.12	no
	Chronic-ELS (flow-through)	87 days	NOEC	0.0077	0.027	3.5	yes
	Chronic-Juvenile Growth (flow-through)	21 days	NOEC	0.37	0.027	0.07	no
Bluegill Sunfish (*Lepomis macrochirus*)	Acute	96 hours	LC_{50}/10:	>2.1	0.027	0.01	no
Green Algae (*Selenastrum capricornutum*)	Acute*	120 hours	LC_{50}/2:	0.00051	0.027	52.9	yes
Blue-green algae (*Anabaena flos-aqua*)	Acute	120 hours	LC_{50}/2:	0.00042	0.027	65.1	yes
Diatom (*Navicula pelliculosa*)	Acute	120 hours	LC_{50}/2:	0.0007	0.027	38.6	yes
Aquatic Vascular Plant (*Lemna gibba*)	Acute	14 days	LC_{50}/2:	0.00021	0.027	131.7	yes
Amphibians (15 cm depth)							
Amphibians	Acute[5]	96 hours	LC_{50}/10:	0.23	0.14	0.62	no
	Chronic[5]	87 days	NOEC	0.0077	0.14	18.6	yes
Marine Species							
Mysid shrimp (*Mysidopsis bahia*)	Acute	96 hours	LC_{50}/2:	0.115	0.027	0.23	no
	Chronic	28 days	NOEC	0.0015	0.027	18.0	yes
Eastern Oyster (*Crassostrea virginica*)	Acute	96 hours	LC_{50}/2:	1.4	0.027	0.02	no
Sheepshead Minnow (*Cyprinodon variegatus*)	Acute	96 hours	LC_{50}/10:	>0.47	0.027	0.06	no
Diatom (*Skeletonema costatum*)	Acute	120 hours	LC_{50}/2:	0.0095[4]	0.027	2.84	yes

[1]Estimated Environmental Concentration (EEC) in water.
[2]Risk Quotient (RQ) = exposure/toxicity. For fish, RQ = EEC in an 80-cm deep water body / (EC_{50} ÷ 10 or LC_{50} ÷ 10); for a chronic exposure: RQ = EEC in an 80-cm deep water body / NOEC; for amphibians, the EEC in a 15 cm-deep water body is used. For aquatic invertebrates and plants, RQ = EEC in a 80-cm deep water body / (EC_{50} ÷ 2 or LC_{50} ÷ 2); for a chronic exposure: RQ = EEC in a 80-cm deep water body / NOEC
[3]Level of Concern (LOC)
Shadded cells indicate that the RQ exceeds the LOC, triggering a refined risk assessment and further characterization where possible.

Table 7 Revised Refined risk assessment on non-target aquatic organisms using Level 1 Drift values (Flumioxazin 51 WDG Herbicide) assuming an application rate of 2 × 214 g a.i./ha and a 30 day interval between applications

Species	Exposure	Study Duration	Endpoint value (mg a.i./L)		EEC[1] value	RQ[2]	LOC[3] Exceeded
Freshwater Species							
Daphnid (*Daphnia magna*)	Acute	48 hours	LC_{50}/2:	2.95	0.00162	<0.01	no
	Chronic	21 days	NOEC	0.05	0.00162	0.03	no
Rainbow Trout (*Onchorhynchus mykiss*)	Acute	96 hours	LC_{50}/10:	0.23	0.00162	0.01	no
	Chronic-ELS	87 days	NOEC	0.0077	0.00162	0.21	no
	Chronic-Juvenile Growth	21 days	NOEC	0.37	0.00162	<0.01	no
Bluegill Sunfish (*Lepomis macrochirus*)	Acute	96 hours	LC_{50}/10:	2.1	0.00162	<0.01	no
Green Algae (*Selenastrum capricornutum*)	Acute	120 hours	LC_{50}/2:	0.00051	0.00162	3.18	yes
Blue-green algae (*Anabaena flos-aqua*)	Acute	120 hours	LC_{50}/2:	0.00042	0.00162	3.90	yes
Diatom (*Navicula pelliculosa*)	Acute	120 hours	LC_{50}/2:	0.0007	0.00162	2.31	yes
Aquatic Vascular Plant (*Lemna gibba*)	Acute	14 days	LC_{50}/2:	0.00021	0.00162	7.90	yes
Amphibians (15 cm depth)							
Amphibians	Acute	96 hours	LC_{50}/10:	0.23[5]	0.0086	0.04	no
	Chronic	87 days	NOEC	0.0077[5]	0.0086	1.11	yes
Marine Species							
Mysid shrimp (*Mysidopsis bahia*)	Acute	96 hours	LC_{50}/2:	0.115	0.00162	0.01	no
	Chronic	28 days	NOEC	0.0015*	0.00162	1.08	yes
Eastern Oyster (*Crassostrea virginica*)	Acute	96 hours	LC_{50}/2:	1.4	0.00162	<0.01	no
Sheepshead Minnow (*Cyprinodon variegatus*)	Acute	96 hours	LC_{50}/10:	0.47	0.00162	<0.01	no
Diatom (*Skeletonema costatum*)	Acute	120 hours	LC_{50}/2:	0.0095[4]	0.00162	0.17	no

[1]Estimated Environmental Concentration (EEC) in water.
[2]Risk Quotient (RQ) = exposure/toxicity. For fish, RQ = EEC in an 80-cm deep water body / (EC_{50} ÷ 10 or LC_{50} ÷ 10); for a chronic exposure: RQ = EEC in an 80-cm deep water body / NOEC; for amphibians, the EEC in a 15 cm-deep water body is used. For aquatic invertebrates and plants, RQ = EEC in a 80-cm deep water body / (EC_{50} ÷ 2 or LC_{50} ÷ 2); for a chronic exposure: RQ = EEC in a 80-cm deep water body / NOEC
[3]Level of Concern (LOC)

[5]the endpoint values for the most sensitive fish species at the appropriate exposure scenario were used as surrogate data for the amphibian risk assessment.
Shadded cells indicate that the RQ exceeds the LOC, triggering a refined risk assessment and further characterization where possible.

Table 8 Revised refined risk assessment on non-target aquatic plants using Level 1 run-off values (Flumioxazin 51 WDG Herbicide) assuming an application rate of 2 × 214 g a.i./ha and a 30 day interval between applications

Species	Exposure	Study Duration	Endpoint value (mg a.i./L)		EEC[1] value	RQ[2]	LOC[3] Exceeded
Freshwater Species							
Aquatic Vascular Plant (*Lemna gibba*)	Acute	14 days	LC_{50}/2:	0.00021	0.00255	12.44	yes

[1]Estimated Environmental Concentration (EEC) in water.
[2]Risk Quotient (RQ) = exposure/toxicity. For fish, RQ = EEC in an 80-cm deep water body / (EC_{50} ÷ 10 or LC_{50} ÷ 10); for a chronic exposure: RQ = EEC in an 80-cm deep water body / NOEC; for amphibians, the EEC in a 15 cm-deep water body is used. For aquatic invertebrates and plants, RQ = EEC in a 80-cm deep water body / (EC_{50} ÷ 2 or LC_{50} ÷ 2); for a chronic exposure: RQ = EEC in a 80-cm deep water body / NOEC
[3]Level of Concern (LOC)
Shadded cells indicate that the RQ exceeds the LOC, triggering a refined risk assessment and further characterization where possible.

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA No.	References
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2.0 Human and Animal Health

PMRA No.	Reference
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1440322	2007, Cross Reference for the Requirement of a Pesticide Handlers Exposure Database Assessment for Flumioxazin 0.25G Herbicide, DACO: 5.3
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3.0 Environment

PMRA No. Reference

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4.0 Value

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B. Additional Information Considered

i) Published Information

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