

## Review of: Watts M. *Painted apple moth eradication programme: health risk and effects* (2003)

By: Dr Deborah Read, a public medicine specialist.

The report focuses on the health risk assessment (HRA) carried out by Auckland DHB although some of the criticisms relate to toxicology in general rather than the specific HRA. The author claims that the conclusion of the HRA of a small risk has been interpreted politically as no risk with claims made of safety and harmlessness and failure to subsequently modify this view in the light of community experience.

A recurrent theme of the report is the perception that community experience has been dismissed and devalued. Although the health effects reported by the community are similar to those in the HRA that are associated with Btk or other components of Foray 48B, and previously reported during Operation Ever Green the author claims there is a self-perpetuating belief among the risk assessors and government that the reported health effects are not caused by Foray 48B.

Most of the health complaints are non-specific and have many possible causes. The background rate in a non-exposed community at the same time of the year to take account of seasonality is needed for more meaningful interpretation. Although there is no evidence other than a temporal and spatial link to spraying that the health effects are caused by the spraying there is also no evidence that they were not caused or contributed to in part by the spraying.

The author refers to multiple chemical sensitivity (MCS). There is considerable debate over what MCS is and whether it is a distinct clinical entity. There is some evidence that in some people chemical exposure can initiate a clinical response that recurs with subsequent exposures to very low levels (below those known to cause toxicity in the general population) of that chemical and structurally unrelated chemicals. Prevalence is less than 1% of the general population.<sup>(1)</sup> It is possible therefore that some people may become sensitised to the spray as a result of repeated exposure and that it could result in MCS in some, albeit a very small number of people.

The author criticises both the HRA and conventional toxicological assessment. Criticisms of the HRA are:

- Failure to substantiate certain statements by providing details (e.g. of likely intake from spraying and intake known to result in gastrointestinal symptoms) or citing references (e.g. studies showing no neurological effects from Btk)
- Inadequate consideration of the inhalation exposure route
- Insufficient acknowledgement of uncertainty resulting in inadequate risk characterisation
- Inclusion of assessment of the effects of the moth but exclusion of the effects of alternatives to aerial spraying of Btk
- Underlying bias towards aerial spraying

- Non-identification of the inert components and their potential toxicity e.g. thought to include benzoic acid which does not have a no observed adverse effect level following inhalation.<sup>(2)</sup> This has resulted in the HRA not being able to be fully independently reviewed.

The HRA also assumed a particular exposure scenario which was less in frequency and duration than what has subsequently eventuated for some people. There is no information in the report as to the number of people for whom exposure has been underestimated by the HRA.

The validity of these criticisms has not been able to be fully assessed as the HRA was unavailable to the reviewer.

Criticisms of conventional toxicological assessment are:

- Failure to consider the toxicity of the mixture as opposed to its individual components
- The effect of different values on judgements and assumptions that are made by assessors

Although the author states that chronic low level exposure is not considered by the conventional toxicological approach it is by mechanisms such as linear extrapolation of carcinogenic effects at high doses to low doses, and identification of no or lowest observed adverse effect levels and use of uncertainty factors when setting exposure limits such as the acceptable daily intake. However as commented on by the author some dose-response relationships are more complex than previously recognised and traditional extrapolation procedures may not provide accurate estimates of response at low doses i.e. the dose-response relationship may be U shaped or inverse U shaped. Whether this applies to Foray 48B or not is unknown.

The author states that risk assessment based on occupational exposure may underestimate risk to the general public due to failure to take into account the healthy worker effect. Whilst it is true that the general population will contain a subpopulation of more susceptible people the average exposure of these people is usually considerably less in frequency, duration and dose than that experienced by workers.

Some of the criticism relates to limitations such as availability of toxicity and exposure data which are common to many HRAs which can only reflect the state of scientific knowledge at the time the HRA is carried out.

There is also mention of the lack of information as to whether the product has been tested for absence of microbiological contaminants (as recommended by the HRA) and enterotoxins.

The report illustrates the differences in perception between population versus individual/highly susceptible subpopulation perspectives. Protection of public health from hazardous substances uses a population approach that looks at the size of the population exposed and its characteristics, toxicity of the substance and exposure to

it. Such an approach accepts that some people (a small number in terms of the total population exposed) will not be fully protected.

Effects that are insignificant, negligible or acceptable on a population basis in terms of both numbers of people affected and the magnitude of the adverse health outcomes will not be to the subgroup of people that are experiencing them. In this regard it is often preferable to refer to tolerable risk which recognises that though the risk may not be acceptable to some it may be tolerable (though not to all) for other reasons such as the benefits from use of the substance.

In conclusion the author raises some valid concerns in particular recognition of the legitimacy of community experience in the face of conflicting previous conclusions. This is not the same as accepting the experience as being caused by the spraying but rather acknowledging the possibility. The concerns are reasonable and highlight different perspectives in particular that a small population risk is not small on an individual or highly susceptible subpopulation basis and a preference among some for a more precautionary approach in the face of incomplete scientific knowledge.

The original exposure assessment may also be insufficient. This is difficult to determine in the absence of information as to the size of the population that are being exposed more frequently and for longer duration than was estimated in the HRA. Though not the main source of exposure residual exposure from surfaces should also be considered.

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<sup>1</sup> Read D. Multiple chemical sensitivities. Wellington: ERMA New Zealand, 2002.

<sup>2</sup> This was not included in the HRA.