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Proposed Registration Decision

PRD2026-07

AQUABAC II XT Biological Larvicide, containing *Bacillus thuringiensis* subsp. *israelensis* serotype H-14, strain BMP-144

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Overview

Proposed Registration Decision for *Bacillus thuringiensis* subsp. *israelensis* serotype H-14, strain BMP-144

Health Canada, pursuant to subsection 28(1) of the *Pest Control Products Act*, is proposing registration for the sale and use of AQUABAC II XT Biological Larvicide, containing *Bacillus thuringiensis* subsp. *israelensis* serotype H-14, strain BMP-144, to control fungus gnats on greenhouse ornamentals (use-site category 6 – Greenhouse Non-Food). 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 sponsor groups, manufacturers, and both provincial and federal governments.

Bacillus thuringiensis subsp. *israelensis* serotype H-14, strain BMP-144 is a microbial pest control agent (MPCA) registered against mosquito larvae in flood water, roadside ditches, storm water retention areas, etc., under use-site category 2 – Aquatic Non-Food. For details, see the Proposed Acceptability for Continuing Registration PACR2006-09, *Re-evaluation of Bacillus thuringiensis* and Re-evaluation Decision RVD2008-18, *Re-evaluation Decision Bacillus thuringiensis*.

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 AQUABAC II XT Biological Larvicide, containing *Bacillus thuringiensis* subsp. *israelensis* serotype H-14, strain BMP-144.

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 acceptable¹ 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 value² when used according to the label directions. Conditions of registration may include precautionary measures on the product label to further reduce risk.

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

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.”

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 AQUABAC II XT Biological Larvicide, containing *Bacillus thuringiensis* subsp. *israelensis* serotype H-14, strain BMP-144, 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 Decision⁴ on AQUABAC II XT Biological Larvicide, containing *Bacillus thuringiensis* subsp. *israelensis* serotype H-14, strain BMP-144, 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 *Bacillus thuringiensis* subspecies *israelensis*, serotype H-14, strain BMP-144?

Bacillus thuringiensis subspecies *israelensis*, serotype H-14, strain BMP-144 is a bacterium that can be found in soil. *Bacillus thuringiensis* bacteria disrupt the digestive system in larvae of certain kinds of insects, causing death. The subspecies *israelensis* is specific to larvae of flies (members of the insect order Diptera) and is often used to control biting flies such as mosquitoes and black flies.

Health considerations

Can approved uses of *Bacillus thuringiensis* subsp. *israelensis* serotype H-14, strain BMP-144 affect human health?

***Bacillus thuringiensis* subsp. *israelensis* serotype H-14, strain BMP-144 is unlikely to affect human health when AQUABAC II XT Biological Larvicide is used according to label directions.**

Potential exposure to *Bacillus thuringiensis* subsp. *israelensis* serotype H-14, strain BMP-144 may occur when handling and applying AQUABAC II XT Biological Larvicide.

When assessing health risks, several key factors are considered:

- the microorganism's biological properties (for example, production of toxic byproducts);
- reports of any adverse incidents;

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*.

- its potential to cause disease or toxicity as determined in toxicological studies; and
- the level to which people may be exposed relative to exposures already encountered in nature to other isolates of this microorganism.

The levels used to assess risks are established 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 that are determined as having no health risks of concern are considered acceptable for registration.

Bacillus thuringiensis subsp. *israelensis* serotype H-14, strain BMP-144 and AQUABAC II XT Biological Larvicide were first registered as pest control products in 1982 and in 2006, respectively. Health Canada re-evaluated the products and approved both for re-registration. At that time, Health Canada published Proposed Acceptability for Continuous Registration PACR2006-09, *Bacillus thuringiensis*.

Studies in laboratory animals describe potential health effects from large doses of exposure to a microorganism and identify any pathogenicity, infectivity, and toxicity concerns. When *Bacillus thuringiensis* was tested on laboratory animals, there was low toxicity following oral, pulmonary and dermal exposures, and no infectivity following oral, pulmonary or intraperitoneal exposures. Furthermore, there was no sign that the MPCA, *Bacillus thuringiensis*, caused any disease.

All microorganisms, including *Bacillus thuringiensis* subsp. *israelensis* serotype H-14, strain BMP-144, contain substances that are potential sensitizers and thus, sensitivity may develop in individuals exposed to potentially large quantities of *Bacillus thuringiensis* subsp. *israelensis* serotype H-14, strain BMP-144.

The end-use product, AQUABAC II XT Biological Larvicide (PCP Reg. No. 27376), is of low acute toxicity via the oral, dermal and inhalation routes of exposure and is classified as an eye irritant, a skin irritant and a potential sensitizer. AQUABAC II XT Biological Larvicide does not contain any formulants of human health concern.

Residues in drinking water and food

Dietary risks from food and drinking water are acceptable.

AQUABAC II XT Biological Larvicide is not registered for food or feed uses and the proposed use expansion to greenhouse ornamentals does not include food crops.

Dietary exposure from drinking water is expected to be low as the label has the necessary mitigation measures to limit contamination of drinking water from the proposed uses of AQUABAC II XT Biological Larvicide. Health risks from residues of *B. thuringiensis* subsp. *israelensis* serotype H-14, strain BMP-144 in drinking water are acceptable due to the low toxicity/pathogenicity profile of *Bacillus thuringiensis*, and its limited exposure following applications of the end-use product.

Risks in residential and other non-occupational environments

Estimated risk for residential and other non-occupational exposure is acceptable.

AQUABAC II XT Biological Larvicide is registered as a commercial biological larvicide end-use product that is used to treat aquatic non-food areas for mosquitos. The new use will include treatment of greenhouse-grown ornamentals by soil drench for fungus gnats. There are no residential uses. The existing label includes measures to prevent bystander and residential exposure such as reducing spray drift. Residential and non-occupational exposure to AQUABAC II XT Biological Larvicide is expected to be low when label directions are observed.

Consequently, the health risk to residents and the general public is acceptable.

Occupational risks from handling AQUABAC II XT Biological Larvicide

Occupational risks are acceptable when AQUABAC II XT Biological Larvicide is used according to the label directions, which include protective measures.

Workers handling AQUABAC II XT Biological Larvicide can come into direct contact with *Bacillus thuringiensis* subsp. *israelensis* serotype H-14, strain BMP-144 through direct contact with skin or through inhalation when applying the product as a soil drench to greenhouse-grown ornamentals.

To protect workers from exposure to AQUABAC II XT Biological Larvicide when applied as a soil drench, the label states that workers must wear personal protective equipment, including a long-sleeved shirt, long pants, waterproof gloves, socks and shoes, and a NIOSH-approved particulate filtering facepiece respirator with any N, R or P filter. The label also includes measures to prevent exposure by reducing spray drift.

The proposed new use does not pose any additional occupational exposure concerns, therefore, the health risks to workers from the proposed use expansion are acceptable when the precautionary statements on the labels are observed.

Environmental considerations

What happens when *Bacillus thuringiensis* subsp. *israelensis* serotype H-14, strain BMP-144 is introduced into the environment?

Environmental risks are acceptable.

The proposed use expansion of *Bacillus thuringiensis* subsp. *israelensis* serotype H-14, strain BMP-144 to greenhouse ornamentals not expected to significantly increase environmental exposure to this microorganism.

As not all species of terrestrial arthropods have been directly assessed for effects at each life stage, the label will include a statement to mitigate the potential risk to beneficial arthropods which may be used in greenhouse IPM programs, as a best practice.

The label will also include a standard statement to manage greenhouse effluent.

Overall, the risks to the environment are acceptable.

Value considerations

What Is the Value of Aquabac II XT Biological Larvicide?

Aquabac II XT Biological Larvicide can control fungus gnats in greenhouse ornamentals.

In addition to its registered uses to control mosquito larvae, AQUABAC II XT Biological Larvicide can be applied as a soil drench on greenhouse-grown ornamentals to control larvae of fungus gnats. Fungus gnat larvae can damage the roots of plants and promote root rot, and emerging adults are a nuisance in retail stores and homes.

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 AQUABAC II XT Biological Larvicide to address the potential risks identified in this assessment are as follows.

Key risk-reduction measures

Human health

The signal words “CAUTION - EYE AND SKIN IRRITANT” and “POTENTIAL SENSITIZER” are on the principal display panel of the AQUABAC II XT Biological Larvicide label. A standard drift statement is required to mitigate exposure to residents and bystanders.

Environment

The AQUABAC II XT Biological Larvicide label will include the following statements: “ENVIRONMENTAL PRECAUTIONS: May be harmful to beneficial insects. Avoid direct contact with beneficial insects when applying the product in the greenhouse.”

“DO NOT allow releases, effluent or runoff from greenhouses containing this product to enter lakes, streams, ponds or other waters.”

Next steps

Before making a final registration decision on AQUABAC II XT Biological Larvicide, containing *Bacillus thuringiensis* subsp. *israelensis* serotype H-14, strain BMP-144, 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 4 June 2026) of this document. Please forward all comments to Pesticides Regulatory Directorate Publications

Section, 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 AQUABAC II XT Biological Larvicide, containing *Bacillus thuringiensis* subsp. *israelensis* serotype H-14, strain BMP-144 (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

AQUABAC II XT Biological Larvicide , containing *Bacillus thuringiensis* subspecies *israelensis*, serotype H-14, strain BMP-144

1.0 The active ingredient, its properties and uses

AQUABAC II XT Biological Larvicide is a commercial class biological larvicide containing *Bacillus thuringiensis* subsp. *israelensis* serotype H-14, strain BMP-144 at 1200 International Toxic Units (ITU) per mg (1.28 billion ITU/kg, minimum).

Refer to the Proposed Acceptability for Continuing Registration PACR2006-09, *Bacillus thuringiensis* which outlines details pertaining to the product characterization and analysis of *Bacillus thuringiensis* subsp. *israelensis* serotype H-14, strain BMP-144 and AQUABAC II XT Biological Larvicide.

1.1 Directions for use

Apply as a soil drench at rates of 1000–2000 mL product/1000 L water ($1.2\text{--}2.4 \times 10^6$ ITU/L) for light to moderate infestations and 2000–4000 mL product/1000 L water ($2.4\text{--}4.8 \times 10^6$ ITU/L) for heavy infestations. Applications should begin when fungus gnats are first detected and repeated weekly (minimum 7 days) when pest monitoring indicates the need.

1.2 Mode of action

Bacillus thuringiensis bacteria produce protein toxins that assume a crystalline structure. When ingested by an insect, the alkaline environment of the insect gut breaks down the crystalline structure, releasing individual protein molecules which then bind to receptors on gut cell membranes and disrupt the cells. The proteins of different subspecies bind to different receptors that are specific to different groups of insects. These bacteria are classified in the IRAC Mode of Action Group 11 (microbial disruptors of insect midgut membranes).

2.0 Methods of analysis

Refer to the PACR2006-09 for details regarding the product characterization and analysis of *Bacillus thuringiensis* subsp. *israelensis* serotype H-14, strain BMP-144 and AQUABAC II XT Biological Larvicide.

3.0 Impact on human and animal health

3.1 Toxicity and infectivity summary

Information pertaining to the toxicity and infectivity of *Bacillus thuringiensis* subsp. *israelensis* serotype H-14, strain BMP-144 and AQUABAC II XT Biological Larvicide can be found in PACR2006-09.

No additional studies or scientific information were required in support of the active ingredient *Bacillus thuringiensis* subsp. *israelensis* strain BMP-144 or the end-use product for the proposed use expansion of AQUABAC II XT Biological Larvicide to greenhouse ornamentals.

Based on testing from various pesticidal strains, *Bacillus thuringiensis* is of low acute oral, pulmonary and dermal toxicity and is not infective or pathogenic following oral, pulmonary or intraperitoneal exposures.

The end-use product, AQUABAC II XT Biological Larvicide, is of low acute toxicity via the oral, dermal and inhalation route of exposure and is classified an eye irritant, a skin irritant and a potential sensitizer. AQUABAC II XT Biological Larvicide does not contain any formulants of human health concern.

3.1.1 Health incident reports

As of 12 September 2025, Health Canada has received one human and one domestic animal incident reports involving *Bacillus thuringiensis*, serotype H-14. The Canadian human moderate severity incident involved exposure to an individual with a history of occupational exposure and sensitivity to a *Bacillus thuringiensis* serotype H-14 product. The individual reported swelling, itchy skin and skin sensitivity following dermal exposure to a product containing *Bacillus thuringiensis*, serotype H-14. The Canadian domestic animal minor severity incident involving a dog potentially ingesting the product from an open product bag. The dog showed symptoms of lethargy and anorexia. Given the limited number of incidents involving *Bacillus thuringiensis*, serotype H-14, no health concerns were identified in this review.

3.1.2 Hazard analysis

The available database in support of *Bacillus thuringiensis* subsp. *israelensis* serotype H-14, strain BMP-144 and AQUABAC II XT Biological Larvicide was previously reviewed from the viewpoint of human health and safety and was determined to be acceptable. No new data were required to support the use expansion to greenhouse ornamentals. Refer to PACR2006-09 for details of the re-evaluation that took place for this active ingredient.

3.2 Occupational, residential and bystander exposure and risk assessment

3.2.1 Occupational and postapplication exposure and risk

AQUABAC II XT Biological Larvicide is currently registered as a commercial larvicide to control mosquito larvae in aquatic non-food areas. The product is diluted and applied using conventional ground spray equipment.

The proposed new application method as a soil drench on greenhouse ornamentals is not expected to result in greater occupational exposure relative to the currently-approved spray methods.

When handled according to the label instructions, occupational exposure is expected to occur primarily by the dermal and, to a lesser extent, inhalation routes for handlers, mixer/loaders, and applicators. Ocular exposure is expected to be minimal. Since unbroken skin is a natural barrier to microbial invasion of the human body, dermal absorption could occur only if the skin were

cut, if the microbe were a pathogen equipped with mechanisms for entry through or infection of the skin, or if metabolites were produced that could be dermally absorbed. *Bacillus thuringiensis* subsp. *israelensis* serotype H-14, strain BMP-144 does not contain any known toxic secondary metabolites and there is no indication that it could penetrate intact skin of healthy individuals.

The existing mitigation measures, which include personal protective equipment (PPE), will also mitigate against exposure from the proposed use expansion. To protect workers from exposure to AQUABAC II XT Biological Larvicide when applied as a soil drench, workers must wear a long-sleeved shirt, long pants, waterproof gloves, socks and shoes, and a NIOSH-approved particulate filtering facepiece respirator with any N, R or P filter. The label also includes measures to prevent bystander and residential exposure such as reducing spray drift.

There is a potential for postapplication exposure to workers entering greenhouses where AQUABAC II XT Biological Larvicide has been applied as a soil drench. Postapplication activities are expected to follow typical agricultural practices for the greenhouse crops, and dermal contact with treated soil is expected to be low.

Precautionary statements (for example, wearing of PPE) on the end-use product labels aimed at mitigating exposure are adequate to protect workers from risk during application and from postapplication exposure. Consequently, occupational risks to workers are acceptable.

3.2.2 Residential and bystander exposure and risk assessment

The proposed expansion of use to greenhouse ornamentals as a soil drench is not a residential use and therefore residential bystander exposure is expected to be similar to the existing commercial use. Consequently, existing mitigation measures are appropriate.

Residential bystander exposure from the commercial use of AQUABAC II XT Biological Larvicide due to drift is mitigated by the inclusion of the standard spray drift statement on the label advising to apply only when the potential for drift beyond the area to be treated is minimal, and to take into consideration wind speed, wind direction, temperature inversions, application equipment, and sprayer setting.

Consequently, the health risks to bystanders and individuals in residential areas from the use of AQUABAC II XT Biological Larvicide are considered acceptable.

3.3 Dietary exposure risk assessment

The existing use pattern of AQUABAC II XT Biological Larvicide does not include any food or feed use, and the proposed use expansion to greenhouse ornamentals also does not include any food or feed use.

Dietary exposure from drinking water is expected to be low as the label has the necessary mitigation measures to limit contamination of drinking water from the proposed uses of AQUABAC II XT Biological Larvicide. The labels will instruct users not to contaminate irrigation or drinking water supplies or aquatic habitats through equipment cleaning or waste disposal. Municipal treatment of drinking water is also expected to further reduce the transfer of residues to drinking water. Furthermore, *Bacillus thuringiensis* subsp. *israelensis* serotype H-14, strain BMP-144 was not observed to cause pathogenicity or infectivity in Tier I studies. Health

risks from residues of *Bacillus thuringiensis* subsp. *israelensis* serotype H-14, strain BMP-144 in drinking water are acceptable due to the low toxicity/pathogenicity profile of *Bacillus thuringiensis*, and its limited exposure following applications of the end-use products.

3.4 Aggregate exposure and risk

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal and inhalation).

In an aggregate risk assessment, the combined potential risk associated with food, drinking water and various residential exposure pathways is assessed. A major consideration is the likelihood of co-occurrence of exposures. Additionally, only exposures from routes that share common toxicological endpoints can be aggregated.

AQUABAC II XT Biological Larvicide is considered to be of low toxicity by the oral and dermal routes, and the end-use product will not be applied near or to drinking water. The label includes statements to minimize non-occupational exposure in residential and commercial areas to the general Canadian population, including infants and children. When the end-use product is used as labelled, there is reasonable certainty that no harm will result from aggregate exposure of residues of *Bacillus thuringiensis* subsp. *israelensis* serotype H-14, strain BMP-144.

3.5 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. In its assessment of common mechanism of toxicity, Health Canada considers both the taxonomy of MPCAs and the production of any potentially toxic metabolites.

For the current evaluation, Health Canada has determined that *B. thuringiensis* subsp. *israelensis* serotype H-14, strain BMP-144 shares a common mechanism of toxicity with other strains of *B. thuringiensis* that are used as MPCAs; *Bacillus thuringiensis* subspecies *kurstaki*, *Bacillus thuringiensis* subspecies *galleriae* strain SDS-502, *Bacillus thuringiensis* subspecies *tenebrionis*, *Bacillus thuringiensis* subspecies *aizawai* strain ABTS-1857, and *Bacillus mycoides* isolate J. The potential health risks from cumulative exposure of *B. thuringiensis* subsp. *israelensis* serotype H-14, strain BMP-144 and these other MPCAs are acceptable when used as labelled given the inherent low toxicity profile of *B. thuringiensis* subsp. *israelensis* serotype H-14, strain BMP-144.

3.6 Maximum residue limits

The specification of a maximum residue limit for *Bacillus thuringiensis* subsp. *israelensis* serotype H-14, strain BMP-144 was not required for the proposed non-food use of the end-use product.

4.0 Impact on the environment

4.1 Fate and behaviour in the environment

Refer to the PACR2006-09 which outlines details pertaining to the environmental fate and toxicology of *B. thuringiensis*, including *Bacillus thuringiensis* subsp. *israelensis* serotype H-14, strain BMP-144 and AQUABAC II XT Biological Larvicide.

There are no changes to the formulation of AQUABAC II XT Biological Larvicide. At this time, the environmental toxicological database for *Bacillus thuringiensis* subsp. *israelensis* serotype H-14, strain BMP-144, and AQUABAC II XT Biological Larvicide, is considered sufficient to assess the risk to the environment from the proposed new use to greenhouse ornamentals.

The use of AQUABAC II XT Biological Larvicide on greenhouse ornamentals is not expected to result in significant exposure to non-target organisms and the risks are therefore acceptable. No additional environmental toxicological information is required.

Not all species of terrestrial arthropods have been directly assessed for effects at each life stage, therefore, the label will include a statement to mitigate the potential risk to beneficial arthropods which may be used in greenhouse IPM programs, as a best practice.

The label will also include a standard statement to manage greenhouse effluent.

4.2 Incident reports related to the environment

A review of incidents related to the environment was not conducted as the proposed expansion of use of AQUABAC II XT Biological Larvicide on greenhouse ornamentals is not expected to result in significant exposure to non-target organisms.

5.0 Value

Aquabac II XT Biological Larvicide is expected to control fungus gnats in greenhouse ornamentals based on extrapolation from a very similar product that is registered for the same use and contains a different strain of the same subspecies and serotype of the bacterial active ingredient.

6.0 Pest Control Product Policy considerations

6.1 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: persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*. The *Pest Control Products Act* requires that the TSMP be given effect in evaluating the risks of a product.

During the review process, *Bacillus thuringiensis* subsp. *israelensis* serotype H-14, strain BMP-144, and AQUABAC II XT Biological Larvicide were assessed in accordance with Regulatory Directive DIR99-03⁵ and evaluated against the Track 1 criteria. Health Canada has reached the conclusion that *Bacillus thuringiensis* subsp. *israelensis* serotype H-14, strain BMP-144, and AQUABAC II XT Biological Larvicide do not meet the Track 1 criteria because the active ingredient is a biological organism and hence is not subject to the criteria used to define persistence, bioaccumulation and toxicity properties of chemical control products.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against Parts 1 and 3 of the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.⁶ The list is used as described in the Science Policy Note SPN2020-01⁷ and is based on existing policies and regulations, including the Toxic Substances Management Policy¹ and *Formulants Policy*,⁸ and taking into consideration the *Ozone-depleting Substance and Halocarbon Alternatives Regulations* under the *Canadian Environmental Protection Act, 1999*, (substances designated under the Montreal Protocol).

Health Canada has reached the conclusion that *Bacillus thuringiensis* subsp. *israelensis* serotype H-14, strain BMP-144 and the end-use product, AQUABAC II XT Biological Larvicide, do not contain any formulants or contaminants identified in the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.

The use of formulants in registered pest control products is assessed on an ongoing basis through Health Canada formulant initiatives and DIR2006-02.

7.0 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 AQUABAC II XT Biological Larvicide, containing *Bacillus thuringiensis* subsp. *israelensis* serotype H-14, strain BMP-144, to control fungus gnats on greenhouse ornamentals.

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.

⁵ DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*

⁶ SI/2005-114, last amended on June 25, 2008. See Justice Laws website, Consolidated Regulations, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.

⁷ Science Policy Note SPN2020-01, *Policy on the List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* under paragraph 43(5)(b) of the *Pest Control Products Act*.

⁸ DIR2006-02, *Formulants Policy and Implementation Guidance Document*.

List of abbreviations

IPM	Integrated Pest Management
IRAC	Insecticide Resistance Action Committee
ITU	International Toxic Units
kg	kilogram(s)
L	litre(s)
mg	milligram(s)
mL	millilitre(s)
MPCA	Microbial Pest Control Agent
NIOSH	National Institute for Occupational Safety and Health
PMRA	Pest Management Regulatory Agency
PPE	Personal Protective Equipment
PRD	Proposed Regulatory Decision
TSMP	Toxic Substances Management Policy

References

A. List of studies/Information submitted by Registrant

1.0 Value

PMRA Document Number	Reference
3223876	2021, Value rationale, DACO: 10.2