EcoHealth

10.1007/s10393-004-0102-x

Short Communications

Precautionary Health Risk Assessment: Case Study of Biological Insecticides

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Published online: 6 October 2004

Abstract In conventional risk assessment approaches, experts define the scientific questions that can legitimately be asked and the burden of proof is on the potentially exposed community to show that a proposal is unsafe. Here I propose an alternative approach, precautionary health risk assessment, in which the scientific questions to be addressed are defined by community consultation. I illustrate the approach with a case study of exposure to biological insecticides. This illustrates how community consultation can have a critical influence on the outcome of a health risk assessment. Government agencies may be reluctant to involve stakeholders in health risk assessments because this involves a loss of political control of the process. However, precautionary approaches are likely to lead to better health outcomes where decision stakes and scientific uncertainty are both high.

Keywords precautionary principle - risk assessment - bioaerosol exposure - *Bacillus thuringiensis*

INTRODUCTION

Conventional quantitative health risk assessment has evolved from toxicological approaches. Individual (usually chemical) exposures of interest are defined and assessed based on existing scientific knowledge, and dose-response relationships from controlled experiments or epidemiological studies are used to provide a quantitative estimate of likely health impacts in the exposed population. A major disadvantage of this approach, from a health perspective, is that advances in scientific knowledge must precede improvements in risk management. This means that health professionals must play a continual game of catch-up as new evidence of health effects emerges.

In response to the limitations of mainstream science in addressing complex environmental issues, where stakes are high and knowledge is limited, precautionary approaches have been advocated (*Ravetz, 2004*; *Grandjean, 2004*). A recent description of a precautionary approach includes the following main elements:

- Upholding the basic right of each individual (and future generations) to a healthy, life-sustaining environment as called for in the United Nations Declaration on Human Rights;
- Action on early warnings, when there is credible evidence that harm is occurring or likely to occur, even if the exact nature and magnitude of the harm are not fully understood;
- Identification, evaluation and implementation of the safest feasible approaches to meeting social needs;
- Placing responsibility on originators of potentially dangerous activities to thoroughly study and minimize risks, and to evaluate and choose the safest alternatives to meet a particular need, with independent review; and
- Application of transparent and inclusive decision-making processes that increase the participation of all stakeholders and communities, particularly those potentially affected by a policy choice (*Lowell Statement on Science and the Precautionary Principle, 2001*).

Unfortunately, a precautionary approach does not fit easily into a conventional framework for quantitative health risk assessment. The purpose of this article is to propose an alternative approach, which I have tentatively called precautionary health risk assessment. Table 1 illustrates some of the conceptual differences between conventional and precautionary health risk assessment. In particular, in conventional approaches, experts define the scientific questions that can legitimately be asked. In precautionary health risk assessment, a process of community consultation defines the scope of scientific questions to be addressed. In the following section, I illustrate the proposed approach with a case study of exposure to biological insecticides. The case study illustrates the utility of a precautionary approach where the stakes are high yet scientific evidence is limited.

Table 1. A Comparison of Typical Conventional and Precautionary Health Risk Assessment Approaches (Expanded from Holling, 1998)

	Risk assessment	
Variable	**Conventional**	**Precautionary**
Causal model	Simple, independent, linear, direct, cause-and-effect	Complex, context dependent, nonlinear, indirect, multiple contributing causes
Epistemology	Positivist	Pluralist
Method	Reductionist, expert driven, experimentation	Holistic, community driven, observation, dialogue
Scope	Limited to quantifiable, short term, local exposures	Any exposure of concern to the community, including at large spatial and temporal scale, qualitative and quantitative
Burden of proof	Proof of risk	Proof of safety
Emphasis on uncertainty	Concern with type I error	Concern with type II error
Evaluation and peer review	Accredited experts	Extended peer community (partial consensus)

Case Study: Community Exposure to Aerial Spraying of Biological Insecticides

Biological insecticides containing *Bacillus thuringiensis* bacteria (*Bt*) and their spores have been widely used for several decades in North America and other countries in order to control mosquitoes and pest species in horticulture and forestry such as the Gypsy Moth (WHO, 1999). Use of these agents to control mosquito vectors of disease has important health benefits. Although biological insecticides have a specific mode of action on target species and are thought to have a good safety profile, members of the community remain concerned, especially where aerial spraying programs have been carried out over large urban populations.

Several studies of communities exposed to aerial spraying of *Bt* products have been carried out in New Zealand, Canada, and North America (Noble et al., 1992; Anonymous, 1993, 1999, 2001a, b; Aer aqua, 2001; Pearce et al., 2002a, b). The largest and most detailed of these have not shown any association between exposure and health effects. Biological insecticides have been subjected to detailed risk assessments by international and national agencies (WHO, 1999; ERMA, 2002; Kalemba et al., 2002). Government agencies have claimed that aerial spraying of *Bt* products is safe on the basis of these assessments.

If, as a starting point, we instead consider the symptoms reported by communities rather than the scientific evidence, a different picture emerges. A proportion of workers (Noble et al., 1992) and individuals resident in communities where *Bt* products have been used (Noble et al., 1992; Anonymous, 2001a, b) describe a pattern of acute symptoms occurring shortly after exposure to the spray, including headache, nasal congestion, sore throat, and burning, itchy, or watery eyes. Is there a plausible explanation? Compare these self-reported symptoms with the following description:

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 (*Bünger et al., 2000*).

The pattern of acute self-reported symptoms in both workers using *Bt* products, and in exposed communities (*Noble et al., 1992*; *Anonymous 2001a*, *b*) is consistent with the acute effects of bioaerosol exposure reported in workers (*Bünger et al., 2000*) and one community based study (*Herr et al., 2003*). The hypothesis that the acute symptoms of exposure to biological insecticides are caused by effects of bioaerosol is biologically plausible, since when sprayed from aircraft, biological insecticides can form a respirable aerosol (*Teschke et al., 2001*). Self-reported symptoms might be affected by serious response bias. However, response bias is unlikely to explain these findings, since a connection between biological insecticides and irritant bioaerosol effects has not been suggested previously in scientific publications or community consultations.

More prolonged symptoms such as skin rash, asthma exacerbations, and flu-like illnesses have also been reported previously in communities and workers exposed to biological insecticides (*Anonymous 1993*; *Bender and Peck, 1996*; *Larsen and Bælum, 2002*). These symptoms could have a range of possible causes (and are more likely to be affected by response bias) but are not inconsistent with reported effects of bioaerosol exposure in workers (*Eduard et al., 2001*; *Larsen and Bælum, 2002*; *Tanaka et al., 2002*).

Understanding of bioaerosol measurement and health effects is limited (*Douwes et al., 2003*). Certain aero-allergens are known to cause acute exacerbations of asthma and it is well-known that long-term occupational exposure to bioaerosols is associated with an increased incidence of respiratory diseases.

Endotoxins produced by Gram-negative bacteria are thought to play a role in bioaerosol-related health effects via CD14 and toll-like receptors (*Douwes et al., 2003*). It has recently been established that peptidoglycans present in the cell walls of Gram-positive bacteria and their spores can also trigger nonspecific inflammatory responses via these same pattern recognition receptors (*Dziarski, 2003*; *Weber et al., 2003*).

Discussion

In this example of aerial spraying of a biological insecticide, communities have been exposed to an agent that is believed to be safe, based on conventional risk assessments. The active ingredient is derived from a ubiquitous soil organism that is not known to be pathogenic, and quality control procedures prevent contamination by unwanted bacteria or toxins. Controlled epidemiological studies have not shown a significant increase in symptoms in exposed communities. The spray has not been shown to be unsafe, therefore it is safe to continue spraying. Yet, as a consequence of allowing experts to determine the legitimate scientific issues for enquiry, regulatory agencies have dismissed a consistent pattern of self-reported symptoms across numerous studies.

Alternatively, consider a precautionary approach. Communities complain of symptoms that are consistent with the effects of bioaerosol exposure. How do we reconcile this insight with the negative results of epidemiological studies? All of the published epidemiological studies have limitations, including subjective or potentially biased assessment of health effects, potential or actual exposure of control groups, and limited duration of follow-up. In particular, the largest of the community surveys included only 500 participants in exposed and unexposed groups. These studies have limited ability to detect effects that occur in a small proportion of exposed people. Therefore, existing prospective community surveys (*Noble et al., 1992*; *Pearce et al., 2002a*, *b*) do not provide strong evidence in support of the long-term safety of *Bt* products in a community setting.

The level of bioaerosol exposure that has been shown to cause occupational disease is higher than that typically experienced by communities exposed to *Bt* products in aerial spraying program. However, since the most sensitive individuals tend to avoid occupations that lead to bioaerosol exposure, dose-response relationships from studies of workers may not give a true picture of effects in communities. The community could be forgiven for concluding that the spray has not been shown to be safe, therefore it is unsafe to continue spraying.

CONCLUSIONS

It would be prudent to avoid aerial spraying of biological insecticides over populated areas until the results of detailed follow-up of exposed populations are available. The case study illustrates how community consultation can have a critical influence on the outcome of a health risk assessment. Genuine community consultation in risk assessment is difficult to achieve and has probably been more widely advocated than practiced (*Parry and Wright, 2003*). Guidelines for health risk assessment need to be explicit about how, when, and with whom, consultation is required.

Encouraging community participation in health risk assessment necessarily leads to a loss of political control of the process by government agencies. This is a trade-off that governments should welcome, in return for policy that more effectively addresses otherwise intractable problems. Candidates for precautionary health risk assessment include any issue in which decision stakes and scientific uncertainty are both high. Prominent examples are the risks of genetically engineered organisms, international trade agreements, and global climate change.

Acknowledgments This article is based on an assessment of the potential health impacts of the Painted Apple Moth aerial spraying program, Auckland, New Zealand, funded by the New Zealand Ministry of Health. I thank the people and the organizations involved, especially those individuals who sent in written submissions.

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