

## Evaluation Report for Category B, Subcategory B.3.1, 3.4, 3.5, 3.8, 3.12 Application

**Application Number:** 2016-6131  
**Application:** B.3.1: Application Rate Increase or Decrease  
B.3.4: Application Method  
B.3.5: Rotational Crops/Plantback Intervals  
B.3.8: Re-entry Interval  
B.3.12: New Host or Site  
**Product:** Mettle 210 ME Fungicide  
**Registration Number:** 32042  
**Active ingredients (a.i.):** Tetraconazole  
**PMRA Document Number:** 2967465

### Purpose of Application

The purpose of this application was to amend the registration of Mettle 125ME by adding new uses on wheat, barley, corn, Crop Subgroup 6C, Crop Subgroup 20A, fruiting vegetables (Crop Group 8-09) and cucurbit vegetables (Crop Group 9).

### Chemistry Assessment

Chemistry assessment was not required for this application.

### Health Assessments

The use pattern of Mettle 210 ME Fungicide represents an expansion of use for tetraconazole with the addition of wheat (durum, winter, spring) barley, dried shelled pea and bean (Crop Subgroup 6C), soybean, rapeseed (Crop Subgroup 20A), corn (field and seed), cucurbit vegetables (Crop Group 9), fruiting vegetables (Crop Group 8-09) and aerial application (to wheat, barley, corn and rapeseed only). An updated quantitative risk assessment for tetraconazole was conducted for mixer/loader/applicators as well as for workers entering treated sites of these crops. No health risks of concern are expected provided workers follow directions and wear personal protective equipment as stated on the label. Requested amendments to the current restricted entry intervals for grapes were not supported.

Residue data from field trials conducted in Canada and the United States were submitted to support the domestic use of Mettle 210 ME Fungicide on wheat (spring, winter and durum), barley, dried shelled pea and bean (Crop Group 6C), corn (field and seed), rapeseed (Crop Subgroup 20A), and the domestic use of Mettle 125 ME Fungicide on Fruiting Vegetables (Crop Group 8-09) and Cucurbit Vegetables (Crop Group 9). Tetraconazole was applied to the crops at

the proposed or exaggerated rates, and harvested according to label directions. In addition, processing studies in treated wheat, canola, tomato and field corn were reviewed to determine the potential for concentration of residues of tetraconazole into processed commodities.

### Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for tetraconazole was based upon the submitted field trial data, and the guidance provided in the [OECD MRL Calculator](#). MRLs to cover residues of tetraconazole in/on crops and processed commodities are proposed as shown in Table 1. Residues in processed commodities not listed in Table 1 are covered under the proposed MRLs for the raw agricultural commodities (RACs).

**Table 1 Summary of Field Trial and Processing Data Used to Support Maximum Residue Limit(s) (MRLs)**

| Commodity         | Application Method/<br>Total Application Rate<br>(g a.i./ha) | PHI<br>(days) | Residues (ppm) |       | Experimental Processing Factor                              | Currently Established MRL (ppm) | Recommended MRL (ppm)                                                   |
|-------------------|--------------------------------------------------------------|---------------|----------------|-------|-------------------------------------------------------------|---------------------------------|-------------------------------------------------------------------------|
|                   |                                                              |               | LAFT           | HAFT  |                                                             |                                 |                                                                         |
| Wheat             | Foliar/220-235                                               | 30-51         | 0.01           | 0.039 | Total bran: 3.7,<br>Whole meal flour:<br>2.0,<br>Germ: 10.6 | -                               | Wheat: 0.05<br>Wheat bran: 0.15<br>Wheat flour: 0.08<br>Wheat germ: 0.5 |
| Barley            | Foliar/217-236                                               | 28-51         | <0.01          | 0.248 | -                                                           | -                               | 0.3                                                                     |
| Dry pea           | Foliar/219-228                                               | 13-18         | <0.01          | 0.048 | -                                                           | -                               | Crop Subgroup 6C:<br>0.09                                               |
| Dry bean          | Foliar/223-229                                               | 13-15         | <0.01          | 0.070 | -                                                           | -                               |                                                                         |
| Rapeseed (canola) | Foliar/224-236                                               | 20-22         | <0.012         | 0.870 | Refined oil: 0.1                                            | -                               | Crop Subgroup 20A: 0.9                                                  |
| Field corn        | Foliar/95-105                                                | 29-95         | <0.01          | <0.01 | -                                                           | -                               | Field corn: 0.01<br>Popcorn: 0.01                                       |
| Cucumber          | Foliar/217-223                                               | 0             | <0.01          | 0.080 | -                                                           | -                               | Cucurbit Vegetables (CG 9): 0.15                                        |
| Cantaloupe        | Foliar/216-220                                               |               | 0.014          | 0.077 |                                                             |                                 |                                                                         |
| Summer squash     | Foliar/217-231                                               |               | <0.01          | 0.047 |                                                             |                                 |                                                                         |
| Bell pepper       | Foliar/144-149                                               | 0             | 0.014          | 0.059 | -                                                           | -                               | Fruiting Vegetables (CG 8-09): 0.3                                      |
| Non-bell pepper   | Foliar/147-148                                               |               | 0.040          | 0.110 | -                                                           | -                               |                                                                         |
| Tomato            | Foliar/144-153                                               |               | 0.016          | 0.097 | Paste:0.3<br>Puree: 0.2<br>Juice: 0.1                       | -                               |                                                                         |

LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial

Based on the dietary burden and residue data, MRLs in livestock commodities in the following table to cover residues of tetraconazole are also proposed.

**Table 2 Proposed MRLs in Livestock Commodities**

| Commodity                                                         | Proposed MRLs (ppm) |
|-------------------------------------------------------------------|---------------------|
| Milk                                                              | 0.06                |
| Cream (milk fat)                                                  | 0.5                 |
| Meat byproducts of cattle, goats, horses and sheep (except liver) | 0.08                |

| <b>Commodity</b>                         | <b>Proposed MRLs (ppm)</b> |
|------------------------------------------|----------------------------|
| Liver of cattle, goats, horses and sheep | 2.0                        |
| Fat of cattle, goats, horses and sheep   | 0.3                        |
| Eggs                                     | 0.01                       |
| Meat and meat byproducts of poultry      | 0.02                       |
| Fat of poultry                           | 0.03                       |

Following the review of all available data, MRLs as proposed in Tables 1 and 2 are recommended to cover residues of tetraconazole. Residues in these crop/livestock commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

### **Environmental Assessment**

Given that this use expansion includes a greater number of field crops, a higher maximum seasonal application rate, a shorter reapplication interval of seven days for some crops (as opposed to the original 14 days), as well as aerial application on some crops, a revised environmental risk assessment was conducted.

Precautionary statements for terrestrial plants, beneficial arthropods, birds and aquatic organisms are present on the label of Mettle 210 ME Fungicide to protect these non-target organisms. In addition, risks are mitigated through the use of buffer zones to protect non-target habitats.

### **Value Assessment**

Rationales and efficacy data from 79 trials conducted in Canada and the USA were submitted in support of the use claims on the Mettle 210ME label. Overall, Mettle 210ME at the proposed rates demonstrated its effectiveness at either level of control or suppression against the target diseases on listed crops, compared to the commercial standards tested in the same efficacy trials.

The supporting evidence confirmed the value of Mettle 210ME on control or suppression of fungal diseases on listed crops. The label expansion of Mettle 210ME will provide Canadian growers with a new product to manage listed diseases on wheat, barley, corn, Crop Subgroup 6C, Crop Subgroup 20A, fruiting vegetables (Crop Group 8-09) and cucurbit vegetables (Crop Group 9).

### **Conclusion**

The PMRA has reviewed the information provided to support the amendment to the Mettle 210ME Fungicide label. Based on the results of this review, the addition of wheat, barley, corn, Crop Subgroup 6C, Crop Subgroup 20A, fruiting vegetables (Crop Group 8-09) and cucurbit vegetables (Crop Group 9) is acceptable.

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