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Re-evaluation Decision

Bacillus thuringiensis

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Re-evaluation Decision

After a re-evaluation of the insecticide *Bacillus thuringiensis*, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration of *Bacillus thuringiensis* products for sale and use in Canada.

An evaluation of available scientific information found that products containing *Bacillus thuringiensis* do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration, new risk-reduction measures must be included on the label of products containing *Bacillus thuringiensis*. Mitigation measures to further protect handlers, bystanders and the environment are specified in this Re-evaluation Decision (Appendix II). Additional data are being requested as a result of this re-evaluation.

The regulatory approach for *Bacillus thuringiensis* was first proposed in Proposed Acceptability for Continuing Registration document PACR2006-09, *Re-evaluation of Bacillus thuringiensis,* a consultation document.[1] This Re-evaluation Decision document[2] summarizes the Agency's decision and the reasons for it. Appendix I summarizes the comments received during the consultation process and the PMRA's response to these comments. The comments did not result in substantive changes to the assessment in PACR2006-09; however, they did result in some revisions to the required label statements. To comply with this decision, registrants of *Bacillus thuringiensis* products will be informed of the specific requirements affecting their product registration(s) and of regulatory options available to them.

For more details on the information presented in this Re-evaluation Decision, please refer to PACR2006-09.

Other Information

For *Bacillus thuringiensis*, comments on PACR2006-09 did not result in significant changes to the science assessments. Therefore, the summary of assessments found in PACR2006-09 serves as an evaluation report. A list of references considered by the Agency in support of the registration decision are found in PACR2006-09.

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

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

Any person may file a notice of objection[3] regarding this decision on *Bacillus thuringiensis* within 60 days from the date of publication of this Re-evaluation Decision document. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Request a Reconsideration of Decision, www.pmra-arla.gc.ca/english/pubreg/reconsideration-e.html), or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

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

Appendix I Comments and Responses

1.0 Comments on Strain Characterization

1.1 One comment that was received suggested that serotyping be a required method for strain characterization.

PMRA Response

The PMRA encourages the use of the best available technology for strain characterization. Applicants may use any combination of such technologies to sufficiently characterize their strain. Serotyping will continue to be considered an acceptable method for strain characterization but will not be a required method.

1.2 Clarification was requested as to whether the purpose of more detailed strain characterization is for assessing strain equivalency among products or to ensure batch to batch consistency.

PMRA Response

Registrants are required to provide sufficient information/data to characterize their strain in order to ensure consistency in the active ingredient. Consistency is required within a product line and not between product lines. Registrants may use any combination of technologies capable of sufficiently characterizing their strain and more specific guidance for strain characterization (e.g. genetic sequencing) is not necessary.

For products being submitted under the policy for the protection of proprietary interests in pesticide data, more detailed strain characterization methods (e.g. molecular analyses) may also be used to establish strain equivalency to already registered microbial pest control agents.

2.0 Comments on Species Grouping

2.1 Some users objected to grouping *B. cereus* and *B. thuringiensis* species as one species.

PMRA Response

The Proposed Acceptability for Continuing Registration (PACR) document notes that grouping *B. cereus* and *B. thuringiensis* as one species has been suggested by some researchers but is not being proposed by the PMRA.

3.0 Comments on Potential Toxicity of *Bacillus thuringiensis* (Bt)

3.1 A user commented that the question of potential toxicity of Bt has been resolved and that there are no safety concerns.

PMRA Response

Certain strains of Bt have been found to produce *B. cereus*-like enterotoxins. Despite uncertainty over whether registered strains produce such toxins in their biologically active forms, there is a level of comfort with currently registered strains due to their long history of safe use. The PMRA will continue to collaborate with its international partners on the most appropriate approach concerning such toxins for new strains of Bt, if and when they are proposed for registration.

4.0 Comments on Quality Control

4.1 One user objected to the requirement for a mouse safety bioassay for each production batch. This requirement was seen as too stringent and inappropriate as Bt strains are generally known to be innocuous.

PMRA Response

The main purpose of the mouse safety bioassay is to test for possible contamination by *B. anthracis* rather than the Bt active ingredient. Therefore, this requirement stands. Testing is to be conducted by the registrant and is not required to be repeated by the user.

4.2 Clarification was required on how manufacturers prove that their products are free of β-exotoxin.

PMRA Response

To demonstrate the absence of β-exotoxin, the PMRA requires submission of the results of a fly larvae bioassay. Waivers from conducting fly larvae bioassays as part of routine batch analysis can be considered if a GLP-compliant preliminary fly larvae bioassay demonstrates lack of β-exotoxin production for the proposed manufacturing method. This preliminary bioassay must include a positive control consisting of a β-exotoxin producing strain of *B. thuringiensis* to ensure that the growth medium and growth conditions are sufficient for β-exotoxin production.

4.3 Clarification was required on when certificates of analysis would be required for every production batch.

PMRA Response

Continued submission of certificates of analysis are only required on a case-by-case basis (e.g. for products that are associated with inconsistent microbiological contamination results in batch analysis screens).

5.0 Comments on Label Potency

5.1 A registrant suggested that potency declarations for Bt labels include a statement indicating that potency measurements are not federally standardized so that it is clear to users that applications are conducted based on the recommended rates as opposed to potency.

PMRA Response

Users are required to follow application rates prescribed on each registered product label. The proposed statement is therefore not necessary. Registrants, however, will not be instructed to remove such statements (i.e. potency measurements are not federally standardized) from their labels.

5.2 A registrant encouraged the PMRA to help establish a recognized global potency standard for *B. thuringiensis* subsp. *kurstaki* (Btk)-based insecticides. In the interim, the registrant proposes that efficacy data be used to compare products in order to establish a relative label potency.

PMRA Response

The PMRA welcomes the establishment of a recognized global potency standard for Btk. However, it is not the role of the PMRA to help establish such a standard or to compare the efficacy of one product versus another. Until such a standard is established, Btk potency units must not be misleading (e.g. suggestion of a standardized or international unit).

6.0 Comments on Storage and Shelf Life

6.1 Some respondents objected to the default storage period of six months.

PMRA Response

The default storage period of six months is only required in the absence of acceptable storage stability data. Storage specifications can be extended beyond six months, if supported by data provided by the registrant.

Existing stocks of end-use products (i.e. that have been manufactured within the last two years) are not subject to the new storage specifications and can continue to be used in order to avoid the need for disposal.

7.0 Comments on Personal Protective Equipment (PPE)

7.1 Given the minimal health risks associated with Bt, a number of registrants and users expressed concern over the required level of PPE (i.e. long-sleeved shirt, long pants, waterproof gloves, shoes plus socks, eye goggles and a NIOSH-approved respirator with an N-95, R-95, or P-95 filter). In particular, the mandated use of the respirator when handling, mixing/loading or applying the product elicited many comments.

PMRA Response

Long-sleeved shirts, long pants, and shoes plus socks are standard PPE for all microbial products and are required to prevent dermal exposure and potential sensitization. For the same reason, waterproof gloves are required for all liquid products, products to be diluted in aqueous solutions or products that are applied to water. The respirator and filter is required because of the potential for sensitization after repeated high exposures to high concentrations via the inhalation route. Furthermore, Bt is known to persist in the lungs if inhaled. The "caution eye irritant" and eye goggle requirement may be removed from the labels of technical products and domestic or commercial class end-use products if supported by eye irritation test data or an acceptable rationale.

7.2 Users of commercial/restricted *B. thuringiensis* subsp. *israelensis* (Bti) products objected to the required PPE. These objections were based on limited exposure to users, the cost of outfitting staff, discomfort and public perception.

PMRA Response

Mixers and loaders of commercial/restricted Bti products are required to wear the listed PPE. Eye goggles, gloves and respirators with the approved filters are relatively inexpensive.
In light of the objections raised, however, the PMRA proposes that Bti applicators may remove gloves, eye goggles and respirators if the design and delivery of the application apparatus reduces exposure to a negligible level.

In response to the concerns over public perception, the required NIOSH-approved respirators are not any more intrusive or threatening in appearance than disposable dust masks and other PPE. These protective measures are unlikely to raise public concerns. Occupational users are exposed to Bt products to a greater degree than the general public and need to be protected accordingly.

8.0 Comments on Precautionary Statements

8.1 A registrant objected to the statements related to sensitization that are required on the label in instances where studies demonstrate a lack of sensitization.

PMRA Response

Sensitization studies only test via the dermal route while other routes of exposure (e.g. inhalation) can also lead to sensitization. Although surveillance reports of large-scale human exposure have been reviewed and have not indicated a strong sensitization concern for the general public, the sensitization statements are precautions that are required mainly for the benefit of users and applicators who face increased exposure.

8.2 A respondent requested that restrictions against applying Bt products over urban areas should be deleted from the label as such a restriction would ban gypsy moth eradication programs.

PMRA Response

The label changes outlined in the PACR do not include any further restrictions on application over urban areas. Aerial application of Bt products over urban areas is not banned but remains a restricted class use.

9.0 Comments on the Environmental Assessment

9.1 Another user objected to grouping *B. thuringiensis* subsp. *kurstaki* (Btk), *B. thuringiensis* subsp. *israelensis* (Bti), and *B. thuringiensis* subsp. *tenebrionis* (Btt) together in the environmental risk assessments.

PMRA Response

Environmental toxicology testing was conducted on Btk, Bti and Btt (see Tables 2, 3 and 4 of the Appendix in PACR2006-09). Environmental fate data are not required provided there are no concerns triggered by environmental toxicology testing.

Some environmental fate information is available on Bti. Bti lacks persistence in water when compared to other conventional mosquito control active ingredients. In water, the toxicity of Bti has generally been found to persist in larval feeding zones for days as opposed to weeks due to sedimentation, degradation in organically enriched habitats, dilution and other factors.

9.2 One respondent suggested that Btk and Bti have not been isolated in Canada. This same respondent suggested that Bti products be X-ray treated to prevent the introduction of a non-indigenous living organism to the environment.

PMRA Response

Btk and Bti have been isolated from at least 37 states in the United States and, for the purposes of this re-evaluation, are considered indigenous to Canada. The health and environmental risks associated with Bti are minimal and do not warrant X-ray treatment prior to application.

9.3 A comment was received about how the labelling statements for addressing aquatic invertebrate (i.e. daphnid) sensitivity would be applied.

PMRA Response

Production of heat labile exotoxins, which are toxic to *Daphnia*, is dependent on the manufacturing process. Registrants are required to optimize and control their manufacturing processes sufficiently to prevent production of significant amounts of these heat labile exotoxins. In addition, each new manufacturing process must be tested by a *Daphnia* study (10-day exposure period using a maximum hazard dose) as an indicator of the level of heat labile exotoxins produced. If the test shows significant lethality and if the exotoxin levels cannot be sufficiently controlled during the manufacturing process, appropriate labelling or mitigation will be required to minimize exposure to daphnids.

10.0 Comments on Application to Aquatic Habitats

10.1 A number of users requested an explanation for limiting the application of Btk and Btt over aquatic habitats. The list of aquatic habitats in which Btk and Btt could not be applied was also considered too restrictive.

PMRA Response

Although the health risks associated with drinking water exposure are negligible and aquatic ecosystem impacts are minimal, Btk and Btt are not intended for use in aquatic environments and such applications should be avoided where possible. Consequently, all Btk and Btt end-use product labels must include the following statement under the **DIRECTIONS FOR USE** section.

> DO NOT apply directly to freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands), estuaries or marine habitats. DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

To provide additional guidance on what constitutes an aquatic habitat, the following statement must also appear under the **DIRECTIONS FOR USE** section of all labels for restricted class (forestry) Btk and Btt end-use products with aerial applications:

> BEFORE AERIAL APPLICATIONS TO FORESTS - Consult the most recent provincially approved topographic maps of the area to be treated (1: 50,000) or more up-to-date information (e.g. GPS systems) to identify sensitive aquatic habitats.
>
> Sensitive aquatic habitats include:

a) All running (lotic) and standing (lentic) water bodies, including impoundments, beaver ponds and bog ponds, that appear on the map or GPS system;
b) Running (lotic) and standing (lentic) water bodies that do not appear on the map or GPS system but are visible from the air.

The PMRA recognizes that the above statements may have alternate meanings to other jurisdictions. Consequently the PMRA, in conjunction with stakeholders, will be discussing alternate wording or revisions to the current standard statement.

10.2 The limitation on using domestic class products in ditches and drains while allowing such uses for commercial and restricted class products was questioned.

PMRA Response

The limitation on using domestic class products in ditches and drains exists because such waters are often contiguous with water on neighbouring properties.

10.3 The limitation on applying Bti to drinking water receptacles was considered too restrictive and broad as some users need to control mosquito larvae in animal water troughs.

PMRA Response

Bti is intended for use in containerized water, such as animal water troughs, that cannot be emptied, drained, flushed or changed at least weekly. The PMRA proposes to modify the reference to drinking water to the following.

> DO NOT apply directly to treated, finished drinking water reservoirs or drinking water receptacles when the water is intended for human consumption.

11.0 Comments on Aerial Application Instructions

11.1 A number of comments were received about the specified meteorological conditions for aerial applications (i.e. no applications when wind speed is greater than 16 km/h). This specification was considered too restrictive as modern equipment could be optimized for aerial spraying and as meteorological conditions could change drastically during the same aerial application period.

PMRA Response

Models used to calculate buffer zones take meteorological conditions into consideration. Given that buffer zones are not required for Bt products, specifying the meteorological conditions is also not required. Instead, the PMRA is proposing to replace the existing specified meteorological conditions (i.e. no applications when wind speed is greater than 16 km/h) with the following.

> Apply only when meteorological conditions at the treatment site allow for complete and even coverage. Apply only when meteorological conditions are in compliance with local and/or provincial authorities.

11.2 A user suggested that the term "tracking" in the aerial application instructions is inaccurate and proposed that it be replaced with the term "guidance".

PMRA Response

The last paragraph in the aerial application instructions can be changed to the following.

> Ensure uniform application by using appropriate marking devices and/or electronic guidance equipment.

12.0 Comments on Irrigation System Applications

12.1 Concerns were raised over the limitation on application using irrigation systems.

PMRA Response

Labels for products with efficacy data supporting application by irrigation systems may remove the limitation. All other end-use products must continue to include the statement limiting application using irrigation systems.

13.0 Comments on Maximum Standing Period for Spray Mixtures

13.1 A number of users found the originally proposed standing period for spray mixtures of 12 hours overly restrictive, and that it would pose significant difficulties in operational applications.

PMRA Response

The maximum standing period for spray mixtures was intended for agricultural or forestry uses where products, and hence the preservatives in the formulation, are directed prior to use. In light of the operational difficulties expected as a result of a 12-hour maximum standing period, the PMRA proposes an increase in the standing time to 18 hours for products. The maximum standing period only applies to products that are diluted prior to application. Furthermore, if supporting data are submitted, the reference to a maximum standing period may be extended.

14.0 Comments on Citations

14.1 One respondent requested the link to the United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) on Bt that was cited in the PACR. It was also requested that the RED on Bt be made available in French.

PMRA Response

The RED on Bt can be found at www.epa.gov/oppsrrd1/REDs/0247.pdf. It is not the role of the PMRA to translate foreign review documents.

15.0 Comments on Resistance Management Statements

15.1 There were numerous concerns raised with the resistance management statements.

PMRA Response

While we recognize that resistance management may not apply in full to all Bt product labels (e.g. forestry products), a resistance management statement is now mandatary on all labels. The resistance management recommendations label statement is a standard label statement, and is required on all end-use products except for homeowner/residential uses. With regards to the concerns that this statement will lead to difficulties with mandatory monitoring, please note that this statement will be placed under the heading “Resistance Management Recommendations”. Therefore, the end user is not required to follow these recommendations, and will not be in violation of the label statements if a resistance management program is not followed. Rather, this statement is to outline good general practices to reduce the risk of the development of resistance in pest populations.

16.0 Comment on Translation

16.1 One respondent commented on a discrepancy with English and French versions of the aerial application Instructions in PACR2006-09. The wording implies onboard spraying equipment and excluded calibrated equipment used on a sling. Therefore, the following was suggested: “Épandre uniquement à l’aide d’un équipement pour aéronef à voilure fixe ou à hélice calibrée pour fonctionner...”

PMRA Response

The suggested wording from the respondent has essentially the same meaning as what is proposed in PACR2006–09. However, if the suggested wording will clarify the aerial application instructions for users, this wording is acceptable.

17.0 Comment on Reviews Underway by the USEPA and European Union

17.1 Because the USEPA and the European Union are conducting re-evaluations of *B. thuringiensis* subspecies and the issue of toxin production in relation to their potential risks to human health and the environment, a user suggested that the PMRA postpone its decision regarding the acceptability of continued registration of Bt until these reviews are completed.

PMRA Response

PMRA has committed to re-evaluate by 2009, all active ingredients and formulated end-use products that were registered before 1995 to ensure that their continued acceptability is examined using current scientific approaches. This decision took into consideration the current knowledge regarding toxins produced by *B. thuringiensis*. As stated in PACR2006-09, the PMRA will continue to work cooperatively with other international authorities in determining an appropriate regulatory position in relation to these toxins.

Appendix II Revised Label Amendments

NOTE: This appendix does not identify all label requirements for individual end-use products such as first aid statements, disposal statements, precautionary statements and supplementary personal protective equipment that may be required. Additional information on labels for currently registered products should not be removed unless it contradicts information in this appendix.

Canadian labels must be amended to include the following statements to further protect handlers, bystanders and the environment.

On the principal display panel

The guarantee sections of the labels for the technical grade active ingredients and end-use products must specify a company-specific strain (or other appropriate) designation of *B. thuringiensis* for the active ingredient.

Until a recognized global potency standard for *B. thuringiensis* subsp. *kurstaki* (Btk)-based insecticides is established, the guarantee sections of the labels for technical and end-use Btk products must not imply a standardized or international potency unit (e.g. billion international units).

The labels for the technical and end-use products must include the signal words "POTENTIAL SENSITIZER" and "CAUTION EYE IRRITANT". The "CAUTION EYE IRRITANT" statement may be waived if indicated by eye irritation test data or an acceptable rationale. The labels must also include the following.

Date of manufacture: _____

The labels for **domestic class end-use products** must include or be updated to include the following statement: "KEEP OUT OF REACH OF CHILDREN".

On the secondary display panel

a) The labels for **technical class products** must include the following statements of precaution and personal protective equipment.

> KEEP OUT OF REACH OF UNAUTHORIZED PERSONNEL. POTENTIAL SENSITIZER. CAUTION EYE IRRITANT. Avoid contact with skin, eyes or clothing. Avoid breathing dust/spray mist. Wear a long-sleeved shirt, long pants, waterproof gloves, shoes and socks, eye goggles and a NIOSH-approved respirator with any N-95, R-95, or P-95 filter for biological products when handling or mixing/loading the product and during all clean-up/repair activities. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

The “CAUTION EYE IRRITANT” and eye goggle requirement may be waived if indicated by eye irritation test data or an acceptable rationale.

b) The labels for domestic class end-use products must include or be updated to include the following statement of precaution and personal protective equipment.

> POTENTIAL SENSITIZER. CAUTION EYE IRRITANT. Avoid contact with skin, eyes or clothing. Avoid breathing dust/spray mist. Wear a long-sleeved shirt, long pants, waterproof gloves, shoes and socks as well as eye goggles when handling or applying the product and during all clean-up activities.

The “CAUTION EYE IRRITANT” and eye goggle requirement may be waived if indicated by eye irritation test data or an acceptable rationale.

c) The labels for commercial class end-use Btk and Btt products must include or be updated to include the following statement of precaution and personal protective equipment.

> KEEP OUT OF REACH OF CHILDREN. POTENTIAL SENSITIZER. CAUTION EYE IRRITANT. Avoid contact with skin, eyes or clothing. Avoid breathing dust/spray mist. Wear a long-sleeved shirt, long pants, waterproof gloves, shoes plus socks, eye goggles and a NIOSH-approved respirator with any N-95, R-95, or P-95 filter for biological products when handling, mixing/loading or applying the product and during all clean-up/repair activities. When applicators use closed systems (e.g. enclosed cabs) the personal protective equipment requirements may be reduced or modified. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

The “CAUTION EYE IRRITANT” and eye goggle requirement may be waived if indicated by eye irritation test data or an acceptable rationale.

d) The labels for restricted class Btk and Btt end-use products must include the following statements of precaution and personal protective equipment.

> KEEP OUT OF REACH OF UNAUTHORIZED PERSONNEL. POTENTIAL SENSITIZER. CAUTION EYE IRRITANT. Avoid contact with skin, eyes or clothing. Avoid breathing dust/spray mist. Wear a long-sleeved shirt, long pants, waterproof gloves, shoes and socks, eye goggles and a NIOSH-approved respirator with any N-95, R-95, or P-95 filter for biological products when handling, mixing/loading or applying the product and during all clean-up/repair activities. When applicators use closed systems (e.g. enclosed cabs) the personal protective equipment requirements may be reduced or modified. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

The "CAUTION EYE IRRITANT" and eye goggle requirement may be waived if indicated by eye irritation test data or an acceptable rationale.

e) The labels for commercial and restricted Bti end-use products must include the following statements of precaution and personal protective equipment.

> .KEEP OUT OF REACH OF UNAUTHORIZED PERSONNEL. POTENTIAL SENSITIZER. CAUTION EYE IRRITANT. Avoid contact with skin, eyes or clothing. Avoid breathing dust/spray mist. Wear a long-sleeved shirt, long pants, waterproof gloves, shoes and socks, eye goggles and a NIOSH-approved respirator with any N-95, R-95, or P-95 filter for biological products when handling, mixing/loading or applying the product and during all clean-up/repair activities. Applicators may remove gloves, eye goggles and respirators if the design and delivery of the application apparatus reduces exposure to a negligible level (e.g. backpack sprayer with application wands that apply product directly over water surface). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

The "CAUTION EYE IRRITANT" and eye goggle requirement may be waived if indicated by eye irritation test data or an acceptable rationale.

f) The labels for the technical class and end-use products must include or be updated to include the following statements under the heading **FIRST AID**.

If on skin or clothing:	Rinse skin immediately with plenty of water. Remove contaminated clothing and wash separately before reuse. If irritation occurs and persists or is severe, seek medical attention.
If in eyes:	Hold eye open and rinse slowly and gently with water. Remove contact lenses, if present, then continue rinsing eye. If irritation occurs and persists or is severe, seek medical attention.
If inhaled:	Move to fresh air, apply respiration if needed and seek medical attention.
If swallowed:	Rinse mouth and throat with copious amounts of water. DO NOT induce vomiting. Promptly contact a physician or poison control centre. DO NOT give anything by mouth to an unconscious person.
General:	Seek medical attention if irritation or signs of toxicity occur and persist or is severe. Take container, label or product name and Pest Control Product Registration Number with you when seeking medical attention.

The TOXICOLOGICAL INFORMATION must include the statement “Treat symptomatically.”

g) The labels for commercial and restricted class end-use products must include the following statement under the heading Resistance-Management Recommendations.

> For resistance management, please note that [insert product name] contains a Group 11 insecticide. Any insect population may contain individuals naturally resistant to [insert product name] and other Group 11 insecticides. The resistant individuals may dominate the insect population if this group of insecticides is used repeatedly in the same site. Other resistance mechanisms that are not linked to site of action but specific for individual chemicals, such as enhanced metabolism, may also exist. The following appropriate resistance management strategies should be followed to delay insecticide resistance:

- Where possible, rotate the use of [insert product's name] and other Group 11 insecticides with different groups that control the same pests in a site.

- Insecticide use should be based on an Integrated Pest Management program that includes scouting, record keeping, and considers cultural, biological and other chemical control practices.

- Monitor treated pest populations for resistance development.

- Contact your local extension specialist or certified crop advisors for any additional pesticide resistance management and/or integrated pest management recommendation for specific site and pest problems in your area.

- For further information or to report suspected resistance, contact [insert registrant's name] at [insert registrant's contact information].

h) The labels for all end-use products must include the following statements under **DIRECTIONS FOR USE**.

> DO NOT allow spray mixture to stand in the tank for more than 18 hours.

[This time period may be extended if there are supporting data and is not required on ready-to-use product labels.]

The labels for all end-use products must include the following statements regarding storage and shelf life.

> In order to ensure microbial purity and potency, [insert product's name] should be stored in the original container at [insert temperature as supported by data] and used within [insert time period as supported by test data] of the date of manufacture.

[In the absence of storage stability data, the label must direct users to store at temperatures between 5–15°C and to use the product within 6 months from the date of manufacture.]

Unless supported by efficacy data, all end-use product labels must include a "DO NOT apply by any type of irrigation system" statement.

i) The labels for all end-use products that have aerial applications must include the following statements.

Aerial Application Instructions:
Apply only by fixed-wing or rotary aircraft equipment that has been functionally and operationally calibrated for the atmospheric conditions of the area and the application rates and conditions of this label.

Label rates, conditions and precautions are product-specific. Apply only at the rate recommended for aerial application on this label. Where no rate for aerial application appears for the specific use, this product cannot be applied by any type of aerial equipment.

Ensure uniform application by using appropriate marking devices and/or electronic guidance equipment.

Use Precautions:
Apply only when meteorological conditions at the treatment site allow for complete and even coverage. Apply only when meteorological conditions are in compliance with local and/or provincial authorities.

Operator Precautions:
DO NOT allow the pilot to mix product to be loaded onto the aircraft. Loading of premixed product with a closed system is permitted. It is desirable that the pilot have communication capabilities at each treatment site at the time of application.

The field crew and the mixer/loaders must wear the personal protective equipment described in the **PRECAUTIONS** section of this label. All personnel on the job site must wash hands and face thoroughly before eating and drinking. Protective clothing, aircraft cockpit and vehicle cabs must be decontaminated regularly.

Product Precautions:
Read and understand the entire label before opening this product. If you have questions, call the manufacturer at [insert toll free number] or obtain technical advice from the distributor or from your provincial agricultural or forestry representative. Application of this specific product must meet and/or conform to the aerial uses and rates on this label.

j) The labels for *B. thuringiensis* subsp. *kurstaki* and *B. thuringiensis* subsp. *tenebrionis* end-use products must include the following statement under the **DIRECTIONS FOR USE** section.

> DO NOT apply directly to freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs, and wetlands), estuaries or marine habitats. DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

In addition, *B. thuringiensis* subsp. *kurstaki* and *B. thuringiensis* subsp. *tenbrionis* restricted class end-use products with aerial applications must also include the following statement under the **DIRECTIONS FOR USE** section.

> BEFORE AERIAL APPLICATIONS TO FORESTS - Consult the most recent provincially approved topographic maps of the area to be treated (1: 50,000) or more up-to-date information (e.g. GPS systems) to identify sensitive aquatic habitats.
>
> Sensitive aquatic habitats include:
> a) All running (lotic) and standing (lentic) water bodies, including impoundments, beaver ponds and bog ponds, that appear on the map or GPS system;
> b) Running (lotic) and standing (lentic) water bodies that do not appear on the map or GPS system but are visible from the air.

The PMRA recognizes that the above statements may have alternate meanings to other jurisdictions. Consequently the PMRA, in conjunction with stakeholders, will be discussing alternate wording or revisions to the current standard statement.

k) The labels for *B. thuringiensis* subsp. *israelensis* end-use products must include the following statement under the **PRECAUTIONS** section.

> DO NOT apply directly to treated, finished drinking water reservoirs or drinking water receptacles when the water is intended for human consumption.

l) Any reference to specific users (e.g. homeowners, cottage owners, rural dwellers) must be deleted from the labels of *B. thuringiensis* subsp. *israelensis* domestic class end-use products, and the following statement must be included in the **DIRECTIONS FOR USE** section.

[insert name of product] is for use only when mosquito larvae are present in:

- standing water wholly confined to the property of the user where there is no existing outflow beyond the property limits that remains for more than a week and cannot be drained (for example, flooded depressions, ponds)

- containerized water (for example, bird baths, flower planters, discarded tires, ornamental ponds and rain barrels) that cannot be emptied, drained, flushed or changed at least weekly

DO NOT apply this product to any water that is designed to flow beyond your property limits (for example, ditches, drains, rain gutters or catch basin sumps that flow into weeping tile beds or municipal storm drain systems). BEFORE APPLYING THIS PRODUCT to a water body where there is a possibility of outflow beyond your property limits, contact your provincial/territorial regulatory authority as a permit may be required.

To help prevent mosquito infestations on your property, get rid of mosquito breeding sites. Do this by emptying, flushing or draining containerized and standing water, wherever practical, at least weekly or more frequently if mosquito larvae are present. For example, remove leaf litter from rain gutters, drill holes in bottoms of tire swings or discarded tires, empty water collected on pool covers, turn over wheelbarrows and other containers, empty trapped water from recycling bins or trash containers, cover rain barrels with fly screen netting, replace water in bird baths and chlorinate swimming pools.

m) The following must be deleted from labels of commercial class products containing *B. thuringiensis* subsp. *israelensis*.

- any reference to specific users, e.g. farmers, cottage owners, rural dwellers; and
- any reference to wholly contained waters, e.g. standing water wholly contained within the property of the user.

In addition, the labels of these products must include the following statement.

Consult provincial/territorial pesticide regulatory officials for required authorization.

Appendix III Additional Data Requirements

The following data are required as a condition of continued registration under section 12 of the *Pest Control Products Act*. The registrants of *B. thuringiensis* are required to provide these data within the time specified in the decision letter.

- complete characterization data, in particular methods to identify their strain, as company-specific strain designations will be required on Canadian-registered product labels
- complete description of physical properties