5. OVERALL REPORT DISCUSSION

5.1 EXPOSED POPULATION

The Asian Gypsy Moth (AGM) eradication programme began using aerial spraying of Foray 48B (a *Btk* based spray) in October 2003 in over 1,253 Hectares of the central Hamilton area

Spraying took place on a total of 8 days and was postponed for a cumulative total of 10 days.

The criteria adopted by the AGM Health Service with respect to drift impacts on the general public were used to define geographical areas affected by aerial spraying. Using census information the residentially exposed population was calculated as 23,598 over the total area that received aerial applications of Foray 48B.

5.2 SAFETY OF BTK SPRAY

Bacillus thuringiensis var kurstaki applied to vegetation has a specific mechanism of action against the intestinal system of leaf eating caterpillars. Use of *Btk* as an agent to control caterpillars has a long established track record of safety for exposed mammals, including humans. This has been most recently summarised in a review publication by the World Health Organisation, International Programme on Chemical Safety (1999).

“Exposure and effects of Bt on humans”.

The field application of Bt products can result in considerable aerosol and dermal exposure of workers. Agricultural uses of Bt can result in Bt contamination of potable water and food. With the exception of case reports on ocular and dermal irritation, no adverse health effects have been documented after occupational exposure to Bt products. Human volunteers ingested and inhaled large quantities of a *Btk* formulation but experienced no adverse health effects. Antibody titres to the vegetative cells, spores and spore-crystal complexes have been demonstrated in workers who spray Bt products; however, no adverse health effects were reported. There have been some case reports on the occurrence of Bt in patients with different infectious diseases. However, none of these studies unequivocally demonstrates an actual risk to human health from the use of Bt. Bt has not been reported to cause adverse effects on human health when present in drinking-water or food.” (Page 4 WHO 1999)

“Conclusions”

Owing to their specific mode of action, Bt products are unlikely to pose any hazard to humans or other vertebrates or to the great majority of non-target

invertebrates provided that they are free from non-Bt micro-organisms and biologically active ingredients other than the ICPs (insecticidal crystal proteins). Bt products may be safely used for the control of insect pests of agricultural and horticultural crops as well as forests. They are also safe for use in aquatic environments including drinking-water reservoirs for the control of mosquito, black fly and nuisance insect larvae. However, it should be noted that vegetative Bt [refers in general to strains of *Bacillus thuringiensis* rather than *Btk* commercial strain] has the potential for the production of Bc [*Bacillus cereus*]-like toxins, the significance of which as a cause of human disease is not known." (Page 4 and page 69 WHO 1999)

The issues identified by WHO relate to the potential for some wild strains of Bt to produce toxins with action similar to *B cereus.* The commercially used strain of *Btk* in Foray 48B is selected for, among other characteristics, its freedom from such properties. (see section 6.3 below).

Another hypothetical issue is whether the aerosols of Foray 48B can act as a type of fine respirable particulate and have toxic effects on the lung. In reality the aerial spray equipment is calibrated to produce droplets outside the respirable range. This issue has been partly addressed in the chapter on aerial *Btk* exposure during the AGM programme (2.2). The remaining unresolved matter is whether a portion of the droplets released from the delivery equipment might not deposit onto surfaces but instead might aerosolise from atmospheric turbulence and result in suspended particulate. The operational practice of the Health Service has been to assume that any such effect is minor and not of consequence to the general public safety (see Appendix A). However, for a few highly sensitive individuals with respect to impaired respiratory function, individual advice by the Health Service has been conservative and presumed there is an unquantified possible risk from exposures that are of no health significance to most other people.

5.3 ENTEROTOXIN
IS COMMERCIAL BTK PRODUCT ASSOCIATED WITH GASTROENTERITIS IN HUMANS?

Bacillus thuringiensis, like other bacteria, produces a number of different toxins (WHO, 1999; Glare 2000; Siegel, 2001). These toxins may include enterotoxins (diarrhoeal type) 'similar to those produced by *B. cereus'* (Glare, 2000). However, as a condition for registration for pesticide use on food in the USA, *Bt* active ingredients must be tested to show the absence of metabolites that are considered hazardous to humans and the environment (Laird, 1990; US EPA, 1998; WHO, 1999; Glare 2000).

Although, the *Bacillus thuringiensis* species is very close to *B. cereus* in its cultural and biochemical characters, it differs by the ability of Bt to produce parasporal crystalline inclusions known for their insecticidal activity. *Bt* isolates can be easily and quickly identified by H-serotyping, which is not a

routine laboratory test (WHO, 1999; de Barjac H).

Pathogenic *B. cereus* is characterised by the presence of specific plasmids, which are not present in *Btk*. These plasmids are the primary determinants of the toxins, which cause the specific pathogenicity of *B. cereus*.

Evidence to date suggests that food poisoning associated with Bt exposure would be unlikely to occur. Siegel offers an explanation why Bt isolates have not been associated with food borne illness in man. He suggested that either the isolates used in commercially produced Bt did not produce enterotoxins under commercial fermentation conditions, or that enterotoxins were absent from the final product because they were degraded by the end of the fermentation run. His argument was supported by the numerous laboratory safety studies that were used to register Bt insecticides (Siegel, 2001).

Foray 48B uses a long established specific strain of *Btk* known to produce a relatively low amount (if any) of enterotoxin. There is no valid evidence to link commercial *Btk* product with any episodes of diarrhoea.

5.4 PATTERNS OF PRESENTATION TO THE AGM HEALTH SERVICE

The AGM Health Service was set up in September 2003 as an independent medical service to provide free health support for residents, as required, to prevent or respond to health effects from spraying. Throughout the course of the eradication programme, and beyond to 20 June 2004, 1,536 householders contacted the health service and were included in a medical records database (health register) with 8,736 associated encounters with health service staff, either “face to face” at consultations or over the telephone. Of the 1,536 householders, 904 called only once.

The analysis of patterns of presentations to the health service has included a subset of 2,872 health symptom/query encounters that arose during a 9-month period up to 20 June 2004 and related to 1,536 individuals. Some individuals who actively refused to identify themselves, or who expressed refusal to have their records included in statistical research (2), were excluded from the analysis. From the commencement of the service, Health Service staff endeavoured to obtain details of all family members who may have had a health concern. Each of these identifiable individuals had a separate record created in the analytical dataset, especially to ensure that age-group analyses were informative.

Analyses of symptomatic patterns from the presentations (encounters) were primarily done using the International Classification of Primary Care 1998 (ICPC-2; second edition). This organises individual symptoms into organ systems. Results for frequencies of presentations from organ systems are shown in the report according to:

residential exposure status

medically diagnosed status
receipt of a Practical Support Plan (PSP)
age and gender

Selected ICPC symptom codes were ascertained based on clinical experience by the Health Service doctors and grouped to provide definitions of typical “clinical syndromes” seen by those doctors. Frequency of occurrence of the syndromes was then described in the report. Finally atopic codes were selected and frequency investigated.

The complexity of concerns voiced by householders contacting the Health Service, reflected the spectrum of frustration and anxiety of the general population in perceived harm and loss of control by a change of environment. This was evident in the subsequent enquiries by householders following every major media release and in reaction to information released by a wellorganised protest lobby. Although stressors such as low flying aircraft, had been assessed prior to the programme, disinformation which caused widespread alarm amongst a small proportion of householders directly affected had not been taken into account, as it had been unforeseen.

Whilst the spray programme caused disruption to the daily life of those relocating, whether on their own accord or with the support of the AGM Health Service, the effects of relocation varied according to situational and individual differences in adapting to such disruption.

Encounters by telephone were most often complex, either because the health of more than one householder was discussed, or that the nature of the health concerns raised included both existing and often multiple medical conditions, which may or may not have relevancy to exposure to Foray 48B.

Enquiries from residents in the area reflect health concerns, but not necessarily the reporting of existing symptoms. For example, respiratory awareness and general health concerns are significantly more common (and more evident) to the population as a whole, than genito-urinary or ear conditions. These patterns therefore may be reflective of normal population health concerns and symptom reporting, which may be prevalent at the time, e.g. seasonal rhinitis due to pollens.

The discussion for chapter 4 systematically outlines the relative frequencies of outcomes, measured as ICPC codes within organ systems, in relation to factors such as exposure, use of PSPs etc. The distribution pattern of reported symptoms from organ systems was stable across age, gender, exposed or not, medically diagnosed or not. However relative frequencies were greatest in women, age groups other than young adults, those with a medical diagnosis, those who had any sort of PSP and markedly greater among those with a relocation PSP. These patterns are somewhat predictable but the surprising

finding has been that the least trends were present for asthma, respiratory (all symptoms) and to a lesser extent skin. This is the opposite of what might be anticipated if there were a community dose-response to an environmental irritant released through aerial spraying.

The PAM programme provided an opportunity to examine, among a largish population exposed to *Btk* aerial spray, patterns of presentations related to health. The contemporaneous AGM programme has provided an opportunity to examine whether experiences were similar in two cities. A detailed comparison will be issued as a subsequent qualitative report. However householders contacted the AGM health service about an even wider range of health symptoms, questions and experiences than was experienced during PAM. Also a markedly larger proportion of the population contacted the Health Service phone line. Symptoms from organ systems expected to relate to airborne irritancy, such as respiratory and skin, showed a lower gradient than other unrelated symptoms in relation to exposure, medical diagnosis or uptake of PSPs. This is not reflective of a dose-response to an environmental agent impacting on skin, eyes, nose throat or airways.

5.5 ODOUR PERCEPTION AND SYMPTOM REPORTING

The AGM eradication programme has been highly controversial. Some residents felt they were being subjected to “chemically toxic bombardment”. These fears could not be assuaged by the disclosure of the component list of Foray 48B for commercial reasons. This led to the perception of a small number of individuals that public officials were not forthcoming with information and that there might be something to hide. Allied to this issue of public perception querying the validity of official health information is the history of occasional discoveries of harm associated with previously trusted products, e.g. asbestos insulation and lead in petrol.

To some extent, highly active and vocal opponents of the programme succeeded in gaining media exposure for their views. Individuals in Hamilton were encouraged via media such as newspapers, talkback radio and internet, and by public meetings held by activists from the West Auckland Painted Apple Moth Programme to attribute any symptoms they may have experienced to the aerial application of Foray 48B.

Protesters at one stage reported the results of an attempt at reverseengineering to identify the spray ingredients. The process was flawed in that it identified “added” chemicals incorrectly (e.g. organic compounds produced by the natural breakdown of foodstuffs in the spray were assumed to be part of the ingredient list). This led to misinformation and fear as to the “toxicity” of the spray and served to further fuel controversy over perceived health effects.

Exposure to significant concentrations of toxically hazardous materials may be

signalled by odour perception and odour-related symptoms, and illness can occur from exposure to some chemicals, but this is frequently not the case. For example, common industrial sulphur gases are often associated with symptom reporting when levels barely exceed the odour threshold. Although physiological activity can partly influence symptoms from airborne chemical exposure, these symptoms can also be influenced by beliefs, or models of exposure risks. An important factor in an individual's response to a chemical is their accumulated knowledge of exposure effects (Dalton, 2002).

Personal and community belief regarding the quality of the environment and risk to an individual's health is an important factor in disease aetiology. Attitudes and opinions influence illness-related behaviour. Psychological factors, especially beliefs about ill-health can play a large part in many illnesses.

Before the discovery of germs, unpleasant odours were believed to be carriers of disease (poisonous miasmas). Latterly this perception is evident in beliefs about becoming sick from exposure to environmental odours.

Psychogenic illness also demonstrates how psychological processes play a part in illness perception; large numbers of individuals report symptoms that cannot be explained or accounted for by medical or environmental testing. Unidentified odours have been documented as eliciting more than 50% of reported outbreaks of psychogenic illness (Colligan, 1982).

Concern about the health effects of exposure to chemicals may in fact increase awareness of common bodily sensations. Vague sensations may be unconsciously magnified and misinterpreted in an attempt to fit expectations. When an individual believes they have suffered chemical exposure involuntarily, symptom perception may be amplified (MacGregor, 1996). The stress engendered by the belief that the individual has been exposed to a chemical hazard itself intensifies somatic responses. Stress-mediated catecholamine release produces responses such as dry mouth and increased heart and respiratory rate, and this response can be misinterpreted as an "exposure reaction".

Differences in personality type can contribute significantly to the variation in symptom and irritant perception in healthy individuals. Negative affectivity (NA), is identified as a unique personality construct featuring: feelings of nervousness and worry, chronic negative mood states, pervasive feelings of discomfort, introspection and the tendency to dwell on the negative aspects of the self and the world (Watson, 1984). Individuals who are high in NA are more likely to experience distress when overt stressors are not present, are over-alert when assessing their environment, interpret vague or ambiguous stimuli in a negative fashion, and report more subjective health complaints (Watson, 1989).

When the media reports the consequences of “exposure” to environmental contamination, they are generally non-specific, common symptoms. In making the link between commonly occurring symptoms and environmental factors, individuals undermine their perceived health status. Negatively interpreting normal symptoms as a pathological response to environmental factors influences health-seeking behaviour. (Petrie, 2001).

Individuals often report physical symptoms attributed to emissions despite the fact that environmental monitoring frequently shows very low levels of airborne contaminants at levels not sufficient to cause acute or sub-acute symptoms. When sensory information is weak, cognitive influence becomes the principal factor guiding interpretation and awareness of sensory and somatic stimuli (Pennebaker, 1982).

Researchers in Ontario, Canada (Luginaah, 2002) studied the community health impact of a five-year emission reduction plan at a refinery in Oakville, Ontario. They found that despite significant improvements in emissions from 1992 to 1997, some residents continued to report adverse health effects at a level inconsistent with emission levels. The investigators felt that the persistence of these health concerns indicated the existence of individuals who may have been reporting ill-health in the absence of harmful effects from the refinery.

Investigators at the California Department of Health Services (Shusterman, 1991) retrospectively reviewed three studies conducted near hazardous waste sites in Southern California. Significantly positive correlations were found between the prevalence of headaches, nausea, eye and throat irritation, and both frequency of odour perception and degree of worry. The authors postulated that odours could function as a sensory cue for the manifestation of stress-related or autonomic symptoms such as headache and nausea among people who had concerns about the quality of their environment. They also stated that the observed increase in throat and eye irritation and its similar pattern with respect to the two variables, may be interpreted as evidence that odour and worry heighten symptom perception or recall (resulting in recall bias). Recall bias occurs when an adverse health outcome, factors like odour perception, or publicity surrounding a contentious environmental issue, influences an individual to remember symptoms. The investigators stated: “Such bias is suspected when uniform elevation of symptoms with diverse etiologies is observed”.

Opinion surveys have shown that heightened risk perception is associated with involuntary exposure, perceived lack of benefit, lack of community control over operations and the “exotic” nature of the threat (i.e. unknown chemicals) (Slovic, 1985). Risk perception is also increased when the public official response to questions from the community regarding potential health

risks are vague, contradictory, not timely, or overly technical (Neutra, 1985).

5.6 REPORTS PENDING

A concurrent, similar symptom report has also been written for the PAM eradication programme, and is currently in Press. A third report will compare both the PAM and AGM studies and is due early next year.

5.7 SELF REPORTED SYMPTOMS DURING OPERATION EVER GREEN

In 1996 and 1997 Foray 48B was used to eradicate the white-spotted tussock moth in the eastern suburbs of Auckland. That programme (Operation Ever Green) affected a resident population of about 81,500, with 5,640 estimated to live in an infested area subject to more extensive spraying. During Operation Ever Green, there were 375 reported health concerns between October 1996 and June 1999, both self reported and including a few reports to the Medical Officer of Health by medical practitioners. Medical practitioners were asked to follow statutory requirements in reporting of any events associated with exposure to the spray for three years from the start of spraying. No systematic problems were reported and no further individual reports occurred after mid 1997. Many householders who reported concerns had not consulted a medical practitioner.

Clusters of reporting occurred in response to publicity, in particular after publicity of the “free phone” system for contact, requests by MAF for public submissions, a telephone survey of households within the quarantine area and membership recruitment by a group of citizens opposed to the spray. An investigation of eight self reported miscarriages, featured in a news story, did not confirm a cluster, when investigated by the Medical Officer of Health.

The most frequently reported specific concern was “fear of unspecified future disease”. The use of International Classification of Primary care (ICPC) to identify concerns by organ system, in order of frequency were: Respiratory (183); General (116), including fear of unspecified disease; Eye (86), including watery, red versus sore; Skin (74) including rashes, Social (73); Neurological (71), including headache; and Psychological (51).

The patterns of self-reported symptoms during that earlier spray programme were not dissimilar to patterns of presentation to the PAM health service, except that fear of unspecified future disease was less common in the later programme. A feature of frequent symptoms is that they arose in the upper respiratory system (including eye) or skin and are common at all times in the community due to prevalence of upper respiratory infections and atopy and allergy to environmental agents such as pollen and dust mite. Headaches are also common, but the background frequency in the community is largely unknown so it is difficult to interpret reported patterns. Most headaches and many upper respiratory symptoms are also self-managed without consultation with a medical practitioner. In contrast to Operation Ever Green,

gastro-intestinal symptoms were frequent in the self-reports from PAM. There was considerable publicity early in the PAM programme about the possibility of such side effects due to the spray, and this may have increased awareness of these symptoms as relevant to report to the PAM health service.

5.8 PREVALENCE OF CONDITIONS IN NEW ZEALAND COMMUNITIES

Appendix H presents information about prevalence within the community of various diseases or allergic or congenital conditions. The reason for inclusion of this information is that individuals with some of the conditions represented in the table in Appendix H, or with other similar conditions, have entered preventive plans for spray avoidance. In each individual instance there are various reasons for the health service doctors to make such a recommendation. It is hardly ever simply based on presence of a particular condition, with the notable exception of severe allergy to foods present in the broth used to ferment the *Btk.* It will be apparent that numbers in PSPs are far fewer than might be anticipated if everyone avoided presence in a spray area by reason of a particular medical condition that concerns some in regard to spraying.

What then are these additional individual risk factors that make spray exposure a potential concern to some? They are individual and clinical, social or philosophical. Clinical risk can be variable depending on the degree of exacerbation or control at any one time of conditions such as asthma or infantile eczema. Individual clinical risk can also be influenced by past experiences of aggravators, especially for people with atopy. Social factors can relate to family circumstances at the time when dealing with ill health in a family member. Philosophical factors may show themselves through individual choices in how to approach self-management of health experiences and environmental exposures.

Clearly most people with asthma or atopy in the community did not contact the AGM health service. Otherwise the service would have been overwhelmed. Some did and a few of those people had clear-cut individual risk that necessitated avoidance of the spray. Others entered personal precautionary plans for a complex combination of reasons including past health experiences, social and philosophical context.

5.9 VALIDITY OF HEALTH RISK ASSESSMENT

A NZ Health Risk Assessment was conducted prior to the PAM programme in Auckland (October 2001 to May 2004) and this indicated that the intended use of Foray 48B against caterpillars would be generally safe for the public. A few individuals might need to take avoidance precautions and many with asthma and skin conditions were advised to maintain preventive medication as a general measure and update self-management plans with their usual doctors. The ARPHS released a Health Risk Assessment in October 2003 specifically related to the AGM programme.

The findings from the ARPHS HRA analysis of the PAM health service experience support the validity of those recommendations. However the experience has also clearly shown that there are some individuals who can be at risk. It is presumed that most such people were identified through selfreferral to the health service after public communications about food allergy and severe asthma. The health service relied on adverse event reporting through statutory channels to the Medical Officers of Health and incident reporting to the health service itself to identify instances where preventive action failed. Detailing the few such occurrences is outside the scope of this report because the information can be individually identifiable. But the few instances that arose reinforced the need for processes put in place by the health service in conjunction with public communications by MAF and efforts by the Regional Public Health Service.