Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Proposed Acceptability for Continuing Registration

PACR2005-09

Re-evaluation of Gibberellin A4A7 and Gibberellic Acid

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 gibberellin A_4A_7 (GIB) and gibberellic acid (GIA). The PMRA has determined that GIB and GIA are acceptable for continued registration with the implementation of additional mitigation measures to further protect workers and the environment. Registrants will be required to submit specified confirmatory data. Upon finalization of the re-evaluation decision, the PMRA will provide registrants of products containing GIB or GIA 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 GIB and GIA. 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 Section at the address below.

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1.0 Background

Health Canada's Pest Management Regulatory Agency (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.

Gibberellin A_4A_7 (GIB) and gibberellic acid (GIA) have 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 GIB and GIA, and concluded that, on the basis of health and environmental risk assessments, they were eligible for reregistration with implementation of mitigation measures. These conclusions were published in a 1995 RED document. The USEPA also published a risk assessment to support an exemption from the requirement of tolerances for plant growth regulators, including GIB and GIA, in the Federal Register in 1998. In its re-evaluation of GIB and GIA, the PMRA based its conclusions on this 1995 RED document and on the 1998 Federal Register, 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 Gibberellin A_4A_7 (GIB) and Gibberellic Acid (GIA)

Active substance:	Gibberellin A_4A_7 (GA_4+GA_7) and gibberellic acid (GA_3)
CAS number:	GA_4: 468-44-0 GA_7: 510-75-8 GA_3: 77-06-5

In Canada, GIB and GIA were first registered in 1980 and 1973, respectively, and are used as commercial plant growth regulators. According to current end-use product labels, GIB is registered for use on lilies (greenhouse and/or outdoor) and apples, and GIA is registered for use on sweet/sour cherries and rhubarb roots. Currently registered Canadian products containing GIB or GIA are listed in Appendix I and II.

Based on the comparison of American and Canadian use patterns, the USEPA assessments described in the RED document and in the 1998 Federal Register are 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 these two documents.

The federal TSMP and Regulatory Directive DIR99-03 were taken into consideration during the review of GIB and GIA, and it was concluded that GIB and GIA are not candidates for Track 1 classification. Technical products are not expected to contain impurities of toxicological concern as identified in Regulatory Directive DIR98-04 or TSMP Track 1 substances as identified in Appendix II of DIR99-03.

3.0 Proposed Re-evaluation Decision

The USEPA published an assessment of reregistration eligibility of GIB and GIA in a 1995 RED and a dietary risk assessment for a selected number of plant growth regulators, including GIB and GIA, in the 1998 Federal Register. These documents addressed the main science areas that are necessary for Canadian regulatory decisions for GIB as well as GIA and addressed uses that are also registered in Canada. The PMRA has determined that GIB and GIA are 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.

In Canada, all GIB end-use products are formulated with 6-benzylaminopurine, which the PMRA is currently re-evaluating. Consequently, GIB end-use products will be acceptable for continued registration when the re-evaluation of 6-benzylaminopurine is also complete. The registrant must implement the most conservative actions resulting from the respective re-evaluation reviews.

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

- A "**PRECAUTIONS**" section must appear on all end-use product labels and must include the following statements:
    - "Wear long pants, a long-sleeved shirt and shoes plus socks during mixing/loading, application, clean-up, and repair activities. In addition, wear chemical-resistant gloves during mixing/loading, clean-up and repair activities."
    - "Do not re-enter or allow re-entry into treated areas until 12 hours after application."
- A "**DIRECTIONS FOR USE**" section must appear on all end-use product labels and must include the following statements:
    - "Airblast application: Do not direct spray above plants to be treated. Turn off outward pointing nozzles at row ends and outer rows. Do not apply when wind speed is greater than 16 km/h at the application site as measured outside of the treatment area on the upwind side."
    - "Do not apply by air."

    In the directions for use on sour cherries:
    - "Observe a minimum interval to harvest of 21 days after treatment."

    In the directions for use on apples:
    - "Observe a minimum interval to harvest of 28 days after treatment."

    In the directions for use on rhubarb:
    - "Observe a minimum interval to harvest of 110 days after treatment."
    - In the directions for use on lilies, information must indicate whether use on lilies is in greenhouse and/or outdoor.

A submission to request label revisions will be required within 90 days of finalization of the re-evaluation decision.

A revised Statement of Product Specification Form for gibberellin A_4 to support the nominal guarantee is also required within 90 days of finalization of the re-evaluation decision.

4.1 Maximum Residue Limits

There are no dietary concerns regarding use of GIB and GIA on food and feed crops reported in the USEPA RED. This document adequately addresses the Canadian dietary exposure. In Canada, GIB is currently registered for use on apples, while GIA is currently registered for use on sweet/sour cherries and rhubarb roots. GIB and GIA are used on agricultural crops in other countries. Currently, Maximum Residue Limits (MRLs) of GIB and GIA and their metabolites must not exceed 0.1 ppm, a general MRL specified in Regulation B.15.002(1) of the Canadian Food and Drug Regulations. 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)]*.

5.0 Additional Data Requirements

The technical registrants of GIB and GIA will be 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).

6.0 Supporting Documentation

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 (*Gibberellic Acid*) is available on the Office of Pesticide Programs' website at www.epa.gov/pesticides/reregistration under Chemical Status.

The risk assessment supporting an exemption from the requirement of tolerances for plant growth regulators published in the Federal Register on 23 October 1998 (*Certain Plant Regulators, Cytokinins, Auxins, Gibberellins, Ethylene, and Pelargonic Acid; Tolerance Exemptions*. Federal Register. 1998. Volume 63, Number 205. Pp. 26882–56886) is available on the Federal Register via the United States Government Printing Office Access (www.access.gpo.gov).

Appendix I Products Containing Gibberellin A_4A_7 Registered in Canada as of 31 December 2004

Product Name	Registrant	Registration Number	Guarantee		Class
			Gibberellin A_4A_7	Other	
Gibberellin A4+A7 Technical Powder	Valent Biosciences Corporation	25532	92%	—	Technical
Promalin Plant Growth Regulator Solution	Valent Biosciences Corporation	27137	1.8%	1.8%*	Commercial
Promalin Plant Growth Regulator Solution	Valent Biosciences Corporation	16636	1.8%	1.8%*	Commercial
Fascination Plant Growth Regulator Solution	Valent Biosciences Corporation	27135	1.8%	1.8%*	Commercial
Accel Plant Growth Regulator Solution	Valent Biosciences Corporation	24593	0.18%	1.8%*	Commercial

* 6-Benzylaminopurine

Appendix II Products Containing Gibberellic Acid Registered in Canada as of 31 December 2004

Product Name	Registrant	Registration Number	Guarantee	Class
Technical Grade Gibberellic Acid	Norac Concepts Inc.	27652	90%	Technical
Falgro Tablet Plant Growth Regulator	Norac Concepts Inc.	27653	1 gram per tablet	Commercial
Activol contains Gibberellic Acid	Norac Concepts Inc.	11904	0.92 gram per tablet	Commercial