

City of Hamilton Public Health Services

2008 Position Paper on the City of Hamilton's Proposed Spring, 2008 Gypsy Moth Control Program using Foray 48B (*Btk- Bacillus thuringiensis ssp kurstaki*)

The City of Hamilton's Public Works Department, in collaboration with several municipalities and agencies spanning from Toronto to Hamilton and the general surrounding area, has a gypsy moth treatment program planned for the spring of 2008. Municipalities and agencies spraying this spring include Toronto, Town of Oakville, City of Burlington, Conservation Halton, Hamilton Conservation Authority, the Royal Botanical Gardens (RBG), and the City of Hamilton. Treatment for all areas involves aerial spraying of the *Bacillus thuringiensis* subspecies *kurstaki* pesticide in specified areas of each affected municipality. The spray program is being coordinated by BioForest Technologies using Zimmer Air as the aerial applicator.

City of Hamilton Public Health Services has no public health based objections to aerial spraying for gypsy moth using Btk; details below further outline Public Health Services' position. Of note, *Bacillus thuringiensis* was also recently re-evaluated by the Pest Management Regulatory Agency (PMRA), an arm of Health Canada, and the decision, published on May 6, 2008, states that, "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". For details on the complete re-evaluation, please refer to <http://www.pmra-arla.gc.ca/english/pdf/rvd/rvd2008-18-eng.pdf>.

Regarding any precautions to protect human health, the PMRA requires no special precautions, however if someone wishes to take some additional steps, they can choose to do so. The Pest Management Regulatory Agency states:

"Members of the public are unlikely to experience *any* [their emphasis] symptoms if inadvertently exposed to Btk spray, and no special precautions are necessary or required. Individuals who have concerns, however, should take reasonable precautions to avoid exposure during a spray program in the same way they would avoid pollen or other airborne materials during days when air quality advisories are issued. They can also reduce exposure by staying indoors with windows and doors shut during the spray period if spraying is taking place in their area, although this is not required by health officials."

City of Hamilton Public Works has, and will continue to provide, information about the spray program and notifications to the public. Meetings have been held at Public Works committee, there has been a public consultation period seeking input about the program- through submitting concerns to the website or to Councillors – and via the four open houses held in the spray zones – Glanbrook, Ancaster, Dundas, and Greensville (Greensville open house was inclusive of Waterdown residents) from April 16 to April 22, 2008.

Notifications about specific spray dates and times include, but are not limited to: website information about the spray program (www.hamilton.ca/gypsymoth), one general notice in the daily newspaper (The Hamilton Spectator ran the ad on Friday, May 2, 2008), ads in local weekly papers, radio ads, notices to be delivered to those in the direct spray zones and abutting areas, by signage in the general areas, and by noting names and contact information for those who contact the telephone line (905-540-5618) requesting additional notification details.

Background

The City of Hamilton is planning a control program for gypsy moth this spring that will include aerial spraying of *Bacillus thuringiensis* subspecies *kurstaki* (Btk) to control gypsy moth larvae (caterpillar stage) in certain areas of the city. An assessment conducted by BioForest Technologies, that assessed the extent of the gypsy moth proliferation in the city, concluded that aerial spraying of Btk was the most practical and cost effective strategy to reduce the gypsy moth population in the areas that were surveyed.

Bacillus thuringiensis subspecies *kurstaki* – Btk- is a bacterium that occurs naturally in soil world wide. It has been used as a biopesticide to control forest caterpillar pests since the mid 1970s. It targets only lepidopterans (moth and butterfly species) that are in the larval stage at the time of spraying; the larvae (caterpillar) must feed on the leaves (foliage) at the time of the spray application of Btk in order to be affected and die off. Btk is approved for organic and non-organic farming use and Foray 48B is listed with OMRI- the Organic Materials Review Institute at http://omri.org/OMRI_datatable.php?search=foray.

Btk is also approved for residential and commercial use including aerial application over residential areas including but not limited to parks and parkland. See complete label information regarding one Btk product, Foray® 48B at http://72.14.205.104/search?q=cache:BoWeo1bpgYQJ:pr-rp.pmra-arla.gc.ca/PR_SOL/pr_web.ve1%3Fp_ukid%3D3093%2520+low+volume+aqueous+concentrate+foray+48B&hl=en&ct=clnk&cd=1 (Or under a search engine such as Google, type in *Low Volume Aqueous Concentrate Foray 48B* and select the first site option in .pdf or html format).

The proposed City of Hamilton *Btk* biopesticide control program is similar to recent moth control programs carried out by the City of Mississauga in 2006 & 2007, and the City of Toronto in 2007. A residential area of Hamilton in the Ancaster area was also treated privately through a group of residents in 2007. Gypsy Moth outbreaks can severely weaken or kill certain species of trees. The caterpillar or larval stage of the insect eats the leaves of trees making them more susceptible to diseases, drought, and damage by other insects.

A review of literature, reports, communication documents, presentations, website information (including the S.T.O.P. document), and conversations with health department staff in Peel, Halton, Valent BioSciences staff, BioForest Technologies, and concerned residents (both on the phone and in person at the gypsy moth open houses hosted by the City of Hamilton), was carried out to assess the possible human health effects of the Btk pesticide. Peel Region Health Department, City of

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Toronto Public Health, and Halton Region Public Health, all had no objections to the use of Btk in the aerial spraying programs in their jurisdictions after their individual reviews.

Hamilton's Public Health Service's assessment concerning aerial spraying of Btk, like Halton's assessment, is restricted to the potential toxicological effects on humans and will not focus on the desired or undesired ecological or environmental effects or on the necessity of using this or other pesticides in this situation.

Note: Hamilton's assessment below includes direct sections courtesy of Halton Region Public Health from their detailed review.

Excerpts are from the November 23, 2007 letter from Halton Region Health Department to City of Burlington regarding the endorsement of the use of Btk:

The commercial name of Btk for this spray program is Foray 48B. This product consists of spores and a unique crystalline protein produced by the *Bacillus thuringiensis* subspecies *kurstaki* bacterium. The formulation of spores and crystalline proteins consist of water and approved ingredients such as corn, potatoes and grains that are combined in fermentation tanks to make the final formulation. According to Valent BioScience, one of the makers of the Btk pesticide, *Bacillus thuringiensis* subspecies *kurstaki* is the Bt most widely used commercially to protect agricultural crops, fruit trees, rural and urban forest from defoliating lepidopteran larvae.

The active ingredient of Foray 48B is the *Bacillus thuringiensis* subspecies *kurstaki* bacterium that has been shown to kill certain caterpillars. Specifically, the protein crystal produced by the bacterium when ingested by the target larvae carries an endotoxin that destroys the gut of the lepidopteran larvae. The release of the endotoxin is dependent on the alkaline environment found in the gut of lepidopteran larvae. Destruction of the gut wall disrupts the insect's feeding which results in death within 2 to 5 days. The acidic stomachs of humans and non-insect animals do not activate Bt toxins. Furthermore, the mechanism of the endotoxin is initiated by their binding to unique receptor sites on the cell membranes of the insect gut. There are no known equivalent sites in mammalian species that could be affected.

In 2006, the Pest Management Regulatory Agency (PMRA) re-evaluated *Bacillus thuringiensis* for continued registration in Canada. Btk has been registered in Canada since 1962. The re-evaluation was based largely on the USEPA Registration Eligibility Decision (RED) published in 1998 and on current knowledge regarding toxins produced by *B. thuringiensis*. In its re-evaluation, Health Canada's PMRA indicated that *Bacillus thuringiensis* is acceptable for continued registration in Canada provided that PMRA's proposed mitigation measures (label statements to protect workers and bystanders) are adopted. Under the Pest Control Products Act (PCPA) in Canada, Foray 48B registration number is 24977.

[Update Note: In May 2008, the re-evaluation decision occurred and Btk can continue to be used in Canada.]

Toxicology

The World Health Organization writes:

Mammalian toxicity studies on Bt-containing pesticides demonstrate that the tested isolates are not toxic or pathogenic (McClintock et al., 1995), as they occur in the products. Toxicity studies submitted to the US Environmental Protection Agency to support registration of Bt subspecies, and reviewed by McClintock et al. (1995), failed to show any significant adverse effects on body weight gain, clinical observations or upon necropsy. Infectivity/pathogenicity studies have shown that the intact rodent system responds as expected to eliminate Bt gradually from the body after oral, pulmonary or intravenous challenge. However, clearance of Bti and Btk is not instantaneous. An intact immune system is not a prerequisite for clearance of Bti and Btk.

Eight human volunteers ingested 1 gram of a Btk formulation (3×10 spores/g of powder) daily for 5 days. Of the eight volunteers, five also inhaled 100 mg of the Btk powder daily for five days. Comprehensive medical examinations immediately before, after, and 4 to 5 weeks later failed to demonstrate any adverse health effects, and all the blood chemistry and urinalysis tests were negative (Fisher & Rosner, 1959).

According to Health Canada, Btk poses little threat to human health either through handling or from being exposed during a spray program. Many studies, as well as surveillance for disease during aerial spraying, have also concluded that there is no evidence of adverse effects from the use of the biological pesticide. In keeping with the findings by the USEPA, the PMRA has indicated that *Bacillus thuringiensis* is not known to exert any effect on the immune or endocrine system. There are also no expected risks from consumption of treated commodities for the general population, children and infants. In addition, health risk associated with drinking water exposure is expected to be negligible due to lack of toxicological concern for *Bacillus thuringiensis*.

There are label directions restricting direct application or contamination of water bodies as well as prohibition of application to treated finished drinking water. A study to assess the length of time that Bt can persist in soil, found the organism up to 8 weeks after treatment. However the vertical percolation rate of Bt in soil was found to be very low in that 90 to 99% of the spores remained in the uppermost 5 cm of soil thereby posing very little risk of the pesticide finding its way into the water table.

There have been some reports that Btk may cause temporary mild irritation to eyes, skin and nose in some people. Studies that looked at hospital emergency room use during Btk aerial spraying program did not observe an increase in hospital use. However, despite this finding, some studies have reported adverse health consequences such as upper airway, gastrointestinal and neuropsychiatric symptoms as well as reduction in overall perception in health in the exposed population. Oregon Department of Agriculture et al., in an

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environmental assessment of a gypsy moth eradication program, stated that the reported effects from Btk are likely transient and pathogenic effects are not likely even in individuals with impaired immune systems.

The World Health Organization (WHO) acknowledges that there are some case reports on the occurrence of Bt in patients with different infectious disease. However according to the WHO, none of the studies demonstrated an actual risk to human health from the use of Bt. In addition, lab test studies where swabs of wounds were taken to determine whether Btk had caused infections have not positively identified Btk as a pathogen. According to researchers in 2001, there had only ever been two cases reported where Btk had caused infections and both were in people with severe burns or blast injuries.

Despite the widespread use of Bt-based products, only two incidents of possible allergic reactions have been reported to the US EPA (McClintock et al., 1995). After detailed analysis, neither of these was considered to be causally related to Bt.

Regarding avoidance of exposure, the PMRA states:

Members of the public are unlikely to experience *any* [their emphasis] symptoms if inadvertently exposed to Btk spray, and no special precautions are necessary or required. Individuals who have concerns, however, should take reasonable precautions to avoid exposure during a spray program in the same way they would avoid pollen or other airborne materials during days when air quality advisories are issued. They can also reduce exposure by staying indoors with windows and doors shut during the spray period if spraying is taking place in their area, although this is not required by health officials.

Hamilton

In addition to Halton's review of scientific studies and documents from respected agencies such as the World Health Organization, Hamilton Public Health Services reviewed several other studies, both opposed to the use of Btk in aerial applications (S.T.O.P. documents, and the Journal of Pesticide Reform article), and those that determine that Btk is not a cause of disease and is not expected to cause adverse health effects in humans (including the AXYS paper, New Zealand studies, and PMRA/Health Canada information).

Discussion

City of Hamilton Public Health Services has no public health objection to the use of Btk in aerial application to control for gypsy moth in Hamilton.

No special precautions are required to be taken by the general public. To reiterate PMRA's information,

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Individuals who have concerns, however, should take reasonable precautions to avoid exposure during a spray program in the same way they would avoid pollen or other airborne materials during days when air quality advisories are issued. They can also reduce exposure by staying indoors with windows and doors shut during the spray period if spraying is taking place in their area, although this is not required by health officials.

Although there have been reports of temporary eye, nose and skin irritation in some people, overall, *Bacillus thuringiensis* subspecies *kurstaki* has been used for a number of years to control forest pests with minimal to no reported adverse health outcomes. Concerns regarding human health effects exist among the public and in the scientific literature. However, the methods used to identify the bacteria in cases of concern have not been conclusive. The PMRA has established a position that Btk poses minimal risk to human health when used as directed. In addition, a review of Health Canada and PMRA documents, research articles in peer reviewed journals, review of information from Peel Public Health, Halton Region Health Department, as well as communication with staff in the two municipalities support the conclusions of “no reported adverse health outcomes” or minimal health risk associated with aerial spraying of *Bacillus thuringiensis* subspecies *kurstaki*.

In conclusion, City of Hamilton Public Health Services has no public health based objections to aerial spraying of Btk as part of the City of Hamilton moth control program provided that the rules of application as outlined by the Pest Control Products Act and other applicable federal or provincial legislation, such as the Ministry of Environment approval process, are strictly upheld. Under these conditions, it is reasonable to expect similar results in Hamilton as occurred in the City of Toronto, and the City of Mississauga. In addition, no calls about health concerns were received in 2007 for the Ancaster area private aerial treatment for gypsy moth.

Reporting Pesticides Incidents

The Pest Management Regulatory Agency now requires mandatory reporting to them by registrants, of any incidents including adverse effects to health. Their fact sheet, Pest Management Regulatory Agency Fact Sheet on Reporting Pesticide Incidents states,

The new *Pest Control Products Act*, provides Health Canada with the authority to require pesticide incident reporting. The Pest Control Products Incident Reporting Regulation (IRR) introduce a mandatory incident reporting requirement for registrants of pesticides in Canada and applicants wishing to register new pesticides in Canada. Registrants and applicants are now required by law to report incidents, including adverse effects to health and the environment, to Health Canada’s Pest Management Regulatory Agency (PRMA) within a set time frame.

The mandatory reporting requirement is to be complemented by a voluntary reporting system that will allow the medical community, various organizations, and individuals to report incidents directly to Health Canada.

Voluntary Incident Reports

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Reports can also be made by individuals by calling the PMRA at 1-800- 267-6315. For more information about Reporting Pesticide Incidents, please see the PMRA website at www.pmra-arla.gc.ca.

If the City of Hamilton receives any calls related to environmental or human health concerns following spray events, details will be referred to the PMRA for their direct investigation.

City of Hamilton Public Works has, and will continue to provide, information about the spray program and notifications to the public and will be contacting those who request to be directly notified. For more information about the gypsy moth program, including the communication plan, spray zones, or other program questions, please contact the gypsy moth phone line at 905-540-5618. or visit www.hamilton.ca/gypsymoth.

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