Received: 01.09.2001 from: Marty Pearce, MPH, Canada

HUMAN HEALTH SURVEILLANCE DURING THE AERIAL SPRAYING FOR CONTROL OF NORTH AMERICAN GYPSY MOTH ON SOUTHERN VANCOUVER ISLAND, BRITISH COLUMBIA, 1999

Abstract
The Capital Health Region coordinated a human health study of possible short term health effects of aerial spraying of the biological pesticide, Bacillus thuringiensis kurstaki, on southern Vancouver Island, Canada in the spring of 1999. The study was performed as a condition necessary for the spraying to take place under a provincial order-in-council.

Notice: By clicking the link below, you will be redirectet to the server of the Capital Health Region, Canada.

See the full report

HUMAN HEALTH SURVEILLANCE DURING THE AERIAL SPRAYING FOR CONTROL OF NORTH AMERICAN GYPSY MOTH ON SOUTHERN VANCOUVER ISLAND, BRITISH COLUMBIA, 1999

A Report to the Administrator, Pesticide Control Act,
Ministry of Environment, Lands and Parks,
Province of British Columbia

Prepared by the Capital Health Region
Office of the Medical Health Officer
Director of Research

December 31, 1999

Updated March 2001

EXECUTIVE SUMMARY

The Capital Health Region coordinated a human health study of possible short term health effects of aerial spraying of the biological pesticide, Foray 48B, on southern Vancouver Island in the spring of 1999. The study was performed as a condition necessary for the spraying to take place under a provincial order-in-council.

The study included a survey of the health of asthmatic children in the region; a survey of the general health of the population; monitoring and analysis of visits to doctors' offices and hospital emergency departments; laboratory surveillance of clinical samples which contained Btk; measurement of environmental levels of Btk; and a review of self-reported complaints of health symptoms made to telephone information and support hotlines.

Results to date show no apparent relationship between aggravation of asthma in children and aerial spraying of Foray 48B. As well, no short-term health effects were detected in the general adult population nor in hospital emergency room visits.

Although some people self-reported symptoms which they attributed to the spray program, the research methods used in this project did not detect any change in health status that could be linked to the spray program.

A single case was reported of a five-year-old child with previously-diagnosed asthma whose symptoms worsened during the spray period. It was not possible to conclude definitively whether this was the result of exposure to the Foray 48B spray or not.

On the basis of these studies, the study committee of the Capital Health Region makes several recommendations to cabinet. These include a recommendation that more health monitoring is needed as part of any future spray programs, that a formal system for sharing information about spray program monitoring and effects between health regions be established, and that public education programs need to be continued as a prominent part of long-term Gypsy Moth control plans.

The Exposure Assessment and Analysis of MSP data were completed in Fall 2000. The findings are discussed in Section 8: Updated Information. These findings do not alter the conclusions regarding short-term health outcomes described during the 1999 aerial spray program.

FOR CONTROL OF NORTH AMERICAN GYPSY MOTH ON SOUTHERN VANCOUVER ISLAND, BRITISH COLUMBIA, 1999

TABLE OF CONTENTS

8.1 Physician Office Visit Data Analysis
8.2 Exposure Study Summary
8.3 Updated Conclusions - March 2001

BTK JOURNAL SUBMISSIONS/PUBLICATIONS - As of March 2001

PREAMBLE

The Human Health Surveillance Scientific Committee (HSSC) has prepared this report on behalf of the Capital Health Region. The report was prepared for and submitted to the Pollution Prevention and Remediation Branch (Pesticide Control Act Administrator), British Columbia Ministry of Environment. The evaluation and conclusions contained in this report have been based on the investigations and research conducted by members of the Committee within the limitations and conditions specific to the 1999 Gypsy Moth Eradication Program in Victoria, British Columbia.

The report is based on information generated through a review of the literature and targeted research and surveillance activities conducted by HSSC members.

SECTION 1
BACKGROUND ON THE 1999 VICTORIA GYPSY MOTH ERADICATION CAMPAIGN
Updated March 2001

SECTION 1 - Background

1.1 The 1999 Victoria Gypsy Moth Eradication Program

Bacillus thuringiensis is an ubiquitous family of rod-shaped bacteria that can naturally be found in soil, foliage, water and air. This species is characterized in part by its ability to form environmentally resistant spores and produce endotoxins that are toxic to insects. The various strains of *B. thuringiensis* target insects such as Lepidopteran (butterflies and moths), Coleopteran (beetles) and Dipteran (flies). Btk is known for its strong activity against Lepidopteran species and limited effects on Coleopteran and Orthopteran species. In order for the toxin to be activated, the Gypsy Moth (*Lymantria dispar*) caterpillar must eat the bacterium. The bacterial toxin is activated only after exposure to alkaline conditions and specific enzymes found in the hindgut of the caterpillar.

The Foray 48B formulation contains a number of intentionally added inert ingredients, also known as formulants. There are a variety of purposes for these compounds which include stickers and binders that help the spray remain on vegetation after it is applied, and compounds to reduce product contamination by other bacteria or yeasts. While the specific ingredients are considered proprietary information, some insights can be gained by a review of the general methods for Btk cultivation and by regulatory requirements. Many of these formulants are found in the US EPA lists of other (inert) pesticide ingredients including List 3 (unclassifiable as to toxicity), List 4A (minimal toxicological concern) or 4B (minimal concern under prescribed conditions of use). However, the nature and amounts of specific inert ingredients can vary between commercial products and are, therefore, considered trade secrets. Compounds in Foray 48B could include residues of the leftover bacteria food such as starches, glucose or sucrose, proteins (usually from corn or soy), water, and a sticking agent. Other food grade materials such as sodium hydroxide and potassium phosphate may be found as basic ingredients of the growth media used to produce Btk bacteria. Chemicals, such as antifoaming agents, may be added to facilitate the growth and recovery of cultivated organisms. Other compounds, including bacterial metabolites, are present but in much smaller quantities.

Because of the large areas involved in the eradication program (approximately 13,400 hectares) and the terrain of the spray area, aerial application of Foray 48B was determined to be the only feasible and effective means to eradicate the Gypsy Moth.The spray was delivered by way of McDonald Douglas DC-6 and Aztec aircraft. The former plane delivered 470 L of spray per minute while the latter delivered 70 L/min. The DC-6 carried 11,350 L of Foray 48B while 580 L were carried in the Aztec. The application rate goal was 4 L per hectare. The target spray droplet size was 110 to 130 micrometres. All spray aircraft were equipped with Differential Global Position Systems (Satloc) that provided the crews with accurate maps of the spray area, including all spray boundaries. Aircraft flight lines and spray deposit were monitored by the Satloc as well as by air and ground observers. Kromecote cards were used to confirm spray distribution and were monitored by Ministry of Forests staff.

1.2 Use of Foray 48B in North America

B. thuringiensis has been used for large-scale forestry and agriculture pest eradication programs in Europe and North America, human disease control programs in Africa, and retail sales for pest control by gardeners and commercial landscapers. The United States Environmental Protection Agency (US EPA) estimated that an average of 1.4 – 2.1 million acres of traditional agricultural crops were treated annually between 1987 and 1996 in the United States alone. An additional 30,000-50,000 acres of nursery and greenhouse plants, 1 – 1.5 million acres for mosquito and blackfly control and 75,000 – 1.5 million acres of forest and parks are annually treated with *B. thuringiensis* compounds. It has been estimated that over one million pounds of Btk are applied annually in the United States to control Gypsy Moths. Btk has been used in pesticide products for almost 40 years. Rachel Carson, author of **Silent Spring**, described *B. thuringiensis* products as an "...important answer to the problems of such forest insects as the budworms and the Gypsy Moth."

In Canada, pest control products must be reviewed and registered by the Pest Management Regulatory Agency (PMRA), a federal agency attached to Health Canada, before they can be sold or used. Products are registered under the Pest Control Products Act. The US EPA performs this function in the United States. Although the exact identity of the inert ingredients is considered a trade secret and not made publicly available, these ingredients must be disclosed to the PMRA before the product can be sold in Canada. PMRA evaluators must decide on a product's toxicity or infectivity to people before registration is granted. Health Canada does not independently conduct health and safety tests of products. Instead it relies upon registrants to submit study results that usually are conducted by independent laboratories and in accordance with internationally accepted experimental guidelines. After reviewing toxicity information on Btk and the inert ingredients in Foray 48B, both the Canadian PMRA and the US EPA have registered Foray 48B for aerial application, including over inhabited areas.

The PMRA reviewed the same types of toxicological information for Foray 48B that were submitted to the US EPA during a recent (1998) re-registration of Foray and Dipel products. All new pesticides, including microbial products such as Foray 48B, are subjected to animal studies in which the product is applied to test animals by mouth, skin and inhalation. Irritation and hypersensitivity potentials of the products are also reviewed. The PMRA reviewed numerous mammalian studies that addressed the acute toxicity and infectivity of Btk through various routes of administration including oral, pulmonary, intravenous and interperitoneal injections. It also looked at skin and eye irritation, skin toxicity and hypersensitivity tests. Additional short-term and chronic dietary exposure studies were also submitted to the PMRA. Although some studies showed that Btk could persist in various organs for up to several weeks after exposure to low and high levels, the PMRA judged that there was no evidence of toxicity, multiplication or infection in laboratory animals. The PMRA indicated that the data available to review for registration of Foray 48B were quite extensive.

Products containing *B. thuringiensis* were first registered for use in the United States in 1961. They were subjected to re-review by the US EPA in 1998 because standards for assessing pesticide safety had been modified in recent years. The US EPA concluded again in 1998 that "all uses, as prescribed {in their review}, will not cause unreasonable risks to humans or the environment". Moreover, the US EPA stated that, "{the} sum total of all toxicity data submitted to the Agency complete with the lack of any reports of significant human health hazards of the various *Bacillus thuringiensis* strains allow for the conclusion that all infectivity/pathogenicity studies normally required under {US regulations} be waived in the future as long as product identity and manufacturing process testing data indicated that there is no mammalian toxicity associated with the strain."

1.3 Spray Zones

In total, 13,398 hectares were treated with aerially applied Foray 48B in four separate blocks: Nanaimo (164 hectares), Duncan (429 hectares), Brentwood Bay (602 hectares), and Greater

Victoria (12,203 hectares) (Figure 1). The areas that were sprayed include a mix of residential and rural areas. Using 1996 Census figures from Statistics Canada, approximately 80,000 residents lived in the intended spray areas.

The Capital Health Region (CHR), with an area of 2,350 square kilometers, is situated on the southern end of Vancouver Island and includes Greater Victoria and several of the Gulf Islands. The entire region had a 1996 total population of 336,488. This area is a popular tourist destination and retirement area because of its coastal location and moderate climate. The largest of the spray areas was in the CHR with approximately 75,420 people living in the spray zone. The average age of the population in the Greater Victoria spray area was approximately 36 years old with the largest age group being 35 to 44 years. Approximately 7% of the population in this area was less than five years of age with approximately 6% over the age of 75. The Brentwood Bay spray area included a population of approximately 2,000 and is also part of the CHR. The average age of the population was 38.4 years with the dominant age group being five to 19 years. Approximately 4% of this population was less than five years of age with approximately 6% over the age of 75.

The Central Vancouver Island Health Region covers a part of Vancouver Island immediately north of Greater Victoria and includes an area of more than 12,300 square kilometers. Both the Duncan and Nanaimo spray areas are included in Central Vancouver Island Health Region. The Nanaimo spray area was relatively small covering a total population of about 625. The average age of the population was 34 years with the largest age group being 25 to 34 years of age. Approximately 8% of the population was less than five years old with 4% over the age of 75.

The Duncan spray area had a population of about 1,160. The average age of this population was 46.3 years of age with the largest age group being that of the 75 and over age. Approximately 7% of this population was under the age of five while 22% were over the age of 75.

1.4 Spray Dates

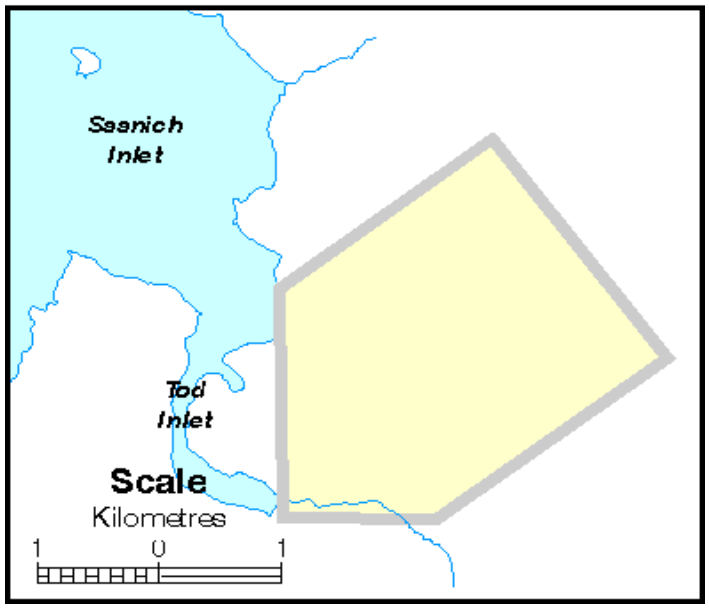
The main Victoria spray area was divided into four sections labeled A1, A2, B1 and B2. The spray dates for these areas and the other spray areas are shown in table 1. Spraying occurred only between sunrise and 7am.

Table 1. Dates of aerial spraying in each of the spray areas.

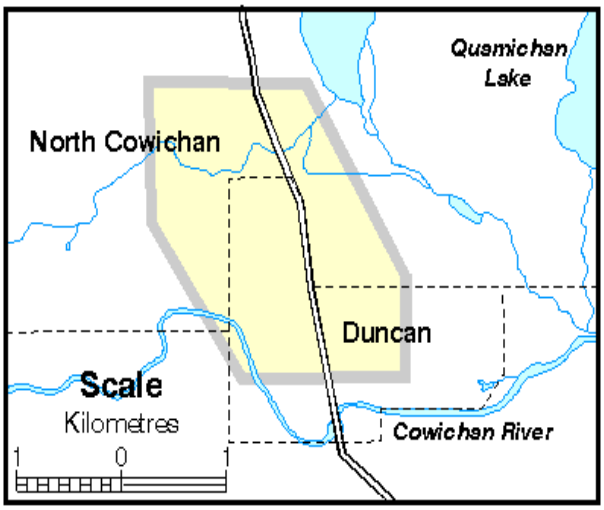
Date	Victoria				Brentwood	Duncan	Nanaimo	Tsawwasen
	A1	B1	A2	B2				
May 8				X	X			
May 9		X	X		X	X		
May 10	X					X		
May 11							X	X
May 19			X	X	X			
May 20	X	X			X	X		

May 21	X					X	X	X
June 8			X	X	X			
June 9	X	X				X	X	
June 10								X

Brentwood Aerial Spraying
602 Hectares



Duncan Aerial Spraying
429 Hectares



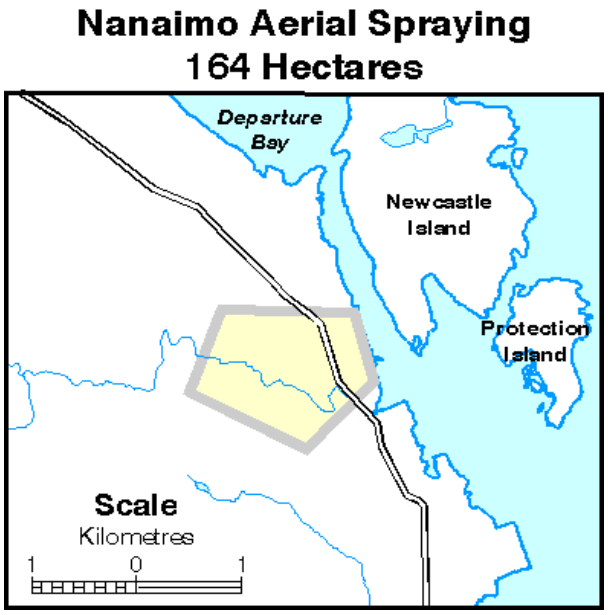


Figure 1. Maps Depicting the Intended Foray 48B Spray Areas on Southern Vancouver Island, 1999 Gypsy Moth Eradication Project.

SECTION 2 - BACKGROUND AND OBJECTIVES

2.1 Health Study Background

Pesticide use permits granted by the B.C. Ministry of Environment, Lands and Parks are open to review and amendment by an appeal panel of the cabinet-appointed Environmental Appeal Board.

A 1998 Victoria area Gypsy Moth ground spray program was the result of an appeal board panel amendment to a permit that had previously been approved by the Ministry of Environment, Lands and Parks. The amendment made to the permit allowed only limited ground spraying rather than aerial application in the parts of the Victoria area where moths were found. The Gypsy Moth control agent used for the ground spray was Foray 48B.

Concerns raised by the public at that appeal board hearing were primarily about possible health effects of aerially applied pesticide exposure for people with allergies, asthma, other respiratory ailments, and immune deficiencies. Despite past appeal boards' rulings that upheld aerial spray permits, this board chose to allow ground spraying only.

Based on their monitoring results after the ground spray program was completed, the Canadian Food Inspection Agency (CFIA) determined that the ground spray program was not successful. To avert the possibility of a major quarantine of plant products moving from B.C. to the U.S., the federal government declared that "regulated areas" would be established for southern Vancouver Island. This affected the movement of logs, Christmas trees and nursery products to the United States. The Provincial Government concluded that the economic and ecological implications of a population of Gypsy Moths becoming established on Vancouver Island were serious enough to warrant further eradication efforts.

The Provincial Government declared the situation an emergency and passed the 1999 North American Gypsy Moth Eradication Program Regulation (Order in Council 169/99) under the Pesticide Control Act (RSBC 1996,c.360,s. 2) and the Plant Protection Act (RSBC 1996,c.

365,s.8(2)(a)). The order-in-council (OIC) allowed aerial spraying during the spring of 1999. Certain conditions were outlined in this OIC including the funding of an independent Health Study. It was prescribed that the CHR in cooperation with other health regions in the spray area conduct the study.

The health study outline was designed based on a thorough review of previous health studies and considered the health concerns raised by the community at the 1998 appeal board hearing.

The CHR established a Health Surveillance Scientific Committee (HSSC) consisting of a community representative and independent experts in public health, epidemiology, clinical microbiology, biological pesticides, and environmental health. The Committee was responsible for the design and independent assessment of the surveillance and research results. The panel limited its activities to the evaluation of direct human disease outcomes. Its evaluation did not consider the effects on socio-economic determinants of health nor health effects on other species or ecosystems. Prior to developing the surveillance program, the HSSC reviewed available information on Foray 48B and the results of surveillance performed previously in B.C. and elsewhere. The HSSC felt it important to build on, rather than just duplicate, the results of previous surveillance. Surveillance activities were designed to focus on those populations and health end points that would be expected to be the most sensitive indicators of potential Foray 48B effects on health.

2.2 Human Health Surveillance Objectives

The goal of this Human Health Surveillance was to summarize and add to the current understanding of the public health effects of aerial spraying of Foray 48B. The goals were to:

- Determine if the spray has any short-term human health effects, and if so, what and at what levels.
- Inform the public about the general health of people in the region before, during and after the spray.
- Provide a basis for public health recommendations in the event of future spray programs.
- Respond to community concerns.
- Publish scientific papers based on the results of the surveillance activities.

Based on a review of the literature, consideration of concerns expressed at the Environmental Appeal Board hearing into the aerial spray program, available resources, and interaction with local experts, the HSSC developed a number of surveillance and research activities. At the outset of the project, the Committee considered the following five questions when developing the surveillance activities:

1. Are there detectable changes in human health outcomes temporally related to the aerial application of Foray 48B or its components?
2. Are there temporal confounders that could result in detected effects?
3. What is the nature of the variation in exposure to the aerial application of Foray 48B or its components?
4. Are there groups at increased risk because of either increased probability of exposure or increased susceptibility as a result of pre-existing medical conditions?

5. What is the public perception of the health effects related to aerial application of Foray 48B?

A goal of the Committee was to design a surveillance program that would build upon the existing scientific understanding of the effects of Btk aerial spraying as well as address concerns expressed by the public. The following topics were identified as the major foci of the surveillance program:

1. Development and application of specific methods to differentiate Btk isolates that occurred naturally from those applied in the spray, in both clinical and environmental isolates.

2. A comparison of health effects occurring in the general population that may not require attendance at hospitals or physician offices.

3. The use of control groups to compare health effects and/or exposures before and after the spray and inside and outside of the spray zone.

4. A detailed study of acute health effects in specific high-risk groups.

5. Surveillance for reports of clinical disease attributed to Btk isolates identical to those in the spray.

6. An evaluation of the distribution of exposure to spray components over time and space using sophisticated air monitoring equipment.

The health surveillance was comprised of seven components:

1. Asthmatic Children's Survey:
   The survey studied the health of children with asthma, both inside and outside the spray areas for any health changes that could be attributed to the spray.

2. General Population Survey:
   This telephone survey documented the health of a group of adults inside and outside the spray area both before and after the spray.

3. Laboratory Surveillance:
   Laboratory analysis was used to find people whose laboratory tests found Btk and to determine the role, if any, it played in being responsible for human disease, and also to identify the specific type of Btk bacteria found in the lab results and compare it to the specific type of Btk used in Foray 48B.

4. Exposure Assessment Measurements:
   Air samples were collected in order to determine the air concentrations of Btk within the spray area, both inside and outside homes, as well as over time.

5. Doctors' Office Visits:
   This information was reviewed for any possible links to the spray program.

6. Emergency Room Visits:
   Information from local hospitals' emergency rooms was studied and compared to previous years, and analyzed to determine any possible links to the spray program.

Telephone Health Support Line Data:
A telephone support line was available to the community during the spray periods and the information collected was summarized in the context of the other surveillance activities.

SECTION 3 - RESULTS

3.1 Evaluation of Human Health Effects

3.1.1 Health Effects Documented from Hospital Records

Four callers to the CHR Health Support Line (see section 3.4 **[correction: section 3.1.3]** for more details) self-reported that they planned to attend or attended an emergency room during the spray period for ailments they believed could be attributed to the spray. However, a review of patient admission data collected from emergency rooms of hospitals serving the spray zones did not demonstrate an increase in overall emergency room visits nor an increase in visits to emergency rooms for complaints that could plausibly be linked to the spray. Admission data were collected from emergency rooms located in and around the spray zones. Data were categorized according to the principal disease affecting patients (ICD-9 codes). The data were graphed to look for any peaks in admissions around the time of the spray and to compare the trends to the same data from the same time period in 1998. Figure 2 shows the three-day moving average of all emergency room visits for people living in the spray zone. There were no significant increases in emergency room visits associated with the spray periods in any of the spray zones. Similarly there was no detectable increase in specific diagnoses that could plausibly be associated with exposure to Foray 48B. These included respiratory illness, chronic obstructive pulmonary disease, asthma, dermatitis, and gastrointestinal illness.

As part of the surveillance program, clinical laboratories servicing the spray zones were asked to forward all laboratory isolates of *Bacillus* spp. from clinical specimens of any type from patients to a reference laboratory for a period during and after the spray program. The goal was to identify any clinical disease, including that occurring in immunocompromised persons, that might be attributed to Btk.

Clinical isolates were first examined for growth characteristics, morphology and biochemical properties to select for possible Btk isolates. These isolates were forwarded to a molecular biology laboratory where they were subjected to molecular techniques to confirm if they were Btk, and if so, if they were the same strain used in Foray 48B (HD-1 strain).

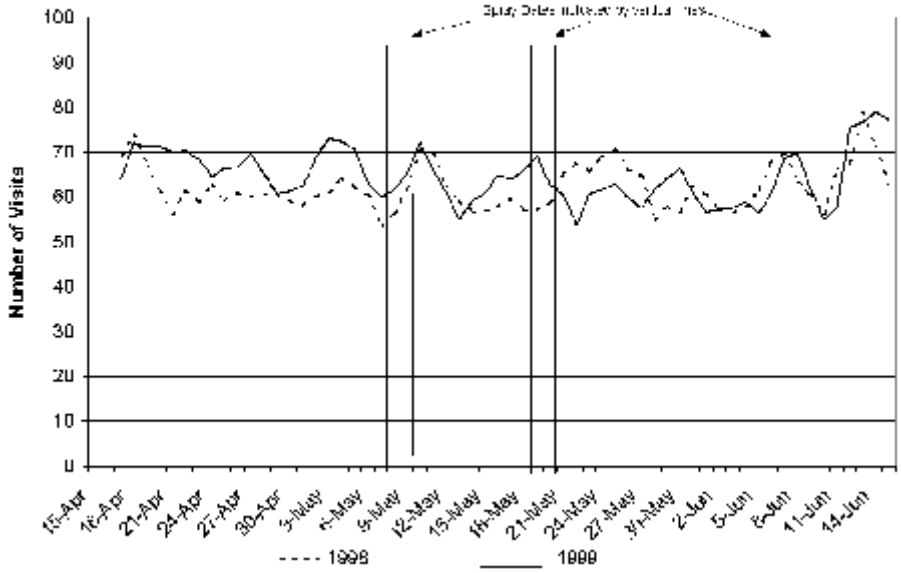


Figure 2. Emergency room visits for all diagnoses for residents of the Victoria spray zone.

The medical history, place of residence and occupation of each patient from which a *Bacillus cereus*-group organism (to which Btk belongs) was recovered was reviewed. The medical history

was examined to see if Btk could be assigned a role as a primary contributor or associated cause of the patient's disease.

A series of strict criteria were established by medical microgiologists based on accepted diagnostic microbiology and infectious disease principles to determine whether or not a Btk isolate could be considered the primary cause of a person's illness. These determinations were made in consultation with the patient's doctor. Based on these criteria, this study was not able to classify Btk as the primary cause of any individual's disease during the 1999 spray program.

Between May 1 and October 1, 1999, 34 isolates of *B. cereus* group were identified. During the same time period in 1998, when the organism was not being actively looked for, six isolates of *B. cereus* group were recovered from clinical specimens from synovial fluid, pleural fluid, urine and various skin site swabs. All of the 1998 isolates were judged to be contaminants.

Seven of the 1999 isolates were confirmed to be Btk at the clinical laboratory based on growth characteristics, morphology and biochemical properties, including the presence of the unique parasporal bodies visualized by phase contrast microscopy. These same seven were validated as Btk HD-1 (the same strain used in Foray 48B) by molecular methods. Six of the seven cases are summarized in table 2 (the seventh is described in section 3.3 **[correction: section 3.1.2]**).

Table 2. Clinical isolates of Btk identified during spray program.

Case	Gender/Age	Diagnosis	Source of Btk	Conclusion
1	Female, 65	Gastroenteritis, dehydration, history of Crohn's	1 of 4 blood cultures grew Btk	Sample contaminant
2	Male, 48	Tuberculosis	Aspirate from neck swelling grew *M. tuberculosis* and Btk	Sample contaminant
3	Infant	Infected incision following surgery	Wound culture grew *Staphylococcus aureus* and Btk	Environmental contaminant
4	Female, 76	Endometrial cancer	Chest fluid culture grew Btk	Sample contaminant
5	Female, 61	Wound infection following surgery	Wound culture grew mix of bacteria including Btk	Environmental contaminant
6	Female, 61	Osteoarthritis of the knee	Knee fluid grew Btk	Sample contaminant

Btk was considered a contaminant in all six of these cases. A sample was considered a contaminant if the Btk isolated was determined to not contribute to the patient's illness or infection, or when recognized pathogens were also recovered in the specimen; and/or the illness resolved without treatment or with treatment with an antibiotic to which Btk is resistant. Sample contamination is considered to have occurred when the Btk was introduced to the sample either during the process of collecting the specimens for examination or during the laboratory handling and processing of the specimens. Environmental contamination is considered to have occurred when Btk has been deposited on the skin or in a wound.

3.1.2 Health Effects in People with Asthma

A study was conducted with the objective of determining if spraying with Foray 48B was associated with an increase in the symptoms in children with asthma. Children with asthma were selected as a group for targeted surveillance because both the published literature and local opponents to the spray program had identified these children as potentially being at increased risk of adverse effects from the spray.

Study participants were recruited from a program serving children with moderate to severe asthma living in the Capital Health Region. These children were followed from one week before the first spraying until five days after the third and last spraying. Twenty-nine children from within the spray area were each matched on gender and age with a control child from outside the spray areas. The Research Review and Ethics Committee of the Capital Health Region approved the study design. Informed written consent was obtained from a parent of each participant.

The respiratory health of the children was measured in two ways. First, the children recorded symptoms daily in a diary. Second, Peak Expiratory Flow Rates (PEFR) were measured and recorded in a chart in the diary twice daily. Two additional questionnaires were used to record past history of the child's asthma, medication use, potential allergens or triggers in the home and other, mainly non-asthmatic, symptoms that the child might have.

The primary determinant of a child's exposure was whether or not the participant's residence was inside the spray zone, but two other measures of exposure were also used. A Kromecote card (used to assess ground level distribution of the spray droplets) was placed outdoors at the residence of each study participant on the evening before a spray. Parents were instructed to take nasal swabs from each participant on the evening before each spray and approximately two hours after the spray. These swabs were assessed for the presence of Btk. Molecular techniques were used to confirm that the isolates were, or were not, Btk of the type used in Foray 48B.

The children living within the spray zone did not have any more asthma symptoms than did those outside the zone, either before or after each spray. Neither the subjects nor the controls developed more asthma symptoms after any of the sprays. There were no significant differences in Peak Expiratory Flow measurements between the subjects and the controls. There were no significant differences between the subjects and their controls at any of the six times, pre-and post-spray, for non-asthmatic symptoms (Figure 3). The symptoms score was recorded in a diary with a higher score resulting from more symptoms. Very few symptoms of any kind were seen.

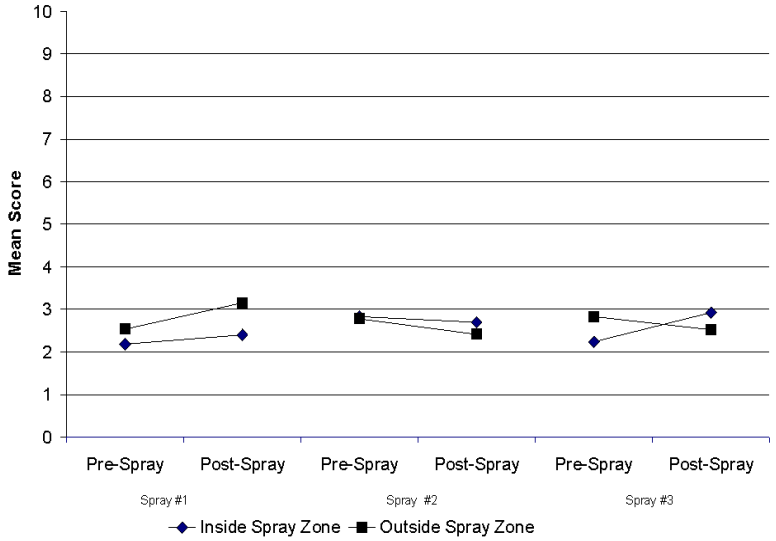


Figure 3. Comparison of pre and post spray non-asthmatic symptom scores for respondents living inside and outside the spray zone from the Asthmatic Children Study.

When the data were evaluated based on a child's nasal swab results, rather than place of residence as a measure of exposure, there was no evidence of worsening of asthma or non-asthmatic symptoms when a child was compared pre- and post-spray.

This study did not show evidence of adverse effects on children with asthma from the use of Foray 48B by aerial spraying. We consider that it is unlikely that the failure to demonstrate adverse effects of the spraying was caused by selection of a group of children with mild asthma. Children are almost always referred to the program that was used for recruiting study participants only after they have visited the Emergency Room or have been hospitalized.

Other parts of this surveillance project support the conclusion of the above study. As part of the general population health survey conducted for this project (see section 3.3. **[correction: section 3.1.3]**) people among a randomly sampled portion of the general population reporting that they had physician-diagnosed asthma did not demonstrate any deterioration in their mental or physical health after the spray. There was also no evidence that people with eczema or seasonal allergies in this sample population were adversely affected.

The surveillance program (clinical specimens, health support line and emergency room visits) did detect one asthmatic child whose asthma symptoms worsened during the spray period. However, without specific medical tests it is not possible to determine what caused his symptoms. This five-year old boy presented to the emergency department on May 21, 1999, with a two-day history of worsening asthma symptoms. During the first spray, his mother noted the child experienced coughing, sniffling and a tickle in his throat that responded to his asthma medication (Ventolin puffer). The child remained indoors with the doors closed during the sprays. His symptoms lasted for two days. On May 21, the child initially had relief with ventolin, but upon visiting the hospital, required the puffer every two hours with only moderate improvement. The child did not show any signs of infection on physical examination or on radiographic examination of his chest. He was treated for his asthma, it improved, and he was sent home. A nose swab taken while he was in hospital grew a pure culture of Btk. This finding is not surprising as we observed Btk in nose swabs from other people before and during the spray program, and the amount of Btk in the environment increased during the spray program. It is not known if the isolate represented Btk that had contaminated surfaces or hairs in the nose or if it had colonized this patient's nose. Given that the child showed no signs of infection and did not reqire antibiotics, it can be concluded that the Btk was not causing

infectious disease. The mother also phoned the CHR Health Support Line to report her son's emergency room visit and symptoms. She self-reported that her son experienced sneezing, shortness of breath, sinus and chest congestion, and nasal discharge. She said the symptoms responded to ventolin, anti-histamine and an herbal remedy. This child lived within the spray zone.

It is possible that something other than the spray triggered the worsening asthma symptoms of this child. For example, an increase in deciduous tree pollen was noted (see section 3.5 **[correction: section 3.2.2]**, Figure 7) at the time this child visited the emergency room. As a GROUP, the children with asthma did not show worsening after the sprays. It would be difficult with our design to show that the spray did not affect an individual child. If it did, however, it could be only a very small number, or the results would have been statistically significant between the groups within and outside of the spray areas.

3.1.3 Health Effects in the General Population

One component of the aerial spray program in Victoria was a health support telephone line for the public. It was operated in tandem with a general information line offered by the Ministry of Forests. The CHR Health Support Line served three main goals:

- to support with medically trained staff health decisions made by the community during the aerial spray program,
- to document self-reported health symptoms among the community, and
- to provide a specific point-of-contact for the general public with the CHR regarding health concerns associated with the spray program.

Two registered nurses staffed health phone lines for 12 hours during the spray days and one day post-spray. Outside the regularly scheduled telephone coverage, calls received on an aswering machine were checked every afternoon. Close contact with the provincial MOTH line enabled the nurses to contact callers with health concerns between spray periods. A standardized form was used to record symptoms, demographic information, self-assessment of severity of symptoms and planned health actions. Callers' addresses were mapped in relation to spray boundaries.
From March until the completion of the spray program, 3,270 calls were made to the Provincial government's MOTH line. During May and June, 162 (5%) "health related calls" were made to this MOTH line (Figure 4). Approximately 64% (104) of the latter calls were referred to the CHR Health Support Line. These calls resulted in 127 health symptom reports. A number of callers (36) included reports for family members as well as themselves generating 66 of the 127 (52%) health symptom reports. Callers were predominantly female (83%). For those addresses that could be coded, it was found that for the CHR, 44 of the 68 callers lived inside the spray zone, while in the Central Vancouver Island Health Region, none of the callers lived within the spray zone.

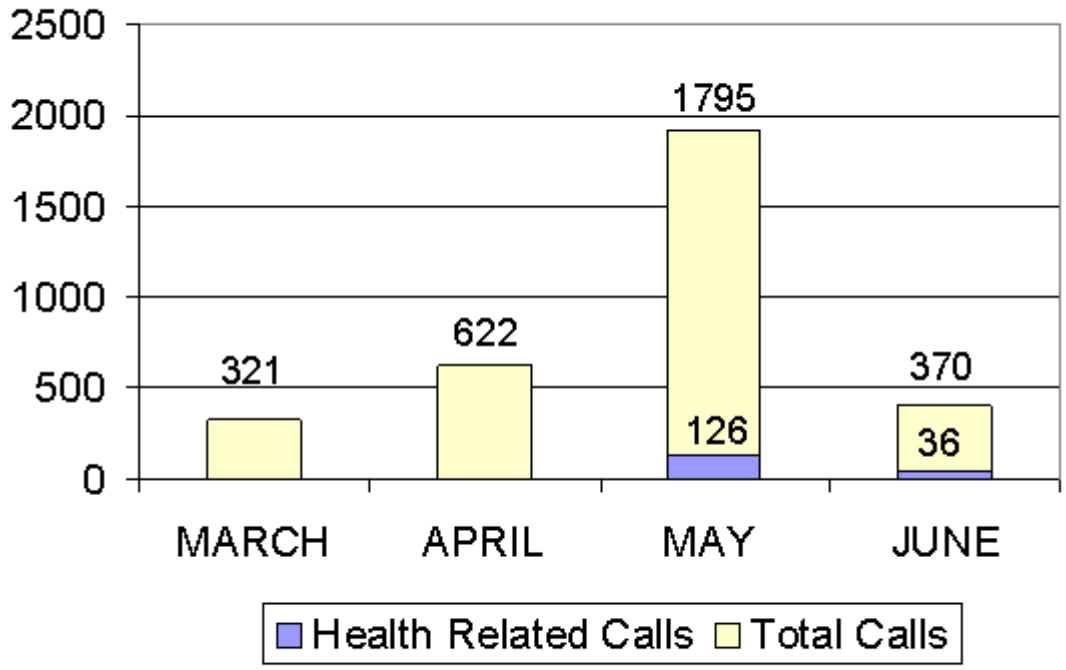


Figure 4. Distribution of Ministry of forest Moth Line Calls showing proportion of health related calls referred to CHR Health Support Line.

The health status of the callers was reported as excellent (46%), good (41%), fair (7%) and poor (6%). Over one half of the health symptom reports (51%) noted pre-existing conditions of allergy, asthma and/or eczema. On average, callers reported three symptoms per report (range 1-12). Headache, shortness of breath, redness, itching, and burning of the eyes, stuffy or runny nose, sore throat, cough and upset stomach or nausea and a "metallic taste" were described. Self-care was the most frequent described planned action. Also, 37 reports planned to follow-up or had visited with a physician and four cases had visited or planned to visit a hospital emergency room.

The symptoms self-reported to the provincial MOTH line and the CHR Health support line are the result of a passive survey in which the caller was sufficiently motivated to call and report symptoms. As the callers are not matched to a control group, it is not possible to make cause-and-effect conclusions regarding the symptoms reported.

The main goal of the health support line was to document what the community reported. The Committee relied upon the controlled study design of the General Population Survey and the review of the Physician Office Visits for an interpretation of possible health symptom increases related to the spray program.

The objective of the General Population Survey was to determine if there were detectable short-term, self-reported physical and mental health effects in adults during the aerial spraying of Foray 48B. This analysis also examined relationships between people's attitude towards the spray program and other factors such as reported symptoms and demographics.

A random sample of phone numbers and related addresses was drawn for households in the CHR. Postal codes were used to identify whether a household was inside or outside of the spray zone. Telephone interviews were conducted on people 19 years of age or older within this random sample. Five attempts at callbacks were attempted before a new number was selected. Respondents were asked questions about their mental and physical health using a standardized form. They were queried about specific symptoms and were asked to provide

certain demographic and geographic information to interviewers. Health-related questions were asked of the same people on two occasions, once before and once after a spray. Eighty-one percent of respondents participated in the post-spray interview.

Of the 3,282 homes called between April 30 and May 5, 1999, 1,250 persons originally agreed to take part in the study. Because of later refusals to finish interviews or other factors, a total of 1,009 surveys were analyzed; 522 respondents lived in the spray zone and 487 lived outside. The two groups were similar with respect to age, gender, income and attitude towards the spray program.

The vast majority of the respondents (98%) were aware of the spray program. More than one-half of participants (56%) supported the spray program and believed the spray was not harmful. Approximately one-quarter of the respondents believed the spray to be harmful to people. Gender and age affected these beliefs in that women and younger adults more often were concerned about health effects and women were less likely to support the spray program.

The General Population Survey was unable to detect any effects of the spray on short-term mental or physical health in members of the general population pre or post spray or for those inside or outside the spray zone. Almost 88% of the participants classified their physical health as good (28%), very good (39%) or excellent (21%). For mental health, 38% of the people classified themselves as excellent, 36% as very good and 18% as good. While gender was not associated with these categories, people with higher incomes were more likely to classify themselves as being in excellent physical and/or mental health. The telephone survey found that only 9% of the respondents reported physician-diagnosed asthma, 16% reported seasonal allergies and 9% reported that they had eczema.

There were no differences in reported symptoms between those inside and outside the spray before the spraying was conducted. For those living inside the spray zone, there was no change in reported symptoms after the spray except for an improvement in the category "other". For those living outside the spray zone, there was an improvement in "unexplained tiredness" after the spraying occurred. One possible explanation for these improvements is the improved weather conditions that were needed for the program to proceed (see section 3.5 **[correction: section 3.2.2]**). There were no differences in other reported symptoms. Based on multivariate analysis, it was seen that the best predictor for the presence of specific symptoms post-spray was if a person reported the same symptoms in the pre-spray interview. Living inside the spray zone was not a predictor for any of the self-reported symptoms.

Based on the standardized measure of health status, there was a small improvement in the average mental health score after the spray period for residents inside and outside the spray zone; again, perhaps a reflection of improvements in the weather. There were no significant changes in the physical health scores (Figure 5).

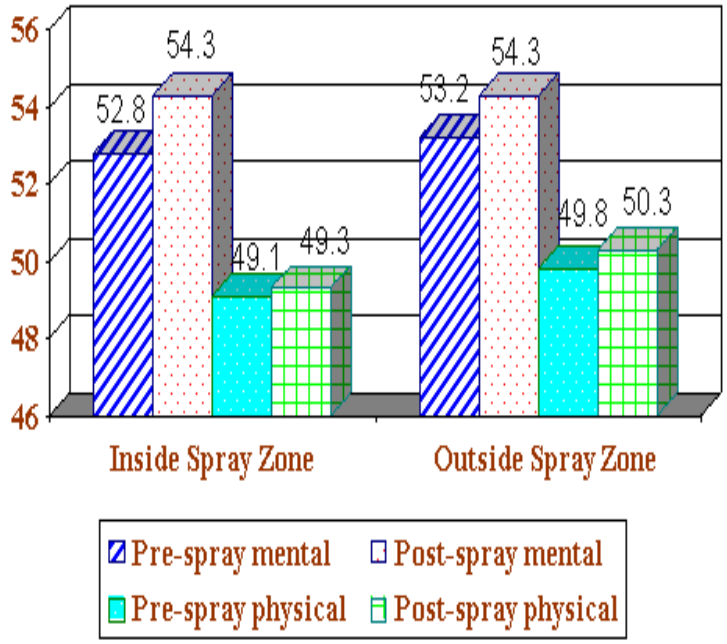


Figure 5. Comparison of Mental and Physical Health Scores from the General Population Survey. A higher score represents better health status.

3.2 Population Exposure

3.2.1 Exposure to Btk

As part of the surveillance efforts in Victoria in 1999, a laboratory study was undertaken to identify *Bacillus thuringiensis* subspecies *kurstaki* HD1 (Btk-HD1) in all samples collected pre and post spray. Air and human (nasal swab from asthma study) samples collected before and after aerial applications of Foray 48B, both in the spray zone and outside of the spray zone, were analyzed for the presence of Btk-HD1. Samples of fruits and vegetables from local food markets, collected pre and post spray, and all clinical isolates from patients suffering bacterial infections that occurred during the spray period were also analyzed for the presence of Btk-HD1. Molecular techniques were used to screen more than 10,000 isolates of bacteria.

The molecular analysis was able to consistently distinguish among different strains of *Bacillus thuringiensis*, as well as between *Bacillus thuringiensis* subspecies *kurstaki* HD1 and *B. cereus*. The bacterium Btk-HD1 was observed on three of 17 (17.6%) food samples, and 131 of 449 (29.0%) nasal swab samples.

Bacillus thuringiensis subspecies *kurstaki* HD1 was detected prior to the application of Foray 48B both inside and outside the spray zone. The number of Btk-HD1 positive samples increased significantly after aerial application of Foray 48B both inside and outside the spray zone (Figure 6). Nasal swabs were collected from volunteers of families who participated in the environmental air monitoring program. Btk-HD1 was positively identified in the nasal swabs of 12 of 13 (92.3%) individuals sampled.

A total of 17 fruit and vegetable swabs were collected during the spray program. Of the eight pre-spray samples, two (25%) were positively identified as Btk-HD1 and of the nine post-spray samples one (12.5%) was positively identified as Btk-HD1. *B. cereus* group isolates were identified in nine environmental samples (such as soil and outdoor surfaces) collected post spray, inside the spray zone. Of these, five (55.5%) were positively identified as Btk-HD1.

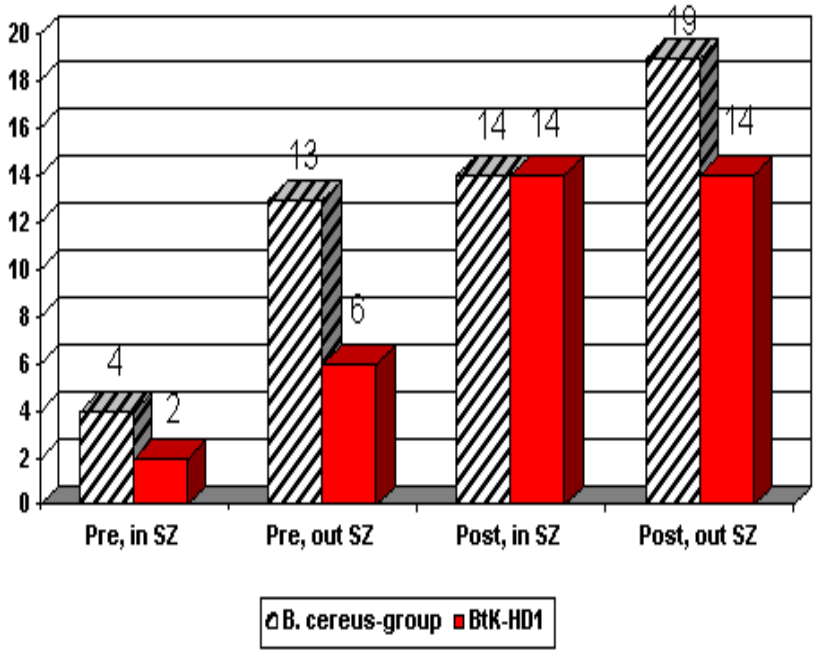


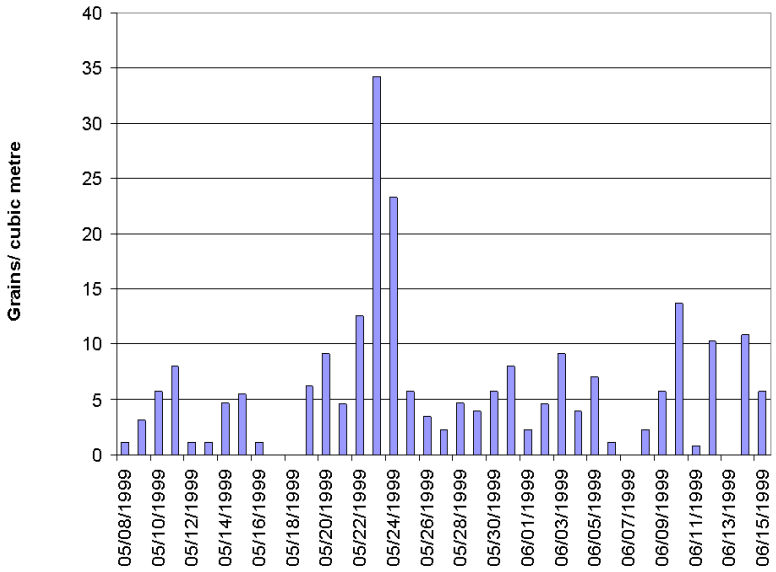
Figure 6. Number of *Bacillus thuringiensis* subspecies *kurstaki* HD1 identified in nasal swabs from the first spray. (SZ=spray zone)

The major conclusions of this phase of the study were: (1) Btk-HD1, the same strain as present in Foray 48B, was present in the environment of Victoria and on fruits and vegetables in local supermarkets prior to aerial application of Foray 48B; and (2) the frequency of Btk-HD1 in the asthma study group increased significantly after each application of Foray 48B, both inside and outside the spray zone. Despite these increases, there were no health effects observed to be associated with the increases.

3.2.2 Exposure to Other Environmental Factors

Because the symptoms that some of the Health Support Line callers attributed to the aerial spray could also be caused by other disease agents or allergens, it was important to consider the possible role of such factors in the health complaints that were reported in Victoria in 1999. Also a review of reportable communicable diseases was conducted utilizing data from the British Columbia Centre for Disease Control. There were no changes noted in the rates of these diseases in either the Capital Health Region or the Central Vancouver Island Health Region between April and July 1999. There were no reported cases of possible *Bacillus cereus* food poisoning in either region during the same period.

Weather conditions during the spring of 1999, as recorded by Environment Canada at Victoria International Airport, were wetter and cooler than normal during April. This forced the spray operations to begin later than usual. The average May temperature was only slightly lower than normal (10.7 C compared to 11.4 C) with 108% of the normal hours of sunshine. Precipitation for the month of May was below average. June was wetter than normal (43.0 mm compared to 27.3 mm) with only 69% of the normal hours of sunshine. A review of pollen data collected in the CHR found moderate levels of deciduous tree pollen, such as poplar and birch, in the air during the second spray period. It is expected that many individuals sensitive to these particular pollens would have experienced allergy symptoms (Figure 7).



* Pollen counted by Aerobiology Research Laboratories

Allergen	Grains per Cubic Metre	Result**
	> 0-15	low
	15-90	moderate
	90-1500	high
	>1500	very high

** Source: American Academy of Allergy, Asthma and Immunology

SECTION 4 - ONGOING INVESTIGATIONS AND WORK

Updated Information - March 2001

Some parts of this surveillance program are not yet available and will be finished in the spring of 2000. An assessment of the patterns of visits to physicians will complete our search for evidence of health effects of the spray. A major part of the ongoing work is a more detailed description of the spread of the spray and opportunities for human exposure. The results of that study will help in making future recommendations about public health precautions at the time of future spray programs.

One of the primary objectives of the study is to add to the published peer reviewed literature on the subject. The HSSC will work towards having the work submitted for publication through the spring of 2000. Publication of the work in peer reviewed journals can be expected in the next 12 to 18 months.

SECTION 5 - GENERAL DISCUSSION

Despite the large volumes of *Bacillus thuringiensis*-based products that have been used for several years, there are very few case reports of human illness due to Btk or other *Bacillus thuringiensis* subspecies. Even in these cases, the precise role of the Btk that was recovered from the patient is unclear. Previous surveillance conducted in Oregon, Washington, Vancouver and New Zealand either found no clinical cases associated with Btk or found cases in which Btk could neither be confirmed nor refuted as a contributing factor to a person's disease.

In their review of human and laboratory data to the US EPA, Mclintock *et al.* (1995) concluded that *B. thuringiensis* subspecies are neither toxic nor pathogenic to mammals, including humans. Despite the extensive use of *B. thuringiensis* pesticides, published reports linking the organism to human infection or disease are limited. One of three published cases was that of a corneal ulcer in an 18 year-old farmer who accidentally splashed a suspension of *B. thuringiensis* pesticide in his eye. Others suggested a more cautious interpretation of this report because of the lack of evidence of vegetative bacilli in the material originally taken from this patient's ulcer, the possiblity of laboratory contamination and the possibility that the organism can persist in a mammal's eye for prolonged periods without causing disease. The second case involved a localized infection of a hand as a result of accidental injection of a suspension of two microorganisms identified as *B. thuringiensis* subspecies *israeliensis* and *Actinetobacter calcoacetius*. The third case involved the recovery of *B. thuringiensis* subsp. *konkukian* from the abscessed thigh of a severely wounded soldier. Isolates obtained from this case were subsequently able to grow and be associated with muscle necrosis in immunosuppressed mice injected intramuscularly with large numbers of bacteria.

B. thuringiensis was also isolated from deep burn wounds from patients in Italy. The same organism was found in water used to treat these patients. The authors of that report concluded that the contaminating bacteria did not come from pesticide residues. It is, however, unclear if this case represents contamination of a wound or infection.

The Oregon State Health Division enrolled clinical laboratories in a surveillance program to assess the impacts of a spray program conducted in Lane County, Oregon in 1985-86. Fifty-five of 95 Bacillus isolates were identified as Btk. (It should be noted that the methods used to identify these organisms are currently not considered to be conclusive). Upon further examination, 52/55 of the isolates were assessed to be probable contaminants. Of the three remaining cases, Btk could neither be ruled in nor ruled out as a cause of the patient's disease. The first case occurred in an elderly immunocompromised person. While the authors felt that laboratory contamination was unlikely in this case, the failure of the patient to respond to antibiotics to which Btk were susceptible suggested a different or additional organism was causing this patient's pneumonia. The lack of any other indications of infection in the second case and lack of evidence of bacterial involvement in her diseased gall bladder argued against a role for Btk as a causal agent. The authors could not determine for the third case if Btk was the primary cause of the abscess occurring in the forearm of an intravenous drug user or if it was a skin or wound contaminant.

Laboratory surveillance conducted in Auckland, New Zealand during a Tussock Moth control program recovered Btk from three clinical isolates; however, clinicians concluded that on no occasion was Btk causally associated with disease; instead all cases represented sample contamination.

Btk was not isolated from any submissions from Washington laboratories, but was isolated from one in Oregon and in 325 cases from the Lower Mainland of B.C. during laboratory-based surveillance conducted in response to 1992 aerial spray campaigns. The Oregon sample was later determined to be sample contamination. None of the 325 isolates of Btk in Vancouver satisfied study criteria for infection. Unfortunately, clinical information was not available on all cases, information about exposure to sprays was based on patient recollection and there were no controls, thus limiting the capacity of the latter study to draw causal conclusions. Differences in the numbers of isolates from each program may be due to the number of people exposed, the number of labs collecting and contributing specimens, and the effort used to capture all isolates.

In each of the above laboratory surveillance programs, the investigators concluded that virtually all of the isolates were the result of sample contamination. A study conducted by the US National Institute for Occupational Safety and Health in association with the 1985 Oregon spray campaign revealed the potential for laboratory contamination. Twenty-three of 24 (96%)

environmental samples collected from laboratories or hospitals after sprays yielded *B. thuringiensis* after only 10 minutes of exposure to the environment.

In the Vancouver study, the rate of visits to hospital emergency departments did not differ before or after the spray period. Moreover, there was no difference in the rate of visits when only people living within the spray zone were considered. The results of surveillance in New Zealand also showed no association between the spray period and hospital visits, physician visits or a variety of reported diagnoses.

Some authors have speculated that the role of *B. thuringiensis* in human gastrointestinal disease has been underestimated because of the difficulties distinguishing *B. thuringiensis* and *B. cereus*, the latter being known to cause gastrointestinal illness. Most of the data supporting this contention has been laboratory-based. *B. thuringiensis* has been associated with one outbreak of gastrointestinal illness. Unfortunately, this study did not examine unaffected people as controls, a step needed before a causal association can be definitively established in an outbreak investigation. Furthermore, the methods used for differentiating the organisms in this case would not be considered definitive. Despite these possible links between *B. thuringiensis* and gastrointestinal illness, disease surveillance data shows that *B. thuringiensis* is unlikely to be a significant contributor to gastrointestinal illness in North America. Experimental work supports the view that Btk has limited capacity to cause human disease if ingested. In one study, 18 people ate one gram of commercial Btk product in capsules each day for five days. No adverse health effects were noted on physical, laboratory or radiological examination. Reports submitted to both the US Department of Agriculture (USDA) and US EPA have concluded that the likelihood of Btk acquiring the food poisoning capacity of *B. cereus* or the likelihood that *B. cereus* toxins are present in commercial Btk preparations is remote.

There have been two studies that, in the absence of any signs of disease, have demonstrated a rise in antibodies specific to Btk in occupationally exposed people. Antibody studies must be interpreted with some caution because of the potential for cross-reactions with other bacilli and the lack of direct evidence linking the formation of "anti-Btk" antibodies with adverse health effects.

Commercial formulations of Btk products could contain materials that have been implicated in food allergies. There is a regulatory requirement to report observed allergic reactions during the manufacture and use of these products. Up until 1995, the US EPA had received only two reports of possible allergic reactions for Btk-based products (the particular products were not specified in the report). One involved a person likely suffering from a previously diagnosed disease that causes rashes (Kawasaki Syndrome). The second involved a person with a history of life-threatening food allergies.

Both the PMRA and US EPA have concluded that animal studies and available human data support the conclusion that Btk-products (including the inert ingredients) are non-toxic and non-infectious at levels present in commercial formulations.

In past surveillance studies, two main methods for collecting self-reports of symptoms occurring during the spraying of Btk have been telephone "hotlines" and self-administered questionnaires. Typically, the most frequently reported symptoms were headaches, upper respiratory tract irritation (cough, sore throat, runny nose), rashes, worsening of pre-existing asthma or allergies, and gastrointestinal illness. Most of these reports were for minor illness lasting only a few hours to a few days; however, some people, especially those who also reported underlying hypersensitivities, reported illness severe enough to warrant medical attention, including visits to emergency rooms.

There are two main difficulties in interpreting self-reported data. First, as medical follow-up was either not conducted or not available for the majority of self-reports, it is not possible to assign definitive diagnoses and thus establish links between the spray and many of the self-

reported signs and symptoms. Second, there were problems in associating a person's health complaint with their exposure to Btk. Without objective measures of exposure it is difficult to make statements on cause-effect relationships.

SECTION 6 - CONCLUSIONS

Updated Conclusions - March 2001

The results of this project did not show a relationship between aerial spraying of Foray 48B and short-term human health effects. Although some people self-reported health problems that they attributed to the spray program, the research and surveillance methods used in this project did not detect any change in health status that could be linked to the spray program. Our results showed that many of the health complaints people reported during the spray were as common in people before the spray as they were shortly after the spray. This conclusion is consistent with those of previous studies of the possible health effects of Btk-based pesticide spray programs.

SECTION 7 - RECOMMENDATIONS

Updated Information - March 2001

It was beyond the scope of this study to monitor all possible health effects of exposure to Foray 48B. However, the results of this study can be used to identify some key issues or unanswered questions that should be considered when planning future health surveillance around aerial spray campaigns.

Recommendation #1
Health monitoring should be part of the planning and evaluation of future spray programs.

- Although no study has demonstrated population effects of aerial spraying, some underlying public concern over health effects remains.
- Continued monitoring is needed to identify rare or unexpected effects of the exposure to the spray and to generate more information to help the public and the government understand the local consequences of aerial spraying of Btk.
- Health monitoring provides public assurance that a mechanism is available to identify, report, and detect individual cases where adverse effects may have been experienced.

Recommendation #2
Health monitoring needs to use a variety of scientific specialties to track the full range of possible health impacts of spray programs.

- An integrated team approach is needed not only for the design and evaluation of health studies, but also for the evaluation of Gypsy Moth control programs within a socio-economic and ecological context.

Recommendation #3
A formal system for sharing information between health regions is needed to make sure surveillance planners can benefit from the experience of past health monitoring programs.

- This system needs to be in place well before a spray program to allow planners the necessary time to design and put their surveillance program into action.

Recommendation #4
Health studies need to be planned well before any spray program begins.

- Studies of the effects of aerial spraying are complex and involve a large number of programs and people. Organizing the wide variety of information needed to monitor health effects can take several months.

- Information on the occurrence of certain health effects in populations before sprays and background information on the presence of Btk in the general environment before the spray are needed to understand surveillance reports.

Recommendation #5
Public education should continue to be a prominent part of long-term Gypsy Moth control plans.

- During spray programs, telephone support should be available to the public to help them deal with health concerns that may arise during a spray program.

  - Health hotline data needs to be linked to general population health surveys to help with their interpretation.

- Research needs to determine the reasons for public concerns and what segments of the population has those concerns in order to develop and deliver the right information to the general public.

  - By identifying details of the public's concerns, surveillance planners will be able to better design projects to produce information relevant to a specific community.

SECTION 8 - UPDATED INFORMATION MARCH 2001

This section provides summary information and conclusions following the completion of the physician office visit analysis and the exposure assessment study, both of which were incomplete at the time of the December 1999 summary report.

8.1 Physician Office Visit Data Analysis

A review of physician office visit data collected from the Medical Services Plan billing records for physicians serving the spray zones was planned. Issues of quality with the MSP data prevented meaningful analysis from being completed.

The main data quality concern centred on the removal of the decimal point in the MSP data set for the ICD code. This had the effect of allowing multiple diagnoses for a single 3-digit ICD code. Therefore, no conclusions could be drawn from the MSP data.

8.2 Exposure Study Summary

This report presents the results of an exposure study which was part of the larger 1999 Victoria health surveillance study undertaken to gather data which would be of use for policy makers, health care providers and members of the public to make decisions about risks which may accompany exposure to the aerial spray of the bacterial insecticide, Foray 48B.

In one part of the exposure study, the undiluted insecticide in the laboratory was examined to determine whether there are ingredients that could be measured in future field studies, and to attempt to answer questions posed by the public regarding chemicals in the insecticide formulation. In the other part of the exposure study, we measured airborne constituents of the Foray 48B during and after spray runs conducted in the Capital Regional District during the spring of 1999.

The questions asked in the laboratory study were:

1. Could the inert ingredients in the formulation easily be identified?

2. Were any of the inert ingredients volatile compounds that could be used as surrogate indicators of exposure?

The questions asked in the field exposure study were:

1. What was the size distribution of the spray droplets, and were the droplets small enough to enter the respiratory tract of people who might be in the area at the time of spraying?

2. Was there protection from inhaling the droplets if one stayed indoors with the doors and windows closed during spraying?

3. Was there a drift of insecticide droplets outside the spray zones?

Ingredients of Foray 48B:

Foray 48B is registered for specific uses by the Pest Management Regulatory Agency of Health Canada. The Material Safety Data Sheet for Foray 48B lists as the active ingredients the spores and delta endotoxin crystal produced by the bacteria, *Bacillus thuringiensis var. Kurstaki* (Btk) HD1 strain. In addition to the Btk there are other ingredients which were not further identified by the manufacturer.
The inert ingredients of Foray 48B were examined to determine whether any of the constituents were volatile, that is, whether the liquid chemical would act more like a gas than a liquid at outdoor and indoor temperatures. Samples of the air immediately above the surface of the insecticide liquid in a closed container were analyzed by gas chromatography/mass spectrometry (GC/MS). Thirty-eight chemicals isolated by this method were identified using standardized, computer-assisted libraries of chemical compounds. Of potential interest were sydnones which may give colour to the product, trimethyl phosphine which may be a contributor to the characteristic unpleasant odour of Foray 48B, and butylated hydroxy toluene and benzoic acid which may be used as preservatives in the Btk suspension media.
None of the volatile chemicals identified in the bulk sample were measurble in the field trials at detection limits in the parts per million range (ppm), the smallest concentration which would be detected using available sampling and analytic techniques.
Analyses for non-volatile components of the insecticide were conducted using high performance liquid chromatography (HPLC). These analyses indicated a complex spectrum of constituents. This is to be expected from Foray 48B's suspension of spores, spore components, endotoxin, additives, wetting agents, sunscreens, and culture media. An extensive research program would be required to identify the compounds in the HPLC analyses.

Air Concentrations of Btk During and After Aerial Spraying:

The air concentrations of Btk during the aerial spraying were measured by collecting airborne droplets containing Btk spores, and counting the colonies of bacteria that grew from the spores when cultured under appropriate conditions. The average culturable airborne Btk concentration measured outside residences in the Victoria spray zone was 739 colony-forming units per cubic meter of air (CFU/m3). We expect that these concentrations may be underestimated because of some limitations of the methods used for quantification of the colonies.
Additional outdoor samples were taken up to 9 days after spraying. Outdoor air concentrations decreased over time. These outdoor samples suggested that airborne Btk concentrations diminish in two phases. There is an initial phase where only half of the original concentration was present after a few hours (in which suceptible Btk may have been killed by UV light). This was followed by a slower decrease in concentration (in which spores may have been diluted by uncontaminated air or removed by slow settling of the small droplets).

Inside residences during spraying, average concentrations were initially 2.3 to 4.6 times lower than outdoors, but at 5-6 hours after spraying began, indoor concentrations exceeded those outdoors, with an average of 244 CFU/m3, possibly because Btk spores may be killed by ultraviolet (UV) light from the sun outdoors, but little UV light is present inside homes. The movement of Btk indoors may have resulted from the movement of family members and study personnel in and out of the residences after the end of the spray period. Indoor measurements were discontinued 6 hours after spraying began.

Drift of Btk Outside the Spray Zone:

Measurements of airborne Btk were made up to the edge of the 1,000-meter "buffer zone" around the spray zone. There was drift of culturable Btk throughout this 125-to 1,000-meter band. Upwind sites usually had Btk concentrations lower than those within the spray zone, but sites downwind of the zone usually had higher concentrations than those in the spray area. This effect increased as wind speeds increased.
Drift of culturable Btk outside the spray zone is expected given the size distributions of the spray droplets measured in the 15 minutes following the start of spraying. The size range of the droplets that remained airborne was 4.3 to 7.2 microns (1 micron = 1/1000th of a meter), much smaller than the 50 to 150 micron droplets which quickly deposited on surfaces inside the spray zone (measured on "Kromecote cards"). These small airborne droplets are not visible to the human eye and can be inhaled into the small airways of the respiratory tract. Factors that may produce smaller droplet sizes may include higher plane speeds, higher wind speeds, and lower relative humidities.

Recommendations:
The results of this study suggest the following recommendations:

- The field exposure study indicated that not only volatile components of the Foray 48B are potentially inhaled. The fine spray droplets include all components of the insecticide formulation, and these could be inhaled and transported into the lower portion of the respiratory tract. Therefore identification of all agents in the formulation is important. A cost-effective method to ease public concerns about the constituents of the formulated Foray 48B would be release of this information by the manufacturer.

- During the spray period, staying indoors with all doors and windows closed resulted in exposures lower than those outdoors. However, exposures indoors increased within 3 hours after spraying and were higher than outdoor concentrations by 5 to 6 hours after spraying began. Indoor concentrations appeared to dissipate much more slowly that outdoor concentrations. In future exposure studies, indoor concentrations should be measured for a longer period of time, up to 9 days after spraying, to determine the half-time of the Btk in indoor environments.

- Drift of the Btk aerosol was detected throughout a zone up to 1 km away from the spray area. Future studies should measure air concentrations more distant that 1 km away from the spray zone to allow estimation of the maximum drift distances. Some factors which contribute to drift, such as wind speed, temperature, and relative humidity, were detected in this study. Studies examining these and other potential explanatory variables (e.g., plane speed) would be valuable.

- Kromecote cards were not an effective indicator of airborne exposures to Btk. If future studies want quantitative exposure measurements, then air sampling techniques rather than surface deposition techniques to estimate air concentrations of Btk should be used.

8.3 Updated Conclusions - March 2001

The following information discusses the conclusions of the overall study as they are affected by the new information presented by the exposure assessment component.

General Population Study

The exposure assessment study has justified the classification of people in the buffer zone as exposed, but has not resolved how far past the buffer exposure occurs. There were no differences in reported symptoms between those inside and outside the spray before the spraying was conducted. For those living inside the spray zone, there was no change in reported symptoms after the spray except for an improvement in the category "other". For those living outside the spray zone, there was an improvement in "unexplained tiredness" after the spraying occurred. The exposure assessment work does not alter the conclusions drawn in the general population study.

Asthma Study

The exposure assessment study has justified the classification of people in the buffer zone as exposed, but has not resolved how far past the buffer exposure occurs. When the asthma study data were evaluated based on a child's nasal swab results, rather than place of residence as a measure of exposure, there was no evidence of worsening of asthma or non-asthmatic symptoms when a child was compared pre- and post-spray regardless of spray zone status. The exposure assessment work does not alter the conclusions drawn in the asthma study.

SECTION 8 - UPDATED INFORMATION MARCH 2001

This section provides summary information and conclusions following the completion of the physician office visit analysis and the exposure assessment study, both of which were incomplete at the time of the December 1999 summary report.

8.1 Physician Office Visit Data Analysis

A review of physician office visit data collected from the Medical Services Plan billing records for physicians serving the spray zones was planned. Issues of quality with the MSP data prevented meaningful analysis from being completed.

The main data quality concern centred on the removal of the decimal point in the MSP data set for the ICD code. This had the effect of allowing multiple diagnoses for a single 3-digit ICD code. Therefore, no conclusions could be drawn from the MSP data.

8.2 Exposure Study Summary

This report presents the results of an exposure study which was part of the larger 1999 Victoria health surveillance study undertaken to gather data which would be of use for policy makers, health care providers and members of the public to make decisions about risks which may accompany exposure to the aerial spray of the bacterial insecticide, Foray 48B.

In one part of the exposure study, the undiluted insecticide in the laboratory was examined to determine whether there are ingredients that could be measured in future field studies, and to attempt to answer questions posed by the public regarding chemicals in the insecticide formulation. In the other part of the exposure study, we measured airborne constituents of the Foray 48B during and after spray runs conducted in the Capital Regional District during the spring of 1999.

The questions asked in the laboratory study were:

1. Could the inert ingredients in the formulation easily be identified?
2. Were any of the inert ingredients volatile compounds that could be used as surrogate indicators of exposure?

The questions asked in the field exposure study were:

1. What was the size distribution of the spray droplets, and were the droplets small enough to enter the respiratory tract of people who might be in the area at the time of spraying?
2. Was there protection from inhaling the droplets if one stayed indoors with the doors and windows closed during spraying?
3. Was there a drift of insecticide droplets outside the spray zones?

Ingredients of Foray 48B:

Foray 48B is registered for specific uses by the Pest Management Regulatory Agency of Health Canada. The Material Safety Data Sheet for Foray 48B lists as the active ingredients the spores and delta endotoxin crystal produced by the bacteria, *Bacillus thuringiensis var. Kurstaki* (Btk) HD1 strain. In addition to the Btk there are other ingredients which were not further identified by the manufacturer.

The inert ingredients of Foray 48B were examined to determine whether any of the constituents were volatile, that is, whether the liquid chemical would act more like a gas than a liquid at outdoor and indoor temperatures. Samples of the air immediately above the surface of the insecticide liquid in a closed container were analyzed by gas chromatography/mass spectrometry (GC/MS). Thirty-eight chemicals isolated by this method were identified using standardized, computer-assisted libraries of chemical compounds. Of potential interest were sydnones which may give colour to the product, trimethyl phosphine which may be a contributor to the characteristic unpleasant odour of Foray 48B, and butylated hydroxy toluene and benzoic acid which may be used as preservatives in the Btk suspension media.
None of the volatile chemicals identified in the bulk sample were measurble in the field trials at detection limits in the parts per million range (ppm), the smallest concentration which would be detected using available sampling and analytic techniques.
Analyses for non-volatile components of the insecticide were conducted using high performance liquid chromatography (HPLC). These analyses indicated a complex spectrum of constituents. This is to be expected from Foray 48B's suspension of spores, spore components, endotoxin, additives, wetting agents, sunscreens, and culture media. An extensive research program would be required to identify the compounds in the HPLC analyses.

Air Concentrations of Btk During and After Aerial Spraying:

The air concentrations of Btk during the aerial spraying were measured by collecting airborne droplets containing Btk spores, and counting the colonies of bacteria that grew from the spores when cultured under appropriate conditions. The average culturable airborne Btk concentration measured outside residences in the Victoria spray zone was 739 colony-forming units per cubic meter of air (CFU/m3). We expect that these concentrations may be underestimated because of some limitations of the methods used for quantification of the colonies.
Additional outdoor samples were taken up to 9 days after spraying. Outdoor air concentrations decreased over time. These outdoor samples suggested that airborne Btk concentrations diminish in two phases. There is an initial phase where only half of the original concentration was present after a few hours (in which suceptible Btk may have been killed by UV light). This was followed by a slower decrease in concentration (in which spores may have been diluted by uncontaminated air or removed by slow settling of the small droplets).
Inside residences during spraying, average concentrations were initially 2.3 to 4.6 times lower than outdoors, but at 5-6 hours after spraying began, indoor concentrations exceeded those outdoors, with an average of 244 CFU/m3, possibly because Btk spores may be killed by ultraviolet (UV) light from the sun outdoors, but little UV light is present inside homes. The movement of Btk indoors may have resulted from the movement of family members and study personnel in and out of the residences after the end of the spray period. Indoor measurements were discontinued 6 hours after spraying began.

Drift of Btk Outside the Spray Zone:

Measurements of airborne Btk were made up to the edge of the 1,000-meter "buffer zone" around the spray zone. There was drift of culturable Btk throughout this 125-to 1,000-meter band. Upwind sites usually had Btk concentrations lower than those within the spray zone, but sites downwind of the zone usually had higher concentrations than those in the spray area. This effect increased as wind speeds increased.
Drift of culturable Btk outside the spray zone is expected given the size distributions of the spray droplets measured in the 15 minutes following the start of spraying. The size range of the droplets that remained airborne was 4.3 to 7.2 microns (1 micron = 1/1000th of a meter), much smaller than the 50 to 150 micron droplets which quickly deposited on surfaces inside the spray zone (measured on "Kromecote cards"). These small airborne droplets are not visible to the human eye and can be inhaled into the small airways of the respiratory tract. Factors that may

produce smaller droplet sizes may include higher plane speeds, higher wind speeds, and lower relative humidities.

Recommendations:

The results of this study suggest the following recommendations:

- The field exposure study indicated that not only volatile components of the Foray 48B are potentially inhaled. The fine spray droplets include all components of the insecticide formulation, and these could be inhaled and transported into the lower portion of the respiratory tract. Therefore identification of all agents in the formulation is important. A cost-effective method to ease public concerns about the constituents of the formulated Foray 48B would be release of this information by the manufacturer.

- During the spray period, staying indoors with all doors and windows closed resulted in exposures lower than those outdoors. However, exposures indoors increased within 3 hours after spraying and were higher than outdoor concentrations by 5 to 6 hours after spraying began. Indoor concentrations appeared to dissipate much more slowly that outdoor concentrations. In future exposure studies, indoor concentrations should be measured for a longer period of time, up to 9 days after spraying, to determine the half-time of the Btk in indoor environments.

- Drift of the Btk aerosol was detected throughout a zone up to 1 km away from the spray area. Future studies should measure air concentrations more distant that 1 km away from the spray zone to allow estimation of the maximum drift distances. Some factors which contribute to drift, such as wind speed, temperature, and relative humidity, were detected in this study. Studies examining these and other potential explanatory variables (e.g., plane speed) would be valuable.

- Kromecote cards were not an effective indicator of airborne exposures to Btk. If future studies want quantitative exposure measurements, then air sampling techniques rather than surface deposition techniques to estimate air concentrations of Btk should be used.

8.3 Updated Conclusions - March 2001

The following information discusses the conclusions of the overall study as they are affected by the new information presented by the exposure assessment component.

General Population Study

The exposure assessment study has justified the classification of people in the buffer zone as exposed, but has not resolved how far past the buffer exposure occurs. There were no differences in reported symptoms between those inside and outside the spray before the spraying was conducted. For those living inside the spray zone, there was no change in reported symptoms after the spray except for an improvement in the category "other". For those living outside the spray zone, there was an improvement in "unexplained tiredness" after the spraying occurred. The exposure assessment work does not alter the conclusions drawn in the general population study.

Asthma Study

The exposure assessment study has justified the classification of people in the buffer zone as exposed, but has not resolved how far past the buffer exposure occurs. When the asthma study

data were evaluated based on a child's nasal swab results, rather than place of residence as a measure of exposure, there was no evidence of worsening of asthma or non-asthmatic symptoms when a child was compared pre- and post-spray regardless of spray zone status. The exposure assessment work does not alter the conclusions drawn in the asthma study.

SUMMARY

Table of Contents:

SECTION 1: Background

1.1 The 1999 Victoria Gypsy Moth Eradication Program

In the spring of 1999, a bacterial pest control product called Foray 48B (manufactured by Abbott Laboratories), was applied by aircraft (aerial spray) to selected areas of Southern Vancouver Island to combat an infestation of the North American Gypsy Moth. Foray 48B contains the bacteria *Bacillus thuringiensis* subspecies *kurstaki* HD1 (Btk-HD1) as the active ingredient. Foray 48B also contains water and other ingredients.

1.2 Use of Foray 48B in North America

Foray 48B and related products have been used extensively around the world in agriculture, forestry, nurseries and home uses for pest control for over four decades. The exact contents of this product are known to the Pesticide Management Regulatory Agency (PMRA) of Health Canada but are not available to the general public. It is registered for use in North America by PMRA and by the United States Environmental Protection Agency. Both these agencies register a product only after a detailed review of data on possible human health and environmental effects of exposure to the product.

1.3 Spray Zones

The areas sprayed were located in both the Capital Health Region (CHR) and Central Vancouver Island Health Regions (CVIHR). In total, 13,398 hectares were sprayed in four separate blocks in

Nanaimo, Duncan, Brentwood Bay, and Greater Victoria. The spray zones included a mix of residential and rural areas. Approximately 80,000 residents lived in the spray zones. Except for providing support through the CHR Health Support Line, the health surveillance program did not include the spray zone on the mainland of the province (Tsawwassen, 60 ha). This area was included at a late stage in the program.

1.4 Spray Dates

Sprays were conducted during three separate time periods: beginning on May 8, May 21, and June 8, 1999. It took between three and four days to complete the spray program on each occasion.

SECTION 2: Background and Objectives

2.1 Health Study Background

During the spring of 1998 an attempt was made to eliminate a Gypsy Moth population found in the Greater Victoria area. The pesticide use permit allowed only limited ground spraying and trapping. The pest control product used for the ground spray was Foray 48B.

By fall 1998 a large population of Gypsy Moth was found to have survived in the treated areas. To avert a widespread quarantine, the Canadian Food Inspection Agency created "restricted areas" for selected locations on Vancouver Island affecting the movement of logs, Christmas trees and nursery products to the United States. During the spring of 1999, an aerial spray program was conducted to eliminate Gypsy Moth in the Southern Vancouver Island Region. The program was conducted without the usual permit process but through a Provincial Cabinet order passed under emergency powers. Order in Council (OIC) 169/99, made under the Plant Protection Act and the Pesticide Control Act, outlined how the 1999 Gypsy Moth Eradication Program was to occur. It also required that the government fund a human health study.

2.2 Human Health Surveillance Objectives

The CHR established a Health Surveillance Scientific Committee (HSSC) consisting of a community representative and independent experts in public health, epidemiology, clinical microbiology, biological pesticides, and environmental health, to conduct the study.

The goals of this Human Health Surveillance were to summarize and add to the current understanding of the public health effects of aerial spraying of Foray 48B and to monitor people in the spray zones for signs of potential health effects caused by the spray. The goals were to:

- Determine if the spray has any short-term human health effects, and if so, what they were and at what levels did they occur.
- Inform the public about the general health of people in the region before, during and after the spray.
- Provide a basis for public health recommendations in the event of future spray programs.
- Respond to community concerns.
- Publish scientific papers based on the results of the surveillance activities.

The health surveillance was comprised of seven components:

1. Asthmatic Children's Survey:
   The survey studied the health of children with asthma, both inside and outside the spray areas, for any health changes that could be attributed to the spray.
2. General Population Survey:
   This telephone survey documented the health of a group of adults inside and outside the spray area both before and after the spray.

3. Laboratory Surveillance:
   Laboratory analysis was used to find people whose lab specimen was identified as containing Btk, to determine the specific type of Btk bacteria found in the specimens, and to compare it to the specific type of Btk used in Foray 48B. The role of the identified bacteria, if any, in human disease was also assessed.

4. Exposure Assessment Measurements:
   Air samples were collected in order to determine the air concentrations of Btk within the spray area, both inside and outside homes, as well as over time.

5. Doctors' Office Visits:
   This information was collected and will be studied for any possible links to the spray program.

6. Emergency Room Visits:
   This information from local hospitals' emergency rooms was studied and compared to previous years, and analyzed for possible links to the spray.

7. Telephone Health Support Line Data:
   A telephone support line was available to the community during the spray periods. Self-reports made to the support line were summarized in the context of the larger study.

SECTION 3: Results

3.1 Evaluation of Human Health Effects

3.1.1 Health Effects Documented from Hospital Records

There was no evidence of an increase in the number of, or reasons for, visits to emergency rooms found in hospital records around the time of the spray. The CHR Health Support Line documented four people who self-reported that they visited or planned to visit a hospital emergency room during the spray period. A review of the emergency room records for these self-reports found one report of worsening symptoms of asthma which is discussed in section 3.1.2. Other illnesses were identified as the cause of the symptoms reported in the other cases. A review of laboratory records found seven clinical specimens with Btk identified. In all cases, Btk was found to **not** be the cause of the person's illness.

3.1.2 Health Effects in People with Asthma

A study of a group of asthmatic children showed no evidence of health effects from the use of Foray 48B by aerial spraying. This relationship held true for pre- and post-spray analyses as well as for comparisons of children living inside and outside of the spray zone. The general population health survey showed no increase in self-reported health complaints from adults with asthma after the spray.

A single case was reported of a five-year-old child with previously-diagnosed asthma whose symptoms worsened during the spray period. It was not possible to conclude definitively whether this was the result of exposure to the Foray 48B spray or not.

3.1.3 Health Effects in the General Population

A survey of the general adult population showed that people had a range of health symptoms before the aerial spray, but no increase was reported after the spray program. The survey did not detect any differences in physical or mental health status between people living inside and outside of the spray zone or, before and after the spray. A small number of the people from inside and outside the spray zone self-reported a range of symptoms to the CHR Health Support Line during the spray program. Symptoms reported were similar in nature to the General Population Survey reports.

3.2 Population Exposure

3.2.1 Exposure to Btk

The same strain of Btk-HD1 as is present in Foray 48B was found on fruits and vegetables in local supermarkets before aerial spraying with Foray 48B. Nasal swabs also found Btk-HD1 in children before the spray program. The exposure to Btk-HD1 in the asthmatic children study group increased after each spraying of Foray 48B, both inside and outside the spray zone. However, based on this human health surveillance study, this did not result in increased health symptoms in asthmatic children or the general population.

3.2.2 Exposure to Other Environmental Factors

A number of the health complaints associated with aerial spraying for Gypsy Moth could also be caused by a number of other disease agents or allergens. It was important to consider the possible role of such factors in the health complaints that were reported in 1999 Human Health Surveillance Study. Patterns of communicable disease reports (such as measles, hepatitis and meningitis) were unchanged in CHR and CVIHR during and for one month following the spray program.

A review of pollen data collected in the Capital Health Region found low levels of weed pollens but moderate levels of deciduous tree pollen, such as poplar and birch, in the air during the second spray period.

Weather conditions during the spray period were warmer, dryer, and sunnier than the prespray period.

SECTION 4: Ongoing Investigation and Work

Some parts of this human health surveillance program are not yet available and will be finished in the spring of 2000. An assessment of the patterns of visits to physicians will complete our search for evidence of health effects of the spray. A major part of the ongoing work is a more detailed description of the spread of the spray and opportunities for human exposure. Publication of the work in peer reviewed journals can be expected in the next 12 to 18 months.

SECTION 5: General Discussion

Despite the large volumes of *Bacillus thuringiensis*-based products that have been used for several years, there are very few case reports of human illness due to Btk or other *Bacillus thuringiensis* subspecies. Even in these cases, the precise role of the Btk that was recovered from the patient is unclear. Previous surveillance conducted in Oregon, Washington, Vancouver and New Zealand either found no clinical cases associated with Btk or found cases in which Btk could not be established as a contributing factor to a person's disease.

SECTION 6: Conclusions

The results of this project did not show a relationship between aerial spraying of Foray 48B and short-term human health effects. Although some people self-reported health problems that they blamed on the spray program, the research and surveillance methods used in this project did not detect a change in population health. Our results showed that many of the health complaints people reported during the spray were as common in people before the spray as they were shortly after the spray. This conclusion is consistent with those of previous studies done both in British Columbia and abroad.

SECTION 7: Recommendations

- That health monitoring continue to be part of the planning and evaluation of future spray programs.
- That health monitoring use a variety of scientific specialties to track the range of potential health impacts of spray programs.
- That health monitoring use a variety of scientific specialties to track the range of potential health impacts of spray programs.
- That a formal system for sharing information between health regions be developed to ensure surveillance planners can benefit from the experience of past health monitoring programs.
- That health studies have sufficient planning lead time before spray program begin.
- That public education and information sharing continue to be a prominent part of long-term Gypsy Moth Management Plans.

SECTION 8: Summary of Work Completed since December 1999 Report

This section provides summary information and conclusions following the completion of the physician office visit analysis and the exposure assessment study, both of which were incomplete at the time of the December 1999 summary report.

BTK JOURNAL SUBMISSIONS / PUBLICATIONS
as of March 2001

Publications:

Pearce, MR Habbick, B Williams, J Eastman, M Newman, M The Effect of Aerial Spraying with Bacillus thuringiensis Kurstaki on Asthmatic Children. CJPH Jan-Feb 2002.

Stephen, C Pearce, MR, Bender, C. Human health effects of aerial spraying of Bacillus thuringiensis kurstaki-based biological pesticides - A review of observational data and overview of surveillance conducted in Victoria, British Columbia, Canada 1999 Environmental Health Review. October 2001.

Teschke K, Chow Y, Bartlett K, Ross A, van Netten C. Spatial and temporal distribution of airborne Bacillus thuringiensis var. kurstaki during an aerial spray program for gypsy moth eradication. Environmental Health Perspectives Volume 109, Number 1, January 2001 (http://ehpnet1.niehs.nih.gov/docs/2001/109p47-54teschke/abstract.html)

van Netten C, Teschke K, Leung V, Chow Y, Bartlett K. The measurement of volatile constituents in Foray 48B, an insecticide prepared from Bacillus thuringiensis var. kurstaki. The Science of the Total Environment Volume 263, Pages 155-160 (18 December 2000)

Valadares de Amorim, G. Whittome, B. Shore, B. Levin, D. Identification of Bacillus thuringiensis subsp. kurstaki Strain HD1-Like Bacteria from Environmental and Human Samples after Aerial Spraying of Victoria, British Columbia, Canada, with Foray 48B. Applied and Environmental Microbiology, March 2001, p. 1035-1043, Vol. 67, No. 3 (http://aem.asm.org/cgi/content/abstract/67/3/1035)