Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Re-evaluation Decision Document RRD2006-19

Oxyfluorfen

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 oxyfluorfen and its associated uses as a herbicide for terrestrial food crops.

On 30 June 2005, Proposed Acceptability for Continuing Registration document PACR2005-03, *Re-evaluation of Oxyfluorfen*, was published for consultation. The PMRA has reviewed the comments received and provides responses in Appendix I of this RRD. These comments did not result in substantive changes to the regulatory decision as described in PACR2005-03.

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

(publié aussi en français) **5 May 2006**

This document is published by the Alternative Strategies and Regulatory Affairs Division, Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6605C
Ottawa, Ontario
K1A 0K9

Internet: pmra_publications@hc-sc.gc.ca
www.pmra-arla.gc.ca
Information Service:
1 800 267-6315 or (613) 736-3799
Facsimile: (613) 736-3758

ISBN: 0-662-43116-2 (0-662-43117-0)
Catalogue number: H113-12/2006-19E (H113-12/2006-19E-PDF)

Appendix I Comments to PACR2005-03 and Responses

1.0 Comments Pertaining to the Environment

1.1 Comment Regarding ASAE Spray Quality Classification

Farmers will not be able to implement the Directions for Use regarding proper spray droplet distribution as they will not know what the American Society of Agricultural Engineers (ASAE) spray quality classification refers to; furthermore, not all TeeJet suppliers know these specifications for their nozzles. The information in this section should be written in a way applicators will understand.

Response
The spray quality classification schemes of the ASAE and the British Crop Protection Council are the principal international classification schemes used by nozzle manufacturers to determine the average droplet size for a given nozzle under certain operating conditions. Information on ASAE nozzle classification is available from all nozzle manufacturers (including TeeJet) and is easily accessible to any applicator through company brochures, published spray nozzle guides for applicators, online user manuals and by telephone operator assistance. All pesticide applicators must have sufficient familiarity with their spray equipment to remain compliant with the product labels.

1.2 Comment Regarding Differences in Buffer Zones for Canada and the United States

Why are the Canadian buffer zones (up to 45 m) larger than the American buffer zones (7.6 m) and why is there a terrestrial buffer zone for Canada when there is none in the United States?

Response
The PMRA is not privy to the decision process that resulted in a 7.6 m buffer zone on American labels. The field sprayer application buffer zones for oxyfluorfen presented in PACR2005-03 have been recalculated based on an updated ground sprayer model used by the PMRA (refer to Appendix II for revised values). For field sprayer application buffer zones, the PMRA uses a Canadian spray drift model based on spray trials conducted in the prairies. Buffer zones are based on the observed toxicity to representative non-target organisms and are expected to protect sensitive non-target habitats. The PMRA is obligated to provide mitigative measures from off-site spray drift to sensitive habitats, both aquatic and terrestrial.

1.3 Comment Regarding the Buffer Zone for Raspberries

Terrestrial buffer zones for raspberries are not necessary because the product is applied in such a way as to prevent drift to the target plants and to nearby vegetation.

Response

After consultation with the British Columbia Ministry of Agriculture and Lands, it was determined that current agricultural practices minimize potential spray drift risks related to pesticide application on raspberry plants. Due to the phytotoxicity of oxyfluorfen to raspberry plants, oxyfluorfen is applied in such a way as to substantially limit spray drift potential (i.e., applied using a low boom apparatus with single nozzles directing the spray to the base of the plants under very low pressure and under very low wind conditions). As a result of the above rationale and based on updated ground sprayer models, the PMRA recalculated the buffer zones for oxyfluorfen for raspberries (refer to Appendix II). In addition, the portion of the label referring to primocane suppression for red raspberries (British Columbia only) must be modified as follows:

> Goal 2XL herbicide should be applied to the primocane row in a minimum of 500 litres of water per hectare. Restrict the spray application to the lower 15 cm of the fruiting canes to minimize crop injury from spray contact. Goal 2XL must be applied using a low pressure mounted spray system (200 to 400 kPa). Follow manufacturers recommendations for maintaining the minimum allowable boom height. The use of drift-reducing shrouds or spray shields is recommended. Spray equipment should be calibrated carefully before each use.
>
> **DO NOT** apply Goal 2XL to raspberry crops when windspeeds exceed 8 km/h.

1.4 Comment Regarding Ditches and Drainage Canals

Buffer zones for dry bulb onions are not economically feasible unless ditches surrounding fields are excluded. Please clarify whether ditches and drainage canals are included under “sensitive terrestrial habitats” or “freshwater habitats”.

Response

Constructed ditches and drainage canals surrounding agricultural fields are <u>not</u> considered to be sensitive terrestrial or aquatic habitats; therefore, they are not identified as such on the product label. The PMRA acknowledges that dry ditches can support a variety of plant life and that wet ditches may act as temporary aquatic habitat; however, these are highly manipulated habitats that are often mowed, dredged and such to maintain their primary function as drainage canals. There may be cases where older ditches that are no longer maintained have become “naturalized” streams with complex ecosystems; therefore, these types of ditches <u>are</u> to be considered as sensitive habitats subject to the identified buffer zones.

The PMRA is currently preparing a booklet on Best Management Practices (BMPs) that will stipulate a no-spray zone adjacent to all watercourses of at least one metre; this will ensure that there is no direct overspray of a pesticide into any aquatic area, including ditches or drainage canals. Although the buffer zone statements currently do not provide a list of excluded habitats, this could be reconsidered following input from public consultations on Regulatory Proposal PRO2005-06, *Agricultural Buffer Zone Strategy Proposal*.

Note that buffer zones for oxyfluorfen have been revised based on updated ground sprayer models. As a result, the buffer zones required for dry bulb onions have been reduced (refer to Appendix II).

1.5 Comment Regarding the Size of Terrestrial Buffer Zones

Why is such a large buffer zone required for terrestrial habitats? Oxyfluorfen is a contact herbicide; therefore, the drift of a few droplets poses little risk to surrounding vegetation. Large terrestrial buffer zones could also encourage the removal of vegetation on farm properties, thereby accelerating runoff and leaching processes.

Response

Buffer zone distances are based on the characteristics of spray drift and the observed toxicity to plants. Lab studies have shown that oxyfluorfen has a toxic effect to plants when sprayed at rates similar to those used in the field. Sufficient amounts of off-site drift onto neighbouring plants could result in plant damage. Therefore, buffer zones are required to protect the health of non-target plants in neighbouring sensitive terrestrial habitats.

The PMRA recognizes that there may be economic consequences to farmers who observe buffer zones, and that this may prompt some to consider removing vegetation. However, farmers and regulators need to keep in mind that buffer zones are only one part of an environmental management plan for farms. Large amounts of vegetation also help farmers by providing valuable windbreaks that in turn prevent soil loss by erosion; by preventing runoff, helping with nutrient management goals; and by providing habitat for beneficial insects and wildlife that would assist with an integrated pest management program. It should also be kept in mind that buffer zones are only required for sensitive habitats downwind of the application area and, if necessary, a previously unsprayed area could be sprayed at another time under favourable meteorological conditions. The PMRA is committed to protecting biodiversity in terrestrial habitats and requires buffer zones to safeguard these areas.

Please note that buffer zones for oxyfluorfen have been revised based on updated ground sprayer models. As a result, terrestrial buffer zones have been reduced (refer to Appendix II).

1.6 Comment Regarding the Approach to Buffer Zones

A result-based approach to setting buffer zones should be recommended, whereby it would be specified on label statements that fish and aquatic organisms must not be harmed from spray drift, runoff or leaching. The details of how this would be accomplished should be left up to the farm operator, with guidance given in a best management practices document, to be distributed via the *Standard for Pesticide Education, Training and Certification in Canada*.

Response
Label instructions to "avoid harm to aquatic [or terrestrial] organisms from spray drift" do not provide applicators with any useful mitigation information. Establishing buffer zones allows applicators to know the impact the product can have if applied too close to sensitive habitats. Most importantly, adverse ecological effects can occur, particularly in aquatic systems, at a scale that would not be immediately obvious to land owners.

When a risk to non-target organisms is identified during the environmental assessment for a product, several options for mitigating risk are considered, one of which is buffer zones. Buffer zones allow for a quantitative reduction in risk, which provides reasonable assurance that non-target organisms will not be affected by spray drift if the label instructions are followed. The PMRA is developing a Spray Drift Best Management Practices booklet. It will be distributed with all new agricultural products and would provide more information on how to reduce spray drift than is currently available on product labels.

1.7 Comment Regarding Volume of Information on Pesticide Labels

Too much information on pesticide labels deters applicators from reading the labels. Please write the section with regards to buffer zones in simpler language so applicators can follow the directions.

Response
The PMRA is aware of the need to keep label information short and concise to promote user compliance and reduce confusion. The PMRA is currently reviewing its buffer zone labelling structure and will be engaging the public for feedback on the amount of information to include on product labels. A document for public comment is targeted for release in 2006. This document is part of a larger labelling initiative underway within the PMRA, which aims to clarify, improve and standardize the language used in Canadian pest control product labels.

1.8 Comment Regarding Interpretation of the Term "Downwind"

Please clarify that "downwind" refers to the fact that if the wind is blowing away from freshwater or terrestrial habitat, the applicator can spray immediately next to these areas.

Response
This is correct; a buffer zone is only required for habitats downwind from the site of application. From a drift perspective, there is little or no risk of drift deposit to sensitive habitats upwind from the point of application. However, farm environmental best management practices and provincial pesticide application standards often require a minimum buffer zone around aquatic habitats to protect against off-site pesticide movement from runoff as well as drift. The PMRA's spray drift buffer zones are not intended to mitigate against other routes of off-site movement such as runoff, leaching or vapour drift.

1.9 Comment Regarding Shroud and Cone Technologies

Cone nozzles are reportedly not effective at reducing drift. Also, what is meant by "field sprayer with shrouds"? Are there any construction criteria? Please clarify which shrouds and cones were used to calculate buffer zone numbers.

Response
The PMRA has buffer zone multipliers for two types of drift reducing technology for field sprayers: shrouds and cones. Field sprayers (i.e., boom sprayers) can be equipped with a tent-like shroud around the length of the boom or with plastic cones fitted around each spray nozzle to minimize spray drift, which means that "cones" does not refer to a type of nozzle. Shroud drift reducing technology has been shown in field tests to reduce overall spray drift by approximately 70% and cones can reduce drift by approximately 30%. The buffer zone values for groundboom sprayers with shrouds or with cones are based on these generic drift reduction factors. To avoid any type of market influence that may place undue limitations on operators, the PMRA is not recommending applicators use a particular type of shroud or cone from any given manufacturer. Rather, these multipliers are intended to be representative for these two specific drift-reducing technologies that can be universally applied to any boom-type field sprayer set-up.

1.10 Comment Regarding Buffer Zones for Strawberries and Onions

Proposed buffer zones for strawberries and onions appear excessive, and producers will not be able to comply with them because they are too large. What reference was used and why are buffer zones for strawberries so much smaller than for onions when the application rates for strawberries are 1.0 L/ha and for onions are 0.5 L/ha? In addition, the PMRA should consider the effect of newer drift reducing technologies, such as air induction or low drift nozzles, and droplet size and water volume factors, that would allow for reduced buffer zones to protect neighbouring sensitive habitats.

Response

Currently, the PMRA uses the no observed effect concentration (NOEC) for fish, *Daphnia* sp., algae or *Lemna* sp. (aquatic organisms) and the EC_{25} (a 25% inhibitory effect in a measurement parameter such as seed germination, seedling emergence, plant height, plant dry weight, shoot length or shoot weight) for terrestrial plants as the endpoints of concern in its risk assessments. In either case, terrestrial or aquatic, the appropriate endpoint of the most sensitive non-target organism is used for the purpose of calculating a buffer zone.

Even though application rates for onions are lower than those for than strawberries, repeat applications to onions are allowed (up to four per year), resulting in a larger cumulative application rate to onions. Therefore, a larger buffer zone is required for onions than for strawberries. However, buffer zones for oxyfluorfen have been revised based on updated ground sprayer models. As a result, buffer zones have been reduced for both strawberries and onions (refer to Appendix II).

The PMRA recognizes that recent improvements in nozzle technology have resulted in a number of low drift nozzles being released on the market and that these nozzles are being used in the field. Unfortunately, the PMRA has not yet been able to review drift reduction data for low drift nozzles; therefore, we are not able to provide buffer zone reductions for their use at this time. The PMRA has recently published Regulatory Proposal PRO2005-06, *Agricultural Buffer Zone Strategy Proposal*, which includes buffer zone reduction strategies based on meteorological and equipment factors that would allow strawberry and onion producers to reduce their buffer zones at their site. The PMRA also intends to examine the effectiveness of using low drift nozzles in its buffer zone strategy and would be interested in reviewing any information/data that other governmental departments, industry or researchers might have on these nozzles.

Appendix II Label Amendments for Oxyfluorfen

Canadian end-use product labels should be amended to include the following statements to further protect workers and the environment.

In the **PRECAUTIONS** section:

- "Wear goggles or a face shield, chemical-resistant gloves, coveralls over a long-sleeved shirt and long pants, chemical-resistant footwear such as rubber boots, and a chemical-resistant apron during mixing, loading, cleanup and repair activities. Applicators must wear chemical-resistant gloves, coveralls over a long-sleeved shirt and long pants, and chemical-resistant footwear such as rubber boots."

- "Do not re-enter treated areas until 24 hours after application to raspberries or strawberries, and 48 hours after application to onions."

- "Remove personal protective equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash hands (or any other skin that came into contact with the product) with soap and water and change into clean clothing."

- "Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."

- "Remove clothing/personal protective equipment immediately if pesticide comes in contact with skin through soaked clothing or spills. Then wash skin thoroughly and put on clean clothing. Wash contaminated clothing before reuse."

In the **ENVIRONMENTAL HAZARDS** section:

- "TOXIC to aquatic organisms and terrestrial plants. Observe buffer zones specified under DIRECTIONS FOR USE."

In the **DIRECTIONS FOR USE** section:

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

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

- "**Buffer zones:**
  The buffer zones specified in the table below are 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, rangelands, and shrublands), sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands), and estuarine/marine habitats.

Method of Application	Crop	Buffer Zones (metres) Required for the Protection of:			
		Aquatic Habitat of Depths:			Terrestrial Habitat
		< 1 m	1–3 m	> 3 m	
Field sprayer*	Dry bulb onion	20	5	3	15
	Strawberry	10	4	2	7
	Raspberry (British Columbia only)+	1	1	1	1

* For field sprayer application, buffer zones can be reduced with the use of drift reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy or ground, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy or ground, the labelled buffer zone can be reduced by 30%.

\+ Application to raspberry crops is restricted to windspeeds of 8 km/h or less."

For primocane suppression on red raspberries (British Columbia only):

Goal 2XL herbicide should be applied to the primocane row in a minimum of 500 litres of water per hectare. Restrict the spray application to the lower 15 cm of the fruiting canes to minimize crop injury from spray contact. Goal 2XL must be applied using a low pressure mounted spray system (200 to 400 kPa). Follow manufacturers recommendations for maintaining the minimum allowable boom height. The use of drift-reducing shrouds or spray shields is recommended. Spray equipment should be calibrated carefully before each use.

"**DO NOT** apply Goal 2XL to raspberry crops when windspeeds exceed 8 km/h."

Appendix III Data Requirements

The United States Environmental Protection Agency (USEPA) required additional surface water monitoring data to confirm that acceptable levels were not exceeded. This is also required by the PMRA. The surface water monitoring study required as a condition of reregistration by the USEPA, with the inclusion of a science-based rationale to support the relevance to Canada, may be acceptable. Any existing Canadian drinking water monitoring data are required. The technical registrant of oxyfluorfen will be required to submit these data within 24 months of finalization of the decision document.

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 maximum residue limits (MRLs).