Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Re-evaluation Decision Document RRD2006-07

Bromacil

The purpose of this Re-evaluation Decision Document (RRD) is to notify registrants, pesticide regulatory officials and the Canadian public that Health Canada's Pest Management Regulatory Agency (PMRA) has re-evaluated the active ingredient bromacil and its associated uses as a herbicide for the control of broadleaf weeds, grasses and brush on non-crop land.

On 23 June 2004, Proposed Acceptability for Continuing Registration document PACR2004-22, *Re-evaluation of Bromacil*, was published for consultation. The PMRA has reviewed the comments received and provides a response in Appendix I of this RRD. These comments did not result in any substantive changes to the regulatory decision described in PACR2004-22.

The PMRA has determined that this active ingredient is acceptable for continued registration. Mitigation measures to further protect workers and the environment are specified in Appendix II of this RRD. The registrants have been informed by letter of the specific requirements, including confirmatory data requirements defined in this RRD (Appendix III), affecting their product registrations and the regulatory options available to comply with this decision.

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Appendix I Comments on PACR2004-22 and Responses

1.0 General Comments

1.1 Requirement to Provide Training Material

The registrant contends that providing training material to applicators in Canada regarding the use of bromacil is unnecessary. Training materials were required in the United States to help mitigate the risk from bromacil used in intensive citrus production in Florida, where soils are very sandy and the water table is shallow. In Canada, the risk of water contamination is significantly lower because bromacil is used only in non-agricultural areas and the volume used per year is very low. Given that there are a number of label amendments to mitigate groundwater risks, the registrant proposes to notify bromacil users by letter of the new label changes.

Response

The PMRA accepts the registrant's proposal of notifying bromacil users of the new label changes by letter.

2.0 Comments Pertaining to the Environment

2.1 Proposed Buffer Zones

The buffer zone proposed in Canada is significantly larger than the buffer zones required in the United States. The registrant believes this to be due to a number of conservative assumptions made by the PMRA in the calculation of the buffer zones. According to the registrant, these conservative assumptions include the use of a calculated no observed effect level value instead of the concentration that has a 50% adverse impact on the population (EC_{50}) from an algal study as well as the use of a conservative scenario including a static, extremely shallow body of water for the calculation of the expected environmental concentration (EEC) of bromacil and the use of a large safety factor (100×). The registrant presented an alternative calculation using a different set of assumptions that resulted in a smaller buffer zone.

Response

In the risk assessment, the PMRA used a no observed effect concentration (NOEC) as the toxicity endpoint of concern. The use of the EC_{50} value implies an acceptance of an initial 50% adverse impact on an aquatic population (in this case, green algae). Although the generation time for algae is very short; there is no definitive information on an appropriate cut-off for recovery of a population; i.e., what toxicity endpoint to use knowing that the population will recover from that initial impact. For this reason, the PMRA has used an estimation of the NOEC to signify that any level of impact is not acceptable.

Based on the use pattern for bromacil, the 15-cm water depth is the standard water depth used for non-cropland applications. This depth was based on a recommendation from the Department of Fisheries and Oceans on the depth of fish-bearing streams in forestry ecosystems.

The statement regarding the PMRA's use of a "100× safety factor " in the buffer zone calculation is unclear. The PMRA does not apply safety factors in the environmental risk assessment.

For estimating buffer zone distances, the PMRA used a ground spray drift model developed from the data of Nordby and Skuterud[1].

For the above-mentioned reasons, the PMRA maintains its position on the buffer zone requirement for bromacil product labels. It should be noted that this buffer zone is only required for groundboom sprays and aquatic habitats. The PMRA has released PRO2005-06, *Agricultural Buffer Zone Strategy Proposal*, which would allow applicators to observe smaller, site-specific buffer zones when specific application techniques are used.

2.2 Water Monitoring

The registrant disagrees with the requirement to monitor levels of bromacil in groundwater in Canada. The study was required in the United States because of potential groundwater contamination from application of bromacil to citrus crops in Florida, where soils are very sandy and the water table is shallow. This monitoring study and other measures implemented in the United States have adequately mitigated the risk of groundwater contamination in that country. In Canada, bromacil is only used in non-agricultural areas and the volume used per year is very low. To the registrant's knowledge, bromacil has not been detected in groundwater as a result of this particular use pattern. Therefore, the risk for groundwater contamination in Canada is significantly lower and the requirement for a Canadian groundwater monitoring study is not warranted.

Response

Although bromacil is registered in Canada for non-cropland use only, potential water contamination could occur due to the leachability and persistence of bromacil. Therefore, the PMRA requires water monitoring data or a scientific rationale requested in the PACR2004-22, *Re-evaluation of Bromacil,* to support the relevant Canadian use pattern.

[1] Nordby, A., and R. Skuterud. 1975. The effects of boom height, working pressure, and wind speed on spray drift. *Weed Research*. **14**: 385–395.

The scientific rationale should include specific information on bromacil use in Canada (e.g., areas of use, volume used in the last five years, typical application rates, etc.), and establish the vulnerability of areas of use to ground water contamination (i.e., provide information on soil type and ground water depth in areas of use). Any existing Canadian water monitoring data should also be submitted.

2.3 Deletion of the Term "Coulee"

The registrant proposes to delete the term "coulee" in the environmental hazard statement as it refers to a landform and is not an aquatic habitat.

Response

The term "coulee" refers to a depression or gully formed in prehistory presumably by water erosion. Thus, it is correct to remove the term coulee from our list of aquatic habitats.

Appendix II Label Amendments for Bromacil

NOTE: The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the following label statements.

The Canadian labels of all bromacil end-use products must be amended as follows.

I) The following statements must be added to the **"PRECAUTIONS"** section,

For all end-use products:

- "Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be allowed in the area during application."

- "Do not use in residential areas. Residential areas are defined as sites where bystanders including children may be potentially exposed during or after applying. This includes around homes, on school grounds, in parks, playgrounds, playing fields, around public buildings or any other areas where the general public including children could be exposed."

- "The use of this chemical may result in contamination of groundwater particularly in areas where soils are permeable (e.g., sandy soil) and/or the depth to the water table is shallow."

- "To reduce runoff from treated areas into aquatic habitats, consider the characteristics and conditions of the site before treatment. Site characteristics and conditions that may lead to runoff include, but are not limited to, heavy rainfall, moderate to steep slope, bare soil, poorly draining soil (e.g., soils that are compacted, fine textured, or low in organic matter such as clay)."

- "Avoid application of this product when heavy rain is forecast."

- Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.

For end-use products formulated as wettable powder, dry flowable and water soluble liquid:

- "Wear long pants, a long-sleeved shirt, shoes and socks when handling this product. In addition, wear chemical-resistant gloves during mixing, loading, clean up and repair activities and during application when using a hand wand or a backpack/knapsack sprayer."

- "Avoid entry into treated area until spray has dried."

For end-use products formulated as wettable powder and dry flowable:

- "Wear a dust mask during mixing/loading."

NOTE: The registrant has the option of packaging the dry flowable/wettable powder end-use product in water soluble bags, in which case, mixer/loaders would no longer be required to wear a dust mask.

For end-use products formulated as pellet:

- "Do not apply by hand."

II) The following statements must be added to the **"DIRECTIONS FOR USE"** section,

For all end-use products:

- "**DO NOT apply by air**."

- "Do not treat ditches, wellheads and bridge approaches. Do not treat sites which are adjacent to and surrounding water supply reservoirs, supply streams, lakes and ponds."

- "DO NOT apply directly to aquatic habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats. Do not contaminate the above aquatic habitats when cleaning and rinsing spray equipment or containers."

For end-use products formulated as wettable powder, dry flowable and water soluble liquid:

- "**DO NOT** apply during periods of dead calm or when winds are gusty.

Buffer zones
A buffer zone of 65 metres is required between the point of direct application and the closest downwind edge of sensitive aquatic habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands).

When a tank mixture is used, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture."

III) Labels of all end-use products must be amended to limit the maximum application rate of bromacil to 13.5 kg per hectare per year and to specify the timing of application as well as the number of applications per year for all uses.

IV) All statements permitting use on ditches, wellheads and bridge approaches must be deleted from the labels of all currently registered end-use products.

Registrants are required to notify bromacil users alerting them to the new label directions pertaining to the mitigation of the risk of water contamination.

Appendix III Data Requirements for Bromacil

The registrant of the technical bromacil is required to submit the following data within 24 months of publication of this decision document.

- Data to address potential exposure through drinking water in Canada are required. Any existing Canadian water monitoring data and the ground water studies requested by the United States Environmental Protection Agency (USEPA) are also required; submission of a science-based rationale may be acceptable.

Registrants should note that specific data, selected from the data package that was submitted to the USEPA to support re-registration, may be required by the PMRA in the future with respect to use expansions, special reviews or minor uses, or to establish maximum residue limits (MRLs).