

**HEALTH RISK ASSESSMENT
OF THE 2002 AERIAL SPRAY
ERADICATION PROGRAMME
FOR THE
PAINTED APPLE MOTH
IN SOME WESTERN SUBURBS OF
AUCKLAND**

A Report to the Ministry of Agriculture and Forestry

**Public Health Service
Auckland District Health Board**

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Glossary

Term	Definition
Acute	Rapid onset.
ADI	Acceptable daily intake.
Aerosol	A number of airborne particles.
Allergy	Sensitivity of an individual to certain foods, pollens, plants, animals producing reactions such as asthma, hay fever or eczema.
Aseptic	The absence of microorganisms that may cause disease.
Auckland District Health Board	Public Health Service, Auckland District Health Board (formerly known as Auckland Healthcare Services Ltd.).
<i>Bacillus anthracis</i>	Bacterium known to cause pneumonia and skin ulcers. If untreated it can be fatal.
<i>Bacillus cereus</i>	Enterotoxin producing bacteria known to cause food poisoning.
Beta-exotoxin	A toxin that is secreted by some strains of <i>Bacillus thuringiensis</i> . It has general toxicity in mammals.
BIU	Billions of international units.
<i>Btk</i>	<i>Bacillus thuringiensis kurstaki</i> .
CAA	Civil Aviation Authority.
Caterpillar	The larval stage of a butterfly or moth.
Chromosome	One of the threadlike structures in a cell nucleus that carries genetic information in the form of genes.
Chronic	Long-term.
DNA	Deoxyribonucleic acid. The genetic material of nearly all living organisms which controls hereditary factors.
Delta-exotoxin	A crystalline protein produced by <i>Bacillus thuringiensis</i> . Active ingredient in <i>Bt</i> insecticides.
Dose	Amount, duration and concentration of a substance applied to an individual or population.
Effect	The result of a cause. Also a synonym in epidemiology for effect measure (a quantity that measures the effect of a factor on the frequency).
Enteritis	Inflammation of the small bowel usually causing diarrhoea.
Enterotoxin	Toxin, usually produced by bacteria, which affect the lining of the intestinal tract, causing enteritis. <i>Bacillus cereus</i> produces specific enterotoxins which cause food poisoning.
EPA	Environmental Protection Agency (United States).
Epidemiology	The study of the distribution and determinants of health-related states or events in specified populations.
Exposure	Contact with a hazard.

Extra chromosomal DNA	DNA that is not incorporated into the chromosomal structure, also known as plasmids.
FAO/WHO	Food and Agriculture Organisation of the United Nations/World Health Organisation.
FDA	Food and Drug Administration (United States).
Frass	Larval excrement.
Foray 48B	<i>Btk</i> -based spray used as an insecticide against the lepidoptera group of insects.
Gene	The basic unit of DNA, which is carried at a particular place on a chromosome.
Germination	The recommencement of growth after being in a resting state.
Hazard	A situation or event of potential harm to humans.
Half-life	The time it takes for half the amount of a substance to decay.
Immunodeficiency	Deficiency of immune system.
Inert ingredients	Ingredients in Foray 48B which do not have a direct effect on the target insect.
Inorganic	Of mineral origin.
Inversion (layer)	An atmospheric condition where the layer of air next to the earth's surface is cooler than an overlying layer.
Larva/e	Insect/s from time of leaving egg till transformation into pupa. In this text used synonymously with caterpillar.
Lepidoptera	Moth or butterfly.
MPCA	Microbial pest control agent.
Micron	Metric unit: 1/1000th of a millimetre.
MAF	Ministry of Agriculture and Forestry (formerly known as MOF).
Meshblock	The smallest geographic area used by Statistics New Zealand in the collection and processing of data.
MOF	Ministry of Forestry.
Mutagenicity	Ability to cause genetic defect.
Non-viable	Incapable of maintaining life. Used in this text to refer to bacterial cells unable to germinate into active forms.
Oncogenicity	Potential for a substance to cause tumours.
Organic	Material from animals or plants (opposite of inorganic).
Osmotic pressure	The force that balances the concentration of dissolved substances across a semipermeable membrane.

Particle	Small droplets or pieces of material (organic or inorganic/ viable or nonviable) that can become airborne. The particles may range in size from individual molecules (0.001µm) and individual bacterial cells (1-2µm), to visible dust particles of 1000µm diameter or larger. A collection of airborne particles is called an aerosol.
Phenotype	The phenotype is the observable characteristics of an organism. That is what an organism looks like and behaves like.
Phenotypic	Relating to phenotype.
Pheromone	Substance secreted and released by an animal for detection and response by another of the same species.
Plasmid	A small, closed entity of double-stranded DNA forming an extrachromosomal self replicating genetic element in many bacteria.
Potable water	Water that meets drinking water standards.
Protease	An enzyme that can break down proteins.
Pupae	The stage of a moth's lifecycle when the caterpillar is inside a cocoon changing into an adult moth.
Riparian	Related to a river bank .
Risk	The probability of harmful consequences arising from a hazard.
Risk communication	An interactive process of exchange of information and opinions among individuals, groups and institutions.
Sensitisation	Stimulation of an immune response to a particular food, vaccine etc.
Spore	In this text refers to encapsulated resting form of bacterial cell.
STOP	Society Targeting the Overuse of Pesticides.
Surveillance	Data collection to detect events or identify trends to initiate public health action.
Symptom	Perceptible change in the body or its function indicating injury or disease.
Synthetic	Made by synthesis to imitate a natural product; artificial.
Teratogenic	A substance which produces abnormalities in an embryo or fetus.
TLA	Territorial Local Authority. A city or district council.

1. EXECUTIVE SUMMARY

Health Risk Assessment of the aerial spray eradication programme for the Painted Apple Moth (*Teia anartoides*) in some western suburbs of Auckland

1. This report assesses the health risks associated with the Ministry of Agriculture and Forestry's (MAF's) 2002-painted apple moth aerial spraying eradication programme in Auckland. This includes targeted spraying of Foray 48B (Valent BioSciences/Abbott Laboratories Ltd) from BK 117 helicopters in the riparian areas of Mcleod Creek, the Whau River and Wairau Creek, Traherne Island and parts of Waikumete Cemetery. Some parts of Parrs Park may be included later in the spray programme. The suburbs involved are Te Atatu South, Glendene, Kelston, Glen Eden and the Avondale Peninsula. MAF aims to apply spray at intervals of three weeks until six to eight applications have occurred. This may extend to 15 applications if rain washes off an application and it has to be repeated.
2. In assessing the risk to health of the programme, we have reviewed current international literature, commissioned toxicological reviews and consulted with community representatives and other key informants. It reviews and updates the 1997 health risk assessment for the White Spotted Tussock Moth eradication programme (Operation Evergreen).
3. This report presents a health risk assessment of the spraying programme, including its method of delivery, and the painted apple moth itself. The main findings are:
 - After 35 years of use the active biological component of Foray 48B, *Bacillus thuringiensis kurstaki* (*Btk*), has never been implicated in human infection.
 - Valent BioSciences/Abbott Laboratories Ltd have rigorous quality control processes to ensure Foray 48B is not contaminated with other organisms or toxins.
 - *Btk* and *Bacillus anthracis* are genetically closely related however they behave quite differently. There is no risk *Btk* will ever behave like *Bacillus anthracis*.
 - The inert chemical components of Foray 48B are registered for use in cosmetics, pharmaceuticals and foods. The levels used in Foray 48B are acceptable however if directly exposed to the spray or substantial spray deposits some people may complain of minor skin, eye and upper respiratory tract irritation, or aggravation of existing asthma or allergies.

- Foray 48B has a distinctive odour which many people will find unpleasant. Some people may experience nausea, headache or other symptoms if exposed to unpleasant smells.
 - There is no evidence Foray 48B causes other health effects such as neurological or autoimmune effects or problems with pregnancy.
 - There is no evidence that Foray 48B causes thyroid dysfunction or abnormalities. However a study is being undertaken, by Auckland District Health Board with assistance from a member of the Society Targeting the Overuse of Pesticides (STOP), to investigate a possible cluster of thyroid disease associated with spraying of Foray 48B in the Eastern Suburbs of Auckland. Though the study is yet to be completed results to date suggest there is no cluster.
 - The risks from exposure to helicopter noise or a helicopter accident are assessed as being extremely small.
 - The potential exists for motor vehicle crash on the NorthWestern Motorway as a result of driver distraction.
 - The risks to health from exposure to an infestation of the painted apple moth are small. These are principally skin lesions, eye irritation and respiratory reactions. Children and those working in gardens, either occupationally or socially are the groups most likely to be exposed.
4. The report provides detailed advice for minimising exposure to the hazards we have described. This advice applies to schools, food hygiene, gardening, drinking water, pool maintenance, cleaning, and specific population groups.
 5. This report contains advice to MAF on steps needed to mitigate health effects.
 6. Adequate health monitoring and support must be in place before starting any further spraying programme. This report makes recommendations for such health monitoring and support, public health management and research.

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- Ministry of Agriculture and Forestry
- Ministry of Health
- Forest Research Institute, Rotorua
- Civil Aviation Authority
- Land Transport Safety Authority
- Valent BioSciences/Abbott Laboratories Ltd

Individuals who contributed to the health risk assessment who were not employed by the above organisations included:

- Dr Peter Wigley, BioDiscoveries Ltd, Auckland
- Dr Teck Lok Wong, ESR: Environments

These individuals have been referenced as citations throughout the report.

The report was peer reviewed by:

- Professor Alistair Woodward, Clinical School of Medicine, University of Otago, Wellington
- Dr Francesca Jenner, Aeráqua, Medical Advisor to the Ministry of Forestry, Auckland.

This health risk assessment was based on the September 1997, Health Risk Assessment Of The Proposed 1997-1998 Control Programme For The White-Spotted Tussock Moth In The Eastern Suburbs Of Auckland.

The team at Auckland District Health Board responsible for writing this report is:

- Dr Karalyn Kalemba, Public Health Medicine Registrar
- Dr Virginia Hope, Public Health Medicine Specialist
- Dr David Sinclair, Public Health Medicine Specialist

Jim Graham (Health Protection Officer) created the Geographic Information System maps (appendices 3-8)

2. TERMS OF REFERENCE

Objectives

1. To provide independent expert advice to MAF on whether the recommendations contained in the September 1997 Health Risk Assessment Report to the Ministry of Health and the Ministry of Forestry remain valid.
2. To assess the health risks of aerial spray programme in the painted apple moth eradication programme for MAF as follows:
 - Aerial spraying one day per week, every three to four weeks, for six to eight sprays using *Btk* in the formulation Foray 48B at five litres per hectare. Spraying is to commence early 2002 and continue for up to 15 sprays in order to obtain a minimum of six effective spray applications.
 - The use of twin-engine BK 117 helicopters equipped with Micronair spray equipment to deliver the aerial spraying programme.
3. To assess the risk to health of exposure to the painted apple moth.
4. To make specific recommendations for mitigating public health risks.

3. INTRODUCTION

The painted apple moth (*Teia anartoides*), a native of Australia, was first found in the west Auckland suburb of Glendene in May 1999. It can severely defoliate host trees and has a broad host range, now known to comprise several native, as well as exotic species.

Two hundred and eighty two female moth traps were laid, from May to September 2001, in Avondale, Glendene, Glen Eden (including Waikumete Cemetery), Kelston and Titirangi to enable accurate delimitation of the area in which the painted apple moth populations are present. In the trapping grid, as of the 7th September 2001, a total of 157 moths from 62 traps have been caught¹.

Initial ground spraying has been conducted in areas harbouring the pest. The aerial spraying programme will be targeted at trees and areas inaccessible to ground spraying. The area to be sprayed totals about 550 hectares and consists of a number of riparian areas of Mcleod Creek, the Whau River and Wairau Creek, Traherne Island and some parts of Waikumete Cemetery and Parrs Park (see Appendix 1). BK117 helicopters will be used and spraying will be conducted at as low as five meters above target vegetation in uninhabited areas. In other areas spraying will occur at 45 metres above target vegetation.

Initially ground spraying was conducted with Lorsban 50 W and Chlorpyrifos 50 W (both are chlorpyrifos). The spray was later changed to Decis Forte (Deltamethrin) because it remains active longer than the Lorsban 50 W and Chlorpyrifos 50 W spray¹. The aerial spray programme will utilise the biological insecticide Foray 48B. This is a commercial formulation, containing, as the active ingredient, the protein crystal products of the bacterial species *Btk*, inactive *Btk* spores, and a number of inert components. These inerts are so named because they are not considered to contribute directly to the insecticide activity of the formulation. The term 'inert' does not necessarily reflect their toxic potential.

There has been extensive work to date done in Auckland to assess health risks posed by aerial spraying of Foray 48B. This work is outlined in Table 3.1.

¹ Ministry of Agriculture and Forestry. <http://www.maf.govt.nz>

Table 3.1 Health risk assessment work to date in the Auckland Region

Date	Report
September 1996	<ul style="list-style-type: none">• Health Risk Assessment Of <i>Btk</i> Spraying In Auckland's Eastern Suburbs To Eradicate White-Spotted Tussock Moth (<i>Orgyia Thyellina</i>)²
September 1996	<ul style="list-style-type: none">• Addendum to Health Risk Assessment Of <i>Btk</i> Spraying In Auckland's Eastern Suburbs To Eradicate White-Spotted Tussock Moth (<i>Orgyia Thyellina</i>)²
September 1997	<ul style="list-style-type: none">• Health Risk Assessment Of The Proposed 1997-1998 Control Programme For The White-Spotted Tussock Moth In The Eastern Suburbs Of Auckland³
January 1998	<ul style="list-style-type: none">• Report To The Ministry Of Forestry. Clarification Of Issues Raised In "Our Case Against Moth Spraying"⁴
May 2001	<ul style="list-style-type: none">• Health Surveillance Following Operation Ever Green: A Programme To Eradicate The White Spotted Tussock Moth From The Eastern Suburbs Of Auckland⁵.

² Health risk assessment of *Btk* spraying in Auckland's Eastern Suburbs to eradicate White-Spotted Tussock Moth (*Orgyia thyellina*). Report to the Ministry of Health and the Ministry of Forestry commissioned by the Northern Regional Health Authority, North Health. Jenner Consultants Ltd. 4th September 1996.

³ Health Risk Assessment Of The Proposed 1997-1998 Control Programme For The White-Spotted Tussock Moth In The Eastern Suburbs Of Auckland. A Report to The Ministry Of Forestry. Public Health Service. Auckland Healthcare Ltd. September 1997.

⁴ Report to the Ministry of Forestry, January 1998. Clarification of Issues raised in "Our Case Against Moth Spraying". Jenner Consultants Ltd.

⁵ Aer'aqua® Medicine Ltd (formerly Jenner Consultants Ltd). Health Surveillance following Operation Ever Green: A programme to eradicate the white-spotted tussock moth from eastern suburbs of Auckland. May 2001.

4. METHODS OF ASSESSMENT

This section has two parts. The first describes the standard methodology used in health risk assessment as identified by the World Health Organisation⁶ and its application to this report. The second describes the methods used to identify the community exposure to hazards associated with the aerial spray programme.

4.1 Health risk assessment

Health risk assessment is the process of determining risks to health attributable to environmental or other hazards.⁶ Four steps are accepted as being essential⁷:

1. *Hazard identification.* Identifying the agent responsible for the health problem, its adverse effects, the population exposed particularly susceptible groups, and the conditions or routes of exposure.
2. *Dose/response assessment.* Describing the potential health effects of the hazard at different levels of exposure.
3. *Exposure assessment.* Estimating the magnitude, duration and frequency of exposure and the number of people exposed via different routes.
4. *Risk characterisation.* Combining steps 2 and 3 to quantify the risk level in a specific population. The end result is a qualitative and, where possible, quantitative statement about the health effects expected and the proportion and number of affected people in a target population, together with estimates of the uncertainties involved.

These steps are shown in Figure 1.

It should be noted that health risk assessment is not an exact science. In assessing the implications of exposure to *Btk* for human health there are many uncertainties. Assessing the hazard involved is a very different matter from the controlled study of single compounds or even simple mixtures in laboratory experiments. A health risk assessment does not prove or disprove safety but rather assesses the level of risk.

There are two principal sources of information on health effects resulting from exposure that can be used to assess health risks. The first is composed of studies on human populations.

⁶ World Health Organisation. *Assessment and management of environmental health hazards.* Mimeograph WHO/PEP/89.6. Geneva: WHO, 1989.

⁷ Public Health Commission. *A guide to health impact assessment. Guidelines for public health services.* Wellington: Public Health Commission, 1995.

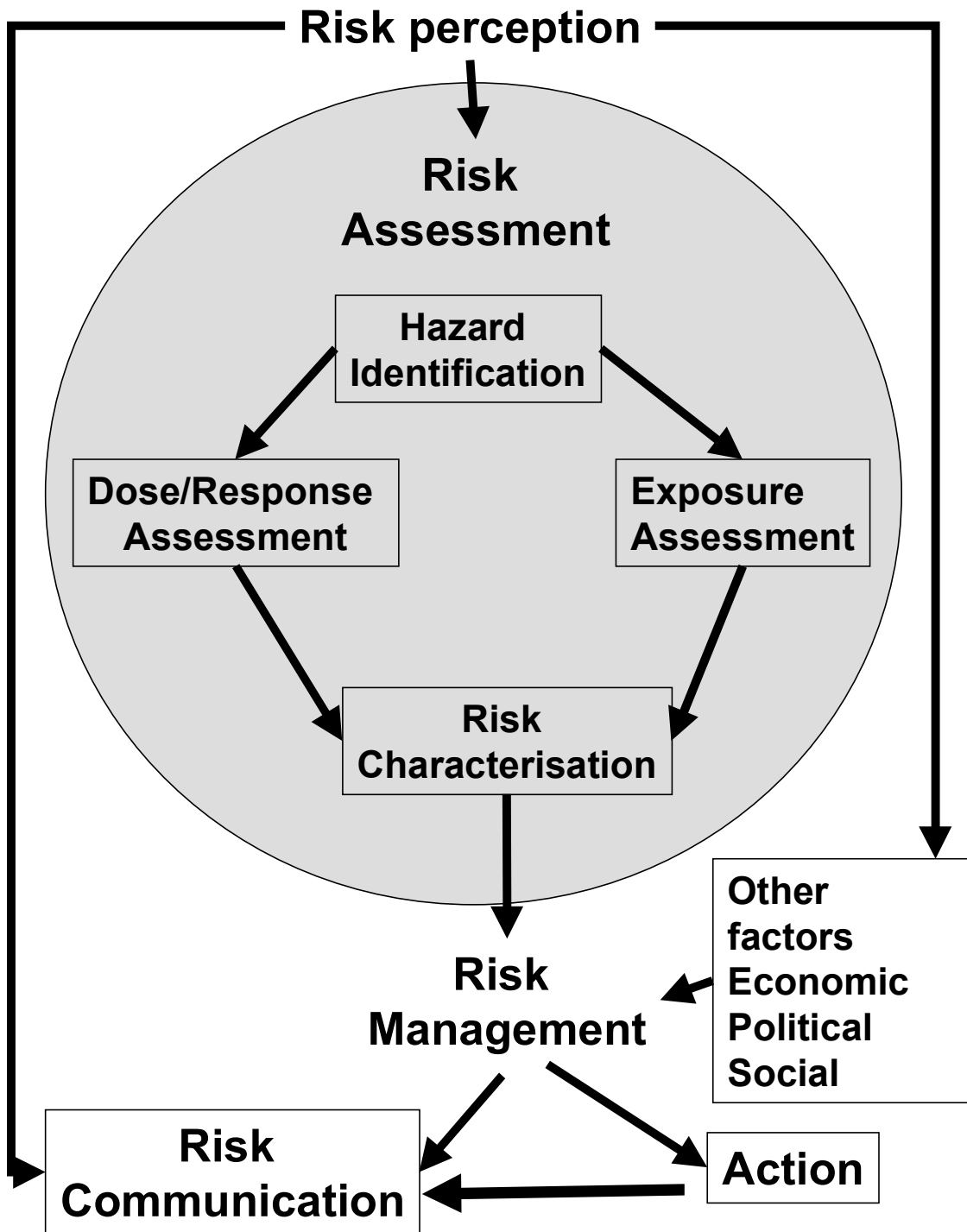


Figure 1. Framework for health risk assessment

The value of such investigations may be limited, due to lack of quantitative information on the concentrations to which people are exposed or on simultaneous exposure to other agents. Also, in epidemiological studies, exposure cannot be controlled for ethical reasons.

The second and most commonly used source is that of toxicity studies using laboratory animals. While done in controlled situations, such studies are generally limited because of the relatively small numbers of animals used and the relatively high doses administered. In addition there is the need to

relate the results to the low doses to which human populations are usually exposed. While well performed epidemiological studies will give reliable information about human health effects, the result of toxicological investigations may or may not be applicable to human populations. They may characterise the nature of a possible effect without necessarily indicating whether those effects may be applied to humans exposed environmentally.

Determining the risk of exposure to hazards often draws on the experiences of occupationally exposed individuals. Exposure limits have been developed for workers related to their exposure for the normal working day over the average worker's lifetime. These are based on the use of recommended protective clothing appropriate to the exposure and the task being performed. The values given cover maximum permissible exposure for a whole working day and the maximum for a short acute exposure.

In contrast, the general population's exposures to a hazard will either be chronic and in low amounts via air, soil or water or acute in possibly higher amounts for a short time. In assessing this risk, the vulnerability of particular groups are taken into account, principally children, pregnant women, the elderly and those with impaired health.

4.2 Methods of assessing community exposure

A number of steps were taken to identify the hazards of the aerial spray programme that might pose a risk to the population, to define the population likely to be exposed to these hazards, to identify possible health effects arising from these hazards, and to identify any subgroups within that population who might be particularly susceptible. These were:

4.2.1 Community inspection

The area to be sprayed was visited and assessed to ensure that information on the ground was consistent with information obtained from databases and to ensure a detailed understanding of key features of the local environment. Local authorities were consulted in order to identify any proposed activities or events planned for the next 12 months which might present a risk of unusual exposure to the pest management programme.

4.2.2 Demography

1996 census data were used to describe the population in the area of the spray programme. Key indicators of health status were estimated for the western suburbs.

4.2.3 Scientific publications

Literature searches were undertaken to identify any recent scientific literature relating to the health effects of the hazards involved. The following databases were searched:

- Adonis 1991-1997
- Biological Abstracts 1980-2001
- Current Contents 1995-2001
- Encyclopedia of Life Science
- Expanded Academic
- Medline 1976-2001
- Science Direct
- SciFinder Scholar
- TOMES Plus (Toxicology, Occupational Medicine and Environmental Series)
- Web of Science 1990-2001

Reports, papers and documents which were reviewed are listed in footnotes.

4.2.4 Internet sites and keywords used in searches

Internet sites were searched using a range of keywords and combinations. These are summarised in Table 4.1.

Table 4.1 Keywords used in database searches

Keywords included:

(combinations of the following keywords were used for literature searches)

Air, *Bacillus*, bioaccumulation, caterpillar, disinfection, EPA, FDA, Foray, gardening, guidelines, health, infection, inoculation, insecticide, *kurstaki*, Lymantriidae, organic, painted apple moth, persistence, tussock moth, *Teia anartoides*, tussockosis, soil, spore, STOP, *thuringiensis*, toxicity, water, 48B.

4.2.5 Community consultation

Community consultation has been undertaken by MAF. The consultation and communication strategy has included:

- Formation of a community advisory group (CAG). The first meeting was held on the 14th of September 2001.
- A public meeting discussing the painted apple moth eradication programme (November 2001)
- Opportunities for CAG to question MAF's independent health adviser and Auckland District Health Board's Medical Officer of Health regarding health issues.
- Circulation of a draft of this Health Risk Assessment to CAG and other stakeholders for comment.
- Letters written to residents living in the intended spray area informing them of details of the spray programme
- Communication between members of STOP, MAF and the Auckland District Health Board.

5. PROFILE OF POPULATION

This section presents information about the physical features, demographics, key health indicators, community features and activities of the spray areas. This characterises the community potentially exposed to the hazards and thereby identifies any groups that might be vulnerable.

5.1 Physical location and characteristics

The aerial spray programme areas in the western suburbs of Auckland are the riparian areas of Mcleod Creek, the Whau River and Wairau Creek; Traherne Island; and some parts of Waikumete Cemetery, totalling approx 550 hectares. Later some parts of Parrs Park may be included. The suburbs involved are Te Atatu South, Glendene, Kelston, Glen Eden and the Avondale Peninsula. The areas to be sprayed are those that are inaccessible to ground spraying. Properties in or within 200m of the spray area are listed in Appendix 2. The census meshblocks containing the spray area, and a 200m buffer around it, are shown in Appendix 3. A 200m buffer is chosen because MAF have identified the environmental conditions necessary to ensure most spray drift will not extend beyond 200m. Spraying will not commence if these environmental conditions are not met. Spray drift may in areas be less than the buffer suggests.

5.2 Demographics

The meshblocks identified in Appendix 3 are the areas demographic information is based upon. The area contained within some meshblocks extends beyond the 200m buffer zone. Therefore, the numbers of people identified in each meshblock will be an over estimate of the number of people actually living in the buffer zone. The demographic data however does not indicate the number of people who move into the spray area for work. The numbers are likely to be large in industrial areas.

The age breakdown of people living within these meshblocks is shown in Table 5.1.

Table 5.1 Population within the area for aerial spray pest management activities, by age group (from 1996 census)

age group	number	% of total
<1	255	1.9
1-4	981	7.3
5-9	1161	8.6
10-14	984	7.3
15-19	957	7.1
20-29	2484	18.4
30-39	2376	17.6
40-49	1725	12.8
50-59	1251	9.3
60-69	855	6.3
70-79	564	4.2
80-89	132	1.0
90+	21	0.2
Total	13521	100.0

data Census 96 Statistics
NZ

The ethnic distribution of people living within these meshblocks is shown in table 5.2.

Table 5.2 Ethnic composition of population within the area for aerial spray pest management activities, by age group (from 1996 census)

Ethnic group	number	% of total
European	7686	56.8
Maori	1854	13.7
Pacific Island	2151	15.9
Asian	1095	8.1
Other	90	0.7
Not specified	906	6.7
Total	13521	100.0

Data Census 96 Statistics NZ

The maps appended show the population density by meshblocks; the distribution of age groups (under fives, school aged children (5-19 years), women in the child-bearing age group (15-45) and older people aged over 65 years) ethnic distribution, income, and measurements of deprivation (Appendix 4 to 8). The measurement of deprivation is the NZDep score. This is a composite score based on the following factors⁸:

⁸ Health Services Research Centre. *NZDep96. Index Of Deprivation. Instruction Book.* May 1998. Victoria University.

- Communication (people with no access to telephone)
- Income (people aged 18-59 receiving a means tested benefit)
- Employment (people aged 18-59 unemployed)
- Income (people living in households with income below an income threshold – adjusted for family composition)
- Transport (people with no access to a car)
- Support (People aged <60 living in a single parent family)
- Qualifications (people aged 18-59 without any qualifications)
- Home ownership (people not living in own home)
- living space (people living in households above bedroom occupancy threshold – adjusted for family composition)

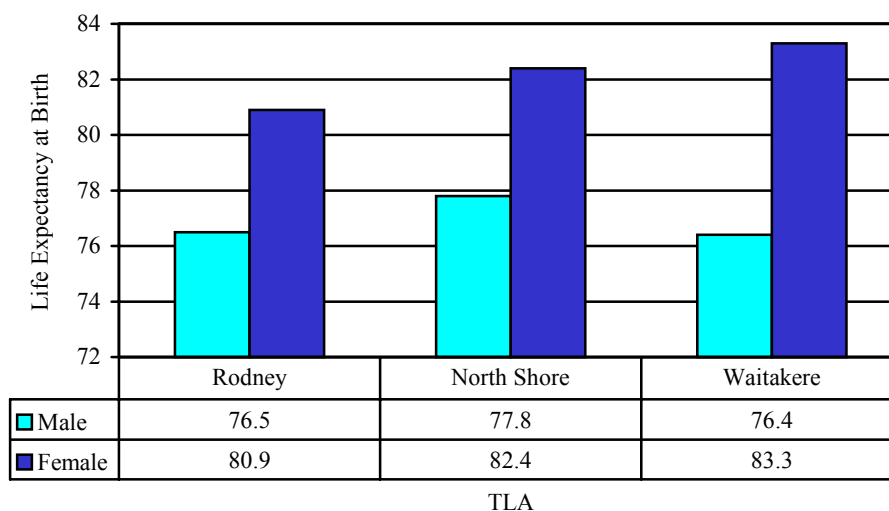
5.2.1 Health status of the population

Life expectancy at birth⁹

Life expectancy at birth is defined as the number of years a newborn would be expected to live based on today’s pattern of death rates. Usually females are expected to live longer than males. Men and women in Waitemata District Health Board (DHB) catchment area had higher life expectancies than any other population in the Northern Region. Waitemata DHB’s catchment area includes residents in the Rodney, North Shore and Waitakere Territorial Local Authorities (TLAs).

When broken down by TLA, males in North Shore and females in Waitakere have the highest life expectancies (see Figure 2).

Figure 2: Life expectancy at birth by TLA, 1996



⁹ Calculated using information from Waitemata District Health Board’s Needs Assessment Report, 2001. (Internal report.)

Birthrate

The number of births that are expected in one year, in the meshblocks containing the spray area, are 242¹⁰. If spraying occurs every three weeks for between six to eight spray applications then the duration of the spray programme will be between four and six months. This will equate to between 81 and 121 births in this time.

Selected health complaints

North Shore Hospital is the designated public hospital for residents living in Waitakere, North Shore and Rodney TLA areas. North Shore Hospital's catchment is split into west and north domicile patients. The patients designated as living in the west domicile include all those living in the spray area, but of course the spray area is a lot smaller than the domicile. The west domicile has 148 000 residents. The numbers and percentages of presentations (admitted and not admitted) to North Shore Hospital, over one year, for selected conditions are shown in Table 5.2.

Table 5.2 Presentations to North Shore Hospital for selected complaints July 1999 to June 2000¹¹

PRESENTATION	Number presenting		Percentage of population presenting	
	North Domicile	West Domicile	North Domicile	West domicile
Chronic obstructive airways disease	368	247	0.18%	0.17%
Respiratory infections/inflammations	396	277	0.20%	0.19%
Bronchitis & asthma	234	167	0.12%	0.11%
Other respiratory system diagnosis	181	120	0.09%	0.08%
Interstitial lung disease	8	8	0.00%	0.01%
Cellulitis	316	190	0.16%	0.13%
Allergic reactions	30	10	0.01%	0.01%
Skin disorders	57	35	0.03%	0.02%

There are a significant number of people who present to North Shore Hospital in one year with respiratory, skin and allergic conditions from the west domicile, however they appear not to differ significantly to those living in the north domicile.

¹⁰ 1999 Data from Waitemata District Health Board's Needs Assessment Report, 2001. (Internal report.)

¹¹ Dataset from Waitemata District Health Board's Health Information Unit. Diagnostic Related Group (DRG) codes are used to identify selected presentations.

5.3 Areas, facilities and industries

All of the Avondale Peninsula beyond Copsey Place contains industrial sites, except the very end of the peninsula which has the Rosebank Park Domain Go Cart Track. There are some industrial sites along McLeod Rd (Te Atatu South) and the western bank of Wairau Creek (Gledene). A 700m stretch of the North Western Motorway runs over Traherne Island. Parrs Park and Waikumete Cemetery are large areas with both dense vegetation and mowed grass areas. There are a number of small parks and reserves within the buffer zone (mowed grass areas will not be directly sprayed by helicopter as a primary target). The remainder of the area within the buffer zone is residential.

There are two rest homes/retirement villages within the 200m buffer zone around the spray area. There are no private hospitals in the area nor are there any commercial horticultural plots. There are four schools and seven early childcare facilities situated within the 200m buffer zone (see Appendix 3).

All of the properties within the area are supplied by reticulated water, however a few households may have chosen to collect roof rainwater as their water source despite being connected to reticulated water supplies.

5.4 Major outdoor events

Table 5.3 Outdoor Events

Time	Day	Date	Venue/Event
	Weekends	27 th April – 19 th May	Trees for babies – planting in four reserves to celebrate new births in the City. (Dates & Locations not yet set contact Jackie Byrd or Andrea Johnston-Taylor at Waitakere City Council)
	Weekends	4 th May – 28 th July	Trees for survival – planting by schools participating in the Trees for Survival programme in association with the ARC and Rotary. (Dates & Locations not yet set contact Jackie Byrd or Andrea Johnston-Taylor at Waitakere City Council)
1.00 pm	Friday Sunday Saturday	– 8 th March – 10 th March 9 th March	Art in the Garden, West Auckland Hospice, 8 Woodford Avenue, Henderson Warriors game at Waitakere Stadium, Central Park Drive, Henderson
9.00 am – 6.00 pm	Saturday	9 th March	The Pasifica Music Festival, Western Springs
9.30 am	Sunday	10 th March	Kiwi Walk Fundraiser, Parrs Park, West Coast Road, Glen Eden
	Friday	22 nd March	Falls Park, Wadcross
10.00 am – 3.00 pm	Friday Saturday Sunday	29 th March 30 th March 31 st March	Easter Easter Easter – Harbour view peoples park, Te Atatu Peninsula 10.00 – 3.00 (Monday Rain Day)
	Monday	1 st April	Easter
	Thursday	25 th April	ANZAC Day
	Friday	– 26 th April –	The Pasifica Music Festival, Western Springs
	Tuesday	30 th April	
	Wednesday	– 1 st May – 5 th	The Pasifica Music Festival, Western Springs
	Sunday	May	

The outdoor events known to date which occur within the vicinity of the spray area during the spray programme are listed in table 5.3. It is expected more will be planned but have not yet been notified to Auckland or Waitakere City Councils. In addition to major outdoor events there are several small activities planned by schools, sporting clubs and recreational groups. Many of these activities occur on weekends and evenings in parks, reserves and schools. On weekends people may arrive early to set up.

6. RISK ASSESSMENT OF SPRAYING PROGRAMME

This section examines the hazards presented by helicopter spraying with Foray 48B. For each of these, the possible routes of exposure are identified, the recent literature regarding possible health effects is commented on and susceptible groups within the population are described. Where possible, the levels of exposure likely with the possible spraying programme are noted, and an assessment of risk made.

6.1 Hazard identification

For this analysis, the hazards of the suggested spraying programme can be categorised as:

- *Microbiological*: The bacterium *Btk* found in Foray 48B;
- *Chemical*: The inert chemical ingredients contained in Foray 48B;
- *Physical*: The hazards associated with aerial spraying. These include aviation accident, noise and road traffic crashes;
- *Psychological*: This includes distress and anxiety.

6.2 Microbiological risks to health

Information about *Btk* contained in the Operation Ever Green Health Risk Assessment of September 1997 has been reviewed in the light of reports in the recent scientific literature and the results of health surveillance following Operation Ever Green. While there is an abundance of papers investigating biological activity, there are relatively few describing possible health effects.

Bacillus organisms are found usually in decaying organic matter, dust, soil, vegetables and water and some species are part of the normal human flora. Despite this widespread distribution of *Bacillus* organisms, they are associated rarely with actual infection and are isolated more frequently as part of the normal human flora.

6.2.1 Characteristics of *Btk*

Bacillus thuringiensis was isolated by Berliner in 1915 from the flour moth collected in the German province of Thuringia. The same organism had already been described by Ishiwata in 1902 as *Bacillus sotto* from Japan where it causes wilt disease in silkworm caterpillars. *Btk* used in Foray 48B occurs naturally in the environment and has not been genetically modified.

Bacillus thuringiensis is closely related to other *Bacillus* species of health significance. The genetic codes of *Bacillus thuringiensis*, *Bacillus cereus* and *Bacillus anthracis* are similar, however the bacteria behave quite differently. Analysis of chromosomal genes indicates that while *Bacillus thuringiensis*, *Bacillus cereus* and *Bacillus anthracis* have identical chromosomal DNA, their most characteristic phenotypic properties are encoded from

extrachromosomal DNA (plasmids): *Bacillus thuringiensis*' characteristic phenotypic property being the production of insecticidal delta-endotoxins¹², *Bacillus cereus*' being the production of enterotoxins and *Bacillus anthracis*' being its potential to cause skin ulcers, pneumonia and death in humans.

The potential exists for this extrachromosomal DNA to be transmissible in nature by direct cell to cell contact between bacteria of the *Bacillus thuringiensis* group.¹³ Manufacturers are aware of this potential (see section 6.2.2). There is evidence some strains of *Bacillus thuringiensis* are capable of producing small amounts of the same enterotoxins as *Bacillus cereus*¹⁴. There is no evidence to suggest DNA transfer between *Bacillus thuringiensis* and *Bacillus anthracis* has ever occurred. This is theoretically possible but highly unlikely in nature, as vegetative *Btk* cells do not multiply well in soils and New Zealand has been considered free of anthrax for more than 40 years. Soil in New Zealand does not favour the growth of *Bacillus anthracis*. It requires areas where the soil is alkaline and has a high content of organic material to become established. Also, these areas must be subject to periodic heavy rainfall, alternating with drought, and must have minimum temperatures of 15.5°C. The lack of suitable areas for the spores to become established in the soil is thought to have prevented the establishment of anthrax in New Zealand¹⁵.

Bacillus thuringiensis produces crystal proteins. When ingested by the caterpillar, the crystal proteins dissolve in the alkaline conditions of the caterpillar gut and are cleaved by proteases, which release the delta-endotoxin. The delta-endotoxin recognises certain receptors on the surface of the insect midgut epithelial cells. A pore-complex forms through the cell membrane, resulting in the loss of potassium ions which affects the insect's ability to regulate osmotic pressure. This ultimately leads to larval death.

Life cycle of *Bacillus thuringiensis*

The bacterial cell occurs in one of two forms: as a vegetative cell or as a spore. The vegetative cell is the 'active' form, which metabolises nutrients. The spore is the 'resting' stage of the bacterium in a resistant encapsulated form. During production of Foray 48B *Bacillus thuringiensis* first propagates in the vegetative phase (in a vat of nutrient fermentation broth). When a critical nutrient becomes depleted, *Bacillus thuringiensis* begins to sporulate, after which cells lyse to release spores and crystal proteins. The material in

¹² Helgason E. et al. *Bacillus anthracis*, *Bacillus cereus*, and *Bacillus thuringiensis* – one species on the basis of genetic evidence. *Applied and Environmental Microbiology*, June 2000. p2627-2630.

¹³ Jarrett, P. and M. Stephenson. Plasmid transfer between strains of *Bacillus thuringiensis* infection of *Galleria-Mellonella* and *Spodoptera-Littoralis*. *Applied and Environmental Microbiology*. 1990; 56 (6): p1608-1614.

¹⁴ Dangaard PH. Diarrhoeal enterotoxin production by strains of *Bacillus thuringiensis*-based insecticides. *FEMS Immunology and Medical Microbiology* 12 (1995) p245-250.

¹⁵ <http://www.maf.govt.nz>

the vat is then concentrated and either dried or mixed with inerts in a liquid form and packaged.¹⁶ See section 6.2.2

The average diameter of spores is one micron, and they tend to collect in clumps of around 10-15 microns in size with drying.¹⁷ *Btk* spores have a viability half life of between 24 to 72 hours. They are very sensitive to ultraviolet radiation (UVR), degrading rapidly when exposed to sunlight, but are significantly more resistant to UVR than vegetative cells. During summertime, it is expected that normal daylight exposure to UVR would result in complete inactivation of 99% of *Btk* spores within 24 hours.^{18 19 20}. Vegetative cells would be expected to be degraded even more rapidly.

¹⁶ Glare TR and O'Callaghan. *Bacillus thuringiensis* Biology, Ecology and safety. 2000. Chichester. John Wiley and sons Ltd.

¹⁷ B Cibulski. Personal communication, 1997.

¹⁸ Martin Gledhill. Personal communication, 4th Sept, 1997. National Radiation Laboratory.

¹⁹ Benoit, T., G. Wilson, D. Bull, A. Aronson. Plasmid-associated sensitivity of *Bacillus thuringiensis* to UV light. *Applied and Environmental Microbiology*. 1990; 56 (8): p2282-2286

²⁰ Jones, D., V. Karunakaran, H. Burges and A. Hacking. Ultra-violet resistant mutant of *Bacillus thuringiensis*. *Journal of Applied Bacteriology*. 1990; 70: p460-463

6.2.2 General manufacturing methods and quality assurance/ quality control for Valent BioSciences/Abbott Laboratories Ltd *Bacillus thuringiensis* products.

Table 6.1 Summary of quality control measures for *Bacillus thuringiensis* products

Hazard	Effect	Foray 48B quality control measure
Contamination with other bacteria (notably <i>Bacillus anthracis</i>)	May contain virulent bacteria which are harmful to mammals	Checked for foreign organisms Mouse feeding tests Checked for production of delta-endotoxin (only produced by <i>Bacillus thuringiensis</i>)
Contamination with <i>Bacillus cereus</i>	Produces enterotoxins	Checked for production of delta-endotoxin (only produced by <i>Bacillus thuringiensis</i>) Checked for absence of enterotoxin
Production of beta-exotoxin	Mutagenic to mammals	Checked for absence of beta-exotoxin
Production of enterotoxins	Gastroenteritis	Checked for absence of enterotoxin
Changes in <i>Btk</i> DNA or alternative forms of <i>Btk</i>	May develop harmful phenotypic properties	Mouse feeding tests Checked for production of delta-endotoxin (only produced by <i>Bacillus thuringiensis</i>)

Bioinsecticide products based upon *Btk* produced for Valent BioSciences by Abbott Laboratories are manufactured by adding a pure culture of *Btk* to a fermentation nutrient mixture. The bacterium that is added to the fermentation mixture is grown under aseptic conditions to ensure culture purity and it is tested to ensure it produces the insecticidal delta-endotoxin. The fermentation ingredients are analysed and approved for use before being used in the process. They are added to potable water and are then sterilized before *Btk* is added.

The culture is added through pre-sterilised lines. Precise environmental conditions are maintained for culture growth and product formation. The mixture of culture and nutrient ingredients is tested twice daily for foreign organisms. Upon completion of the fermentation process, the product is separated from the waste liquids to make a concentrated slurry of active

ingredients. This slurry consists of *Btk* spores, active protein crystals, cell debris, glucose polymer residuals from the fermentation substrate and other cell wall components. It is tested for mouse safety and insecticidal potency. The slurry is then either formulated directly to a final aqueous based product or spray dried to a technical powder. The aqueous formulation has approved anti-microbial preservatives added. The technical powder is later formulated to a powder, granular, oil or aqueous based final product. All undergo further processing to further minimise the potential for the growth of foreign organisms.

Throughout the process product contact surfaces, equipment and transfer lines are cleaned and sanitised to control the introduction of unwanted organisms. Valent BioSciences/Abbott Laboratories Ltd. have written procedures that describe the proper clothing requirements, room entry and exit, room cleaning, room air quality and microbial environmental monitoring procedures. There is a formal system for identifying, analysing and managing threats to quality.

All *Btk* products manufactured must pass specific quality tests prior to release for sale. The testing is required for each batch of final product to ensure product efficacy, optimal physical properties, and the absence of pathogens. Written specifications, controlled by a designated quality assurance division within the manufacturing company, are maintained for each product. Only after a batch has passed all specification is it released for sale.

The product can be shipped to customers by bulk tankers. Manufacturers maintain procedures for cleaning tankers used to transport the product.

Beta-exotoxin

Valent BioSciences/Abbott Laboratories Ltd. are required by the US-EPA to ensure that *Btk* strains do not produce Beta-exotoxins.

‘Some strains of Bacillus thuringiensis have been reported to produce beta-exotoxin. The Bacillus thuringiensis strain used in our products has been reported to be capable of making small quantities of beta-exotoxin. To assure the absence of beta-exotoxin, each new lyophilized culture is tested for the absence of beta-exotoxin. In addition periodic monitoring of production batches is also performed to provide an additional level of assurance that there is no potential hazard. Our strains and manufacturing conditions do not produce beta-exotoxins.’²¹

Changes in DNA and alternative forms of the microbial pest control agent (MPCA).

On the possibility of changes in DNA (spontaneous mutation) of *Bacillus thuringiensis* during production, the manufacturers are aware of the possibility and are confident the risk is insignificant.

*'It is unlikely that unintentional ingredients will occur in fermentation of Bacillus thuringiensis as a result of spontaneous mutation or alternative forms of the MPCA. Spontaneous mutations in most cultures occur at very low rates and should be at too low a concentration to pose any significant risk in the final product. Similarly the stability of the genes and plasmids can be associated with active crystal production in our Bacillus thuringiensis strains, as measured on preparation of new master stock culture batches, and measured by the consistent batch to batch quality of the active crystal protein by HPLC and insect bioassay monitoring. These data suggest insignificant risk associated with alternate forms of the MPCA.'*²¹

Independent laboratory testing in New Zealand through Auckland Healthcare Services Ltd. of each batch of Foray 48B used in the 1996/97 Auckland spray programme (Operation Ever Green) confirmed there were no contaminants i.e. each batch showed a pure culture of *Btk* only. Any bacterial contaminants would have resulted in the affected batch being rejected prior to use²².

Anthrax as a possible contaminant

Contamination in production:

The mouse safety test was specifically designed by the US EPA to test for anthrax. Lamana and Jones²³ reported LD₅₀ values of *Bacillus anthracis* following intraperitoneal and subcutaneous injection into mice of as low as two spores and three vegetative cells. The equivalent dose for *Bacillus thuringiensis* in mice are one million to one trillion times higher (10⁶ to 10¹²). The one million spores required for the test would give good indication of any infectious or injury-causing organism being present. Even though the formulated product is generally not re-tested immediately prior to application, the historical use of Foray and our other *Bacillus thuringiensis* products indicate that *Bacillus anthracis* has not been present²⁴.

Deliberate contamination after manufacture:

Foray 48B is packed in a 55 gallon blue HDPE tighthead drum (ie a thick blue plastic drum), with two thick white bungs (caps). Both bungs are crimped with a white safety seal with black text that reads "Sealed for your protection. To remove, puncture and tear off." The manufacturer's name

²¹ Valent BioSciences Corporation. *General manufacturing methods and quality assurance/quality control of Bacillus thuringiensis products at Abbott Laboratories.* Oct 2001.

²² Jenner Consultants Ltd. Report to the Ministry of Forestry, January 1998, *Clarification of issues raised in "Our Case Against Moth Spraying"*.

²³ Lammana C. and Jones L. 1963. Lethality for mice of vegetative and spore forms of *Bacillus cereus* and *Bacillus cereus* like insect pathogens injected intraperitoneally and subcutaneously. *J. Bacteriol.* 85, 532-535. In: Siegal JP. Minireview. The Mammalian safety of *Bacillus thuringiensis* Based insecticides. *Journal of Invertebrate Pathology.* 77, p13-21 (2001)

²⁴ Personal communication with Valent BioSciences Corporation. *General manufacturing methods and quality assurance/quality control of Bacillus thuringiensis products at Abbott Laboratories.* Oct 2001.

"Rieke®" is embossed on the seal. The safety seals ensure that the bungs can not be removed without a very clear indication. The thickness of the bungs would make injection through them extremely unlikely.

6.2.3 Sources of *Btk*

Bacillus thuringiensis is the most widely used bioinsecticide in the world, accounting for over 90% of all commercial sales²⁵. *Bacillus thuringiensis* has been used as an insecticide for over 35 years. In New Zealand, various formulations containing *Btk* have been registered for use as ground sprays on food crops including avocados, tomatoes and kiwi fruit, and approved for application up to the day of harvest.

In recent years, the gene that encodes the *Btk* toxin has been used in transgenic plants i.e. plants genetically manipulated by the insertion of another organism's genes into the plant genome.^{26 27} The insecticidal crystal proteins are produced continually in the plant tissue so that any caterpillars feeding on the plant will be killed by the toxin. The first successful attempts to use *Btk* genes in plants were reported in 1987. There are now a number of transgenic plants which contain the *Btk* gene for endotoxin expression. These include cotton²⁸, corn²⁸, tomatoes and potatoes.²⁸ In May 1995, NewLeaf Russet Burbank potatoes became the first genetically modified, insect-resistant crop to receive full US federal regulatory approval for commercialisation²⁹. In 1996, conditional approval was granted for a transgenic field corn to be produced.²⁹ To date, these have not been cultivated commercially in New Zealand.

6.2.4 Routes of exposure to *Btk*

Routes by which *Btk* could conceivably cause infection in humans include:

- inhalation of spores into the nose and respiratory tract;
- oral ingestion of *Btk* spores or bacterial toxins;
- inoculation of wounds;
- ocular exposure.

²⁵ Glare TR and O'Callaghan. *Bacillus thuringiensis* Biology, Ecology and safety. 2000. Chichester. John Wiley and sons Ltd.

²⁶ Faust, R., F. Reichelderfer, C. Thorne. Possible uses of recombinant DNA for genetic manipulations of entomopathogenic bacteria. In: N. Panopoulos (ed). *Genetic Engineering in the Plant Sciences*. Praeger. 1981.

²⁷ Grierson, D. (ed) *Plant Genetic Engineering*. 1991. New York. Chapman and Hall.

²⁸ Peferoen, M. Progress and prospects for field use of B.t genes in crops. *Trends in Biotechnology*.1997; 15: p173-177.

²⁹The International Consortium on Agricultural Biotechnology Research (ICABR)
<http://www.economia.uniroma2.it/conferenze/icabr01/nontechabsrtact2001/Araji2.htm>

Inhalation of spores

Inhalation of *Btk* spores was an expressed concern among residents of the Eastern Suburbs³⁰. A brief outline of the functions and defences of the respiratory system is therefore appropriate.

The respiratory system begins at the mouth and nose and includes the nasopharynx, pharynx, oropharynx and larynx. These regions constitute the upper respiratory passages. The lower respiratory tree is comprised of the tracheobronchial passages where the branches of the respiratory passages divide repeatedly into smaller passages, and the gas-exchange region of the lungs, the alveoli. This latter area represents the most sensitive area in the respiratory tract.

There are four main components in the defences of the respiratory system:

- Mechanical filtering occurs in both the upper mouth, and lower respiratory tree;
- Fluid lining the airways protects the gas-exchange structures and by means of the “mucociliary elevator” brings any particles up the respiratory tract to the larynx where they can be swallowed and taken into the gastrointestinal tract.;
- Macrophages, resident in the alveoli, digest and remove particles from the surface;
- The immune system of the lung, which includes antibody production and lymphocyte-mediated antigen elimination.

Table 6.2 describes the methods by which particles are removed from the respiratory tract.

On average freshly sprayed Foray 48B occurs as 100-150µm diameter droplets with an estimated 50 spores per droplet.³¹ In the West Auckland spray programme the height the spray will be dropped from is very low (five metres) in some areas so the droplets are expected to be bigger than 150µm in these areas. Droplets in the 100-150µm range are not expected to penetrate further than the upper respiratory passages. When droplets dry, spores form agglomerations of approximately 10-15µm diameter. Such particles would be expected to penetrate only as far as the upper/lower respiratory tract. Individual *Btk* spores are approximately one micron in diameter. Therefore a potential for inhalation into the upper and lower respiratory tracts exists but penetration into the alveolar regions is unlikely.

³⁰ STOP and Auckland Healthcare meeting. 26th August, 1997.

³¹ Estimate based on droplet size, spray concentration and volume of spray administered per hectare.

Table 6.2 Inhaled particle size, level and mechanism of removal³²

Particle size	Area of removal in the respiratory tract	Removal mechanism
>10µm in size	Upper respiratory tract (Nasal passages and mouth down to the trachea)	Sedimentation and impaction onto the air passages followed by removal by fluids back up to the larynx and into the gastrointestinal tract. All particles are removed within 6 to 8 hours.
1-10µm in size	Upper/lower respiratory tract (Bronchi)	Sedimentation and impaction onto the air passages followed by removal by fluids back up to the larynx and into the gastrointestinal tract. All particles are removed within 6 to 8 hours.
less than 1µm in size	Lower respiratory tract/ alveolar region (Bronchioles and alveoli)	Brownian diffusion or electrostatic deposition onto upper/lower respiratory passages. Those particles deposited in the gas-exchange region are engulfed by alveolar macrophages, which are then removed via the mucociliary escalator. Particles may also become sequestered in the interstitium within macrophages where they remain indefinitely.

Nasal carriage

An epidemiological study conducted by Noble *et al*³³ in Vancouver following a *Btk* aerial spray programme found that although nasal carriage increased during the spray periods; it was not found to be associated with adverse consequences. Nor was nasal carriage more likely in patients with symptoms possibly related to spray exposure. Laboratory surveillance showed no association of clinical isolates with illness.

An aerial application of Foray 48B was carried out on the 9th to 10th of May, 19th to 21st of May and 8th to 9th of June 1999 to control European gypsy moth populations in Victoria, British Columbia. Environmental air and water samples, and nasal swabs were taken before and after spraying. *Btk* was isolated in environmental air and water samples, and nasal swabs before spraying. The presence of *Btk* in human nasal passages increased significantly after the application of Foray 48B, both inside and outside (controls) the spray zone. People having nasal swabs taken were asked to

³² Rom WN. *Environmental And Occupational Medicine*. Second Edition. Boston. Little Brown, 1992.

³³ Noble MA, Riben PD, Cook GJ. *Microbiological and Epidemiological Surveillance Programme to Monitor the Health Effects of Foray 48B Btk Spray*. Vancouver, BC: 1992.

stay indoors, with doors and windows shut, while spraying occurred and up until they had their nasal swabs taken 2hrs later. The controls lived up to 1.5km from the border of the spray area. There is no comment in this study as to whether controls complied with the requirements for them to stay in their houses or whether they had open fireplaces in their houses (large entry route for spray). There is no information on the distance spray drift was predicted to go under environmental conditions existing at the time of spraying³⁴. Spraying in the west Auckland programme will not go ahead on days when significant spray drift is predicted beyond 200m³⁵.

Ingestion

Btk crystal proteins are not toxic in the mammalian gut. In the highly alkaline environment of lepidoptera midguts, activation of the crystal proteins occurs via discrete proteolysis by insect gut enzymes and may occur concomitantly with the solubilisation step.³⁶ In contrast, in the highly acidic environment of the human gut, the *Btk* crystal proteins are denatured and inactivated by the gut proteases, forming small peptides and free amino acids. There is no evidence to date to show that mammalian gut has receptors to the *Btk* delta-endotoxin³⁷.

Btk spores have not been shown to cause illness in human feeding studies. This is discussed fully in section 6.2.5.

Inoculation of wounds and ocular exposure

There has never been any evidence of dermal or ocular infectivity of *Bacillus thuringiensis* strains tested under normal conditions. There are three reported cases of infection due to dermal inoculation with *Bacillus thuringiensis*. In one case a British researcher who accidentally injected the webspace between his third and fourth fingers with a mixed culture of *Bacillus thuringiensis israelensis* (10⁶ colony forming units (cfu)) and *Acinetobacter calcoaceticus var. anitratus* developed infection. In the second case an intravenous drug user had *Btk* isolated from a wound, however it is not clear whether *Bacillus thuringiensis* species were a primary causative organism in either case. The third case did not involve normal circumstances. A French soldier wounded by a land mine blast developed abscesses and *Bacillus thuringiensis konkukian* was isolated from the abscesses. The injury involved soil covered shrapnel causing massive injury. The soldier's body was under considerable stress in the time following injury. These areas and others are discussed fully in Section 6.2.5.

³⁴ Valadares de Amorim G. 2001. 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. P1035-1043.

³⁵ Teschke K et al. Spatial And Temporal Distribution Of Airborne *Bacillus Thuringiensis* Var. *Kurstaki* During An Aerial Spray Program For Gypsy Moth Eradication. *Environmental Health Perspectives*. Vol 109 (1) Jan 2001.

³⁶ Grierson, D. (ed) Plant Genetic Engineering. New York. Chapman and Hall. 1991

³⁷ Betz FS. Safety and advantages of *Bacillus thuringiensis*-protected plants to control insect pests. *Regulatory toxicology and pharmacology*. 32, p156-173 (2000)

Passage of *Btk* across the placenta

In order to cross the placenta *Btk* spores would first need to gain entry into the maternal circulation. This is extremely unlikely given normal host defences. There is restricted passage through the placental barrier. Although some bacteria, viruses and protozoa are capable of crossing the placenta, *Bacillus species* have not been noted in studies of antenatal infections.³⁸

Risk of contamination of the Foray 48B by other organisms/chemicals

Valent BioSciences/Abbott Laboratories Ltd. have rigorous quality control systems in place to ensure the Foray 48B formulation is not contaminated by other organisms or chemicals. See the section 6.2.2. Independent laboratory testing of each batch of *Btk* used in the 1996/97 Auckland spray programme confirmed there were no contaminants i.e. each batch showed a pure culture of *Btk* only. Any bacterial contaminants would have resulted in the relevant batch being rejected³⁹.

Spray drift

The distance spray drift extends is dependant on the factors identified below.

- Wind speed
- Wind direction
- Humidity
- Presence of an inversion layer
- Atmospheric stability
- Droplet size
- Volatility of the agrichemical
- Height of release of the agrichemical
- Aircraft speed
- Terrain type

MAF have identified which environmental conditions are necessary in order to limit spray drift from the direct spray area. Modelling has enabled conditions to be identified where 90% of spray will be deposited with 200 meters of the target. Spraying will not occur on days when it is expected that significant spray drift will extend beyond 200 metres. In some areas helicopters will be able to fly as low as five metres above vegetation so drift in these areas is expected to be well under 200 meters. 95% of spray drift will be deposited within 260 metres of the target. The distance the remaining 5% of spray drifts is very difficult to predict because it is very much dependant on atmospheric conditions on the day.

³⁸ Sperling RS, Newtom RE, Gibbs RS. Intraamniotic infection in low-birth-weight infants. *Journal of Infectious Diseases* 1988; 157: p113-117.

³⁹ Report to the Ministry of Forestry, January 1998. Clarification of Issues raised in "Our Case Against Moth Spraying". Jenner Consultants Ltd.

6.2.5 Health effects

A comprehensive search of literature from 1976 to mid-2001 was carried out, with the following studies identified as relevant to the potential for *Bacillus thuringiensis* to cause adverse effects on human health.

Gastrointestinal illness

Damgaard et al 1995 demonstrated *Bacillus* culture from Foray 48B was capable of producing diarrhoeal enterotoxin during the growth of the vegetative stage but the volumes produced were only three per cent of what control cultures of *Bacillus cereus* were capable of producing⁴⁰.

There have been at least 13 rat and 3 human studies done using a challenge with oral spores with no evidence of toxicity^{41,42,43}. In some of these studies viable organisms were found in the stool for some time after the ingestion of spores had stopped. If the organisms were capable of causing a gastroenteritis like illness they should have had the opportunity to do so but did not cause disease despite germination.

Noble's surveillance studies done in conjunction with the Vancouver spray programme showed no cases with signs and symptoms suggestive of food poisoning or watery diarrhoea⁴⁴. Some cases were reported in an Oregon study looking at the health effects of *Btk* after a spray programme there but it is not clear the incidence was higher than that in the non-exposed community⁴⁵.

It might be argued that persons who are taking antacids or antagonists of acid production in the stomach (ranitidine, cimetidine or omeprazole) have not been specifically challenged with *Btk* spores and could be vulnerable to the delta-endotoxin. Against this is the fact that these agents are extremely commonly used and would have been common in the populations in Vancouver, Oregon and Auckland. It would thus be remarkable that no increase in cases of gastrointestinal symptoms had occurred in these studies. Even with these drugs it is not clear that the pH in the intestine would be alkaline enough to activate the toxin as the pH required for

⁴⁰ Daamgard PH. Diarrhoeal enterotoxin production by strains of *Bacillus thuringiensis* isolated from commercial *Bacillus thuringiensis*-based insecticides. *FEMS Immunology and Medical Microbiology*. 1995; 12: p245-50

⁴¹ The Mammalian safety of *Bacillus thuringiensis* Based insecticides. *Journal of Invertebrate Pathology*. 77, p13-21 (2001)

⁴² Betz FS. Safety and advantages of *Bacillus thuringiensis*-protected plants to control insect pests. *Regulatory toxicology and pharmacology*. 32, p156-173 (2000)

⁴³ Report to the Ministry of Forestry, January 1998. Clarification of Issues raised in "Our Case Against Moth Spraying". Jenner Consultants Ltd.

⁴⁴ Noble MA, Riben PD, Cook GJ. Microbiological and Epidemiological Surveillance Programme to Monitor the Health Effects of Foray 48B *Btk* Spray. Vancouver, BC: 1992.

⁴⁵ Washington State Department Of Health. Report Of Health Surveillance Activities, Asian Gypsy Moth Control Program. March 1993.

solubility of the delta-endotoxin is 9 to 10. The addition of reducing agents at pH 7 does not enable the delta-endotoxin to completely dissolve⁴⁶.

Soft tissue infection

Health surveillance following Operation Ever Green uncovered no laboratory (community and hospital pathology laboratories) reports of invasive infections with *Btk*⁴⁷.

One well quoted study involved the isolation of four environmental strains of *Bacillus thuringiensis* from infected burns wounds and from the water used to treat them. The two patients from whom swabs were taken had deep burns involving 30-70% of their body surface area. The bacterial isolates had previously been identified as *Bacillus cereus*⁴⁸ and the purpose of the study was to investigate whether supposedly *Bacillus cereus* cultures were in fact *Bacillus thuringiensis*. It was found that the bacteria had originated from the hot water supply. Both burns victims had been immersed in warm water upon arrival at the burns centre. Such patients are highly immunosuppressed and thereby susceptible to various infectious diseases. These isolates were not derived from insecticides and were considered to be of environmental origin. The authors concluded that these organisms 'do not constitute any health hazards when used as a microbial insecticide'⁴⁹.

One of the key case reports, used to implicate *Bacillus thuringiensis* as a pathogen, involved a farm worker with a corneal ulcer from which *Bacillus thuringiensis* was isolated⁵⁰. The description of events suggests direct eye trauma from spraying is possible in this case. Corneal ulcers have many causes, including trauma (abrasion) and bacterial, viral, and fungal infections. The patient was initially treated with corticosteroids which are known to suppress local immune mechanisms and are therefore not normally applied in situations involving infection. Isolation of *Bacillus thuringiensis* from the ulcer could either be from colonisation rather than infection. This conclusion is supported by a study conducted during Operation Ever Green. An individual photographing the low flying aircraft at the time of spraying was coated in the Foray 48B spray. Four days after the incident the individual, in the absence eye symptoms, had a swab taken.

⁴⁶ Communication from Teck Lok Wong reported in: Report to the Ministry of Forestry, January 1998. Clarification of Issues raised in "Our Case Against Moth Spraying". Jenner Consultants Ltd.

⁴⁷ Aer'aqua® Medicine Ltd (formerly Jenner Consultants Ltd). Health Surveillance following Operation Evergreen: A programme to eradicate the white spotted tussock moth from eastern suburbs of Auckland. May 2001.

⁴⁸ Valentino, L. and Torregrossa, M. Risk of *Bacillus cereus* and *Pseudomonas aeruginosa* nosocomial infections in a burns centre: the microbiological monitoring of water supplies for a preventative strategy. *Water Science and Technology*. 1995; 31: p37-40

⁴⁹ Daamgard P, Granum P, Bresciani M, et al. Characterisation of *Bacillus thuringiensis* isolated from infections in burns wounds. *FEMS Immunology and Medical Microbiology*. 1997;18: p47-53

⁵⁰ Samples J.R. and Buettner H. 1983. Ocular infection caused by a biological insecticide. *Journal of Infectious Diseases*. 148. 614.

The swab grew *Btk* proving persistence of the *Bacillus* rather than invasive disease⁵¹.

A British researcher who accidentally injected the webspace between his third and fourth fingers with a mixed culture of *Bacillus thuringiensis israelensis* (10⁶ cfu) and *Acinetobacter calcoaceticus var. anitratus* developed lymphangitis. The patients required intravenous gentamicin, erythromycin and benzylpenicillin accompanied by decompression of the tendon sheath, and recovered after 5 days. In the report the authors speculated that proteases from *A. calcoaceticus var. anitratus* activated *Bacillus thuringiensis israelensis* protoxin, but in vascular permeability reaction tests that evaluated each isolate separately *A. calcoaceticus var. anitratus* produced a strong reaction with necrosis. Culture filtrates of neither strain were lethal when injected intravenously into mice but a filtrate from a mixed culture was consistently lethal when injected intravenously⁵².

There is no clear evidence *Bacillus thuringiensis* was the sole cause of the infection. It is more likely the causative agent was *Acinetobacter calcoaceticus var. anitratus*, which is a gram-negative *Bacillus* commonly isolated from the hospital environment and hospitalised patients. *Acinetobacter* is an organism of low virulence, but it is known to be capable of causing infection⁵³.

In 1995 a 28-year-old French soldier while in former Yugoslavia stepped on a land mine. He sustained multiple compound fractures to his left lower leg. He later developed abscess of the left thigh and knee. A biopsy specimen of the knee grew *Bacillus thuringiensis konkukian* (the author doesn't note whether this was a pure culture). Researchers injected this culture under the skin of mice. All mice given 10⁷ cfu developed inflammatory skin lesions. The lesions healed spontaneously in non-immunosuppressed mice after 48 hours but increased in the immunosuppressed mice. The mice were killed and *Bacillus thuringiensis konkukian* was cultured from the skin of the immunosuppressed mice. In this case with the French soldier the mode of infection was unusual, (i.e. massive lower limb injury from foreign bodies heavily coated with soil, which deeply penetrated the limb), and the soldier's body was under a large amount of stress from the injury (he was suffering haemorrhagic shock on arrival at the field hospital)⁵⁴. This is the only human case of *Bacillus thuringiensis* infection noted to date where *Bacillus thuringiensis* appears to be the sole organism isolated.

⁵¹ Report from Dr P Wigley, BioDiscovery Ltd. Auckland. 12.10.01.

⁵² Warren RE, et al. *Bacillus thuringiensis var israelensis*: protoxin activation and safety. *Lancet*. 1(8378):p678-679, 1984 Mar 24.

⁵³ <http://www.emedicine.com/med/topic3456.htm>

⁵⁴ Eric Hernandez et al. 1998. *Bacillus thuringiensis subsp. Konkukian* (serotype H34) superinfection: Case report and experimental evidence of pathogenicity in immunosuppressed mice. *Journal of clinical microbiology*. July 1998. P 2138-2139.

Infectious diseases

Concerns have been expressed regarding the potential for *Btk* to predispose to invasive meningococcal disease, tuberculosis, measles or other serious infectious diseases involving the respiratory system. A laboratory study by E Hernandez suggested co-infection of mice with influenza A virus and *Btk* caused mortality in the mice (not a natural host of the virus)⁵⁵. However there is no epidemiological evidence that the presence of *Btk* causes respiratory tract infections or promotes infection by other microorganisms. Surveillance studies after spraying in Vancouver in 1992, British Columbia in 1999 and health surveillance following Operation Ever Green revealed no evidence of increased lower respiratory disease. No increase in the incidence of meningococcal disease following Operation Ever Green was found.

Pregnancy

There is no evidence that Foray 48B causes miscarriages nor would it be expected to given the findings of medical, biological and toxicological research. Health surveillance following Operation Ever Green revealed no statistical difference in birth weight, gestational age or birth defects for babies born to mothers living in the spray area at the time of spraying compared with mothers living out of the spray area⁵⁶.

Mutagenicity

A beta-exotoxin, which is known to be produced by some strains of *Bacillus thuringiensis* and is likely to produce mutagenic effects in mammals, is not produced by the strains and manufacturing conditions of Valent BioSciences/Abbott Laboratories Ltd. By US law conventional *Bacillus thuringiensis* products are not allowed to contain beta-exotoxin. There is no evidence any other component in Foray 48B is mutagenic^{57,58}.

Allergy

A health survey was conducted among farm workers before and after exposure to *Bacillus thuringiensis* insecticide. Farm workers who picked vegetables sprayed with *Btk* were assessed before commencing work, then one month and four months after work commenced. Spraying was continuous throughout the harvest season. A group of low exposure (pickers of an unsprayed onion crop situated 3km away) and medium exposure workers (vegetable washer and packers) were also assessed. Skin test reactivity to spore extracts was significantly higher among high exposure workers and rates increased significantly among this group over the season. Nasal carriage of the commercial *Bacillus thuringiensis* organism occurred in most exposed workers. Antibodies to the *Bacillus thuringiensis* organism

⁵⁵ Hernandez E. et al. Super-Infection By *Bacillus Thuringiensis* H34 Or 3a3b Can Lead To Death In Mice Infected With The Influenza A Virus. *FEMS Immunology And Medical Microbiology*. 29 (2000) p177-181.

⁵⁶ Aer'aqua® Medicine Ltd (formerly Jenner Consultants Ltd). Health Surveillance following Operation Evergreen: A programme to eradicate the white spotted tussock moth from eastern suburbs of Auckland. May 2001.

⁵⁷ *Btk* Project ID JDP - *Btk* - 2, Abbott Laboratories, June 1996

⁵⁸ Jim Waters. Toxicologist. New Zealand Ministry of Health. Oct 2001.

were present more in high exposure groups suggesting sensitisation to the organism occurs. There was however no evidence of occupationally associated respiratory symptoms among any of the group studied⁵⁹. Health surveillance following Operation Ever Green revealed:

- No evidence of new onset of asthma during spraying
- No pattern of increased consultation for pre-existing asthma associated with spraying
- No increase in consultation rates for lower respiratory problems, which include serious lung diseases.
- No obvious pattern of problems with eye, skin or upper respiratory symptoms
- No cases of anaphylaxis

Thyroid disease

There are no reports in the literature of thyroid disease resulting from exposure to *Btk*. A possible cluster of cases of thyroid disease following Operation Ever Green has been notified to Auckland District Health Board's Public Health Office. This possible cluster is currently being investigated in conjunction with a STOP member, however results to date suggest no cluster exists.

Other health effects/cases noted in the literature

Periodontitis

There was a report by Helgason et al (2000) of *Bacillus cereus* and *Bacillus thuringiensis* being associated with periodontitis, however the author inaccurately did not recognise *Bacillus cereus* and *Bacillus thuringiensis* as separate species. None of the bacteria studied in this report were capable of producing parasporal protein crystals hence none will be *Btk* derived from Foray 48B⁶⁰.

Neurological/autoimmune effects

There is no scientific evidence that *Btk* can cause neurological or autoimmune effects. While some bacterial toxins can cause neurological effects including tetanus and botulism, in both these cases disease is manifested by paralysis or spasms which does not occur with *Btk*. Headaches are extremely common and have multiple causes which are often difficult to determine. At present there is no convincing evidence to suggest bacterial toxins are a significant cause of headaches. Health surveillance following Operation Ever Green revealed no increase in presentations to

⁵⁹Bernstein IL. Immune responses in farm workers after exposure to *Bacillus thuringiensis* pesticides. *Environmental Health Perspectives*. Vol 107(7) July 1999.

⁶⁰ Helgason, E. et al. 2000. Genetic structure of population of *Bacillus cereus* and *B. thuringiensis* isolates associated with periodontitis and other human infections. *Journal of Clinical Microbiology* 38, p1615-1622.

general practitioners for headache symptom or autoimmune disorders following spraying. In addition there were no new cases of chronic fatigue syndrome reported by residents in the spray area.

Laboratory isolates

A well quoted study, by Green et al (1990), about *Bacillus thuringiensis* products reports results of a prospective study in areas where crop spraying with *Btk* had been carried out. Three of 55 isolates of *Btk* from patients were considered as possible pathogens. In all of these cases *Btk* was cultured apparently from a normally sterile site.

In one case, *Btk* was cultured from one of four blood culture bottles taken from a patient who was severely ill with a malignancy and had received immunosuppressive therapy. There were signs of lung infection but no specimens were obtained from this site. The patient died despite receiving antibiotics which should have been active against this organism. The most likely explanation is of contamination occurring at the time of inoculation of the blood culture bottle, from the needle penetrating the patient's skin.

In case two, *Btk* was cultured from a broth culture of bile but not from seven plates, which were directly inoculated. The fact that only one of eight cultures was positive, slow growth of the organism (five days) and lack of clinical features of infections mitigate against invasive infection.

In case three, *Btk* was isolated from an area of haematoma/infection on the arm of an intravenous drug user. *Btk* could have been an infecting organism in this case but contamination is also possible⁶¹.

6.2.6 Exposure assessment

Literature databases from 1980 to 2001 were examined and relevant studies were found regarding the persistence of *Btk* in the environment, including its persistence on plants, in soil, in air and water. The findings are relevant when assessing human exposure to *Btk*, particularly when susceptible groups are considered.

Persistence on plants

Bacillus thuringiensis has been shown to occur naturally on plants at a frequency of approximately 0.1% of the total *Bacillus cereus/thuringiensis* population.⁶² Over 64% of this population was found to be *Btk* suggesting that the population naturally persisted either because of propagation or through dispersal by insect larvae.

⁶¹ Green M.G. et al. Public Health Implications Of The Microbial Pesticide *Bacillus Thuringiensis*: An Epidemiological Study, Oregon , 1985 To 1986. *American Journal Of Public Health*. 1990. p848-852.

⁶² Damgaard P, Hansen, B, Pedersen, J, Eilenberg, J. Natural occurrence of *Bacillus thuringiensis* on cabbage foliage and in insects associated with cabbage crops. *Journal of Applied Microbiology*. 1997; 82: p253-58.

Sundaram *et al* investigated the effect of Foray 48B spray in an aerial spray programme at a concentration of 1500-1600ng/g foliage. *Bacillus thuringiensis* was recovered from foliage for up to ten days. It was found that the average half life of the spores was 27 hours.⁶³ Li and Fitzpatrick 1996 used Foray 48B under laboratory conditions to determine the optimal spray volume (litres/hectare) and application rate (BIU/hectare). Depending on these two variables the two sprays were found to have a half-life of disappearance of 2-7 days.⁶⁴

During the Auckland spray programme (1996-1997) research was undertaken to determine the persistence of viable spores on leaf surfaces. It was found that 10^3 cells/cm² were recovered from leaf surfaces (including pohutukawa and camellia, both of which have large surface areas with high exposure to sunlight).⁶⁵ These results are surprisingly high given the well-documented UVR-inactivation of spores noted previously.

Persistence in soil

In a study assessing the natural occurrence and persistence of *Btk* in the white-spotted tussock moth outbreak area, Broadwell *et al* (1996) recovered over 2800 *Bacillus species* isolates from soil in the suggested spray area prior to spraying. Of these, 378 isolates belonged to the *Bacillus thuringiensis* group; 28 (7.4%, or 1.4% of the total *Bacillus species* population) of these were shown to be similar to the *Btk* isolate in Foray 48B. These *Btk* isolates were collected from six of 100 sites sampled.⁶⁵ The researchers concluded that *Btk* isolates similar to that in Foray 48B are an indigenous but infrequent component of the Auckland soil environment.

Studies in New Zealand and overseas to determine the persistence of spores in soil have drawn the following conclusions:

- *Only spores survive in soil; vegetative cells do not survive in soil.* Spores are quiescent in soil and do not become vegetative cells until suitable conditions arise (i.e. during lepidoptera infection).⁶⁶
- *Spores do not normally grow into vegetative cells in natural soils.* They are outcompeted by the indigenous microbiota in natural soils and only grow sporadically in sterilised (autoclaved at 121°C, 21kPa), nutrient supplemented soils.^{67 68}

⁶³ Sundaram, A, Sundaram K., Nott R., Curry J., and Sloane L. Persistence of *Bacillus thuringiensis* deposits in oak foliage, after aerial application of Foray 48B using rotary pressure atomisers. *Journal of Environmental Science and Health*. 1997; 32: p71-105.

⁶⁴ Li, S., and Fitzpatrick S. The effects of application rate and spray volume of efficacy of two formulations of *Bacillus thuringiensis* Berliner var *kurstaki* against *Choristoneura rosaceana* (Harris) on raspberries. *Canadian Entomologist*. 1996; 128: p605-612.

⁶⁵ Peter Wigley. BioDiscovery. Personal communication. 1st September 1997.

⁶⁶ Akiba, Y. Microbial ecology of *Bacillus thuringiensis*. VI. Germination of *Bacillus thuringiensis* spores in the soil. *Applied Entomology and Zoology*. 1986; 21: p76-80.

⁶⁷ West, A., Burges H., Dixon T. and Wyborn C. Effect of incubation in non-sterilised and autoclaved arable soil on survival of *Bacillus thuringiensis* and *Bacillus cereus* spore inocula. *New Zealand Journal of Agricultural Research*. 1985; 28: p559-566.

- *Spore numbers decrease very slowly in soils.* One study found that, in the initial two weeks after spraying, spore numbers decreased ten-fold only, after which numbers remained constant for over eight weeks with no germination into vegetative cells.⁶⁹ Other studies have supported these findings.⁷⁰ However, a New Zealand study found spore numbers decreased exponentially over time.⁷¹ Overall, these data suggest that spore persistence in the soil does occur and that there will be residual viable spores in the soil for an extended period of time.

Given the high spore numbers found on foliage it is likely that spore numbers in the soil, rain splash and dust of the sprayed areas in Auckland are high.⁷² Further work is underway to establish the exact decline of spores in Auckland soils⁷³. However, previous research would suggest that although spores numbers may not decrease dramatically, their activation into vegetative forms is highly unlikely. Even active vegetative cells will not persist in the competitive microbial environment.

***Btk* persistence in the air**

After spraying, *Btk* spores will be contained within droplets of approximately 100-150µm diameter^{74,75}. These droplets are too large to be inhaled. Dried spray will leave spores attached to surfaces, possibly for extended periods of time. The persistence of spores in the outdoor environment has implications for the presence of spores within households. A study of spore levels in houses during and immediately after spraying found high levels of spores (maximum of approximately 1000 spores/m³)⁷⁶. These air-borne spores may accumulate on surfaces within houses, acting as a reservoir for *Btk* over extended periods of time. The concentrations of *Btk* spores in the indoor air were comparable to the numbers of spores from highly allergenic fungi such as *Aspergillus* and *Penicillium*, to which many people are constantly exposed.⁷⁶

⁶⁸ West A, Burges H, Dixon T. and Wyborn C. Survival of *Bacillus thuringiensis* and *Bacillus cereus* spore inoculation in soil: effects of pH, moisture, nutrient availability and indigenous micro-organisms. *Soil Biology and Biochemistry*. 1985; 17: p657-66.

⁶⁹ Petras S, Casida L. Survival of *Bacillus thuringiensis* in soil. *Applied and Environmental Microbiology*. 1985; 50: p1496-1501

⁷⁰ Saleh SM, Harris RF, Allen ON. Fate of *Bacillus thuringiensis* in soil: effect of soil pH and organic amendment. *Canadian Journal of Microbiology*. 16(8):p677-680, 1970 Aug

⁷¹ West A, Burges H, Wyborn C. Effects of incubation in natural and autoclaved soil upon potency and viability of *Bacillus thuringiensis*. *Journal of Invertebrate Pathology*,. 1984; 44: p121-127.

⁷² Peter Wigley. BioDiscovery. Personal communication. 1st September 1997

⁷³ Bio discovery NZ Ltd. PhD thesis in progress on the persistence of *Btk* in soil.

⁷⁴ *Report on droplet size tests conducted for Foray 48B*, Department of Chemical and Process Engineering, University of Canterbury, 27th May 1997.

⁷⁵ MAF. Personal communication. Spray drift modeling 2001.

⁷⁶ Thorogood R, Broadwell A, Chilcott C, Wigley P. *Aerial spraying of Bacillus thuringiensis var kurstaki in Auckland: Btk spore penetration into dwellings and persistence of air-borne Btk spores. Report to the Ministry of Forestry*. Auckland: Auckland Asthma Society and Allergen Control Services, and Biodiscovery New Zealand Ltd, December 1996

As follow up to the aerial application of Foray 48B in Victoria, British Columbia, in 1999, people having nasal swabs taken were asked to stay indoors with doors and windows shut while spraying occurred and up until they had their nasal swabs taken 2hrs later. The presence of *Btk* in human nasal passages increased significantly after the application of Foray 48B suggesting the spores can find their way indoors even though doors and windows are closed. There however was no comment from the authors regarding participant compliance or any details on house type such as the presence of an open fire place.⁷⁷.

The Building Research Association of New Zealand (BRANZ) have graded air tightness of typical New Zealand houses (see Table 6.3). A pollutant dispersion study conducted in a house classified as having average airtightness showed it took on average 53 minutes for half of the content of sulphur hexafluoride pumped into the house to leave the building with the doors and windows shut.

Table 6.3 Classification of residential building airtightness.

Type description	Building description
Airtight	Post 1960 houses with a simple rectangular single story floor plan of less than 120m ² and airtight joinery (windows with airtight seals)
Average	Post 1960 houses of larger simple designs with airtight joinery
Leaky	Post 1960 houses of more complex* building shapes and with unsealed windows
Draughty	All pre 1960's houses with strip flooring and timber windows.

*Complex designs are taken as having a floor plan that is other than a simple rectangle or L shape. Often these will have multiple floor levels and more complex architectural features such as bay windows and multifaceted walls.

All types of house listed in Table 6.3 exist in the spray zone. Particles of Foray 48B will be larger than those of sulphur hexafluoride and therefore not move as freely into buildings, however it is expected some of the Foray 48B formula will make its way into some residential houses despite windows and doors being closed and fireplaces covered.

⁷⁷ Valadares de Amorim G. 2001. 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. P1035-1043.

***Btk* persistence in water**

Persistence of *Btk* spores in water was monitored during a spray programme in Nova Scotia between the summers of 1979 and 1980⁷⁸. *Btk* was recovered from water samples up to at least 13 days after spraying but no replication (i.e. growth of vegetative cells) was observed. No *Btk* were recovered from shellfish.

Survival patterns of *Btk* in distilled and tap water were similar, with an exponential decrease leading to 30% survival after 60 days. In sea water there was only 10% survival after 30 days while in lake water there was 50% survival after 60 days. In all situations, the greatest decrease in numbers occurred over the first 20 days.⁷⁸

Btk is very sensitive to chlorination. It is destroyed instantaneously in chlorinated water at 100 parts per million of chlorine.⁷⁹ In tap water at pH 7.2 and at a temperature of 20°C with chlorine in a concentration of 1.5 parts per million, 99% inactivation of *Btk* occurred within 60 minutes. More than 30 minutes and at least 1mg/L of chlorine is required to significantly reduce *Btk* numbers.⁷⁸ The concentration of chlorine recommended in swimming pools is significantly higher (Australian and New Zealand Standard 5826 for Free Available Chlorine: most desirable range: 1.0g/m³-2.0g/m³).

Susceptible groups

Children could be expected to have a high likelihood of exposure to *Btk* through the routes noted above. Ingestion of soil is a likely mode for younger children. It is estimated that a two-year old child may ingest around 100mg of soil per day through normal play activities, hand sucking, nail biting and the like.⁸⁰ Vigorous outdoor play and working among garden foliage and lawns, and indoor activities in which dust is stirred up, also pose a potential hazard through skin and eye contact, and inhalation.

Two animal studies by Hernandez E. et al (1999 and 2000) suggest immunocompromised mice may be susceptible to infection with *Btk* however this has not been proven to date in human epidemiological studies^{81,82}.

⁷⁸ Menon, A., Mestral J. Survival of *Bacillus thuringiensis* var *kurstaki* in waters. *Water, Air and Soil Pollution*. 1984; 25: p265-274.

⁷⁹ B Cibulski, Abbott Laboratory. Personal communication, 1997.

⁸⁰ Ministry of Health. *Environmental case management of lead exposed children. Interim guidelines for public health services*. Wellington: Ministry of Health, 1996.

⁸¹ Hernandez et al. *Bacillus thuringiensis* serotype H34 isolated from human and insecticidal strains serotypes 3a3b and h14 can lead to death of immunocompetent mice after pulmonary infection. *FEMS Immunology and Medical Microbiology* 24 (1999) p43-47.

⁸² Hernandez E. et al. Super-Infection By *Bacillus Thuringiensis* H34 Or 3a3b Can Lead To Death In Mice Infected With The Influenza A Virus. *FEMS Immunology And Medical Microbiology*. 29 (2000) p177-181.

6.2.7 Risk characterisation

Having reviewed the additional information available regarding the safety of *Btk*, we have confidence that there is no need to alter the conclusions drawn in the earlier risk assessment. We conclude that there is no significant evidence that *Btk* used will:

- lead to infection or compromise of the respiratory tract in immunocompetent individuals
- cause gastrointestinal infection
- cause primary or secondary infection of wounds in immunocompetent individuals
- cause corneal ulcers
- cause illness through infection, in particular infection leading to miscarriage, birth defects, or prematurity
- predispose to important infections with other bacteria and viruses, in particular respiratory infections, meningococcal disease, and those infections leading to miscarriage, birth defects, or prematurity
- be contaminated through the manufacturing process of Foray 48B resulting in opportunities for infection by other organisms
- be capable of producing mutagenic toxins or enterotoxins
- cause neurological or autoimmune effects

6.3 Chemical risks to health

Residents present in the area during spraying operations could be exposed to Foray 48B via dermal contact, inhalation, and/or ingestion. A worst-case exposure scenario would involve being out in the open during spraying operations, with contributions from dermal and inhalation routes and consuming exposed food and water.

This section presents a toxicological assessment of the chemical components involved in such an exposure.

6.3.1 Hazard identification

A detailed assessment has been performed by a New Zealand Ministry of Health toxicologist.⁸³

Foray 48B contains *Btk* spores in the processed slurry from the fermentation process. The processed slurry includes active protein crystals, cell debris, glucose polymer residuals, water and “inert” chemical compounds. The list of “inert” ingredients has not been released to the public in New Zealand or elsewhere for commercial and legal reasons, although it has been made available to MAF, the Ministry of Health and the Auckland DHB. All of the listed ingredients are approved in New Zealand for use in food, cosmetics, toiletries or medicines. All except one of the ingredients are on the US

⁸³ Jim Waters, Toxicologist, New Zealand Ministry of Health.

Environmental Protection Agency's approved list of ingredients for pesticides under list 4B – (substances with sufficient data to substantiate they can be used safely in pesticide products)⁸⁴). The one exception is on List 3 but has closely related compounds on list 4B⁸⁵.

Agar is used in the culture process. The medium used for the fermentation of *Bacillus thuringiensis* species contains the usual nutrient groups: nitrogen, carbohydrate, trace elements, and salts. Nitrogen is provided from sources such as soy, yeast, corn, and fish. Carbohydrate sources include corn, flour, dextrose, sucrose, and soy oil. Trace elements used can include magnesium, manganese, zinc, potassium, sodium, calcium and/or iron. Salts used can include ammonium salts. No meat or meat by-products are used in the manufacture process. Other additives include preservatives, which prevent contamination, acid regulators, inert diluents, suspension agents and emulsifiers.

The updated toxicological risk assessment on the current inert ingredients (seven compounds) in Foray 48B draws the following conclusions:

- The inert ingredients are used commonly in food, pharmaceutical and cosmetics products. All are approved and licensed for their respective uses.
- There have been a small number of reports of hypersensitivity and irritation, represented by contact dermatitis, eye and respiratory sensitivity from some of the products. Two anaphylactic reactions have been reported in association with one of the products. The result of excess intake of one of the compounds is flatulence, abdominal pain and diarrhoea. However, sensitisation generally requires a substantial initial exposure, which is unlikely in this situation other than occupation exposure.
- Foray 48B spray is moderately acidic (pH 4.1-4.8 as a 10% solution in water⁸⁶) and so can be expected to cause eye, nose, throat and skin

⁸⁴ <http://www.epa.gov/opprd001/inerts/lists.html>

⁸⁵ An analysis of Foray 48B was undertaken in 1999 in Canada using gas chromatography/mass spectroscopy (GC/MS) for volatile components and high pressure liquid chromatography (HPLC) for liquids (Teschke K et al. Airborne exposure to *Bacillus thuringiensis* var *kurstaki* during Gypsy Moth eradication. Final report to the Capital Health Region. University of British Columbia, May 2000). These tests only indicate whether a substance is present in the sample, and not its concentration. No volatile compounds were detected during a field trial of the spraying. Analysis of samples taken directly from the Foray 48B container identified 38 compounds, of which only 2 are on the ingredient list. At least ten (mostly siloxanes) may be related to plastics used for storage or sampling or are artifacts from the analytical equipment. The fermentation mixture may have contained or produced small amounts of some of the other substances detected, or some may be produced during sample processing (which includes heating the sample to 280°C), or there may have been contaminants. Only 2 – acetic acid and benzoic acid – are on the EPA list 4B. The Canadian list identifies butylated hydroxytoluene (BHT), and trimethyl phosphine, but neither are among the listed ingredients. The Canadian analysis was not able to detect 5 of the seven listed ingredients. Because of its limitations, the Canadian analysis is of limited use for this health risk assessment.

⁸⁶ Materials safety data sheet for Foray 48B. Valent BioSciences/Abbott Laboratories Ltd.

irritation for some people, depending on exposure. Acidic aerosols can have an effect on lung function of asthmatics, but not on non asthmatics, with the exposure level expected in this West Auckland spray programme.

- Special attention has been paid to community concerns in reviewing the toxicological literature to date with respect to miscarriages, birth defects, and prematurity. No papers were found associating the inert ingredients in Foray 48B with prematurity, birth defects or miscarriages after extensive database searches using Medline (1976-2001). There was no evidence from the health surveillance work from Operation Ever Green that these problems occurred⁸⁷.

Foray 48B has a strong smell, described variously as yeasty, like old urine or decaying rubbish. Many people will find the spray's smell unpleasant. Offensive odours can give some people nausea, headaches or other symptoms, even though there is no harm being done.

There are no reports in the literature of thyroid disease resulting from exposure to Foray 48B. A possible cluster of cases of thyroid disease following Operation Ever Green have been notified to Auckland District Health Boards Public Health Office and are currently being investigated in conjunction with a member of STOP, however results to date indicate no link between Foray 48B and thyroid disease. See section 6.2.5.

6.3.2 Routes of exposure

The residents and those entering the spray area may be exposed to the spray for a short period of time during and after the time of the actual aerial spraying. The application rate of Foray 48B will be five litres per hectare. This will amount to 500mg of Foray 48B per square metre. Properties undergoing 15 applications will receive 7.5g of Foray 48B per square metre and properties undergoing eight applications of Foray 48B will receive 4.0g of Foray 48B per square metre.

Minute amounts of inert ingredients might be found in soil and represent a possible route of exposure. Very small amounts of inert ingredients may potentially be found in roof-collected water and in swimming pools. They may also be found on food left uncovered indoors during spraying.

6.3.3 Profile of exposure in the at-risk population

Depending on the timing of the spraying, those individuals who are on their way to work, school or who work outdoors may be more exposed than others. These include schoolchildren, those who travel by foot or by bicycle to work and those in outdoor occupations, such as gardeners.

⁸⁷ Aer'aqua[®] Medicine Ltd (formerly Jenner Consultants Ltd). Health Surveillance following Operation Evergreen: A programme to eradicate the white spotted tussock moth from eastern suburbs of Auckland. May 2001.

Exposure to minuscule amounts of inert ingredients may be possible through soil contact. As noted previously, young children may ingest up to 100mg of soil per day. Soil may also be consumed with root vegetables. Ingestion of Foray 48B as a consequence of dermal contact or consumption of exposed food or drink is a possible minor route.

Dermal contact with suspended Foray 48B in the air or on exposed surfaces would be expected to be the primary route of exposure for residents who are outside during the spray program.

As noted in Section 6.2.4, the spray drop size is respirable into the upper respiratory regions, making inhalation is a possible exposure route.

Limited data are available to enable exposure assessment, especially for inhalation risk. NOELs (no observed effect level) could not be confirmed for any of the three exposure routes (dermal, inhalation or oral).

The conclusions of this toxicological assessment are:

- The available toxicology database on Foray 48B is limited.
- If people are directly under the path of the helicopter, the spray may coat them, but we expect that this will happen infrequently. In most instances, the exposure will be indirect leading to low doses to the skin, and will be unlikely to cause irritation.
- The likelihood of exposure to the spray causing an asthma episode in a member of the public is considered negligible (conclusion made in consultation with an asthma specialist).
- For all inert components the exposure received by eating all the Foray 48B that may land in a 1m² area after 15 aerial applications is no more than the acceptable daily intakes⁸⁸ (ADI) recommended by the FAO/WHO.
- The exposures that could result from the use of this spray could not give rise to sufficient intake into the human body to produce any of the symptoms: flatulence; abdominal pain; or diarrhoea.

6.3.4 Risk characterisation

It is expected that oral exposure to the inert ingredients through ingesting food and water would be similar to that from consumption of food under normal circumstances.

The inhalation of the inert ingredients has been less well studied. While very small amounts (in the proportions of the inert ingredients as they are present in the spray) may be inhaled, adverse health effects have neither been reported nor are they expected.

We continue to hold the opinion that the inert ingredients of Foray 48B are of low toxicity and that the only possible effect is that a small number of

⁸⁸ Based on calculation using a 15.0kg person (equates to the weight of a three year old child).

individuals may demonstrate hypersensitivity to the inert ingredients as a result of previous exposure in food, cosmetics and pharmaceutical agents. The low levels in Foray 48B are not expected to lead to hypersensitivity to foods after exposure.

6.4 Physical risks to health

6.5 Noise

Noise is defined as 'unwanted sound'. The intensity of noise is measured in decibels (dB). The amount of noise associated with the possible programme relates to noise likely to be generated by twin-engine BK 117 helicopters flying at low levels over populated areas for prolonged periods of time.

6.5.1 Routes of exposure

Aural; sensory neurological system (vibration).

6.5.2 Health effects

Possible health effects associated with exposure to noise can be categorised as auditory and extra-auditory effects. Auditory effects include noise-induced temporary threshold shift, noise-induced hearing loss, acoustic trauma and acoustic pain. Extra-auditory effects include annoyance, distraction, sleep disturbance, stress, startle responses, circulatory system changes (e.g. alterations in blood pressure), effects on equilibrium and fatigue.⁸⁹

6.5.3 Dose response assessment

Sudden loud noise is more likely to induce acute acoustic trauma, whereas long-term exposure to noise at levels greater than 85 dB leads to chronic hearing loss.⁸⁹

6.5.4 Profile of exposure in the at-risk population

BK 117 helicopters are common in Auckland skies, and are known not to be excessively noisy. The amount and type of noise is difficult to predict. There is a potential for blade slap which causes sudden increased noise levels and thereby risk of startle responses.⁹⁰

Groups in the populations who may be concerned include pregnant women, those with some existing hearing impairment, people with chronic fatigue and those with cardiovascular conditions. Pregnant women need not be concerned regarding any adverse effect on the developing fetus as the amniotic fluid acts as a muffler and reduces external noise.

⁸⁹ Rom WN. Environmental and occupational medicine. Second edition. Boston: Little, Brown, 1992.

⁹⁰ Michael Hart, Crown Public Health. Personal communication, 4 September 1997.

6.5.5 Risk characterisation

It is likely that the risk of adverse health effects from noise is not significantly greater than that presented by similar aircraft that operate over suburban Auckland, or by those that took part in the Operation Ever Green programme. This was assessed as being unlikely to cause injury to hearing nor other permanent harm. There are, however, nuisance effects though there were no formal complaints to the Public Health Service during Operation Ever Green regarding noise.

6.6 Physical risks to health: Aviation Incidents

The Civil Aviation Authority (CAA) has responsibility for safeguarding the public during aerial operations, including ensuring that aircraft operated over residential areas are operated with due regard to the public safety.

The CAA has granted permission for the use of BK117 helicopters in the spray programme. They are permitted to fly at 5 metres above uninhabited areas such as Traherne Island and some parts of Waikumete Cemetery, otherwise the minimum height permitted is 45 metres.

The CAA stipulate the helicopter used had to be capable of maintaining a specified climb profile to enable a safe landing in case of emergency. The CAA's decision to use BK117 helicopters (a type of turbine twin engine helicopter) is based on the fact that the BK117 can maintain the specified climb profile and statistics show that (generically) twin-engined helicopters are safer than single-engined and turbine engines are safer than piston engines. While New Zealand's accident database is too small to provide reliable accident probabilities for various types of aircraft, overseas information obtained by the CAA confirms this viewpoint. See Table 6.4.

For comparison, the 12-month moving average accident rates for New Zealand helicopters as at December 1996 was 8 per 100 000 flying hours on commercial passenger freight operations (mainly using twin and single turbine helicopters) and 24 per 100 000 on other commercial operations (a mixture of piston, single, and twin turbine helicopters).

New Zealand statistics cannot be stratified by type of helicopter for direct comparison with the overseas information. However, the lower rate for the predominantly turbine-engined class of helicopters in New Zealand and for that class of helicopter in overseas information suggests that this is the safest choice of helicopter for the possible future spraying programme.

Table 6.4. Helicopter accident rates (all causes) in accidents per 100 000 hours for Canada, UK and US, 1980s

Type	Canada (1982-87)	UK (1980-87)	USA (1984-88)
Single-engine piston	33.53	73.79	17.83
Single-engine turbine	9.86	17.12	5.49
Twin-engine turbine	4.67	4.83	4.37

In addition to being capable of maintaining a specified climb profile, to enable a safe landing in case of emergency, specific safety requirements stipulated by the CAA included:

- The use of two pilots in the aircraft at all times
- Notification of the operation to the CAA as soon as possible so a restricted area could be zoned and notice given to other aviators
- An emergency plan including liaison with regional authorities and fire, police, ambulance, civil defence, and airway services
- Operations be carried out under daylight hours and involve visual flight conditions i.e. the operation cannot occur in murky weather
- A minimum fuel reserve enabling 30 minutes of flying time
- Approval of all spray equipment to ensure secure attachment
- Capability of a specified positive climb gradient given the maximum intended load
- Identification of structures and obstacles that may be a risk to the safety of the aircraft and crew
- Identification of sensitive areas such as schools and hospitals
- Aircraft have approved communication equipment
- Up to date regular helicopter maintenance as well as a 100 hour check immediately prior to commencement of the programme
- A ground staff safety programme to be established and be included in the operational plan
- Pilots maintain:
 - Commercial pilots licences
 - Class one medical certificates
 - Grade one agricultural and chemical ratings
 - Pilots be under the control of a chief pilot who:
 - Must be approved by the CAA
 - Must be onsite
 - Must have a radio which permits communication with other pilots and aviation control authorities

Documentation of the operation required, in addition to details of the factors mentioned above, included:

- Identification of pilots involved
- A map of the treatment area including take off and landing paths
- Registration of aircraft
- Certification and service documentation
- Names and qualifications of senior ground personnel and respective roles
- Details of timing of operation
- Name and contact details of the emergency plan liaison person in each agency
- Evidence all notification requirements have been met
- Details of airfield and landing areas to be used plus evidence of permission to land there⁹¹.

6.7 Physical risks to health: Road traffic incidents

One part of the spray area, Traherne Island, includes a 700 metre stretch of the North Western Motorway, which has a 100km/hr speed limit. Traffic flow peaks in the early morning 7am to 9am when spraying is most likely to occur. Low flying helicopters may pose a risk to motorists because of distraction. There were no motor vehicle, bicycle or pedestrian accidents reported in association with Operation Ever Green⁹². On discussion with the Land Transport Safety Authority this risk is more significant than with Operation Evergreen because traffic speed is higher.

6.8 Psychological risks

This health risk assessment commenced about the time of the September 11th terrorist attacks on the United States of America. Shortly after the attacks crop dusting planes were grounded in the US because of the fear of an aerial drop of anthrax. In the weeks following September 11th anthrax had been mailed to government and media agencies in the US resulting in deaths from inhalation anthrax, non fatal cases of inhalation anthrax and cases of skin anthrax. There have been dozens of incidents of white powder being found in mail packages around New Zealand. Fortunately none have proven positive for anthrax. Recently the US and its allies engaged in retaliative bombing attacks on Afghanistan. In this political environment it would not be surprising if residents in the spray area suffer anxiety both from low flying aircraft and spraying.

⁹¹ Personal communication with CAA. 4th February 2002.

⁹² Aer'aqua[®] Medicine Ltd (formerly Jenner Consultants Ltd). Health Surveillance following Operation Evergreen: A programme to eradicate the white spotted tussock moth from eastern suburbs of Auckland. May 2001.

On the basis of previous spraying programmes in Auckland, we expect an appreciable degree of anxiety in the exposed population. People are generally more likely to be anxious or concerned about exposures or events over which they have little control, or where they do not know (and fear) possible effects. Some individuals with existing anxiety disorders could experience an exacerbation of their condition, specifically those symptoms related to planes and spraying.

Anticipated sources of anxiety and stress include:

- Concerns for children, pregnant women, and vulnerable groups
- The means of minimising personal exposure
- Concerns about handling exposed surfaces
- The means of cleaning food and indoor and outdoor surfaces
- Low flying aerial spray helicopters in the wake of the September 11th terrorist attacks on the United States
- Media publicity of exaggerated claims of adverse effects and risks

In the programme, any aerial spraying will be restricted to the use of less intrusive helicopters, and limited to a smaller area. The psychological status of the community before, during and after to spray programme is being assessed by the University of Auckland's Behavioral Science Department⁹³.

⁹³ Professor Keith Petrie, Department of Behavioral Science, University of Auckland.

7. RISK ASSESSMENT OF EXPOSURE TO THE PAINTED APPLE MOTH

This section examines the potential for adverse health effects resulting from establishment of the painted apple moth in Auckland, should eradication efforts fail.

7.1 Hazard identification

The painted apple moth (*Teia anartoides*) is a member of the family Lymantriidae. Lymantriidae is



Figure 3. Black form of the caterpillar



Figure 4. Yellow form of the caterpillar



Figure 5. Brown form of the caterpillar

the family of tussock moths named so because the caterpillars of many members have four long dense dorsal tufts of hair. These hairs, or setae, are of four kinds, two of which are hollow and attached to glandular cells. These setae are implicated in causing skin, eye and respiratory reactions in humans.

The painted apple moth has four life stages the egg, the caterpillar, the pupae (cocoon), and the moth. Two to three generations of the moth may occur in one year, however at any one time one can expect to find all life stages present. The females are unusual in that they are flightless and have no wings. Therefore one will often find a cocoon, female moth and egg mass in the same place.

The painted apple moth caterpillar is usually brown and hairy, although the colour can vary from yellow to black. Whatever colour it is, characteristically it has four pale tufts of hair on abdominal segments 1-4, and also a tuft on its tail, and also two black tufts on its head pointing diagonally left and right like a pair of horns. Behind the dorsal tufts are two red markings, surrounding dorsal glands on segments 6 and 7.

The caterpillars feed on a variety of plants: in suburban gardens they have been found on: roses and geranium. In plantation forests they are pests on Monterey Pine. In the wild they feed on Spider Flowers, Bottlebrush, Paperbark, Wattles, and even ferns.



Figure 6. Male moth



Figure 7. Male moth



Figure 8. Flightless female

The males grow to a length of about 2 cms. The females grow to about 3 cms. They pupate amongst the leaves of their foodplant in a sparse cocoon that they decorate with hairs from their larval skin, making these cocoons likely to cause irritation too. The adults emerge after a few days. The female adult is dull brown, fat and flightless. She stays beside her cocoon emitting a scent (pheromone) to attract males. She lays eggs on and around her cocoon after fertilisation. She has a length of about 1 cm.

The male has dark brown patterned forewings, and orange hind wings with a black border. He has a wing span of about 2 cms. Despite the females being flightless, the species is found over most of Australia including Tasmania. The newly hatched caterpillars have a special way of dispersing by spinning threads of silk which are caught in the wind ("ballooning").

The hazards resulting from a situation in which the painted apple moth population establishes may be categorised as biological/physical, chemical and psychological:



Figure 9. Male and female moths with egg mass

Biological/Physical Contact with larval stages of the painted apple moth is known to cause adverse health effects, including skin lesions, eye irritation and respiratory reactions. In extreme situations, surface water can be so contaminated with frass (larval excrement) that it affects water quality. This may be enhanced by degradation of the vegetative canopy leading to an increase in water runoff.⁹⁴

Chemical. If the painted apple moth is allowed to proliferate unchecked, home gardeners and commercial growers may resort to using potentially more toxic chemical insecticides to prevent damage to their plants.

Psychological. Destruction of amenity plants and unpleasant experiences of contact with the painted apple moth have the potential for generating anger, stress and anxiety.

⁹⁴ Corbett ES. *Gypsy moth defoliation impacts on water quality and quantity*. University Park, PA: US Department of Agriculture Interagency Gypsy Moth Research Forum, 1992.

7.1.1 Routes of exposure

Exposure to larva stages is more common than to other life stages (egg, pupa, adult). The routes of exposure include skin contact with larvae, inhalation of fragments of shed outer skin, contact of eyes with these setae-containing fragments and ingestion of water containing larval frass.⁹⁴

7.1.2 Health effects

Adverse effects on human health from contact with moth larvae or their hairs entrapped in shed pupa have been reported in the following literature. No reports were found of adverse health effects from exposure to eggs or adult stages.

Perlman *et al* in 1976 described an association between an unusually heavy infestation of the tussock moth *Orgyia pseudotsugata* McDonnough in forested areas of Oregon and a high incidence of skin and mucus membrane symptoms in people occupationally exposed to high concentrations of particulate matter from the caterpillar.⁹⁵ The authors gave this condition the name 'tussockosis' and cited studies showing that the material from the moth was both allergenic and irritant in nature. In a more detailed account, Press *et al* in 1977 described a high incidence of itching of skin and eyes, nasal discharge, cough and at times respiratory difficulty among people working in the region.⁹⁶ The source of allergy/irritation was suspected as being secretions or hairs in the moth larvae or pupae.

A 1990 paper by Ooi *et al* described an outbreak of acute pruritic rash associated with an increase in Asian tussock moth larvae in 141 residents of a Singapore high-rise public housing estate following a short dry spell.⁹⁷ The aetiology was confirmed *in vivo* by patch testing with crude moth material and *in vitro* by eliciting a response similar to that mediated by histamine when an aqueous extract of moth setae was applied to isolated guinea pig ileum.⁹⁸

A more substantial body of literature describes the health effects of gypsy moth (*Lymantria dispar*) which belongs to the same family (lymantriidae) as painted apple moth and is also a serious forest pest. A comprehensive and detailed review of the literature is found in a document written for the US Department of Agriculture by Durkin *et al* in 1995. The authors cite studies in which gypsy moth infestations are associated with skin lesions, eye irritation and respiratory reactions.

⁹⁵ Perlman F, Press E, Googins JA, *et al*. Tussockosis: reactions to Douglas fir tussock moth. *Annals of Allergy*. 1976; 36: p302-307.

⁹⁶ Press E, Googins JA, Poareo H, Jones K. Health hazards to timber and forestry workers from the Douglas fir tussock moth. *Archives of Environmental Health*. 1977; 32: p206-210.

⁹⁷ Ooi PL, Goh KT, Lee HS, Goh CL. Tussockosis: an outbreak of dermatitis caused by tussock moths in Singapore. *Contact Dermatitis*.; 199; 124: p197-200.

⁹⁸ Lee HS, Tan GH, Khoo YM, *et al*. Tussock moth dermatitis: evidence for histamine involvement. *Reviews of Environmental Health*. 1991; 9: p11-15.

Skin effects from gypsy moths in humans have usually resulted from exposure to the first larval instars. Whole first instars as well as the setae of larger caterpillars, contain histamine, a compound that causes urticaria, a condition characterised by itchy weals up to 12 mm in diameter surrounded by an area of erythema and typical of dermal contact with gypsy moth larvae⁹⁹.

In a 1984 telephone survey of 1000 residents of two communities in Massachusetts, one highly infested and the other minimally infested, the risk of developing a skin rash over a one-week period was 10.4% in the highly infested community compared with only 1.6% in the minimally infested community. Previous contact in an earlier year or direct contact (the larvae crawled on them) was more likely to be associated with an additional increase in risk.¹⁰⁰

In an infestation in Newton, Connecticut, 7.2% of 2 600 students in four schools developed urticarial reactions, 50% of which occurred in the first week when first larval instars were emerging. In Bristol, Connecticut, 10.7% of the total student enrolment of 12 500 children developed rashes.¹⁰¹

Eye and respiratory effects are less well documented than skin effects. In one small study of staff in laboratories conducting research on insects, four out of ten workers with a history of adverse reactions to gypsy moths had eye irritation, and two had respiratory reactions (sneezing or runny nose).¹⁰² The severity of these effects was not well characterised; however, they appear to have been reversible. One journal article reports four cases of caterpillar hair induced keratitis (inflammation of the cornea of the eye)¹⁰³.

An adverse effect on water quality has been described at a time of heavy infestation. Increased runoff during active defoliation was associated with faecal streptococci levels in stream water as high as 25 000/100mL and faecal coliform densities in excess of 90/100mL. New Zealand drinking water standards stipulate that at least 98% of samples taken from within a water supply distribution zone should contain *no* faecal coliforms in 100 mL.¹⁰⁴

⁹⁹ Durkin PR, Fanfarillo PA, Campbell R, Meylan W, Gray DA, Diamond G. *Human health risk assessment for the gypsy moth control and eradication program*. Radnor, PA: US Department of Agriculture, Forest Service and North-Eastern Area State and Private Forestry; 1995.

¹⁰⁰ Tuthill, RW, Canada AT, Wilcock K. An epidemiology study of gypsy moth rash. *American Journal of Public Health*. 1984; 78: p799-803.

¹⁰¹ Anderson JF, Furniss WE. Epidemic of urticaria associated with first-instar larvae of the gypsy moth (Lepidoptera: Lymantriidae). *Journal of Medical Entomology*;. 1983; 20: p146-150.

¹⁰² Etkind PH, O'Dell TM, Canada AT. The gypsy moth caterpillar: a significant new occupational and public health problem. *Journal of Occupational Medicine*;. 1982; 24: p659-62.

¹⁰³ Teske et al. Caterpillar induced keratitis. *Cornea*. 10(4) p317-321. 1991.

¹⁰⁴ Ministry of Health. *Drinking water standards for New Zealand 1995*. Wellington: Ministry of Health, 1995.

Infestations of the gypsy moth have been regarded as highly undesirable by communities because of their nuisance value, potential for causing aesthetic damage to the environment and to a lesser extent, adverse human health effects.¹⁰⁵ These factors can be associated with stress in some individuals.

7.2 Exposure assessment

The most accurate method of estimating established populations is by counting egg masses in field sampling. However, the most relevant factor from a health perspective is the probability of coming into contact with a larva. This relates both to human behaviour - time spent outdoors and other activities likely to result in contact with larvae, and the density of the larval population in an area. Establishing a more precise relationship of egg mass density to larval population density to human exposure is not possible because of factors such as insect pathogens, competition for food, and adverse weather conditions.

7.3 Dose-response assessment

Skin reactions are the most easily measured and are likely to be the most sensitive effect; if exposure levels are less than those at which a substantial increase in skin irritation is observed, other effects are not likely to be seen.

Durkin *et al* used data from two reports of gypsy moth skin reactions in school children to develop models of the relationship between egg mass density and the extra risk of skin rashes; and the probability of a reaction following exposure to larvae. However, there are a number of limitations. Firstly, the use of egg mass density as a surrogate for exposure to early instar larvae is questionable, for reasons noted above. Secondly, because of the limitations of the data the confidence intervals around estimates derived from these models are unable to be calculated, and so the precision of the estimates is questionable.

7.4 Risk characterisation

Durkin *et al*'s characterisation of the risk for workers and the general public to gypsy moth exposure are shown in Table 7.1. While used with some reservations, these estimates provide a guide to the level of risks associated with exposure to the painted apple moth.

¹⁰⁵ Miller JD, Lindsay BE. Willingness to pay for a state gypsy moth control program in New Hampshire: a contingent valuation case study. *Journal of Economic Entomology*; 1993; 86: p828-37.

Table 7.1 Adverse human health effects associated with exposure to the gypsy moth

Level of infestation	Egg masses/acre	Extra risk*
General Public		
<i>Sparse</i>	50	<0.1 - 0.2%
<i>Moderate</i>	50-500	0.2 -1.0%
<i>Heavy</i>	500-5000	1.0-7.0%
<i>Extreme</i>	20 000	13.0%
Workers and other exposed individuals		
NA	NA	10%-100%

NA=not applicable

*The proportion of the public or workers/exposed individuals that would have adverse health effects after a sufficiently high level of exposure

Groups most likely to be exposed include children (climbing trees, playing outdoors among shrubs) and garden workers (handling foliage).

8. OVERALL HEALTH RISK CHARACTERISATION

In this section, we combine the findings of the risk assessments to arrive at an overall comment on the likely risks to human health from the possible pest management programme options.

8.1 Spraying programme

8.1.1 *Btk*

We conclude that there is no significant evidence that spraying Foray 48B will cause illness through infection, or predispose people to other infections, or lead to miscarriage, premature births or birth defects. Nor is there evidence that the strain used will be capable of producing toxic, neurological or autoimmune effects, or thyroid disease. Theoretically immunocompromised individuals may be vulnerable though there has been no evidence of this to date following exposures comparable to those from a spray programme.

8.1.2 Chemical

The inert ingredients of Foray 48B are of low toxicity. The level of exposure to the inert ingredients will generally be so small as to preclude any significant effects in the general population, but small numbers of individuals who have previously developed hypersensitivity to particular components in the culture broth or inert ingredients may be vulnerable to exposure to these minute amounts. It is very unlikely that people would develop new hypersensitivities because of exposure to Foray 48B during this programme. Foray 48B is moderately acidic so would be expected to cause eye, nose, throat and skin irritation in some people directly exposed and could affect people with severe or uncontrolled asthma or skin conditions. The pungent odour could give some people short term nausea or headache.

8.1.3 Noise

The noise generated by the spray programme is considered to be unlikely to cause injury to hearing or other permanent harm. It may however, be of nuisance value.

8.1.4 Aviation accident

Given the data supplied by the CAA, (Table 6.4) and assuming a total of 100 hours flying time by a twin engine helicopter, the number of expected accidents of any cause would be 0.0004. Therefore the risk of an aviation accident is assessed as being very small from the use of BK 117 helicopters.

8.1.5 Road traffic incidents

The risks of increased road traffic incidents due to the possible spray programme are assessed as being extremely small and confined mostly to the North Western Motorway.

8.1.6 Psychological risks

We anticipate that an appreciable number of people will experience anxiety and anger before and during the spray programme.

8.1.7 Overall risk assessment of spray programme

We conclude that the risks to human health from the combined components of the possible spray programme are small. However, based on the results of the previous spray programme and extensive review of the literature, there are likely to be a substantial number of complaints regarding minor physical irritations, annoyance and psychological stress.

8.2 Painted apple moth

The health risks associated with exposure to the painted apple moth are principally skin lesions, eye irritation and respiratory reactions. There is a demonstrable dose-response effect related to egg masses/acre for related species, with the groups most likely to be exposed being children and those working in gardens, either occupationally or socially.

8.3 Discussion

Many occupational and environmental health hazards present as an increased reporting of non-specific symptoms such as headache, backache, eye and respiratory irritation, tiredness, memory problems and poor concentration. The pattern and number of such symptoms are remarkably constant from hazard to hazard suggesting that common psychological and social factors, not directly related to the exposure may be involved.

The majority of the health effects described are common. The rates reported are not noticeably different from those found in questionnaire studies carried out on the general population and are less than those described in an environmental incident (Table 8.1).

Table 8.1. Symptoms reported in surveys of the general population and following environmental incidents.

Symptom	Incident ¹⁰⁶		Population studies
	Expose	control	
Respiratory	44%	36%	41% (wheezing) ¹⁰⁷
Skin	15%	4%	22% (rash, ever) ¹⁰⁷
Eye irritation	28%	11%	10% ¹⁰⁷
Headaches	32%	14%	38% (tension) ¹⁰⁸
Anxiety	18%	4%	10% ¹⁰⁹

A model has been proposed which identifies the issues that need to be considered in any epidemiological study of non-specific symptoms.¹¹⁰ (Figure 10)

Whatever the cause of their symptoms, a proportion of the population exposed to the spray programme consider their health to have been affected by it. This is related in time by them to this exposure and has resulted in a perceived deterioration in their physical and mental well-being.

The current methods of surveillance, based principally on hospital discharge and death data, would not identify the type of non-specific symptoms described. Indeed only a minority of them would be seen by doctors or other health care services. However, evidence from studies of other environmental exposures would suggest they are not good predictors of major illnesses. While existing surveillance systems would detect individual cases of major illnesses, determining whether they have occurred apart from by chance is more difficult. New cases of a common disorder are more likely to have occurred by chance. New cases of a rare disease would need to be examined considering the epidemiological criteria for causation (see section 9), and comparing the case numbers to those that have occurred in previous years.

¹⁰⁶ Campbell D, Cox D, Crum J *et al.* Initial effects of the grounding of the tanker *Braer* on health in Shetland. *British Medical Journal.* 1993; 307: p1251-1255

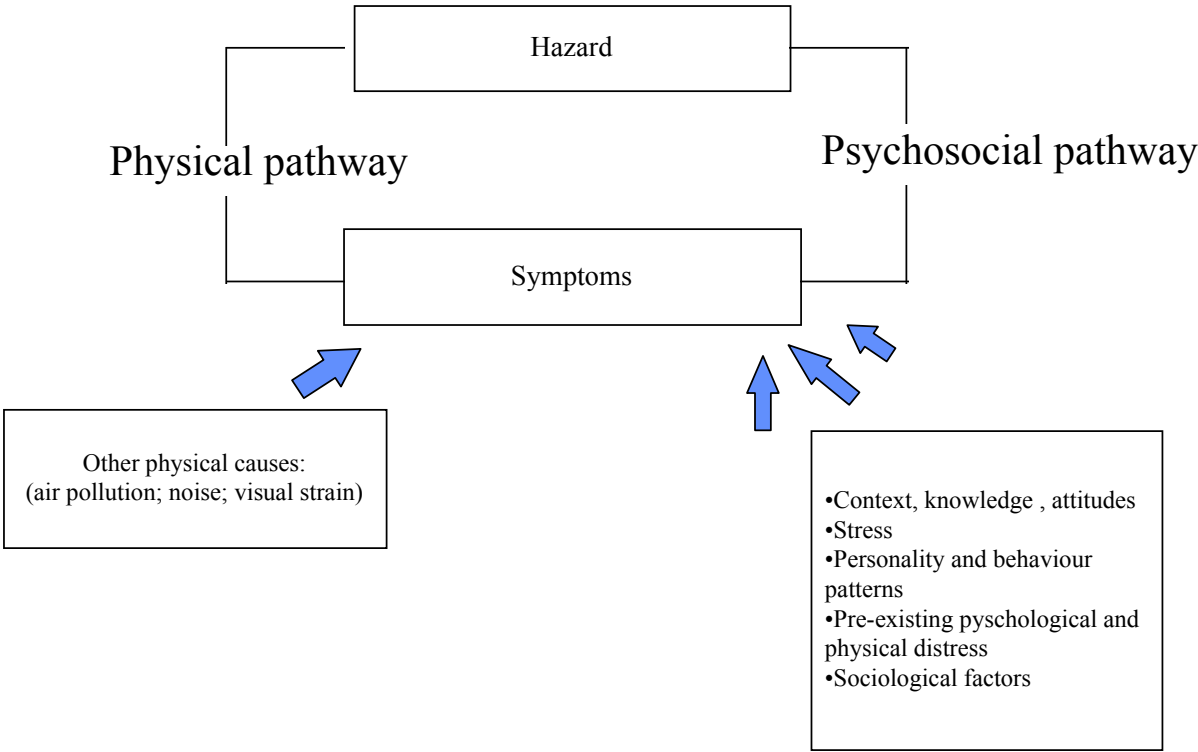
¹⁰⁷ Stewart AW, Asher MI, Clayton TO, *et al.* The effect of season-of-response to ISAAC questions about asthma, rhinitis and eczema in children, *International Journal of Epidemiology;* 1997; 26: p126-136.

¹⁰⁸ Abu-Arefeh, I., Russell G. Prevalence of headache and migraine in schoolchildren. *British Medical Journal.* 1994; 309: p765-769

¹⁰⁹ Goldberg, G., Kay C. Psychiatric morbidity in general practice and the community. *Psychology-medicine.* 1976; 6 (4): p565-569.

¹¹⁰ Spurgeon A, Gompertz D, Harrington JM. Modifiers of non-specific symptoms in occupational and environmental syndromes. *Occupational and Environmental Epidemiology* 1996; 53: p361-366.

Figure 10. Pathways from hazard to symptoms



8.4 Overall characterisation of health risk

We have not identified quantifiable risks of specific diseases in association with the spray programme. However, we would expect an increase in minor irritant symptoms, non-specific health complaints and anxiety in association with the programme.

There are quantifiable health risks associated with exposure to the painted apple moth caterpillar and pupae themselves.

9. ASSESSMENT OF UNCERTAINTY

Health risk assessment is a tool, which needs judgement to be used effectively, as there are always uncertainties and gaps in knowledge. Health risk assessment doesn't set out to prove that something is safe, only to assess known or likely effects. No substance, not even everyday food and drink items, can be conclusively proven to be safe for everyone, but this does not mean that risk assessment is not useful. It would be misleading to conclude that since there are uncertainties about a substance that it is therefore unsafe and should not be used. Rather, known or likely risks must be controlled, and where there is uncertainty commensurate caution is needed.

Research, experimental and observational, can demonstrate if there are harmful effects from an exposure and the levels at which these occur. However, the absence of some effect under particular exposure conditions does not prove safety because:

- there is an enormous number of other effects and exposure conditions which have not been tested
- not demonstrating an effect (eg at very low exposure) is not the same as proving there is no effect
- associations can be shown conclusively between exposure and disease but not between exposure and the absence of disease.

The organism *Btk* has never been clearly shown in microbiological studies to be associated with illness through infection under normal circumstances. There has only ever been one case of a *Bacillus thuringiensis* species being associated with illness (French soldier with *Bacillus thuringiensis konkukian* related infection of landmine injuries). *Btk* has never been shown in microbial studies to change the balance of micro-organisms on the skin and Foray 48B has never shown to be contaminated during the manufacturing process. However, studies have not been performed specifically among individuals with a range of illnesses to prove conclusively that they have not had infections with *Btk*. Such studies have rarely, if ever, been performed for any other potentially infective agents either.

FAO/WHO acceptable daily intake (ADI) information is available for all chemical ingredients of Foray 48B. Some of these are based on long term animal studies. There are difficulties in relating these to humans, especially in a unique programme with multiple exposures occurring in a relatively short time period. However there is some human information particularly in relation to any acute and irritant effects and sensitisation.

Environmental epidemiology studies have to estimate not only exposure to the agent being examined but also other substances to which people are exposed at home, at work or in the general environment which could also have an effect. Differentiating these exposures and effects is an important

part of the research methodology. This is difficult in the Painted Apple Moth Eradication Programme as *Btk* is an environmental bacteria and the inert components of Foray 48B are common food, toiletry, cosmetic and pharmaceutical additives.

While an epidemiological study may demonstrate no statistically significant effect in a whole group of persons studied, there may be a small number of individuals who have experienced a health problem caused by the exposure being examined. This highlights the differences between statistical significance, clinical significance and public health significance. An observed effect may be statistically significant without being of importance in illness or public health terms and vice-versa. Similarly, public health significance and clinical significance are not necessarily the same. A number of epidemiological criteria are commonly used to judge whether an association might be causal or not.¹¹¹ These have been considered in the process of writing this Health Risk Assessment particularly when considering findings of Operation Ever Green health surveillance. They include:

- *Consistency* - with other studies in different settings using different methods.
- *Strength of association* - the size of the risk as measured by statistical tests.
- *Specificity* - a single putative cause produces a specific effect(s).
- *Dose-response relationship* - an increasing level of exposure increases risk.
- *Temporal relationship* - exposure always precedes effect.
- *Biological plausibility* - the association is consistent with current understanding of biological processes.

¹¹¹ Hill AB. The environment and disease: Association or causation? *Proc Royal Society of Medicine* 1965; 58: p295-300.

10. RECOMMENDATIONS FOR RISK MANAGEMENT AND COMMUNICATION

Our recommendations regarding the aerial spray programme relate to public health advice, operational advice to the MAF, surveillance, public health management and research.

10.1 Public health advice

We do not expect toxic effects or infection from Foray 48B spray though if directly exposed to the spray or substantial spray deposits some people may complain of minor skin, eye and upper respiratory tract irritation, or aggravation of existing asthma or allergies. However, there is appreciable concern in the community and the lack of adequate epidemiological information will compound this anxiety. Therefore, we advocate a precautionary approach and a policy of prudent avoidance to minimise exposure where possible.

Our advice with regard to the spraying programme remains as stated in the Health Risk Assessment of September 1997 (pages 64-65) with some minor modifications. Much of the advice is standard advice given in everyday circumstances.

10.1.1 General advice

Schools

We do not advise the closure or evacuation of schools or early childhood centres, as has been suggested by some individuals. Schools should not be sprayed at times when children are likely to be outdoors. Classes outdoors should be relocated indoors if possible when spraying is known to be occurring during school hours. Normal hygiene practices such as hand washing before eating should be reinforced.

Food hygiene

While not predicting any implications for food safety from the programme we reiterate general food hygiene advice. Care should be taken therefore to ensure that food preparation and storage is hygienic and minimises the risk of food poisoning. To ensure food safety, we recommend the following:

- Wash vegetables and fruit before eating
- Cooked food should be cooked thoroughly; juices from meats should run clear, not pink.
- Always store food under refrigerated conditions.
- Always reheat food until it is piping hot.
- Wash hands with hot soapy water before beginning food preparation.
- Wash cutting boards and cooking implements before and after use.

- Do not wipe hands on dishcloths - use a disposable towel or a clean hand towel.

Drinking water

There are standard procedures for ensuring the safety of untreated water used for human consumption. A household collecting roof water should ensure its roof and tank are well maintained, and a suitable filter or treatment system is used. For further information contact the duty Health Protection Officer at Auckland District Health Board's Public Health Office for detailed advice tailored to individual water collecting and storage systems.

Gardening

Specific advice to gardeners during the spray programme is as follows:

- Avoid contact with any painted apple moth caterpillars and pupae.
- Covers should not be placed over vegetables or plants to protect them from spraying. This may protect the larvae and decrease the efficacy of the spray programme.
- If eye irritation occurs, rinse with water or commercial eyewash.
- If contact with skin causes irritation, wash spray off affected area.

General advice to gardeners:

- Wash vegetables and fruit before eating
- Use old clothes, gloves and protective clothing when gardening
- Wash hands after handling soil/ plants
- Prevent children eating soil.
- Avoid breathing in dust when gardening or turning compost. If you are concerned, wear a mask.

Pool maintenance

It is recommended that regular pool maintenance is observed.

- Organic material such as leaves should be removed from the pool immediately.
- Covers should be placed over pools when they are not in use
- Pools should have adequate levels of free available chlorine. Recommended levels, as set by the Australian and New Zealand Standard, are 1.0g/m³-2.0g/m³

Cleaning outdoor surfaces

Foray 48B used in this programme is water based and does not contain any oil based components and is therefore water soluble. It can be removed from cars, chairs, windows etc. by rinsing with water. Outdoor tables and barbecues should be cleaned with hot soapy water as usual before use.

10.1.2 Advice for people with specific health concerns

Asthma

We recommend the following steps for those advised by a doctor that they have asthma:

- Make sure you have an up-to-date asthma management plan;
- If you are advised to take peak flow measurements continue these with normal frequency;
- Ensure you have a current supply of your usual preventer and reliever inhalers or medicines;
- If you are at all concerned individually do not hesitate to phone your local doctor or nurse.
- Postpone jogging or other outdoor activities while spraying is in progress and for 2 hours afterwards
- If you are indoors follow the advice in section 10.1.3 below.
- Avoid contact with any painted apple moth caterpillars and pupae

Skin disease

We recommend the following for people who have a diagnosed skin condition:

- Rinsing with water is likely to remove any traces of spray if you have had a skin exposure;
- Ensure you have a current supply of your usual topical preparations or medicines;
- If you are at all concerned do not hesitate to phone your local doctor or nurse.
- Avoid contact with any painted apple moth caterpillars and pupae

10.1.3 Others including children, pregnant women and the immunosuppressed

People who wish to take a precautionary approach could observe the following recommendations:

- For a few hours after application there will be settling of the spray. During this period, close windows and doors and place newspaper over any open fireplace. This will reduce downdrafts or air currents from outside entering the house. Stay indoors for about 2 hours after the spraying has finished. After this time open doors and windows and go outside as you normally would.

10.2 Operational Advice for MAF

- We recommend the spraying be limited to targeted high risk areas.
- We recommend spraying commence as soon as possible to avoid the necessity for more widespread spraying in the future.
- Spraying should be conducted at times of day to minimise human exposure, for example avoiding times when children are walking to or from school.

- Spraying should avoid times when major outdoor events are planned. See table 5.3.
- Spraying should be avoided on weekends in areas where sporting and community activities will be occurring
- Residents should be advised in advance of spray times so they can avoid direct exposure if they wish.
- We recommend that consultation be undertaken before any significant change to published procedures are introduced.
- We recommend spraying not occur over the North Western Motorway during peak traffic period 7am to 9am and 4pm to 6pm.
- We are confident manufacturer's quality control procedures are sufficient to ensure no beta-exotoxin or enterotoxins are present, however we consider it is prudent to check for contamination of the product.
 - Product from each barrel should be tested for specific pathogens such as *Pseudomonas aeruginosa* and *Salmonella species*.
 - In addition maximum levels of *Coliforms*, *Streptococci*, *Salmonella*, *fungi* and *yeast* need to be established for each batch.
 - Each batch should be specifically tested for *Bacillus anthracis*

10.3 Health monitoring and support

10.3.1 Laboratory

Throughout the spray programme it should be determined whether any *Btk* isolated from medical laboratories represent the replication of vegetative cells or merely persistence of spores. In addition any *Bacillus* isolates should be typed.

10.3.2 Epidemiology

Measuring the incidence and prevalence of some of the reported symptoms associated with the spray programme has major methodological problems. However key health outcome indicators specific to expected health outcomes should be examined (this should include motor vehicle crashes). Self-reported health events should be individually investigated as deemed appropriate and all should be recorded with sufficient information of the individual case to permit further investigation if required at a later date.

The problem of examining rare health events in a relatively small population will have to be recognised and any investigation should use sound epidemiological methods.

10.4 Health services and advice

In light of general health concerns expressed regarding the spray programme by members of the community consideration should be given to an independent health Helpline operating according to agreed protocols.

It is expected there will be a number of people who will want to discuss their personal health conditions with a medical professional and receive advice tailored to their personal circumstances. The majority of these people will have mild to moderate pre-existing conditions. A service should be provided where these people have an opportunity to discuss their concerns with an appropriately qualified medical professional. In most cases it will be more appropriate for individuals to consult with their regular general practitioner, as they will know the individual better than another medical practitioner will. This is particularly the case for asthma patients.

The available health professional could be a nurse who refers more medically complicated individuals to an appointed general practitioner. This general practitioner in turn could discuss any individuals, with severe medical conditions, with their present medical specialist in order to provide tailored advice. If the individual doesn't have a specialist and needs one, one should be provided. Barriers to accessing these medical professionals should be mitigated.

There is no medical evidence that any form of detoxification following spraying is necessary. No treatments/interventions other than those recommended by a registered medical practitioner should be taken.

It is apparent that there have been psychological effects both from the previous programme and the current possibility of further spraying. Public health and other advice will attempt to mitigate public concern in the event of further spraying. It is important that these messages are appropriately and effectively delivered.

10.5 Research

Additional information is required to further define risk in terms of bioaccumulation, persistence in media (air, water, soil), and viability. Research is currently being done into the persistence of *Btk* spores in soil¹¹².

There may also be value in further investigating specific clinical conditions to establish if there might be a causal association with any of the hazards outlined in this report. A case control study or a cluster study would be appropriate investigations if specific health conditions come to light. A cohort study is not appropriate (A non-technical explanation is provided in Appendix 9.)

¹¹² Bio discovery NZ Ltd. PhD thesis in progress on the persistence of *Btk* in soil.

11. STANDARD DISCLAIMER

Professional liability of Auckland District Health Board for the attached report:

The attached report has been prepared by Auckland District Health Board, in some parts from records and information furnished by MAF. As the Ministry's instructions did not require us to audit these records, we have not done so and therefore do not accept responsibility for the accuracy of the material from which the report was prepared apart from responsibility for accuracy of our own work.

The advice contained within the report is given in good faith on the basis of information supplied. By relying on the advice, the acceptor agrees that Auckland District Health Board shall not be liable for any economic loss or damage arising directly or indirectly from the supply or use of the advice.

Appendix 1: Aerial photograph of the spray area.

Note:

- **Parrs Park may also be sprayed later in the programme (not shown in the photograph)**
- **Yellow graphics indicate targeted spray areas**
- **White graphics indicate blanket spray areas.**

Appendix 2: Properties in the spray area and properties in a 200m buffer around it

Appendix 3: Meshblocks containing the spray area and a 200m buffer around it

Appendix 4: Population density within meshblocks containing the spray area and a 200m buffer around it

Appendix 5: Age distribution within meshblocks containing the spray area and a 200m buffer around it

Appendix 6: Ethnic distribution within meshblocks containing the spray area and a 200m buffer around it

Appendix 7: Income within meshblocks containing the spray area and a 200m buffer around it

Appendix 8: NZDep score within meshblocks containing the spray area and a 200m buffer around it

Appendix 9: Explanation of the limitations of any cohort study investigating health effects from Foray 48B

Explanation of the limitations of any cohort study investigating health effects from Foray 48B.

A cohort study is an observational study that follows a large population, commonly over years, comparing health outcomes between people who have and have not been exposed to a hypothesised health hazard. The populations can be studied as time passes (prospective cohort), or historical information can be examined (retrospective cohort) to help determine whether a suspected health hazard causes illness or disease.

Before the study starts it is necessary to know what health effects are suspected for a specific health hazard so that relevant information can be gathered from participants. Many illnesses have more than one possible cause, for example lung cancer can be caused by cigarette smoke or it can be caused by x-ray radiation. In order to determine whether a suspected health hazard causes disease it is necessary to identify other causes of the disease and consider these when assessing the risk of the suspected hazard. The example below demonstrates how one could fail to recognise a health hazard if other factors were not considered.

Example:

A population of 100 000 which is exposed to a possible chemical hazard is compared to another population of 100 000 not exposed to the chemical hazard. The suspected health effect from the chemical is lung cancer. The exposed population has 22 cases of the lung cancer diagnosed in one year while the unexposed population has 19 cases diagnosed. One may falsely conclude that the chemical has no health effect. However if the populations are examined, considering other causes of lung cancer such as smoking, it can be seen that the chemical may actually cause lung cancer. See the figure below.

Exposed population		Unexposed population	
10 000 smokers	90 000 non-smokers	90 000 smokers	10 000 non-smokers
4 lung cancers	18 lung cancers	18 lung cancers	1 lung cancers

If smokers are compared with smokers the risk for those exposed to the chemical is 4/10 000 compared with 18/90 000 (i.e. 0.0004 compared with 0.0002) which means those who are exposed to the chemical have twice the risk of lung cancer. If non-smokers are compared with non-smokers the risk for those exposed to the chemical is 18/90 000 compared with 1/10 000 (i.e. 0.0002 compared with 0.0001) which means those who are exposed to the chemical have twice the risk of lung cancer.

This is a simplistic example but it demonstrates how other factors can distort findings. A cohort study would have to examine several factors, which may contribute to the development of disease (confounders). For example exposure to x-rays would need to be looked at in the example above so one would have to split the population again for comparison. See the figure below. Exposed smokers not x-rayed would have to be compared with non-exposed smokers not x-rayed and so on.

Exposed population		Unexposed population	
10 000 smokers not x-rayed	90 000 non-smokers not x-rayed	90 000 smokers not x-rayed	10 000 non- smokers not x-rayed
3 lung cancers	16 lung cancers	17 lung cancers	1 lung cancers
smokers x-rayed			non smokers x-rayed
1 lung cancer	non smokers x-rayed 2 lung cancers	smokers x-rayed 1 lung cancers	0 lung cancers

As more and more 'confounders' are analysed the number of cases needed to be sure the result didn't occur by chance increases. This is the case even when the prevalence of 'confounders' is similar in the exposed group and the comparison group.

Relevance for the possibility of a cohort study in West Auckland

One factor which makes the study technically difficult is identifying possible health effects to question participants about. Out of the hundreds of diseases possible in the human body, a decision would need to be made about which ones are suspected to be caused by Foray 48B. This is not an easy task.

Foray 48B has been sprayed around the world for more than 35 years. If health effects from exposure to Foray 48B were common it is expected that they would have been recognised by now. Any health effects are likely to be rare and therefore a cohort study is likely to require a large number of

participants, easily more than 200 000. The number of people at most exposed to Foray 48B spray in the West Auckland Painted Apple moth Eradication Programme will be less than 13 500. The incidence of many cancers for example is lower than the fictitious lung cancer used in the example above. Cancer of the lung, bronchus and trachea as a group has an incidence of 29/100 000 however this group includes many different types of cancer.

Types of studies such as cluster investigations or case control studies can potentially be useful for the follow up of specific health effects. A cluster study is one where a group of people with the same disease come forward identifying a possible common cause. The group are investigated to determine whether the rate of disease is greater than that of the general population. A case control study is one where a group of individuals with the same disease come forward a common cause is suspected but not identified. The group is compared to a similar group without disease to determine if the individuals with disease have an exposure in common.

Conclusion

- Any health effects from Foray 48B other than those described in this report would be expected to be rare.
- Of all the diseases possible in the human body it is not possible to guess which ones may be caused by Foray 48B, if any.
- With a rare disease very large numbers of people need to be studied to be sure a particular hazard causes the disease.
- A cohort study is not an appropriate study to look for health effects from Foray 48B in the small population in West Auckland.
- Looking at a group of people with the same disease who suspect it was caused by Foray 48B is an appropriate means of investigation (cluster study or case control study).
- Whichever study is used (cohort, cluster or case control) people will not be prevented from developing illness if an exposure is hazardous.