Proposed Registration Decision PRD2014-24

Metconazole

(publié aussi en français)

11 December 2014

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario K1A 0K9

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

Canada

ISSN: 1925-0878 (print)
1925-0886 (online)

Catalogue number: H113-9/2014-24E (print version)
H113-9/2014-24E-PDF (PDF version)

Table of Contents

Overview

Proposed Registration Decision for Metconazole

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 Metconazole Technical Fungicide and Caramba Fungicide containing the technical grade active ingredient metconazole, to control or suppress important diseases of cereal crops, soybeans, and sugarbeets.

Metconazole Technical Fungicide (Registration Number 29766) and Caramba Fungicide (Registration Number 29767) are conditionally registered in Canada for use on Use-Site Category (USC) 13 (Terrestrial Food Crops) and USC 14 (Terrestrial Feed Crops). The detailed review for Metconazole Technical Fungicide and Caramba Fungicide can be found in Evaluation Report ERC2011-02, *Metconazole*. A portion of the data requirements identified for the conditional registration were addressed in an application to register the end-use product Tourney Fungicide (Registration Number 30928), of which the detailed review can be found in PRD2013-11, *Metconazole*. The remaining data requirements identified for the conditional registration are being addressed in the current applications. The current applications were submitted to convert Metconazole Technical Fungicide and Caramba Fungicide from conditional registration to full registration for USC 13 and USC 14.

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

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Metconazole Technical Fungicide and Caramba 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 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 metconazole, 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 metconazole, 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 Metconazole?

Metconazole is a triazole fungicide (Group 3) that inhibits sterol biosynthesis. The end-use product, Caramba Fungicide, is a chemical fungicide that contains 90 g/L metconazole formulated as an emusulfiable concentrate for use on cereals, soybeans and sugar beets to control or to suppress certain foliar fungal diseases.

---

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*.

Health Considerations

Can Approved Uses of Metconazole Affect Human Health?

Products containing Metconazole are unlikely to affect your health when used according to label directions.

Potential exposure to metconazole may occur through the diet (food and water) or when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

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

The technical grade active ingredient, metconazole, was moderately toxic to rats and highly toxic to mice when given as a single oral dose. It was of low acute dermal toxicity to rats and rabbits and of low inhalation toxicity to rats. It was moderately irritating to the eyes and non-irritating to the skin of rabbits. It was not a potential skin sensitizer to guinea pigs. The signal words, "DANGER – POISON" and "EYE IRRITANT" have been included on the label in light of these findings. The end-use product, Caramba Fungicide, was found to be of low oral, dermal and inhalation toxicity in rats. It was moderately irritating to the eyes and minimally irritating to skin of rabbits and not a dermal sensitizer in guinea pigs. The label statements "WARNING – EYE IRRITANT" and "Causes eye irritation", "DO NOT get in eyes" are required.

Health effects in animals given repeated daily doses of metconazole over longer periods of time were decreased body weights, effects in blood (regenerative anaemia) and microscopic changes to the liver, spleen and adrenal glands. There was no evidence that metconazole damaged genetic material. Skin tumours in male mice were observed following oral administration. There was no evidence of cancer in rats.

When metconazole was orally or dermally administered to pregnant rabbits, cranio-facial malformations were observed in fetuses. Limb-flexure malformations were observed in fetuses when metconazole was administered dermally to pregnant rabbits. These effects were observed at doses that were not toxic to the mother, indicating that the fetus is more sensitive to metconazole than the adult animal. Due to the serious nature of these endpoints, extra protective factors were applied during the risk assessment to further reduce the allowable level of human exposure to metconazole.

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

Residues in Water and Food

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

Aggregate dietary intake estimates (food plus drinking water) revealed that the general population, females 13-49 years old, and infants less than one year old, the subpopulation which would ingest the most metconazole relative to body weight, are expected to be exposed to less than 56% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from metconazole is not of health concern for all population subgroups. There are no lifetime cancer risks of concern from the use of metconazole.

The acute dietary (food plus drinking water) intake estimate for females 13-49 years old was approximately 82% of the acute reference dose, and is not of health concern.

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

The storage stability study, analytical methodology data and rationale to waive confirmatory trials conducted on wheat, barley, rye and oats in Canada submitted to support the conversion from conditional to full registration are adequate. The MRLs of 0.15 ppm in/on wheat and sugar beet roots, 2.5 ppm in/on barley, 1.0 ppm in/on oats, 0.25 ppm in/on rye and 0.05 ppm in/on dry soybeans specified for metconazole do not need to be revised as a result of this assessment. Refer to Health Canada's MRL database (http://pr-rp.hc-sc.gc.ca/mrl-lrm/index-eng.php) for a list of the MRLs established for this active ingredient.

Occupational Risks From Handling Caramba Fungicide

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

Farmers and custom applicators who mix, load or apply Caramba Fungicide as well as field workers re-entering freshly treated fields can come in direct contact with metconazole residues on the skin. Therefore, the label specifies that anyone mixing/loading and applying Caramba Fungicide must wear long-sleeved shirts, long pants, chemical-resistant gloves, socks and footwear during mixing/loading, application, clean-up and repair. In addition goggles or a face shield is required during mixing/loading. Gloves are not required during application. For workers handling more than 300 L of Caramba Fungicide per day, a closed mixing/loading system is required. The label also requires that workers do not enter treated fields for 12 hours after application. Taking into consideration these label statements, the number of applications and the expectation of the exposure period for handlers and workers, there are no risks of concern (cancer and non-cancer).

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

Environmental Considerations

What Happens When Metconazole Is Introduced Into the Environment?

When used according to the label directions, metconazole does not pose an unacceptable risk to the environment.

Caramba Fungicide, containing metconazole, enters the environment when used as a foliar-treatment fungicide on agricultural crops including cereals, soybeans and sugarbeets. While metconazole generally breaks down relatively slowly, it can break down more rapidly in the presence of microorganisms in both aquatic and terrestrial environments. Metconazole dissolves readily in water and has the potential to move through soil and thus could reach groundwater under certain conditions. Specific instructions are provided on product labels to prevent carryover, groundwater contamination and runoff into aquatic habitats. Metconazole is unlikely to enter the atmosphere and be transported to areas far removed from where it was applied.

Metconazole is not expected to accumulate in the tissues of organisms.

Metconazole presents a negligible risk to terrestrial invertebrates including earthworms and honeybees, and freshwater invertebrates. As at high enough concentrations it could pose a risk to certain non-target organisms (terrestrial plants, small wild mammals, amphibians, freshwater fish, freshwater plants, marine invertebrates); spray buffer zones are specified on the label to protect terrestrial, freshwater and estuarine/marine habitats adjacent to treated areas. Toxicity statements are also specified on the product label for terrestrial plants, mammals, and aquatic organisms.

Value Considerations

What Is the Value of Caramba Fungicide?

Caramba Fungicide controls or suppresses important diseases of cereal crops, soybeans, and sugarbeets.

Caramba Fungicide offers Canadian growers an additional option for rotation with current products. Caramba Fungicide can be an important tool when used in an Integrated Pest Management (IPM) program in conjunction with other elements such as resistant varieties, cultural controls and predictive models.

Measures to Minimize Risk

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

The key risk-reduction measures being proposed on the label of Caramba 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 coming into direct contact with Caramba Fungicide on the skin or through inhalation of spray mists, anyone mixing, loading and applying Caramba Fungicide must wear long-sleeved shirts, long pants, chemical-resistant gloves, socks and footwear during mixing/loading, application, clean-up and repair. In addition goggles or a face shield is required during mixing/loading. Gloves are not required during application. For workers handling more than 300 L of Caramba Fungicide per day, a closed mixing/loading system is required. In addition, standard label statements to protect against drift during application were added to the label.

Environment

Refer to ERC-2011-02 for the measures to minimize environmental risk from metconazole exposure resulting from the use of Caramba Fungicide. The only amendment to the previously reported measures is the size of spray buffer zones has been updated to 50 m for aerial application and 2 m for ground application to protect sensitive aquatic habitats.

Next Steps

Before making a final registration decision on metconazole, 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 metconazole (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

Metconazole

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Information on the identity of metconazole can be found under ERC2011-02, *Metconazole*.

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

Information on the physical and chemical properties of the technical and end-use product can be found under ERC2011-02.

1.3 Directions for Use

On cereals and sugar beets, Caramba Fungicide may be applied prior to disease development or at the onset of disease symptoms. Rates for control or suppression of leaf diseases on cereals fall between 0.5–0.7 L/ha; fusarium head blight is suppressed at 1.0 L/ha. One application may be made to cereals. Two applications at 1.0–1.25 L/ha may be applied to sugarbeets on a 14 day schedule. On soybeans, two applications of Caramba Fungicide can be applied from vegetative through the full seed stage at a rate of 0.7 L/ha on a 10–21 day interval to suppress Asian soybean rust.

1.4 Mode of Action

Information on the mode of action of metconazole can be found under ERC2011-02.

2.0 Methods of Analysis

A summary of the analytical methods previously reviewed for metconazole and the rationale for the regulatory decision can be found under ERC2011-02.

2.1 Methods for Residue Analysis

An acceptable enforcement method was developed for the determination of metconazole in plant matrices based on method D0508. The liquid chromatography method with tandem mass spectrometry (LC-MS/MS) fulfilled the requirements with regards to specificity, accuracy and precision at the limit of quantitation.

An acceptable enforcement method was developed for the determination of metconazole in animal matrices based on the multiresidue method DFG S-19. The liquid chromatography method with tandem mass spectrometry (LC-MS/MS) provides two MS/MS transitions for confirmatory purposes. The method fulfilled the requirements with regards to specificity, accuracy and precision at the limit of quantitation.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

A summary of toxicology can be found under PRD2013-11, *Metconazole*.

3.1.1 Incident Reports

Since 26 April 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA. Information on the reporting of incidents can be found on the Pesticides and Pest Management portion of Health Canada's website. Incidents were searched and reviewed for the active ingredient metconazole. As of 8 July 2014, the PMRA had received seven human and one domestic animal incident report involving metconazole.

All reported symptoms were minor or moderate in severity. The symptoms reported in four of the incidents were determined to have some degree of association with the reported exposure. Exposure to metconazole occurred either via drift from the application site, during application activities or through contact with a treated area. Given the nature of effects reported, no significant risks from the use of products containing metconazole have been identified in this review.

3.1.2 *Pest Control Products Act* Hazard Characterization

Information on hazard characterization can be found under PRD2013-11.

3.2 Acute Reference Dose (ARfD)

Information on acute reference dose can be found under ERC2011-02.

3.3 Acceptable Daily Intake (ADI)

Information on acceptable daily intake can be found under ERC2011-02.

3.3.1 Cancer Assessment

Based on new information referred to in the evaluation of Tourney Fungicide, there was adequate evidence to support a threshold-based approach to the assessment of skin tumours in male mice. The dietary reference dose (in other words, the ADI) and the selected margins of exposure (MOEs) for occupation and bystander exposure provide a sufficient margin to this endpoint. Additional information is provided in the registration document for Tourney Fungicide.

3.4 Occupational and Residential Risk Assessment

3.4.1 Toxicological Endpoints

A list of toxicological endpoints can be found under PRD2013-11.

Occupational exposure to metconazole is characterized as short- to intermediate-term in duration and is predominantly by the dermal and inhalation routes.

3.4.2 Occupational Exposure and Risk

3.4.2.1 Mixer/loader/applicator Exposure and Risk Assessment

Individuals have potential for exposure to Caramba Fungicide during mixing, loading and application. Dermal and inhalation exposure estimates for workers mixing/loading and applying were generated from PHED Version 1.1. Chemical-specific data for assessing human exposures during pesticide handling activities were not submitted.

Exposure to workers mixing, loading and applying Caramba Fungicide is expected to be short- to intermediate term in duration and to occur primarily by the dermal and inhalation routes. Exposure estimates were derived for mixer/loaders and applicators applying Caramba Fungicide to cereals, soybeans and sugar beets using groundboom and aerial application equipment. The exposure estimates are based on mixers/loaders/applicators wearing a single layer of clothing and gloves.

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

Exposure estimates were compared to the toxicological endpoints (NOAEL: no observed adverse effects level) to obtain the margin of exposure; the target MOE is 1000.

Table 3.4.2.1.1 PHED unit exposure estimates for mixer/loaders and applicators wearing proposed PPE while handling Caramba Fungicide (g/kg a.i. handled/day)

Scenario		Dermal	Inhalation	Total unit exposure (dermal + inhalation)
Mixer/loader PHED estimates (Liquid)				
A	Open mixing/loading (single layer and gloves)	51.14	1.6	52.74
B	Open mixing/loading (coveralls, single layer and gloves)	32.77	1.6	34.37
C	Closed mixing/loading (single layer and gloves)	18.95	0.11	19.06
Applicator PHED estimates				
D	Groundboom open cab (single layer, no gloves)	32.98	0.96	33.94
E	Groundboom closed cab (single layer, no gloves)	11.05	0.06	11.11
F	Aerial - liquid (single layer, no gloves)	9.66	0.07	9.73

The mixer/loader/applicator risk assessment was first conducted for workers wearing baseline personal protective equipment (PPE) (Table 3.4.2.1.2). MOEs for farmers and aerial applicators reach the target MOE of 1000 when workers wear baseline PPE (single layer and gloves during mixing/loading, no gloves during application). Exposure estimates do not reach the target MOE for custom applicators using groundboom application equipment and chemical handlers mixing/loading product for aerial application. As such, further mitigation is required for these workers.

Table 3.4.2.1.2 Chemical handler risk assessment for M/L/A scenarios wearing a single layer and gloves for mixer/loaders and a single layer and no gloves for applicators

Scenario	Rate (kg a.i./ha)	ATPD* (ha/day)	kg a.i. handled	Daily exposure† (g/kg bw/day)		Combined MOE‡
				Dermal	Inhalation	
Cereals (wheat, rye, barley, oats)						
GB M/L/A Farmer	0.09	107	9.6	0.0101	0.000308	2034
GB M/L/A Custom	0.09	360	32.4	0.0341	0.00104	**605**
Aerial M/L	0.09	400	36	0.0230	0.00072	**887**
Aerial A	0.09	400	36	0.00435	0.0000315	6225
Soybeans and cereals (lower rate)						
GB M/L/A Farmer	0.063	107	6.7	0.00709	0.000216	2906
GB M/L/A Custom	0.063	360	22.7	0.0238	0.000726	**864**
Aerial M/L	0.063	400	25.2	0.0161	0.000504	1267
Aerial A	0.063	400	25.2	0.00304	0.0000221	8892
Sugar beets						
GB M/L/A Farmer	0.11	107	11.8	0.0124	0.000377	1664
GB M/L/A Custom	0.11	360	39.6	0.0416	0.00127	**495**
Aerial M/L	0.11	400	44	0.0281	0.00088	**726**
Aerial A	0.11	400	44	0.00531	0.0000385	5093

GB = groundboom, M/L/A = mixer/loader/applicator, M/L = mixer/loader, A = applicator
* ATPD = area treated per day; value from Default Area Treated per day tables (August, 2009)
† Daily exposure = (PHED unit exposure [g/kg a.i. handled] × ATPD [ha/day] × Rate [kg a.i./day])/(80 kg bw)
‡ NOAEL = 30 mg/kg bw/day for dermal exposure and NOAEL = 2 mg/kg bw/day for inhalation exposure. Combined MOE = 1/(1/Dermal MOE + 1/Inhalation MOE). Target MOE = 1000

To mitigate the exposure to within acceptable levels, risk assessments were also conducted using other scenarios. Table 3.4.2.1.3 summarizes the PHED estimates for mixer/loader/applicators and the required engineering controls to reach the target MOE of 1000. For aerial mixer/loaders, closed mixing/loading equipment is required when handling more than 32 kg a.i./day (approximately 350 L product/day). For custom workers using groundboom application equipment, closed cab tractors are required for all workers. In addition, when handling more than 27.5 kg a.i./day (approximately 300 L product/day), closed mixing/loading equipment is required to reach the target MOE.

Table 3.4.2.1.3 Mitigated chemical handler risk assessment for M/L/A scenarios wearing a single layer and gloves for mixer/loaders and a single layer and no gloves for applicators

Scenario	Rate (kg a.i./ha)	ATPD* (ha/day)	Kg a.i. handled	Daily exposure† (g/kg bw/day)		Combined MOE‡
				Dermal	Inhalation	
Cereals (wheat, rye, barley, oats)						
Custom GB Open M/L Closed Cab A	0.09	360	32.4	0.0252	0.000672	**851**
Custom GB Closed M/L Closed Cab A	0.09	360	32.4	0.0122	0.0000689	2276
Aerial Closed M/L	0.09	400	36	0.00853	0.0000495	3236
Soybeans and cereals (lower rate)						
Custom GB Open M/L Closed Cab A	0.063	360	22.7	0.0176	0.000471	1215
Aerial Open M/L	0.063	400	25.2	0.0161	0.000504	1267
Sugar beets						
Custom GB Open M/L Closed Cab A	0.11	360	39.6	0.0308	0.000822	**696**
Custom GB Closed M/L Closed Cab A	0.11	360	39.6	0.0149	0.0000842	1862
Aerial Closed M/L	0.11	400	44	0.0104	0.0000605	2648

GB = groundboom, M/L/A = mixer/loader/applicator, M/L = mixer/loader, A = applicator
* ATPD = area treated per day; value from Default Area Treated per day tables (August, 2009)
† Daily exposure = (PHED unit exposure [g/kg a.i. handled] × ATPD [ha/day] × Rate [kg a.i./day])/(80 kg bw)
‡ NOAEL = 30 mg/kg bw/day for dermal exposure and NOAEL = 2 mg/kg bw/day for inhalation exposure. Combined MOE = 1/(1/Dermal MOE + 1/Inhalation MOE). Target MOE = 1000

3.4.2.2 Exposure and Risk Assessment for Workers Entering Treated Areas

There is potential for exposure to workers re-entering areas treated with Caramba Fungicide. The duration of exposure is considered to be of short- to intermediate-term duration, and the primary route of exposure for workers re-entering treated areas would be through dermal contact with treated foliage.

Dermal exposure to workers entering treated areas is estimated by coupling dislodgeable foliar residue values with generic activity-specific transfer coefficients. Chemical-specific dislodgeable foliar residue data were not submitted. As such, a default dislodgeable foliar residue value of 25% of the application rate was used in the exposure assessment.

Exposure estimates were compared to the toxicological endpoint to obtain the MOE; the target MOE is 1000.

Workers are assumed to be working for four hours per day, based on the submitted rationale for the original Caramba submission which supports the claim that scouting is not conducted for a full 8-hour workday.

Postapplication exposure was calculated on the day of the last application (Table 3.4.2.2). MOEs for cereals, soybeans and sugarbeets are above the target MOE on the day of application and therefore not of concern.

Table 3.4.2.2 Postapplication exposure and risk estimates for re-entry workers scouting and irrigating

Crop(s)	App rate (g/cm^2)	Number of apps	Min app interval	Peak DFR* (g/cm^2)	Transfer coefficient† (cm^2/hr)	Exposure‡ (mg/kg bw/day)	MOE¶	REI
Cereals	0.9	1	-	0.225	1100	0.0124	2424	12 hours
Soybeans	0.63	2	10 days	0.2124	1100	0.0117	2568	12 hours
Sugar beets	1.125	2	14 days	0.3456	210	0.00363	8264	12 hours

* Peak DFR determined using default of 25% dislodgeable from foliage, 10% dissipation per day
† Transfer coefficients from ARTF database:
‡ Exposure = (Peak DFR [g/cm^2] × TC [cm^2/hr] × 4 hr/day) / (80 [kg bw] × 1000 [g/mg]). A duration of exposure of 4 hours per day was used based on the rationale submitted for Caramba Fungicide.
¶ Based on NOAEL of 30 mg/kg bw/day, target MOE of 1000 from a dermal developmental study

3.4.3 Bystander Exposure and Risk

Bystander exposure should be negligible since the potential for drift is expected to be minimal. Application is limited to agricultural crops only when there is low risk of drift to areas of human habitation or activity such as houses, cottages, schools and recreational areas, taking into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings. The standard drift statement appears on the registered product label.

3.5 Food Residues Exposure Assessment

3.5.1 Residues in Plant and Animal Foodstuffs

A summary of the data previously reviewed and the rationale for the regulatory decision can be found under ERC2011-02.

The storage stability data requirements identified in ERC2011-02 were submitted and deemed to be adequate. The data demonstrate that the storage conditions and intervals in the field rotational crop study are acceptable. An acceptable rationale to waive confirmatory supervised residue trials conducted in Canada on wheat, barley, oats and rye using an end-use product containing metconazole was also provided. The MRLs of 0.15 ppm in/on wheat and sugar beet roots, 2.5 ppm in/on barley, 1.0 ppm in/on oats, 0.25 ppm in/on rye and 0.05 ppm in/on dry soybeans specified for metconazole do not need to be revised as a result of this assessment.

3.5.2 Dietary Risk Assessment

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

3.5.2.1 Chronic Dietary Exposure Results and Characterization

The following criteria were applied to the refined chronic analysis for metconazole: domestic predicted percent crop treated data, default and experimental processing factors (where available), residues based on supervised trial median residue (STMdR) and anticipated residues for all animal commodities. The refined chronic dietary exposure from all supported metconazole food uses (alone) for the total population, including infants and children, and all representative population subgroups is 3.6% of the acceptable daily intake (ADI). Aggregate exposure from food and drinking water is considered acceptable. The PMRA estimates that chronic dietary exposure to metconazole from food and drinking water is 18% (0.000791 mg/kg bw/day) of the ADI for the total population. The highest exposure and risk estimate is for all infants (< 1 year) at 56% (0.002436 mg/kg bw/day).

3.5.2.2 Acute Dietary Exposure Results and Characterization

The following assumptions were applied in the refined acute analysis for metconazole: predicted percent crop treated data for blended commodities only, default and experimental processing factors (where available), maximum field trial residue values on domestic crops and imports (where available), and anticipated residues in animal commodities. The refined acute dietary exposure (food alone) for all supported metconazole registered commodities is estimated to be 18.6% (0.000372 mg/kg bw) of the ARfD for females 13–49 years old (95^{th} percentile, deterministic). Aggregate exposure from food and drinking water is considered acceptable: 82.0% (0.001641 mg/kg bw) of the ARfD for females 13–49 years old.

3.5.3 Aggregate Exposure and Risk

The aggregate risk for metconazole from the uses on the Caramba Fungicide label consists of exposure from food and drinking water sources only; there are no residential uses.

3.5.4 Maximum Residue Limits

Refer to Health Canada's MRL database (http://pr-rp.hc-sc.gc.ca/mrl-lrm/index-eng.php) for a list of the MRLs established for metconazole. Based on this assessment, no revision to the MRLs is required.

4.0 Impact on the Environment

The fate and environmental behaviour of metconazole, formulated as Caramba Fungicide, as well as its impacts on non-target terrestrial and aquatic organisms, have been previously assessed for foliar-treatment use on agricultural food crops (ERC2011-02). New ecotoxicity and fate data were evaluated under the environmental review for the use of metconazole in the formulation of Tourney Fungicide on turf (PRD2013-11). The submitted data (two aerobic soil biotransformation studies, a chronic toxicity study on chironomids and a full life cycle study of freshwater fish) satisfy the environmental requirements for the registered foliar agricultural uses of metconazole and the environmental risk assessment has been updated to include this information.

4.1 Fate and Behaviour in the Environment

The physico-chemical properties and the environmental behaviour of metconazole have been reviewed and characterized previously (ERC2011-02 and PRD2013-11). The updated environmental fate information did not result in changes to environmental and drinking water exposure estimates for metconazole when applied as Caramba Fungicide.

4.2 Environmental Risk Characterization

The environmental risk assessment for non-target terrestrial and aquatic organisms as a result of the foliar-treatment use of Caramba Fungicide on food crops (ERC2011-02) has been updated to include the additional data reviewed under PRD2013-11. The updated sections of the risk assessment are presented below.

For chironomids, using the stated ecotoxicity endpoint and the estimated exposure concentration resulting from the maximum registered use rate of metconazole (225 g a.i./ha/season on sugar beets), the level of concern (LOC) is not exceeded (Appendix 1, Table 5). Thus, there are no major concerns regarding the proposed use of Caramba Fungicide affecting freshwater sediment-dwelling invertebrates.

When this assessment is conducted using the results of the full life cycle study of the fathead minnow, the LOC is exceeded at the screening level. Once drift is taken into account, the LOC is no longer exceeded for ground application; however, it is still exceeded for aerial application. When the exposure scenario is refined for run-off, the LOC is also still exceeded (Appendix 1, Tables 5, 6 and 7).

Although the LOC is exceeded for the fathead minnow; the risk quotient (RQ) values are slightly lower than those already established for the early life stage (ELS) of rainbow trout. As the endpoint from the ELS rainbow trout study was previously identified as the most sensitive aquatic endpoint, the outcome of the aquatic risk assessment and risk mitigation measures are not altered by the new study data.

Risk mitigation for sensitive aquatic organisms includes precautionary label statements of metconazole toxicity. In addition, risk mitigation for non-target aquatic organisms includes the requirement of spray buffer zones up to 2 metres in size for ground application and 50 metres in size for aerial application.

4.3 Incident Reports

Since 26 April 2007, registrants have been required by law to report incidents to the PMRA that include adverse effects to Canadian health and environment. Incidents were searched and reviewed for the active ingredient metconazole.

As of 8 July 2014, the PMRA has received one minor environmental incident report involving the active, metconazole. According to the report, an aerial application of a product containing metconazole resulted in an unknown number of dead fish in a pond located in Manitoba. The symptoms described in the incident were reported to have some association with the reported exposure.

As the report indicated that the product in question was co-formulated with another active ingredient with known toxicity to fish, there is some uncertainty regarding whether the possible cause of the incident was metconazole, the other active ingredient, or both.

No significant environment risks from the use of products containing metconazole have been identified in this review.

5.0 Value

5.1 Effectiveness Against Pests

5.1.1 Acceptable Efficacy Claims

Three small scale trials conducted in Canada (Ontario, Manitoba) in 2007 were submitted that compared water volumes representative of aerial application and of ground application to demonstrate equivalent efficacy between the two application methods of Caramba Fungicide.

The performance of the aerial treatment was statistically comparable to the ground application treatment and the commercial standards; however, the treatment consistently resulted in numerically lower control of disease incidence and severity compared to the ground application treatment. The applicant pointed out that it is difficult to get good coverage when applying ultra-low volume sprays with a hand wand, which may explain this trend. The lower levels of control observed in the aerial treatment did not reduce yield, as the results were comparable or numerically better than the ground application treatment and the commercial standards.

Application timing for fusarium head blight can be quite narrow. Growers are currently using aerial application to treat large areas in short time frames and for treating wet areas inaccessible by ground equipment.

The applicant has demonstrated the value of aerial application to treat cereal crops to control or suppress major cereal diseases. Based on the importance of the tested crops and diseases, the results of these trials can be extrapolated to sugarbeet and soybean.

5.2 Economics

The registrant outlined the economic value of using Caramba Fungicide to suppress fusarium head blight through yield increases and indicated that the increased income resulting from application of this product adequately covers the cost of aerial application.

5.3 Sustainability

5.3.1 Survey of Alternatives

A number of fungicides are registered on the labelled crops to control or suppress plant diseases registered on the Caramba Fungicide label. Refer to Appendix 1, Table 8 for further information on alternative products.

5.3.2 Compatibility with Current Management Practices Including Integrated Pest Management

Information on integration into IPM programs can be found under ERC2011-02.

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

Resistance information can be found under ERC2011-02.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

Metconazole and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03[4] and evaluated against the Track 1 Criteria (ERC2011-02, PRD2013-11).

6.2 Formulants and Contaminants of Health or Environmental Concern

Formulants and contaminants of Health or Environmental Concern were assessed in ERC2011-02. The formerly published conclusions apply to the current submission with the following exception:

During the original review process, a statement indicating the toxicity of aromatic petroleum distillates was deemed necessary for the end-use product, Caramba Fungicide. However, upon further review, it has been determined that the statement is not required and may be removed from the end-use product label.

7.0 Summary

7.1 Human Health and Safety

The human health toxicology review can be found under PRD2013-11.

The nature of the residues in plants and animals is adequately understood. Refer to ERC2011-02 for information pertaining to the residue definition. The proposed uses of metconazole do not constitute a health risk of concern for chronic (cancer and non-cancer) or acute dietary exposure (food and drinking water) to any segment of the population, including infants, children, adults and seniors. Refer to Health Canada's MRL database (http://pr-rp.hc-sc.gc.ca/mrl-lrm/index-eng.php) for the list of MRLs established for metconazole.

Mixer, loader and applicators handling Caramba Fungicide and workers re-entering treated areas are not expected to be exposed to levels of metconazole that will result in health risks of concern when Caramba Fungicide is used according to label directions. The personal protective equipment on the product label is adequate to protect workers.

7.2 Environmental Risk

The overall conclusions of the environmental assessment for the foliar use of Caramba Fungicide have previously been published (ERC2011-02). It should be noted that the size of spray buffer zones has been updated to a maximum of 2 m for ground use and 50 m for aerial use for aquatic habitats.

7.3 Value

The submitted value information is sufficient to meet the conditions of registration. Aerial application is fully supported on cereals, sugarbeet and soybean.

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 Metconazole Technical Fungicide and Caramba Fungicide containing the technical grade active ingredient metconazole, to control or suppress important diseases of cereal crops, soybeans, and sugarbeets.

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

♀	female
µg	microgram(s)
a.i.	active ingredient
ADI	acceptable daily intake
apps	applications
ARfD	acute reference dose
ARTF	Agriculture Re-entry Task Force
ATPD	area treated per day
bw	body weight
CAF	composite assessment factor
cm	centimetre(s)
cm^2	centimetre(s) squared
DACO	data code
DEEM	Dietary Exposure Evaluation Model
DFG S-19	Modular multi-residue method of Deutsche Forschungsgemeinschaft German Research Foundation
DFR	dislodgable foliar residue
EEC	estimated environmental concentration
ELS	early life stage
ERC	evaluation report
g	gram(s)
GB	groundboom
gen pop	general population
ha	hectare(s)
hr	hour(s)
ID	identification
IPM	integrated pest management
kg	kilogram(s)
L	litre(s)
LC	liquid chromatography
LOC	level of concern
LOQ	limit of quantitation
m	metre(s)
MB	Manitoba
mg	milligram(s)
min	minimum
M/L/A	mixers, loaders and applicators
MOE	margin of exposure
MRL	maximum residue limit
MS	mass spectrometry
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
ON	Ontario
PHED	Pesticide Handlers Exposure Database
PMRA	Pest Management Regulatory Agency

PPE	personal protective equipment
ppm	parts per million
PRDD	Proposed Registration Decision
REI	re-entry interval
RQ	risk quotient
STMdR	supervised trial median residue
TC	transfer coefficient
TGAI	technical grade active ingredient
USC	Use-Site Category
var.	variant

Appendix I Tables and Figures

Table 1 Residue Analysis

Matrix	Method ID	Analyte	Method Type	LOQ		Reference
Plant	D0508	Metconazole (*cis*- and *trans*-isomers) and the metabolites M21, M11 and M30	LC-MS/MS (enforcement)	0.01 ppm	For metconazole as the sum of the LOQ of 0.005 ppm for each of the *cis*- and *trans*-isomers; and, for each of the metabolites M21, M11, M30	2335256
Animal	DFG Method S-19	Metconazole **(***cis*- and *trans*-isomers)	LC-MS/MS (enforcement)	0.01 ppm	For metconazole as the sum of the LOQ of 0.005 ppm for each of the *cis*- and *trans*-isomer	2335254, 2335255

Note: refer to ERC2011-02, *Metconazole* for methods previously reviewed.

Table 2 Toxicology Endpoints for Use in Health Risk Assessment for Metconazole

Exposure Scenario	Study	Point of Departure and Endpoint	CAF[1] or Target MOE
Acute dietary females ages 13-49	PMRA 1405646 Rabbit Oral Developmental Toxicity Study	NOAEL = 2 mg/kg bw Increased craniofacial malformations and liver variations.	1000
	ARfD (♀ 13-49) = 0.002 mg/kg bw		
Acute dietary general population	Not required		
Chronic dietary females ages 13-49	PMRA 1405646 Rabbit Oral Developmental Toxicity Study	NOAEL = 2 mg/kg bw/day Increased craniofacial malformations and liver variations.	1000
	ADI (♀ 13-49) = 0.002 mg/kg bw/day		
Chronic dietary general population	Combined Oral Rat Chronic and Oncogenicity Studies	NOAEL = 0.44 mg/kg bw/day Increased vacuolation of the adrenal cortex in males and females and necrotic inflammatory foci and clear cell foci in the liver of males	100

Exposure Scenario	Study	Point of Departure and Endpoint	CAF[1] or Target MOE
	ADI (gen pop) = 0.0044 mg/kg bw/day		
Short-term & Intermediate – term dermal	Rabbit Dermal Developmental Toxicity Study	NOAEL = 30 mg/kg bw/day Increased craniofacial and limb flexure malformations	1000
Short-term & Intermediate-term inhalation[2]	PMRA 1405646 Rabbit Oral Developmental Toxicity Study	NOAEL = 2 mg/kg bw/day Increased craniofacial malformations and liver variations.	1000
Cancer	Cancer risk (threshold) was addressed through the selected toxicology endpoints.		

[1] CAF (composite assessment factor) refers to a total of uncertainty and *Pest Control Products Act* factors for dietary assessments; MOE refers to a target MOE for occupational assessments

[2] Since an oral NOAEL was selected, an inhalation absorption factor of 100% (default value) was used in route-to-route extrapolation.

Table 3 Food Residue Chemistry Summary

Freezer Storage Stability – Lettuce, Radish (Tops and Roots) and Wheat (Forage, Grain and Straw)	PMRA 2335258
Samples of homogenized lettuce leaves, radish tops, radish roots, wheat forage, wheat grain and wheat straw, each spiked at 0.1 ppm with *cis*- and *trans*-metconazole were stored at ~-20°C for 0 days, 1 month (35 days), 7 months (217 days), 12 months (365 days), 18 months (549 days) and 22 months (673 days). Method D0508 was used for the determination of *cis*- and *trans*-metconazole residues in these commodities. The data indicate that residues of *cis*- and *trans*-metconazole are stable under frozen storage for up to ~22 months (673 days) in lettuce leaves, radish tops, radish roots, wheat forage, wheat grain and wheat straw.	

Table 4 Food Residue Chemistry Overview of Metabolism Studies and Risk Assessment

Dietary Risk From Food and Water			
Refined chronic (cancer and non-cancer) dietary exposure analysis **Estimated chronic drinking water concentration = 30 μg/L**	**Population**	**Estimated Risk % of Acceptable Daily Intake (ADI)**	
		Food Alone	**Food and Water**
ADI = 0.0044 mg/kg bw/day	**All infants < 1 year**	8.2	55.4
	Children 1–2 years	12.5	33.8
	Children 3 to 5 years	9.5	29.5
	Children 6–12 years	5.8	19.6
	Youth 13–19 years	3.2	13.6
	Adults 20–49 years	2.5	15.9
	Adults 50+ years	2.4	16.6
	Total population	3.6	18.0
ADI = 0.002 mg/kg bw/day	**Females 13-49 years**	5.4	34.8
Refined acute dietary exposure analysis, 95th percentile **ARfD = 0.002 mg/kg bw** **Estimated acute drinking water concentration = 30 μg/L**	**Population**	**Estimated Risk % of Acute Reference Dose (ARfD)**	
		Food Alone	**Food and Water**
	Females 13-49 years	18.60	82.04

Table 5 Screening Level Assessment for Chironomids and Fathead Minnow [1,2]

Organism	Test Substance and Exposure Period	Description of Ecotox Endpoint	Ecotox Endpoint Value (mg a.i./L)	Uncertainty Factor	Water Depth (cm)	EEC Value (mg a.i./L)	RQ	LOC exceeded
Freshwater Species								
Chironomid (*Chironomus riparius*)	**TGAI** - metconazole: 28-day chronic - spiked sediment	**NOEC** (mortality)	5.6	1	80	0.0218	0.004	No
Fathead minnow (*Pimephales promelas*)	**TGAI** - metconazole: 180-day Full life cycle	**NOEC** (mortality, repro, growth and liver toxicity)	0.0032	1	80	0.0218	6.81[3]	Yes

Notes:
[1] For a comprehensive review summary of the ecotoxicity of metconazole to chironomids and full life cycle of fathead minnow, see PRD2013-11, Section 4.22, and Appendix I, Tables 10 – 13
[2] For comprehensive summary tables of the ecotoxicity of metconazole to the full suite of non-target organisms, see Evaluation Report ERC2011-02, Appendix I, Tables 16 and 17
[3] Highlighted RQ values indicate that a refined risk assessment is required.

Table 6 Refined Risk Assessment for Fathead Minnow Exposed to Metconazole Spray Drift[1,2]

Refined Scenario	Organism	Test Substance and Exposure Period	Description of Ecotox Endpoint	Ecotox Endpoint Value (mg a.i./L)	Uncertainty Factor	Water Depth (cm)	Refined EEC Value (mg a.i./L)	Refined RQ	LOC exceeded
	Freshwater Species								
Ground Boom (Field) Sprayer Medium (6% drift)	Fathead minnow (*Pimephales promelas*)	**TGAI** - metconazole: 180-day Full life cycle	**NOEC** (mortality, repro, growth and liver toxicity)	0.0032	1	80	0.0013	0.41	No
Aerial - Medium (23% drift)	Fathead minnow (*Pimephales promelas*)	**TGAI** - metconazole: 180-day Full life cycle	**NOEC** (mortality, repro, growth and liver toxicity)	0.0032	1	80	0.005	1.57	Yes[3]

Notes:
[1] For a comprehensive review summary of the ecotoxicity of metconazole to chironomids and full life cyle of fathead minnow, see PRD2013-11, Section 4.22, and Appendix I, Tables 10 – 13

[2] For comprehensive summary tables of the ecotoxicity of metconazole to the full suite of non-target organisms, see Evaluation Report ERC2011-02, Appendix I, Tables 16 and 17
[3] Highlighted RQ values indicate that a refined risk assessment is required.

Table 7 Refined Risk Assessment for Fathead Minnow Exposed to Metconazole Run-Off[1,2]

Organism	Test Substance and Exposure Period	Description of Ecotox Endpoint	Ecotox Endpoint Value (mg a.i./L)	Uncertainty Factor	Water Depth (cm)	Refined EEC Value (mg a.i./L)	Refined RQ	LOC exceeded
Freshwater Species								
Fathead minnow (*Pimephales promelas*)	**TGAI** - metconazole: 180-day Full life cycle	**NOEC** (mortality, repro, growth and liver toxicity)	0.0032	1	80	0.028	8.75	Yes[3]

Notes:
[1] For a comprehensive review summary of the ecotoxicity of metconazole to chironomids and full life cyle of fathead minnow, see PRD2013-11, Section 4.22, and Appendix I, Tables 10 – 13
[2] For comprehensive summary tables of the ecotoxicity of metconazole to the full suite of non-target organisms, see Evaluation Report ERC2011-02, Appendix I, Tables 16 and 17
[3] Highlighted RQ values indicate that a refined risk assessment is required.

Table 8 Alternative Active Ingredients Registered for Crops and Pests Registered on the Caramba Fungicide Label (as of October 2013).

Crop	Disease	Active Ingredients (Mode of Action Group)
Wheat	Fusarium head blight (*Fusarium graminearum*)	tebuconazole (3) prothioconazole (3) chlorothalonil (M) *Bacillus subtilis* var. *amyloliquefaciens* (NC)
	Leaf rust (*Puccinia recondita*)	propiconazole (3) prothioconazole (3) fluxapyroxad (7) penthiopyrad (7) azoxystrobin (11) pyraclostrobin (11) picoxystrobin (11) mancozeb (M)
	Tan spot (*Pyrenophora tritici-repentis*)	propiconazole (3) tebuconazole (3) prothioconazole (3) fluxapyroxad (7) azoxystrobin (11)

Crop	Disease	Active Ingredients (Mode of Action Group)
		pyraclostrobin (11) trifloxystrobin (11) chlorothalonil (M) mancozeb (M)
	Spot blotch (*Cochliobolus sativus*)	fluxapyroxad (7) pyraclostrobin (11)
	Septoria leaf blotch (*Septoria tritici, S. nodorum*)	propiconazole (3) tebuconazole (3) prothioconazole (3) fluxapyroxad (7) penthiopyrad (7) azoxystrobin (11) pyraclostrobin (11) trifloxystrobin (11) picoxystrobin (11) chlorothalonil (M) mancozeb (M) extract of *Reynoutria sachalinensis* (NC)
Barley	Fusarium head blight (*Fusarium graminearum*)	metconazole + pyraclostrobin (3+11)prothioconazole (3)
	Spot blotch (*Cochliobolus sativus*)	propiconazole (3) tebuconazole (3) prothioconazole (3) fluxapyroxad (7) pyraclostrobin (11) propiconazole + trifloxystrobin (3+11) tebuconazole + trifloxystrobin (3+11) metconazole + pyraclostrobin (3+11)
	Leaf rust (*Puccinia hordei*)	propiconazole (3) azoxystrobin (11) fluoxastrobin (11) tebuconazole + trifloxystrobin (3+11)
	Net blotch (*Pyrenophora teres*)	propiconazole (3) tebuconazole (3) prothioconazole (3) fluxapyroxad (7) azoxystrobin (11) pyraclostrobin (11) tebuconazole + trifloxystrobin (3+11) metconazole + pyraclostrobin (3+11)

Crop	Disease	Active Ingredients (Mode of Action Group)
	Scald (*Rhynchosporium secalis*)	propiconazole (3) tebuconazole (3) prothioconazole (3) fluxapyroxad (7) azoxystrobin (11) pyraclostrobin (11) propiconazole + trifloxystrobin (3+11) tebuconazole + trifloxystrobin (3+11) metconazole + pyraclostrobin (3+11)
Oat	Fusarium head blight (*Fusarium graminearum*)	metconazole + pyraclostrobin (3+11)
	Septoria leaf blotch (*Septoria avenae*)	propiconazole (3) azoxystrobin (11) propiconazole + trifloxystrobin (3+11) tebuconazole + trifloxystrobin (3+11)
	Crown rust (*Puccinia coronata*)	propiconazole (3) tebuconazole (3) prothioconazole (3) propiconazole + trifloxystrobin (3+11) tebuconazole + trifloxystrobin (3+11) metconazole + pyraclostrobin (3+11)
Triticale	Leaf rust (*Puccinia recondita*)	fluxapyroxad (7) penthiopyrad (7) picoxystrobin (11) metconazole + pyraclostrobin (3+11) fluxapyroxad + pyraclostrobin (7+11)
	Spot blotch (*Cochliobolus sativus*)	fluxapyroxad (7) metconazole + pyraclostrobin (3+11) fluxapyroxad + pyraclostrobin (7+11)
	Septoria leaf blotch (*Septoria tritici, S. nodorum*)	fluxapyroxad (7) azoxystrobin (11) picoxystrobin (11) azoxystrobin + propiconazole (11+3) fluxapyroxad + pyraclostrobin (7+11)
	Tan spot (*Pyrenophora tritici-repentis*)	fluxapyroxad (7) azoxystrobin (11)

Crop	Disease	Active Ingredients (Mode of Action Group)
		azoxystrobin + propiconazole (11+3) metconazole + pyraclostrobin (3+11) fluxapyroxad + pyraclostrobin (7+11)
Rye	Fusarium head blight (*Fusarium graminearum*)	prothioconazole (3) metconazole + pyraclostrobin (3+11)
	Leaf rust (*Puccinia recondita*)	fluxapyroxad (7) penthiopyrad (7) pyraclostrobin (11) picoxystrobin (11)
Soybean	Asian soybean rust (*Phakopsora pachyrhizi*)	tebuconazole (3) prothioconazole (3) fluxapyroxad (7) penthiopyrad (7) pyraclostrobin (11) picoxystrobin (11) propiconazole + trifloxystrobin (3+11) tebuconazole + trifloxystrobin (3+11)
Sugarbeet	Cercospora leaf spot (*Cercospora beticola*)	thiophanate-methyl (1) prothioconazole (3) difenoconazole (3) triticonazole (3) fluxapyroxad (7) pyraclostrobin (11) mancozeb (M) copper hydroxide (M) metiram (M) azoxystrobin + difenoconazole (11+3)

Table 9 Use (label) Claims Proposed by Applicant and Whether Acceptable or Unsupported

Use claim	PMRA comments
Aerial application to cereal crops, sugarbeet and soybean using a water volume of 50 L/ha.	Aerial application at the proposed water volume is supported for all crops.

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

Please refer to the Maximum Residue Limit Database in the Pesticides and Pest Management section of Health Canada's website for the established MRLs for metconazole.

References

A. List of Studies/Information Submitted by Registrant

1.0 Human and Animal Health

PMRA Document Number	Reference
2335256	2006, Amended Final Report: Method Validation Of BASF Analytical Method D0508 The Determination of Residues of Metconazole (BAS 555 F) and Its Metabolites in Plant Matrices Using LC/MS/MS, DACO: 7.2.1, 7.2.2, and 7.2.3
2335254	2010, Metconazole: Validation of the Multi-Residue Enforcement Method DFG S19 for the Determination of Residues in Liver and Kidney, using LC/MS/MS, DACO 7.2.1, 7.2.2, and 7.2.3
2335255	2010, Final Report 1 of 2: Determination of Metconazole (BAS 555 F) in Animal Matrices – Independent Laboratory Validation, DACO 7.2.1, 7.2.2, and 7.2.3
2335258	2011, Freezer Storage Stability of Metconazole (BAS 555 F, Cis and Trans-Isomer) in Rotational Crop Plant Samples, DACO: 7.3
2335259	2006, Amended Final Report: Freezer Storage Stability of BAS 555 F (Metconazole) and Its Metabolites in Plant Samples, DACO: 7.3
2335260	2013, Metconazole Submission 2007-2949 Conditions of Registration, DACO: 7.4.1

2.0 Value

PMRA Document Number	Reference
2335249	2013, Efficacy: Small-Scale Trials (Field, Greenhouse)-Report, DACO: 10.2.3.3
2335251	2013, Efficacy: Small-Scale Trials (Field, Greenhouse)-Raw data, DACO: 10.2.3.3