Assessment of the potential health impacts of the 'Painted Apple Moth' aerial spraying programme, Auckland

for the New Zealand Ministry of Health

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Executive summary

Background

Since January 2002, the Ministry of Agriculture and Forestry (MAF) has been undertaking aerial applications of Foray 48B in Auckland in an effort to eradicate the Painted Apple Moth. Foray 48B is a commercial insecticide containing Bacillus thuringiensis (*Bt*), a spore-producing bacterium that is toxic to certain insects. The Ministry of Health asked researchers at the Wellington School of Medicine, to

"…receive, collect, and summarize reports from the public, community groups, territorial authorities, Aer Aqua and the Auckland Regional Public Health Service (as well as other stakeholders, community groups, organisations and individuals) on the health concerns, symptoms and effects associated with the Foray 48B aerial spraying programme ... review existing scientific knowledge relevant to these health concerns symptoms and effects, and recommend (but not carry out) scientifically robust methods of further study."

We report the views of those who participated in meetings or responded to our requests for submissions as faithfully as possible. These methods allow us to describe the *range* of reported health effects, symptoms, and concerns in the community. However, using these methods we cannot determine the frequency of reported health effects, symptoms, and concerns in the wider community.

Focus groups

The study included four formal focus groups, as well as additional community data gained from various interactions within community networks around the Waitakere City Council. The data gathered in each forum builds a consistent picture; that the aerial spray programme is reported to have had multiple impacts on the health, well-being and everyday life of many Waitakere City residents. Those with existing conditions, such as asthma and hay fever, often reported that these conditions were aggravated following exposure to spray.

Many expressed concern for the young and elderly. Some expressed uncertainty about health effects in future generations. Other impacts included disruption of day to day life, compounded by lack of certainty about which day the spraying would occur. All participants reported staying indoors and closing windows when the spraying occurred.

There were frustrations over having to wash cars, windows and laundry. In many cases, we were told, the disruptions of everyday life were exacerbated by a lack of timely and meaningful information about what to expect, the spray times, and the spray ingredients. We were told that a lack of information has also resulted in increased uncertainty and concern about the sprays toxicity, and a decreased confidence in government.

All of the focus groups reported concerns over the effectiveness, impartiality and fairness of the MAF health service and some people reported they are reluctant to use the services.

Health concerns reported in submissions

In response to a call for submissions, the most frequently reported symptoms were

- Irritant symptoms: sore throat, headache, blocked nose (25% of all reported symptoms)
- Respiratory symptoms: chest tightness, asthma exacerbation, cough (16%)
- Gastrointestinal symptoms: diarrhoea, vomiting, stomach cramps (14%)
- Flu- like symptoms: fever, malaise, swollen glands (13%)
- Skin rash (9%)

Similar symptoms have been reported in other studies of workers and communities exposed to aerial spraying of products containing *Bt*, both in New Zealand and overseas.

Review of scientific literature

Workers and communities exposed to *Bt* products have reported acute irritant symptoms (such as sore throat, headache, blocked nose). More chronic symptoms, such as exacerbations of asthma, skin rashes or flu-like symptoms have less frequently been reported.

Several studies of communities exposed to aerial spraying of *Bt* products have been carried out in New Zealand, Canada, and North America.

These have not shown any association between exposure and health effects. We do not question the accuracy of these findings, which do provide some reassurance. However, the level of reassurance that can be derived from these results depends upon the quality and size of the studies. All of the epidemiological studies that we have reviewed have limitations, and they have limited ability to detect effects that occur in a small proportion of exposed people.

We recommend that further epidemiological studies are carried out, with sufficient statistical power to provide adequate reassurance to exposed communities in the event that no health effects are found.

Risk assessments

The prediction of the Auckland DHB risk assessment (for MAF, 2002) that: "…some people may complain of minor skin, eye and upper respiratory tract irritation, or aggravation of existing asthma or allergies..." (Kalemba et al. 2002) was accurate.

The Environmental Risk Management Authority (ERMA) assessment of Bactur 48LC appears to have been based, at least in part, on the questionable assumption that short term irritant effects of *Bt* products are only seen in laboratory animals or workers exposed to relatively high doses – and do not occur in communities exposed to aerial spraying of *Bt* products.

We recommend that the safety of biological insecticides be reassessed by ERMA and that Workplace Exposure Standards for bioaerosols be developed in New Zealand.

Exposure assessments

The pattern of reported acute and chronic symptoms in workers and communities exposed to Foray 48B is consistent with the known effects of bioaerosol exposure. This has not previously been noted and bioaerosol effects have not been specifically addressed by previous studies. When sprayed from aircraft, *Bt* products are detectable in indoor and outdoor air as very fine acidic "bioaerosol" particles that may be inhaled deep into the lungs. This raises the theoretical potential for *Bt* products to cause a range of chronic respiratory diseases that have been documented in people exposed to bioaerosols in the workplace.

The level of exposure causing occupational diseases is probably substantially higher than that typically experienced by New Zealand communities exposed to *Bt* aerial spraying programmes. On the other hand, the most sensitive individuals tend to avoid occupations that lead to bioaerosol exposure, so that studies of workers may not give a true picture of the likely effect in communities. As far as we are aware, there are no studies of the potential long term effects of exposure to *Bt* products from aerial spraying operations on either communities or workers.

Provided that communities are supportive of the proposal, we recommend that such studies are carried out in New Zealand.

In a study of bioaerosol effects in the community, total bacteria were measured at concentrations of 5,000 to 10,000 cfu/m^3. This level was sufficient to cause detectable health effects in that population. Only two published studies have assessed exposure levels during spraying of *Bt.* The first of these reported levels of up to 4000 cfu/m^3 in the "general spray area" while the second reported levels of up to 1600 cfu/m^3 (which was the upper limit of detection in that study).

We recommend further study of exposure to *Bt* under New Zealand conditions, including detailed computer modelling of previous exposures.

The literature indicates that *Bt* products have the potential to cause health impacts in sensitive individuals. Among other mechanisms, bacterial toxins can cause health effects by stimulating innate immune responses. Effects on health via this mechanism are not specific to a particular species of bacteria. Recent results suggest that this mechanism can be triggered by Gram positive bacteria and their spores, which contain a class of chemical called peptidoglycans. *Bt* products may cause allergy to chemical or biological components of the spray. This is likely to affect a small proportion of exposed people, but clinical testing of a representative sample of people could quantify this.

We recommend immunological testing of a representative sample of people from the community.

Background

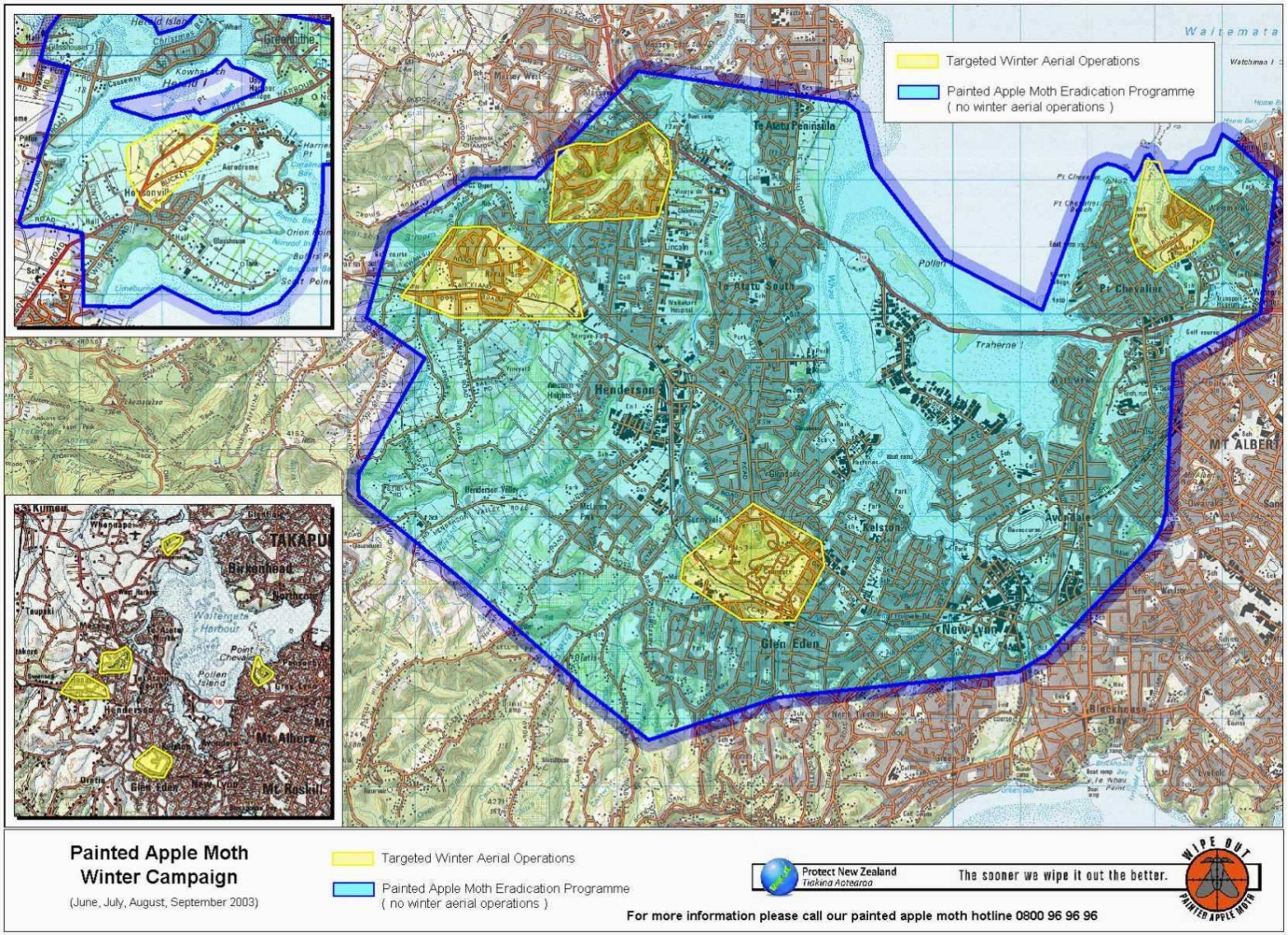
Since January 2002, the Ministry of Agriculture and Forestry (MAF) has been undertaking aerial applications of Foray 48B over western Auckland in an effort to eradicate the Painted Apple Moth (PAM). The target area for the spraying programme (population about 160,000) is shown below (see map). MAF has funded a health monitoring and treatment service but there are anecdotal and published reports of health concerns, which the MAF-funded programme may not collect. The Minister of Health has directed the Ministry to "contract a university to receive written submissions from the public regarding their health concerns related to PAM. The University will analyse these and report their findings to the Director of Public Health." A media statement was released announcing the proposal and has received generally positive support from all political parties, the territorial authorities in west Auckland, and the community.

The Wellington School of Medicine was asked to "…receive, collect, and summarize reports from the public, community groups, territorial authorities, Aer Aqua and the Auckland Regional Public Health Service (as well as other stakeholders, community groups, organisations and individuals) on the health concerns, symptoms and effects associated with the Foray 48B aerial spraying programme ... review existing scientific knowledge relevant to these health concerns symptoms and effects, and recommend (but not carry out) scientifically robust methods of further study."

ESR was subcontracted by the Wellington School of Medicine to conduct the focus group component of this wider inquiry. The data obtained from the focus groups would compliment the call for written submissions on health effects. In total, four focus group interviews were conducted with Maori, Pacific, and migrant groups in the Waitakere area. Data obtained from the focus groups, and from several Waitakere City Council community and governance forum informs this report.

We discussed the project with officials from MAF, Waitakere City Council and the Auckland Regional Public Health Service. Aer Aqua did not respond to our requests for a meeting. We summarize written reports from the public and from community groups.

Literature searches for "Bacillus thuringiensis" and "Foray 48B" were conducted on the internet, including Medline and Web of Science databases. Where possible, original articles were reviewed in full. Where relevant, in cases in which it was not possible to obtain full copies of original articles, citations in authoritative sources have been included. The review was limited to studies of humans or human cells. Animal studies were not considered as we believe that such studies may be misleading when applied to human health issues, and are outside our range of expertise.


Targeted Winter Aerial Operations
Painted Apple Moth Eradication Programme
(no winter aerial operations)
Painted Apple Moth
Winter Campaign
(June, July, August, September 2003)
Targeted Winter Aerial Operations
Painted Apple Moth Eradication Programme
(no winter aerial operations)
Protect New Zealand
Tiakina Aotearoa
The sooner we wipe it out the better.
WIPE OUT
PAINTED APPLE MOTH
For more information please call our painted apple moth hotline 0800 96 96 96

The Methods for Collecting the Data:

In this report, we use three main data sources:

1. **focus groups**
2. **written submissions**
3. **literature searches**

1. The focus group interview is an exploratory tool that yields 'rich' qualitative data (Fern 2001; Grbich 1999; Krueger & Casey 2000; Madriz 2000; Miles & Huberman 1994; Rice & Ezzy 1999) in which key patterns or themes can be detected. An increasingly popular method for health research, the focus group is "a collectivist rather than individual research method that focuses on the multivocality of participants' attitudes, experience, and beliefs" (Madriz, 2000; 836). This method also allows the researcher to observe group dynamics and everyday interactions between the participants, adding to the richness of the data.

2. There were three sources of information from submissions:

> (a) Advertisements requesting written submissions were placed in local newspapers.
> (b) Photocopies of 311 submissions to CC-PAM were made available to us after names and other personally identifying details had been removed.
> (c) The Auckland Regional Public Health Service provided their summary of letters on health related concerns to Waitakere City Council.

3. The literature review begins with the epidemiological data and ends with laboratory studies.

The structure of the report and the order in which we document these data sources reflects our emphasis on first describing the experience of communities and individuals and secondly trying to understand the reported experience in terms of scientific knowledge.

The Focus Group technique
In context of the wider Wellington School of Medicine study, the focus group approach allows for a point of triangulation (Rice & Ezzy 1999), namely to test whether the data obtained from these fora gives similar or different results to the written submissions and other components of the wider research. It also provides a means of obtaining information arising out of the interaction of participants; information that might not otherwise be obtained.

Furthermore in this instance, the focus group method enabled something of a dual task; of research (using the focus group to explore and test existing knowledge); and consultation (in providing a forum for dialogue, and satisfying expectations amongst some locals that the voices of their community be heard by government). However, whilst those participating may have felt they were being consulted, in the sense of being listened to, the researchers were careful to point out throughout that they did not represent government, nor did they carry a mandate to convey a government response.

Essentially the focus group method is a group interviewing tool to obtain data. It is not a method for decision making or developing two way dialogue.

Targeting for the Focus Groups

Because there were not resources or a mandate in this project for full public or community consultation, the focus groups were selected carefully. There were resources available for four to five focus groups to be conducted. The following criteria helped guide the selection:

- People living in the Waitakere area within the aerial spray zone
- Voices not already heard in the process, (groups who might not voice their concerns in writing, and those whose concerns may not already be articulated by the interest groups opposing the spray)

On this basis, it was decided to target the following groups within the Waitakere community:

- Mana whenua, tangata whenua, taurahere - pan-tribal (urban Maori)
- Pacific peoples
- Migrant groups

Arguably, some Pakeha and others living in the Waitakere area also may not be well represented in the written submission process. The limited resources for this project resulted in the decision to target viewpoints from the groups above.

A decision was also made not to include existing interest groups around the issue, on the basis that their view points were documented in governance processes to date. However, Ranui Action Project (RAP), a group with some involvement in forum opposing the spray campaign were invited to be part of the focus group research. This was on the basis that RAP are based within the spray zone and provide health and community services to Maori, Pacific, and others in their area. Thus, they were felt to have good local knowledge and networks, and be able to comment on health concerns, symptoms and effects in their community. RAP unfortunately did not respond in time to be included in the research.

Process for Setting Up the Focus Groups

Given that people from specific groups were sought as participants, a purposive sampling approach was adopted (Rice & Ezzy; 1999). Because of the limited resources for the project, the researcher relied heavily on local knowledge for advice on which groups ought to be approached to participate in the research.

Firstly the researcher contacted local authorities, especially Waitakere City Council, and health providers such as A+ Health, and the Waitemata District Health Board to explain the project and focus group targets. Key people within these organisations advised on who they felt needed to be included in the research.

With guidance, the researcher began by contacting mana whenua for the Waitakere area, Ngati Whatua and Te Kawerau a Maki.

People within the Ngati Whatua Corporate were interested in receiving a copy of the final report but deferred involvement to Ngati Whautua o Orakei Maori Trust Board. In turn Ngati Whautua o Orakei Maori Trust Board deferred to Te Whanau o Waipareira and Hoani Waititi Marae, as those best representing Maori living in the West Auckland area .

Te Kawerau a Maki Trust represent the ancestral claims to the area of Te Kawerau a Maki. Ngati Whatua also claims mana whenua to this city. Both mana whenua have claims being heard before the Waitangi Tribunal. Te Kawerau a Maki Trust and Ngati Whatua were closely involved in the consultation with MAF, and are currently negotiating a Memorandum of Understanding for local Maori with MAF. In talking with local Maori about the area, it was ascertained that Te Kawerau did not have a marae inside the spray area. Based on the early conversations about the focus of this research, local capacity and timing, a decision was made not to conduct a formal focus group with Te Kawerau a Maki. Some data was instead collected from informal interviews with key people from Te Kawerau a Maki Trust.

For West Auckland, Ngati Whatua and Te Kawerau a Maki are tangata whenua with mana whenua, the responsibility for protocol for the area. Waitakere is unique in that alongside Te Kawerau o Maki and Ngati Whatua, Te Whanau o Waipareira are also recognised as tangata whenua and have an important presence in the area. Aspects of this relationship are detailed in the Te Whanau o Waipareira Report (Waitangi Tribunal Report 1998). Te Whanau o Waipareira Trust act for the health and wellbeing of urban or pan-tribal Maori in the West Auckland area and are the key provider of a range of health and other services for Maori, and the wider Waitakere community. There is an intimate connection between Te Whanau Waipareira and Hoani Waititi marae, with this being an important physical space for pan-tribal Maori living in Waitakere.

A colleague used a similar process of local networking and referral to bring together a group of Pacific health providers in the Waitakere area.

For the migrant focus group, the researcher firstly contacted the Auckland Refugee and Migrant Services and was referred to coordinators within the Waitemata District Health Board who organised the group. The group who attended were not appointed spokespeople from different refugee and migrant communities as expected, but a group of Chinese and Korean hospital volunteers. Whilst sometimes these arrangements were not exactly what the researcher had in mind, the data gained from this focus group nonetheless gave valuable insights.

Local knowledge and networks were key to the utility of the focus group approach for this research. Given that the lead research organisations were Wellington based, the local knowledge and advice was especially necessary, and a huge strength. In response to local advice, the research mandate began to broaden slightly into consultation. Mainly this was about keeping those representing Maori and Pacific interests in key governance forum informed of the research. Thus, as well as the four

focus groups, the report looks also at the data obtained from various governance forum associated with the Waitakere City Council.

After negotiating access to each organisation, a time and date was arranged for people to attend a group interview. An information sheet was emailed to a contact person within each of the organisations approached (see Appendix 1). These people were asked if they could invite others they thought might be interested from their organisation. Refreshments were provided for those attending. Limits were made by the researchers on the number of people attending, with 6-10 being the optimum number for each group. This was so that the group dynamics and data could be managed effectively.

Data Collection

At the meeting, each person attending was given an information sheet outlining the purpose of the research and what would be done with the data (see Appendix 2). The researcher talked through these agreements with the group. There was opportunity for the group to ask questions before giving verbal consent for the interview to be recorded electronically. Where possible this data was later transcribed.

The focus groups were mostly facilitated by the author, with the questions on the information sheets used to guide the conversation. For the Wai Health interview two researchers were available to facilitate. The Pacific focus group was arranged and facilitated by a Pacific researcher from the Wellington School of Medicine. Notes were taken at this group, with a summary provided for this analysis.

In the focus groups and other forum the researchers were identified as the 'painted apple moth ladies" or the "people from MAF". Many of the people we met were upset with the government and wanted answers to their questions; "when it is going to end ?" being most commonly asked. A distancing from MAF and government was helpful in introducing the research and setting up the focus group as a comfortable talking space.

Data Analysis

Using the transcripts, a general inductive approach was used where each transcript was read individually with key patterns and themes coded by the researcher. Field notes and observations from each of the focus groups and from interactions in other governance forum also inform the analysis.

Patterns in the data between the different groups were similarly coded to inform the summary and recommendations. Rather than dissect the data from each of the group into different analytic themes for discussion, a decision was made to present the data from each group as a cohesive story or statement, with a descriptive commentary from the researcher. This technique was used to preserve the authenticity and integrity (including depth, intensity and linked concepts) of the ideas explored within each group, and to privilege the each group's collective voice, rather than the researchers interpretation. Where a transcript was obtained, an opportunity was given for a representative from each group to comment on their transcript and a draft analysis of the data for their group. This helped ensure validity or authenticity of the data (Miles & Huberman 1994). To further ensure the integrity of the local data and accuracy of

interpretation (Yanow 2003), drafts of the focus group report were reviewed by key advisors from the Waitakere City Council.

Limits of the Focus Group Method

For this project, perhaps the key limitation is the ability to determine the extent (frequency or intensity) to which the issues discussed in the focus groups are experienced across the wider community. The focus group is a qualitative, not a quantitative method of inquiry. As such, it is not an appropriate method for obtaining statistical data (Rice & Ezzy 1999; Krueger & Casey 2000), or for making quasi-statistical extrapolations. For instance, whilst respiratory and sinus problems were commonly raised in each of the groups, the focus group data can not be used to measure how prevalent these conditions are within the wider community, or the extent to which the people in the focus group represent the concerns of the wider community. Knowledge of distribution in health or value patterns across the spray area population would have been best attained using a survey method.

The focus group is also not an appropriate research tool to ensure demographic representation for ethnicity, age, gender, socio-economic status or other characteristics. Whilst for some research, different types of representation can be structured, the scope of this project meant that any attempt to do this would have been tokenistic. While certain demographic characteristics, such as ethnicity, were sought, it would be impossible to structure attendance at the focus group to ensure fair representation of a myriad of diverse 'positions' and individual viewpoints within the different ethnic communities. Thus, this method does not guarantee reliable representation within a given community a) in the range of concerns expressed and whether the members that attend on the day represent and articulate the viewpoints of those in their wider community; or b) in how well the people at the table represent gender, age, ethnic or socio-economic distributions across their professional group or the wider community.

As in any research, the subjectivity or standpoint of the researcher can limit the effectiveness of the methods in exploring or surfacing issues (Miles & Huberman 1994; Rice & Ezzy 1999, 37). Likewise, the researchers standpoint can skew or bias the interpretation and presentation of the results. A rigorous process for peer review can help minimise this effect. Another source of potential bias is that the people most likely to attend a focus group may be those motivated by a strong interest in the topic (Krueger & Casey 2000, 80).

Constraints in time and budget were other significant limitations for the effectiveness of this component of the research as a tool to access the voices of the Waitakere community and explore health and other impacts of the PAM aerial spray programme.

In order to get the best view possible of health concerns across a community, and thus address some of these limitations, a decision was made to use the Pacific and one of the Maori focus groups to target people working within key health provider organisations. It was felt that health professionals working within these organisations would be well placed to comment on health concerns and other effects that they saw across their client population.

The Data from the Focus Groups

This section presents the data obtained from each of the focus groups. Background information on composition, and, where appropriate, the role each group plays in the Waitakere community is firstly given, with the researcher's presentation and commentary on the data following.

Hoani Waititi Marae

Background

Hoani Waititi marae is located in Glen Eden, Waitakere City. According to locals, this area is heavily sprayed. Hoani Waititi is the place of grounding and expression for the pan-tribal kaupapa for Maori living in the Waitakere area. Established in the early 1960's and named after John Waititi, a prominient Maori Educationalist , Hoani Waititi is seen as an integral part of evolution of Te Whanau o Waipareira, and in its establishment became a place for Maori coming to live in the Waitakere area "to learn from", "belong to and identify with". This was a place to ensure that Maori culture and traditions could continue in a city environment (Waitangi Tribunal Report 1998; 38). The Hoani Waititi community and infrastructure continues to grow, and includes kura and recreational facilities.

Composition

Six kuia and kaumatua in the middle-aged to older age group attended the meeting. Gender was evenly balanced. All were very warm and welcoming of the researcher and were grateful to have their concerns heard. All were angry about the impacts of the spray programme on their health and community. Unfortunately the data was not recorded electronically and is based on the interviewers notes. The notes were returned to Hoani Waititi for amendment.

Data

The dominant theme from the interview data is that spray has impacted negatively on the health and wellbeing of the community. The negative impacts on health have been intensified by lack of information.

A key finding is that the information distributed by MAF about the PAM aerial spray campaign did not reach those living at Hoani Waititi marae. For kaumatua and others staying on the marae grounds, there is no mailbox on the street.

"We have a post office box yes, .. we don't have a mailbox on the main road, the postie doesn't come down to our houses, so we don't get any information that way"

For those attending the focus group, this meant that the first knowledge they had of the spray campaign starting, was when the plane flew overhead.

"when the plane sprayed on top of me that's when I first knew … now I know when I hear it, I run inside"

Others had seen news items on the television, but remember it becoming a news item only after the public complained.

"there was some stuff on TV at the start, but this was only after the spraying started and the community reacted", .. "and the health effects were never mentioned"

At this point the researcher asked to what extent Hoani Waititi or the Waitakere City Council's Te Taumata Runanga group were included in decision making. The views from the group were as follows;

"MAF made this decision, the council was anti this. This was a decision from the government in Wellington, it was not a local decision"

"it was very top down"

"the community was not consulted, and ways of approaching this, other than the aerial spraying, were not considered"

The fact that those attending the group did not have prior knowledge of the date of the first spray, or what to expect when the spray programme commenced, may account for some of the anger in the group. Also, there was strong feeling that this was not a decision that they had been involved in. Had the decision been made locally, the approach for eradication may have been very different"

"Its costing millions, I get really angry when I think that money could go into paying the community, PD gangs, unemployed or others to do this from the ground"

"yes, why do they have to do it from the planes, it would be better from the ground, the sprayers can get underneath the trees from the ground."

The group question both the efficiency and equity of MAF's chosen approach. The money could be used for more effective eradication programmes and could benefit the community.

As well as anger, a further consequence of the lack of information and lack of ownership or involvement in the decision, is a high degree of uncertainty. Of all the groups, Hoani Waititi expressed the strongest concern about uncertainties and the safety of the spray for future generations. These concerns might also be stronger because of the age of the people attending this focus group, and their status and role as kaitiaki or guardians for their community. Acknowledging this, the frustration at their lack of knowledge seems to underpin the ways that these concerns are articulated;

"This goes further than today. We don't know if it's going to be one of those things like DDT or Agent Orange. There's a lot we don't know here"

"What about our children in 10 or 20 years time?, what about them?"

"Yes I have a lot of questions – we haven't even been told what's in the stuff!"

The conversation moves to what the spray looks and feels like:

"I see that stuff on my car, this sticky yellow gunge and I know its not good for me"

“it tastes bad, a metallic taste” … “my eyes sting”

The group describes impacts on everyday life and disruptions to routine. These include the extra cost and labour involved in washing windows, washing cars, and rewashing all the laundry on the line during the spray:

“I get sick of cleaning the car, its really difficult to get the stuff off, its really sticky, that’s what gets me … “we don’t need this extra work on top of what we already do”

“For me, I don’t like the way it turns the curtains yellow – who’s going to pay for that?”

“we shut the windows but it still gets in, its sits outside for days, we get exposed when we go outside” … “and we bring it inside on our clothes, it gets everywhere”

The last comment reveals how people take precautions, but cannot avoid contact with the spray. The person making these comments is frustrated by the lack of control they have over the exposure.

Noise is also an issue with the low flying application method being invasive and discomforting. One person was talking on the telephone and could not continue the conversation whilst the plane flew overhead:

“The planes fly really low too, I feel I could almost touch them with my hand if I stood on the roof”

“and its not just one spray, each time it’s a spray day, its up and down, up and down, they fly over five or six times” … “and the noise … ”

Most profound for this group are the health concerns:

“the asthma and respiratory problems are the worst, for all of us in this room, our health has gotten worse since the spray programme started”

“I never used a puffer until last year”

“I’ve been in hospital with respiratory problems four times this year – I’ve been really sick, pneumonia, .. we now have a nebuliser at home for me, I never used to need that”.

“it affects my liver, my kidneys, I can feel it”

For this group of elders the effects of the spray in aggravating existing conditions are serious, and for one have resulted in repeated hospitalisation. The researcher asks if they have considered leaving the area on the spray days.

“we go inside and shut the windows, we don’t go out of the area, we don’t get notified when it is happening so we don’t know to make plans to leave the area or anything”

"It's not knowing when the spraying will occur. There has been no information for us".

The people are deeply frustrated by the lack of information. They explain that this makes it difficult for themselves and other families to make decisions to protect their health.

Further questioning revealed that there are numbers of people in the community who are sick but are not seeking medical advice. All the people in the focus group suffered respiratory affects, but most did not go to their doctor and only some went to the pharmacy for medication. No one in the group knew the MAF helpline number, nor did they see any point in going to the MAF doctors who were felt to be a waste of time and there only "to tell you that you were not sick".

There is also worry about the effects of the spray on the young ones, and those who are pregnant. Again precautions are taken:

"we keep them in doors when the spraying happens, but it is still outside the next day, and the next"

"we worry about the ones that are pregnant too, we tell them to stay inside"

Other less immediate impacts on health and nutrition may result from a decline in the consumption of locally grown and home garden produce. Some in the group are reluctant to purchase fruit and vegetables that have been locally grown. Lack of choice is noted:

"even the fruit and veges we buy from the local shops have probably been sprayed so we can't avoid it"

Children are not encouraged to eat fruit or play outdoors after spraying, but the elders can not control this totally. Depending on the frequency of the spray, the decisions for children to play indoors could impact on lifestyle and physical activity patterns, and have health implications.

"we need to tell the young ones to wash the fruit, but they don't always do this, they are used to seeing an apple in the tree and eating it – so that is something we try to change"

"we are concerned about the elders and the mokopuna, some of our children and grandchildren get rashes when the spray happens"

"its in the rivers, the streams and the kids play in that"

"we know of quite a few families who have stopped growing their own vegetables since the spray started"

As well as impinging on mahinga kai, and the rights of the tangata whenua to live off the land, there are detrimental economic impacts from decision not to grow vegetables, and to purchase produce grown away from the area.

Near the end of the interview, the people in the group continue to feel angry.

"we don't know when it is going to end"

"we have had enough and would like to stop" … "yes when's it going to stop?"

"I'll tell you too, this wouldn't happen if we lived in Howick, I think its happening here because we are poor !".

The researcher asks if there are any benefits. The viewpoints are unanimous and forthcoming.

"I haven't seen any benefits"

"there are no benefits whatsoever"

"this is what we hear from our community, there is nothing positive for us here"

"yes, we listen to what our community says, there are no good reports from them"

Wai Health (Te Whanau o Waipareira)

Background
Wai Health is the health provider services for the community of Waitakere. It is a key structure in the umbrella of the Te Whanau o Waipareira Trust.

As discussed earlier, and elaborated in the Te Whanau o Waipareira Report, Te Whanau o Waipareira does not claim to represent tangata whenua, but rather "exercises a mandate in respect of a community of Maori who have come together for the purpose of maintaining cultural integrity in an urban environment". A "pan-tribal" organisation that deals with "cultural, social, educational, and health issues" (Waitangi Tribunal Report 1998; 37), it is also "largest service provider in West Auckland" (Waitangi Tribunal Report 1998; 14). Having momentum long before this, Te Whanau o Waipareira officially came into being in 1981, with a charitable trust structure adopted in 1984. It's growth is described in the Treaty Report as an evolution of the whanau support structures that emerged in response to rapid urbanisation of Maori, and the growth of West Auckland as major settlement (Waitangi Tribunal Report 1998; 34).

Composition
Approximately ten people were at the focus group, with some movement in and out throughout the korero. Those attending were predominantly Maori and predominantly women, with only one man present. All were health providers, promoters or educators working for Wai Health. All were lively and vocal, and felt strongly that the spray programme had impacted negatively on the health of the community. Whilst they were very welcoming of the two researchers, they made it clear they were angry with government. As in other forum, it was emphasised that the

researchers role was to help ensure that the voices of the community were heard by government.

Data
In this group the lack of information was a point of frustration which became a dominant theme.

"Just sprayed. It wasn't until later that people started to be getting crook, or whatever, and then you got the protests happening. Then a bit more information".

"And all right if you're reading Healthy Options or Organic NZ - they had a lot in it right from day one".

"Ha! How many Maori's and PI's read those?
Or how many people understand their language? Yeah, that's right!"

In the absence of information from the government, people begin investigating the issue themselves. The point was made also that this alternative information is not accessible to Pacific or Maori audiences, suggesting that many are particularly reliant on information from government. The group was however concerned at the quality of the government information.

"I think it's just been total propaganda. We've been fed lies – it's all lies, about that it's not going to harm us. It's crap".

"You didn't get a lot of information in terms of what actually was in spray. We still don't really know that!"

"It's interesting, the longer it's gone on, the more advertising of spray dates in our local paper …. So they've put it in our local paper so it's suddenly gone from a really small ad to the whole of the back page. Now to pay for the whole of the back page, even in the local rag, is reasonable money, you know, but it's got bigger. And it's got a map, and colour".

"They send you a magnet, you know, for the fridge? – "Spray the Apple Moth".

"Where did you put that? … In the rubbish!"

Whilst the point is made that the advertising and information has increased as the campaign has continued, the absence of quality information at the start has impacted in deeply ingrained feelings of suspicion, distrust and hostility - the placing of the fridge magnet in the rubbish being symbolic of this. There is recognition in the practical risk communication literature that once established, feelings of distrust are difficult to undo (see Chess & Hance 1989; Jaeger et al 2001; Sandman, 1993).

Issues of fairness and equity also feature from the Wai Health group, with questions about the costs of the advertising, and the unfair distribution of risk that they feel stigmatises poorer communities. Another person suggests alternative ways to spraying which might benefit and involve the community:

"What about Herne Bay and Ponsonby – there's a direct correlation on how the advertising got bigger and more expensive once it went to the rich parts of town".

"We're the pilot, we're the test group. We're the guineapigs. "Let's try it on that low socio-economic, you know, those Westies - those Maoris and Islanders – "

"Why didn't they take everybody out from the West that's actually unemployed and get them to spray on the ground – provide employment for people. Because you see there'd be millions of dollars actually going into this which is just going from one government coffer to the other. But actually we could have employed people in our community and it could have been a community project – given back to the community to actually carry out and take some responsibility for. But no-no-no, this gets driven from Wellington – "let's just spray the whole lot of them". I just think it's outrageous.

The conversation in the group turns to consultation and decision making:

"Well probably just really the whole concept of consultation, not only terms of being Treaty partners, but also as providers of health. You can give us information, you can do that without even consulting. So we can actually understand, so that when people actually come to see us we're able to explain to them what's happening".

"But there's just none of that, been no education programme at all. And I know on one hand it would defeat their purpose of saying there's nothing wrong but even so, you can't just up and spray everybody and then not actually talk about what it is you are attempting to do, or how you are attempting to do that. And we have consultation on every other thing you can name. But something like this – no consultation at all".

"Where's the treaty partnership now? There is none".

"Good point. Just makes a mockery …"

There was also concern that the lack of consultation and meaningful information had impacted on the quality of information that Wai Health providers were able to pass on to their clients, and that this compromised their ability to deliver health advice.

"…a bit more consultation at ground level and not just through their offices and other organisations. As health providers we have to be seen like, more so, preventing health issues and if MAF come more so towards their sort of organisations we'd understand a bit more and so would our clients".

All in the group agreed that minor adverse health effects were being felt widely by people in the community:

"Respiratory – and a lot of the kids find it hard to breathe when that plane's been over, they come up in rashes, headaches, runny noses, sore eyes. Yeah, all that stuff".

There were also reports of more serious effects:

"… Breathing – for babies. And the eczema is really bad, eh … My boy … he gets that around the spraying, look how bad it eats into his skin".

"My partner couldn't go to work the days they were spraying because of the effect it was having. Massive nose bleeds. Like, three a night. And copious amounts of snot, and watery eyes and coughing and respiratory problems to the point where he couldn't even breathe properly".

Many who had existing health or allergy conditions found these were aggravated by exposure to the spray.

"My sister has to hole up in bed for the day because she gets quite bad hay fever and asthma and eczema – and that just irritates it. The eczema starts to swell and she can't breathe. … She gets nauseous, ends up vomiting, that kind of thing, and it goes round in cycles.

"That's what the doctors have said … they wouldn't say it was a direct result of the spray, but what they're actually saying … is that a precondition is exacerbated by the spraying. That's what they're saying. And where you've got someone with asthma or something, it's worse, it gets worse".

Another person tells of her friend, a solo parent whose son is highly allergic to soy, an ingredient in the spray.

"They pay for the room [at a motel] and have given her a phone. They don't pay for gas, food, anything else. …She's had to take him to specialists which she's all had to pay for herself to get confirmation that this is an existing condition that he has. … Her water rates bill was $600 for the last six months because when she comes home she has to spray her whole house!"

'Waitakere is water metered, and for those seriously affected by the spray the clean up costs are significant and are not met by MAF. This burden of cost is felt to be unfair and unjust".

In this forum, the MAF doctors were also poorly perceived:

"They try to fob you off. I had to take my whanau to the MAF doctor that they send you to because I thought why the hell should we have to pay for this. And you go to their doctor, and he was .. um .. trying to put it on other things. Like blame it on past health problems. And say it was not related. And I thought, we are wasting our time here – you're just going to tell us the MAF story – and that's who you work for, that's who's paying you. So forget it, and stick it".

"You tried their helpline too eh – and they were really rude? You know, I mean, "Help"??"

The impacts on lifestyle were also a source of frustration:

"You have to reschedule your whole lifestyle to when they're going to fly around in the planes."

"And don't put your washing out. You can't take your kids out to play… your whole lifestyle. It's sticky, sticky."

"Yeah, even your washing, and your vege gardens. I wonder about the swimming pools, and the kids are getting ready to go swimming at the schools – they're not covered. So all that shit goes in the pools."

"They are saying we're making an effort to do it while the kids are in class but the reality is they do it when they can, when the wind's right."

This last comment reveals how people in the group have the impression that MAF is primarily concerned with measures to eradicate a threat to biosecurity and the environment. Their experience has led to an understanding that the impacts on human health are a secondary priority for MAF.

The smell and feel of the spray also creates strong reactions:

"If you see how it looks on your car – mmm, the residue - yeah, mmmm – I just wonder what it must do! And it smells like somebody's peed all over the place. I was saying to my son in the caravan "You been doing the mimi inside?" - 'cos it stinks. It smells of pee."

"Bloody horrible anyway. It is, it's yukky horrible, sticky, smelly".

"It makes food taste funny. It's like the tastebuds just went totally off and nothing tasted right".

" …you piece it together. From the gunk I see on the cars I wonder what it must be when it lands on the kids when they're playing outside. That gunk on the car is shocking".

What can be drawn from the data is that the embodied experience - the physical feeling of exposure; the smell, touch, sight, taste and hearing - is important. In the 'piecing together', the participant refers to a process of 'sensemaking' (Weick 1995) that occurs in the absence of 'sensemaking support systems' (Weick 1995;179), such as meaningful information, that might guide experience. In this context the adverse physical impressions such as smell and stickiness may be seen as 'cues' (Weick 1995; 49) or 'signals' (Sandman 1995; 25) that, in this instance, create greater anxiety about the toxicity of the substance.

The group also noted the extra labour, costs and inconvenience of redoing laundry, and cleaning cars and windows. There was also mention of the effects on the environment and waterways, although, perhaps reflecting the professions of those at the table, the human health issues were of greater concern.

Pacific island focus group

Background

One of the focus groups carried out in West Auckland was hosted by West Fono. West Auckland Pacific Island Health Fono Inc. is a primary and secondary health care organisation dedicated to improving the health of Pacific communities. Set up in 1989, it became an incorporated society in 1990 with a key objective to provide health care to all Pacific people that is affordable, accessible and culturally appropriate. West Fono also has strong ties with Waipareira Trust.

Composition
The focus group was attended by 13 West Auckland Pacific health workers, the majority of whom work at West Fono. Gender was evenly divided. This focus group was organised and facilitated by a Pacific researcher from the Wellington Medical School. The meeting lasted for approx one hour. Notes taken by a staff member from West Fono, and a summary of these notes was forwarded to the ESR researcher.

Data
Health effects reported by the health workers in their family and client population included rashes, itchiness, head aches, and tiredness. These were mostly noted in children and some adults. The rashes and itchiness seemed to follow the spraying time. Some people reported being emotional and moody during spraying time.

The impacts on community and day to day life included mothers being more concerned about their kids during spraying time, especially when the children are at school or travelling to and from school. Others reported that cars and clothes got dirty during the spraying, creating more work cleaning.

The cost of having to relocate to another place and seeing doctors was mentioned. One person in the focus group had been to see one of the free doctors, and felt that the doctor was trying to say there is nothing wrong with the spraying.
The health workers felt that people would talk about the spray amongst themselves, but would not tell their doctor or nurse. A receptionist noted that patients would talk to them about the effect of spraying, but then don't report it to their doctor.

Generally it was felt that there was not enough consultation with the Pacific community. Lack of information was also an issue with some in the group wanting to know more about the program and also wanting information about the purpose of the spray programme. The members of the Pacific focus group felt it would be good to have the information from MAF available in different languages to inform people.

Migrant Group

Background
It was hoped that the migrant focus group could comprise of spokespeople from different refugee or recent immigrant communities. The focus group was, however, attended by a group of Asian women who gave a valuable insight into the attitudes and experiences from their community.

Composition
This focus group was held at an interview room in Waitakere hospital. Six women attended, 5 Chinese, one Korean. Two women seemed younger in age whilst others were middle aged. The women in the group were from a pool of volunteers providing

translator and support services to the Waitakere Hospital. Whilst the group perhaps did not provide the diversity expected, the data obtained gives valuable insight into the experiences of a group of women who do not have active interests or involvement in the PAM decision making process.

Data

Only one person in the group had experienced health problems following exposure to the spray. They had strong concerns about the spray programme. The others in the group seemed resigned to the spray programme going ahead, but did note that they could have been given more information about possible side effects. It was noted by all the group members that Chinese tend not to complain about what the government does, and that this is a cultural thing. The researcher also noticed in the discussion that the older women were more outspoken, and the younger women in the group tended to defer to the older women. The younger ones in the group were very quiet, but did get more vocal near the end of the interview.

The narrative from the one person who had experienced ill health following exposure is interesting;

"I was in the car arriving at the hospital. The plane was flying quite low and then I looked "Oh, they're spraying!" and I thought I'd better stay in the car until after it's gone. . So after it's gone -- hospital from the carpark to the hospital - it came back I was actually caught under those thing, on my way back finish my walk from the car. The spray was horrible".

"I was very sick for four days. I can't talk, I was just coughing and coughing. My husband kept saying, "Go and see the doctor". I'm not going to see the doctor – you have to pay forty dollars so the doctor can say take a couple of panadol – that's what the GP say. So I didn't go, so in the end I just got something from the chemist, can't remember what. I was coughing for two weeks".

"The person was unexpectedly caught under the spray and had a strong adverse reaction. The reluctance to go to the doctor points to patterns of self management and underreporting that perhaps follows on from the groups observation that Chinese people tend not to complain.

In this persons account a theme becomes apparent of disjuncture between an individual physical or grounded experience, and the 'removed' statements from government about what to expect. Equally significant is the way that this disjuncture gives rise to uncertainty, and then to doubt and distrust in government.

"…they say it is water-based but how come its staying on my windscreen like glue. I don't understand that – the Ministry not telling the truth - I think they are lying - a lot".

The effects on day to day life are apparent for others in the group.

"Normally if I know they are going to spray, I make sure all my windows are closed. My house has a lot of glass around, so it was pretty hot in the summer when they're spraying. Unbearable, if you are in the house".

"It's very hard cleaning."

"One morning about five o'clock I heard they were flying over probably -- that was obviously in my area, so "Oh! they're spraying today". So I thought, "Oh, I better not put my washing out." But sometimes I put my washing out the night before – and so I have to wash it again".

It was noted that the optimum times for spraying coincide with the best weather for getting laundry dry.

"I get agitated. I think "I can't do this – I can't do that". So frustrating. "Oh, it's my day off, I could do this, I could do that". So restricted me from doing a lot of things".

"Yes, some people are scared. I am scared, the first time. They very low, and they big noise."

As well as staying inside, members of the group take other precautions. In this instance the exercising of consumer choice may have adverse effects on the local growers economy.

"I used to, but not any more now, get my vegetable from those market places. I don't know whether they are exposed to spray or not, so I stopped buying them".

Whilst only one person in the group experienced an adverse reaction to the spray and only two people in the group knew immediate family members or neighbours who had health concerns, they had heard of some people getting sick:

I" think that if people normally do not enjoy good health, probably it affects them more than the ordinary healthy person".

Whilst stating that the spray programme was positive for New Zealand's environment and economy, later in the interview all felt that the government should have given more information about possible health effects. Most in the group did ,however, feel that they were well informed about the purpose of the spraying, and had gained information from the radio, the newspaper or from leaflets in their mailbox.

"Now even though they are in the paper, they announce it, they send a letter saying they are spraying on a certain day, but usually – most of the time the day they are supposed to spray it's raining so they cancel that and do it on some other day so we don't know".

There was some concern that the information about the spray times was not often accurate, making planning difficult.

One of the younger women in the group questioned the effectiveness of the programme and whether other options might not work just as well:

"I wonder what is best way to kill the apple moths - because it affects people's health. Is there another way to reduce the side effects? Doesn't say anything about the other way. Just to keep spraying."

"Does this programme really work, works well? How many times in one year do they spray?"

"Yes .. even if it takes a longer time. First the Government should consider about people's health"

In closing and asking for further comments, the woman most affected by the spray alluded to a bad experience with the MAF hotline:

"Oh yes, that's one thing: we have a number that we can ring up. It's very hard to get through. Once I ring up, I ring up the minute I heard the plane "Are you spraying?" - " Yes" - and they hang up straight away! Didn't give me a chance to say anything!"

Others agreed that this was unsatisfactory:

"Yes! What's the point of ringing up? Hard to get through, and you get through and that happens!"

Whilst most felt that they had been informed of the spray programme with leaflets in the mail box, they also pointed to a lack of information about the possible effects on health. Most in the group did not report significant adverse health effects, but did question the management of the program in terms of effectiveness and responsiveness to human health concerns.

Other Data

In the process of setting up and conducting the focus groups, other data was also obtained. This is not included in the focus group discussion as the focus group method was not applied. The insights from these other forum do help build a picture of health concerns and other effects in Waitakere and thus are incorporated to the analysis.

Waitakere City Council

Approached early on to help guide the researchers to the right people to talk with for the focus groups, the Waitakere City Council played an important role in 'opening doors'. This included an opportunity to briefly announce the focus group research, make connections and receive feedback from different advisory forum, namely Te Taumata Runanga, Te Kawerau a Maki Trust, and the Pacific Island Advisory Board. A focus group for staff and elected councillors was organised at the last minute in response to a challenge earlier in the week from the Mayor, Honourable Bob Harvey and a councillor when introducing the research to Te Taumatua Runanga forum.

Te Taumata Runanga

Background

Te Taumata Runanga was jointly established by the Maori community and Waitakere City Council in 1991, and became a standing committee of Council in 1993. It is a forum for regular communication to ensure Maori are given a voice and input into policy development and decision making within Waitakere City Council. There were twelve original member organisations, including Waitakere City Council. There are now ten; Te Kawerau a Maki, Te Runanga o Ngati Whatua, Te Ropu Wahine Maori Toko I Te Ora, Te Whanau o Waipareira Trust, Te Ropu Kaumatua o Waipareira, Hoani Waititi Marae, Te Piringatahi o Te Maungarongo Marae, Kakariki Marae, Te Roopu Puawai o Waitakere, and Te Atatu. At present there are ten standing members on Te Taumata Runanga.

Findings

It was observed that those in Te Taumata Runanga seemed to be well informed and have a good knowledge of the purpose of the spray programme. Several questioned "when is it going to end ?", but generally the members of the group did not react strongly to the announcement that research into potential health effects was being undertaken.

Some members expressed concern about the impacts of the spray on the health of the young and elderly. In some side conversations others expressed annoyance at the extra work of cleaning cars and windows.

Using the networks from Te Taumata Runanga, there were opportunities to talk with some people working in the Maori consultation forum for the PAM spray programme. The consultation forum with MAF had been developed as an initiative from the Maori community, and had close links including representation from some members of Te Taumata Runanga.

Later that week, the researcher conducted a short interview with a Te Kawerau a Maki Trust member involved in MAF's consultation with iwi. This person seemed satisfied and had experienced this as 'very good'. They did say they were aware that some people in Waitakere wanted more information, particularly on exactly what ingredients were in the spray. They also mentioned that suggestions to MAF, such as having a Maori doctor, have not been followed. Whilst the consultation was generally felt to be good, they described the spray as 'not the best thing to have', and reported some respiratory effects, namely tightness of breath. "The consultation with Maori is good, but breathing it in is a different story."

A community meeting had also provided an opportunity to ask several kaumatua associated with Te Taumata Runanga forum informal questions about whether they felt any impacts from the spray programme. Commenting on the MAF consultation, one observed, "the process was there, MAF kept Maori informed, but then did not like to listen to concerns or modify the actions".

On health effects, this person described how he had walked outside in the spray once and got a rash on his neck. His doctor was unable to help treat the rash because they

could not get information from MAF about the spray ingredients. Because he did not know what was in the spray, this person felt uncomfortable eating and growing vegetables in their garden, "gardening is expensive if you can't eat the food".

Similar to the data shared by Maori and others in the focus groups, this points to a cycle where the lack of information from the government has created uncertainty and distrust. The uncertainties impact on the lifestyle decisions that people make, which in turn have detrimental economic and health effects. The kaumatua also had concerns for the health effects on children, the mess and extra work in cleaning cars and windows, and the danger of low flying planes in urban areas.

Te Taumata Runanga raised other opportunities. The Mayor of Waitakere had attended the Te Taumata Runanga forum to present on a separate issue. In the discussion following the PAM research presentation, he issued a challenge that the researchers also might consider incorporating the views of the councillors. "I am more worried on this than any other issue. There is a lot of stress on elected people from this issue. We are worried about the unknown, long term health effects". The Mayor elaborated that were adverse effects from the spray to be proven in future, it would weigh heavily on his conscience, "I would feel so guilty".

Another councillor elaborated on the burden of responsibility, describing how the elected officials bore the brunt of local reaction to what was essentially a central government decision. "The stress on us as decision makers is ongoing. For example, my carpet layer got really angry about the spray and was asking me, 'what are you guys doing to us?' "

Pacific Island Advisory Board

The Pacific Island Advisory Board has similar standing and role in relation to the Waitakere City Council, but with representation and accountability being to the Pacific, rather than Maori community. The researchers introduced the project to PIAB so they would know what was happening, and have an opportunity to comment and ask questions. The members of this group seemed agitated with, "when is it going to stop ?", being the first question asked in this forum. Another member said, "there is still a deep resentment by everyone that we're being sprayed by a chemical that we don't know the formulation for". One in the group mentioned "concern in the community that some children are getting sick", with another stating that "there is no actual evidence that the concerns relate to the spray, people are putting two and two together". Another person questioned, "if someone from the community says they do have problems about their health, what are you going to do to address this?". There seemed a lot of confusion within the group about who to contact with health concerns, and the group felt this was an issue for the wider Pacific community. "Not a lot of the people here have been using the free health services, they might not be aware of the services". The researchers had to work hard in this forum to demark themselves from MAF.

Elected councillors and officials

Responding to the Mayor of Waitakere's challenge at Te Taumata Runanga earlier in the week, a focus group was set up at the council offices for interested councillors and staff to attend. The meeting was scheduled Friday midday with a free lunch offered to those attending. No one came to this. Lack of interest may have been a factor. Other likely reasons included the late notice given for the meeting, in that an announcement was circulated to elected council members and staff by email the day before. This followed approval from the council executive. Furthermore, few staff seemed to be around on Friday, and a fire drill had occurred earlier that morning, perhaps impacting on work priorities for the day. In the absence of formal focus group data, the comments of the Mayor and councillor in the Te Taumata Runanga provides the viewpoints of some of the elected members.

In the course of the research, council staff also shared their views in casual conversation on the impacts of the spray programme for the council. Whilst these were not the driving focus of the research and were not explored deeply, some interesting data was nonetheless obtained.

Some felt the spray programme had impacted "dramatically". They thought that 'the city's leadership may have been caught off guard with the issue', and were now 'having to shoulder local community discontent and anger'. They cited frustration at 'not being fully informed by the key ministries about what the real issues and consequences were, and are … '. Also, it was felt that the staff at Waitakere City Council responsible for implementing key elements of the central government strategy were "stretched", and lacked a complete picture of what was going on. This staff member also questioned potential "long-term spray effects … on human beings" as well as "the environment, eco-systems and the like".

Another staff member stated personal concerns. Experiencing persistent chest problems and coughing since the spray programme began, they noted trade-offs with positive effects for their garden, but negative effects on their health. "It seems good for my orchids, but not so good for my health"

Many of the staff spoken to at the council linked coughing and respiratory complaints with the spray days.

Written submissions

Background

There were three sources of submissions:

(a) Advertisements requesting written submissions were placed in local newspapers. There were 93 responses.

(b) Photocopies of 311 submissions to CC-PAM were made available to us after names and other personally identifying details had been removed. These submissions had been received too late to be included in an interim summary (Blackmore, 2003).

(c) Summary of Letters on Health Related Concerns to Waitakere City Council, 2003

The main symptoms reported are summarised in Table 1. The most commonly reported symptoms from each source are: sore eyes, sore throat, headache, blocked nose, cough, asthma, diarrhoea, vomiting, stomach cramps, fever, malaise, swollen glands, skin rash. Following other researchers, we have grouped the major symptoms into categories including irritant, respiratory, gastrointestinal and skin.

Each respondent was assigned to a single category. The purpose of this analysis is to describe the range of symptoms reported, and to give an approximate indication of their relative frequency among respondents. These results **cannot** be extrapolated to the whole community, since individuals with symptoms are more likely to respond.

	(a) WSM		(b) CC-PAM		(c) WCC	
Symptoms reported	N	%	N	%	N	%
Irritant: sore eyes, sore throat, headache, blocked nose	23	25%	80	26%	114	49%
Respiratory: cough, asthma	15	16%	52	17%	62	26%
Gastrointestinal: diarrhoea, vomiting, stomach cramps	13	14%	40	13%	10	4%
Flulike illness: fever, malaise, swollen glands	12	13%	35	11%	-	
Skin rash	8	9%	32	10%	23	10%
No health problems mentioned	5	5%	20	6%	-	
Bleeding nose, ulcer on nose/eye or mouth	5	5%	18	6%	-	
Chronic fatigue syndrome	5	5%	11	4%	4	2%
Psychological	2	2%	10	3%	-	
Arthritis	1	1%	4	1%	-	
Other	4	4%	9	3%	22	9%
Total	93		311		235	

The similarity between responses from WSM and CC-PAM sources is striking, though the responses are not independent. Some people are likely to have sent the same (or similar) submission to two or more groups. Some biases may also have been introduced in the interpretation of responses.

Selected excerpts from submissions requested by Wellington School of Medicine are given below. These are intended to illustrate a range of severity but do not represent the full range of symptoms reported to us.

> "Horrible headache from the spray, despite keeping inside with windows closed."
>
> "…the smell of the spray permeated the building. By the end of the day I had a headache and a sore throat."
>
> "Every time they spray (even though we aren't in the spray zone) I get a headache and sore eyes. I can't even open my eyes because they're so sore. (There are hot spots on both sides of our house)"
>
> "The symptoms of the malady are likened to the flu, triggered by a virulently itchy and profusely runny nose causing lengthy and embarrassing bouts of sneezing, the eyes itch and are very watery becoming sore as do the whole of the nasal passages. The attacks can last several hours from start to finish."
>
> "I am concerned about the effects of the painted apple moth spray on my self and my family and your recent advertising has prompted me to contact you. At the commencement of the spray campaign all members of my family suddenly had severe sore throats and raw nasal linings which took quite some time to heal."
>
> "On 3 occasions in the past year I have contracted severe influenza like symptoms 2 to 3 days after the aerial drop. I have not had flu at any other time during this period."
>
> "When they first started spraying I came down with what I thought was a chronic chest infection. I didn't think it was the spray because I was outside the spray zone. However, the chest infection started when the spraying did and stopped about 3-4 days after the spraying stopped. I eventually went to my doctor and he says I'm highly allergic to the spray."
>
> "Red bloodshot stingy eyes, nose bleeds, uncontrolled asthma, wheezy, nausea, fatigue, sinus infections, rashes, worsening allergic reactions to things tolerated before. The whole family is affected to varying degrees … we are all asthmatics and have pre-existing allergies, however [becoming] harder and harder to control."

Literature review

We review community health concerns reported in overseas and New Zealand studies of populations living in areas where spraying programmes have occurred, and summarize relevant New Zealand risk assessments. Next, we consider what is known about the exposures resulting from spraying programmes. Finally, we assess the potential for Bt to cause disease in humans, including assessment of the health effects of bioaerosols and data from laboratory studies.

Community health concerns

Overseas studies

The relevant overseas literature includes reports of health surveillance programmes following aerial spraying in Canada, (Noble et al. 1992; Bender and Peck 1996; Anon 1999; Anon 2001a) and North America (Anon 1993; Anon 2001b).

Noble et al. (1992) examined health records in a community following spraying of *Bt*. No illness or infections were attributed to *Bt* following review of 3500 hospital admissions, 1140 general practice records and 400 *Bt*-positive bacterial cultures from 10 hospitals. *Bt* was isolated from several body sites, including blood, body fluids, eyes, nose and tissue samples. The authors concluded that these were due to contamination. However, it was reported that spray workers

> "frequently developed symptoms of headache, nose, throat and eye irritation, dry skin and chapped lips" (Noble et al. 1992)

A telephone hotline received over 20,000 calls. Of these, about a thousand were "health related" and of these,

> "… 247 calls represented complaints from individuals who reported being in the spray zone or exposed to the spray, and who attribute their symptoms to that exposure." (Noble et al. 1992)

The reported symptoms were classified as "seasonal allergy symptoms" (19%); "flu-like symptoms" (17%); "respiratory" (17%); "nose/throat" (10%); "skin" (8%); "gastrointestinal" (7%); "other" (7%); "headache" (6%); 'eyes" (2%).

Two studies of communities exposed during *Bt* spraying in Canada in 1992 and again in 1994 contain reports of "allergic rhinitis symptoms, exacerbations of asthma, and skin reactions" (Anon 1993; Bender and Peck 1996), cited in (Bernstein et al. 1999).

During aerial spraying for Gypsy moth in Seattle, the following symptoms were reported by 59 persons in 50 households out of an estimated residential population of 6,600 (Anon 2001b):

- "Upper respiratory and nasal symptoms: nasal congestion, sore or scratchy throat, productive and/or persistent cough, watery eyes, headache.

- Irritant symptoms: burning or itchy eyes, burning in throat, nasal irritation, dry cough, itchy skin, or headache.
- Airways involvement: trouble breathing, chest tightness, or asthma reaction.
- Flu- like or viral symptoms diarrhoea, nausea, vomiting, fever, body aches, headache, or dizziness.
- Skin rash"

The authors commented that:

> "A number of the reports received [by the Department of Health] appeared to be temporally linked to the spraying. These included a skin rash that appeared within four hours of direct exposure to spray droplets and cases of adult asthma that worsened after each application. A number of persons who reported irritant effects such as burning eyes and nose noted that their symptoms followed each application. There appears to be a gap between what people living in sprayed communities report and what epidemiological tools have been able to detect. Data collected with a passive surveillance system will not be able to further resolve this apparent inconsistency." (Anon 2001b)

The largest and most detailed study to date was conducted during aerial spraying for control of Gypsy moth in Vancouver Island, 1999 (affected population, 80,000). This study consisted of the following components:

> "1. Asthmatic Children's Survey
> The survey studied the health of children with asthma, both inside and outside the spray areas, for any health changes that could be attributed to the spray.
>
> 2. General Population Survey
> This telephone survey documented the health of a group of adults inside and outside the spray area both before and after the spray.
>
> 3. Laboratory Surveillance
> Laboratory analysis was used to find people whose lab specimen was identified as containing *Bt*, to determine the specific type of *Bt* bacteria found in the specimens, and to compare it to the specific type of *Bt* used in Foray 48B. The role of the identified bacteria, if any, in human disease was also assessed.
>
> 4. Exposure Assessment Measurements
> Air samples were collected in order to determine the air concentrations of *Bt* within the spray area, both inside and outside homes, as well as over time.
>
> 5. Doctors' Office Visits
> This information were collected and will be studied for any possible links to the spray program. [In the event, it proved impossible to analyse these data, due to inaccuracy in the recording of ICD codes]
>
> 6. Emergency Room Visits

> This information from local hospitals' emergency rooms was studied and compared to previous years, and analyzed for possible links to the spray.
>
> 7. Telephone Health Support Line Data
> A telephone support line was available to the community during the spray periods. Self-reports made to the support line were summarized in the context of the larger study." (Anon 1999)

The authors' conclusions were as follows:

> "The results of this project did not show a relationship between aerial spraying of Foray 48B and short-term human health effects. Although some people self reported health problems that they attributed to the spray program, the research and surveillance methods used in this project did not detect any change in health status that could be linked to the spray program. Our results showed that many of the health complaints people reported during the spray were as common in people before the spray as they were shortly after the spray. This conclusion is consistent with those of previous studies of the possible health effects of *Bt*k–based pesticide spray programs." (Anon 1999; Anon 2001a)

The study of children with asthma (the Asthmatic Children's Survey, point 1, above) has subsequently been published separately as (Pearce et al. 2002a).

> "A pre/post matched pairs cohort design was used [n=85]. Children living in the spray zone were matched with children outside of the spray zone. Peak Expiratory Flow Rates, asthma symptoms and non-asthma symptoms were recorded in diaries. There were no differences in asthma symptom scores between subjects and controls, neither before nor after the spray; nor were there significant changes in Peak Expiratory Flow Rates for subjects after the spray period. No evidence of adverse effects from the use of the biological pesticide was found."

The telephone survey of residents (General Population Survey, point 2, above) has been published separately as (Pearce et al. 2002b). A total of 2127 telephone numbers were called, but only 1009 people completed both pre and post spray interviews; about half of these were inside the spray zone. The authors concluded that:

> "There were no significant changes in physical health scores and a small improvement in the average post spray mental health score…" (Pearce et al. 2002b)

Interpretation of overseas studies

Population-based surveillance has covered large populations (tens of thousands of people) during and after spraying operations. This provides limited reassurance that exposure to *Bt* does not cause a large increase in serious diseases. However, surveillance provides limited information because the study population is not well defined and there is no control group. A major limitation of previous community surveys is that the "control" (unexposed) populations were potentially or actually exposed to *Bt* as a result of spray drift during the spraying operations. The sample

sizes are not large enough to detect infrequent health effects and the follow up times are insufficently long to detect chronic effects.

New Zealand studies

Several studies have been carried out following aerial spraying with *Bt* products in Auckland in recent years. About 80,000 people were living in the spray zone during aerial spraying for eradication of white spotted tussock moth in the eastern suburbs of Auckland, 1996-7. The implementation of health surveillance was required by government and included:

> "(a) Documentation and investigation of self-reported concerns;
> (b) Health surveillance using sentinel general medical practitioners;
> (c) Review of health data from suitable sources;
> (d) Birth outcomes analysis;
> (e) A register of individuals exposed to the Btk spray." (Aer'aqua 2001)

The following self-reported symptoms were recorded:

- Fear of disease
- Headache
- Asthma
- Sneezing/runny nose
- Throat symptoms
- Skin rash/ itch
- Irritable/angry / stress
- Hay fever / allergy
- Sleep disturbance
- Noise
- Miscarriage / query about pregnancy

> "Reported concerns were followed up through a process of interview, requests to consent to obtaining relevant information from health care practitioners, review by a panel of medical specialists of recorded concerns and any available medical information, and where appropriate additional personal medical assessments. This process did not identify any significant diseases attributable to the spraying." (Aer'aqua 2001)

Health surveillance using sentinel general medical practitioners included two practices, one located in the centre of the spray zone and one on the periphery.

> "Each patient was classified according to their street address (at the time of spraying) as either Zone A - residentially exposed to spraying between October 1996 and April 1997 by DC-6 and helicopter; Zone B - residentially exposed to DC-6 spraying between October and December 1996; or Zone C - not residentially exposed to spraying." (Aer'aqua 2001)

There was no evidence of:

- new onset of asthma
- increased consultation for pre-existing asthma
- chronic fatigue syndrome
- increase in presentations for autoimmune disorders
- increase in consultation rates for lower respiratory problems
- any obvious pattern of problems with headache, eye, skin or upper respiratory symptoms.

> "For three years from the start of Operation Ever Green, general medical practitioners in the area were asked to inform the Medical Officer of Health about any health problems which they thought might be associated with spraying. There were no systematic problems reported and no further individual reports after mid 1997."
>
> "Many of the 375 individuals reporting health concerns had not consulted a medical practitioner about those concerns. However, their concerns were part of a spectrum of symptoms commonly taken to a family doctor. It was considered that patterns of consultations observable within general medical practices (family doctors) could indicate whether any change in frequency of health conditions was associated with the spraying." (Aer'aqua 2001)

The overall conclusions were as follows:

> "No adverse health patterns were found, once patterns were examined at a population level. The frequency of occurrence of the following was no different from natural variation: early births; small babies; birth defects; consultation rates with sentinel family doctors for asthma, other respiratory problems, headaches, skin or eye symptoms, and autoimmune disorders.
>
> There was a pattern of self-reports by residents to MAF for irritant respiratory, skin and eye symptoms at the time of spraying and a level of expressed concern about potential future disease. A voluntary register of residents exposed to the longer duration programme was well supported and has been placed in the National Archives (Auckland Regional Office) to assist with any future health studies."(Aer'aqua 2001)

Following aerial spraying for eradication of Painted Apple Moth in Waitakere City, the following symptoms were reported in response to a request for submissions (Blackmore 2003) – in descending order of frequency:

- neurological - headache
- eye - general
- respiratory - cough
- respiratory - throat sore / painful / burning
- general - sick/unwell
- respiratory - asthma aggravation
- digestive - diarrhoea

- respiratory - breathing difficulties
- psychological - distress
- general - fatigue - lethargic
- general - anxiety - allergy/skin disease
- skin - rash
- respiratory - nose - congestion / runny
- digestive - nausea
- general - flu-like symptoms
- digestive - stomach pains/cramps/upset
- respiratory - nose - sinusitis
- skin - rash localised
- respiratory - chest pain
- general - mouth / tongue / lips
- psychological - anger
- respiratory - general
- digestive - vomiting
- general - fatigue - wiped out
- neurological - dizziness / losing balance
- respiratory - nose - bleeding
- skin - itch
- eye - conjunctivitis
- musculoskeletal
- respiratory - nose - sore / painful / burning
- psychological - stress
- respiratory - asthma new

> "Three hundred and ninety seven incidents (397) have been reported to end of year 2002, with nearly 1400 specific effects detailed. These range from health complaints of an irritant and debilitating nature, through serious exacerbations of pre-existing conditions, to such severe effects that some people's lives and livelihoods have been quite simply devastated." (Blackmore, 2003)

A separate questionnaire-based study included recording of symptoms before and after the spraying began.

> "Two hundred and ninety two residents within the …spray zone were recruited by a door-to-door survey of homes within the most intensively sprayed area ten weeks prior to the first aerial spraying. Participants completed a symptom checklist and a questionnaire measuring health perceptions. Three months after the start of spraying, 181 (62%) of the original participants responded to a similar postal questionnaire. Symptom reports, health perceptions and visits to healthcare providers were compared between the baseline and the follow-up questionnaire. Rates of symptom complaints in respondents with previously diagnosed asthma, hay fever, or other allergies were compared to those in respondents without these prior health conditions." (Petrie et al. 2003)

Symptom complaints appeared to increase following the aerial spraying. A separate questionnaire-based survey of schools in west Auckland received 320 responses. Over half reported "adverse effects" from the spray. (NZEI 2003)

> "Many cited serious health effects, rashes, nausea, persistent coughing, breathlessness, asthma attacks, mucous in nose and throat, tightness in chest, difficulty in breathing, allergic (histamine) reactions, swollen and sore throats, sores around mouth, watery eyes and bronchial problems. Often, many of these symptoms lasted for days and even weeks and recurred on subsequent spray days. One teacher enclosed a statement from her doctor that indicated that "her ill health seems to be coinciding with PAM spray". The doctors diagnosis was Chronic Rhinitis. Many teachers stated they had observed many of the above reactions in the children under their care." (NZEI 2003)

In a survey of employees at a factory in the spray zone, 29 health effects were reported. Of those reporting any symptoms:

- 35% suffered eye problems (itchy, watery or sore eyes)
- 38% suffered lung and/or respiratory problems. (Difficulty breathing, asthma attack, respiratory irritation, nosebleeds, sinus pain and sneezing, pre-existing allergies had worsened).
- 7% suffered skin burning or irritation.
- 10% developed headache.
- 3% suffered swelling of the face and eyes.
- 7% had to obtain medical attention and treatment. (Blackmore 2003)

Similar results were recorded in a subsequent survey at the same factory (Douglas Pharmaceuticals, personal communication).

Reports from the PAM health service are summarized in Appendix 3. Because we received no response to our requests to meet staff of Aer Aqua, we do not attempt to further describe or interpret these data in this report.

Interpretation of New Zealand studies

None of the studies reviewed here provide strong evidence that aerial spraying of Bt products *either do or do not* have adverse health impacts.

Population-based surveillance has covered large populations (tens of thousands of people) during and after spraying operations. This provides limited reassurance that exposure to *Bt* does not cause a large increase in serious diseases. However, surveillance provides limited information because the study population is not well defined and there is no control group. The health surveillance following "Operation Ever Green" (Aer'aqua 2001) examined health outcomes for a period of two years after the spraying, including residents' self-reported health concerns, consultation rates at family doctors, and a review of routine health data sources. A limitation of this study is the possibility that control populations living outside the spray zones were actually exposed, via spray drift. At the time when this programme was designed, the potential extent of spray drift was not appreciated. It may be possible to obtain very useful information from a reanalysis of these data, under the assumption that all of the population followed up were exposed.

The questionnaire based studies provide evidence of the range of symptoms reported but do not allow causal interpretation to be made with confidence due to lack of a control group. The results of one study that did include a control group is unfortunately unreliable, since the reporting period was longer for the follow-up questionnaire than for the initial questionnaire.

New Zealand risk assessments

Auckland DHB risk assessment for MAF, 2002

A health risk assessment of the aerial spray eradication programme for the painted apple moth in West Auckland reached the following conclusions (Kalemba et al. 2002):

> "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 … problems with pregnancy... thyroid dysfunction or abnormalities."

Environmental Risk Management Authority assessment of Bactur 48LC

The Environmental Risk Management Authority (ERMA) recently approved an application to import insecticide "Bactur 48LC" containing *Bt* (ERMA 2002). This assessment appears to have been based, at least in part, on the questionable assumption that short term irritant effects of *Bt* products are only seen in laboratory animals or workers exposed to relatively high doses – and do not occur in communities exposed to aerial spraying of *Bt* products.

The lack of New Zealand Workplace Exposure Standards for bioaerosols is unsatisfactory and should be addressed by Government. Some countries do have relevant exposure standards (Denmark, Sweden and the Netherlands). We have not been able to obtain the original sources for these, but it has been reported that in the Netherlands there is a proposed occupational exposure limit of 50 endotoxin units (EU)/m^3, equivalent about 4.5 ng/m^3, over an 8 hour period (Heederick and Douwes

1997). Quotations of relevant sections for the assessment of health risk are given in Appendix 4.

Exposure assessments (overseas)

Bt has been grown in stool samples from agricultural workers using *Bt* products and from nasal swabs in communities exposed to *Bt* (De Amorim et al. 2001; Jensen et al. 2002b). However, presence of *Bt* was reported to be unrelated to symptoms in either of these studies. Several studies have quantified exposure to *Bt*-containing products. Elliot et al (1988) reported maximum exposures of over 10,000 colony forming units per cubic meter (cfu/m^3) in spray workers:

> "The concentration of spores ranged from 0 to 1.1×10^4 cfu/m^3 for individual workers, the highest concentration being incurred by a spray card checker who was in brief contact with the material. For non-working individuals, the average *Bt* exposure was 1.3×10^3 cfu/m^3. In the spray area, a general survey showed concentrations of 0 to 4.2×10^3 cfu/m^3." (Elliott et al. 1988), cited in cited in (WHO 1999).

Noble et al. (1992)

> "…studied aerosol *Bt* exposure and subsequent nose and throat carriage of *Bt* by workers during a major spray programme for gypsy moth… The mean exposure values ranged from 3,000 to 5,900,000 *Bt* spores/m^3 … Nearly all the workers exposed to higher concentrations for several shifts (5 to 20) were culture-positive for *Bt*, and the majority of the workers remained culture-positive for 14 to 30 days." (Noble et al. 1992).

As part of the Vancouver Island study in Canada, (Anon 1999), researchers measured exposure to Foray 48B. Airborne *Bt* was measured both indoors and outdoors using bacterial culture of samples collected on Teflon filters. The size distribution of the aerosol droplets was also measured. Spray drift was measured 1km from the intended site; *Bt* concentrations were related to wind speed and direction rather than distance from the spray zone (Teschke et al. 2001).

The intended droplet size was 110-125 micrometers. Large particles, which constitute the bulk of the spray mass, settle quickly, leaving the very small particles suspended in the air, often for many hours or days. In many aerosols, there are often large numbers of small particles which only account for a few percent of the total spray volume. The median aerodynamic diameter was found to be 4-7 micrometers. After 5 minutes, the majority of particles were found to be less than 5 micrometers:

> "A series of three six-stage Andersen samples were taken for 5 min each. The first sample started at the time the airplane passed overhead (T0–T5), the second 2.5 min later (T2.5–T7.5), and the third 7.5 min later (T7.5–T12.5). Eighty percent of the bacterial colonies appeared in the upper two stages of the sampler in the T0–T5 sampling period; however, in the later samples 62% of the colonies were in the lowest four stages, representing aerosols < 5 µm, which settle very slowly." (Teschke et al. 2001)

The extent of drift outside the spray zone was thought to be due to the presence of these fine droplets. Maximum outdoor exposures of greater than 1,600 cfu/m^3 occurred after 2-3 hours, while indoor exposures were found to exceed outdoor levels after 5-6 hours. The study did not attempt to quantify levels of exposure above 1,600 cfu/m^3 (Teschke et al. 2001).

Measurement of exposure using viable spore counts will underestimate total exposure, since non viable matter (including non viable spores) will not be measured. Volatile chemical constituents of the spray were also measured by ambient air sampling (van Netten et al. 2000). The authors reported that

> "…Foray 48B is associated with few volatile agents which only could be measured under strict laboratory conditions and are not present in sufficient quantities in a vapour form to pose a health hazard during spray operations..."

The level of exposure to volatile components of the spray is likely to be very low, but could still cause allergic responses. Other adverse effects from the so-called "inert" ingredients seem unlikely. For this reason, we do not considered exposure to "inert" ingredients further here.

In relation to the biological components of *Bt*, one other relevant study has recently been published. Hendriksen and Hansen (2002) reported that *Bt*:

> "… survives as spores for long periods in bulk soil, a relatively protected environment… survival of *Bt* is a more dynamic process than previously thought, involving germination, possible cell divisions, and sporulation. These observations may have major implications for the understanding of the ecology of *Bt* in the environment, for its use as a microbial pest control agent, and the associated risk assessments." (Hendriksen and Hansen 2002)

Exposure assessment (New Zealand)

We are not aware of any systematic monitoring of human exposures during the spraying operations in New Zealand. In an attempt to assess the approximate level of exposure during the spraying programme in West Auckland in 2003, we have analysed data from the Henderson air quality monitoring station. Auckland Regional Council provided hourly carbon monoxide (CO) and particulate matter (PM_{10}) for January – August 2003. Climate data (hourly dry bulb temperature, humidity, wind speed and direction) were provided by NIWA.

MAF provided a table indicating on which days aerial spraying operations occurred. As this did not include start and finish times, we generated a spray indicator variable which was set equal to one from 0500H on spray day to midnight on completion day (inclusive), and zero otherwise. Seasonal changes in PM_{10} were removed using a lowess smoother of bandwidth 0.1.

The resulting seasonally adjusted PM_{10} was regressed against climate data, carbon monoxide and the spray indicator variable. The results suggested a small but measurable effect of the spraying programme on ambient PM_{10} as measured at Henderson, with a maximum increase in hourly PM_{10} of 2.5µg/m^3 after a lag time of 6 hours. Over the whole 8-month period, there were 455 hours in which the spraying

occurred (as defined by the indicator variable), equivalent to about 19 days exposure, (or about 30 days per year).

Potential health effects of bioaerosols

When sprayed from aircraft, Foray 48B forms a *bioaerosol* (a fine suspension of biological matter in air). We have therefore reviewed what is known about the health effects of this general type of exposure. It is well established that bioaerosols cause respiratory diseases in exposed workers. Non-viable microorganisms and the biologically active chemicals that they produce can cause health effects through toxic and immunological mechanisms (Eduard et al. 2001). Bünger et al, (2000) state that

> "The primary effect of exposure to bioaerosols is often an inflammatory response of the upper airways with congested nose, sore throat, and dry cough often in connection with symptoms of the eyes like redness and tears (mucous membrane irritation), subsiding several hours after the end of exposure."

Studies have examined effects on workers exposed to organic dusts, in agriculture, food processing and waste management. In one study, these irritant symptoms were reported by household waste collectors more than unexposed workers (Wouters et al. 2002). Evidence of upper airway inflammation was found after "moderate" exposure to endotoxins. However, in this case the exposure also included fungal spores (Heldal et al. 2003). Other less frequent effects of bioaerosol exposure in studies of exposed workers include toxic reactions, allergic reactions, respiratory and skin infections, asthma exacerbations and other chronic diseases of the respiratory system (Bünger et al. 2000; Douwes et al. 2003).

The only relevant study of the general population that we are aware of used a questionnaire survey to investigate the effects of bioaerosols on symptoms in residents living near a compost manufacturing site. Bronchitis, coughing, shortness of breath, smarting eyes, tiredness and shivering were reported more frequently in residents living near the site, where measured exposure to bioaerosols were highest. However, there was no increase in doctor-diagnosed illness in the exposed group (Herr et al. 2003).

Total bacteria were measured at concentrations of 5,000 to 10,000 cfu/m^3. The authors state that these levels "…exceeded occupational threshold levels recommended in Denmark and Sweden…" also that *"airway inflammation [is] to be expected after frequent exposure to micro-organisms in the range 10,000-100,000 cfu/m^3 "* – with reference to (Millner 1995).

It is not clear which features of respirable particles are responsible for these effects, but there is evidence that aeroallergens may be involved (most dramatically in triggering epidemics of asthma). It is also well established that fine particles cause increased daily mortality in exposed communities. Most research has focussed on the effect of exposures due to combustion processes, but there is limited evidence that bacterial toxins could also be involved (WHO 2003).

Potential pathogenicity of Bacillus thuringiensis

Subspecies of *Bt* can produce toxins with a specific mode of action via receptors present only in target species of insect. Because this receptor is not present in humans, the toxin cannot have harmful effects in humans via this mechanism. There is limited evidence that *Bt* can cause corneal ulcer (Samples and Buettner 1983) and soft tissue infection (Damgaard et al. 1997). Since clinical tests do not normally distinguish B. thuringiensis from the closely related pathogen, B. cereus (WHO, 1999), the significance of B. thuringiensis as a cause of human disease is not known.

Bt (*Berliner* strain) was found to be non toxic in one early study. Eighteen human volunteers ingested 1 gram of a commercial insecticide called Thuricide daily for 5 days. The volunteers swallowed capsules containing 3×10^9 spores/g of powder in a "diatomaceous earth filler". Five of the volunteers also inhaled 100 mg of powder daily for five days, via an "Abbott inhalator". Medical examinations and laboratory tests before, just after and 4 to 5 weeks after exposure did not demonstrate any adverse health effects. (Fisher and Rosner 1959)

However, the exposure likely from the inhalation experiment is unclear, and the number of participants is rather small. Contradictory results have been reported (Pivovarov et al. 1977):

> "Pivovarov et al. reported that ingestion of foods contaminated with *Bt*g at concentrations of 10^5 to 10^9 cells/g caused nausea, vomiting, diarrhoea and tenesmus, colic-like pains in the abdomen, and fever in three of the four volunteers studied. The toxicity of the *Bt*g strain may have been due to beta-exotoxin." (Ray 1990), cited in (WHO, 1999)

Note that it is not clear that these studies used the subspecies of *Bt* that is currently used in commercial preparations. *Bt* products used in New Zealand is said to be tested for the presence of unwanted toxins (Kalemba et al. 2002). However, it is not clear how sensitive or reliable these tests are, since there are no widely accepted test protocols for organisms. Bacteria can also produce a range of toxins during growth. If bacteria from *Bt* products grow after release, this could result in human exposure to toxins even if no toxins were present in the original product (Hendriksen and Hansen 2002; Huttunen et al. 2003).

In relation to *Bt*, most attention to date has focussed on *enterotoxins*, which cause gastrointestinal symptoms. Enterotoxin-producing strains of *Bt* have been isolated from commercial insecticides (Damgaard 1995), food (Damgaard et al. 1996; Phelps and McKillip 2002) and stool samples of workers using *Bt* insecticides (Jensen et al. 2002a; Jensen et al. 2002b). *Bt* has been implicated in one outbreak of gastroenteritis (Jackson et al. 1995).

Commercially available bacterial *endotoxin* assays depend on detection of lipopolysaccarides in the cell wall of Gram negative bacteria. Gram positive bacteria such as *Bt* have different cell walls, which do not contain lipopolysaccarides. However, all bacterial cell walls contain another molecule called peptidoglycan. This class of molecule is not be detectable by standard assays for endotoxin but has similar adverse effects, via similar molecular mechanisms (Dziarski 2003). There is recent

evidence that Gram positive bacteria can trigger immune responses in the lungs (Becker et al. 2002; Weber et al. 2003).

Laboratory studies of exposed workers

Bt is known to cause certain immune responses in exposed workers. One study:

> "…demonstrated antibody titres in 11 of 107 workers exposed to *Bt* during a 2-year spraying period. By the middle of the spray operation, seven had developed titres to spore-crystal complexes, six to vegetative cells, and one to spores. Their titres tended to be low, but were higher in those exposed for a second year. Two months after the exposure ended, nine workers were retested. Of these workers, five had no detectable antibodies to the spore-crystal complexes, and four who had been among those with the highest titres against vegetative cells had significantly lower titres." (Laferrière et al. 1987), cited in (WHO, 1999).

Bernstein et al (1999) conducted laboratory tests on farm workers before and after exposure to *Bt*-based pesticides. They reported no evidence of respiratory symptoms resulting from exposure.

> "…there was a significant ($p < 0.05$) increase in the number of positive skin tests to spore extracts 1 and 4 months after exposure to *Bt* spray. The number of positive skin test responses was also significantly higher in high ($p < 0.05$) than in low- or medium-exposure workers. The majority of nasal lavage cultures from exposed workers were positive for the commercial *Bt* organism, as demonstrated by specific molecular genetic probes… Specific IgG and IgE antibodies to vegetative organisms were present in all groups of workers. Exposure to *Bt* sprays may lead to allergic skin sensitization and induction of IgE and IgG antibodies, or both." (Bernstein et al. 1999)

A Danish follow up study of 579 agricultural workers exposed to biological insecticides, including *Bt* products reported a high prevalence of irritation in eyes and airways, allergic rhinitis and asthma (Larsen and Bælum 2002):

> "… In greenhouses using Bacillus thuringiensis products increased prevalence of itching in the eyes at work and of frequency of more than once a week were seen. The persons who handled Bacillus thuringiensis product had more chest tightness than the rest while in the follow up an increased incidence of itching in the eyes was seen in greenhouses using Bacillus thuringiensis...
>
> There was no difference in the lung function and in histamine sensitivity between subjects exposed to the products and those not in contacts with the products.
>
> There were measurable IgE antibodies against the different products. The prevalence of antibodies above the detection limits was highest for the Verticillium lecanii and the Bacillus thuringiensis products … There was no clear relation with the measures of individual exposure. Especially, no sensitization was seen in the highly exposed persons who had handled and sprayed out the products. During the one year follow up the levels of

antibodies for the individual were stable and there was no sign of increased sensitization.

The incidence of new symptoms was about 10% and only in a few symptoms the incidence was related to the measures of exposure or sensitization. Due to the relatively few new symptoms in the short follow up the power of this part of the study for detecting exposure-response relationship is low.

… persons with one or more positive prick tests as an indicator of atopy showed higher prevalence of eye and nose symptoms as well as diagnosed asthma than the non-atopics. Furthermore, the incidence of new symptoms during follow-up in the group of atopic persons was considerably higher than among the non-atopic persons and persons with house dust mite allergy were over represented in the group that left the study between the first and second examination. This could indicate a "healthy worker effect" due to the different exposures in the greenhouses. The evaluation of health effects should therefore mainly be based on measures of incidence and the study has therefore been extended for three years to achieve a higher power.

In conclusion the study showed a relatively high prevalence of symptoms among greenhouse workers and there was a limited relation to estimates of exposure to Bacillus thuringiensis and Trichoderma harzianum but not to Verticillium lecanii or Paecilomyces fumosoroseus products…"

Laboratory experiments using cell cultures

Bt derived from commercial insecticides has been shown to be capable of producing cytotoxic effects in cell cultures which are similar to those caused by the known pathogen, Bacillus cereus. It was reported that the most toxic substances were released "soon after spores germinated and began proliferating." (Tayabali and Seligy 2000)

Rodríguez-Orozco et al, (2000) report that the precursor of a *Bt* toxin was found to have strong adjuvant properties. (This means that it stimulates immune responses to other substances administered concurrently). Much of this work has been done using mouse cells and is outside the scope of this review. However, responses were also seen in human peripheral monocytes (white blood cells):

"… intense phagocytic stimulation and proliferation of monocytes induced by Cry1Ac … suggests that monocyte activation and proliferation are significantly involved in the adjuvant effect of the protoxin." (Rodríguez-Orozco et al. 2000)

Huttunen et al (2003) investigated the ability of bacteria and fungal spores to stimulate the production of cytokines – chemical messengers that are involved in inflammatory responses. B. cereus was shown to be capable of inducing inflammatory responses. At higher doses, there was evidence of cytotoxic effects (cell damage). These authors reported that:

"Altered growth and sporulation environments… may provoke normally innocuous microbes to produce components and/or metabolites that trigger

inflammatory responses and cytotoxicity. This implies that the potential to cause adverse effects may be site specific." (Huttunen et al. 2003)

Discussion

We report the views of those who participated in meetings or responded to our requests for submissions as faithfully as possible. These methods allow us to describe the *range* of reported health effects, symptoms, and concerns in the community. However, using these methods we cannot determine the frequency of reported health effects, symptoms, and concerns in the wider community.

Focus groups

The study included four formal focus groups, as well as additional community data gained from various interactions within community networks around the Waitakere City Council. The data gathered in each forum builds a consistent picture; that the aerial spray programme is reported to have had multiple impacts on the health, well-being and everyday life of many Waitakere City residents. Those with existing conditions, such as asthma and hay fever, often reported that these conditions were aggravated following exposure to spray.

Many expressed concern for the young and elderly. Some expressed uncertainty about health effects in future generations. Other impacts included disruption of day to day life, compounded by lack of certainty about which day the spraying would occur. All participants reported staying indoors and closing windows when the spraying occurred.

There were frustrations over having to wash cars, windows and laundry. In many cases, we were told, the disruptions of everyday life were exacerbated by a lack of timely and meaningful information about what to expect, the spray times, and the spray ingredients. We were told that a lack of information has also resulted in increased uncertainty and concern about the sprays toxicity, and a decreased confidence in government.

All of the focus groups reported concerns over the effectiveness, impartiality and fairness of the MAF health service and some people reported they are reluctant to use the services.

Health concerns reported in submissions

In response to a call for submissions, the most frequently reported symptoms were

- Irritant symptoms: sore throat, headache, blocked nose (25% of all reported symptoms)
- Respiratory symptoms: chest tightness, asthma exacerbation, cough (16%)
- Gastrointestinal symptoms: diarrhoea, vomiting, stomach cramps (14%)
- Flu- like symptoms: fever, malaise, swollen glands (13%)
- Skin rash (9%)

Similar symptoms have been reported in other studies of workers and communities exposed to aerial spraying of products containing *Bt*, both in New Zealand and overseas.

Epidemiological studies

Workers and communities exposed to *Bt* products have reported acute irritant symptoms (such as sore throat, headache, blocked nose). More chronic symptoms, such as exacerbations of asthma, skin rashes or flu-like symptoms have less frequently been reported.

Several studies of communities exposed to aerial spraying of *Bt* products have been carried out in New Zealand, Canada and North America. We do not question the accuracy of these findings, which do provide some reassurance. However, the level of reassurance that can be derived from these results depends upon the quality and size of the studies. All of the epidemiological studies that we have reviewed have limitations, and they have limited ability to detect effects that occur in a small proportion of exposed people. Methodological limitations include:

- small sample sizes (therefore a lack of statistical power to detect a health effect, even if present) (Noble et al. 1992; Anon 1999; Aer'aqua 2001; Anon 2001a; Pearce et al. 2002a; Pearce et al. 2002b; Petrie et al. 2003)
- subjective or potentially biased assessment of health effects (Petrie et al. 2003)
- potential or actual exposure of control groups (Noble et al. 1992; Anon 1999; Aer'aqua 2001; Anon 2001a; Pearce et al. 2002a; Pearce et al. 2002b)
- limited duration of follow up (Noble et al. 1992; Anon 1999; Aer'aqua 2001; Anon 2001a; Pearce et al. 2002a; Pearce et al. 2002b)

The largest of the community surveys have included, at most, 500 participants in "exposed" and "unexposed" groups. These surveys have limited ability to detect effects that occur in a small proportion of exposed people. For example, suppose we know that a given symptom actually occurs in 50% of unexposed people, and 55% of exposed people. In order to have 95% confidence of being able to demonstrate that symptoms are experienced more frequently in the exposed group, a study would need over 2000 people in each of the exposed and unexposed groups. This example assumes a standard (95%) level of statistical significance.

The existing community surveys (Noble et al. 1992; Aer'aqua 2001; Pearce et al. 2002a; Pearce et al. 2002b) cannot prove that *Bt* products cause no important health impacts in exposed communities. Health impacts can be substantial and important whilst at the same time being difficult or impossible to measure without careful study of very large populations.

We recommend that further epidemiological studies are carried out, with sufficient statistical power to provide adequate reassurance to exposed communities in the event of negative results (ie. that no health effects are detected).

New Zealand risk assessments

The prediction of the Auckland DHB risk assessment (for MAF, 2002) that: "…some people may complain of minor skin, eye and upper respiratory tract irritation, or aggravation of existing asthma or allergies..." (Kalemba et al. 2002) was accurate.

The Environmental Risk Management Authority (ERMA) assessment of Bactur 48LC appears to have been based, at least in part, on the questionable assumption that short term irritant effects of *Bt* products are only seen in laboratory animals or workers exposed to relatively high doses – and do not occur in communities exposed to aerial spraying of *Bt* products.

Some countries do have relevant exposure standards (Denmark, Sweden and the Netherlands). We have not been able to obtain the original sources for these, but it has been reported that in the Netherlands there is a proposed occupational exposure limit of 50 endotoxin units/m^3, equivalent about 4.5 ng/m^3, over an 8 hour period (Heederick and Douwes 1997).

We recommend that the safety of biological insecticides be reassessed by ERMA and that Workplace Exposure Standards for bioaerosols be developed in New Zealand.

If an exposure standard has been set for one of the components of a product in undiluted form, then this standard may also be relevant to any product containing the substance.

Exposure assessments

The pattern of reported acute and chronic symptoms in workers and communities exposed to Foray 48B is consistent with the known effects of bioaerosol exposure. This has not previously been noted and bioaerosol effects have not been specifically addressed by previous studies. When sprayed from aircraft, *Bt* products are detectable in indoor and outdoor air as very fine acidic "bioaerosol" particles that may be inhaled deep into the lungs. This raises the theoretical potential for *Bt* products to cause a range of chronic respiratory diseases that have been documented in people exposed to bioaerosols in the workplace.

The level of exposure causing occupational diseases is probably substantially higher than that typically experienced by New Zealand communities exposed to *Bt* aerial spraying programmes. On the other hand, the most sensitive individuals tend to avoid occupations that lead to bioaerosol exposure, so that studies of workers may not give a true picture of the likely effect in communities. As far as we are aware, there are no studies of the potential long term effects of exposure to *Bt* products from aerial spraying operations on either communities or workers.

Provided that communities are supportive of the proposal, we recommend that such studies are carried out in New Zealand.

In a study of bioaerosol effects in the community, total bacteria were measured at concentrations of 5,000 to 10,000 cfu/m^3. This level was sufficient to cause detectable health effects in that population. Only two published studies have assessed exposure levels during spraying of *Bt.* The first of these reported levels of up to 4000 cfu/m^3 in the "general spray area" while the second reported levels of up to 1600 cfu/m^3 (which was the upper limit of detection in that study).

We recommend further study of exposure to *Bt* under New Zealand conditions, including detailed computer modelling of previous exposures.

The literature indicates that *Bt* products have the potential to cause health impacts in sensitive individuals. Among other mechanisms, bacterial toxins can cause health effects by stimulating innate immune responses. Effects on health via this mechanism are not specific to a particular species of bacteria. Recent results suggest that this mechanism can be triggered by Gram positive bacteria and their spores, which contain a class of chemical called peptidoglycans.

Potential pathogenicity of Bacillus thuringiensis

In surveillance studies, *Bt* products have not been shown to cause serious infections. However, since clinical tests do not normally distinguish B. thuringiensis from the closely related pathogen, B. cereus, the significance of B. thuringiensis as a cause of human disease is not known. If bacteria from *Bt* products grow after release, this could potentially result in human exposure to toxins even if no toxins were present in the original product.

Among other mechanisms, bacterial toxins can cause health effects by triggering innate immune responses. Effects on health via this mechanism are not specific to a particular species of bacteria. Recent results suggest that this can be caused by Gram positive bacteria and their spores, which contain a class of chemical called peptidoglycans.

Laboratory studies

The literature indicates that *Bt* products have the potential to cause health impacts in sensitive individuals. *Bt* products may cause allergy to chemical or biological components of the spray. This is likely to affect a small proportion of exposed people, but clinical testing of a representative sample of people could quantify this.

We recommend immunological testing of a representative sample of people from the community.

Specific immunological responses have been detected in workers, including skin sensitivity to *Bt. Bt* derived from commercial insecticides has been shown to be capable of producing cytotoxic effects in cell cultures.

The public health significance of these findings is not clear.

Recommendations for future study

Exposure assessments

Analysis of air quality monitoring data for all Auckland monitoring stations with hourly particulate data available for the years 2002-3.

Modelling of the probable spatial and temporal distribution exposure to Foray 48b and potentially active chemical and biological constituents during aerial spraying.

Clinical testing

Immunological testing of individuals if sensitisation is suspected clinically.

Immunological testing of a representative sample from the community.

Objective tests of individuals with symptoms temporally related to the spraying, including exacerbation of existing conditions. (eg. respiratory function tests, nasal lavage). Similar assessment of a sample of people on the White Spotted Tussock moth register, with emphasis on respiratory disease and allergies.

Epidemiological studies

Reanalysis of White Spotted Tussock moth data to account for possible exposure of 'control' groups.

Studies of symptom prevalence in a representative sample children and adults in Auckland census areas. Symptoms to be considered include those relevant to respiratory health, asthma and allergies, gastrointestinal and skin diseases. Previous studies with relevant data on respiratory health, asthma and allergies have been published and may well be worth repeating.

Time series studies of routinely collected mortality and morbidity data for Auckland CAUs, 2000-2003. (eg mortality, hospital admissions, prescription data, GP data where available).

Long term follow up of exposed communities for chronic respiratory diseases.

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Appendices

Appendix 1 Information about the focus groups for the Painted Apple Moth study

Background

The Ministry of Agriculture and Forestry (MAF) have been undertaking aerial applications of Foray 48B over western Auckland in an effort to eradicate the Painted Apple Moth (PAM). MAF have funded a health monitoring service, but there may be some health and related concerns that we do not know about.

The Ministry of Health has contracted a university (Wellington School of Medicine and Health Sciences, University of Otago) to receive written submissions from the public regarding their health concerns related to the PAM spraying programme. Several focus group interviews are also being conducted as part of the university study.

Purpose of the Focus Groups

The focus groups are designed to supplement the written submissions and ensure that some groups who have not yet voiced their health or related concerns, are given an opportunity to do so. We would like to see if there are any health and wider impacts - environmental, economic, every day and community life.

We would like to set up focus groups for the following;
- Maori
- Pacific Island
- Recent immigrants or refugees

What will the focus group involve ?

The focus group will involve 6 or 7 people responding to some questions. The discussion will be recorded.

It will be explained that the information would be used for a written report, but that no individual would be personally identified. Those attending will be asked for written or verbal consent to this.

The focus group would be between 1 and 2 hours long. Refreshments would be provided.

What is the process for setting the focus groups up ?

We need to get some good talkative people to attend. It would be easy if this were piggybacked onto an existing group that met regularly. We are hoping that a person from a local health organisation could advise on who to ask and how to best set this up.

It would also be good if a local person could help introduce the group and ask the questions. This would allow the researcher to take notes and record the group discussion.

Jinny Baker, a social scientist with the Institute for Environmental Science and Research (ESR) will sit in on the meeting to record and take notes. Her contact phone number is (04) 914 0693.

Questions for Focus Groups:

- Welcome and introductions
- Explanation of Project and use of information
- Written or verbal consent

1. How did you become aware of the Painted Apple Moth (PAM) Spray Programme?

2. What information have you been given about the Painted Apple Moth Spray Programme ?

3. Do you have any concerns about the spray programme ?

4. Has the spray programme impacted upon your life ?

5. Has the spray programme impacted upon your health ?

6. How has the spray programme affected people that you know in their everyday lives?

7. Overall, how do you think the spray programme has impacted upon your community ?

Appendix 2 Questions for focus groups

Background

The Ministry of Agriculture and Forestry (MAF) have been undertaking aerial applications of Foray 48B over western Auckland in an effort to eradicate the Painted Apple Moth (PAM). MAF have funded a health monitoring service, but there may be some health and related concerns that we do not know about.

The Ministry of Health has contracted a university (Wellington School of Medicine and Health Sciences, University of Otago) to receive written submissions from the public regarding their health concerns related to the PAM spraying programme. Several focus group interviews are also being conducted as part of the university study.

Purpose of the Focus Groups

The focus groups are designed to supplement the written submissions and ensure that some groups who have not yet voiced their health or related concerns, are given an opportunity to do so. We would like to see if there are any health and wider impacts - environmental, economic, every day and community life.

What will be done with the information from the Focus Group

- The information will be recorded electronically.
- Anything that you say in the focus group interview will be kept confidential. Individuals will not be mentioned by name. The report will be written so that any views come from the group as a whole, or where different views are expressed from 'some people', or 'a person in the group'.
- A written transcript will be produced and if participants would like, a copy of this can be given to the host organisation. (This is providing there are no failures with the equipment and transcribing process)
- The information will be written up in a report. A draft of this report will be given to the Wellington School of Medicine. Following approval from the Wellington Medical School, a copy of the report on the focus group research will be given to the organisations participating. The Wellington School of Medicine will use the information from the focus group report for a larger report to the Ministry of Health. Some changes may be made in this process.

Questions for Focus Groups:

1. How did you become aware of the Painted Apple Moth (PAM) Spray Programme ?

2. What information have you been given about the Painted Apple Moth Spray Programme ?

3. Do you have any concerns about the spray programme ?

4. Has the spray programme impacted upon your life ?

5. Has the spray programme impacted upon your health ?

6. How has the spray programme affected people that you know in their everyday lives?

7. Overall, how do you think the spray programme has impacted upon your community ?

If you have any questions or concerns, please contact the researcher;

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Appendix 3 Excerpt from PAM Health Service Reports to MAF and Ministry of Health

The reports contains the numbers and estimated rates of:

- people who have called and/or been assessed by the PAM Health Service
- reasons for people having Practical Support Plans; and
- severity of the reasons for the Plans

These figures do not represent the number of people who have had actual reactions to the spray. The information has been supplied by the PAM Health Service, Aer'aqua Medical Services.

Numbers of people assessed by the PAM Health Service

The following table summaries the information contained in the "Health Service Activity Report". A denominator of 160,000 resident population is assumed for the entire programme although any particular spray will involve some varying proportion of the overall population.

Cumulative number of new people calling the service with health concerns (from 30 Dec 01 to 28 Sept 03)	3,385	21 per thousand
Cumulative number of new people with Practical Support Plans (from 30 Dec 01 to 28 Sept 03)	633	3.9 per thousand
Cumulative number of residents assessments by a doctor in conjunction with the PAM support service (from 30 Dec 01 to 28 Sept 03)	1,265	7.9 per thousand
Cumulative number of specialist medical assessments to 28 Sept 03	196	1.2 per thousand

A practical support plan includes anything from a warning call to inform of spray schedule to relocation in a motel

Primary medical justification for a practical support plan:

Allergy – prior history of allergy to relevant food or preservative	55	0.34 per thousand
Asthma – prior history of any severity	192	1.2 per thousand
Skin condition including eczema, but not concomitant asthma	34	0.19 per thousand
Lower or upper respiratory but not asthma	45	0.28 per thousand
General symptoms including irritant type at spray time	122	0.76 per thousand
CFS or chemical sensitivities	64	0.4 per thousand
Medical illness with immune suppression	30	0.19 per thousand
Situational stress or pregnancy	87	0.54 per thousand

Medical justification for the Practical Support Plans

The "justification" listed is the one overriding reason for each person to receive a PSP, not the presence or otherwise of each condition or occurrence of a reaction

Note: Epidemiological patterns, among the residents with self-reported concerns, is part of Health Service Monitoring and reported separately

Patterns of justification cumulative to date	
Food allergy relevant to spray constituents, including asthma from food and multiple food allergies in young children where there is a likelihood of further manifestations of allergy developing.	38
Allergy relevant to non-food constituents of the spray, includes specific medically recognised allergy to preservatives etc.	17
Skin condition, pre-existing skin condition where precautions to prevent direct spray contact are in place, includes eczema.	34
Asthma, medical history of asthma of any severity and spray exposure precautions are in place. This is not a measure of people with aggravation of asthma due to spraying.	161
Asthma and eczema, Both asthma and eczema are medical problems and spray exposure precautions are in place.	31
Lower respiratory other than asthma, where there is a medical diagnosis of such conditions as bronchiectasis, congenital lung conditions, emphysema, alveolitis and spray exposure precautions are in place.	24
Upper respiratory, where there is a medical diagnosis of such pre-existing conditions as chronic sinusitis, tonsillitis, rhinitis, and spray exposure precautions are in place.	21
Irritant symptoms post spray including confirmed, suspected or clearly not spray related, includes sore or puffy eyes, sneezing, cough, sore throat, nausea, headaches, gastric upset, itching, transient rash, also odour problems.	122
Chronic fatigue syndrome or multiple chemical sensitivities, including self declared ME, history of spray poisonings, fibromyalgia not associated with underlying connective tissue disorder, sensitive to sprays.	64
Immune suppression of medical significance including leukaemia, HIV, post chemotherapy, SLE, fibromyalgia secondary to underlying connective tissue disorder, autoimmune disease.	30
Situational stress associated with contemporaneous medical illness or underlying psychological morbidity relevant to spraying for example war trauma, anxiety disorder.	70
Pregnancy and baby where there is no other medical problem and spray exposure precautions are in place.	17
Total*	629

* This figure represents the total number of people who have had any category of justification at any point where they have a Practical Support Plan.
Some people may have consecutive justifications. The total is slightly greater than the number of people who have ever had a Practical Support Plan (626).

Description of health events

Medical severity among those who have ever received Practical Support Services

All householders who have ever had a Practical Support Plan have been assigned one of the following categories of severity:

Highest severity	Eg anaphylaxis to relevant foods, multiple severe food allergies in child, very severe asthma	7%	0.27 per thousand
Significant medical	Eg definite or unstable asthma, eczema or upper respiratory with significant severity	29%	1.1 per thousand
Other medical	Eg short-term irritant symptoms or mild respiratory, mild skin problems, headaches,	29%	1.1 per thousand
Precautionary because of previous medical diagnosis	Eg lower respiratory: alveolitis, emphysema, bronchiectasis; lichen planus, immune disorders, rheumatoid arthritis, SLE, past/current history of Chronic Fatigue Syndrome, and major medical problems not known to be at specific risk of aggravation by spray exposure	19%	0.74 per thousand
Mainly psychosocial justification	Eg pregnancy or situational stress as justification, general concerns about spraying	16%	0.62 per thousand

HEALTH SERVICE MEDICAL UPDATE

	Totals	Jan-02	Feb-02	Mar-02	Apr-02	May-02	Jun-02	Jul-02	Aug-02	Sep-02	Oct-02	Nov-02	Dec-02	Jan-03	Feb-03	Mar-03	Apr-03	May-03	Jun-03	Jul-03
Individuals with new medical condition		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Individuals with pre-existing condition aggravated by spray		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Medical problems assessed																				
No of new residents with health concerns		206	121	81	45	42	33	42	27	126	504	492	403	189	423	290	174	92	23	27
Cumulative no. of residents with health concerns	3,340																			
No of new PSPs		15	14	35	16	18	0	23	3	7	74	82	110	30	68	58	61	5	3	4
Cumulative no. of PSPs	626																			
No assessed by GP – PAM support service		59	29	27	38	23	13	5	9	27	70	127	184	90	101	184	56	106	51	34
Cumulative no. assessed by GP	1,233																			

Appendix 4 Extracts from ERMA decision (ERMA, 2002)

"8.5 *Btk* has been used in commercial pest management for over 30 years in Canada and the United States. This has included programmes in large urban areas, for example 19,000 hectares in Vancouver in 1992. Extensive studies have been carried out during that time, as required by the United States Environmental Protection Agency and Health and Welfare Canada and no significant adverse effects on animal or human health were recorded. All North American studies to date show no public health concerns, despite long-term large-scale use of *Btk* in aerial pest management programmes.

8.6 **In extremely rare cases**, people spraying *Btk* may develop minor, transient irritations such as dry skin, chapped lips, itchy red and burning eyes, runny noses and nasal stuffiness. However, spray workers studied in Vancouver who reported such problems had been exposed to up to 500 times more *Btk* than a member of the public outdoors would be during the spray operation.

8.7 From the information provided, I consider that the application is unlikely to have an impact on the relationship between Māori culture and their traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna and other taonga. This is on the condition that the product is used in accordance with the HSNO controls established for this application, and in accordance with any other relevant controls applying under other legislation.

Setting of EEL (Control Code E1)

9.1 This default control requires that an EEL (Environmental Exposure Limit) is established. This can either be the default value, Regulation 32, or one set in accordance with Regulations 33 to 43 of the Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001.

9.2 Regulation 33 allows for the setting of EEL values different from the default values. EELs may be set for one or more environmental media.

9.3 However, *Btk* is a natural bacterium in the environment. It is also specific to its range of target organisms and when released from the formulated matrix is rapidly degraded in the aquatic environment.

9.4 Therefore, I consider the adverse effects of BACTUR 48 LC to be **less than normal for this classification** and I consider this control can be deleted under s77(4)(a) of the Act.

Setting of Application Rate (Control Code E2)

9.5 This control requires that an application rate be set if an EEL is set. Regulation 48(2)(a) of the Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 allows the application rate to be set at the rate specified by the applicant in the application. As an EEL has not been set for BACTUR 48 LC then this control is not applicable.

Toxic Substance Controls (Control codes T1, T2)

9.6 Regulation 11(1) of the Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 determines when an ADE (Acceptable Daily Exposure value) is required to be set. If all three of the requirements of this regulation are not met then no ADE is set.

Regulation 11 states:

> (1)This regulation applies to a class 6 substance if-
> (a) it is likely to be present in-
> (i) 1 or more environmental media; or
> (ii) food; or
> (iii) other matter that might be ingested;
> AND
> (b) it is a substance to which a person is likely to be exposed on 1 or more occasions during the lifetime of the person; AND
> (c) exposure to the substance is likely to result in an appreciable toxic effect.

9.7 As I consider that exposure to BACTUR 48 LC is unlikely to result in an appreciable toxic effect to the skin and eyes of exposed people I consider that the condition in Regulation 11(1)(c) is not met. Therefore there is no requirement to set an ADE, and the control is not applicable. I have based this conclusion on the observation that while the hazardous property thresholds of BACTUR 48 LC for skin and eye irritancy are triggered on the basis of tests of laboratory animals, very similar products have been used extensively in New Zealand and off shore and **there have been no reports of such effects seen in exposed humans** (see paragraph 8.5), except in rare cases where workers regularly exposed to high concentrations have shown some minor effects (see paragraph 8.6).

9.8 A workplace exposure standard (WES) is essentially intended for inhalation exposure scenarios in the workplace. Regulation 29 of the Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 determines when a Workplace Exposure Standard is required to be set.

> (1) This regulation and regulation 30 apply to a class 6 substance if-
> (a) under the temperature and pressure the substance is to be used in, it can become airborne and disperse in air in the form of inspirable or respirable dusts, mists, fumes, gases, or vapours; and
> (b) human exposure to the substance is primarily through the inhalation or dermal exposure routes; and
> (c) the toxicological and industrial hygiene data available for the substance is sufficient to enable a standard to be set.
> (2) One or more workplace exposure standards may be set for a substance by the Authority to protect persons from the adverse effects of toxic substances.

9.9 I note that OSH has not set any exposure standard for BACTUR 48 LC or any of its main components. I note that **there is an exposure standard for one of the components in its undiluted form but that this standard is not applicable to diluted formulations.**

9.10 In relation to BACTUR 48 LC, I consider that requirements (1)(a) and (b) of regulation 29 may be met in the workplace, but that requirement (1)(c) is not met in that there is not, or does not appear to be, data of a sufficient standard available.

9.11 Therefore I consider that no WES needs to be set and this control is not applicable.

…[sections 9.12…9.17 removed for brevity]

The use of BACTUR 48 LC in mass aerial spraying

9.18 The hazard profile presented by this substance is similar to, and certainly no greater than, substances already in use in New Zealand for similar purposes. Accordingly there is no reason to think that the use of BACTUR 48 LC poses risks, when used en masse for aerial spraying, which are different from those posed by similar sprays which are already in such use.

9.19 It is noted that these substances are suitable, and are used in New Zealand, for large scale application for control of pests. Although it is not in the scope of the HSNO Act to set specific controls to cover these situations, care should be exercised to ensure that unnecessary exposure to people is minimised, and that people likely to be exposed are fully informed of the circumstances, and in a position to take action on their own account.

Decision

10.1 In accordance with section 28A(2)(b) of the HSNO Act, and clause 24 of the Methodology the approach adopted when considering this application was to evaluate the substance to determine whether the substance had one or more hazardous properties and if each of those hazardous properties met the criteria for least degree of hazard for that property. Then, having regard to the default controls triggered by the classification, potentially significant residual risks and associated costs were identified for assessment in accordance with clauses 12, 13, 33 and 34. Finally, the default controls were reviewed to address their application to this substance (clause 35), and to address any residual risks.

10.2 Having considered the risks associated with the lifecycle of BACTUR 48 LC, I am satisfied that the residual risks or costs associated with this substance, taking account of the controls, **are sufficiently low to be acceptable** (clause 12)." (ERMA 2002) emphasis added.

Appendix 5 Review comments on the first draft

This appendix includes peer reviews from Donald Campbell, Graeme Fleming, Donald Hannah, Virginia Hope and David Sinclair. The review comments from Virginia Hope and David Sinclair included detailed annotations to the draft text, which are also reproduced here in full, along with our initial responses.

Reviewer: Dr Donald Campbell FFPHM, FAFPHM
Public Health Physician

Commissioner: Simon Hales, Research Fellow, NCEPH, Australian National University

Title: Assessment of the potential health impacts of the "Painted Apple Moth" aerial spraying programme, Auckland, New Zealand

Material: A draft document of 53 pages was supplied.

BACKGROUND

This Ministry of Health commissioned this work from the Wellington School of Medicine. The contractors were required to "receive, collect, and summarise reports from the public, community groups, territorial authorities, Ae'r Aqua and Auckland Regional Public Health Service) as well as other stakeholders, community groups, organisations and individuals) on their health effects, symptoms and concerns associated with the Foray 48B aerial spraying programme. The report includes a review of existing knowledge relevant to these health effects, symptoms and concerns, and recommends scientifically robust methods of further study."

METHODS

Qualitative – focus groups were held targeting Mäori, Pacific peoples and migrant groups. These were analysed using a narrative analysis approach.
Data description – information was collected and described from public submissions and from submissions to CC-PAM.
Literature review – on the Internet, including Medline and Web of Science databases using two key phrases.

COMMENTS

Information collection

The contractors were asked the receive reports from the public, community groups etc. Holding focus groups and advertising for submissions fulfilled this. The focus groups held were selected and constructed on ethnic bases, utilising key informants. A noticeable gap and possible bias is that no focus groups were held for the NZ European population (70% of the all ages Waitemata DHB 2001 Census population). The only ability this largest group of the resident population appears to have had to contribute was in response to the submission process, through community groups with special interests (e.g. CC-PAM), or via the local politicians. The participants in three of the four groups came from health related backgrounds, thereby introducing the possibility that their contributions were from a health rather than a community

perspective. If health contributions were being sought an omission is an input from the full range of primary care providers within the spray area.

The focus groups do not appear to have been held in a standard manner with regards to recording and therefore it is not possible to determine if there are biases in the material subjected to narrative analyses. Similarly the meetings held with ethnic political groups.

Numbers of symptom groupings reported in response to the submission process and to CC-PAM are described. However data that is being collected by Ae'r Aqua during this programme and that collected during the White Tussock Moth campaign are not described in a similar fashion when referred to in the literature review.

Analysis

Narrative analysis is used appropriately to describe the findings of the individual focus groups. However a short summation is attempted of the groups and it is not clear on what basis this was made, especially as it includes interactions with community networks.

There seem to be a problem with the symptom data reported from the submission process. The numbers of symptoms reported equals the number of submissions. This means that 88 of those who responded to the public advertisements (93) reported having experienced a symptom that fell within the groupings used but each individual had one symptom only. Similarly with the CC-PAM information there were 311 submissions with 291 symptoms. Did each individual have only one symptom or is a symptom (or absence of) considered a single report?

Within the literature review there are calculations made to demonstrate exposure. These are inappropriately placed and do not describe adequately the basis on which they are made.

A general comment is that discussion is included with the analysis which makes it difficult to follow the analysis and, later, to see where the conclusions flow from.

Literature review

The literature review is mainly descriptive rather than critique, with several almost quotations included, rather than summaries of the material cited. Some critical appraisal does happen but often elsewhere in the document (e.g. sample size issue). As presented, the reader could be confused as to whether the various studies, especially human health ones, are being accepted as published.

There seems to be some selectivity in the literature used. No material is cited from overseas (e.g. US EPA) risk assessments while much of the health information is, appropriately, from outside New Zealand. The literature on self reporting of symptoms, especially after chemical exposures, and their lack of specificity is not explored nor that surrounding voluntary and involuntary risks and risk communication.

Discussion

It would be useful to have a discussion section that pulled together the findings from the data collection and analysis and the literature review. By this means the biases, validity, strengths etc of the information used could be clearly identified and the evidence on which the conclusions are based weighed. Some of this is done under the "Conclusion" heading. I would suggest that "Conclusion" is a more appropriate heading for the Executive Summary. While this work is not required to attribute causality it might be useful to use the Bradford Hill model as a means of structuring the discussion.

Reference is made to the risk communication issues in the Analysis section but they do not carry through to the Recommendations. Nowhere in the document is there mention of the underlying epidemiological issues that dog this project – that a prospective cohort study was not established either for the White Tussock Moth or at least for the Painted Apple Moth programmes. Both of these have important bearing on health impacts and their assessment.

Recommendations

It is not made clear when these are presented that the project brief restricted the recommendations to scientifically robust methods of further study. While not dissenting from any of those listed, indeed most are required, it is not clear where, based on the earlier work, the supporting evidence for their need has originated. Most are because of the lack of this information but many of these deficiencies have not been identified earlier in the report. The recommendations are just bald statements without reference to where the need/gap has arisen from; for example the "map study" of asthma prevalence cites a previous study that is neither mentioned in the document nor the References. The 'robustness' of the study recommendations are not examined at all, e.g. the proposed time series studies may have sample size issues.

Executive Summary

Some parts of this, especially that within the literature review, would be more appropriately placed in the discussion. No mention is made of the inherent problems in this work – bias, retrospective, relatively small published literature etc.

CONCLUSION

In reviewing this document I have based my opinions on the premise that the report should confirm with normal scientific processes and writing conventions. The report does address all parts of the project brief. However it can be argued that the collection and summation of reports does not adequately cover the whole community who could be affected or are in a position to contribute useful information. The literature review lacks a critical element to it. In my view the report as a whole needs some

restructuring so that it more closely follows scientific conventions. Most of the required material is there but neither the review nor the data analysis and interpretation sufficiently challenges them. The recommendations require to more clearly based on the evidence presented previously in the document and their scientific robustness examined.

Comments by

Graeme Fleming,
General Manager Environmental Services
Municipal Offices
Garden Place, Hamilton

Thank you for your invitation to review this document. Before giving my comments, I would like to refer you to my previous advice to you regarding the limitations of my experience and qualifications in this field. With this in mind, I can comment as follows.

THE BRIEF

The brief, while clear, has considerable limitations. It does not allow the research to complete a full risk assessment taking into consideration other functions, such as mitigation and health risk avoidance techniques. In that respect, it was unclear to me what the overall intent of the brief was.

Other factors not considered and important to local government are to what extend the health effects can be described as "injurious or offensive to health" (Health act 1956). While this involves legal interpretation, it should be seen as a primary consideration and test for any health research of this nature to be founded on.

OVERALL LAYOUT

The report is easy to read and understandable to a layperson. It is, however, verbose in many places and would benefit from the use of appendices, which would enable the key components and analysis to be highlighted more clearly.

I have some concern that the Executive Summary does not fully reflect the limitations of the study and in particular the points made regarding self-reporting of symptoms.

PART 1 – FOCUS GROUP

The attention to indigenous people and in particular Maori, highlighted a number of serious communication challenges, however, overall the process of self-reporting and voluntary attendance at meetings did not provide sufficient independent evidence to be confident of results.

It is unclear why the majority of this research was conducted on Maori, as this did not appear to form part of the brief. Notwithstanding these limitations, the report highlights a number of fundamental issues, including:

1) The lack of trust in Government and its agencies

2) The fear of future effects

3) The fear of "mass dosing" by chemicals

Overall, this part of the study was not convincing either in its methodology, its statistical relevance, inherent bias and the apparent involvement of the researcher in the issues raised. Social research is inherently affected by the researcher's bias. It is not clear how any bias was managed or accounted for in this research.

PART 2 – HEALTH RESEARCH

The review highlighted the consistency of variable results from the studies undertaken over a number of years. It is acknowledged that it cannot be proven that BTK causes no health effects. In fact it is likely, due to many of the reported symptoms being associated with bioaerosals, that some health effects are likely.

What is not clear is whether the level of risk is unacceptable. As the study does not complete a risk assessment based on existing knowledge and mitigation procedures, the results do not answer this question.

The authors may also wish to consider the findings of Dr Peter Di Marco, who also reviewed the literature on behalf of Hamilton City Council. This report places considerably more weight on dosage and frequency in addition to outliing in some detail the placebo effect generated by aerial spraying. (Report available from Hamilton City Council or the Ministry of Health).

Overall, the report takes a precautionary approach based on likelihood rather than statistically based research.

RECOMMENDATIONS

All appear reasonable based on the findings of the authors. The responsibility for completing such studies and their interpretation should be made clear in order that one point of Government contact can be made for the public.

The report suggests that ERMA assessments were incorrect and in that respect a recommendation should be made to address this.

Thank you for the opportunity to assess this report.

Comments by

Donald Hannah,
ERMA New Zealand,
P O Box 131,
Wellington
New Zealand

on the review draft of the

"Assessment of the potential health impacts of the "Painted Apple Moth" aerial spraying programme, Auckland, New Zealand"

by staff of the Wellington School of Medicine for the New Zealand Ministry of Health

February 2004.

Introduction

1. The following comments are made with a view to enabling the review to more fully meet the requirements of the terms of reference cited. I have not commented on the typographical errors, confusion in following the formatting and some of the grammatical errors (data "are", plural of forum is either fora or forums, etc).

2. These comments are my personal views and do not represent, nor purport to represent, the views of the New Zealand Environmental Risk Management Authority

Background section

3. I'm bemused why animal studies were not considered. It is from these studies that data on acute toxicity, chronic toxicity etc are primarily established. Relying solely on human exposure and human cell-line studies severely limits the ability to conclude causality of effects from exposure.

Focus groups

4. The review does not clearly put the role of focus groups into context. Focus groups are only part of social science research methods and are a qualitative mechanism for establishing themes, issues and research questions. In themselves they provide little other diagnostic data. This should be more clearly articulated and the conclusions qualified with this information.

5. Focus groups should be selected to give a broad coverage of the population that would be the subject of subsequent quantitative research. In this way the range of themes, issues and research questions can be more confidently identified for subsequent investigation. The focus groups selected in this review involve Maori, Pacific Island and Asian groups. This gives the impression that other groups, especially European (New Zealand pakeha) are of such small presence in the exposed population that they did not warrant study. Evidence should be given to support this observation. Likewise the socio-economic spectrum of the focus groups, and its relation to the exposed population, should also be described. I have read several reports, some authored by WSM staff, that show that socio-economic status is a determinant of health status.

6. Thus, to determine the validity of the issues relevant to the exposed population, the extent to which the focus groups selected reflect the demographic and socio-economic spread of the population should be discussed. The conclusions and summary should stress these limitations.

Written submissions

7. The analysis and commentary of the written submissions obtained (93 from newspaper advertisements and 311 from the CC group) should also include analysis of the limitations of these data sources. If efforts have been made to control for selection bias and other confounding factors these efforts should be discussed. The relevance of the quantitative analysis (e.g. irritancy … 25%) reported needs discussion and qualification, otherwise it should be deleted and the responses used only to describe the range of symptoms reported.

Other data sources

8. There is no discussion of other data sources that may have been used. I strikes me that records of visits to the MAF doctors might have been made available. Were they sought and what did they contain? What other sources of community information could be sought. Discussion of the limitations of the data sources is lacking.

Literature review

9. I found this section quite confusing, sometimes contradictory and thus hard to critique. On one hand there is discussion of the limitations of the NZ, Canadian and North American (what is the difference between these last two categorisations?) community studies that casts doubt of the veracity of the conclusion that they have not shown any association between exposure and (adverse?) health effects. On the other hand, there appears to be credence given to the reports of the community group sourced data (Blackmore and NZEI) without similar discussion and analysis of scientific method or rigour used in these studies.

10. Further (and maybe I'm a little sensitive) there is criticism of the ERMA conclusion as being based on "… *the incorrect assumption that …irritant effects … are only seen in laboratory animals…*" whereas the peer reviewed North American and NZ studies show no association between exposure and health effects. Kalemba says people may complain of some effects but the association and causality of these effects with exposure was not established in that report.

Bioaerosols

11. This section needs further expert review. The hypothesis that aerial spraying is creating aerosols that have the potential to cause the effects reported in the occupationally exposed populations is untested. While I am not that expert I do know that the size of aerosol production is dependent on a variety of parameters such as nozzle size, flow rate, solution composition and viscosity, and atmospheric temperature and humidity. It seems to me that not demonstrating that the aerosols the population is exposed to are sufficiently similar to the aerosols the referenced occupational population is exposed to casts doubt on the validity of this information.

12. Further, the extent to which the previously referenced NZ and North American studies addressed this issue (and if they did not why not) should be discussed.

Recommendations for further research

13. These seem quite comprehensive. I think that making it clear that in addition to the epidemiological studies, quantitative research on the range and distribution of reported health effects, appropriately controlled for potentially confounding demographic and socio-economic factors, would provide clearer insight into the relevance of matters covered in this review.

Executive Summary

14. This needs much tighter editing. There are statements made here that I could not trace into the body of the review. There are also speculative conclusions made that seem at odds with the conclusions of peer review publications. The review will benefit from having a good science editor write the executive summary after reading the review report.

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Peer review of "Assessment of the potential health impacts of the "Painted Apple Moth" aerial spraying programme, Auckland, New Zealand", by Wellington School of Medicine, Draft dated December 2003

David Sinclair and Virginia Hope
Public Health Medical Specialists
Auckland Regional Public Health Service

February 2004

Background

Auckland Regional Public Health Service (ARPHS) (and its predecessors) has had extensive involvement with the two moth eradication aerial spray programmes in Auckland.

During the White Spotted Tussock Moth programme in 1996/97 this included

- preparation of two health risk assessments on aerial application of Btk in conjunction with Jenner Consultants (subsequently AerAqua Medical Services), and a HRA on another insecticide which was not used, based on the HRA.
- responding to phone calls and letters from the public on health concerns,
- advising the Ministry of Forestry on health-related issues and
- research work for the health surveillance programme following the spray programme

For the Painted Apple Moth programme, ARPHS:

- prepared an updated health risk assessment
- provided advice to MAF on health-related issues
- provided advice to the PAM Health Service
- responded to phone calls and letters from the public on health concerns

ARPHS's involvement in the PAM programme has been much less than it was for the WSTM programme because of the establishment of the PAM Health Service. Clinical enquiries were referred to this service, as ARPHS does not have the clinical capacity or funding for this work

Dr Hope was on the Epidemiology Advisory Group for the Long Term Health Surveillance Programme for Operation Evergreen and is on the Technical Advisory Group for the Southern Saltmarsh Mosquito eradication programme. Dr Sinclair is on the Ministry of Agriculture and Forestry's Health Advisory Group established to provide advice on the health issues related to control of moth pests.

The review comments reflect this organisation's involvement in the aerial spray programmes, through preparing the risk assessment reports, dealing with people with health concerns and effects, and from experience of the community dynamics and operational issues.

Most comments are given as boxed italics in the text of the report

General comments

The report includes useful information on symptoms, which is consistent with a range of other sources from most spraying programmes in New Zealand and elsewhere. However, the report needs substantial revision before it is rigorous enough for publication or used to inform policy. We have provided detailed comments (hence the time taken) because there are significant gaps in the report, and significant problems with the interpretation of research information. We will need to see and provide comments on the next draft before being prepared to be acknowledged as peer reviewers.

The focus group section of the report provides useful feedback, and illustrates some important aspects of community perceptions and problems with communication. The focus group section is primarily reporting of the meetings, and doesn't include much depth of qualitative analysis. As noted in the method section, the focus group work was limited to selected Maori, Pacific and Asian groups. It would be difficult to extrapolate to the rest of the Maori, Pacific and Asian communities, let alone the other residents in the spray zones. There is no analysis of the veracity of statements made, which would be expected for this type of work: verbatim reporting rumour is insufficient basis for potential changes in policy or programmes (e.g. on funding for advertising).

There is no reporting on the key informant interviews/meetings with ARPHS, Aeraqua, interest groups and MAF. This needs to be included.

The literature review section is limited in scope, and would have benefited from a more extensive review of existing health-related literature and consideration of Bt biology and ecology. A number of conclusions and inferences made in the report are not substantiated by research evidence, or are not validly drawn from that research. These are noted in the annotated text below, and we have provided extensive comment because of the limitations of the analysis. The draft has dabbled in some aspects of Bt biology, but hasn't dealt with the range of relevant published material in depth, and doesn't convey an understanding of the relevant aspects of Bt biology for

human health. We strongly recommend a wider consideration of health and biological information. The monograph by Glare and O'Callaghan, from AgResearch Lincoln, would be a useful starting point. We recommend that detailed input be sought from microbiologists familiar with the relevant material on Bacillus species.

The review doesn't cover the inactive ingredients or culture materials to any extent, both of which have been of public interest, and are likely to be the source of most symptoms. Unfortunately, the ingredient list has not been released, but the general nature of them is known publicly. Comment from a toxicologist familiar with insecticides would have been useful. Of possible use may be a summary paper prepared by ARPHS prior to the Asian Gyspy moth spray programme in Hamilton in late 2003 (copy attached to e-mail), and the review undertaken for the Hamilton City Council by an Australian toxicologist (copy attached to e-mail).

The literature review does not analyse information on specific conditions or concerns raised by the public or the focus groups, such as asthma, gastrointestinal illness or allergy, in a systematic way. The section on potential pathogenicity (primarily about infection) is limited, and would benefit from inclusion of wider information sources, such as information on manufacturing processes and quality control.

There is no assessment of whether the PAM Health Service was useful to the community as a whole.

The research recommendations seem rather unstructured, and need further description. How do they relate to unanswered questions identified in the report?

We'd strongly recommend that an atmospheric scientist familiar with the Auckland situation review the section on aerosol exposure and PM_{10}, as initial feedback from a NIWA scientist was that the method was questionable. Hamilton City Council's toxicology report includes some approximate exposure calculations which may be useful.

A specific survey may have been a better method to assess the breadth and extent of responses to the spray programme than focus groups, or at least to supplement them, although this could be seen as research and so outside the scope of the project.

Overall, we consider that the report has a considerable way to go before it can fulfil the terms of references.

Annotated text of Draft Report

[Comments in italics and boxed]

Executive summary

Background

Since January 2002, the Ministry of Agriculture and Forestry have been undertaking aerial applications of Foray 48B in Auckland in an effort to eradicate the Painted Apple Moth. Foray 48B is a commercial insecticide containing Bacillus thuringiensis (*Bt*), *you should be a bit more exact – F48B contains specific strains of Bt var kurstaki]We are aware that there are different strains of Bt but find this simplification helpful* -a spore-producing bacterium that is toxic to certain insects. Researchers at the Wellington School of Medicine were asked, by the Ministry of Health, to

"…receive, collect, and summarize reports from the public, community groups, territorial authorities, Aer Aqua and the Auckland Regional Public Health Service (as well as other stakeholders, community groups, organisations and individuals) on the health effects, symptoms and concerns associated with the Foray 48B aerial spraying programme. To summarize existing scientific knowledge relevant to the health effects, symptoms and concerns and recommend (but not carry out) scientifically robust methods for further study.."

Health concerns reported in submissions and/or focus groups

In response to a call for submissions, the most frequently reported symptoms were

- Irritant symptoms: sore throat, headache, blocked nose (25%)
- Respiratory symptoms: chest tightness, asthma exacerbation, cough (16%)
- Gastrointestinal symptoms: diarrhoea, vomiting, stomach cramps (14%)
- Flu- like symptoms: fever, malaise, swollen glands (13%)
- Skin rash (9%)

Similar symptoms have been reported in other studies of workers and communities exposed to aerial spraying of products containing *Bt*, both in New Zealand and overseas.

[Other examples being the feedback to the Waitakere City Council in early 2003 (see attached summary for Hamilton AGM programme), and the Canadian research. Many of the respiratory symptoms may well be attributable to the irritant effect. It would have been useful to know the duration of irritant symptoms – for many people these would have been very short lived, going from the experience of callers, and personal exposure of one of us (DS).] The gastrointestinal symptoms are more difficult to assess, given the lack of pathogenicity of Bt preparations in experimental feeding studies.] no response needed here

Those with existing conditions, such as asthma and hay fever, often reported that these conditions were aggravated following exposure to spray. About 5% of people

who wrote in *of* ***people who wrote in*** *– this in no way relates to the whole population and shouldn't be implied that it does. You'd need to do surveys to establish symptom prevalence/incidence OK good point, text amended* reported no health effects *should you differentiate health effect from health concerns and symptom which may or may not indicate a health effect ? where possible, we will interpret where concerns or symptoms may relate to serious health impacts (eg chronic disease) ~~.~~? E.g. if you get shampoo in your eye, it stings, but is this a health effect? Probably not, even through there will be a physiological effect and conjunctival cell damage…*. Many expressed concern for the young and elderly. Some expressed uncertainty about health effects for future generations.

Other impacts included disruption of day to day life, compounded by lack of certainty about which day the spray would occur. All participants reported staying indoors and closing windows when the spraying occurred. There were frustrations over having to wash cars, windows and laundry.
This is important, and confirms feedback from elsewhere.

Review of scientific literature

Bt products have been used as insecticides since the 1950s. *Bt* is closely related to Bacillus cereus, a bacterium which is known to cause food poisoning. *[You haven't pointed out that Bt is closely related to B anthracis, cause of anthrax and a bio-terrorism weapon [(;->)].OK- There is a lot of material which should come between the two sentences at the start of this paragraph, on Bt biology, ecology, the range of research on it and its effects on mammals including humans etc.we have focussed on the epidemiological evidence since that is our area of expertise]* Because normal clinical practice does not distinguish between Bacillus cereus and Bacillus thuringiensis, the relative contribution of these Bacillus species to human disease is unknown. Foray 48B contains a particular subspecies called Bacillus thuringiensis *kurstaki (Btk).*

[This paragraph is quite misleading, as it could be read to imply that Bt could be widely causing food poisoning, without it being distinguished from B cereus, of which there is little (or no) evidence in our view, that would be a reasonable conclusion. A basic knowledge of the genetics and taxonomy of the Bacillus genus, their toxins and their biological action would have been useful for your background information OK, we are aware of these issues and will add a summary. Bc and Bt are not differentiated in routine diagnostic medical laboratories, but we are aware of situations where Bt has been identified from clinical specimens in Auckland laboratories. However, the speciation of Bacillus should be well known to research microbiologists working in the topic, so researchers should be using techniques which do differentiate them. The PAM HRA did review at least one paper where the differentiation was not made, leading to some dubious conclusions, as you're in danger of doing here.

During the PAM programme we enquired with the local laboratory about differentiating Bacillus isolates, but this did not progress primarily because of cost. However, it would be possible to see if there were different rates of isolation of bacillus species in the spray area, compared with an unexposed control community, although this would be rather insensitive.

Glare and O'Callaghan's monograph would be a useful starting point for you, as would be a review of genetic taxonomy by XXX. We were informed by the manufacturer that manufacturing standards for Bt-based insecticides from the USEPA require assays of enterotoxin and have quite tight controls. The fact that enterotoxin is not present in the product when sprayed does not preclude the possibility of enterotoxin being produced during subsequent growth in the environment - or people… see: (Jensen et al. 2002a; Jensen et al. 2002b;Hendriksen and Hansen 2002)]

In previous surveys of spray workers and communities exposed to *Bt* products, there have often been reports of short term irritant symptoms (such as sore throat, headache, blocked nose). More serious symptoms, such as exacerbations of asthma, skin rashes or flu-like symptoms have less frequently been reported. The pattern of reported symptoms in workers and communities exposed to Foray 48B is consistent with the known effects of bioaerosol exposure.

[See below for comments re asthma and bioaerosols]

The literature indicates that Foray 48B may have the potential to cause more serious health impacts in sensitive individuals. *Bt* products have the theoretical potential to cause allergy to chemical or biological components of the spray. When sprayed from aircraft, *Bt* products has been shown to be present in indoor and outdoor air as very fine acidic "bioaerosol" particles that may be inhaled deep into the lungs. This raises the theoretical potential for *Bt* products to cause a range of chronic respiratory diseases that have been documented in people exposed to bioaerosols in the workplace.

[See below for comments on speculating beyond the weight of evidence.]

The level of exposure causing these occupational diseases is probably substantially higher than that typically experienced by New Zealand communities exposed to *Bt* aerial spraying programmes. On the other hand, the most sensitive individuals tend to avoid occupations that lead to bioaerosol exposure, dose-response relationships from studies of workers probably underestimate effects in communities. As far as we are aware, there are no studies of the potential long term effects of exposure to *Bt* products from aerial spraying operations on either communities or workers.

More speculatively, there is also the theoretical potential for other human diseases triggered by biologically active chemicals produced during growth of *Bt*. In toxicology experiments using human cell cultures, growth of *Bt* has been shown to have a variety of effects, including cell damage and immunological effects. The public health significance of these findings is unclear.

[In this sort of report, speculation without substantial backing from research information is not valid. Our conclusions have "substantial backing from research information" as given in the references.

Among other things, it tends to fuel the "Harrison's Index" response - the spray must be presumed to cause all diseases starting with A unless proved otherwise (which is impossible of course), even if biologically implausible, and there's always B and C and others to follow. In the case of Bt, the theoretical potential has often been disappointed by actual research.]

Several studies of communities exposed to aerial spraying of *Bt* products have been carried out in New Zealand, Canada and North America. The largest and most detailed of these have not shown any association between exposure and health effects. However, all of the epidemiological studies that we have reviewed have one or more limitations, including:

- small sample sizes (therefore a lack of statistical power to detect a health effect, even if present) (Noble et al. 1992; Anon 1999; Aer'aqua 2001; Anon 2001a; Pearce et al. 2002a; Pearce et al. 2002b; Petrie et al. 2003)
- subjective or potentially biased assessment of health effects (Petrie et al. 2003)
- potential or actual exposure of control groups (Noble et al. 1992; Anon 1999; Aer'aqua 2001; Anon 2001a; Pearce et al. 2002a; Pearce et al. 2002b)
- limited duration of follow up (Noble et al. 1992; Anon 1999; Aer'aqua 2001; Anon 2001a; Pearce et al. 2002a; Pearce et al. 2002b)

The largest of the community surveys have included, at most, 500 participants in "exposed" and "unexposed" groups. These surveys have limited ability to detect effects that occur in a small proportion of exposed people. For example, suppose we know that a given symptom actually occurs in 50% of unexposed people, and 55% of exposed people. In order to have 95% confidence of being able to demonstrate that symptoms are experienced more frequently in the exposed group, a study would need over 2000 people in each of the exposed and unexposed groups. This example assumes a standard (95%) level of statistical significance.

The existing community surveys (Noble et al. 1992; Aer'aqua 2001; Pearce et al. 2002a; Pearce et al. 2002b) cannot prove that *Bt* products cause no important health impacts in exposed communities. Health impacts can be substantial and important whilst at the same time being difficult or impossible to measure without careful study of very large populations.

[It's important not to fall into the trap of the impossibility of proving absolute safety, as the paragraphs above are in danger of doing. The inference certainly reads that absolute safety cannot be shown, therefore any adverse effect is plausible. This is not tenable. The issue is not absolute safety (which we agree is not attainable), it is about what level of uncertainty is acceptable. The existing evidence does not allow us to exclude the possibility that a given symptom or disease increases from 50% (in the unexposed community) to 55% (in the exposed community).

It's reasonable to assume that the researchers haven't set out to "prove" safety of Bt sprays, rather to describe the situation and assess possible causal links (which has proved difficult to find anything other than self-limiting irritation and related

symptoms, and possible GI symptoms for some Bt strains within the populations of the studies.

In the health risk assessment and management arena it's generally better to describe what is know[n] with reasonable confidence, make judgements based on available evidence about what's uncertain and identify areas where further research would be needed, but avoid speculation. Conversely (and importantly in a regulatory and pragmatic environment), what can be said from the community-based research listed and laboratory research is that if there is a problem it is probably less than XYZ, and the question is then whether this is acceptable (and to whom). Agreed. What we are saying (above) is that there is currently a high level of uncertainty, and that on current epidemiological evidence, an increase in symptoms from 50% to 55% cannot be excluded. We do not describe that as acceptable (we are not in a position to) and we do "and identify areas where further research" as you suggest.

You have failed to note that the largest population-based surveillance studies have covered tens of thousands of people. Population-based surveillance has covered large populations (as noted in the main text). This provides limited reassurance that exposure to Bt probably does not cause a dramatic increase in serious disease. It is not good evidence of overall safety.

While noting that self-reported data are subject to potentially serious biases, we note that:

- *Bt* products can form a bioaerosol
- the most frequently reported symptoms are consistent with the known acute effects of bioaerosols, and
- these symptoms are reported to occur in the hours or days following exposure

[Further than this, you can actually say that irritant effects (which are generally transient and self-limiting) are well described, as would be expected from a mildly acidic and hypertonic aerosol. No response needed -See below for other comments re bioaerosols.

Recommendations

Background

Since January 2002, the Ministry of Agriculture and Forestry (MAF) have been undertaking aerial applications of Foray 48B over western Auckland in an effort to eradicate the Painted Apple Moth (PAM). MAF have funded a health monitoring and treatment service but there are anecdotal and published reports of health concerns, which the MAF-funded programme may not collect.

[It would be worthwhile at least characterising these situations.– A number of people have called the APRHS with symptoms or concerns who have not gone to the PAM health service (PAMHS), or have not been satisfied with the result. These range from those who don't believe that the PAMHS could be objective because of their funding source, those where there may well have been an error, to those whose symptoms are clearly not related to spraying (eg no plausible exposure), but the caller won't accept this. However, it's worth pointing out that the nature of the symptoms which these callers had is quite consistent with the range of symptoms which people who did go to the PAMHS had. The range of symptoms of PAM HS callers is also entirely consistent with the people who wrote to WSM for this project] OK.– this is helpful additional information which we will include in the updated report.

The Minister of Health has directed the Ministry to "contract a university to receive written submissions from the public regarding their health concerns related to PAM. The University will analyse these and report their findings to the Director of Public Health." A media statement was released announcing the proposal and has received generally positive support from all political parties, the territorial authorities in west Auckland and the community.

The Wellington School of Medicine was asked to "…receive, collect, and summarize reports from the public, community groups, territorial authorities, Aer Aqua and the Auckland Regional Public Health Service (as well as other stakeholders, community groups, organisations and individuals) on their health concerns associated with the Foray 48B aerial spraying programme... review existing scientific knowledge relevant to these health concerns, and recommend (but not carry out) scientifically robust methods of further study."

AerAqua is currently undertaking a detailed analysis of presenting health issues for the >3000 callers to the PAM Health Service. This will be a crucial information source, giving more detailed information than any study to date, but isn't mentioned in this report. Recommend you contact AerAqua on this. We did ask them, but received no response.

ESR was subcontracted by the Wellington School of Medicine to conduct the focus group component of this wider inquiry. The data obtained from the focus groups would compliment the call for written submissions on health effects. In total, four focus group interviews were conducted with Maori, Pacific and migrant groups in the Waitakere area. Data obtained from the focus groups, and from several Waitakere City Council community and governance forum informs this report.

Literature searches for “Bacillus thuringiensis” and “Foray 48B” were conducted on the internet, including Medline and Web of Science databases. Where possible, original articles were reviewed in full. Where relevant, in cases in which it was not possible to obtain full copies of original articles, citations in authoritative sources have been included. The review was limited to studies of humans or human cells. Animal studies were not considered.

[The resulting reference list, however, is quite limited, compared with that in the HRAs from NZ and elsewhere, and the cross-referenced sources from those papers. The review would benefit from being based on a broader understanding of the biology, ecology physico-chemistry and physiology of the organism and the spray materials, and their interaction with and effects on human (and other mammalian/vertebrate) physiology. We have included those references which we consider the most relevant to the public health issues.–The risk is a report which picks interesting or new information, and takes it out of context, so opening the possibility of selective interpretation by the reports’ many audiences. Selective interpretation is a risk regardless of how the report is written. We prefer not to exclude information simply on the grounds that it might be misinterpreted.]

Focus groups

Methods

The Focus Group technique

The focus group interview is an exploratory tool that yields 'rich' qualitative data in which key patterns or themes can be detected. An increasingly popular method for health research, "the focus group is a collectivist rather than individual research method that focuses on the multivocality of participants' attitudes, experience, and beliefs" (Madriz 2000). This method also allows the researcher to observe group dynamics and everyday interactions between the participants, adding to the richness and authenticity of the data.

In context of the wider Wellington School of Medicine study, the focus group approach allows for triangulation (Ezzy and Rice 1999) to test whether the data obtained from these forum gives similar or different results to the written submissions and other components of the research.

Furthermore in this instance, the focus group method enabled something of a dual task; of research (using the focus group to explore and test existing knowledge), and consultation (in providing a forum for dialogue, and satisfying expectations amongst some locals that the voices of their community be heard by government). However, whilst those participating may have felt they were being consulted, in the sense of being listened to, the researchers were careful to point out throughout that they did not represent government, nor did they carry a mandate to convey a government response. Essentially the focus group method is a group interviewing tool to obtain data. It is not a method for decision making or developing two way dialogue.

Targeting for the Focus Groups

Because there were not resources or a mandate in this project for full public or community consultation, the focus groups were selected carefully. The following criteria helped guide the selection;

- People living in the Waitakere area within the aerial spray zone.
- Voices not already heard in the process, (groups who might not voice their concerns in writing, and those whose concerns may not already be articulated by the interest groups[1] opposing the spray)

On this basis, it was decided to target the following groups within the Waitakere community;

- Mana whenua, tangata whenua, taurahere - pan-tribal (urban Maori)
- Pacific peoples
- Migrant groups

[1] These include CCPAM, (Painted Apple Moth Community Coalition), STOP (Society Targeting Overuse of Pesticides), SAS (Stop Aerial Spraying), WASP (West Aucklander's Against Aerial Spraying), MASK, (Mothers Against Spraying Kids), TASK (Teachers Against Spraying Kids), PANANZ (Pesticide Action Network Aotearoa NZ), GASP (Group Against Aerial Spraying), Sprayfree Coalition, No Way Spray, and the Spray Action Group.

Whilst the decision was made not to include interest groups, Ranui Action Project (RAP), a group with some involvement in forum opposing the spray campaign were invited to be part of the focus group research. This was on the basis that RAP are based within the spray zone and provide health and community services to Maori, Pacific, and others in their area. Thus, they were felt to have good local knowledge and networks, and be able to comment on health effects and other effects in their community. RAP unfortunately did not respond in time to be included in the research.

Process for Setting Up the Focus Groups

Firstly the researcher contacted local authorities, especially Waitakere City Council, and health providers such as A+ Health, and the Waitemata District Health Board to explain the project and focus group targets. Key people within these organisations advised on who they felt needed to be included in the research.

With guidance, the researcher began by contacting mana whenua for the Waitakere area, Ngati Whatua and Te Kawerau a Maki.

People within the Ngati Whatua Corporate were interested in receiving a copy of the final report but deferred involvement to Ngati Whautua o Orakei Maori Trust Board. In turn Ngati Whautua o Orakei Maori Trust Board deferred to Te Whanau o Waipareira and Hoani Waititi Marae, as those best representing Maori living in the West Auckland area[2].

Te Kawerau a Maki Trust represent the ancestral claims to the area of Te Kawerau a Maki. Ngati Whatua also claims mana whenua to this city. Both mana whenua have claims being heard before the Waitangi Tribunal. Te Kawerau a Maki Trust and Ngati Whatua were closely involved in the consultation with MAF, and are currently negotiating a Memorandum of Understanding for local Maori with MAF. In talking with local Maori about the area, it was ascertained that Te Kawerau did not have a marae inside the spray area. Based on the early conversations about the focus of this research, local capacity and timing, a decision was made not to conduct a formal focus group with Te Kawerau a Maki. Some data was instead collected from informal interviews with key people from Te Kawerau a Maki Trust.

For West Auckland, Ngati Whatua and Te Kawerau a Maki are tangata whenua with mana whenua, the responsibility for protocol for the area. Waitakere is unique in that alongside Te Kawerau o Maki and Ngati Whatua, Te Whanau Waipareira are also recognised as tangata whenua and have an important presence in the area. Aspects of this relationship are detailed in the Te Whanau o Waipareira Report (1998). Te Whanau o Waipareira Trust act for the health and wellbeing of urban or pan-tribal Maori in the West Auckland area and are the key provider of a range of health and other services for Maori, and the wider Waitakere community. There is an intimate connection between Te Whanau Waipareira and Hoani Waititi marae, with this being an important physical space for pan-tribal Maori living in Waitakere.

[2] Waitakere demographics typify many urban settlements, where taurahere or pan-tribal Maori have a significantly larger population base in the area than the mana whenua.

A colleague used similar process of local networking and referral to bring together a group of Pacific health providers in the Waitakere area.

For the migrant focus group, the researcher firstly contacted the Auckland Refugee and Migrant Services and was referred to coordinators within the Waitemata District Health Board who organised the group. The group who attended were not leaders from different refugee and migrant communities, but a group of Chinese and Korean hospital volunteers. Whilst this was not exactly what the researcher had in mind, the data gained in this group gave valuable insights.

Local knowledge and networks were key to the utility of the focus group approach for this research. Given that the lead research organisations were Wellington based, the local knowledge and advice was especially necessary, and a huge strength. In response to local advice, the research mandate began to broaden slightly into consultation. Mainly this was about keeping those representing Maori and Pacific interests in key governance forum informed. Thus, as well as the four focus groups, the report looks also at the data obtained from various governance forum associated with the Waitakere City Council.

After negotiating access to each organisation, a time and date was arranged for people to attend a group interview. An information sheet was emailed to a contact person within each of the organisations approached. These people were asked if they could invite others they thought might be interested from their organisation. Refreshments were provided for those attending. The researchers imposed limits on the number of people attending, in order that the group dynamics and data could be managed effectively.

Data Collection

At the meeting, each person attending was given an information sheet outlining the purpose of the research and what would be done with the data. The researcher talked through these agreements with the group. There was opportunity for the group to ask questions before giving verbal consent for the interview to be recorded electronically. Where possible this data was later transcribed.

The focus groups were mostly facilitated by the author, with the questions on the information sheets used to guide the conversation. For the Wai Health interview two researchers were available to facilitate. The Pacific focus group was arranged and facilitated by a Pacific researcher from the Wellington School of Medicine. Notes were taken at this group, with a summary provided for analysis.

Could you include the questions from the information sheet please. To what extent were the focus group discussions structured? How was data structured and analysed to be useable for the qualitative analysis, e.g. identification of meta-themes?

In the focus groups and other forum the researchers were identified as the ‘painted apple moth ladies” or the “people from MAF”. Many of the people we met were upset with the government and wanted answers to their questions, - “when it is going to end ?” being most commonly asked. A distancing from MAF and government was

helpful in introducing the research and setting up the focus group as a comfortable talking space.

Data Analysis

Using the transcripts, a general inductive approach was used where each transcript was read individually with key patterns and themes coded by the researcher. Patterns in the data between the different groups were similarly coded with the analysis presented for discussion. Field notes and observations from each of the focus groups and from interactions in other governance forum also inform the analysis.

Limits of the Focus Group Method

For this project, perhaps the key limitation is the ability to determine the extent (frequency or intensity) to which the issues discussed in the focus group are experienced across the wider community. For instance, whilst respiratory and sinus problems were commonly raised in each of the groups, the data from the focus groups is not useful in measuring how prevalent these conditions are within the wider community, or the extent to which the people in the focus group represent the concerns of the wider community. Knowledge of distribution in health or value patterns across the spray area population would have been best attained using the survey method.

The focus group is also limited as a tool for ensuring demographic representation. Whilst for some research[3], different types of representation can be structured, the scope of this project meant that any attempt to do this would have been tokenistic. Whilst certain demographic characteristics, such as ethnicity, were sought, it is impossible to structure attendance at the focus group to ensure fair representation of a myriad of diverse 'positions' and individual viewpoints within the different ethnic communities. Thus, this method does not guarantee reliable representation within a given community[4] a) in the range of concerns expressed and whether the members that attend on the day represent and articulate the viewpoints of those in their wider community (although the researcher can ask questions to help determine this); or b) in how well the people at the table represent gender, age, ethnic or class distributions across their professional group or the wider community.

Constraints in time and budget were other significant limitations for the effectiveness of this component of the research as a tool to access the voices of the Waitakere community and explore health and other impacts of the PAM aerial spray programme.

In order to address some of these limitations, and get the best view possible of health concerns across a community, the Pacific and one of the Maori focus groups targeted people working within key health provider organisations.

[3] These would typically be focus groups associated with product or clinical research.
[4] May need a definition of community (refs)

Results

This section presents the data obtained from each of the focus groups. Background information on composition, and, where appropriate, the role each group plays in the Waitakere community is firstly given with the researchers presentation and commentary on the data following.

Hoani Waititi Marae

Background

Hoani Waititi marae is located in part of Waitakere which, according to locals, is heavily sprayed. Hoani Waititi is the place of grounding or focal point for the pan-tribal kaupapa for Maori living in the Waitakeri area. Established in the early 1960's and named after John Waititi, a prominient Maori Educationalist , Hoani Waititi is seen as an integral part of evolution of Te Whanau o Waipareira, and in its establishment became a place for Maori coming to live in the Waitakere area "to learn from", "belong to and identify with". This was a place to ensure that Maori culture and traditions could continue in a city environment. The Hoani Waititi community and infrastructure continues to grow, and includes kura and recreational facilities.

Composition

Six kuia and kaumatua in the middle-aged to older age group attended the meeting. Gender was evenly balanced. All were very warm and welcoming of the researcher and were grateful to have their concerns heard. All were angry about the impacts of the spray programme on their health and community. Unfortunately the data was not recorded electronically and is based on the interviewers notes. The notes were returned to Hoani Waititi for amendment.

Data

The dominant theme of this interview is the lack of information, with significant impacts ensuing for the health and wellbeing of the community.

A key finding is that the information distributed by MAF about the PAM aerial spray campaign did not reach those living at Hoani Waititi marae. For kaumatua and others staying on the marae grounds, there is no mailbox on the street.

"We have a post office box yes… we don't have a mailbox on the main road, the postie doesn't come down to our houses, so we don't get any information that way"

For those attending the focus group, this meant that the first knowledge they had of the spray campaign starting, was when the plane flew overhead.

"when the plane sprayed on top of me that's when I first knew … now I know when I hear it, I run inside"

Others had seen news items on the television, but remember it becoming a news item only after the public complained.

"there was some stuff on TV at the start, but this was only after the spraying started and the community reacted", .. "and the health effects were never mentioned"

At this point the researcher asked to what extent Hoani Waititi or the Waitakere City Council's Te Taumata Runanga group were included in decision making. The views from the group were as follows;

> *"MAF made this decision, the council was anti this. This was a decision from the government in Wellington, it was not a local decision"*
>
> *"it was very top down"*
>
> *"the community was not consulted, and ways of approaching this, other than the aerial spraying, were not considered"*

The fact that those attending the group did not have prior knowledge of the date of the first spray, or what to expect when the spray programme commenced, may account for some of the anger in the group. Also, there was strong feeling that this was not a decision that they had been involved in. Had the decision been made locally, the approach for eradication may have been very different;

> *"Its costing millions, I get really angry when I think that money could go into paying the community, PD gangs, unemployed or others to do this from the ground"*
>
> *"yes, why do that have to do it from the planes, it would be better from the ground, the sprayers can get underneath the trees from the ground "*

The group question both the efficiency and equity of MAF's chosen approach. The money could be used for more effective eradication programmes and could benefit the community.

As well as anger, a further consequence of the lack of information and lack of ownership or involvement in the decision, is a high degree of uncertainty. Of all the groups, Hoani Waititi expressed the strongest concern about uncertainties and the safety of the spray for future generations. These concerns might also be stronger because of the age of the people attending this focus group, and their status and role as kaitiaki or guardians for their community. Acknowledging this, the frustration at their lack of knowledge seems to underpin the ways that these concerns are articulated;

> *"This goes further than today. We don't know if it's going to be one of those things like DDT or Agent Orange. There's a lot we don't know here"*
>
> *"What about our children in 10 or 20 years time, what about them?"*
>
> *"Yes I have a lot of questions – we haven't even been told what's in the stuff !"*

The conversation goes to what the spray looks and feels like.

"I see that stuff on my car, this sticky yellow gunge and I know its not good for me"

"it tastes bad, a metallic taste" … "my eyes sting"

The group continues, describing impacts on everyday life and disruptions to routine. These include the extra cost and labour involved in washing windows, washing cars, and rewashing all the laundry on the line during the spray.

"I get sick of cleaning the car, its really difficult to get the stuff off, its really sticky, that's what gets me … "we don't need this extra work on top of what we already do"

"For me, I don't like the way it turns the curtains yellow – who's going to pay for that ?"

"we shut the windows but it still gets in, its sits outside for days, we get exposed when we go outside" … "and we bring it inside on our clothes, it gets everywhere"

The last comment reveals how people take precautions, but cannot avoid contact with the spray. The person making these comments is frustrated by the lack of control they have over the exposure.

Noise is also an issue with the low flying application method being invasive and discomforting. One person was talking on the telephone and could not continue the conversation whilst the plane flew overhead.

"The planes fly really low too, I feel I could almost touch them with my hand if I stood on the roof"

"and its not just one spray, each time it's a spray day, its up and down, up and down, they fly over five or six times" … "and the noise … "

Most profound for this group are the health effects;

"the asthma and respiratory problems are the worst, for all of us in this room, our health has gotten worse since the spray programme started"

"I never used a puffer until last year"

"I've been in hospital with respiratory problems four times this year – I've been really sick, pneumonia, .. we now have a nebuliser at home for me, I never used to need that".

"it affects my liver, my kidneys, I can feel it"

For this group of elders the effects of the spray in aggravating existing conditions are serious, and for one have resulted in repeated hospitalisation. The researcher asks if they have considered leaving the area.

"we go inside and shut the windows, we don't go out of the area, we don't get notified when it is happening so we don't know to make plans to leave the area or anything"

The lack of information makes it difficult for the family to make decisions to protect their health. Further questioning revealed that there are numbers of people in the community who are sick but are not seeking medical advice. All the people in the focus group suffered respiratory affects, but most did not go to their doctor and only some went to the pharmacy for medication. No one in the group knew the MAF helpline number, nor did they see any point in going to the MAF doctors who were felt to be a waste of time and there only "to tell you that you were not sick".

There is also worry about the effects of the spray on the young ones, and those who are pregnant. Again precautions are taken.

"we keep them in doors when the spraying happens but it is still outside the next day, and the next"

"we worry about the ones that are pregnant too, we tell them to stay inside"

Other less serious impacts on health relate to nutrition. Lack of choice is a theme, with some in the group reluctant to purchase fruit and vegetables that have been locally grown.

"even the fruit and veges we buy from the local shops have probably been sprayed so we can't avoid it"

Children are not encouraged to eat fruit or play outdoors after spraying, but the elders can't control this totally. Depending on the frequency of the spray, these choices could impact on healthy lifestyle.

"we need to tell the young ones to wash the fruit, but they don't always do this, they are used to seeing an apple in the tree and eating it – so that is something we try to change"

"we are concerned about the elders and the mokopuna, some of our children and grandchildren get rashes when the spray happens"

"its in the rivers, the streams and the kids play in that"

"we know of quite a few families who have stopped growing their own vegetables since the spray started"

As well as impinging on mahinga kai, and the rights of the tangata whenua to live off the land, there are detrimental economic impacts from decision not to grow vegetables, and to purchase produce grown away from the area.

Near the end of the interview, the people in the group continue to feel angry.

"we don't know when it is going to end"

"we have had enough and would like to stop" … "yes when's it going to stop?"

"I'll tell you too, this wouldn't happen if we lived in Howick, I think its happening here because we are poor !".

The researcher asks if there are any benefits. The viewpoints are unanimous and forthcoming.

"I haven't seen any benefits"

"there are no benefits whatsoever"

"this is what we hear from our community, there is nothing positive for us here"

"yes, we listen to what our community says, there are no good reports from them"

Wai Health (Te Whanau o Waipareira)

Background

Wai Health is the health provider services for the community of Waitakere. It is a ket structure in the umbrella of the Te Whanua o Waipareira Trust.

As discussed earlier, and elaborated in the Te Whanau o Waipareira Report, Te Whanau o Waipareira does not claim to represent tangata whenua, but rather "exercises a mandate in respect of a community of Maori who have come together for the purpose of maintaining cultural integrity in an urban environment". A "pan-tribal" organisation that deals with "cultural, social, educational, and health issues" it is also "largest service provider in West Auckland". Having momentum long before this, Te Whanau o Waipareira officially came into being in 1981, with a charitable trust structure adopted in 1984. It's growth is described in the Treaty Report as an evolution of the whanau support structures that emerged in response to rapid urbanisation of Maori, and the growth of West Auckland as major settlement.

Composition

Approximately ten people were at the focus group, with some movement in and out throughout the korero. Those attending were predominantly Maori and predominantly women, with only one man present. All were health providers, promoters or educators working for Wai Health. All were lively and vocal, and felt strongly that the spray programme had impacted negatively on the health of the community. Whilst they were very welcoming of the two researchers, they made it clear they were angry at government. As in other forum, it was emphasised that the researchers role was to help ensure that the voices of the community were heard by government.

Data

In this group the lack of information was a point of frustration which became a dominant theme.

> *Just sprayed. It wasn't until later that people started to be getting crook, or whatever, and then you got the protests happening. Then a bit more information.*
>
> *And all right if you're reading Healthy Options or Organic NZ - they had a lot in it right from day one.*
>
> *Ha! How many Maoris and PIs read those?*
> *Or how many people understand their language? Yeah, that's right!*

In absence of information from the government, people begin investigating the issue themselves. The point was made that many of the alternative information is not accessible to Pacific or Maori audiences.

> *I think it's just been total propaganda. We've been fed lies – it's all lies, about that it's not going to harm us. It's crap.*
>
> *You didn't get a lot of information in terms of what actually was in spray. We still don't really know that !*
>
> *It's interesting, the longer it's gone on, the more advertising of spray dates in our local paper … So they've put it in our local paper so it's suddenly gone from a really small ad to the whole of the back page. Now to pay for the whole of the back page, even in the local rag, is reasonable money, you know, but it's got bigger. And it's got a map, and colour.*
>
> *They send you a magnet, you know, for the fridge? – "Spray the Apple Moth".*
>
> *Where did you put that? … In the rubbish!*

Whilst the point is made that the advertising and information has increased as the campaign has continued, the absence of quality information at the start has impacted in deeply ingrained feelings of suspicion, distrust and hostility - the placing of the fridge magnet in the rubbish being symbolic of this. Once established, these feelings are difficult to undo. Issues of fairness and equity also feature in the Wai Health group with questions about the costs of the advertising, and the unfair distribution of risk which they feel stigmatises poorer communities.

Another person suggests alternative ways to spraying which might benefit and involve the community.

> *What about Herne Bay and Ponsonby – there's a direct correlation on how the advertising got bigger and more expensive once it went to the rich parts of town.*

Have you thought about trying to verify this? It would be important finding if true.

> We're the pilot, we're the test group. We're the guineapigs. "Let's try it on that low socio-economic, you know, those Westies - those Maoris and Islanders –

Why didn't they take everybody out from the west that's actually unemployed and get them to spray on the ground – provide employment for people. Because you see there'd be millions of dollars actually going into this which is just going from one government coffer to the other. But actually we could have employed people in our community and it could have been a community project – given back to the community to actually carry out and take some responsibility for. But no-no-no, this gets driven from Wellington – "let's just spray the whole lot of them". I just think it's outrageous.

Interesting illustration of frustration leading to speculation about what could have been done or decision processes. Employing lots of people to find moths was tried in the depression in North America but failed. Ground spraying was undertaken in the PAM programme but couldn't halt the spread of the moth (this was widely publicised). Consultation was undertaken with representatives appointed by iwi, but did people in the focus groups know about this? Obviously not. What can be done in future? Suggestions welcome.. Decision-making needs to take into account community concerns and feedback – our experience with the PAM programme was that MAF did attempt to change the spray and health programmes when issues were raised.

The conversation in the group turns to consultation and decision making.

Well probably just really the whole concept of consultation, not only terms of being Treaty partners, but also as providers of health. You can give us information, you can do that without even consulting. So we can actually understand, so that when people actually come to see us we're able to explain to them what's happening.

But there's just none of that, been no education programme at all. And I know on one hand it would defeat their purpose of saying there's nothing wrong but even so, you can't just up and spray everybody and then not actually talk about what it is you are attempting to do, or how you are attempting to do that. And we have consultation on every other thing you can name. But something like this – no consultation at all.

Where's the treaty partnership now? There is none.

Good point. Just makes a mockery …

All in the group agreed that minor adverse health effects were being felt widely by people in the community.

Respiratory – and a lot of the kids find it hard to breathe when that plane's been over, they come up in rashes, headaches, runny noses, sore eyes. Yeah, all that stuff.

There were also more serious effects;

… Breathing – for babies. And the eczema is <u>really bad</u>, eh? My boy … He gets that around the spraying, look how bad it eats into his skin.

My partner couldn't go to work the days they were spraying because of the effect it was having. Massive nose bleeds. Like, three a night. And copious amounts of snot, and watery eyes and coughing and respiratory problems to the point where he couldn't even breathe properly.

One person tells of her friend a solo parent who's son is highly allergic to soy (one of the ingredients in the spray).

> They pay for the room and have given her a phone. They don't pay for gas, food, anything else. …She's had to take him to specialists which she's all had to pay for herself to get confirmation that this is an existing condition that he has. … Her water rates bill was $600 for the last six months because when she comes home she has to spray her whole house !

Waitakere is water metered and for those seriously affected by the spray, the clean up costs are significant. These are not met by MAF.

In this forum, the MAF doctors were also poorly perceived.

They try to fob you off. I had to take my whanau to the MAF doctor that they send you to because I thought why the hell should we have to pay for this. And you go to their doctor, and he was .. um .. trying to put it on other things. Like blame it on past health problems. And say it was not related. And I thought, we are wasting our time here – you're just going to tell us the MAF story – and that's who you work for, that's who's paying you. So forget it, and stick it.

You tried their helpline too eh – and they were really rude? You know, I mean, "Help"??

The impacts on lifestyle were also a source of frustration.

You have to reschedule your whole lifestyle to when they're going to fly around in the planes

And don't put your washing out. You can't take your kids out to play… your whole lifestyle. It's sticky, sticky

Yeah, even your washing, and your vege gardens. I wonder about the swimming pools, and the kids are getting ready to go swimming at the schools – they're not covered. So all that shit goes in the pools

They are saying we're making an effort to do it while the kids are in class but the reality is they do it when they can, when the wind's right

This last comment reveals the groups understanding the MAF is primarily concerned with measures to eradicate the threat to biosecurity, with the impacts on human health being a secondary priority.

The smell and feel of the spray also creates strong reactions.

If you see how it looks on your car – mmm, the residue - yeah, mmmm – I just wonder what it must do! And it smells like somebody's peed all over the place. I was saying to my son in the caravan "You been doing the mimi inside?" - 'cos it stinks. It smells of pee.

Bloody horrible anyway. It is, it's yukky horrible, sticky, smelly.

It makes food taste funny. It's like the tastebuds just went totally off and nothing tasted right.

The group also noted the extra labour, costs and inconvenience of redoing laundry, and cleaning cars and windows. There was also concern for the effects on the environment and waterways, although, perhaps reflecting the professions of those at the table, the human health issues were of greater concern.

West Fono

Background

West Auckland Pacific Island Health Fono Inc. is a primary and secondary health care organisation dedicated to improving the health of Pacific communities. Set up in 1989, it became an incorporated society in 1990 with a key objective to provide health care to all Pacific people that is affordable, accessible and culturally appropriate. West Fono also has strong ties with Waipareira Trust.

Composition

A group was conducted at West Fono and was attended by 13 West Auckland Pacific health providers, the majority whom work at West Fono. This focus group was organised and facilitated by a Pacific researcher from the Wellington Medical School. The meeting lasted for approx one hour. Notes taken by a staff member from West Fono, and a summary of these notes was forwarded to the ESR researcher.

Data

Health effects observed by the health providers in their whanau and client population included rashes, itchiness, head aches, and tiredness. The rashes and itchiness seemed to follow the spraying time. Some people reported being emotional and moody during spraying time.

The impacts on community and day to day life included mothers being more concerned about their kids during spraying time, especially when the children are at school or travelling to and from school. Others reported that cars and clothes got dirty during the spraying, creating more work cleaning.

The cost of having to relocate to another place and seeing doctors was mentioned. One person in the focus group had been to see one of the free doctors, and felt that the doctor was trying to say there is nothing wrong with the spraying

The health providers felt that people would talk about the spray amongst themselves, but would not tell their doctor or nurse. A receptionist noted that patients would talk to them about the effect of spraying, but then don't report it to their doctor.

Generally it was felt that there was not enough consultation with the Pacific community. Lack of information was also an issue with some in the group wanting to know more about the program and also wanting information about the purpose of the spray programme. The members of the Pacific focus group felt it would be good to have the information from MAF available in different languages to inform people.

Migrant Group

Background

It was hoped that the migrant focus group could comprise of leaders from different refugee communities. The focus group was however attended by a group of Asian women who gave a valuable insight into the attitudes and experiences from their community.

Composition

This focus group was held at an interview room in Waitakere hospital, six women attended, 5 Chinese, one Korean, two women seemed young in age whilst others middle aged. The women in the group were from a pool of volunteers providing translator and support services to the Waitakere Hospital. Whilst the group did not provide the different ethnic mix that the researcher expected, the data obtained gives a valuable insight into the experiences of a group of women who might not normally have a strong voice in the decision making process.

Data

Only one person in the group experienced health problems following exposure to the spray. They had strong concerns about the spray programme. The others in the group seemed resigned to the pray programme going ahead, but did note that they could have been given more information about possible side effects. It was noted by all the group members that Chinese tend not to complain about what the government does, and that this is a cultural thing. The researcher also noticed in the discussion that the older women were more outspoken, and the younger women in the group tended to defer to the older women. The younger ones in the groups were very quiet, but did get more vocal near the end of the interview.

The narrative from the one person who had experienced ill health following exposure is interesting;

> *I was in the car arriving at the hospital. The plane was flying quite low and then I looked "Oh, they're spraying!" and I thought I'd better stay in the car until after it's gone. . So after it's gone -- hospital from the carpark to the hospital - it came back I was actually caught under those thing, on my way back finish my walk from the car. The spray was horrible.*

I was very sick for four days. I can't talk, I was just coughing and coughing. My husband kept saying, "Go and see the doctor". I'm not going to see the doctor – you have to pay forty dollars so the doctor can say take a couple of panadol – that's what the GP say. So I didn't go, so in the end I just got something from the chemist, can't remember what. I was coughing for two weeks.

The person was unexpectedly caught under the spray. This prompts questions about the extent to which the element of surprise and the unknown might influence strong adverse health reactions. The reluctance to go to the doctor points to patterns of self management and underreporting which other health research suggests ? might be stronger in Asian communities.

As in the other focus groups, the importance of embodied experience; the disjuncture between the physicality of the individual experience and the 'removed' statements from government, and the way in which this disjuncture creates doubt and distrust is also thematic.

they say it is water-based but how come its staying on my windscreen like glue. I don't understand that – the Ministry not telling the truth - I think they are lying - a lot.

The effects on day to day life are also apparent for others in the group.

Normally if I know they are going to spray, I make sure all my windows are closed. My house has a lot of glass around, so it was pretty hot in the summer when they're spraying. Unbearable, if you are in the house.

It's very hard cleaning

One morning about five o'clock I heard they were flying over probably -- that was obviously in my area, so "Oh! they're spraying today". So I thought, "Oh, I better not put my washing out." But sometimes I put my washing out the night before – and so I have to wash it again.

It was noted that the optimum times for spraying coincide with the best weather for getting laundry dry.

I get agitated. I think "I can't do this – I can't do that". So frustrating. "Oh, it's my day off, I could do this, I could do that". So restricted me from doing a lot of things.

Yes, some people are scared. I am scared, the first time. They very low, and they big noise

As well as staying inside, members of the group take other precautions. In this instance the exercising of consumer choice may have adverse effects on the local growers economy.

I used to, but not any more now, get my vegetable from those market places. I don't know whether they are exposed to spray or not so I stopped buying them.

One of the younger women in the group questioned the effectiveness of the programme and whether other options might not work just as well.

I wonder what is best way to kill the apple moths - because it affects people's health. Is there another way to reduce the side effects? Doesn't say anything about the other way. Just to keep spraying.

Does this programme really work, works well? How many times in one year do they spray?

Yes .. even if it takes a longer time. First the Government should consider about people's health ??

In closing and asking for further comments, the woman most affected by the spray alluded to a bad experience with the MAF hotline.

Oh yes, that's one thing : we have a number that we can ring up. It's very hard to get through. Once I ring up, I ring up the minute I heard the plane "Are you spraying?" - " Yes" - and they hang up straight away! Didn't give me a chance to say anything!

Others agreed that this was unsatisfactory;

Yes! What's the point of ringing up? Hard to get through and you get through and that happens !

Whilst most felt that they had been informed of the spray programme with leaflets in the mail box, they also pointed to a lack of information about the possible effects on health. Whilst most in the group were did not experience significant adverse health effects, they did question the management of the program in terms of effectiveness and responsiveness to human health concerns.

Other Data

In the process of setting up and conducting the focus groups, other data was also obtained.

Waitakere City Council

Approached early on to help guide the researchers to the right people to talk with for the focus groups, the Waitakere City Council played an important role in 'opening doors'. This included an opportunity to briefly announce the focus group research, make connections and receive feedback from different advisory forum, namely Te Taumata Runanga, and the Pacific Island Advisory Board. A focus group for staff and elected councillors was organised at the last minute in response to a challenge earlier

in the week from the Mayor, Honourable Bob Harvey and a councillor when introducing the research to Te Taumatua Runanga forum.

Te Taumata Runanga

Background

Approx ten members, Maori Advisory Committee for the Waitakere City Council, operative for over ten years, two way communication bring issues to the councils attention, plus eyes and ears for feedback to Maori community on what the council is doing.

Findings

It was observed that those in Te Taumata Runanga seemed to be well informed and have a good knowledge of the purpose of the spray programme. Several questioned "when is it going to end ?", but generally the members of the group did not react strongly to the announcement that research into health effects was being undertaken.

The Mayor of Waitakere attended the Te Taumata forum to present another issue. In the discussion after the PAM research was presented, he issued a challenge that the researchers also might consider incorporating the views of the councillors.

"I am more worried on this than any other issue. There is a lot of stress on elected people from this issue. We are worried about the unknown, long term health effects". The Mayor elaborated that were adverse effects proven in the future, this would weigh heavily on his conscience. "I would feel so guilty".

Another councillor elaborated on the burden of responsibility, describing how the elected officials bore the brunt of local reaction to what was essentially a central government decision. "The stress on us as decision makers is ongoing. For example, my carpet layer got really angry about the spray and was asking me, 'what are you guys doing to us?' "

Pacific Island Advisory Board

The Pacific Island Advisory Board has similar standing and role in relation to the Waitakere City Council, but with representation and accountability being to the Pacific, rather than Maori community.

Introduced project to PIAB so they would know what was happening and have an opportunity to comment and ask questions.

Members seemed agitated, the first question asked in this forum was "When is it going to stop ?". Another member said, "there is still a deep resentment by everyone that we're being sprayed by a chemical that we don't know the formulation for". One in the group mentioned "concern in the community that some children are getting sick", with another stating that "there is no actual evidence that the concerns relate to the spray, people are putting two and two together". Another person questioned, "if someone from the community says they do have problems about their health, what are you going to do to address this ?". There seemed a lot of confusion within the group about who to contact with health concerns, this seeming to represent the wider Pacific

community. "Not a lot of the people here have been using the free health services, they might not be aware of the services". The researchers also had to work hard in this forum to demark themselves from MAF.

Elected councillors

Responding to the Mayor of Waitakere's challenge at Te Taumata Runanga earlier in the week, a focus group was set up at the council offices for interested councillors and staff to attend. The meeting was scheduled Friday midday with a free lunch offered to those attending. No one came to this. Lack of interest may have been a factor. Other likely reasons included the late notice given for the meeting, in that an announcement was circulated to elected council members and staff by email the day before. This followed approval from the council executive. Furthermore, few staff seemed to be around on Friday, and a fire drill had occurred earlier that morning, perhaps impacting on work priorities for the day.

In the absence of further focus group data, the comments of the Mayor and other councillor in the Te Taumata Runanga may be considered.

Staff

Other council staff shared their views on the impacts of the spray programme for the council, although these views are not explored as well as could be as they are not the driving focus of this research. Nonetheless interesting data was obtained.
Some felt the spray programme had impacted "dramatically". They thought that 'the city's leadership may have been caught off guard with the issue', and were now 'having to shoulder local community discontent and anger'. They cited frustration at 'not being fully informed by the key ministries about what the real issues and consequences were, and are … '. Also, it was felt that the staff at Waitakere City Council responsible for implementing key elements of the central government strategy were "stretched", and lacked a complete picture of what was going on. This staff member also questioned potential "long-term spray effects … on human beings" as well as "the environment, eco-systems and the like".

Another staff member stated personal concerns. Experiencing persistent chest problems and coughing since the spray programme began, they noted trade-offs with positive effects for their garden, but negative effects on their health. "It seems good for my orchids but not so good for my health"

Many of the staff spoken to at the council linked coughing and respiratory complaints with the spray days.

Others

In the course of doing the research, there were opportunities to make contact with other Maori working in advisory or related organisations with some interest in the PAM spray programme.

A community meeting also provided an opportunity to ask several kaumatua informally if they felt any impacts from the spray programme. Commenting on the MAF consultation, a kaumatua observed, "the process was there, MAF kept Maori informed, but then did not like to listen to concerns or modify the actions".

On health effects, one kaumatua had walked outside in the spray once and got a rash on his neck. His doctor was unable to help treat the rash because they could get information from MAF about the spray ingredients. Because he did not know what was in the spray, this person felt uncomfortable eating and growing vegetables in their garden, "gardening is expensive if you can't eat the food".

Similar to data shared by Maori and others in the focus groups, this points to a cycle where the lack of information from the government has created uncertainty and distrust. The uncertainties impact on the lifestyle decisions that people make, which in turn have detrimental economic and health effects.

The kaumatua also had concerns for the health effects on children, the mess and extra work in cleaning cars and windows, and the danger of low flying planes in urban areas. .

In the words of another younger person involved in the MAF consultation, "the consultation with Maori is good, but breathing it in is a different story." An interesting theme.

Findings and analysis for the focus group data

The study included four formal focus groups, as well as additional community data gained from various interactions within community networks around the Waitakere City Council. Overall, but with particular emphasis on the focus group data, what did the research say about the impacts of the aerial spray programme on the health, well-being and everyday life of residents of Waitakere; on relationships between central government agencies and Maori; and on dynamics between central, local government and community ? Acknowledging the limits in scope, some important themes can be observed.

Impacts on health

Elders – respiratory, asthma
Young ones – ezema, skin rashes
General – across population – coughing, sinus, eye irritation

There is significant disjuncture between the messages given by a government agency, (in this instance MAF's statements that "the spray is safe" for human health), and the lived experience, in that some people in the community have mild to severe reactions.

The use of MAF health services

Data from all the groups suggests that underreporting is prevalent.

Reluctance to use MAF health services wit the community perceiving conflict of interest and stories of experiences to this effect transmitted by word of mouth. Additionally these is a general reluctance to go to the Drs, cost may be a significant factor with much of Waitakere being low decile (NZ dep index). There was also some questioning of the Dr's ability to treat allergenic conditions, other than give panadol.

Central government relationships with Maori community

"the consultation with Maori is good, but breathing it in is a different story."
In established forum within the Waitakere City Council at higher levels – ie council forum and relationships with mana whenua and tangata whenua, there seems to be satisfaction with MAF's consultation around the spray campaign.

Our understanding is that consultation with Maori was undertaken through iwi-authorised channels, which wouldn't have involved the entire Maori community.

Others alluded that whilst forum had been established whereby dialogue could occur, this was 'one way' or top down' in that MAF seemed reluctant to listen to any suggestions or change from the path its chose to progress. For instance, it was suggested that a MAF employ a Maori doctor, or that alternative eradication methods to aerial spraying be developed with local Maori. Neither recommendation was adopted by MAF.

Recommendations may well have been considered but not adopted.

These feelings of satisfaction were however counterbalanced by strong feelings from Hoani Waititi and Wai Health that the consultation with Maori and the wider community was poor.

Several public consultation meetings were held, but often degenerated into shouting matches. Consultation and community feedback did affect the way the programme was undertaken.

There seems to be a pattern where those most involved in the decision making process are more satisfied and comfortable with the decision, whatever undesirable effects may ensue. This also is commonly known in the risk communication literature.

Also, that those most affected by the spray – feel a burden on health and lifestyle impact which was perhaps not adequately explained in early consultation. Participants perceived that MAF retreated from a consultation role as public hostility toward the campaign increased – a reaction to the public reaction.

Another part of the dynamic was the role of interest/opposition groups. The contrast with the White Spotted Tussock Moth programme is noteworthy, where there was much less public opposition and much less organised opposition. The two may be linked, and it would have been useful to assess the influence of opposition groups on public perception as an independent factor. These are social and political processes with their own dynamics…

Observed here is that the community loses trust and confidence in government authorities; this is expressed as anger and hostility; the government agency retreats from contact with the community; as consequence the community feels further distance and becomes angrier. This pattern is noted in the risk communication literature (Sandman etc) .

a bit more consultation at ground level and not just through their offices and other organisations. As health providers we have to be seen like, more so, preventing health issues and if MAF come more so towards their sort of organisations we'd understand a bit more and so would our clients.

Central and local government relationships

Strained, bear burden of uncertainty, seem to be a buffer between community and central govt, stretched with extra work, unequal relationship lack of knowledge and decision making power for this issue.

What is this sentence about?

Summary

The focus group and ancillary data gathered for this project gives evidence that the PAM spray programme has had multiple impacts on the Waitakere community.

This is a generalisation which would be difficult to make with any confidence from the data presented. What you can say is that the spray programme is perceived to have had multiple effects on people who attended the focus group meetings.

Frequently reported health effects include coughing, respiratory and sinus problems, headaches, skin rashes and eye irritations. Those with existing conditions, such as asthma and hay fever, find these conditions aggravated following exposure to spray.

Again, this is a generalisation/extrapolation that can't be made validly from the information presented. Information from the PAM Health Service, clinical assessments from respiratory physicians and from calls to us and GP feedback is, for instance, that few people have had aggravation of asthma, and now new onset adult asthma has been identified (an often proposed effect). The statement conflicts with the Canadian research information finding no difference in childhood asthma events for people inside and outside the spray areas.

Many interviewed had concern for the young and elderly. Some expressed uncertainty about health effects for future generations. Such concerns seem to be compounded by lack of information from government.

While people might express concern about the young and elderly and future generations, you need to go to the next stage and actually assess whether the concerns are justified from what is known about the spray and its effects from other information sources. Have you verified that there was a lack of information from government? What was found from the focus groups are expressed concerns, but no indication of how that relates to actual problems. That these concerns exist identifies a number of issues but not necessarily a health problem.

Other impacts included disruption on day to day life, compounded by lack of certainty about which day the spray would occur. All participants reported staying indoors and closing windows when the spraying occurred. There were frustrations over having to wash cars, windows and laundry.

[The focus group section provides useful information which should be able to be used for improving how agencies deal with this type of programme.

A lot of public information was distributed (mail, newspapers, leaflets, posters, radio, TV etc), and many of the points raised in the focus groups were covered. We understand that MAF went through a fairly extensive iwi consultation process.

Information may well not have got to some people, or may not have been regarded as worthwhile taking note of prior to the spray operations, or may have been lost, or may not have been comprehensible etc, and written information has less impact than spoken for some people etc. Some qualitative analysis on this would have been useful, rather than accepting that information was insufficient.

There are some concerns and fears that no amount of "information" can address. If people were not accessing the health and personal support services which were available (which over 3000 people called and 800 people had support plans from at various stages of the spray programme), then these need to be made more available and responsive.

The analysis doesn't look at the perception gaps between these particular groups and those responsible for the programme. Were there plausible or practical ways of overcoming those gaps? What veracity do the perceptions (and some rumours) have? E.g. the claim/rumour that advertising only expanded when rich suburbs were included in the spray zone can be treated as a potentially verifiable (or falsifiable) proposition. Some of this type of analysis would have been useful. How widely held were these perceptions within the groups, or were there subgroups who took strident positions (pro or anti)? To what extent could self-selection of participants have influenced the discussion? Did people who weren't interested turn up? How did the group dynamics affect the discussion?

As noted in the method section, the focus group method doesn't gauge the scope or extent of issues, but identifies and categorises them, and gives some indication of the range of feeling evoked. A random interview method would likely have given a different set of perspectives which would also have been useful. For instance, the Exec Summary seems to infer that health effects were almost universal, whereas other local information sources don't support this. On what grounds was this inference made?

Written submissions

Background

There were two sources of submissions:

(a) Advertisements requesting written submissions were placed in local newspapers. There were 93 responses.

(b) In addition, photocopies of 311 submissions to CC-PAM were made available to us after names and other personally identifying details had been removed. These submissions had been received too late to be included in an interim summary (Blackmore, 2003).

[In addition, the Waitakere City Council invited people to write in. A summary is included in the summary paper for the Hamilton AGM spray programme, attached. There is probably a large overlap between the 3 groups. OK – we'll include this]

The symptoms reported are summarised in Table 1. The most commonly reported symptoms from each source are: sore eyes, sore throat, headache, blocked nose, cough, asthma, diarrhoea, vomiting, stomach cramps, fever, malaise, swollen glands, skin rash.

[The irritant symptoms and headache have been reported from elsewhere, but the gastrotintestinal and other symptoms generally haven't been. Unfortunately there's no comparison with the underlying background rate in the community. Such comparison would not be valid, due to response bias Much of the research has looked at severe, acute affects, rather than the effect on self-limiting and self-managed symptoms.]

The similarity between responses from the two sources is striking, though the two sets of responses are not independent. Since some people are likely to have sent the same (or similar) submission to Wellington School of Medicine and to CC-PAM.

[This was also the case for the Waitakere City Council invitation to write to them, where the overlap with other sets of respondents (e.g. the PAM Health Service, calls and letters to ARPHS) was quite large.] People's experience is real, but obviously these exercises aren't representative. Agreed - no response needed

…Some biases may also have been introduced in the interpretation of responses. Selected excerpts from submissions requested by Wellington School of Medicine are given below. These are intended to illustrate a range of severity but do not represent the full range of symptoms reported to us.

> "Horrible headache from the spray, despite keeping inside with windows closed."
>
> "…the smell of the spray permeated the building. By the end of the day I had a headache and a sore throat."
>
> "Every time they spray (even though we aren't in the spray zone) I get a headache and sore eyes. I can't even open my eyes because they're so sore. (There are hot spots on both sides of our house)"

"The symptoms of the malady are likened to the flu, triggered by a virulently itchy and profusely runny nose causing lengthy and embarrasing bouts of sneezing, the eyes itch and are very watery becoming sore as do the whole of the nasal passages. The attacks can last several hours from start to finish."

"I am concerned about the effects of the painted apple moth spray on my self and my family and your recent advertising has prompted me to contact you. At the commencement of the spray campaign all members of my family suddenly had severe sore throats and raw nasal linings which took quite some time to heal."

"On 3 occasions in the past year I have contracted severe influenza like symptoms 2 to 3 days after the aerial drop. I have not had flu at any other time during this period."

"When they first started spraying I came down with what I thought was a chronic chest infection. I didn't think it was the spray because I was outside the spray zone. However, the chest infection started when the spraying did and stopped about 3-4 days after the spraying stopped. I eventually went to my doctor and he says I'm highly allergic to the spray."

"Red bloodshot stingy eyes, nose bleeds, uncontrolled asthma, wheezy, nausea, fatigue, sinus infections, rashes, worsening allergic reactions to things tolerated before. The whole family is affected to varying degrees … we are all asthmatics and have pre-existing allergies, however [becoming] harder and harder to control."

	Wellington School of Medicine		CC-PAM	
Symptoms reported	number	percentage	number	percentage
Irritant: sore eyes, sore throat, headache, blocked nose	23	25%	80	26%
Respiratory: cough, asthma	15	16%	52	17%
Gastrointestinal: diarrhoea, vomiting, stomach cramps	13	14%	40	13%
Flulike illness: fever, malaise, swollen glands	12	13%	35	11%
Skin rash	8	9%	32	10%
No health problems mentioned	5	5%	20	6%
Bleeding nose, ulcer on nose/eye or mouth	5	5%	18	6%
Chronic fatigue syndrome	5	5%	11	4%
Psychological	2	2%	10	3%
Arthritis	1	1%	4	1%
Other	4	4%	9	3%
Total	93		311	

[The range of symptoms and concerns are similar to those reported to the PAM HS and to Waitakere City Council. The absence of clinical assessment does limit how much can be concluded agreed – no response needed (e.g. several people complained of new onset adult asthma related to the spray programme to Waitakere City Council. Three people were reviewed by an independent doctor, who concluded that they did not have new onset of adult asthma). Some people in the affected community will have been newly diagnosed with asthma during 2002-2004. How would we know whether or not new asthma was related to the spray?]

Literature review

We review community health concerns reported in overseas and New Zealand studies of populations living in areas where spraying programmes have occurred, and summarize relevant New Zealand risk assessments. Next, we consider what is known about the exposures resulting from spraying programmes. Finally, we assess the potential for Bt to cause disease in humans, including assessment of the health effects of bioaerosols and data from laboratory studies.

[There are a number of other research reports which haven't been reviewed but are referred to in various HRAs, or referenced in papers which have been reviewed. These should be included. {details requested} You haven't made any reference to the PAM Health Service information, which would have been useful.]that's because we did not get a response from them

Community health concerns

Overseas studies

The relevant overseas literature includes reports of health surveillance programmes following aerial spraying in Canada, (Noble et al. 1992; Bender and Peck 1996; Anon 1999; Anon 2001a) and North America (Anon 1993; Anon 2001b).

Noble et al. (1992) examined health records in a community following spraying of *Bt*. No illness or infections were attributed to *Bt* following review of 3500 hospital admissions, 1140 general practice records and 400 *Bt*-positive bacterial cultures from 10 hospitals. *Bt* was isolated from several body sites, including blood, body fluids, eyes, nose and tissue samples. The authors concluded that these were due to contamination. However, it was reported that spray workers

> "frequently developed symptoms of headache, nose, throat and eye irritation, dry skin and chapped lips" (Noble et al. 1992)

A telephone hotline received over 20,000 calls. Of these, about a thousand were "health related" and of these,

> "… 247 calls represented complaints from individuals who reported being in the spray zone or exposed to the spray, and who attribute their symptoms to that exposure." (Noble et al. 1992)

The reported symptoms were classified as "seasonal allergy symptoms" (19%); "flu-like symptoms" (17%); "respiratory" (17%); "nose/throat" (10%); "skin" (8%); "gastrointestinal" (7%); "other" (7%); "headache" (6%); 'eyes" (2%).

Two studies of communities exposed during *Bt* spraying in Canada in 1992 and again in 1994 contain reports of "allergic rhinitis symptoms, exacerbations of asthma, and skin reactions" (Anon 1993; Bender and Peck 1996), cited in (Bernstein et al. 1999).

During aerial spraying for Gypsy moth in Seattle, the following symptoms were reported by 59 persons in 50 households out of an estimated residential population of 6,600 (Anon 2001b):

- "Upper respiratory and nasal symptoms: nasal congestion, sore or scratchy throat, productive and/or persistent cough, watery eyes, headache.
- Irritant symptoms: burning or itchy eyes, burning in throat, nasal irritation, dry cough, itchy skin, or headache.
- Airways involvement: trouble breathing, chest tightness, or asthma reaction.
- Flu- like or viral symptoms diarrhoea, nausea, vomiting, fever, body aches, headache, or dizziness.
- Skin rash"

The authors commented that:

> "A number of the reports received [by the Department of Health] appeared to be temporally linked to the spraying. These included a skin rash that appeared within four hours of direct exposure to spray droplets and cases of adult asthma that worsened after each application. A number of persons who reported irritant effects such as burning eyes and nose noted that their symptoms followed each application. There appears to be a gap between what people living in sprayed communities report and what epidemiological tools have been able to detect. Data collected with a passive surveillance system will not be able to further resolve this apparent inconsistency." (Anon 2001b)

The largest and most detailed study to date was conducted during aerial spraying for control of Gypsy moth in Vancouver Island, 1999 (affected population, 80,000). This study consisted of the following components:

> "1. Asthmatic Children's Survey
> The survey studied the health of children with asthma, both inside and outside the spray areas, for any health changes that could be attributed to the spray.
>
> 2. General Population Survey
> This telephone survey documented the health of a group of adults inside and outside the spray area both before and after the spray.
>
> 3. Laboratory Surveillance
> Laboratory analysis was used to find people whose lab specimen was identified as containing *Bt*, to determine the specific type of *Bt* bacteria found in the specimens, and to compare it to the specific type of *Bt* used in Foray

48B. The role of the identified bacteria, if any, in human disease was also assessed.

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

5. Doctors' Office Visits
This information were collected and will be studied for any possible links to the
spray program. [In the event, it proved impossible to analyse these data, due to inaccuracy in the recording of ICD codes]

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

7. Telephone Health Support Line Data
A telephone support line was available to the community during the spray periods. Self-reports made to the support line were summarized in the context of the larger study." (Anon 1999)

The authors conclusions were as follows:

> "The results of this project did not show a relationship between aerial spraying of Foray 48B and short-term human health effects. Although some people self reported health problems that they attributed to the spray program, the research and surveillance methods used in this project did not detect any change in health status that could be linked to the spray program. Our results showed that many of the health complaints people reported during the spray were as common in people before the spray as they were shortly after the spray. This conclusion is consistent with those of previous studies of the possible health effects of *Bt*k–based pesticide spray programs." (Anon 1999; Anon 2001a)

The study of children with asthma (the Asthmatic Children's Survey, point 1, above) has subsequently been published separately as (Pearce et al. 2002a).

> "A pre/post matched pairs cohort design was used [n=85]. Children living in the spray zone were matched with children outside of the spray zone. Peak Expiratory Flow Rates, asthma symptoms and non-asthma symptoms were recorded in diaries. There were no differences in asthma symptom scores between subjects and controls, neither before nor after the spray; nor were there significant changes in Peak Expiratory Flow Rates for subjects after the spray period. No evidence of adverse effects from the use of the biological pesticide was found."

The telephone survey of residents (General Population Survey, point 2, above) has been published separately as (Pearce et al. 2002b). A total of 2127 telephone numbers were called, but only 1009 people completed both pre and post spray interviews; about half of these were inside the spray zone. The authors concluded that:

"There were no significant changes in physical health scores and a small improvement in the average post spray mental health score…"

A major limitation of these studies is that the "control" (unexposed) population was found to be exposed to *Bt* in the environment, both before spraying began, and as a result of spray drift during the spraying operations. The sample sizes are also not large enough to detect small health effects.

[However, you need to take into account the dose and exposure route here. Bt species are naturally occurring soil organisms, and may have been used in previous spray programmes, so background exposure would be expected from the environment and locally generated dust. There was no assessment of background exposure. However, during spray programmes, exposure of people in the spray zone rises several orders of magnitude (as it does for occupational exposure), and the drift is quite small, in comparison.-we don't think that can be stated with confidence- Exposure to drift will happen, and the Teschke findings indicate that this can be for a kilometer or more. However, it's biologically implausible to infer that the effect on asthma from exposure to drift at 1km away should be equated with exposure from direct exposure in the spray zone. In effect, this would say that there is no dose-response relationship, and that any dose will produce the same effect. What the Canadian researchers we have previously contacted state is that despite the background exposure and drift, there is no evidence of an effect on childhood asthma from exposure.We don't disagree with that conclusion. We suggest contacting them directly. The information on which we base our conclusions is given in the peer-reviewed papers published by the group, and referenced in our report.

{the following is more relevant to For instance, droplet size distribution was assessed for MAF with about 0.17% being under 14 microns. At an application rate of 5 l/ha this is equivalent of 8.5 g/ha. The PM10 component would be smaller, depending on the spray nozzle characteristics and atmospheric conditions. This estimated exposure sounds reassuringly low. Teschke et al have shown that exposure is measureable - However, exposure to micro-organisms is difficult to define. Also of importance is that Btk is only a small component of the F48B spray (~2.1%), and people would not have a high inhalation exposure to the other components unless sprayed. We do not dispute the fact that Btk is a small component of the spray. It is also the active ingredient!

New Zealand studies

Several studies have been carried out following aerial spraying with *Bt* products in Auckland in recent years. About 80,000 people were living in the spray zone during aerial spraying for eradication of white spotted tussock moth in the eastern suburbs of Auckland, 1996-7. The following symptoms were reported:

- Fear of disease
- Headache
- Asthma
- Sneezing/runny nose
- Throat symptoms
- Skin rash/ itch

- Irritable/angry / stress
- Hay fever / allergy
- Sleep disturbance
- Noise
- Miscarriage / query about pregnancy

"Reported concerns were followed up through a process of interview, requests to consent to obtaining relevant information from health care practitioners, review by a panel of medical specialists of recorded concerns and any available medical information, and where appropriate additional personal medical assessments. This process did not identify any significant diseases attributable to the spraying.

For three years from the start of Operation Ever Green, general medical practitioners in the area were asked to inform the Medical Officer of Health about any health problems which they thought might be associated with spraying. There were no systematic problems reported and no further individual reports after mid 1997.

Many of the 375 individuals reporting health concerns had not consulted a medical
practitioner about those concerns. However, their concerns were part of a spectrum of
symptoms commonly taken to a family doctor. It was considered that patterns of consultations observable within general medical practices (family doctors) could indicate whether any change in frequency of health conditions was associated with the spraying." (Aer'aqua 2001)

There was no evidence of:

- new onset of asthma;
- increased consultation for pre-existing asthma
- chronic fatigue syndrome
- increase in presentations for autoimmune disorders
- increase in consultation rates for lower respiratory problems
- any obvious pattern of problems with headache, eye, skin or upper respiratory symptoms.

[A fuller description of the methodology involved in the Operation Evergreen surveillance should be included and all aspects of the programme described. The analysis of hospital admissions for various conditions, for instance, has not been included. Rigorous assessment of the report should be made] *OK – we agree that more discussion of this report may be helpful. We will also add a new "Epidemiological assessment" section*

Following aerial spraying for eradication of Painted Apple Moth in Waitakere City, the following symptoms were reported– in descending order of frequency (Blackmore 2003):

- neurological - headache
- eye - general
- respiratory - cough
- respiratory - throat sore / painful / burning
- general - sick/unwell
- respiratory - asthma aggravation
- digestive - diarrhoea
- respiratory - breathing difficulties
- psychological - distress
- general - fatigue - lethargic
- general - anxiety - allergy/skin disease
- skin - rash
- respiratory - nose - congestion / runny
- digestive - nausea
- general - flu-like symptoms
- digestive - stomach pains/cramps/upset
- respiratory - nose - sinusitis
- skin - rash localised
- respiratory - chest pain
- general - mouth / tongue / lips
- psychological - anger
- respiratory - general
- digestive - vomiting
- general - fatigue - wiped out
- neurological - dizziness / losing balance
- respiratory - nose - bleeding
- skin - itch
- eye - conjunctivitis
- musculoskeletal
- respiratory - nose - sore / painful / burning
- psychological - stress
- respiratory - asthma new

"Three hundred and ninety seven incidents (397) have been reported to end of year 2002, with nearly 1400 specific effects detailed. These range from health complaints of an irritant and debilitating nature, through serious exacerbations of pre-existing conditions, to such severe effects that some people's lives and livelihoods have been quite simply devastated." (Blackmore, 2003)

[The method should be described (self report) and rigorous assessment made. OK- we will include an assessment A summary of the responses to the Waitakere City Council invitation in early 2003 should be included, OK- with an assessment.OK]

A separate questionnaire-based study included recording of symptoms before and after the spraying began.

> "Two hundred and ninety two residents within the…spray zone were recruited by a door-to-door survey of homes within the most intensively sprayed area ten weeks prior to the first aerial spraying. Participants completed a symptom checklist and a questionnaire measuring health perceptions. Three months after the start of spraying, 181 (62%) of the original participants responded to a similar postal questionnaire. Symptom reports, health perceptions and visits to healthcare providers were compared between the baseline and the follow-up questionnaire. Rates of symptom complaints in respondents with previously diagnosed asthma, hay fever, or other allergies were compared to those in respondents without these prior health conditions." (Petrie et al. 2003)

Symptom complaints appeared to increase following the aerial spraying, but these results are unfortunately unreliable, since the reporting period was longer for the follow-up questionnaire than for the initial questionnaire.

[The method should be described (it is – see above) and rigorous assessment made OK- we will add. Another problem was the lack of a contemporaneous unexposed control group]

A separate questionnaire-based survey of schools in west Auckland received 320 responses. Over half reported "adverse effects" from the spray. (NZEI 2003)

> "Many cited serious health effects, rashes, nausea, persistent coughing, breathlessness, asthma attacks, mucous in nose and throat, tightness in chest, difficulty in breathing, allergic (histamine) reactions, swollen and sore throats, sores around mouth, watery eyes and bronchial problems. Often, many of these symptoms lasted for days and even weeks and recurred on subsequent spray days. One teacher enclosed a statement from her doctor that indicated that "her ill health seems to be coinciding with PAM spray". The doctors diagnosis was Chronic Rhinitis. Many teachers stated they had observed many of the above reactions in the children under their care." (NZEI 2003)

[The method should be described and some assessment made OK.]

In a survey of employees at a factory in the spray zone, 29 health effects were reported. Of those reporting any symptoms:

- 35% suffered eye problems (itchy, watery or sore eyes)
- 38% suffered lung and/or respiratory problems. (Difficulty breathing, asthma attack, respiratory irritation, nosebleeds, sinus pain and sneezing, pre-existing allergies had worsened).
- 7% suffered skin burning or irritation.
- 10% developed headache.
- 3% suffered swelling of the face and eyes.
- 7% had to obtain medical attention and treatment. (Blackmore 2003)

[The method should be described and some assessment made OK]

Similar results were recorded in a subsequent survey at the same factory (Douglas Pharmaceuticals, personal communication).

New Zealand risk assessments

Auckland DHB risk assessment for MAF, 2002

A health risk assessment of the aerial spray eradication programme for the painted apple moth in West Auckland reached the following conclusions (Kalemba et al. 2002):

> "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 … problems with pregnancy... thyroid dysfunction or abnormalities."

[The method should be described and some assessment made- OK]

Environmental Risk Management Authority assessment of Bactur 48LC

The Environmental Risk Management Authority (ERMA) recently approved an application to import insecticide "Bactur 48LC" containing Bt (ERMA 2002). The following quotations are particularly relevant sections for the assessment of health risk:

> "8.5 *Btk* has been used in commercial pest management for over 30 years in Canada and the United States. This has included programmes in large urban areas, for example 19,000 hectares in Vancouver in 1992. Extensive studies have been carried out during that time, as required by the United States Environmental Protection Agency and Health and Welfare Canada and no significant adverse effects on animal or human health were recorded. All North American studies to date show no public health concerns, despite long-term large-scale use of *Btk* in aerial pest management programmes.

8.6 **In extremely rare cases**, people spraying *Btk* may develop minor, transient irritations such as dry skin, chapped lips, itchy red and burning eyes, runny noses and nasal stuffiness. However, spray workers studied in Vancouver who reported such problems had been exposed to up to 500 times more *Btk* than a member of the public outdoors would be during the spray operation.

8.7 From the information provided, I consider that the application is unlikely to have an impact on the relationship between Māori culture and their traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna and other taonga. This is on the condition that the product is used in accordance with the HSNO controls established for this application, and in accordance with any other relevant controls applying under other legislation.

Setting of EEL (Control Code E1)

9.1 This default control requires that an EEL (Environmental Exposure Limit) is established. This can either be the default value, Regulation 32, or one set in accordance with Regulations 33 to 43 of the Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001.

9.2 Regulation 33 allows for the setting of EEL values different from the default values. EELs may be set for one or more environmental media.

9.3 However, *Btk* is a natural bacterium in the environment. It is also specific to its range of target organisms and when released from the formulated matrix is rapidly degraded in the aquatic environment.

9.4 Therefore, I consider the adverse effects of BACTUR 48 LC to be **less than normal for this classification** and I consider this control can be deleted under s77(4)(a) of the Act.

Setting of Application Rate (Control Code E2)

9.5 This control requires that an application rate be set if an EEL is set. Regulation 48(2)(a) of the Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 allows the application rate to be set at the rate specified by the applicant in the application. As an EEL has not been set for BACTUR 48 LC then this control is not applicable.

Toxic Substance Controls (Control codes T1, T2)

9.6 Regulation 11(1) of the Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 determines when an ADE (Acceptable Daily Exposure value) is required to be set. If all three of the requirements of this regulation are not met then no ADE is set.

Regulation 11 states:

(1) This regulation applies to a class 6 substance if-

(a) it is likely to be present in-

(i) 1 or more environmental media; or

(ii) food; or

(iii) other matter that might be ingested; AND

(b) it is a substance to which a person is likely to be exposed on 1 or more occasions during the lifetime of the person; AND

(c) exposure to the substance is likely to result in an appreciable toxic effect.

9.7 As I consider that exposure to BACTUR 48 LC is unlikely to result in an appreciable toxic effect to the skin and eyes of exposed people I consider that the condition in Regulation 11(1)(c) is not met. Therefore there is no requirement to set an ADE, and the control is not applicable. I have based this conclusion on the observation that while the hazardous property thresholds of BACTUR 48 LC for skin and eye irritancy are triggered on the basis of tests of laboratory animals, very similar products have been used extensively in New Zealand and off shore and **there have been no reports of such effects seen in exposed humans** (see paragraph 8.5), except in rare cases where workers regularly exposed to high concentrations have shown some minor effects (see paragraph 8.6).

9.8 A workplace exposure standard (WES) is essentially intended for inhalation exposure scenarios in the workplace. Regulation 29 of the Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 determines when a Workplace Exposure Standard is required to be set.

(1) This regulation and regulation 30 apply to a class 6 substance if-

(a) under the temperature and pressure the substance is to be used in, it can become airborne and disperse in air in the form of inspirable or respirable dusts, mists, fumes, gases, or vapours; and

(b) human exposure to the substance is primarily through the inhalation or dermal exposure routes; and

(c) the toxicological and industrial hygiene data available for the substance is sufficient to enable a standard to be set.

(2) One or more workplace exposure standards may be set for a substance by the Authority to protect persons from the adverse effects of toxic substances.

9.9 I note that OSH has not set any exposure standard for BACTUR 48 LC or any of its main components. I note that **there is an exposure standard for one of the components in its undiluted form but that this standard is not applicable to diluted formulations.**

9.10 In relation to BACTUR 48 LC, I consider that requirements (1)(a) and (b) of regulation 29 may be met in the workplace, but that requirement (1)(c) is not met in that there is not, or does not appear to be, data of a sufficient standard available.

9.11 Therefore I consider that no WES needs to be set and this control is not applicable.

…[sections 9.12…9.17 removed for brevity]

The use of BACTUR 48 LC in mass aerial spraying

9.18 The hazard profile presented by this substance is similar to, and certainly no greater than, substances already in use in New Zealand for similar purposes. Accordingly there is no reason to think that the use of BACTUR 48 LC poses risks, when used en masse for aerial spraying, which are different from those posed by similar sprays which are already in such use.

9.19 It is noted that these substances are suitable, and are used in New Zealand, for large scale application for control of pests. Although it is not in the scope of the HSNO Act to set specific controls to cover these situations, care should be exercised to ensure that unnecessary exposure to people is minimised, and that people likely to be exposed are fully informed of the circumstances, and in a position to take action on their own account.

Decision

10.1 In accordance with section 28A(2)(b) of the HSNO Act, and clause 24 of the Methodology the approach adopted when considering this application was to evaluate the substance to determine whether the substance had one or more hazardous properties and if each of those hazardous properties met the criteria for least degree of hazard for that property. Then, having regard to the default controls triggered by the classification, potentially significant residual risks and associated costs were identified for assessment in accordance with clauses 12, 13, 33 and 34. Finally, the default controls were reviewed to address their application to this substance (clause 35), and to address any residual risks.

10.2 Having considered the risks associated with the lifecycle of BACTUR 48 LC, I am satisfied that the residual risks or costs associated with this substance, taking account of the controls, **are sufficiently low to be acceptable** (clause 12)." (ERMA 2002) emphasis added.

This quotation is rather long, and could usefully be edited down. OK Bactur is a different manufacture process and formulation from Foray. Of more relevance would be ERMA's assessment of the new formulation of F48B, done in 2002, concluding that the risk profile was the same. OK- We will try to locate this. However, the main issues are common to all of the biological insecticides.

We agree that ERMS's assumption that irritant symptoms are rare is incorrect. You'd have to ask ERMA whether they would have changed their classification if they had the correct information, but given the level of e.g. irritant symptoms, we'd expect not. The effects don't reach the thresholds in the HSNO Regulations. OK-no response needed

Exposure assessments (overseas)

Bt has been grown in stool samples from agricultural workers using *Bt* products and from nasal swabs in communities exposed to *Bt* (De Amorim et al. 2001; Jensen et al. 2002b). However, presence of *Bt* was reported to be unrelated to symptoms in either of these studies. Several studies have quantified exposure to *Bt*-containing products. Elliot et al (1988) reported maximum exposures of over 10,000 colony forming units per cubic meter (cfu/m^3) in spray workers:

> "The concentration of spores ranged from 0 to 1.1×10^4 cfu/m^3 for individual workers, the highest concentration being incurred by a spray card checker who was in brief contact with the material. For non-working individuals, the average *Bt* exposure was 1.3×10^3 cfu/m^3. In the spray area, a general survey showed concentrations of 0 to 4.2×10^3 cfu/m^3." (Elliott et al. 1988), cited in cited in (WHO, 1999 – *not in your reference list OK-added]*).

Noble et al. (1992)

> "…studied aerosol *Bt* exposure and subsequent nose and throat carriage of *Bt* by workers during a major spray programme for gypsy moth… The mean exposure values ranged from 3,000 to 5,900,000 *Bt* spores/m^3 … Nearly all the workers exposed to higher concentrations for several shifts (5 to 20) were culture-positive for *Bt*, and the majority of the workers remained culture-positive for 14 to 30 days." (Noble et al. 1992).

As part of the Vancouver Island study in Canada, (Anon 1999), researchers measured exposure to Foray 48B. Airborne *Bt* was measured both indoors and outdoors using bacterial culture of samples collected on Teflon filters. The size distribution of the aerosol droplets was also measured. Spray drift was measured 1km from the intended site; *Bt* concentrations were related to wind speed and direction rather than distance from the spray zone (Teschke et al. 2001).

The intended droplet size was 110-125 micrometers, but the median aerodynamic diameter was found to be 4-7 micrometers. The majority of droplets were found to be less than 5 micrometers in diameter 5 minutes after spraying began. The extent of drift outside the spray zone was thought to be due to the presence of these fine droplets.

[This is incorrect. Not clear what is "incorrect" here. There were 2 methods used for collecting spray droplets in Teschke's report. Andersen samplers were used, but these only count small particles, and lump everything > 7microns together. They also used Kromecote cards which collected large spray droplets.

[Teschke reports (summary p iii) that the average sizes of particles that remained air-borne (?after 15 minutes) (from the Andersen samplers) were 4.3 to 7.2 microns, "much smaller than the 50 to 150 micron droplets which quickly deposited on surfaces inside the spray zone" (measured on Kromecote cards.) However, this seems different to how it is described in the method section (p 7), and reported on p 25 as sampling for 15 mins. Agreed that -tThere is some lack of clarity- no response needed

[Our rough spreadsheet estimates (attached), based on MAF's information on size distribution, indicates that mean particle diameter would be around 20 microns, and >99% of the mass of spray would be in particles >=20 microns. I.e. the mass of material is in large particles, but the number of very small particles is far higher than the larger particles. What would be potentially useful (and doesn't seem to be in the Teschke report) is calculation of the distribution of spray particle masses (in addition to counts) from the spray, and the proportion of the total mass of sprayed material. On the other hand, it may be that particle number is more important than mass.

[We sent Teschke's report to Gavin Fisher at NIWA, who had difficulty coming to a conclusion from the information presented.

[What it is probably valid to conclude is that

(1) particles less than 10 microns are produced in small quantities (primarily by the spray nozzle). Evaporation would decrease particle size, dependent on humidity and temperature, however the spray ingredients include a fairly hygroscopic component, which will tend to retain water. Additional energy would be needed to break particles into smaller sized, given the cohesive/adhesive nature of the spray. If particles collide, they'd tend to stick together, althlugh some smaller particles may be produced);

(2) the PM10 particles (probably) constitute less than 0.15% of the mass of the spray, although they could be produced in quite large numbers, and could account for around 1% (or higher) of particle numbers;

(3) this equates to less than 7.5 ml/ha (with spray rate of 5 l/ha);

(4) they remain suspended for prolonged periods, (days?) and so will drift with air movement;(several kilometeres? tens of kilometers?) OK. This has implications for exposure assessment in relatiuon to potential future studies.

(5) the small particles are likely to get into houses, and this may be reflected in the delay in reaching peak concentrations in indoor air, beyond the time when the large particles have already dropped out of the air. –OK, this may have implications for recommendations about staying indoors?

Maximum outdoor exposures of greater than 1,600 cfu/m^3 occurred after 2-3 hours, while indoor exposures were found to exceed outdoor levels after 5-6 hours. The study did not attempt to quantify levels of exposure above 1,600 cfu/m^3 (Teschke et al. 2001).

[It's worth while adding that the maximum outdoor counts were considerably higher than the maximum indoor counts, and total count was also greater outdoors than in, as you'd expect. Unfortunately they stopped monitoring indoor air after a few hours, so didn't get an accurate assessment of the rate of change in concentration over time. The counts also didn't relate to particle size, and hence the relative dermal/mucosal and respiratory exposure. What it looks like is happening from the diagrams is that there is a similar shaped exposure curve for both indoors and outdoors, which is delayed for indoor exposure, with peak and total exposure less indoors. You'd expect that the spray particles getting into a house would be relatively small, resulting in lower dermal/mucosal exposure, but having respiratory exposure.]OK – suggests that further study is needed?

Measurement of exposure using viable spore counts will underestimate total exposure, since non viable matter (including non viable spores) will not be measured. Volatile chemical constituents of the spray were also measured by ambient air sampling (van Netten et al. 2000). The authors reported that

> "…Foray 48B is associated with few volatile agents which only could be measured under strict laboratory conditions and are not present in sufficient quantities in a vapour form to pose a health hazard during spray operations..."

[The list of 38 volatiles is curious. It probably contains a number of artifacts (e.g. the siloxanes), or heat decomposition products from the samples (which are heated to 280°). Our PAM HRA made some comment, such as on the mismatch between the volatiles list and the ingredients list, which might be useful to consider. The researchers were looking for markers for exposure, since they'd found Btk in the environment already, but didn't detect anything in the actual field trial. When DS visited the people from Capital Health in Victoria, on Vancouver Island, they were doubtful about the usefulness of the info. Agreed- which is why we do not dwell on this (see next paragraph, below)

[There are other non-volatile components, which could be measured, some of which are ubiquitous.]

The level of exposure to volatile components of the spray is likely to be very low, but could still cause allergic responses. Other adverse effects from the so-called "inert" ingredients seem unlikely. For this reason, we do not considered exposure to "inert" ingredients further here.

[It's a bit more subtle than this. The inerts form only a small proportion of the spray, but spent culture material is also present, and could potentially be an allergen. Jim Waters, who was the Ministry of Health's toxicologist at the time, didn't think that there was enough of the inerts in the spray to could cause sensitisation (although at higher doses some could be). It may well be that people who are already (?highly) sensitised to some components (either one of the inerts or spent broth material) could have some reaction. We based our advice on this, but Francesca Kelly would be a better source of info on possible cases. OK- will update recommendations to reflect this]

In relation to the biological components of *Bt*, one other relevant study has recently been published. Hendriksen and Hansen (2002) reported that *Bt*:

> "… survives as spores for long periods in bulk soil, a relatively protected environment… survival of *Bt* is a more dynamic process than previously thought, involving germination, possible cell divisions, and sporulation. These observations may have major implications for the understanding of the ecology of *Bt* in the environment, for its use as a microbial pest control agent, and the associated risk assessments." (Hendriksen and Hansen 2002)

Exposure assessment (New Zealand)

We are not aware of any systematic monitoring of human exposures during the spraying operations in New Zealand. In an attempt to assess the level of exposure during the spraying programme in West Auckland in 2003, we have analysed data from Henderson air quality monitoring station. Auckland Regional Council provided hourly carbon monoxide (CO) and particulate matter (PM_{10}) for January – August 2003. Climate data (hourly dry bulb temperature, humidity, wind speed and direction) were provided by NIWA.

MAF provided a table indicating on which days aerial spraying operations occurred. As this did not include start and finish times, we generated a spray indicator variable which was set equal to one from 0500H on spray day to midnight on completion day (inclusive), and zero otherwise. Seasonal changes in PM_{10} were removed using a lowess smoother of bandwidth 0.1.

The resulting seasonally adjusted PM_{10} was regressed against climate data, carbon monoxide and the spray indicator variable. The results suggested a small but measurable effect of the spraying programme on ambient PM_{10} as measured at Henderson, with a maximum increase in hourly PM_{10} of 2.5µg/m^3 after a lag time of 6 hours. Over the whole 8-month period, there were 455 hours in which the spraying occurred (as defined by the indicator variable), equivalent to about 19 days exposure, (or about 30 days per year).

[DS discussed this section with Gavin Fisher at NIWA, who had significant doubts about whether this was a valid method or use of the data. Suggest you contact him directly. *We expect there to be some fine particulate, and it is unsurprising that it is measurable using this standard statistical approach.*

[Spraying usually started about 7 am, and would be finished by mid afternoon on large spray days. MAF should be able to tell you what the approx total time of typical spraying was (~7 hours?), which was split over 2 or sometimes 3 days (although mostly done on day one). Would this affect the modelling?]. *We have requested the start and finish times from MAF, but not yet received these data.*

Potential pathogenicity of Bacillus thuringiensis

There is limited evidence that *Bt* can cause corneal ulcer (Samples and Buettner 1983) and soft tissue infection (Damgaard et al. 1997).

[There are some subtleties here too. Some Bt varieties have been found in isolated cases as (presumably) weak opportunistic organisms, generally where there is trauma (e.g. the corneal ulcer case was a farm worker who was sprayed in the eyes while spraying (i.e. short range, possibly fairly high pressure) or the soldier who stood on a land mine) or in association with known, more aggressive pathogens (e.g. the lab worker who got a hand infection from an accidental injection of a mixed culture of Bt and Acinetobacter calcoaceticus var anitratus*, and an injecting drug user case). These aren't the type of exposure which occurs to the general population during a spray programme.* *Agreed, but that doesn't mean that this evidence is irrelevant.*

[The corneal ulcer situation is complicated by other findings that Bt can be found in conjunctiva for some time after exposure without causing infection (?transient colonisation?). Also the degree of trauma to produce a corneal abrasion needs to be considered. They can also be found for some time in nasal secretions and in the GI tract without any indication of infection.] *–no response needed*

Since clinical tests do not normally distinguish B. thuringiensis from the closely related pathogen, B. cereus (WHO, 1999), the significance of B. thuringiensis as a cause of human disease is not known.

[This statement is open to some misinterpretation so needs clarifying. It could equally be read as "significance unknown, but likely to be a common and serious pathogen" or "significance unknown, but unlikely to be a common and serious pathogen". The weight of evidence seems to lie with the latter.
Not clear what evidence is referred to here. The point is that B. thuringiensis is not usually distinguished from B. cereus…
Presumably part of the reason that the two are not differentiated in clinical laboratories is that there is no indication to do so. Bt experimentally is not a (strong) pathogen, whereas Bc is, either via toxin production or direct invasion (of relevance here is Bc as a known pathogen in orbital cellulitis – We haven't been able to find any references about Bacillus-related orbital cellulitis and farm workers). We'd recommend contacting Travis Glare or Maureen O'Callaghan at AgResearch Lincoln re the taxonomy and laboratory issues.

Bt (*Berliner* strain) was found to be non toxic in one early study. Eighteen human volunteers ingested 1 gram of a commercial insecticide called Thuricide daily for 5 days. The volunteers swallowed capsules containing 3×10^9 spores/g of powder in a "diatomaceous earth filler". Five of the volunteers also inhaled 100 mg of powder daily for five days, via an "Abbott inhalator". Medical examinations and laboratory tests before, just after and 4 to 5 weeks after exposure did not demonstrate any adverse health effects. (Fisher and Rosner 1959)

[As always, caution is needed when comparing Bt strains. Thuricide is a Btk product, not currently registered in NZ, according to the ACVM website]
no response needed

However, the exposure likely from the inhalation experiment is unclear, and the numbers are rather small. Contradictory results have been reported (Pivovarov et al. 1977):

> "Pivovarov et al. reported that ingestion of foods contaminated with *Bt*g at concentrations of 10^5 to 10^9 cells/g caused nausea, vomiting, diarrhoea and tenesmus, colic-like pains in the abdomen, and fever in three of the four volunteers studied. The toxicity of the *Bt*g strain may have been due to beta-exotoxin." (Ray 1990), cited in (WHO, 1999)

[The Bt galleriae *strain referred to here was from a Russian manufactured product from the mid 1970s (see Glare and O'Callaghan), with uncertain manufacturing quality control and uncertain production of toxins other than the delta endotoxin.*

Certainly Bt strains can produce other toxins, but the question here is to what extent this happens for the F48B strain of Btk, and to what extent culture, manufacturing and quality control processes can reduce this in the product as used in the field.- agreed, no response needed]

Note that it is not clear that these studies used the subspecies of *Bt* that is currently used in commercial preparations. Foray 48B used in New Zealand is said to be tested for the presence of unwanted toxins (Kalemba et al. 2002). However, it is not clear how sensitive or reliable these tests are, since there are no widely accepted test protocols for organisms . Bacteria can also produce a range of toxins during growth. If bacteria from Foray 48B grow after release, this could result in human exposure to toxins even if no toxins were present in the original product.

[The F48B product has to meet EPA manufacturing quality control standards which includes various toxin assays and rejection criteria for batches. This should be quite detailed, and according to Ian Gear at MAF, (who visited the plant recently) similar to FDA criteria for cultures used in Abbott Laboratories' drug manufacture. The criteria may include post-manufacture culture, but you'd have to confirm this. MAF has batch-tested each shipment arriving here looking for non-Btk contaminants, but you'd have to confirm with them what is done. US EPA set and monitor the criteria, so if you want to review the validity of their method would need some rigorous research information. The final sentence needs to be backed up with evidence otherwise it is open to various interpretations. –OK, will add a reference
To what extent does expression of toxins in the environment which aren't produced during culture/manufacture actually happen? To what extent is the genome of the F48B Btk strain capable of producing other toxins? (the genetic research on this strain is quite extensive, but totally unintelligible to me)The genetic coding of toxins is carried by plasmids which are readily exchanged between species (including other species present in the environment)

In relation to *Bt*, most attention to date has focussed on *enterotoxins*, which cause gastrointestinal symptoms. Enterotoxin-producing strains of *Bt* have been isolated from commercial insecticides (Damgaard 1995), food (Damgaard et al. 1996; Phelps and McKillip 2002) and stool samples of workers using *Bt* insecticides (Jensen et al. 2002a; Jensen et al. 2002b). *Bt* has been implicated in one outbreak of gastroenteritis (Jackson et al. 1995).

[The Damgaard 1996 paper shows the Btk strains capable of producing an enteroxin, but the relative importance of this vis a vis B cereus would need assessment by a microbiologist familiar with the topic. The Jackson paper does raise interesting questions about some Bt strains as gastrointestinal pathogens, including to what extent culture and manufacturing processes can control enterotoxin production. This is information you'd need to get from the manufacturer or US regulators. The Phelps paper would need interpretation by someone more familiar with the molecular genetics.] Not clear why the following requires understanding of mo0lecular genetics: Enterotoxin-producing strains of *Bt* have been isolated from food (Phelps)

Commercially available bacterial *endotoxin* assays depend on detection of lipopolysaccarides in the cell wall of Gram negative bacteria. Gram positive bacteria such as *Bt* have different cell walls, which do not contain lipopolysaccarides.

However, all bacterial cell walls contain another molecule called peptidoglycan. This class of molecule is not be detectable by standard assays for endotoxin but has similar adverse effects, via similar molecular mechanisms (Dziarski 2003). There is recent evidence that Gram positive bacteria can trigger immune responses in the lungs (Becker et al. 2002; Weber et al. 2003).

[Has a microbiologist familiar with Bacillus needs reviewed this material in detail? We're not sure what conclusion or inference is being made here. What is the context? Do all G+ve organisms do this, and if so, is there anything exceptional about Bt? What is the clinical or public health significance of what's reported here? Some proper analysis is needed. etc]OK-will include a discussion of this issue.

Laboratory studies of exposed workers

Bt is known to cause certain immune responses in exposed workers. One study:

> "…demonstrated antibody titres in 11 of 107 workers exposed to *Bt* during a 2-year spraying period. By the middle of the spray operation, seven had developed titres to spore-crystal complexes, six to vegetative cells, and one to spores. Their titres tended to be low, but were higher in those exposed for a second year. Two months after the exposure ended, nine workers were retested. Of these workers, five had no detectable antibodies to the spore-crystal complexes, and four who had been among those with the highest titres against vegetative cells had significantly lower titres." (Laferrière et al. 1987), cited in (WHO, 1999).

[The cited paper is an unpublished one which we haven't located. We could not locate it either - but it is reasonable to trust WHO to cite accurately-]

Bernstein et al (1999) conducted laboratory tests on farm workers before and after exposure to *Bt*-based pesticides. They reported no evidence of respiratory symptoms resulting from exposure.

> "…there was a significant ($p < 0.05$) increase in the number of positive skin tests to spore extracts 1 and 4 months after exposure to *Bt* spray. The number of positive skin test responses was also significantly higher in high ($p < 0.05$) than in low- or medium-exposure workers. The majority of nasal lavage cultures from exposed workers were positive for the commercial *Bt* organism, as demonstrated by specific molecular genetic probes… Specific IgG and IgE antibodies to vegetative organisms were present in all groups of workers. Exposure to *Bt* sprays may lead to allergic skin sensitization and induction of IgE and IgG antibodies, or both." (Bernstein et al. 1999)

[An immunological response such as this to an organism is expected, but doesn't necessarily indicate illness. This paper is referred to in the PAM HRA] –no response needed

A Danish follow up study of 579 agricultural workers exposed to biological insecticides, including *Bt* products reported a high prevalence of irritation in eyes and airways, allergic rhinitis and asthma (Larsen and Bælum 2002):

"… In greenhouses using Bacillus thuringiensis products increased prevalence of itching in the eyes at work and of frequency of more than once a week were seen. The persons who handled Bacillus thuringiensis product had more chest tightness than the rest while in the follow up an increased incidence of itching in the eyes was seen in greenhouses using Bacillus thuringiensis...

There was no difference in the lung function and in histamine sensitivity between subjects exposed to the products and those not in contacts with the products.

There were measurable IgE antibodies against the different products. The prevalence of antibodies above the detection limits was highest for the Verticillium lecanii and the Bacillus thuringiensis products … There was no clear relation with the measures of individual exposure. Especially, no sensitization was seen in the highly exposed persons who had handled and sprayed out the products. During the one year follow up the levels of antibodies for the individual were stable and there was no sign of increased sensitization.

The incidence of new symptoms was about 10% and only in a few symptoms the incidence was related to the measures of exposure or sensitization. Due to the relatively few new symptoms in the short follow up the power of this part of the study for detecting exposure-response relationship is low.

… persons with one or more positive prick tests as an indicator of atopy showed higher prevalence of eye and nose symptoms as well as diagnosed asthma than the non-atopics. Furthermore, the incidence of new symptoms during follow-up in the group of atopic persons was considerably higher than among the non-atopic persons and persons with house dust mite allergy were over represented in the group that left the study between the first and second examination. This could indicate a "healthy worker effect" due to the different exposures in the greenhouses. The evaluation of health effects should therefore mainly be based on measures of incidence and the study has therefore been extended for three years to achieve a higher power.

In conclusion the study showed a relatively high prevalence of symptoms among greenhouse workers and there was a limited relation to estimates of exposure to Bacillus thuringiensis and Trichoderma harzianum but not to Verticillium lecanii or Paecilomyces fumosoroseus products…"

[It would be interesting to see the full paper in English. (it's not available in English as far as we know) What was the detailed method? Was this a cohort study? How complete was the follow-up? If it was extensive, you'd expect to be able to sort out some of the healthy worker effect (i.e. people moving away from exposure if symptomatic). The irritant symptoms are well known. How well was the question of atopy and its relationship to exposure and/or symptoms worked through? Etc]-OK-will include a copy of this paper as an appendix.

Potential health effects of bioaerosols

When sprayed from aircraft, Foray 48B forms a *bioaerosol* (a fine suspension of biological matter in air). We have therefore reviewed what is known about the health effects of this general type of exposure. It is well established that bioaerosols cause respiratory diseases in exposed workers. Non-viable microorganisms and the biologically active chemicals that they produce can cause health effects through toxic and immunological mechanisms (Eduard et al. 2001). Bünger et al, (2000) state that

> "The primary effect of exposure to bioaerosols is often an inflammatory response of the upper airways with congested nose, sore throat, and dry cough often in connection with symptoms of the eyes like redness and tears (mucous membrane irritation), subsiding several hours after the end of exposure."

Studies have examined effects on workers exposed to organic dusts, in agriculture, food processing and waste management. In one study, these irritant symptoms were reported by household waste collectors more than unexposed workers (Wouters et al. 2002). Evidence of upper airway inflammation was found after "moderate" exposure to endotoxins. However, in this case the exposure also included fungal spores (Heldal et al. 2003). Other less frequent effects of bioaerosol exposure in studies of exposed workers include toxic reactions, allergic reactions, respiratory and skin infections, asthma exacerbations and other chronic diseases of the respiratory system (Bünger et al. 2000; Douwes et al. 2003).

The only relevant study of the general population that we are aware of used a questionnaire survey to investigate the effects of bioaerosols on symptoms in residents living near a compost manufacturing site. Bronchitis, coughing, shortness of breath, smarting eyes, tiredness and shivering were reported more frequently in residents living near the site, where measured exposure to bioaerosols were highest. However, there was no increase in doctor-diagnosed illness in the exposed group (Herr et al. 2003).

Total bacteria were measured at concentrations of 5,000 to 10,000 cfu/m^3. The authors state that these levels "…exceeded occupational threshold levels recommended in Denmark and Sweden…" also that *"airway inflammation [is] to be expected after frequent exposure to micro-organisms in the range 10,000-100,000 cfu/m^3 "* – with reference to (Millner 1995).

[Compost, of course, contains a myriad of organisms, including fungi some of which are pathogenic or allergenic. Similarly, the range of bacteria in compost includes known human pathogens such as Legionella species and Clostridia species. A more detailed analysis of the relevance to Bt spray is needed. –that would be helpful, but is not possible given current our understanding of bioaerosol effects. How do the figures relate to results from Teschke, where some of the counts were lower, but weren't quantified above 1600/m3?] -the figures cannot be related to Teschke, since those researchers did not attempt to quantify exposure above 1600 cfu/m^3

It is well established that fine particles (PM_{10} and finer) cause cardiorespiratory diseases and increased daily mortality in exposed communities. It is not clear which

features of respirable particles are responsible for these effects, but there is evidence that bacterial toxins may be involved (WHO 2003).

[The section on bioaerosols is useful and worth exploring further. My reading, from your references and a few other papers, is that many of the effects are highly substance-specific (microbiological and/or physico-chemical), rather than generic effects. That is probably true of some effects, but not all. -Specific research would be needed on Btk products such as F48B to attempt to get some clarification and quantification. We agree that this would be helpful, but not necessary before reaching our conclusions. Which of the listed symptoms are generic? The irritant effects seem non-specific to bacterial cell wall components. We've thought about the irritant symptoms as being possibly related to pH, hypertonicity, or particular organic acids in the product. That is possible, but fails to explain the specificity of the symptoms. Much of the upper airway and mucosal symptoms are likely to be from larger particles, rather than PM10 size, but what implications does this have for assessing effect? Presumably, effects on respiratory disease are more likely if respirable particles are inhaled.

[In the Herr paper, what bacterial/fungal species were identified? How do they relate to the type of situation encountered with Btk spray programmes? Is there an indication of severity, other than no apparent increase in doctor-diagnosed illness? One of the things we're interested in exploring is the extent of self-managed and self-limiting symptoms, which could be annoying and somewhat disruptive, but don't end up with acute or severe symptoms. What physiological effect could be observed below anything of clinical, epidemiological or public health importance? All interesting and important questions, but we do not feel that a specific response is needed.

The WHO report comments that bacterial endotoxins tend to be concentrated in the PM10 fraction, rather than the PM 2.5 fraction which WHO is now advising is the more important for air pollution effect. That is controversial and unclear at present. The report also notes that health effects (of what?) have not been shown at low concentrations. Not clear what you are referring to. Particulate effects on short term mortality have been shown at very low levels, though this may not be due to bioaerosol effects. A fuller analysis of the relevance of the WHO report would have been beneficial. This is interesting but, in our view, not sufficiently central to the issue at hand to warrant detailed review here.

Laboratory experiments

Bt derived from commercial insecticides has been shown to be capable of producing cytotoxic effects in cell cultures which are similar *[actually reported as being "identical" OK]* to those caused by the known pathogen, Bacillus cereus. *[?and B anthracis? What's the inference? OK- will check the source.]* It was reported that the most toxic substances were released "soon after spores germinated and began proliferating." (Tayabali and Seligy 2000)

[This looks like they've identified a pathway for spore activation which is shared in common between Bt and Bc. Presumably, the subsequent biological effect then depends on the specific endotoxin or enterotoxin produced, there being no equivalent receptor for the Bt delta-endotoxin in mammals, and low or no production of Bc

emetic and diarrhoeal toxins by Bt. The biological effect is almost certainly highly complex, but need not depend upon Bt delta-endotoxin at all. Innate immune effects are likely to be important (see Dziarski review) We agree that Bt delta-endotoxin is not particularly likely to be relevant to most human health effects. - but see Rodríguez-Orozco.

Have you had a look at this in relation to other research on activation of Bt spores, of which there is quite a bit? No – we are not aware of that work { request details} This research was done on in vitro cell cultures, rather than in physiologically relevant situations, such as in mammalian gut conditions. Recalling that Btk spores activate ideally in the alkaline caterpillar gut, through the action of their alkaline-activated delta-endotoxin, what effect does mammalian gut acid/bile/enzymes have on this toxin production? -Has this been observed in vivo in mammalian systems? As above - Bt delta-endotoxin is unlikely to be relevant to human health effects- but see next paragraph.

Compare with B cereus emetic toxin which is biologically active in acid conditions, presumably through receptor-specific action, or the diarrhoeal toxin which is active in more alkaline small intestine.

Rodríguez-Orozco et al, (2000) report that the precursor of a *Bt* toxin was found to have strong adjuvant properties. (This means that it stimulates immune responses to other substances administered concurrently). Much of this work has been done using mouse cells and is outside the scope of this review. However, responses were also seen in human peripheral monocytes (white blood cells):

> "… intense phagocytic stimulation and proliferation of monocytes induced by Cry1Ac … suggests that monocyte activation and proliferation are significantly involved in the adjuvant effect of the protoxin." (Rodríguez-Orozco et al. 2000)

[You'd need to show how this would relate to in vivo situations] We agree that it would be helpful to have advice from an immunologist on this point.

Huttunen et al (2003) investigated the ability of bacteria and fungal spores to stimulate the production of cytokines – chemical messengers that are involved in inflammatory responses. B. cereus was shown to be capable of inducing inflammatory responses. At higher doses, there was evidence of cytotoxic effects (cell damage). These authors reported that:

> "Altered growth and sporulation environments… may provoke normally innocuous microbes to produce components and/or metabolites that trigger inflammatory responses and cytotoxicity. This implies that the potential to cause adverse effects may be site specific." (Huttunen et al. 2003)

[Has this finding been repeated for Bt, in addition to B cereus? This may have some relevance for the trauma-associated opportunistic infections referred to above. Is this more so for Btk than other organisms? (No indication that it is). To what extent is the B cereus response related to its toxins, recalling that they're different from the Bt toxins, with different methods of action. The biological effect is almost certainly

highly complex, but need not depend upon Bt toxins. Innate immune effects are likely to be important (see Dziarski review)

Conclusions

The focus groups and other data gathered for this project suggest that the PAM spray programme has had multiple impacts on the Waitakere community. In the focus groups, frequently reported symptoms included coughing, respiratory and sinus problems, headaches, skin rashes and eye irritations. Those with existing conditions, such as asthma and hay fever, may report that these conditions are aggravated following exposure to the spray. Many interviewed had concern for the young and elderly. Some expressed uncertainty about health effects for future generations. Such concerns seem to be compounded by lack of information from government. Other impacts included disruption on day to day life, compounded by lack of certainty about which day the spray would occur. All participants reported staying indoors and closing windows when the spraying occurred. There were frustrations over having to wash cars, windows and laundry.

It is difficult to make valid extrapolations from the focus group results. Since you didn't do any random survey work, you can only get themes expressed by the groups, and don't have the full range of perspectives. As an example, the NZEI survey concluded that the spray had caused a lot of illness and disruption in schools, but a survey of school principals and administrators (done for ARPHS) found that overall, spraying had been a relatively minor inconvenience for the schools, with few pupils away on spray days, many as a precaution rather than as a result of illness. Perspective is important. The "lack of information from government" statement seems inconsistent with the amount of effort put into providing information through multiple sources. An analysis of the relationship between expressed concerns and assessed risk would have been useful. (request social scientists to respond to this)

As in previous surveys of spray workers and communities exposed to *Bt* products, there have often been reports of short term irritant symptoms (such as sore throat, headache, blocked nose). More serious symptoms, such as exacerbations of asthma, skin rashes or flu-like symptoms have less frequently been reported. The pattern of reported symptoms in workers and communities exposed to Foray 48B is consistent with the known effects of bioaerosol exposure. You need to differentiate generic effects (mostly physiochemical origin) from those related to specific bio-aerosols We cannot do this.

The literature indicates that Foray 48B may have the potential to cause more serious health impacts in sensitive individuals. *Bt* products have the theoretical potential to cause allergy to chemical or biological components of the spray. When sprayed from aircraft, *Bt* products has been shown to be present in indoor and outdoor air as very fine acidic "bioaerosol" particles that may be inhaled deep into the lungs. This raises the theoretical potential for *Bt* products to cause a range of chronic respiratory diseases that have been documented in people exposed to bioaerosols in the workplace.

See previous comments about speculation. In a report like this speculation is unwarranted. Re-word, based on weight of evidence. OK-will reword this bases on weight-of-evidence

The level of exposure causing these occupational diseases is probably *[certainly- we would like to agree, but since there has been virtually no monitoring of exposure, cannot do so. The exposure has been measure up to 1600 cfu/m, but may be higher since that was theupper limit of detection in that study (Teschke et al)]* substantially higher than that typically experienced by New Zealand communities exposed to *Bt* aerial spraying programmes. On the other hand, the most sensitive individuals tend to avoid occupations that lead to bioaerosol exposure, so that studies of workers may not give a true picture of the likely effect in communities. As far as we are aware, there are no studies of the potential long term effects of exposure to *Bt* products from aerial spraying operations on either communities or workers.

More speculatively, there is also the theoretical potential for other human diseases triggered by biologically active chemicals produced during growth of *Bt*. In toxicology experiments using human cell cultures, growth of *Bt* has been shown to have a variety of effects, including cell damage and immunological effects. The public health significance of these findings is unclear.

[See previous comments on speculation – recommend re-wording based on weight of evidence] -"The public health significance of these findings is unclear." Should we remove the whole paragraph in order to avoid misinterpretation? We disagree

Several studies of communities exposed to aerial spraying of *Bt* products have been carried out in New Zealand, Canada and North America. The largest and most detailed of these have not shown any association between exposure and health effects. However, all of the epidemiological studies that we have reviewed have one or more limitations, including:

- small sample sizes (therefore a lack of statistical power to detect a health effect, even if present) (Noble et al. 1992; Anon 1999; Aer'aqua 2001; Anon 2001a; Pearce et al. 2002a; Pearce et al. 2002b; Petrie et al. 2003)
- subjective or potentially biased assessment of health effects (Petrie et al. 2003)
- potential or actual exposure of control groups (Noble et al. 1992; Anon 1999; Aer'aqua 2001; Anon 2001a; Pearce et al. 2002a; Pearce et al. 2002b)
- limited duration of follow up (Noble et al. 1992; Anon 1999; Aer'aqua 2001; Anon 2001a; Pearce et al. 2002a; Pearce et al. 2002b)

The largest of the community surveys have included, at most, 500 participants in "exposed" and "unexposed" groups. These surveys have limited ability to detect effects that occur in a small proportion of exposed people. For example, suppose we know that a given symptom actually occurs in 50% of unexposed people, and 55% of exposed people. In order to have 95% confidence of being able to demonstrate that symptoms are experienced more frequently in the exposed group, a study would need

over 2000 people in each of the exposed and unexposed groups. This example assumes a standard (95%) level of statistical significance.

However, the largest population-based studies have involved over 80,000 people (e.g. Operation Evergreen), and detected no adverse events, within the limitations of its methodology. *–OK. we will add a comment about Operation Evergreen here.*

The existing community surveys (Noble et al. 1992; Aer'aqua 2001; Pearce et al. 2002a; Pearce et al. 2002b) cannot prove that *Bt* products cause no important health impacts in exposed communities. Health impacts can be substantial and important whilst at the same time being difficult or impossible to measure without careful study of very large populations.

[See previous comments on this] It's extremely unlikely that there will ever be a large cohort study, *Perhaps. That is not up to us to decide.* *so we'll always have to make judgements from the range of available information.* *-No response needed*

While noting that self-reported data are subject to potentially serious biases, we note that:

- *Bt* products can form a bioaerosol
- the most frequently reported symptoms are consistent with the known acute effects of bioaerosols, and
- these symptoms are reported to occur in the hours or days following exposure

New Zealand risk assessments

Auckland DHB risk assessment for MAF, 2002

The prediction that:

"…some people may complain of minor skin, eye and upper respiratory tract irritation, or aggravation of existing asthma or allergies." (Kalemba et al. 2002)

Proved to be accurate.

Environmental Risk Management Authority assessment of Bactur 48LC

This assessment appears to have been based, in part, on the incorrect assumption that short term irritant effects of *Bt* products are only seen in laboratory animals or workers exposed to relatively high doses – and do not occur in communities exposed to aerial spraying of *Bt* products.

[Agree] *. No response needed*

The lack of New Zealand Workplace Exposure Standards for bioaerosols is unsatisfactory and should be addressed by Government. Some countries do have relevant exposure standards (Denmark, Sweden and the Netherlands). We have not

been able to obtain the original sources for these, but it has been reported that in the Netherlands there is a proposed occupational exposure limit of 50 endotoxin units (EU)/m^3, equivalent about 4.5 ng/m^3, over an 8 hour period (Heederick and Douwes 1997).

It seems to us that if an exposure standard has been set for one of the components of a product in undiluted form, then this standard may also be relevant to any product containing the substance.

Recommendations for future study

Exposure assessments

Analysis of air quality monitoring data for all Auckland monitoring stations with hourly PM available 2002-3.

Modelling of the probable spatial and temporal distribution exposure to Foray 48b and potentially active chemical and biological constituents during aerial spraying.

Clinical testing

Appropriate immunological testing of individuals if sensitisation is suspected clinically.

Objective tests individuals with symptoms temporally related to the spraying, including exacerbation of existing conditions. (eg respiratory function tests, nasal lavage). Similar assessment of a sample of people on the White Spotted Tussock moth register, with emphasis on respiratory disease and allergies.

Epidemiological studies

Reanalysis of White Spotted Tussock moth data to account for possible exposure of 'control' groups.

Redo of the "map study" of asthma prevalence (Lewis, et al) for Auckland electorates.

Time series studies of routinely collected mortality and morbidity data for selected Auckland CAUs, 2002-2003. (eg hospital admissions, prescription data, GP data where available).

Long term follow up of exposed communities for chronic respiratory diseases.

[Would need to relate to research on chronic respiratory effects from short term exposures such as this, where there isn't infection (cf brohnchiectasis or CORD) or acute physiological/toxicological/immunological effect (e.g. long term occupational exposure to specific antigens or pathogens.] *No response needed*

[Although outside the scope of this project, a counterfactual analysis could be useful] *No response needed*