Re-evaluation Decision RVD2024-06

Agrobacterium radiobacter Strain K84 and its Associated End-use Product

Final Decision

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Re-evaluation decision for *Agrobacterium radiobacter* strain K84 and associated end-use product

Under the authority of the *Pest Control Products Act*, all registered pesticides must be re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they meet current health and environmental standards and have value. The re-evaluation considers data and information from pesticide manufacturers, published scientific reports and other regulatory agencies, as well as comments received during public consultations. Health Canada applies internationally accepted risk assessment methods as well as current risk management approaches and policies.

This document presents the final re-evaluation decision[1] for the re-evaluation of *Agrobacterium radiobacter* strain K84 including responses to comments received, and the required label updates. All products containing *Agrobacterium radiobacter* strain K84 regulated under the *Pest Control Products Act* in Canada are subject to this re-evaluation decision.

Agrobacterium radiobacter strain K84 is a naturally occurring soil-dwelling, gram-negative, short-rod aerobic bacterium used as a bactericide to control crown gall disease on seeds and nursery stock of stone fruit, pome fruit, berries, tree nuts, ornamental flowers, shrubs and trees as well as grapes and hops. The end-use product is applied to seeds, seedlings and cuttings (rootstock and rooted) at planting as a dip treatment only. The mode of action of *Agrobacterium radiobacter* strain K84 is through direct competition that is primarily facilitated by the production of a bacteriocin specific against certain pathogenic strains of Agrobacterium spp.

Currently registered end-use product containing *Agrobacterium radiobacter* strain K84 can be found in the Pesticide Product Information Database and in Appendix I. The Proposed Re-evaluation Decision PRVD2023-04, *Agrobacterium radiobacter strain K84 and its Associated End-use Product*[2] containing the evaluation and proposed decision for *Agrobacterium radiobacter* strain K84, underwent a 90-day consultation period ending on 26 November 2023. PRVD2023-04 proposed continued registration of *Agrobacterium radiobacter* strain K84 and its associated registered end-use product for sale and use in Canada, with updates to label directions and precautions to reflect the current labelling standards and to improve clarity (Appendix IV).

Health Canada received comments during the public consultation. Commenters are listed in Appendix II. The comments are summarized in Appendix III along with the responses by Health Canada. The comments did not result in revisions or changes to the proposed re-evaluation decision as described in PRVD2023-04. A reference list of information used as the basis for the proposed re-evaluation decision is included in PRVD2023-04.

[1] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

[2] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

Re-evaluation decision for *Agrobacterium radiobacter* strain K84

Health Canada has completed the re-evaluation of *Agrobacterium radiobacter* strain K84. Under the authority of the *Pest Control Products Act*, Health Canada has determined that continued registration of products containing *Agrobacterium radiobacter* strain K84 is acceptable. An evaluation of available scientific information found that the use of *Agrobacterium radiobacter* strain K84 products meets current standards for protection of human health and the environment and have acceptable value when used according to revised conditions of registration which includes label amendments.

Risk mitigation measures

Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures to protect human health and the environment and must be followed by law. The required updated label statements, as a result of the re-evaluation of *Agrobacterium radiobacter* strain K84, are summarized below. Refer to Appendix IV for details.

Label improvements to meet current standards:

Human Health

- Updated standard label statements related to precautions including personal protective equipment.

Implementation of the re-evaluation decision

Regulatory Directive DIR2018-01, *Policy on Cancellations and Amendments Following Re-evaluation and Special Review* provides general timelines for implementation of post-market decisions. When an amendment to a registration is determined to be necessary, such as the need for additional risk mitigation measures, there will be an implementation period of up to two (2) years from the date of the decision to transition to selling and using the product with the newly amended labels, if risks during this period are considered acceptable. Potential risks (human health and the environment) from the use of products containing *Agrobacterium radiobacter* strain K84 are considered acceptable during the implementation period under the current label use conditions. Therefore, the required label updates will be implemented within 24 months following the publication of the re-evaluation decision document.

Next steps

To comply with this decision, the required amendments (label updates) must be implemented on all product labels no later than 24 months after the publication date of this decision document. Accordingly, both registrants and retailers will have up to 24 months from the date of this decision document to transition to selling the product with the newly amended labels. Similarly, users will also have the same 24-month period from the date of this decision document to transition to using the newly amended labels, which will be available on the Public Registry.

Refer to Appendix I for details on specific products impacted by this decision.

Other Information

Any person may file a notice of objection[3] regarding this decision on *Agrobacterium radiobacter* strain K84 and its associated end-use products within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management Section of the Canada.ca website (Public Engagement Portal - Public Engagement Forms - Notice of Objection) or contact PMRA's Pest Management Information Service.

The relevant confidential test data on which the decision is based (as referenced in PRVD2023-04) are available for public inspection, upon application, in PMRA's Reading Room. For more information, please contact the Pest Management Information Service.

[3] As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Registered product containing *Agrobacterium radiobacter* strain K84 in Canada

Table 1 Product containing *Agrobacterium radiobacter* strain K84 requiring (label) amendments[1]

Registration number	Marketing class[2]	Registrant	Product name	Formulation type	Active ingredient[3]
21106	C	AG BioResearch LTD.	DyGall	Live Organism	5E9 CFU/g

1 as of 7 May 2024, excluding discontinued products or products with a submission for discontinuation

2 C = Commercial

3 *Agrobacterium radiobacter* strain K84, CFU = Colony Forming Units

Appendix II List of commenters to PRVD2023-04

List of commenters' affiliations for comments submitted in response to PRVD2023-04

Category	Commenter
Growers	Qualitree
Growers	Upper Canada Growers
Growers	J. C. Bakker & Sons Nurseries
Public	General Public

Appendix III Comments and Responses

Health Canada received five written comments during the public consultation for the *Agrobacterium radiobacter* strain K84 proposed re-evaluation decision. Commenter's affiliation is listed in Appendix II. The comments were considered during the final decision phase of this re-evaluation. The summarized comments and Health Canada's responses are provided below.

1.0 Comments related to the value assessment

1.1 Comment

Three comments received included a letter of support for the proposed continued registration of the active as indicated in PRVD2023-04. It stated the importance of *Agrobacterium radiobacter* strain K84 in many nurseries and greenhouses for its use against crown gall disease.

Health Canada response

Health Canada recognizes the importance of *Agrobacterium radiobacter* strain K84 as a tool to fight crown gall disease. Health Canada has determined that continued registration of products containing *Agrobacterium radiobacter* strain K84 is acceptable with label updates. Users in nurseries and greenhouses will continue to have access to the product.

1.2 Comment

Two general comments were received from the public related to animal testing in toxicological studies. The comment suggested that animal testing was used in the toxicological studies of the *Agrobacterium radiobacter* strain K84 re-evaluation.

Health Canada response

With respect to animal testing, Health Canada requires information on the potential toxic effects of pesticides to protect human health and the environment from potential risks. Toxicity information typically includes, in part, animal testing data generated by pesticide manufacturers. These studies are conducted according to international testing protocols, which includes requirements to ensure protection of the welfare of laboratory animals. However, for the re-evaluation of *Agrobacterium radiobacter* strain K84, Health Canada neither received nor requested additional animal studies.

While animal toxicity testing currently plays a critical role in assessing human health and environmental risks from exposure to pesticides, Health Canada supports the reduction of unnecessary animal testing where scientifically justified. To this end, Health Canada does consider requests from pesticide manufacturers to waive requirements for animal studies or to consider validated non-animal alternatives in hazard assessment whenever possible, provided that the same level of protection of human health or the environment is maintained. For example, Health Canada issued guidance for industry on the waiving of mammalian acute toxicity studies in 2013 (https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/guidance-waiving-bridging-mammalian-acute-toxicity-tests-pesticides.html).

Health Canada is also an active participant in various international activities aimed at reducing animal testing while ensuring the protection of human health and the environment. Continued participation in these activities is important to encourage adoption of alternative approaches to animal testing.

Appendix IV Label amendments for products containing *Agrobacterium radiobacter strain K84*

Information on labels of currently registered products should not be removed unless it contradicts the label statements provided below.

1. Under PRECAUTIONS section, update the personal protection equipment with:

   "a long-sleeved shirt, long pants, protective eyewear (goggles), waterproof gloves, socks and shoes, and a NIOSH-approved particulate filtering facepiece respirator with any N, R, or P filter when handling, mixing, loading, or applying the product, and during all clean-up/repair activities."

2. Under PRECAUTIONS section, add the label statement as follows:

   "KEEP TREATED SEED OUT OF REACH OF CHILDREN AND ANIMALS"