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PRD2009-08

Proposed Registration Decision

Boscalid

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Overview

Proposed Registration Decision for Boscalid

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 Boscalid Technical Fungicide, Lance WDG Fungicide (formerly BAS 510 02F Crop Fungicide) and Cadence WDG Fungicide (formerly BAS 510 02F Turf Fungicide), containing the technical grade active ingredient boscalid to control diseases in numerous agricultural crops and golf course turfgrass.

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.

Boscalid Technical Fungicide (Registration Number 27494), Lance WDG Fungicide (Registration Number 27495) and Cadence WDG Fungicide (Registration Number 27496) are currently conditionally registered in Canada. The detailed review of these products can be found in Regulatory Note REG2004-02, *Boscalid/BAS 510*. The purpose of the current applications is to convert Boscalid Technical Fungicide, Lance WDG Fungicide and Cadence WDG Fungicide from conditional to full registration.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Boscalid Technical Fungicide, Cadence WDG Fungicide and Lance WDG Fungicide.

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 acceptable¹ 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 value² 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

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."

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 boscalid, the PMRA will consider all comments received from the public in response to this consultation document.³ The PMRA will then publish a Registration Decision⁴ on boscalid 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 Boscalid?

Boscalid is the active ingredient in the two end-products, Lance WDG Fungicide and Cadence WDG Fungicide. These fungicides are used in agricultural crops and golf course turfgrass to control fungal diseases.

Health Considerations

Can Approved Uses of Boscalid Affect Human Health?

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

A detailed assessment of the toxicology database for Boscalid Technical Fungicide, Lance WDG Fungicide and Cadence WDG Fungicide is presented in REG2004-02, *Boscalid/BAS 510*.

As indicated in REG2004-02, results of the dermal sensitization study for the technical grade active ingredient and the formulated products were negative; however, the dose levels for challenge treatment were not considered to be adequate for determination of skin sensitization potential. The new toxicology data provided to address this data gap were assessed and it was determined that the doses used for induction and challenge were adequate for the determination of skin sensitization potential. Based on the information provided, Boscalid Technical Fungicide, Cadence WDG Fungicide and Lance WDG Fungicide are not dermal sensitizers in guinea pigs. Consequently, the statement "Potential skin sensitizer" is removed from the label.

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*.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Aggregate dietary intake estimates (food plus water) revealed that the general population and children, the subpopulation which would ingest the most boscalid relative to body weight, are expected to be exposed to less than 23% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from exposure to boscalid residues is not of concern for any of the population sub-groups.

Animal studies revealed no acute health effects. Consequently, a single dose of boscalid is not likely to cause acute health effects in the general population (including infants and children).

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 under the authority of the *Food and Drugs Act* 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.

Confirmatory data were provided in support of Lance WDG Fungicide. The revised MRLs for this active ingredient can be found in Established Maximum Residue Limit EMRL2008-02, *Transitioning the Legal Establishment of Maximum Residue Limits (MRLs) for Pesticides From the Food and Drugs Act to the Pest Control Products Act: Establishment of MRLs*.

Environmental Considerations

What Happens When Boscalid is Introduced Into the Environment?

Boscalid enters the environment when used as a fungicide on agricultural crops and golf course turfgrass.

Boscalid is persistent in the environment. Although it does have low mobility in soils, it may move to aquatic areas through spray drift or surface erosion. Boscalid was not acutely toxic to most of the terrestrial species tested, with the exception of vascular plants. Buffer zones have been implemented to mitigate this risk. Boscalid was found to be highly toxic to marine organisms; however, no risk was found. Boscalid was moderately toxic to fresh water aquatic species and a risk was determined, therefore, buffer zones were only necessary for freshwater habitat.

Value Considerations

What Is the Value of Boscalid?

Boscalid controls fungal diseases in agricultural crops and golf course turfgrass.

Lance WDG Fungicide is used as a spray application to the foliage in several crops (canola, dry and succulent beans, lentils, chickpeas, berries group, bulb vegetables group, carrots, fruiting vegetables, grapes, field lettuce (head and leaf), potatoes, stone fruits group, strawberries, cucurbit vegetables, succulent and dried shelled peas and alfalfa grown for seed production) for the control of diseases caused by fungal pathogens.

Cadence WDG Fungicide is used to control fungal disease on golf course turfgrass.

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 Cadence WDG Fungicide and Lance WDG Fungicide 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 having direct skin contact with Cadence WDG Fungicide and Lance WDG Fungicide, individuals must wear long-sleeved shirt, long pants and chemical resistant gloves during mixing, loading, application, clean up and repair as well as goggles or a face shield during mixing/loading.

Environment

Because there is a risk to aquatic organisms and terrestrial plants with the application of Cadence WDG Fungicide and Lance WDG Fungicide, appropriate buffer zones have been established and must appear on the product labels.

Next Steps

Before making a final registration decision on boscalid, 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 PMRA 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 boscalid (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

Boscalid

1.0 The Active Ingredient, Its Properties and Uses

A detailed assessment of the chemistry database for Boscalid Technical Fungicide, Cadence WDG Fungicide and Lance WDG Fungicide is presented in Regulatory Note REG2004-02 *Boscalid/BAS 510*. No chemistry data were required as a condition of registration, therefore, no amendments to the previous chemistry assessment were necessary.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

A detailed assessment of the methods for analysis of the active ingredient and formulation analysis is presented in REG2004-02. No methods for analysis data were required as a condition of registration; therefore, no amendments to the previous assessment were necessary.

2.2 Methods for Residue Analysis

2.2.1 Methods for Residue Analysis of Plants and Plant Products

The requested information on the data gathering and the enforcement methods for residue analysis of plant and plant products have been submitted to the PMRA and have been found to be satisfactory. The evaluation of these data is presented below.

The data gathering method (LC-MS/MS D9908) and the enforcement method (GC-MS (SIM) D0008) have been reviewed and found to be adequate in the determination of boscalid residues in plant commodities.

The procedure for the analytical methods was revised to state that analytical reference standards of boscalid and various metabolites (M510F01, M510F49, M510F51, and M510F53) in solution should be stored no longer than two months before replacement, either refrigerated in the dark or at room temperature with daylight exposure.

2.2.2 Methods for Residue Analysis of Food of Animal Origin

The requested information on the data gathering and the enforcement methods for residue analysis of food of animal origin have been submitted to the PMRA and have been found to be satisfactory. The evaluation of these data is presented below.

The data gathering method (LC-MS/MS D471/0) and the enforcement method (GC-ECD DFG S19) have been reviewed and found to be adequate in the determination of boscalid and the

hydroxy metabolites (M510F01 and M510F02) residues in animal commodities. A common moiety method (GC-MS Method 476/0) using microwave extraction was also developed to determine non-extractable residues of boscalid in liver and milk.

A waiver rationale was provided, in lieu of radiovalidation data, to support the data gathering and enforcement analytical methods used for the determination of boscalid equivalent residues in animal matrices. The extraction procedures used for the hen and goat metabolism studies were similar to the procedures used in the data gathering and enforcement methods. The extraction procedures used in the goat and hen metabolism studies were able to extract the relevant boscalid residues (76.4% to 100% of the total radioactive residue). The waiver request for radiovalidation studies is acceptable.

The procedure for the analytical methods have been revised to state that analytical reference standards of boscalid and various metabolites (M510F01, M510F49, M510F51, and M510F53) in solution should be stored no longer than two months before replacement, either refrigerated in the dark or at room temperature with daylight exposure.

3.0 Impact on Human and Animal Health

A detailed assessment of the toxicology database for Boscalid Technical Fungicide, Lance WDG Fungicide and Cadence WDG Fungicide is presented in REG2004-02.

The requested dermal sensitization study and additional toxicology information were submitted to the PMRA and have been found to be satisfactory. The evaluation of these data is presented below.

3.1 Toxicology Summary

During the initial review, results of the dermal sensitization study for the technical grade active ingredient and the formulated end-use products were negative; however, dose levels for challenge treatment were not considered to be adequate for determination of skin sensitization potential. A new skin sensitization study (Maximization) for the active ingredient and a rationale justifying dose selection for the sensitization study with the end-use products were considered to be acceptable. Boscalid Technical Fungicide, Lance WDG Fungicide and Cadence WDG Fungicide are not considered to be dermal sensitizers in guinea pigs.

The developmental neurotoxicity study was previously classified as “acceptable/non-guideline” due to the lack of positive control data and limited data for the learning and memory test. Review of the submitted positive control study and additional information pertaining to the learning and memory test satisfied the requirements for an upgrade in study classification from “acceptable/non-guideline” to “acceptable”. These findings support the previous conclusions of the rat developmental neurotoxicity study (refer to REG2004-02). Refer to Appendix I, Table 1.

3.2 Determination of Acute Reference Dose

Refer to REG2004-02 for the assessment and determination of the acute reference dose.

3.3 Determination of Acceptable Daily Intake

Refer to REG2004-02 for the assessment and determination of the acceptable daily intake.

3.4 Food Residues Exposure Assessment

3.4.1 Dietary Risk Assessment

Chronic dietary risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM-FCID™, Version 2.03).

3.4.1.1 Chronic Dietary Exposure Results and Characterization

A basic and refined chronic dietary exposure assessment was performed taking into account proposed MRLs for crops and animal matrices (meat, meat by-products and milk). Aggregate exposure to boscalid from all supported food uses and water is considered acceptable. The highest aggregate exposure and risk estimate is for children 1 to 2 years old at 23% (0.0321 mg/kg bw/day) of the acceptable daily intake.

3.4.1.2 Acute Dietary Exposure Results and Characterization

Animal studies revealed no acute health effects.

3.4.2 Maximum Residue Limits

Table 3.4.2.1 Proposed Maximum Residue Limits

| Commodity | Recommended MRL (ppm) |
|--|-----------------------|
| Lowbush blueberries* | 11 |
| Caneberries (Crop Subgroup 13A)* Bushberries (Crop Subgroup 13B, except lowbush blueberries)* | 6.0 |
| Fruiting vegetables (Crop Group 8)** | 1.4 |
| Chinese cucumbers***, cucumbers*** | 0.5 |

* EMRL2008-02 established an MRL of 3.5 for berry commodities but a higher MRL is required to accommodate residues found in additional supervised residue trials conducted to support the conversion from conditional to full registration.

** EMRL2008-02 established an MRL of 1.0 ppm for fruiting vegetable commodities but a higher MRL is required to accommodate residues found in additional supervised residue trials conducted to support the conversion from conditional to full registration.

*** EMRL2008-02 established an MRL of 0.2 ppm for Chinese cucumbers and cucumbers but a higher MRL is required to accommodate residues found in additional supervised residue trials conducted to support the conversion from conditional to full registration.

For additional information on MRLs in terms of the international situation and trade implications, refer to Appendix II (Supplemental Maximum Residue Limit Information–International Situation and Trade Implications).

The field trial data are summarized in Appendix I, Table 2. Crop Groups: Numbers and Definitions are presented in Appendix III.

4.0 Impact on the Environment

A detailed assessment of the environmental impact of boscalid is presented in REG2004-02.

4.1 Effects on Non-Target Species

During the original review, there were concerns about the concentration of boscalid in nectar and pollen due to the persistent and systemic nature of the compound. The applicant submitted a number of studies that addressed the residues of boscalid in plant matter (grain, plant above ground) and the residues in honey.

Boscalid residues on winter and spring rape sprayed with boscalid formulations were determined in 29 locations in central and northern Europe. From these data, residues were estimated for multiple applications, resulting in maximum exposure of 12.12 µg a.i./bee/day. This is much lower than the acute no observed effect concentration (NOEC) of 100 µg a.i./bee, therefore, the risk is negligible. Residues in honey were below the limit of detection for all but one sample, therefore, accumulation in honey is not expected.

To estimate risk of potential adverse effects on non-target species, a quotient method is used. The risk quotient (RQ) is calculated by dividing the exposure estimate by a value representing a toxicity endpoint. A screening-level risk assessment is initially performed using the expected environmental concentrations (EECs) for a worst-case scenario (for example, direct overspray of a body of water) and the most sensitive toxicity endpoint. Low risk is predicted if the RQ is less than the trigger value of one. In these cases, no further assessment is done. For those groups of organisms for which the RQ is equal to or greater than one, a refined assessment is undertaken. A refined assessment takes into consideration more realistic exposure scenarios (for example, drift to non-target habitats and runoff to water bodies) and may consider different toxicity endpoints.

4.1.1 Effects on Terrestrial Organisms

The requested information on the effects of boscalid on parasitoids and predatory mites has been submitted to the PMRA and found to be acceptable. The evaluation of these data is presented below.

Ten predator and parasite toxicity studies were submitted. Four of these (predatory mite, predatory beetle, spider and parasitic wasp) were reviewed in depth. For the remaining studies, only the findings were reviewed. Boscalid was not found to have toxic effects on these test organisms at the concentrations tested. The lowest NOEC was 1.22 kg a.i./ha, the lowest concentration tested. A foliar half-life for boscalid was 22 days, therefore, the EEC on plants after the maximum of six applications was calculated to be 1232.7 g a.i./ha. Risk for predator and parasites is determined by dividing the EEC (foliar or soil) by the lethal response (LR₅₀). In these studies, no LR₅₀ could be calculated as there were no effects. Therefore, risk was

calculated based on the NOEC value from the study. This resulted in an overestimation of the risk. Three scenarios resulted in RQ greater than 1. However, based on the very conservative nature of the toxicity study and the methods for determining EEC, risk to predators and parasites is not expected.

During the original review, there were concerns regarding the risk to birds feeding on turf areas sprayed with boscalid, therefore, a new reproduction study was required. Since the original review, it has been determined that herbivorous birds cannot be used in a reliable reproduction study, therefore, this data requirement is no longer necessary.

4.1.2 Effects on Aquatic Organisms

A detailed assessment of the effects of boscalid on aquatic organisms is presented in REG2004-02.

5.0 Value

A detailed assessment of the value of Cadence WDG Fungicide and Lance WDG Fungicide is presented in REG2004-02. The requested information on Botrytis grey mould control in berries and aerial application of Lance WDG Fungicide has been submitted to the PMRA and found to be acceptable. The evaluation of these data is presented below.

5.1 Effectiveness Against Pests

To address the issue of Lance WDG Fungicide efficacy on berry crops, three trials conducted on raspberries were submitted. One trial was rejected since the number of applications (six) was in excess of the maximum allowed on the label (four). The remaining trials showed good to excellent control of disease incidence. In trial #1, 68% control and 81% control were demonstrated after three applications and four applications, respectively. In trial #2, 84% control was demonstrated after four applications. Only the label rate (0.56 kg product/ha) was tested. However, this is sufficient to demonstrate that four applications of Lance WDG Fungicide applied at the label rate will provide good to excellent control of Botrytis grey mold on raspberries. These results along with the earlier trials on strawberries are sufficient to show consistent efficacy on berry crops.

To address the issue of aerial application of Lance WDG Fungicide, twelve efficacy trials were submitted which demonstrated that one to two aerial and ground applications of Lance WDG Fungicide at 112 to 393 g a.i./ha with a water volumes of 37 to 45 L/ha and 100 to 112 L/ha, respectively, provided similar efficacy for the control of sclerotinia stem rot on canola, ascochyta blight on chickpea, white mould on dry bean and early blight on potato. Based on the results of these efficacy trials, aerial application of Lance WDG Fungicide is acceptable.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The management of toxic substances is guided by the federal government's Toxic Substances Management Policy (TSMP), which puts forward a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. The policy provides decision makers with direction and sets out a science based management framework to ensure that federal programs are consistent with its objectives. One of the key management objectives is virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative. These substances are referred to in the policy as Track 1 substances.

During the review process, boscalid was assessed in accordance with the PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*. Substances associated with the use of boscalid were also considered, including major transformation products formed in the environment, microcontaminants in the technical product and formulants in the end-use products. The PMRA has reached the following conclusions:

- Boscalid does not meet the criteria for bioaccumulation.
- Boscalid does not form any major transformation products under field conditions.
- Boscalid (technical grade) does not contain manufacturing by-products (microcontaminants).
- The end-use products, Lance WDG Fungicide and Cadence WDG Fungicide, do not contain any formulants that are known to be TSMP Track 1 substances. All formulants are either USEPA List 3 or List 4A/B.

Therefore, the use of boscalid is not expected to result in the entry of Track 1 substances into the environment.

7.0 Summary

7.1 Human Health and Safety

The nature of the residue in plants and animals is adequately understood. The residue definition for risk assessment and enforcement is boscalid in plants. The residue definition is boscalid and the hydroxy metabolites M510F01 (free), and M510F02 (bound), expressed as parent equivalents in foods of animal origin. The proposed uses of boscalid do 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.

7.2 Environmental Risk

Boscalid is persistent in the environment. There is a risk to aquatic organisms and terrestrial plants, therefore, buffer zones are required.

7.3 Value

The use of Lance WDG Fungicide as a spray application to foliage in several crops (canola, dry and succulent beans, lentils, chickpeas, berries group, bulb vegetables group, carrots, fruiting vegetables, grapes, field lettuce (head and leaf), potatoes, stone fruits group, strawberries, cucurbit vegetables, succulent and dried shelled peas and alfalfa grown for seed production) for the control of diseases caused by fungal pathogens is acceptable with no further conditions.

The use of Cadence WDG Fungicide to control fungal diseases on golf course turfgrass is acceptable with no further conditions.

8.0 Proposed Regulatory Decision

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 Boscalid Technical Fungicide, Lance WDG Fungicide (formerly BAS 510 02F Crop Fungicide) and Cadence WDG Fungicide (formerly BAS 510 02F Turf Fungicide), containing the technical grade active ingredient boscalid to control diseases in numerous agricultural crops and golf course turfgrass.

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

List of Abbreviations

| | |
|-------------------------|--|
| a.i. | active ingredient |
| DT ₅₀ | dissipation time 50% (the dose required to observe a 50% decline in the test population) |
| EEC | estimated environmental concentration |
| g | gram |
| GAP | good agricultural practices |
| GC | gas chromatography |
| ha | hectare(s) |
| kg | kilogram |
| <i>K</i> _{ow} | <i>n</i> -octanol–water partition coefficient |
| L | litre |
| LR ₅₀ | lethal rate 50% |
| MRL | maximum residue limit |
| NAFTA | North American Free Trade Agreement |
| NOEC | no observed effect concentration |
| PBI | plantback interval |
| PHI | preharvest interval |
| PMRA | Pest Management Regulatory Agency |
| ppm | parts per million |
| RQ | risk quotient |
| <i>t</i> _{1/2} | half-life |
| TSMP | Toxic Substances Management Policy |
| µg | micrograms |

Appendix I Tables and Figures

Table 1 Acute Toxicity of Boscalid Technical Fungicide (formerly BAS 510) and Its Associated End-use Products, Cadence WDG Fungicide (formerly BAS 510 02F Turf Fungicide) and Lance WDG Fungicide (formerly BAS 510 02F Crop Fungicide)

| Study Type | Species | Result | Comment | Reference |
|--|------------|----------|--|--------------------|
| Acute Toxicity of Boscalid Technical Fungicide | | | | |
| Skin sensitization (Maximization) | Guinea pig | Negative | Under the conditions of this study, Boscalid Technical Fungicide was not considered to be a dermal sensitizer. The dose level used for induction and challenge treatment were considered to be adequate. No label comment required. | 1104200 |
| Acute Toxicity of Lance WDG Fungicide and Cadence WDG Fungicide | | | | |
| Skin sensitization (Maximization) | Guinea pig | Negative | Under the conditions of this study, Lance WDG Fungicide and Cadence WDG Fungicide were not considered to be a dermal sensitizer. The dose level used for induction and challenge treatment were considered to be adequate. No label comment required. | 1104226 1104227 |

Table 2 Integrated Food Residue Chemistry Summary**Summary of Residue Data from Crop Field Trials with Boscalid**

| Commodity | Total Applic. Rate (kg a.i./ha) | PHI (days) | Residue Levels (ppm) | | | | | | |
|---|---------------------------------|------------|----------------------|--------|------|-------|---------------|------|-----------|
| | | | N | Min. | Max. | HAFT* | Median (STMR) | Mean | Std. Dev. |
| Bulb Vegetables (Crop Group 3) – GAP: Max of 6 applications; 1.98 kg a.i./ha/season; PHI = 7 d | | | | | | | | | |
| Reference: 2001-1027; 2001-1036; 2001-1043 | | | | | | | | | |
| Green onion | 2.03 to 2.05 | 7 | 6 | 1.06 | 2.94 | 2.72 | 2.18 | 2.08 | 0.84 |
| Bulb onion | 2.00 to 2.05 | 7 | 12 | 0.03 | 1.03 | 0.93 | 0.11 | 0.25 | 0.33 |
| Reference: 2005-3930; 2005-3931; 2005-3932 – Confirmatory Trials | | | | | | | | | |
| Green onion | 1.96 to 2.04 | 6-7 | 4 | 1.99 | 2.30 | 2.20 | 2.06 | 2.10 | 0.14 |
| Bulb onion | 1.98 to 2.03 | 6-7 | 8 | 0.05 | 2.82 | 2.61 | 0.84 | 1.09 | 1.01 |
| Fruiting Vegetables (Crop Group 8) – GAP: Max of 5 applications; 1.1 kg a.i./ha/season; PHI = 1d | | | | | | | | | |
| Reference: 2001-1027; 2001-1036; 2001-1043 | | | | | | | | | |
| Tomato | 1.22 to 1.25 | 0 | 24 | <0.05 | 0.99 | 0.92 | 0.29 | 0.40 | 0.26 |
| Pepper (bell) | 1.00 to 1.04 | 0 | 12 | <0.05 | 0.34 | 0.29 | 0.12 | 0.14 | 0.09 |
| Pepper (non-bell) | 1.01 to 1.02 | 0 | 6 | 0.13 | 0.96 | 0.83 | 0.29 | 0.42 | 0.33 |
| Reference: 2005-3930; 2005-3931; 2005-3932 – Confirmatory Trials | | | | | | | | | |
| Tomatoes | 1.20 to 1.29 | 0 | 14 | 0.17 | 0.63 | 0.56 | 0.30 | 0.35 | 0.16 |
| Pepper (non-bell) | 1.22 | 0 | 2 | 0.53 | 0.54 | 0.54 | 0.54 | 0.54 | -- |
| Pepper (bell) | 1.20 to 1.34 | 0 | 4 | 0.15 | 1.37 | 1.35 | 0.77 | 0.76 | 0.34 |
| Cucurbits (Crop Group 9) – GAP: Max of 4 applications; 1.288 kg a.i./ha/season; PHI = 0d | | | | | | | | | |
| Reference: 2001-1027; 2001-1036; 2001-1043 | | | | | | | | | |
| Cantaloupe | 1.34 | 0 | 12 | 0.22 | 1.48 | 1.27 | 0.46 | 0.57 | 0.38 |
| Cucumber | 1.32 to 1.35 | 0 | 12 | <0.05 | 0.16 | 0.14 | 0.10 | 0.10 | 0.04 |
| Summer Squash | 1.34 to 1.38 | 0 | 10 | 0.10 | 1.08 | 0.98 | 0.17 | 0.35 | 0.37 |
| Reference: 2005-3930; 2005-3931; 2005-3932 – Confirmatory Trials | | | | | | | | | |
| Cucumber | 1.32 to 1.35 | 0 | 8 | < 0.05 | 0.31 | 0.31 | 0.18 | 0.19 | 0.11 |
| Cantaloupe | 1.32 to 1.34 | 0 | 4 | 0.12 | 0.60 | 0.56 | 0.34 | 0.35 | 0.25 |
| Summer squash | 1.33 to 1.34 | 0 | 8 | 0.09 | 0.31 | 0.26 | 0.18 | 0.18 | 0.09 |
| Reference: 2001-1027; 2001-1036; 2001-1043; 2005-3930; 2005-3931; 2005-3932 | | | | | | | | | |
| Cucumber | 1.32 to 1.35 | 0 | 20 | 0.05 | 0.31 | 0.31 | 0.11 | 0.13 | 0.09 |
| Stone Fruits (Crop Group 12) – GAP: Max of 5 applications; 1.3 kg a.i./ha/season; PHI = 0d | | | | | | | | | |
| Reference: 2001-1027; 2001-1036; 2001-1043 | | | | | | | | | |
| Peach - CONC | 1.28 to 1.30 | 0 | 9 | 0.16 | 0.66 | -- | 0.48 | 0.45 | 0.16 |
| Peach - DIL | 1.28 to 1.31 | 0 | 9 | 0.19 | 0.75 | -- | 0.42 | 0.43 | 0.20 |
| Plum - CONC | 1.28 to 1.29 | 0 | 6 | 0.08 | 0.57 | -- | 0.15 | 0.21 | 0.18 |
| Plum - DIL | 1.28 to 1.29 | 0 | 6 | 0.10 | 0.34 | -- | 0.20 | 0.21 | 0.11 |
| Cherry - CONC | 1.29 to 1.30 | 0 | 6 | 0.64 | 1.64 | -- | 1.00 | 1.06 | 0.37 |
| Cherry - DII | 1.29 | 0 | 6 | 0.74 | 1.51 | -- | 1.31 | 1.23 | 0.31 |
| Reference: 2005-3930; 2005-3931; 2005-3932 – Confirmatory Trials | | | | | | | | | |
| Peach - CONC | 1.27 to 1.31 | 0 | 8 | 0.47 | 1.20 | 1.19 | 0.74 | 0.77 | 0.29 |
| Plum - CONC | 1.27 to 1.31 | 0 | 8 | 0.09 | 0.85 | 0.70 | 0.50 | 0.47 | 0.23 |
| Cherry - CONC | 1.53 | 0 | 2 | 1.28 | 1.70 | 1.49 | 1.49 | -- | -- |
| Berries (Crop Group 13) – GAP: Max of 4 applications; 1.56 kg a.i./ha/season; PHI = 0d | | | | | | | | | |
| Reference: 2001-1027; 2001-1036; 2001-1043 | | | | | | | | | |
| Blueberry, highbush | 1.65 to 1.70 | 0 | 12 | 0.49 | 2.50 | 2.34 | 1.39 | 1.39 | 0.53 |
| Raspberry red | 1.67 to 1.69 | 0 | 8 | 1.39 | 3.31 | 2.69 | 1.83 | 2.06 | 0.72 |
| Reference: 2005-3930; 2005-3931; 2005-3932 – Confirmatory Trials | | | | | | | | | |
| Raspberry, red | 1.60 to 1.67 | 0 | 6 | 2.40 | 4.37 | 3.73 | 3.19 | 3.22 | 0.75 |
| Blueberry (lowbush) | 1.60 to 1.67 | 0 | 6 | 4.27 | 7.35 | 6.83 | 6.43 | 5.98 | 1.32 |

| Commodity | Total Applic. Rate (kg a.i./ha) | PHI (days) | Residue Levels (ppm) | | | | | | |
|--|---------------------------------|------------|----------------------|-------|-------|-------|---------------|-------|-----------|
| | | | N | Min. | Max. | HAFT* | Median (STMR) | Mean | Std. Dev. |
| Blueberry (highbush) | 1.60 to 1.67 | 0 | 6 | 2.42 | 4.03 | 3.79 | 2.78 | 3.02 | 0.63 |
| Reference: 2001-1027; 2001-1036; 2001-1043; 2005-3930; 2005-3931; 2005-3932 | | | | | | | | | |
| Raspberry, red | 1.60 to 1.69 | 0 | 14 | 1.39 | 4.37 | 3.73 | 2.46 | 2.56 | 0.81 |
| Blueberry (highbush) | 1.60 to 1.70 | 0 | 18 | 0.49 | 4.03 | 3.79 | 1.49 | 1.93 | 0.96 |
| Strawberries – GAP: Max of 5 applications; 1.96 kg a.i./ha/season; PHI = 0d | | | | | | | | | |
| Reference: 2001-1027; 2001-1036; 2001-1043 | | | | | | | | | |
| Strawberry | 2.03 to 2.12 | 0-1 | 16 | 0.16 | 1.16 | 1.00 | 0.54 | 0.55 | 0.26 |
| Grapes – GAP: Max of 5 applications; 1.12 kg a.i./ha/season; PHI = 14d | | | | | | | | | |
| Reference: 2001-1027; 2001-1036; 2001-1043 | | | | | | | | | |
| Grape - CONC | 1.22 to 1.24 | 14 | 12 | 0.27 | 3.10 | 2.97 | 0.65 | 1.15 | 1.09 |
| Grape - DIL | 1.19 to 1.25 | 14 | 12 | 0.31 | 2.16 | 2.08 | 0.88 | 1.01 | 0.66 |
| Reference: 2005-3930; 2005-3931; 2005-3932 – Confirmatory Trials | | | | | | | | | |
| Grapes, fruit | 1.24 to 1.26 | 13-14 | 8 | 0.80 | 3.24 | 3.13 | 2.06 | 2.04 | 0.86 |
| Radishes – Not on LANCE Label | | | | | | | | | |
| Reference: 2001-1027; 2001-1036; 2001-1043 | | | | | | | | | |
| Radish, roots | 1.14 to 1.20 | 0 | 10 | 0.06 | 0.61 | 0.60 | 0.21 | 0.27 | 0.21 |
| Radish, roots | 1.14 to 1.20 | 3 | 10 | 0.06 | 0.46 | 0.45 | 0.21 | 0.23 | 0.14 |
| Radish, roots | 1.14 to 1.20 | 7 | 10 | <0.05 | 0.23 | 0.21 | 0.12 | 0.13 | 0.06 |
| Radish, roots | 1.14 to 1.20 | 10 | 10 | <0.05 | 0.16 | 0.16 | 0.08 | 0.09 | 0.04 |
| Radish, tops | 1.14 to 1.20 | 0 | 10 | 20.7 | 61.4 | 54.9 | 25.2 | 30.8 | 13.5 |
| Radish, tops | 1.14 to 1.20 | 3 | 10 | 2.65 | 43.9 | 37.5 | 7.81 | 13.3 | 13.5 |
| Radish, tops | 1.14 to 1.20 | 7 | 10 | 1.65 | 10.5 | 10.5 | 4.63 | 5.60 | 3.17 |
| Radish, tops | 1.14 to 1.20 | 10 | 10 | 0.80 | 7.78 | 7.17 | 2.57 | 3.11 | 2.44 |
| Reference: 2005-3930; 2005-3931; 2005-3932 – Confirmatory Trials | | | | | | | | | |
| Radish, tops | 1.09 to 1.16 | 0 | 4 | 19.7 | 34.2 | 33.1 | 27.8 | 27.4 | 6.9 |
| Radish, roots | 1.09 to 1.16 | 0 | 4 | 0.18 | 0.88 | 0.53 | 0.44 | 0.49 | 0.29 |
| Mint – Not on LANCE Label | | | | | | | | | |
| Reference: 2001-1027; 2001-1036; 2001-1043 | | | | | | | | | |
| Mint, tops | 1.78 to 1.80 | 7 | 10 | 6.65 | 36.4 | 32.8 | 15.7 | 19.8 | 10.8 |
| Reference: 2005-3930; 2005-3931; 2005-3932 – Confirmatory Trials | | | | | | | | | |
| Mint, tops | 2.0 to 2.03 | 7 | 4 | 7.6 | 11.2 | 10.85 | 9.55 | 9.48 | 1.66 |
| Spinach – Not on LANCE Label | | | | | | | | | |
| Reference: 2005-3930; 2005-3931; 2005-3932 | | | | | | | | | |
| Spinach Leaves | 0.880 to 0.914 | 0 | 22 | 12.6 | 41.8 | 39.5 | 23.3 | 23.9 | 9.0 |
| Spinach Leaves | 0.880 to 0.914 | 7 | 18 | 4.5 | 21.3 | 21.0 | 8.3 | 9.8 | 6.1 |
| Spinach Leaves | 0.880 to 0.914 | 14 | 16 | 0.17 | 17.8 | 17.1 | 4.4 | 6.4 | 5.9 |
| Celery – Not on LANCE Label | | | | | | | | | |
| Celery Leaves/stalk | 0.877 to 0.973 | 0 | 32 | 1.8 | 19.7 | 19.0 | 8.2 | 8.7 | 5.5 |
| Celery Leaves/stalk | 0.877 to 0.973 | 7 | 26 | 0.3 | 11.0 | 9.8 | 3.4 | 3.6 | 3.2 |
| Celery Leaves/stalk | 0.877 to 0.973 | 14 | 24 | 0.2 | 9.8 | 9.3 | 1.3 | 2.2 | 2.6 |
| Head Lettuce – GAP: Max of 2 applications; 400 g a.i./ha/season; PHI = 14d | | | | | | | | | |
| Reference: 2001-1027; 2001-1036; 2001-1043 | | | | | | | | | |
| Head lettuce (with wrapper leaves) | 1.10 to 1.13 | 0 | 2 | 5.00 | 6.69 | 5.84 | 5.84 | 5.84 | -- |
| | 1.10 to 1.13 | 7 | 2 | 0.30 | 0.50 | 0.40 | 0.40 | 0.40 | -- |
| | 1.10 to 1.13 | 14 | 16 | 0.08 | 6.15 | 5.42 | 2.55 | 2.42 | 1.57 |
| | 1.10 to 1.13 | 21 | 2 | 0.06 | 0.08 | 0.07 | 0.07 | 0.07 | -- |
| | 1.10 to 1.13 | 28 | 2 | <0.05 | <0.05 | <0.05 | <0.05 | <0.05 | -- |
| Head Lettuce (without wrapper leaves) | 1.10 to 1.13 | 0 | 2 | 0.31 | 0.33 | 0.32 | 0.32 | 0.32 | -- |
| | 1.10 to 1.13 | 7 | 2 | 0.08 | 0.09 | 0.09 | 0.09 | 0.09 | -- |
| | 1.10 to 1.13 | 14 | 2 | <0.05 | <0.05 | <0.05 | <0.05 | <0.05 | -- |
| | 1.10 to 1.13 | 21 | 2 | <0.05 | <0.05 | <0.05 | <0.05 | <0.05 | -- |
| | 1.10 to 1.13 | 28 | 2 | <0.05 | <0.05 | <0.05 | <0.05 | <0.05 | -- |

| Commodity | Total Applic. Rate (kg a.i./ha) | PHI (days) | Residue Levels (ppm) | | | | | | |
|---|---------------------------------|------------|----------------------|-------|------|-------|---------------|-------|-----------|
| | | | N | Min. | Max. | HAFT* | Median (STMR) | Mean | Std. Dev. |
| Reference: 2005-3930; 2005-3931; 2005-3932 – Confirmatory Trials | | | | | | | | | |
| Head Lettuce (with wrapper leaves) | 1.14 to 1.21 | 0 | 10 | 0.69 | 9.63 | 2.24 | 2.34 | 3.58 | 3.12 |
| | 1.14 to 1.21 | 2 | 2 | 1.2 | 1.49 | 1.35 | 1.35 | 1.35 | -- |
| | 1.14 to 1.21 | 4 | 2 | 0.98 | 1.09 | 1.04 | 1.04 | 1.04 | -- |
| | 1.14 to 1.21 | 6 | 2 | 0.42 | 0.81 | 0.62 | 0.62 | 0.62 | -- |
| Leaf Lettuce - GAP: Max of 2 applications; 400 g a.i./ha/season; PHI = 14d | | | | | | | | | |
| Reference: 2001-1027; 2001-1036; 2001-1043 | | | | | | | | | |
| Leaf Lettuce | 1.10 to 1.14 | 0 | 2 | 15.6 | 18.5 | 17.1 | 17.1 | 17.1 | -- |
| | 1.10 to 1.14 | 7 | 2 | 7.78 | 12.4 | 10.1 | 10.1 | 10.1 | -- |
| | 1.10 to 1.14 | 14 | 16 | 0.36 | 10.4 | 9.56 | 3.17 | 4.35 | 3.43 |
| | 1.10 to 1.14 | 21 | 2 | 0.31 | 0.35 | 0.33 | 0.33 | 0.33 | -- |
| | 1.10 to 1.14 | 28 | 2 | <0.05 | 0.11 | 0.08 | 0.08 | 0.08 | -- |
| Reference: 2005-3930; 2005-3931; 2005-3932 – Confirmatory Trials | | | | | | | | | |
| Leaf Lettuce | 1.09 to 1.15 | 0 | 10 | 11.8 | 23.6 | 21.5 | 14.85 | 15.95 | 3.51 |
| Leaf Lettuce | 1.09 to 1.15 | 2 | 2 | 8.3 | 9.2 | 8.8 | 8.8 | 8.8 | -- |
| Leaf Lettuce | 1.09 to 1.15 | 4 | 2 | 7.2 | 9.0 | 8.1 | 8.1 | 8.1 | -- |
| Leaf Lettuce | 1.09 to 1.15 | 6 | 2 | 4.7 | 5.4 | 5.1 | 5.1 | 5.1 | -- |

HAFT* Highest Field Trial Average

CONC Concentrated Formulation

DIL Diluted Formulation

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

The data submitted provides evidence that the current MRL of 1.0 ppm for Crop Group 2, as rotational crops, is acceptable. Also, a plantback interval (PBI) of 14 days is appropriate.

| Commodity | Applic. Rate (kg a.i./ha) | PBI (days) | Residue Levels (ppm) | | | | | | |
|--------------------|---------------------------|------------|----------------------|-------|-------|-------|---------------|-------|-----------|
| | | | n | Min. | Max. | HAFT* | Median (STMR) | Mean | Std. Dev. |
| Sugar beet, roots | 2.03 to 2.05 | 14 | 14 | <0.05 | <0.05 | <0.05 | <0.05 | <0.05 | - |
| Sugar beet, tops | | | 22 | <0.05 | 0.097 | 0.067 | <0.05 | 0.054 | 0.012 |
| Garden beet, roots | 2.00 to 2.04 | 14 | 4 | <0.05 | <0.05 | <0.05 | <0.05 | <0.05 | - |
| Garden beet, tops | | | 4 | <0.05 | <0.05 | <0.05 | <0.05 | <0.05 | - |
| Turnip roots | 2.02 to 2.08 | 13 to 14 | 14 | <0.05 | 0.059 | 0.055 | <0.05 | 0.051 | 0.002 |
| Turnip tops | | | 13 | <0.05 | 0.113 | 0.082 | <0.05 | 0.059 | 0.019 |

HAFT* Highest Field Trial Average

Table 3 Screening Level Risk Assessment on Non-target Species

| Risk to Terrestrial Organisms | | | | | |
|-------------------------------|----------|------------------------|--|-----|------------|
| Organism | Exposure | Endpoint value | EEC | RQ* | Risk |
| Invertebrates | | | | | |
| <i>Typhlodromus pyri</i> | contact | NOEC= 1.83 kg a.i./ha | 0.54 kg a.i./ha/application ¹ | 0.3 | Negligible |
| | | | 1.2 kg a.i./ha/season ² | 0.7 | Negligible |
| <i>Paradosa</i> sp. | contact | NOEC = 1.23 g a.i./ha | 0.54 kg a.i./ha/application | 0.3 | Negligible |
| | | | 2.0 kg a.i./ha/season ³ | 1.6 | * |
| <i>Poecilus cupreus</i> | contact | NOEC = 1.22 kg a.i./ha | 0.54 kg a.i./ha/application | 0.4 | Negligible |
| | | | 2.0 kg a.i./ha/season | 1.6 | * |
| <i>Aphidius rhopalosiphi</i> | contact | NOEC = 1.83 kg a.i./ha | 0.54 kg a.i./ha/application | 0.3 | Negligible |
| | | | 1.2 kg a.i./ha/season | 1.1 | * |

* Note, for predator and parasites, RQ's are determined by dividing the EEC by the Lethal Response (LR₅₀). However, as there were no effects in the studies submitted, no LR₅₀ were determined. Therefore, risk was based on NOECs and these RQ values are seen as over estimations of the risk. Due to the lack of effect in the studies, the risk to predators and parasites is expected to be very limited.

¹ Maximum single application of boscalid (bulb vegetable group).

² Maximum amount of boscalid expected on foliage after six applications at 0.54 kg a.i./ha.

³ Maximum amount of boscalid expected in soil after six applications of 0.54 kg a.i./ha.

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

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the field crop trials used to generate residue chemistry data.

Table 1 compares the proposed MRLs in Canada, tolerances in the United States (listed in 40 CFR Part 180 by pesticide) and Codex MRLs (Codex MRLs searchable by pesticide or commodity).

Table 1 Differences Between Canadian MRLs and in Other Jurisdictions

| Food Commodity | Canadian MRL (ppm) | American Tolerance (ppm) | Codex MRL (ppm) |
|---|--------------------|------------------------------|--------------------|
| Lowbush blueberries | 11 | 13 (Bushberry, subgroup 13B) | 10 |
| Caneberries (Crop Subgroup 13A) | 6.0 | 6.0 | 10 |
| Bushberries (Crop Subgroup 13B, except lowbush blueberries) | 6.0 | 13 (Bushberry, subgroup 13B) | 10 |
| Fruiting vegetables (Crop Group 8) | 1.4 | 1.2 | No MRL established |
| Chinese cucumbers, cucumbers | 0.5 | 0.5 | No MRL established |

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

Appendix III Crop Groups: Numbers and Definitions

| Crop Group Number | Name of the Crop Group | Food Commodities Included in the Crop Group |
|-------------------|---------------------------------|--|
| 8 | Fruiting vegetables | Bell peppers Eggplants Groundcherries Non-bell peppers Pepinos Pepper hybrids Tomatillos Tomatoes |
| 13A | Berries Caneberries subgroup | Blackberries Loganberries Raspberries |
| 13B | Berries Bushberries subgroup | Currants Elderberries Gooseberries Highbush blueberries Huckleberries Lowbush blueberries |

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