Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Proposed Acceptability for Continuing Registration

PACR2006-02

Re-evaluation of Acifluorfen

The purpose of this document is to inform registrants, pesticide regulatory officials and the Canadian public that Health Canada's Pest Management Regulatory Agency (PMRA) has re-evaluated acifluorfen. The PMRA is proposing that acifluorfen is acceptable for continued registration. Additional mitigation measures to further protect workers and the environment are identified in this document. Registrants will be required to submit specified confirmatory data. Upon finalization of the re-evaluation decision, the PMRA will provide registrants of products containing acifluorfen with specific direction on how to address these measures and requirements.

This Proposed Acceptability for Continuing Registration (PACR) document provides a rationale for the proposed regulatory decision for acifluorfen. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications at the address below.

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1.0 Background

The PMRA is re-evaluating all pesticides, both active ingredients and formulated end-use products, that were registered prior to 31 December 1994 to ensure that their continued acceptability is examined using current scientific approaches. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Acifluorfen has been re-evaluated by the PMRA under Re-evaluation Program 1 as described in DIR2001-03. Under Program 1, the PMRA relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents, to assess Canadian pest control products. For products to be re-evaluated under Program 1, there must exist a suitable foreign review that meets the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Based on the outcome of foreign reviews, the PMRA will propose, under Program 1, a regulatory decision and appropriate mitigation measures for Canadian uses of an active ingredient.

The USEPA conducted a re-evaluation of acifluorfen and concluded that, on the basis of health and environmental risk assessments, it was eligible for reregistration with implementation of mitigation measures. These conclusions were published in a 2004 RED document for acifluorfen. In its re-evaluation of acifluorfen, the PMRA based its conclusions on this 2004 RED document, taking into account the Canadian use pattern and issues (e.g., the federal Toxic Substances Management Policy). A review of the chemistry of Canadian products was also conducted.

2.0 Re-evaluation of Acifluorfen

Active substance:	Acifluorfen
Common name:	Acifluorfen
Chemical name:	
IUPAC:	Sodium 5-(2-chloro-α,α,α-trifluoro-*p*-tolyloxy)-2-nitrobenzoate
CAS:	Sodium 5-[2-chloro-4-(trifluoromethyl)-phenoxy]-2-nitrobenzoate
CAS number:	62476-59-9

In Canada, acifluorfen was first registered in 1993. According to current end-use product label, this active ingredient is registered for use in Eastern Canada to control certain

broadleaf weeds and to suppress specific perennial weeds in soybean. Canadian products containing acifluorfen are listed in Appendix I.

Based on the comparison of American and Canadian use patterns, the USEPA assessment described in the RED document for acifluorfen is considered to be an adequate basis for the proposed Canadian re-evaluation decision. The details of the assessments conducted by the USEPA are presented in the RED for acifluorfen.

The federal Toxic Substances Management Policy and Regulatory Directive DIR99-03 were taken into consideration during the review of acifluorfen, and it was concluded that acifluorfen is not a candidate for Track 1 classification. The technical product is not expected to contain impurities of toxicological concern as identified in Regulatory Directive DIR98-04 or Toxic Substances Management Policy Track 1 substances as identified in Appendix II of DIR99-03.

3.0 Proposed Re-evaluation Decision

The USEPA published a RED document for acifluorfen addressing the main science areas that are necessary for Canadian regulatory decisions, i.e., human health and the environment. This document addressed uses of acifluorfen that are also registered in Canada. The PMRA is proposing that acifluorfen is acceptable for continued registration with the implementation of the mitigation measures specified in Section 4.0 of this PACR. Registrants will be required to submit the confirmatory data identified in Section 5.0.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document to allow interested parties an opportunity to provide input into the proposed re-evaluation decision. Registrants of products containing acifluorfen should not apply for label amendments or submit the additional data as described in Section 5.0 during this comment period; they will be informed by letter of the specific instructions for addressing label changes and data requirements once the re-evaluation decision has been finalized.

4.0 Proposed Regulatory Actions

Canadian technical active ingredient and end-use product labels should be amended to reflect the following:

- A revised guarantee statement on the label, to read “Acifluorfen (present as sodium salt)”.

Canadian end-use product labels should be amended to reflect the following:

I) The **“PRECAUTIONS”** section must include the following statement:

- "It is recommended that this product not be applied in a way that will contact workers or other persons, either directly or through drift. Only handlers wearing personal protective equipment may be in the treatment area during application."

II) The **"DIRECTIONS FOR USE"** section must include the following statements:

- "**DO NOT** enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours."

- "**DO NOT** apply this product directly to aquatic habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs, ditches and wetlands), estuaries or marine habitats."

- "Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification."

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

- "**Buffer zones**:

  A buffer zone of 15 metres is required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, pastures, rangelands and shrublands).

  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."

- "**DO NOT** contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes."

III) The following statement must be removed from the section **"DIRECTIONS FOR USE"**:

- "Ground equipment used with standard flat fan nozzles delivered at 200 to 400 litres/ha and at a pressure of 275 to 400 kPa."

IV) The **"ENVIRONMENTAL HAZARDS"** section must include the following statements:

- "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 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."

- "Observe buffer zones as specified under "Directions for Use"."

The label amendments presented above do not include all label requirements for the end-use product, such as first aid statements, disposal statements, precautionary statements, and supplementary protective equipment. Additional information on the label of currently registered product should not be removed unless it contradicts the above label statements. A submission to request label revisions will be required within 90 days of finalization of the re-evaluation decision.

4.1 Maximum Residue Limits

There are no dietary concerns regarding use of acifluorfen on food and feed crops reported in the USEPA RED. This document adequately addresses the Canadian dietary exposure from domestic and imported foods.

Where no specific maximum residue limit (MRL) for a pest control product has been established in the Food and Drug Regulations, subsection B.15.002(1) applies. This requires that residues do not exceed 0.1 ppm and has been considered a general MRL for enforcement purposes. Currently, residues of acifluorfen and its metabolites in all agricultural commodities, including those approved for treatment in Canada are regulated by subsection B.15.002(1). However, changes to this general MRL may be implemented in the future, as indicated in Discussion Document DIS2003-01, *Revocation of the 0.1 ppm General maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002 (1)]*. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRL to be promulgated

5.0 Data Requirements

The technical registrant of acifluorfen will be required to submit the following within 90 days of finalization of the re-evaluation decision:

- a revised Statement of Product Specification Form (SPSF), which is based on the analytical results of the corresponding acid form of the active ingredient and all impurities as well as on dry weight basis to below 0.1%.

Registrants should note that specific data, selected from the data package that was submitted to the USEPA to support reregistration of this active ingredient, may be required by the PMRA in the future with respect to use expansions, special reviews or minor uses, or to establish MRLs.

6.0 Supporting Documentation

The PMRA documents, such as DIR2001-03, and DACO tables can be found on our website at www.pmra-arla.gc.ca. PMRA documents are also available through the Pest Management Information Service. Phone: 1 800 267-6315 within Canada or 1 (613) 736-3799 outside Canada (long distance charges apply); Fax: (613) 736-3798; E-mail: pmra_infoserv@hc-sc.gc.ca.

The federal TSMP is available through Environment Canada's website at www.ec.gc.ca/toxics.

The USEPA RED document, *Reregistration Eligibility Decision for Sodium Acifluorfen, Case No. 2605*, as well as the R.E.D Facts for sodium acifluorfen are available on the Office of Pesticide Programs' website at www.epa.gov/pesticides/reregistration under Chemical Status.

Appendix I Products Containing Acifluorfen Registered in Canada as of 26 May 2005

Product Name	Registrant	Registration Number	Guarantee	Class
Sodium Acifluorfen Technical	United Phosphorus Inc.	23314	43% w/w	Technical Active
Blazer Herbicide	United Phosphorus Inc.	23315	240 g/L	Commercial