



# Regulatory Decision Document

**RDD2001-03**

## **Primisulfuron-methyl**

The active ingredient primisulfuron-methyl and the formulated end-use product Beacon 75 WG herbicide, containing primisulfuron-methyl, for control of quackgrass and specific broadleaf weeds in field corn in eastern Canada are eligible for full registration under Section 13 of the Pest Control Products Regulations.

This Decision Document outlines this stage of the Pest Management Regulatory Agency's regulatory decision-making process concerning the use of primisulfuron-methyl (Beacon 75 WG) for control of quackgrass and specific broadleaf weeds in field corn.

*(publié aussi en français)*

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## **1.0 Introduction**

This Decision Document outlines the Pest Management Regulatory Agency's (PMRA) regulatory decision-making process concerning the use of Beacon 75 WG herbicide containing the active ingredient primisulfuron-methyl, for control of quackgrass and specific broadleaf weeds in field corn in eastern Canada.

## **2.0 Background**

The PMRA carried out an assessment of available information in accordance with Section 9 of the Pest Control Products (PCP) Regulations. The assessment found that there was sufficient information, pursuant to Section 18.b, to allow a determination of the safety, merit, and value of primisulfuron-methyl and the formulated end-use product Beacon 75 WG manufactured by Syngenta Crop Protection. The PMRA concluded that the use of Beacon 75 WG in accordance with the label accompanying the product has merit and value consistent with Section 18.c of the PCP Regulations and does not entail an unacceptable risk of harm under Section 18.d.

This product was proposed for registration in Proposed Regulatory Decision Document [PRDD2001-02](#). Comments received by the PMRA concerning [PRDD2001-02](#) are presented in Appendix I.

## **3.0 Regulatory Decision**

Based on the considerations outlined above, Primisulfuron-methyl Technical and Beacon 75 WG herbicide for control of quackgrass and specific broadleaf weeds in field corn, are eligible for full registration, pursuant to Section 13 of the PCP Regulations.

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## Appendix I Comments and Responses

Comments were received by the PMRA from government concerning the [PRDD2001-02](#) *Primisulfuron-methyl* published on March 29, 2001. The comments related to assessment methodology for health and environmental aspects of primisulfuron-methyl and Beacon 75 WG. The PMRA has consolidated and summarized the comments received and provides responses to the comments below:

### 1.0 Methods for residue analysis

#### 1.1 Comment on PRDD2001-02 section 2.3.2 and 2.3.3

Residues were not analyzed by state-of-the-art instrumentation. The methods presented were for high performance liquid chromatography (HPLC) with ultraviolet (UV) detection. The high performance liquid chromatography with tandem mass spectrometry (LC-MS-MS) would be orders of magnitude more sensitive. The limits of quantification (LOQs) are given in the .05 ppm range which seems high. Mass spectrometry methods would also be more specific.

#### 1.2 Response

It is stated in the PRDD document that an HPLC method with UV detection was used to determine residues of primisulfuron-methyl in corn and animal matrices. The reported LOQ was 0.01 ppm for corn grain and processed commodities as well as milk samples. For animal tissues, eggs and forage/silage, the LOQ was 0.05 ppm. It is not uncommon for the LOQ to be higher in animal commodities particularly when the UV detection is at 234 nm. An HPLC with UV detection is current methodology used by registrants and the Canadian Food Inspection Agency for data gathering and enforcement purposes. Although mass spectrometry is used as a confirmatory method and it is also submitted to us for review, it should be noted that LC-MS-MS/GC-MS-MS (gas chromatography with tandem mass spectrometry) are not necessarily more specific or sensitive for all matrices.

### 2.0 Operator exposure assessment

#### 2.1 Comment on PRDD2001-02 section 3.6.1

We would not consider the applicator's handling of field formulations in glass jars to be equivalent to the water-soluble bags.

## **2.2 Response**

In the occupational exposure study used for the primisulfuron-methyl exposure and risk assessment, operators were provided with the pre-measured product in a glass jar. In order to ensure this procedure was representative of workers handling water-soluble bags, the PMRA compared results obtained from this study with results obtained from studies in which water-soluble bags were used. Results were consistent and it was determined that this procedure was acceptable.

## **3.0 Expected environmental concentration**

### **3.1 Comment on PRDD2001-02 section 5.2.4**

It was not clear where the estimate of 2-5% of seasonal applications lost to aquatic ecosystems comes from.

### **3.2 Response**

Estimates of the percentage of applied pesticides that will be present in surface runoff are provided in a paper by R.D. Wauchope (*Wauchope, R.D. 1978. The pesticide content of surface water draining from agricultural fields - a review. J. Environ. Qual. 7(4): 459-472*). For wettable powder formulations, this value is 2 to 5% of the applied pesticide.

## **4.0 Effects of aquatic biotransformation products**

### **4.1 Comment on PRDD2001-02 sections 5.2.3 and 6.2**

While several aquatic aerobic biotransformation products were noted and identified, none of these was tested in any of the aquatic bioassays.

### **4.2 Response**

Studies of the effects on non-target aquatic organisms are conducted with the active ingredient. The need for studies on the toxicity of major transformation products is based on the persistence of these compounds in an aquatic environment.

Aerobic aquatic biotransformation is a major route of transformation of primisulfuron-methyl in aquatic environments, with greater than 40% of the initially applied parent compound detected as carbon dioxide in laboratory studies with pond and river sediment/water systems at the end of the 273-day study period. Analysis of the data from the aerobic aquatic transformation study indicated that there is little potential for persistence and accumulation of the parent compound and all but one of the major transformation products in aquatic systems. There were insufficient data to estimate a

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rate of dissipation of CGA-239771. The aquatic buffer zone (26 m) and the restriction regarding application soon after rainfall or if there is a forecast of rain (see [PRDD2001-02](#) section 6.4) will mitigate the potential for the parent compound and, thus, its transformation products to enter aquatic environments.

Based on these considerations, studies on the toxicity of the major transformation products to aquatic organisms were not requested.

## **5.0 Reproductive effects in fish**

### **5.1 Comment on PRDD2001-02 section 6**

While it appears that reproductive effects were evaluated for mammals and some wildlife, no evaluation on fish reproduction was made.

### **5.2 Response**

Chronic studies with fish, including reproductive effects, are conditionally required. The need for these studies is based on the results of acute toxicity studies with fish, the persistence of the compound in an aquatic environment, the number of applications per season, and the potential for bioaccumulation.

Primisulfuron-methyl is classified as slightly toxic to rainbow trout and practically non-toxic to bluegill sunfish. It is classified as slightly to moderately persistent under aerobic aquatic conditions. Application of Beacon 75 WG is restricted to a single treatment per growing season. The octanol-water partition coefficient ( $K_{ow}$ ) value for primisulfuron-methyl (1.15) indicates a low potential for bioconcentration and bioaccumulation. In addition, reproductive concerns were not identified in other vertebrate species (birds and mammals).

Also, as discussed above, the aquatic buffer zone and restrictions on application during or after rainfall will mitigate entry of primisulfuron-methyl residues into aquatic systems.

Based on these considerations, a reproductive study with fish was not requested.