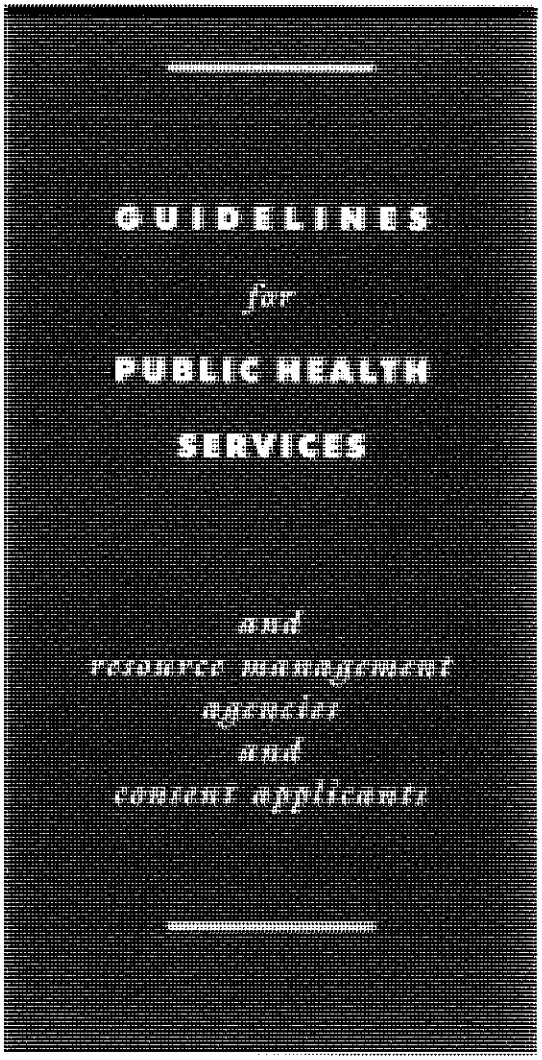
RISK ASSESSMENT:

A "user friendly" guide



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Foreword

As Maori have long known, the health of individuals and populations cannot be separated from the health of the environment. As a society, we make decisions which collectively influence our social, cultural, and economic behaviour, and consequently the sustainability of natural and physical resources, and the health of people and communities.

The Resource Management Act 1991 recognises that people and communities are part of the environment, and that decision making in relation to sustainable management should include, amongst other things, consideration of actual and potential effects on people and communities. The Public Health Commission (PHC) has recently published a *Guide to Health Impact Assessment*, (PHC, 1995), which has been developed to assist in this process.

Risk Assessment: A 'User Friendly' Guide is complementary to the *Guide to Health Impact Assessment*, and provides a more detailed framework for public health risk assessment, as part of the health impact assessment process.

In the course of developing this guide, the PHC sought comments on a discussion document prepared in March 1995. Of 250 copies of the discussion document sent out for comment, 27 submissions were received, (a list of those submissions is provided at the end of this document). Where possible and appropriate, the comments from these submissions have been incorporated into this guide. I would like to thank Dr Simon Hales for managing the development of this guide and those organisations and individuals who have contributed.

Dr Gilliam Durham
Chief Executive
Public Health Commission

Contents

Introduction: risk assessment as a component of health impact assessment

This guide is the second in a series relating to health impact assessment and is complementary to the *Guide to Health Impact Assessment* (PHC, 1995).

The purpose of this guide is to explain the basic principles of risk assessment as applied to public health issues. It is intended to assist public health services, local government agencies, private consultants, and resource consent applicants who are involved with health impact assessment (HIA) as part of the assessment of effects on the environment outlined in the Resource Management Act 1991.

Risk assessment is a central component of HIA. The preceding preliminary analysis, and subsequent risk communication[1], risk management and implementation stages require a greater degree of public input, whilst risk assessment is mainly a technical process. However, public consultation may also be required at the risk assessment stage, particularly where there is disagreement over the scientific approach used.

[1] Risk communication may be the subject of a future publication.

Risk Assessment

Decision makers need estimates of the magnitude of the health effects predicted to arise as a result of a decision. Risk assessment uses scientific data to provide this type of estimate, which may be qualitative or quantitative. However, it is important to recognise that risk assessment is not an exact science. There are important limitations on the types of estimate that risk assessment can provide, and the degree of uncertainty associated with these estimates is often great. Whilst quantitative estimates are desirable, in practice this is often impossible, because the required information is not available.

Risk assessment is a generic process, which can, in principle, be applied to any type of "exposure". In practice, public health risk assessment has generally focused on the effects of hazards in the physical environment, such as cancer-causing chemicals. Current developments, particularly in the field of epidemiology, will allow the scope of HIA to be broadened to encompass a much wider range of issues such as micro-biological hazards, noise, levels of physical exercise, unemployment, and other social issues. Whilst quantitative estimates are currently more often available for cancer than for other health effects, in many cases, cancer may not be the most important health outcome resulting from a given exposure. It is better to have an approximate answer to the right question than an exact answer to the wrong one.

It is assumed that the range of issues to be addressed by the HIA process has already been identified, as outlined in *A Guide to Health Impact Assessment* (PHC, 1995). The next step is to try to predict, for each of these issues, the nature and magnitude of the main health impacts in the population concerned (the "risk population"). The framework for risk assessment is summarised in *Figure 1*. This illustrates how scientific studies can be used to predict health impacts, by answering the following questions:

For each issue identified by the preceding stages of HIA

1 What exposures are likely to arise in relation to the issue?

For each exposure identified

2 Is there evidence from epidemiology or from experimental studies, that the exposure may be associated with health effects (positive or negative)?

For each health effect identified

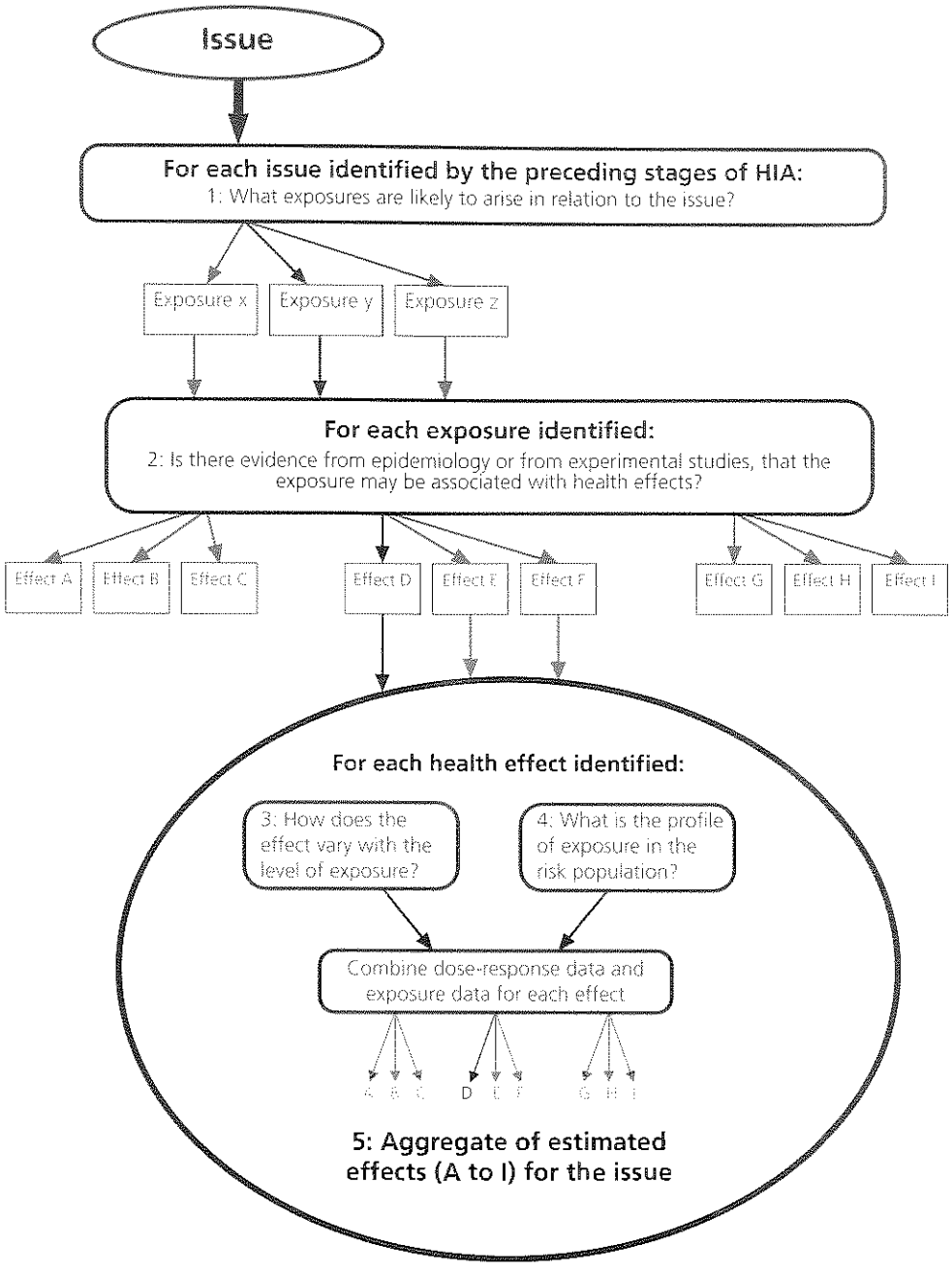
3 How does the effect vary with the level of exposure?

4 What is the profile of exposure in the risk population?

5 What is the aggregate effect in the risk population? (McMichael, 1993).

Steps 1 and 2 are together termed "hazard identification". Step 3 is "dose response assessment"; step 4 is "exposure assessment"; and step 5 is "risk characterisation". These steps will now be considered in more detail.

FIGURE 1: Overview of risk assessment



1 What 'exposures' are likely to arise?

In principle, any effect which alters the environment may have important direct or indirect public health consequences and may be thought of as an "exposure". In practice, it will usually be necessary to focus on a few such exposures which are likely to be the most important (for example, exposure "y" in *Figure 1*). Public health expertise may be helpful in advising on the types of exposure which should be considered further. One source of such advice is the public health unit of the local Crown health enterprise.

The amount of detail required in this aspect of the risk assessment depends upon the scale and likely significance of the actual or potential health impacts. Where there is uncertainty about the public health significance of a particular exposure, it is prudent to assume that the exposure may be important, and formally assess the available evidence relating to that exposure. It is important to be able to justify any decision to disregard a given exposure at this early stage of the risk assessment.

2 Is there evidence in the scientific literature of health effects associated with this exposure?

A literature search will often be required to answer this question, and electronic databases, including CD-ROM sources, may be helpful. All of the available evidence should be assessed, including both toxicological and epidemiological data, whether qualitative or quantitative. Various systems are used to classify toxicity (eg, the International Agency for Research on Cancer has developed a widely used system for classifying cancer-causing agents). The information available about the health effects likely to result from a given exposure is often incomplete. Because of this, it is appropriate to take a precautionary approach in public health risk assessment. The precautionary principle states that:

> "Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." (UNCED, 1992).

This means that possible health effects should not be ignored, simply because the relevant scientific evidence is inconclusive. An assessment of potentially serious or irreversible health effects should be conveyed to decision makers.

3 How does the health effect vary with the level of exposure?

Evidence relating to this question is also derived from toxicological and epidemiological studies.

Use of toxicological (experimental) studies

Scientists can assess the relationship between the level of exposure to a substance (or "dose") and outcomes (or "responses"), by performing controlled experiments. In these experiments, animals or living cells are systematically exposed to a range of doses of the substance under investigation. The outcomes in exposed animals are usually compared to those in "control" animals, in which no exposure to the substance occurs, but all other factors are kept the same.

This type of experiment, if carefully performed, can provide good evidence that a given exposure causes the observed responses *under the conditions of the experiment.* In scientific jargon, such an experiment has high "internal validity".

Because it would almost always be unethical to study the effects of harmful exposures on humans using this experimental design, the results of animal experiments are often "extrapolated" to give estimates of dose response relationships in human populations.[2] However, there is uncertainty about the relevance of animal experiments to "real world" exposures of human populations. In scientific terms, the "external validity" of such experiments may be quite limited.

In an attempt to allow for quantitative differences in response between animals and humans, dose response estimates from animal experiments are usually multiplied by an "uncertainty" factor when extrapolating the results to human populations. A further uncertainty factor may be applied to take account of variations in individual sensitivity to exposure in humans.

There may also be qualitative differences in response between animals and humans. For example, no animal model is available for the effects of lead exposure on higher mental functioning in humans (McMichael, 1991).

Use of epidemiological data

Where possible, dose response estimates from relevant epidemiological studies should be used as the basis for risk assessment. For major public health issues, the best starting point is a critical review of the evidence in good scientific journals. However, review articles rapidly become out of date, and the most recent evidence should also be assessed if possible.

It is important to assess critically the validity of each relevant study. As for experimental studies, this should include an assessment of the validity of the results as they apply to *the subjects in the study*, (internal validity) and the extent to which the results can be generalised to the *risk population* (external validity).

Epidemiological studies may be weaker than animal studies in terms of internal validity, but are generally much stronger in terms of external validity. Issues which need to be considered when assessing internal validity include the effects of chance, bias and confounding. The strength of an individual study depends in part on the study design. For example, a randomised controlled trial is less likely to be affected by confounding than an ecological study.

Factors which may affect external validity include population factors and exposure factors. Two questions are relevant here:

- Is the risk population comparable in terms of susceptibility?

Differences in age structure, ethnicity, genetic factors, health status, or other exposures, (including many economic, social, cultural, behavioural, and physical environmental factors), may have important effects on dose response relationships.

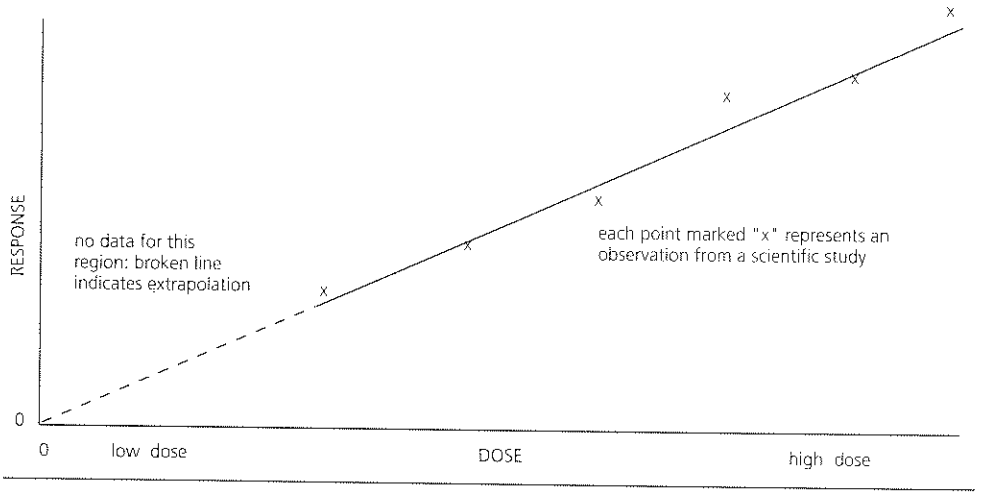
- Are the characteristics of the exposure in the risk population comparable to those in the study population?

Usually, there are important differences in terms of the magnitude of the dose, the rate at which the dose is received, and the route or duration of the exposure.

[2] It is not intended to imply that animal experiments are necessarily ethically acceptable.

For example, the effects of high dose exposure are usually studied, since this makes it easier to overcome statistical uncertainty without the need to study very large numbers of people. However, in the risk population, the exposure is usually low dose. This means that, in order to predict the effect of exposure in the risk population, it is often necessary to extrapolate from high dose exposure (in the study) to low dose exposure (in the risk population). At the low levels of exposure actually experienced by the risk population, it is difficult to detect the existence of associated health effects in an epidemiological study (see *Figure 2*). However, this does not mean that such low dose exposures are unimportant in public health terms. If the exposed population is large, the health impact may be substantial, even if it cannot be directly observed scientifically.

FIGURE 2: Extrapolation from high dose to low dose



In many studies, the exposure is short term, (years), but it is the effect of long term exposure (such as over a whole lifetime), that is of most interest. Even if the total dose is comparable, the pattern of exposure may affect the outcome. For example, intermittent exposure may have a proportionately greater effect than continuous exposure.

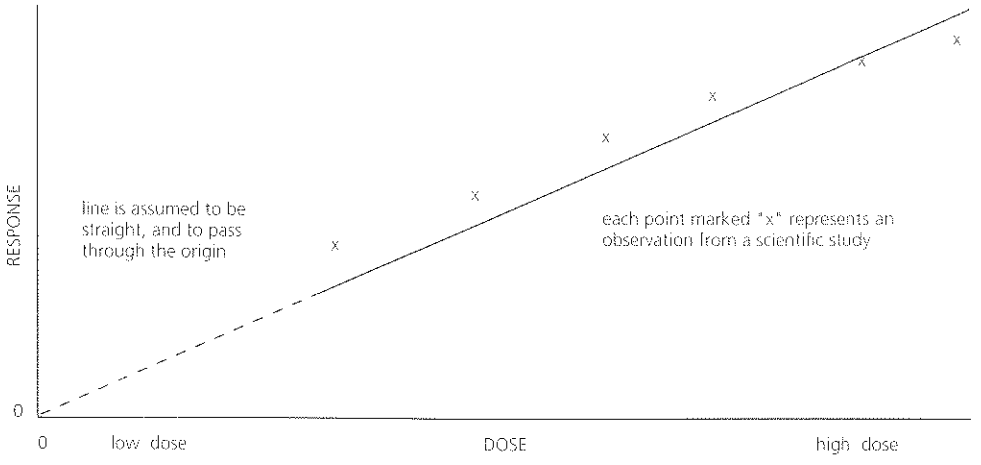
Where sufficient information is available, it may be possible to "adjust for" (take account of) differences between the study population and the risk population, in terms of some of the factors mentioned above. It is not generally possible to take account of all of the factors which may affect dose response relationships. The best that can be achieved is an estimate, based on the assumption that the most important factors have been included.

Expressing dose response relationships numerically

In extrapolating effects at high doses to those at low doses, it is necessary to use a mathematical model, which makes predictions about the relationship between dose and response at low doses.

For exposures that cause cancer, a "linear" (straight line), no-threshold model is often assumed. The linear no-threshold model predicts that *a given increase in exposure* causes a *fixed increase in risk*, regardless of the initial level of exposure (see *Figure 3*). A useful feature of this model is that it allows the health impact of a change in the average level of exposure in a population to be estimated, without the need for more detailed information about individual exposures.

FIGURE 3: Linear, no-threshold dose response graph



However, it could be argued that the line drawn in *Figure 3* is in the wrong place: that the line would "fit the data" better if it was a convex (upward bulging) curve. Extrapolating this curve to the origin of the graph would imply a greater effect for a given exposure, in the region shown by the broken line. In this case, assuming a linear, no-threshold model would underestimate the true effect in the low dose region. For a concave dose response curve, the opposite would be the case.

Various mathematical models can be tested statistically, in an attempt to determine which model best fits the observed data. However, the true dose response graph may not be a straight line or even a simple curve. It is often not possible to decide, scientifically, which of several possible models gives the best description of the observations (that is, fits the data best). In terms of the example illustrated in *Figure 3*, it might not be possible to determine scientifically, whether a straight line or a curved line would be the most accurate.

Cancer risk

At the individual level, cancer risk may be expressed in terms of the predicted increase in risk for a given level of exposure.[3] The "cancer potency factor" (CPF) expresses potency in terms of the increased risk of cancer predicted to result from continuous exposure to a specified "unit dose" of the cancer causing agent, over a whole lifetime. The unit dose may be defined as, for example, one milligram of a substance per kilogram of body weight per day, or – in abbreviated form – mg/kg/day (USEPA, 1993).

Alternatively, the same information may be expressed in terms of the dose (for example, in mg/kg/day) which is predicted to give rise to a specified increase in individual lifetime risk, for example, a one-in-a-million chance of a specified event (such as death from cancer resulting from the exposure). This is termed the "risk specific dose".

[3] The magnitude of the risk is expressed as a probability. For example, there is a chance of 1 in 2 that heads will show when you toss a coin. At the population level, risk can be expressed in terms of the number of events (such as deaths from cancer), predicted to occur per year.

Non-cancer risk

For non-cancer effects, it is generally assumed that there is a *threshold dose*, below which no health effects are predicted to occur. Dose response data are available for some types of exposure, based on epidemiological studies. In other cases, an estimate of the threshold can be made, based on toxicological data. Whilst it is logically impossible to scientifically prove the absence of an effect, it is possible to determine the *highest dose at which no adverse effect is observed*. This is termed the no observed adverse effect level (NOAEL).[4]

Typically, the NOAEL is divided by several uncertainty factors, to give a reference dose (RfD). The reference dose is a scientific estimate of the overall dose from all sources below which no appreciable health risk is likely to occur, following long term exposure. Uncertainty factors are designed to account appropriately for:

- the fact that the true threshold is likely to be lower than the NOAEL
- differences in sensitivity between species, and
- sensitive subgroups within human populations, such as children, or chronically ill people.

Other exposure standards

A variety of other exposure standards are based on epidemiological and/or toxicological dose response data, and usually incorporate uncertainty factors, as described above. For example, standards may be based on studies of effects in workers, often exposed at relatively high doses, extrapolated to effects in the general population, exposed at low doses. An uncertainty factor is appropriate here, for example, to account for sensitive subgroups in the general population.[5]

Standards may be set with the intention of reducing adverse effects to an "acceptable" level, or alternatively, with the intention of preventing adverse effects altogether. The acceptability (or otherwise) of public health risk should be decided on the basis of wide consultation with all affected parties, as part of the risk management stage that follows risk assessment. It is important for affected parties to understand the scientific basis of any standards that are used as part of a risk assessment, including the magnitude of any uncertainty factors. There are also several general problems with exposure standards, which users should be aware of:

- setting standards for specific exposures usually ignores the fact that there may be multiple sources and routes of exposure. A piecemeal approach to limiting exposures from single sources may not be adequate to limit the effects of exposure from all sources combined. For example, water quality standards may not take into account exposure via food
- dealing with each exposure separately is unlikely to account adequately for cumulative or synergistic effects of multiple different exposures

[4] For exposures that cause both cancer and non-cancer effects, the NOAEL may still be a useful concept for the non-cancer effects.

[5] Note that it may not be appropriate to apply workplace exposure standards to the general population, even with an uncertainty factor, since other issues, relating to the acceptability of risk, also need to be considered. For example, workers may expose themselves to hazards in order to receive some direct benefit, whereas the general population may be unable to avoid exposure, and usually will not directly benefit.

- the magnitude of uncertainty factors is often arbitrary, and may not be sufficiently conservative to avoid adverse health effects, or alternatively may impose unnecessarily stringent conditions
- there is a general lack of good quality data (especially quantitative data) on health effects. For example, only a small minority of chemicals in current use have been formally evaluated (McMichael, 1991).

These problems all need to be considered when using exposure standards to estimate public health risk. Decision makers should be aware that, historically, exposure standards have often been progressively lowered over time, as new studies have revealed previously unsuspected health effects. However, exposure standards are useful if applied with care, in that they allow those without specific expertise in epidemiology to contribute to risk assessment.

The problems referred to in the above list should be addressed where possible. For example, risk assessors can consider all likely routes and sources of exposure, consider the possibility of cumulative effects of different exposures, use appropriate dose response data that accounts for known synergisms, and be explicit about the uncertainty factors used.

Where there is a lack of quantitative data on dose response relationships, a qualitative estimate of the public health importance of a given exposure can be provided. Assessment of the scientific evidence relating to some exposures may be very difficult, or adequate evidence may not be available. In these cases it is appropriate for risk assessors to seek specialist advice.

4 What is the profile of exposure in the risk population?

The next stage of risk assessment is to assess the size and characteristics of the population exposed, and the levels of exposure which are likely to arise within the population. The term "profile of exposure" refers to the distribution of exposure in the population. For the reasons discussed above, there may be subgroups within the population to which different dose response estimates apply. If so, it is necessary to estimate the exposure in each subgroup, so that the relevant dose response and exposure estimates can be combined appropriately in the next stage of the risk assessment.

The exposed population may consist of just a few people in the case of a small local development, or potentially the entire world population in the case of persistent pollutants such as organochlorine chemicals. Exposure assessment often focuses on hazards of chemicals in the environment. However, in principle any type of exposure can be assessed. Exposure assessment involves

> '... measuring or estimating concentration or intensity, duration, and frequency of exposures to an agent present in the environment ...' (Heinzow and McLean, 1994).

Exposure assessment may include carrying out surveys, the analysis of existing monitoring data, exposure modelling, or a combination of these. Ideally, exposure assessment should be based on reliable, valid, specific, and relevant measurements in representative individuals or groups. In practice, it is usually necessary to rely on less-than-perfect information for ethical, practical and cost reasons. The assumptions that are required to do this introduce uncertainties, which should be made explicit and rigorously assessed.

Where there is wide variation in true levels of exposure, and the dose response relationship is non-linear, the use of average exposure levels may greatly underestimate the overall health impact. Some groups may be more highly exposed than the average, for example, because of their social or cultural circumstances. Some ethnic or socio-economic groups may also be particularly sensitive, for example, because of genetic factors, or the presence of other exposures. These people may experience health effects at lower levels of exposure than other groups.

The information available to assess exposure is often incomplete, and resource constraints may not permit a very detailed analysis. The extent of the exposure assessment should be in proportion to the likely public health impact. Detailed exposure assessment may involve sophisticated mathematical modelling techniques, backed up by extensive measurements of actual levels in the environment.

Generally, however, it should at least be possible to calculate plausible upper and lower estimates for the level of exposure and the size of the population affected. It should always be possible to provide some assessment of exposure, even if this is only semi-quantitative or qualitative (USEPA, 1993).

5 What is the aggregate effect in the risk population?

The final step in risk assessment is to combine the dose response data with the exposure data, to give an estimate of the magnitude of each health impact that has been considered. Where subgroups have been identified to which different dose response estimates apply, the relevant dose response estimates are multiplied by the exposure estimates for each subgroup. The results for each subgroup can then be added together to give an overall estimate for each health impact. Decision makers should also be given the estimates for individual subgroups, as this enables them to consider equity issues during risk management.

Where more than one health effect has been identified, the overall estimate of health impact is the aggregate of the individual impacts. There are various methods available for ranking and comparing individual health impacts (see, for example, USEPA, 1993).

Assessment of uncertainty

The uncertainties associated with the hazard identification, dose response assessment and exposure assessment need to be taken into account when describing public health risks. Plausible upper and lower estimates of health impact can be calculated based on the plausible range of values for the dose response and exposure estimates. It is important that decision makers are provided with information about the uncertainty associated with risk estimates. This enables them to take a precautionary approach, for example, by providing a reasonable margin of safety, even where the magnitude of a given effect is very uncertain.

Example: Health Risks from Exposure to Dioxins

Issue

Dioxins are a group of chemicals with similar structure and properties, and are of public health concern because they are:

- amongst the most toxic substances known
- persistent in the environment (not broken down easily) and
- bioaccumulative (increase in concentration on moving up the food chain).

Dioxins are released into the environment mainly as unwanted by-products of combustion processes, industrial processes and chemical manufacture. As a result they are widespread in the environment and in food, although at very low levels. The main route of human exposure is thought to be via food, particularly animal products.

The principal mechanism of action of dioxins is thought to be via a specific cellular receptor.[6] The toxicity of an individual compound may be estimated by measuring activity at this receptor. The overall toxicity of a mixture of dioxin-like compounds is conventionally estimated by combining the individual activities of the compounds which are present, to give a 'toxic equivalent' (TEQ).

Is there evidence from epidemiology or from experimental studies, that the exposure may be associated with health effects?

There is a large body of scientific data suggesting that, in animals, exposure to dioxins causes a wide variety of effects, including biochemical changes, chloracne (a skin disease), developmental abnormalities, immunological impairment, reduced reproductive capacity, and cancers. There is limited epidemiological evidence that some of these effects occur in humans. The effects will be considered in two categories: cancer effects and non-cancer effects.

Cancer Effects

How does the effect vary with the level of exposure?

Based on animal experiments, authoritative opinion suggests that the dose of dioxin which gives rise to an additional lifetime cancer risk of 1 in a 1,000,000 is about 0.01pg (TEQ)/kg/day [USEPA, personal communication, August 1994].[7]

[6] This is a receptor of unknown function called the "Ah" receptor.

[7] This is the "risk specific dose", assuming a linear, no-threshold model. pg = picogramme, or 10^{-12}g See Covello and Merkhofer (1993) for a discussion of dioxin risk estimates.

What is the profile of exposure in the risk population?

There is little information available on exposure to dioxins in New Zealand. Study of dioxins in breast milk can give an idea of exposure levels in the population. Bates et al (1994) have studied dioxins and other contaminants in the breast milk of a small group of New Zealand women. A similar study in Germany found levels about twice as high as in the New Zealand study (Beck et al, 1994). In Germany, the average intake of dioxins in food has been estimated from food monitoring data (Beck et al, 1994). Dividing this German estimate by two, (to reflect the difference between the levels found in breast milk in the two countries), average intake in New Zealand can be crudely estimated to be about 1pg(TEQ)/kg/day.

The size of the risk population is large, since everyone is exposed at some level.

What is the aggregate effect in the risk population?

The exposure estimate is 100 times higher than the risk specific dose. Current levels of exposure are therefore estimated to give rise to an average individual lifetime cancer risk from dioxins of about 1 in 10,000. (Note that this is very small in relation to the risk of cancer from all causes combined, which is about 1 in 4).

Expressing the estimated risk in another way, for every 10,000 New Zealanders exposed to dioxins at an average dose of 1pg(TEQ)/kg/day throughout their lifetimes, it is estimated that one person will contract cancer as a result of that exposure. For 3,500,000 New Zealanders, a total of 350 cancers are predicted to occur during their lifetime, or 350/70=5 cancers per year, assuming an average lifetime of 70 years.

Non-Cancer Effects

How does the effect vary with the level of exposure?

Reliable quantitative dose response estimates are unavailable. Current opinion suggests that a threshold is likely to exist for non-cancer effects. No observed adverse effect levels, (NOAELs), have been determined in animal experiments, for various effects. For many of these effects, current estimated average levels of exposure are within an order of magnitude of the NOAEL. In humans, physiological changes have been observed experimentally, at or near current average exposure levels [USEPA, personal communication, August 1994].

By convention, an uncertainty factor of 10 is used to account for extrapolation from animals to humans, and a further uncertainty factor of 10 is used to account for sensitive human populations. The reference dose (RfD) can therefore be estimated by dividing the NOAEL by a factor of 100. In practice, this means that the RfD is 10 to 100 times lower than current exposure levels.

What is the profile of exposure in the risk population?

This is the same as under *Cancer Effects*.

What is the aggregate effect in the risk population?

Physiological changes of uncertain significance may be present in groups with average levels of exposure, whilst more highly exposed groups are likely to have an increased incidence of adverse effects including developmental abnormalities, immunological impairment, reduced reproductive capacity in men, and endometriosis in women.

Discussion of Uncertainty

There are many assumptions underlying the above estimates. Some of the most important are as follows:

In the dose response assessment it is assumed that:

- the results of animal studies can be extrapolated to humans
- a linear, no-threshold model is appropriate
- the uncertainty factors used are appropriate
- when assessing the effects of dioxins, the effects of other exposures can be ignored.

For the exposure assessment, it is assumed that:

- the only important route of exposure to dioxins is via food
- measurements of dioxins in food samples are valid, and can be generalised to the diet actually consumed by the population
- TEQ is a valid method of estimating the exposure to a mixture of dioxins
- measurement of dioxins in breast milk is a valid method of estimating exposure
- the limited data on dioxins in breast milk can he generalised to the whole population [USEPA, personal communication, August 1994].

All of these assumptions are subject to scientific debate. The combined effect of all of the assumptions is that the overall risk estimates are highly uncertain. It is reasonable to conclude from the available evidence that dioxins have the *potential* to produce health effects, which may nevertheless be difficult to detect with current epidemiological methods. Because the exposed population is large, the overall health impact of dioxins is potentially substantial. Although cancer is the only outcome for which a quantitative estimate has been made, cancer may not be the most important outcome of dioxin exposure. Confidence in the risk assessment would be improved by better evidence of effects in humans, and by improved exposure assessment (for example, more extensive surveys of dioxin levels in humans).

Conclusion

Public health risk assessment is a rapidly developing field. The accuracy of risk estimates is limited by the availability of data and resources, and it is important that the scale of any risk assessment is in proportion to the likely magnitude of the public health risk. However, within these limitations, it is also important that the best available information is conveyed to decision makers in a form which is understandable, and enables good decisions to be made.

Risk assessment is largely a technical process, but there will often also be policy issues involved. People involved in HIA processes should not hesitate to consult widely, both in terms of technical and policy issues. This will help to ensure that the results of risk assessment are widely understood, accepted and applied.

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For information on chemical hazards, various CD-ROM sources are available, (New Zealand suppliers for these include EBSCO NZ: telephone (09) 524 8229 and Geac Computers NZ: telephone (09) 309 1860):

CHEM BANK, (US Department of Transportation Coast Guard; US Environmental Protection Agency; US National Institute of Occupational Safety and Health; US National Library of Medicine; US National Technical Information Service)

IARCancerDisc, (International Agency for Research on Cancer)

Micromedex Health, Safety and Environmental Series, (Micromedex, Colorado, USA)

PolTox Series, (US National Library of Medicine, Cambridge Scientific Abstracts, International Food Information Service)

TOXLINE, (National Chemicals Inspectorate, Sweden; US National Library of Medicine).

Glossary

Adjustment A summarising procedure for a statistical measure in which the effects of differences in the composition of the populations being compared have been minimised by statistical methods (Last, 1988).

Bias Deviation of results or inferences from the truth, or processes leading to this deviation. (More generally:) ...any trend in the collection, analysis, interpretation, or review of data that can lead to conclusions that are systematically different from the truth (Last, 1988).

Bioaccumulation The process by which certain chemicals increase in concentration on moving up the food chain.

Cancer potency factor (CPF) expresses potency in terms of the increased risk of cancer predicted to result from continuous exposure to a specified "unit dose" of the cancer causing agent, over a whole lifetime.

Confounding A situation in which the effects of two processes are not separated. The distortion of the apparent effect of an exposure on risk brought about by the association with other factors that can influence the outcome (Last, 1988).

Dose response relationship A relationship in which a change in amount, intensity or duration of exposure is associated with a change in the risk of a specified outcome (adapted from Last, 1988).

Ecological study A study in which the units of analysis are populations or groups of people, rather than individuals (Last, 1988).

Environment Includes

- ecosystems and their constituent parts, including people and communities
- all natural and physical resources
- amenity values, and
- the social, economic, aesthetic, and cultural conditions which affect the matters above or which are affected by those matters.

Epidemiology The study of the distribution and determinants of health-related states or events in specified populations, and the application of this study to the control of health problems.

Exposure A measure of the amount of a factor to which a population is exposed. This may include, for example, the concentration in the environment of physical agents such as chemical contaminants, physiological or genetic characteristics, behaviour, and social factors such as job status or income level. In contrast, dose is normally used to describe internal exposure to physical agents only.

External validity	The extent to which the results of a scientific study can be generalised (applied) to the risk population.
Hazard	A source or situation of potential harm.
Health impact assessment (HIA)	A systematic process to assess the actual or potential effects of policies, objectives, programmes, plans, consents, or activities on the health of individuals, groups or communities. An assessment of risks to people either directly or indirectly as a result of environmental conditions or hazards.
Incidence	The number of instances of illness commencing, or of persons falling ill, during a given period in a specified population (Last, 1988).
Internal validity	The scientific validity of the results of a study, as they apply to the subjects in the study.
Local government agencies	These include regional councils and territorial authorities (district or city councils).
No observed adverse effect level	(NOAEL) in a scientific study, the highest dose at which no adverse effect is observed.
Public health	The science and art of preventing disease, prolonging life, and promoting health through organised efforts of society.
Public health agencies	These include public health units of Crown health enterprises, and territorial authorities (city and district councils) in terms of their environmental health functions.
Randomised controlled trial	An experiment in which subjects in a population are randomly allocated into groups, usually called "study" and "control" groups, to receive or not to receive an experimental intervention (for example, a medical treatment). The results are assessed by rigorous comparison of the outcomes in the study and control groups (adapted from Last, 1988).
Reference dose	(RfD) a scientific estimate of the total dose from all sources below which no appreciable health risk is likely to occur, following long term exposure.
Resource consents	Include land use consents, subdivision consents, coastal permits, water permits and discharge permits, as described in s 87 of the Resource Management Act.
Risk	The probable incidence of unwanted events. The likelihood of a specified undesired event occurring within a specified period or in specified circumstances. The probability of harmful consequences arising from a hazard. In quantitative terms, risk can be expressed in values ranging from zero (no possible harm) to one (a certainty that harm will occur).
Toxic equivalent	(TEQ) a measure of the toxicity of a mixture of dioxins.

Submissions Received on the Draft of *Risk Assessment: a "User Friendly" Guide*

The Public Health Commission gratefully acknowledges the contributions of the following:

1 New Zealand Local Government Association Inc

2 Waipa District Council

3 Land Transport Safety Authority

4 Healthcare Otago

5 Health Research Council of New Zealand

6 Matamata Piako District Council

7 Transit New Zealand

8 Hutt Valley Health

9 MidCentral Health

10 Department of Public Health
Wellington School of Medicine

11 Lincoln University

12 Healthlink South

13 Coast Health Care Limited

14 Healthcare Hawkes Bay

15 Agcarm (Agricultural Chemical & Animal Remedies Manufacturers' Association of New Zealand Inc)

16 World Health Organization

17 Accident Rehabilitation and Compensation Insurance Corporation

18 Healthcare Otago Limited

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26 New Zealand Chemical Industry Council Inc*

27 Ministry of Agriculture and Fisheries*

* These submissions were received too late to be considered