

# **Painted Apple Moth Eradication Programme**

## **Health Risks and Effects**

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## **MEMORANDUM**

**Subject: Painted Apple Moth Eradication Programme – Health Risk and Effects**

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**Date: January 10, 2003**

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## **INTRODUCTION**

1. This document has been produced at the request of Stop Aerial Spraying after advice received from Sir Geoffrey Palmer.
2. It relates to the Ministry of Agriculture and Forestry's (MAF's) aerial spraying campaign over parts of West Auckland to eradicate the Painted Apple Moth (PAM).
3. In particular it addresses the adverse health effects apparently experienced by members of the community exposed to the aerially applied insecticide Foray 48b.
4. I have been requested to apply the findings of my PhD thesis (Watts 2000) to the situation, taking into account the health effects apparently experienced, the government's assessment of the health risk and the reasons for the difference between the two.
5. In producing this paper I have studied three health risk assessments (HRAs) of Foray 48b produced for MAF (Kalemba et al. 2002, Auckland Healthcare 1997, Auckland Healthcare & Jenner Consultants 1996a and 1996b); the Health Surveillance report following the previous Foray 48B aerial spraying operation (Aer'Aqua 2001); the interim community-based report on the health effects in West Auckland (Blackmore 2003); some of the available scientific papers on Foray 48b and its ingredients in so far as they are known; and medical and scientific research that applies to the situation. The primary document used is the Kalemba HRA as it is the most recent health risk assessment.
6. This paper does not give a detailed assessment of the HRAs or the hazards inherent in Foray 48B, but merely provides some illustrative examples of problems with the Kalemba methodology that may have led to assumptions by some that exposure to Foray 48B would not result in unacceptable health effects.

## SUMMARY

7. Within the detailed material in the Kalembe HRA can be found evidence of health effects resulting from either the Btk or the chemical components of the formulation that are similar to those experienced by the community as presented in the Blackmore report.
8. These symptoms also correspond to the symptoms self-reported during the Operation Ever Green programme during which the same formulated product, Foray 48b, was sprayed over East Auckland (Aer'Aqua 2001).
9. Thus both the commissioned health risk assessment and health surveillance reports identify the symptoms reported by, so far, 315 people in West Auckland.
10. The Aer'Aqua report, however, concludes that there is no evidence linking these symptoms with the spray, a finding that has been subsequently interpreted to mean that they are not linked, which is a different matter and not proven. The interpretation by Robert Isbister, General Manager of the PAM Operation, has been that there were no health *complaints* from the spraying in East Auckland (Isbister 2002).
11. The Kalembe report concludes that the aerial Foray 48B spraying can be expected to cause eye, nose, throat and skin irritation, short term nausea and headache, could affect severe or uncontrolled asthma, and an appreciable number of people are likely to experience anxiety and asthma (p 55-6). It concludes that the risks to human health are "small" (p 56). It also states "we do not expect toxic effects or infection from Foray 48B though . . . some people may complain of minor skin, eye and upper respiratory tract irritation, or aggravation of existing asthma or allergies (p.61). Note this last sentence says 'complain' rather than 'experience'.

Subsequent political interpretation by medical personnel, MAF technical personnel and politicians has led to the expressed view firstly that any health effects will be "insignificant" (Kelly 2001), then that the spray has a "proven safety record" (Sutton 2002a), has a "clean bill of health" and is "harmless to humans and animals" (Kelly 2002).

12. The consequence is that the government has proceeded to apply the spray from the air, provided money for health 'advice', but failed to acknowledge that the health effects do in fact appear to be significant at least to the people experiencing them, although subsequently the Minister for Biosecurity has announced that 5 percent of people are allergic to the spray (Sutton 2002b).
13. There are a number of problems inherent in the Kalembe HRA:

- a conservative value bias that favours positivist science and its lack of evidence rather than the protection of public health;
- hence a disinclination to pay heed to the symptoms reported by exposed communities;
- hence also an inclination to minimise the significance of potential effects on the effected people;
- an assessment of exposure that differs significantly from the actual exposure being experienced by many people in the community; it should be remembered that risk is a product of both inherent hazard and exposure and if the exposure assessment is wrong so too will be the risk assessment;
- the failure to identify the chemical ingredients in the formulated product so that the assessment can itself be assessed;
- the failure to adequately characterise the risk of inhalation of one of the known chemical components, benzoic acid;
- the generalised nature of the report, omitting all modelling details and reasons for arriving at a number of unsupported assumptions, which again prevents the assessment being independently thoroughly critiqued.

14. As a result of the last point I have assumed that standard toxicological assessment procedures have been used for assessing the chemical components, which would then result in the following failures to reflect the actual experience of the community:

- failure to determine the effects and toxicity of chemicals when inhaled as opposed to dermal contact or ingestion;
- failure to determine the effects of the mixture of chemicals that constitutes Foray 48B, allowing for synergistic or additive effects, as opposed to assessing each chemical as if it were the only chemical to which people would be exposed;
- failure to determine the effects of ongoing low dose exposure, as opposed to one-off exposure to toxic levels;
- basing acceptable risk on occupational exposure;
- a particular value basis that guides the judgements and assumptions on which so much of risk assessment is based, and which appears to favour PAM eradication rather than public health protection.

15. A brief review of some of the literature pertaining to one of the known chemical components, benzoic acid, has been used to illustrate one methodological flaw in the Kalemba HRA: lack of characterisation of inhalation toxicity and risk. Whilst benzoic acid is regarded as being of low toxicity when ingested, except to those people allergic to it, there is no known safe level of exposure by inhalation, a common source of exposure for West Aucklanders: “as the rat inhalation studies showed adverse effects at all doses studied, it is not possible to identify a level of inhalation exposure that is without risk” (EC 2002).

16. The commissioned risk assessors, technical people and politicians have largely acknowledged at least some of the potential health effects but have dismissed them because they are determined that they are *insignificant* or *acceptable*. But a number of people in the West Auckland community have found that the effects are *significant* and *unacceptable* to them.

In other words, what is of significance and what is acceptable depends very much on the viewpoint of the perceiver. The health effects apparently being experienced in West Auckland are of significance to the people experiencing them and have been found to be not acceptable. That they are regarded as being acceptable by the government in no way diminishes the adverse effect on the health of the people concerned.

17. Health risk assessments and toxicological risk assessments are inherently uncertain because of the large gaps in available data, and the limitations in methodology. The outcome can never be claimed to be certain, yet often it is interpreted in this manner, especially if the community reports symptoms that the assessment did not determine were likely to occur. The results of health surveillance are also inherently uncertain because of the difficulties in causally linking effect with exposure.

Community experience can be useful in providing valid information on apparent effects, and should be taken seriously, especially where that information confirms previous community experience and hazards identified as pertaining to the substances involved even if the risk of experiencing them is determined to be low.

#### **A. FINDINGS OF THE HEALTH SURVEILLANCE FOLLOWING OPERATION EVERGREEN (AER'AQUA 2001).**

During the Operation Ever Green programme in 1996-7 the spray Foray 48B was aerially applied over parts of East Auckland. The area included a resident population of 81,389, with a smaller population of 5,640 that were subjected to a longer duration aerial programme.

A health surveillance programme was undertaken. This included:

- documentation and investigation of self-reported concerns;
- use of sentinel doctors;
- review of health data from "suitable" sources;
- birth outcomes analysis;
- a register of individuals exposed to the Btk spray.

A report of the findings was then made to MAF. The part of this report of most concern here is the analysis of the health symptoms reported by 375 people, for these symptoms are similar to those experienced in West Auckland.

General	122	fear of disease	68
		no fear of disease	19
		allergy	12
Blood	5		
Digestive	40		
Eye	88		
Ear	9		
Circulatory	4		
Musculoskeletal	12		
Neurological	74	headache	64
Psychological	53	irritable/angry	19
		situational stress	18
		sleep disturbance	10
Respiratory	223	asthma	46
		sneezing/runny nose	43
		throat symptoms	42
		other nose symptoms	21
		hay fever	15
Skin	77	localised rash	31
		skin itch	19
		general rash	13
Metabolic	3		
Urology	2		
Pregnancy	33	confirmed pregnancy	12
		miscarriage	8
		query about pregnancy	8
Female system	6		
Male	2		
Social	73	pets, disruption to lifestyle, smell, home gardens	43
		fear of illness	18
		neighbourhood conditions	15
Other		noise	10

Taken from: Aer'Aqua 2001; pp 4,15,17.

The report concludes that “no adverse health patterns were found, once patterns were examined at a population level” (p x), and “among those medically

reviewed, no individual was identified as having a significant adverse outcome attributable to the Btk spraying” (p18).

For example, the report stated (p 35), that there was:

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

[Note that there are a number of omissions from this list relating to symptoms reported, e.g. aggravation of existing asthma, headaches].

The conclusions of this report support the findings of the pre-spray Health Risk Assessment (Auckland Healthcare & Jenner Consultants 1996a) co-authored by the same author, Dr Francesca Jenner/Kelly of Aer’Aqua Medicine formerly Jenner consultants. It also confirms the second health risk assessment carried out during the programme (Auckland Healthcare 1997). This HRA acknowledges reports, during and after the 1996/97 spray programme, of “minor eye, throat and skin irritations and headaches”, but concluded “we found no evidence of a causal association with Foray 48B spray” (p v). Note that a lack of evidence of causal association is *not* evidence that there is no link. It is not proof that the effects did not occur as a result of the spray. In this succession of reports, involving some of the same authors, there is a discernible tendency to confirm previous findings, rather than to question them in the face of contradictory community reports.

The Aer’Aqua report did not state the possible or probable cause of the symptoms, reported by the 375 people, that appeared to be contemporaneous with the spraying. In other words, the report has interpreted an absence of a “medical event” at a population level, together with no proof of a link between Foray 48B spraying and a “significant adverse outcome” for an individual (p 18), as “no significant diseases attributable to the spraying” (p vi). This should *not* be reinterpreted to mean that the symptoms experienced by the 375 people were *not* caused by the spray. That is not proven by this health surveillance. The only interpretation that should be placed on the report is that there is no proven link.

## **B. FINDINGS OF THE WEST AUCKLAND COMMUNITY-BASED HEALTH MONITORING**

Following the announcement of the proposal to aerial spray parts of West Auckland with Foray 48B, a community-based group of concerned citizens (the Painted Apple Moth Community Coalition - CC-PAM), was formed to enable public participation and input into the decision-making process, and ensure health protection was a prime consideration. When this group became aware that

the same problems experienced in Operation Evergreen of under-recording and devaluation of health effects were occurring, a community-run health and incident reporting system was introduced. An interim analysis of the results is provided by Blackmore (2003), and summarised below in Table 2.

It reveals a prevalence of respiratory effects, followed by neurological, digestive and skin problems, and psychological effects among the 315 people reporting symptoms by the end of 2002.

General	291	anxiety – health concerns	49
		allergy - sensitised	8
		anaphylactic collapse	6
		fatigue	54
		flu-like symptoms	22
		general health effects	119
hospitalised/A&E	14	mouth/tongue/lips	19
Digestive	109	diarrhoea	35
		nausea	22
		pain/cramps	21
		vomiting	17
Endocrine/Metabolic	9	hypothyroidism	1
Eye	78	general	61
		conjunctivitis	13
		ulcers	4
Ear	7		
Circulatory	10		
Musculoskeletal	13		
Neurological	128	headache	86
		disoriented	6
		dizziness/loss of balance	17
		numbness/tingling	3
Psychological	77	anger	18
		depression	3
		distress	33
		insomnia	3
		panic	5
		stress	10
Respiratory	329	asthma, aggravated	41
		asthma, new	10
		breathing difficulties	35
		chest pain	20
		cough	55

		general	18
		infection	9
		nose bleed	17
		nose congested/runny	23
		nose - sinusitis	21
		nose - sore, burning	11
		sneezing	6
		throat symptoms	53
Skin	78	itch	17
		rash, general	26
		rash, localised	21
Urology	3		
Pregnancy	12	concerns	6
		miscarriage	6
Social	253	affected work	34
		lost job	5
		had to move house	14
		pets/animals affected	38
Total symptoms:			1397
Number of people:			315
Taken from: Blackmore (2003)			

Blackmore (2003) should be consulted for greater detail.

### **C. THE 2002 HEALTH RISK ASSESSMENT (KALEMBA et al. 2002)**

This assessment was the primary health report underpinning the decision to aerial spray West Auckland with Foray 48B. It in turn was based on the September 1997 assessment (Kalembe et al. 2002, p 6), but also drew extensively on the conclusions of the health surveillance carried out after Operation Evergreen (Aer'Aqua 2001).

It pertained to aerial spraying events, one day per week, every three to four weeks, for six to eight sprays, and up to 15 sprays if necessary. Subsequent verbal communication with MAF and Auckland Healthcare reveals that the HRA is regarded as being relevant to any number of Foray 48B aerial spray events people may be exposed to. In other words they believe the extent and duration of exposure to the spray to be of no consequence. This paper will show that failure to adequately characterise exposure is a significant problem.

The conclusions of the Kalembe assessment include:

- After 35 years of use the active biological component of Foray 48B, *Bacillus thuringiensis kurstaki* (Btk) has never been implicated in human infection.
- 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 that Foray 48B causes thyroid dysfunction or abnormalities.

There are a number of problems with the way in which the assessment was carried out, which mean that these conclusions do not reveal the whole picture. Some of these problems are briefly canvassed below.

## ***Btk***

### *Neurological effects*

Kalembe et al. assert (p 35) that there is no evidence that Btk can cause neurological or autoimmune effects, but fail to cite any studies that show it does not cause these effects. The lack of evidence may simply result from a lack of studies. Neurological studies are not commonly carried out on pesticides other than organophosphates and carbamates (ACVM 1998; Newman-Martin 1992; Watts 2000). There is a tendency to assume that unless a pesticide affects the cholinesterase levels as do the organophosphates and carbamates, they will have no other neurological effects. But clinical experience with multiple chemical sensitivity has shown that neurological symptoms are common regardless of the nature of the chemical(s) that trigger the onset or re-emergence of the sensitivity (e.g. Davidoff & Keyl 1996; Ziem & McTamney 1997). Severe bacterial infection has been posited as a cause for the onset of MCS in rare cases (Rea 1992). Admittedly, in the West Auckland situation, it is more likely the chemical components of Foray 48B are causing the apparent neurological symptoms than the Btk, but the section in the HRA on the chemical component does not address neurological effects at all, so it is discussed here to draw attention to an unsafe assumption about neurological effects.

Studies for autoimmune effects are rarely carried out on any pesticides.

The authors back their conclusion of no neurological effects by stating that headaches can be caused by many things and that there was no increase in presentation to general practitioners for headache symptoms during Operation Ever Green. Most people do not go to doctors for headache remedies, so this is not surprising, but 64 people did self-report problems with headaches - a pattern repeated in West Auckland. Headaches are not assessed during toxicological tests, so the toxicological literature would provide no guidance here. The HRA is silent on other neurological symptoms reported from West Auckland, such as disorientation, dizziness, loss of balance, numbness and tingling. Again, toxicological studies do not usually measure these symptoms, so it is only repeated experiences of exposure that would provide guidance here. These symptoms can be an expression of multiple chemical sensitivity (e.g. Levy 1997).

### *Gastrointestinal effects*

Kalemba et al. report that “there is evidence some strains of *Bacillus thuringiensis* are capable of producing small amounts of the same enterotoxin as *Bacillus cereus*”. They cited a paper by Damgaard (1995) which refers to the enterotoxins produced by a *Bacillus* culture from Foray 48B causing diarrhoea.

There were a small number of gastrointestinal disorders reported during Operation Evergreen (40), but there appears to be a significantly greater number of occurrences in West Auckland: 109 cases including 39 of diarrhoea (Blackmore 2003).

However the Kalemba HRA discounts any risk of gastrointestinal effects from Foray 48B for two reasons:

- The manufacturer checks for presence of enterotoxins before release of the product for sale. No information is given on these tests: neither testing procedures, sensitivity of tests, nor incidence of contamination. Kalemba et al. have failed to take into account that some enterotoxin may in fact be present in the Foray 48B as a result of errors in laboratory procedure and testing. Such errors are not uncommon. But the authors appear to have taken the manufacturers assurance as evidence of fact.
- Kalemba et al. assumes that if gastro-enteritis were to occur as a result of exposure to Foray 48b, it would have shown up in previous spraying operations in Vancouver, Oregon and Auckland [Operation Evergreen]. There are two problems with this reasoning:
  - i) firstly, it assumes that that there is no variation in the quality of the product, which is an unreasonable assumption for any pesticide manufacturing process let alone for a biological product; and
  - ii) secondly, it ignores the reports from both Oregon and Auckland. The HRA acknowledges that in the Oregon spray programme some cases of gastrointestinal illness were reported “but it is not clear the incidence was

higher than that in the non-exposed community". In Auckland (Operation Evergreen) 40 people are recorded as having reported digestive "health concerns" (Aer'Aqua Medicine 2001).

The HRA states that the Foray 48B used during the 1996/97 operation was tested in Auckland for bacterial contaminants, although it does not indicate if this includes the enterotoxin. A report on the findings (Jenner 1998) was made to the Ministry of Forestry (Kalemba et al. 2001, p 25) but I have been unable to obtain a copy of this report.

The HRA does not indicate that such testing is being carried out for the PAM operation, but recommends that it should be (p 64). No information has been made available on any proposal for actual testing or any results, and in the absence of such it could be assumed that the current use of Foray 48B does not involve pre-testing in New Zealand for the enterotoxin, or contamination with *Bacillus cereus* or other microbiological contaminants.

### **Chemical components**

The chemical components of Foray 48B remain largely a mystery. We know it contains "as the active ingredient the protein crystal products of the bacterial species Btk, inactive Btk spores, and a number of chemicals referred to as 'inerts' because they are not considered to contribute directly to the insecticidal activity of the product. The term inert does not necessarily reflect their toxic potential". (Kalemba 2002, p 8)

An undated MAF Factsheet, "About Btk – including Foray 48B", claims that the "spray contains mostly water, traces of essential elements, minerals or salts, and "inert ingredients such as thickening, sticking and wetting agents. All the ingredients (as assessed by New Zealand medical experts) are of extremely low toxicity". The Kalemba HRA refers to these as preservatives, acid regulators, inert diluents, suspension agents and emulsifiers, acknowledging that there are seven compounds involved (p 42).

The ingredients as described by the 1997 HRA are as follows:

Water	>70%
Btk	10-20%
Stabiliser	10-20%
Other inerts	<10%

We have good reasons to believe that the chemical fraction includes benzoic acid and methyl paraben. These were identified by Dr Jim Waters of the Ministry of Health to the Tussock Moth Science Panel as components of the Foray 48B used in Operation Evergreen (Anon 1996). The Kalemba HRA consistently refers to the HRA for that spray operation and to the ensuing health surveillance to

support its conclusions on Foray 48B (e.g. pp 4,43), so it is reasonable to conclude that the same formulation is involved in both spray programmes. The Kalemba HRA also refers to benzoic acid (p 43).

The Kalemba HRA is extremely light on details of the assessment of the risks pertaining to the non-Btk elements of Foray 48b. This is in part because of the secrecy surrounding the identity of the actual ingredients. No account is given of the methodology by which the conclusions have been reached, therefore it is impossible to fully assess either the robustness of the methodology or the validity of the conclusions. However it is possible to make some comments, based on the assumption that the process used most likely conforms to the standard regulatory toxicological assessment approach. It is possible also to illustrate one defect in this approach using the example of benzoic acid.

The HRA (p 41) acknowledges the following known health effects of exposure to the inert ingredients:

- hypersensitivity and irritation, represented by contact dermatitis, eye and respiratory sensitivity;
- anaphylaxis;
- flatulence, abdominal pain, diarrhoea.

These effects are then discounted because the HRA asserts, without evidence, that such effects “generally” require a “substantial initial exposure” which is not expected in this instance for the community. However the word ‘generally’ indicates that this does not apply to all people or all circumstances. In other words, on-going low doses exposure may be sufficient cause rather than an initial substantial exposure. This potential is supported by medical literature that confirms many cases of multiple chemical sensitivity (MCS) arise from on-going low dose exposure rather than initial high exposure (Cullen, Pace & Redlich 1992; Rea 1992; Miller 1997). Once MCS is established even a very low level exposure can be sufficient to trigger adverse health effects (Ziem 1994; Bell et al. 1997). The issue of exposure, and this document’s inadequate assessment of it, will be addressed below.

The HRA (p 42) also acknowledges these expected health effects as a result of the chemical components:

- eye, nose, throat and skin irritation caused by the acidity of the formulation;
- adverse effect on lung function of asthmatics caused by the acidity;
- nausea, headaches and other symptoms caused by the unpleasant smell, although it also describes these symptoms as being of “no harm”. [That is not normally how people who experience nausea and headaches would judge the experience.]

All of these symptoms have been experienced by the community.

As previously stated the assessment does not include information on neurological and immune system effects, leaving the only pronouncements in the document on these as a negative statement relating to Btk.

<u>Table 3: Summary of symptoms identified by Kalemba et al. (2001) as hazards inherent to the ingredients of Foray 48B</u>	
General	aggravation of allergies anaphylaxis
Digestive	abdominal pain diarrhoea flatulence nausea
Eye	irritation, sensitivity
Neurological	headache
Psychological	anger anxiety
Respiratory	aggravation of asthma nose irritation respiratory sensitivity throat irritation upper tract irritation
Skin	contact dermatitis irritation

### Benzoic acid

This section should not be regarded as a risk assessment of benzoic acid. It is merely a brief review of two recent assessment documents of international standing, pointing out some of the material that could account for the health effects apparently experienced after exposure to Foray 48B. The two documents are provided by the European Commission (EC 2002); and the International Programme on Chemical Safety (IPCS 2000), a joint venture of the United Nations Environmental Programme, the International Labour Organization, and the World Health Organization. Both were apparently omitted from the Kalemba HRA.

Human exposure to benzoic acid has been reported to result in asthma, urticaria, rhinitis, and anaphylaxis (EC 2002). It is known also to exacerbate existing asthma (IPCS 2000). Some people have an allergy to benzoic acid and it should be regarded as a potential sensitiser (EC 2002). The EC concluded that "It is apparent from the limited reports available that benzoic acid may be irritant to skin and eyes" (EC 2002, p10).

Clinical signs of intoxication with benzoic acid in laboratory animals include diarrhoea, muscle weakness, tremors, hypoactivity and emaciation. The IPCS (p 14) reported additional symptoms in cats, in feeding trials, of aggression, hyperaesthesia, collapse and death, with histopathological examination revealing degenerative changes of liver, kidneys, and lung. Cats are very much more sensitive to benzoic acid than other mammals it appears - probably the result of cats' limited ability to conjugate xenobiotics (EC 2002, p11). This is perhaps the reason for the prevalence of ill-health amongst cats reported by the West Auckland community, with 23 cat reports and 11 dog reports. Symptoms reported for cats included sore eyes, lethargy, low energy, stiff, vomiting, dull fur, unwell, and loss of appetite (Blackmore 2003).

Benzoic acid occurs as a natural compound present in food commodities and is also used as a food additive. In its commercial form benzoic acid is produced by oxidation of toluene. From the literature it would appear that ingestion poses low risk, but problems may well arise from inhalation.

In 2000 the IPCS (p 5) concluded that

“as there are no adequate studies available on inhalation exposure, a tolerable concentration for exposure by inhalation cannot be calculated”.

However two years later the EC (2002, p 10) concluded that

“as the rat inhalation studies showed adverse effects at all doses studied, it is not possible to identify a level of inhalation exposure that is without risk”.

The IPCS document (p 17) also identified that there is no available database for repeat dermal exposure, or long-term exposure to benzoic acid, a common situation of exposure for West Aucklanders.

Thus it can be concluded that Foray 48B may in fact be more toxic than the HRA would indicate, when taking into account the risk from inhalation, if indeed it does contain benzoic acid. Certainly, also, the absence of data on long-term exposure to benzoic acid should preclude any conclusion about the safety of long-term exposure to Foray 48B – again if it contains benzoic acid.

The HRA acknowledges that the inhalation effects of the chemical compounds have not been well studied. But it also states that adverse health effects have not been reported for inhalation of the inert ingredients nor are they expected (p 44). As has been demonstrated this is not true for benzoic acid: there is an inhalation risk.

## ***Exposure assessment***

This part of the HRA contains a significant number of flaws, principally flaws of assumption.

Firstly, the document states that “the general population’s exposures to a hazard will either be chronic and in low amounts via air, soil or water or acute in possibly higher amounts for a short time” (Kalemba et al. 2001, p 12). It omits to acknowledge that both can happen concurrently, as may be the case with some exposures to Foray 48B.

The exposure assessment for the PAM operation is premised on exposure during a short period of time, during or after the spray application. Experience in West Auckland has been that some people may be exposed directly to the spray up to five times in one day – in addition to the residual spray in their homes and work places (Blackmore 2003). Thus the exposure assessment in this report appears to significantly underestimate the actual exposure people are experiencing, and hence the conclusions it reaches cannot be supported.

It does acknowledge that schoolchildren may be more exposed than others (Kalemba et al. 2002, p 43), and this is borne out by experience: there have been reports of direct contact with the spray on the way to and from school and during lunchtime (Blackmore 2003).

The HRA states that dermal contact would be expected to be the primary route of exposure for residents outside, adding that inhalation is a possible route (p 44). In my view this expectation may have led to an underestimation of the exposure via inhalation. It would not be possible to avoid inhalation if present in the spray zone during aerial spraying (unless one wore a respirator).

The report states that:

- limited data are available to assess exposure, especially for inhalation risk;
- NOELs (no observed effects levels) could not be confirmed for 3 exposure routes – dermal, inhalation, oral;
- the available toxicology base for Foray 48B is limited;
- assessment is based on “infrequent” direct exposure to spray; mostly exposure will be indirect leading to low doses to the skin unlikely to cause irritation;
- there is negligible likelihood of spray causing an asthma episode [the reason for this conclusion is not provided];
- the estimated exposure via ingestion is no more than the acceptable daily intake as recommend by FAO/WHO for each of the inert ingredients;
- “the exposures that could result from the use of this spray would not give rise to sufficient intake into the human body to produce any of the symptoms: flatulence; abdominal pain; or diarrhoea.”

This last, bald, statement is unsupported by any evidence of mathematical modelling and cannot be substantiated, especially in light of:

- the above statement in the HRA that limited data are available to assess exposure;
- the available toxicological database on Foray 48b is limited;
- the assumption that people would only be exposed directly once to the spray per spray event, when in fact some people have been exposed at least five times per event, experiencing both dermal and inhalation routes of exposure at home, on their way to school or work, waiting at train stations, etc, and also to persistent residual exposure in places of work, learning and/or residence (Blackmore 2003).

The document states that “it is expected that oral exposure to the inert ingredients through ingesting food and water would be similar to that from consumption of food under normal circumstances. There is no reason given for this assumption, and it cannot be substantiated, given the known penetration of the spray, at least the Btk spores, into residences and their persistence there. This persistence gives rise to ample opportunity for contamination of food especially as it is prepared and consumed. Admittedly the studies relate to the Btk spores not the chemical components of the spray, but in the absence of any studies on the entry and persistence of these chemicals into buildings the precautionary approach requires that those characterising the active ingredient guide the characterisation of the full spray.<sup>1</sup> This is open to challenge of course, but it becomes a question of values: in the absence of information, do you err on the side of public health, or do you err on the side of the chemical?

The assessment then concludes, again without presenting the rationale, that “the only possible effect is that of a small number of individuals [who] may demonstrate hypersensitivity to the inert ingredients as a result of previous exposure” (p 44-5). This means the authors have concluded that the ongoing exposure to the mixture of chemicals in Foray 48B through inhalation and dermal absorption cannot cause the onset of hypersensitivity. This assumption is not supported by medical evidence relating to multiple chemical sensitivity, as already stated, and no evidence is provided in the HRA to support this assumption.

### ***Other methodological flaws***

Additional flaws in the standard toxicological procedures may compound the errors already described. These are:

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<sup>1</sup> Teske et al.'s (2000) study on airborne exposure to Foray 48B notes that the "droplets which stay suspended in air include all components of the insecticide formulation, and can be inhaled". The only measurement of spray penetration used is the culture of Btk.

- characterising risk on the basis of occupational exposure;
- increased toxicity of some chemicals via inhalation;
- non-positive doses responses;
- the effects of mixtures of chemicals at low levels of exposure;
- the effects of value systems on the judgements and assumptions that guide a risk assessment.

Each of these compounding problems is reviewed briefly below.

i. *Occupational exposure*

As noted by Kalemba et al. (2000, p12), determining the risk of exposure to hazards often draws on the experiences of occupationally exposed individuals. Exposure limits have been developed for workers related to their exposure for the normal working day over the average worker's lifetime. These are based on the use of recommended protective clothing, but the people of West Auckland do not wear this when they are exposed, and in instances of repeated direct exposure together with persistent exposure in the home and work place, it is conceivable that a person may in fact absorb more of the chemical than the occupationally exposed.

Additionally there is the impact of the "well-documented 'healthy worker effect'" (Au et al. 1999, p 505). The documentation shows that workers with exposure to hazardous agents have an overall lower mortality rate than the general population. Au et al. (1999) proposed that this effect may be a result of "unrecognized occupational selection pressure against genetically susceptible individuals" (p 501). They were referring to inheritance of "unfavourable" alleles of the polymorphic genes responsible for metabolizing chemicals" (p 501). In their study of twenty Costa Rican farmers, they found significantly fewer with the unfavourable alleles than in the control group of workers not exposed to pesticides, thus leading them to hypothesize about the selection of a relatively "resistant" work force (p 505).

The conclusion is that if risk assessment is based on risk through occupational exposure, it may underestimate risk to the general public.

ii. *Inhalation toxicity*

As has been shown with benzoic acid, the toxicity of a chemical when inhaled can be greater than for exposure by the oral or dermal route.

Much of the toxicological hazard data is gained by administering the pesticide, to laboratory animals, by either interperitoneal or oral means, and this may not provide accurate data about the risks when the pesticide is inhaled. US EPA scientists Whalan & Pettigrew (1998) illustrated this problem with the observation that two organophosphate insecticides - mevinphos and methyl parathion - are

equally toxic by the oral route but, when inhaled, mevinphos is 130 times more toxic than parathion.

These examples [sic] demonstrate how reliance on mixed-route data can dangerously undermine a risk characterisation. Because absorption across the respiratory mucosa tends to be far greater and more rapid than by oral and dermal routes, inhalation MOEs [margins of exposure] based on NOELs from these other routes will most likely underestimate the hazard, even as much as several orders of magnitude. The danger lies in not knowing the extent of the error.

Whalan & Pettigrew 1998, p 5.

In the absence of evidence to the contrary it would be prudent to assume that the risk characterisation for the Foray 48B components relies on non-inhalation data and therefore probably under-estimates the risk.

### *iii. Non-positive dose-response*

Risk assessment relies on a theory of positive dose-response: the higher the level of exposure to a chemical the greater the effect. This means that if an effect does not occur at a high dose, it is assumed to not occur at much lower levels of exposure. Toxicological procedures are based on administering high doses of a single chemical to laboratory animals and measuring what happens. Mathematical models are then used to extrapolate the effects seen at high doses to predict those that will occur at low doses.

However, inaccuracies in risk assessment arise if the dose-response is not a positive one, as has been found to happen in some instances. Timbrell (1991) reported that "there is usually no dose-response relationship for immune responses, as the magnitude of the response is dependent on the type of reaction of the endogenous immune system, not on the concentration of the foreign compound" (p 257). In other words immune system effects of Foray 48B would not necessarily depend on a high level of exposure. Since data is most likely lacking for the effects of the chemical components on the immune system (for these tests are not commonly carried out), it would not be possible to state an exposure level at which these effects may or may not occur.

Lovell (1993) noted that "the methods of deactivation [of a chemical] occurring at high doses may be different from those operating at lower, more realistic dose levels" (p.447). This view is echoed by a number of other researchers, particularly in the field of endocrine disruption: Vom Saal found an inverted U shaped dose-response curve when investigating low doses of the synthetic hormone DES, meaning that the greatest response occurred at medium exposure levels. Colborn et al. (1996, p170) concluded that "neither linear nor always moving in the same direction, the inverted U seems characteristic of hormone systems and

it means that they do not conform to the assumptions that underlie classical toxicology—that a biological response always increases with dose.” This may have particular importance in West Auckland if any of the chemicals in Foray 48B is an endocrine disruptor. The HRA is silent on this.

Inverse dose-responses have also been found in levels of somatotrophin<sup>2</sup> and immune parameters<sup>3</sup> in laboratory rats exposed to the insecticide aldicarb. Additionally, low doses of a mixture of fifteen commonly used pesticides have been found to cause a significant increase in levels of 8-OH-2-deoxyguanosine in DNA, an indicator of oxidative damage mediated by free radicals and believed to result in cellular ageing and cancer (Lodovic et al. 1994). Higher doses did not cause this effect, but did result in reduced levels of the detoxification product benzo[a]pyrene hydroxylase and *N*-demethylase. The interpretation of these findings is that the higher doses of these pesticides caused a depression of the cellular mechanism resulting in an inhibition of the oxidative damage seen at low dose exposure. The authors of the study referred to the low doses they used as being "comparable to human exposure" (Lodovic et al. 1994, p 166).

The conclusion to be reached from these findings is that exposure to low doses of pesticides, such as may typify the West Auckland experience, may be more damaging to health than the higher doses used in laboratories to determine the supposed level of safety.

#### *iv. Effects of mixtures of chemicals*

Standard toxicological tests are carried out on single chemicals, even though toxicological texts all acknowledge the potential effects of mixtures of chemicals. These effects may simply be additive or they may be synergistic. Additive effects occur when two or more chemicals act at the same site in the body, altering the same process by different mechanisms (Carpenter et al. 1998, p.1264). Synergism involves the interaction of two or more chemicals in such a way that the toxic effect of the combination is greater than the sum of the individual toxic effects (Arnold et al. 1996).

Risk assessment assumes that a person is exposed to only one chemical at a time, which is obviously not what happens with the application of a mixture of chemicals like Foray 48B. But there have been several studies recently that demonstrate the synergistic effects of chemicals, particularly on neurological, endocrine, immune or developmental functions, which are especially sensitive, according to Porter et al. (1993, p.16).

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<sup>2</sup> Porter, Green, Debbink & Carlson 1993.

<sup>3</sup> Olson, Erickson, Hinsdill, Wyman, Porter, Binning, Bidgood & Nordheim 1987; Shiraz, Erickson, Hinsdill, & Wyman 1990.

- Porter et al. (1993) found interactive effects between three pesticides (aldicarb, methomyl and metribuzin) on thyroxine levels in rats. They noted that "the same concentrations and mixtures of these three pesticides have now been shown to be implicated in learning impairment and other neurological functions, immune parameter changes, and endocrine changes, and concluded that the results "strongly suggest the need to reassess currently allowed 'safe' levels of chemicals" (p.15).
- In their subsequent five-year study, Porter et al. (1999) found that "thyroid hormone concentration change was consistently a response due to mixtures, but not usually to individual chemicals" (p.136). Earlier studies had also indicated that "neurological, endocrine, immune and developmental effects may show up only when pesticides are tested in combination" (p.135).<sup>4</sup>

#### v. *Effects of value systems*

Risk assessment is a highly subjective process, fraught with uncertainty because of a lack of accurate data. It depends on a large number of assumptions and judgements, all of which are guided by the value system of the assessor and his/her institution. Values are inculcated in risk assessment at every step of the way: how risk is defined and the problem structured, what toxicological parameters are judged salient, what assumptions are made about fate, transport, exposure, and receptor behaviour, which methods are used for handling uncertainty, how much data is gathered, which models are selected for use in estimating risk, how to handle cumulative effects, which data sources are used, etc.

The profound influence of values on the outcome of a risk assessment is illustrated by a Canadian case involving the banning of the herbicide alachlor. Three different institutions, including the government and the herbicide manufacturer, estimated the exposure risk for the herbicide and their estimations ranged from 2.7mg/kg to 0.0000009 mg/kg. This meant that alachlor either did or did not constitute a risk of cancer, depending on whether the value system was based on protecting human health, or on protecting economic interests (Brunk et al. 1998, p 104). If the values are stripped away from that risk assessment, the outcome of the assessment can be no more precise than that alachlor may or may not cause cancer.

I have found the Kalemba HRA to exhibit a bias in favour of the aerial application of Foray 48B. The signs are often subtle but may at times be very obvious. For example, the inclusion of an assessment of the effects of the moth itself in a health risk assessment of aerial spraying indicates a clear bias in favour of moth eradication – especially in the absence of a similar assessment of the ground

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<sup>4</sup> Boyd, Weiler & Porter 1990; Porter *et al.* 1993.

spraying with the synthetic pyrethroid Decis (deltamethrin). Both of these assessments have a place in a risk-benefit assessment, but neither in a health risk assessment of aerial spraying Foray 48B. The authors appeared to be at pains to justify the eradication programme.

There is a systematic discounting of reported effects of Btk and Foray 48B exposure throughout the Kalemba HRA as there was also in the Aer'Aqua Health Surveillance. Where data is lacking the assumption is made that the effect will be absent, e.g. neurological effects, inhalation toxicity. The risk characterisation, building on its previous assumptions and value judgements then asserts that the risk is small. This cannot be justified on a scientific basis. The assessment should say that because data on long-term exposure is lacking, the risks from long term exposure cannot be ascertained. Instead it concludes the risks are small. It seriously underestimates exposure.

If the value bias were to be in favour of public health, or even neutral, the HRA would have looked more closely at the health effects reported from previous occasions, instead of dismissing them because they are unproven. There is no adequate explanation of the effects reported by the community during Operation Ever Green; they have been simply discounted because they do not fit with the methods chosen to determine if there was an effect (e.g. no extra headaches presenting to general medical practitioners). Similar effects have also been experienced in previous overseas aerial spray operations, and again in West Auckland, but each time they are discounted because they are not expected on the basis of the scientific literature – which in fact mostly likely has never set out to determine whether or not these effects will occur. Where one piece of literature dismisses community reports, so another one cites this report as support for the belief that there won't be any health effects of this nature. In such a situation the cumulative weight of experience should be taken into account. If there are repeated incidents of reported symptoms that cannot be casually linked or regarded as statistically significant in each instance, then a weight of evidence approach should be used. Whilst that weight of evidence could be said to have not existed within New Zealand before Operation Ever Green (and if overseas reports are discounted), that is no longer the case after the experience with the PAM programme to date.

The HRA notes that similar symptoms are reported for many occupational and environmental health hazards, but then makes the assumption that because the symptoms are similar they are probably related to psychological and social factors rather than as a result of exposure to the hazard. This type of thinking is reminiscent of the view that was taken of multiple chemical sensitivity (MCS) more than a decade ago: because people who experienced this problem reported similar symptoms regardless of the chemicals exposed to, and because many of the sufferers were middle aged women, the cause was assumed to be psychological factors relating to boredom and neurosis rather than chemical exposure (e.g. Black et al. 1990). A wealth of clinical data and medical review

has subsequently supported the existence of MCS as a reaction to chemicals. The rationale presented in the Kalemba HRA of discounting similar symptoms from environmental exposures is construed as being based on a lack of understanding of the nature of the response to ongoing exposure to low doses of mixtures of chemicals and is rejected.

On the basis of the Aer'Aqua Health Surveillance, together with a lack of evidence of problems amongst the literature selected for review, the Kalemba HRA assesses that the overall risk to health from aerial applied Foray 48B is "small", but there are likely to be a substantial number of complaints regarding minor physical irritations, annoyance and psychological stress. What does 'small' mean in the context of a community, and the context of one person's health?

#### **D. GOVERNMENT PRONOUNCEMENTS ON HEALTH RISK:**

There appear to be a wide range of interpretations of the health risk advice given to the government, each influenced by the value judgements of the interpreter concerned.

- Minister of Biosecurity, Jim Sutton, in a press release on 3 July 2002 referred to "the proven safety record of the Btk spray". Note this comment is not supported by science. As advised by Kalemba et al. 2002, "a health risk assessment does not prove or disprove safety, but rather assesses level of risk".
- Minister of Biosecurity, Jim Sutton announced in a press release on 17 December, 2002, that 5 percent of the population are allergic to Foray 48B, and this has been recognised by the government. No source has been found for this information.
- There appears to be no report by the government or commissioned by the government on the actual health effects experienced in West Auckland. If such a report does exist it is not in the public arena.

*MAF Biosecurity Foray 48B Fact Sheet* asserted the following, based on the Health Risk Assessment 2001:

- Btk does not cause infection
- The protein crystals Btk produces are not toxic to people
- Some people who have severe allergies to specific ingredients in the nutrient broth may be affected, others will not.
- The chemical components of Foray 48B (preservatives, sticking agents and acid regulators) are registered for use in cosmetics, medicines and/or foods. People are commonly exposed to these at home and they are regarded as safe for use in Foray 48B.

- Some people will notice minor skin, eye, nose or throat irritation if directly exposed to the spray or large spray deposits.
- There is no evidence that Foray 48B causes health effects such as neurological or autoimmune effects or problems with pregnancy or birth defects, or makes asthma worse.

Auckland District Health Board's Public Health Protection Office, in the fact sheet "Foray 48B Spraying in West Auckland", 21 December 2001 (Kelly 2001) asserted:

- Some of the components of the spray have been noted to cause skin irritation and allergy when used in pharmaceutical and cosmetic products and foods, "the level of exposure expected from the spray programme is not expected to cause these effects though people may attribute them to the spray"
- "No significant health effects are expected from the spray programme".

Despite these assertions, the community is still reporting adverse health effects that look remarkably similar to the hazards identified by the Kalembe HRA as being inherent to the components of the mixture of substances that is called Foray 48B, as a comparison of Tables 1,2, and 3 will reveal.

## **CONCLUSION**

This paper has demonstrated that there are a number of flaws in the Kalembe HRA, which result in an inadequate depiction of the real risks to which West Aucklanders are exposed from the aerial application of Foray 48 B. The HRA does identify potential symptoms of exposure; these correspond closely with those experienced during Operation Ever Green, and now also reported from West Auckland. But then it discounts any likelihood of significant effect actually being experienced, describing the risks as small. It is suggested that this conclusion is reached in part because of inadequate characterisation of exposure, especially to inhalation of the chemical components of the spray. It is also in part because the underlying value system that so influences the many assumptions and judgements inherent in a risk assessment, in this instance, favours the eradication programme.

The HRA has subsequently been turned into a series of political statements used to justify the continued exposure of people to the spray. In the process the health effects that members of the community are experiencing, perhaps as a result of the spray, are discounted and trivialised. They are regarded as being of no real significance or as being acceptable, when in fact they are significant health problems for the people concerned who have judged them to be not acceptable.

It is not possible to prove that the health effects result from the spray, just as it was not possible to determine that the health effects reported during Operation Ever Green were or were not caused by the spray. Nor can the risk assessment, with its many gaps in data, provide any certainty. But as it does identify the same symptoms that exposed people have reported from at least two aerial spraying operations, then a case may be made for acknowledging the validity of community experience.

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