Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Regulatory Note

REG2000-02

Bromoxynil Use on Bromoxynil-Tolerant Canola Varieties

Based on the evaluation of health, environmental and value data made available, this new use has demonstrated safety, merit and value. In consideration of all available information, the Pest Management Regulatory Agency has determined that this new use for bromoxynil is acceptable for registration.

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Bromoxynil is registered in Canada as a post emergent herbicide to control broadleaf weeds in a number of crops including wheat (spring, winter and durum), barley, oat, fall rye, corn (sweet and field), alfalfa (seedling and established), triticale, canary grass and numerous forage grasses (seedling applications only).

An application was received by the Pest Management Regulatory Agency to expand the bromoxynil use pattern to include treatment on genetically modified canola varieties that are tolerant to this herbicide. To support this application, the registrant submitted health, environmental and value data.

Selected canola varieties have been modified so that they can metabolize bromoxynil (which has herbicidal activity) to the 3,5-dibromo-4-hydroxybenzoic acid (DBHA), which is not herbicidally active. The studies provided reaffirm that the residue of concern is the parent bromoxynil and its acid metabolite DBHA. The analyses of plants taken at the interim stage of growth (stage 4) showed that the genetically modified canola plants had metabolized the bromoxynil through and beyond the DBHA acid metabolite stage. At the final harvest stage, the transformed canola plants had extensively metabolized the bromoxynil in the foliage, giving rise to significant amounts of polar materials and thus forming the extractable residue. In the conventional canola, bromoxynil was the principal component of the residue, at both the interim and final harvest stages.

The analytical method used for the analysis of collected samples and enforcement of the tolerances has been validated. The method involves alkaline hydrolysis in methanolic KOH to convert residues to bromoxynil, followed by cleanup on a Florisil column, and determination by gas chromatography with a mass selective detector.

Supervised residue trials conducted on bromoxynil tolerant canola in Canada between 1996 and 1997 have shown that the maximum residues of bromoxynil and the DBHA acid metabolite in canola seeds, were less than 0.05 parts per million (ppm) each. In these trials, samples were collected 71-119 days following the last application of bromoxynil at rates up to the recommended Canadian rate. Consequently, a maximum residue level of 0.1 ppm should be established to cover residues of bromoxynil and DBHA in bromoxynil tolerant canola.

The chronic dietary risk assessment indicated that the existing and proposed uses of bromoxynil would not pose an unacceptable dietary risk (both food and water) to any segment of the population, including infants, children and seniors. The average potential daily intake was 19% of the allowable daily intake, established at 0.003 mg/kg body weight. The highest potential daily intake/allowable daily intake percentage was for children 1–6 years of age, calculated to be approximately 35%.

An environmental assessment has concluded that the new use of bromoxynil is acceptable, providing the most restrictive buffer zone is observed when tank mixing with another herbicide product.

A value assessment has determined that bromoxynil tolerant canola varieties are tolerant to this herbicide when used in accordance with the use directions identified on the label. The addition of a gene to canola has had no cost in terms of crop tolerance or yield, while maintaining broadleaf weed control.

Also, as part of the value assessment, the issue of whether this pesticide was registered in the United States for the specific use and whether it had a tolerance in the United States was considered. Because bromoxynil is not registered for use on canola and does not have a tolerance or an allowable residue level in the United States, this could result in the treated canola not being allowed entry into the United States market.

To mitigate this aspect of value considerations, it was required as a condition of registration that a note be put on the label stating: “Import tolerance and registration applications have been filed in the United States. However, this is not yet a registered use in the United States and no import tolerance has yet been established in the United States.”

Based on the evaluation of health, environmental and value data made available, this new use has demonstrated safety, merit and value. In consideration of all available information, the Pest Management Regulatory Agency has determined that this new use for bromoxynil is acceptable for registration.