# Proposed Acceptability for Continuing Registration

#### PACR2004-41

## Re-evaluation of Paraquat Dichloride

The purpose of this document is to inform registrants, pesticide regulatory officials and the Canadian public that the Pest Management Regulatory Agency (PMRA) has completed a re-evaluation of paraquat dichloride. The PMRA has determined that paraquat dichloride is acceptable for continued registration provided that the proposed mitigation measures are adopted. Additional data requirements are identified. Upon finalization of the re-evaluation decision, the PMRA will provide registrants of products containing paraquat dichloride 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 paraquat dichloride. 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 the Publications Coordinator 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 (EPs), that were registered prior to 31 December 1994 to ensure that their continued acceptability is examined using current scientific approaches. Regulatory Directive <u>DIR2001-03</u>, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Paraquat dichloride 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 paraquat dichloride and concluded that, on the basis of health and environmental risk assessments, it was eligible for reregistration with the implementation of mitigation measures. These conclusions were published in a 1997 RED document for paraquat dichloride. In its re-evaluation of paraquat dichloride, the PMRA based its conclusions on this 1997 RED document, taking into account the Canadian use pattern and Canadian issues (e.g., the federal Toxic Substances Management Policy [TSMP]). A review of the chemistry of Canadian products was also conducted.

#### 2.0 Re-evaluation of paraquat dichloride

Common name: paraquat dichloride

Chemical name: 1,1'-dimethyl-4,4'-bipyridinium dichloride

Chemical family: bipyridylnium, dipyridylnium

CAS registry number: 1910-42-5

Empirical formula:  $C_{12}H_{14}Cl_2N_2$ 

In Canada, paraquat dichloride was first registered in 1963. According to current EP labels, it is registered in Canada for use in a variety of fruit, vegetable and other field crops as well as shelterbelts. Currently registered Canadian products containing paraquat dichloride are listed in Appendix I. Registered uses of paraquat dichloride are listed in Appendix II.

Based on the comparison of American and Canadian use patterns, the USEPA assessment described in the RED document for paraquat dichloride 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 USEPA RED for paraquat dichloride.

The federal TSMP and Regulatory Directive <u>DIR99-03</u> were taken into consideration during the review of paraquat dichloride, and it was concluded that paraquat dichloride is not a TSMP Track 1 substance. The technical product is not expected to contain impurities of toxicological concern as identified in Regulatory Directive <u>DIR98-04</u> or TSMP Track 1 substances as identified in Appendix II of DIR99-03.

#### 3.0 Proposed re-evaluation decision

The USEPA published a RED document for paraquat dichloride addressing the main science areas that are necessary for Canadian regulatory decisions, i.e., human health and the environment. This document addressed uses of paraquat dichloride that are also registered in Canada. Based on the USEPA RED and Canadian use pattern, the PMRA has determined that paraquat dichloride is acceptable for continued registration provided that the mitigation measures specified in Section 4.0 are adopted. Additional data requirements are 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 paraquat dichloride should not apply for label amendments or submit the additional data 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

Based on the USEPA RED and the Canadian use pattern, Canadian EP label must be amended to include the following statements to further protect workers and the environment.

- 1. The following statement must be added to the "Precautions" section of the label:
  - Wear coveralls over a long-sleeved shirt and long pants during application with a backpack sprayer.
- 2. In the "Directions for Use" section pertaining to all uses of paraquat dichloride, the following statements must be added:
  - Do not use in residential areas or areas where bystanders may come into contact with treated foliage (e.g., lawns, walks, driveways, tennis courts or similar areas). Residential areas are defined as sites where bystanders including children may be potentially exposed during or after spraying. This includes around homes, school, parks, playgrounds, playing fields, public buildings or any other areas where the general public including children could be exposed.
  - Do not apply in conditions where the product may drift to areas of human habitation or to areas in which human activity occurs such as houses, cottages, schools and parks. Take into consideration meteorological conditions (e.g. wind speed, wind direction, temperature) as well as application equipment and sprayer settings used for application.
  - **DO NOT** apply during periods of dead calm or when winds are gusty.
  - **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, pastures, rangelands and shrublands) and sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, coulees, 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.

Method of application	Buffer zone (m) for protection of:				
	Terrestrial habitats	Aquatic habitats of water depths:			
Ground boom sprayer	25	< 1 m	1–3 m	> 3 m	
		60	50	40	

- For **non-spot** applications with backpack sprayers, apply paraquat up to a maximum rate of 0.7 kg a.i./ha in a minimum water volume of 187 L/ha.
- 3. The registrants have agreed to discontinue the following uses:
  - Use-Site Category (USC) # 2—Aquatic Non-food Sites;
  - USC # 4—Forest and Woodlots;
  - USC # 16—Industrial and Domestic Vegetation Control Non-food Sites (including chemical mowing); and
  - USC #30—Turf.

Registrants are required to remove references to the above uses from the EP label.

A submission to request label revisions is required within 90 days of finalization of the reevaluation decision.

#### 4.1 Maximum residue limits

Paraquat is currently registered for use on a number of food and feed crops in Canada, and there are currently no maximum residue limits (MRLs) specified for paraquat in Table II, Division 15 of the Canadian Food and Drug Regulations. Paraquat is used on agricultural crops in other countries. Currently, any residues of paraquat on food grown in or imported to Canada must not exceed 0.1 ppm, a general MRL specified in subsection B.15.002(1) of the Food and Drug Regulations. However, changes to this general MRL may be implemented in the future, as indicated in the Discussion Document DIS2003-01, Revocation of the 0.1 ppm General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)].

#### 5.0 Additional data requirements

The technical registrant(s) of paraquat dichloride is required to submit the following within 24 months of finalization of the re-evaluation decision:

• all data (as they relate to the Canadian use pattern) submitted to the USEPA in response to the data call-in prior to the reregistration in the United States and USEPA Data Evaluation Reports (DERs);

- all data (as they relate to the Canadian use pattern) that were required by the USEPA as a condition of reregistration of paraquat dichloride;
- a commitment and schedule to address Canadian requirements that are not addressed through submission of the data outlined above. These are outlined in the PMRA's data code (DACO) tables for USCs # 4, 13 and 14. The registrant is required to address the following sections of DACO tables:
  - for the TGAI: DACOs 2 through 9, inclusive
  - for the EP: DACOs 5 through 9, inclusive

The above data and additional data may be required sooner if expansion of current uses of paraquat dichloride is requested.

#### 6.0 Supporting documentation

PMRA documents, such as DIR2001-03, and DACO tables can be found on our website at <a href="www.pmra-arla.gc.ca">www.pmra-arla.gc.ca</a>. 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: <a href="mailto:pmra">pmra</a> infoserv@hc-sc.gc.ca.

The federal TSMP is available through Environment Canada's website at <a href="https://www.ec.gc.ca/toxics">www.ec.gc.ca/toxics</a>.

The USEPA RED document (*Paraquat Dichloride*) is available on the Office of Pesticide Programs' website at <a href="https://www.epa.gov/pesticides/reregistration">www.epa.gov/pesticides/reregistration</a> under Chemical Status.

# Appendix I Products containing paraquat dichloride registered in Canada as of 31 March 2004

Product name	Class	Guarantee	Registrant	Registration number
Gramoxone Liquid Herbicide	Commercial	200 g/L	Syngenta Crop Protection Canada Ltd.	8661
Paraquat Technical (PAQ)	Technical	32%		21247
Gramoxone PDQ Liquid Non- Selective Herbicide	Agricultural	Paraquat 132 g/L Diquat 66 g/L		25448 1
Paraquat Dichloride Manufacturing Concentrate	Manufacturing Concentrate	32%		21273
CO-OP Weedrite Granular Herbicide	Domestic	Paraquat 2.5% Diquat 2.5%	Interprovincial Cooperation Ltd.	10627 <sup>2</sup>
Later's Pronto Weed and Grass Killer	Domestic	Paraquat 0.15 g/L Diquat 0.15 g/L	NuGro IP Inc.	24357 <sup>3</sup>

Product 25448 was discontinued on 31 May 2003 and will expire on 31 May 2006. This product was not included in this review.

<sup>2</sup> Product 10627 will be discontinued on 31 December 2004 and will expire on 31 December 2005. This product was not included in this review.

Product 24357 was discontinued on 31 December 2001 and will expire on 31 December 2004. This product was not included in this review.

# Appendix II Currently registered Canadian paraquat dichloride uses

	USC	Site		
2	Aquatic Non-food Sites	Aquatic weeds		
4	Forests and Woodlots	Shelterbelts, nursery crops		
7	Industrial Oil Seed Crops and Fibre Crops	Flax (for linoleum production)		
13	Terrestrial Feed Crops	Field crops: corn, alfalfa (established), barley, canary seed, canola, dry common beans, field peas, flax (including low linolenic acid varieties), mustard, oats, rye, soybeans, sunflowers, triticale, wheat  Pasture renovation (minimum tillage), roughland pasture renovation (birdsfoot trefoil), alfalfa (established)		
14	Terrestrial Food Crops	Field crops: barley, canola, corn, dry common beans, field peas, flax (including low linolenic acid varieties), lentils, mustard, oats, potatoes, rye, soybeans, sunflowers, triticale, wheat, asparagus  Filberts and hazelnuts		
		Vegetable crops: beets, beans (all types), carrots, cole crops, cucumbers, onion, peas, and turnips		
		Fruit crops: apples, apricots, cherries, currants, gooseberries, highbush blueberries, peaches, pears, blackberries, loganberries, red raspberries, strawberries		
16	Industrial and Domestic Vegetation Control for Non-food Sites	Non-crop land (industrial sites and rights-of-way)		
27	Ornamentals Outdoor	Filberts and hazelnuts		
30	Turf	Turf		