Health Canada Santé Canada

# Evaluation Report for Category B, Subcategory 2.6, 3.4, 3.11, 3.12 Application

**Application Number:** 2016-5746
**Application:** B.2.6: New Combination of Technical Grade Active Ingredients
B.3.4: New Application Method
B.3.11: New Pests
B.3.12: New Site or Host
**Product:** Zolera FX Fungicide
**Registration Number:** 33367
**Active ingredients (a.i.):** Fluoxastrobin and Tetraconazole
**PMRA Document Number: 2967459**

## Purpose of Application

The purpose of this application was to register the end use product, Zolera FX Fungicide, for use on wheat, barley, corn, dried shelled pea and bean (Crop Subgroup 6C), soybean, and rapeseed (Crop Subgroup 20A) to provide protection against certain foliar diseases.

## Chemistry Assessment

Zolera FX Fungicide is formulated as an emulsifiable concentrate containing fluoxastrobin at a nominal concentration of 200 g/L and tetraconazole at a nominal concentration of 200 g/L. This end-use product has a density of 1.12 g/mL and pH of 6.67. The required chemistry data for Zolera FX Fungicide have been provided, reviewed and found to be acceptable.

## Health Assessments

Zolera FX Fungicide is of low acute toxicity in rats via the oral, dermal, and inhalation routes. It was non-irritating to the eyes and slightly irritating to the skin of rabbits. It was a dermal sensitizer in mice.

The use pattern of the end use product, Zolera Fungicide represents an expansion of use for fluoxastrobin with the application to Crop Subgroup 6C (including dry peas, dry beans, lentils and chickpeas) and Crop Subgroup 20A (including canola) and an expansion of use for tetraconazole with the application to wheat (durum, winter, spring) barley, dried shelled pea and bean (Crop Subgroup 6C), soybean, rapeseed (Crop Subgroup 20A), corn (field and seed) and aerial application to wheat (durum, winter, spring), barley and corn.



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Quantitative risk assessments for both fluoxastrobin and tetraconazole were 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.

Residue data from field trials conducted in Canada and the United States were submitted for tetraconazole (S2016-6131/5735) and fluoxastrobin (S2016-5745) to support the domestic use of Mettle 125 ME, Mettle 210 ME and Evito 480 SC Fungicides on wheat (spring, winter and durum), barley, dried peas and beans (Crop Group 6C), corn (field and seed), soybean and rapeseed (Crop Subgroup 20A). Fluoxastrobin and tetraconazole were applied to various crops at the proposed rates, and harvested according to label directions. In addition, processing studies in various treated crops were reviewed to determine the potential for concentration of residues of fluoxastrobin and tetraconazole into processed commodities. The same data were assessed under the framework of this application to support the registration of Zolera FX Fungicide (an end use product with fluoxastrbin and tetraconazole).

**Environmental Assessment**

Given that the use of Zolera FX Fungicide is a use expansion which 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 for tetraconazole. Precautionary statements for terrestrial plants, beneficial arthropods, birds and aquatic organisms are present on the label of Zolera FX Fungicide to protect these non-target organisms. In addition, risks are mitigated through the use of buffer zones to protect non-target habitats.

Buffer zones for fluoxastrobin were recalculated for this combination product. Based on the risk identified to non-target organisms from fluoxastrobin, buffer zones are required to protect amphibian, freshwater and marine habitats.

**Value Assessment**

Rationales and efficacy data from 36 trials conducted in Canada and the USA were submitted in support of the use claims on the Zolera FX label. Efficacy of Zolera FX on the target diseases was tested in forms of Zolera FX formulation or tank-mixing two relevant active ingredients, tetraconazole and fluoxastrobin, at the comparable application rates as formulated in Zolera FX Fungicide. Zolera FX treatments have demonstrated an acceptable level of disease control or suppression under adequate disease pressure, for uses against listed diseases on wheat, barley, canola, pea and lentil. A similar level of disease control can also be expected for uses against listed disease on corn and soybean as stated in the registrant’s rationales.

The supporting evidence confirmed the value of Zolera FX on control or suppression of fungal diseases on listed crops. The registration of Zolera FX will provide Canadian growers with a new product to manage these important diseases on wheat, barley, canola, pea, lentil, soybean and corn.

## Conclusion

The PMRA has reviewed the information provided in support of the end use product Zolera FX Fungicide. Based on the results of this review, Zolera FX Fungicide is acceptable for registration.

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