Proposed Registration Decision PRD2026-05

AGRI-MEK SC, containing Abamectin

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Overview

Proposed Registration Decision for Abamectin

Health Canada, pursuant to subsection 28(1) of the *Pest Control Products Act*, is proposing registration for the sale and use of AGRI-MEK SC, containing the technical grade active ingredient abamectin, to control stem and bulb nematodes (*Ditylenchus dipsaci*) on garlic bulbs. This evaluation was completed under the User Requested Minor Use Label Expansion program, which is a cooperative program between Agriculture and Agri-Food Canada and Health Canada and includes participation by sponsors groups, manufacturers, and both provincial and federal governments.

Abamectin is an acaricide/insecticide registered for use on a wide-range of outdoor field-grown fruit and vegetable crops, outdoor ornamentals, greenhouse vegetables and greenhouse ornamentals for the control or suppression of a variety of agricultural pests such as mites, sawflies, moths, thrips, leafminers, psyllids, aphids and certain beetles (use-site categories 5, 6, 12, 13, 14, 27 and 33). It is also registered for commercial and domestic indoor and/or outdoor structural use to control cockroaches and ants (use-site category 20). For details, see Proposed Registration Decision PRD2001-01, *Abamectin – Raid Max Roach Bait*, Registration Decision RD2001-02, *Abamectin Raid Max Roach Bait*, Proposed Re-evaluation Decision PRVD2023-01, *Abamectin and Its Associated End-use Products* and Re-evaluation Decision RVD2025-04, *Abamectin and Its Associated End-use Products.*

An evaluation of available scientific information found that, under the approved conditions of use, the health and environmental risks and the value of the pest control product is acceptable.

This Overview describes the key points of the evaluation, while the Science evaluation provides detailed technical information on the human health, environmental and value assessments of AGRI-MEK SC, containing abamectin.

What does Health Canada consider when making a registration decision?

The primary objective of the *Pest Control Products Act* is to prevent unacceptable risks to individuals and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include precautionary measures on the product label to further reduce risk.

1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act.*

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

To reach its decisions, Health Canada applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children). They also consider the unique characteristics of organisms in the environment. These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how Health Canada regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and pest management portion of Canada.ca.

Before making a final registration decision on AGRI-MEK SC, containing abamectin, Health Canada will consider any written comments received from the public directly related to the proposed decision in this consultation document.[3] Health Canada will then publish a Registration Decision[4] on AGRI-MEK SC, containing abamectin, which will include the decision, the reasons for it, a summary of comments received on the proposed registration decision and Health Canada's response to these comments.

For more details on the information presented in this Overview, please refer to the Science evaluation of this consultation document.

What is abamectin?

Abamectin is an insecticide, miticide, and nematicide registered against insect and mite pests on fruit and vegetable crops. It affects nerve and muscle action by disrupting the nervous system leading to paralysis and death.

Health considerations

Can approved uses of abamectin affect human health?

AGRI-MEK SC, containing abamectin, is unlikely to affect your health when used according to label directions.

Potential exposure to abamectin may occur through the diet (food and drinking water), when handling and applying the end-use product, or when coming into contact with treated surfaces. When assessing health risks, two key factors are considered: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are selected to protect the most sensitive human population (for example, children and nursing mothers). As such, sex and gender are taken into account in the risk assessment. Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose level at which no effects are observed. The health effects noted in animals occur at dose levels more than 100-times higher (and often much higher)

[3] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.
[4] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

than levels to which humans are normally exposed when pesticide products are used according to label directions.

In laboratory animals, the end-use product AGRI-MEK SC, containing abamectin, was of high acute toxicity via the oral route; consequently, the signal word and hazard statement "DANGER – POISON" are required on the label. It was of low acute toxicity via the dermal route and was of moderate acute toxicity via the inhalation route of exposure. It was not irritating to the eyes or skin, and did not cause an allergic skin reaction.

Prior to the initial registration of abamectin, registrant-supplied short- and long-term (lifetime) animal toxicity tests, as well as information from the published scientific literature, were assessed for the potential of abamectin to cause neurotoxicity, immunotoxicity, chronic toxicity, cancer, reproductive and developmental toxicity, and various other effects. The most sensitive endpoints for risk assessment were effects on the nervous system. There was an indication that the young animal was more sensitive than the adult animal. The risk assessment protects against the effects noted above and other potential effects by ensuring that the level of exposure to humans is well below the lowest dose level at which these effects occurred in animal tests.

Occupational risks from handling AGRI-MEK SC

Occupational risks are not of health concern when AGRI-MEK SC is used according to the proposed label directions, which include protective measures.

Workers mixing, loading or applying AGRI-MEK SC, and workers handling treated garlic while planting can be exposed to abamectin residues through direct skin contact or through inhalation. Therefore, the label specifies that anyone mixing, loading and applying AGRI-MEK SC must wear a long-sleeved shirt, long pants, chemical-resistant gloves, a respirator, socks and chemical-resistant footwear. The label also requires that workers handling treated garlic seed cloves after treatment to wear a long-sleeved shirt, long pants, and chemical-resistant gloves. Furthermore, the label prohibits workers from planting treated garlic cloves by hand. Taking into consideration the proposed label statements, type of application (soak tank) and the duration of exposure for handlers and postapplication workers, the risks to these individuals from exposure to AGRI-MEK SC are not of health concern when the end-use product is used according to the proposed label directions.

Health risks to bystanders

Bystander risks are not of health concern when AGRI-MEK SC is used according to the proposed label directions.

The potential for bystander exposure is anticipated to be negligible since there is no potential for spray drift given the application method. Therefore, health risks to bystanders are not of concern when the end-use product is used according to the label directions.

Residues in food and drinking water

Dietary risks from food and drinking water are not of health concern.

Aggregate acute dietary (food plus drinking water) intake estimates indicated that the general population and all population subgroups are exposed to less than 41% of the acute reference dose, and therefore are not of health concern.

Aggregate chronic dietary (food plus drinking water) intake estimates indicated that the general population and all population subgroups are exposed to less than 23% of the acceptable daily intake, and therefore are not of health concern.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act.* The dietary risks from the consumption of foods are shown to be acceptable when abamectin is used according to the supported label directions. Furthermore, the established 0.01 ppm MRL for residues of abamectin in/on garlic is adequate, therefore, a new MRL is not being proposed as a result of this assessment.

To support the use expansion to garlic, requirements stipulated in SPN2018-01 "Guidance on Streamlined Residue Chemistry Data Requirements for Seed Treatment Uses and Potato Seed-Piece Applications" (19 March 2018) were considered. As abamectin is currently registered for foliar use on garlic, and the combined foliar plus garlic clove soak treatment rate does not exceed 125% of the registered maximum seasonal foliar application rate, no additional residue chemistry data are required given that a complete residue chemistry database is available to support the foliar use. The MRL for abamectin in/on garlic established in support of the foliar use also covers the residues expected from the garlic clove soak treatment.

Environmental considerations

What happens when abamectin is introduced into the environment?

When AGRI-MEK SC is used according to label directions, the environmental risk associated with the new use of abamectin on garlic cloves is acceptable.

Abamectin is currently used as a spray on several types of agricultural crops while they are growing outdoors. The proposed use on garlic cloves is not expected to increase the exposure of plants and animals in the environment to abamectin compared to its current uses on outdoor crops. Thus, the environmental risk resulting from the use of AGRI-MEK SC on garlic cloves is acceptable when users follow current label directions.

Value considerations

What is the value of AGRI-MEK SC?

AGRI-MEK SC controls stem and bulb nematodes (SBN) on garlic.

AGRI-MEK SC is applied to garlic bulbs to control stem and bulb nematodes (*Ditylenchus dipsaci*) that are on or near the planted bulb. The registration of this pesticide use offers an additional method of managing SBN in combination with soil fumigants and an in-furrow product that manages nematodes in the soil. Abamectin is the only insecticide belonging to the mode of action Group 6, and therefore is a valuable tool in resistance management.

Measures to minimize risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human health and the environment. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of AGRI-MEK SC, containing abamectin to address the potential risks identified in this assessment are as follows.

Key risk-reduction measures

Human health

To reduce the potential exposure of workers to abamectin through direct skin contact or inhalation of sprays, workers mixing, loading and applying AGRI-MEK SC and performing cleaning and repair activities must wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks, chemical-resistant footwear. In addition, mixer/loaders and applicators must wear a respirator with a NIOSH-approved organic-vapour-removing cartridge with a prefilter approved for pesticides, or a NIOSH-approved canister approved for pesticides.

The label also requires postapplication workers to wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes while handling treated garlic seed cloves or when working with or around equipment used to transport and plant treated garlic. Furthermore, the planting of treated garlic cloves by hand is prohibited.

Environment

No additional mitigation label statements are required on the label of AGRI-MEK SC.

Next steps

Before making a final registration decision on AGRI-MEK SC, containing abamectin, Health Canada will consider any written comments received from the public that are directly related to this proposed decision, such as comments directed to the science evaluation, in response to this consultation document up to 45 days from the date of publication (by 12 June 2026) of this document. Please forward all comments to Pesticides Regulatory Directorate's Publications,

through the Public Engagement Portal (Public Engagement Forms – Consultation Comment). Health Canada will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed decision and Health Canada's response to these comments.

Other information

When Health Canada makes its registration decision, it will publish a Registration Decision on AGRI-MEK SC, containing abamectin (based on the Science evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the Pesticides Regulatory Directorate's Reading Room. For more information or if you have questions, please contact the Pesticides Information Service.

Science evaluation

Abamectin, AGRI-MEK SC

1.0 The active ingredient, its properties and uses

1.1 Directions for use

Garlic bulbs are soaked in a solution of 0.858 mL AGRI-MEK SC in one liter of water for four hours. The bulbs are then allowed to dry and are planted within a week of treatment.

1.2 Mode of action

Abamectin is classified as a Group 6 insecticide/miticide by the Insecticide Resistance Action Committee (IRAC) that disrupts the nervous system of insects and mites by activating the gamma-aminobutyric acid (GABA) system. It stimulates the release of GABA, an inhibitory neurotransmitter, which in turn promotes the influx of chloride ions into nerve and muscle cells, causing hyperpolarization. This hyperpolarization disrupts the normal transmission of nerve impulses, leading to paralysis and eventually death.

2.0 Impact on human and animal health

2.1 Toxicology summary

A detailed review of the toxicology database for abamectin was conducted previously and is summarized in the Proposed Registration Decision, PRD2001-01. The toxicology assessment was subsequently updated in 2016 to include the review of new studies and summarized in an Evaluation Report.[5] These assessments from 2001 and 2016 were then relied upon for the hazard characterization within the re-evaluation of abamectin in 2023, summarized in PRVD2023-01. Overall, the scientific quality of the data is acceptable and the database is considered adequate to characterize the potential health hazards associated with abamectin.

Following repeated short-term to chronic exposure of abamectin, the primary target of toxicity was the nervous system. Abamectin was not considered mutagenic and there was no evidence of carcinogenicity. In the prenatal and postnatal toxicity testing of abamectin, evidence of sensitivity of the young was observed as well as a steep dose-response. In offspring in the reproductive toxicity and developmental neurotoxicity studies, decreased body weight as well as clinical signs and mortality beginning shortly after birth occurred in the absence of any effects in maternal animals. In the developmental toxicity studies, serious effects in the form of fetal malformations were observed in the absence of maternal toxicity in rodents and in the presence of maternal toxicity in rabbits. As detailed in the 2016 Evaluation Report,[5] concern for these findings is tempered by the fact that the rodent neonate is more sensitive than the human neonate with respect to abamectin toxicity due to differences in the ontogeny of P-glycoprotein expression and blood-brain barrier development. Abamectin is a substrate for P-glycoprotein,

[5] Evaluation Report for Category B, Subcategory 5.0 Application. New Maximum Residue Limits for Previously Assessed Abamectin Technical. Registration Number 24484. Application Number 2013-4347. PMRA 2566198.

which is a protein that mediates the active transport of molecules across cellular membranes, including the blood brain barrier, and plays an important role in protecting the brain from neurotoxic substances. In rodents, the blood-brain barrier is not completely developed in the fetus/neonate, and is not expressed until approximately post-natal day (PND) 7, and not fully developed to adult levels until around PND 28. For these reasons, newborn rodent pups have an increased susceptibility to abamectin toxicity compared to adult rodents. Human infants, on the other hand, are born with an intact blood-brain barrier and P-glycoprotein is fully expressed before birth. For these reasons, the *Pest Control Products Act* (PCPA) factor was retained for risk assessment but reduced to threefold to address sensitivity of the young.

An updated literature search was conducted for the current assessment, and no published scientific studies that would impact the previous human health hazard assessment were identified as of 3 September 2025. A scan of international regulatory decisions released subsequent to the previous detailed assessment was also conducted and did not yield any information that impacted the previous assessment. Toxicology reference values for use in the human health risk assessment were reported previously in PRVD2023-01 are also reported in Appendix I, Table 1.

Acute toxicity studies conducted with the end-use product AGRI-MEK SC were assessed previously.[6] In rats, AGRI-MEK SC was of high acute toxicity via the oral route, of low acute toxicity via the dermal route, and of moderate acute toxicity via the inhalation route of exposure. It was not irritating to the eyes or skin of rabbits, and was not a dermal sensitizer in guinea pigs when tested using the Buehler method.

2.2 Route and duration of exposure

Occupational exposure to abamectin for mixers, loaders, applicators, and postapplication workers (planters) is characterized as short-term (<30 days) in duration and is predominantly by the dermal and inhalation routes.

2.3 Dermal absorption

A dermal absorption value of 1% was used in the risk assessment for abamectin based on a well conducted monkey in vivo study and on current practices and policies.

2.4 Occupational and residential risk assessment

2.4.1 Acute hazards of AGRI-MEK SC and mitigation measures

The acute hazard assessment indicated that in rats, AGRI-MEK SC was of high acute toxicity via the oral route, of low acute toxicity via the dermal route, and of moderate acute toxicity via the inhalation route of exposure. It was not irritating to the eyes or skin of rabbits, and was not a dermal sensitizer in guinea pigs when tested using the Buehler method. Based on these acute hazards, a long-sleeved shirt, long pants, socks, shoes, and chemical-resistant gloves are required for workers during mixing, loading, application, clean-up and repair. A respirator is also required during mixing/loading and application.

[6] Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 3.10, 3.12, 3.13 Application. Application Number 2013-5526. PMRA 2412062.

2.4.2 Occupational exposure and risk assessment

2.4.2.1 Mixer, loader and applicator exposure and risk assessment

Individuals have potential for exposure to abamectin during mixing, loading, application, clean-up and repair. Dermal and inhalation exposure estimates were generated from the Agricultural Handlers Exposure Task Force (AHETF) database for mixers, loaders and applicators applying AGRI-MEK SC to garlic cloves in a soaking solution. The personal protective equipment (PPE) in the risk assessment is based on handlers wearing a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes (Appendix I, Table 2).

Dermal exposure was estimated by coupling the unit exposure values with the amount of product handled per day and the dermal absorption value of 1%. Inhalation exposure was estimated by coupling the unit exposure values with the amount of product handled per day with 100% inhalation absorption. Exposure was normalized to mg/kg bw/day by using 80 kg adult body weight.

The estimated amount of garlic that could be treated in a single day was 4 totes each containing 450 L of soaking solution. The target concentration of abamectin in solution is 0.0721 g a.i./L. Therefore, the estimated amount of abamectin handled per day based on preparing 4 batches of 450 L of solution is 130 g a.i./day. This is considered a worst-case scenario estimate given that, although 4 totes of cloves can theoretically be treated by one individual in one day, these totes will not require a full 450 L of solution to be added for each treatment event (Appendix I, Table 3).

Exposure estimates were compared to the selected toxicological reference value to obtain the margin of exposure (MOE); the target MOE is 300. Dermal and inhalation MOEs were combined, since the dermal and inhalation reference values are based on the same toxicological effects. Calculated MOEs are greater than the target MOE of 300 for all chemical handler scenarios for agriculture crops and are therefore not of health concern (Appendix I, Table 3).

2.4.2.2 Postapplication exposure and risk assessment

There is potential for exposure to workers handling treated garlic cloves to move them from the treatment container to a storage bin for drying. This is performed by mechanical means such as by forklift. Subsequently, the treated and dried cloves are then transferred to the planting equipment in a similar manner. The treated cloves are then planted using mechanical planters. These activities and the sources of exposure are considered similar to the activities monitored during a potato seed piece planting study (see PRD2016-20).

In this study, workers were monitored while performing the activities of transferring treated potato seed pieces from storage or treatment area to transport vehicles, loading treated seed into the planter and planting activities such as driving the tractor, and removing blockages. The activities monitored within the surrogate potato seed piece study are similar to those anticipated for garlic. However, the level of contact with treated garlic cloves is expected to be much lower, particularly in comparison to the individuals on the back of the planter from the potato study. Several of the activities monitored in the back of planter group involved direct contact with the treated potatoes, including contact with hands and feet.

From this study, dermal and inhalation exposure estimates were derived for workers handling AGRI-MEK SC treated garlic seed cloves while wearing a long-sleeved shirt, long pants, and chemical-resistant gloves. The dermal unit exposure was adjusted for a dermal absorption of 1%. Exposures were estimated by coupling the unit exposure values with the amount of active ingredient anticipated to be handled per day. The estimated amount handled per day of 36.74 g a.i./day is derived based on seeding rate information, and the estimated amount of abamectin absorbed by the clove during treatment (Appendix I, Table 4).

Exposure estimates were compared to the toxicological reference value to obtain the margin of exposure (MOE); the target MOE is 300. Exposures and risks to the planter exposures (back of planter workers, planter drivers, and mostly loaders) are not of health concern. MOEs for these activities exceed the target MOE of 300 (Appendix I, Table 4). There are no exposure data available to adequately characterize exposure incurred while planting by hand. Therefore, a label statement that prohibits the planting of treated garlic seed cloves by hand is required.

2.4.3 Residential exposure and risk assessment

2.4.3.1 Handler exposure and risk assessment

AGRI-MEK SC is not a domestic class product; therefore, a residential handler exposure assessment is not required.

2.4.3.2 Postapplication exposure and risk assessment

AGRI-MEK SC is not a domestic class product and is not intended for use in residential settings; therefore, a residential postapplication exposure assessment is not required.

2.4.4 Bystander exposure and risk assessment

Bystander exposure is considered negligible as application is limited to garlic soaking tanks. Therefore, bystander exposure and risk are not of health concern.

2.5 Dietary exposure and risk assessment

2.5.1 Dietary risk assessment

Acute and chronic dietary risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM–FCID™, Version 4.02, 05-10-c), which incorporates consumption data from the National Health and Nutrition Examination Survey/What We Eat in America (NHANES/WWEIA) for the year 2005-2010.

2.5.1.1 Acute dietary exposure results and risk characterization

The following assumptions were applied in the refined acute analysis for abamectin: maximum residues in CFIA 2017-2021 monitoring data, the highest average field trial (HAFT) residue levels detected in the available crop field trials, anticipated residues in ruminant animal commodities, and Canadian MRLs, American Tolerances or Codex MRLs. Residue data were translated from representative commodities in the crop groups to other commodities within the crop group according to Health Canada's guidelines. All crops were assumed to be 100% treated.

Default and experimental food processing factors were applied for relevant processed commodities. Where possible, experimental processing factors were extrapolated according to OECD Guidelines. The refined acute dietary exposure (food alone) for all supported abamectin food commodities and imported commodities is estimated to be less than 40% (0.000667 mg/kg bw/day) of the ARfD for all population subgroups (95th percentile, deterministic). Aggregate exposure from food and drinking water is considered acceptable: less than 41% of the ARfD for all population subgroups.

2.5.1.2 Chronic dietary exposure results and characterization

The following assumptions were applied to the refined chronic analysis for abamectin: mean values of the CFIA 2017–2021 monitoring data, the median residue levels detected in the available crop field trials, anticipated residues in ruminant animal commodities, and Canadian MRLs/American Tolerances or Codex MRLs. Residue data were translated from representative commodities in the crop groups to other commodities within the crop group according to Health Canada's guidelines. Percent crop treated information (both Canadian and United States) was used and default and experimental food processing factors were applied for relevant processed commodities. Where possible, experimental processing factors were extrapolated according to OECD Guidelines. The refined chronic dietary exposure (food alone) from all supported abamectin food commodities and imported commodities for the total population, including infants and children, and all representative population subgroups is less than 21% of the acceptable daily intake (ADI). Aggregate exposure from food and drinking water is considered acceptable. Health Canada estimates that chronic dietary exposure to abamectin from food and drinking water is less than 8% (0.000028 mg/kg bw/day) of the ADI for the total population. The highest exposure and risk estimate is for children 1–2 years old at less than 23% (0.000089 mg/kg bw/day) of the ADI.

2.6 Aggregate exposure and risk assessment

For abamectin, the aggregate assessment consisted of combining food and drinking water exposure only, since residential exposure is not expected.

2.7 Cumulative assessment

The *Pest Control Products Act* requires that Health Canada consider the cumulative non-occupational exposure to pesticides with a common mechanism of toxicity, based on the likelihood that people may be exposed to more than one of these pesticides at the same time. Accordingly, an assessment of a potential common mechanism of toxicity with other pesticides was undertaken for the active ingredient abamectin.

Abamectin belongs to the avermectin class of insecticides and shares a similar toxicological profile with another member of this class, emamectin benzoate. The United States Environmental Protection Agency (USEPA) has determined that there is evidence to suggest these chemicals may have a common mechanism of toxicity related to gamma-aminobutyric receptor mediated neurotoxicity (USEPA, 2017). Although abamectin is the only member of the avermectins registered as a pesticide in Canada, another member, emamectin benzoate, is registered as a pesticide for uses on food crops in the United States and thus Canadians could potentially be exposed to this pesticide via imported food commodities.

A qualitative cumulative risk assessment was conducted for abamectin and emamectin under the Proposed Re-evaluation Decision for abamectin (PRVD2023-01), in which based on the available food monitoring data from the Canadian Food Inspection Agency (CFIA) and/or the United States Department of Agriculture (USDA) Pesticide Data Program (PDP), it was determined that no co-occurrence of quantifiable residues originating from either abamectin or emamectin are expected on any crops. This determination still holds true as the most recent monitoring data available found no detectable residues of emamectin in food commodities (2015–2021 from CFIA, and 2014–2023 from USDA PDP). In addition, there is no dietary exposure from drinking water or residential exposure to emamectin since it is not registered for use in Canada. As such, cumulative risks from potential co-exposure to abamectin and emamectin through food, drinking water and residential exposure, where relevant, are acceptable.

The proposed expansion of use for abamectin is on garlic for the control of stem and bulb nematode by soaking the garlic bulbs. No increase in dietary exposure is expected, as residues of abamectin from the use of AGRI-MEK SC on garlic will be covered by the established MRL of 0.01 ppm on garlic, and the application rate proposed for garlic bulbs does not represent an increase over the registered application rates for abamectin. No residential exposure is expected. Therefore, the contribution of exposure to the cumulative risk of abamectin and emamectin will not be impacted by the new proposed use of abamectin.

2.8 Maximum residue limit

An MRL of 0.01 ppm is currently established for residues of abamectin in/on garlic based on the registered foliar use. In line with the criteria outlined in SPN2018-01 “Guidance on Streamlined Residue Chemistry Data Requirements for Seed Treatment Uses and Potato Seed-Piece Applications” (19 March 2018), the garlic clove soak treatment rate does not exceed 125% of the registered maximum seasonal foliar application rate. As such, the existing MRL of 0.01 ppm also covers residues expected from the garlic clove soak use. Dietary risks from the consumption of food commodities were shown to be acceptable when abamectin is used according to the supported label directions. Foods containing residues of abamectin from the use of AGRI-MEK SC on garlic at the established MRL of 0.01 ppm are safe to eat.

The acute and chronic dietary risk estimates are summarized in Appendix I, Table 5.

3.0 Impact on the environment

3.1 Fate and behaviour in the environment

The fate and environmental behaviour of abamectin have been previously assessed in the Health Canada Proposed Re-evaluation Decision document for abamectin (PRVD2023-01) and the Re-evaluation Decision (RVD2025-04). Briefly, in soil under field conditions, abamectin residues are non-persistent to slightly persistent with low potential for carry over to the next growing season and leaching to groundwater. In water, laboratory studies indicate that phototransformation of abamectin is rapid while aerobic biotransformation is slower. Abamectin is not likely to bioaccumulate in aquatic organisms.

3.2 Environmental risk characterization

The environmental risks from application of abamectin to outdoor crops have been previously assessed in PRVD2023-01 and RVD2025-04. Potential risks to bees, beneficial arthropods, birds, small wild mammals, and aquatic organisms were identified and it was concluded that risks to the environment were acceptable when label directions were followed.

The proposed use on garlic cloves is expected to result in much lower environmental exposure to abamectin compared to registered uses on other outdoor crops for the following reasons:

- The maximum yearly field application rate for abamectin associated with planting of treated garlic cloves is approximately 12 g a.i./ha, which is less than half of the yearly maximum of 38 g a.i./ha registered for spray application of abamectin on field crops. Burial of treated garlic cloves also results in less applied abamectin available for transport via drift or runoff to water bodies compared to spray applications/residues on soil and plant surfaces.
- Garlic cloves will be buried beneath the soil surface when planted in the field and thus may not be a favorable food choice for wild animals compared to more easily accessible or appealing food sources. As abamectin is not systemic, it is not expected to travel throughout the plant and be present in emerged garlic. Furthermore, garlic is not known to be an attractive food source for wild animals and instead may repel wild birds and mammals. For example, garlic juice and garlic oil are components in certain products used to repel birds, deer, rabbits, and hares.

Overall, the proposed use does not present an increase in risk to non-target terrestrial and aquatic organisms compared to registered uses of abamectin.

4.0 Incident reports

Health incident reports

As of 5 September 2025, 34 human incidents and 109 domestic animal incidents involving abamectin have been submitted to Health Canada.

Twelve human incidents were considered to be at least possibly related to the reported abamectin product. In 5 incidents, people were exposed to domestic class abamectin bait products formulated as solid or dust. The reported exposure scenarios included contact with product residues following application. The severity of effects reported in people were mainly minor (for example, cough, nausea, skin irritation). In 7 incidents, the reported exposure scenario occurred in an occupational setting and involved exposure to commercial class products during application activities (for example, accidental spray/spill, applying product without wearing personal protective equipment). The effects reported in incidents included moderate severity effects such as loss of coordination or ataxia.

Most domestic animal incidents (75 incidents) were considered to be at least possibly related to abamectin. Sixty-four of these incidents involved domestic class bait products formulated as solid, gels, or dust that were used in residential settings (for example, inside the home). Eleven incidents were associated with accidental ingestion of corn or cotton seed treated with abamectin

and other active ingredients (for example, azoxystrobin, fludioxonil, thiamethoxam, metalaxyl-m) by domestic animals (for example, cows, sheep). The effects reported in animals included minor effects such as vomiting, diarrhea, lethargy to more serious effects such as muscle twitching or animal death.

Overall, most of the human and domestic animal incidents involved bait products that were used at residential sites and therefore were not considered relevant to the registered use pattern of AGRI-MEK SC (in other words, for use on crops) or the proposed use pattern (in other words, for use on garlic seed/bulbs). There were a few domestic animal incidents involving a similar use pattern as the proposed use pattern, however, these incidents occurred in the US, with American products that contain abamectin co-formulated with other active ingredients. Furthermore, these incidents involved a different type of seed (in other words, corn or cotton seed). There were a low number of human incidents that involved accidental exposures during mixing/loading application activities or individuals not wearing the required personal protection equipment. The label for the product AGRI-MEK SC contains precautionary statements and personal protective equipment requirements to minimize dermal and inhalation exposure during product use. No additional mitigation measures are recommended following this incident report review.

Environment incident reports

As of 5 September 2025, no environmental incident reports involving abamectin have been submitted to Health Canada beyond those considered in PRVD2023-01.

5.0 Value

Three efficacy trials conducted in Brazil in 1999 and in Ontario between 2010 and 2013 were reviewed in support of the claim of control of SBN on garlic. The trials demonstrated a significant decrease in nematodes present on garlic bulb tissue and an increase in garlic yield. The results of these trials supported the value of the claim.

Stem and bulb nematodes (*Ditylenchus dipsaci*) feed on cells near the basal root plate of young garlic seedlings early in the season causing rot in roots and bulbs. Mature plants experience root loss and infestation can result in soft, discoloured, deformed bulbs, leading to yield losses. Nematodes present on garlic bulbs in storage will continue to damage the bulbs.

Currently registered products to manage SBN include soil fumigants and an in-furrow product that control the nematodes in the soil. AGRI-MEK SC controls nematodes on the planted garlic and in the soil near the bulb. The registration of this product for use on garlic offers an additional method of control for growers with a new mode of action to reduce the risk of development of resistance in the pest.

5.0 Pest Control Product Policy considerations

5.1 Toxic Substances Management Policy considerations

The *Toxic Substances Management Policy* (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances, in other words,

those that meet all four criteria outlined in the policy. Health Canada has previously conducted a TSMP assessment for abamectin and reached the conclusion that abamectin and its transformation products do not meet all of the TSMP Track 1 criteria. Refer to PRVD2023-01 for additional detail on the assessment.

5.2 Formulants and contaminants of health or environmental concern

Health Canada has previously reached the conclusion that AGRI-MEK SC does not contain any formulants or contaminants identified in Parts 1 or 3 of the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*. Refer to PRVD2023-01 for additional detail.

6.0 Proposed regulatory decision

Health Canada, pursuant to subsection 28(1) of the *Pest Control Products Act*, is proposing registration for the sale and use of AGRI-MEK SC, containing the technical grade active ingredient abamectin, to control stem and bulb nematodes (*Ditylenchus dipsaci*) on garlic bulbs.

An evaluation of available scientific information found that, under the approved conditions of use, the health and environmental risks and the value of the pest control products are acceptable.

List of abbreviations

µg	microgram(s)
ADI	acceptable daily intake
AHETF	Agricultural Handlers Exposure Task Force
a.i.	active ingredient
ARfD	acute reference dose
bw	body weight
CAF	composite assessment factor
CFIA	Canadian Food Inspection Agency
g	gram
GABA	gamma-aminobutyric acid
HAFT	highest average field trial
IRAC	Insecticide Resistance Action Committee
kg	kilogram(s)
L	litre(s)
MRL	maximum residue limit
mg	milligram(s)
MOE	margin of exposure
NOAEL	no observable adverse effect level
PCPA	*Pest Control Products Act*
PDP	Pesticide Data Program
PMRA	Pest Management Regulatory Agency
PND	post-natal day
PPE	personal protective equipment
ppm	parts per million
PRD	Proposed Registration Decision
PRVD	Proposed Re-evaluation Decision
RVD	re-evaluation decision
SBN	stem and bulb nematode
TSMP	Toxic Substances Management Policy
US	United States
USDA	United States Department of Agriculture
USEPA	United States Environmental Protection Agency

Appendix I Tables and figures

Table 1 Toxicology reference values for use in health risk assessment for abamectin

Exposure scenario	Study	Point of departure and endpoint	CAF[1] or Target MOE
Acute dietary general population	Acute oral neurotoxicity study in rats, supported by 12-week dietary study in dogs	NOAEL = 0.5 mg/kg bw Based on decreased splay reflex in rats at 1.5 mg/kg bw and mydriasis observed in dogs at 1.0 mg/kg bw/day	300
	ARfD = 0.0017 mg/kg bw		
Repeated dietary	Oral developmental neurotoxicity study	Offspring NOAEL = 0.12 mg/kg bw/day Based on decreased pup body weight at 0.2 mg/kg bw/day	300
	ADI = 0.0004 mg/kg bw/day		
Incidental oral (acute)	Acute oral neurotoxicity study in rats, supported by 12-week dietary study in dogs	NOAEL = 0.5 mg/kg bw Based on decreased splay reflex in rats at 1.5 mg/kg bw and mydriasis observed in dogs at 1.0 mg/kg bw/day	300
Incidental oral (short-term)	Oral developmental neurotoxicity study	Offspring NOAEL = 0.12 mg/kg bw/day Based on decreased pup body weight at 0.2 mg/kg bw/day	300
Dermal[2] and Inhalation[3] (all durations)	Oral developmental neurotoxicity study	Offspring NOAEL = 0.12 mg/kg bw/day Based on decreased pup body weight at 0.2 mg/kg bw/day	300
Aggregate - All routes and durations of exposure	Oral developmental neurotoxicity study	Offspring NOAEL = 0.12 mg/kg bw/day Based on decreased pup body weight at 0.2 mg/kg bw/day	300
Cancer	No treatment-related tumours were observed, therefore a cancer risk assessment is not required		

[1] CAF (composite assessment factor) refers to a total of uncertainty and PCPA factors for dietary assessment. MOE (margin of exposure) refers to a target MOE for occupational and residential assessments.

[2] Since an oral NOAEL was selected, a dermal absorption factor of 1% was used in route-to- route extrapolation.

[3] Since an oral NOAEL was selected, an inhalation absorption factor of 100% (default value) was used in route-to- route extrapolation.

Table 2 AHETF unit exposure estimates for mixer/loaders and applicators handling AGRI-MEK SC to treat garlic seed cloves as a soak (µg/kg a.i. handled)

Exposure scenario and PPE	Dermal	Dermal absorbed[1]	Inhalation[2]
PPE: Single layer and chemical-resistant gloves			
Mixer/loader and applicator- AHETF estimates			
AHETF - Open mixing/loading of liquids, baseline PPE	58.5	0.585	0.63

1 Adjusted with dermal absorption factor 1%.
2 Light inhalation rate

Table 3 Mixer/loader/applicator exposure and risk assessment

Exposure scenario	Unit exposure (µg/kg a.i. handled)[1]	Amount handled/day[2] kg a.i. /day	Daily exposure (mg/kg bw/day)[3]	MOE[4]
Worst Case exposure scenario is where 450L of treatment solution is prepared 4 times per day. PPE: Single layer and chemical-resistant gloves				
Open Mixing/Loading	1.215	0.130	1.97×10^{-6}	60 779

1 Unit exposure based on AHETF
2 Based on use information (DACO 5.2); 4 batches of 450 L of prepared solution at a concentration of 0.0721 g a.i./L.
3 Daily exposure = (Unit exposure × Amount handled per day) / (80 kg bw × 1000 µg/mg)
4 Based on NOAEL = 0.12 mg/kg bw/day, target MOE = 300 (see Table 1)

Table 4 Postapplication exposure and risk estimates for workers handling garlic seed cloves treated with abamectin

Activity	Dermal unit exposure (µg/kg a.i.)[1]	Inhalation unit exposure (µg/kg a.i.)[1]	Amount handled/day (kg a.i. /day)[2]	Daily exposure (mg/kg bw/day)[3]	MOE[4]
Back of planter workers	28.53	62.52	0.03674	4.18×10^{-5}	2870
Planter drivers and mostly loaders	3.67	18.53	0.03674	1.02×10^{-5}	11 769

1 Calculated using the 1% dermal absorption, based on an individual wearing long-sleeves, long pants, chemical resistant gloves, shoes and socks. No respirator.
2 The estimated amount of a.i. per clove (1.3×10^{-4} g a.i./clove) is based on the volume of solution absorbed 107 L per 58 500 cloves (Use Information-DACO 5.2). The amount handled per day is then calculated using the maximum of 279 000 cloves planted per day (1.3×10^{-4} g a.i./clove × 279 000 cloves/day)
3 Exposure = Daily exposure = (Unit exposure × Amount handled per day) / (80 kg bw × 1000 µg/mg)
4 Based on a NOAEL of 0.12 mg/kg bw/day, target MOE = 300 (see Table 1)

Table 5 Food residue chemistry overview of risk assessment

Dietary risk from food and drinking water			
	Population	**Estimated risk % of acute reference dose (ARfD)**	
		Food alone	**Food and drinking water**
Refined acute dietary exposure analysis, 95th percentile **ARfD = 0.0017 mg/kg bw** **Estimated acute drinking water concentration = 0.0009 ppm**	All infants <1 year	20.4	24.0
	Children 1–2 years	39.3	40.1
	Children 3–5 years	34.4	35.8
	Children 6–12 years	18.9	20.1
	Youth 13–19 years	11.3	12.4
	Adults 20–49 years	12.8	14.5
	Adults 50+ years	14.1	15.6
	Females 13-49 years	12.6	14.0
	Total population	16.1	17.5
	Population	**Estimated risk % of acceptable daily intake (ADI)**	
		Food alone	**Food and drinking water**
Refined chronic dietary exposure analysis **ADI = 0.0004 mg/kg bw/day** **Estimated chronic drinking water concentration = 0.00028 ppm**	All infants <1 year	12.8	18.1
	Children 1–2 years	20.4	22.3
	Children 3–5 years	13.5	15.1
	Children 6–12 years	7.2	8.3
	Youth 13–19 years	4.0	5.0
	Adults 20–49 years	4.5	5.9
	Adults 50+ years	4.7	6.1
	Females 13-49 years	4.3	5.7
	Total population	5.7	7.1

References

A. List of studies/information submitted by registrant

1.0 Human and animal health

PMRA Document Number	Reference
2918546	2018, D.3.1: 2017-0348 – Agri Mek Insecticide/Miticide (abamectin) for control of bulb and stem nematode on garlic. DACO 5.2 requirements as requested in letter from Health Canada dated July 5, 2018, DACO: 5.2

2.0 Environment

PMRA Document Number	Reference
2719185	2017, URMULE form Appendix I, DACO: 8.6.2

3.0 Value

PMRA Document Number	Reference
2719181	1999, The effect of abamectin on garlic infected by *Ditylenchus dipsaci*, DACO: 10.2.3.3(D)
2719182	2012, Efficacy of abamectin as a seed dip for the control of seed borne bulb and stem nematode in garlic cv Music 2011, DACO: 10.2.3.3(D)
2719183	2013, Effect of applying different rates of Agrimek as a drench over bulb and stem nematode infested garlic cv Music compared to soaking cloves in an Agrimek solution prior to planting on yield, nematode damage and nematode populations in the bulbs at harvest in 2013, DACO: 10.2.3.3(D)

B. Additional information considered

i) Unpublished information

1.0 Human and animal health

PMRA Document Number	Reference
3817770	USEPA, 2017. Avermectin Macrocyclic Lactones, Abamectin and Emamectin. Cumulative Screening Risk Assessment